

18717

THE STATE OF SOUTH CAROLINA

In the Court of Appeals

APPEAL FROM ORANGEBURG COUNTY
Court of Common Pleas
James C Williams, Jr , Circuit Court Judge

ORIGINAL

Case No 08- CP-38-826

Kareem J Graves and Tara Graves, individually and as duly appointed
personal representatives of the Estate of India Iyanna Graves Appellants

vs

CAS Medical Systems, Inc Respondent

Record on Appeal
Volume IV

J Edward Bell, III
~~Thomas W. Bell, III~~
The Bell Legal Group, LLC
232 King Street
Georgetown, SC 29442
Tel 843-546-2408
Fax 843-546-9604
Attorney for the Appellants

RECEIVED
DEC 06 2010
SC Court of Appeals

Clarke W Dubose
Haynsworth Sinkler Boyd, P A ,
1201 Main Street, 22nd Floor,
(29201-3226)
Post Office Box 11889
Columbia, South Carolina 29211-
1889
Attorney for the Respondent

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Volume IV

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The undersigned certifies, pursuant to Rule 209(c), SCAR, that the Record on Appeal contains no matter which is irrelevant to the Appeal



J Edward Bell, III
Thomas W Winslow
Law Offices of J Edward Bell LLC
232 King Street
Georgetown, S C 29440

November 5, 2010

MEDWATCH

1E FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: DMB No. 0515-0201 Expires: 9/30/07
See DMB Instructions

My report #	2244861200200032
UPID report #	
FDA Use Only	

A. Patient information			
1. Patient identifier UNK	2. Age at time of event UNK or Date of birth UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK lb or kg

B. Adverse event or product problem	
1. ☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
☐ other	
3. Date of event (m/d/yyyy)	4. Date of this report (m/d/yyyy)
07/00/02	08/20/02
5. Describe event or problem	

Home Care Dealer reports that the monitor while on a simulator would not pick up a signal and that the alarm was not heard at self test

6. Relevant tests/laboratory data including dates

NA



7. Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

C. Suspect medication(s)			
1. Name (give labeled strength & ml/labeler if known)			
#1 NA			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) (month/year)	
#1 NA		#1 NA	
#2 NA		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 NA		#1 ☐ yes ☐ no ☒ doesn't apply	
#2		#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 NA		#1 NA	
#2		#2	
8. NDC # - for product problems only (if known)			
NA - -			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
NA			

D. Suspect medical device	
1. Brand name	
Heart Rate Respiration Monitor	
2. Type of device	
Breathing Frequency Monitor	
3. Manufacturer name & address	
Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441	
4. Operator of device	
☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (m/d/yyyy)	
NA	
6. Model #	
9700B	
7. Catalog #	
NA	
8. Serial #	
30200991	
9. Lot #	
NA	
10. Other #	
RGA 13511	
9. Device available for evaluation? (Do not send to FDA)	
☐ yes ☒ no ☐ returned to manufacturer on (m/d/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter			
1. Name & address		phone #	
Home Respiratory Care 5201 West 46th ST Indianapolis IN 46254		317-290-0202	
2. Health professional?		3. Occupation	
☐ yes ☒ no		Home Care Dealer	
4. Initial reporter also sent report to FDA			
☐ yes ☐ no ☒ unk			

001582



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

001501

Medication and Device Experience Report (continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Refer to guidelines for specific instructions

Page 2 of 2

FDA Use Only

E. For use by user facility/distributor-devices only

Check one ☐ user facility ☐ distributor		2. UFDist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (month/year)		7. Type of report ☐ initial ☐ follow-up # _____	8. Date of this report (month/year)
9. Approximate age of device	10. Event problem codes (refer to coding manual)		
patient code	_____	_____	_____
device code	_____	_____	_____
11. Report sent to FDA? ☐ yes (month/year) ☐ no		12. Location where event occurred	
13. Report sent to manufacturer? ☐ yes (month/year) ☐ no		☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____	
14. Manufacturer name/address			

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☒ not returned to mfr ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code.		4. Device manufacture date (month) UNK	
5. Labeled for single use? ☐ yes ☒ no		6. Evaluation codes (refer to coding manual)	
method		_____	
results		_____	
conclusions		_____	
7. If remedial action initiated check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f) list correction/removal reporting number NA		10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data	

G. All manufacturers

1. Contact office - name/address (& mailing site for devices) CAS Medical Systems Inc 44 E Industrial Rd Branford CT 06405 Attn: Ron Jeffrey Note: CAS purchased product line after this device was manufactured from Nelcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441		2. Phone number 203-488-6056
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other Dealer		4. Date received by manufacturer (month/year) 07/23/02
5. (A) NDA # NA IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes		6. If IND protocol # NA
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ Initial ☐ follow-up # _____		8. Adverse event term(s) NA
9. If report number 4861200200032		

NA

001583

A public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any aspect of this collection of information, including suggestions for reducing this burden, to Washington, D.C. 20543.

Drugs R. ports Clearance Office
Paperwork Reduction Project (0918-0221)
Haber R. Humphrey Building, Room 531-41
200 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor and person is not required to respond to, collection of information unless it displays currently valid OMB control number.

Please DO NOT RETURN this form to this address

CAS Medical Systems Inc.

13511

DATE ISSUED

7/23/02

CUSTOMER

HOME RESPIRATORY CARE

CUSTOMER

7285

MODEL

AMI PLUS W/MODEM

SERIAL

Y 30200991

NO. OF TIMES

REPAIRED

BT

01-05 0170

WARRANT

Not

CUSTOMER COMMENTS

NOT HAVING ALARM BEING HEARD ON SELF TEST WON'T PICK UP SIGNAL ON
SIMULATOR

REPAIR SECTION

R2

REPAIR COMMENTS

9/26/02 UNIT MISSING AT CAS CAN'T CLOSE PER L. HOTTIN CLOSE RGA
REPLACEMENT SENT SN Y 30201503R ON SO # 39701

INVESTIGATION

MDR 00032 sent 8/20/02 Found out later that unit was lost and thus complaint not
verified

CLOSED BY

R Jeffrey

DATE CLOSED

11/22/02

001534

ENT-RED JUL 26 2002

PRODUCT INFORMATION FORM (PIF)

RGA OR PC <u>13511</u>		PATIENT INJURY OR DEATH ☒ YES ☐ NO	
PRODUCT COMPLAINT ☒ YES ☐ NO		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A	FORM FILLED OUT BY <u>Daly</u>	CUSTOMER NAME <u>Name Respiratory</u>	
	DATE OF THIS REPORT <u>7/23/02</u>	ADDRESS <u>5201 W. 46th St</u>	
	PRODUCT <u>9700 B</u>	<u>Indianapolis IN 46254</u>	
	LOT/SERIAL # <u>4-30200991</u>	COMPLAINANT <u>Epic</u>	
	QUANTITY <u>1</u>	PHONE <u>317-290-0202</u>	
INFORMATION DETAILS.			CHECK IF OUT OF BOX FAILURE ☐
- Not having alarm being heard on - Self test - Won't plu signal on Simulator			
<u>072302A</u> ACTION TAKEN THUS FAR			
B	DATE LOGGED AT QA. <u>7/26/02</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION		
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS).		
	<u>Not in as per 8/19/02 L.H.</u>		
	<u>Unit lost - will not return</u>		
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>sent udon #00032 8/20/02</u>			
REASON FOR NO REPLY TO COMPLAINANT		026055	
CLOSE OUT			
SIGNATURE <u>[Signature]</u>		DATE <u>11-22-02</u>	

PFC- 15

DATE 07/25/03

**CUSTOMER
RETURNS**

4. Will CEMENT
1.25

SFLD RU 7285
HOME RESPIRATOR CARE
520 WEST 46TH ST
INDIANAPOLIS, IN 46254
ATTN ACCOUNTS PH 98LL

[illegible]

DATE NOTIFIED	DATE RECEIVED	CUST PDS	FLYER	SALESMAN	TAX
07-25-82		072302A	ERIC		07

FREICH,

TERMS
24 13 14 20

DATE

LINE	QTY	UNIT PRICE	TOTAL
1	1	1.00	1.00
2	1	1.00	1.00
3	1	1.00	1.00
4	1	1.00	1.00
5	1	1.00	1.00
6	1	1.00	1.00
7	1	1.00	1.00
8	1	1.00	1.00
9	1	1.00	1.00
10	1	1.00	1.00
11	1	1.00	1.00
12	1	1.00	1.00
13	1	1.00	1.00
14	1	1.00	1.00
15	1	1.00	1.00
16	1	1.00	1.00
17	1	1.00	1.00
18	1	1.00	1.00
19	1	1.00	1.00
20	1	1.00	1.00
21	1	1.00	1.00
22	1	1.00	1.00
23	1	1.00	1.00
24	1	1.00	1.00
25	1	1.00	1.00
26	1	1.00	1.00
27	1	1.00	1.00
28	1	1.00	1.00
29	1	1.00	1.00
30	1	1.00	1.00
31	1	1.00	1.00
32	1	1.00	1.00
33	1	1.00	1.00
34	1	1.00	1.00
35	1	1.00	1.00
36	1	1.00	1.00
37	1	1.00	1.00
38	1	1.00	1.00
39	1	1.00	1.00
40	1	1.00	1.00
41	1	1.00	1.00
42	1	1.00	1.00
43	1	1.00	1.00
44	1	1.00	1.00
45	1	1.00	1.00
46	1	1.00	1.00
47	1	1.00	1.00
48	1	1.00	1.00
49	1	1.00	1.00
50	1	1.00	1.00
51	1	1.00	1.00
52	1	1.00	1.00
53	1	1.00	1.00
54	1	1.00	1.00
55	1	1.00	1.00
56	1	1.00	1.00
57	1	1.00	1.00
58	1	1.00	1.00
59	1	1.00	1.00
60	1	1.00	1.00
61	1	1.00	1.00
62	1	1.00	1.00
63	1	1.00	1.00
64	1	1.00	1.00
65	1	1.00	1.00
66	1	1.00	1.00
67	1	1.00	1.00
68	1	1.00	1.00
69	1	1.00	1.00
70	1	1.00	1.00
71	1	1.00	1.00
72	1	1.00	1.00
73	1	1.00	1.00
74	1	1.00	1.00
75	1	1.00	1.00
76	1	1.00	1.00
77	1	1.00	1.00
78	1	1.00	1.00
79	1	1.00	1.00
80	1	1.00	1.00
81	1	1.00	1.00
82	1	1.00	1.00
83	1	1.00	1.00
84	1	1.00	1.00
85	1	1.00	1.00
86	1	1.00	1.00
87	1	1.00	1.00
88	1	1.00	1.00
89	1	1.00	1.00
90	1	1.00	1.00
91	1	1.00	1.00
92	1	1.00	1.00
93	1	1.00	1.00
94	1	1.00	1.00
95	1	1.00	1.00
96	1	1.00	1.00
97	1		

PART# 01-05 0170
AMI FLHS, 0700B, ENGLISH 4/MODEM.

Under Warranty, NO
REASONS RETURNED
DB NON-WARRANTY, 391-21-30-1 160t

SN	1-20600951	SCHED DATE	QTY
		27-20 0'	

**5/14-20 00391
 NOT HAVING ALARM BEING
 HEARD ON SELF TEST,
 WON'T PICK UP SIGNAL
 ON SIMULUP

026056

DATE: 11/15/74

09/26/02

RGAINDEX

INVOICE# 68328

SOLD TO

SHIP TO

HOME RESPIRATORY CARE
5201 WEST 46TH ST
INDIANAPOLIS, IN 46254
ATTN ACCOUNTS PAYABLE

HOME RESPIRATORY CARE
5201 WEST 46TH ST
INDIANAPOLIS, IN 46254
ATTN ERIC

CUSTOMER	CUSTOMER CITY	CUSTOMER	TERMS	PARTIALS	SHIP VIA
RETURN NO.	PEP DATE	PURCHASE ORDER NO.		ALLOWED	
13511	07/25/02	072302A	12X-10 N 30	YES	UPS 2 DAYS

QTY	QTY ON HAND	QTY	UNIT	PRICE	AMOUNT
NO ORDERED	NO ORDERED	DESCRIPTION	(SHIPPED)	PRICE	AMOUNT

[illegible]

026057

SUBTOTAL	0 00
SHIPPING	0 00
TAX	0 00
NET TOTAL	0 00

001506

CAS MAIL BOX SIGNATURE		13511
HOME RESPIRATORY CARE		7/23/02
AMI PLUS W/MODEM	SERIAL Y 30200991	7285
01-05 0170	WARRANTY No	
CUSTOMER COMMENTS	NOT HAVING ALARM BEING HEARD ON SELF TEST WON'T PICK UP SIGNAL ON SIMULATOR	
REPAIR SECTION		
REPAIR COMMENTS	9/26/02 UNIT MISSING AT CAS CAN'T CLOSE PER L. HOTTIN CLOSE RGA REPLACEMENT SENT SN Y 30201503R ON SO # 39701	
INVESTIGATION	MDR 00032 sent 8/20/02 Found out later that unit was lost and thus complaint not verified	
CLOSED BY R Jeffrey	11/22/02	

026058

EDWATCH FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities
distributors and manufacturers for
MANDATORY reporting

Form Approved: OMB No. 0915-0045 Expires: 12/31/00
See OMB statement on www.gsa.gov

MR report # **2244861200200082** 50
 UNF001 report #
 FDA Use Only

Page **1** of **2**

Patient information

1. Patient identifier
 2. Age at time of event: **UNK**
 or Date of birth: **UNK**
 3. Sex **UNK**
☐ female
☐ male
 4. Weight **UNK** lbs
 or **UNK** kgs

Adverse event or product problem

Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)
 Comes attributed to adverse event (check all that apply)
☐ death (mortality)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other
 Date of event: **07/00/02**
 Date of this report: **08/16/02**
 Describe event or problem

e Home Care Dealer reports that the monitor's service light
 keeps coming on without an audible alarm. Comment is most
 likely based on the monitor's memory printout rather than a missing
 audible alarm sound.

Relevant tests/laboratory data, including dates

NA

Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)

NA

C. Suspect medication(s)

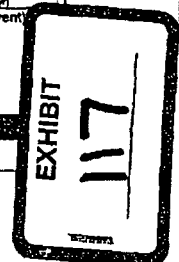
1. Name (give labeled strength & manufacturer if known)
 #1 **NA**
 #2
 2. Dose, frequency & route used
 #1 **NA**
 #2
 3. Therapy dates (if unknown give duration)
 #1 **NA**
 #2
 4. Diagnosis for use (indication)
 #1 **NA**
 #2
 5. Event abated after use stopped or dose reduced
 #1 ☐ yes ☐ no ☒ doesn't apply
 #2 ☐ yes ☐ no ☒ doesn't apply
 6. Lot # (if known)
 #1 **NA**
 #2
 7. Exp. date (if known)
 #1 **NA**
 #2
 8. Event reappeared after reintroduction
 #1 ☐ yes ☐ no ☒ doesn't apply
 #2 ☐ yes ☐ no ☒ doesn't apply
 9. NDC # - for product problems only (if known)
 #1 **NA**
 #2
 10. Concomitant medical products and therapy dates (exclude treatment of event)
NA

D. Suspect medical device

1. Brand name: **Heart Rate Respiration Monitor**
 2. Type of device: **Breathing Frequency Monitor**
 3. Manufacturer name & address:
Nelcor Puritan Bennett
2800 Northwest Blvd
Pittsburgh, MN 55441
 4. Operator of device:
☐ health professional
☒ lay user/patient
☐ other
 5. Expiration date (m/d/yyyy):
NA
 6. Model #: **9700A**
 7. If implanted give date (m/d/yyyy):
NA
 8. If explanted give date (m/d/yyyy):
NA
 9. Device available for evaluation? (Do not send to FDA)
☒ yes ☐ no ☐ returned to manufacturer on **07/23/02**
 10. Concomitant medical products and therapy dates (exclude treatment of event)
NA

E. Initial reporter

1. Name & address: **Procure Home Medical**
709 Northway Drive
Anchorage, AK 99508
 phone #: **907 274-0770**
032619
 2. Health professional?
☐ yes ☒ no
 3. Occupation:
Home Care Dealer
 4. Initial report also sent report to FDA:
☐ yes ☐ no ☒ unknown



Submission of a report does not constitute an
 admission that medical personnel, user facility,
 distributor, manufacturer or product caused or
 contributed to the event.

A Form 3500A

001508

Notification and Device
Experience Report
(continued)

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Guidelines for specific instructions

Page 2 of 2

FDA Use Only

For use by user facility/distributor-devices only

1. Check one ☐ user facility ☐ distributor		2. UFI/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (m/d/yyyy)		7. Type of report ☐ initial ☐ follow-up # _____	8. Date of this report (m/d/yyyy)
9. Approximate age of device	10. Event problem codes (refer to coding manual)		
patient code	_____ - _____ - _____		
device code	_____ - _____ - _____		
11. Report sent to FDA? yes _____ (m/d/yyyy) no _____		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____	
13. Report sent to manufacturer? yes _____ (m/d/yyyy) no _____		14. Manufacturer name/address	

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code.		4. Device manufacture date (m/d/yyyy) 02/10/98	
5. Labeled for single use? ☐ yes ☒ no		6. Evaluation codes (refer to coding manual)	
method	10	33	_____ - _____
results	710	100	_____ - _____
conclusions	54	63	_____ - _____
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☐ unknown	
9. If action reported to FDA under 21 USC 360(i) list correction/removal reporting number			

10 ☒ Additional manufacturer narrative and/or 11 ☐ Corrected data

H-6(Results/ conclusions)

Service report stated Eprom not seated down all the way
Probably not a factor in problem. Microphone needing
replacement was a solution to the problem which was that the
alarm was heard but microphone did not pick it up and reported to
memory download that it was not heard

Replacing the alarm beeper was as a precaution

032620

All manufacturers

Contact office - name/address (& mailing site for devices)		2. Phone number	
AS Medical Systems Inc 4 E. Industrial Rd ranford CT 06405 Attn: Ron Jeffrey Note: CAS purchased product line after this device was manufactured from Bellco Puritan Bennett 800 Northwest Blvd Plymouth MN 55441		203-488-6056	
Date received by manufacturer (m/d/yyyy) 3/7/16/02		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other Dealer	
4. IF IND protocol # na		5. (A) NDA # na IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes	
Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ Initial ☐ follow-up # _____		6. Advise event term(s) NA	
7. Mfr report number 861200200032 30 EP 6 12			

A public reporting burden for this collection of information has been estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

1. Reports Clearance Office
Department of Health and Human Services
Hubert H. Humphrey Building, Room 527-01
200 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number.

PI 83 DO NOT RETURN this form to this address

DA Form 3500A back

CAS MACHINERY MEDICAL
13479
DATE CLOSED 7/16/02

CUSTOMER PROCARE HOME MEDICAL CUSTOMER 6628

MODEL AMI MONITOR W/O MODEM SERIAL # 480288

PART # 01 05 0162 No

CUSTOMER COMMENTS
THE LIGHT KEEPS COMING ON NO ALARM DOWNLOAD SAYS HEART BEAT THIS
UNIT WAS IN A FEW TIMES FOR THE SAME PROBLEM

REPAIR SECTION
PART 2 0328 28 02 0 PART 3 0309 28 02 0 PART 4 28 02-0361 PART 5 21 01-0886

REPAIR COMMENTS
REPLACED SONALARMS AND MICROPHONE TIE WRAPPED EPROM DOWN AS A
PRECAUTION INTALLED A MODEM PATCH COVER PASSED ALL FUNTIONAL AND
FINAL TESTS

INVESTIGATION
COULD NOT VERIFY COMPLAINT MONITOR HAS ALL UPDATES VERSION 13 0
PERFORMED DOWNLOAD EPROM NOT SEATED ALL THE WAY INTO SOCKET FIRST
DOWNLOAD INDICATED NO AUDIO ALARM SECOND DOWNLOAD WAS FINE TAPED
DOWN BATTERY LID MDR # 00030 sent 8/16/02 see it.

CLOSED BY R Jeffrey DATE CLOSED 8/16/02

032621

ENTERED JUL 18 2002 *Carroll*

PRODUCT INFORMATION FORM (PIF)

RGA OR PC <u>13479</u>		PATIENT INJURY OR DEATH Y ☐ N ☒	
PRODUCT COMPLAINT Y ☐ N ☒		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD <u>(6628)</u>	
A.	FORM FILLED OUT BY <u>Dotty</u>	CUSTOMER NAME <u>Procure Home Med</u>	
	DATE OF THIS REPORT <u>7/16/02</u>	ADDRESS <u>709, No Way Dr</u>	
	PRODUCT <u>9708A 08/16/02</u>	<u>Anchorage AK 99508</u>	
	LOT/SERIAL # <u>480288</u>	COMPLAINANT <u>Carol</u>	
	QUANTITY <u>1</u>	PHONE <u>907-274-0770</u>	
INFORMATION DETAILS			CHECK IF OUT OF BOX FAILURE ☐
<u>The life keeps coming on - no alarm - but download states heartbeat</u> <u>* Unit has been in several times - same problem</u>			
ACTION TAKEN THUS FAR			
B.	DATE LOGGED AT QA <u>7/18/02</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION		
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)		
	<u>SEE Access @ 8/16/02 See Service Report</u>		
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>Mon # 00032³⁰⁰ Sent 8/16/02</u> <u>See Service Report</u>			
REASON FOR NO REPLY TO COMPLAINANT			026133
CLOSE OUT			
SIGNATURE <u>[Signature]</u>		DATE <u>8/16/02</u>	

CAS MEDICAL SYSTEMS INC FORM 21-04-0045 REV 04

		13479
		7/16/02
CUSTOMER	PROCARE HOME MEDICAL	6628
MODEL	AMI MONITOR W/O MODEM	480288
PART	01-05 0162	No
CUSTOMER COMMENTS	THE LIGHT KEEPS COMING ON NO ALARM DOWNLOAD SAYS HEART BEAT THIS UNIT WAS IN A FEW TIMES FOR THE SAME PROBLEM	
REPAIR SECTION		
PA 22 0328 28-02-0	PA 23 0309 28-02-0	28 02 0361 21 01 0886
REPAIR COMMENTS	REPLACED SONALARMS AND MICROPHONE TIE WRAPPED EPROM DOWN AS A PRECAUTION INTALLA A MODEM PATCH COVER PASSED ALL FUNTIONAL AND FINAL TESTS	
INVESTIGATION	COULD NOT VERIFY COMPLAINT MONITOR HAS ALL UPDATES VERSION 13 0 PERFORMED DOWNLOAD EPROM NOT SEATED ALL THE WAY INTO SOCKET FIRST DOWNLOAD INDICATED NO AUDIO ALARM SECOND DOWNLOAD WAS FINE TAPED DOWN BATTERY LID MDR # 00030 sent 8/16/02 see it	
CLOSED BY	R Jeffrey	8/16/02
026140		

CAS MEDICAL SYST IS INC.
 MEDICAL TECHNOLOGY APPLIED TO MEDICINE
 44 EAST INDUSTRIAL RD., BRANFORD, CT 06405
 203-488-6058 FAX 203-488-9438

Page 1 of 1
 DATE 08/15/02

CUSTOMER RETURN

PACKED BY: MEN

SOLD TO 068
 PROCAPE HOME MEDICAL
 709 NORTHWAY FIVE
 ANCHORAGE AL 99508

SHIP 1 LESS
 10942 HOURS 00:00
 10942 HOURS 00:00
 10942 HOURS 00:00

ATTN: ACCOUNTS PAYABLE

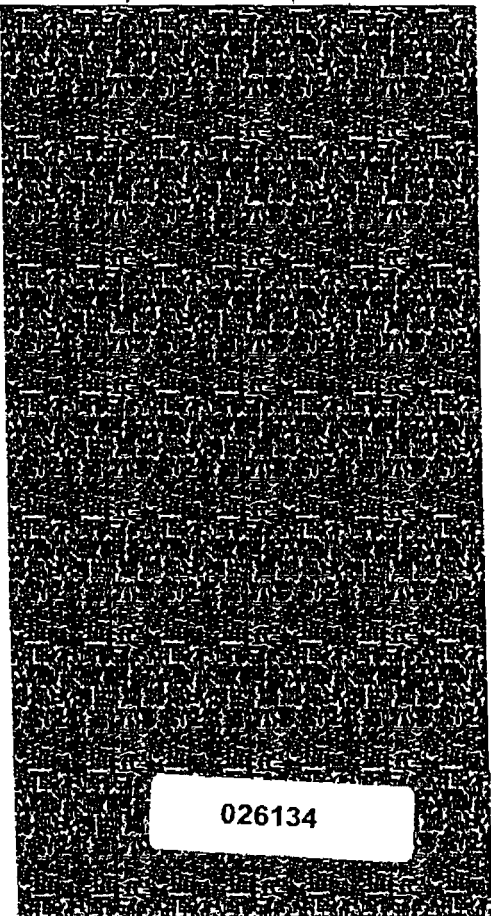
DATE NOTIFIED	DATE RECEIVED	CUST PO#	BUYER	SALESMAN	TAX
07-16-02	07-23-02		CAROL		1.04

FRIGHT	TERMS	DATE
	10-1-30	07-16-02

LI#	PART#	DESC	QTY	RET	UNIT PRICE

1 101 05 0160
 101 MONITOR W MODEM
 Under warranty NO
 RESUME RETURNED
 08 NON-WARRANTY 101-0-52- 1606
 SN 490720
 SCHED-DATE DTV
 07-16-02
 THE LIGHT KEEPS COMING
 ON-NO ALARM DOWNLOAD
 SAYS HEART BEAT-***
 THIS UNIT WAS IN A FEW
 TIM S FOR THE SAME
 PROBLEM PLS CHECK
 IT OUT *****

*See attached
 for part #
 change
 Ann
 8-16-02*



026134

SERVICE REPORT

SECTION A Procedure Number		CUSTOMER <u>PRO CARE HOME MEDICAL</u>	
IGA # or S/O # <u>13479</u>	MODEL # <u>9200 w/8 MODEM</u>	SERIAL # <u>480288</u>	ESTIMATE REQUIRED ☐ Wait for customer approval
DATE RECEIVED <u>7-23-02</u>	CUSTOMER TRACKING No <u> </u>		
LOCATION of LABEL <u> </u>			

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	Patient Cable	Carrying Case
Battery	Temp Probe	
SPO2 Sensor	AC Line Cord	

Cuff and Size

Pass/Replace

CUSTOMER REQUEST/COMPLAINT

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement. THE LIGHT KEEPS COMING ON - NO ALARM - DOWNLOAD SAYS HEART BEAT THIS UNIT WAS IN A FEW TIMES FOR THE SAME PROBLEMS PLEASE CHECK IT OUT

INITIAL FINDINGS

MONITOR HAS ALL UPDATES VERSION 13.0 Performed download EPROM not seated all the way into socket First download indicated no audio alarm Second download was fine. Taped down battery lid

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) N PO Number Obtained (Y/N) ☐ PO #

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification	<u>Other Replaced sonalarms and microphone. Re-wrapped EPROM down (as a pre-caution) INSTALLED</u>
☒ Passed all functional tests	
☒ Passed all final tests	

A MONITOR PATCH COVER

ECN Update # 032622

	Rec.	2Min.	Final	Repair	Total	Date to QA
TECH			<u>Paul</u>	<u>Paul</u>		<u>8-14-02</u>
DATE			<u>8-14-02</u>	<u>8-14-02</u>	Time	
LABOR			<u>5</u>	<u>10</u>	<u>15</u>	

 CAS MEDICAL SYSTEMS, INC. TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number	SVC9700PUL	Rev	B	9700X Parts Used List

Qty	Part Number	Description
	15-06-0099	9700 Software
	15-06-0105	9700G German Software
	15-06-0103	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	03-09-0225	Battery Alarm board
	17 08-0371	150VAC 150pfd Varistor
	02 03 0038	1 1/4 Conductive Tape
	16-04-0190	1ufd Capacitor (R225)
	17 09-0325	10K SMT Resistor (R999)
	16-04-0085	0 1ufd cap (C235)
	29 01-0218	Feet case
	28-02-0275	Foot Rubber (square)
0	28-02-0402	Remote Alarm Gasket

S/O #

RGA #

13479

S/N

480288

Date

8-14-03

Other Parts Used

Qty	Part Number	Description
	21 01-1190	Ami Battery Drawer Label
1	28-02-0328	CAP DUST 25 PIN
1	28-02-0408	Clear Polyester Label
	21-01-1055	AMI Battery Seal
	21-01-1001	AMI Warranty Void Label
	21 01-1004	AMI Plus Battery Label
	21-01 1009	AMI Plus Warranty Void Label
	03-08-0351	AMI Plus Battery Assembly
	22 02-0112	Patient Cable Jack
	17 08-0123	1Meg Resistor - AMI Plus
	18-01-0042	2 20 AWG Red Wire AMI Plus
2	03-08-0309	Sonabert
2	28-02-0275	Sonabert gaskets
1	28-02-0361	Microphone
1	21-01-0586	MCDEM PATCH CORD

032624

REPORT Single Run Summary

TECHNICAL REPORT 2126

JAL NUMBER 480288

TEST RESULTS PASSED

REVISION 13 *Ami Final Test*

TEST DATE 8/14/02

MODEL NUMBER L-9700/G/S

PART NUMBER Y-006122-0XA



TIME	TEST	TEST DESCRIPTION	STATUS
11 44 03 AM	1	Initial Power Up	PASSED
11 44 04 AM	2	Version & Serial Number Verification	PASSED
11 44 44 AM	3	Time & Date	PASSED
11 45 21 AM	4	Patient Setup	PASSED
11 45 32 AM	5	Patient Limits	PASSED
11 45 40 AM	6	Access Code	PASSED
11 46 13 AM	7	O2 Desat	PASSED
11 54 09 AM	8	Signal Quality Indicator	PASSED
11 57 00 AM	9	Resp Detect min, mid, and max	PASSED
11 58 11 AM	10	ECG Crosstalk	PASSED
12 02 31 PM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
10 13 PM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
12 11 22 PM	13	Apnea Alarm ECG = RESP	PASSED
12 12 09 PM	14	Human Alarm Condition - Heart Slow	PASSED
12 13 12 PM	15	Human Alarm Condition - Apnea	PASSED
12 13 31 PM	16	Power Alert Function	PASSED
12 13 40 PM	17	WatchDog Test	PASSED
12 15 07 PM	18	Data Transfer & Recording Verification	PASSED

032625

PERATOR Bruce M. Wooding

STATION ID 1

RUN ID 1530

PAGE 1

001517

CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English *w/out modem*
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 480288
WORK ORDER # _____
RGA # 13479

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3. REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete
and conforms to test data specifications
4.2 If this is an RGA, verify accessories are with
unit if applicable

✓
✓

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

032626

CAS MEDICAL SYSTEMS INC.

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 2 OF 3

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST. CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING

7.1 Power up unit under test

- A) LED lights strobe through self-test
- B) LCD display strobes through self-test
Parameters
- C) Alarm sounds at both front and
rear panel locations
- D) When patient leads disconnected from
monitor the front panel alarms

✓
✓
✓
✓

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR.
As followed

- 120 BPM
- 50 BREATH

8.1 With unit under test connected to simulator, verify the following

- A) Heartbeat and Respiration LED s flash
- B) Remove patient leads from monitor
Patient Lead LED lights and alarms from
front panel
- C) Replace patient leads on monitor the
alarm is off and Patient Loose Lead
LED remains on.
- D) Press reset to turn Loose Lead
LED off
- E) Press APNEA button on simulator
The alarm turns on along with
APNEA LED
- F) Press APNEA button again.
After 20 seconds audio alarm turns
off but APNEA LED remains on.
- G) Turn the monitor off (press RESET and
POWER simultaneously) wait about 30 sec
and verify you hear a double beep

PASS

FAIL

✓
✓
✓
✓
✓
✓
✓

032627

Jeffrey, Ron

^ L
To Blanusa Tracy
Cc Wednesday August 14 2002 9 35 AM
Subject Jeffrey Ron
Hottin Lenny
RE RGA13479

Ron

I have checked the history on this particular RGA. it belongs to ProCare in Alaska, S/N 480288 since last February- this unit has been in five times already prior to the issuing of RGA #13479

RGA #7080 2/5/01 Broken Patient Cable Jack
RGA #7785 3/14/01 - Replaced Battery Recertification ~ we clear & working
RGA #9266 6/01/01 Service light kept coming on service dept cleared memory service light no longer flashes
RGA #10837 - 9/24/01 - Service light kept coming on our service dept cleared memory service light no longer flashes
RGA #30504 - 3/13/02 ESD Update Service light problem CAS updated unit, cleared memory service light no longer a problem

From info
- a new
Battery

New RGA #13479 - Bruce Wooding has the unit, just did a download off the unit, needs to evaluate the download and then hook up to a simulator He will let us know what he finds from the download

If you have any other questions please let me know

Thanks
Tracy

No Service Light Prob in
download Not picking up
Sound of alarm

-----Original Message-----

From Jeffrey Ron
Sent Tuesday August 13 2002 3:50 PM
To Hottin Lenny
Cc Blanusa Tracy Saccavino Doty
Subject RGA13479

This 9700A should receive some priority as it has been in before I cannot determine from the recorded comments if an MDR (due Thursday) is required It probably is but could we get more input from the customer? Thanks

Ron Jeffrey
Director Regulatory Affairs
CAS Medical Systems Inc
44 E Industrial Rd
Branford CT 06405 USA
rjeffrey@casmed.com

032628

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0910-0231 Expires 01/01/01
Do not duplicate

MDR report #	2244861200200041
UFDist report #	
FDA Use Only	

A. Patient information

1 Patient identifier UNK	2 Age at time of event: UNK or Date of birth: UNK	3 Sex UNK ☐ female ☐ male	4 Weight UNK lbs or kg

B. Adverse event or product problem

1 ☐ Adverse event and/or ☒ Product problem (e.g. defects/malfunctions)	
2 Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
☐ other	

3 Date of event (m/d/yyyy)	4 Date of this report (m/d/yyyy)
10/00/02	11/25/02

5 Describe event or problem

The dealer reports that the monitor's green respiration and heart rate light stopped for a long period of time with no audible alarms

6 Relevant tests/laboratory data including dates

NA

7 Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2	
2 Dose frequency & route used	3 Therapy dates (if unknown give duration) (months for best estimate)
#1 NA	#1 NA
#2	#2
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6 Lot # (if known)	7 Exp date (if known)
#1 NA	#1 NA
#2	#2
8 Event appeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9 NDC # - for product problems only (if known)	
NA -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1 Brand name	
Heart Rate Respiration Monitor	
2 Type of device	
Breathing Frequency Monitor	
3 Manufacturer name & address	4 Operator of device
CAS Medical Systems Inc 44 E. Industrial Rd Branford CT 06405	☒ health professional ☐ lay use /patient ☐ other
5 Expiration date (m/d/yyyy)	6 model #
NA	
7 If implanted give date (m/d/yyyy)	8 If explanted give date (m/d/yyyy)
NA	NA
9. Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 10/29/02 (m/d/yyyy)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

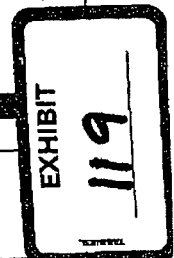
E. Initial reporter

1 Name & address	phon #
South West SIDS PSA 100 Medical Dr RM 220 Lake Jackson TX 77566	979-299-2814
032640	
2 Health professional?	3 Occupation
☒ yes ☐ no	Home Care Dealer
4 Initial reporter also sent report to FDA	
☐ yes ☐ no ☒ nk	



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event



001521

Medication and Device Experience Report

continued)

to guidelines for specific instructions

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

Page 2 of 2

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food Drug Administration

FD-302 (Rev. 10-1-95)

I. For use by user facility/distributor-devices only

1. Check one ☐ user facility ☐ distributor		2. UFI/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (month/year)		7. Type of report ☐ initial ☐ follow-up # _____	
8. Date of this report (month/year)		9. Approximate age of device	
10. Event problem codes (refer to coding manual)		11. Report sent to FDA? ☐ yes (month/year) ☐ no	
12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____		13. Report sent to manufacturer? ☐ yes (month/year) ☐ no	
Manufacturer name/address			

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code: _____		4. Device manufacture date (month/year) 05/15/01	
5. Labeled for single use? ☐ yes ☒ no		6. Evaluation codes (refer to coding manual)	
method		10 - 33 - - -	
results		708 - - - -	
conclusions		71 - 65 - 74 - -	
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f) list correction/removal reporting number NA		10. Additional manufacturer narrative and/or 11. Corrected data NA	

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)		2. Phone number	
CAS Medical Systems Inc 44 E Industrial Rd Branford CT 06405 Attn: Ron Jeffrey		203-488-6056	
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other DEALER		4. Date received by manufacturer (month/year) 10/28/02	
5. (A) NDA # NA IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes		6. If IND protocol # NA	
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ initial ☐ follow-up # _____		8. Adverse event term(s) NA	
9. Mfr report number 744861200200041			

032641

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington, D.C. 20201

FD-302 (Rev. 10-1-95)
Paperwork Reduction Project (99-0291)
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

As agency may not conduct or sponsor or not person is not required to respond to collection of information unless it displays currently valid OMB control number

Please DO NOT RETURN this form to this address

AS MEDICALS

60018

10/28/02

CUSTOMER: SOUTH WEST SIDS PSA

6215

MODEL: AMI PLUS W/MODEM

10118093

01 05 0170

No

CUSTOMER COMMENTS:

RED TAG RON JEFFREY SERVICE LIGHT STAYS ON GREEN RESPIRATION AND
HEART RATE LIGHT STOP FOR A LONG PERIOD OF TIME WITH NO ALARMS UNIT
WAS IN 6/4/02 UNDER RGA # 13173 FOR A SERVICE LIGHT PROBLEM

REPAIR COMMENTS:

PARTS: 28 02 0328

28-02 0408

21-01 1004

21-01 1009

REPAIR COMMENTS:

NO SERVICE LIGHT PROBLEMS AT ALL, ATTACHED COPY OF DOWNLOAD PASSED
ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION:

UNIT HAS ALL UPDATES NO PROBLEM FOUND DOWNLOAD OK MONITOR TESTED
FOR 2 WEEKS AND IT WORKS NORMALLY BATTERY DATED 12/01 NOT 2 YRS OLD
YET MDR 00041 sent 11/25/02

CLOSED BY:

R Jeffrey

11/25/02

032644

✓ ENTERED OCT 29 2002 *QML*

PRODUCT INFORMATION FORM (PIF)

RGA OR PC <u>600018</u>		PATIENT INJURY OR DEATH Y ☐ N ☒		6215
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD		
A	FORM FILLED OUT BY <u>JDH</u>	CUSTOMER NAME <u>S.W. Sips</u>		
	DATE OF THIS REPORT <u>10/28/02</u>	ADDRESS <u>100 Medical Dr Pm 200</u>		
	PRODUCT <u>9700B</u>	<u>Lake Jackson, TX 77566</u>		
	LOT/SERIAL # <u>10118093</u>	COMPLAINANT <u>Ruby</u>		
	QUANTITY <u>1</u>	PHONE <u>979-299-2814</u>		
INFORMATION DETAILS				CHECK IF OUT OF BOX FAILURE ☐
<u>Service light stay on</u>				
<u>Green respiration & heart rate light stay for a long period of time w/ no alarms</u>				
<u>Unit was in 6/4/02 PGA 13173 for service life problem</u>				
<u>[REDACTED]</u>				
ACTION TAKEN THUS FAR				
B	DATE LOGGED AT QA <u>10/29/02</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION			
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)			
	<u>See Service Report</u>			
REASON FOR NO INVESTIGATION		AUTHORIZED BY		
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)				
<u>MDR # 00041 Sent 11/25/02</u>				
<u>See Service Report</u>				
018696				
REASON FOR NO REPLY TO COMPLAINANT				
CLOSE OUT				
SIGNATURE <u>Ruby</u>		DATE <u>11-25-02</u>		

PRODUCT INFORMATION FORM (PIF)

RGA OR PC <u>60018</u>		PATIENT INJURY OR DEATH. Y ☐ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A	FORM FILLED OUT BY <u>Ruby</u>	CUSTOMER NAME <u>S.W. Sips</u>	
	DATE OF THIS REPORT <u>10/28/02</u>	ADDRESS <u>100 Medical Dr Pm 2X</u>	
	PRODUCT <u>9700B</u>	<u>Lake Jackson, TX 77566</u>	
	LOT/SERIAL # <u>10118093</u>	COMPLAINANT <u>Ruby</u>	
	QUANTITY <u>1</u>	PHONE <u>979-299-2814</u>	
INFORMATION DETAILS			CHECK IF OUT OF BOX FAILURE ☐
<u>= Service light stay on</u> <u>Green respiration & heart rate light stay for a long period of time w/ no alarms</u> <u>Unit was in 6/4/02 RGA 13173 for service life problem</u>			
ACTION TAKEN THUS FAR			
B	DATE LOGGED AT QA <u> </u> / <u> </u> / <u> </u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION		
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)		
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
018711			
REASON FOR NO REPLY TO COMPLAINANT			
CLOSE OUT			
SIGNATURE		DATE	

SERVICE REPORT

SECTION A Procedure Number

RGA # or S/O #	60018	CUSTOMER	South west SIDS PSA
MODEL #	9700B w/modern	SERIAL #	40118093
DATE RECEIVED	10 29 02	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No	
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patent Cable		Carrying Case	
Battery		Temp Probe			
SPO2 Sensor		AC Line Cord			
Cuff and Size					
Pass/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification
 ☐ Preventative Maintenance
 ☐ Data Download
 ☐ Evaluation Request

☒ Customer Statement Service light stays on, Green expiration and heart rate light stay for long period of time. With no alarm unit was in 6/4/02 RGA 18173 for service light problem.

INITIAL FINDINGS

unit - had all updates, no problem found downloading ok, monitor tested for 2 weeks and it works normally. MONITOR HAS ALL UPDATES BATTERY DATED 12/01. BATTERY ONLY 7 YEARS OLD YET

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ N PO Number Obtained (Y/N) ☒ N PO # _____

☐ QA Required
 ☐ Engineering Required
 ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification ☒ Passed all functional tests ☒ Passed all final tests	Other <u>attach copy of downloading</u> <u>MONITOR HAS ALL UPDATES</u> <u>NO SERVICE LIGHT PROBLEMS ANY MORE</u> <u>AT ALL</u>

ECN Update # _____

032642

	Rec.	2Min	Final	Repair	Total
TECH			CRK		
DATE			11-19-02		
LABOR			1/2		1/2

Date to QA

11-22-02

Module
Module

Medical Systems
POLICY APPLIED TO MEDICINE
SVC9700PUL

SERVICE PROCESS

Sht. 1 of 1

Rev D 9700X Parts Used List / Leakage Tests

Other Parts Used

Part Number	Description	Qty	Part Number	Description
15-06-0099	9700 Software		21-01 1190	AMI Battery Drawer Label
15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
03-09 0225	Battery Alarm board		21-01 1001	AMI Warranty Void Label
17 08-0371	150VAC 150pfid Vanstor	1	21-01 1004	AMI Plus Battery Label
02-03-0038	1 1/4 Conductive Tape	1	21-01 1009	AMI Plus Warranty Void Label
16-04-0190	1uFd Capacitor (R225)	1	03-08-0351	AMI Plus Battery Assembly
17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack
16-04-0085	0 1ufo cap (C235)		17-08-0123	1Meg Resistor AMI Plus
29-01-0218	Feet case		18-01-0042	2 20 AWG Red Wire - AMI Plus
28-02-0275	Foot Rubber (square)		03-08-0314	AMI Battery Assembly
0 28-02 0402	Remote Alarm Gasket			

S/C# or RGA# 60018 S/N 10118093

Final Test Data Sheet

Tested By _____

This page not sent

PASS ☐ FAIL ☐

TEST	FAIL	REWORK	REJECT
6 1 5 Cr			
6 2 5 Leakage Test (Chassis)			uA <15 LA
6 2 7 Leakage Test (Patent Lead)			uA <15 LA

Failure Detail _____

Created on: 01/17/2001

Last Update: 09/25/2002

Printed on: 01/15/02

032643

001527

PAGE 1 OF 1

DATE 10/28/02

ACKNOWLEDGEMENT
60018

SOLD TO 6215
SOUTH WEST SIDS PSA
100 MEDICAL DR RM 220
LAKE JACKSON, TX 77566

SHIP TO: 6215
SOUTH WEST SIDS PSA
100 MEDICAL DR RM 220
LAKE JACKSON, TX 77566

ATTN ACCOUNTS PAYABLE

ATTN KATHY

FREIGHT

TERMS
27-10 N 30

SHIP-VIA
UPS 3 DAYS

1/ PART# 01-05-0170
AMI PLUS, 9700B, ENGLISH W/MODEM
Under Warranty NO
REASONS RETURNED
98 NON-WARRANTY, 501-0-50-1, 1607
SN 1011809C
SCHED-DATE 01/
10-28-02 1

SERVICE LIGHT STAYS ON
GREEN RESPIRATION AND
HEART RATE LIGHT STOP
FOR A LONG PERIOD OF
TIME WITH NO ALARMS
UNIT WAS IN 6/4/02
UNDER RGA# 13173 FOR
A SERVICE LIGHT PROBLEM
*****RED TAG*****
*****RON JEFFREY*****

018697

001528

Preliminary Study Report

Ami Apnea Monitor

Summary Report

« Patient Information »

Gender [None]
Birth Date 10/29/02

10118093

Gestational
Study Age

[Not Entered]

40 weeks
0 0 weeks

« Study Ends »

Ami Monitor 10/29/02 Tue
Rep Gen PC 10/29/02 Tue

13 58 20
13 42 01

[At Time Of Transfer]

« Monitor Setup »

Aux 1 Signal O2 Satur
Aux 2 Signal PulseRate
Aux 3 Signal Airflow

HR Slow Mode
Event Capture
Apnea 50%
HFast 0%

3 Consec Beats
Longest Events
HSlow 50%
Desat 0%

« Monitor Limits »

Apnea Alarm 15 Sec
Heart Slow 80 BPM
Heart Fast 225 BPM

Apnea Log
Heart Slow
Heart Fast
Desaturation

10 Sec
80 BPM
225 BPM
85 % Sat

« Recorded Events »

Monitor Logs 7 of 2000
Patient Logs 1 of 2000
Event Waves 0 0% Filled

Study Start
Study Period
Monitor Time

10/23/02 Wed 15.23
5 Days 23 Hours
1 Min 38 Secs [0 0%]

« Recorded Waveforms »

No Waveforms Available

« Events Counted »

Monitor Ons 3
Apneas 0
Desaturations 0
Loose Leads 1

Monitor Offs 2
Heart Slows 0
Heart Fast 0

« Modem Answer Only »

« System Version »

Serial Numb 10118093
Access Code [NONE]

Ami Monitor 13 00 28 NOV-01
Report Generator 01 1a 19-Mar 99

Copyright (c) 1997 98 Nellcor Puritan Bennett Inc. [»

018702

10118093 #[Not Entered]

Page 1

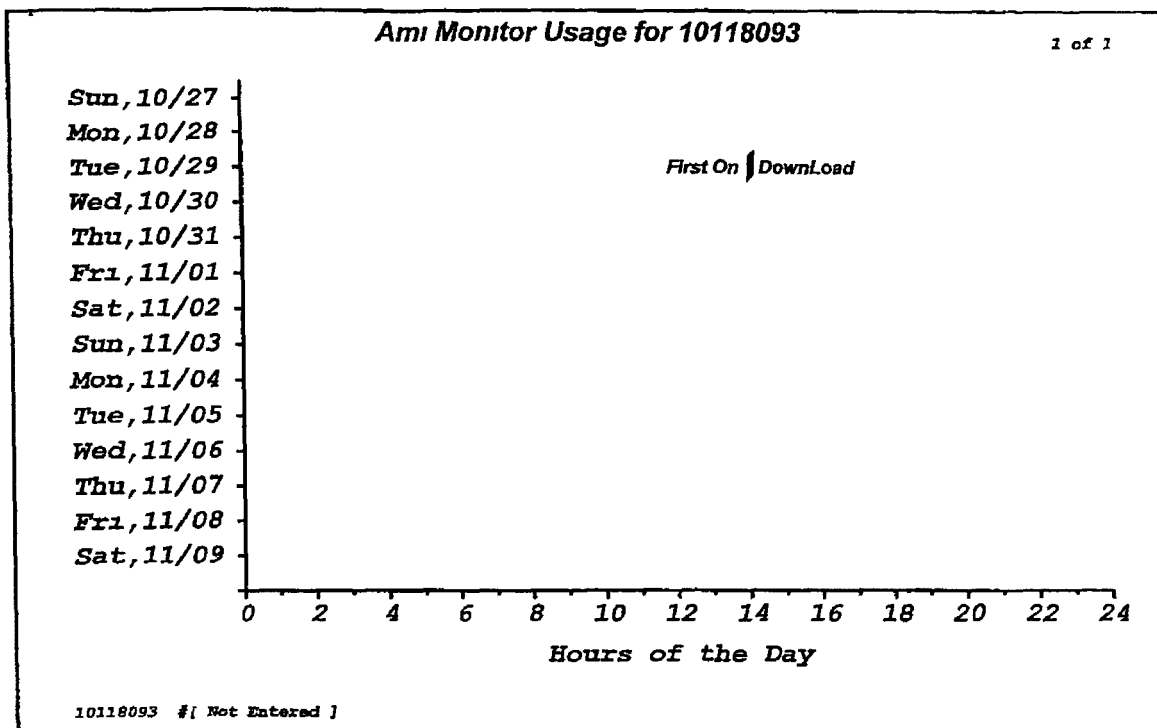
10/29/02 13 58

001529

Nelcor Puritan Bennett

AmI Apnea Monitor Patient Logs

	Date	Time	Event Type	Event Duration
1	10/29	13 53 10	Loose Lead	2 Secs
	10/29	13 58.20	Received 1 Patient Log	
	Copyright (c) 1997 98		Nelcor Puritan Bennett Inc.	



018704

Nellcor Puritan Bennett

Ami Apnea Monitoring Periods

Previous Recording Session Cleared

10/23	15:23 10	thru	10/23	15 23 49	39 Secs
10/29	13 52 40	thru	10/29	13 53 12	32 Secs
10/29	13 57 12	thru	10/29	13 57:39	27 Secs

Duration of the Study Period Was	5 Days 23 Hours
Total Time Monitor Was Recording	1 Min 38 Secs
Total Time Monitor Was Turned Off	5 Days 23 Hours
% of Study Period Monitor Was On	0 0%

Copyright (c) 1997 98

Nellcor Puritan Bennett Inc.

2

018705

10118093 #[Not Entered]

Page 1

10/29/02 13 58

001532

Neilcor Puritan Bennett

AmI Apnea Monitor All Study Logs

	Date	Time	Event Type	
< 1 >	09/19	16 35 43	Monitor Powered Up	
< 2 >	10/23	15 23 10	New Recording Start	
< 3 >	10/23	15 23 49	Monitor Powered Down	
< 4 >	10/29	13 52 40	Monitor Powered Up	
1	10/29	13 53 10	Loose Lead	2 Secs
< 5 >	10/29	13 53 12	Monitor Powered Down	
< 6 >	10/29	13 57 12	Monitor Powered Up	
< 7 >	10/29	13 57 39	Detection Disabled	
<Ami>	10/29	13 58.20	Received 7 Monitor Logs	
	10/29	13 58.20	Received 1 Patient Log	

Event Count Totals

3 Monitor Ons	2 Monitor Offs
0 Apneas	0 Heart Slows
0 Desaturations	0 Heart Fasts
1 Loose Leads	

Copyright (c) 1997 98

Neilcor Puritan Bennett, Inc

018706

CUSTOMER RETURN TRAVELLER

**** RECEIVING ****

RECEIVER# 41219
CR# LI# CR60018 1
DATE RECEIVED 10-29-02
PACKING LIST# 00
NO OF CARTONS 1
CUST# CUST NAME 6215 SOUTH WEST SIDS PSA
PART# REV 01-05-0170 REV 12
DESCRIPTION AMI PLUS, 9700B, ENGLISH W/MODEM
ACCT# 500-0-50-1
QUANTITY RECEIVED 1
PO#
CONTACT NAME KATHY
CONTACT PHONE 979-299-2814
TAKEN BY DOTTY
SERIAL NUMBERS 10118093

RETURN CODES/REASONS

98 NON-WARRANTY, 501-0-50-1, 1607

COMMENTS

SERVICE LIGHT STAYS ON
GREEN RESPIRATION AND
HEART RATE LIGHT STOP
FOR A LONG PERIOD OF
TIME WITH NO ALARMS
UNIT WAS IN 6/4/02
UNDER RGA# 13173 FOR
A SERVICE LIGHT PROBLEM
*****RED TAG*****
*****RON JEFFREY*****

**** INSPECTION ****
Date of Inspection 11/26/02
Inspector's Initials J
AQL Level
Total Qty Inspected 1 EA
Inspected-Loss Qty 0 EA
Total Qty Accepted 1 EA
Total Qty Rejected 0 EA

**** STORES ****
Received By
Received Qty
Stock Date
Stocked By
Stocked Qty
Stock Location
Variance Qty
New Qty On-Hand

Oct 11-19-02
MONITOR NEEDS BASIC FUNCTIONAL
TESTS. MONITOR WAS RUN
FOR TWO WEEKS WITH OUT
ANY PROBLEMS AT ALL
MONITOR HAS ALL UPDATES

BATTERY DATED 12/01.
BATTERY NOT 2 YEARS
OLD YET

OTT
N/K
Called Southwest SIDS PSA
on 11/25/02 and spoke to
Kathy Informed her that
CAS could not duplicate the
problem She had no further
details to offer

MM 018707

CAS MEDICAL SYSTEMS INC.

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 10118093
WORK ORDER # _____
RGA # 60018

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01 0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21 01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21 01 0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01 1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03 08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete
and conforms to test data specifications
4.2 If this is an RGA, verify accessories are with
unit if applicable

✓
N/A

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

018708

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 3 OF 3

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:

- ↓
- 8.3.1 Display will say "NEW PATIENT", press for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.
 - 8.3.2 Press Mode button until you reach time/date setting. Verify time/date stamp is correct.
 - 8.3.3 Press mode button. Display will ask if test is complete. Press enter then press for yes and verify unit under test turns off.

PASS

☒ Inspection of unit is completed and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY

JS

Date

11-26-08

FAIL

☐ Reason for rejection:

QA Inspector

Date

Correction made

QA Inspector

Date

018709

001536

CAS MEDICAL SYSTEMS, INC.

TECHNOLOGY APPLIED TO MEDICINE

14 EAST INDUSTRIAL RD. BRANFORD CT 06405

203-488-8056 FAX 203-488-9438

PAGE 1 OF 1

DATE 10/28/02

CUSTOMER RETURNS

ACKNOWLEDGEMENT

60018

SOLD TO 6215

SOUTH WEST SIDS PSA
100 MEDICAL DR RM 220
LAKE JACKSON, TX 77566

ATTN ACCOUNTS PAYABLE

SHIP TO 6215

SOUTH WEST SIDS PSA
100 MEDICAL DR RM 220
LAKE JACKSON, TX 77566

ATTN KATHY

DATE NOTIFIED	DATE RECEIVED	CUSTOMER	BUYER	SALESMAN	TAX
10-28-02					

FREIGHT	TERMS	SHIP-VIA
	24-10 N 30	UPS 3 DAYS

LT#	PART#	DESC	QTY	RET	UNIT PRICE
11	01-05-0170		1		0 00
		AMI PLUS, 9700B, ENGLISH W/MODEM			
		Under Warranty NO			
		REASONS RETURNED			
		98 NON-WARRANTY, 501-0-50-1, 1607			
		SN 10118093			
		SCHED-DATE QTY			
		10-28-02 1			
		SERVICE LIGHT STAYS ON			
		GREEN RESPIRATION AND			
		HEART RATE LIGHT STOP			
		FOR A LONG PERIOD OF			
		TIME WITH NO ALARMS			
		UNIT WAS IN 6/4/02			
		UNDER RGA# 13173 FOR			
		A SERVICE LIGHT PROBLEM			
		*****RED TAG*****			
		*****RON JEFFREY*****			

018710

001537



FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved OMB No. 0910-0291 Expires 01/31/03
See OMB statement on reports

MDR report #
2244861200200042
Official report #
FDA Use Only

A. Patient information

Patient identifier UNK	2. Age at time of event UNK or Date of birth UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or kgs

In confidence

3. Adverse event or product problem☐ Adverse event and/or ☒ Product problem (e.g. defects/malfunctions)Outcomes attributed to adverse event
(check all that apply)

☐ death (mandatory)	☐ disability
☐ life threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

Date of event
(mandatory) 10/00/024. Date of this report
(mandatory) 12/02/02

D. describe event or problem

Home Care Dealer reports that when testing monitor on a simulator unit is not alarming when it should and that alarms are not consistent.

Relevant tests/laboratory data including dates

NA

Other relevant history including preexisting medical conditions (e.g. allergies, race pregnancy smoking and alcohol use hepatic/renal dysfunction etc.)

NA

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose frequency & route used	3. Therapy dates (if unknown give duration) Route (or best estimate)
#1 NA	#1 NA
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 NA	#1 NA
#2	#2
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441	4. Operator of device ☐ health professional ☒ lay user/patient ☐ other
5. Expiration date (mandatory) NA	6. model # 9700A
7. If implanted give date (mandatory) NA	catalog # NA
8. If explanted give date (mandatory) NA	serial # 482564
	lot # NA
	other # RGA14064
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☒ returned to manufacturer on 11/06/02 (mandatory)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1. Name & address Procure Home Medical 709 Northway Drive Anchorage AK 99508	phone # 907 274-0770 032645	
2. Health professional? ☐ yes ☒ no	3. Occupation Home Care Dealer	4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

EXHIBIT

120

001538

Medication and Device Experience Report

(continued)

3 guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user, facility, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 2

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

FDA Use Only

For use by user facility/distributor—devices only

Check one ☐ user facility ☐ distributor		2. UFDist report number	
User facility or distributor name/address			
Contact person		5. Phone Number	
Date user facility or distributor became aware of event (month/year)	7. Type of report ☐ initial ☐ follow-up # _____	8. Date of this report (month/year)	
App oxim t age of device	10. Event problem codes (refer to coding manual) patient code _____ - _____ - _____ device code _____ - _____ - _____		
11. Report sent to FDA? ☐ yes _____ (month/year) ☐ no		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ treatment facility ☐ outpatient treatment facility ☐ other _____ specify _____	
13. Report sent to manufacturer? ☐ yes _____ (month/year) ☐ no		Manufacturer name/address	

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code _____		4. Device manufacture date (month/year) 07/14/99	
5. Labeled for single use? ☐ yes ☒ no			
6. Evaluation codes (refer to coding manual) method 10 - 33 - _____ - _____ results 708 - _____ - _____ - _____ conclusions 78 - 71 - _____ - _____			
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
		9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number NA	
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data			

G. All manufacturers

1. Contact office - name/address (& mailing site for devices) CAS Medical Systems Inc 44 E Industrial Rd Branford CT 06405 Attn: Ron Jeffrey Note: CAS purchased product line after this device was manufactured from Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441		2. Phone number 203-488-6056	
4. Date received by manufacturer (month/year) 10/31/02		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other DEALER	
6. If IND protocol # NA		5. (A) NDA # NA IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes	
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ initial ☐ follow-up # _____		8. Adverse event term(s) NA	
Mfr report number _44861200200042			

The public reporting system for this collection of information has been limited to average one-page responses, including the time for review. Instructions regarding filing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. See 4 comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden.

FDA Form 3500A back

DEHS Report Clear to Office
Paperwork Reduction Project (2010-0231)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor and persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address

032646

001539

C/S Medical Systems, Inc.		14054	
DATE RECEIVED		10/31/02	
CUSTOMER	PROCARE HOME MEDICAL		CUSTOMER # 6628
MODEL	AMI W/MODEM	SERIAL #	482564
PART #	01-05-0163	WARRANTY	No
CUSTOMER COMMENTS: UNIT HAS ALREADY BEEN UPDATED WHEN PROCARE TESTS UNIT USING A SIMULATOR, UNIT IS NOT ALARMING WHEN IT SHOULD BE ALARMS ARE NOT CONSISTENT			
REPAIR SECTION			
PART #	28-02-0328	PART #	28-02-0408
PART #	21-01-1055	PART #	21-01-1001
REPAIR COMMENTS: REPROGRAMMED EPROM AS A PRECAUTION PASSED ALL FUNCTIONAL AND FINAL TESTS			
INVESTIGATION: MDR # 200200042 sent 12/02/02 COMPLAINT COULD NOT BE VERIFIED MONITOR HAS ALL UPDATES 13.0 VERSION BATTERY DATED 3/01 SVC. STICKER MISSING MONITOR WORKS FINE ACCORDING TO DOWNLOAD MONITOR RESPONDED TO ALL THE EVENTS BATTERY NOT 2 YRS OLD YET			
CLOSED BY		DATE CLOSED	

024743

PRODUCT INFORMATION FORM (PIF)

IOR PC # <u>14064</u> CT COMPLAINT Y ☒ N ☐		PATIENT INJURY OR DEATH Y ☐ N ☒ IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
FORM FILLED OUT BY <u>JB</u> DATE OF THIS REPORT <u>10/31/02</u> PRODUCT <u>9700A</u> LOT/SERIAL # <u>482564</u> QUANTITY <u>1</u>		CUSTOMER NAME <u>Procare</u> ADDRESS <u>Anchorage, AK</u> COMPLAINANT <u>Rachel</u> PHONE <u>907-274-0770</u>	
INFORMATION DETAILS <u>Unit has already been updated</u> <u>* When testing unit on simulator, unit</u> <u>is not alarming when it should be -</u> <u>alarms are not consistent</u>			
ACTION TAKEN THUS FAR			

DATE LOGGED AT QA <u>11/01/02</u> ☐ CHECK H	ACTION
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENT) <u>SEE SOURCE Report</u>	You will get a S/R on this I don't need it Close upon S/R arrival R-
REASON FOR NO INVESTIGATION	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS) <u>UUR # 200200042 Sent 12-2-02</u> <u>See source Report</u>	024733
REASON FOR NO REPLY TO COMPLAINANT	
CLOSE OUT SIGNATURE <u>[Signature]</u>	DATE <u>12/23/02</u>

CAS MEDICAL SYSTEMS, INC. FORM 21-0-0045 REV 0-

DATE 11/01/52

RECEIVED
FEB 11 1964

407 MILITARY
754

SOLD TO EECF
FRODOPE HOME MEDICAL
729 NORTHWAY DP VE
ANCHORAGE AK 99508

SHIF 1 LEE
FBI FLE 30 1 DICH
72 NL TI 1 1 F
FBI 1 1 1 1 1

ATTN: OLD COLLETS PAYABLE

FTM 11-1 NL

DATE NOTIFIED	DATE RECEIVED	CUST. NO.	BUYER	SALESMAN	TAX
11-01-82			RACHEL	1	0

WEIGHT	1	TERMS	1	PL - 10
	1	24-10 N 30	1	115 700 F

LINE	QTY	UNIT	PRICE	AMOUNT	TAX	TOTAL
1	1	UNIT	100.00	100.00	0.00	100.00
2	1	UNIT	200.00	200.00	0.00	200.00
3	1	UNIT	300.00	300.00	0.00	300.00
4	1	UNIT	400.00	400.00	0.00	400.00
5	1	UNIT	500.00	500.00	0.00	500.00
6	1	UNIT	600.00	600.00	0.00	600.00
7	1	UNIT	700.00	700.00	0.00	700.00
8	1	UNIT	800.00	800.00	0.00	800.00
9	1	UNIT	900.00	900.00	0.00	900.00
10	1	UNIT	1000.00	1000.00	0.00	1000.00
11	1	UNIT	1100.00	1100.00	0.00	1100.00
12	1	UNIT	1200.00	1200.00	0.00	1200.00
13	1	UNIT	1300.00	1300.00	0.00	1300.00
14	1	UNIT	1400.00	1400.00	0.00	1400.00
15	1	UNIT	1500.00	1500.00	0.00	1500.00
16	1	UNIT	1600.00	1600.00	0.00	1600.00
17	1	UNIT	1700.00	1700.00	0.00	1700.00
18	1	UNIT	1800.00	1800.00	0.00	1800.00
19	1	UNIT	1900.00	1900.00	0.00	1900.00
20	1	UNIT	2000.00	2000.00	0.00	2000.00
21	1	UNIT	2100.00	2100.00	0.00	2100.00
22	1	UNIT	2200.00	2200.00	0.00	2200.00
23	1	UNIT	2300.00	2300.00	0.00	2300.00
24	1	UNIT	2400.00	2400.00	0.00	2400.00
25	1	UNIT	2500.00	2500.00	0.00	2500.00
26	1	UNIT	2600.00	2600.00	0.00	2600.00
27	1	UNIT	2700.00	2700.00	0.00	2700.00
28	1	UNIT	2800.00	2800.00	0.00	2800.00
29	1	UNIT	2900.00	2900.00	0.00	2900.00
30	1	UNIT	3000.00	3000.00	0.00	3000.00
31	1	UNIT	3100.00	3100.00	0.00	3100.00
32	1	UNIT	3200.00	3200.00	0.00	3200.00
33	1	UNIT	3300.00	3300.00	0.00	3300.00
34	1	UNIT	3400.00	3400.00	0.00	3400.00
35	1	UNIT	3500.00	3500.00	0.00	3500.00
36	1	UNIT	3600.00	3600.00	0.00	3600.00
37	1	UNIT	3700.00	3700.00	0.00	3700.00
38	1	UNIT	3800.00	3800.00	0.00	3800.00
39	1	UNIT	3900.00	3900.00	0.00	3900.00
40	1	UNIT	4000.00	4000.00	0.00	4000.00
41	1	UNIT	4100.00	4100.00	0.00	4100.00
42	1	UNIT	4200.00	4200.00	0.00	4200.00
43	1	UNIT	4300.00	4300.00	0.00	4300.00
44	1	UNIT	4400.00	4400.00	0.00	4400.00
45	1	UNIT	4500.00	4500.00	0.00	4500.00
46	1	UNIT	4600.00	4600.00	0.00	4600.00
47	1	UNIT	4700.00	4700.00	0.00	4700.00
48	1	UNIT	4800.00	4800.00	0.00	4800.00
49	1	UNIT	4900.00	4900.00	0.00	4900.00
50	1	UNIT	5000.00	5000.00	0.00	5000.00
51	1	UNIT	5100.00	5100.00	0.00	5100.00
52	1	UNIT	5200.00	5200.00	0.00	5200.00

FART# 01-05-0163
AMI MONITOR W MODEM

Under Warranty NO
REASON⁴ RETURNED
98 NON-WARRANTY 501 0 00-1, 1507

54 102-6
=CHEV D-1E PT
11-01-02

UNIT HAS ALREADY BEEN
UPDATED, WHEN PROCEED
TESTS UNIT USING A
SIMULATOR, UNIT IS NOT
ALARMING WHEN IT SHOULD
BE ALARMS ARE NOT
CONSISTENT

024734

SERVICE REPORT

TION A Procedure Number		CUSTOMER	
3A # or S/O #	14064	PROCARE HOME MEDICAL	
MODEL #	9700A W/MODEM	SERIAL #	482564
DATE RECEIVED	11-06-02	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No	
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patient Cable		Carrying Case	
Battery		Temp Probe			
SPO2 Sensor		AC Line Cord			
off and Size					
Pass/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification
 ☐ Preventative Maintenance
 ☐ Data Download
 ☐ Evaluation Request

☒ Customer Statement: UNIT HAS ALREADY BEEN UPDATED, WHEN PROCARE TESTS UNIT USING A SIMULATOR, UNIT IS NOT ALARMING WHEN IT SHOULD BE, ALARMS ARE NOT CONSISTENT

INITIAL FINDINGS

MONITOR HAS ALL UPDATES, 13.0 VERSION. BATTERY DATED 3/01.
SEPARATE STATEMENT IS MISSING, monitor works fine down loading also
shows that monitor response on all the events, pass all tests. BATTERY NOT
 Has the customers statement been verified? ☐ YES ☒ NO ☒ N/A (no customer statement)

Warranty (Y/N) ☒ N PO Number Obtained (Y/N) ☒ N PO # _____

☐ QA Required
 ☐ Engineering Required
 ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification ☒ Passed all functional tests ☒ Passed all final tests	Other <u>reprogram CPm as 9.00000000</u> <u>procedure attach copy of downloading</u> <u>MONITOR HAS ALL UPDATES</u> <u>CUSTOMER'S COMPLAINT WAS NOT VERIFIED</u>

ECN Update # _____ 032649

	Rec	2Min	Final	Repair	Total	Date to QA
TECH			CBH	mm		
DATE			11-27-02	11/20/02	Time	
LABOR			1/2	1/2	1	

CUSTOMER RETURN TRAVELLER

RECEIVING ***

RECEIVER# 41339
 CR# LI# CR14064 1
 DATE RECEIVED 11-06 02
 PACKING LIST# 00
 NO OF CARTONS 1
 CUST# CUST NAME 6628 PROCARE HOME MEDICAL
 PART# REV 01-05-0163 REV 00
 DESCRIPTION AMI MONITOR W MODEM
 ACCT# 500-0-50-1
 QUANTITY RECEIVED 1
 PO#
 CONTACT NAME RACHEL
 CONTACT PHONE 907/274-0770
 TAKEN BY TRACY
 SERIAL NUMBERS 402564

RETURN CODES/REASONS

98 NON-WARRANTY, 501-0-50-1, 1007

COMMENTS

**UNIT HAS ALREADY BEEN
 UPDATED, WHEN PROCARE
 TESTS UNIT USING A
 JATOR, UNIT IS NOT
 ALARMING WHEN IT SHOULD
 BE, ALARMS ARE NOT
 CONSISTENT

**** INSPECTION **** 12-04-02
 Date of Inspection
 Inspector's Initials *JS*
 AQL Level
 Total Qty Inspected 1 EA
 Inspected-Loss Qty 0 EA
 Total Qty Accepted 1 EA
 Total Qty Rejected 0 EA

**** STORES ****
 Received By
 Received Qty _____ EA
 Stock Date
 Stocked By
 Stocked Qty _____ EA
 Stock Location
 Variance Qty _____ EA
 New Qty On-hand _____ EA

CU# 11-27-02
 MONITOR NEEDS BASIC FUNCTIONAL
 TESTS. MONITOR NEEDS TECHNITION'S
 ANALYSES. MONITOR HAS ALL UPDAI
 BATTERY DATED, 3/01. BATTERY
 NOT 2 YEARS OLD YET.

