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 III

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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

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November 5, 2010

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go under clothes and instead of just letting it beep I would cut it off until -- I mean, if it was right there and I could stick it, I would put it back and then I would reset it, but if it was under a t-shirt and I had to go through a lot of clothes, I would just cut it off

Q Now, you said that you shared duties helping your sister out with your mother, is that correct?

A Yes

Q That's a yes?

A Yes

Q And your mother did not like using the monitors, did she?

MR WINSLOW Object to the form

THE WITNESS Not that I know of I don't know I don't --

BY MR BESLEY

Q Did your mother feel comfortable using the monitors?

A Yes

Q She did?

A She knew how to do it just like I knew how to do it

Q But did she ever express to you a

Q The alarm, I've heard it, it's so loud it kind of hurts your ears --

A Yeah

Q -- and a beep sounds like, you know, turning your cell phone on or off, so I wanted to make sure you and I were talking about the same thing You're talking about the alarms?

A The alarms That's what y'all call them I'm saying a beep, but it's still the noise that comes up when you have got apnea or it comes up with loose leads

Q And the problem that you were referring to was the fact that it would sometimes go off -- the alarm would go off when it did not need to be going off?

A Yeah

Q That's yes?

A Yes

Q Now, after India's death did you continue to use the monitors on the other two babies?

A Yes

Q Were there any problems at any point until the time they had to quit using monitors?

A Say that again

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STATE OF SOUTH CAROLINA)
)
COUNTY OF RICHLAND)

IN THE COURT OF COMMON PLEAS

CIVIL ACTION NO 06-CP-40-7398

KAREEM J GRAVES and TARA GRAVES Individually and as duly appointed personal representatives of the ESTATE OF INDIA IYANNA GRAVES)
)
Plaintiffs)
)
vs)
)
CAS MEDICAL SYSTEMS INC)
)
Defendants)

THE VIDEOTAPED DEPOSITION
UPON ORAL EXAMINATION OF

DONNA ALFORD WILKINS M D ,

a witness produced and sworn before me Mary Beth Schafer, RPR a Notary Public at large in and for the State of Indiana, taken on behalf of the Defendant at Ball Memorial Hospital 2401 University Avenue Maria Bingham Building Conference Room 1033 Muncie Delaware County Indiana on July 25 2008 commencing at approximately 9 00 a m , pursuant to the South Carolina Rules of Civil Procedure

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THE VIDEOGRAPHER We are back on record
It's 11 05
QUESTIONS BY MR DUBOSE
Q Doctor, when we went off the record, you were looking at the download to give an answer to the question of when in your opinion the child was at a point when she could not be resuscitated
A Correct
Q And do you have anything to add to what we were talking about in that regard before we went off the record?
A No
Q Other than what we've talked about, are there any other factors, documents, records or medical studies that support your opinion that this child could have been revived on the night of April 10 and 11?
MR WINSLOW Object to the form
A No, other than just my experience in the NICU of babies that have episodes like she was having, that they can have a very low heart rate and become -- and be apneic, and usually if they're stimulated, then they will start breathing, and their heart rate picks up and they're resuscitatable and don't actually need CPR like Tara did to her
Q Do you know whether the children that you're referring to in these NICUs were experiencing sudden infant death

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syndrome?
A No
Q Do you know whether in the NICU here at Ball Memorial Hospital you ever successfully resuscitated a child having a SIDS event?
MR WINSLOW Object to the form
A I can't recall any baby that we would assume it had a SIDS event Usually there's some other etiology of why they're apneic and bradycardic They're septic They have meningitis There's something else going on that makes them have a severe episode -- that severe an episode, airway obstruction, whatever We would never say, well, that was a SIDS event I mean we don't put that -- or an acute life-threatening event We don't call them an ALTE We call them apneic and brady episodes in the nursery, so
Q So the answer to my question would be what?
A No
Q Is there any medical literature that you can point me to that supports what you're telling us today, that the child could have been revived?
A No
Q Have you discussed this part of your opinion that India Graves could have been revived with any of your colleagues?

A No
Q Have you done any research to determine what the medical literature would say with regard to a situation like India's and whether she would be revived or could be revived, I beg your pardon?
A I'm basing it on the fact that the episode lasted so long that had intervention happened, that she would have been resuscitated If all of a sudden it alarmed, she was asystolic, immediately I would say no, she probably couldn't have been resuscitated, but this is a long period over an hour of bradycardia, hypoxia I mean she is slowing dying over this hour, and I think she could have been resuscitated
Q My question was a little more particular than that I'm going to get the court reporter to read it back
(The requested material is read by the court reporter)
A Answer is no
Q Have you contacted or in any fashion any SIDS experts to determine whether or not on the night of April 11, 2004, India Graves could have been revived when she began having this episode?
A No
Q Do you consider yourself an expert in SIDS?
A No

Q And why not?
A I mean we -- well, I take that back The only instance that we might do that would be a sibling of a SIDS If mom has a history, although nobody has proven, you know, that they need to be monitored, but they're always very uptight after having a SIDS baby, so they have another newborn, and often we'll send those babies home on monitors
Q Other than situations where you have a family who has already had one child die of SIDS, why is it your -- not your practice to send monitors home with children to guard against sudden infant death syndrome?
A Because there's no proof that a monitor is going to prevent a SIDS
Q When you send parents or caregivers home with monitors for their newborns, do you have a discussion with them about what the monitor can and cannot do?
A Yes
Q Tell us what you tell the caregivers
A Well, we tell them initially if the baby is on oxygen that the monitor should be on 24/7 initially, and that they should make a log of the alarms that they hear go off and what it's alarming for, and how they found the baby, what they had to do If the baby was pink and everything was fine, you know, they need to write that

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down and take that to their pediatrician when they are seen and just continually keep a log And, you know, we tell them that, you know, a monitor is not necessarily going to save a baby's life, yes

Q And why do you tell them that the monitor will not necessarily save the baby's life?

A Because it won't I mean if it was proven to do that, you would -- if we wanted to really prevent SIDS, we'd sent every single newborn born home on a monitor if we really thought it was going to make our SIDS zero percent

Q And when you tell them that, are you contemplating a properly functioning monitor?

A Oh, yes

Q And so essentially what you're telling the parents when you send them home with a monitor from the -- from your hospital is that assuming the monitor functions properly, it's not necessarily going to save your baby's life?

A That's right

Q Okay In looking at the download Exhibit 3

A Okay

Q Let me get you to turn to a page we've looked at before, page 2 of the summary of the log

A Okay

possibly been helpful to had the monitor on during that time period?
A No
Q You don't think we could look back at that download for that period and get any indication as to what happened to India?
A No
Q Because we don't have the monitor on, and, therefore, don't have a download, we don't know whether India was having bradycardia events and apnea events during that time period, do we?
A No
Q We talked early in the deposition about the postmortem and whether you agree or disagree with it Have you independently arrived at a diagnosis as to what happened to India?
A That she just became bradycardic and apneic and died
Q Beyond that?
A No
Q Have you arrived at a diagnosis?
A No
Q And is it fair to say then that you don't have a medical opinion as to what caused India's condition that led to her death?
A No

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Q Let me rephrase that question if I may, Doctor, to get a clearer answer, and it's not your fault It's mine Do you have, Doctor, a medical opinion as to what led to the condition that India suffered the night she died?

MR WINSLOW Object to the form

A I mean whether this was just severe episodes because of her prematurity, I don't know They didn't prove any infection They wrote it off as a SIDS because they didn't find a pathological reason for her death So I don't know, I mean

Q Well, just to be clear, my question was whether you have made an independent determination of what caused the condition that led to her death?

A No

Q When we were talking about the download a little while ago, you found one entry, if we could call it that, that you weren't clear on, that didn't seem clear to you Are there any others that you have a question about?

A No, I don't think so That's the only one

Q Are you qualified to testify whether or not the decline in India leading to her death that is shown on the download, Exhibit 3, is typical or not typical of a SIDS death?

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April 24, 2008

Donna A Wilkins, M D
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RE Kareem J Graves, et al vs Ashby Medical, Inc , et al
C/A No 06-CP-28-421

Dear Dr Wilkins

With regards to the above referenced matter, I kindly ask you to provide me with (3) available deposition dates for the month of May and first week of June Please be advised this case will be going to trial the week of June 16th and therefore, I would like to confirm your availability, if possible, please place a hold for the week of June 16, 2008 I will confirm your designated date for testimony when the trial nears Lastly, I am enclosing the following depositions for your review

- Deposition of Jane V Gwinn, M D ,
- Deposition of C Guy Castles, III, M D ,
- Deposition of Steven Elliot,
- Deposition of Tara Graves,
- Deposition of Kareem Graves,
- Deposition of April Simmons,

After reviewing the depositions please contact our office to discuss your opinion. If you have any questions or need further information, please do not hesitate to contact me or my paralegal, Stephanie Miller at (843) 546-2408

With kindest regards, I am

Yours Truly,

Thomas William Winslow

TWW/sam
Enclosures (6)

TOM CELL

DEFENDANT'S EXHIBIT 7 7-25-08

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April 3 2009

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The Honorable James C Williams, Jr
Chief Administrative Judge
Circuit Court One
PO Box 1949
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Re *Kareem J Graves et al. v CAS Medical Inc et al*
Civil Action No 08-CP-38-826

Dear Judge Williams

At the last hearing on March 17 I had advised the Court that I would be able to supplement Plaintiff's discovery responses in this case within 30 days

Since that hearing I have been in contact with my experts and they have informed me that they are preparing for final exams (both of these experts are professors) They have begun the process of pulling out the bad code but have asked if I would be able to obtain a continuance to further test and study this software While the experts understand the urgency of complying with the Court's ruling, they are asking for additional time to work on these issues as well as prepare for final exams They are asking for an additional 60 to 90 days in order to complete final exams and finish dissecting the code