\$
 BASIC 100
 TECHNITION ANALYSES 75
\$ 175

024741

CUSTOMER RETURN TRAVELLER

RECEIVABLES

RECEIVED# 41330
 CR# 1# CR14864 1
 DATE RECEIVED 11-06-02
 PACKING LIST# 06
 NO OF CARTONS 1
 CUST# CUST NAME 0620 PROCORE HOME MEDICAL
 PART# REV 01-05-0163 REV 00
 DESCRIPTION API MONITOR W WOODEN
 ACCT# 500-8-50-1
 QUANTITY RECEIVED 1
 PC# Rachel
 CONTACT NAME RACHEL
 CONTACT PHONE 507-274-8770
 TAKEN BY TRACY
 SERIAL NUMBERS 402504

RETURN CODES/REASONS

90 NON-WARRANTY, 50-8-50-1, 1007

COMMENTS

**UNIT HAS ALREADY BEEN
 UPDATED, WHEN PROCORE
 TTT'S UNIT USING A
 ATOP, UNIT IS NOT
 ALARM AS WHEN IT SHOULD
 BE, ALARMS ARE NOT
 CONSISTENT

*** INSPECTION ***

Date of Inspection
 Inspector's Initial
 Ad Level
 Total Qty Inspected _____ EA
 Rejected-Low Qty _____ EA
 Total Qty Accepted _____ EA
 Total Qty Rejected _____ EA

*** STORES ***

Reviewed By
 Received Qty _____ EA
 Stock Date
 Stocked By
 Stocked Qty _____ EA
 Stock Location
 Warehouse Qty _____ EA
 New Qty Churned _____ EA

OK per
 CUST
 12/3/02
 TB

Xplease send copy of
 Download back w/Unit

Call 11-07-02

MONITOR NEEDS BASIC FUNCTIONAL
 TESTS. MONITOR NEEDS TECHNICIAN'S
 ANALYSIS. MONITOR HAS ALL UPDATES
 BATTERY DATED, 3/01 BATTERY
 NOT 2 YEARS OLD YET.

\$100
 BASIC

TECHNICAL ANALYSIS 75

\$175
 L/H

024738

Reprogrammed
 EPROM
 downloaded
 unit
 monitor
 to all
 client

		SERVICE PROCESS		Sht. 1 of 1
Process Number SVC9700PUL		Rev 0	9700X Parts Used List / Leakage Tests	

Other Parts Used		
Qty	Part Number	Description
	15-06-0099	9700 Software
	15-06-0105	9700G German Software
	15-06-0103	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	03-09-0225	Battery Alarm board
	17-08-0371	150VAC 150pfd Varistor
	02-03-0038	1/4 Conductive Tape
	16-07-0190	1uF Capacitor (R225)
	17-09-0325	10K SMT Resistor (R999)
	16-04-0085	0.1uF cap (C235)
	29-01-0218	Feet case
	26-02-0275	Foot Rubber (square)
0	28-02-0402	Perote Alarm Gasket

Qty	Part Number	Description
	21-01-1190	AMI Battery Drawer Label
1	28-02-0328	CAP DUST 25 PIN
1	28-02-0408	Clear Polyester Label
1	21-01-1055	AMI Battery Seal
1	21-01-1001	AMI Warranty Void Label
	21-01-1004	AMI Plus Battery Label
	21-01-1009	AMI Plus Warranty Void Label
	03-08-0351	AMI Plus Battery Assembly
	22-02-0112	Patient Cable Jack
	17-08-0123	1Meg Resistor AMI Plus
	18-01-0042	2 20 AWG Red Wire - AMI Plus
	03-08-0314	AMI Battery Assembly

S/O# or RGA # 14064 S/N 482564

Final Test Data Sheet				
Tested By <u>CPH</u>		Date <u>11-27-02</u>	PASS ☒	FAIL ☐
Item	Test Description	Pass/Fail	Measurement	Spec. Limit
6.1.5	Ground Wire Resistance	✓		
6.2.5	Leakage Test (Chassis)	✓	003 uA	<15 uA
6.2.7	Leakage Test (Patient Lead)	✓	003 uA	<15 uA

Failure Detail _____

032647

REPORT Single Run Summary

TECHNICAL REPORT 2126

SERIAL NUMBER 482564

TEST RESULTS PASSED

REVISION 13 Am1 w/Modem Final Test

TEST DATE 11/27/02

MODEL NUMBER L-9700A

PART NUMBER Y-006122 10A



TIME	TEST	TEST DESCRIPTION	STATUS
11 54 48 AM	1	Initial Power Up	PASSED
11 54 48 AM	2	Version & Serial Number Verification	PASSED
11 55 28 AM	3	Time & Date	PASSED
11 56 03 AM	4	Patient Setup	PASSED
11 56 28 AM	5	Patient Limits	PASSED
11 56 36 AM	6	Access Code	PASSED
11 57 09 AM	7	O2 Desat	PASSED
12 08 16 PM	8	Signal Quality Indicator	PASSED
12 11 02 PM	9	Resp Detect min, mid, and max	PASSED
12 12 13 PM	10	ECG Crosstalk	PASSED
12 16 04 PM	11	ECG Detect min mid, max Rate & Amplitude	PASSED
2 20 08 PM	12	Reverse Leads ECG Detect min, mid max Rate & Amp	PASSED
2 21 15 PM	13	Apnea Alarm ECG - RESP	PASSED
12 22 02 PM	14	Human Alarm Condition Heart Slow	PASSED
12 23 04 PM	15	Human Alarm Condition Apnea	PASSED
12 35 41 PM	16	Power Alert Function	PASSED
12 35 47 PM	17	WatchDog Test	PASSED
12 39 03 PM	18	Data Transfer & Recording Verification	PASSED

032648

OPERATOR Andrew Hamblin

STATION ID 4

RUN ID 824

PAGE 1

001547

CUSTOMER RETURN TRAVELLER

RECEIVING ***

EA CR# 4'339
 FLI# CR1-864 1
 E RECEIVED 11-06-02
 KING LIST# 20
 OF CARTONS. 1
 TA CUST NAME 6020 PROCARE HOME MEDICAL
 REV 01-05-0103 REV 00
 DESCRIPTION PMI MONITOR & MODEM
 T# 500-0-50-1
 QUANTITY RECEIVED 1
 CONTACT NAME RACHEL
 CONTACT PHONE 907/274-8770
 TAKEN BY TRACY
 SERIAL NUMBERS 402564

TURN CODES/REASONS

NON-WARRANTY, 501-0-50-1, 1007

REMARKS

UNIT HAS ALREADY BEEN
 DATED, WHEN PROCARE
 STC UNIT USING A
 JN, UNIT IS NOT
 WORKING WHEN IT SHOULD
 , ALARMS ARE NOT
 RESISTANT

** INSPECTION ***

Date of Inspection _____
 Inspector's Initial _____
 Level _____
 Total Qty Inspected _____ EA
 Inspected - Lo 5 Qty _____ EA
 Total Qty Accepted _____ EA
 Total Qty Rejected _____ EA

** STORES ***

Review By _____
 Received Qty _____ EA
 Lock Date _____
 Locked By _____
 Locked Qty _____ EA
 Lock Location _____
 Variance Qty _____ EA
 New Qty On Hand _____ EA

CMT 11-27-02
 MONITOR NEEDS BASIC FUNCTIONAL
 TESTS. MONITOR NEEDS TERNATION'S
 ANALYSES. MONITOR HAS ALL UPDATES
 BATTERY DATED, 3/01. BATTERY
 NOT 2 YEARS OLD YET.

\$
 BASIC 100
 TERNATION ANALYSIS 75
 \$ 175

032650

Preliminary Study Report

Ami Apnea Monitor

Summary Report

Ben # 14064

SN # 482564

« Patient Information »

[Changed at Transfer]

482564

[Not Entered]

[Not Entered]

Gender [None]
 Birth Date 11/20/02

Gestational 40 weeks
 Study Age 0 0 weeks

« Study Ends »

Ami Monitor 11/20/02 Wed
 Rep Gen PC 11/20/02 Wed

08 47 15
 11 46 46

[At Time Of Transfer]

« Monitor Setup »

Aux 1 Signal O2 Satur
 Aux 2 Signal PulseRate
 Aux 3 Signal Airflow

HR Slow Mode 3 Consec Beats
 Event Capture Longest Events
 Apnea 50% HSlow 50%
 HFast 0% Desat 0%

« Monitor Limits »

Apnea Alarm 15 Sec
 Heart Slow 80 BPM
 Heart Fast 225 BPM

Apnea Log 10 Sec
 Heart Slow 85 BPM
 Heart Fast 200 BPM
 Desaturation 85 % Sat

« Recorded Events »

Monitor Logs 11 of 2000
 Patient Logs 7 of 2000
 Event Waves 2.8% Filled

Study Start 10/29/02 Tue 11 18
 Study Period 3 Weeks 1 Day
 Monitor Time 4 Mins 7 Secs [0 0%]
 Periodic Br 1 Min 32 Secs

« 5 Recorded Waveforms »

Apneas 3
 Desaturations 0

Heart Slows 1
 Heart Fast 1
 Study Is Not Reviewed

« Events Counted »

Monitor Ons 3
 Apneas 3
 Desaturations 0
 Loose Leads 2

Monitor Offs 2
 Heart Slows 1
 Heart Fast 1

« Modem Answer Only »

« System Version »

Serial Numb 482564
 Access Code [NONE]

Ami Monitor 13 00 28-NOV-01
 Report Generator 01 1a 19 Mar 99

Copyright (c) 1997 98 Nellcor Puritan Bennett Inc [B-]

032651

482564 # [Not Entered]

Page 1

11/20/02 08 47

001549

Neilcor Puntan Bennett

Ami Apnea Monitor Patient Logs

	Date	Time	Event Type	Event Duration
1	10/29	11 20 15	Loose Lead	1 Sec
2	10/29	11 20 21	Loose Lead	1 Sec
3	10/29	11 21 12 ‡	Heart Slow •	8 Secs
4	10/29	11 21 20 †	Heart Fast •	1 Mins 53 Secs
5	10/29	11 21 45 ‡	Apnea •	16 Secs
6	10/29	11 22 15 †	Apnea •	22 Secs
7	10/29	11 22 54 ‡	Apnea	17 Secs

11/20 08 47 15

Received 7 Patient Logs

Copyright (c) 1997 98

Neilcor Puntan Bennett Inc

032652

**482564 [Not Entered]
Event List**

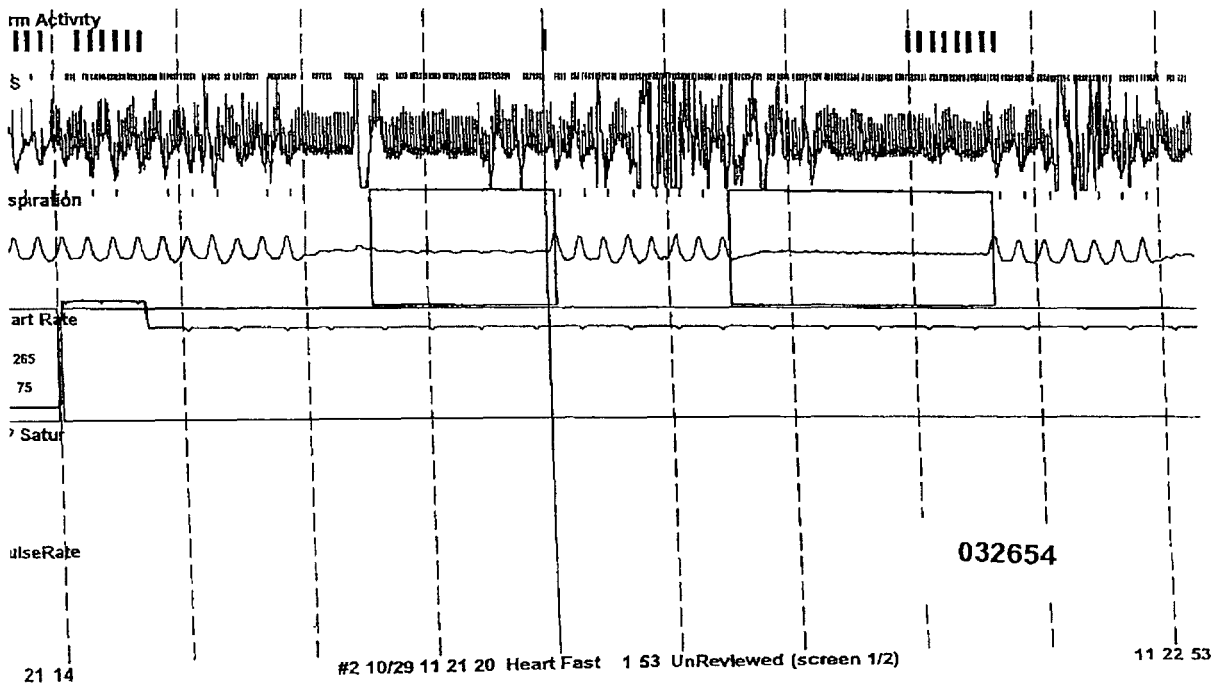
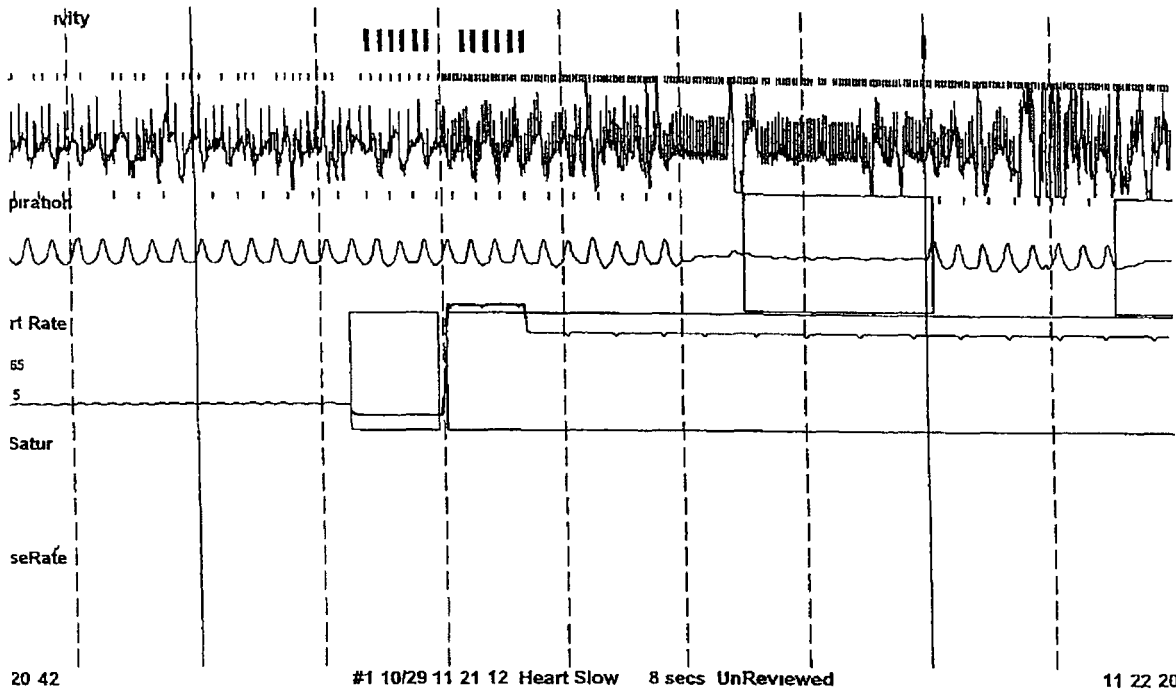
#	Date	Time	Event	Duration	Reason
1	10/29	11 21 12	Heart Slow	8 secs	UnReviewed
2	10/29	11 21 20	Heart Fast	1 53	UnReviewed
3	10/29	11 21 45	Apnea	16 secs	UnReviewed
4	10/29	11 22 15	Apnea	22 secs	UnReviewed
5	10/29	11 22 54	Apnea	17 secs	UnReviewed

Page 1

032653

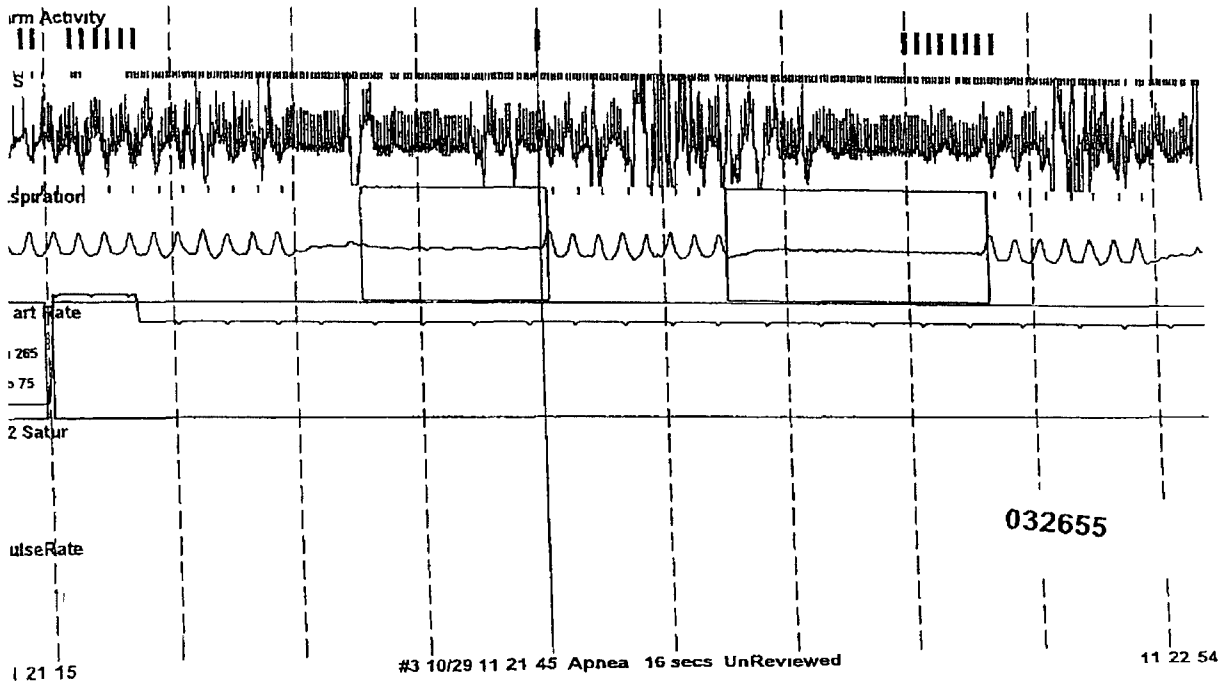
001551

482564 [Not Entered]

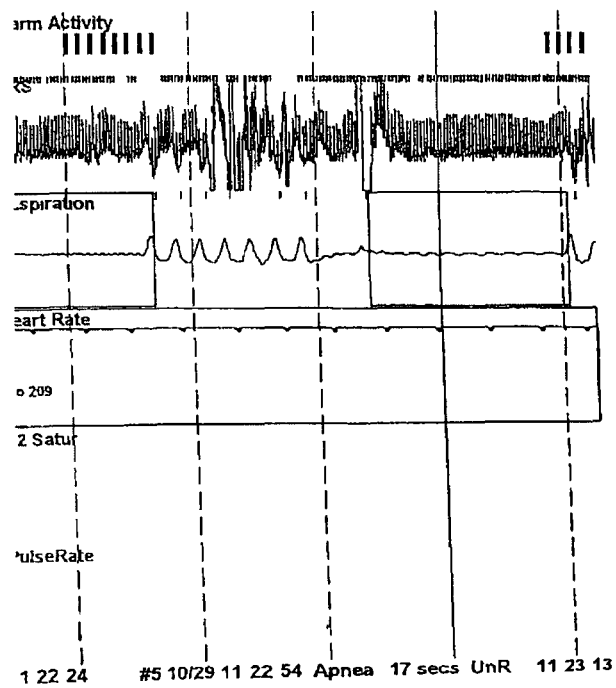
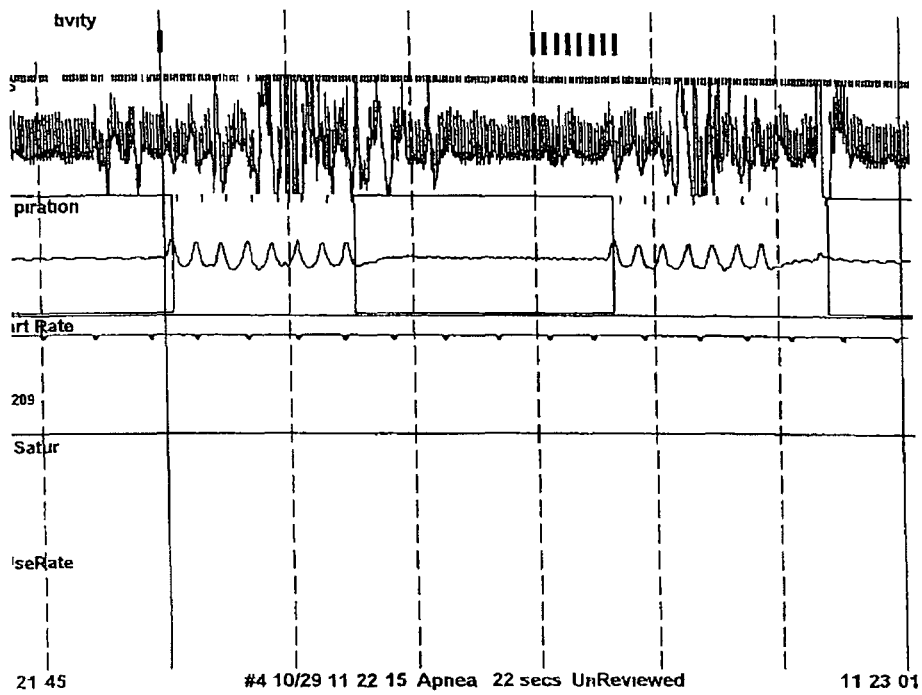


482564 [Not Entered]

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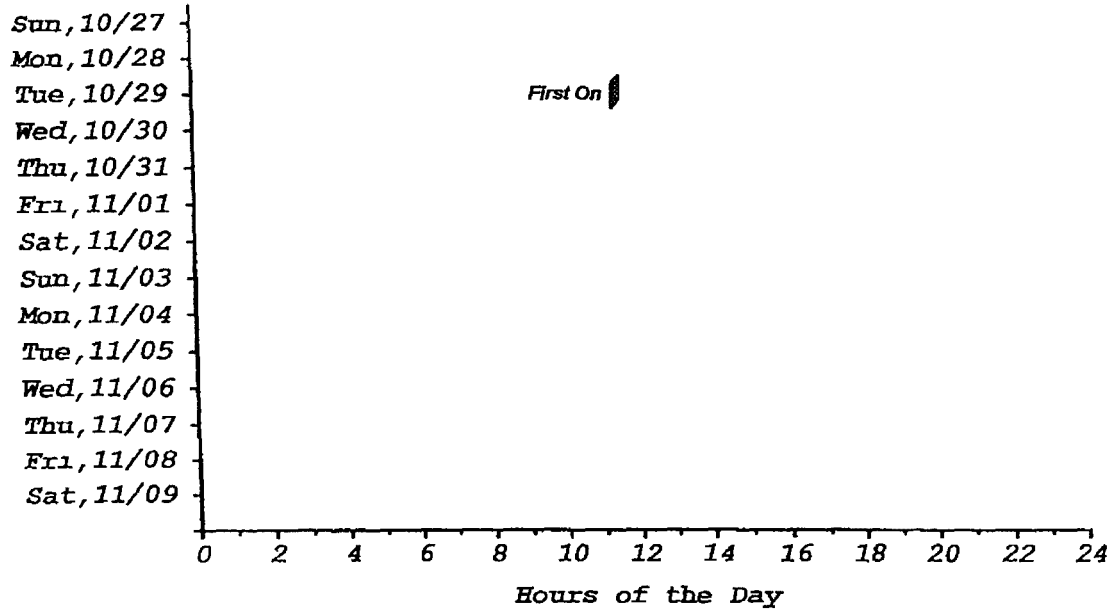
482564 [Not Entered]



032656

Ami Monitor Usage for 482564

1 of 2

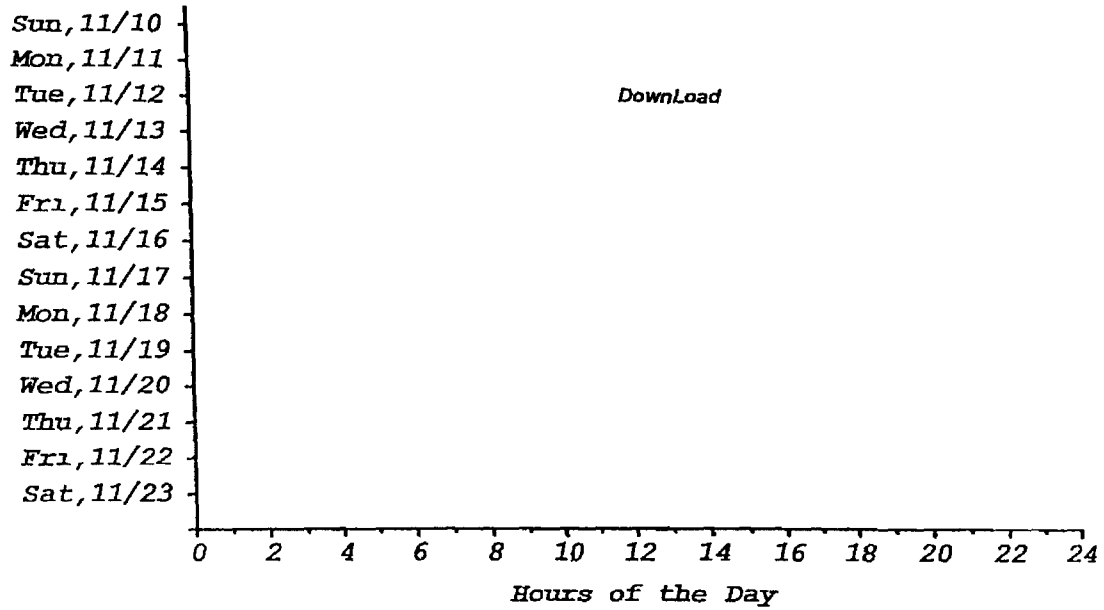


482564 # [Not Entered]

032657

Ami Monitor Usage for 482564

2 of 2



482564 # [Not Entered]

032658

001556

Nellcor Puntan Bennett

Amí Apnea Monitoring Periods

10/29	11 18 59	thru	10/29 11 19 11	12 Secs
10/29	11 19 43	thru	10/29 11 23 12	3 Mins 29 Secs
11/20	08 46 16	thru	11/20 08 46 42	26 Secs

Duration of the Study Period Was	3 Weeks 1 Day
Total Time Monitor Was Recording	4 Mins 7 Secs
Total Time Monitor Was Turned Off	3 Weeks 1 Day
% of Study Period Monitor Was On	0 0%

Copyright (c) 1997 98

Nellcor Puntan Bennett, Inc

032659

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Form Approved OMB No. 0918-0251 Expires: 01/23/01
See OMB statement on reverse

MDR report #	2244861200200040
UPDRG report #	
FDA Use Only	

Page 1 of 2

Patient information			
1. Patient identifier IK	2. Age at time of event or Date of birth UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or UNK kgs
Adverse event or product problem			
☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)			
Outcomes attributed to adverse event (check all that apply)			
☐ death (immediate) ☐ life-threatening ☐ hospitalization - initial or prolonged ☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other			
5. Date of event (month/day/yr) 11/00/02	6. Date of this report (month/day/yr) 11/22/02		
Describe event or problem			

Home Care Dealer reports that the service light alarms but the front and rear audible alarms are not heard

Relevant tests/laboratory data including dates

NA

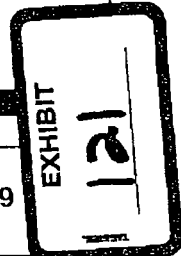
Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

C. Suspect medication(s)	
1. Name (give labeled strength & manufacturer if known)	
#1 NA	#2
2. Dose, frequency & route used	
#1 NA	#2
3. Therapy dates (if unknown give duration) (month/day/yr)	
#1 NA	#2
4. Diagnosis for use (indication)	
#1 NA	#2
5. Event abated after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	#2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	
#1 NA	#2
7. Exp date (if known)	
#1 NA	#2
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	#2 ☐ yes ☐ no ☒ doesn't apply
9. NDC # - for product problems only (if known)	
NA -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device	
1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address Nelcor Puritan Bennett 2800 Northwest Blvd Plymouth, MN 55441	
4. Operator of device ☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (month/day/yr) NA	
6. Model # 9700A	
7. If implanted give date (month/day/yr) NA	
8. If explant d give date (month/day/yr) NA	
9. Device available for evaluation? (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on (month/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter			
1. Name & address Baptist Home Medical Equipment 1600 Century Center Parkway 101 Memphis TN 38134		phone # 901 373-8485	
2. Health professional? ☐ yes ☒ no		3. Occupation Home Care Dealer	
4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk		032629	



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

001558

EDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities
distributors and manufacturers for
MANDATORY reporting

Form Approved OMB No. 09-04291 Exp. 12/31/01
See OMB statement for details

MDR report #	2244861200200040
UMDR report #	
FDA Use Only	

Page 1 of 2

A. Patient information

1. Patient identifier	2. Age at time of event	3. Sex	4. Weight
JNK	UNK	UNK	UNK
	or	☐ female	lbs
	Date of birth	☐ male	or
	UNK		kgs

B. Adverse event or product problem

☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

Date of event (mortality)	4. Date of this report (mortality)
11/00/02	11/22/02
Describe event or problem	

Home Care Dealer reports that the service light alarms but the front and rear audible alarms are not heard

Relevant tests/laboratory data including dates

NA

Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepato-renal dysfunction, etc.)

NA

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown give duration)
#1 NA	#1 NA
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 NA	#1 NA
#2	#2
8. NDC # - for product problems only (if known)	8. Event reappeared after introduction
NA -	#1 ☐ yes ☐ no ☒ doesn't apply
	#2 ☐ yes ☐ no ☒ doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name	
Heart Rate Respiration Monitor	
2. Type of device	
Breathing Frequency Monitor	
3. Manufacturer name & address	4. Operator of device
Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441	☐ health professional ☒ lay user/patient ☐ other
5. Expiration date (mortality)	6. Model #
NA	9700A
7. If implanted give date (mortality)	8. Serial #
NA	481248
8. If explanted give date (mortality)	9. Lot #
NA	na
	10. Other #
	RGA14028
9. Device available for evaluation? (Do not send to FDA)	
☐ yes ☐ no ☐ returned to manufacturer on (mortality)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1. Name & address	phone #
Baptist Home Medical Equipment 1600 Century Center Parkway 101 Memphis TN 38134	901 373-8485
2. Health professional?	
☐ yes ☒ no	
3. Occupation	4. Initial reporter also sent report to FDA
Home Care Dealer	☐ yes ☐ no ☒ unknown



DA F rm 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

001559

CAS Medical Systems, Inc

RGA # 14028

DATE ISSUED 10/25/02

CUSTOMER BAPTIST HOME MEDICAT EQUIP

CUSTOMER# 6627

MODEL AMI W/MODEM

SERIAL # 481248

OF TIMES
RETURNED

PART # 01 05 0163

WARRANTY No

CUSTOMER COMMENTS SERVICE LIGHT ALARMS FRONT & REAR ALARMS ARE NOT HEART SERVICE LIGHT
FLASHES

REPAIR SECTION

PART2 # 28-02 0328

PART3 # 28-02 0408

PART4 # 21 01 1055

PART5 # 21 01 1001

REPAIR COMMENTS ADJUSTED ALARM POSITION AS A PRECAUTION ATTACHED COPY AT DOWNLOADING
PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION COULD NOT VERIFY COMPLAINT DOWNLOADING SHOWS NOTHING WRONG WORKS
FINE HAS ALL UPDATES BATTERY DATED 1/01 NOT 2 YRS OLD YET MDR 00040
sent 11/22/02

CLOSED BY R. Jeffrey

DATE CLOSED 11/22/02

032631

ENTERED OCT 28 2002

PRODUCT INFORMATION FORM (PIF)

RGA OR PC <u>14928</u>		PATIENT INJURY OR DEATH Y ☐ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A	FORM FILLED OUT BY <u>Dolly</u>	CUSTOMER NAME <u>Cas Medical</u>	01
	DATE OF THIS REPORT <u>10/25/02</u>	ADDRESS <u>1600 Century Oaks Pkwy Ste 101</u>	
	PRODUCT <u>9700A / 9700B</u>	<u>Memphis, TN - 38134</u>	
	LOT/SERIAL # <u>SEE BELOW</u>	COMPLAINANT <u>Sammy</u>	
	QUANTITY <u>5</u>	PHONE <u>901-372-8485</u>	
INFORMATION DETAILS			CHECK IF OUT OF BOX FAILURE ☐
<u>482282 - Casting broken around front speaker</u>			
✓	<u>481086 - Failed simulation - front alarm not heard - service light flashes</u>		
✓	<u>481248 - Service life alarms - front & rear alarms are not heard - service light flashes</u>		
<u>✓ 30200190 - Unable to connect to computer ports screws too long</u>			
<u>✓ 30200358 - " " " " " " " "</u>			
ACTION TAKEN THUS FAR			
B	DATE LOGGED AT QA <u>10/28/02</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION		
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)		
	<u>see S/R</u>		
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>MDR for S/N 481248 #200200040 sent 11-22-02</u>			
<u>all others, see Service Reports</u>			
REASON FOR NO REPLY TO COMPLAINANT		030276	
CLOSE OUT			
SIGNATURE		DATE	

SERVICE REPORT

SECTION A Procedure Number

A # or S/O # 14028

CUSTOMER Boyer's home medical equip

MODEL # 9700A w/modern

SERIAL # 481248

DATE RECEIVED

11/04/02

ESTIMATE REQUIRED ☒ wait for customer approval

CUSTOMER TRACKING No

LOCATION of LABEL

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger ☐
Battery ☐
SPO2 Sensor ☐

Patent Cable ☐
Temp Probe ☐
AC Line Cord ☐

Carrying Case ☐

Off and Size

Ass/Replace

CUSTOMER REQUEST/COMPLAINT

☐ Recertification

☐ Preventative Maintenance

☐ Data Download

☐ Evaluation Request

Customer Statement

Service light alarms front and rear alarms
are not heard - Service light - Alarms, call
B/Y Repair

INITIAL FINDINGS

down loading show nothing wrong, monitor revealed
and in work line MONITOR HAS ALL UPDATES. BATTERY NOT
DATED, 1/1. BATTERY NOT 2 YEARS OLD YET MONITOR'S LED TEST
Has the customer's statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N)

☒

PO Number Obtained (Y/N)

☒

PO #

☐ QA Required

☐ Engineering Required

☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification

☒ Passed all functional tests

☒ Passed all final tests

Other adjust alarm position as per spec
Procedure attach copy of downloading
MONITOR HAS ALL UPDATES.
WARRANTY FOR 11/1/02
NO SERVICE LIGHT PROBLEMS ANYMORE

ECN Update #

032634

	Rec	2Min	Final	Repair	Total
TECH			<u>PLH</u>	<u>mm</u>	
DATE			<u>11-11-02</u>	<u>11-8-02</u>	
LABOR			<u>1/2</u>	<u>1/2</u>	<u>1</u>

Date to QA

11-14-02

SERVICE REPORT

SECTION A Procedure Number 115/02

RGA # or S/O # 14028

MODEL # 9700 A w modem

DATE RECEIVED 11 4 02

CUSTOMER Baptist home medical equip

SERIAL # 481086

ESTIMATE REQUIRED ☒ Wait for customer approval

CUSTOMER TRACKING No _____

LOCATION or LABEL _____

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger ☐
 Battery ☐
 SPO2 Sensor ☐

Patient Cable ☐
 Temp Probe ☐
 AC Line Cord ☐

Carrying Case ☐

Cuff and Size ☐
 Pass/Replace ☐

CUSTOMER REQUEST/COMPLAINT

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement Failed simulation test from alarm
Not heard service light flashes call B/Y
Repairs

INITIAL FINDINGS

internal mic not picking up alarm front alarm
not heard. MONITOR HAS ALL UPDATES. BATTERY DATED 5/01
BATTERY NOT 2 YEARS OLD YET

Has the customers statement been verified? ☒ YES ☐ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ N PO Number Obtained (Y/N) ☒ N PO # _____

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification Other adjusting alarm position
☒ Passed all functional tests attach copy of download
☒ Passed all final tests MONITOR HAS ALL UPDATES
NO SERVICE LIGHT PROBLEM

ECN Update # _____

030286

	Rec	2Min.	Final	Repair	Total	Date to QA
TECH			<u>CLM</u>	<u>mm</u>		
DATE			<u>11-11-02</u>	<u>11-8-02</u>		
LABOR			<u>1/2</u>	<u>1/2</u>	<u>1</u>	<u>11-15-02</u>

Justification for not submitting an MDR after a review of the Ami Service Report.

R. Jeffrey
July 16, 2002

Reason for consideration

Service reports arrive and are reviewed. There are statements by the service person saying, "Front alarm not heard" and or "Rear alarm not heard"

Background

At a point early on in the update program it was discovered that simply closing the case top could cause the gasket occlusion that obstructed the microphone sound hole. This accounted for the subsequent service light flashing. It was learned that removing a small portion of the case rib structure could alleviate the pressure on the alarm gasket.

In nearly all cases of the service report review, the monitors have been in to CAS for the ESD update. Something happened during the update / testing process where the alarms position in relation to the microphone changed or the top case cover pressed closed an opening in the alarm gasket that normally permits the microphone to detect the sound of the alarm(s).

The complaint

If a monitor is subject to this condition the customer will get all lights flashing indicating a monitor fault. The monitor cannot be used until the condition is cleared. The customer is forced to return the monitor to CAS for the fix described above.

Reason for no hazard

- The customer has not reported an actual loss of audible alarm. The problem is detected in the start-up routine and not while the monitor is in a normal functioning state. The user has a monitor that visually has indicated a fault not permitting its use.
- CAS has an awareness of this problem in production and service due to the rotational positioning of the alarm.
- The alarm not being heard is a factor of the either microphone not picking up the occluded and muffled sound and not due to a loss of audible output.
- The service check of the units has not shown the alarm assemble to be defective nor is there a history of problematic alarms.
- The operator manual states that when the service light is lit the monitor should be cycled off and on and if it persists remove from service immediately.

030287



DATE OF

DATE 10/28/02



ACKNOWLEDGMENT
1402F

SQLI TO 6627
BAPTIST HOME MEDICAL EQUIP **
1500 CENTURY CENTER PKWY-101
MEMPHIS, TN 38114
ATTN: SPMMY

SHIP TO 6627
BAPTIST HOME MEDICAL EQUIP **
600 CENTURY CENTER PKWY-101
MEMPHIS, TN 38114
ATTN: SPMMY

DATE	NO	TO	DATE	NO	TO	BUYER	SALESMAN	TAX
						SPMMY	1	0%

FRIGHT	TERMS	SHIP-VIA
	27-0 N 30	UPS

QTY	RET	UNIT	PRICE

PART# 01-05-0163
AMI MONITOR W MOICM

Under Warranty NO
REASONS RETURNED
38 NON-WARRANTY 10-0 50- 1607

SN 482282
SCHED-DATE QTY
0-25-02 1

BROKEN FRONT CASE AROUND
THE SPEAKER
CALL B/4 REPAIRS

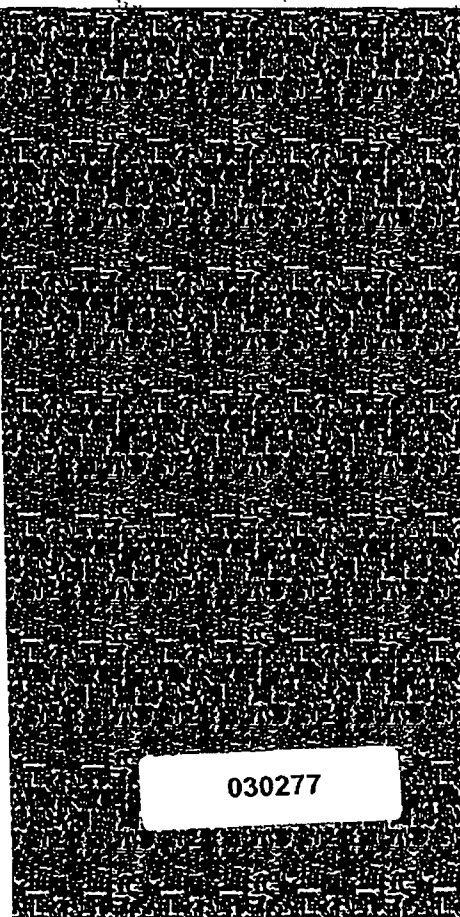
PART# 01 05-0163
AMI MONITOR W MODEM

Under Warranty NO
REASONS RETURNED
38 NON-WARRANTY, 501-0 50-1, 1607

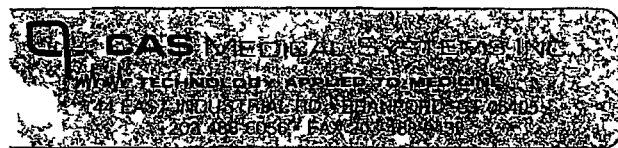
SN 481086
SCHED-DATE QTY
10-25-02 1

FAILED SIMULATION TEST
FRONT ALARM NOT HEARD
SERVICE LIGHT FLASHES
CALL B/4 REPAIRS

PART# 01-05-0163
AMI MONITOR W MODEM



030277



PAGE 1 OF 1

DATE 10/28/02



ACKNOWLEDGEMENT
14026

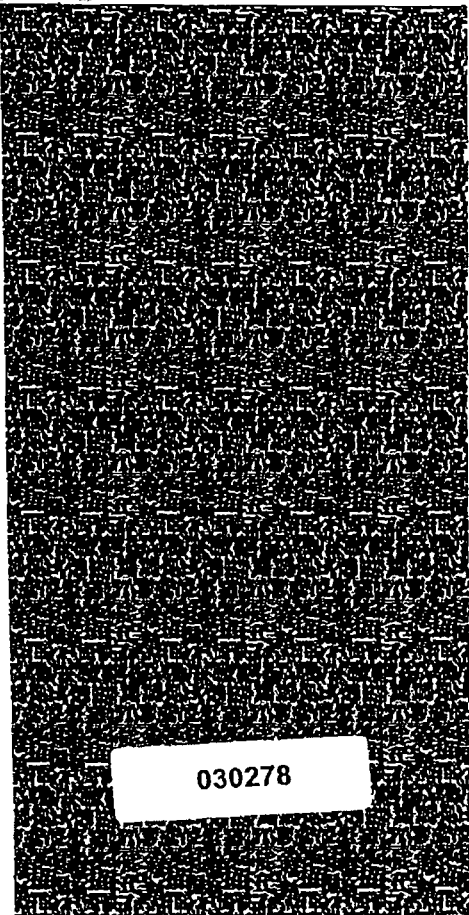
SOLD TO 6627
BAPTIST HOME MEDICAL EQUIP **
1600 CENTURY CENTER PLWY-101
MEMPHIS, TN 38124
ATTN: SAMMY

SHIP TO 6627
BAPTIST HOME MEDICAL EQUIP **
1600 CENTURY CENTER PLWY 101
MEMPHIS TN 38124
ATTN: SAMMY

DATE	BUYER	SALESMAN	TAX
10/28/02	SAMMY		110%

FRIGHT	TERMS	SHIP-VIA	QTY	REI	UNIT PRICE
	17-10 N 30	UPS			

Under Warranty NO
REASONS RETURNED
99 NON-WARRANTY, 501-0-50-1, 1607
SN 481248
SCHED-DATE QTY
10-25-02 1
SERVILE LIGHT ALARMS
FRONT & REAR ALARMS ARE
NOT HEARD-SERVILE LIGHT
FLASHES
CALL B4 REPAIRS
PART# 01-05-0170
AMT PLUS 9700B, ENGLISH W/MODEM
Under warranty NO
REASONS RETURNED
98 NON-WARRANTY 501-0-50-1, 1607
SN 1-0000190
SCHED-DATE QTY
10-25-02 1
UNABLE TO CONNECT TO
THE COMPUTER PORT-
SCREWS ARE TOO TIGHT
CALL B 4 REPAIRS
PART# 01-05-0170
AMT PLUS 9700B ENGLISH W/MODEM
Under Warranty NO





PAGE 1

DATE 10/28/02



ACKNOWLEDGEMENT
1402A

POLD TO 6027
BAPTIST HOME MEDICAL EQUIP **
100 CENTURY CENTER PKWY-101
MEMPHIS TN 38134

SHIP TO 6027
BAPTIST HOME MEDICAL EQUIP **
100 CENTURY CENTER PKWY-101
MEMPHIS, TN 38134

ATTN SAMMY

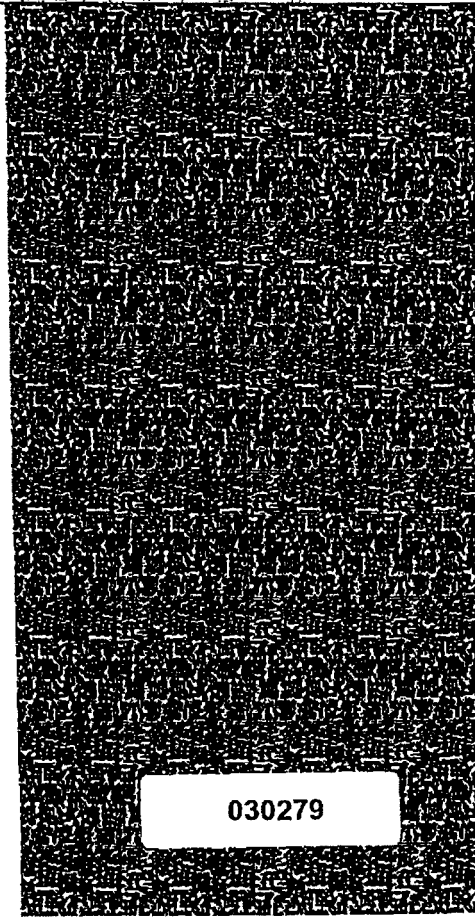
ATTN SAMMY

BUYER	SALESMAN	TAX
SAMMY		110%

FREIGHT	TERMS	SHIP-VIA
	27-10 11 30	UPS

QTY RET	UNIT PRICE

REASONS RETURNED
98 NON-WARRANT 301-0-50-1, 1007
SN Y-30200058
SCHED-DATE QTY
10-25-02 1
UNABLE TO CONNECT TO
COMPUTER PORTS
SCREWS ARE TOO LARGE
CALL R/A REPAIRS



030279

CUSTOMER RETURN TRAVELLER

1 0 ***

4127-
CR14028 3
11-04-02
00

ME 6627 BAPTIST HOME MEDICAL EQUIP **
21-05-0163 REV 30-20200-12212
AMI MONITOR w MODEL
500-0-50-1

IVED

SAMMY
001-373-8485
DOTTY
+812+8

EASO S

ARRANTY, 521-2-50-1, 1607

ALARMS
ARMS ARE
-IGHT

S

ON ****11-1502
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tia's

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3+y
ted
ad

MONITOR NEEDS BASIC FUNCTIONAL
TESTS MONITOR NEEDS TECHNICIANS
LABOR MONITOR HAS ALL UPDATES
BATTERY DATED 1/01 BATTERY
NOT 2 YEARS OLD YET.

BASIC \$100

LABOR 75

\$175

WARRANTY JOB

Cost 11-11-02

11-11-02

030285

NIBP Module
SP02 Module

SERVICE PROCESS

9700X Parts Used Lis / Lease

Other Parts Used

Number	Description
15-06-0099	9700 Software
15-06-0105	9700G German Software
15-06-0103	9700S Spanish Software
15-01 0335	IC 74AC00 (U23 & U28)
03-09-0225	Battery Alarm board
17 08 0371	150VAC 150pfd Varistor
02-03-0038	1 1/4 Conductive Tape
16-04-0190	1uF Capacitor (R225)
17-09 0325	10K SMT Resistor (R999)
16-04-0085	0 1uF cap (C235)
29-01-0218	Fest case
28-02-0275	Foot-Rubber (square)
28-02-0402	Remote Alarm Gasket

Qty	Part Number	Description
	21-01 1190	AMI Battery Draw
1	28-02-0328	CAP DUST 25 0 V
1	28-02-0408	Clear Polyester Label
1	21-01 1055	AMI Battery Seal
1	21-01 1001	AMI Warranty Void Label
1	21-01 1004	AMI Plus Battery Label
1	21 01 1009	AMI Plus Warranty Void Label
1	03-08-0351	AMI Plus Battery Assembly
	22-02-0112	Patent Cable Jack
	17 08-0123	1Meg Resistor AMI Plus
	18-01-0042	2 20 AWG Red Wire - AMI Plus
	03-08-0314	AMI Battery Assembly

S/O# or PGA #

14028

S/N

481248

Final Test Data Sheet

Tested By	ALH	Date	11-11-02	PASS	☒	FAIL	☐
6 1 5	Ground Wire Resistance	✓					
6 2 5	Leakage Test (Chassis)	✓		1102 uA		<15 uA	
6 2 7	Leakage Test (Patient Lead)	✓		1002 uA		<15 uA	

Failure Detail

ated on: 01/17/2001

Last Update: 09/25/2007

Printed on: 10/15/02

032632

REPORT Single Run Summary

TECHNICAL REPORT #126

SERIAL NUMBER 481248

TEST RESULTS PASSED



NELLCOR
PURITAN
BENNETT.

VISION 13 Ami w/Modem, Final Test
TEST DATE 11/11/02

MODEL NUMBER L-9700A
PART NUMBER Y-006122-10A

TIME	TEST	TEST DESCRIPTION	STATUS
12 04 00 PM	1	Initial Power Up	PASSED
12 04 00 PM	2	Version & Serial Number Verification	PASSED
12 04 40 PM	3	Time & Date	PASSED
12 05 01 PM	4	Patient Setup	PASSED
12 05 25 PM	5	Patient Limits	PASSED
12 05 33 PM	6	Access Code	PASSED
12 06 06 PM	7	O2 Desat	PASSED
12 07 23 PM	8	Signal Quality Indicator	PASSED
12 10 15 PM	9	Resp Detect min, mid, and max	PASSED
12 11 25 PM	10	ECG Crosstalk	PASSED
12 15 20 PM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
12 19 27 PM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
12 20 35 PM	13	Apnea Alarm ECG = RESP	PASSED
12 21 21 PM	14	Human Alarm Condition - Heart Slow	PASSED
12 22 24 PM	15	Human Alarm Condition - Apnea	PASSED
1 20 25 PM	16	Power Alert Function	PASSED
1 21 40 PM	17	WatchDog Test	PASSED
1 38 31 PM	18	Data Transfer & Recording Verification	PASSED

032635

OPERATOR Andrew Hamblin

STATION ID 2

RUN ID 2961

PAGE 1

001570

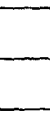
8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the  and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:

- ↓
- 8.3.1 Display will say 'NEW PATIENT' press  for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.
 - 8.3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct.
 - 8.3.3 Press mode button, display will ask if test is complete. Press enter then press  for yes and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY Date 11-15-02

FAIL

☐ Reason for rejection: _____

QA Inspector _____ Date _____

Correction made: _____

QA Inspector _____ Date _____

032636

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0560 AMI- English
03-08-0384 AMI- Spanish
03-08-0385 AMI- German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0386 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 481248
WORK ORDER # N/A
RGA # 14028

TEST EQUIPMENT REQUIRED

EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0034
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1190
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete and conforms to test data specifications
4.2 If this is an RGA verify accessories are with unit if applicable

✓
✓

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

032637

Nellcor Puritan Bennett

Ami Apnea Monitor All Study Logs

	Date	Time	Event Type	
1 >	09/04	16 00 30	Monitor Powered Up	
2 >	09/20	14 01 02	New Recording Start	
3 >	09/20	14 01 22	Monitor Powered Down	
4 >	09/20	14 04 52	Monitor Powered Up	
5 >	09/20	14 05 18	Detection Disabled	
6 >	09/20	14 06 06	New Recording Start	
7 >	09/20	14 06 14	Monitor Powered Down	
8 >	11/07	12 12 29	Monitor Powered Up	
9 >	11/07	12 12 59	Detection Disabled	
1	11/07	12 12 59	Loose Lead	1 Sec
Ami >	11/07	12 13.21	Received 9 Monitor Logs	
	11/07	12 13.21	Received 1 Patient Log	

Event Count Totals

3 Monitor Ons	2 Monitor Offs
0 Apneas	0 Heart Slows
0 Desaturations	0 Heart Fasts
1 Loose Leads	

Copyright (c) 1997 98

Nellcor Puritan Bennett Inc

032638

CUSTOMER RETURN TRAVELLER

** RECEIVING ****

VER# 41274
 LI# CR140CB 3
 TO RECEIVED 11-04-02
 CHINO LIST# 40
 OF CARTONS 1
 ST# CUST NAME 6627 BAPTIST HOME MEDICAL EQUIP **
 RT# REV 21 05-0163 REV 20220202-1212
 DESCRIPTION 4MI MONITOR W WOODEN
 CT# 500-0-50-1
 AM111 RECEIVED
 # 272
 MTRACT NAME CAMP
 MTRACT PHONE 901-373-8485
 INC# 27 DDTY
 RIAL NUMBER 451248

OK per
 cust
 TB
 11/14/02

TRM CODES/REASONS

NON-WARRANTY, 501-0-53-1, 1627

MENTS

1/ SE LIGHT ALARMS
 10IT & REAR ALARMS ARE
 11 EMPD-BER CC LIGHT
 2015-
 1 B- ALPAIRS

SECTION ****

1e u inspection
 10pe u u u 111111
 11 111111
 tal City expected
 111111 111111
 val u 111111
 val u 111111
 val u 111111

STORES ****

111111 111111
 111111 111111
 111111 111111
 111111 111111
 111111 111111
 111111 111111
 111111 111111
 111111 111111

11-11-02
 MONITOR NEEDS BASIC FUNCTIONAL
 TESTS. MONITOR NEEDS TELEVISION
 LABOR MONITOR HAS ALL UPDATES
 BATTERY DATED 1/01. BATTERY
 NOT 2 YEARS OLD YET.

LVM
 11/13/02
 TB

\$100
 Basic
 Labor 75
 \$175

WARRANTY JOB
 Cont 11-11-02
 11-11-02

032639

LED WATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved OMB No. 0910-0291 Expires 01/31/01
See OMB statement on reverse

MDR report #	2244861200300010
UKR/ML report #	
FDA Use Only	

A. Patient information

1. Patient identifier	2. Age at time of event: UNK	3. Sex: UNK ☐ female ☐ male	4. Weight: UNK lbs or kg
UNK	Date of birth:		
In confidence			

B. Adverse event or product problem

☐ Adverse event and/or	☒ Product problem (e.g. defects/malfunctions)
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

5. Date of event (mortality): 04/00/03	6. Date of this report (mortality): 05/23/03

Describe event or problem

The home care dealer reports that there are irregular apnea alarming situations leading to inconsistency. There are alarms when there should not be and it has been known to not alarm when it should.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose, frequency & route used	
#1 NA	
#2	
3. Therapy dates (if unknown give duration) (mortality)	
#1 NA	
#2	
4. Diagnosis for use (indication)	
#1 NA	
#2	
5. Event abated after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)	
#1 NA	
#2	
7. Exp date (if known)	
#1 NA	
#2	
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name	
Heart Rate Respiration Monitor	
2. Type of device	
Breathing Frequency Monitor	
3. Manufacturer name & address	
Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441	
4. Operator of device	
☐ health professional ☒ lay use /patient ☐ other	
5. Expiration date (mortality)	
NA	
6. Model #	
9700A	
7. If implanted give date (mortality)	
NA	
8. If explanted give date (mortality)	
NA	
9. Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 04/30/03 (mortality)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

3. Relevant tests/laboratory data including dates

NA

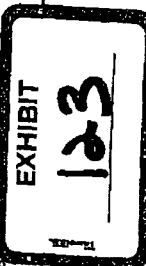
7. Other relevant history including preexisting medical condition (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

E. Initial reporter

1. Name & address		phone #
Procure Home Medical 709 Northway Drive Anchorage AK 99508		907 274-0770
2. Health professional?		3. Occupation
☒ yes ☐ no		Home Care Dealer
4. Initial reporter also sent report to FDA		
☐ yes ☐ no ☒ unk		

032667



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

001575

Education and Device Experience Report

Refer to guidelines for specific instructions

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

Page 2 of 2

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

FDA Use Only

For use by user facility/distributor-devices only	
Check one ☐ user facility ☐ distributor	2. UFI/ist report number
User facility or distributor name/address	
Contact person	5. Phone Number
Date user facility or distributor became aware of event (month/year)	7. Type of report ☐ initial ☐ follow-up #
Approximate age of device	8. Date of this report (month/year)
10. Event problem codes (refer to coding manual)	
patient code	
device code	
1. Report sent to FDA? ☐ yes (month/year) ☐ no	12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other: specify
3. Report sent to manufacturer? ☐ yes (month/year) ☐ no	
Manufacturer name/address	

3. All manufacturers	
Contact office - name/address (& mailing site for devices)	2. Phone number
CAS Medical Systems, Inc. 44 E. Industrial Rd. Branford CT 06405 Attn: Ron Jeffrey Note: CAS purchased product line after this device was manufactured from Nellcor Puritan Bennett 2800 Northwest Blvd. Plymouth MN 55441	203-488-6056
1. Date received by manufacturer (month/year) 04/28/03	3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other: DEALER
5. IF IND protocol # NA	5. (A) NDA # NA IND # PLA # pre-1938 ☐ yes OTC product ☐ yes
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up #	8. Adverse event term(s) NA
Report number 00300010	

H. Device manufacturers only	
1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other	2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code	4. Device manufacture date (month) 04/09/98
	5. Labeled for single use? ☐ yes ☒ no
6. Evaluation codes (refer to coding manual)	
method	10 - 33
results	708
conclusions	71
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other	8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number	
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data	
032668	

For this collection of information has been estimated: average one-
the time for reviewing instructions, searching existing data sources,
data needed, 4 copy, 100 and reviewing the collection of infor-
mation for reducing this burden.

DIH13 Reports Clearance Office
Paperwork Reduction Project (0510-0291)
Mable H. Houghway Building, Room 821-H
200 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor
and a person is not required to respond
to a collection of information unless it displays
currently valid OMB control number.

Please DO NOT RETURN this
form to this address

15100
4/28/03
CUSTOMER: PROCARE HOME MEDICAL
MODEL: AMI W/MODEM
SERIAL: 480899
01 05 0163
No
CUSTOMER COMMENTS: IRREGULAR APNEA ALARMS WHEN IT SHOULDN'T AND DOESN'T WHEN IT SHOULD

REPAIR SECTION
1 1190 28 02 0
28 02-0408
21 01 1055
1 1001 03 08-0
REPAIR COMMENTS: INSTALLED ECN UPDATE 6754 AND AN AMI BATTERY ASSY LITHIUM 3 691 PASSED ALL FUNCTIONAL AND FINAL TESTS
INVESTIGATION: 13 0 VERSION MONITOR HAS ALL UPDATES EXCEPT 6754 BATTERY DATED 1/01 DOWNLOAD SHOWS APNEA SIGNALS BUT CAN'T DUPLICATED PROBLEM NEEDS RECERT WITH A NEW BATTERY DUE TO OUTDATED BATTERY MDR 200300010 sent 5/23/03

CLOSED BY: R Jeffrey
DATE CLOSED: 5/23/03

032673

AS MEDICAL SYSTEMS INC.		15100
DATE: 4/28/03		
SHIP TO: PROCARE HOME MEDICAL	6628	
MODEL: AMI W/MODEM	SERIAL: 480899	
01 05 0163	WARRANTY: No	
<i>Have Bruce Sign off when all other units are done R</i> ALAR APNEA, ALARMS WHEN IT SHOULDN'T AND DOESN'T WHEN IT SHOULD		
1 1190, 28-02-0	28-02 0408	21 01 1055
1 1001 03 08-0		
INSTALLED ECN UPDATE 6754 AND AN AMI BATTERY ASSY LITHIUM 3 691 PASSED ALL FUNCTIONAL AND FINAL TESTS		
13 0 VERSION MONITOR HAS ALL UPDATES EXCEPT 6754 BATTERY DATED 1/01 DOWNLOAD SHOWS APNEA SIGNALS BUT CAN'T DUPLICATED PROBLEM NEEDS RECERT WITH A NEW BATTERY DUE TO OUTDATED BATTERY MDR 200300010 sent 5/23/03		
10015118	R Jeffrey	5/23/03
023798		

ENTERED APR 30 2003

PRODUCT INFORMATION FORM (PIF)

RGA OR PC # <u>15100</u>		PATIENT INJURY OR DEATH Y ☒ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A.	FORM FILLED OUT BY <u>IB</u>	CUSTOMER NAME <u>Procare</u>	
	DATE OF THIS REPORT <u>4/28/03</u>	ADDRESS <u>Anchorage, AK</u>	
	PRODUCT <u>9700A(3), 9700B(1)</u>	COMPLAINANT <u>Kerry</u>	
	LOT/SERIAL # <u>See below</u>	PHONE <u>907-274-0770</u>	
	QUANTITY <u>4</u>		
INFORMATION DETAILS			
✓	S/N 10222011 - pc jack pins broken + are		CHECK IF OUT OF BOX FAILURE ☐
	inside unit		
✓	S/N 482311 - pc jack broken - pushed inside		
✓	S/N 482412 - Unit makes a Whistling Sound		
✓	S/N 480899 - irregular apnea alarm		
	alarms when it shouldn't		
	and doesn't when it should		
	not consistent		
ACTION TAKEN THUS FAR			
B.	DATE LOGGED AT QA <u>4/30/03</u>		☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)			
<u>see Service Report(s)</u>			
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>S/N 480899 - MON # 2003 00010 sent 5/23/03</u>			
<u>see attached</u>			
023787			
REASON FOR NO REPLY TO COMPLAINANT			
CLOSE OUT		DATE <u>6/5/03</u>	
SIGNATURE <u>[Signature]</u>			

CAS MEDICAL SYSTEMS INC FORM 21-04-0045 REV 04

Q. CAS METER, INC.
 100 WILSON AVENUE, SUITE 100
 CHICAGO, ILL. 60642
 (312) 462-1100

SOLD TO 6F2E
FROCAE HOME MEDICAL
203 NORTHWAY DRIVE
ANCHORAGE, AK 99508

SHIP TO 6622
PROCAKE HOME MEDICAL
701 NORTHWAY DRIVE
ANCHORAGE, AK 99508

STTM RECEIVING

ALLEN S. LEVINSON, JR.