Also your Honor may recall that he requested the parties to advise of any case law regarding the production of native formats of the expert reports I have received a letter from Mr DuBose stating that he is unable to locate any such case law on point, however, still he claims this to be discoverable It is Plaintiff's position that such native formats of the report, are not discoverable as they were merely works in progress The production of such items would run shivers down the spine of all litigation attorneys and experts alike as an expert would be fearful of making the slightest of changes to any report for fear the opposing counsel would claim that the attorney and/or expert had changed their opinion As the Court and defense counsel is well aware an expert may draft a report and counsel may assist with formatting changes Should the Court rule that the native format is discoverable, both plaintiff's and the defense bar would also fear to make even the slightest of formatting changes, even if done (as is the case in most instances) to simply comply with local rules, or else they would be accused of changing the experts opinion Lastly at best the most information that could be gleaned from such a native format could only really be used as fodder for cross examination Clearly defense counsel is on some rabbit trail, and the production of such information is of no real value in this case or in the pursuit of judicial economy

With kindest regards I remain

Yours very truly

Thomas W Winslow
Attorney at Law

TWW/scs

cc Clarke W DuBose Esquire

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April 7 2009

VIA EMAIL

The Honorable James C Williams Jr
Chief Administrative Judge – Circuit 1
Orangeburg County Courthouse
190 Gibson Street
Orangeburg, SC 29116

Re *Kareem J Graves and Tara Graves individually and as duly appointed personal representatives of the Estate of India Iyanna Graves v CAS Medical Systems Inc*
Civil Action No 08 CP 38-826
HSB File No 08965 0013

Dear Judge Williams

I received today a copy of plaintiffs counsel s letter to you dated April 3 and am writing to respond to plaintiffs request for an extended period to provide expert opinion on the software defect alleged to exist in my client s product the AMI Plus monitor I will respond in a separate letter to the question of production of plaintiffs experts draft reports which is a more complex issue

CAS Medical objects to plaintiffs request for an extended additional period of time to develop expert testimony In short plaintiffs have already had far too much time to obtain this information, as is illustrated by the fact that CAS first requested these opinions by interrogatories dated September 14 2006 Plaintiffs current request for time can only be seen as an attempt to further delay this case presumably in hopes of gaining some strategic advantage thereby

A more detailed chronology of the length of time plaintiffs have had to obtain meaningful expert opinions from plaintiffs should make this clear India Graves died on April 11 2004 Suit was brought on April 9 2006 On September 14 2006 CAS served on plaintiffs its first interrogatories that included its expert opinion interrogatory Plaintiffs did not answer this discovery until January 8, 2007, but failed in their answers to identify any computer expert naming instead only a medical expert

After repeated discussions with plaintiffs counsel CAS counsel on April 24 2007 wrote him a letter insisting on these answers within a reasonable time The expert interrogatory was not answered so CAS moved to compel on July 2 2007 CAS followed this with a motion for summary judgment dated October 5 2007 when it became clear that nothing short of the threat of dismissal would compel plaintiffs to name their experts on the critical issue in the case

Plaintiffs counsel attempted to postpone the hearing on the motions claiming he needed more time to get the expert opinions but the hearing went forward on October 14 2007 Plaintiffs avoided a determination on the merits by supplying opinion affidavits of computer expert Lively and biomedical engineer Painter dated October 12 2007 Although the affidavits fell short of identifying the defects that allegedly caused the monitor to fail CAS had no real choice but to withdraw its motion and depose the experts

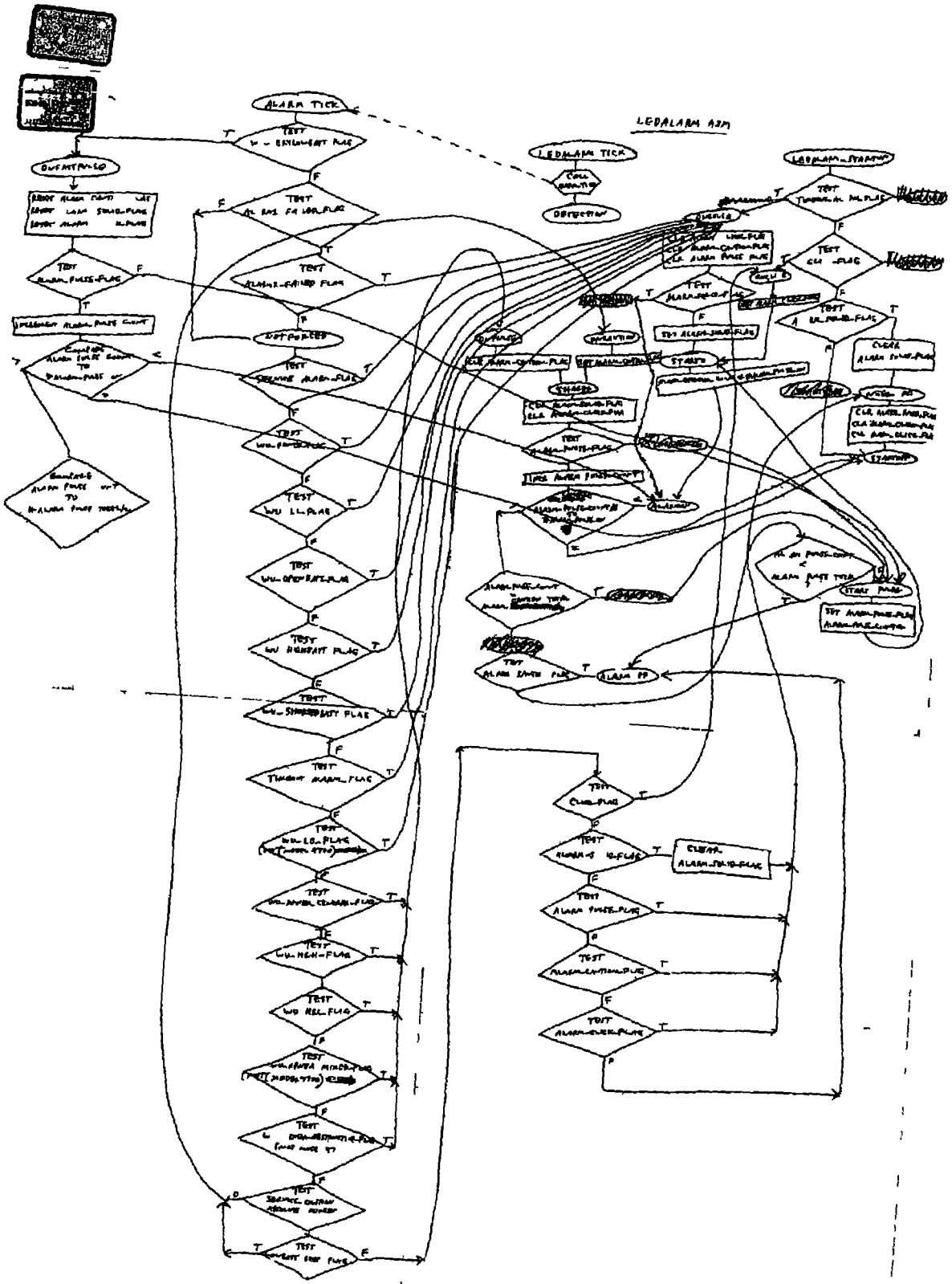
Plaintiffs experts were to be available in January and notices were sent accordingly but again plaintiffs counsel delayed the case going forward by delaying these depositions Lively and another computer expert, Daugherity, were not made available for deposition until May of 2008 and were deposed on May 22 23 2008 As the Court has seen despite plaintiffs representation that both were fully prepared for their depositions neither had identified any causative defect within the code itself and neither was prepared at all to testify as to how the monitor could reflect that its internal microphone heard the alarms if the alarms did not sound In fact they did not understand that the monitor recorded this information

Plaintiffs then requested the software for Report Generator which is the program that when loaded on a personal computer allows a user to download the event log from the monitor In November of 2008 plaintiffs requested and were provided (on November 20 2008) with the source code for Report Generator which is separate software that will give the trained viewer a better understanding of how the program works It is important to note that a defect in Report Generator if one existed would have nothing to do with the monitor not alarming CAS does not believe a defect in Report Generator could affect the substance of the log as it appears in the printed patient report in this case either but such a defect could in no way cause an alarm to fail since Report Generator as its name states generates reports and does not control the operation of the monitor

In conclusion CAS has been trying to obtain meaningful expert opinions supporting plaintiffs allegations for a full 2 1/2 years CAS s efforts have been blocked or delayed time after time by plaintiffs In light of this record of delay plaintiffs present request for months of additional time is completely unreasonable CAS therefore requests that the Court deny any further extension to plaintiffs and likewise deny any formal motion plaintiffs might make for reconsideration or modification of the Court s order

Yours truly

Clarke W DuBose
CWD/kg
cc Thomas W Winslow Esq (via email)


ALARM TICK
LEDALARM ASM
LEDALARM TICK
LEDALARM_STAMPER

Preliminary Study Report | Ami Apnea Monitor | Summary Report

« Patient Information » | Graves India
1 803 518-8869 | PRMH 021404

« Study Ends »

Ami Monitor	04/12/04 Mon	09 44 04	
Rep Gen PC	04/12/04 Mon	10 39 27	[At Time Of Transfer]

« Monitor Setup »

Aux 1 Signal	O2 Satur	HR Slow Mode	5 Second Delay
Aux 2 Signal	PulseRate	Event Capture	FIFO Full Dura
Aux 3 Signal	*Position*		

« Monitor Limits »

Apnea Alarm	20 Sec	Apnea Log	20 Sec
Heart Slow	80 BPM	Heart Slow	80 BPM
Heart Fast	250 BPM	Heart Fast	250 BPM
		Desaturation	85 % Sat

« Recorded Events »