023788

001580

ACKNOWLEDGEMENT
15100

SOLD TO 6628
PROCARE HOME MEDICAL
709 NORTHWAY DRIVE
ANCHORAGE, AK 99508

SHIP TO 6628
PROCARE HOME MEDICAL
709 NORTHWAY DRIVE
ANCHORAGE, AK 99508

ATTN ACCOUNTS PAYABLE

ATTN RECEIVING

FREIGHT	TERMS	SHIP-VIA
	2X-10 N 30	UFS

98 NON-WARRANTY, 501-0-50-1, 1609

SN 482412

SCHED-DATE	QTY
04-28-03	1

UNIT MAKES A WHISTLING
SOUND

4) IAFTH 01-05-01E3
AMI MONITOR W MODEM

Under Warranty NO
REASONS RETURNED

98 NON-WARRANTY, 501 0-50-1, 1609

SN: 480899

SCHED-DATE	QTY
04 28-03	1

IRREGULAR APNEA ALARMS
WHEN IT SHOULDN'T AND
DOESN'T WHEN IT SHOULD

023789

SECTION A Procedure Number

SERVICE REPORT

GA # or S/O #	15100-4	CUSTOMER	PROCASE HOME MEDICAL
MODEL #	9200A W/MODEM	SERIAL #	480899
DATE RECEIVED	4-30-03	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No	480899 1459
		LOCATION of LABEL	TC

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patent Cable		Carrying Case	
Battery		Temp Probe			
SPO2 Sensor		AC Line Cord			
Cuff and Size					
Pass/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification
 ☐ Preventative Maintenance
 ☐ Data Download
 ☐ Evaluation Request

☒ Customer Statement. IRREGULAR APNEA. ALARMS WHEN IT SHOULDN'T AND DOESN'T WHEN IT SHOULD.

INITIAL FINDINGS

13.0 VERSION MONITOR HAS ALL UPDATES EXCEPT 6754 BATTERY PWRD/C1 DOWN LOADING CHARGES OPEN 5/9/03, BUT CAN DUPLICATE PROBLEM MONITOR NEEDS RECERTIFICATION, WITH A NEW BATTERY, DUE TO OUTDATED BATTERY.

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ PO Number Obtained (Y/N) ☒ PO # B8051403

☐ QA Required
 ☐ Engineering Required
 ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☒ Recertified to meet manufacture's specification ☐ Passed all functional tests ☒ Passed all final tests	Other <u>ECN update</u> <u>INSTALLLED</u> <u>or downloading</u> <u>INSTALLLED A NEW BATTERY ASSEMBLY</u>

LITHIUM 3691

ECN Update # 6754 032669

	Rec	2Min	Final	Repair	Total Time	Date to QA
TECH	<u>CH</u>		<u>CH</u>			<u>5-19-03</u>
DATE	<u>5-9-03</u>		<u>5-9-03</u>			
R	<u>1/2</u>		<u>1/2</u>		<u>1</u>	

CAS Medical Systems

Ami Apnea Monitor All Study Logs

Date	Time	Event Type
< 1 >	04/15	16 05 30 Monitor Powered Up
< 2 >	04/15	16 05 30 New Patient Name [Not Entered]
< 3 >	04/15	16 05 30 New Patient Number [Not Entered]
< 4 >	04/15	16 05 30 New Monitor Settings HRate 3 R-R Beats
Aux 1 O2 Satur		Aux 2 PulseRate
Evt Capture Mode		Aux 3 Airflow
Reserved Memory		Longest Events
< 5 >	04/15	Apnea 50%
Alarm » Apnea 15		HSlow 50%
Log » Apnea 10		Settings Changed
< 6 >	04/15	HSlow 80
< 7 >	04/15	HFast 225
< 8 >	04/15	HSlow 85
1 04/15	16 06 58 ‡	HFast 200 Desat 85
2 04/15	16 07 08 ‡	Finish Monitor Setup
3 04/15	16 07 25 ‡	Monitor Powered Down
4 04/15	16 08 00 ‡	Monitor Powered Up
5 04/15	16 08 22	* 9 Secs
6 04/15	16 08 47 ‡	* 8 Secs
7 04/15	16 09 11	Apnea 12 Secs
8 04/15	16 09 26	* 19 Secs
< 9 >	04/15	Loose Lead 1 Sec
< 10 >	05/02	Apnea * 22 Secs
< 11 >	05/02	Loose Lead 1 Sec
<Ami>	05/02	Loose Lead 1 Sec
05/02	08 45 12	Monitor Powered Down
		Monitor Powered Up
		Detection Disabled
		Received 11 Monitor Logs
		Received 8 Patient Logs

Event Count Totals.

3 Monitor Ons	2 Monitor Offs
3 Apneas	1 Heart Slows
0 Desaturations	1 Heart Fast
3 Loose Leads	

Copyright (c) 2002

CAS Medical Systems Inc

023791

Q-CAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number SVC9700PUL		Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software	1	21-01-1190	AMI Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)	1	21-01-1055	AMI Battery Seal
	03-09-0225	Battery Alarm board	1	21-01-1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor		21-01-1004	AMI Plus Battery Label
	02-03-0038	1 1/4" Conductive Tape		21-01-1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-08-0325	10K SMT Resistor (R989)		22-02-0112	Patent Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor - AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)	1	03-08-0314	AMI Battery Assembly
1	28-02-0402	Remote Alarm Gasket			

S/O# or RGA # 15100-4 S/N 480899

Final Test Data Sheet				
Tested By: <u>CLH</u>		Date: <u>5-9-03</u>		PASS ☒ FAIL ☐
Step Description	PASS	FAIL	Measurement	Specification
6.1.5 Ground Wire Resistance	☒	☐		
6.2.5 Leakage Test (Chassis)	☒	☐	003 uA	<15 uA
6.2.7 Leakage Test (Patent Lead)	☒	☐	003 uA	<15 uA

Failure Detail: _____

023792

CUSTOMER RETURN TRAVELLER

**** RECEIVING ****

RECEIVER# 44341
 CR# LI# CR15100 4
 DATE RECEIVED 04-30-03
 PACKING LIST# 00
 NO OF CARTONS 1
 CUST# CUST NAME 6628 PROCARE HOME MEDICAL
 PART# REV 01-05-0163 REV 14200200200
 DESCRIPTION AMI MONITOR W MODEM
 ACCT# 500-0-50-1
 QUANTITY RECEIVED 1
 PO#
 CONTACT NAME
 CONTACT PHONE
 TAKEN BY TB/DC
 SERIAL NUMBERS 480899

RETURN CODES/REASONS

98 NON-WARRANTY, 501-0-50-1, 1609

COMMENTS

IRREGULAR APNEA ALARMS
 WHEN IT SHOULDN'T AND
 DOESN'T WHEN IT SHOULD

**** INSPECTION ****
 Date of Inspection 5/30/03
 Inspector's Initials RL
 AQL Level
 Total Qty Inspected 1
 Inspected-Loss Qty 0
 Total Qty Accepted 1
 Total Qty Rejected 0

**** STORES ****
 Received By
 Received Qty
 Stock Date
 Stocked By
 Stocked Qty
 Stock Location
 Variance Qty
 New Qty On-Hand

023793

Estimate of Repairs

RGA # 15100-4 Customer PROLIFE HOME MEDICAL Model 9700A W/MODEM S/N 4-80 899

Repair Estimate Comments (Define Work to be done)

MONITOR NEEDS RECERTIFICATION, WITH A NEW BATTERY, DUE TO
OUTDATED BATTERY, 1/01. MONITOR NEEDS ECN 675f MANUA
HAS ALL OTHER UPDATES.

RECIERT

Item 1	P/N <u>03 08 0314 AM BATTERY</u>	Price <u>\$ 225</u>
Item 2	P/N _____	Price _____
Item 3	P/N _____	Price _____
Item 4	P/N _____	Price _____
Functional Test	<u>✓</u>	Price <u>N/C</u>
Labor Hours	_____	Price _____

Total Estimate \$ 225 5/14/03

Contact person/Date approved Rachel 5/14/03

PO # LB051403

CAS FORM 21-04-0267 Rev 00

023794

REPORT Single Run Summary

TECHNICAL REPORT #126

TRIAL NUMBER 480899

TEST RESULTS PASSED

REVISION 13 Amu w/Modem Final Test

TEST DATE 5/9/03

MODEL NUMBER L-9700A

PART NUMBER Y-006122-10A



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
11 52 06 AM	1	Initial Power Up	PASSED
11 52 06 AM	2	Version & Serial Number Verification	PASSED
11 52 46 AM	3	Time & Date	PASSED
11 53 21 AM	4	Patient Setup	PASSED
11 53 31 AM	5	Patient Limits	PASSED
11 53 38 AM	6	Access Code	PASSED
11 54 12 AM	7	O2 Desat	PASSED
11 55 29 AM	8	Signal Quality Indicator	PASSED
11 58 17 AM	9	Resp Detect min, mid, and max	PASSED
11 59 28 AM	10	ECG Crosstalk	PASSED
12 03 23 PM	11	ECG Detect min, mid max Rate & Amplitude	PASSED
12 07 31 PM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
12 08 38 PM	13	Apnea Alarm ECG = RESP	PASSED
12 09 25 PM	14	Human Alarm Condition - Heart Slow	PASSED
12 10 28 PM	15	Human Alarm Condition - Apnea	PASSED
12 21 10 PM	16	Power Alert Function	PASSED
12 21 16 PM	17	WatchDog Test	PASSED
12 28 36 PM	18	Data Transfer & Recording Verification	PASSED

032670

OPERATOR Andrew Hamblin

STATION ID 4

RUN ID 1788

PAGE 1

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CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 480899
WORK ORDER # NA
RGA # 15100-4

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete
and conforms to test data specifications.
4.2 If this is an RGA, verify accessories are with
unit if applicable

✓
NA

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

032672

AS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 3 OF 3

3.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the  and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:

3.3.1 Display will say "NEW PATIENT" press  for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.

3.3.2 Press Mode button until you reach time/date setting. verify time/date stamp is correct.

3.3.3 Press mode button, display will ask if test is complete. Press enter then press  for yes, and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY RL

Date 5/20/03

☐

Reason for rejection _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

032671

EDWATCH

DA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved OMB No. 0918-0291 Expires 01/01/01
See OMB Statement on revenue

Alt report #	2244861200300012
UP/Dist report #	
FDA Use Only	

Patient information

1 Patient identifier	2 Age at time of event or Date of birth	3 Sex	4 Weight
K	UNK UNK	UNK ☐ female ☐ male	UNK lbs or kgs

confidence

Adverse event or product problem

☐ Adverse event and/or ☒ Product problem (e.g. defects/malfunctions)

It comes attributed to adverse event (check all that apply)

- ☐ death (mortality)
- ☐ life-threatening
- ☐ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other

5 Date of event (mortality)	6 Date of this report (mortality)
05/00/03	06/26/03

Describe event or problem

The care dealer reports what they were told by the user (rents) that this monitor did not alarm during an apnea

Relevant tests/laboratory data including dates

The care company did a download of memory to find that there is an apnea event and no indication of an alarm problem

Other relevant history including preexisting medical condition (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

4

C. Suspect medication(s)

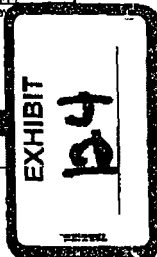
1 Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2	
2 Dose, frequency & route used	3 Therapy dates (if unknown give duration) (mortality)
#1 NA	#1 NA
#2	#2
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6 Lot # (if known)	7 Exp date (if known)
#1 NA	#1 NA
#2	#2
8 Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9 MDC # - for product problems only (if known)	
NA -	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1 Brand name	
Heart Rate Respiration Monitor	
2 Type of device	
Breathing Frequency Monitor	
3 Manufacturer name & address	4 Operator of device
Neelcor Puntan Bennett 2800 Northwest Blvd Plymouth MN 55441	☐ health professional ☒ lay user/patient ☐ other
5 Expiration date (mortality)	6
NA	model # 9700A
7 If implanted give date (mortality)	8
NA	catalog # NA
9	serial # 482976
10	lot # NA
11	other # RGA15276
12 Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 06/06/03 (mortality)	
13 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1 Name & address	phone #
Accurate Biomed Services 12035 12th Street Eagleview MO 64442	660-867-5660
2 Health professional?	
☒ yes ☐ no	
3 Occupation	
Home Care Dealer	
4 Initial reporter also sent report to FDA	
☐ yes ☐ no ☒ unk	



Submission of a report does not constitute an admission that medical personnel, user facility distributor, manufacturer or product caused or contributed to the event.

Information and Device Incidence Report

Submission of a report does not constitute
an admission that medical personnel, user
facility distributor manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

to guidelines for specific instructions

Page 2 of 2

FDA Use Only

On Use by user facility/distributor-devices only	
1. Check one user facility ☐ distributor ☐	2. UF/Dist report number
3. User facility or distributor name/address	
4. Contact person	
5. Phone Number	
6. Is user facility or distributor aware of event (month/year)	7. Type of report ☐ initial ☐ follow-up #
8. Date of this report (month/year)	
9. Proximate location of device	10. Event problem codes (refer to coding manual) patient code - device code
11. Report sent to FDA? yes (month/year) no	12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other specify
13. Report sent to manufacturer? yes (month/year) no	
14. Manufacturer name/address	

H. Device manufacturers only	
1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other	2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code	4. Device manufacture date (month/year) 11/01/00
	5. Labeled for single use? ☐ yes ☒ no
6. Evaluation codes (refer to coding manual) method 10 86 results 708 conclusions 71	
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other	8. Use of device ☐ initial use of device ☐ reuse ☒ unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number	

All manufacturers	
1. Contact office - name/address (& mailing site for devices) S Medical Systems Inc E Industrial Rd Anford Ct 06405 Attn: Ron Jeffrey ite CAS purchased product line after this vice was manufactured from floor Puntan Bennett 00 Northwest Blvd ymouth MN 55441	
2. Date received by manufacturer (month/year) 5/30/03	2. Phone number 203-488-6056
3. If IND protocol # A	3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☒ distributor ☒ other DEALER
4. Type of report (check all that apply) 5-day ☐ 15-day 10-day ☐ periodic 1 ☐ follow-up #	5. (A) NDA # NA IND # PLA # pre-1938 ☐ yes OTC product ☐ yes
6. Mfr report number 244861200300012	7. Adverse event term(s) NA

10 ☒ Additional manufacturer narrative and/or 11 ☐ Corrected data
H6 (86) Unit evaluated to confirm or refute the complaint.
Awaiting approval for other unrelated repairs

032675

public reporting rden for this collection. Information has been submitted to various
per region including the time reviewing no. Since searching editing data sources
hering and maintaining th data needed. d completing and reviewing the collection of info
on. Send comme regarding his urde strate or y other aspect of this colle Ben of
reaction, including suggestion to re clin this rde in.

FD/RS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building Room 531-H
224 Independence Avenue SW
Washington, D.C. 20201

An agency may not conduct or sponsor
and persons its of required to respond to
collection of information unless it displays
currently valid OMB control number

Please DO NOT RETURN this
form to this address

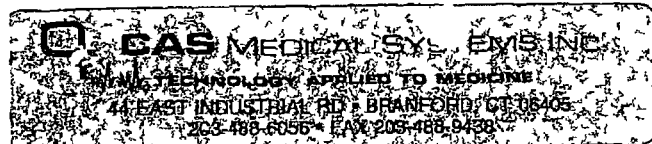
✓ EN1 1ED JUN 2 2003 *Am*
#6914

PRODUCT INFORMATION FORM (PIF)

RGA OR PG # <u>15230</u>		PATIENT INJURY OR DEATH Y ☒ N ☐	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A. FORM FILLED OUT BY <u>JB</u>		CUSTOMER NAME <u>Accurate Biomedical</u>	
DATE OF THIS REPORT <u>5/30/03</u>		ADDRESS <u>12035 12th St</u>	
PRODUCT <u>9700A</u>		<u>Fayetteville, MO 64442</u>	
LOT/SERIAL # <u>482976</u>		COMPLAINANT <u>Judy</u>	
QUANTITY <u>1</u>		PHONE <u>660/867-5660</u>	
INFORMATION DETAILS		CHECK IF OUT OF BOX FAILURE ☐	
<u>Screen light stays on even after</u>			
<u>powering off + back on -</u>			
<u>-parent states unit did not alarm during</u>			
<u>an apnea (download embedded Apnea)</u>			
<u>*also due for recent</u>			
<u>*call West of repair</u>			
ACTION TAKEN THUS FAR			
B. DATE LOGGED AT QA <u>6/2/03</u> ✓ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION			
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)			
<u>See Service Report</u>			
<u>Service Manager reports that monitor did alarm and no problem</u>			
<u>was found in this preliminary evaluation of 6/26/03</u>			
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>See Service Report</u>			
<u>UDR # 200300012 sent 6/26/03</u>			
019536			
REASON FOR NO REPLY TO COMPLAINANT			
CLOSE OUT			
SIGNATURE <u>[Signature]</u>		DATE <u>9-16-03</u>	

CAS MEDICAL SYSTEMS INC FORM 21-04-0045 REV 04

15276					
5/30/03					
CUSTOMER: ACCURATE BIOMED SERVICES	6914				
MODEL: AMI W/MODEM	482976				
PROB: 01-05 0163	No				
CUSTOMER COMMENTS: SERVICE LIGHT STAYS ON EVEN AFTER POWERING UNIT OFF AND BACK ON SEVERAL TIMES. PARENTS INDICATED UNIT DID NOT ALARM DURING APNEA. DOWNLOAD CONFIRMED APNEA. UNIT ALSO DUE FOR RECERT.					
REPAIR SECTION: <table border="1"> <tr> <td>2 0435 21 01 1</td> <td>2 0328, 28-02 0</td> <td>1 1055 21 01</td> <td>03-08 0314</td> </tr> </table>		2 0435 21 01 1	2 0328, 28-02 0	1 1055 21 01	03-08 0314
2 0435 21 01 1	2 0328, 28-02 0	1 1055 21 01	03-08 0314		
REPAIR COMMENTS: RECERT TO MEET MFG SPECIFICATIONS. INSTALLED ECN 6813 AND AN AMI BATTERY ASSY. PASSED ALL FUNCTIONAL AND FINAL TESTS.					
INVESTIGATION: /VER 13 0 NEEDS ECN 6813. INTERNAL MIC DIDN'T PICK UP ALARM SIGNAL. DOWNLOAD HAS NO APNEA ACTIVITIES. TESTED FOR APNEA AND PASSED BATTERY. INSTALLED 5/01 MDR 200300012 sent 6/26/03.					
CLOSED BY: R Jeffrey	9/16/03				
032676					



1 OF 1 OF 1

DATE 05/30/03

CUSTOMER
RETURNS

ACKNOWLEDGEMENT
15c70

SOLD TO 6914
ACCURATE BIOMED SERVICES
12035 12TH STREET
EAGLEVILLE, MO 64442

SHIP TO 6914
ACCURATE BIOMED SERVICES
12035 12TH STREET
EAGLEVILLE MO 64442

ATTN ACCOUNTS PAYABLE

ATTN RECEIVING

DATE NOTIFIED	DATE RECEIVED	CLST	PO#	BUYER	SALESMAN	TAX
05-30-03				JUDY		1107

FREIGHT	TERMS	SHIP-VIA	QTY REL	UNIT PRICE
	2% 10 N 70	UES		

LINE	PART#	DESC	QTY	PRICE
1	PART# 01-05 0163	MT MON TOR W MODEM		
		Under Warranty NO		
		CHASSIS RETURNED		
		ALARMS NOT WORKING		
		SERVICE LIGHT		
		FUNCTIONAL CHASSIS RECEIVED		
		NO WARRANTY, 501-0 50-1, 1609		
	SN: 18237			
	SCHD-DATE	QTY		
	05 30-02	1		
		SERVICE LIGHT STAYS ON		
		EVEN AFTER POWERING UNIT		
		OFF AND BACK ON SEVERAL		
		TIMES		
		**F4PENT 5 INDICATED		
		UNIT DID NOT ALARM		
		LOADING TONEA DOWNLOAD		
		CONFIRMED HANEA		
		**UNIT ALSO DUE FOR		
		REPAIR**		
		CALL FOR ESTIMATE ON		
		REPAIR**		

019537

SERVICE REPORT

SECTION A

RGA # or S/O #	15276-1	CUSTOMER	ACCURATE RIMMED SERVICES
MODEL #	97MA W/MODEM	SERIAL #	482976
DATE RECEIVED	6-6-03	ESTIMATE REQUIRED	☒ Wait for customer approval
		CUSTOMER TRACKING No	NA
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patient Cable		Carrying Case	
Battery		Temp Probe		Cuff Hose	
SPO2 Sensor		AC Line Cord			
Cuff and Size					
Pass/Replace					

CUSTOMER REQUEST/COMPLAINT

Reason code

1725-26 98

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement: SERVICE LIGHT STAYS ON EVEN AFTER POWERING UNIT OFF AND BACK ON SEVERAL TIMES, PARENT'S INDICATED UNIT DID NOT ALARM DURING APNZA, DOWNLOAD CONFIRMED APNZA, UNIT ALSO DUE FOR RECERT. CALL W/ESTIMATE OF REPAIR

INITIAL FINDINGS: VERSION 13.0, monitor needs reset ECN 6813 update, internal mic didn't pick alarm signal downloading has no apnea active has monitor tested for apnea and passed MONITOR HAS ALL OTHER UPDATES. BATTERY INSTALLED, 5/01

Has the customers statement been verified?

☐ YES

☒ NO

☐ N/A (no customer statement)

Warranty (Y/N) ☒ N

PO Number Obtained (Y/N) ☒ Y

PO # 12110

032677

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

59

☒ Recertified to meet manufacture's specification
☒ Passed all functional tests
☒ Passed all final tests

Work Performed: INSTALLED ECN 6813. MONITOR HAS ALL OTHER UPDATES. INSTALLED A+B BATTERY ASSEY

(over) ECN Update # 6813

Lithium 3691

Total Labor Time

1

Technicians Initials

QUT

DATE to QA

9-2-03

QA Approval

RL

QA Date

9/2/03

CAS MEDICAL SYSTEMS INC

TECHNOLOGY APPLIED TO MEDICINE

44 EAST INDUSTRIAL ROAD BRANFORD CONNECTICUT 06405

203-488-6056
(FAX) 203-488-9438

Estimate of Repairs

RGA # 15276-1 Customer ACCURATE BIOMED Model 9700A W/MODEM S/N 482976
SERVICES

Repair Estimate Comments (Define Work to be done)

MONITOR NEEDS RECALIBRATION, WITH A NEW BATTERY, DUE TO
OUTDATED BATTERY 5/03 ⁴⁴⁴ 6/03, 5/01 MONITOR HAS ALL UPDATES
EXCEPT G754 THE MAJOR PART OF CUSTOMERS COMPLAINT WILL
BE FIXED BY PCN ⁶⁸¹³ ~~6754~~, THE FUNNEL,

RECAP

Item 1	P/N <u>03-08-0314 AM BATTERY</u>	Price <u>\$ 725</u>
Item 2	P/N _____	Price _____
Item 3	P/N _____	Price <u>1</u>
Item 4	P/N _____	Price _____
Functional Test	<u>✓</u>	Price <u>N/C</u>
Labor Hours	<u>1/2</u>	Price <u>N/C</u>

Total Estimate

\$ 725

Contact person/Date approved

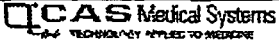
Dennis 8/29/03

PO #

12110

CAS FORM 21-04-0267 Rev 00

032678

 CAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Shk 1 of 1
Process Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software	1	21-01 1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)	1	21-01 1055	AMI Battery Seal
	03-09-0225	Battery Alarm board	1	21-01 1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor		21-01 1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17 09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor AMI Plus
	29-01 0218	Feet, case		18-01-0042	2' 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)	1	03-08-0314	Ami Battery Assembly
0	28-02 0402	Remote Alarm Gasket			
1	28-02-0435	FUNNEL			

S/O# or RGA # 15276-1 SIN 482976

Final Test Data Sheet					
Tested By <u>Curt</u>		Date <u>9-2-03</u>		PASS ☒	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance	☒	☐		
6.2.5	Leakage Test (Chassis)	☒	☐	001 uA	<15 uA
6.2.7	Leakage Test (Patent Lead)	☒	☐	002 uA	<15 uA

Failure Detail: _____

032679

Single Run Summary
CAL REPORT #126
AL NUMBER 482976

TEST RESULTS PASSED

VISION 13 Amu w/Modem Final Test
TEST DATE 9/2/03

MODEL NUMBER L-9700A
PART NUMBER Y-006122 10A



TIME	TEST	TEST DESCRIPTION	STATUS
9 00 47 AM	1	Initial Power Up	PASSED
9 00 47 AM	2	Version & Serial Number Verification	PASSED
9 01 26 AM	3	Time & Date	PASSED
9 02 29 AM	4	Patient Setup	PASSED
9 02 39 AM	5	Patient Limits	PASSED
9 02 46 AM	6	Access Code	PASSED
9 03 20 AM	7	O2 Desat	PASSED
9 04 39 AM	8	Signal Quality Indicator	PASSED
9 07 29 AM	9	Resp Detect min, mid, and max	PASSED
9 08 39 AM	10	ECG Crosstalk	PASSED
9 12 31 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
9 16 35 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
9 17 43 AM	13	Apnea Alarm ECG = RESP	PASSED
9 18 29 AM	14	Human Alarm Condition - Heart Slow	PASSED
9 19 32 AM	15	Human Alarm Condition - Apnea	PASSED
9 27 40 AM	16	Power Alert Function	PASSED
9 27 48 AM	17	WatchDog Test	PASSED
9 31 21 AM	18	Data Transfer & Recording Verification	PASSED

032680

OPERATOR: Andrew Hamblin

STATION ID 4

RUN ID 2403

PAGE 1

001598

CAS Medical Systems

Ami Apnea Monitor

All Study Logs

Date	Time	Event Type
< 1 >	05/14	12:48 31 Monitor Powered Up
< 2 >	05/16	16 27 57 New Recording Start
< 3 >	05/16	16 29 09 Monitor Powered Down
< 4 >	06/17	11 23 36 Monitor Powered Up
1 06/17	11 24 06	Loose Lead 4 Secs
< 5 >	06/17	11 24 08 Front Alarm Not Heard
< 6 >	06/17	11 24 10 Detection Disabled
2 06/17	11 24 10	Battery Getting Low 1 Sec
3 06/17	11 25 12	Battery Getting Low 1 Sec
< 7 >	06/17	11 25 15 Monitor Powered Down
< 8 >	06/17	11 26 02 Monitor Powered Up
4 06/17	11 26 31	Loose Lead 17 Secs
< 9 >	06/17	11 26 33 Front Alarm Not Heard
5 06/17	11 26 35	Battery Getting Low 14 Secs
< 10 >	06/17	11 26 49 Detection Disabled
<Ami>	06/17	11 27 07 Received 10 Monitor Logs
06/17	11 27 07	Received 5 Patient Logs

Event Count Totals

3 Monitor Ons	2 Monitor Offs
0 Apneas	0 Heart Slows
0 Desaturations	0 Heart Fasts
2 Loose Leads	

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CAS Medical Systems Inc

032681

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
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REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 482976
WORK ORDER # NA
RGA # 15276-1

TEST EQUIPMENT REQUIRED
EdeqTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete
and conforms to test data specifications
4.2 If this is an RGA, verify accessories are with
unit if applicable.

✓
NA

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

032682



CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 2 OF 3

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST. CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING

7.1 Power-up unit under test

A) LED lights strobe through self-test	<u>✓</u>	<u> </u>
B) LCD display strobes through self-test	<u>✓</u>	<u> </u>
Parameters	<u> </u>	<u> </u>
C) Alarm sounds at both front and rear panel locations	<u>✓</u>	<u> </u>
D) When patient leads disconnected from monitor the front panel alarms	<u>✓</u>	<u> </u>

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR.
As followed

- 120 BPM
- 60 BREATH

8.1 With unit under test connected to simulator verify the following

	PASS	FAIL
A) Heartbeat and Respiration LED's flash.	<u>✓</u>	<u> </u>
B) Remove patient leads from monitor Patient Lead LED lights and alarms from front panel.	<u>✓</u>	<u> </u>
C) Replace patient leads on monitor the alarm is off and Patient Loose Lead LED remains on.	<u>✓</u>	<u> </u>
D) Press reset to turn Loose Lead LED off.	<u>✓</u>	<u> </u>
E) Press APNEA button on simulator The alarm turns on along with APNEA LED	<u>✓</u>	<u> </u>
F) Press APNEA button again. After 20 seconds audio alarm turns off but APNEA LED remains on.	<u>✓</u>	<u> </u>
G) Turn the monitor off (press RESET and POWER simultaneously) wait about 30 sec and verify you hear a double beep	<u>✓</u>	<u> </u>

032683

TA SHEET

CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 3 OF 3

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the [] and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:



8.3.1 Display will say "NEW PATIENT" press [] for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.

8.3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct.

8.3.3 Press mode button, display will ask if test is complete. Press enter then press [] for yes and verify unit under test turns off.

PASS

☒ Inspection of unit is completed and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY RL

Date 9/2/03

FAIL

☐ Reason for rejection: _____

QA Inspector: _____ Date: _____

Correction made: _____

QA Inspector: _____ Date: _____

032684

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page ____ of ____

Form Approved, OMB No. 0916-0291 Expires: 01/31/01
See OMB's statement on reuse

MDR report #	2244861200300015
UFDOL report #	
FDA Use Only	

A. Patient information

1 Patient identifier UNK In confidence	2 Age at time of event: UNK or Date of birth: UNK	3 Sex UNK ☐ female ☐ male	4 Weight UNK lbs or UNK kgs

B. Adverse event or product problem

1 ☐ Adverse event and/or ☒ Product problem (e.g. defects/malfunctions)
2 Outcomes attributed to adverse event (check all that apply)
☐ death (mortality) ☐ life-threatening ☐ hospitalization - initial or prolonged ☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other

3 Date of event (mortality) 08/00/03	4 Date of this report (mortality) 09/24/03

5 Describe event or problem

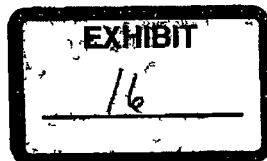
Home care dealer reports that this monitors audio alarm is not working all the time

6 Relevant tests/laboratory data including dates

NA

7 Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepato-renal dysfunction, etc.)

NA



C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2	
2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) (include for best estimate)
#1 NA	#1 NA
#2	#2
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6 Lot # (if known)	7 Exp. date (if known)
#1 NA	#1 NA
#2	#2
8 Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9 NDC # - for product problems only (if known)	
NA -	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1 Brand name Heart Rate Respiration Monitor	
2 Type of device Breathing Frequency Monitor	
3 Manufacturer name & address CAS Medical Systems, Inc 44 E Industrial Rd. Branford CT 06405	4 Operator of device ☐ health professional ☒ lay user/patient ☐ other
5 Expiration date (mortality) NA	6 If implanted, give date (mortality) NA
7 If explanted, give date (mortality) NA	8 If explanted, give date (mortality) NA
9 Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☐ returned to manufacturer on (mortality)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1 Name & address Northwest Medical 1010 SE Stark Portland OR 97214	2 phone # 503-234-6219
2 Health professional? ☐ yes ☒ no	3 Occupation Home Care Dealer
4 Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk	



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A

000252

Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

omission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Page ____ of ____

FDA Use Only

For use by user facility/distributor—devices only

1. Check one ☐ user facility ☐ distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (month/year)	7. Type of report ☐ initial ☐ follow-up # _____	8. Date of this report (month/year)	
9. Approximate age of device	10. Event problem codes (refer to coding manual) patient code _____ - _____ - _____ device code _____ - _____ - _____		
11. Report sent to FDA? ☐ yes _____ (month/year) ☐ no	12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____		
13. Report sent to manufacturer? ☐ yes _____ (month/year) ☐ no	Manufacturer name/address		

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☐ yes ☐ evaluation summary attached ☒ no (attach page to explain why not) or provide code 02		4. Device manufacture date (month/year) 08/30/01	
5. Labeled for single use? ☐ yes ☒ no			
6. Evaluation codes (refer to coding manual) method _____ results _____ conclusions _____			
7. If remedial action initiated check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number			
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data			

G. All manufacturers

1. Contact office — name/address (& mailing site for devices) CAS Medical Systems Inc 44 E. Industrial Rd Branford CT 06405 Attn: Ron Jeffery		2. Phone number 203-488-6056	
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other Dealer		4. Date received by manufacturer (month/year) 08/28/03	
5. (A) NDA # NA IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes		6. If IND protocol # na	
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ initial ☐ follow-up # _____		8. Adverse event term(s) NA	
Mfr report number 244861200300015			

This public reporting burden for this collection of information has been estimated to average one-hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington, D.C. 20503.

U.S. Department of Health and Human Services
Paperwork Reduction Project (0910-0281)
Hubert H. Humphrey Building, Room 531-H
201 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor
and a person is not required to respond to,
a collection of information unless it displays
currently valid OMB control number.

Please DO NOT RETURN this
form to this address.

FDA Form 3500A - back

000253

[REDACTED]		15710
[REDACTED]		8/28/03
CUSTOMER	NORTH WEST MEDICAL	6942
MODEL	AMI PLUS W/MODEM	10133073
DATE	01-05-0170	No
AUDIO ALARM NOT WORKING ALL THE TIME, ESD UPDATE		
[REDACTED]		
9-0225 17-08-0	2-0402 28-02-0	2-0408 21-01-0
11009 18 01 0		
RECERT TO MEET MFG SPECIFICATIONS INSTALLED ESD UPDATE ECN 6813 AND 5554 BATTERY LITHIUM 3 691 PASSED ALL FUNCTIONAL AND FINAL TESTS		
[REDACTED]		
/COULD NOT DUPLICATE COMPLAINT NEEDS ESD UPDATE VER 12 0 BATTERY DATED 6/01 OUTDATED NEEDS RECERT W/BATTERY ECN S 6813 5554 AUDIO ALARM WORKS FINE MDR 200300015 sent 9/24/03		
[REDACTED]		
By	R Jeffrey	10/10/03

000254

SERVICE REPORT

SECTION A

RGA # or S/O #	15710-7	CUSTOMER	NORTH WEST MEDICAL
MODEL #	9700B w/MODEM	SERIAL #	10133073
DATE RECEIVED	9-8-03	ESTIMATE REQUIRED	☒ Wait for customer approval.
		CUSTOMER TRACKING No	NA
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger ☐
Battery ☐
SPO2 Sensor ☐

Patient Cable ☐
Temp Probe ☐
AC Line Cord ☐

Carrying Case ☐
Cuff Hose ☐

Cuff and Size ☐
Pass/Replace ☐

CUSTOMER REQUEST/COMPLAINT

Reason code

98 17

☐ Recertification

☐ Preventative Maintenance

☐ Data Download

☐ Evaluation Request

☒ Customer Statement: CALL w/ESTIMATE AUDIO ALARM NOT WORKING ALL THE TIME.

(over)

INITIAL FINDINGS

MONITOR NEEDS ESD UPDATE. VERSION 12.0. BATTERY DATE 6/01 MONITOR NEEDS ECN 6813 AND 5594. MONITOR NEEDS RECERTIFICATION, WITH A NEW BATTERY, DUE TO OUTDATED BATTERY. Audio alarms work fine.

(over)

Has the customers statement been verified?

☐ YES

☒ NO

☐ N/A (no customer statement)

Warranty (Y/N) ☒ N

PO Number Obtained (Y/N) ☒ N

PO #

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

59

☒ Recertified to meet manufacture's specification

☒ Passed all functional tests

☒ Passed all final tests

Work Performed INSTALLED ESD UPDATE

INSTALLED ECN'S 6813 AND 5594

"THIS IS AN ESD JOB"

Lithium 3691

(over) ECN Update # 6813, 5594

DATE to QA

Total Labor Time

1

Technicians Initials

CLH

QA Approval

RL

QA Date

9/29/03

000255

SECTION C

Software Update	Apnea Monitor Rev		NIBP Module	
	Control Board		SPO2 Module	

SECTION D

Service parts replaced during repair

Part Number	Description	Reason	
		Cosmetic	Failure

Customer Request/Complaint Cont.

Initial Findings Cont.

Work Performed Cont.

000256

CUSTOMER RETURN TRAVELLER

*** RECEIVING ***

RECEIVER# 46292
 CR# LI# CR15710 7
 DATE RECEIVED 09-08 03
 PACKING LIST# 00
 NO OF CARTONS 7
 CUST# CUST NAME 6942 NORTH WEST MEDICAL
 PART# REV 01-05-0170 REV 00)00)14)14)14)14
 DESCRIPTION AMI PLUS,9700B,ENGLISH W/MODEM
 ACCT# 500 0-50 1
 QUANTITY RECEIVED 1
 PO#
 CONTACT NAME JANE ALBRECHT
 CONTACT PHONE
 TAKEN BY TRACY
 SERIAL NUMBERS 10133073

RETURN CODES/REASONS

17 ALARMS NOT WORKING

9899 NON WARRANTY, 501 0-50 1

1804 QNH 99-03

COMMENTS

ESD UPDATE

**AUDIO ALARM NOT WORKING

THE TIME**

CALL W/ESTIMATE

*** INSPECTION ***

Date of Inspection 9/29/03

Inspector's Initials RL

AQL Level

Total Qty Inspected

1

Inspected Loss Qty

0

Total Qty Accepted

1

Total Qty Rejected

0

*** STORES ***

Received By

Received Qty

Stock Date

Stocked By

Stocked Qty

Stock Location

Variance Qty

New Qty On-Hand

- 000257

CUSTOMER RETURN TRAVELLER

RECEIVING ***

46345
 IN CR15718 8
 RECEIVED 09-10-83
 NO LIST# 00
 CARTONS 00
 CUST NAME. 6942 NORTH WEST MEDICAL
 REV 99-05-0001 REV 002002142142142142
 IPTION. ESD UPDATE - AMI / AMI PLUS
 500-0-50-1
 ITY RECEIVED 7

CT NAME. JANE ALBRECHT
 CT PHONE.
 BY TRACY
 NUMBERS. Y-30201252, Y-30201012, Y-30201052, 10133073, Y-30201303, 400207, 401055

✓ CODES/REASONS

SERVICE LIGHT
 ESD UPDATE, 501-0-50-1, 1004

INSPECTION ***
 of Inspection
 tor's Initials

Inspected _____
 ted-Loss Qty _____
 Qty Accepted _____
 Qty Rejected _____

STORES ***
 ed By _____
 ed Qty _____
 Date _____
 d By _____
 d Qty _____
 Location. _____
 re Qty _____
 / On-Hand _____

- 000253

EQUIPMENT RETURN FORM

PATIENT NAME _____ DATE _____

PARENT NAME. _____ BY _____

ACCOUNT NUMBER _____

OFFICE PDX EUG ACE FAI LGR OTHER

REASON

~~SECRET~~ EQUIPMENT EXCHANGE

 EQUIPMENT DISCONTINUED

 TESTING EQUIPMENT

 FROM REPAIR OR NEW

 INTEROFFICE TRANSFER

OTHER

EQUIPMENT TYPE

~~X~~ AMI ___ MMU ___ SLEEP STUDY ___ WALLABY

 CPAP NEBULIZER BREAST PUMP

 OTHER

SERIAL NUMBER 10133073

RECEIVED BY PICK-UP DROPOFF UPS GREYHOUND FX AIR

OTHER _____

DATE OF SERVICE. _____

DATE DISCONTINUED OR EXCHANGE: 7/25/63

EQUIPMENT CONDITION *Alarm Audio alarm not working.*

all the time

EQUIPMENT DISPOSTION

TESTED BY _____ DATE TESTED _____

REPAIRED BY _____ DATE REPAIRED _____

CLINICIAN SIGNATURE _____ DATE _____

000259

Estimate of Repairs

THIS IS AN EID JOB

RGA # 15710-7 Customer NORTH WEST MEDICAL Model 9700B W/MADE S/N 10133073

Repair Estimate Comments (Define Work to be done)

MONITOR NEEDS RECALIBRATION, WITH A NEW BATTERY, DUE TO
OUTDATED BATTERY, G/O.L. MONITOR NEEDS ESD UPDATE.
MONITOR NEEDS ECU'S 6813 AND 5554.

	<u>RECEIPT</u>		
Item 1	P/N <u>03-08 0351 AMH PLUS BATTERY</u>	Price	<u>\$ 50</u>
Item 2	P/N _____	Price	_____
Item 3	P/N _____	Price	_____
Item 4	P/N _____	Price	_____
Functional Test	<u>✓</u>	Price	<u>N/C</u>
Labor Hours	_____	Price	_____

Total Estimate

\$ 50

J.D.
9/24/03

DO NOT replace
battery -
turn w/ their
battery in unit

Contact person/Date approved

Jane 9/26/03

PO # _____

CAS FORM 21-04-0267 Rev 00 000269

		SERVICE PROCESS		Shd. 1 of 1
Process Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
1	15-06-0099	9700 Software		21-01-1180	AMI Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
1	03-09-0225	Battery Alarm board		21-01-1001	AMI Warranty Void Label
2	17-08-0371	150VAC, 150pfd Varistor	1	21-01-1004	AMI Plus Battery Label
1	02-03-0038	1 1/4" Conductive Tape	1	21-01-1009	AMI Plus Warranty Void Label
1	18-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patient Cable Jack
	18-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor - AMI Plus
	29-01-0218	Feet, case	1	18-01-0042	2" 20 AWG Red Wire - AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	AMI Battery Assembly
1	28-02 0402	Remote Alarm Gasket			
1	28-02 0435				

S/O# or RGA # 15710-7 S/N 10133073

Final Test Data Sheet				
Tested By <u>CPH</u>		Date <u>9-24-03</u>		PASS ☒ FAIL ☐
Step No.	Description	PASS	FAIL	Measurement
6.1.5	Ground Wire Resistance	✓		
6.2.5	Leakage Test (Chassis)	✓		.001 uA
6.2.7	Leakage Test (Patient Lead)	✓		.002 uA

Failure Detail _____

000261

REPORT Single Run Summary

TECHNICAL REPORT #126

SERIAL NUMBER. 10133073

TEST RESULTS PASSED

REVISION 13 *Ami Plus w/Modem, Final Test*

TEST DATE 9/24/03

MODEL NUMBER. Y-9700B

PART NUMBER. Y-006122-00B



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
7 29 24 AM	1	Initial Power Up	PASSED
7 29 24 AM	2	Version & Serial Number Verification	PASSED
7 30 04 AM	3	Time & Date	PASSED
7 30 40 AM	4	Patient Setup	PASSED
7 30 50 AM	5	Patient Limits	PASSED
7 30 58 AM	6	Access Code	PASSED
7 31 31 AM	7	O2 Desat	PASSED
7 37 27 AM	8	Signal Quality Indicator	PASSED
7 40 19 AM	9	Resp Detect min, mid, and max	PASSED
7 41 31 AM	10	ECG Crosstalk	PASSED
7 45 25 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
7 49 31 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
7 50 38 AM	13	Apnea Alarm ECG = RESP	PASSED
7 51 24 AM	14	Human Alarm Condition - Heart Slow	PASSED
7 52.28 AM	15	Human Alarm Condition - Apnea	PASSED
7 56 01 AM	16	4.2 VDC +/- 100mV Verification	PASSED
7 57 31 AM	17	WatchDog Test	PASSED
8 02 13 AM	18	Data Transfer & Recording Verification	PASSED

000262

OPERATOR. Andrew Hamblin

STATION ID 4

RUN ID- 2515

PAGE 1

001613

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 10133073
WORK ORDER # NA
RGA # 15710-7

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

4.1 Review and confirm all test data is complete
and conforms to test data specifications

✓

4.2 If this is an RGA, verify accessories are with
unit if applicable

NA

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓

✓

✓

7 FUNCTIONAL SELF TEST

000263

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor
and patient settings. Press the and enter button at the same time. Turn monitor power on
and follow the prompt on display as follows

- ↓
- 8.3.1 Display will say "NEW PATIENT", press for yes indication, it will then ask if you are
sure. Press enter and verify clear memory is displayed.
- 8.3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct.
- 8.3.3 Press mode button, display will ask if test is complete. Press enter then press for yes,
and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY RL

Date 9/29/03

FAIL

☐ Reason for rejection. _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

000264



For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Form Approved OMB No. 0910-0291 Expires: 01/31/01
See OMB statement on reverse

MDR report #	2244861200300017
UF/DMA report #	
FDA Use Only	

USA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

Patient information			
1. Patient identifier	2. Age at time of event or Date of birth. 03/28/03	3. Sex ☒ female ☐ male	4. Weight UNK lbs or kgs

Adverse event or product problem	
☒ Adverse event and/or	☐ Product problem (e.g., defects/malfunctions)
Outcomes attributed to adverse event check all that apply)	
☒ death (mortality)	☐ disability
☐ life threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
☐ other	
5. Date of event (mortality) 08/30/03	4. Date of this report (mortality) 10/17/03

Home care dealer reports that the baby was released from the hospital 2 days prior to the baby's death. Baby was on a ventilator as well as the apnea monitor while at home for respiratory problems. The family stated that there was no alarms at the time of the incident. The memory download (obtained by the home care dealer) states loose lead alarms, extended heart slow low battery and front alarm not heard. The parents identified a problem and called paramedics who then removed the baby from monitor and ventilator and transported to the hospital. Not clear if baby died in transport or at the hospital.



Relevant tests/laboratory data including dates

Prior to the monitor arriving at CAS, the monitor's owner (Naptime) evaluated monitor and found no problems.

Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Baby was on a ventilator and apnea monitor and said to have respiratory problems.



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)	
1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose, frequency & route used	
#1 NA	
#2	
3. Therapy dates (if unknown, give duration) (month/day/yr)	
#1 NA	
#2	
4. Diagnosis for use (indication)	
#1 NA	
#2	
5. Event abated after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)	
#1 NA	
#2	
7. Exp. date (if known)	
#1	
#2	
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA - -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device	
1. Brand name: Heart Rate Respiration Monitor	
2. Type of device: Breathing Frequency Monitor	
3. Manufacturer name & address	
Nelcor Puritan Bennett 2800 northwest Blvd Plymouth MN 55441	
4. Operator of device	
☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (month/day/yr)	
NA	
6. Model #	
9700B	
7. If implanted, give date (month/day/yr)	
NA	
8. If explanted, give date (month/day/yr)	
NA	
9. Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 10/08/03 (month/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter	
1. Name & address	
Naptime 1280 West Lambert Suite B Brea CA 92821	
phone # 562-691 7161	
001564	
2. Health professional?	3. Occupation
☐ yes ☒ no	Home Care Dealer
4. Initial reporter also sent report to FDA	
☐ yes ☒ no ☐ k	

001616

**Education and Device
Experience Report**
(continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

guidelines for specific instructions

Page 2 of 2

FDA Use Only

I. Use by user facility/distributor-devices only

Check one
☐ user facility ☐ distributor

2. UF/Dist report number

User facility or distributor name/address

Contact person

5. Phone Number

Date user facility or distributor became aware of event (month/year)

7. Type of report
☐ initial
☐ follow-up #

8. Date of this report (month/year)

Approximate age of device

10. Event problem codes (refer to coding manual)

patient code - - -
device code - - -

Report sent to FDA?
yes (month/year)
no

Report sent to manufacturer?
yes (month/year)
no

12. Location where event occurred
☐ hospital ☐ outpatient diagnostic facility
☐ home ☐ ambulatory surgical facility
☐ nursing home ☐ outpatient treatment facility
☐ other specify

Manufacturer name/address

H. Device manufacturers only

1. Type of reportable event
☒ death
☐ serious injury
☐ malfunction (see guidelines)
☐ other

2. If follow-up what type?
☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. Device evaluated by mfr?
☐ not returned to mfr
☒ yes ☒ evaluation summary attached
☐ no (attach page to explain why not) or provide code

4. Device manufacture date (month/year)
unk

5. Labeled for single use?
☐ yes ☒ no

6. Evaluation codes (refer to coding manual)

method 10 - 33 - -
results 708 - - -
conclusions 68 - - -

7. If remedial action initiated, check type
☐ recall ☐ notification
☐ repair ☐ inspection
☐ replace ☐ patient monitoring
☐ relabeling ☐ modification/adjustment
☐ other

8. Usage of device
☐ initial use of device
☐ reuse
☒ unknown

9. If action reported to FDA under 21 USC 360(k), list correction/removal reporting number

10 ☒ Additional manufacturer narrative and/or 11 ☐ Corrected data

All manufacturers

Contact office - name/address (& mailing site for devices)

AS Medical Systems Inc
1 E Industrial Rd
ranford CT 06405 Attn: Ron Jeffrey
ote: CAS purchased product line after this
evice was manufactured from
ellcor Puntan Bennett
900 Northwest Blvd
lymouth MN 55441

2. Phone number
203-488-6056

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☒ other Dealer

Date received by manufacturer (month/year)
9/18/03

4. IND protocol #

1a Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☐ follow-up #

5. (A)NOA # NA
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

8. Adverse event term(s)
NA

4fr report number
244861200300017

H6 (68) Monitor alarms worked correctly and alarm as they should
The user is audibly alerted! There was a service light alarm due to
the acoustical direction of the alarm sound not getting to the
microphone When the sound is not picked up by the microphone
a message is logged in memory that Front Alarm is Not Heard A
fix for this (ECN 6813) permits the microphone to hear and make
note of the alarm sound

001565

public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information, sending comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 5314
200 Independence Avenue S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor
and persons are not required to respond to
a collection of information unless it displays
currently valid OMB control number

Please DO NOT RETURN this
form to this address

CAS Medical Systems

60022

10/6/03

CUSTOMER

NAPTIME HOME CARE

7456

MODEL

AMI PLUS W/MODEM

SERIAL

Y 30200151R

PART

01 05 0170R

No

CUSTOMER COMMENT

RED TAG INFANT EXPIRED ON 8/30/03 WHILE BEING MONITORED W/THIS UNIT AS WELL AS A VENTILATOR NAPTIME PERFORMED DOWNLOAD SHOWING NUMEROUS LOOSE LEAD ALARMS HEART SLOW ALARMS FOR PERIOD OF 5 MIN BATT LOW FRONT ALARM NOT HEARD WANTS EVALUATED

REPAIR SECTION

2 0435 28 02 0

28 02-0408

21 01 1004

21 01 1009

REPAIR COMMENT

INSTALLED ECN 6813 PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION

ALARMS WERE REPORTED TO WORK WHEN UNIT WAS CHECKED OUT NAPTIME GOT MACHINE ON 9/17 IT WAS REPORTED THAT A NURSING SERV DID NOT SHOW UP THAT NIGHT VER 13 0 DOWNLOAD SHOWS MON RESPONDED TO ALL ACTIVITIES MDR 200300017 sent 10/17/03

CLOSED BY

R Jeffrey

10/22/03

001566

See RGA 60022

✓ ENTERED SEP 30 2003 QML

RGA OR
P.C.# 04279

ADVERSE EVENT FORM (AEF)

Use for documenting required information for adverse event complaints

Date form filled out 9/18/03 Person filling out form A Cop (rewritten by R Jeffrey)

Date CAS first learned of event 9/18/03 Event described as Death ✓ Injury

Company and person reporting Naptune Home Care (Mark Hicks)

Address & phone # 1280 West Lambert Suite B

Brea, CA 92821 502-691-7161

Product Description. Model AMI Serial/Lot number Y30200151R Electrodes used

Date of event 8/30/03 Event time of day 10 PM ^{9/24/03} Patient DOB 3/28/03 Gest. Age

Patient Male Female ☒ Product first used on patient Date Time of day

Patient's state of health prior to event Patient went home Friday & died on Saturday
Patient was on Ventilator

Description of event or problem Parent heard no alarms. Mother said that
Monitor should have alarmed. The log shows numerous heart
no alarms and loose leads (especially one 6 hr loose lead at
around the time of death)

Distributors evaluation

Distributor downloaded memory Yes ☒ No Results?

Has memory been erased? Will distributor report to FDA

Additional information Alarms were reported to work when unit
was checked out Naptune got machine on 9/17/03. Sending
it to a 3rd party Biomed place for evaluation

It was reported that a nursing service did not show up
that night

(Use backside to log additional information and communications)

21-04-0223 REV 02

01/17/03
see updated information on 10/6/03 AEF form 10/17/03

001567

NEED PIF CALL

Jeffrey, Ron

From NaptimeHomecare@aol.com
Sent. Thursday September 18 2003 4 22 PM
To rjeffrey@casmcd.com
Subject. Down Load from Monitor involved in patient death.

Ron

Here is the down load from Jovana Morals this patient passed away on 8-31-03 The incident occurred on 8-30-03 at approximately 10 00 PM

The family is stating there were no alarms at the time of the incident.

If you need to talk with me my phone number is 562-691-7161.

Thanks

Mark Hicks

9/19/03

001568

001620

mary

000151

TEST RESULTS PASSED



NELLCOR
PURITAN
BENNETT.

Ami Plus w/Modem Final Test
10/9/03

MODEL NUMBER Y-9700B
PART NUMBER Y-006122-00B

TIME	TEST	TEST DESCRIPTION	STATUS
11 15 57 AM	1	Initial Power Up	PASSED
11 15 57 AM	2	Version & Serial Number Verification	PASSED
11 16 36 AM	3	Time & Date	PASSED
11 16 57 AM	4	Patient Setup	PASSED
11 17 21 AM	5	Patient Limits	PASSED
11 17 29 AM	6	Access Code	PASSED
11 18 02 AM	7	O2 Desat	PASSED
11 19 38 AM	8	Signal Quality Indicator	PASSED
11 22 28 AM	9	Resp Detect min, mid, and max	PASSED
11 23 39 AM	10	ECG Crosstalk	PASSED
11 27 33 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
11 31 39 AM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
11 32 45 AM	13	Apnea Alarm ECG = RESP	PASSED
1 33 31 AM	14	Human Alarm Condition - Heart Slow	PASSED
1 34.20 AM	15	Human Alarm Condition - Apnea	PASSED
11 45 29 AM	16	4 2 VDC +/- 100mV Verification	PASSED
11 45 37 AM	17	WatchDog Test	PASSED
11 48 52 AM	18	Data Transfer & Recording Verification	PASSED

SERVICE REPORT

SECTION A

1# or S/O #	60022	CUSTOMER	NAPTime
MODEL #	10803	SERIAL #	Y80200151
DATE RECEIVED	97008 w/m	ESTIMATE REQUIRED	☐ Wait for customer approval.
		CUSTOMER TRACKING No	
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patent Cable		Carrying Case	
Battery		Temp Probe		Cuff Hose	
SPO2 Sensor		AC Line Cord			
Cuff and Size					
Pass/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification	☐ Preventative Maintenance	☐ Data Download	☐ Evaluation Request
☒ Customer Statement <i>Replaced Tag & PLS see customer</i>			
<i>Return to customer</i>			

INITIAL FINDINGS

MONITOR VER 13.0, download showing that monitor response to all the Activity, even alarms where function correctly but there was service light because the internal mic didn't detect the 9/10/03 signal - Front alarm works fine - ^{ECN} update is required, BATTERY INSTALLED 11/02 BATTERY NOT 2 YEARS OLD YET. (over)

Has the customers statement been verified? ☒ YES ☐ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ PO Number Obtained (Y/N) ☐ PO #

SERVICE FINDINGS/OTHER SERVICE PERFORMED

☐ Recertified to meet manufacture's specification	Problem Area Code	59
☒ Passed all functional tests	Work Performed	<i>downloading, ECN update</i>
☒ Passed all final tests		<i>6813 INSTALLED, MONITOR HAS ALL OTHER UPDATES</i>

(over) ECN Update # 6813

Total Labor Time

QA Approval

Technicians Initials

QA Date

DATE to QA

10-17-03

CAS Medical Systems Inc Form 21 04-0027 Rev 10

CAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Shl. 1 of 1
Process Number SVC9700PUL		Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used		
Qty	Part Number	Description
	15-06-0099	9700 Software
	15-06-0105	9700G German Software
	15-06-0103	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	03-09-0225	Battery Alarm board
	17-08-0371	150VAC 150pfd Varistor
	02-03-0038	1 1/4 Conductive Tape
	16-04-0190	1ufd Capacitor (R225)
	17 09-0325	10K SMT Resistor (R999)
	16-04-0085	0 1ufd cap (C235)
	29-01-0218	Feet, case
	28-02-0275	Foot-Rubber (square)
0	28-02-0402	Remote Alarm Gasket
1	28 02-0435	

Qty	Part Number	Description
	21-01-1190	Ami Battery Drawer Label
1	28-02-0328	CAP DUST 25 PIN
1	28-02-0408	Clear Polyester Label
	21-01 1055	AMI Battery Seal
	21-01-1001	AMI Warranty Void Label
1	21-01-1004	AMI Plus Battery Label
1	21-01 1009	AMI Plus Warranty Void Label
	03-08-0351	AMI Plus Battery Assembly
	22-02-0112	Patient Cable Jack
	17-08-0123	1Meg Resistor - AMI Plus
	18-01-0042	2" 20 AWG Red Wire - AMI Plus
	03-08-0314	Ami Battery Assembly

S/O# or RGA # 60022 S/N Y302 00151

Final Test Data Sheet					
Tested By <u>Cut</u>		Date <u>10-9-03</u>		PASS ☒	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance	✓			
6.2.5	Leakage Test (Chassis)	✓		002 uA	<15 uA
6.2.7	Leakage Test (Patient Lead)	✓		003 uA	<15 uA

Failure Detail _____

001571

RGA OR 60022
PC #

ADVERSE EVENT FORM (AEF)

Use for documenting required information for adverse event complaints

Date form filled out 10/6/03 Person filling out form Tracy Blahusa

Date CAS first learned of event 10/6/03 Event described as Death ☒ Injury

Company and person reporting Naptune

Address & phone # 1280 West Lambert, Ste B

Brea, CA 562-691-7161 (Kelly)

Monitor description Model 97003 Serial number Y-30200151 Electrodes used ?

Date of event 8/30/03 Event time of day ? Patient DOB 3/28/03 Gest. Age ?

Patient Male ? Female ☒ Monitor first used on patient Date ? Time of day ?

Patient's state of health prior to event Infant released from hospital 3

Days prior to event

Description of event or problem Patient expired, Baby was on
a ventilator as well as Apnea monitor for
respiratory problems.

Distributors evaluation

Distributor downloaded memory Yes ☒ No Results? loose lead alarms Apnea Heart

Has memory been erased? slow for a period of 5 minutes Will distributor report to FDA requested CAS to

Additional information also got battery low message - report

Because of numerous loose lead alarms, parents took
baby off monitor to take her to the hospital unsure
if baby expired during route to hospital or at hospital

*Download also showed Front alarm not heard copy of

(Use backside to log additional information and communications) Download 21-04 0223 REV 01

will be with monitor

001572



October 6 2003

CAS Medical
Attn Lenny Hottin Service Manager
44 E. Industrial Road
Branford CT 06405

Re Mallinkrodt Ami Plus Monitor
Serial Number Y30200151

RGA #60022

Per my conversation with Tracy Blanus (Fax 203-488-9438) enclosed please find the above referenced apnea monitor and a copy of the DL report which was performed on 9/16/03

Please perform a PM and check machine We have reports showing the front alarm is not working Also as per our conversation, please report this incident to the FDA.

We had a patent on this monitor that expired. We need the results returned to us ASAP (as well as returning the monitor)

Thank you


Kelli Schneider
Office Manager

1280 WEST LAMBERT ROAD #8 BREA CA. 92821 PHONE 562-691-7161 FAX 562-691 7162

- 001573

1d 14 06 2003 12 25PM P1

FRX NO 15626917162

FROM NAPTIME

001625

tyco

Healthcare

Kendall

Richard E. George
Risk Manager

McDonnell Boulevard
St. Louis, MO 63134

Tel 314-654-5723
Fax 314-654-3156
richard.george
@tycohealthcare.com
www.kendallhq.com

RECEIVED DEC 06 2004

December 1, 2004

VIA CERTIFIED MAIL,
RETURN RECEIPT REQUESTED

Louis P. Scheps
President and CEO
CAS Medical Systems, Inc
44 East Industrial Road
Branford, CT 06405

Re Two Indemnity Notifications
Dates of Events August 30, 2003 and May 8, 2004

Dear Mr. Scheps

We have received and reviewed your correspondence dated November 12, 2004 alerting Nellcor Puritan Bennett Inc. of "two incidents that may potentially result in claims" as noticed under MDR 200300017 and MDR 200400008. We have also reviewed the Asset Purchase and Sale Agreement, dated November 29, 2000 (the "Purchase Agreement"), between CAS Medical Systems Inc. and Nellcor Puritan Bennett Inc.

We acknowledge your notice of these events, however, at the present time these "incidents" do not constitute "claims" seeking "damages" as specified in the Purchase Agreement between our companies. Accordingly, Sections 7.2 and following related sections of the Purchase Agreement are not implicated at this time, and accordingly no investigation and/or follow-up activity needs to be initiated at this time.

If a claim is presented on either of these matters, we would ask that you immediately notify the undersigned in accordance with the terms of the Purchase Agreement and we will then consider the matter and discuss the initiation of any claim-handling activity.

If in the meantime you have any questions or would like to discuss this matter further, please feel free to contact me.

Sincerely,



Richard E. George
Risk Manager - Tyco Healthcare

REG/cmi

001574

001626

WATCH

IE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0910-0281 Expires: 01/31/01
See OMB Internet at reverse

MDR report #	2244861200300018
UFDist report #	
FDA Use Only	

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth.	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or UNK kgs
JNK	UNK UNK		

In confidence

B. Adverse event or product problem

☐ Adverse event and/or	☒ Product problem (e.g. defects/malfunctions)
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

5. Date of event (m/d/yyyy)	6. Date of this report (m/d/yyyy)
12/00/03	12/29/03

Describe event or problem

Home Care Dealer reports that the monitor beeps one time but does not further alarm. No other details were stated.

7. Relevant tests/laboratory data including dates

NA

8. Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose frequency & route used	
#1 NA	
#2	
3. Therapy dates (if unknown give duration) (month to best estimate)	
#1 NA	
#2	
4. Diagnosis for use (indication)	
#1 NA	
#2	
5. Event abated after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)
#1 NA	#1 NA
#2	#2
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name	
Heart Rate Respiration Monitor	
2. Type of device	
Breathing Frequency Monitor	
3. Manufacturer name & address	
Nellcor Puntan Bennett 2800 Northwest Blvd Plymouth MN 55441	
4. Operator of device	
☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (m/d/yyyy)	
na	
6. Model #	
9700A	
7. If implanted give date (m/d/yyyy)	
na	
8. If explanted, give date (m/d/yyyy)	
na	
9. Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 12/09/03 (m/d/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

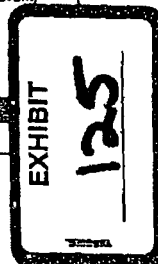
E. Initial reporter

1. Name & address	phone #
Nurses Unlimited 715 No Texas St. Odessa TX 79761	432 550-5041
032693	
2. Health professional?	3. Occupation
☐ yes ☒ no	Home Care Dealer
4. Initial reporter also sent report to FDA	
☐ yes ☐ no ☒ nk	



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



001627

Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user, facility, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 2

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

FDA Use Only

I. For use by user facility/distributor devices only

Check one ☐ user facility ☐ distributor		2. UFDist report number	
User facility or distributor name/address			
Contact person		5. Phone Number	
3. Date user facility or distributor became aware of event (month/day/yr)	7. Type of report ☐ Initial ☐ follow-up #	8. Date of this report (month/day/yr)	
9. Approximate age of device	10. Event problem codes (refer to coding manual) patient code: - - device code: - -		
11. Report sent to FDA? ☐ yes (month/day/yr) ☐ no	12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other		
13. Report sent to manufacturer? ☐ yes (month/day/yr) ☐ no	14. Manufacturer name/address		

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code.		4. Device manufacture date (month/yr) 08/24/98	
		5. Labeled for single use? ☐ yes ☒ no	
6. Evaluation codes (refer to coding manual) method: 10 33 results: 708 conclusions: 71			
7. If remedial action initiated check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(n) list correction/removal reporting number			

10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

NA

032694

G. All manufacturers

1. Contact office - name/address (& mailing site for devices) CAS Medical Systems Inc 44 E Industrial Rd Branford CT 06405 Note: CAS purchased product line after this device was manufactured from Nelcor Puritan Bennett 2800 Northwest Blvd Plymouth Mn 55441		2. Phone number 203-488-5065	
4. Date received by manufacturer (month/day/yr) 12/01/03		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☒ distributor ☐ other	
6. If IND protocol # na	5. (A) NDA # na IND # PLA # pre-1938 ☐ yes OTC product ☐ yes	8. Adverse event term(s) na	
7. Type of report (check all that apply) ☐ 5 day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up #	J. Mfr report number 2244861200300018		

The public release of information for this collection of information has been estimated to require one hour per person, including the time for review of the data, searching existing data sources, gathering the data, and reviewing the collection of data for any other aspect of collection of information, including its use for redaction of this burden.

DHHS Reports Clearance Office
Permit Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 331
205 Independence Avenue SW
Washington, D.C. 20502

An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number.

Please do NOT RETURN this form to this address

CAS Medical Systems, Inc.

16205

12/1/03

CUSTOMER: NURSES UNLIMITED

6966

MODEL: AMI W/MODEM

480680

PART: 01 05 0163

No

CUSTOMER COMMENTS: APNEA BEEPS ONCE AND DOESN'T ALARM

PAIR SECTION

1 0335 03-09-0

4 0190 17 09-0

28-02-0275

1 1190, 28-02-0

REPAIR COMMENTS

RECERT TO MEET MFG SPECIFICATIONS INSTALLED ESD UPDATE NEW AMI BATTERY ASSY AND ECN UPDATE 6813 AND 5554 PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION

Customers claim unfounded

CORRECTIVE ACTION

MDR 200300018 sent 12/30/03

CLOSED BY

R Jeffrey

1/7/04

032698

ENTERED DEC 1 2003

PRODUCT INFORMATION FORM (PIF)

GA OR PC # <u>116203</u>		PATIENT INJURY OR DEATH Y ☐ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
FORM FILLED OUT BY <u>TB</u>		DATE OF THIS REPORT <u>12/1/03</u>	
PRODUCT <u>4700A</u>	LOT/SERIAL # <u>480680</u>	QUANTITY <u>1</u>	
CUSTOMER NAME <u>Nurses Unlimited</u>		BILLING	
ADDRESS <u>cdosy, TX</u>		CUSTOMER NAME <u>1</u>	
COMPLAINANT <u>Elyssa Valdez</u>		ADDRESS _____	
PHONE <u>432 550-5041</u>		_____	
INFORMATION DETAILS		CHECK IF OUT OF BOX FAILURE ☐	
<u>Apnea beeps once and doesn't</u>			
<u>alarm</u>			

ACTION TAKEN THUS FAR			

DATE LOGGED AT QA <u>12/1/03</u>		☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION	
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)			

REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
_____		<u>Ron - [Signature]</u>	
REASON FOR NO REPLY TO COMPLAINANT		032695	
CLOSE OUT		DATE _____	
SIGNATURE _____			

SERVICE REPORT

ACTION A

# or S/O #	16205-1	CUSTOMER	NURSES UNLIMITED
MODEL #	9700A W/MODEM	SERIAL #	480680
DATE RECEIVED	12-9-03	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No	000741
		LOCATION of LABEL	TC

ACTION B

EMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patent Cable		Carrying Case	
Battery		Temp Probe		Cuff Hose	
SPO2 Sensor		AC Line Cord			

Weight and Size				
Wash/Replace				

CUSTOMER REQUEST/COMPLAINT

Reason code

98 99 97

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

Customer Statement: APNEA BEEPS ONCE AND DOESN'T ALARM

INITIAL FINDINGS MONITOR NEEDS ESD UPDATE. 11 09 VERSION. BATTERY DATE 12/01. MONITOR NEEDS RECERTIFICATION, WITH A NEW BATTERY, DUE TO OUTDATED BATTERY. MONITOR NEEDS ECU'S 6813 AND 5554. MONITOR NEEDS ESD UPDATE until works fine for apnea.

detection and repairs occurred as the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ N PO Number Obtained (Y/N) ☒ Y PO # 13255 032696

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

59.77

☒ Recertified to meet manufacture's specification
☒ Passed all functional tests
☒ Passed all final tests

Work Performed INSTALLED ESD UPDATE
INSTALLED ECU'S 6813 AND 5554.
INSTALLED A AMI BATTERY ASSY.