Monitor Logs	28 of 2000	Study Start	04/01/04 Thu 12 16
Patient Logs	*79 of 2000*	*Study Period*	1 Week 4 Days
Event Waves	26 1% Filled	Monitor Time	3 Days 14 Hours [32 7%]
		Periodic Br	3 Hours 59 Mins [4 6%]

« 31 Recorded Waveforms »

Apneas	13	Heart Slows	17
Desaturations	0	Heart Fasts	1
		Study Is Not Reviewed	

« Events Counted »

Monitor Ons	14	Monitor Offs	13
Apneas	13	Heart Slows	17
Desaturations	0	Heart Fasts	1
Loose Leads	40		

« Modem Answer Only »

« System Version »

Serial Numb	10114701	Ami Monitor	13 00 28 NOV 01
Access Code	8782	Report Generator	01 1a 19 Mar 99

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Daugherity
EXHIBIT NO 7

ASHBY MEDICAL Ami Apnea Monitor All Study Logs

	Date	Time	Event Type		
< 1 >	02/13	15 56 32	Monitor Powered Up		
< 2 >	04/01	12 18 40	New Recording Start		
< 3 >	04/01	12 18 57	Monitor Powered Down		
< 4 >	04/01	12 18 46	Monitor Powered Up		
1	04/01	18 07 46	Battery Getting Low	2 Hours	31 Mins
2	04/01	20 39 17	Battery Very Low	30 Secs	
< 5 >	04/02	08 39 10	Monitor Powered Down		
< 6 >	04/03	01 31 31	Monitor Powered Up		
< 7 >	04/03	08 12 06	Monitor Powered Down		
< 8 >	04/03	22 14 22	Monitor Powered Up		
3	04/04	01 34 59	Battery Getting Low	39 Mins	34 Secs
4	04/04	08 22 50	Loose Lead		2 Secs
< 9 >	04/04	08 23 04	Monitor Powered Down		
< 10 >	04/04	20 39 41	Monitor Powered Up		
5	04/05	04 12 19	Loose Lead		1 Sec
6	04/05	04 12 19	Loose Lead		1 Sec
7	04/05	04 12 20	Loose Lead		51 Secs
8	04/05	04 13 10	Loose Lead		1 Sec
9	04/05	04 13 11	Loose Lead		1 Sec
10	04/05	04 13 12	Loose Lead		1 Sec
11	04/05	04 13 12	Loose Lead		1 Sec
< 11 >	04/05	09 05 33	Monitor Powered Down		
< 12 >	04/05	11 50 34	Monitor Powered Up		
12	04/05	13 00 40	Loose Lead		12 Secs
< 13 >	04/05	13 00 53	Monitor Powered Down		
< 14 >	04/05	13 28 09	Monitor Powered Up		
13	04/05	13 32 17 ‡	Heart Fast	*	2 Secs
14	04/05	14 16 40	Loose Lead		1 Sec
15	04/05	15 24 23	Battery Getting Low	1 Mins	22 Secs
< 15 >	04/05	15 25 45	Monitor Powered Down		
< 16 >	04/05	21 36 32	Monitor Powered Up		
16	04/05	23 49 10	Battery Getting Low	6 Mins	34 Secs
17	04/06	02 11 05	Loose Lead		1 Sec
18	04/06	02 20 46	Loose Lead		1 Sec
19	04/06	02 21 06	Loose Lead		1 Sec
20	04/06	07 41 04	Loose Lead		13 Secs
< 17 >	04/06	07 41 17	Monitor Powered Down		
< 18 >	04/07	21 11 26	Monitor Powered Up		
< 19 >	04/08	07 34 49	Monitor Powered Down		
< 20 >	04/08	20 51 32	Monitor Powered Up		
< 21 >	04/08	20 54 44	Monitor Powered Down		
< 22 >	04/08	20 55 34	Monitor Powered Up		
21	04/08	21 18 44	Loose Lead		1 Sec
22	04/08	21 18 46	Loose Lead		1 Sec
23	04/08	22 01 12 ‡	Apnea		30 Secs
24	04/09	00 47 04	Loose Lead		1 Sec
25	04/09	00 47 35	Battery Getting Low	2 Hours	51 Mins
26	04/09	00 47 51	Loose Lead		1 Sec
27	04/09	00 48 42	Loose Lead		1 Sec
28	04/09	02 03 32	Loose Lead		1 Sec
29	04/09	02 03 36	Loose Lead		1 Sec
30	04/09	02 03 39	Loose Lead		1 Sec
31	04/09	02 04 49	Loose Lead		1 Sec
32	04/09	02 04 56	Loose Lead		1 Sec
33	04/09	02 04 57	Loose Lead		1 Sec

34	04/09	02 05 01	Loose Lead	1 Sec	
35	04/09	02 05 08	Loose Lead	36 Secs	
36	04/09	02 05 44	Loose Lead	1 Sec	
37	04/09	02 05 44	Loose Lead	1 Sec	
38	04/09	02 05 45	Loose Lead	1 Sec	
39	04/09	02 05 46	Loose Lead	1 Sec	
40	04/09	02 05 46	Loose Lead	1 Sec	
41	04/09	02 05 48	Loose Lead	2 Secs	
42	04/09	02 05 49	Loose Lead	1 Sec	
43	04/09	02 05 49	Loose Lead	1 Sec	
44	04/09	03 38 38	Battery Very Low 4 Mins	3 Secs	
45	04/09	03 40 44	Loose Lead	8 Secs	
< 23 >	04/09	03 42 40	Monitor Powered Down		
< 24 >	04/10	20 52 38	Monitor Powered Up		
46	04/10	20 53 08	Loose Lead	24 Secs	
< 25 >	04/10	20 53 32	Monitor Powered Down		
< 26 >	04/10	21 16 59	Monitor Powered Up		
47	04/10	21 28 03	Loose Lead	1 Sec	
48	04/10	21 28 40	Loose Lead	1 Sec	
49	04/10	21 36 11	Battery Getting Low 4 Mins	56 Secs	
50	04/10	22 30 17	Loose Lead	1 Sec	
51	04/11	01 39 56 ‡	Heart Slow	2 Mins	6 Secs
52	04/11	01 40 50 ‡	Apnea	21 Secs	
53	04/11	01 41 11 †	Apnea *	36 Secs	
54	04/11	01 42 12 †	Heart Slow *	11 Secs	
55	04/11	01 44 19 ‡	Heart Slow	11 Secs	
56	04/11	01 44 31 †	Heart Slow	41 Secs	
57	04/11	01 45 18 †	Heart Slow	8 Secs	
58	04/11	01 45 28 ‡	Heart Slow	17 Secs	
59	04/11	01 45 52 †	Heart Slow	6 Secs	
60	04/11	01 46 06 †	Heart Slow	25 Secs	
61	04/11	01 46 33 ‡	Heart Slow	21 Secs	
62	04/11	01 47 13 †	Heart Slow	7 Secs	
63	04/11	01 47 22 †	Heart Slow *	15 Secs	
64	04/11	01 47 39 ‡	Heart Slow	18 Secs	
65	04/11	01 47 59 †	Heart Slow	11 Secs	
66	04/11	01 48 11 ‡	Heart Slow	1 Mins	17 Secs
67	04/11	01 49 30 †	Heart Slow	27 Secs	
68	04/11	01 49 32 ‡	Apnea	26 Secs	
69	04/11	01 49 58 †	Apnea	30 Secs	
70	04/11	01 49 59 ‡	Heart Slow	1 Hours	0 Mins
71	04/11	01 50 36 ‡	Apnea	54 Secs	
72	04/11	01 51 37 ‡	Apnea *	1 Mins	13 Secs
73	04/11	01 52 57 ‡	Apnea	1 Mins	14 Secs
74	04/11	01 54 10 ‡	Apnea	5 Mins	31 Secs
75	04/11	01 59 41 ‡	Apnea	1 Mins	12 Secs
76	04/11	02 00 53 ‡	Apnea	32 Mins	51 Secs
77	04/11	02 33 44 ‡	Apnea	15 Mins	57 Secs
78	04/11	02 49 41 ‡	Apnea	33 Secs	
79	04/11	02 50 15 ‡	Heart Slow	18 Secs	
< 27 >	04/11	02 50 31	Monitor Powered Down		
< 28 >	04/12	09 41 00	Monitor Powered Up		
< 29 >	04/12	09 41 27	Detection Disabled		
<Amr>	04/12	09 44 04	Received 29 Monitor Logs		
	04/12	09 44 04	Received 79 Patient Logs		