THIS IS AN ESD JOB.

(over) ECU Update # 6813

1104 3691

Total Labor Time

1

Technicians Initials

CLH

DATE to QA

12-22-03

QA Approval

RL

QA Date

12/22/03

Medical Systems APPLIED TO MEDICINE		SERVICE PROCESS		Shl 1 of 1
Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
1	15-06-0099	9700 Software	1	21 01 1190	Ami Battery Drawer Label
1	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
1	15-06-0103	9700S Spanish Software	1	28-02 0408	Clear Polyester Label
2	15-01-0335	IC 74AC00 (U23 & U28)	1	21-01-1055	AMI Battery Seal
1	03-09-0225	Battery Alarm board	1	21 01 1001	AMI Warranty Void Label
2	17-08-0371	150VAC 150pfd Vanstor		21-01 1004	AMI Plus Battery Label
1	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
1	16-04-0190	1ufd Capacitor (R225)		03 08-0351	AMI Plus Battery Assembly
1	17 09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack
1	16-04-0085	0 1ufd cap (C235)		17 08-0123	1Meg Resistor AMI Plus
1	29-01-0218	Feet, case		18-01 0042	2" 20 AWG Red Wire AMI Plus
1	28-02-0275	Foot-Rubber (square)	1	03-08-0314	Ami Battery Assembly
1	28-02 0402	Remote Alarm Gasket			
1	28 02-0435	FUNNEL			

S/O# or RGA # 16305-1 S/N 480680

Final Test Data Sheet					
Tested By <u>ATLH</u>		Date <u>12 22 03</u>		PASS ☒	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6 1 5	Ground Wire Resistance	☒	☐		
6 2 5	Leakage Test (Chassis)	☒	☐	001 uA	<15 uA
6 2 7	Leakage Test (Patient Lead)	☒	☐	001 uA	<15 uA

Failure Detail _____

032697

MEDWATCH

MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved OMB No. 0910-0291 Expires 12/31/07
See OMB statement on revers

MDR report #	2244861200400001
UFDist report #	
FDA Use Only	

Patient information			
1. Patient Identifier VK	2. Age at time of event UNK or Date of birth. UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or UNK kgs

Adverse event or product problem	
☐ Adverse event and/or	☒ Product problem (e.g., defects/malfunctions)
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

5. Date of event (mortality) 12/00/03	6. Date of this report (mortality) 01/12/04

Describe event or problem

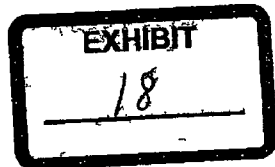
The Home Care Dealer reports that the monitor did not alarm for an event where the mother found her baby turning blue and not breathing. CPR was administered and the baby turned out fine. While the monitor was being analysed by dealer the download from memory was found to be unusual in that events could not be recorded properly.

Relevant test/laboratory data including dates

NA

Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA



1A Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)	
1. Name (give labeled strength & ruf/labeler if known)	
#1 NA	
#2	
2. Dose, frequency & route used	
#1 NA	
#2	
3. Therapy dates (if unknown, give duration) (month/day/yr)	
#1 NA	
#2	
4. Diagnosis for use (indication)	
#1 NA	
#2	
5. Event abated after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)	
#1 NA	
#2	
7. Exp. date (if known)	
#1 NA	
#2	
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device	
1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address Nellcor Puritan Bennett 2800 Northwest Blvd Plymouth Mn 55441	
4. Operator of device ☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (month/day/yr) NA	
6. If implanted, give date (month/day/yr) NA	
7. If explanted, give date (month/day/yr) NA	
8. If explanted, give date (month/day/yr) NA	
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☒ returned to manufacturer on 12/19/03 (month/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter	
1. Name & address Ashby Medical 123 Centum Drive Suite 1 Irmo SC 29063	phone # 800 229-7561 001657
2. Health professional? ☐ yes ☒ no	3. Occupation Home Care Dealer
4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unknown	

001633

**Education and Device
Experience Report**
(continued)

Submission of a report does not constitute
an admission that medical personnel, user,
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Refer to guidelines for specific instructions

Page 2 of 2

FDA Use Only

F. Use by user facility/distributor—devices only

Check one
☐ user facility ☐ distributor

2. UF/Dist report number

User facility or distributor name/address

Contact person

5. Phone Number

Date user facility or distributor
became aware of event
(month/day/yr)

7. Type of report
☐ Initial
☐ follow-up # _____

8. Date of this report
(month/day/yr)

Approximate
age of device

10. Event problem codes (refer to coding manual)

patient code _____
device code _____

Report sent to FDA?

☐ yes _____
☐ no (month/day/yr)

Report sent to manufacturer?

☐ yes _____
☐ no (month/day/yr)

Manufacturer name/address

12. Location where event occurred

☐ hospital ☐ outpatient
☐ home ☐ diagnostic facility
☐ nursing home ☐ ambulatory
☐ outpatient surgical facility
☐ treatment facility
☐ other _____

All manufacturers

Contact office—name/address (& mailing site for devices)

AS Medical Systems Inc
4 E Industrial Rd
Hartford CT 0645 Attn Ron Jeffrey
Note: CAS purchased product line after this
device was manufactured from
Ellcor Puritan Bennett
800 Northwest Blvd
Lymouth MN 55661

Date received by manufacturer
(month/day/yr)

2/15/03

If IND protocol #

Type of report
(check all that apply)

☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☐ final ☐ follow-up # _____

Manufacturer report number

2244861200400001

5. (A) NDA # NA

IND # _____

PLA # _____

pre-1938 ☐ yes

OTC product ☐ yes

8. Adverse event term(s)

NA

2. Phone number

203-488-6056

3. Report source
(check all that apply)

☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☒ other
Dealer

H. Device manufacturers only

1. Type of reportable event

☐ death
☐ serious injury
☒ malfunction (see guidelines)
☐ other _____

2. If follow-up what type?

☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. Device evaluated by mfr?

☐ not returned to mfr
☒ yes ☒ evaluation summary attached
☐ no (attach page to explain why not)
or provide code _____

4. Device manufacture date
(month/yr)

UNK

5. Labeled for single use?

☐ yes ☒ no

6. Evaluation codes (refer to coding manual)

method 10 - 33 - _____
results 708 - 100 - _____
conclusions 71 - _____

7. If remedial action initiated
check type

☐ recall ☐ notification
☐ repair ☐ inspection
☐ replace ☐ patient monitoring
☐ relabeling ☐ modification/
adjustment
☐ other _____

8. Usage of device

☐ initial use of device
☐ reuse
☒ unknown

9. If action reported to FDA under
21 USC 360(f), list correction/removal
reporting number

10. ☒ Additional manufacturer narrative and/or 11. ☐ Corrected data

H6 (100) - Monitor actually had two reported problems. No
problem was found with the monitor's ability to alarm as it should.
This was the reason for the MDR. A time control problem was the
cause of the monitor not being able to record events. Loose
crystals were found to be the root cause. The monitor is suspect
as being dropped.

001658

Public reporting burden for this collection of information has been estimated to average one
page response, including the time for reviewing instructions, searching existing data sources,
gathering and maintaining the data needed, and completing and reviewing the collection of information.
Send comments regarding this burden estimate or any other aspect of this collection of information,
including suggestions for reducing this burden, to Washington, D.C. 20201

DHHS Reports Clearance Office
Paperwork Reduction Project (8910-0281)
Robert H. Humphrey Building Room 631-H
200 Independence Avenue S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor
and a person is not required to respond to,
collection of information unless it displays
this valid OMB control number

Please DO NOT RETURN this
form to this address

✓ ENTERED DEC 15 2003 *Jim*

✓
RED TAG

PRODUCT INFORMATION FORM (PIF)

RGA OR PC # <u>116100</u>		PATIENT INJURY OR DEATH Y ☐ N ☒		6233
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD		
A.	FORM FILLED OUT BY <u>Ron Jeffrey</u>		DATE OF THIS REPORT <u>12-15-03</u>	
	PRODUCT <u>Ami Monitor</u>		LOT/SERIAL # <u>Y30201449</u> QUANTITY <u>1</u>	
	CUSTOMER NAME <u>Ashby Medical</u>		BILLING CUSTOMER NAME _____	
	ADDRESS _____		ADDRESS _____	
	COMPLAINANT <u>Steve Elliot</u>		_____	
PHONE <u>800 229-7561</u>		_____		
INFORMATION DETAILS				
<u>ON 12-12-03 @ 3:30 the monitor apparently did</u>				CHECK IF OUT OF BOX FAILURE ☐
<u>Not alarm for an event. Mother found baby blue and not</u>				
<u>breathing. CPR administered and baby now is fine. Dealer</u>				
<u>report unusual behavior of downloaded data. Monitor has</u>				
<u>worked fine in the past. It was reported that the apnea light</u>				
<u>worked later on. Jensen electrodes were used. ²⁻⁵⁻⁰² Dealer</u>				
<u>suspects obstructive apnea. Download not erased and</u>				
<u>a hard copy is coming</u>				
ACTION TAKEN THUS FAR				
<u>None</u>				
B.	DATE LOGGED AT QA <u>12/15/03</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION			
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)			
	<u>Arrived w/ download print out on 12/15/03. Sticker says-</u>			
	<u>'Last serviced by CAS on 2/23/03'</u>			
	<u>See Service report</u>			
REASON FOR NO INVESTIGATION		AUTHORIZED BY		
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)				
<u>Sent MDR # 200400001 1-12-04</u>				
020407				
REASON FOR NO REPLY TO COMPLAINANT				
CLOSE OUT				
SIGNATURE <u>Ron Jeffrey</u>		DATE <u>1-12-04</u>		

CAS MEDICAL SYS. INC.

MINI TECHNOLOGY APPLIED TO MEDICINE

44 EAST INDUSTRIAL RD. BRANFORD, CT 06405

203 488-6056 FAX 203 488-9438

1001

DATE 12/15/03

ACKNOWLEDGEMENT
11109

SOLD TO 6233
A HAY MEDICAL
123 CENTRUM DRIVE
SUITE 1
BRANFORD, CT 06405

SHIP TO 6233
A HAY MEDICAL
123 CENTRUM DRIVE
SUITE 1
BRANFORD, CT 06405

ATTN: ACCOUNTS PAYABLE

ATTN: RECEIVING

DATE NOTIFIED	DATE RECEIVED	POST BOX	BUYER	SALESMAN	TAX
12-15-03			STEVE ELLIOT		110%

WEIGHT	TERMS	SHIP - VIA
	15-30 N 30	UPS

LINE	DESCRIPTION	QTY	UNIT PRICE

LINE# 01 35 0120
ONE (1) 35" MONITOR WITH WOODM

Under warranty and
has been returned
17" monitor not working
20" monitor warranty 01 0 10-1 1011

CH Y 0101440
ORDER DATE 010
12-15-03

ON 12/15/03 03 30
THE MONITOR APPARENTLY
DID NOT ALARM FOR AN
EVENT MONITOR FOUND BABY
FLAT AND NOT BREATHING
ALL ADMINISTERED AND LATE
HOW TO FINE DEALER
KEEPTO UNUSUAL BEHAVIOR
OF DOWNLOADED DATA
MONITOR HAS WORKED FINE
THE LAST IT WAS
RECORDED THAT THE ALARM
LIGHT FLICKED LATER ON
JANUARY 10 PROBLEMS WERE
GIVEN BY THE SUSPECT
DESTRUCTIVE AFTER
DOWNLOAD NOT PERCEIVED AND A
UNUSUAL IS COMING
RED TAG FOR TERRY

020408

16100	
12/15/03	
CUSTOMER	ASHBY MEDICAL
CUSTOMER	6233
MODEL	AM1 PLUS W/MODEM
SERIAL	Y 30201449
PART	01 05-0170
WARRANTY	No
CUSTOMER COMMENTS	RED TAG RJ ON 12/12/03 @ 3 30 THE MON DID NOT ALARM FOR AN EVENT MOTHER FOUND BABY BLUE AND NOT BREATHING CPR ADMINISTERED & BABY IS FINE DEALER REPORTS UNUSUAL BEHAVIOR OF DOWNLOADING DATA. MON WORKED FINE IN PAST APNEA LIGHT WORKED LATER ON
REPAIR SECTION	
09 0225 28-02-04	02 0328, 28 02 04
1 1004, 21-01-1	08 0351, 19-01-04
REPAIR COMMENTS	RECERT TO MEET MFG SPECIFICATION ATTACHED COMPLETE TEST SHOWING MONITOR RESPONDS TO ALL THE EVENTS BEFORE THE MONITOR REPAIRED INSTALLED ECN UPDATE 6813 NEW BATTERY AND X2 CRYSTAL AND BATTERY ALARM BOARD PASSED ALL FUNCTIONAL AND FINAL TESTS
INVESTIGATION	No problem was found with the monitor's ability to alarm. [R.J.] RESPONDS TO ALL ACTIVITIES AND ALARMS ACCURATELY BUT UNABLE TO RECORD EVENTS DUE TO TIME CONTROL PROBLEM NEEDS RECERT ECN UPDATE NEW BATTERY HAS LOOSE X2 CRYSTAL, MONITOR DROPPED
CONTRACT/REWORKS	MDR # 200400001 sent 1/12/04
020409	

SERVICE REPORT RED TAG

SECTION A

GA # or S/O #	16100-1	CUSTOMER	ASHRAY MEDICAL
MODEL #	9700B w/MODEM	SERIAL #	Y-30201449
DATE RECEIVED	12-19-03	ESTIMATE REQUIRED	☐ Wait for customer approval.
		CUSTOMER TRACKING No	NA
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	Patient Cable	Carrying Case
Battery	Temp Probe	Cuff Hose
SPO2 Sensor	AC Line Cord	

Cuff and Size				
Pass/Replace				

CUSTOMER REQUEST/COMPLAINT

Reason code

17-98-

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement ON 12/12/03 @ 2:30 THE MONITOR APPARENTLY DID NOT ALARM FOR EVENT MOTHER FOUND BABY ALIVE AND NOT BREATHING. CPR ADMINISTERED AND BABY NOW IS FINE DEALER REPORTS UNUSUAL BEHAVIOR OF DOWNLOADED DATA MONITOR HAS WORKED FINE IN THE PAST IT WAS REPORTED THAT THE ADNZA (over) INITIAL FINDINGS MON. NOT responds for all the activities and alarm exactly accurate, but unable to record events

Due to time control problem, time and date stays the same wouldnt change mon. for needs repair with recert, ecn update and new battery → (over)

Has the customers statement been verified? ☒ YES ☐ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ N

PO Number Obtained (Y/N) ☐

PO #

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

☐ Recertified to meet manufacture's specification
☐ Passed all functional tests
☐ Passed all final tests

Work Performed attach complete test showing that monitor responds to all the events before the monitor repaired. install ecn update

new battery and X2 crystal battery alarm board

(over) ECN Update #

Total Labor Time

Technicians Initials

DATE to QA

QA Approval

QA Date

INC

Software Update	Apnea Monitor Rev		NIBP Module	
	Control Board		SPO2 Module	

SECTION D

Parts replaced during repair

Part Number	Description	Reason	
		Cosmetic	Failure

Customer Request/Complaint Cont.

RIGHT WORKED LATER ON JENSEN ELECTRONICS WERE USED. DEALER SUSPECTS
 DESTRUCTIVE APNEA. DOWNLOAD NOT ERASED AND A HARDCOPY IS COMING.
 R2D TAG RON JEFFREY

Findings Cont.

monitor has loose x2 crystal on side was tested, it
 seems that monitor was dropped, replacement of x2
 is required, monitor will be under test for the weekend.

Work Performed Cont.

001660

QCAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Shk 1 of 1
Process Number SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests		

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01 1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
1	03-09-0225	Battery Alarm board		21-01 1001	AMI Warranty Void Label
	17-08-0371	150VAC 150pfd Varistor		21-01-1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)	1	03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack
	16-04 0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor AMI Plus
	29-01-0218	Feet, case		18-01-0042	2' 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	Ami Battery Assembly
1	28-02-0402	Remote Alarm Gasket	1	17-01-0022	X 2 CR2032

S/O# or RGA # 16100-1 SIN Y-30201449

Final Test Data Sheet					
Tested By _____		Date _____		PASS ☐	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance				
6.2.5	Leakage Test (Chassis)			uA	<15 uA
6.2.7	Leakage Test (Patent Lead)			uA	<15 uA

Failure Detail: _____

421661

MEDWATCH

MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved, OMB No. 0910-0291 Expires: 01/01/01
See OMB statement on reverse

MDR report #	2244861200400005
UPDR report #	
FDA Use Only	

A. Patient information			
1. Patient identifier JNK	2. Age at time of event or Date of birth: UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or kg

B. Adverse event or product problem	
☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)	
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality) ☐ life-threatening ☐ hospitalization - initial or prolonged	☐ disability ☐ congenital anomaly ☐ required intervention to prevent permanent impairment/damage ☐ other
Date of event (mortality) 02/00/04	Date of this report (mortality) 03/02/04
Describe event or problem	

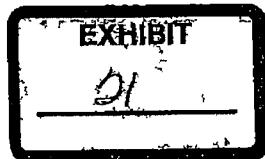
The home care dealer reports that the monitor turns itself on and off in between power up and power down. They further claim that the monitor did not alarm when it should have.

Relevant tests/laboratory data, including dates

NA

Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler if known)			
#1 NA			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown give duration)	
#1 NA		#1 NA	
#2		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 NA		#1 ☐ yes ☐ no ☒ doesn't apply	
#2		#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 NA		#1 NA	
#2		#2	
8. NDC # - for product problems only (if known)			
#1			
#2			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
NA			

D. Suspect medical device			
1. Brand name Heart Rate Respiration Monitor			
2. Type of device Breathing Frequency Monitor			
3. Manufacturer name & address		4. Operator of device	
CAS Medical Systems Inc 44 E Industrial Rd Branford CT 06405		☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (mortality)		6. If implanted give date (mortality)	
NA		NA	
7. If explanted give date (mortality)		8. If explanted give date (mortality)	
NA		NA	
9. Device available for evaluation? (Do not send to FDA)			
☒ yes ☐ no ☐ returned to manufacturer on 02/12/04			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
NA			

E. Initial reporter			
1. Name & address		phone # 414-327 2295	
Aurora Home Medical 11333 W National Ave Milwaukee WI 53227			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
☒ yes ☐ no	Home Care Dealer	☐ yes ☐ no ☒ unk	

000368

Medication and Device Experience Report (continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

to guidelines for specific instructions

Page 2 of 2

FDA Use Only

For use by user facility/distributor—devices only	
Check one ☐ user facility ☐ distributor	2. UF/Dist report number
User facility or distributor name/address	
Contact person	5. Phone Number
Date user facility or distributor became aware of event (month/year)	7. Type of report ☐ initial ☐ follow-up # _____
8. Date of this report (month/year)	
Approximate age of device	10. Event problem codes (refer to coding manual)
patient code	_____ - _____ - _____
device code	_____ - _____ - _____
11. Report sent to FDA? ☐ yes (month/year) ☐ no	12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____
13. Report sent to manufacturer? ☐ yes (month/year) ☐ no	
Manufacturer name/address	

G. All manufacturers	
1. Contact office — name/address (& mailing site for devices)	2. Phone number
CAS Medical Systems Inc. 44 E Industrial Rd Branford CT 06405 Attn Ron Jeffrey	203-488-6056
4. Date received by manufacturer (month/year) 02/03/04	3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other Dealer
5. (A) NDA # NA IND # _____ PLA # _____ pre-1938 ☐ yes OTC product ☐ yes	
6. If IND protocol # NA	
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ initial ☐ follow-up # _____ Report number 2244861200400005	8. Adverse event term(s) NA

H. Device manufacturers only	
1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____	2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code.	4. Device manufacture date (month/year) 03/17/03
	6. Labeled for single use? ☐ yes ☒ no
8. Evaluation codes (refer to coding manual)	
method	10 33
results	708
conclusions	71
7. If remedial action initiated check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____	8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown
9. If action reported to FDA under 21 USC 360b(f), list correction/removal reporting number NA	
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data NA	

The public reporting burden for this collection of information has been estimated to average two-hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

OMB Reports Clearance Office
Paperwork Reduction Project (0918-0291)
Robert H. Humphrey Building, Room 331-H
205 Independence Avenue, S.W.
Washington, D.C. 20501

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address

100369

16537									
2/5/2004									
Aurora Home Medical									
01-05-0170	Yes								
CUST STATES UNIT TURNING ITSELF ON/OFF IN BETWEEN THEY GET CHECK SUM ERROR, ALSO STATES MONITOR DIDNT ALARM WHEN IT SHOULD HAVE									
<table border="1"> <tr> <td>PART #</td> <td>28-02-0328</td> <td>PART #</td> <td>28-02-0408</td> <td>PART #</td> <td>21-01 1004</td> <td>PART #</td> <td>21-01 1009</td> </tr> </table>		PART #	28-02-0328	PART #	28-02-0408	PART #	21-01 1004	PART #	21-01 1009
PART #	28-02-0328	PART #	28-02-0408	PART #	21-01 1004	PART #	21-01 1009		
STEP BY STEP DOWNLOAD ATTACHED PASSED ALL FUNCTIONAL AND FINAL TESTS									
COULD NOT DUPLICATE COMPLAINT 14 0 VER. HAS ALL UPDATES BATTERY INSTALLED 3/03 TESTED SINCE IT WAS RECEIVED BATTERY NOT 2 YRS OLD YET WORKS FINE									
MDR 200400005 sent 3/2/04									
CLOSED BY	R. Jeffrey								
DATE CLOSED	3/2/04								

002212

✓ ENTERED FEB 10 2004

PRODUCT INFORMATION FORM (PIF)

RGA OR PC. <u>16537</u>		PATIENT INJURY OR DEATH Y ☐ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A.	FORM FILLED OUT BY <u>TB</u>		DATE OF THIS REPORT <u>2/5/04</u>
	PRODUCT <u>9723B</u>	LOT/SERIAL # <u>10312036</u>	QUANTITY <u>1</u>
	CUSTOMER NAME <u>Aurora Home Medical</u>		BILLING CUSTOMER NAME _____
	ADDRESS <u>Milwaukee, WI</u>		ADDRESS _____
	COMPLAINANT <u>Bill</u>		_____
PHONE <u>414/327-2295</u>		_____	
INFORMATION DETAILS			
<u>Mtr turning itself on/off</u>			
<u>Inbetween power up/power down would get</u>			
<u>battery dying msg TB2/5103 Check Sum error-</u>			
<u>Says Monitor did not alarm-</u>			
<u>download Shows 84 on, 83 off, 221</u>			
<u>1000 Lead, 128 Slow ttr, 43 Fast ttr</u>			
ACTION TAKEN THUS FAR			

B.	DATE LOGGED AT QA <u>2/10/04</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION		
	INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS)		
	<u>See Service Report</u>		

REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)		016827	
<u>See Service Report</u>			
<u>Work # 200400005 sent 3/2/04</u>			
REASON FOR NO REPLY TO COMPLAINANT			

CLOSE OUT		DATE <u>3-2-04</u>	
SIGNATURE <u>Rouff</u>		_____	

SERVICE REPORT

SECTION A

A # or S/O #	<u>1653T-1</u>	CUSTOMER	<u>AURORA HOME MEDICAL</u>
MODEL #	<u>9700B W/MODEM</u>	SERIAL #	<u>10312036</u>
DATE RECEIVED	<u>2-12-04</u>	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No	<u>N/A</u>
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)			
Charger	☐	Patient Cable	☐
Battery	☐	Temp Probe	☐
SPO2 Sensor	☐	AC Line Cord	☐
Carrying Case	☐	Cuff Hose	☐
Cuff and Size	☐	☐	☐
Pass/Replace	☐	☐	☐
CUSTOMER REQUEST/COMPLAINT		Reason code <u>14 Y9</u>	
☐ Recertification	☐ Preventative Maintenance	☐ Data Download	☐ Evaluation Request
☒ Customer Statement <u>CUSTOMER STATES UNIT IS TURNING ITSELF ON AND OFF, IN BETWEEN POWER UP AND POWER DOWN. THEY WOULD GET CHECK SUM ERROR, ALSO STATES MONITOR DID NOT ALARM WHEN IT SHOULD HAVE; DOWNLOAD SHOWED 84 TURN ON; (over) INITIAL FINDINGS 14.0 VERSION. MONITOR HAS ALL UPDATES, SATISFIED/INSTALLED, 3/03, monitor cant just turn u self on then backoff just like that it u on the only way is to turn it off press in reset and power together or u will stay on till the battery is dead. monitor was tested since day on (over)</u>			
Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)			
Warranty (Y/N)	☒ Y	PO Number Obtained (Y/N)	☐
		PO #	
SERVICE FINDINGS/OTHER SERVICE PERFORMED		Problem Area Code ☐	
☐ Recertified to meet manufacture's specification	Work Performed <u>attach step by step</u>		
☒ Passed all functional tests	<u>notation downloading</u>		
☒ Passed all final tests			
(over) ECN Update #			

Total Labor Time

QA Approval

Technicians Initials

QA Date

DATE to QA

0011370

SECTION C

Software Update	Apnea Monitor Rev		NIBP Module	
	Control Board		SPO2 Module	

SECTION D

Service parts replaced during repair

Part Number	Description	Reason	
		Cosmetic	Failure

Customer Request/Complaint Cont.

83 TURN OFF; 221 LOOSE LEAD; 12 & FAST HEART RATE;
 PLEASE MAKE SURE THIS UNIT GETS A THOROUGH EVALUATION.
 CUSTOMER WANTS A COMPLETE REPORT OF HOW WE TEST THIS
 UNIT AND AS TO WHAT WE FIND.

Initial Findings Cont.

Work Performed Cont.

-- 000371

QCAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01-1180	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21-01-1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor		21-01 1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
	16-04-0180	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patient Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	Ami Battery Assembly
1	28-02-0402	Remote Alarm Gasket			

S/O# or RGA # 16537-1 S/N 10312038

Final Test Data Sheet				
Tested By: _____		Date: _____		PASS ☐ FAIL ☐
Step Description	PASS	Fail	Measurement	Specification
 6.1.5 Ground Wire Resistance				
6.2.5 Leakage Test (Chassis)			uA	<15 uA
6.2.7 Leakage Test (Patient Lead)			uA	<15 uA
Failure Detail _____				

Created on 01/17/2001

Last Update:09/25/2002

Printed on 12/16/2002
000372

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ ModemSERIAL # 1036693
WORK ORDER # NA
RGA # 17795TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASSFAIL

- 4.1 Review and confirm all test data is complete and conforms to test data specifications
- 4.2 If this is an RGA, verify accessories are with unit if applicable

✓
NA

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASSFAIL

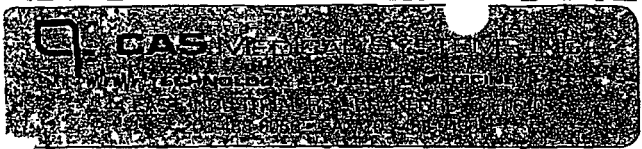
6 VISUAL INSPECTION

- 6.1 Inspect AMI Plus monitor for workmanship
- 6.2 Inspect labels for legibility
- 6.3 Is monitor clean?

✓
✓
✓

FUNCTIONAL SELF TEST

000288



PAGE 1 OF 2

DATE 02/09/04



ACKNOWLEDGEMENT
16537

SOLD TO 7040
AURORA HOME MEDICAL
11333 W NATIONAL AVE
MILWAUKEE, WI 53227
ATTN ACCOUNTS PAYABLE

SHIP TO 7040
AURORA HOME MEDICAL
11333 W NATIONAL AVE
MILWAUKEE, WI 53227
ATTN RECEIVING



FFRUGHT | TERMS | SHIP-VIA
| 2-10 N 30 | UFS

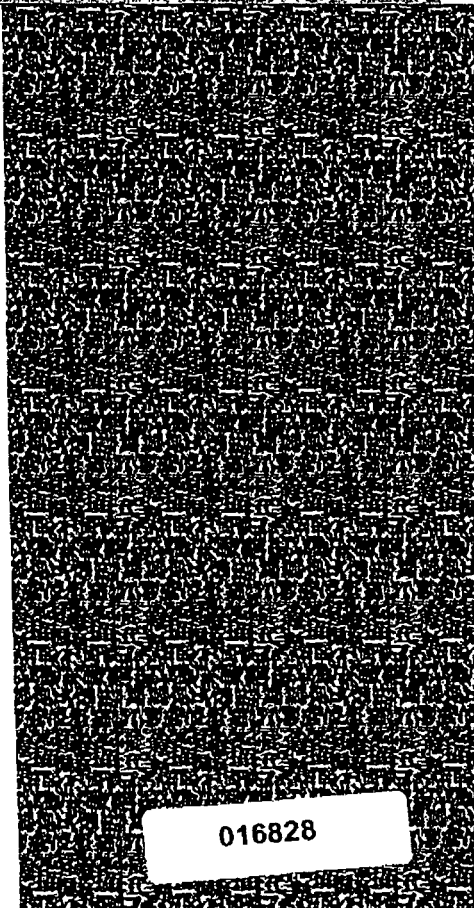


PHIT# 01-05-0170
AMI PLUS 9700B, ENGLISH W/MODEM

Under Warranty YES
REASONS RETURNED
14 ERRATIC OPER/INACC READINGS
99 WARRANTY, 532-0-50-1 1712

SN 10310036
SCHED-DATE QTY
02-09-04 1

**CUSTOMER STATES UNIT
IS TURNING ITSELF ON
AND OFF, INBETWEEN POWER
UP AND POWER DOWN - THEY
WOULD GET CHECK SUM
ERROR,
ALSO STATES MONITOR
DID NOT ALARM WHEN IT
SHOULD HAVE DOWNLOAD
SHOWED 8, TURN ON 80
TURN OFF 20, LOOSE LEAD
128 FLOW HEART RATE
42 FAST HEART RATE,
***--PLEASE MAKE SURE
THIS UNIT GETS A
THOROUGH EVALUATION--
--CUSTOMER WANTS A
COMPLETE REFUND OF HOW
WE TEST THIS UNIT AND AS
TO WHAT WE FIND*****



016828

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 10312036
WORK ORDER # 24784
RGA # N/A

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

- 4 TEST SHEET INSPECTION
- 4.1 Review and confirm all test data is complete and conforms to test data specifications ✓
- 4.2 If this is an RGA, verify accessories are with unit if applicable N/A
- 5 INSPECT UNIT FOR LABELING
- Refer to required drawings specified in paragraph 3
- 6 VISUAL INSPECTION
- 6.1 Inspect AMI Plus monitor for workmanship ✓
- 6.2 Inspect labels for legibility ✓
- 6.3 Is monitor clean? ✓
- 7 FUNCTIONAL SELF TEST
- PASS FAIL
- 002213

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21 04-0220
REVISION 03
PAGE 2 OF 3

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING

7 1 Power up unit under test.

- A) LED lights strobe through self-test
- B) LCD display strobes through self-test
Parameters
- C) Alarm sounds at both front and
rear panel locations
- D) When patient leads disconnected from
monitor the front panel alarms

✓

✓

✓

✓

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR.

As followed

- 120 BPM
- 60 BREATH

8 1 With unit under test connected to simulator, verify the following

PASS

FAIL

- A) Heartbeat and Respiration LED s flash
- B) Remove patient leads from monitor
Patient Lead LED lights and alarms from
front panel
- C) Replace patient leads on monitor the
alarm is off and Patient Loose Lead
LED remains on
- D) Press reset to turn Loose Lead
LED off
- E) Press APNEA button on simulator
The alarm turns on along with
APNEA LED
- F) Press APNEA button again
After 20 seconds audio alarm turns
off but APNEA LED remains on
- G) Turn the monitor off (press RESET and
POWER simultaneously) wait about 30 sec
and verify you hear a double beep

✓

✓

✓

✓

✓

✓

✓

✓

002214

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 3 OF 3

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:

8 3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct

PASS

MONITOR ACCEPTED FOR DISTRIBUTION BY

Date _____

FAIL

Reason for rejection.

QA Inspector

Date _____

Correction made

QA Inspector

Date _____

002215

001652

CAS MEDICAL SYSTEMS INC
REFERENCE PROCEDURE

P3352

W/O # 24784

TEST DATA SHEET

FORM 21-04-0242

REVISION 00.

PROCESS TEST DATA SHEET

MODEL 9700 SERIES MONITOR

-08-0360 ☒	English AMI Plus	SERIAL NUMBER	<u>10312036</u>	Software Ver	<u>14</u>
-08-0384 ☐	Spanish AMI Plus	Main Board #	<u>4844-</u>	Modem #	<u>8241975</u>
-08-0382 ☐	English AMI	TESTED BY	<u>JVK</u>	DATE	<u>4-9-03</u>
-08-0380 ☐	Spanish AMI				
-08-0381 ☐	German AMI				
		PASS ☒	FAIL ☐		

ITEM	DESCRIPTION	TEST	RESULT	REMARKS
3.2	VISUAL INSPECTION	☒	N/A	N/A
3.4.2	Current, lithium w/Nicad	☒	0.01 mV	< 0.40 mV
3.4.3	Current, lithium w/o Nicad	☒	0.59 mV	< 3.30 mV
3.4.5	Current, power off	☒	0.19 mV	< 0.43 mV
3.5.6	Double beep on power down	☒	N/A	N/A
3.6.2	Current, power on w/o alarm	☒	3.89 mV	< 45.0 mV
3.8.2	Low Battery Caution	☒	4.66 VDC	4.57 - 4.77 VDC
3.9.2	Low Battery Alarm	☒	4.30 VDC	4.29 - 4.49 VDC
3.10.6	AC Current (US Versions)	☒	80.9 mA	50 to 120 mA
3.10.6	AC Current (International)	☒	N/A	25 to 60 mA

FAILURE DETAIL

FINAL TEST DATA SHEET

MODEL 9700 SERIES MONITOR

TESTED BY		<u>JVK</u>	DATE		<u>4-11-03</u>
		PASS ☒	FAIL ☐		

ITEM	DESCRIPTION	TEST	RESULT	REMARKS
8.4	Burn In	☒	On 4-9-03 13:00 Off 4-10-03 13:30	N/A
9.1.5	Ground Wire Resistance	☒		
9.2.5	Leakage (Chassis)	☒	0.0 uA	< 15 uA
9.2.7	Leakage (Patient Leads)	☒	0.0 uA	< 10 uA

FAILURE DETAIL After 750 alarms & several power cycles unit 10312036 passed tests w/o issuing "Service Night" error AK & GLL 4/11/03 002216

REPORT Single Run Summary

TECHNICAL REPORT #2126

SERIAL NUMBER 10312036

TEST RESULTS PASSED

REVISION 14 *Ami Plus w/Modem, Final Test*

TEST DATE 4/11/03

MODEL NUMBER Y 9700B

PART NUMBER Y-006122-00B



**NELLCOR
PURITAN
BENNETT.**

TIME	TEST	TEST DESCRIPTION	STATUS
7 13 32 AM	1	Initial Power Up	PASSED
7 13 32 AM	2	Version & Serial Number Verification	PASSED
7 14 13 AM	3	Time & Date	PASSED
7 14 34 AM	4	Patient Setup	PASSED
7 14 44 AM	5	Patient Limits	PASSED
7 14 51 AM	6	Access Code	PASSED
7 15 25 AM	7	O2 Desat	PASSED
7 16 40 AM	8	Signal Quality Indicator	PASSED
7 19 35 AM	9	Resp Detect min, mid, and max	PASSED
7 20 46 AM	10	ECG Crosstalk	PASSED
7 24 40 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
7 28 42 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
7 29 49 AM	13	Apnea Alarm ECG = RESP	PASSED
7 30 35 AM	14	Human Alarm Condition - Heart Slow	PASSED
7 31 38 AM	15	Human Alarm Condition - Apnea	PASSED
7 31 58 AM	16	4.2 VDC +/- 100mV Verification	PASSED
7 32 06 AM	17	WatchDog Test	PASSED
7 36 46 AM	18	Data Transfer & Recording Verification	PASSED

002217

OPERATOR Svetlana Kriger

STATION ID 5

RUN ID 1103

PAGE 1

001654

LEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved OHS No. 1010-0291 Expires 11/31/01
See OHS statement on reverse

Mfr report # 2244861200400004
LrFBI report #
FDA Use Only

Patient information			
1 Patient identifier INK	2 Age at time of event UNK or Date of birth UNK	3 Sex ☐ female ☒ male	4 Weight UNK lbs or kg

Adverse event or product problem	
☒ Adverse event and/or ☐ Product problem (e.g. defects/malfunctions)	
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality) ☐ life-threatening ☐ hospitalization - initial or prolonged	☐ disability ☐ congenital anomaly ☒ required intervention to prevent permanent impairment/damage ☐ other

5 Date of event (mortality) 02/00/04	6 Date of this report (mortality) 03/02/04

Describe event or problem

The home care dealer reports that the mom was transferring the baby into a car seat and talking to a neighbor at the same time. The mom turned to look at the monitor and saw the apnea light on. She then looked at the baby to find him turning blue. Mom says here was no audible alarm. Her first attempt to stimulate the baby was not successful. She then started CPR and was successful at that.

Relevant tests/laboratory data including dates

NA

Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA

C. Suspect medication(s)			
1 Name (give labeled strength & mfr/labeler if known)			
#1 NA			
#2			
2. Dose frequency & route used		3. Therapy dates (if unknown give duration)	
#1 NA		#1 NA	
#2		#2	
4. Diagnosis for use (indication)		5. Event based after use stopped or dose reduced	
#1 NA		#1 ☐ yes ☐ no ☒ doesn't apply	
#2		#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 NA		#1 NA	
#2		#2	
8. Event reappeared after reintroduction			
#1 ☐ yes ☐ no ☒ doesn't apply			
#2 ☐ yes ☐ no ☒ doesn't apply			
9. NDC # - for product problems only (if known)			
-			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
NA			

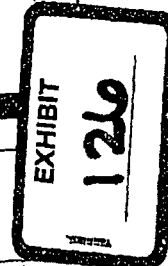
D. Suspect medical device	
1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address Netcor Puritan Bennett 2800 Northwest Blvd Plymouth, MN 55441	4. Operator of device ☐ health professional ☒ lay use /patient ☐ other
5. Expiration date (mortality) NA	6. If implanted give date (mortality) NA
7. If explanted give date (mortality) NA	8. If explanted give date (mortality) NA
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☐ returned to manufacturer on 02/06/04 (mortality)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter			
1. Name & address Aurora Home Medical 11333 W. National Ave Milwaukee WI 53227		phone # 414-327 2295 032699	
2. Health professional? ☒ yes ☐ no	3. Occupation Home Care Dealer	4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ u k	



1A Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



001655

Education and Device Experience Report

() ()
See guidelines for specific instructions

Submission of a report does not constitute
an admission that medical personnel user
facility distributor manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Page 2 of 2

FDA Use Only

For use by user facility/distributor—devices only

Check one ☐ user facility ☐ distributor		2 UF/Dist report number	
User facility or distributor name/address			
Contact person		5 Phone Number	
Date user facility or distributor became aware of event (month/year)	7 Type of report ☐ initial ☐ follow-up #	8 Date of this report (month/year)	
Approximate age of device	10 Event problem codes (refer to coding manual) patient code - - - device code - - -		
Report sent to FDA? ☐ yes (month/year) ☐ no	12 Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other specify		
Report sent to manufacturer? ☐ yes (month/year) ☐ no	Manufacturer name/address		

H. Device manufacturers only

1 Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other		2 If follow-up what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3 Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☒ evaluation summary attached ☐ no (attach page to explain why not) or provide code		4 Device manufacture date (month/year) 11/18/99	
5 Labeled for single use? ☐ yes ☒ no			
6 Evaluation codes (refer to coding manual) method 10 33 - - - results 708 - - - conclusions 71 - - -			
7 If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other		8 Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9 If action reported to FDA under 21 USC 360c(f) list correction/removal reporting number na			
10 ☐ Additional manufacturer narrative and/or 11 ☐ Corrected data na			

I. All manufacturers

Contact office—name/address (& mailing site for devices)		2 Phone number	
AS Medical Systems Inc 4 E Industrial Rd Stranford CT 06405 Attn Ron Jeffrey Note CAS purchased product line after this device was manufactured from Jellcoor Puntan Bennett 1800 Northwest Blvd Plymouth MN 55441		303 488 6056	
Date received by manufacturer (month/year) 02/03/04	5 (A) NDA # NA	3 Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other Dealer	
If IND protocol # NA	IND #	8 Adverse event term(s) NA	
Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ Initial ☐ follow-up #	PLA #	pre-1938 ☐ yes OTC product ☐ yes	
report number 2244861200400004			

032700

no public reporting burden for this collection of information has been estimated to average one hour per response including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington, D.C. 20503

DRBS Reports Clearance Office
Paperwork Reduction Project (8910-0091)
Robert M. H. Emphrey Building, Room 321-H
200 Independence Avenue S.W.
Washington, D.C. 20201

A agency may not conduct or sponsor
and persons are not required to respond to
collection of information unless it displays
this valid OMB control number

Please DO NOT RETURN this
form to this address

DA Form 3500A back

001656

SERVICE REPORT

"BED TAG"

SECTION A

A # or S/O # <u>60024</u>	CUSTOMER <u>AURORA HOME MEDICAL</u>
MODEL # <u>9700 + W/MODEM</u>	SERIAL # <u>482983 88 2/1/01</u>
DATE RECEIVED <u>2-6-04</u>	ESTIMATE REQUIRED ☐ Wait for customer approval
	CUSTOMER TRACKING No <u>N/A</u>
	LOCATION of LABEL _____

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	☐	Patient Cable	☒	Carrying Case	☐
Battery	☐	Temp Probe	☐	Cuff Hose	☐
SPO2 Sensor	☐	AC Line Cord	☐		

uff and Size				
ass/Replace				

CUSTOMER REQUEST/COMPLAINT

Reason code

98/31

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

Customer Statement UNIT WAS BEING USED ON INFANT IN THE HOME;
INFANT CODED, THEY WERE ABLE TO REVIVE INFANT AND INFANT
IS NOW HOSPITALIZED; AURORA HOME MEDICAL NEEDS A DETAILED
REPORT AS TO HOW THIS UNIT WAS TESTED AND IF WE (over)
INITIAL FINDINGS monitor has all updates

monitor Response accurate and normal to all activities, down -
Loading shows no errors or any history. monitor will be tested
carefully for every function. monitor passed all tests at ATO
(Station)

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement) (over)

Warranty (Y/N) ☐ PO Number Obtained (Y/N) ☐ PO # _____

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

☐ Recertified to meet manufacture s specification

Work Performed downloading, final

☒ Passed all functional tests

test sheet

☒ Passed all final tests

032701

(over) ECN Update # _____

Total Labor Time

Technicians Initials

DATE to QA

QA Approval

QA Date

QCAS Medical Systems CAA TECHNOLOGY APPLIES TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01 1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21-01 1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfid Varistor		21-01 1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R899)		22-02-0112	Patent Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor - AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot Rubber (square)		03-08-0314	Ami Battery Assembly
1	28-02-0402	Remote Alarm Gasket			

S/O# or RGA # 60024 S/N 482923

Final Test Data Sheet					
Tested By: _____		Date: _____		PASS ☐	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance				
6.2.5	Leakage Test (Chassis)			uA	<15 uA
6.2.7	Leakage Test (Patent Lead)			uA	<15 uA

Failure Detail _____

032702

Jeffrey, Ron

From Terry Crain [tacrain@msn.com]
Sent Wednesday, March 17, 2004 6:02 PM
To Anthony Cop, Jeffrey__Ron, Lenny Hottin, Laurel Wichman, Charlie Foster, Andrew Kersey
Cc Lisa Wilson, Steve Otis
Subject Fw:

All,
this is the file on the baby from Aurora VNA in Milwaukee where the baby turned blue. It is an AMiRG file. The waveforms show the monitor doing what it is supposed to do, however, the QRS is really funky after the "disorganized breathing episodes" — think it's SVT episodes after the "suspected mixed or obstructive apnea" — doubt the child ever lost a pulse, monitor didn't alarm for apnea because of motion of the baby in the car carrier. The folks at the VNA have a much better understanding of service lights, checksum errors, impedance pneumography technology and why it does what it does, the CAS Express was loaded on all computers except right now it isn't functional on Cindi's, hers has Win95, but they are working on fixing that situation. Also, they should be ordering a bench tester. They now have access to all the maintenance manuals, clinical and caregiver manuals from the website, (people really like this!), so thanks.

They also were not correctly reading the reports from the RG downloads, not correlating dates and times of monitor on's and off's, just looking at how many of each was recorded and claiming the monitor was doing it all by itself — so, this is now straightened out.
It was a wonderful day!
Ter

Terry Crain

CAS Medical Systems
Regional Sales Manager
VM 800-227 4414 ext 6452
Cell 210 416 3852
tacrain@msn.com

— Original Message —

From cindy.heinen@aurora.org
To tacrain@msn.com
Sent Tuesday, March 16, 2004 10:54 AM

(See attached file 00004 ami)

3/18/04

032703

001659



FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0910-0281 Expires: 01/31/01
See OMB statement on reuse

Mfr report #	2244861200400006
USFDA report #	
FDA Use Only	

Patient information			
1. Patient Identifier JNK	2. Age at time of event UNK or Date of birth UNK	3. Sex UNK ☐ female ☐ male	4. Weight UNK or UNK lbs or UNK kgs

Adverse event or product problem	
☐ Adverse event and/or	☒ Product problem (e.g. defects/malfunctions)
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

Date of event (mortality)	03/00/04	4. Date of this report (mortality)	04/09/04

Describe event or problem

The parents reported to the home care dealer that their babies lips turned blue and they called the paramedics. The report stated that the monitors alarms alerted the parents but that the monitor did not capture events that were happening when mother called in for a download

C. Suspect medication(s)	
1. Name (give labeled strength & mfr/labeler if known)	
#1	NA
#2	
2. Dose, frequency & route used	
#1	NA
#2	
3. Therapy dates (if unknown give duration) (month or to start/end)	
#1	NA
#2	
4. Diagnosis for use (indication)	
#1	NA
#2	
5. Event abated after use stopped dose reduced	
#1	☐ yes ☐ no ☒ doesn't apply
#2	☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	
#1	NA
#2	
7. Exp date (if known)	
#1	NA
#2	
8. Event reappeared after reintroduction	
#1	☐ yes ☐ no ☒ doesn't apply
#2	☐ yes ☐ no ☒ doesn't apply
9. NDC # - for product problems only (if known)	
#1	NA
#2	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device	
1. Brand name	
Heart Rate Respiration Monitor	
2. Type of device	
Breathing Frequency Monitor	
3. Manufacturer name & address	
Nelcor Puritan Bennett 2800 Northwest Blvd Plymouth, MN 55441	
4. Operator of device	
☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (mortality)	
NA	
6. If implanted give date (month/year)	
NA	
7. If explanted, give date (mortality)	
NA	
8. Device available for evaluation? (Do not send to FDA)	
☒ yes ☐ no ☐ returned to manufacturer on 03/23/04 (mortality)	
9. Concomitant medical products and therapy dates (exclude treatment of event)	
na	

E. Initial reporter	
1. Name & address	
Baptist Home Medical Equipment 1600 Century Center Parkway 101 Memphis TN	
2. Health professional	
☐ yes ☒ no	
3. Occupation	
Home Care Dealer	
4. If reporter is not reporting to FDA	
☒ yes ☐ no ☐ unk	

6. Relevant tests/laboratory data including dates
NA

7. Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
NA



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

001660

EXHIBIT
128

Education and Device Experience Report

(continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

See guidelines for specific instructions

Page 2 of 2

FDA Use Only

For use by user facility/distributor-devices only

Check one
☐ user facility ☐ distributor

User facility or distributor name/address

Contact person

5 Phone Number

Date user facility or distributor
became aware of event
(month/year)

7 Type of report
☐ initial
☐ follow-up #

8 Date of this report
(month/year)

Approximate
age of device

10 Event problem codes (refer to coding manual)

patient
code

device
code

Report sent to FDA?

☐ yes (month/year)
☐ no

Report sent to manufacturer?

☐ yes (month/year)
☐ no

Manufacturer name/address

12 Location where event occurred

☐ hospital ☐ outpatient
☐ home ☐ diagnostic facility
☐ nursing home ☐ ambulatory
☐ outpatient surgical facility
☐ treatment facility
☐ other

H. Device manufacturers only

1 Type of reportable event

☐ death
☐ serious injury
☒ malfunction (see guidelines)
☐ other

2. If follow-up, what type?

☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3 Device evaluated by mfr?

☐ not returned to mfr
☒ yes ☒ evaluation summary attached
☐ no (attach page to explain why not)
or provide code

4 Device manufacture date
(month)

03/30/00

5 Labeled for single use?

☐ yes ☒ no

6 Evaluation codes (refer to coding manual)

method 10 33
results 708
conclusions 72 78

7 If remedial action initiated
check type

☐ recall ☐ notification
☐ repair ☐ inspection
☐ replace ☐ patient monitoring
☐ relabeling ☐ modification/
adjustment
☐ other

8 Usage of device

☐ initial use of device
☐ reuse
☒ unknown

9 If action reported to FDA under
21 USC 360(f) list correction/removal
reporting number

10 Additional manufacturer narrative and/or 11 Corrected data

I. All manufacturers

Contact office - name/address (& mailing site for devices)

CAS Medical Systems Inc
44 East Industrial Rd
Branford Ct 06405 Attn: Ron Jeffrey
Note: CAS purchased product line after this
device was manufactured from
Nellcor Puritan Bennett
2800 Northwest Blvd
Plymouth, MN 55441

2. Phone number

203-488-6056

3 Report source
(check all that apply)

☐ foreign
☐ study
☐ literature
☐ consumer
☐ health
professional
☐ user facility
☐ company
representative
☒ distributor
☐ other

Date received by manufacturer
(month/year)

03/12/04

IF IND protocol #

(A) NDA # NA

IND #

PLA #

p e-1938 ☐ yes

OTC ☐ yes

product

7 Type of report
(check all that apply)

☐ 5 day ☐ 15-day
☐ 10-day ☐ periodic
☒ Initial ☐ follow-up #

8 Adverse event term(s)

na

9 report number

44-4861200400006

032710

The public reporting burden for this collection of information has been estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington, D.C. 20201

FD-1085 Report Clearance Office
Paperwork Reduction Project (910-0291)
Hubert H. Humphrey Bldg, Room 521-H
300 Ind. Dependence Avenue S.W.
Washington, D.C. 20201

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FDA Form 3500A back

001661

CUSTOMER		BAPTIST HOME MEDICAL		60026	
				3/12/04	
MODEL		AMI W/MODEM		483602	
PART		01 05 0163		No	
CUSTOMER COMMENTS RED TAG LEN HOTTIN CHILDS LIPS TURNED BLUE PARAMEDICS CALLED MONITOR DID NOT CAPTURE EVENTS THAT WERE HAPPENING APNEA NOT REPORTED AT TIME OF EVENT MON ALERTED PARENTS BECAUSE APNEA LIGHT WAS LIT HIGH HR SHOWS ON DOWNLD W/NO WAVEFORMS					
REPAIR SECTION					
PART #		28 02 0402		PART # 28 02 0328	
				PART # 28 02 0408	
REPAIR COMMENTS RECERT TO MEET MFG SPECIFICATIONS INSTALLED NEW AMI BATTERY ASSY LITHIUM 3 690 ATTACHED TEST DOWNLOADING AND FULL TEST PROCEDURE TEST SHEETS TESTED IN 2 DIFFERENT STATIONS PASSED ALL FUNCTIONAL AND FINAL TESTS					
INVESTIGATION TESTED FOR APNEA AND RESPONDED ACCURATELY PASSED ALL TESTS TESTED 3 WKS CUST INFO IS NOT CLEAR BECAUSE HE MENTIONED THAT AN APNEA WAS DETECTED & HE SENDS BACK THE MON W/O ANY DOWLDNG 130 VER MDR 200400006 SENT 4/9/04					
CORRECTIVE ACTION SEE REPAIR COMMENTS					
CLOSED BY R JEFFREY					
DATE CLOSED 4/9/04					

032711

SERVICE REPORT "RED TAG"

SECTION A

RG# or S/O #	6026-1	CUSTOMER	BAPTIST HOME MEDICAL GROUP
MODEL #	9700A w/ MONITOR	SERIAL #	483602
DATE RECEIVED	3-23-04	ESTIMATE REQUIRED	☐ Wait for customer approval.
		CUSTOMER TRACKING No	N/A
		LOCATION of LABEL	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patient Cable		Carrying Case	
Battery		Temp Probe		Cuff Hose	
SPO2 Sensor		AC Line Cord			

Cuff and Size				
Pass/Replace				

CUSTOMER REQUEST/COMPLAINT

Reason code

3198

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement: AEF FORM FILLED OUT - CHILD TURNED BLUE, PARAMEDICS WERE CALLED, MONITOR DID NOT CAPTURE EVENTS THAT WERE HAPPENING, APNEA NOT REPORTED AT TIME OF EVENT, MONITOR ALERTED PARENTS BECAUSE APNEA LIGHT WAS LT. HIGH HR SHOWN ON DOWNLOAD WITH NO WAVEFORMS - ONLY 1 APNEA WAS (over) INITIAL FINDINGS

As soon as monitor was received it was tested for Apnea and the Responding was Accurate, monitor pass all tests tested for 3 weeks, customers information is not clear because he mention that apnea was detected and he sends back the monitor without any downloading, Recert 8 Dec 7/04, MONITOR (over)

Has the customers statement been verified? ☐ YES ☐ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ N

PO Number Obtained (Y/N) ☒ Y

PO # DANITA

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

59

☒ Recertified to meet manufacture's specification

☒ Passed all functional tests

☒ Passed all final tests

Work Performed attach test downloading

also fill test procedure test sheets

MONITOR HAS ALL UPDATES

INSTALLED AAMI BATTERY Assy

q150 test was done in two different stations (over)

ECN Update #

LITHIUM 5690

Total Labor Time

Technicians Initials

TLH

DATE to QA

4-8-04

QA Approval

QA Date

QCAS Medical Systems TECHNOLOGY APPLIED TO RESCUE		SERVICE PROCESS		Std. 1 of 1
Process Number SVC9700PUL		Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01 1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01 1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21-01 1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor		21-01-1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape		21-01 1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patient Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	Ami Battery Assembly
1	28-02-0402	Remote Alarm Gasket			

S/O# or RGA # 6026-1 S/N 483602

Final Test Data Sheet				
Tested By <u>CCCH</u>		Date <u>4-8-04</u>		PASS ☒ FAIL ☐
Step Description	PASS	FAIL	Measurement	Specification
 6.1.5 Ground Wire Resistance	☒			
6.2.5 Leakage Test (Chassis)	☒		002 uA	<15 uA
6.2.7 Leakage Test (Patient Lead)	☒		005 uA	<15 uA

Failure Detail _____

032714

REPORT Single Run Summary

TECHNICAL REPORT #126

SERIAL NUMBER 483602

TEST RESULTS PASSED

REVISION 13 *Ami w/Modem, Final Test*

TEST DATE 4/ 8/04

MODEL NUMBER L-9700A

PART NUMBER Y-006122 10A



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
8 15 46 AM	1	Initial Power Up	PASSED
8 15 46 AM	2	Version & Serial Number Verification	PASSED
8 16 26 AM	3	Time & Date	PASSED
8 17 01 AM	4	Patient Setup	PASSED
8 17 11 AM	5	Patient Limits	PASSED
8 17 18 AM	6	Access Code	PASSED
8 17 52 AM	7	O2 Desat	PASSED
8 19 13 AM	8	Signal Quality Indicator	PASSED
8 22 00 AM	9	Resp Detect min, mid and max	PASSED
8 23 11 AM	10	ECG Crosstalk	PASSED
8 27 05 AM	11	ECG Detect min, mid max Rate & Amplitude	PASSED
8 31 10 AM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
8 32 18 AM	13	Apnea Alarm ECG = RESP	PASSED
8 33 05 AM	14	Human Alarm Condition - Heart Slow	PASSED
8 34 07 AM	15	Human Alarm Condition - Apnea	PASSED
9 12 09 AM	16	Power Alert Function	PASSED
9 12 14 AM	17	WatchDog Test	PASSED
9 15 34 AM	18	Data Transfer & Recording Verification	PASSED

032715

OPERATOR Andrew Hamblin

STATION ID 4

RUN ID 3441

PAGE 1

001666

MEDWATCHFor use by user facilities
importers, distributors and manufacturers
for MANDATORY reportingThe FDA Safety Information and
Adverse Event Reporting ProgramPage 1 of 2

FDA Use Only

A. PATIENT INFORMATION			
1 Patient Identifier IG	2 Age 1 Time 1 Event: or Date of Birth 12/30/2003	3 Sex ☒ Female ☐ Male	4 Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1 ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)			
2 Outcomes Attributed to Adverse Event (Check all that apply)			
☐ Death 4/11/04 (m/d/yr) ☐ Life-threatening ☐ Hospitalization Initial or prolonged ☐ Disability ☐ Congenital Anomaly ☐ Required Intervention to Prevent Permanent Impairment/Damage ☐ Other			
3 Date of Event (m/d/yr) 04/11/04		4 Date of This Report (m/d/yr) 06/14/2007	
5 Describe Event or Problem PARENTS CLAIM MONITOR DID NOT ALARM WHEN MOTHER AWOKE AND FOUND HER CHILD NOT BREATHING. EMS WAS CALLED AND ATTEMPTED RESUSCITATION WITHOUT SUCCESS. CAUSE OF DEATH WAS SAID TO BE SIDS.			
6 Relevant Tests/Laboratory Data, including Dates			
7 Other Relevant History (Include: e.g., P. existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) ONE OF 3 PREMATURE TRIPLETS ALL ON BREATHING FREQUENCY MONITORING			

C. SUSPECT MEDICATION(S)			
1 Name (Give labeled strength & manufacturer if known)			
#1 NA			
#2 NA			
2 Dose, Frequency & Route Used		3 Therapy Dates (If unknown, give duration from/to (or best estimate))	
#1 NA		#1	
#2		#2	
4 Indication for Use (Indication)		5 Event Abated After Use Stopped or Dose Reduced	
#1 NA		#1 ☐ Yes ☐ No ☒ Doesn't Apply	
#2		#2 ☐ Yes ☐ No ☒ Doesn't Apply	
6 Lot # (if known)	7 Exp. Date (if known)	8 Event Reappeared After Reintroduction?	
#1 NA	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply	
#2	#2	#2 ☐ Yes ☐ No ☒ Doesn't Apply	
9 NDC# (For product problems only) NA - -			
10 Concomitant Medical Products and Therapy Dates (Exclude treatment of event) NA			
D. SUSPECT MEDICAL DEVICE			
1 Brand Name HEART RATE RESPIRATION MONITOR			
2 Type of Device BREATHING FREQUENCY MONITOR			
3 Manufacturer Name, City and State CAS MEDICAL SYSTEMS INC BRANFORD CT 06405 USA			
4 Model # 9700A	Lot # NA	5 Operator of Device	
Catalog # NA	Expiration Date (m/d/yr) NA	☐ Health Professional ☒ Lay User/Patient ☐ Other	
Serial # 10114701	Other #		
6 If Implanted, Give Date (m/d/yr)		7 If Explanted, Give Date (m/d/yr)	
8 Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☒ No			
9 If Yes to Item No. 8 Enter Name and Address of Reprocessor			
10 Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☒ No ☐ Returned to Manufacturer on (m/d/yr)			
11 Concomitant Medical Products and Therapy Dates (Exclude treatment of event) NA			

E. INITIAL REPORTER			
1 Name and Address		Phone # 843 546 2408	
J EDWARD BELL 232 KING ST PO BOX 2590 GEORGETOWN SC 29440		032783	
2 Health Professional?	3 Occupation	4 Initial Reporter Also Sent Report to FDA	
☐ Yes ☒ No	ATTORNEY	☐ Yes ☒ No ☐ Unk	



Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (9/03)

EXHIBIT
129

**Medication and Device
Experience Report**
(Continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility importer distributor manufacturer or
product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Refer to guidelines for specific instructions

Page 2 of 2

FOR USE BY USER FACILITY/IMPORTER (Devices Only)			
1 Check On ☒ User Facility ☐ Importer		2. UFI/Importer Report Number	
3 User Facility or Importer Name/Address			
4 Contact Person		5 Phone Number	
6 Date User Facility or Importer Became Aware of Event (mo/day/yr)		7 Type of Report ☐ Initial ☐ Follow-up # _____	
8 Date of This Report (mo/day/yr)			
9 Approximate Age of Device		10 Event Problem Codes (Refer to coding manual) Patient Code _____ Device Code _____	
11 Report Sent to FDA? ☐ Yes _____ (mo/day/yr) ☐ No		12 Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other _____ (Specify)	
13 Report Sent to Manufacturer? ☐ Yes _____ (mo/day/yr) ☐ No			
14 Manufacturer Name/Address			

G. ALL MANUFACTURERS	
1 Contact Office Name/Address (and Manufacturing Site for Devices) CAS Medical Systems Inc Attn: Ron Jeffrey 44 East Industrial Rd Branford CT 06405	
2 Phone Number 203 488 6056	
3 Report Source (Check all that apply) ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☒ Other Plaintiff	
4 Date Received by Manufacturer (mo/day/yr) 5/22/06	5 (A) NDA # _____ IND # _____ PLA # _____ Pre-1938 ☐ Yes OTC Product ☐ Yes
6 If IND Give Protocol # _____	7 Type of Report (Check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ Periodic ☒ Initial ☐ Follow-up # _____
8 Adverse Event Term(s)	
9 Manufacturer Report Number 224861200700004	

H. DEVICE MANUFACTURERS ONLY	
1 Type of Reportable Event ☒ Death ☐ Serious Injury ☒ Malfunction ☐ Other	
2 If Follow-up What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation	
3 Device Evaluated by Manufacturer? ☒ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:	
4 Device Manufacture Date (mo/yr) 04/01	
5 Labeled for Single Use? ☐ Yes ☒ N	
6 Evaluation Codes (Refer to coding manual) Method _____ Results _____ Conclusions _____	
7 If Remedial Action Initiated Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other	
8 Usage of Device ☒ Initial Use of Device ☐ Reuse ☐ Unknown	
9 If action reported to FDA under 21 USC 360(f) is a correction/removal report, give number	

10 ☒ Additional Manufacturer Narrative and/or 11 ☐ Corrected Data
This monitor was named in a patient lawsuit that CAS learned of on May 22 2006. The actual monitor never returned to CAS. It was only realized this week that the 30 day initial reporting deadline was in effect from the point in which CAS was made aware of the incident even if it was in the form of a suit being served. In an effort to manage the lawsuit the MDR reporting task was forgotten.

032784

The public reporting burden for this collection of information has been estimated to average one hour per response including the time for reviewing instructions searching existing data sources gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to

FORM FDA 3500A (9/03) (Back)

Department of Health and Human Services
Food and Drug Administration
MedWatch HFD-410
5600 Fishers Lane
Rockville MD 20857

Please DO NOT RETURN this form to this address.

OMB Statement:
An agency may not conduct or sponsor
and a person is not required to respond
to a collection of information unless it
displays a currently valid OMB control
number

MEDWATCH

A MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0513-0291 Expires: 01/01/07
See OMB submission on reverse

MDR report #	2244861200400007
UFDist report #	
FDA U Only	

A. Patient information

1. Patient identifier UNK	2. Age at time of event: UNK or Date of birth: UNK	3. Sex: UNK ☐ female ☐ male	4. Weight: UNK lbs or kg

B. Adverse event or product problem

☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

5. Date of event (month/day/yr) 05/00/04	6. Date of this report (month/day/yr) 05/24/04

7. Describe event or problem

The home care dealer reports the comments of the parents that the monitor was not alarming. The baby was having "blue spells" and was feeding at the time.

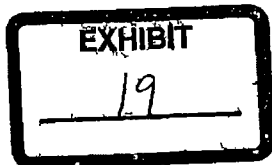
After finding unit to work correctly dealer asked for a second opinion and evaluation.

8. Relevant tests/laboratory data, including dates

The home care dealer could not confirm the complaint. The monitor worked fine.

7. Other relevant history including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NA



FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 NA	#1 NA
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 NA	#1 NA
#2	#2
8. Event repeated after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address CAS Medical Systems Inc 44 East Industrial Rd Branford CT 06405	4. Operator of device ☐ health professional ☒ lay user/patient ☐ other
5. Expiration date (month/day/yr) NA	6. Model # 9700B
7. If implanted, give date (month/day/yr) NA	8. If explanted, give date (month/day/yr) NA
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☐ returned to manufacturer on 05/11/04	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1. Name & address Pediatric Home Services 2800 Cleveland Ave North Roseville MN 55113	phone # 651-642 1825
2. Health professional? ☐ yes ☒ no	
3. Occupation Home Care Dealer	
4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk	

001669

Medication and Device Experience Report

(continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Refer to guidelines for specific instructions

Page 2 of 2

FDA Use Only

For use by user facility/distributor-devices only

1. Check one ☐ user facility ☐ distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (month/year)		8. Date of this report (month/year)	
7. Type of report ☐ initial ☐ follow-up #			
9. Approximate age of device		10. Event problem codes (refer to coding manual)	
		patient code - - -	
		device code - - -	
11. Report sent to FDA? ☐ yes (month/year) ☐ no		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other specify	
13. Report sent to manufacturer? ☐ yes (month/year) ☐ no			
Manufacturer name/address			

G. All manufacturers

1. Contact office - name/address (& mailing site for devices) CAS Medical Systems Inc 44 East Industrial Rd Branford CT 06405 Attn Ron Jeffrey		2. Phone number 203-488-6056	
4. Date received by manufacturer (month/year) 05/04/04		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☒ distributor ☐ other	
5. If IND protocol # NA		5 (A) NDA # NA	
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ Initial ☐ follow-up #		IND # PLA # pre-1938 ☐ yes OTC product ☐ yes	
8. Adverse event term(s) NA			
Report number 44861200400007			

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code		4. Device manufacture date (month/year) 05/30/03	
5. Labeled for single use? ☐ yes ☒ no			
6. Evaluation codes (refer to coding manual)			
method	10	86	
results	100		
conclusions	67		
7. If remedial action initiated check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number			
10. ☒ Additional manufacturer narrative and/or 11. ☐ Corrected data			

H3 Evaluation begun but not complete

H6 - (86) Initial download evaluated Memory stored alarms indicating correct performance Other aspects still being evaluated

H6 (100) Unit being run for extended period Incomplete at this time but not expected to be problematic

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FD-1033 Report Clearance Office
Paperwork Reduction Project (0918-0281)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, D.C. 20220

An agency may not conduct or sponsor
and a person is not required to respond to,
or furnish information in response to, a
collection of information unless it displays
currently valid OMB control number.

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000374

[REDACTED]

RGA # 60027

DATE ISSUED 5/4/04

CUSTOMER PEDIATRIC HOME SERVICES CUSTOMER 6724

MODEL AMI PLUS W/MODEM SERIAL 10320144 # OF TIMES RETURNED

PART 01-05-0170 WARRANTY Yes

CUSTOMER COMMENTS: INFANT WAS HAVING BLUE SPELLS, UNIT WAS NOT ALARMING. INFANT IS NOW IN HOSPITAL, PHS TESTED THIS UNIT. COULD NOT CONFIRM STATED COMPLAINT. SENDING TO CAS FOR FURTHER TESTING

REPAIR SECTION

PART 28-02-0328 PART 28-02 0408 PART 21-01 1004 PART 21-01 1009

REPAIR COMMENTS: PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION: COULD NOT DUPLICATE COMPLAINT. ACCORDING TO DOWNLOADING MONITOR RESPONDED TO ALL THE EVENTS WHICH TOOK PLACE WHEN MONITOR WAS CONNECTED TO A PATIENT. ALSO STEP BY STEP TESTS WERE DONE TO MONITOR & IT SHOWS NOTHING BUT ACCURACY & NORMAL OPER. ARR. 5/11/04

CORRECTIVE ACTION: SEE REPAIR COMMENTS. ASSIGNED MDR# 200400007 (SENT 5/24/04)

CLOSED BY: RON JEFFREY

DATE CLOSED: 6/11/04

000375

SERVICE REPORT

"MED TAG"

SECTION A

REGA # or S/O #	60027-1	CUSTOMER	PEDIATRIC HOME SERVICES
MODEL #	97003 W/MODEM	SERIAL #	10320144
DATE RECEIVED	5-11-04	ESTIMATE REQUIRED	☐ Wait for customer approval.
		CUSTOMER TRACKING No	038629
		LOCATION of LABEL	TOP ENCLOSURE

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	☐	Patient Cable	☐	Carrying Case	☐
Battery	☐	Temp Probe	☐	Cuff Hose	☐
SPO2 Sensor	☐	AC Line Cord	☐	TEST Sheets	☒
Cuff and Size	☐	☐	☐	☐	☐
Pass/Replace	☐	☐	☐	☐	☐

CUSTOMER REQUEST/COMPLAINT

Reason code

17, 99

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement ALARMS NOT WORKING. INFANT WAS HAVING BLUE PELLETS; UNIT WAS NOT ALARMING; INFANT IS NOT IN HOSPITAL. NPHS TESTED THIS UNIT; COULD NOT CONFIRM STATED COMPLAINT; SENDING TO CAS FOR FURTHER TESTING; SEND REPORT W/UNIT (over)

INITIAL FINDINGS

According to what downloading indicates monitor respond to all the events which took place when monitor was connected to apparent, also step by step tests was done to the monitor and it shows nothing but accuracy and normal operation (over)

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ Y

PO Number Obtained (Y/N) ☒ N

PO #

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code

59

☐ Recertified to meet manufacture's specification

☒ Passed all functional tests

☒ Passed all final tests

Work Performed

down loading and test sheets attached.

(over) ECN Update #

Total Labor Time

1

Technicians Initials

mm

DATE to QA

5/28/04

QA Approval

RL

QA Date

5/28/04

11011376

CUSTOMER RETURN TRAVELLER

RECEIVING ****

V 50751
 ID CR60027 1
 RECEIVED 05-11-04
 T DUE DATE
 NG LIST# 00
 CARTONS 1
 CUST NAME 6724 PEDIATRIC HOME SERVICES
 REV 01-05-0170 REV 15
 IPTION AMI PLUS 9700B, ENGLISH W/MODERN
 500 0-50 1
 ITY RECEIVED 1
 CT NAME ISSA
 .T PHONE
 BY TRACY
 NUMBERS 10320144

CODES/REASONS

ALARMS NOT WORKING
 WARRANTY 532-0-50 1 1713

ITS

UNIT WAS HAVING
 UNIT WAS
 ARMING, INFANT IS
 HOSPITAL,

 TESTED THIS UNIT,
 NOT CONFIRM STATED
 INT, SENDING TO
 FOR FURTHER TESTING
 REPORT W/UNIT AS
 FINDINGS BACK WITH

 RED TAG**
 TN RON JEFFREY***

INSPECTION ****
 f inspection 5/28/04
 tor s Initials RL
 vel
 Qty Inspected 1 EA
 ted Loss Qty 0 EA
 Qty Accepted 1 EA
 Qty Rejected 0 EA

STORES ****

d By
 y
 Date
 d By
 d Qty
 Location
 ice Qty
 EA
 EA
 EA
 EA

0000377

2800 Cleveland
Rose Hill
6.1-042 1823

Date 5-4-04

RETURN AUTHORIZATION EQUIPMENT PROCESSING

S/N 10320144 PPD BY Issa

EQUIP MODEL Ami plus

PHS CUSTOMER OWNED YES/NO YES CUSTOMER ISSA

REASON FOR RETURN baby is having blue spells while feeding
Ami Monitor is not alarming? baby is in Hospital

INSTRUCTIONS please do further testing to make sure
Monitor is working properly. Thanks

VENDOR CAS Medical PO =

ADDRESS 44 E Industrial Rd Pin = 60027

Brandford CT 06405 WARRANTY

CONTACT Tracy NON WARRANTY

PHONE = 1-800-227-4414 RETURNED FOR CREDIT

DATE RETURNED TO PHS RECEIVED BY

REPLACEMENT S/N EST REPAIR TIME

ESTIMATE/COST INVOICE #

1000-205

000378

 Q-CAS Medical Systems TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number SVC9700PUL		Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01-1180	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01-1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21 01 1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor	1	21-01 1004	AMI Plus Battery Label
	02-03-0038	1 1/4" Conductive Tape	1	21-01 1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor - AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot Rubber (square)		03-08-0314	Ami Battery Assembly
0	28-02 0402	Remote Alarm Gasket			
MONITOR HAS BEO 68"3 PANNEL					

S/O# or RGA # 60027-1 S/N 10320144

Final Test Data Sheet				
Tested By: <u>CELH</u>		Date: <u>5-27-04</u>		PASS ☒ FAIL ☐
Step	Description	PASS	Fail	Measurement
6.1.5	Ground Wire Resistance	✓		
6.2.5	Leakage Test (Chassis)	✓		002 uA
6.2.7	Leakage Test (Patient Lead)	✓		002 uA

Failure Detail _____

100379

REPORT Single Run Summary

TECHNICAL REPORT 2126

SERIAL NUMBER. 10320144

TEST RESULTS PASSED

VISION 14 *Ami Plus w/Modem Final Test*

TEST DATE 5/27/04

MODEL NUMBER. Y-9700B

PART NUMBER. Y-006122-00B



**NELLCOR
PURITAN
BENNETT.**

TIME	TEST	TEST DESCRIPTION	STATUS
8 13 51 AM	1	Initial Power Up	PASSED
8 13 51 AM	2	Version & Serial Number Verification	PASSED
8 14 30 AM	3	Time & Date	PASSED
8 14 51 AM	4	Patient Setup	PASSED
8 15 01 AM	5	Patient Limits	PASSED
8 15 08 AM	6	Access Code	PASSED
8 15 42 AM	7	O2 Desat	PASSED
8 16 59 AM	8	Signal Quality Indicator	PASSED
8 19 50 AM	9	Resp Detect min, mid, and max	PASSED
8 21 00 AM	10	ECG Crosstalk	PASSED
8 24 54 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
8 29 00 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
9 30 09 AM	13	Apnea Alarm ECG = RESP	PASSED
8 30 57 AM	14	Human Alarm Condition - Heart Slow	PASSED
8 32 01 AM	15	Human Alarm Condition - Apnea	PASSED
8 35 04 AM	16	4 2 VDC +/- 100mV Verification	PASSED
8 35 14 AM	17	WatchDog Test	PASSED
8 40 27 AM	18	Data Transfer & Recording Verification	PASSED

000380

OPERATOR. Andrew Hamblyn

STATION ID 4

RUN ID 3681

PAGE 1

001676

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English

03-08-0384 AMI+ Spanish

03-08-0385 AMI+ German

03-08-0382 AMI English

03-08-0381 AMI German

03-08-0380 AMI Spanish

03-08-0383 AMI English w/ Modem

SERIAL # 10320144
WORK ORDER # NA
RGA # 60037-1

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

4.1 Review and confirm all test data is complete
and conforms to test data specifications

✓

4.2 If this is an RGA, verify accessories are with
unit if applicable

✓

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

PASS

FAIL

6 VISUAL INSPECTION

6.1 Inspect AMI Plus monitor for workmanship

✓

6.2 Inspect labels for legibility

✓

6.3 Is monitor clean?

✓

7 FUNCTIONAL SELF TEST

000381

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor
and patient settings. Press the and enter button at the same time. Turn monitor power on
and follow the prompt on display as follows

- 8.3.1 Display will say "NEW PATIENT", press  for yes indication, it will then ask if you are
sure. Press enter and verify clear memory is displayed.
- 8.3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct.
- 8.3.3 Press mode button, display will ask if test is complete. Press enter, then press  for yes,
and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure

MONITOR ACCEPTED FOR DISTRIBUTION BY RLDate. 5/28/04

FAIL

☐ Reason for rejection. _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

000382

Find Record		60027 5/4/2004								
CUSTOMER	PEDIATRIC HOME SERVICES	6724								
MODEL	AMI PLUS W/MODEM	10320144								
DATE	01-05-0170	Yes								
CUSTOMER COMMENTS	INFANT WAS HAVING BLUE SPELLS UNIT WAS NOT ALARMING INFANT IS NOW IN HOSPITAL PHS TESTED THIS UNIT COULD NOT CONFIRM STATED COMPLAINT SENDING TO CAS FOR FURTHER TESTING									
REPAIR SECTION <table border="1"> <tr> <td>PART 2</td> <td>28-02-0328</td> <td>PART 3</td> <td>28-02-0408</td> <td>PART 4</td> <td>21-01 1004</td> <td>PART 5</td> <td>21-01 1009</td> </tr> </table>			PART 2	28-02-0328	PART 3	28-02-0408	PART 4	21-01 1004	PART 5	21-01 1009
PART 2	28-02-0328	PART 3	28-02-0408	PART 4	21-01 1004	PART 5	21-01 1009			
REPAIR COMMENTS	PASSED ALL FUNCTIONAL AND FINAL TESTS									
INVESTIGATOR	COULD NOT DUPLICATE COMPLAINT ACCORDING TO DOWNLOADING MONITOR RESPONDED TO ALL THE EVENTS WHICH TOOK PLACE WHEN MONITOR WAS CONNECTED TO A PATIENT ALSO STEP BY STEP TESTS WERE DONE TO MONITOR & IT SHOWS NOTHING BUT ACCURACY & NORMAL OPER. ARR. 5/11/04									
CORRECTIVE ACTION	SEE REPAIR COMMENTS ASSIGNED MDR# 200400007 (SENT 5/24/04)									
CLOSED BY RON JEFFREY DATE CLOSED 6/11/04										

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CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/ Modem

SERIAL # 10320144
WORK ORDER # 25254
RGA # NA

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

4 TEST SHEET INSPECTION

PASS

FAIL

- 4.1 Review and confirm all test data is complete
and conforms to test data specifications
4.2 If this is an RGA, verify accessories are with
unit if applicable.

✓
NA

5 INSPECT UNIT FOR LABELING

Refer to required drawings specified in paragraph 3

6 VISUAL INSPECTION

PASS

FAIL

- 6.1 Inspect AMI Plus monitor for workmanship
6.2 Inspect labels for legibility
6.3 Is monitor clean?

✓
✓
✓

7 FUNCTIONAL SELF TEST

002219

CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 2 OF 3

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST. CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING

7.1 Power-up unit under test.

- A) LED lights strobe through self-test.
- B) LCD display strobes through self test
Parameters
- C) Alarm sounds at both front and
rear panel locations
- D) When patient leads disconnected from
monitor the front panel alarms

✓
✓
✓
✓

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR.
As followed

- 120 BPM
- 60 BREATH

8.1 With unit under test connected to simulator verify the following:

	PASS	FAIL
A) Heartbeat and Respiration LED's flash.	✓	_____
B) Remove patient leads from monitor Patient Lead LED lights and alarms from front panel	✓	_____
C) Replace patient leads on monitor the alarm is off and Patient Loose Lead LED remains on.	✓	_____
D) Press reset to turn Loose Lead LED off	✓	_____
E) Press APNEA button on simulator The alarm turns on along with APNEA LED	✓	_____
F) Press APNEA button again. After 20 seconds and no alarm turns off but APNEA LED remains on.	✓	_____
G) Turn the monitor off (press RESET and POWER simultaneously) wait about 30 sec and verify you hear a double beep	✓	_____

002220

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the [] and enter button at the same time. Turn monitor power on and follow the prompt on display as follows:



8.3.1 Display will say 'NEW PATIENT' press [] for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.

8.3.2 Press Mode button until you reach time/date setting. verify time/date stamp is correct.

8.3.3 Press mode button, display will ask if test is complete. Press enter then press [] for yes and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure.

MONITOR ACCEPTED FOR DISTRIBUTION BY LS-

Date 7-7-03

FAIL

☐ Reason for rejection: _____

QA Inspector: _____ Date: _____

Correction made: _____

QA Inspector: _____ Date: _____

002221

CAS MEDICAL SYSTEMS, INC
REFERENCE PROCEDURE
WP3352
W/O # 25254

TEST DATA SHEET
FORM 21 04-0242
REVISION 01

IN PROCESS TEST DATA SHEET		MODEL 9700 SERIES MONITOR			
03-08-0360 ☒ English AMI Plus 03-08-0384 ☐ Spanish AMI Plus 03-08-0382 ☐ English AMI 03-08-0380 ☐ Spanish AMI 03-08-0381 ☐ German AMI		SERIAL NUMBER <u>10320-144</u> Main Board # <u>11844-00915</u> TESTED BY <u>MG</u>	Software Ver <u>14</u> Modem # <u>2072853</u> DATE <u>7/1/03</u>		
		PASS ☒	FAIL ☐		
STEP	DESCRIPTION	PASS	FAIL	MEASUREMENT	SPECIFICATION
2 3 2	VISUAL INSPECTION	☒	☐	N/A	N/A
2 3 4 2	Current lithium w/Nicad	☒	☐	.0 mV	< 0 40 mV
2 3 4 3	Current, lithium w/o Nicad	☒	☐	.6 mV	< 3 30 mV
2 3 4 5	Current power off	☒	☐	.2 mV	< 0 43 mV
2 3 5 6	Double beep on power down	☒	☐	N/A	N/A
2 3 6 2	Current, power on w/o alarm	☒	☐	35.4 mV	< 45 0 mV
2 3 8 2	Low Battery Caution	☒	☐	4 62 VDC	4 57 4 77 VDC
2 3 9 2	Low Battery Alarm	☒	☐	4 36 VDC	4 29 4 49 VDC
2 3 10 6	AC Current (US Versions)	☒	☐	69.4 mA	50 to 120 mA
10 6	AC Current (International)	☐	☐	N/A mA	25 to 60 mA

FAILURE DETAIL

FINAL TEST DATA SHEET		MODEL 9700 SERIES MONITOR			
		TESTED BY <u>MG</u>	DATE <u>7/7/03</u>		
		PASS ☒	FAIL ☐		
STEP	DESCRIPTION	PASS	FAIL	MEASUREMENT	SPECIFICATION
2 8 4	Burn In	☒	☐	On 7/1/03 2 60 Off 7/2/03 2 00	N/A
2 9 1 5	Ground Wire Resistance	☒	☐		
2 9 2 5	Leakage (Chassis)	☒	☐	0 uA	< 15 uA
2 9 2 7	Leakage (Patient Leads)	☒	☐	0 uA	< 10 uA
2 11 3	Front Alarm Evaluation	☒	☐	N/A	N/A

FAILURE DETAIL

REPORT Single Run Summary

TECHNICAL REPORT 2126

SERIAL NUMBER 10320144

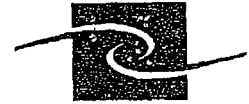
TEST RESULTS PASSED

REVISION 14 *Ami Plus w/Modem Final Test*

TEST DATE 7/7/03

MODEL NUMBER Y 9700B

PART NUMBER Y-006122-00B



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
10 59 54 AM	1	Initial Power Up	PASSED
10 59 54 AM	2	Version & Serial Number Verification	PASSED
11 00 29 AM	3	Time & Date	PASSED
11 00 50 AM	4	Patient Setup	PASSED
11 01 00 AM	5	Patient Limits	PASSED
11 01 07 AM	6	Access Code	PASSED
11 01 41 AM	7	O2 Desat	PASSED
11 02 58 AM	8	Signal Quality Indicator	PASSED
11 05 48 AM	9	Resp Detect min, mid, and max	PASSED
11 06 59 AM	10	ECG Crosstalk	PASSED
11 10 38 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
11 14 39 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
11 15 48 AM	13	Apnea Alarm ECG = RESP	PASSED
11 16 34 AM	14	Human Alarm Condition - Heart Slow	PASSED
11 17 38 AM	15	Human Alarm Condition - Apnea	PASSED
11 23 19 AM	16	4 2 VDC +/- 100mV Verification	PASSED
11 23 27 AM	17	WatchDog Test	PASSED
11 27 24 AM	18	Data Transfer & Recording Verification	PASSED

002223

OPERATOR Marybeth Gaignano

STATION ID 3

RUN ID 1355

PAGE 1

001684



MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

FDA Approved: OMB No. 0918-0291 Expires: 01/31/01
See OMB statement on reverse

MDR report #	2244861200400016
UFI/DAI report #	
FDA Use Only	

A. Patient information			
1. Patient identifier NK	2. Age at time of event UNK or Date of birth	3. Sex UNK ☐ female ☐ male	4. Weight UNK lbs or kgs

B. Adverse event or product problem	
☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)	
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
☐ other	
5. Date of event (mortality) 10/31/04	6. Date of this report (mortality) 12/06/04

Home care dealer reports the information from the parent that her baby while being breastfed had choked, turned blue and became unresponsive. The mother called 911 and baby turned out fine from the incident. The mother claims the monitor did not alarm.

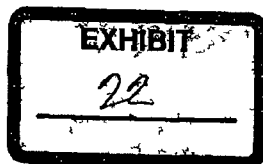
The distributor wants unit and its download evaluated.

Relevant tests/laboratory data including dates

JA

Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

VA



A Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)	
1. Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 NA	#1 NA
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2 ☐ yes ☐ no ☒ doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 NA	#1 NA
#2	#2
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA - -	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device	
1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address CAS Medical Systems Inc 44 East Industrial Rd Branford CT 06405	4. Operator of device ☐ health professional ☒ lay user/patient ☐ other
5. Expiration date (mortality) NA	6. If implanted, give date (mortality) NA
7. If explanted, give date (mortality) NA	8. If explanted, give date (mortality) NA
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☒ returned to manufacturer on 12/02/04 (mortality)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter	
1. Name & address Pediatric Home Services 2800 Cleveland Ave N Roseville MN 55113	2. Phone # 651-642 1825
3. Health professional? ☐ yes ☒ no	
4. Occupation Home Care Dealer	
5. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk	

000289

001685

Medication and Device Experience Report

continued)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Page 2 of 2

FDA Use Only

F. For use by user facility/distributor—devices only

1. Check one ☐ user facility ☐ distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
Contact person		5. Phone Number	
Date user facility or distributor became aware of event (month/year)		7. Type of report ☐ initial ☐ follow-up #	8. Date of this report (month/year)
Approximate age of device	10. Event problem codes (refer to coding manual)		
patient code			
device code			
1. Report sent to FDA? ☐ yes (month/year) ☐ no		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____	
1. Report sent to manufacturer? ☐ yes (month/year) ☐ no			
Manufacturer name/address			

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☐ yes ☐ evaluation summary attached ☒ no (attach page to explain why not) or provide code 81		4. Device manufacture date (month/year) 03/17/03	
		5. Labeled for single use? ☐ yes ☒ no	
6. Evaluation codes (refer to coding manual)			
method			
results			
conclusions			
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f)(1) list correction/removal reporting number			
10. ☒ Additional manufacturer narrative and/or 11. ☐ Corrected data			

H3 Monitor did arrive at CAS 12/2/04 and received a basic checkout. Although no problem is recorded monitor is not finished being evaluated

I. All manufacturers

Contact office - name/address (& mailing site for devices)		2. Phone number 203-488-6056	
AS Medical Systems Inc 1 East Industrial Rd Hartford CT 06405 Attn: Ron Jeffrey		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☒ distributor ☐ other _____	
Date received by manufacturer (month/year) 1/05/04	5. (A) NDA # NA		
IND protocol # 9	IND # _____		
Type of report (check all that apply) 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ Initial ☐ follow up # _____	PLA # _____		
1. Report number 44001200400016	pre-1938 ☐ yes OTC product ☐ yes		
	8. Adverse event term(s) NA		

Reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington, D.C. 20201

OMB Reports Clearance Office
Paperwork Reduction Project (0913-0281)
Robert H. Muzphery Building, Room 821-H
200 Independence Avenue, S.W.
Washington, D.C. 20201

An agency may not conduct or sponsor and a person is not required to respond to, collection of information unless it displays a currently valid OMB control number

Please DO NOT RETURN this form to this address

000297

18090	
Find Repair	DATE ISSUED 11/5/2004
CUSTOMER PEDIATRIC HOME SERVICES	CUSTOMER 6724
MODEM AMI PLUS W/MODEM	SERIAL # 10312100
PART # 01-05-0170	WARRANTY Yes
CUSTOMER COMMENTS: MOTHER WAS BREAST FEEDING INFANT. INFANT CHOKED AND TURNED BLUE AND BECAME UNRESPONSIVE. CALLED 911. MONITOR DID NOT ALARM WHEN EVENT TOOK PLACE. TEST & SEND A COPY OF DOWNLOAD BACK W/UNIT. AEF FORM FILLED OUT AND GIVEN TO RON.	
REPAIR SECTION: PART # 28-02-0328 PART # 28-02-0408 PART # 21-01 1004 PART # 21-01 1009	
REPAIR COMMENTS: PASSED ALL FUNCTIONAL AND FINAL TESTS	
INVESTIGATION: 14.0 VER. HAS ALL UPDATES. BATTERY INSTALLED 3/03. DOWNLOADING SHOWS THAT THERE WERE ACTIVITIES TAKING PLACE AND VERY WELL DETECTED. UNIT TESTED CAREFULLY SINCE THE DATE IT WAS RECEIVED AND FOUND NOTHING WRONG. DETAILED FUNCTIONAL TEST WILL BE PERFORMED.	
CORRECTIVE ACTION: MDR sent 12/6/04 SEE REPAIR COMMENTS	

CLOSED BY RON JEFFREY

DATE CLOSED 12/27/04

002199

RGA OR PC# <u>28090</u> PRODUCT COMPLAINT Y ☒ N ☐	PATIENT INJURY OR DEATH Y ☐ N ☒ IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD
FORM FILLED OUT BY <u>Moe</u> DATE OF THIS REPORT <u>11/8/04</u>	
PRODUCT <u>9700 B</u> LOT/SERIAL # <u>10312100</u> QUANTITY <u>1</u>	
CUSTOMER NAME <u>Pediatric home suc</u> ADDRESS <u>2800 Cleveland Ave N.</u> <u>Minnetonka 55113</u> COMPLAINANT <u>Chris</u> PHONE <u>651 642 1828</u>	BILLING CUSTOMER NAME _____ ADDRESS _____
INFORMATION DETAILS CHECK IF OUT OF BOX FAILURE ☐	
<u>Baby turns Blue</u> <u>monitor didnt Alarm!!</u> <u>Customer Needs Test Results</u>	
ACTION TAKEN THUS FAR	
DATE LOGGED AT OA <u>12/2/04</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION	
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS) <u>See Service Report</u>	
REASON FOR NO INVESTIGATION	AUTHORIZED BY
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS) <u>MRE # 200400016 Sent 12/6/04</u> <u>See Service Report</u> 020780	
REASON FOR NO REPLY TO COMPLAINANT	
CLOSE OUT SIGNATURE <u>[Signature]</u>	DATE <u>12/27/04</u>

RGA OR 18290
PC #

ADVERSE EVENT FORM (AEF)

Use for documenting required information for adverse event complaints

Date form filled out 11/12/04 Person filling out form T Blanusza
Date CAS first learned of event 11/5/04 Event described as Death _____ Injury _____
Company and person reporting Pediatric Home Services
Address & phone # 2800 Cleveland Ave, N.
Roseville, MN 55113
Product Description Model 9700B Serial/Lot number 10312100 Electrodes used KlearTrace
Date of event 10/31/04 Event time of day 2 DOAM Patient DOB 9/10/04 Gest. Age 48 wks (2 wks old)
Patient Male _____ Female ☒ Product first used on patient Date 10/15/04 Time of day _____
Patients state of health prior to event Infant born premature
Description of event or problem MOTHER was breastfeeding her infant,
baby choked, turned blue and became
unresponsive. Mother called 911 States Monitor
did not alarm
Distributors evaluation Dist wants unit evaluated & downloaded
to be sent back w/unit
Distributor downloaded memory Yes _____ No ☒ Results? _____
Has memory been erased? _____ Will distributor report to FDA _____
Additional information Baby is doing fine

Use backside to log additional information and communications)

21-04-0223 REV 02

000291

RED TAG!

SERVICE REPORT

SECTION A

C/A # or S/O # <u>18090-1</u>	CUSTOMER <u>PEDIATRIC HOME SERVICES</u>
MODEL # <u>9700B W/MODEM</u>	SERIAL # <u>10312100</u>
DATE RECEIVED <u>12-2-04</u>	ESTIMATE REQUIRED ☐ Wait for customer approval
CUSTOMER TRACKING No <u>N/A</u>	
LOCATION of LABEL _____	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	_____	Patient Cable	_____	Carrying Case	_____
Battery	_____	Temp Probe	_____	Cuff Hose	_____
SPO2 Sensor	_____	AC Line Cord	_____		

Cuff and Size	_____	_____	_____	_____	_____
Pass/Replace	_____	_____	_____	_____	_____

CUSTOMER REQUEST/COMPLAINT

Reason code 17,99

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement MOTHER WAS BEAST FEEDING INFANT, INFANT CHOKED AND TURNED BLUE AND BECAME UNRESPONSIVE; CALL 911 - MONITOR DID NOT ALARM WHEN EVENT TOOK PLACE. PLEASE

ST UNIT AND SEND A COPY OF THE DOWNLOAD BACK (over)

INITIAL FINDINGS NO VERSION. MONITOR HAS ALL UPDATES. BATTERY

INSTALLED, 3/03 downloading, shows that things were

activities took place and very well detected, unit tested

correctly since the date it was received and found

nothing was detected functional test will be performed (over)

Has the customer's statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ PO Number Obtained (Y/N) ☐ PO # _____

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Problem Area Code _____

☐ Recertified to meet manufacture's specification	Work Performed <u>downloading,</u>
☒ Passed all functional tests	_____
☒ Passed all final tests	_____

copy of the downloading to be send (over) ECN Update # _____

to customer

Total Labor Time	_____	Technicians Initials	_____	_____	DATE to QA
QA Approval	_____	QA Date	_____		

000293

CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

03-08-0360 AMI+ English
03-08-0384 AMI+ Spanish
03-08-0385 AMI+ German

03-08-0382 AMI English
03-08-0381 AMI German
03-08-0380 AMI Spanish
03-08-0383 AMI English w/Modem

SERIAL # 10312100
WORK ORDER # 24784
RGA # N/A

TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 REQUIRED DRAWINGS

DESCRIPTION	ENGLISH DRAWING #	SPANISH DRAWING #
POWER LABEL	N/A	21-01-0874
CROSS-CONNECT LABEL	N/A	21-01-0846
EMI LABEL	21-01-0932	03-08-0934
MODEM LABEL	21-01-0871	N/A
SERIAL # LABEL	21-01-0884	21-01-0858
DEVICE TRACKING LABEL	21-01-0931	N/A
CE LABEL	N/A	21-01-1199
SERVICE LABEL	21-01-0935	21-01-0936
MONITOR FINAL ASSEMBLY	03-08-0360	03-08-0384

- 4 TEST SHEET INSPECTION
- | | PASS | FAIL |
|---|------------|-------------|
| 4.1 Review and confirm all test data is complete and conforms to test data specifications | <u>/</u> | <u> </u> |
| 4.2 If this is an RGA, verify accessories are with unit if applicable | <u>N/A</u> | <u> </u> |
- 5 INSPECT UNIT FOR LABELING
- Refer to required drawings specified in paragraph 3
- | | PASS | FAIL |
|--|----------|-------------|
| 6 VISUAL INSPECTION | | |
| 6.1 Inspect AMI Plus monitor for workmanship | <u>/</u> | <u> </u> |
| 6.2 Inspect labels for legibility | <u>/</u> | <u> </u> |
| 6.3 Is monitor clean? | <u>/</u> | <u> </u> |
- 7 FUNCTIONAL SELF TEST

002201

CAS MEDICAL SYSTEMS INC

QA DATA SHEET

FORM 21-04-0220

REVISION 03

PAGE 2 OF 3

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST. CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING

7.1 Power-up unit under test

- A) LED lights strobe through self-test.
- B) LCD display strobes through self-test
Parameters
- C) Alarm sounds at both front and
rear panel locations
- D) When patient leads disconnected from
monitor the front panel alarms

✓

✓

✓

✓

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR
As followed

- 120 BPM
- 60 BREATH

3.1 With unit under test connected to simulator verify the following

	PASS	FAIL
A) Heartbeat and Respiration LED's flash.	✓	_____
B) Remove patient leads from monitor Patient Lead LED lights and alarms from front panel.	✓	_____
C) Replace patient leads on monitor the alarm is off and Patient Loose Lead LED remains on.	✓	_____
D) Press reset to turn Loose Lead LED off.	✓	_____
E) Press APNEA button on simulator The alarm turns on along with APNEA LED	✓	_____
F) Press APNEA button again. After 20 seconds audio alarm turns off but APNEA LED remains on.	✓	_____
G) Turn the monitor off (press RESET and POWER simultaneously) wait about 30 sec and verify you hear a double beep	✓	_____

702202

CAS MEDICAL SYSTEMS INC

QA DATA SHEET
FORM 21-04-0220
REVISION 03
PAGE 3 OF 3

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings Press the and enter button at the same time Turn monitor power on and follow the prompt on display as follows



- 8 3 1 Display will say "NEW PATIENT", press for yes indication, it will then ask if you are sure Press enter and verify clear memory is displayed.
- 8 3 2 Press Mode button until you reach time/date setting verify time/date stamp is correct
- 8 3 3 Press mode button, display will ask if test is complete Press enter then press for yes, and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure

MONITOR ACCEPTED FOR DISTRIBUTION BY

Date

3/26/03

FAIL

☐ Reason for rejection _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

002203

CAS MEDICAL SYSTEMS, INC
REFERENCE PROCEDURE

3352
W/O # 24784

TEST DATA SHEET
FORM 21-04-0242
REVISION 00

PROCESS TEST DATA SHEET

MODEL 9700 SERIES MONITOR

8-0360 ☒	English AMI Plus	SERIAL NUMBER <u>10312100</u>	Software Ver <u>14</u>
8-0384 ☐	Spanish AMI Plus	Main Board # <u>11844-00573</u>	Modem # <u>8242018</u>
8-0382 ☐	English AMI	TESTED BY <u>SVK</u>	DATE <u>3-21-03</u>
8-0380 ☐	Spanish AMI		
8-0381 ☐	German AMI	PASS ☒	FAIL ☐

TEST	RESULT	UNIT	REMARKS
1 VISUAL INSPECTION	✓	N/A	N/A
1.2 Current, lithium w/Nicad	✓	0.01 mV	< 0.40 mV
1.3 Current, lithium w/o Nicad	✓	0.65 mV	< 3.30 mV
1.5 Current power off	✓	0.23 mV	< 0.43 mV
5.1/5.2 Double beep on power down	✓	N/A	N/A
5.2 Current, power on w/o alarm	✓	450 mV	< 450 mV
3.2 Low Battery Caution	✓	4.69 VDC	4.57 4.77 VDC
3.2 Low Battery Alarm	✓	4.41 VDC	4.29 4.49 VDC
AC Current (US Versions)	✓	894 mA	50 to 120 mA
10.6 AC Current (International)	N/A	N/A	25 to 60 mA

FAILURE DETAIL

AL TEST DATA SHEET

MODEL 9700 SERIES MONITOR

TESTED BY <u>SVK</u>		DATE <u>3-24-03</u>	
PASS ☐		FAIL ☐	

TEST	RESULT	UNIT	REMARKS
4 Burn In	✓	On <u>3.21.03</u> <u>8.50</u> Off <u>3.24.03</u> <u>8.30</u>	N/A
1.5 Ground Wire Resistance	✓		
2.5 Leakage (Chassis)	✓	0.0 uA	< 15 uA
2.7 Leakage (Patient Leads)	✓	0.0 uA	< 10 uA

FAILURE DETAIL

002204

REPORT Single Run Summary

TECHNICAL REPORT 0126

SERIAL NUMBER 10312100

TEST RESULTS PASSED

REVISION 14 *Ami Plus w/Modem Final Test*

TEST DATE 3/24/03

MODEL NUMBER Y 9700B

PART NUMBER Y-006122 00B



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
10 14 02 AM	1	Initial Power Up	PASSED
10 14 02 AM	2	Version & Serial Number Verification	PASSED
10 14 41 AM	3	Time & Date	PASSED
10 15 17 AM	4	Patient Setup	PASSED
10 15 26 AM	5	Patient Limits	PASSED
10 15 33 AM	6	Access Code	PASSED
10 16 07 AM	7	O2 Desat	PASSED
10 17 24 AM	8	Signal Quality Indicator	PASSED
10 20 14 AM	9	Resp Detect min, mid, and max	PASSED
10 21 25 AM	10	ECG Crosstalk	PASSED
10 25 15 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
10 29 20 AM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
10 30 27 AM	13	Apnea Alarm ECG = RESP	PASSED
10 31 12 AM	14	Human Alarm Condition - Heart Slow	PASSED
10 32 02 AM	15	Human Alarm Condition - Apnea	PASSED
10 35 13 AM	16	4.2 VDC +/- 100mV Verification	PASSED
10 35 39 AM	17	WatchDog Test	PASSED
10 39 51 AM	18	Data Transfer & Recording Verification	PASSED

002205

OPERATOR Svetlana Kruger

STATION ID 5

RUN ID 1036

PAGE 1

001696

CAS MEDICAL SYSTEMS INC
REFERENCE PROCEDURE
WP3352
IO # 24784

TEST DATA SHEET
FORM 21-04-0242
REVISION 00

PROCESS TEST DATA SHEET		MODEL 9700 SERIES MONITOR	
08-0360 ☒	English AMI Plus	SERIAL NUMBER <u>10312100</u>	Software Ver <u>14</u>
08-0384 ☐	Spanish AMI Plus	Main Board # <u>11844-</u>	Modem # <u>824</u>
08-0382 ☐	English AMI	TESTED BY <u>SVK</u>	DATE <u>4-9-03</u>
08-0380 ☐	Spanish AMI	PASS ☐	FAIL ☐
08-0381 ☐	German AMI		
FAILURE DETAIL			
2	VISUAL INSPECTION	N/A	N/A
4.2	Current, lithium w/Nicad	N/A	mV < 0.40 mV
4.3	Current, lithium w/o Nicad	N/A	mV < 3.30 mV
4.5	Current, power off	N/A	mV < 0.43 mV
5.6	Double beep on power down	N/A	N/A
6.2	Current power on w/o alarm	N/A	mV < 45.0 mV
8.2	Low Battery Caution	N/A	VDC 4.57 - 4.77 VDC
9.2	Low Battery Alarm	N/A	VDC 4.29 - 4.49 VDC
10.6	AC Current (US Versions)	N/A	mA 50 to 120 mA
1.6	AC Current (International)	N/A	mA 25 to 60 mA

FAILURE DETAIL

PROCESS TEST DATA SHEET		MODEL 9700 SERIES MONITOR	
		TESTED BY <u>SVK</u>	DATE <u>4-9-03</u>
		PASS ☐	FAIL ☐
FAILURE DETAIL			
8.4	Burn In	N/A	On _____ Off _____ N/A
9.1.5	Ground Wire Resistance		
9.2.5	Leakage (Chassis)	✓	00 uA < 15 uA
9.2.7	Leakage (Patient Leads)	✓	00 uA < 10 uA

FAILURE DETAIL Passed after > 50 reads off alarms
w/o "Service Light" error. CH 4/9/03

002206

REPORT Single Run Summary

TECHNICAL REPORT 2126

SERIAL NUMBER 10312100

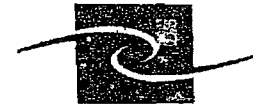
TEST RESULTS PASSED

REVISION 14 *Ami Plus w/Modem, Final Test*

EST DATE 4/9/03

MODEL NUMBER Y 9700B

PART NUMBER Y-006122-00B



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
9 00 18 AM	1	Initial Power Up	PASSED
9 00 18 AM	2	Version & Serial Number Verification	PASSED
9 00 58 AM	3	Time & Date	PASSED
9 01 21 AM	4	Patient Setup	PASSED
9 01 31 AM	5	Patient Limits	PASSED
9 01 39 AM	6	Access Code	PASSED
9 02 13 AM	7	O2 Desat	PASSED
9 03 32 AM	8	Signal Quality Indicator	PASSED
9 06 22 AM	9	Resp Detect min, mid and max	PASSED
9 07 34 AM	10	ECG Crosstalk	PASSED
9 11 33 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
9 15 38 AM	12	Reverse Leads ECG Detect min mid, max Rate & Amp	PASSED
9 16 47 AM	13	Apnea Alarm ECG = RESP	PASSED
9 17 34 AM	14	Human Alarm Condition - Heart Slow	PASSED
9 18 37 AM	15	Human Alarm Condition - Apnea	PASSED
9 19 14 AM	16	4.2 VDC +/- 100mV Verification	PASSED
9 19 22 AM	17	WatchDog Test	PASSED
9 23 24 AM	18	Data Transfer & Recording Verification	PASSED

002207

OPERATOR Svetlana Kriger

STATION ID 3

RUN ID 1171

PAGE 1

001698

TECHNOLOGY APPLIED TO MEDICINE
EAST INDUSTRIAL RD. CHAMBERS CT 06406
203-886-6085 FAX 203-886-6086

DATE 12/06/04

CUSTOMER
RETURNS

NO RELEASE
11

SOLD TO 6724
PEDIATRIC HOME SERVICES
2800 CLEVELAND AVE NORTH
ROSCVILLE, MN 55113

SHIP TO 6724
PEDIATRIC HOME SERVICES
300 CLEVELAND AVE NORTH
ROSCVILLE, MN 55113

ATTN ACCOUNTS PAYABLE

ATTN RECEIVING

BUYER	SALESMAN	TAX
REG		1104

FREIGHT	TERMS	NET 30 DAYS

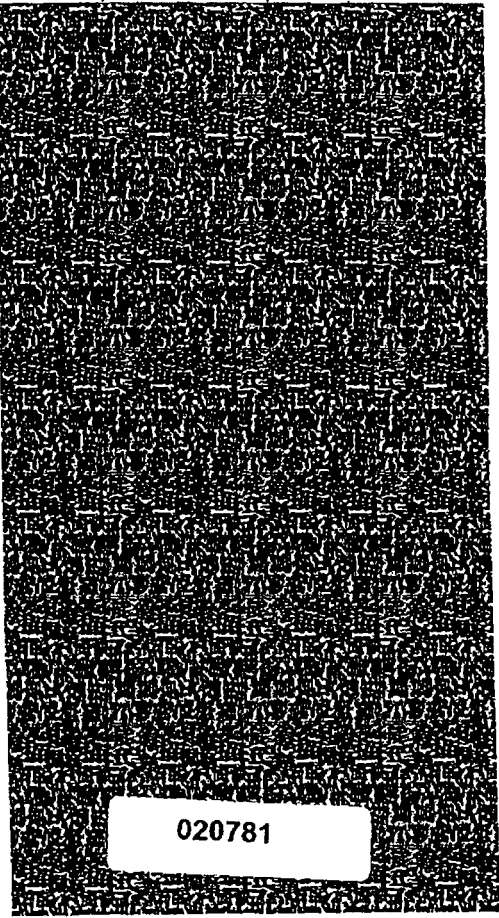
QTY	RET	UNIT PRICE

11 PART# 01 0J-0170
AMI PLUS 9700D, ENGLISH W/MODEM

Under Warranty YES
REASONS RETURNED
1/ ALARMS NOT WORKING
99 WARRANTY, 53C-0-J0-1, 1715

SN 10312100
SCHED-DATE QTY
12-02-04 1

**MOTHER WAS BREAST
FEEDING INFANT, INFANT
CHOKED AND TURNED BLUE
AND BECAME UNRESPONSIVE
CALL 911 - MONITOR DID
NOT ALARM WHEN EVENT
TOOK PLACE
***PLEASE TEST UNIT
AND SEND A COPY OF THE
DOWNLOAD BACK WITH THE
UNIT**
**AEF FORM FILLED OUT
AND GIVEN TO RON
TEFFLEY**



020781

Jeffrey, Ron

From Jeffrey Ron
Sent: Monday, December 06, 2004 9:44 AM
To: Hottel, Lenny
Subject: Blanus, Tracy
RGA 18090 PHS
Importance: High

Lenny, This return will likely be a MDR: baby choked, turned blue, paramedics involved and parent says unit did not alarm. Could we look carefully at the download for any evidence of unit not alarming, aside from typical performance checks? Keep me posted please. Thanks.

Ron Jeffrey
Director, Regulatory Affairs
CAS Medical Systems, Inc.
(203) 488-6056

CAS Medical Systems

AmI Apnea Monitor

Patient Logs

	Date	Time	Event Type	Event Duration
	10/27	12 07 34 ‡	Heart Fast	3 Secs
2	10/27	12.08.48	Heart Fast	1 Sec
3	10/27	12:11:04 ‡	Heart Fast	3 Secs
4	10/27	12 11 47 †	Heart Fast	1 Sec
5	10/27	12.12.16	Loose Lead	3 Secs
6	10/27	12 12.23	Loose Lead	1 Sec
7	10/27	12 12.32	Loose Lead	1 Sec
8	10/27	12.13.26	Heart Fast	2 Secs
9	10/27	12 17 40	Loose Lead	1 Sec
0	10/27	12.20 00 ‡	Heart Slow	8 Secs
1	10/27	12.20.35	Loose Lead	1 Sec
2	10/27	19 12 49	Loose Lead	8 Secs
3	10/27	19 12 58	Loose Lead	1 Sec
4	10/27	19 12.59	Loose Lead	1 Sec
5	10/28	03 42:03	Heart Fast	2 Secs
6	10/28	03 43 47 ‡	Heart Fast	3 Secs
7	10/28	09 06 34	Loose Lead	2 Secs
8	10/28	09 06 37	Loose Lead	1 Sec
9	10/28	09 06 40 ‡	Heart Slow	7 Secs
0	10/28	10 53 31 ‡	Heart Slow	10 Secs
1	10/28	12.57 07	Heart Fast	2 Secs
2	10/28	13 00 32 ‡	Heart Fast	2 Secs
3	10/28	13.26 57 ‡	Heart Slow	6 Secs
4	10/28	13 33 50 ‡	Heart Slow	6 Secs
5	10/28	13 34 07 †	Heart Slow	6 Secs
6	10/28	13 42 39 ‡	Heart Slow	7 Secs
7	10/28	13 44 48 ‡	Heart Slow	16 Secs
8	10/28	15 57 42 ‡	Heart Slow	7 Secs
9	10/29	09 14 02 ‡	Heart Slow	5 Secs
	10/29	15 12 35	Loose Lead	1 Mins 22 Secs
	10/29	15 15 01	Loose Lead	5 Secs
	10/29	15 16.26	Loose Lead	5 Secs
	10/29	15 20 06	Loose Lead	24 Secs
	10/29	15.22 06	Loose Lead	33 Secs
	10/29	18.28 50	Loose Lead	1 Sec
	10/29	22 02 33 ‡	Heart Fast	2 Secs
	10/30	01.21 10 ‡	Heart Slow	5 Secs
	10/30	12.29.02	Battery Cell Shorted	1 Sec
	10/30	12 40 00 ‡	Heart Slow	8 Secs
	10/30	16 36 04 ‡	Heart Slow	5 Secs
	10/30	17 30 51 ‡	Apnea	21 Secs
	10/31	02.22 13 ‡	Apnea	27 Secs
	10/31	02.22 48 ‡	Heart Slow	9 Secs
	10/31	02.22 57 ‡	Heart Fast	4 Secs
	11/02	09 47 32	Loose Lead	32 Secs
	11/02	09 50 56	Loose Lead	1 Sec

12/09 09 18.20

Received 46 Patient Logs

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CAS Medical Systems Inc

2100 #[Not Entered]

Page 1

12/09/04 09 18

000295

001701

Eliminary Study Report

Ami Apnea Monitor

Summary Report

Patient Information »

10312100

[Not Entered]

Transfer Date [None]
12/09/04

Gestational
Study Age

40 weeks
0 0 weeks

Study Ends »

Monitor 12/09/04 Thu
p Gen PC 12/09/04 Thu

09 18 20
09 12.42

[At Time Of Transfer]

Monitor Setup »

1 Signal O2 Satur
2 Signal PulseRate
3 Signal Airflow

RR Slow Mode
Event Capture

5 Second Delay
FIFO Full Dura

Monitor Limits »

Apnea Alarm 20 Sec
Heart Slow 80 BPM
Heart Fast 225 BPM

Apnea Log 15 Sec
Heart Slow 90 BPM
Heart Fast 225 BPM
Desaturation 80 % Sat

Recorded Events »

Monitor Logs 43 of 2000
Segments 46 of 2000
Event Waves 24 6% Filled

Study Start 10/27/04 Wed 12 13
Study Period 6 Weeks 1 Day
Monitor Time 3 Days 12 Hours [8 1%]
Periodic Br 13 Hours 33 Mins [16 1%]

Recorded Waveforms »

Leads 2
Disturbances 0

Heart Slows 14
Heart Fast 7
Study Is Not Reviewed

Events Counted »

Monitor On 19
Leads 2
Disturbances 0
Leads 18

Monitor Offs 18
Heart Slows 14
Heart Fast 11

Dem Answer Only »

Item Version »

Number 10312100
Study Code [NONE]

Ami Monitor 14 00 06-AUG-02
Report Generator 2 00 3/14/02

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CAS Medical Systems Inc

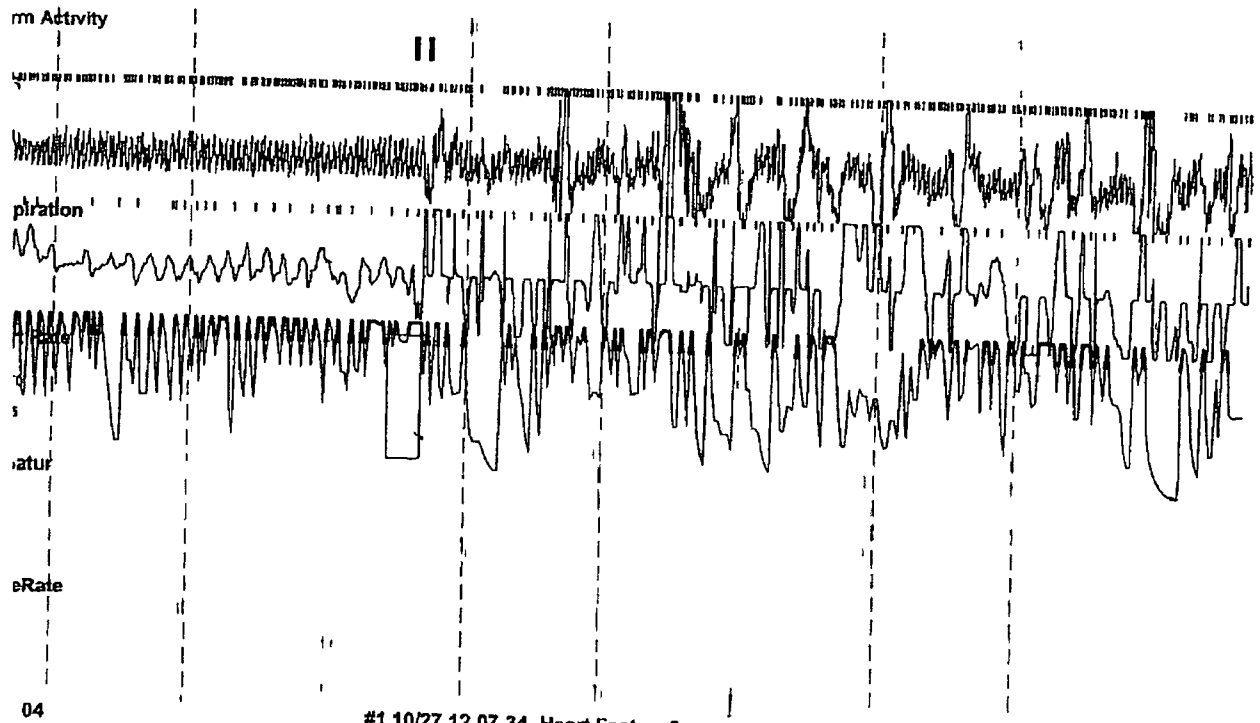
10312100 [Not Entered]
Event List

#	Date	Time	Event	Duration	Reason
1	10/27	12.07 34	Heart Fast	3 secs	UnReviewed
2	10/27	12 11 04	Heart Fast	3 secs	UnReviewed
3	10/27	12 11.47	Heart Fast	1 secs	UnReviewed
4	10/27	12.20-00	Heart Slow	8 secs	UnReviewed
5	10/28	03 43.47	Heart Fast	3 secs	UnReviewed
6	10/28	09 06 40	Heart Slow	7 secs	UnReviewed
7	10/28	10 53 31	Heart Slow	10 secs	UnReviewed
8	10/28	13-00 32	Heart Fast	2 secs	UnReviewed
9	10/28	13.26 57	Heart Slow	6 secs	UnReviewed
10	10/28	13 33 50	Heart Slow	6 secs	UnReviewed
11	10/28	13 34 07	Heart Slow	6 secs	UnReviewed
12	10/28	13 42 39	Heart Slow	7 secs	UnReviewed
13	10/28	13.44 48	Heart Slow	16 secs	UnReviewed
14	10/28	15 57 42	Heart Slow	7 secs	UnReviewed
15	10/29	09 14 03	Heart Slow	5 secs	UnReviewed
16	10/29	22.02.33	Heart Fast	2 secs	UnReviewed
17	10/30	01 21 11	Heart Slow	5 secs	UnReviewed
18	10/30	12 40 00	Heart Slow	8 secs	UnReviewed
19	10/30	16 36 05	Heart Slow	5 secs	UnReviewed
20	10/30	17 30 51	Apnea	21 secs	UnReviewed
21	10/31	02.22 13	Apnea	27 secs	UnReviewed
22	10/31	02 22.48	Heart Slow	9 secs	UnReviewed
23	10/31	02.22 57	Heart Fast	4 secs	UnReviewed

000297

1 12100 [Not Entered]

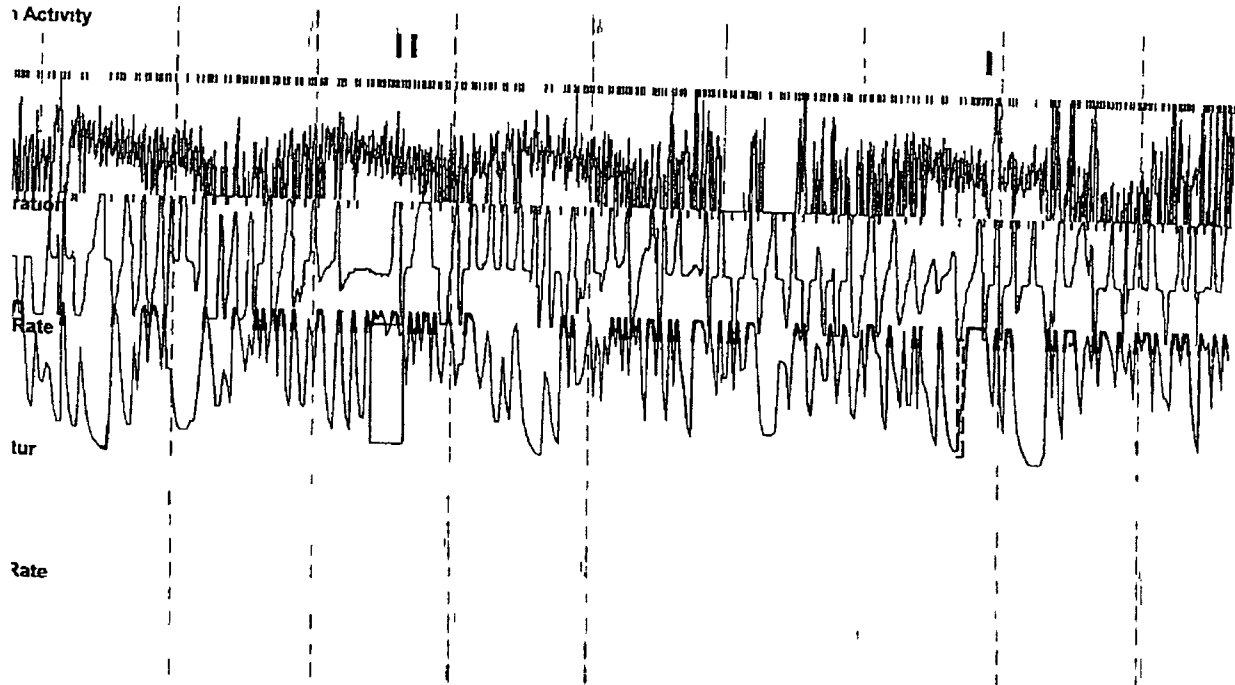
rm Activity



#1 10/27 12 07 34 Heart Fast 3 secs UnReviewed

12 08 37

1 Activity

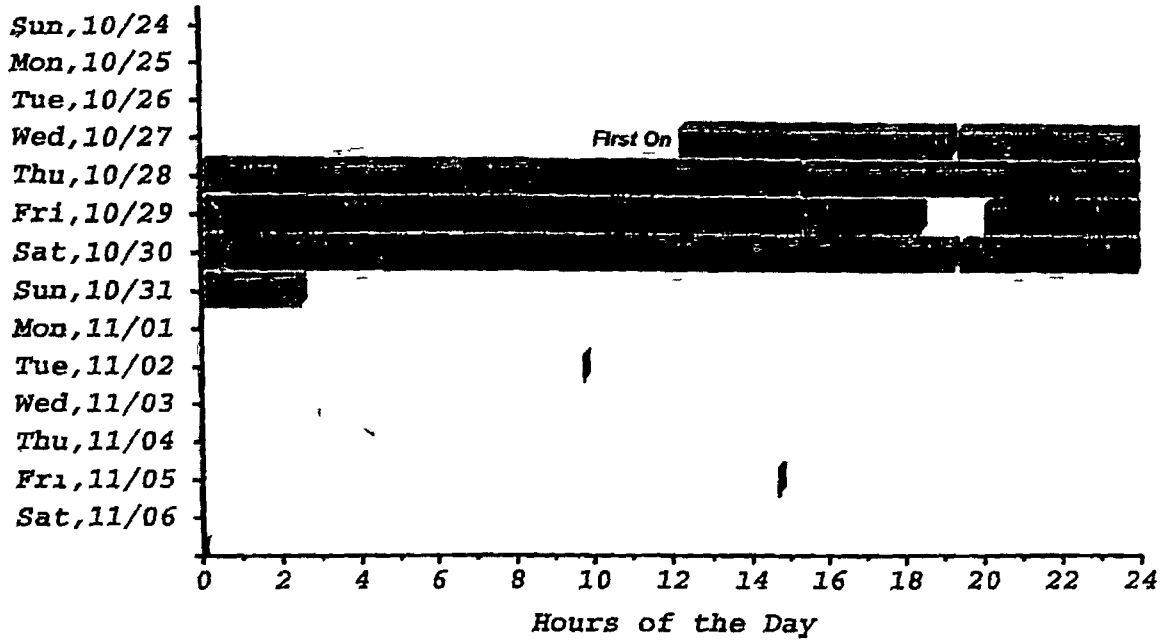


#2 10/27 12 11 04 Heart Fast 3 secs UnReviewed

12 12 07

Ami nitor Usage for 10312100

1 of 4

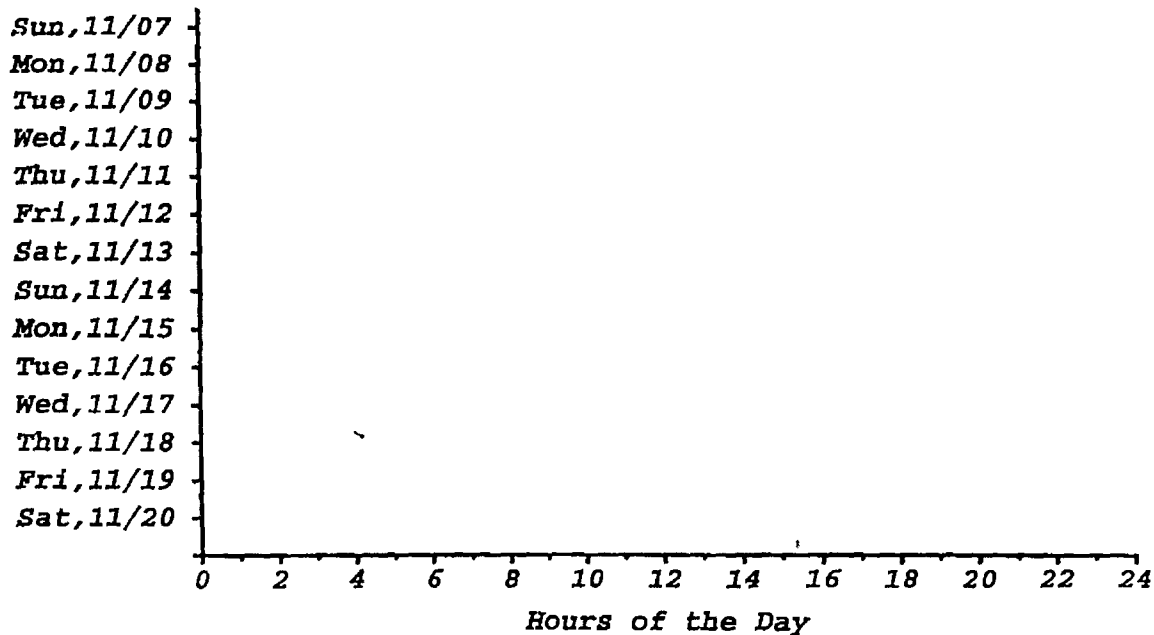


10312100 # [Not Entered]

000299

Amr Monitor Usage for 10312100

2 of 4



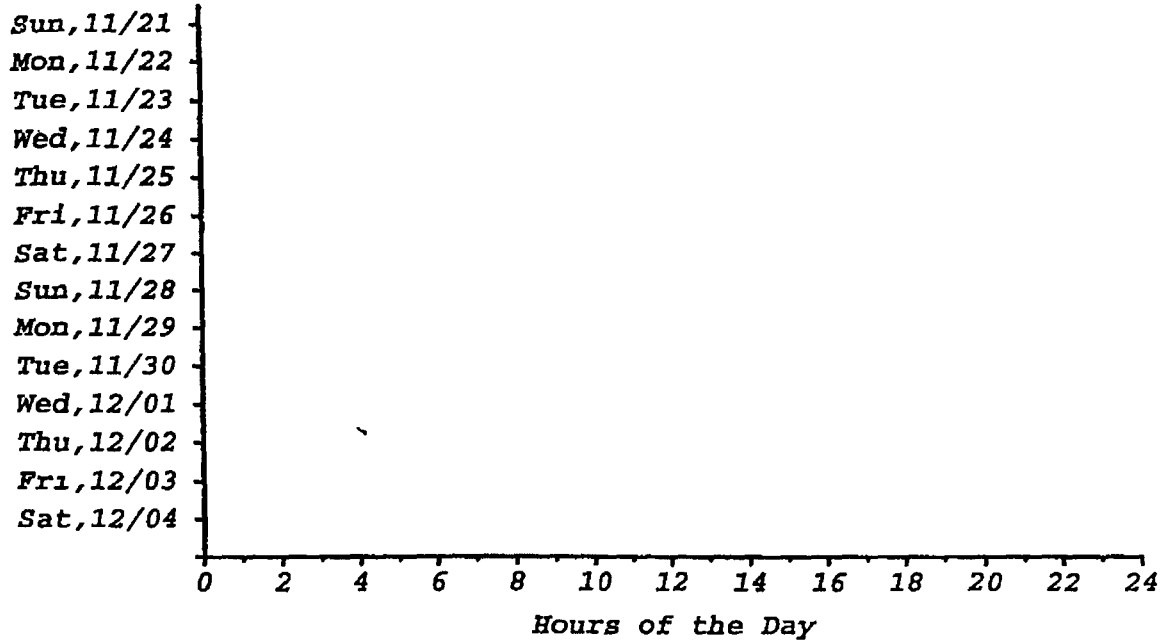
10312100 #1 Not Entered 1

000309

001706

Am onitor Usage for 10312100

3 of 4



10312100 # [Not Entered]

000321

CAS Medical Systems

Apnea Monitoring Periods

Previous Recording Session Cleared

7	12 13.26	thru	10/27	12.14 14	48 Secs
10/27	12 16 40	thru	10/27	19 15 13	6 Hours 59 Mins
10/27	19 26 18	thru	10/28	15 16 33	19 Hours 50 Mins
10/28	15 17 09	thru	10/28	15 17.53	44 Secs
10/28	15.23.29	thru	10/29	15 14:00	23 Hours 51 Mins
10/29	15 14 31	thru	10/29	15 15:07	36 Secs
10/29	15 15.57	thru	10/29	15 16.32	35 Secs
0/29	15 17.23	thru	10/29	15:20:30	3 Mins 7 Secs
0/29	15 21 37	thru	10/29	15.22 40	1 Min 3 Secs
0/29	15.26 29	thru	10/29	18.28 51	3 Hours 2 Mins
0/29	20:08 46	thru	10/30	19 18 01	23 Hours 11 Mins
0/30	19.27 39	thru	10/31	02 19.27	6 Hours 52 Mins
0/31	02.21 13	thru	10/31	02.25.39	4 Mins 26 Secs
0/31	02.26.23	thru	10/31	02.31 47	5 Mins 24 Secs
1/02	09 47:03	thru	11/02	09 48:05	1 Min, 2 Secs
1/02	09 50.24	thru	11/02	09 50 58	34 Secs
1/02	10:26 12	thru	11/02	10.26.29	17 Secs
1/05	14 40 07	thru	11/05	14 45 11	5 Mins 4 Secs
1/09	09 15 17	thru	12/09	09 15 43	26 Secs

Duration of the Study Period Was
 Total Time Monitor Was Recording
 Total Time Monitor Was Turned Off
 of Study Period Monitor Was On

6 Weeks 1 Day
 3 Days 12 Hours
 5 Weeks 4 Days
 8 1%

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CAS Medical Systems Inc

0003 3

MEDWATCH

U.S. FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0915-0291 Expires 01/01/05
See OMB statement on reverse

MDR report #	2244861200400015
LD/CDR report #	
FDA Use Only	

A. Patient information

1. Patient identifier NA	2. Age at time of event NA or Date of birth NA	3. Sex NA ☐ female ☐ male	4. Weight NA lbs or kgs

In confidence

B. Adverse event or product problem

☐ Adverse event and/or	☒ Product problem (e.g. defects/malfunctions)
Outcomes attributed to adverse event (check all that apply)	
☐ death (mortality)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
	☐ other

Date of event (mortality)	10/00/04	Date of this report (mortality)	11/01/04

Describe event or problem

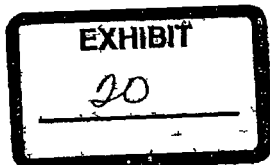
Home care dealer reports the user's (parents) comments that the monitor reported multiple heart slow and apnea fights but never gave any audio alarms. The parents say they were with the baby the whole time.

Relevant tests/laboratory data, including dates

A

Other relevant history including preexisting medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepato-renal dysfunction, etc.)

A



Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer if known)	
#1 NA	
#2	
2. Dose, frequency & route used	
#1 NA	
#2	
3. Therapy dates (if unknown, give duration)	
#1 NA	
#2	
4. Diagnosis for use (indication)	
#1 NA	
#2	
5. Event started after use stopped or dose reduced	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
6. Lot # (if known)	
#1 NA	
#2	
7. Exp. date (if known)	
#1 NA	
#2	
8. Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9. NDC # - for product problems only (if known)	
NA	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1. Brand name Heart Rate Respiration Monitor	
2. Type of device Breathing Frequency Monitor	
3. Manufacturer name & address CAS Medical Systems Inc 44 East Industrial Rd Branford Ct. 06405	
4. Operator of device ☐ health professional ☒ lay user/patient ☐ other	
5. Expiration date (mortality)	
NA	
6. Model # 9700B	
7. If implanted, give date (mortality)	
NA	
8. If explanted, give date (mortality)	
NA	
9. Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☐ returned to manufacturer on 10/07/04 (mortality)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

E. Initial reporter

1. Name & address Pediatric Home Services 2800 Cleveland Ave. North Roseville MN 55113		phone # 651-642 1825
2. Health professional? ☐ yes ☒ no	3. Occupation Home Care Dealer	4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ no

000279

001709

Medication and Device Experience Report

(continued)
refer to guidelines for specific instructions

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Page 2 of 2

FDA Use Only

For use by user facility/distributor-devices only

Check one ☐ user facility ☐ distributor		2 UP/Dist report number	
User facility or distributor name/address			
Contact person		5 Phone Number	
Date user facility or distributor became aware of event (month/year)		7 Type of report ☐ initial ☐ follow-up #	8 Date of this report (month/year)
Approximate age of device	10 Event problem codes (refer to coding manual)		
patient code	-		
device code	-		
Report sent to FDA? yes (month/year) no		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other specify	
Report sent to manufacturer? yes (month/year) no			
Manufacturer name/address			

H. Device manufacturers only

1 Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code:		4. Device manufacture date (month/year) 02/07/03	
		5. Labeled for single use? ☐ yes ☒ no	
6. Evaluation codes (refer to coding manual)			
method	10	31	
results	708	100	
conclusion	71	74	
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number			

10. ☒ Additional manufacturer narrative and/or 11 ☐ Corrected data
H6 (100) - Enough testing was done to disprove claim Unit remains to be tested on automated test fixture

All manufacturers

Contact office - name/address (& mailing site for devices)		2. Phone number 203-488-6056	
AS Medical Systems Inc 1 East Industrial Rd Hartford CT 06405 Attn: Ron Jeffrey		3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☒ distributor ☐ other	
Date received by manufacturer (month/year) 1/04/04	5. (A) NDA # NA		
IND protocol # A	IND #		
Type of report (check all that apply) 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ Initial ☐ follow-up #	PLA #		
Mfr report number 1200400015	pre-1938 ☐ yes OTC product ☐ yes		
8. Adverse event term(s) NA			

Public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington, D.C. 20503.