Event Count Totals

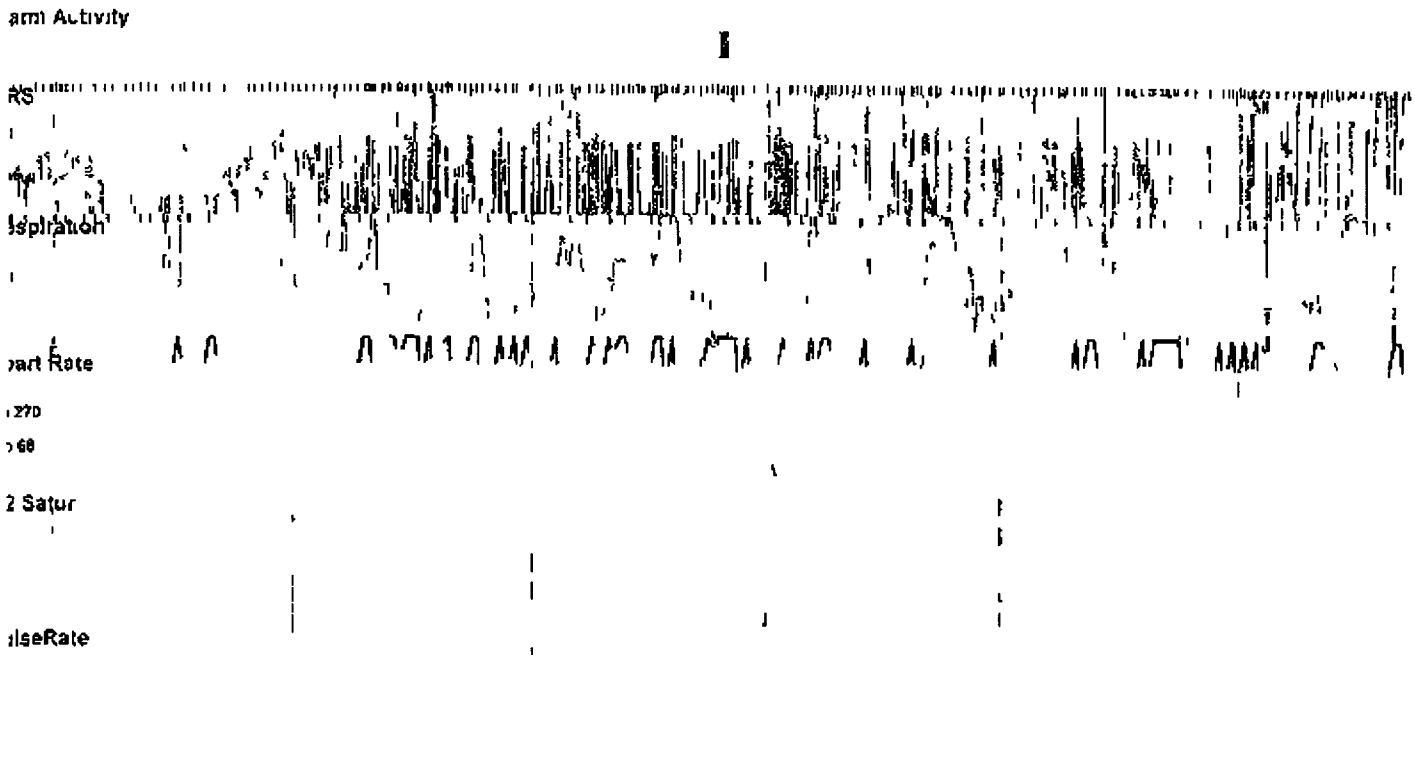
14 Monitor Ons	13 Monitor Offs
13 Apneas	17 Heart Slows
0 Desaturations	1 Heart Fasts
40 Loose Leads	

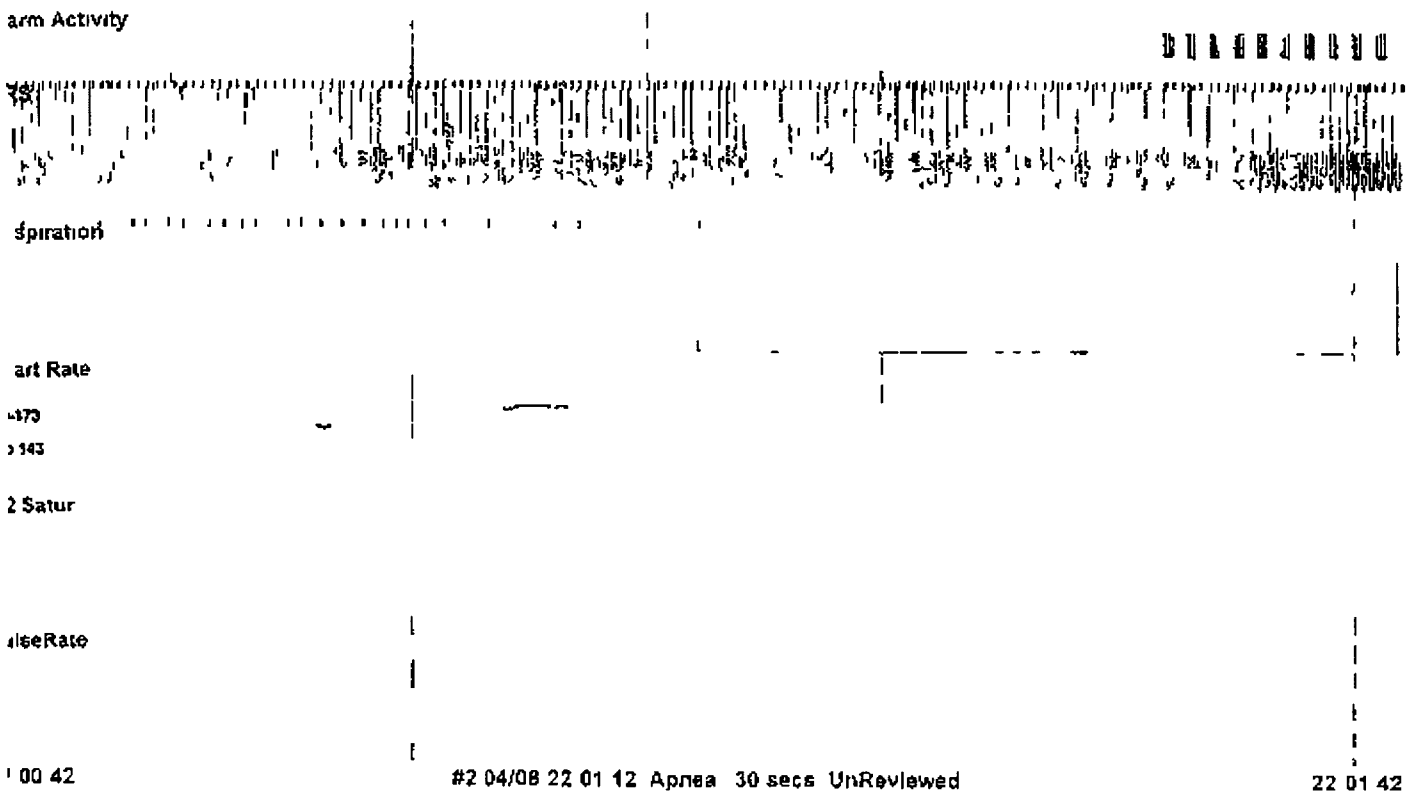
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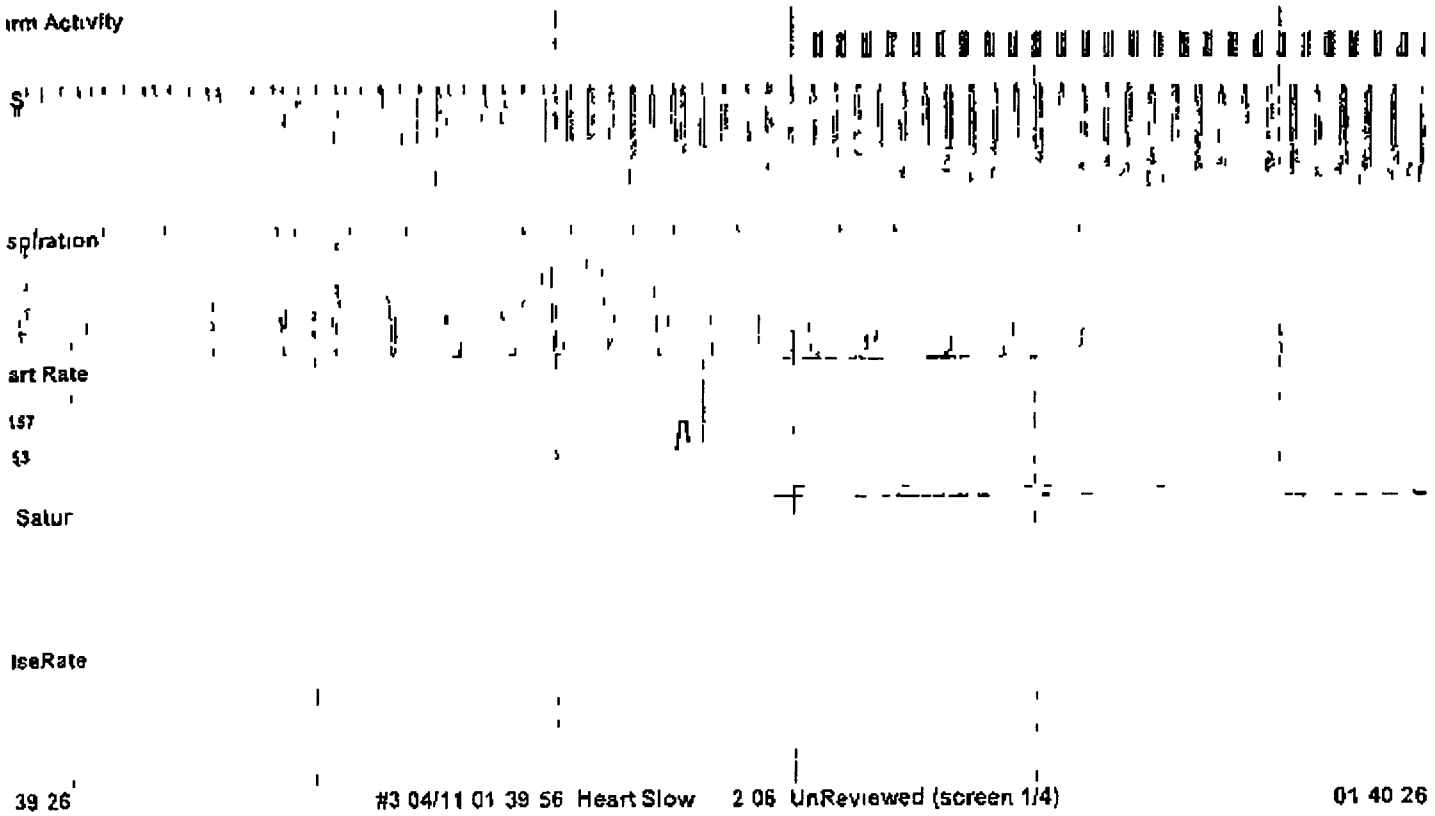
Graves,India PRMH 021404
Event List