2003 Reports Clearance Office
Paperwork Reduction Project (0918-4291)
Hubert H. Humphrey Building, Room 3314
200 Independence Avenue, S.W.
Washington, D.C. 20501

An agency may not conduct or sponsor and persons are not required to respond to, collection of information unless it displays currently valid OMB control number.

Please DO NOT RETURN this form to this address

000280



RGA # 17795

Find Record

DATE ISSUED 10/4/04

CUSTOMER PEDIATRIC HOME SERVICES

CUSTOMER# 6724

MODEL AMI PLUS W/MODEM

SERIAL # 10306693

OF TIMES
RETURNED

PART # 01-05 0170

WARRANTY No

CUSTOMER COMMENTS MULTIPLE HEART SLOW AND APNEA LIGHTS AND NEVER GAVE AUDIO ALARM
PARENTS WERE WITH THE BABY THE WHOLE TIME

REPAIR SECTION

PART2 28-02-0435 PART3 # 28 02-0328 PART4 # 28 02-0408 PART5 # 1 1004 21 01 1

REPAIR COMMENTS INSTALLED ECN 6813 PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION 14 0 VER HAS NO DATA TO DOWNLOAD AS SOON AS MONITOR WAS REC'D BOTH
ALARMS WERE TESTED & WORK FINE ALSO MONITOR RESPONDS TO DIFFERENT
EVENTS ACCURATELY NEEDS FUNCTIONAL TEST NO SVC LIGHT FOUND SHOWING
AND ALARM PROBLEMS HAS ALL UPDATES EXCEPT 681

CORRECTIVE ACTION SEE REPAIR COMMENTS MDR 200400015 sent 11/1/04

CLOSED BY R Jeffrey

DATE CLOSED 12/3/04

000281

SERVICE REPORT

SECTION A

RG# or S/O #	17795-1	CUSTOMER	PEDIATRIC HOME SERVICES
MODEL #	9700 B W/MODEM	SERIAL #	10306693
DATE RECEIVED	10-7-04	ESTIMATE REQUIRED	☐ Wait for customer approval
		CUSTOMER TRACKING No.	N/A 087498
		LOCATION of	TDP PASE

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger		Patient Cable		Carrying Case	
Battery		Temp Probe		Cuff Hose	
SPO2 Sensor		AC Line Cord			

Cuff and Size: _____
 Pass/Replace: _____

CUSTOMER REQUEST/COMPLAINT Reason code: 3198

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☒ Customer Statement. MULTIPLE HEART SLOW AND APNEA LIGHTS AND NEVER GAVE AUDIO ALARM, PARENTS WERE WITH THE BABY THE WHOLE TIME.

INITIAL FINDINGS 1400 VERSION (over)
Monitor has no data in order to download.
As soon as monitor was received both alarms were tested
and they works had also monitor respond to different events
accurately needs functional test, also no service light
found showing and alarms problems. MONITOR HAS ALL UPDATES (over) 6813

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement)

Warranty (Y/N) ☒ PO Number Obtained (Y/N) ☒ PO # _____

SERVICE FINDINGS/OTHER SERVICE PERFORMED Problem Area Code: 5977

☐ Recertified to meet manufacture's specification

☒ Passed all functional tests

☒ Passed all final tests

Work Performed: MON 908
MON # 1004 INSTALLED ECN 6813
MONITOR HAS ALL OTHER UPDATES
"NO CHARGES"

(over) ECN Update # 6813

Total Labor Time

Technicians Initials

DATE to QA

QA Approval

QA Date

000282

SECTION C

Software Update

Apnea Monitor Rev

NIBP Module

Control Board

SPO2 Module

SECTION D

Service parts replaced during repair

Part Number	Description	Reason	
		Cosmetic	Failure

Customer Request/Complaint Cont.

Initial Findings Cont.

BATTERY INSTALLED, 2/03. BATTERY NOT 2 YEARS
OLD YET?

Work Performed Cont.

000283

QCAS Medical Systems QUALITY ASSURED TECHNOLOGY APPLIED TO MEDICINE		SERVICE PROCESS		Sht. 1 of 1
Process Number SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests		

			Other Parts Used		
Qty	Part Number	Description	Qty	Part Number	Description
	15-08-0099	9700 Software		21-01-1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01-1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21-01-1001	AMI Warranty Void Label
	17-08-0371	150VAC, 150pfd Varistor	1	21-01-1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape	1	21-01-1009	AMI Plus Warranty Void Label
	16-04-0190	1ufd Capacitor (R225)		03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patient Cable Jack (AMI)
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor - AMI Plus
	29-01-0218	Feet case		18-01-0042	2" 20 AWG Red Wire - AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	Ami Battery Assembly
0	28-02-0402	Remote Alarm Gasket		03-08-0334	PATIENT CABLE JACK (AMI PLUS)
1	28-02-0435	FANNEL			

S/O# or RGA # 17795-1 SN 10306693

Final Test Data Sheet					
Tested By <u>CECH</u>		Date <u>11-12-04</u>		PASS ☒	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance	☒	☐		
6.2.5	Leakage Test (Chassis)	☒	☐	.004 uA	<15 uA
6.2.7	Leakage Test (Patient Lead)	☒	☐	.006 uA	<15 uA

Failure Detail _____

ORT Single Run Summary

TECHNICAL REPORT 0126

SERIAL NUMBER 10306693

TEST RESULTS PASSED

REVISION 14 Ami Plus w/Modem Final Test

TEST DATE 11/11/04

MODEL NUMBER Y-9700B

PART NUMBER Y-006122-00B



NELLCOR
PURITAN
BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
9 45 28 AM	1	Initial Power Up	PASSED
9 45 28 AM	2	Version & Serial Number Verification	PASSED
9 46 04 AM	3	Time & Date	PASSED
9 46 25 AM	4	Patient Setup	PASSED
9 46 35 AM	5	Patient Limits	PASSED
9 46 42 AM	6	Access Code	PASSED
9 47 16 AM	7	O2 Desat	PASSED
9 48 32 AM	8	Signal Quality Indicator	PASSED
9 51 25 AM	9	Resp Detect min, mid, and max	PASSED
9 52 38 AM	10	ECG Crosstalk	PASSED
9 56 29 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
10 00 32 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
10 01 38 AM	13	Apnea Alarm ECG = RESP	PASSED
10 02 25 AM	14	Human Alarm Condition - Heart Slow	PASSED
0 03 27 AM	15	Human Alarm Condition - Apnea	PASSED
10 03 57 AM	16	4 2 VDC +/- 100mV Verification	PASSED
10 04 59 AM	17	WatchDog Test	PASSED
10 09 04 AM	18	Data Transfer & Recording Verification	PASSED

000285

OPERATOR Svetlana Kriger

STATION ID 5

RUN ID 1081

PAGE 1

001715

8.3 CLEARING MEMORY

At the bottom side of unit you will find the LCD display with monitor and patient settings. Press the and enter button at the same time. Turn monitor power on and follow the prompt on display as follows

- ↓
- 8.3.1 Display will say "NEW PATIENT", press for yes indication, it will then ask if you are sure. Press enter and verify clear memory is displayed.
- 8.3.2 Press Mode button until you reach time/date setting, verify time/date stamp is correct.
- 8.3.3 Press mode button, display will ask if test is complete. Press enter, then press for yes, and verify unit under test turns off.

PASS

☒ Inspection of unit is completed, and in accordance with this procedure

MONITOR ACCEPTED FOR DISTRIBUTION BY ADDate 12-3-04

FAIL

☐ Reason for rejection: _____

QA Inspector _____ Date _____

Correction made: _____

QA Inspector _____ Date _____

0011286

CONNECT DC POWER CONVERTER AND PATIENT
CABLE TO UNIT UNDER TEST CONNECT PATIENT
CABLE (RA/LA) TO 2301 SIMULATOR AND VERIFY
THE FOLLOWING:

7 1 Power-up unit under test.

- A) LED lights strobe through self-test.
- B) LCD display strobes through self-test
Parameters.
- C) Alarm sounds at both front and
rear panel locations
- D) When patient leads disconnected from
monitor the front panel alarms

✓
✓
✓
✓

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO
2301 SIMULATOR, SET THE VALUES TO THE SIMULATOR.
As followed.

- 120 BPM
- 60 BREATH

8 1 With unit under test connected to simulator verify the following:

	PASS	FAIL
A) Heartbeat and Respiration LED s flash.	✓	_____
B) Remove patient leads from monitor Patient Lead LED lights and alarms from front panel.	✓	_____
C) Replace patient leads on monitor, the alarm is off and Patient Loose Lead LED remains on	✓	_____
D) Press reset to turn Loose Lead LED off.	✓	_____
E) Press APNEA button on simulator The alarm turns on along with APNEA LED	✓	_____
F) Press APNEA button again. After 20 seconds audio alarm turns off but APNEA LED remains on	✓	_____
G) Turn the monitor off (press RESET and POWER simultaneously) wait about 30 sec and verify you hear a double beep	✓	_____

000287



RGA # 17795

DATE ISSUED 10/4/04

Find Record

CUSTOMER PEDIATRIC HOME SERVICES

CUSTOMER# 6724

MODEL AMI PLUS W/MODEM

SERIAL # 10306693

OF TIMES
RETURNED

PART # 01-05 0170

WARRANTY No

CUSTOMER COMMENTS

MULTIPLE HEART SLOW AND APNEA LIGHTS AND NEVER GAVE AUDIO ALARM
PARENTS WERE WITH THE BABY THE WHOLE TIME

REPAIR SECTION

PART2 28-02-0435

PART3 # 28-02 0328

PART4 # 28 02 0408

PART5 # 1 1004 21 01 1

REPAIR COMMENTS

INSTALLED ECN 6813 PASSED ALL FUNCTIONAL AND FINAL TESTS

INVESTIGATION

14 OVER HAS NO DATA TO DOWNLOAD AS SOON AS MONITOR WAS REC'D BOTH
ALARMS WERE TESTED & WORK FINE, ALSO MONITOR RESPONDS TO DIFFERENT
EVENTS ACCURATELY NEEDS FUNCTIONAL TEST NO SVC LIGHT FOUND SHOWING
AND ALARM PROBLEMS HAS ALL UPDATES EXCEPT 6813AMR
12-15-04

CORRECTIVE ACTION

SEE REPAIR COMMENTS MDR 200400015 sent 11/1/04

CLOSED BY R Jeffrey

DATE CLOSED 12/3/04

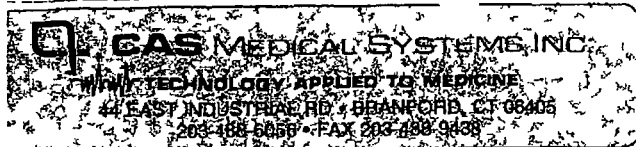
020900

✓ ENTERED OCT 6 2004

PRODUCT INFORMATION FORM (PIF)

RGA OR PC # <u>17795</u>		PATIENT INJURY OR DEATH Y ☐ N ☒	
PRODUCT COMPLAINT Y ☒ N ☐		IF YES DISCONTINUE USE OF THIS FORM USING 21-04-0223 INSTEAD	
A. FORM FILLED OUT BY <u>AMK</u>		DATE OF THIS REPORT <u>10-4-04</u>	
PRODUCT <u>Ami</u>		LOT/SERIAL # <u>1030693</u> QUANTITY <u>1</u>	
CUSTOMER NAME <u>PEDIATRIC HOME SV</u>		BILLING CUSTOMER NAME _____	
ADDRESS _____		ADDRESS _____	
COMPLAINANT <u>JESSA</u>		_____	
PHONE <u>651-642-1825</u>		_____	
INFORMATION DETAILS		CHECK IF OUT OF BOX FAILURE ☐	
<u>Multiple heart slow apnea lights</u> <u>and never gave audio alarm</u> <u>Parents were with baby the whole time.</u>			
ACTION TAKEN THUS FAR.			

B. DATE LOGGED AT QA <u>10/5/04</u> ☐ CHECK HERE IF COMPLAINT IS A REPORTABLE MALFUNCTION			
INVESTIGATION RESULTS (ATTACH SUPPORT DOCUMENTS):			
<u>In house service check did not find a problem.</u>			
<u>See Service Report</u>			
REASON FOR NO INVESTIGATION		AUTHORIZED BY	
CORRECTIVE ACTION AND DISPOSITION (ATTACH SUPPORTING DOCUMENTS)			
<u>Sent MDR # 200400015 11-1-04</u>			
<u>Check P & Return</u>			
020898			
REASON FOR NO REPLY TO COMPLAINANT			
CLOSE OUT			
SIGNATURE <u>[Signature]</u>		DATE <u>12-3-04</u>	



PAGE 1 OF 1

DATE 10/05/04

CUSTOMER
RETURNSACKNOWLEDGEMENT
17795SOLD TO 6724
PEDIATRIC HOME SERVICES
2800 CLEVELAND AVE NORTH
ROSEVILLE, MN 55113SHIPPED TO 6724
PEDIATRIC HOME SERVICES
2800 CLEVELAND AVE NORTH
ROSEVILLE, MN 55113

ATTN: ACCOUNTS PAYABLE

ATTN: RECEIVING

DATE ORDERED	DATE RECEIVED	CUST PO#	BUYER	SALESMAN	TAX
10-25-04			ISSA		1107
FREIGHT	TERMS	SHIP-VIA			
	NET 30 DAYS	UPS			
LT#	PART#	DESC	QTY	RET	UNIT PRICE
11	PART# 01-05-0170				
	HMI PLUS, 9700B, ENGLISH W/MODEM				
	Under Warranty NO				
	REASONS RETURNED				
	31 MISCELLANEOUS (LIST RTNS)				
	98 NON WARRANTY 501-0-30 1 1615				
	SN 10706693				
	SCHED-DATE	CTY			
	10-05-04				
	MULTIPLE HEART SLOW AND				
	APNEA LIGHTS AND NEVER				
	GAVE AUDIO ALARM PARENTS				
	WERE WITH THE BABY THE				
	WHOLE TIME				

020899

MEDWATCHThe FDA Safety Information and
Adverse Event Reporting ProgramFor use by user facilities
importers, distributors and manufacturers
for MANDATORY reportingPage 1 of 2Form Approved: OMB No. 0910-0291 Expires 03/31/05
See OMB statement on reverse.

Mfr Report # 2244861200700003

UFI/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1 Patient Identifier KS	2 Age at Time of Event or Date of Birth 05/24/2005	3 Sex ☒ Female ☐ Male	4 Weight lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM1 ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2 Outcomes Attributed to Adverse Event (Check all that apply)	☒ Disability ☐ Congenital Anomaly ☐ Required Intervention to Prevent Permanent Impairment/Damage ☒ Other: BRAIN DAMAGE

3 Date of Event (mo/day/year) 10/13/05	4 Date of This Report (mo/day/year) 06/14/2007

5 Describe Event or Problem

PARENT'S CLAIM MONITOR DID NOT ALARM AT THE TIME WHEN THERE WAS A PROLONGED LOOSE LEAD INDICATION AS DETAILED IN THE PRINTOUT OF THE MEMORY DOWNLOAD AS A RESULT THE BABY ALLEGEDLY WENT FOR SOME PERIOD OF TIME WITHOUT MONITORING AS EXPECTED AND THEN HAD AN EVENT THAT LIMITED OXYGEN INTAKE THE BABY IS REPORTED TO HAVE SUFFERED BRAIN DAMAGE

C. SUSPECT MEDICATION(S)

1 Name (Give labeled strength & manufacturer if known)
#1 NA
#2 NA

2 Dose, Frequency & Route Used	3 Therapy Dates (If unknown, give duration from/to (or best estimate))
#1 NA	#1
#2	#2

4 Diagnosis for Use (Indication)	5 Event Abated After Use Stopped or Dose Reduced?
#1 NA	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☒ Doesn't Apply

6 Lot # (if known)	7 Exp. Date (if known)	8 Event Reappeared After Reintroduction?
#1 NA	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☒ Doesn't Apply

9 NDC# (For product problems only)
NA

10 Concomitant Medical Products and Therapy Dates (Exclude treatment relevant)
NA

D. SUSPECT MEDICAL DEVICE

1 Brand Name HEART RATE RESPIRATION MONITOR

2 Type of Device BREATHING FREQUENCY MONITOR

3 Manufacturer Name City and State
MALLINCKRODT 2800 NORTHWEST BLVD PLYMOUTH MN 55441

4 Model # 9700A	Lot # NA	5 Operator of Device ☐ Health Professional ☒ Lay User/Patient ☐ Other
Catalog # NA	Expiration Date (mo/day/yr)	
Serial # Y 30200355	Other #	

6 If Implanted, Give Date (mo/day/yr)

7 If Explanted, Give Date (mo/day/yr)

8 Is this Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☒ No

9 If Yes to Item 8 Enter Name and Address of Reprocessor

10 Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☒ No ☐ Returned to Manufacturer on (mo/day/yr)

11 Concomitant Medical Products and Therapy Dates (Exclude treatment relevant)

NA

E. INITIAL REPORTER

1 Name and Address Phone # 512 463 5560

TOMMY R HASTINGS HASTINGS LAW FIRM PC 10077 GROGANS MILL RD SUITE 275 THE WOODLANDS TX 77380	032781

2 Health Professional? ☐ Yes ☒ No	3 Occupation ATTORNEY	4 Initial Reporter Attributable Report to FDA ☐ Yes ☒ No ☐ Unk

BLACK INK

PLEASE TYPE OR



Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (9/03)

EXHIBIT

132

Medication and Device Experience Report

(Continued)

Submission of a report does not constitute an admission that medical personnel user facility importer distributor manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

Refer to guidelines for specific instructions

Page 2 of 2

FOR USE BY USER FACILITY/IMPORTER (Devices Only)	
1 Check One ☐ User Facility ☐ Importer	2 UF/Importer Report Number
3 User Facility or Importer Name/Address	
4 Contact Person	5 Phone Number
6 Date User Facility or Importer Became Aware of Event (mo/day/yr)	7 Type of Report ☐ Initial ☐ Follow-up # _____
8 Date of This Report (mo/day/yr)	
9 Approximate Age of Device	10 Event Problem Codes (Refer to coding manual) Patient Code _____ Device Code _____
11 Report Sent to FDA? ☐ Yes (mo/day/yr) ☐ No	12 Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other (Specify) _____
13 Report Sent to Manufacturer? ☐ Yes (mo/day/yr) ☐ No	
14 Manufacturer Name/Address	

G. ALL MANUFACTURERS	
1 Contact Office Name/Address (and Manufacturing Site for Devices) CAS Medical Systems Inc Attn Ron Jeffrey 44 East Industrial Rd Branford CT 06405 Note CAS purchased product line from Mallinckrodt after this device was produced by Mallinckrodt See D3	2 Phone Number 203 488 6056
3 Report Source (Check all that apply) ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☒ Other Plaintiff	
4 Date Received by Manufacturer (mo/day/yr) 8/25/06	5 (A)NDA # _____ IND # _____ PLA # _____ Pre-1938 ☐ Yes OTC Product ☐ Yes
6 IF IND GI # Protocol #	
7 Type of Report (Check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ Periodic ☒ Initial ☐ Follow-up # _____	8 Adverse Event Term()
9 Manufacturer Report Number 2244861200700003	

The public reporting burden for this collection of information has been estimated to average one hour per response including the time for reviewing instructions searching existing data sources gathering and maintaining the data needed and completing and reviewing the collection of information Send comments regarding this burden estimate or any other aspect of this collection of information including suggestions for reducing this burden to

FORM FDA 3500A (9/03) (Back)

H. DEVICE MANUFACTURERS ONLY	
1 Type of Reportable Event ☐ Death ☐ Serious Injury ☒ Malfunction ☐ Other _____	2 If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3 Device Evaluated by Manufacturer? ☒ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:	4 Device Manufacture Date (mo/yr) 06/00
	5 Labeled for Single Use? ☐ Yes ☒ No
6 Evaluation Codes (Refer to coding manual) Method _____ Results _____ Conclusions _____	
7 If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other _____	8 Usage of Device ☐ Intended Use of Device ☒ Reuse ☐ Unknown
9 If action reported to FDA under 21 USC 360(f), list correction/removal reporting number	

10 ☒ Additional Manufacturer Narrative and/or 11 ☐ Corrected D I

This monitor was named in a patient lawsuit that CAS learned of on August 25 2006 The actual monitor never returned to CAS It was only realized this week that the 30 day initial reporting deadline was in effect from the point in which CAS was made aware of the incident even if it was in the form of a suit being served In an effort to manage the lawsuit the MDR reporting task was forgotten

032782

Department of Health and Human Services
Food and Drug Administration
MedWatch, HFD-410
5600 Fishers Lane
Rockville MD 20857

Please DO NOT RETURN this form to this address.

OMB Statement
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number

MEDWATCH

1A MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved: OMB No. 0910-0281 Expires: 01/01/01
See OMB statement on reverse

MDR report #	2244861200500003
UFI/DOI report #	
FDA Use Only	

A. Patient information

1 Patient identifier JNK	2 Age at time of event or Date of birth UNK	3 Sex UNK ☐ female ☐ male	4 Weight UNK lbs or UNK kgs

B. Adverse event or product problem

☐ Adverse event and/or ☒ Product problem (e.g., defects/malfunctions)	
Outcomes attributed to adverse event (check all that apply)	
☐ death (immediate)	☐ disability
☐ life-threatening	☐ congenital anomaly
☐ hospitalization - initial or prolonged	☐ required intervention to prevent permanent impairment/damage
☐ other	
5 Date of event (month/day/yr) 03/00/05	6 Date of this report (month/day/yr) 04/08/05
Describe event or problem	

Home Care Dealer reports that the user claims the monitor alarms to not work.

Relevant tests/laboratory data including dates

IA

Other relevant history including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

IA

EXHIBIT

23

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known)	
#1 NA	
#2 NA	
2 Dose, frequency & route used	3 Therapy dates (if unknown give duration) (month/day/yr)
#1 NA	#1 NA
#2	#2
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced
#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2 NA	#2 ☐ yes ☐ no ☒ doesn't apply
6 Lot # (if known)	7 Exp date (if known)
#1 NA	#1 NA
#2	#2
8 Event reappeared after reintroduction	
#1 ☐ yes ☐ no ☒ doesn't apply	
#2 ☐ yes ☐ no ☒ doesn't apply	
9 NDC # - for product problems only (if known)	
NA - -	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
NA	

D. Suspect medical device

1 Brand name Heart Rate Respiration Monitor	
2 Type of device Breathing Frequency monitor	
3 Manufacturer name & address Neilcor Puritan Bennett 2800 Northwest Blvd Plymouth MN 55441	4 Operator of device ☐ health professional ☒ lay user/patient ☐ other
5 Expiration date (month/day/yr) na	
6 model # 9700B	
7 If implanted give date (month/day/yr) na	
8 If explanted give date (month/day/yr) na	
9 Device available for evaluation? (Do not send to FDA) ☒ yes ☐ no ☐ returned to manufacturer on 03/24/05 (month/day/yr)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
na	

E. Initial reporter

1 Name & address Great Plains Health 506 North 32nd Street Billings MT 59101	2 Health professional? ☒ yes ☐ no	3 Occupation Home Care Dealer	4 Initial reporter also sent report to FDA ☐ yes ☐ no ☒ k

001611



Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

001723

Medication and Device Experience Report (continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user, facility, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 2

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration

FDA Use Only

F. For use by user facility/distributor—devices only

Check one ☐ user facility ☐ distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (m/d/yyyy)		7. Type of report ☐ initial ☐ follow-up # _____	
8. Date of this report (m/d/yyyy)			
9. Approximate age of device		10. Event problem codes (refer to coding manual) patient code _____ - _____ - _____ device code _____ - _____ - _____	
11. Report sent to FDA? ☐ yes _____ (m/d/yyyy) ☐ no		12. Location where event occurred ☐ hospital ☐ outpatient diagnostic facility ☐ home ☐ ambulatory surgical facility ☐ nursing home ☐ outpatient treatment facility ☐ other _____ specify _____	
13. Report sent to manufacturer? ☐ yes _____ (m/d/yyyy) ☐ no			
Manufacturer name/address			

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☒ malfunction (see guidelines) ☐ other _____		2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation	
3. Device evaluated by mfr? ☐ not returned to mfr ☒ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code _____		4. Device manufacture date (moyr) 05/00/97	
5. Labeled for single use? ☐ yes ☒ no			
6. Evaluation codes (refer to coding manual) method: 10 - 26 - _____ - _____ results: 710 - 137 - 420 - _____ conclusions: 61 - _____ - _____ - _____			
7. If remedial action initiated, check type ☐ recall ☐ notification ☐ repair ☐ inspection ☐ replace ☐ patient monitoring ☐ relabeling ☐ modification/adjustment ☐ other _____		8. Usage of device ☐ initial use of device ☐ reuse ☒ unknown	
9. If action reported to FDA under 21 USC 360(f) list correction/ removal reporting number			
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data			

G. All manufacturers

Contact office - name/address (& mailing site for devices)

CAS Medical System Inc
14 East Industrial Rd
Stratford Ct. 06405 Attn: Ron Jeffrey
Note: CAS purchased product line after this device was manufactured from
Bellcor/Puntan Bennett
800 Northwest Blvd
Bryn Mawr, MN 55441

Date received by manufacturer (m/d/yyyy)

13/10/05

If IND protocol #

3

Type of report (check all that apply)

☒ 5-day ☐ 15-day

☐ 10-day ☐ periodic

☐ Initial ☐ follow-up # _____

Report number

2448612005000003

5 (A) NDA # NA

IND #

PLA #

pre-1938 ☐ yes

OTC product ☐ yes

8. Adverse event term(s)

NA

2. Phone number

203-488-6056

3. Report source (check all that apply)

- ☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☒ other
Dealer

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington, DC 20503.

Form 3500A back

DRUGS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Robert H. Humphrey Building, Room 331-H
28 Independence Avenue, S.W.
Washington, DC 20201

A person may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address

001612

001724

Find record 214	
DATE ISSUED 3/10/2005	
CUSTOMER	GREAT PLAINS HEALTH
MODEL	AMI PLUS W/MODEM
SERIAL	Y-30201400
PART #	01-05-0170
WARRANTY	No
CUSTOMER COMMENTS	ALARMS DONT WORK
REPAIR SECTION	
PART #	28-02-0435
PART #	21-01 1004
PART #	21-01 1009
PART #	03-08-0351
REPAIR COMMENTS	RECERT TO MEET MFG SPECIFICATIONS INSTALLED NEW BATTERY AND ECN 6813 PASSED ALL FUNCTIONAL AND FINAL TESTS
INVESTIGATION	DUE FOR RECERT DEAD BATTERY NEEDS ECN 6813 ALARM TESTED OK AT RECEIPT OF MONITOR
CORRECTIVE ACTION	SEE REPAIR COMMENTS MDR 200500003 sent 4/8/05
CLOSED BY	IRON JEFFREY
DATE CLOSED	4/20/05

002235

W O 271

SERVICE REPORT

SECTION A

RGA # or S/O # <u>214</u>	CUSTOMER <u>GREAT PLAINS</u>
MODEL # <u>Q700B</u>	SERIAL # <u>4-30201400</u>
DATE RECEIVED <u>3-10-05</u>	ESTIMATE REQUIRED ☐ Wait for customer approval
CUSTOMER TRACKING No _____	
LOCATION of LABEL _____	

SECTION B

ITEMS RETURNED WITH UNIT (Include serial number or lot number)

Charger	Patient Cable	Carrying Case
Battery	Temp Probe	Cuff Hose
SPO2 Sensor	AC Line Cord	

Cuff and Size _____
Pass/Replace _____

CUSTOMER REQUEST/COMPLAINT Reason code 17

☐ Recertification ☐ Preventative Maintenance ☐ Data Download ☐ Evaluation Request

☐ Customer Statement ARNEA ALARM NOT WORKING

INITIAL FINDINGS DUE FOR RE-CERT (BATT DEAD) (over)
NEEDS ECU Q813
ALARM TESTED OK AT RECEIPT OF MONITOR

Has the customers statement been verified? ☐ YES ☒ NO ☐ N/A (no customer statement) (over)

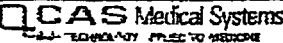
Warranty (Y/N) ☒ PO Number Obtained (Y/N) ☐ PO # _____

SERVICE FINDINGS/OTHER SERVICE PERFORMED Problem Area Code 59, 192

☒ Recertified to meet manufacture's specification Work Performed NEW BATT
☒ Passed all functional tests RE-CERT
☒ Passed all final tests

L360 (over) ECU Update # 6813

Total Labor Time <u>1.0</u>	Technicians Initials <u>RN</u>	DATE to QA <u>4-6-05</u>
QA Approval <u>AD</u>	QA Date <u>4-14-05</u>	- 001613

		SERVICE PROCESS		SHL 1 of 1
Process Number	SVC9700PUL	Rev D	9700X Parts Used List / Leakage Tests	

Other Parts Used

Qty	Part Number	Description	Qty	Part Number	Description
	15-06-0099	9700 Software		21-01-1190	Ami Battery Drawer Label
	15-06-0105	9700G German Software	1	28-02-0328	CAP DUST 25 PIN
	15-06-0103	9700S Spanish Software	1	28-02-0408	Clear Polyester Label
	15-01-0335	IC 74AC00 (U23 & U28)		21-01-1055	AMI Battery Seal
	03-09-0225	Battery Alarm board		21-01-1001	AMI Warranty Void Label
	17-08-0371	150VAC 150pfd Varistor	1	21-01-1004	AMI Plus Battery Label
	02-03-0038	1 1/4 Conductive Tape	1	21-01-1009	AMI Plus Warranty Void Label
	18-04-0190	1ufd Capacitor (R225)	1	03-08-0351	AMI Plus Battery Assembly
	17-09-0325	10K SMT Resistor (R999)		22-02-0112	Patent Cable Jack (AMI)
	16-04-0085	0 1ufd cap (C235)		17-08-0123	1Meg Resistor AMI Plus
	29-01-0218	Feet, case		18-01-0042	2" 20 AWG Red Wire AMI Plus
	28-02-0275	Foot-Rubber (square)		03-08-0314	Ami Battery Assembly
	28-02-0402	Remote Alarm Gasket		C3 08-0334	PATIENT CABLE JACK (AMI PLUS)
1	28-02-0435	TUNNEL		29-01-217	TOP CASE AMI
				29-01-215	TOP CASE AMI+

S/O# or RGA # 214

S/N Y-30201400

Final Test Data Sheet					
Tested By <u>SJ</u>		Date <u>4-15-05</u>		PASS ☒	FAIL ☐
Step	Description	PASS	FAIL	Measurement	Specification
6.1.5	Ground Wire Resistance	✓			
6.2.5	Leakage Test (Chassis)	✓		1 uA	<15 uA
6.2.7	Leakage Test (Patent Lead)	✓		1 uA	<15 uA

Failure Detail: _____

091614

Single Run Summary
CAL REPORT 0126
SERIAL NUMBER 30201400

TEST RESULTS PASSED

REVISION 13 *Ami Plus w/Modem, Final Test*
TEST DATE 4/7/05

MODEL NUMBER Y 9700B
PART NUMBER Y-006122-00B



TIME	TEST	TEST DESCRIPTION	STATUS
7 47 59 AM	1	Initial Power Up	PASSED
7 47 59 AM	2	Version & Serial Number Verification	PASSED
7 48 39 AM	3	Time & Date	PASSED
7 49 03 AM	4	Patient Setup	PASSED
7 49 18 AM	5	Patient Limits	PASSED
7 49 28 AM	6	Access Code	PASSED
7 52 17 AM	7	O2 Desat	PASSED
7 53 35 AM	8	Signal Quality Indicator	PASSED
7 56 28 AM	9	Resp Detect min, mid and max	PASSED
7 57 39 AM	10	ECG Crosstalk	PASSED
8 01 33 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
8 05 42 AM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
8 06 49 AM	13	Apnea Alarm ECG = RESP	PASSED
8 07 36 AM	14	Human Alarm Condition - Heart Slow	PASSED
8 08 38 AM	15	Human Alarm Condition - Apnea	PASSED
8 15 47 AM	16	4 2 VDC +/- 100mV Verification	PASSED
8 16 25 AM	17	WatchDog Test	PASSED
8 38 17 AM	18	Data Transfer & Recording Verification	PASSED

- 001615



Article Link: <http://children.webmd.com/tc/sudden-infant-death-syndrome-sids-overview>

children's health

Sudden Infant Death Syndrome (SIDS) - Topic Overview

What is sudden infant death syndrome (SIDS)?

Sometimes a baby who seems healthy dies during sleep. This is called sudden infant death syndrome or SIDS. SIDS is also known as crib death.

In most cases, a parent or caregiver places the baby down to sleep and returns later to find the baby has died. It's no one's fault. SIDS can happen even when you do everything right.

Although SIDS is rare, it is one of the most common causes of death in babies between 1 and 12 months of age. Most babies who die of SIDS are between the ages of 2 and 4 months.

What causes SIDS?

Doctors don't know what causes SIDS. It seems to happen more often in premature and low-birth-weight babies. It also is seen more often in babies whose mothers did not get medical care during the pregnancy and in babies whose mothers smoke. SIDS may also be more likely in babies who were part of a multiple pregnancy (for example, twins or triplets) or whose mothers are younger than 20.

When babies sleep on their bellies, they may not breathe well. Not too long ago, side sleeping was said to be okay. But babies placed on their sides can easily roll onto their bellies and could have trouble breathing.

Researchers are studying the possibility that SIDS may be caused by problems with how well the brain controls breathing, heart rate and rhythm, and/or temperature during the first few months of life. More research on this is needed.

What are the symptoms?

SIDS has no symptoms or warning signs. Babies who die of SIDS seem healthy before being put to bed. They show no signs of struggle and are often found in the same position as when they were placed in the bed.

How is SIDS diagnosed?

SIDS is named the cause of death only when no other cause is found. To find out why a baby died, medical experts review the baby's and parents' medical histories, study the area where the baby died, and do an autopsy.

What can you do to reduce the risk of SIDS?

There is no sure way to prevent SIDS, but doing certain things may help protect a baby.¹

The most important thing you can do is to always place your baby to sleep on his or her back rather than on the stomach or side.

- Don't smoke while you are pregnant. Also, do not let anyone smoke around your baby after he or she is born.
- For the first 6 months, have your baby sleep in a crib in the same room where you sleep.
 - Make sure the baby sleeps on a firm mattress (with a fitted sheet).
 - Don't put anything in the crib that a baby can pull over his or her head, such as blankets, comforters, stuffed toys, or pillows.
 - If you use bumper pads, use ones that are thin and firm, and make sure they are attached tightly to the crib.
 - Keep the room warm enough so that your baby can sleep in lightweight clothes without a blanket.

Consider offering your baby a pacifier at nap time and bedtime. This may help prevent SIDS, though experts do not know why. If you breast feed, wait until your baby is about a month old before you start giving him or her a pacifier.

continued

Make sure your baby's caregivers know what you expect them to do. Don't assume they know what to do to help reduce the risk of SIDS.

Frequently Asked Questions**Learning about sudden infant death syndrome (SIDS)**

- ♦ What is SIDS?
- ♦ What causes SIDS?
- ♦ What can I do to help prevent it?
- ♦ Who is affected by SIDS?

Being diagnosed

- ♦ What are the symptoms?
- ♦ Can an exam or test predict which babies are at risk for SIDS?

End-of-life issues

- ♦ What kinds of feelings are common after the loss of a baby?

WebMD Medical Reference from Healthwise



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SUDDEN INFANT DEATH SYNDROME (SIDS) TOPICS**Topic Overview**

Health Tools

Symptoms

Exams and Tests

Treatment Overview

Prevention

Home Treatment

Other Places To Get Help

Related Information

References

Credits

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My Notes

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• Weight Loss Wisdom



Go To Statement Considered Harmful

Key Words and Phrases go to statement, jump instruction, branch instruction, conditional clause, alternative clause, repetitive clause, program intelligibility, program sequencing
CE Categories 4 22 5 23 5 24

EDITOR

For a number of years I have been familiar with the observation that the quality of programmers is a decreasing function of the density of go to statements in the programs they produce. More recently I discovered why the use of the go to statement has such disastrous effects and I became convinced that the go to statement should be abolished from all "higher level" programming languages (i.e. everything except perhaps plain machine code). At that time I did not attach too much importance to this discovery, I now submit my considerations for publication because in very recent discussions in which the subject turned up, I have been urged to do so.

My first remark is that although the programmer's activity ends when he has constructed a correct program, the process taking place under control of his program is the true subject matter of his activity for it is this process that has to accomplish the desired effect, it is this process that in its dynamic behavior has to satisfy the desired specifications. Yet once the program has been made, the "making" of the corresponding process is delegated to the machine.

My second remark is that our intellectual powers are rather geared to master static relations and that our powers to visualise processes evolving in time are relatively poorly developed. For that reason we should do (as wise programmers aware of our limitations) our utmost to shorten the conceptual gap between the static program and the dynamic process, to make the correspondence between the program (spread out in text space) and the process (spread out in time) as trivial as possible.

Let us now consider how we can characterize the progress of a process. (You may think about this question in a very concrete manner: suppose that a process considered as a time succession of actions is stopped after an arbitrary action, what data do we have to fix in order that we can redo the process until the very same point?) If the program text is a pure concatenation of say assignment statements (for the purpose of this discussion regarded as the descriptions of single actions) it is sufficient to point in the program text to a point between two successive action descriptions. (In the absence of go to statements I can permit myself the syntactic ambiguity in the last three words of the previous sentence if we parse them as "successive (action descriptions)" we mean successive in text space, if we parse as "(successive action) descriptions" we mean successive in time.) Let us call such a pointer to a suitable place in the text a textual index.

When we include conditional clauses (if B then A), alternative clauses (if B then A_1 else A_2), choice clauses as introduced by C. A. R. Hoare (case [i] of $A_1, A_2, \dots, A_n$), or conditional expressions as introduced by J. McCarthy ($B_1 \rightarrow E_1, B_2 \rightarrow E_2, \dots, B_n \rightarrow E_n$) the fact remains that the progress of the process remains characterised by a single textual index.

As soon as we include in our language procedures we must admit that a single textual index is no longer sufficient. In the case that a textual index points to the interior of a procedure body the

dynamic progress is only characterised when we also give to which call of the procedure we refer. With the inclusion of procedures we can characterise the progress of the process via a sequence of textual indices, the length of this sequence being equal to the dynamic depth of procedure calling.

Let us now consider repetition clauses (like, while B repeat A or repeat A until B). Logically speaking, such clauses are now superfluous because we can express repetition with the aid of recursive procedures. For reasons of realism I don't wish to exclude them: on the one hand repetition clauses can be implemented quite comfortably with present day finite equipment, on the other hand the reasoning pattern known as induction makes us well equipped to retain our intellectual grasp on the processes generated by repetition clauses. With the inclusion of the repetition clauses textual indices are no longer sufficient to describe the dynamic progress of the process. With each entry into a repetition clause however we can associate a so called "dynamic index" inexorably counting the ordinal number of the corresponding current repetition. As repetition clauses (just as procedure calls) may be applied nestedly we find that now the progress of the process can always be uniquely characterised by a (mixed) sequence of textual and/or dynamic indices.

The main point is that the values of these indices are outside programmer's control, they are generated (either by the write up of his program or by the dynamic evolution of the process) whether he wishes or not. They provide independent coordinates in which to describe the progress of the process.

Why do we need such independent coordinates? The reason is—and this seems to be inherent to sequential processes—that we can interpret the value of a variable only with respect to the progress of the process. If we wish to count the number n of people in an initially empty room we can achieve this by increasing n by one whenever we see someone entering the room. In the in-between moment that we have observed someone entering the room but have not yet performed the subsequent increase of n its value equals the number of people in the room minus one!

The unbridled use of the go to statement has an immediate consequence that it becomes terribly hard to find a meaningful set of coordinates in which to describe the process progress. Usually people take into account as well the values of some well chosen variables but this is out of the question because it is relative to the progress that the meaning of these values is to be understood! With the go to statement one can, of course, still describe the progress uniquely by a counter counting the number of actions performed since program start (via a kind of normalised clock). The difficulty is that such a coordinate, although unique, is utterly unhelpful. In such a coordinate system it becomes an extremely complicated affair to define all those points of progress where say n equals the number of persons in the room minus one!

The go to statement as it stands is just too primitive, it is too much an invitation to make a mess of one's program. One can regard and appreciate the clauses considered as bridling its use. I do not claim that the clauses mentioned are exhaustive in the sense that they will satisfy all needs but whatever clauses are suggested (e.g. abortion clauses) they should satisfy the requirement that a programmer independent coordinate system can be maintained to describe the process in a helpful and manageable way.

It is hard to end this with a fair acknowledgment. Am I to

judge by whom my thinking has been influenced? It is fairly obvious that I am no uninfluenced by Peter Landin and Christopher Strachey. Finally I should like to record (as I remember it quite distinctly) how Heinz Zemanek at the pre ALGOL meeting in early 1959 in Copenhagen quite explicitly expressed his doubts whether the go to statement should be treated on equal syntactic footing with the assignment statement. To a modest extent I blame myself for not having then drawn the consequences of his remark.

The remark about the undesirability of the go to statement is far from new. I remember having read the explicit recommendation to restrict the use of the go to statement to alarm exits but I have not been able to trace it. Presumably it has been made by C. A. R. Hoare. In [1 Sec 3.2.1] Wirth and Hoare together make a remark in the same direction in motivating the case construction. Like the conditional it mirrors the dynamic structure of a program more clearly than go to statements and switches and it eliminates the need for introducing a large number of labels in the program.

In [2] Giuseppe Jacopini seems to have proved the (logical) superfluity of the go to statement. The exercise to translate an arbitrary flow diagram more or less mechanically into a jumpless one however is not to be recommended. Then the resulting flow diagram cannot be expected to be more transparent than the original one.

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2. BÖHM, CORRADO AND JACOPINI, GIUSEPPE. Flow diagrams: Turing machines and languages with only two formation rules. *Comm. ACM* 9 (May 1966) 366-371.

EDSGER W. DIJKSTRA
Technological University
Brindhoven, The Netherlands

Language Protection by Trademark Ill advised

Key Words and Phrases: TRAC languages, procedure-oriented language, proprietary software, protection of software, trademarks, copyright, protection, patent, protection, standardization, licensing, Mooers doctrine.

CP Categories: 2.12.2.2, 4.0.4.2

EDITOR

I would like to comment on a policy published 25 August 1967 by the Rockford Research Institute Inc. for trademark control of the TRAC language 'originated by Calvin N. Mooers of that corporation. It is the belief at Rockford Research that an aggressive course of action can and should be taken to protect the integrity of its carefully designed languages. Mr. Mooers believes that well-drawn standards are not enough to prevent irresponsible deviations in computer languages and that therefore

Rockford Research shall insist that all software and supporting services for its TRAC languages and related services be furnished for a price by Rockford or by sources licensed and authorized by Rockford in a contract arrangement. Mooers policy which applies to academic institutions as well as commercial users includes authorized use of the algorithm and primitives of a specific TRAC language, authorization for experimentation with the language.

I think that this attempt to protect a language and its software by controlling the name is very ill advised. One is reminded of the COMIT language whose developers (under V. Yngve) restricted

its source level distribution. As a result that effort was bypassed by the people at Bell Laboratories who developed SNOBOL. The latter language and its software were inevitably superior, and were immediately available to everyone including the right to make extensions. Later versions benefitted from meritorious extensions by 'irrepressible young people' at universities with the result that SNOBOL today is an important and prominent language while COMIT enjoys relative obscurity.

Mr. Mooers will find that new TRAC-like languages will appear whose documentation because of the trademark restriction cannot mention TRAC. Textbook references will be similarly inhibited. It is unfortunate.

BERNARD A. GALLER
University of Michigan
Ann Arbor, Mich. 48104

Mr. Mooers's Reply

EDITOR

Professor Galler's letter commenting on our Rockford Research policy statement on software protection of 25 August 1967 opens the discussion of what may be a very significant development to our computing profession. This policy statement applies to our TRAC (TM) computer controlling languages. The statement includes a new doctrine of software protection which may be generally applicable to a variety of different kinds of complex computer systems, computer services, languages, and software. Already it is evident that this doctrine has a number of interesting legal and commercial implications. It is accordingly appropriate that it be subject to critical discussion.

The doctrine is very simple. For specificity I shall describe it in regard to the TRAC languages which we have developed. (1) Rockford Research has designated itself as the sole authority for the development and publication of authentic standards and specifications for our TRAC languages and (2) we have adopted TRAC as our commercial trademark (and service mark) for use in connection with our computer controlling languages, our publications providing standards for the languages and any other related goods or services.

The power of this doctrine derives from the unique manner in which it serves the interests of the consuming public—the people who will be using computer services. The visible and recognized TRAC trademark informs this public—the engineers, the sociology professors, the business systems people, and the nonprogrammers everywhere—that the language or computer capability identified by this trademark adheres authentically and exactly to a carefully drawn Rockford Research standard for one of our TRAC languages or some related service. This is in accord with a long commercial and legal tradition.

The evils of the present situation and the need to find a suitable remedy are well known. An adequate basis for proprietary software development and marketing is urgently needed, particularly in view of the doubtful capabilities of copyright, patent, or 'trade secret' methods when applied to software. Developers of valuable systems—including languages—deserve to have some vehicle to give them a return. On the user side the nonexistence of standards in the computer systems area is a continuing nuisance. The proliferation of dialects on valuable languages (e.g. SNOBOL or FORTRAN) is sheer madness. The layman user (read "nonprogrammer") who now has access to any of several dozen computer facilities (each with incompatible systems and dialects) needs relief. It is my opinion that this new doctrine of autonomous standardization coupled with resort to commercial trademark can provide a substantial contribution to remedying a variety of our problems in this area.

Several points of Professor Galler's letter deserve specific comment. The full impact of our Rockford Research policy (and

TECHNISCHE HOGESCHOOL EINDHOVEN

NEDERLAND

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THE NETHERLANDS

DEPARTMENT OF MATHEMATICS

NOTES ON STRUCTURED PROGRAMMING

by

Prof dr Edsger W Dijkstra

T H -Report 70-WSK-03

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EWD249

NOTES ON STRUCTURED PROGRAMMING

by

prof dr Edsger W Dijkstra

August 1969

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To my reader

These notes have the status of "Letters written to myself" I wrote them down because, without doing so, I found myself repeating the same arguments over and over again. When reading what I had written, I was not always too satisfied

For one thing, I felt that they suffered from a marked verbosity. Yet I do not try to condense them (now), firstly because that would introduce another delay and I would like to "think on", secondly because earlier experiences have made me afraid of being misunderstood. Many a programmer tends to see his (sometimes rather specific) difficulties as the core of the subject and as a result there are widely divergent opinions as to what programming is really about.

For another thing, as a document this is very incomplete. I am only too aware of the fact that it ends in mid-air. Yet I have decided to have these notes duplicated, besides some practical considerations mainly to show what I have thought to those who expressed interest in it or to those whose comments I would welcome.

I hope that, despite its defects, you will enjoy at least parts of it. If these notes prove to be a source of inspiration or to give you a new appreciation of the programmer's trade, some of my goals will have been reached.

Edsger W Dijkstra

On our inability to do much

I am faced with a basic problem of presentation. What I am really concerned about is the composition of large programs, the text of which may be, say, of the same size as the whole text of this booklet. Also I have to include examples to illustrate the various techniques. For practical reasons, the demonstration programs must be small, many times smaller than the "life-size programs" I have in mind. My basic problem is that precisely this difference in scale is one of the major sources of our difficulties in programming.

It would be very nice if I could illustrate the various techniques with small demonstration programs and could conclude with "and when faced with a program a thousand times as large, you compose it in the same way." This common educational device, however, would be self-defeating as one of my central themes will be that any two things that differ in some respect by a factor of already a hundred or more, are utterly incomparable.

History has shown that this truth is very hard to believe. Apparently we are too much trained to disregard differences in scale, to treat them as "gradual differences that are not essential." We tell ourselves that what we can do once, we can also do twice and by induction we fool ourselves into believing that we can do it as many times as needed, but this is just not true! A factor of a thousand is already far beyond our powers of imagination.

Let me give you two examples to rub this in. A one-year old child will crawl on all fours with a speed of, say, one mile per hour. But a speed of a thousand miles per hour is that of a supersonic jet. Considered as objects with moving ability the child and the jet are incomparable, for whatever one can do the other cannot and vice versa. Also one can close one's eyes and imagine how it feels to be standing in an open place, a prairie or a sea shore, while far away a big, reinless horse is approaching at a gallop, one can "see" it approaching and passing. To do the same with a phalanx of a thousand of these big beasts is mentally impossible. Your heart would miss a number of beats by pure panic, if you could!

To complicate matters still further, problems of size do not only cause me problems of presentation, but they lie at the heart of the subject widespread

underestimation of the specific difficulties of size seems one of the major underlying causes of the current software failure. To all this I can see only one answer, viz to treat problems of size as explicitly as possible. Hence the title of this section

To start with, we have the "size" of the computation, i.e. the amount of information and the number of operations involved in it. It is essential that this size is large, for if it were really small, it would be easier not to use the computer at all and to do it by hand. The automatic computer owes its right to exist, its usefulness, precisely to its ability to perform large computations where we humans cannot. We want the computer to do what we could never do ourselves and the power of present-day machinery is such that even small computations are by their very size already far beyond the powers of our unaided imagination.

Yet we must organize the computations in such a way that our limited powers are sufficient to guarantee that the computation will establish the desired effect. This organizing includes the composition of the program and here we are faced with the next problem of size, viz the length of the program text, and we should give this problem also explicit recognition. We should remain aware of the fact that the extent to which we can read or write a text is very much dependent on its size. In my country the entries in the telephone directory are grouped by town or village and within each such group the subscribers are listed by name in alphabetical order. I myself live in a small village and given a telephone number I have only to scan a few columns to find out to whom the telephone number belongs, but to do the same in a large city would be a major data processing task!

It is in the same mood that I should like to draw the reader's attention to the fact that "clarity" has pronounced quantitative aspects, a fact many mathematicians, curiously enough, seem to be unaware of. A theorem stating the validity of a conclusion when ten pages full of conditions are satisfied is hardly a convenient tool, as all conditions have to be verified whenever the theorem is appealed to. In Euclidean geometry, Pythagoras' Theorem holds for any three points A, B and C such that through A and C a straight line can be drawn orthogonal to a straight line through B and C. How many mathematicians appreciate that the theorem remains applicable when some or all of the points A, B and C coincide? Yet this seems largely responsible for the convenience with which Pythagoras Theorem can be

used

Summarizing as a slow-witted human being I have a very small head and I had better learn to live with it and to respect my limitations and give them full credit, rather than to try to ignore them, for the latter vain effort will be punished by failure

On the reliability of mechanisms

Being a programmer by trade, programs are what I am talking about and the true subject of this section really is the reliability of programs. That, nevertheless, I have mentioned "mechanisms" in its title is because I regard programs as specific instances of mechanisms, and that I wanted to express, at least once, my strong feeling that many of my considerations concerning software are, *mutatis mutandis*, just as relevant for hardware design.

Present-day computers are amazing pieces of equipment, but most amazing of all are the uncertain grounds on account of which we attach any validity to their output. It starts already with our belief that the hardware functions properly.

Let us restrict, for a moment, our attention to the hardware and let us wonder to what extent one can convince oneself of its being properly constructed. Some years ago a machine was installed on the premises of my University, in its documentation it was stated that it contained, among many other things, circuitry for the fixed-point multiplication of two 27-bit integers. A legitimate question seems to be: "Is this multiplier correct, is it performing according to the specifications?"

The naive answer to this is "Well, the number of different multiplications this multiplier is claimed to perform correctly is finite, viz 2^{54} , so let us try them all." But, reasonable as this answer may seem, it is not, for although a single multiplication took only some tens of microseconds, the total time needed for this finite set of multiplications would add up to more than 10 000 years! We must conclude that exhaustive testing, even of a single component such as a multiplier, is entirely out of the question. (Testing a complete computer on the same basis would imply the established correct processing of all possible programs.)

A first consequence of the 10 000 years is that during its life-time the multiplier will be asked to perform only a negligible fraction of the vast number of all possible multiplications it could do: practically none of them! Funny enough, we still require that it would do any multiplication correctly when ordered to do so. The reason underlying this fantastic quality requirement is that we do

not know in advance, which are the negligibly few multiplications it will be asked to perform. In our reasoning about our programs we talk about "the product" and have abstracted from the specific values of the factors. We do not know them, we do not wish to know them, it is not our business to know them, it is our business not to know them! Our wish to think in terms of the concept "the product", abstracted from the specific instances occurring in a computation is granted, but the price paid for this is precisely the reliability requirement that any multiplication of the vast set will be performed correctly. So much for the justification of our desire for a correct multiplier.

But how is the correctness established in a convincing manner? As long as the multiplier is considered as a black box, the only thing we can do is "testing by sampling", i.e. offering to the multiplier a feasible amount of factor pairs and checking the result. But in view of the 10 000 years, it is clear that we can only test a negligible fraction of the possible multiplications. Whole classes of in some sense "critical" multiplications may remain untested and in view of the reliability justly desired, our quality control is still most unsatisfactory. Therefore it is not done that way.

The straightforward conclusion is the following: a convincing demonstration of correctness being impossible as long as the mechanism is regarded as a black box, our only hope lies in not regarding the mechanism as a black box. I shall call this "taking the structure of the mechanism into account".

From now onwards the type of mechanisms we are going to deal with are programs. (In many respects, programs are mechanisms much easier to deal with than circuitry which is really an analogue device and subject to wear and tear.) And also with programs it is fairly hopeless to establish the correctness beyond even the mildest doubt by testing without taking their structure into account. In other words, we remark that the extent to which the program correctness can be established is not purely a function of the program's external specifications and behaviour but depends critically upon its internal structure.

Recalling that our true concern is with really large programs, we observe as an aside that the size itself requires a high confidence level for the individual program components. If the chance of correctness of an individual component equals

p, the chance of correctness of a whole program, composed of N such components, is something like

$$P = p^N$$

As N will be very large, p should be very, very close to 1 if we desire P to differ significantly from zero'

When we now take the position that it is not only the programmer's task to produce a correct program but also to demonstrate its correctness in a convincing manner, then the above remarks have a profound influence on the programmer's activity the object he has to produce must be usefully structured

The remaining part of this monograph will mainly be an exploration of what program structure can be used to good advantage In what follows it will become apparent that program correctness is not my only concern, program adaptability or manageability will be another This stress on program manageability is my deliberate choice, a choice that, therefore, I should like to justify

While in the past the growth in power of the generally available equipment has mitigated the urgency of the efficiency requirements, this very same growth has created its new difficulties Once one has a powerful machine at one's disposal one tries to use it and the size of the problems one tackles adjusts itself to the scope of the equipment no one thinks about programming an algorithm that would take twenty years to execute With processing power increased by a factor of a thousand over the last ten to fifteen years, Man has become considerably more ambitious in selecting problems that now should be "technically feasible" Size, complexity and sophistication of programs one should like to make have exploded and over the past years it has become patently clear that on the whole our programming ability has not kept pace with these exploding demands made on it

The power of available equipment will continue to grow we can expect manufacturers to develop still faster machines and even without that development we shall witness that the type of machine that is presently considered as exceptionally fast will become more and more common The things we should like to do with these machines will grow in proportion and it is on this extrapolation that I have formed my picture of the programmer's task

My conclusion is that it is becoming most urgent to stop to consider programming primarily as the minimization of a cost/performance ratio. We should recognize that already now programming is much more an intellectual challenge. The art of programming is the art of organizing complexity, of mastering multitude and avoiding its bastard chaos as effectively as possible.

My refusal to regard efficiency considerations as the programmer's prime concern is not meant to imply that I disregard them. On the contrary, efficiency considerations are recognized as one of the main incentives to modifying a logically correct program. My point, however, is that we can only afford to optimize (whatever that may be) provided that the program remains sufficiently manageable.

Let me end this section with a final aside on the significance of computers. Computers are extremely flexible and powerful tools and many feel that their application is changing the face of the earth. I would venture the opinion that as long as we regard them primarily as tools, we might grossly underestimate their significance. Their influence as tools might turn out to be but a ripple on the surface of our culture, whereas I expect them to have a much more profound influence in their capacity of intellectual challenge.

Corollary of the first part of this section

Program testing can be used to show the presence of bugs, but never to show their absence.

On our mental aids

In the previous section we have stated that the programmer's duty is to make his product "usefully structured" and we mentioned the program structure in connection with a convincing demonstration of the correctness of the program

But how do we convince? And how do we convince ourselves? What are the typical patterns of thought enabling ourselves to understand? It is to a broad survey of such questions that the current section is devoted. It is written with my sincerest apologies to the professional psychologist, because it will be amateurishly superficial. Yet I hope (and trust) that it will be sufficient to give us a yardstick by which to measure the usefulness of a proposed structuring

Among the mental aids available to understand a program (or a proof of its correctness) there are three that I should like to mention explicitly

- 1) Enumeration
- 2) Mathematical induction
- 3) Abstraction

On enumeration

I regard as an appeal to enumeration the effort to verify a property of the computations that can be evoked by an enumerated set of statements performed in sequence, including conditional clauses distinguishing between two or more cases. Let me give a simple example of what I call "enumerative reasoning"

It is asked to establish that the successive execution of the following two statements

```
"dd = dd / 2,
  if dd ≤ r do r := r - dd"
```

operating on the variables "r" and "dd" leaves the relations

$$0 \leq r < dd \quad (1)$$

invariant. One just "follows" the little piece of program assuming that (1) is satisfied to start with. After the execution of the first statement, which halves

the value of dd , but leaves r unchanged, the relations

$$0 \leq r < 2 * dd \quad (2)$$

will hold. Now we distinguish two mutually exclusive cases

1) $dd \leq r$ Together with (2) this leads to the relations

$$dd \leq r < 2 * dd, \quad (3)$$

In this case the statement following do will be executed, ordering a decrease of r by dd , so that from (3) it follows that eventually

$$0 \leq r < dd,$$

i.e. (1) will be satisfied

2) non $dd \leq r$ (i.e. $dd > r$) In this case the statement following do will be skipped and therefore also r has its final value. In this case " $dd > r$ " together with (2), which is valid after the execution of the first statement leads immediately to

$$0 \leq r < dd$$

so that also in the second case (1) will be satisfied

Thus we have completed our proof of the invariance of relations (1), we have also completed our example of enumerative reasoning, conditional clauses included

On mathematical induction

I have mentioned mathematical induction explicitly because it is the only pattern of reasoning that I am aware of that eventually enables us to cope with loops (such as can be expressed by repetition clauses) and recursive procedures. I should like to give an example

Let us consider the sequence of values

$$d_0, d_1, d_2, d_3, \quad (1)$$

given by

$$\text{for } i = 0 \quad d_i = D \quad (2a)$$

$$\text{for } i > 0 \quad d_i = f(d_{i-1}) \quad (2b)$$

where D is a given value and f a given (computable) function. It is asked to make the value of the variable " d " equal to the first value d_k in the sequence that satisfies a given (computable) condition " prop ". It is given that such a value exists for finite k . A more formal definition of the requirement is to establish the relation

$$d = d_k \quad (3)$$

where k is given by the (truth of the) expressions

$$\text{prop}(d_k) \quad (4)$$

$$\text{and } \underline{\text{non prop}}(d_1) \quad \text{for all } i \text{ satisfying } 0 \leq i < k \quad (5)$$

We now consider the following program part

$$\begin{aligned} & "d = D \\ & \quad \underline{\text{while non prop}}(d) \underline{\text{do}} d = f(d)" \end{aligned} \quad (6)$$

in which the first line represents the initialization and the second one the loop, controlled by the (hopefully self-explanatory) repetition clause while do (In terms of the conditional clause if do, used in our previous example, a more formal definition of the semantics of the repetition clause is by stating that

$$\underline{\text{"while B do S"}}$$

is semantically equivalent with

$$\begin{aligned} & \underline{\text{"if B do}} \\ & \quad \underline{\text{begin S, while B do S end}} \end{aligned}$$

expressing that "non B" is the necessary and sufficient condition for the repetition to terminate)

Calling in the construction "while B do S" the statement S "the repeated statement" we shall prove that in program (6)

after the n -th execution of the repeated statement will hold (for $n \geq 0$)

$$d = d_n \quad (7a)$$

$$\text{and } \underline{\text{non prop}}(d_1) \quad \text{for all } i \text{ satisfying } 0 \leq i < n \quad (7b)$$

The above statement holds for $n = 0$ (by enumerative reasoning), we have to prove (by enumerative reasoning) that when it holds for $n = N$ ($N \geq 0$), it will also hold for $n = N + 1$

After the N-th execution of the repeated statement relations (7a) and (7b) are satisfied for $n = N$. For the N+1st execution to take place, the necessary and sufficient condition is the truth of

$$\text{non prop}(d)$$

which, thanks to (7a) for $n = N$ ($i.e. d = d_N$) means

$$\text{non prop}(d_N)$$

leading to condition (7b) being satisfied for $n = N + 1$. Furthermore, $d = d_N$ and (2b) leads to

$$f(d) = d_{N+1}$$

so that the net effect of the N+1st execution of the repeated statement

$$"d = f(d)"$$

established the relation

$$d = d_{N+1}$$

$i.e.$ relation (7a) for $N = N + 1$ and thus the induction step (7) has been proved

Now we shall show that the repetition terminates after the k-th execution of the repeated statement. The n-th execution cannot take place for $n > k$ for (on account of 7b) this would imply

$$\text{non prop}(d_k)$$

thereby violating (4). When the repetition terminates after the n-th execution of the repeated statement, the necessary and sufficient condition for termination, viz

$$\text{non}(\text{non prop}(d))$$

becomes, thanks to (7a)

$$\text{prop}(d_n) \tag{8}$$

This excludes termination for $n < k$, as this would violate (5). As a result the repetition will terminate with $n = k$, so that (3) follows from (7a), (4) follows from (8) and (5) follows from (7b). Which terminates our proof.

Before turning our attention away from this example illustrating the use of mathematical induction as a pattern of reasoning, I should like to add some remarks, because I have the uneasy feeling that by now some of my readers—in particular experienced and competent programmers—will be terribly irritated, viz those

readers for whom program (6) is so obviously correct that they wonder what all the fuss is about "Why his pompous restatement of the problem as in (3), (4) and (5), because anyone knows what is meant by the first value in the sequence, satisfying a condition? Certainly he does not expect us, who have work to do, to supply such lengthy proofs, with all the mathematical dressing, whenever we use such a simple loop as that?" Etc

To tell the honest truth: the pomp and length of the above proof infuriate me as well! But at present I cannot do much better if I really try to prove the correctness of this program. But it sometimes fills me with the same kind of anger as years ago the crazy proofs of the first simple theorems in plane geometry did, proving things of the same degree of "obviousness" as Euclid's axioms themselves

Of course I would not dare to suggest (at least at present!) that it is the programmer's duty to supply such a proof whenever he writes a simple loop in his program. If so, he could never write a program of any size at all! It would be as impractical as reducing each proof in plane geometry explicitly and in extenso to Euclid's axioms (Cf. Section "On our inability to do much")

My moral is threefold. Firstly, when a programmer considers a construction like (6) as obviously correct, he can do so because he is familiar with the construction. I prefer to regard his behaviour as an unconscious appeal to a theorem he knows, although perhaps he has never bothered to formulate it, and once in his life he has convinced himself of its truth, although he has probably forgotten in which way he did it and although the way was (probably) unfit for print. But we could call our assertions about program (6), say, "The Linear Search Theorem" and knowing such a name it is much easier (and more natural) to appeal to it consciously

Secondly, to the best of my knowledge, there is no set of theorems of the type illustrated above, whose usefulness has been generally accepted. But we should not be amazed about that, for the absence of such a set of theorems is a direct consequence of the fact that the type of object -- i.e. programs -- has not settled down. The kind of object the programmer is dealing with, viz. programs, is much less well-established than the kind of object that is dealt with in plane geometry. In the mean time the intuitively competent programmer is probably the one who confines himself, whenever acceptable, to program structures with which he is very

familiar, while becoming very alert and careful whenever he constructs something unusual (for him) For an established style of programming, however, it might be a useful activity to look for a body of theorems pertinent to such programs

Thirdly, the length of the proof we needed in our last example is a warning that should not be ignored There is of course the possibility that a better mathematician will do a much shorter and more elegant job than I have done Personally I am inclined to conclude from this length that programming is more difficult than is commonly assumed; let us be honestly humble and interpret the length of the proof as an urgent advice to restrict ourselves to simple structures whenever possible and to avoid in all intellectual modesty "clever constructions" like the plague

On abstraction

At this stage I find it hard to be very explicit about the role of abstraction, partly because it permeates the whole subject Consider an algorithm and all possible computations it can evoke: starting from the computations the algorithm is what remains when one abstracts from the specific values manipulated this time The concept of "a variable" represents an abstraction from its current value It has been remarked to me (to my great regret I cannot remember by whom and so I am unable to give credit where it seems due) that once a person has understood the way in which variables are used in programming, he has understood the quintessence of programming We can find a confirmation for this remark when we return to our use of mathematical induction with regard to the repetition: on the one hand it is by abstraction that the concepts are introduced in terms of which the induction step can be formulated; on the other hand it is the repetition that really calls for the concept of "a variable" (Without repetition one can restrict oneself to "quantities" the value of which has to be defined at most once but never has to be redefined as in the case of a variable)

There is also an abstraction involved in naming an operation and using it on account of "what it does" while completely disregarding "how it works" (In the same way one should state that a programming manual describes an abstract machine the specific piece of hardware delivered by the manufacturer is nothing but a

-usually imperfect'- mechanical model of this abstract machine) There is a strong analogy between using a named operation in a program regardless of "how it works" and using a theorem regardless of how it has been proved. Even if its proof is highly intricate, it may be a very convenient theorem to use.

Here, again, I refer to our inability to do much Enumerative reasoning is all right as far as it goes, but as we are rather slow-witted it does not go very far. Enumerative reasoning is only an adequate mental tool under the severe boundary condition that we use it only very moderately. We should appreciate abstraction as our main mental technique to reduce the demands made upon enumerative reasoning.

(Here Mike Woodger, National Physical Laboratory, Teddington, England, made the following remark, which I insert in gratitude. "There is a parallel analogy between the unanalyzed terms in which an axiom or theorem is expressed and the unanalyzed operands upon which a named operation is expected to act.")

An example of a correctness proof.