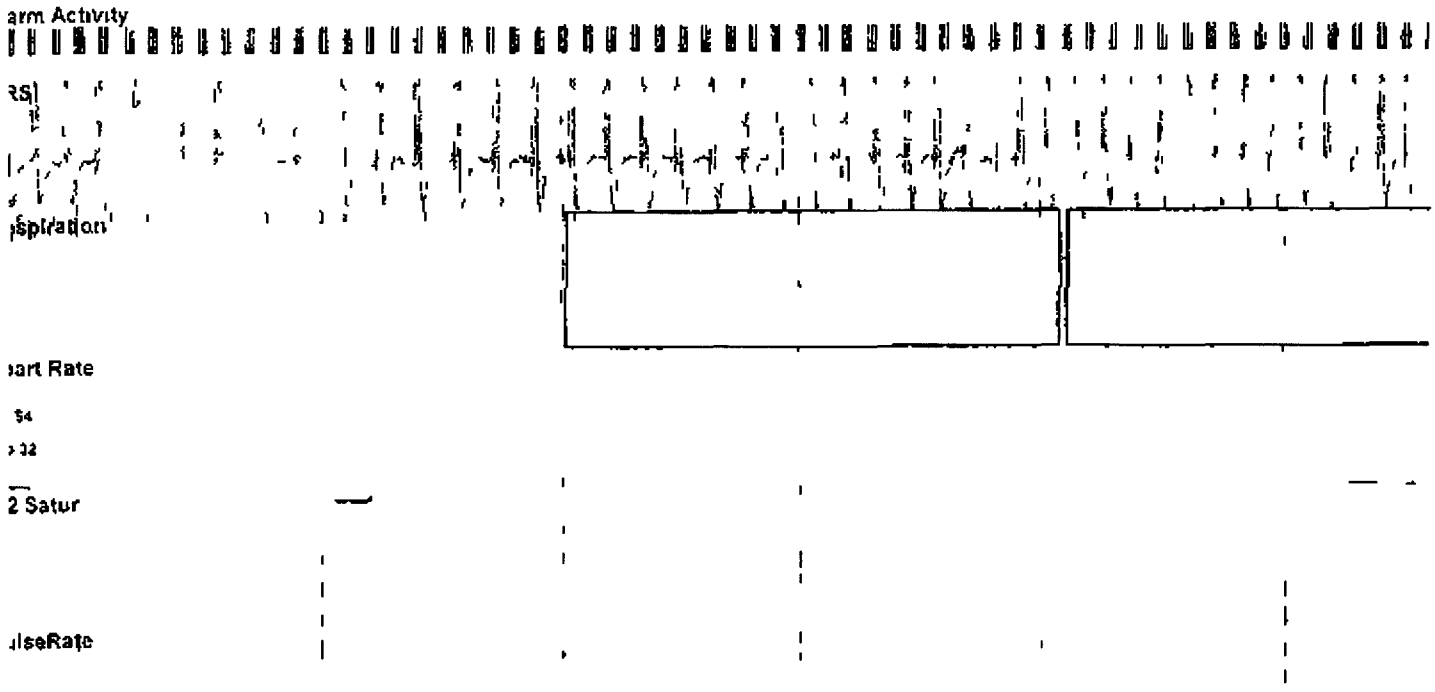
#	Date	Time	Event	Duration	Reason
1	04/05	13 32 17	Heart Fast	2 secs	UnReviewed
2	04/08	22 01 12	Apnea	30 secs	UnReviewed
3	04/11	01 39 56	Heart Slow	2 06	UnReviewed
4	04/11	01 40 50	Apnea	21 secs	UnReviewed
5	04/11	01 41 11	Apnea	36 secs	UnReviewed
6	04/11	01 42 12	Heart Slow	11 secs	UnReviewed
7	04/11	01 44 19	Heart Slow	11 secs	UnReviewed
8	04/11	01 44 31	Heart Slow	41 secs	UnReviewed
9	04/11	01 45 18	Heart Slow	8 secs	UnReviewed
10	04/11	01 45 28	Heart Slow	17 secs	UnReviewed
11	04/11	01 45 52	Heart Slow	6 secs	UnReviewed
12	04/11	01 46 06	Heart Slow	25 secs	UnReviewed
13	04/11	01 46 33	Heart Slow	21 secs	UnReviewed
14	04/11	01 47 13	Heart Slow	7 secs	UnReviewed
15	04/11	01 47 22	Heart Slow	15 secs	UnReviewed
16	04/11	01 47 39	Heart Slow	18 secs	UnReviewed
17	04/11	01 47 59	Heart Slow	11 secs	UnReviewed
18	04/11	01 48 11	Heart Slow	1 17	UnReviewed
19	04/11	01 49 30	Heart Slow	27 secs	UnReviewed
20	04/11	01 49 32	Apnea	26 secs	UnReviewed
21	04/11	01 49 58	Apnea	30 secs	UnReviewed
22	04/11	01 49 59	Heart Slow	9 30	UnReviewed
23	04/11	01 50 38	Apnea	54 secs	UnReviewed
24	04/11	01 51 37	Apnea	1 13	UnReviewed
25	04/11	01 52 57	Apnea	1 14	UnReviewed
26	04/11	01 54 10	Apnea	5 31	UnReviewed
27	04/11	01 59 41	Apnea	1 12	UnReviewed
28	04/11	02 00 53	Apnea	9 30	UnReviewed
29	04/11	02 33 44	Apnea	9 30	UnReviewed
30	04/11	02 49 41	Apnea	33 secs	UnReviewed
31	04/11	02 50 15	Heart Slow	18 secs	UnReviewed

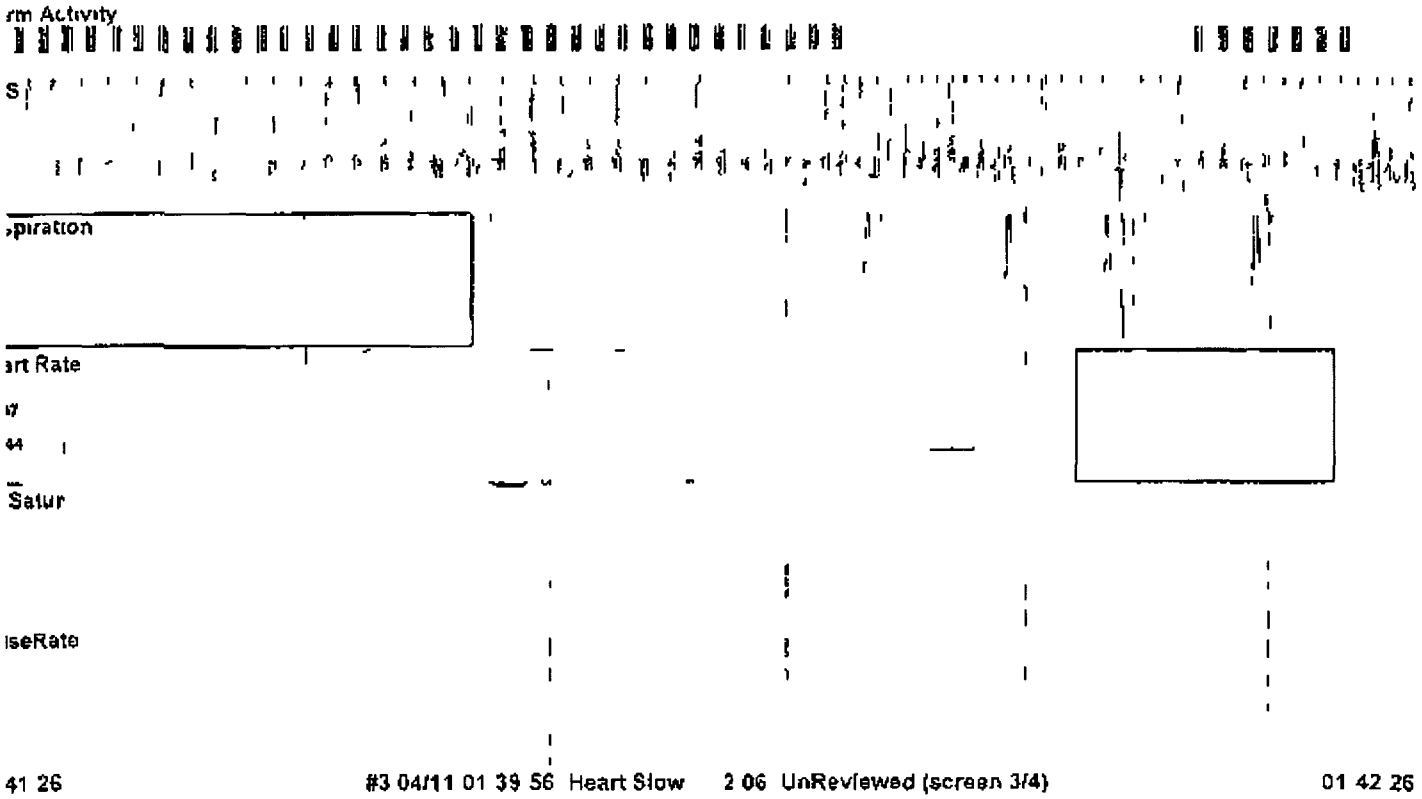
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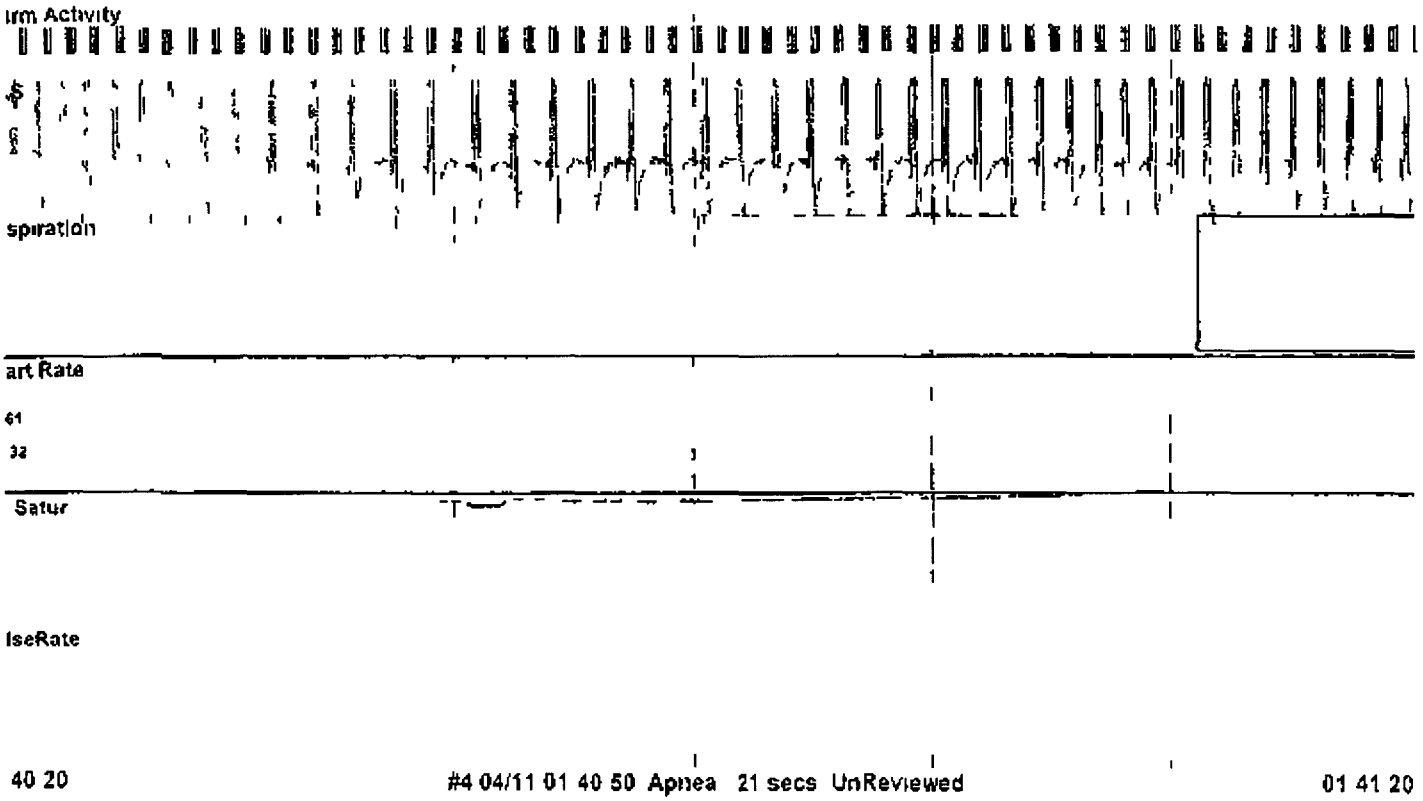




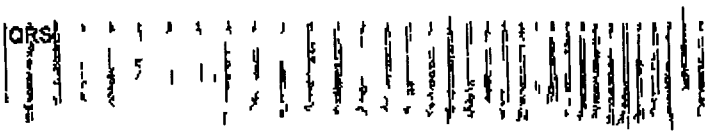

rm Activity
spiration
art Rate
157
53
Satur
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39 26
#3 04/11 01 39 56 Heart Slow 2 06 UnReviewed (screen 1/4)
01 40 26


arm Activity
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40 26
#3 04/11 01 39 56 Heart Slow 2 06 UnReviewed (screen 2/4)
01 41 26

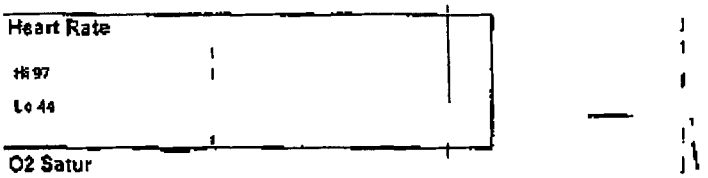

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41 26
#3 04/11 01 39 56 Heart Slow 2 06 UnReviewed (screen 3/4)
01 42 26


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40 20
#4 04/11 01 40 50 Apnea 21 secs UnReviewed
01 41 20