Let us consider the following program section, where the integer constants a and d satisfy the relations

$$a \geq 0 \quad \text{and} \quad d > 0$$

```

"integer r, dd,
r := a, dd = d;
while dd ≤ r do dd = 2 * dd,
while dd ≠ d do
  begin dd = dd / 2,
    if dd ≤ r do r = r - dd
  end"
```

To apply the Linear Search Theorem (see Section "On our mental aids", subsection "On mathematical induction") we consider the sequence of values given by

$$\begin{aligned} \text{for } i = 0 & \quad dd_i = d \\ \text{for } i > 0 & \quad dd_i = 2 * dd_{i-1} \\ \text{from which} & \quad dd_n = d * 2^n \end{aligned} \quad (1)$$

can be derived by normal mathematical techniques, which also tell us that (because $d > 0$) for finite r

$$dd_k > r$$

will hold for some finite k , thus ensuring that the first repetition terminates with

$$dd = d * 2^k$$

Solving the relation

$$d_i = 2 * d_{i-1}$$

$$\text{for } d_{i-1} \text{ gives } d_{i-1} = d_i / 2$$

and the Linear Search Theorem then tells us, that the second repetition will also terminate (As a matter of fact the second repeated statement will be executed exactly the same number of times as the first one)

At the termination of the first repetition,

$$dd = dd_k$$

and therefore, $0 \leq r < dd$ (2)

holds. As shown earlier (Section "On our mental aids ", subsection "On enumeration") the repeated statement of the second clause leaves this relation invariant. After termination (on account of "while $dd \neq d$ do") we can conclude

$$dd = d$$

which together with (2) gives

$$0 \leq r < d \quad (3)$$

Furthermore we prove that after the initialisation

$$dd \equiv 0 \pmod{d} \quad (4)$$

holds, this follows, for instance, from the fact that the possible values of dd are -see (1)- $d * 2^i$ for $0 \leq i \leq k$

Our next step is to verify, that after the initial assignment to r the relation

$$a \equiv r \pmod{d} \quad (5)$$

holds

- 1) It holds after the initial assignments
- 2) The repeated statement of the first clause (" $dd = 2 * dd$ ") maintains the invariance of (5) and therefore the whole first repetition maintains the validity of (5)
- 3) The second repeated statement consists of two statements. The first (" $dd = dd/2$ ") leaves (5) invariant, the second one also leaves (5) invariant for either it leaves r untouched or it decreases r by the current value of dd , an operation which on account of (4) also maintains the validity of (5). Therefore the whole second repeated statement leaves (5) invariant and therefore the whole repetition leaves (5) invariant. Combining (3) and (5), the final value therefore satisfies

$$0 \leq r < d \quad \text{and} \quad a \equiv r \pmod{d}$$

i.e. r is the smallest non-negative remainder of the division of a by d

Remark 1 The program

```

"integer r, dd, q,
  r = a; dd := d, q = 0,
  while dd ≤ r do dd = 2 * dd,
  while dd ≠ d do
    begin dd := dd / 2, q = 2 * q,
      if dd ≤ r do begin r = r - dd, q = q + 1 end
    end

```

assigns to q the value of the corresponding quotient. The proof can be established by observing the invariance of the relation

$$a = q * dd + r$$

(I owe this example to my colleague N G de Bruijn)

Remark 2 In the subsection "On mathematical induction" we have proved the Linear Search Theorem. In the previous proof we have used another theorem about repetitions (a theorem that, obviously, can only be proved by mathematical induction, but the proof is so simple that we leave it as an exercise to the reader), viz that if prior to entry of a repetition a certain relation P holds, whose truth is not destroyed by a single execution of the repeated statement, then relation P will still hold after termination of the repetition. This is a very useful theorem, often allowing us to bypass an explicit appeal to mathematical induction. (We can state the theorem a little bit sharper, in the repetition

```

"while B do S"

```

one has to show that S is such that the truth of

P and B

prior to the execution of S implies the truth of

P

after its execution)

Remark 3 As an exercise (for which acknowledgement is due to James King, CMU, Pittsburgh, USA) for the reader, prove that with integer A, B, x, y and z and

$$A > 0 \text{ and } B \geq 0$$

after the execution of the program section


```

"x = A; y := B, z = 1;
  while y  $\neq$  0 do
    begin if odd(y) do begin y = y - 1, z = z * x end,
          y = y / 2, x = x * x
    end
  finally z = AB will hold

```

The proof has to show that (in spite of "y = y / 2") all variables keep integer values, the method shows the invariance of

$$x > 0 \text{ and } y \geq 0 \text{ and } A^B = z * x^y$$

On the validity of proofs versus the validity of implementations

In the previous section I have assumed "perfect arithmetic" and in my experience the validity of such proofs often gets questioned by people who argue that in practice one never has perfect arithmetic at ones disposal admissible integer values usually have an absolute upper bound, real numbers are only represented to a finite accuracy etc So what is the validity of such proofs?

The answer to this question seems to be the following If one proves the correctness of a program assuming an idealized, perfect world, one should not be amazed if something goes wrong when this ideal program gets executed by an "imperfect" implementation Obviously! Therefore, if we wish to prove program correctness in a more realistic world, the thing to do is to acknowledge right at the start that all operations appealed to in the program (in particular all arithmetic operations) need not be perfect, provided we state -rather axiomatically- the properties they have to satisfy for the proper execution of the program, i.e. the properties on which the correctness proof relies (In the example of the previous section this requirement is simply exact integer arithmetic in the range $[0, 2a]$)

When writing a program operating on real numbers with rounded operations, one must be aware of the assumptions one makes, such as

$$\begin{aligned} b > 0 \text{ implies } a + b &\geq a \\ a * b &= b * a \\ -(a * b) &= (-a) * b \\ 0 * x &= 0 \\ 0 + x &= x \\ 1 * x &= x \quad \text{etc etc} \end{aligned}$$

Very often the validity of such relations is essential to the logic of the program For the sake of compatibility, the programmer would be wise to be as undemanding as possible, whereas a good implementation should satisfy as many reasonable requirements as possible

This is the place to confess one of my blunders In implementing ALGOL 60 we decided that " $x = y$ " would deliver the value true not only in the case of exact equality, but also when the two values differed only in the least significant

digit represented, because otherwise it was so very improbable that the value true would ever be computed. We were thinking of converging iterations that could oscillate within rounding accuracy. While we had been generous (with the best of intentions') in regarding real numbers as equal, it quickly turned out that the chosen operation was so weak as to be hardly of any use at all. What it boiled down to was that the established truth of $a = b$ and $b = c$ did not allow the programmer to conclude the truth of $a = c$. The decision was quickly changed. It is since that experience that I know that the programmer can only use his tool by virtue of (a number of) its properties; conversely, the programmer must be able to state which properties he requires. (Usually programmers don't do so because, for lack of tradition as to what properties can be taken for granted, this would require more explicitness than is otherwise desirable. The proliferation of machines with lousy floating-point hardware -together with the misapprehension that the automatic computer is primarily the tool of the numerical analyst- has done much harm to the profession')

On understanding programs

In my life I have seen many programming courses that were essentially like the usual kind of driving lessons, in which one is taught how to handle a car instead of how to use a car to reach one's destination

My point is that a program is never a goal in itself, the purpose of a program is to evoke computations and the purpose of the computations is to establish a desired effect. Although the program is the final product made by the programmer, the possible computations evoked by it -the "making" of which is left to the machine'- are the true subject matter of his trade. For instance, whenever a programmer states that his program is correct, he really makes an assertion about the computations it may evoke.

The fact that the last stage of the total activity, viz the transition from the (static) program text to the (dynamic) computation, is essentially left to the machine is an added complication. In a sense the making of a program is therefore more difficult than the making of a mathematical theory. Both program and theory are structured, timeless objects. But while the mathematical theory makes sense as it stands, the program only makes sense via its execution.

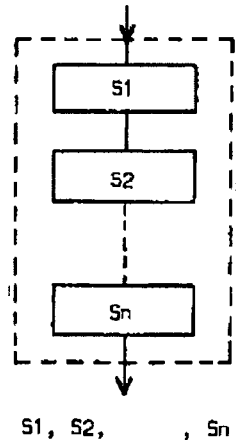
In the remaining part of this section I shall restrict myself to programs written for a sequential machine and I shall explore some of the consequences of our duty to use our understanding of a program to make assertions about the ensuing computations. It is my (unproven) claim that the ease and reliability with which we can do this depends critically upon the simplicity of the relation between the two, in particular upon the nature of sequencing control. In vague terms we may state the desirability that the structure of the program text reflects the structure of the computation. Or, in other terms, "What can we do to shorten the conceptual gap between the static program text (spread out in "text space") and the corresponding computations (evolving in time)?"

It is the purpose of the computation to establish a certain desired effect. When it starts at a discrete moment t_0 it will be completed at a later discrete moment t_1 and we assume that its effect can be described by comparing "the state at t_0 " with "the state at t_1 ". If no intermediate states are taken into consideration

the effect is regarded as being established by a primitive action

When we do take a number of intermediate states into consideration this means that we have parsed the happening in time. We regard it as a sequential computation, i.e. the time-succession of a number of subactions and we have to convince ourselves that the cumulative effect of this time-succession of subactions indeed equals the desired net effect of the total computation

The simplest case is a parsing, a decomposition, into a fixed number of subactions that can be enumerated. In flowchart form this can be represented as follows



The validity of this decomposition has to be established by enumerative reasoning. In this case, shortening of the conceptual gap between program and computation can be achieved by requiring that a linear piece of program text contains names or descriptions of the subactions in the order in which they have to take place. In our earlier example (invariance of $0 \leq r < dd$)

```

"dd := dd / 2,
  if dd ≤ r do r = r - dd"
  
```

this condition is satisfied. The primary decomposition of the computation is into a time-succession of two actions; in the program text we recognize this structure

```

"halve dd,
  reduce r modulo dd"
  
```

We are considering all initial states satisfying $0 \leq r < dd$ and in all computations then considered, the given parsing into two subactions is applicable

So far, so good

The program, however, is written under the assumption that "reduce r modulo dd" is not a primitive action, while "decrease r by dd" is. Viewing all possible happenings during "reduce r modulo dd" it becomes then relevant to distinguish that in some cases "decrease r by dd" takes place, while in the other cases r remains unchanged. By writing

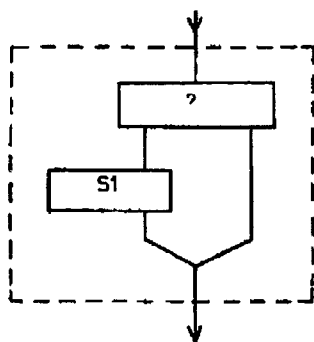
"if $dd \leq r$ do decrease r by dd"

we have represented that at the given level of detail the action "reduce r modulo dd" can take one of two mutually exclusive forms and we have also given the criterion on account of which the choice between them is made. If we regard "if $dd \leq r$ do" as a conditional clause attached to "decrease r by dd" it is natural that the conditional clause is placed in front of the conditioned statement. (In this sense the alternative clause

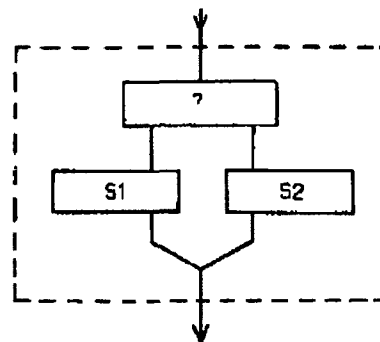
"if condition then statement 1 else statement 2"

is "over-ordered" with respect to "statement 1" and "statement 2" they are just two alternatives that cannot be expressed simultaneously on a linear medium.)

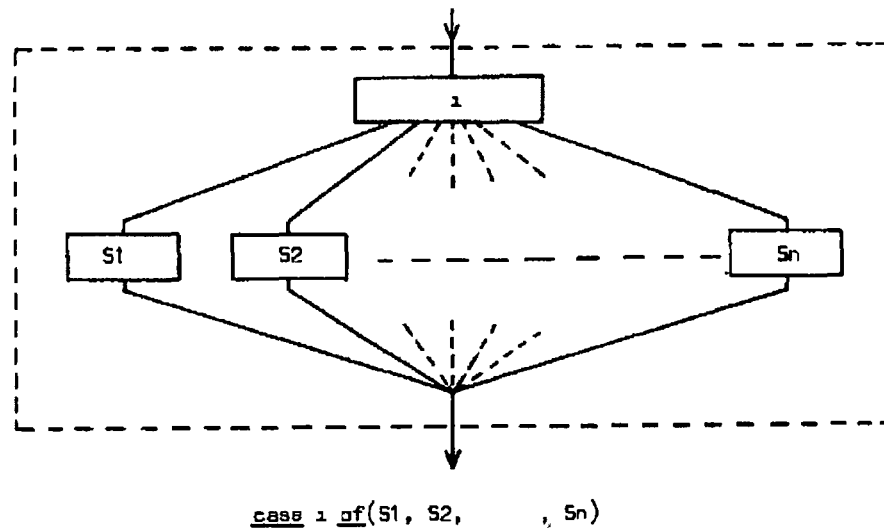
The alternative clause has been generalized by C. A. R. Hoare whose "case-of" construction provides a choice between more than two possibilities. In flowchart form they can be represented as follows:



if ? do S1

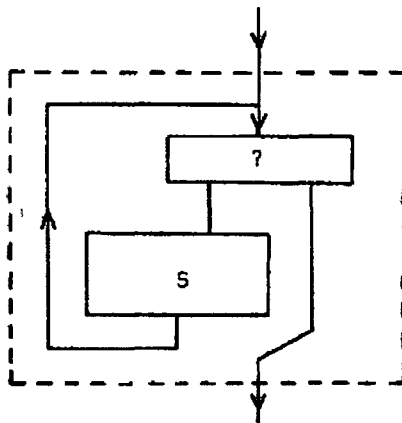


if ? then S1 else S2

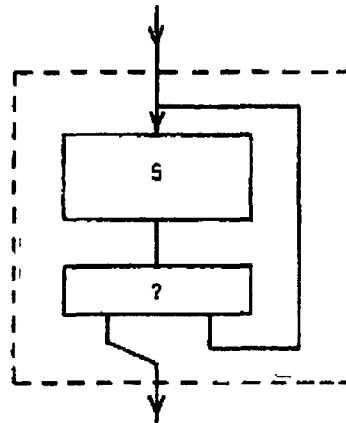


These flowcharts share the property that they have a single entry at the top and a single exit at the bottom as indicated by the dotted block they can again be interpreted (by disregarding what is inside the dotted lines) as a single action in a sequential computation. To be a little bit more precise we are dealing with a great number of possible computations, primarily decomposed into the same time-succession of subactions and it is only on closer inspection - i.e. by looking inside the dotted block - that is revealed that over the collection of possible computations such a subaction may take one of an enumerated set of distinguished forms.

The above is sufficient to consider a class of computations that are primarily decomposed into the same set of enumerated subactions, they are insufficient to consider a class of computations that are primarily decomposed into a varying number of subactions (i.e. varying over the class of computations considered). It is here that the usefulness of the repetition clauses becomes apparent. We mention "while condition do statement" and "repeat statement until condition" that may be represented in flowchart form as follows.



while ? do S



repeat S until ?

These flowcharts also share the property of a single entry at the top and a single exit at the bottom. They enable us to express that the action represented by the dotted block is on closer inspection a time-succession of "a sufficient number" of subactions of a certain type.

We have now seen three types of decomposition, we could call them "concatenation", "selection" and "repetition" respectively. The first two are understood by enumerative reasoning, the last one by mathematical induction.

The programs that can be written using the selection clauses and the repetition clauses as only means for sequencing control, permit straightforward translation into a programming language that is identical but for the fact that sequencing control has to be expressed by jumps to labelled points. The converse is not true. Alternatively restricting ourselves to the three mentioned types of decomposition leads to flowcharts of a restricted topology compared with the flowcharts one can make when arrows can be drawn from any block leading into any other. Compared with that greater freedom, to restrict oneself to the clauses presents itself as a sequencing discipline.

Why do I propose to adhere to this sequencing discipline? The justification for this decision can be presented in many ways and let me try a number of them in the hope that at least one of them will appeal to my readers.

Eventually, one of our aims is to make such well-structured programs that the

intellectual effort (measured in some loose sense) needed to understand them is proportional to program length (measured in some equally loose sense) In particular we have to guard against an exploding appeal to enumerative reasoning, a task that forces upon us some application of the old adage "Divide and Rule", and that is the reason why we propose the step-wise decompositions of the computations

We can understand a decomposition by concatenation via enumerative reasoning (We can do so, provided that the number of subactions into which the computation is primarily parsed, is sufficiently small and that the specification of their net effect is sufficiently concise I shall return to these requirements at a later stage, at present we assume the conditions met) It is then feasible to make assertions about the computations on account of the program text, thanks to the triviality of the relation between the progress through the computations and the progress through the program text In particular if on closer inspection one of the subactions transpires to be controlled by a selective clause or a repetition clause, this fact does not impose any burden on the understandability of the primary decomposition, because there only the subaction's net effect plays a role

As a corollary if on closer inspection a subaction is controlled by a selective clause the specific path taken is always irrelevant at the primary level (the only thing that matters is that the correct path has been taken) And also if on closer inspection a subaction is controlled by a repetitive clause, the number of times the repeated statement has been executed is, as such, irrelevant (the only thing that matters is that it has been repeated the correct number of times)

We can also understand the selective clauses as such, viz by enumerative reasoning, we can also understand the repetition clause, viz by mathematical induction For all three types of decomposition -and this seems to me a great help- we know the appropriate pattern of reasoning

There is a further benefit to be derived from the proposed sequencing discipline In understanding programs we establish relations In our example on enumerative reasoning we established that the program part

```
"dd = dd / 2,
  if dd ≤ r do r = r - dd"
```

leaves the relation

$$0 \leq r < dd$$

invariant Yet, even if we can ensure that these relations hold before execution of the quoted program part, we cannot conclude that they always hold, viz not necessarily between the execution of the two quoted statements In other words: the validity of such relations is dependent on the progress of the computation, and this seems typical for a sequential process

Similarly, we attach meanings to variables a variable may count the number of times an event of a given type has occurred, say the number of lines that has been printed on the current page Transition to the next page will be followed immediately by a reset to zero, printing a line will be followed immediately by an increase by 1 Again, just before resetting or increasing this count, the interpretation "number of lines printed on the current page" is non-valid To assign such a meaning to a variable, again, can only be done relative to the progress of the computation This observation raises the following question "How do we characterize the progress of a computation?"

In short, we are looking for a co-ordinate system in terms of which the discrete points of computation progress can be identified, and we want this co-ordinate system to be independent of the variables operated upon under program control. if we need values of such variables to describe progress of the computation we are begging the question, for it is precisely in relation to this progress that we want to interpret the meaning of these variables

(A still more stringent reason not to rely upon the values of variables is presented by a program containing a non-ending loop, cycling through a finite number of different states Eternal cycling follows from the fact that at different points of progress the same state prevails But then the state is clearly incapable of distinguishing between these two different points of progress')

We can state our problem in another way Given a program in action and suppose that before completion of the computation the latter is stopped at one of the discrete points of progress How can we identify the point of interruption, for instance if we want to redo the computation up to the very same point? Or also

if stopping was due to some kind of dynamic error, how can we identify the point of progress short of a complete memory dump?

-) For the sake of simplicity we assume our program text spread out in (linear) text space and assume an identifying mechanism for the program points corresponding to the discrete points of computation progress, let us call this identifying mechanism "the textual index" (If the discrete points of computation progress are situated in between successive statement executions, the textual index identifies, say, semicolons) The textual index is a kind of generalized order counter, its value points to a place in the text

- If we restrict ourselves to decomposition by concatenation and selection, a single textual index is sufficient to identify the progress of the computation With the inclusion of repetition clauses textual indices are no longer sufficient to describe the progress of the computation With each entry into a repetition clauses, however, the system could introduce a so-called "dynamic index", inexorably counting the ordinal number of the corresponding current repetition, at termination of the repetition the system should again remove the corresponding dynamic index As repetition clauses may occur nested inside each other, the appropriate mechanism is a stack (i.e. a last-in-first-out-memory) Initially the stack is empty; at entry of a repetition clause a new dynamic index (set to zero or one) is added on the top of the stack, whenever it is decided that the repetition is not terminated the top element of this stack is increased by 1, whenever it is decided that a repetition is terminated, the top element of the stack is removed (This arrangement reflects very clearly that after termination of a repetition the number of times, even the fact that it was a repetition, is no longer relevant)

- As soon as the programming language admits procedures, then a single textual index is no longer sufficient In the case that a textual index points to the interior of a procedure body, the dynamic progress of the computation is only characterized when we also describe to which call of the procedure we refer, but this can be done by giving the textual index pointing to the place of the call With the inclusion of the procedure the textual index must be generalized to a stack of textual indices increased by one element at procedure call and decreased by one element at procedure return

The main point is that the values of these indices are outside the programmer's control, they are defined (either by the write-up of his program or by the dynamic evolution of the current computation) whether he likes it or not. They provide independent co-ordinates in which to describe the progress of the computation, a "variable-independent" frame of reference in which meanings to variables can be assigned.

There is, of course, even with the free use of jumps, a programmer independent co-ordinate system in terms of which the progress of a sequential computation can be described uniquely, viz a kind of normalized clock that counts the number of "discrete points of computation progress" passed since program start. It is unique, but utterly unhelpful, because the textual index is no longer a constituent component of such a co-ordinate system.

The moral of the story is that when we acknowledge our duty to control the computations (intellectually) via the program text evoking them, that then we should restrict ourselves in all humility to the most systematic sequencing mechanisms, ensuring that "progress through the computation" is mapped on "progress through the text" in the most straightforward manner.

On comparing programs.

It is a programmer's everyday experience that for a given problem to be solved by a given algorithm, the program for a given machine is far from uniquely determined. In the course of the design process he has to select between alternatives, once he has a correct program, he will often be called to modify it, for instance because it is felt that an alternative program would be more attractive as far as the demands that the computations make upon the available equipment resources are concerned.

These circumstances have raised the question of the equivalence of programs: given two programs, do they evoke computations establishing the same net effect? After suitable formalization (of the way in which the programs are given, of the machine that performs the computations evoked by them and of the "net effect" of the computations) this can presumably be made into a well-posed problem appealing to certain mathematical minds. But I do not intend to tackle it in this general form. On the contrary, instead of starting with two arbitrarily given programs (say independently conceived by two different authors) I am concerned with alternative programs that can be considered as products of the same mind and then the question becomes: how can we conceive (and structure) those two alternative programs so as to ease the job of comparing the two?

I have done many experiments and my basic experience gained by them can be summed up as follows. Two programs evoking computations that establish the same net effect are equivalent in that sense and a priori not in any other. When we wish to compare programs in order to compare their corresponding computations, the basic experience is that it is impossible (or fruitless, unattractive, or terribly hard or what you wish) to do so when on the level of comparison the sequencing through the two programs differs. To be a little bit more explicit: it is only attractive to compare two programs and the computations they may possibly evoke, when paired computations can be parsed into a time-succession of actions that can be mapped on each other and the corresponding program texts can be equally parsed into instructions, each corresponding to such an action.

This is a very strong condition. Let me give a first example

Excluding side-effects of the boolean inspections and assuming the value "B2" constant (i.e. unaffected by the execution of either "S1" or "S2"), we can establish the equivalence of the following two programs

```
"if B2 then
  begin while B1 do S1 end
  else
    begin while B1 do S2 end" (1)
```

and

```
"while B1 do
  begin if B2 then S1 else S2 end" (2)
```

The first construction is primarily one in which sequencing is controlled by a selective clause, the second construction is primarily one in which sequencing is controlled by a repetitive clause. I can establish the equivalence of the output of the computations, but I cannot regard them as equivalent in any other useful sense. I had to force myself to the conclusion that (1) and (2) are "hard to compare". Originally this conclusion annoyed me very much. In the meantime I have grown to regard this incomparability as one of the facts of life and, therefore, as one of the major reasons why I regard the choice between (1) and (2) as a relevant design decision, that should not be taken without careful consideration. It is precisely its apparent triviality that has made me sensitive to the considerations that should influence such a choice. They fall outside the scope of the present section but I hope to return to them later.

Let me give a second example of incomparability that is slightly more subtle.

Given two arrays $X[1:N]$ and $Y[1:N]$ and a boolean variable "equal", make a program that assigns to the boolean variable "equal" the value "the two arrays are equal element-wise". Empty arrays (i.e. $N = 0$) are regarded as being equal.

Introducing a variable j and giving to "equal" the meaning "among the first j pairs no difference has been detected", we can write the following two programs

```
"j = 0, equal = true,
  while j  $\neq$  N do
    begin j := j + 1, equal = equal and (X[j] = Y[j]) end" (3)
```

and

```
"j := 0; equal = true,
  while j  $\neq$  N and equal do
    begin j = j + 1, equal = (X[j] = Y[j]) end"      (4)
```

Program (4) differs from program (3) in that repetition is terminated as soon as a pair-wise difference has been detected. For the same input the number of repetitions may differ in the two programs and therefore the programs are only comparable in our sense as long as the last two lines of the programs are regarded as describing a single action, not subdivided into subsections. But what is their relation when we do wish to take into account that they both end with a repetition? To find this out, we shall prove the correctness of the programs.

On the arrays X and Y we can define of $0 \leq j \leq N$ the $N + 1$ functions $EQUAL_j$ as follows

```
for j = 0      EQUALj = true ,
for j > 0      EQUALj = EQUALj-1 and (X[j] = Y[j])      (5)
```

In terms of these functions it is required to establish the net effect

equal = EQUAL_N

Both programs maintain the relation

equal = EQUAL_j (6)

for increasing values of j, starting with j = 0

It is tempting to regard both programs (3) and (4) as alternative refinements of the same (abstract) program (7)

```
"j = 0, equal = EQUAL0,
  while "perhaps still: equal  $\neq$  EQUALN" do
    begin j = j + 1; "equal = EQUALj" end"      (7)
```

in which "perhaps still: equal $\neq$ EQUAL_N" stands for some sort of still open primitive. When this is evaluated

equal = EQUAL_j

will hold and the programs (3) and (4) differ in that they guarantee on different

criterie that "equal" will have its final value $EQUAL_N$

In program (3) the criterion is very naive, viz

$$j = N$$

At the beginning of the repeated statement

$$\text{equal} = EQUAL_j$$

still holds After the execution of " $j = j + 1$ " therefore

$$\text{equal} = EQUAL_{j-1}$$

holds and the assignment statement

$$\text{"equal} = \text{equal} \text{ and } (X[j] = Y[j])"$$

is now a straightforward transcription of the recurrence relation (5)

To come to program (4) some analysis has to be applied to the recurrence relation (5), from which can be derived (by mathematical induction again) that $EQUAL_j = \text{false}$ implies $EQUAL_N = \text{false}$, and therefore $EQUAL_j = \text{false}$ implies $EQUAL_j = EQUAL_N$. If this situation arises, the equality " $\text{equal} = EQUAL_N$ " can also be guaranteed and this leads to program (4). The set of (sub)computations the repeated statement has to cope with in program (4) is restricted to those with the initial state " $\text{equal} = \text{true}$ " and therefore in program (4) the assignment " $\text{equal} = EQUAL_j$ " can be abbreviated to

$$\text{"equal} = (X[j] = Y[j])"$$

And now it is clear why the introduction of (7) as an abstraction of (3) and (4) was misleading. With "perhaps still $\text{equal} \neq EQUAL_N$ " we have stated the meaning of truth and falsity of a boolean expression without stating the expression itself and that was very tricky. We have tried to interpret (7) as a program in which part of the sequencing at its own level was undefined and varying over its refinements. As a result we have tried to view the last lines of (7) as a model for the last lines of both (3) and (4), but this was misleading because the computations to be evoked by them cannot be brought into a one-to-one correspondence.

So much about programs that we consider as incomparable. Examples of comparable programs will be encountered in the following sections. A final remark: we have stated

that "paired computations can be parsed into a time-succession of actions that can be mapped on each other" We have not required that actions so paired should have the same net effect' We may compare alternative programs for the same job but also different programs for similar jobs.

A first example of step-wise program composition

In the section "On understanding programs " I have stressed the need for systematic sequencing so that the structure of the computations could be reflected in the structure of our program in this way we can speak of the joint structuring of program and computations In the current section I shall now try to give a little bit more content to the still rather vague notion of structuring computations It will be a first effort to exploit our powers of abstraction to reduce the appeal made to enumerative reasoning, it will be a consequent application of the decompositions mentioned in the section "On understanding programs "

Instead of presenting (as a ready-made product) what I would call a well-structured program I am going to describe in very great detail the composition process of such a program I do this because programs are not there on the contrary, they have to be made, and the kind of programs I am particularly interested in are those which I feel to be reasonably well suited to our powers of construction and conception

The task is to instruct a computer to print a table of the first thousand prime numbers, 2 being considered as the first prime number

Note 1. This example has been chosen because on the one hand it is sufficiently difficult to serve as a model for some of the problems encountered in programming, and on the other hand its mathematical background is so simple and familiar that our attention is not usurped by the problem

Note 2 I do not claim that my final program will be "the best one", measured by whatever yardstick any of my readers might care to choose At least two readers of a previous version of this presentation -in which remainders were computed via a divide operation- reacted quite vehemently to it "But everyone knows that the most efficient way to generate prime numbers is by using the Sieve of Eratosthenes " thereby blocking their ability to read any further'

The basic pattern of my approach will be to compose the program in minute steps, deciding each time as little as possible As the problem analysis proceeds, so does the further refinement of my program

When an algorithm has to be made, the desired computation has to be composed from actions corresponding to a well-understood instruction repertoire

The simplest form of the program is

description 0

begin "print first thousand prime numbers" and

and when "print first thousand prime numbers" refers to an instruction from the well-understood repertoire, then description 0 solves the problem. For the sake of argument we assume that this instruction does not occur in the well-understood repertoire. Therefore we have to conceive a computation composed from "more primitive" actions that establishes the desired net effect. Our first proposal is to separate the generation of the prime numbers and their printing, and we propose description 1

begin variable"table p",

"fill table p with first thousand prime numbers",

"print table p"

end,

describing that our computation consists of a time-succession of two actions and takes place in a state space containing a single variable, called "table p". The first action assigns a value to this variable, the second action is controlled by the (then current) value of this variable.

Again, when "fill table p with first thousand prime numbers" and "print table p" occur in the well-understood repertoire (and "table p" occurs among the implicitly available resources) then our problem is solved. Again, for the sake of argument, we assume this not to be the case. This means that in our next refinement we have to express how the effect of these two actions can be established by two further (sub)computations. Apart from that we have to decide, how the information to be contained in the intermediate value of the still rather undefined object "table p" is to be represented.

Before going on, I would like to stress how little we have decided upon when writing down description 1, and how little of our original problem statement has been taken into account. We have assumed that the availability of a resource "table p" (in some form or other) would permit us to compute the first thousand prime numbers.

before printing starts, and under this assumption we have exploited that the computation of the primes can be conceived independently of the printing. Of our original problem statement we have not taken into account very much more than that at least a thousand different prime numbers do exist (we had to assume this for the problem statement to make sense). At this stage it is still fairly immaterial what the concept "prime number" really means. Also we have not committed ourselves in the least as regards the specific layout requirements of the print-out to be produced. Apparently it is the strength of our approach that the consequences of these two rather independent aspects of our original problem statement seem to have been allocated in the respective refinements of our two constituent actions. It suggests that we have been more or less successful in our effort to apply the golden principle "divide and rule".

Resuming our discussion, however, we have to ask ourselves, to what extent the two subcomputations can now be conceived independently of each other. To be more precise "Have we now reached the stage that the design of the two subalgorithms (that have to evoke the two subcomputations) can be conceived by two programmers, working independently of each other?"

When the two actions can no longer be regarded as invoked by instructions from the well-understood repertoire, neither can the variable "table p" any longer be regarded as an implicitly available resource. And in a way similar to the one in which we have to decompose the actions into subcomputations, we have to choose how the variable "table p" will be composed, viz. what data structure we select to represent the information to be handed over via "table p" from the first action to the second. At some point this has to be decided and the questions are "when?" and "how?"

In principle, there seem to be two ways out of this. The first one is to try to postpone the decision on how to structure "table p" into (more neutral, less problem-bound) components. If we postpone the decision on how to structure "table p", the next thing to do is to refine one of the actions or both. We can do so, assuming a proper set of operations on the still mysterious object "table p", finally we collect these operations and in view of their demands we design the most attractive structure of "table p".

Alternatively, we can try to decide, here and now, upon the structure of "table p". Once it has been decided how the table of the first thousand primes will be represented, the refinements of both actions can be done fairly independently of each other

Both ways are equally tricky, for what will be an attractive algorithm for, say, the first subcomputation will greatly depend on the ease and elegance with which the assumed operations on "table p" can be realized, and if one or more turn out to be prohibitively clumsy, the whole edifice falls to pieces. Alternatively, if we decide prematurely upon a structure for "table p" we may well discover that then the subcomputations turn out to be awkward. There is no way around it: in an elegant program the structure of "table p" and the computations referring to it must be well-matched. I think that the behaviour of the efficient programmer can be described as trying to take the easiest decision first, that is the decision that requires the minimum amount of investigation (trial and error, iterative mutual adjustment etc.) for the maximum justification of the hope that he will not regret it.

In order not to make this treatment unduly lengthy we assume that the programmer finds the courage to decide that now the structure of "table p" is the first thing to be decided upon. Once this position has been taken, two alternatives immediately present themselves. On the one hand we can try to exploit that "a table of the first 1000 primes" is not just a table of a thousand numbers -as would be a table of the monthly wages of 1000 employees in a factory- but that all these numbers are different from each other. Using this we can arrange the information with a linear boolean array (with consecutive elements associated with consecutive natural numbers) indicating whether the natural number in question is a prime number or not. Number theory gives us an estimation of the order of magnitude of the thousandst prime number and thereby a boundary of the length of the array that will suffice. If we arrange our material in that way we have prepared an easy mechanism to answer the question "is n (less than the maximum) prime or not?" Alternatively, we can choose an integer array in which the successive prime numbers will be listed. (Here the same estimate, obtained by means of number theory, will be used, viz. when a maximum value of the integer array elements needs to be given a priori.) In the latter form we create a mechanism suited to answer the question "what is the value of the k -th prime number, for $k \leq 1000$?"

We grant the programmer the courage to choose the latter representation. It seems attractive in the printing operation in which it is requested to print the prime numbers and not to print natural numbers with an indication whether they are prime or not. It also seems attractive for the computing stage, if we grant the programmer the clairvoyance that the analysis of whether a given natural number is a prime number or not, will have something to do with the question of whether prime factors of the number to be investigated can be found.

The next stage of our program refinement then becomes the careful statement of a convention regarding the representation of the still mysterious object "table p" and a redefinition of the two operations in terms of this convention.

The convention is that the information to be contained in "table p" will be represented by the values of the elements of the "integer array p[1:1000]", such that for $1 \leq k \leq 1000$ p[k] will be equal to the k-th prime number, when the prime numbers are arranged in order of increasing magnitude. (If a maximum value of the integers is implicitly understood, we assume that number theory allows us to state that this is large enough.)

When we now want to describe this new refinement we are faced with a new difficulty. Our description 1 had the form of a single program, thanks to the fact that it was a refinement of the single action named "print the first thousand prime numbers", referred to in description 0. (In more conventional terms description 1 could have the form of a procedure body.) This no longer holds for our next level, in which we have to refine (simultaneously, in a sense) three named entities, viz "table p" and the two actions, and we should invent some sort of identifying terminology indicating what refines what.

For the continuation of our discussion we make a very tentative proposal. We say description 0 is a valid text expressed in terms of a single named action "print first thousand prime numbers", let this be identified by the code Oa.

Description 1 is called "1" because it is the next refinement of description 0, it contains a refinement of Oa --the only term in which description 0 is expressed-- and is itself expressed in terms of three named entities to which we attach the codes

"table p"	1a
"fill table p with first thousand prime numbers"	1b
"print table p"	1c

code numbers, starting with 1, because description 1 is expressed in terms of them, and "a", "b" and "c" being attached for the purpose of distinction

Now we have to describe our convention chosen for the representation of the information to be contained in "table p", but this convention pertains to all three elements 1a, 1b and 1c. Therefore we call this description 2, it should contain the descriptions of the three separate elements (I use the equality sign as separator)

description 2

1a	=	"integer array p[1 1000]"
1b	=	"make for k from 1 through 1000 p[k] equal to the k-th prime number"
1c	=	"print p[k] for k from 1 through 1000"

Description 2 is expressed in terms of three named entities to which we give (in the obvious order) the codes 2a, 2b and 2c. (In code numbers, description 2 is very meagre it just states that for 1a, 1b and 1c, we have chosen the refinements 2a, 2b and 2c respectively.)

Remark In the representation of the information to be contained in "table p", we have chosen not to exploit the fact that each of the values to be printed occurs only once, nor that they occur in the order of increasing magnitude. Conversely, this implies that the action that has to take place under the name of 2c is regarded as a specific instance of printing any set of thousand integer values (it could be a table of monthly wages of thousand numbered employees!). The net effect of the printing action in this example is as uniquely defined as the first thousand prime numbers are: we conceive it, however, as a specific instance of a larger class of occurrences. In the further refinement of 2c we deal with this whole class, the specific instance in this class being defined by the values of the elements of the array p. When people talk about "defining an interface" I often get the feeling that they overlook the presupposed generalization, the conception of the class of "possible" actions.

When 2b and 2c occur among the well-understood repertoires of instructions

(and therefore 2a among the resources implicitly available) our whole problem is solved. For the sake of argument we again assume this not to be the case, and so we find ourselves faced with the task of conceiving subcomputations for the actions 2b and 2c. But now, thanks to the introduction of level 2, the respective refinements of 2b and 2c can be designed independently.

The refinement of 2b "make for k from 1 through 1000 p[k] equal to the k-th prime number"

We are looking for description 2b1, i.e. the first refinement of 2b. We introduce a fresh numbering after 2b (rather than calling our next description "3 something") in order to indicate the mutual independence of the refinements of 2b and 2c respectively.

In description 2b1 we have to give an algorithm describing how the elements of the array p will get their values. This implies that we have to describe, for instance, in what order this will happen. In our first refinement we shall describe just that and preferably nothing more. An obvious, but ridiculous version starts as follows (with "version number" enclosed within parentheses):

2b1(1)

begin p[1] = 2, p[2] = 3, p[3] = 5, p[4] = 7, p[5] = 11, end

implying that the programmer's knowledge includes that of a table of the first thousand primes. We shall not pursue this version as it would imply that the programmer hardly needed the machine at all.

The first prime number being given (= 2), the thousandth being assumed unknown to the programmer, the most natural order in which to fill the elements of the array p seems to be in the order of increasing subscript value, and if we express just that we arrive (for instance) at

2b1(2)

begin integer k, j, k = 0, j = 1,

while k < 1000 do begin "increase j until next prime number",

k = k + 1, p[k] = j end

end

By identifying k as the number of primes found and by verifying that our first prime number ($= 2$) is indeed the smallest prime number larger than 1 ($=$ the initial value of j), the correctness of $2b1(2)$ is easily proved by mathematical induction (assuming the existence of a sufficient number of primes)

Description $2b1(2)$ is a perfect program when the operation described by "increase j until next prime number" --call it $2b1(2)a$ -- occurs among the repertoire, but let us suppose that it does not. In that case we have to express in a next refinement how j is increased (and, again, preferably nothing more). We arrive at a description of level $2b2(2)$

```
2b1(2)a =
begin boolean jprime,
  repeat j = j + 1
    "give to jprime the meaning j is a prime number"
  until jprime
end
```

Remark Here we use the repeat-until clause in order to indicate that j has always to be increased at least once

Again its correctness can hardly be subject to doubt. If, however, we assume that the programmer knows that, apart from 2, all further prime numbers are odd, then we may expect him to be dissatisfied with the above version because of its inefficiency. The price to be paid for this "lack of clairvoyance" is a revision of version $2b1(2)$. The prime number 2 will be dealt with separately, after which the cycle can deal with odd primes only. Instead of $2b1(2)$ we come to $2b1(3)$

```
begin integer k, j, p[1] = 2, k = 1, j = 1,
  while k < 1000 do
    begin "increase odd j until next odd prime number",
      k = k + 1, p[k] = j
    end
  end
```

where the analogous refinement of the operation between quotes --" $2b1(3)a$ "-- say-- leads to the description on level $2b2(3)$

```

2b1(3)a =
  begin boolean jprime,
    repeat j = j + 2,
      "give for odd j to jprime the meaning j is a prime number",
    until jprime
  end

```

The above oscillation between two levels of description is in fact nothing else but adjusting to our convenience the interface between the overall structure and the primitive operation that has to fit into this structure. This oscillation, this form of trial and error, is definitely not attractive, but with a sufficient lack of clairvoyance and being forced to take our decisions in sequence, I see no other way we can regard our efforts as experiments to explore (at a rather low cost) where the interface can probably be most conveniently chosen.

Remark Both 2b1(2) and 2b1(3) can be loosely described as

```

begin "set table p and j at initial value",
  while "table p not full" do
    begin "increase j until next prime number to be added",
      "add j to table p"
    end
  end

```

but we shall not do this as the sequencing in the two versions differs and -see "On comparing programs"- we regard them as "incomparable". By choosing 2b1(3) we decide that our trial 2b1(2) -as 2b1(1)- is no longer applicable and therefore rejected.

The change from 2b1(2) to 2b1(3) is justified by the efficiency gain at the levels of higher refinement. This efficiency gain is earned at level 2b2, 'cause now j can be increased by 2 at a time. It will also manifest itself in the still open primitive at level 2b2(3) where the algorithm for "give for odd j to jprime the meaning j is a prime number" has only to cater for the analysis of odd values of j.

Again in 2b2(3) we have refined 2b1(3) with an algorithm which solves our

problem when "give for odd j to j prime the meaning j is a prime number" -call it "2b2(3)a"- occurs among the well-understood repertoire. We now assume that it does not, in other words we have to evoke a computation deciding whether a given odd value of j has a factor. It is only at this stage that the algebra really enters the picture. Here we make use of our knowledge that we only need to try prime factors. Furthermore we shall use the fact that the prime numbers to be tried can already be found in the filled portion of the array p .

We use the facts that

- 1) j being an odd value, the smallest potential factor to be tried is $p[2]$,
1 is the smallest prime number larger than 2
- 2) the largest prime number to be tried is $p[\text{ord}-1]$ when $p[\text{ord}]$ is the smallest prime number whose square exceeds j .

(Here I have also used the fact that the smallest prime number whose square exceeds j can already be found in the table p . In all humility I quote Don Knuth's comment on an earlier version of this program, where I took this fact for granted

"Here you are guilty of a serious omission! Your program makes use of a deep result of number theory, namely that if p_n denotes the n -th prime number we always have

$$p_{n+1} < p_n^2$$

Paccavi)

If this set is not empty, we have a chance of finding a factor, and as soon as a factor has been found, the investigation of this particular j value can be stopped. We have to decide in which order the prime numbers from the set will be tried, and we shall do so in order of increasing magnitude, because the smaller a prime number the larger the probability of its being a factor of j .

When the value of ord is known we can give for "give for odd j to j prime the meaning j is a prime number" the following description on level 2b3(3)

2b2(3)a =

```
begin integer n, n = 2, jprime = true
  while n < ord and jprime do
    begin "give to jprime the meaning  $p[n]$  is not a factor of  $j$ ", n = n + 1 end
  end
```

But the above version is written on the assumption that the value of `ord`, a function of `j`, is known. We could have started this refinement with

```
begin integer n, ord,
      ord = 1, while p[ord]  $\neq$  2 do ord = ord + 1,
```

i.e. recomputing the value of "ord" afresh, whenever it is needed. Here some trading of storage space for computation time seems indicated. Instead of recomputing this function whenever we need it, we introduce an additional variable `ord` for its current value. It has to be set when `j` is set, it has to be adjusted when `j` is changed.

This, alas, forces upon us some reprogramming. One approach would be to introduce, together with `j`, an integer variable `ord` and to scan the programs in order to insert the proper operations on `ord`, whenever `j` is operated upon. I do not like this because at the level at which `j` is introduced and has a meaning, the function "ord" is immaterial. We shall therefore try to introduce `ord` only at its appropriate level and we shall be very careful.

For 2b "make for `k` from 1 through 1000 `p`[`k`] equal to the `k`-th prime number" we write (analogous to level 2b1(3))

```
level 2b1(4)
begin integer k, j, p[1] = 2, k = 1,
      "set j to one",
      while k < 1000 do
        begin "increase odd j until next odd prime number",
          k = k + 1; p[k] := j
        end
      end
```

expressed in terms of

```
2b1(4)a   "increase odd j until next odd prime number"
2b1(4)b   "set j to one"
```

In our next level we only introduce the subcomputation for 2b1(4) a, the other is handed down.

level 2b2(4)

2b1(4)a =

begin boolean jprime,

repeat "increase j with two",

 "give for odd j to jprime the meaning j is a prime number"

until jprime

end,

2b1(4)b = 2b2(4)b

expressed in terms of

2b2(4)b still meaning "set j to one"

2b2(4)c "increase j with two"

2b2(4)d "give for odd j to jprime the meaning j is a prime number"

It is only at the next level that we need to talk about ord. Therefore we now write

level 2b3(4) integer ord,

2b2(4)b =

begin j = 1, "set ord initial" end,

2b2(4)c =

begin j = j + 2, "adjust ord" end,

2b2(4)d =

begin integer n; n = 2, jprime = true,

while n < ord and jprime do

begin "give to jprime the meaning p[n] is not a factor of j",

 n = n + 1

end

end

expressed in terms of

2b3(4)a "set ord initial"

2b3(4)b "adjust ord"

2b3(4)c "give to jprime the meaning p[n] is not a factor of j"

In our next level we give two independent refinements (Note We could have given them in successive levels, but then we should have to introduce an arbitrary ordering to these two levels. We could also try to treat the refinements separately

-1 e as separately as 2b and 2c-, but we feel that it is a little premature for this drastic decision) We are going to express

- 1) that, ord being a non-decreasing function of j and j only increasing in value, adjustment of ord implies a conditional increase,
- 2) that, whether $p[n]$ is a factor of j is given by the question whether the remainder equal zero

This leads to

level 2b4(4)

2b3(4)a = 2b4(4)a

2b3(4)b =

begin while "ord too small" do "increase ord by one" end,

2b3(4)c =

begin integer r,

"make r equal to remainder of j over $p[n]$ ",

jprim = (r $\neq$ 0)

end

expressed in terms of

2b4(4)a still meaning "set ord initial"

2b4(4)b "ord too small"

2b4(4)c "increase ord by one"

2b4(4)d "make r equal to remainder of j over $p[n]$ "

If we have a built-in division, the implementation of "make r equal to the remainder of j over $p[n]$ " can be assumed to be an easy matter. The case that the refinement of 2b4(4)d can be treated independently is now left to the interested reader. To give the algorithm an unexpected turn we shall assume the absence of a convenient remainder computation. In that case the algorithm

"r = j, while r > 0 do r := r - $p[n]$ "

would lead to the (non-positive) remainder but it would be most unattractive from the point of view of computation time. Again this asks for the introduction of some additional tabulated material (similar to the way in which "ord" has been introduced)

We want to know whether a given value of j is a multiple of $p[n]$ for $n < \text{ord}$. In order to assist us in this analysis we introduce a second array in the elements

of which we can store multiples of the successive prime numbers, as close to j as is convenient. In order to be able to give the size of the array we should like to know an upper bound for the value of ord , of course, 1000 would be safe, but number theory gives us 30 as a safe upper bound. We therefore introduce

integer array $\text{mult}[1:30]$

and introduce the convention that for $n < \text{ord}$, $\text{mult}[n]$ will be a multiple of $p[n]$ and will satisfy the relation

$$\text{mult}[n] < j + p[n]$$

a relation that remains invariantly true under increase of j . Whenever we wish to investigate, whether $p[n]$ is a factor of j , we increase $\text{mult}[n]$ by $p[n]$ as long as

$$\text{mult}[n] < j$$

After this increase $\text{mult}[n] = j$ is the necessary and sufficient condition for j to be a multiple of $p[n]$.

The low maximum value of ord has another consequence: the inspection "ord too small" can be expressed by

$$p[\text{ord}] \uparrow 2 \leq j$$

but this inspection has to be performed many times for the same value of ord . We may assume that we can speed up matters by introducing a variable (called "square") whose value equals $p[\text{ord}] \uparrow 2$.

So we come to our final

level 2b5(4)

integer square , integer array $\text{mult}[1:30]$,

2b4(4)a =

begin $\text{ord} := 1$, $\text{square} = 4$ end,

2b4(4)b =

($\text{square} \leq j$),

2b4(4)c =

begin $\text{mult}[\text{ord}] = \text{square}$, $\text{ord} = \text{ord} + 1$, $\text{square} = p[\text{ord}] \uparrow 2$ end,

2b4(4)d =

begin while $\text{mult}[n] < j$ do $\text{mult}[n] = \text{mult}[n] + p[n]$, $r = j - \text{mult}[n]$ end

which has made our computation close to an implementation of the Sieve of Eratosthenes!

Note In the refinement of 2b4(4)d, when $\text{mult}[n]$ is compared with the current value of j , $\text{mult}[n]$ is increased as much as possible, this could have been done in steps of $2 * p[n]$, because we only submit odd values of j and therefore are only interested in odd multiples of $p[n]$ (The value of $\text{mult}[1]$ remains, once set, equal to 4)

The refinement of 2c "print $p[k]$ for k from 1 through 1000" is left to the reader I suggest that the table should be printed on five pages, each page containing four columns with fifty consecutive prime numbers

* * *

Here I have completed what I announced at the beginning of this section, viz "to describe in very great detail the composition process of such a [well-structured] program" I would like to end this section with some comments

The most striking observation is that our treatment of a very simple program has become very long, too long indeed to my taste and wishes, even if I take into account that essentially we did two things we made a program and we discussed extensively the kind of considerations leading to it. It is not so much the length of the latter part that bothers me (writers fill whole novels with the description of human behaviour), what bothers me is the length of the texts at the various levels. Therefore we may expect that notational technique will be one of our main concerns

But we have also had encouraging experiences. Giving full recognition to the fact that the poor programmer cannot decide all at once, we succeeded to a large extent in building up this program one decision at a time, and in our example quite a lot of programming was already done in its definite form while major decisions were still left open. Irrespective of whether the final decisions are taken this way or that way, the coding of the earlier levels remains valid. In view of the requirement of program manageability, this is very encouraging

On program families

In our previous section we have considered the design of a program for a given task, but in doing so, we have considered our final program as an isolated object, a structure standing all by itself and to be judged on its private merits. Its structure was the result of successive decompositions; the purpose of this structure was to make a program in such a way that its correctness could be proved without undue intellectual labour.

In this section I am going to explain why I prefer to regard a program not so much as an isolated object, but rather as a member of a family of "related programs". In traditional terminology we can think about related programs either as alternative programs for the same task or as similar programs for similar tasks.

Why cannot the programmer confine his attention to the program he has to make and why has he to take into account such a whole family as well? For one thing, it is hard to claim that you know what you are doing unless you can present your act as a deliberate choice out of a possible set of things you could have done as well. But if we want to give due recognition to the difficulties that are specific to the construction of large complicated programs, there is a very practical justification. (And we have to recognize these specific difficulties: experience has shown that someone's proven ability to do an excellent job of a given scale is by no means a guarantee that, when faced with a much larger job, he will not make a mess of it.)

Certainly, one of the properties of large programs is that they have to be modified in the course of their life-time. A very common reason is that the program, although logically correct, turns out to evoke unsatisfactory computations (for instance unsatisfactory in one or more quantitative aspects). A second reason is that, although the program is logically correct and even satisfactorily meeting the original demands, it turns out to be a perfect solution for not quite the right problem, one is faced with a restatement of the problem and adaptation of the program.

The naive approach to this situation is that we must be able to modify an existing program (and for this the curious term "program maintenance" has established

itself) The task is then viewed as one of text manipulation, as an aside we may recall that the need to do so has been used as an argument in favour of punched cards as against paper tape as an input medium for program texts. The actual modification of a program text, however, is a clerical matter, which can be dealt with in many different ways, my point is that if we have our grip on the program text primarily as on a linear sequence of symbols, the task to establish and to describe what has to be modified tends to become prohibitively difficult when the texts get longer and longer.

If a program has to exist in two different versions, I would rather not regard (the text of) the one program as a modification of (the text of) the other one. It would be much more attractive if the two different programs could, in some sense or another, be viewed as, say, different children from a common ancestor, where the ancestor represents a more or less abstract program, embodying what the two versions have in common. Hopefully, this common ancestor can be readily recognized in the (pre-)documentation. The intentions are

- 1) that the two versions share their respective correctness proofs as far as possible,
- 2) that the two versions share (mechanically) as far as possible the common (or "equal") coding,
- 3) that the regions affected by the modification are already well-isolated, a condition which is not met when the transition requires "brain-made" modifications scattered all over the text.

Well, this is a lofty goal. It has been inspired by the potential similarity between the task of program modification and program composition. When a program has been built up to an intermediate stage of refinement, what has then been written down is in fact a suitable "common ancestor" for all possible programs produced by further refinements. It is the similarity between "the decision to be changed" and "the decision still left open" in both cases we are left with what remains when we abstract from such a decision.

There is a second source of inspiration to be found in our experience. In the process of step-wise program composition, proceeding from outside inwards, going towards progressive refinements, we have in the earlier stages not only postponed deciding how certain things would be done, but we have also postponed

committing ourselves as to exactly what had to be done with progressing refinement more detail about the actual problem statement has been brought into the picture (later examples will show this even more clearly than the problem of the prime table) As a result, our first levels of refinement are equally applicable for the members of a whole class of problem statements.

In other words, in the step-wise approach it is suggested that even in the case of a well-defined task, certain aspects of the given problem statement are ignored at the beginning. That means that the programmer does not regard the given task as an isolated thing to be done, but is invited to view the task as a member of a whole family, he is invited to make the suitable generalizations of the given problem statement. By successively adding more detail he eventually pins his algorithm down to a solution for the given problem.

All this is well-known, each competent programmer does so all the time. Yet I stress it for a variety of reasons. If the given problem statement is an elaborate affair, it is too much to be grasped in a single glance, he must approach (and dissect) the problem statement in this way (see the section "On our inability to do much"). Secondly, if the given problem is perfectly defined, it is a wise precaution to anticipate as many future changes in the problem statement as one can foresee and accommodate. This remark is not an invitation to make one's program so "general" that it becomes, say, unacceptably inefficient, as might easily happen, when the generalizations of the problem statement are ill-considered (which might easily happen when they have been dictated by the Sales Department!). But in my experience, even in traditional programming, it is a very worthwhile exercise to look for feasible generalizations of conceivable utility, because such considerations may give clear guidance as to how the final program should be structured. But such considerations boil down to conceiving (more or less explicitly) a whole program family!

In an earlier section ("On the reliability of mechanisms") the need for careful program structuring has been put forward as a consequence of the requirement that program correctness can be proved. In this section we are faced with another reason: program structure should be such as to anticipate its adaptations and modifications. Our program should not only reflect (by structure) our understanding of it, but it should also be clear from its structure what sort of adaptations can be catered for smoothly. Thank goodness, the two requirements go hand in hand.

On trading storage space for computation speed

In present-day sequential computers (spring 1969) we can distinguish two main components, an active one (the processor) and a passive one (the store). The active component has the specific function to be fast, the passive one has the specific function to be large. The following is written on the assumption that this functional division is here to stay for a sufficient period of time to make a study of its consequences relevant.

From the point of view of the programmer storage space and computation time are then two distinct resources and I regard it as one of the responsibilities of the programmer -rather than of the system- to allocate them, i.e. to divide the load between them. It is to the consequences of this responsibility that the present section is devoted. This section is not devoted to techniques of estimating the various loads, i.e. to give quantitative criteria by which to influence the programmer's choice: it is devoted to the logical relation between the alternatives between which the programmer may choose.

Note It is not inconceivable that some of the choices can be left to the system. In all but the most trivial cases, however, design and establishment of the equivalence seem to require mathematical invention from the side of the programmer. All efforts to automate this problem-solving activity fall outside the scope of this monograph.

In its most simple form we are faced with a computation that regularly needs the value of "FUN(arg)", where "FUN" is a given, computable function defined on the current value of one or more stored variables, collectively called "arg". In version A of the program, only the value of arg is stored and the value of FUN(arg) is computed whenever needed. In version B, an additional variable, "fun" say, is introduced, whose sole purpose is to record the value of "FUN(arg)" corresponding to the current value of arg.

Where version A has

"arg = " (i.e. assignment to arg)

version B will have

"arg = , fun = FUN(arg)"

thereby maintaining the relation

fun = FUN(arg)

As a result of the validity of this relation, wherever version A calls for the evaluation of FUN(arg), version B will call for the current value of the variable fun

There are two possible reasons to prefer version B to version A. When the value of FUN(arg) is more frequently requested than assignments to arg take place, version B could require less computation time. If necessary the technique can be refined by the introduction of a further (boolean) variable "fun up to date", indicating whether the relation "fun = FUN(arg)" is assumed to hold. Assignment to arg is then associated with

"fun up to date = false" ;

whenever the value of FUN(arg) is needed, inspection of this boolean variable will tell, whether FUN(arg) has to be computed afresh; if so, the computed value will be assigned to fun and in accordance with its meaning "fun up to date" will be set to true. Let us call the last program version C. It is clear that these three programs, only differing where version A assigns to arg or uses the value of FUN(arg) are equivalent as far as their output is concerned, it is certainly not inconceivable that version B or C is derived from version A by mechanical means.

But quite often the situation is not as simple as that and now we come to the second reason for introducing such a variable "fun". Often it is very unattractive to compute FUN(arg) from scratch for arbitrary values of arg, while it is much easier to compute how the value of FUN(arg) changes when the value of arg is changed. In that case, the adjustment of the value of "fun" is more intimately linked with the nature of the functional dependence than is suggested by

"arg = ; fun = FUN(arg)"

Often this possibility is not only intimately linked to the nature of the functional dependence, but also to the "history of the variable arg" as the computation proceeds. We have seen a very striking example in the program for the

prime table (see Section "A first example of step-wise program composition") with the introduction of "ord", which is functionally dependent on "j", viz "ord" is the minimum value satisfying

1)

$$p[\text{ord}] \neq j$$

where the adjustment of "ord" was a very attractive operation thanks to the fact that "j" was monotonically increasing in time

In my understanding of programs I want such additional variables that store redundant information, to be clearly recognized as such, even if it is a somewhat undefined functional relationship as in the case of the table "mult" from the same example. I am strongly inclined to view such programs as, say, optimizing refinements of a more abstract program, even when the optimization effected by the additional variables is essential when we want to make a program with a realistic performance. From the point of view of efficiency such an additional variable may be so vital that it may strike one as irresponsible daydreaming to conceive a level in which its presence has been abstracted from. The way in which such an additional variable is manipulated is often experienced as the body of the algorithm. It is often there that we harvest the fruits of our mathematical ingenuity. The point is that, although the possibility of at least one such optimizing refinement is essential for making something with a realistic performance, on closer inspection one often discovers that such an optimizing refinement is far from unique, even on its coarsest level.

Note. I remember one program in which the additional information was so redundant that not only the value of "fun" could be derived from that of "arg" but also the other way round. Suddenly the relation between "fun" and "arg" became symmetric and I have been seriously bothered by the question what did entitle me to treat them so asymmetrically. The program in question generated all the solutions of a combinatorial puzzle. On closer inspection it turned out that there was a second combinatorial puzzle, where it could be proved that there existed a one-to-one correspondence between the solutions of the two problems. If I had solved the second combinatorial problem I would have found the role of "fun" and "arg" interchanged. In traditional programming, where such functional dependencies are not explicitly shown, the two puzzles would probably be solved by identical programs, whereas I made two differently structured programs. And I think rightly

so, for the single program for the two puzzles needed a different proof for its correctness, depending on which puzzle it was supposed to solve and this seems somewhat unfair when we also wish that our understanding of the computations be reflected in the structure of our programs'

On a program model

Before we have a program we must have composed it, after we have a program -if there was any sense in making it- we shall have it executed. In this section I shall not stress the activities of program composition and of program execution too much and I shall try to view the program as a static object. We want to view it as a highly structured object and our main question is: what kind of structures do we envisage and why? Our hope is that eventually we shall arrive at a program structure that is both nice to compose and nice to execute. Mentally, of course, I am unable to ignore these processes, but at present I do not want to discuss them, in particular I do not want to discuss a design methodology (whether to work "from outside inwards" or the other way round), nor do I want to discuss implementation consequences now. Again, in order not to complicate matters too much, I shall restrict myself to sequential programs.

If I judge a program by itself, my central theme, I think, is that I want the program written down as I can understand it, I want it written down as I would like to explain it to someone. But without further qualification these are just motherhood statements, so let me try and see whether I can be more specific.

Let us consider a very simple computation, in which three distinct actions can be distinguished to take place in succession, say input of data, manipulation (i.e. the computation proper) and the output of the results. One way of representing the program is as a long string of statements.

begin

end

A next form adds some labels for explanatory purposes.

begin

begin of input

begin of manipulation

begin of output

end

suggesting to us, when we read the text , what is going to happen next

Still better, we write

begin

input begin

end,

manipulation begin

end,

output: begin

end

end

where the labels are considered less as markers of points in the program text than as names of regions -as indicated by the bracket pairs "begin - end"- that follow the label, or as names of the three actions in which the computation has been decomposed. But if we take this point of view, the three "labels" are still comments, i.e. explanatory noise for the benefit of the interested (human) reader, whereas I would like to consider them as an integral part of the program. I want my program text to reflect somewhere the fact that the computation has been decomposed into a time-succession of the three actions, whatever form these might take upon closer inspection. A way of doing this is to write somewhere the (textual) succession of the three (abstract) statements

"input; manipulation, output"

on the understanding that the time-succession of these three actions will indeed be controlled from the above textual succession, whereas the further refinements of these three actions will be given "somewhere else", perhaps separately, but certainly without relative ordering

Well, if closed subroutines had not been invented more than twenty years ago, this would have been the time to do it! In other words we are returning to familiar grounds, to such an extent even that many of my readers will feel cheated! I don't, because one should never be ashamed of sticking to a proven method as long as it is satisfactory. But we should get a clear picture of the benefits we should like to derive from it, if necessary we should adjust it, and finally we should create a discipline for using it. Let me therefore review the subroutine concept, because my appreciation for it has changed in the course of the last year.

I was introduced to the concept of the closed subroutine in connection with the EDSAC [1], where the subroutine concept served as the basis for a library of standard routines. Those were the days when the construction of hardware was a great adventure and many of the standard routines were means by which (scarce) memory and computation time could be traded for circuitry as the order code did not comprise a divide instruction, they had subroutines for division. Yet I do not remember having appreciated subroutines as a means for "rebuilding" a given machine into a more suitable one - curiously enough. Nor do I remember from those days subroutines so much as objects to be conceived and constructed by the user to reflect his analysis; they were more the standard routines to be used by the user. Eventually I saw them mainly as a device for the reduction of program length. But the whole program as such remained conceived as acting in a single homogeneous store, in an unstructured state space, the whole computation remained conceived as a single sequential process performed by a single processor. In the following years, in the many programming courses I gave, I have preached the gospel faithfully and I have often explained how the calling sequence handed over the return address and how the subroutine would then begin by setting "the link" - i.e. the return jump - at its own end. At present I would rather view the main program as having its own instruction counter that just continues "counting" upon the completion of the subroutine execution and would certainly not regard the "sleeping value" as a parameter handed over to the subroutine. (Still the old view has found its way into the hardware of many machines. We have seen machines in which a subroutine jump stored the link at "address zero" of the subroutine and ordered instruction fetch to be resumed at "address one", an arrangement which makes re-entrant code and recursive subroutines somewhat hard to implement. And even in this decade we find machines which store at program interrupt the "program status" of the interrupted program at a location associated with the interrupt rather than with

the interrupted program')

Ten years later, when ALGOL 60 emerged, the scene changed and we did not talk any more about closed subroutines we called them "procedures" instead. They remained to be appreciated by the programmer as a very handy means for shortening the program text, and more and more programmers started to use them for the purpose of structuring, so that program adaptation to foreseen changes in problem specification could be confined to the replacement of one or more procedure bodies, or to a procedure call with some actual parameters changed. But the main novelty was the concept of the local variables.

This was reflected in two important aspects. The first one was the concept of "scope", i.e. the idea that not all variables are homogeneously accessible all through the program: local variables of a procedure are inaccessible from outside the procedure body because outside it they are irrelevant. What local variables a procedure needs to do its private task is its private concern, is no concern of the calling main program and the fact that the main program can (and must) be conceived independently of these local variables is judiciously reflected. We may have some misgivings about the specific scope rules, as embodied in ALGOL 60, but we should appreciate them as a very significant step in the right direction.

The second aspect of the novelty was given by the fact that procedures could be used recursively, more precisely, that a procedure was allowed to call itself, either directly or indirectly. The virtue of this facility has been the subject of many hot debates, as far as I can see the discussion has died down. The argument against recursive procedures was always an efficiency argument: non-re-entrant code could be executed so much more efficiently. But with the advent of multiprogramming another need for flexible storage allocation has emerged. And if there are still machines in which non-re-entrant code can be executed much more efficiently, i.e. in which the use of recursive routines is punished by too heavy a penalty, then I would venture the opinion that the structure of such a machine should now be called somewhat old-fashioned. The recursive procedure, however, forced upon us the recognition of the difference between its (static) text and its (dynamic) activation - its "incarnation" as it has been called. The procedure text is one thing, the set of local variables it operates upon this time is quite another matter.

So far, so good, but now some of its shortcomings (and I don't care, whether you call them linguistic or conceptual) Local variables are "created" upon procedure entry, and are "annihilated" upon procedure exit. It is precisely this automatic control over the life-time of variables pertaining to a procedure incarnation that allows us to implement the (recursive) procedures by means of a stack (i.e. a last-in-first-out storage arrangement). The fact that local variables pertaining to an incarnation only exist during the incarnation make it impossible for the procedure to transmit information behind the scenes from one incarnation to the next. To overcome this the concept "own" has been introduced, but this is no solution to the problem what own variables are really good for becomes very unclear in the case of recursion and, secondly, it is impossible to write a set of procedures sharing a number of own variables (We can simulate this by declaring them in an outer block, embracing the procedure declarations, but then the scope rules make them too generally accessible they can then no longer be regarded as "behind the scenes") Our conclusion -by no means new and by no means only mine'- is that the concept "own" as introduced in ALGOL 60 must be regarded as ill-considered, and that we must look for new ways to control and describe life-time, accessibility and identity of local variables.

But I have still another complaint about the procedure concept, and that is that it is still primarily regarded as a means for shortening the program text (although it may be a text of unknown length as in the case of recursion). The semantics of the procedure call are described in terms of the famous "copy rule" the procedure call is to be understood as a short-hand, because, semantically speaking, we should replace it with a copy of the text of the procedure body (with suitable adjustments of identifiers and substitutions for parameters) whereupon the thus modified text will be executed by the same machine as the one executing the main program. It remains (a representation for) a single program text to be executed by a single sequential machine. And it is precisely this picture of a single machine that does not satisfy me any longer.