Alarm Activity

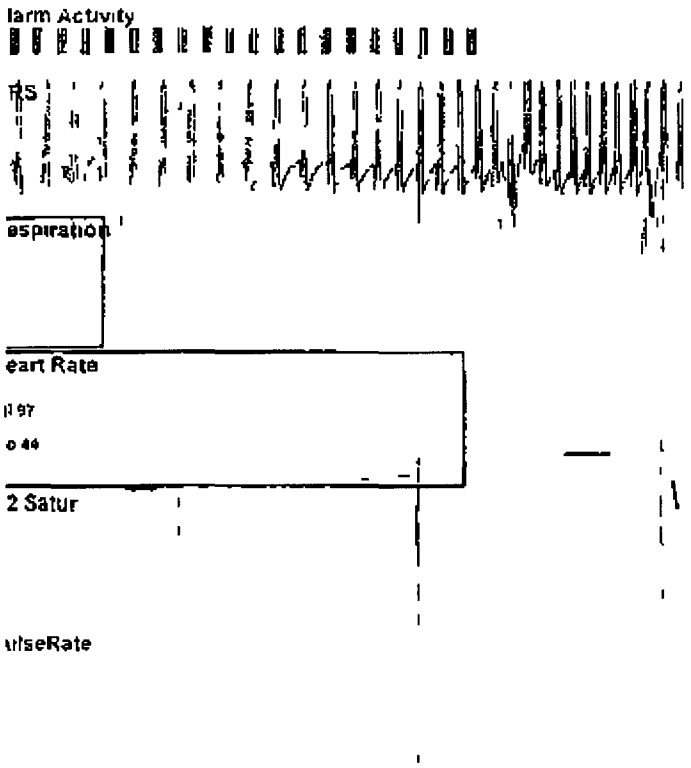


Respiration

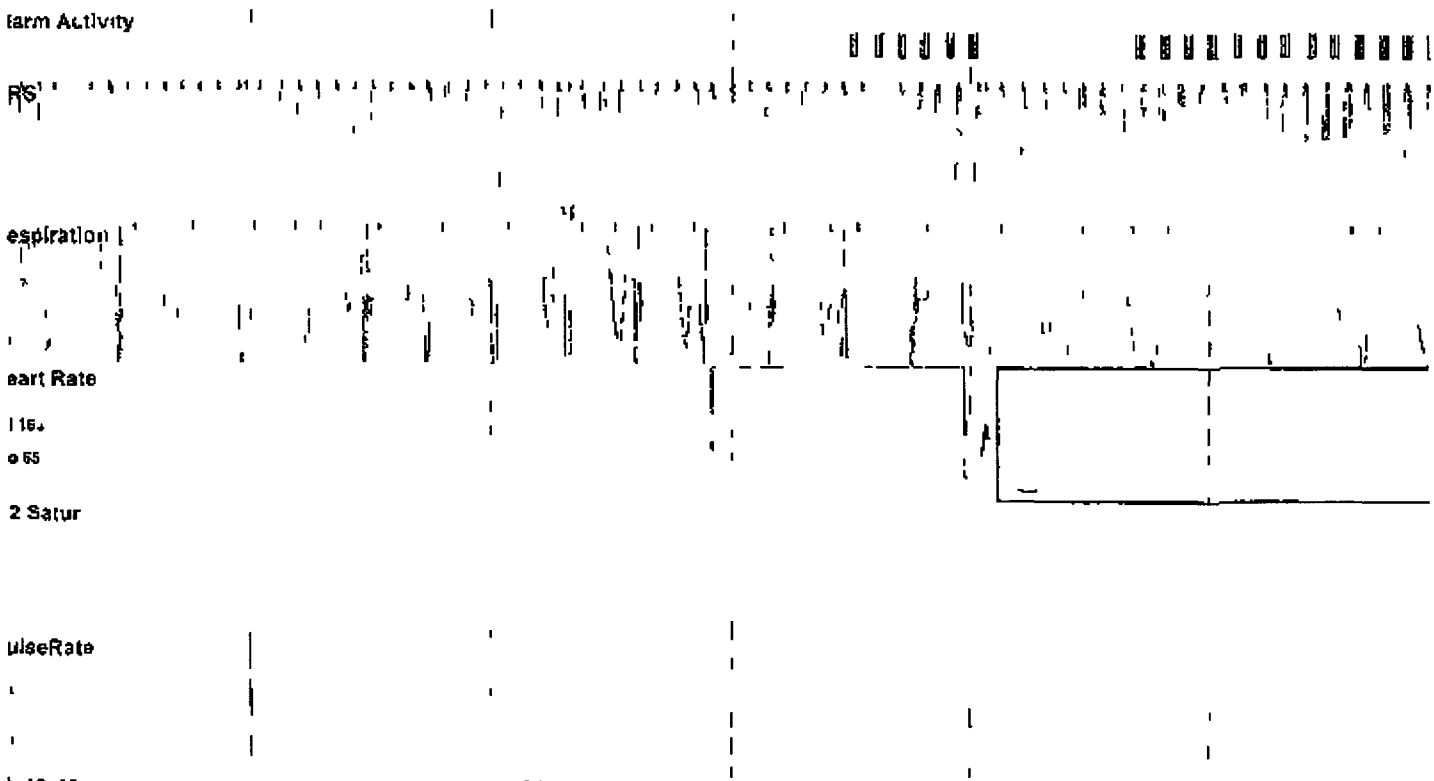


PulseRate

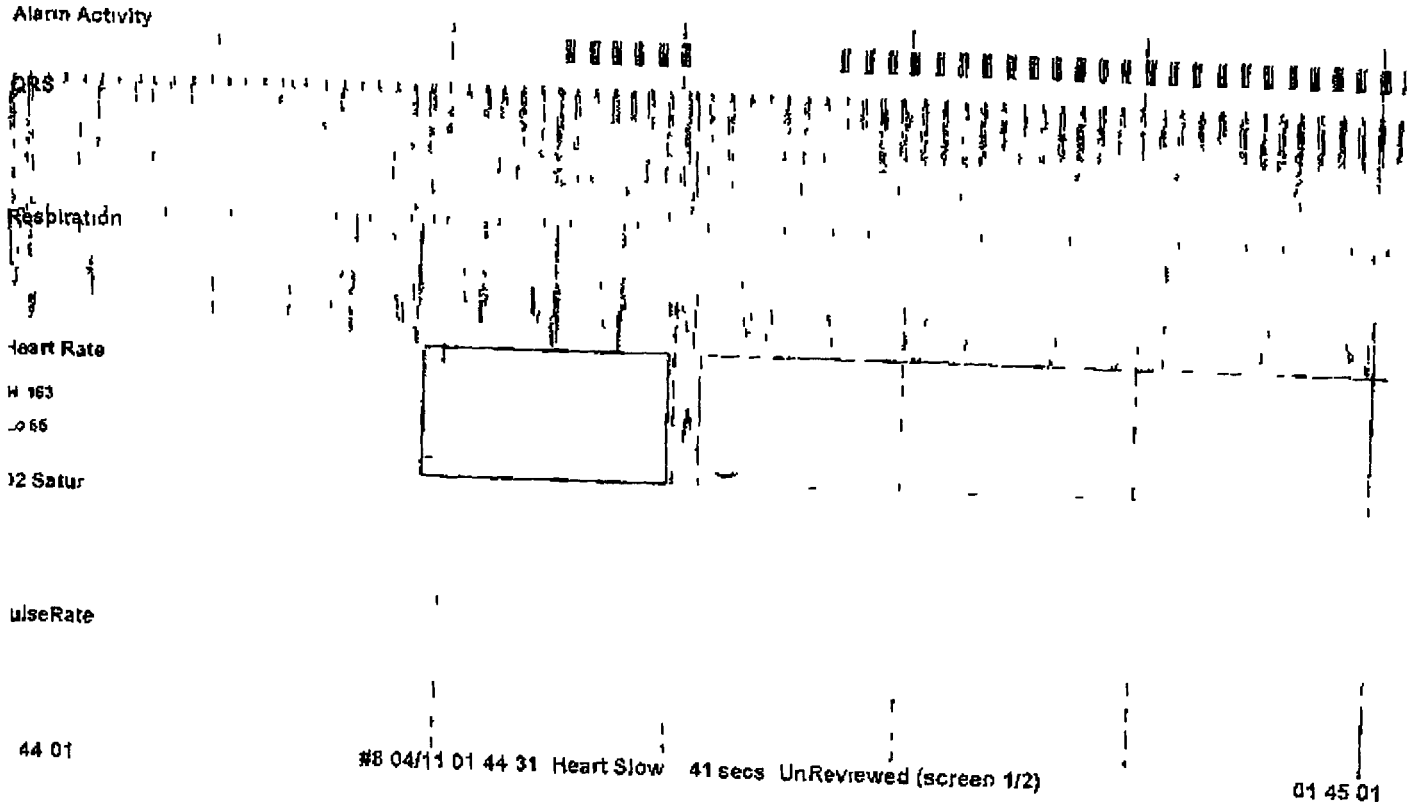
01 41 41 #5 04/11 01 41 11 Apnea 36 secs UnRev 01 42 11