I want to view the main program as executed by its own, dedicated machine, equipped with the adequate instruction repertoire operating on the adequate variables and sequenced under control of its own instruction counter, in order that my main program would solve my problem if I had such a machine. I want to view it that way, because it stresses the fact that the correctness of the main

program can be discussed and established regardless of the availability of this (probably still virtual) machine: I don't need to have it, I only need to have its specifications as far as relevant for the proper execution of the main program under consideration

For me, the conception of this virtual machine is an embodiment of my powers of abstraction, not unlike the way in which I can understand a program written in a so-called higher level language, without knowing how all kinds of operations (such as multiplication and subscription) are implemented and without knowing such irrelevant details as the number system used in the hardware that is eventually responsible for the program execution

In actual practice, of course, this ideal machine will turn out not to exist, so our next task -structurally similar to the original one- is to program the simulation of the "upper" machine. In programming this simulation we have to decide upon data structures to provide for the state space of the upper machine, furthermore we have to make a bunch of algorithms, each of them providing an implementation of an instruction assumed for the order code of the upper machine. Finally, the "lower" machine may have a set of private variables, introduced for its own benefit and completely outside the realm and scope of the upper machine. But this bunch of programs is written for a machine that on all probability will not exist, so our next job will be to simulate it in terms of programs for a next-lower machine, etc. until finally we have a program that can be executed by our hardware.

If we succeed in building up our program along the lines just given, we have arranged our program in layers. Each program layer is to be understood all by itself, under the assumption of a suitable machine to execute it, while the function of each layer is to simulate the machine that is assumed to be available on the level immediately above it.

Why this model? What are the benefits we hope to derive from it? Let me try to list them.

1) Our experience as recorded in "A first example of step-wise program composition" strongly suggests that the arrangement of various layers, corresponding to different levels of abstraction, is an attractive vehicle for program composition.

- 2) It is not vain to hope that many a program modification can now be presented as replacement of one (virtual) machine by a compatible one
- 3) We may hope that the model will give us a better grip on the problems that arise when a program has to be modified while it is in action. If a machine at a given level is stopped between two of its instructions, all lower machines are completely passive and can be replaced, while all higher machines must be regarded as engaged in the middle of an instruction: their state must be considered as being in transition. In a sequential machine the state can only be interpreted inbetween instruction executions and the picture of this hierarchy of machines, each having its own instruction counter -"counting its instructions"- seems more profitable if we wish to decide at any given moment, what interpretations are valid. In the usual programming language in which computational progress is measured in a homogeneous measure -say "the grain" of one statement- I feel somewhat helpless when faced with the question of which interpretations are valid when
- 4) We may hope that the model will even assist us in recovery problems -total or partial- when some malfunctioning has been detected. (Recently I have been involved in the design and construction of a multiprogramming system, but one of the most annoying things was our total inability to estimate (mechanically) the scope of the disaster when a memory cell gave a parity alarm. The only safe reaction we could implement was instantaneous machine stop, hardly a solution to be proud of')
- 5) The picture of a layered hierarchy of machines provides a counter poison to one of the dangers evoked by ruthless application of the principle "Divide and Rule", viz. that different components are programmed so independently of each other that duplication of work (or worse) takes place. The fact that a layer contains "a bunch of programs" to be executed by some conceptual machine stresses the fact that the programs of this bunch are invited to share the same primitives. Separation of tasks is a good thing, on the other hand we have to tie the loose ends together again'

[1] "The Preparation of Programs for an Electronic Digital Computer, with Special Reference to the EDSAC and the use of a Library of Subroutines", M V Wilkes, D J Wheeler and S Gill, Addison-Wesley Press, 1951

A second example of step-wise program composition

With a picture of program structure as a layered hierarchy of machines emerging, my fingers are itching to play with it, i.e. to make another program. The notational techniques employed should not be regarded as a well-considered proposal: they have been chosen to suit my fancy and should be regarded as part of the experiment.

The problem is the following one. There is given a line printer which is controlled by two commands "NLCR" (New Line Carriage Return) which defines the utmost left position of the next line as the "currently printable position", and the command "PRSYM(n)" which prints a character identified by the value of the integer parameter n on the currently printable position and defines the position immediately to the right of the printed position as the new currently printable position. (For our discussion we can regard lines of infinite length as permissible.) We shall only make use of two specific values of n , called "space" and "mark" respectively. "PRSYM(space)" causes the currently printable position to remain blank, "PRSYM(mark)" will print a given, visible character, some sort of asterisk say.

Furthermore two integer functions of an integer argument are given, satisfying

$$\text{for } 0 \leq i < 1000 \quad 0 \leq f_x(i) < 100 \quad \text{and} \quad 0 \leq f_y(i) < 50$$

Now we have to make a program printing 50 lines, numbered from top to bottom by a y -co-ordinate running from 49 through 0, the positions on a line being numbered from left to right by an x -co-ordinate running from 0 through 99. On the thousand positions (or less in the case of coincidence) given by

$$x = f_x(i) \text{ and } y = f_y(i) \text{ for some } i \text{ satisfying } 0 \leq i < 1000$$

a mark has to be printed; all other positions on the paper have to remain blank. In other words a curve is given in a discrete parameter representation and we wish to use the line printer as a digital plotter.

I have used this problem extensively in viva voce examinations and the majority of the students quickly discover that, due to the absence of NLCR (Old

Line Carriage Return) and of a "backspace", the order in which the printable positions have to be served is dictated by the printing commands and, secondly, that this order has nothing to do with the order of the marks if we number them, say, in the order of increasing i . As a result they quickly conclude that the use of storage seems indicated: first the thousand i -values should be scanned, i is the page image should be stored in a convenient manner, while afterwards, under control of the stored image, the page should be printed. (To be more precise we assume that the computer has sufficient store for this purpose and that the computation of the function values " $fx(i)$ " and " $fy(i)$ " may be so time-consuming that we wish to have them computed only once for each i -value.)

We now document this design decision, and I propose the following piece of text

```
COMPFIRST
  begin
    draw {build, print},
    var image,
    instr build(image), print(image)
  end
```

The above piece of documentation, which is considered as an integral part of the final program, should be interpreted as follows

It refers to a machine called "COMPFIRST" (we use capitals for machine names and try to express the type of decision reflected in the program made for them)

The next line gives a named algorithm: its name is "draw" (this being assumed to be the name of the total program to be made, that has to "draw" a curve), the algorithm expresses the desired time-succession of two actions, building the image in store, followed by printing paper under control of the stored value

In the last two lines we give the declarations (or declaration headings), naming the components of the machine for which the above algorithm is intended. The first line describes that the name "image" will be used for the data structure

that has to accommodate the page image, the variable "image" is the only component of the state space of this machine. Its instruction code comprises two instructions, named "build" and "print" respectively.

Before proceeding, it should be noted that we have used some abbreviations of which I don't know yet whether they are very wise or very foolish. They have both to do with the fact that the variable "image" is a unique variable of this type.

If the state space should have contained two images, I would have written

```
"type image,  
image var image1, image2"
```

expressing that the state space comprises two variables (called "image1" and "image2" respectively), with the same set of possible values, this set being characterized by their type, called "image". In a later step the type image would enjoy further detailing and this would apply to both variables. As the set of variables of this type contains only one element, I have ventured not to distinguish between the set (called "image") and its only element (also called "image"). When descriptions in COMPFIRST (such as "build(image)") refer to "image", they refer to the variable, when later structuring detail is given, it refers to the type image.

The last line contains the code of instructions which are like the procedure heading. In general they contain the type of the parameters, where the call contains the variables as actual parameters. Again this seems foolish if the parameter is uniquely given by its type and for this reason we have mentioned the actual parameter in the declaration, and have omitted the mentioning of "image" in the code describing the algorithm "draw". Thus we can reserve the explicitly mentioned actual parameters for the case where this combinatorial freedom is actually used.

Before proceeding, I would like to stress that our little algorithm named "draw" can and should be regarded as a program written for a machine. We should write the manual for this machine, in it we have to state

- 1) that the operation "build" assigns a value to the variable "image" specifying the image to be printed on paper as given by the functions fx and fy

2) that the operation "print" prints the picture on paper as specified by the current value of the variable "image".

) The fact that it can really be regarded as an algorithm for a machine is perhaps most easily seen when we consider alternative algorithms for "draw" e.g.

draw {print, build}

is wrong, because now the action "print" is undefined,

draw: {build; build, print}

is correct but unnecessarily time-consuming, because the second action "build" assigns to "image" the value it already has,

draw {build, print, print}

would make sense: it would print the picture twice

We now resume our programming task. If we had machine "COMPFIRST" at our disposal, the little program named "draw" to be executed by it would do the job. For the sake of argument and in order to be realistic we now assume that we do not have at our disposal such a machine tailored to our needs, and therefore our next task (similar to the previous one) is to make such a machine.

There are three named entities assumed, viz "build", "print" and "image", where the first two refer to the latter one. As a consequence, a further detailing of the latter one will affect the two first ones, also, it is very hard to give any further detailing of the action "print" without any further commitments as to the structure of "image". The action "build", however, admits a further detailing all by itself. And it is for that reason that we take "build" as our first candidate for further refinement.

We have to describe, how the variable "image" will get its value corresponding to the proper positioning of the thousand marks. As a total operation, it assigns a value to a variable, whose earlier value was undefined; anticipating that the marks will be added "one at a time", we see, that addition of a next mark will turn out to be an action operating on an already defined value of the variable "image". It therefore seems attractive to view the whole setting of the marks as operating on an already defined value, viz the one corresponding to the blank page. This decision leads to

CLEARFIRST

begin

build {clear, setmarks},

instr clear(image), setmarks(image)

end

where the action "clear" assigns to image the value corresponding to a picture of fifty blank lines, where the action "setmarks" adjusts the initial value of image to the one in which the thousand (or less) marks of the curve have been added

Again, CLEARFIRST is a machine for which alternative programs could have been written, e g

build {clear}

would make sense, but would produce fifty blank lines as output;

build {setmarks, clear}

would contain an undefined operation,

build: {clear, clear, setmarks}

would contain a superfluous operation, just as

build {clear; setmarks, setmarks}

would, because the second action "setmarks" would only add marks to the picture that would already be there and therefore would not change the value of "image"

(Note on notation used The algorithm explaining "build" in terms of "clear" and "setmarks" does so without explicitly mentioning "image", because we do not wish to use the actual parameter notation in algorithms unless its actual combinatorial freedom is in fact used in this machine

Furthermore, "build" being a one-parameter operation no separate identifier for its formal parameter has been introduced Also this abbreviation on my part could turn out to be very unwise)

The next step in the design of the computation -because it can be made without any further commitments- is to describe how the thousand marks of the curve will be dealt with in turn For the time being I propose the following write-up

ISCANNER

```

begin integer i,
  setmarks {i = 0, while i < 1000 do {add mark, i plus 1}},
  instr add mark(i, image)
end

```

This algorithm is to be understood in a machine whose instruction repertoire comprises "add mark(i, image)" which will change the value of "image" in accordance with the addition of the i-th mark. It describes the order in which the marks are dealt with, it shows that all marks will be dealt with exactly once.

But this is not all. A new variable (viz "i") has been introduced, the algorithm appeals to a set of actions referring to this variable ("i = 0", "i < 1000" and "i plus 1") and if I were completely consistent, it seems that I should list them at the bottom, as possibly requiring further clarification at a later stage, just as "add mark". I have not done so (I have treated them along the same lines as the while-do clause). From the point of view of language semantics this separate treatment of an implicitly understood type integer does not seem attractive, and it seems hard to justify, why the type integer is treated differently from the type "image" both are implicitly understood in this machine.

Yet I have done it. All the time I design programs for non-existing machines and add "if we now had a machine comprising the primitives here assumed, then the job is done". This is, logically speaking, correct, in practice it is a joke, because we know very well that we cannot assume a general purpose machine to be available whose instruction code is so very well tailored to our needs. We should not close our eyes -nor feign to do so!- to our responsibility to provide such primitives in a later stage of the design. When I now appeal to a well-understood type "integer" and the operations defined on variables of such a type in this exceptional manner, I do so with the intention of expressing that -although these facilities have to be provided in some form or another- providing these facilities falls outside the scope of the programmer's responsibility and also that the programmer will accept any reasonable implementation of them.

Again we are left with a primitive that admits further refinement without commitments regarding the other primitives. We have to describe how dealing with

mark no 1 can be expressed in terms of dealing with a position on the page we create the machine dealing with the computation of this position

COMPP05

```

begin integer x,y,
  add mark {x = fx(1), y:= fy(1), mark pos},
  instr mark pos (x, y, image)
end

```

where "mark pos" will change the current value of the variable "image" in accordance with the addition of a mark with the co-ordinates "x" and "y" on the picture to be printed

(Note In the last refinement it is explicitly assumed that the functions $fx(1)$ and $fy(1)$ can be evaluated in any order of their argument values. If these two thousand function values were to be read from an input stream, pair wise in a prescribed order of 1-values, then the last two machines would have to be merged into a single one)

By now I see no possibility of further refinement without committing myself to the structure of the still rather vague type "image". How do we propose that this value will be stored? We have to structure the variables of type "image", or, what amounts to exactly the same thing, we have to choose a representation for its possible values

While lecturing at various places I have described versions of this program to different audiences, and it may be worth-while to point out that at least twice part of my audience was deeply troubled by the time I had reached this stage. They felt for instance, that I could not claim that my program, as far as developed, was correct, they objected to my remark that

```
draw {build; print, print}
```

would produce the same picture twice, for how did I know, that "print" did not (by means of some side-effect) change the value of "image" before I had made the primitive "print"? The answer to this, of course, is that "print" has to do what has been stated and should not do what has not been stated. But then more objections came. I had failed to show that the representation was unique, perhaps it was such, that "print" was only a partial function, undefined for some possible values of

"image", etc. The answer to this seems to be the following: legitimate as such concerns are, they should be dealt with at the right moment, i.e. not before we are committing ourselves to a representation. It is apparently the strength of our approach that so much of the program could be written down independently of the representation to be chosen for the values of the type "image". What we have done so far seems indeed a judicious exploitation of our power of abstraction (here abstraction of the particular representation to be chosen for the data structure "image").

But even if we now come to the conclusion that the time has come to decide upon the data structure for the type "image" we still don't need to commit ourselves completely. Faced with the question how to structure our variable now, we can take our decisions step-wise, just as we have done with the algorithmic refinements encountered so far.

We recall that the origin of the problem was to be found in the circumstance that the printing primitives "PRSYM" and "NLCA" forced the computation to produce the picture line after line going from top to bottom. Let us try to give recognition to that fact by regarding the image as composed of an array of lines. I then come to the following next level.

```

LINER
  begin integer j,
  image {array line[0 49]},
  print {j = 49; while j ≥ 0 do {lineprint(line[j]), j minus 1}};
  clear {j = 49; while j ≥ 0 do {lineclear(line[j]); j minus 1}};
  mark pos {linemark(line[j])},
  type line;
  instr lineprint(line), lineclear(line), linemark(x, line)
  end

```

In the last line but one we have introduced a type called "line", a type, I recall, is regarded as a collection of distinguishable values and a variable of such a type can, at any moment, have one of this collection as its value. The first line of code expresses that the type "image" is composed of an array of 50 elements of type "line", numbered from 0 through 49, and, being the only type composed from

this type, again we abstain from introducing a new identifier (wisely or not)

Then, "print", "clear", and "mark pos", being operations that were understood as operating on an "image" are translated in algorithms expressed in terms of operations on a line. In the code of these algorithms, the (true) actual parameter specifies which line, at the end of the description we give the instruction list, indicating that the actions operate on "a line" we have given the type, but not the parameter

This level introduces some new features. To start with (as in explaining "image") we treat the structural refinement of a data type on a footing very similar to the algorithmic refinements (as applied to "print", "clear" and "mark pos"). Before this level, our approach could have been regarded as an effort to establish a discipline for "subroutinization" -if the reader will excuse this horrible term'-, now we observe that that characterization of our effort covers only half of what we are trying to do, as we are trying to apply a similar technique to data structures as well. Secondly, our previous machine explained just one entity (instruction or data type) in contrast to "LINER", which explains a whole bunch of them. The point is that we try to associate with each level a separate design decision, the decision taken here is to understand the image from now onwards in terms of lines, and therefore all operations dealing with an image as such have to be translated in terms of operations dealing with its lines. The image has been "explained away", the only unusual type we still have to deal with is the type "line" and that is what we are going to do now. I draw your attention to the fact that in the level to come, we have to deal with lines that lines are used to compose images from is no longer relevant.

To represent a line we have many different possibilities, e.g. a list of the x-co-ordinates of the positions where a mark should be printed (possibly sorted in order of increasing x-value), a boolean array of 100 elements, each element indicating whether the corresponding position on the line of the picture should be marked, or an integer array of 100 elements, each element having the value "mark" or "space" of the PRSYM-parameter for the corresponding printable position. The last representation caters for extension when different curves (with different marks) have to be printed in the same picture, therefore we select the last one. This leads to

LONGREP

```

begin integer k,
  line {integer array sym[0 99]];
  lineprint {k = 0, while k < 100 do {PRSYM(sym[k]), k plus 1}, NLCR},
  lineclear {k = 0, while k < 100 do {sym[k] = space, k plus 1}};
  linemark {sym[x] := mark}
end

```

This however leads to an implementation filling out the line with spaces at the righthand side of the rightmost mark it is like banging the space bar until the bell rings when we want to effect the transition to a new paragraph while writing a letter'

The next version suppresses superfluous PRSYM-commands and even leaves those elements of the variable of type "line" undefined that do not need to be defined With each line a counter "f" is associated, giving the number of PRSYM-commands to be given for that line Clearing a line now shrinks into setting "f" to zero'

SHORTREP

```

begin integer k,
  line: {integer f, integer array sym[0 99]],
  lineprint {k = 0, while k < f do {PRSYM(sym[k]), k plus 1}, NLCR},
  lineclear: {f = 0},
  linemark {sym[x] = mark;
            if f ≤ x do {k := f, while k < x do {sym[k] := space, k plus 1},
                      f = x + 1}}
end

```

Note added later

The above program is essentially the program as I have shown it to at least five different audiences Now, two months later, while thinking at leisure about correctness proofs, I suddenly realize that the given algorithm for "linemark" betrays my past, for it is a piece of lousy coding, compared with the following alternative


```
linemark {while f ≤ x do {sym[f] = space, f plus 1},
          sym[x] := mark}
```

a version which guarantees that whenever "sym[x] := mark" is executed, the relation "x < f" will always be satisfied it is precisely the function of the first line to see to this. The reader is invited to try to understand both versions of linemark and to compare both reasonings. He will then agree with my judgement that the original version is lousy.

The second version jumped into my mind on account of the following observation. The conditional clause

"if B do S"

is used in programs in two different ways. On the one hand we have the applications, in which the execution of the statement S does not invalidate the truth of B, on the other hand we have the situations in which the execution of the statement S is guaranteed to invalidate the truth of B. In the latter case, it is the function of the conditional statement to ensure that after its execution B will not hold. It is then, essentially, a shortcut for

"while B do S",

which has the property of invalidating the truth of B (provided that it stops), but the justification of the shortcut requires a separate proof that the repeated statement will be executed at most once. (In "A first example of step-wise program composition" we did not bother to introduce this shortcut on level 2b4(4) where we wrote

"while "ord too small" do "increase ord by one" ,

here a conditional clause would have done the job!)

On what we have achieved

One of the metaphors in which I find myself thinking about the program structure envisaged regards the program as a necklace, strung from individual pearls

We have described the program in terms of levels and each level contained "refinements" of entities that were assumed available in higher levels. These refinements were either dynamic refinements (algorithms) or static refinements (data structures) to be understood by an appropriate machine. I use the term "pearl" for such a machine, refinements included

Our previous program consists of a necklace of six pearls, in order either

COMPFIRST
CLEARFIRST
ISCANNER
COMPPPOS
LINER
LONGREP

or

COMPFIRST
CLEARFIRST
ISCANNER
COMPPPOS
LINER
SHORTREP

LONGREP and SHORTREP are two different pearls, they explain the same concepts (from the "upper face") into the same concept (of the "lower face"); only the particular refinements differ: they are as alternative programs for the same job and the same machine

Changing a program will be treated as replacing one or more pearls of the original necklace by one or more other pearls. The pearl is the individual unit from which programs are composed. Making a program (as a member of a class of related programs) is now regarded as a two-stage process: making pearls (more than

strictly necessary) and then stringing a fitting necklace out of (a selection of) them

The reasons for this two-stage approach are many. In designing a program we have to consider many, many alternative programs and once our program is finished, we will have to change it (into one of the alternative ones). As long as programs are regarded as linear strings of basic symbols of a programming language and, accordingly, program modification is treated as text manipulation on that level, then each program modification must be understood in the universe of all programs ('right or wrong') that can be written in that programming language. No wonder that program modification is then a most risky operation! The basic symbol is too small and meaningless a unit in terms of which to describe this. The pearl, embodying the independent design decision or, as the case may be, an isolated aspect of the original problem statement, is meant to be the natural unit for such modifications.

To rephrase the same argument with the birth of ALGOL 60, syntax was discovered as a powerful means for expressing structure in a program text. (Syntax became so glorified that many workers in the field identified Computing Science with Syntactic Analysis!) It was slightly overlooked, however, that by expressing structure via syntax, this structure is only given very indirectly, i.e. to be derived by means of a parsing algorithm to be applied to a linear sequence of basic symbols. This hurts if we realize that many a program modification leaves large portions of the structure unaffected, so that after painful re-parsing of the modified text the same structure re-emerges! I have a strong feeling that the adequacy of context-free methods for the representation of structure has been grossly overestimated. (In my immediate environment the following program bug in an ALGOL 60 program was brought to my attention. A program produced erroneous output with a completely checking implementation which in addition to the program text requires a final "progend" after the last "end", this additional character is refused everywhere else so that a correct "begin - end" bracketing can be established. It turned out that

- 1) somewhere in the program a closing string quote was omitted,
- 2) somewhere further down in the program text an opening string quote was omitted,
- 3) the "begin - end" structure of the resulting program was syntactically correct,
- 4) the identifiers declared between the two omissions were only used between the two omissions, so that even context-dependent checks were unable to give alarm

Having already my doubt as to the adequacy of context-free methods for expressing macroscopic structure, I was delighted when this bug was shown to me')

) The more I think about pearls, the more I feel that something like them is the only way out of it, if we recognize our responsibility to take (for a large program) say a thousand (possible) versions into consideration. You cannot expect the programmer to make all these thousand versions from scratch, independent of each other. The only way I see to produce such a potential variety is by a combinatorial technique, i.e. by making more pearls (say 250) than needed for a single necklace (say 200) and stringing a necklace from a particular selection. I see no other feasible way. The other mechanism to achieve great variety by combinatorial means is permutation, but this is denied to us because the final necklace must be a fitting necklace and, given the pearls, the order in which they have to be strung on the thread to produce a fitting necklace is pretty well defined. And also: if it is not, the permissible change of order is pretty irrelevant'

Also, the pearl gives a clear status to an "incomplete" program, consisting of the top half of a necklace. It can be regarded as a complete program to be executed by a suitable machine (of which the bottom half of the necklace gives a feasible implementation). As such, the correctness of the upper half of the necklace can be established regardless the choice of the bottom half. Between two successive pearls we can make a "cut" which is a manual for a machine, provided by the part of the necklace below the cut and used by the program represented by the part of the necklace above the cut. This manual serves as an interface between the two parts of the necklace. We feel this form of interface more helpful than regarding data-representation as an interface between operations, in particular more helpful towards ensuring the combinatorial freedom required when a program has to be adapted.

Another remark concerns the range of validity of concepts along the necklace. For instance, the concept "image" is introduced in our top pearl "COMPFIRST" and is explained away in our bottom pearl but one, viz. "LINER". If we now come to the conclusion that the program as envisaged is too demanding on storage space so that we cannot afford to introduce the variable "image", we are faced with a major program revision and we have to replace the top five pearls by other ones, because that is the range of validity of the concept "image". The bottom pearl

(either "LONGREP" or "SHORTREP"), however, can be retained (I mention this as an example of the fact that pearl exchange is by no means restricted to exchange of the bottom pearl)

With respect to the validity range of concepts along the necklace I would like to ask your attention for an observation which thrilled me the first time I made it (In retrospection it is pretty obvious and that is exactly why it may be worth-while to be explicit about it) With each pearl we associate "an independent design decision" and the ordering of the pearls along the necklace therefore implies an ordering of the design decisions Can we change this order? Yes, we can, although we then have different pearls By way of experiment I have followed the well-known advice if you are faced with two primitives -in our case "build" and "print"- decide immediately upon their interface -in our example "image"- so that the two primitives can now be refined independently of each other So I did, and I came to the following form of necklace

```
COMPFIRST
LINER'
CLEARFIRST'
ISCANNER'
COMPPPOS'
SHORTREP
```

(the four middle pearls being primed to indicate that they refer to different pearls, although they embody the same decisions as the ones in the original set) The resulting program is much messier Why?

Along the necklace we can indicate for each concept its range of validity of course they overlap and we can view them as the individual threads from which the whole explanation is twined, as a kind of "logical rope" The messy version has a logical rope twined from more and sometimes longer individual threads its logical rope is thicker, the whole construction is more tightly interconnected The observation thrilled me because it gave a very convincing demonstration (at least for me') that elegance, clarity and the like have indeed marked quantitative aspects (as Mozart knew many of his compositions that make one catch one's breath are misleadingly simple, they seem to be made just out of practically nothing')

We can phrase the observation in more technical terms. The primed version is messy because the image is explained away in terms of lines at too early a stage, thereby forcing us to explain "CLEARFIRST", "ISCANNER" and "COMPPDS" in terms of lines, while they could still be explained in terms of the image, i.e. independent of the representation to be chosen for it. Or, in other words, in the original version we have made a more judicious exploitation of our power of abstraction than in the primed one. The larger the number of pearls independent of the particular representation, the more adaptable one's program and the more easily understandable -because that set of pearls can be understood at a higher level of abstraction. The experience seems to indicate that the goals of adaptability and clarity have been given some substance and (what is more) go by their very nature hand in hand. This is very encouraging (although not surprising).

It also gives -me at least- a somewhat clearer picture of the scope of my present efforts. Whatever I shall develop, it will not be a General Problem Solver, not a mechanical one, not even one written for the benefit of the human problem solver. But it may give the human some appreciation for the various aspects of "elegance" of a solution when he succeeds in finding one. And as such it may give him a guide line.

On grouping and sequencing

While we are considering a programming tool in which explicit recognition has been given to the hierarchy of levels of abstraction, the present section is also applicable to programming in programming languages as they are understood today, viz on a constant semantic level (And there is a fair chance that the current section has its morals outside the restricted field of programming, for it seems to be concerned with problem solving in general)

I shall illustrate my point with two examples, both of which, again, I have used in viva voce examinations I owe the first example to Niklaus Wirth

The problem is to construct a program generating non-empty sequences of 0's, 1's and 2's without non-empty, element-wise equal, adjoining subsequences, generating these sequences in alphabetical order until a sequence of length 100 (i.e. of 100 digits) has been generated The programmer may make use of the knowledge that a sequence of length 100 and satisfying the conditions actually exists The start of the list of sequences to be generated is

```

0
01
010
0102
01020
010201
0102010
0102012

```

Each solution (apart from the first one) is an extension (by one digit) of an earlier solution and the algorithm is therefore a straightforward backtracking one

We are looking for the "good" sequences, we assume a primitive available for the investigation of whether a trial sequence is good If it is good, the trial sequence is printed and extended with a zero to give the next trial sequence, if the trial sequence is no good, we perform on it the operation "increase" to get

the next trial sequence, i.e. final digits = 2 are removed and then the last remaining digit is increased by 1 (The operations "extend with zero" and "increase" guarantee that trial sequences are generated in alphabetical order, the solutions, being a selection from them, will then be printed in alphabetical order as well) The algorithm will start investigating the following trial sequences, those marked by an asterisk will be rejected as "no good":

```

      0
*    00
      01
      010
*    0100
*    0101
      0102
      01020
*    010200
      010201
      0102010
*    01020100
*    01020101
*    01020102
*    0102011
      0102012

```

I found the majority of my students inclined to make a program with the following structure

```

"set trial sequence to single zero,
  repeat if good then
      begin print trial sequence; extend trial sequence with zero end
      else
          increase trial sequence
  until length = 101"

```

Although a program along these lines produces the correct output, objections can -and to my taste should- be made against it. The first objections regards the stopping criterion when a solution of length 100 has been printed, we (knowing the

algorithm) can deduce that after that for the first time the trial sequence will have length = 101 and this is now the criterion to stop, but this is a rather indirect and tortuous way to establish the stopping criterion (How tortuous it is was clearly demonstrated by those students who did not see that an unnecessary trial sequence was generated and declared for the trial sequence an array of 100 elements instead of 101) The second objection is that the operation "increase trial sequence" never increases its length after rejection of a trial sequence a superfluous test on the length is performed (When I used this example for student examination examinations I had not stressed very explicitly in my lectures any problem solving principles, so my disappointment was not too severe In a sense I am glad to have observed these examinations, for it was for me an incentive to stress problem solving principles as far as I could find, formulate and teach them)

The program to which the above objections do not apply treats the empty sequence as a virtual solution, not to be printed It has -to the same level of detail- the following structure

```
"set trial sequence empty,
  repeat extend trial sequence with zero,
    while no good do increase trial sequence,
      print trial sequence
  until length = 100"
```

Here length is the length of the solution printed (if any), thus avoiding the tortuous reasoning for the stopping criterion Also no superfluous last trial sequence (never to be investigated) will be generated, thanks to the fact that we have two loops inside each other, superfluous length testing no longer occurs Those for whom efficiency is the main criterion will probably be most convinced by the last observation I myself, who attach considerable importance to understandability, am attracted to the latter program because I c nterpret it as a further refinement of the program structure

```
"set sequence empty,
  repeat transform sequence to next solution,
    print sequence
  until length = 100"
```

This (more abstract) program is only concerned with sequences that are solutions:

on this level of description one can ignore that the transition from one solution to the next takes place via a sequence of trial solutions that turn out to be failures

I owe to Joe Weizenbaum the second example. Make a program that, for given positive integer n , determines the smallest number s that can be decomposed into the sum of two n -th powers in at least two non-trivially different ways

(for $n = 1$ $s = 2 = 0^1 + 2^1 = 1^1 + 1^1$
 $n = 2$ $s = 25 = 0^2 + 5^2 = 3^2 + 4^2$
 $n = 3$ $s = 1729 = 1^3 + 12^3 = 9^3 + 10^3$
 $n = 4$ $s = 635318657 = 59^4 + 158^4 = 133^4 + 134^4$)

When I first used this example in an oral examination, it took the student twenty minutes to get somewhat familiar with the problem and he then sketched a searching algorithm which -when patched up- could indeed find a number that allowed multiple decompositions into sums of two n -th powers, but he could not prove that when his algorithm produced a value s that it would be the minimum value (As a matter of fact he had, up till then, ignored that part of the problem statement)

He then regrouped his forces and made a program of the following form

```
"integer s, k,
s := 1,
repeat s = s + 1,
    k = "the number of ways in which s can be decomposed as the sum
        of two n-th powers"
until k > 1
```

thus arriving at a hopelessly inefficient algorithm. The error he made was the decision at too early a stage to investigate the natural numbers in succession, the overwhelming majority of which are not decomposable at all. Reasoning that the value we are looking for is the smallest decomposable number satisfying an additional property, one comes to an algorithm whose first sketch could be

```

integer k, s, t,
t := 1 (and further initialization),
repeat s = "smallest decomposable value larger than t",
    k = "the number of ways the above minimum is obtained"
    t = s
until k > 1"

```

By storing a collection of triples (number pairs with their corresponding s-value), among which each time the pair(s) with minimum s-value exceeding t will occur and adjusting this collection each time t is increased, a program emerges that is orders of magnitude more efficient, t jumping from decomposable value to the next decomposable value. Programming (or problem solving in general?) as the judicious postponement of decisions and commitments!

A Practitioner's Approach

Roger S. Pressman

achieve these (and many other) capabilities you will design and construct WebApp functional components that are similar in form to software components for conventional software

WebApp functionality is delivered as a series of components developed in parallel with the information architecture to ensure that they are consistent. In essence you begin by considering both the requirements model and the initial information architecture and then examining how functionality affects the user's interaction with the application, the information that is presented, and the user tasks that are conducted.

During architectural design, WebApp content and functionality are combined to create a functional architecture. A *functional architecture* is a representation of the functional domain of the WebApp and describes the key functional components in the WebApp and how these components interact with each other.

For example, the pan and zoom functions for the **SafeHomeAssured.com** video surveillance capability are implemented as part of a **CameraControl** component. Alternatively, pan and zoom can be implemented as the operations *pan()* and *zoom()* which are part of a **Camera** class. In either case, the functionality implied by pan and zoom must be implemented as modules within **SafeHomeAssured.com**.

10.5 DESIGNING TRADITIONAL COMPONENTS

KEY POINT

Structured programming is a design technique that constrains logic flow to three constructs: sequence, condition, and repetition.

The foundations of component level design for traditional software components⁷ were formed in the early 1960s and were solidified with the work of Edsger Dijkstra and his colleagues ([Boh66] [Dij65] [Dij76b]). In the late 1960s Dijkstra and others proposed the use of a set of constrained logical constructs from which any program could be formed. The constructs emphasized 'maintenance of functional domain.' That is, each construct had a predictable logical structure and was entered at the top and exited at the bottom, enabling a reader to follow procedural flow more easily.

The constructs are sequence, condition, and repetition. *Sequence* implements processing steps that are essential in the specification of any algorithm. *Condition* provides the facility for selected processing based on some logical occurrence, and *repetition* allows for looping. These three constructs are fundamental to *structured programming*—an important component level design technique.

The structured constructs were proposed to limit the procedural design of software to a small number of predictable logical structures. Complexity metrics (Chapter 23) indicate that the use of the structured constructs reduces program complexity and thereby enhances readability, testability, and maintainability. The use of

⁷ A traditional software component implements an element of processing that addresses a function or subfunction in the problem domain or some capability in the infrastructure domain. Often called modules, procedures, or subroutines, traditional components do not encapsulate data in the same way that object-oriented components do.

a limited number of logical constructs also contributes to a human understanding process that psychologists call *chunking*. To understand this process, consider the way in which you are reading this page. You do not read individual letters but rather recognize patterns or chunks of letters that form words or phrases. The structured constructs are logical chunks that allow a reader to recognize procedural elements of a module rather than reading the design or code line by line. Understanding is enhanced when readily recognizable logical patterns are encountered.

Any program, regardless of application area or technical complexity, can be designed and implemented using only the three structured constructs. It should be noted, however, that dogmatic use of only these constructs can sometimes cause practical difficulties. Section 10.5.1 considers this issue in further detail.

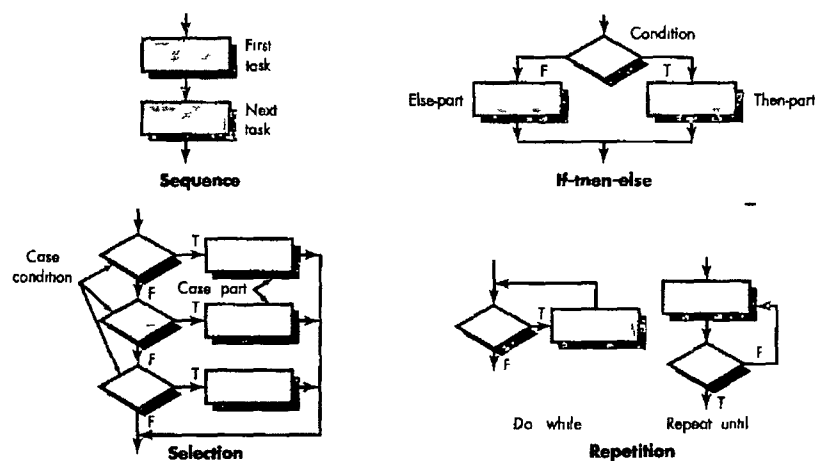
10.5.1 Graphical Design Notation

A picture is worth a thousand words, but it's rather important to know which picture and which 1000 words. There is no question that graphical tools, such as the UML activity diagram or the flowchart, provide useful pictorial patterns that readily depict procedural detail. However, if graphical tools are misused, the wrong picture may lead to the wrong software.

The activity diagram allows you to represent sequence, condition, and repetition—all elements of structured programming—and is a descendent of an earlier pictorial design representation (still used widely) called a *flowchart*. A flowchart, like an activity diagram, is quite simple pictorially. A box is used to indicate a processing step. A diamond represents a logical condition, and arrows show the flow of control. Figure 10.10 illustrates three structured constructs. The *sequence* is

FIGURE 10.10

Flowchart constructs



General Principles of Software Validation; Final Guidance for Industry and FDA Staff

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**U S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**



SECTION 4. PRINCIPLES OF SOFTWARE VALIDATION

This section lists the general principles that should be considered for the validation of software

4.1 REQUIREMENTS

A documented software requirements specification provides a baseline for both validation and verification. The software validation process cannot be completed without an established software requirements specification (Ref. 21 CFR 820.3(z) and (aa) and 820.30(f) and (g)).

4.2 DEFECT PREVENTION

Software quality assurance needs to focus on preventing the introduction of defects into the software development process and not on trying to 'test quality into' the software code after it is written. Software testing is very limited in its ability to surface all latent defects in software code. For example, the complexity of most software prevents it from being exhaustively tested. Software testing is a necessary activity. However, in most cases software testing by itself is not sufficient to establish confidence that the software is fit for its intended use. In order to establish that confidence, software developers should use a mixture of methods and techniques to prevent software errors and to detect software errors that do occur. The 'best mix' of methods depends on many factors including the development environment, application, size of project, language, and risk.

4.3 TIME AND EFFORT

To build a case that the software is validated requires time and effort. Preparation for software validation should begin early, i.e., during design and development planning and design input. The final conclusion that the software is validated should be based on evidence collected from planned efforts conducted throughout the software lifecycle.

4.4 SOFTWARE LIFE CYCLE

Software validation takes place within the environment of an established software life cycle. The software life cycle contains software engineering tasks and documentation necessary to support the software validation effort. In addition, the software life cycle contains specific verification and validation tasks that are appropriate for the intended use of the software. This guidance does not recommend any particular life cycle models – only that they should be selected and used for a software development project.



C by Dissection

Third Edition



The Essentials of C Programming

Al Kelley / Ira Pohl
University of California, Santa Cruz



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Consider a construction of the form

```
do
    statement
while (expr),
next statement
```

First *statement* is executed and *expr* is evaluated. If the value of *expr* is nonzero (*true*), then control passes back to the beginning of the do statement and the process repeats itself. When *expr* is zero (*false*) then control passes to *next statement*.

As an example suppose we want to read in an integer and want to insist that the integer be positive. The following code will do the job.

```
do {
    printf('Input a positive integer  ')
    scanf('%d', &n),
    if (error = (n <= 0))
        printf('ERROR Negative value not allowed\n\n')
} while (error),
```

As long as a nonpositive integer is entered, the user will be notified with a request for a positive integer. Control will exit the loop only after a positive integer has been entered.

3 15 The goto Statement

The **goto** statement is considered a harmful construct in most accounts of modern programming methodology. It causes an unconditional jump to a labeled statement somewhere in the current function. Thus it can undermine all the useful structure provided by other flow of control mechanisms (if, if-else for while do and switch).

Since a **goto** jumps to a labeled statement we need to discuss this construct first. A labeled statement is of the form

```
label statement
```

where *label* is an identifier. Some examples of labeled statements are

```

    bye exit(1),
    L444 a = b + c,
    bug1 bug2 bug3 printf( bug found\n ), /* multiple labels */

```

but not

```

    333 a = b + c, /* 333 is not an identifier */

```

Label identifiers have their own name space. This means that the same identifier can be used both for a label and a variable. This practice however is considered bad programming style and should be avoided.

Control can be unconditionally transferred to a labeled statement by executing a goto statement of the form

```
goto label
```

An example would be

```

goto error,

error {
    printf( An error has occurred - bye!\n' ),
    exit(1)
}

```

Both the goto statement and its corresponding labeled statement must be in the body of the same function. Here is a more specific piece of code that makes use of a goto

```

while (scanf( %lf , &x) == 1) {
    if (x < 0.0)
        goto negative_alert,
    printf( %f %f %f\n , x sqrt(x), sqrt(2 * x)),
}

negative_alert
if (x < 0.0)
    printf( Negative value encountered!\n ),

```

This code can be rewritten in a number of ways without using a goto. Here is one way

```

while (scanf( "%lf  &x) == 1 && x >= 0 0)
    printf("%f  %f  %f\n", x, sqrt(x), sqrt(2 * x)),
    if (x < 0 0)
        printf('Negative value encountered!\n '),

```

In general, `goto` should be avoided. It is a primitive method of altering the flow of control, which is unnecessary in a richly structured language. Labeled statements and `gotos` are the hallmark of incremental patchwork program design. A programmer who modifies a program by adding `gotos` to additional code fragments soon makes the program incomprehensible.

When should a `goto` be used? A simple answer is never. Indeed, one cannot go wrong by following this advice. However, in some rare instances, which should be carefully documented, a `goto` can make the program significantly more efficient. In other cases it can simplify the flow of control. This may occur, for example, if we are in a deeply nested inner loop and we want program control to jump to the outermost level of the function.

3 16 The break and continue Statements

Two special statements,

`break` and `continue`,

interrupt the normal flow of control. The `break` statement causes an exit from the innermost enclosing loop or `switch` statement (discussed in the next section). In the following example, a test for a negative argument is made, and if the test is true, a `break` statement is used to pass control to the statement immediately following the loop.

```

while (1) {
    scanf("%lf", &x),
    if (x < 0 0)
        break,          /* exit loop if x is negative */
    printf( "%f\n", sqrt(x)),
}

/* break jumps to here */

```

This is a typical use of `break`. What would otherwise be an infinite loop is made to terminate upon a given condition tested by the `if` expression.

The `continue` statement causes the current iteration of a loop to stop and the next iteration to begin immediately.

```
while (cnt < n) {
    scanf( "%lf", &x),
    if (x > -0.01 && x < +0.01)
        continue,          /* disregard small values */
    ++cnt,
    sum += x,
    /* continue transfers control here to begin next iteration */
}
```

The `continue` statement may only occur inside `for`, `while`, and `do` loops. As the examples show, `continue` transfers control to the end of the current iteration whereas `break` terminates the loop.

In the presence of a `continue` statement, a `for` loop of the form

```
for (expr1, expr2, expr3) {
    statements
    continue,
    more statements
}
```

is equivalent to

```
expr1
while (expr2) {
    statements
    goto next,
    more statements
next
    expr3,
}
```

which is different from

```

    expr1,
    while (expr2) {
        statements
        continue,
        more statements
    }
    expr3,

```

See exercise 25 on page 135 for a convenient way to test this

3 17 The switch Statement

The `switch` is a multiway conditional statement generalizing the `if-else` statement. The following is a typical example of a `switch` statement.

```

switch (val) {
case 1
    ++a_cnt,
    break,
case 2
case 3
    ++b_cnt,
    break,
default
    ++other_cnt,
}

```

Notice that the body of the `switch` statement in the example is a compound statement. This will be so in all but the most degenerate situations. The controlling expression in the parentheses following the keyword `switch` must be of integer type (see Chapter 6 "The Fundamental Data Types"). In the example, it is just the `int` variable `val`. After the expression is evaluated, control jumps to the appropriate case label. The constant integral expressions following the case labels must all be unique. Typically the last statement before the next case or `default` label is a `break` statement. If there is no `break` statement, execution "falls through" to the next statement in the succeeding case. Missing `break` statements are a frequent

cause of error in switch statements. There may be at most one default label in a switch. Typically it occurs last, although it can occur anywhere. The keywords case and default cannot occur outside of a switch.

The Effect of a switch

- 1 Evaluate the switch expression
- 2 Go to the case label having a constant value that matches the value of the expression found in step 1. If a match is not found, go to the default label if there is no default label, terminate the switch.
- 3 Terminate the switch when a break statement is encountered, or by "falling off the end."

Let us review the various kinds of jump constructs that are available to us. These include the goto, break, continue, and return. ~~The goto is unrestricted in its use and should be avoided as a dangerous construct.~~ The break statement may be used in loops and is important to the proper structuring of the switch statement. The continue statement must be used within loops and is often unnecessary. The return statement must be used in functions that return values. It will be discussed in Chapter 4, "Functions and Structured Programming."

3.18 Nested Flow of Control

Flow of control statements such as if, for, while, and switch statements can be nested within themselves and within one another. Although such nested control constructs can be quite complicated, some have a regular structure and are easily understood.

One of the more common nested flow of control constructs makes repeated use of if-else statements. Its general form is given by

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Learning Activities

- 17 Test goto c with many different inputs to verify that it behaves as you expected¹
- 18 Modify the program goto c by moving the printf() call labeled error and the subsequent exit() statement to the end of the function main() Try to compile and execute the modified program Try to explain what happens and why

A Word of Warning¹

Much has been written about the use and misuse of the goto statement. Although, opinions differ on the proper use of this statement, most authorities agree that indiscriminate use of the goto statement is one deterrent to structured programming.

In addition to the effect that goto has on the structure of a program, situations arise in the source code where the effects of using goto have some unexpected deleterious consequences. A major example of this is when the goto statement is used to jump into the middle of a block, as in the following code segment

```

iochar = getchar(),
if ( isdigit( iochar ))
    goto calculate

                                /* other code */

{
    int i = 0                    /* a block */
                                /* local variable */
    while ( isdigit( iochar )) {
        i = i + 1
                                /*labeled statement */
calculate for ( j = 1 j < i j++ )
        sum = 10 * ( iochar - 0 )
        iochar = getchar()
    }                            /* end while */
}                                /* end block */

```

¹ Some compilers will issue a warning message for this program since the function convert() does not actually return a value when an error occurs. The program could be rewritten to eliminate this warning, but much of the existing C code that uses the goto to handle errors will have this structure

The local variable `i` in the block is not guaranteed to be initialized properly when the block is not entered from the top. If the block is entered by means of the `goto` statement above, the value of `i` could be garbage. The code would be unreliable.

6.7 If There's Time or Need Using Recursion

Recursion occurs when a function or subprogram calls itself or calls a function which in turn calls the original function. C allows recursion.

In mathematics, a recurrence relation is a formula in which the desired expression involving a positive integer, n , is described in terms of corresponding values for integers less than n . Initial conditions or starting values (usually for $n = 0$, or $n = 1$) must also be given. The following formulas for powers of x and for factorials are simple examples of recurrence relations.

	Formula	Initial Condition
Power	$x^n = x \cdot x^{n-1}$	$x^0 = 1$
Factorial	$n! = n \cdot (n-1)!$	$0! = 1$

Using the initial condition, the formulas can be evaluated for any positive integer n . For example, $4!$ can be calculated using the recurrence relation in the following steps:

$$\begin{aligned}
 4! &= 4 \cdot 3! && \text{using } n! = n \cdot (n-1)! \\
 &= 4 \cdot 3 \cdot 2! && \text{using } (n-1)! = (n-1) \cdot (n-2)! \\
 &= 4 \cdot 3 \cdot 2 \cdot 1! \\
 &= 4 \cdot 3 \cdot 2 \cdot 1 \cdot 0! \\
 &= 4 \cdot 3 \cdot 2 \cdot 1 \cdot 1 && \text{using } 0! = 1 \\
 &= 24
 \end{aligned}$$

One way of implementing a recurrence relation on a computer is to code a recursive function. As the initial condition allows the calculation of a recurrence relation to terminate, it also provides a way of terminating the sequence of recursive calls of a function. It is extremely important that every recursive function be given a termination condition that is sure to occur. Otherwise, the execution would be out of control.

A recursive function to calculate factorials is demonstrated in the program `recurs.c` in Example 6-10. The function `main()` serves only as a driver to call the recursive function and output the value returned by the function.



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Structured programming with go to statements

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↑ ABSTRACT

For serious students of structured programming, and also for language designers Knuth's "Structured Programming with go to Statements" is probably the paper to read. It is by far the most complete description of structured programming of all the selections in this book. Even though it originally was published in late 1974, Knuth's ideas have not aged a bit.

The title, as Knuth acknowledges, is somewhat of a misnomer. I should confess that the title of this article was chosen primarily to generate attention. Indeed, he is not arguing that structured programming always should be carried out with go to statements. Instead, as he says, "what I am really doing is striving for a reasonably well-balanced viewpoint about the proper role of go to statements." Like a number of other authors whose views are presented in this book, Knuth seems deeply concerned that the average programmer will over-react to the "no go to" philosophy. Reflecting that concern, the first few pages of Knuth's paper give an indication of the fanaticism of its time -- a fanaticism that has largely died away.

For history buffs, Knuth has carefully documented the origins of structured programming. He claims that the programming style now referred to as "structured programming" actually was first practiced by D. V. Schorre in 1960, and that was followed by publication of the work of Peter Naur in 1963 and of George Forsythe in 1964 -- all of this before the better known works of Dijkstra, and of Böhm and Jacopini.

There are three major themes in Knuth's paper, and a vast number of examples to illustrate each one. One theme -- a familiar one. If you've read many of the other papers in this book is that a program needs to be rewritten several times before it can be considered a truly good program. As Knuth says:

I learned again that I should always keep looking for improvements even when I have a satisfactory program. Indeed, one gets the impression that Knuth views this as the major virtue of

structured programming The requirement to eliminate gotos forces the programmer to rewrite and thus think more about what he was trying to accomplish with his program

A second theme - one that you won't find in any of the other papers - is that efficiency is important in some programming applications; and that the programmer needs the freedom to use gotos to optimize critical portions of a program. Actually, Martin Hopkins makes the same point in "A Case for the GOTO" [Paper 9] but he does so much less forcefully than Knuth. Knuth recognizes the danger of overemphasizing optimization; as he says, "premature optimization is the root of all evil." And, he does state that only three percent of the code in a typical program ever needs to be optimized, but for that critical three percent he demonstrates that structured code often is twenty to thirty percent less efficient than equivalent code with gotos. Unfortunately, the point is repeated so many times with so many examples that the average reader is likely to conclude that Knuth is obsessed with efficiency. However, given the number of authors exhorting programmers to ignore efficiency altogether, it is probably very healthy to have someone argue for a careful consideration of program efficiency.

Knuth's third main theme is that structured programming could be made much more practical with the addition of a few language constructs. In addition to constructs like LEAVE and BREAK, Knuth argues for a "situation" construct patterned after a proposal originally made by C.T. Zahn.

In keeping with the heretical title of his paper, Knuth introduces a fourth theme. There are times when the programmer should put gotos into his code rather than take them out. For example, gotos can be used to convert recursion to iteration, or to implement coroutines, or to eliminate Boolean variables by branching into common code. In this context, Knuth suggests the following strategy: First write the program in a structured manner to convince yourself that it is correct; then transform it into an efficient program, possibly by introducing some goto statements; and finally, leave the original structured code behind as documentation so that subsequent readers can understand how the transformation took place. Whether the average programmer would go through these steps in an orderly, formal way is something worth pondering. My own suspicion is that it won't work, but I'm often branded a skeptic.

To conclude, it's probably best not to read Knuth's paper in one sitting, for you almost surely will become mentally fatigued by the eight major examples, each of which is rewritten three or four (or more!) times in an ALGOL-like pseudocode. Read the paper piece by piece and do read the code -- you'll learn a lot from it!

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Note: OCR errors may be found in this Reference List extracted from the full text article. ACM has opted to expose the complete list rather than only correct and linked references.

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W WITHDRAW W

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↑ **Collaborative Colleagues**

D. Knuth colleagues

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Structured Programming with go to Statements

DONALD E. KNUTH

Stanford University Stanford California 94305

A consideration of several different examples sheds new light on the problem of creating reliable well-structured programs that behave efficiently. This study focuses largely on two issues: (a) improved syntax for iterations and error exits, making it possible to write a larger class of programs clearly and efficiently without go to statements; (b) a methodology of program design, beginning with readable and correct but possibly inefficient programs that are systematically transformed if necessary into efficient and correct but possibly less readable code. The discussion brings out opposing points of view about whether or not go to statements should be abolished, some merit is found on both sides of this question. Finally, an attempt is made to define the true nature of structured programming and to recommend fruitful directions for further study.

Keywords and phrases: structured programming, go to statements, language design, event indicators, recursion, Boolean variables, iteration, optimization of programs, program transformations, program manipulation systems, searching, Quicksort, efficiency.

CR categories: 4.0, 4.10, 4.20, 5.20, 5.5, 6.1, (5.23, 5.24, 5.25, 5.27)

You may go when you will go,
And I will stay behind

—*Edna St. Vincent Millay* [66]

Most likely you go your way and I'll go mine

—*Song title by Bob Dylan* [88]

Do you suffer from painful elimination?

—*Advertisement, J. B. Williams Co.*

INTRODUCTION

A revolution is taking place in the way we write programs and teach programming because we are beginning to understand the associated mental processes more deeply. It is impossible to read the recent book *Structured programming* [17, 55] without having it

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change your life. The reasons for this revolution and its future prospects have been aptly described by E. W. Dijkstra in his 1972 Turing Award Lecture "The Humble Programmer" [27].

As we experience this revolution, each of us naturally is developing strong feelings one way or the other, as we agree or disagree with the revolutionary leaders. I must admit to being a non-humble programmer, egotist.

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cal enough to believe that my own opinions of the current trends are not a waste of the reader's time. Therefore I want to express in this article several of the things that struck me most forcefully as I have been thinking about structured programming during the last year, several of my blind spots were removed as I was learning these things, and I hope I can convey some of my excitement to the reader. Hardly any of the ideas I will discuss are my own, they are nearly all the work of others, but perhaps I may be presenting them in a new light. I write this article in the first person to emphasize the fact that what I'm saying is just one man's opinion; I don't expect to persuade everyone that my present views are correct.

Before beginning a more technical discussion I should confess that the title of this article was chosen primarily to generate attention. There are doubtless some readers who are convinced that abolition of *go to* statements is merely a fad, and they may see this title and think "Aha! Knuth is rehabilitating the *go to* statement, and we can go back to our old ways of programming again." Another class of readers will see the heretical title and think, "When are diehards like Knuth going to get with it?" I hope that both classes of people will read on and discover that what I am really doing is striving for a reasonably well balanced view point about the proper role of *go to* statements. I argue for the elimination of *go to*'s in certain cases, and for their introduction in others.

I believe that by presenting such a view I am not in fact disagreeing sharply with Dijkstra's ideas, since he recently wrote the following: "Please don't fall into the trap of believing that I am terribly dogmatic about [the *go to* statement]. I have the uncomfortable feeling that others are making a religion out of it, as if the conceptual problems of programming could be solved by a single trick, by a simple form of coding discipline!" [29]. In other words, it seems that fanatical advocates of the New Programming are going overboard in their strict enforcement of morality and purity in programs. Sooner or later people are going to find that their beautifully structured

programs are running at only half the speed—or worse—of the dirty old programs they used to write, and they will mistakenly blame the structure instead of recognizing what is probably the real culprit—the system overhead caused by typical compiler implementation of Boolean variables and procedure calls. Then we'll have an unfortunate counter revolution, something like the current rejection of the 'New Mathematics' in reaction to its over-zealous reforms.

It may be helpful to consider a further analogy with mathematics. In 1904, Bertrand Russell published his famous paradox about the set of all sets which aren't members of themselves. This antinomy shook the foundations of classical mathematical reasoning, since it apparently brought very simple and ordinary deductive methods into question. The ensuing crisis led to the rise of 'intuitionist logic', a school of thought championed especially by the Dutch mathematician, L. E. J. Brouwer, intuitionism abandoned all deductions that were based on questionable nonconstructive ideas. For a while it appeared that intuitionist logic would cause a revolution in mathematics. But the new approach angered David Hilbert, who was perhaps the leading mathematician of the time. Hilbert said that "For bidding a mathematician to make use of the principle of the excluded middle is like forbidding an astronomer his telescope or a boxer the use of his fists." He characterized the intuitionist approach as seeking 'to save mathematics by throwing overboard all that is troublesome. They would chop up and mangle the science. If we would follow such a reform as they suggest, we could run the risk of losing a great part of our most valuable treasures' [80, pp. 98-99, 148-150, 154-157, 184-185, 268-270].

Something a little like this is happening in computer science. In the late 1960's we witnessed a 'software crisis', which many people thought was paradoxical because programming was supposed to be so easy. As a result of the crisis, people are now beginning to renounce every feature of programming that can be considered guilty by virtue of its association with difficulties. Not only go to statements are being questioned,

we also hear complaints about floating point calculations, global variables, semaphores, pointer variables, and even assignment statements. Soon we might be restricted to only a dozen or so programs that are sufficiently simple to be allowable, then we will be almost certain that these programs cannot lead us into any trouble, but of course we won't be able to solve many problems.

In the mathematical case, we know what happened. The intuitionists taught the other mathematicians a great deal about deductive methods, while the other mathematicians cleaned up the classical methods and eventually "won" the battle. And a revolution did, in fact, take place. In the computer science case, I imagine that a similar thing will eventually happen: purists will point the way to clean constructions, and others will find ways to purify their use of floating point arithmetic, pointer variables, assignments, etc., so that these classical tools can be used with comparative safety.

Of course all analogies break down, including this one, especially since I'm not yet concerted enough to compare myself to David Hilbert. But I think it's an amusing coincidence that the present programming revolution is being led by another Dutchman (although he doesn't have extremist views corresponding to Brouwer's), and I do consider assignment statements and pointer variables to be among computer science's "most valuable treasures."

At the present time I think we are on the verge of discovering at last what programming languages should really be like. I look forward to seeing many responsible experiments with language design during the next few years, and my dream is that by 1984 we will see a consensus developing for a really good programming language (or, more likely, a coherent family of languages). Further more, I'm guessing that people will become so disenchanted with the languages they are now using—even COBOL and FORTRAN—that this new language UTOPIA 84, will have a chance to take over. At present we are far from that goal, yet there are indications that such a language is very slowly taking shape.

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Structured programming with go to statements

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↑ ABSTRACT

For serious students of structured programming, and also for language designers, Knuth's "Structured Programming with go to Statements" is probably the paper to read. It is by far the most complete description of structured programming of all the selections in this book. Even though it originally was published in late 1974, Knuth's ideas have not aged a bit.

The title, as Knuth acknowledges, is somewhat of a misnomer. "I should confess that the title of this article was chosen primarily to generate attention. Indeed, he is not arguing that structured programming always should be carried out with goto statements, instead, as he says, "what I am really doing is striving for a reasonably well-balanced viewpoint about the proper role of go to statements." Like a number of other authors whose views are presented in this book, Knuth seems deeply concerned that the average programmer will over-react to the "no goto" philosophy. Reflecting that concern, the first few pages of Knuth's paper give an indication of the fanaticism of its time --- a fanaticism that has largely died away.

For history buffs, Knuth has carefully documented the origins of structured programming. He claims that the programming style now referred to as "structured programming" actually was first practiced by D. V. Schorre in 1960, and that was followed by publication of the work of Peter Naur in 1963 and of George Forsythe in 1964 -- all of this before the better-known works of Dijkstra, and of Born and Jacopini.

There are three major themes in Knuth's paper, and a vast number of examples to illustrate each one. One theme --- a familiar one, if you've read many of the other papers in this book is that a program needs to be rewritten several times before it can be considered a truly good program. As Knuth says, "I learned again that I should always keep looking for improvements, even when I have a satisfactory program." Indeed, one gets the impression that Knuth views this as the major virtue of structured programming. The requirement to eliminate gotos forces the programmer to rewrite and thus think more about what he was trying to accomplish with his program.

A second theme --- one that you won't find in any of the other papers - is that efficiency is important in some programming applications and that the programmer needs the freedom to use gotos to optimize critical portions of a program. Actually, Martin Hopkins makes the same point in "A Case for

the GOTO" [Paper 9], but he does so much less forcefully than Knuth. Knuth recognizes the danger of overemphasizing optimization, as he says, "premature optimization is the root of all evil." And, he does state that only three percent of the code in a typical program ever needs to be optimized, but for that critical three percent, he demonstrates that structured code often is twenty to thirty percent less efficient than equivalent code with gotos. Unfortunately, the point is repeated so many times, with so many examples, that the average reader is likely to conclude that Knuth is obsessed with efficiency. However, given the number of authors exhorting programmers to ignore efficiency altogether, it is probably very healthy to have someone argue for a careful consideration of program efficiency.

Knuth's third main theme is that structured programming could be made much more practical with the addition of a few language constructs. In addition to constructs like LEAVE and BREAK, Knuth argues for a "situation" construct patterned after a proposal originally made by C. T. Zahn.

In keeping with the heretical title of his paper, Knuth introduces a fourth theme. There are times when the programmer should put gotos into his code, rather than take them out. For example, gotos can be used to convert recursion to iteration, or to implement coroutines, or to eliminate Boolean variables by branching into common code. In this context, Knuth suggests the following strategy: First, write the program in a structured manner to convince yourself that it is correct, then, transform it into an efficient program, possibly by introducing some goto statements, and, finally, leave the original structured code behind as documentation, so that subsequent readers can understand how the transformation took place. Whether the average programmer would go through these steps in an orderly, formal way is something worth pondering. My own suspicion is that it won't work, but I'm often branded a skeptic.

To conclude: It's probably best not to read Knuth's paper in one sitting, for you almost surely will become mentally fatigued by the eight major examples, each of which is rewritten three or four (or more!) times in an ALGOL-like pseudocode. Read the paper piece by piece, and do read the code --- you'll learn a lot from it!

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tab 14

**PLAINTIFF'S
EXHIBIT**

24

Infant CPR

Performing CPR

In most cases when a baby dies from SIDS it is not preventable and there is nothing a parent or carer can do to revive the baby. However, occasionally a parent or carer finds the baby soon after their breathing has stopped and performing mouth to mouth resuscitation (or CPR - cardiopulmonary resuscitation) is able to revive them.

If you have concerns about SIDS (or have lost a previous baby) you may consider learning Infant CPR during the pregnancy (which is different from child or adult CPR). Some hospitals teach infant CPR to parents whose baby were born very prematurely before taking their baby home after spending an extended time in the intensive care ward. Infant CPR can be used for babies up to 12 months of age.

NOTE Reading about how to perform infant CPR is not enough to teach you how to do it correctly. The following information is guide only. You should attend an approved course to learn CPR. For example through St John's Ambulance, their website is

www.stjohn.org.au

Performing CPR If you can't detect signs of your baby breathing and they are limp and unable to be roused or woken (their skin and lips may also look a dusky grey or purple blue colour, especially if they are fair skinned) you need to call an ambulance or get someone who is with you to call the ambulance.

Call 000 in Australia

Try and stay calm. Even though the situation is frightening, your baby needs you to keep a cool head to perform CPR. Take note of the time if you remember and how you found the baby, the way they were lying if they were covered with bedclothes etc. Sometimes picking up the baby and stimulating them by touching them or tickling their feet will prompt them to breathe (do not shake them vigorously, this can hurt them). If they are not responding, you will need to help them to breathe with mouth to mouth resuscitation. This can be done by

- Laying the baby flat on their back on a firm surface, with their head lying straight or in a sniffing position (do not tilt their head right back)
- Hold the baby's chin with your fingers (being careful not to lean on their neck)
- Place your mouth over the baby's **NOSE and MOUTH** forming a tight seal. **PUFF** every 2 seconds (**DO NOT BLOW**). Use only as much air as you can keep in your cheeks to inflate the baby's lungs with each breath. You may need to continue this until help arrives. The baby's chest should rise and fall with each puff. If not, reposition your mouth to get a tighter seal.

It is usually possible to feel a newborn's heartbeat by placing your fingers in the middle of their chest with the index and middle fingers. A pulse may also be felt in their groin (either side) or more easily on the inside of their arm, half way between their shoulder and elbow. If your baby remains unconscious after giving several breaths with mouth to mouth resuscitation and you are unable to feel a pulse (feel for at least 5 seconds) you may need to start heart compressions. This can be done by

- 1. Positioning your index and middle fingers in the middle of the baby's chest on their breastbone, in line between the baby's nipples
- 2. Press down with 2 fingers to a depth of about 2 cms at a rate of 2 per second, keeping the fingers on the chest at all times. Do 4 compressions over 2 seconds, then perform mouth-to-mouth resuscitation with 1 breath before repeating the 4 compressions and then 1 breath again.
- 3. After one minute of doing this continually, check for a pulse. If a pulse is felt but the baby is not breathing, continue the breaths, giving 1 every 2 seconds. If no pulse is felt, continue the cycle of chest compressions and breaths (4 compressions to 1 breath) until the baby responds or help arrives.

SIDS Considerations

A baby dying is undoubtedly one of the most devastating experiences a parent could ever have to face. The profound pain that follows can be intensely consuming and often misunderstood by family and friends. No parent wishes to hear, nor discover that their baby has died. It is difficult to even describe how parents may feel at that instant. Disbelief, shock, immense emotional pain, and feeling like their heart is breaking. For parents who have lost a baby or young child through SIDS, it is extremely hard to accept the fact there may be no answers as to 'Why?'

The emotions and grief experienced and the many issues relating to the death of a baby are dealt with in baby dying. However, there are a few aspects that are different in the case of a baby dying from SIDS.

Police involvement

Doctor's certification

Autopsy and coroner's investigation

Police involvement It is a requirement of law in Australia that police are involved (by visiting the house) if a baby is thought to have died from SIDS. This is not related to accusations of guilt on the part of the parents or carer but a necessary part of the steps that need to be taken to determine the cause of death in the baby. It is normal for parents (or the carer) to feel an enormous sense of responsibility. This can contribute to a profound sense of chaos and unreality and perhaps that you are losing control. It is important to understand that the cause of SIDS is outside your control, although this issue can be very hard to deal with.

Doctor's certification A certification of death must be issued by a medical practitioner. This is also a requirement of law. You will need to call your local doctor to come and perform this duty. They can also provide information and support.

Autopsy and coroner's investigation An autopsy is required in

every case of suspected SIDS and the coroner must report on this to confirm that the death was not preventable. This can be distressing but may also relieve feelings of guilt when a cause is not found. In many cases an autopsy is performed within 24 to 48 hours but the final results are usually not available until all the tests are completed which can take up to 12 weeks.

You should be allowed to spend adequate time with your baby to hold them and say goodbye perhaps even accompany them to the place where the autopsy will be performed. For more information about keeping mementos and funeral arrangements you can read [baby dying](#).

THE STATE OF SOUTH CAROLINA

In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas
James C Williams, Jr , Circuit Court Judge

Case No CA-08-CP38-826

Kareem J Graves and Tara Graves,
individually and as duly appointed personal
representatives of the Estate of India Iyanna Graves

Appellants,

vs

CAS Medical Systems, Inc

Respondent

PROOF OF SERVICE

I certify that I have served one (1) copy of the Record on Appeal, by depositing a copy of it in the United States Postal Service, shipping prepaid, on December 3, 2010, addressed to Respondent s attorney of record, Clarke W Dubose, Esquire, Haynsworth Sinkler Boyd, P A , 1201 Main Street, 22nd Floor, Columbia, South Carolina 29201-3226

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J Edward Bell, III
Thomas William Winslow
The Bell Legal Group, LLC
232 King Street
Georgetown, SC 29442
Tel 843-546-2408
Fax 843-546-9604
Attorney for the Appellants

December 3, 2010
Georgetown, SC