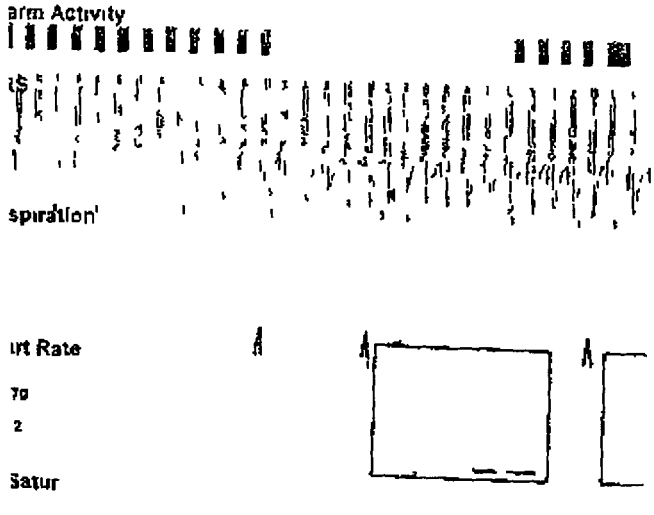


41 42 #6 04/11 01 42 12 Heart Slow 11 secs 01 42 11

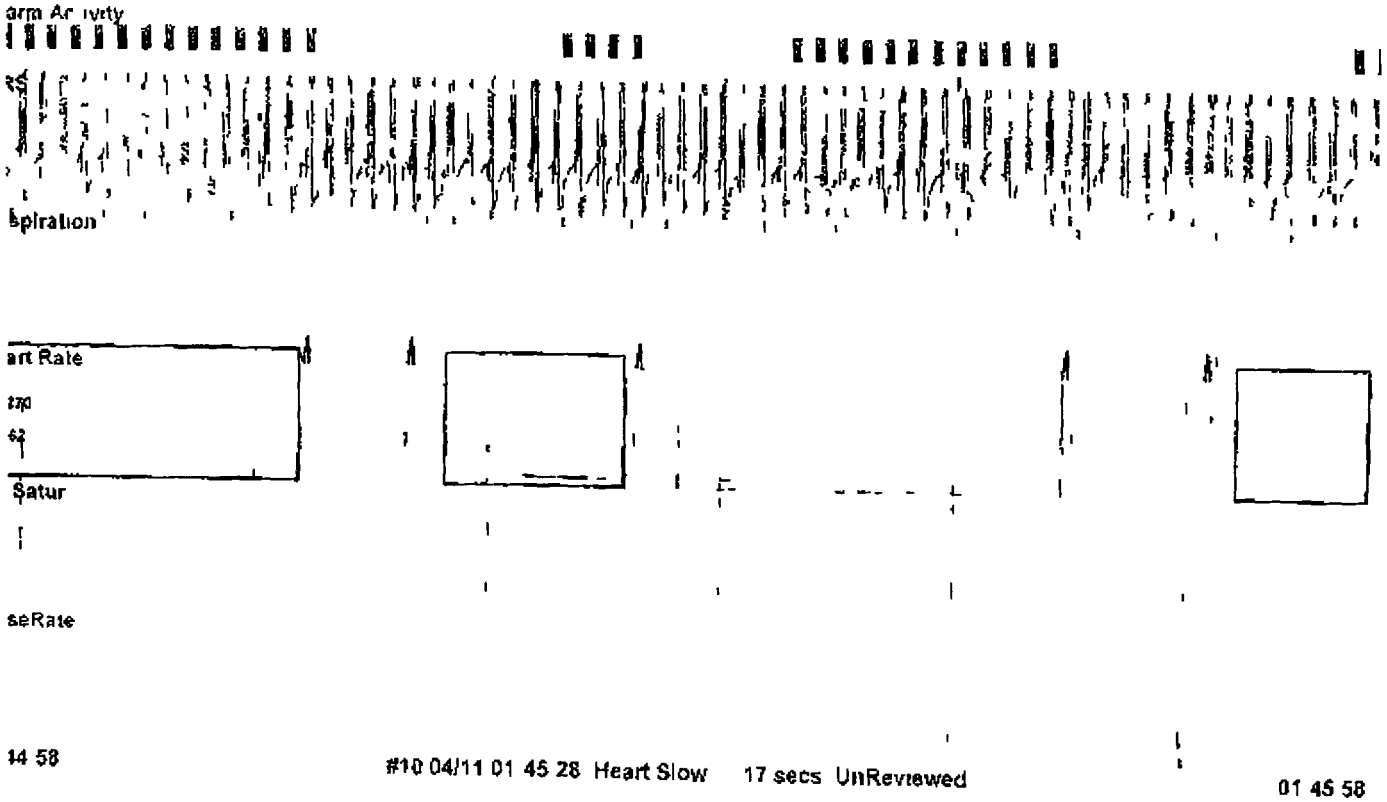


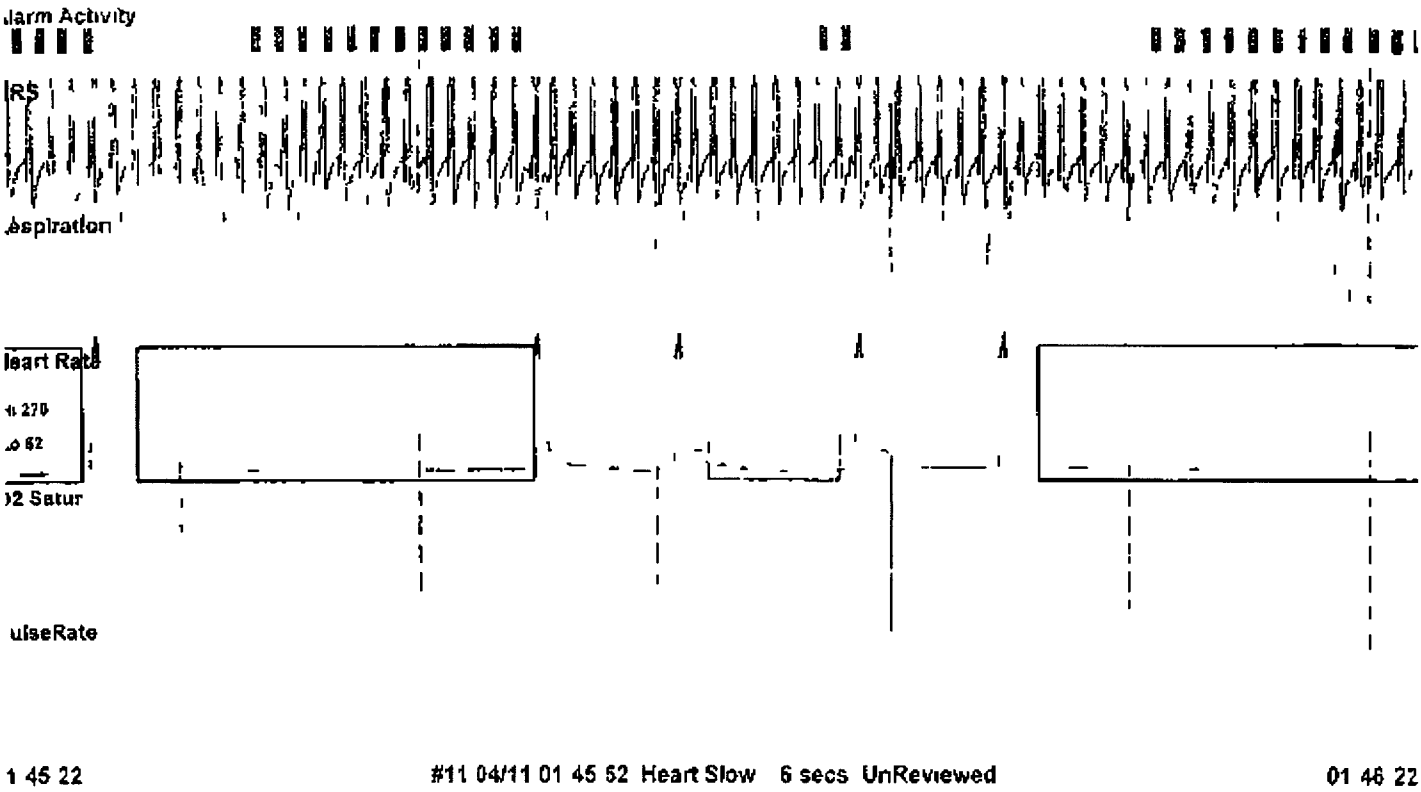
43 49 #7 04/11 01 44 19 Heart Slow 11 secs UnReviewed 01 44 49

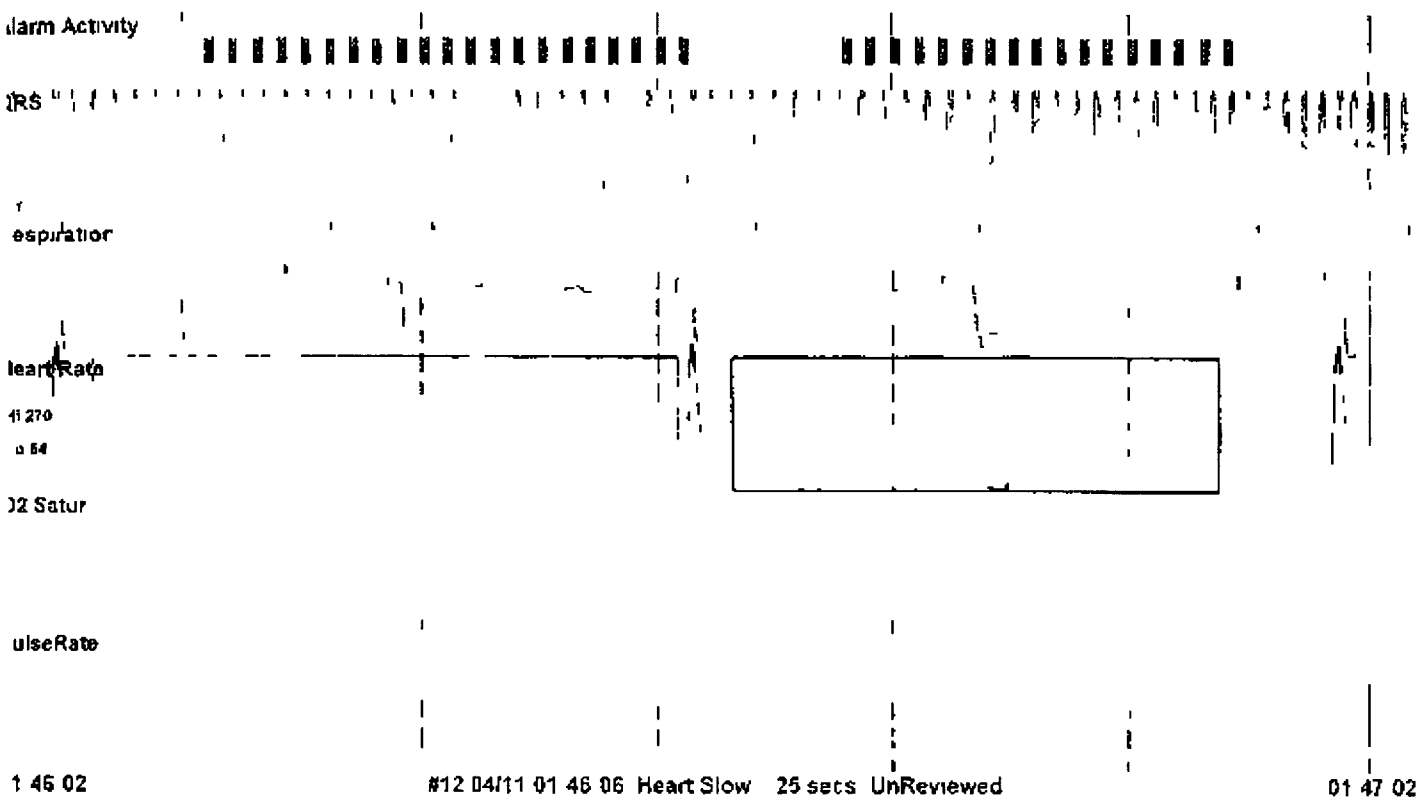

Alarm Activity
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44 01
#8 04/11 01 44 31 Heart Slow 41 secs UnReviewed (screen 1/2)
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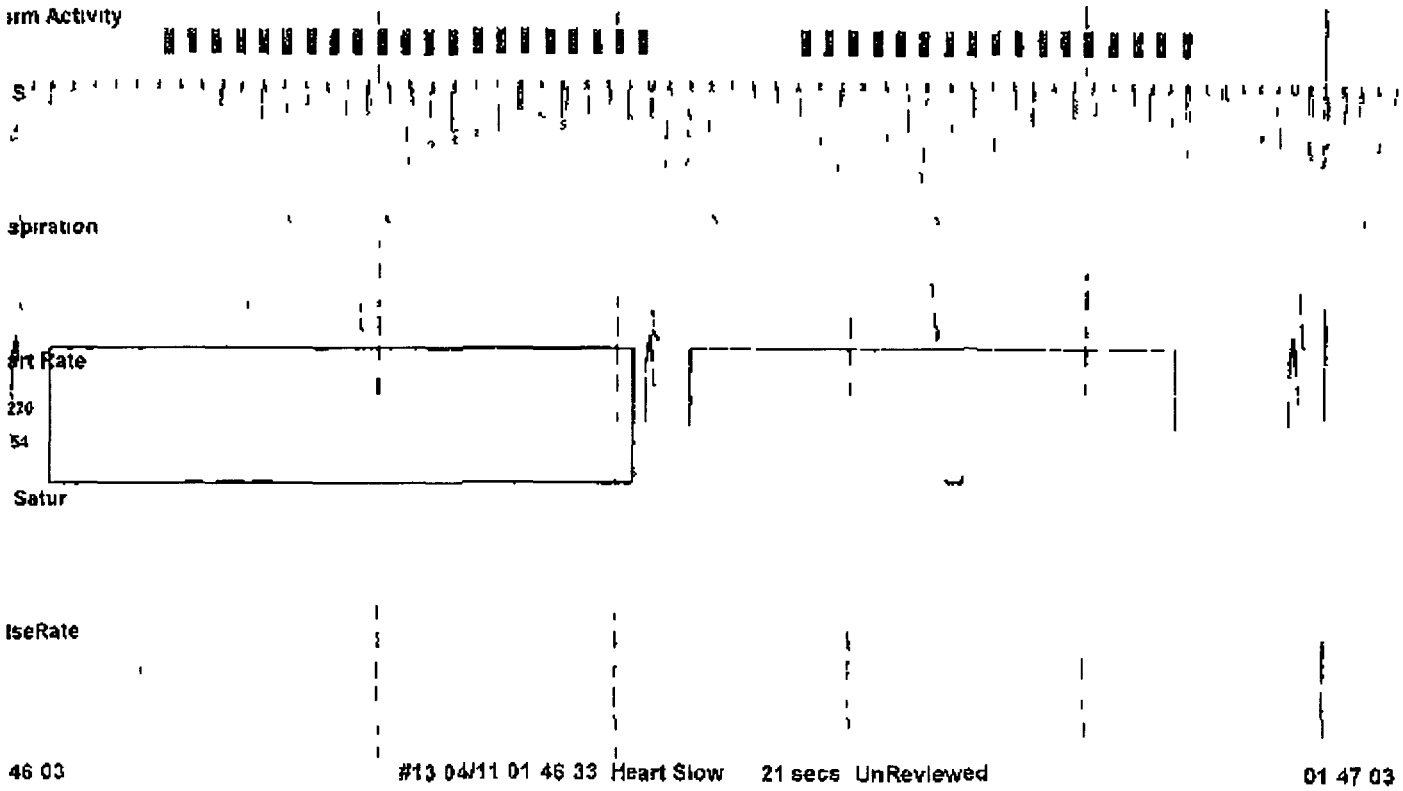

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#8 04/11 01 44 31 Heart Slow 41 secs 01 45 30

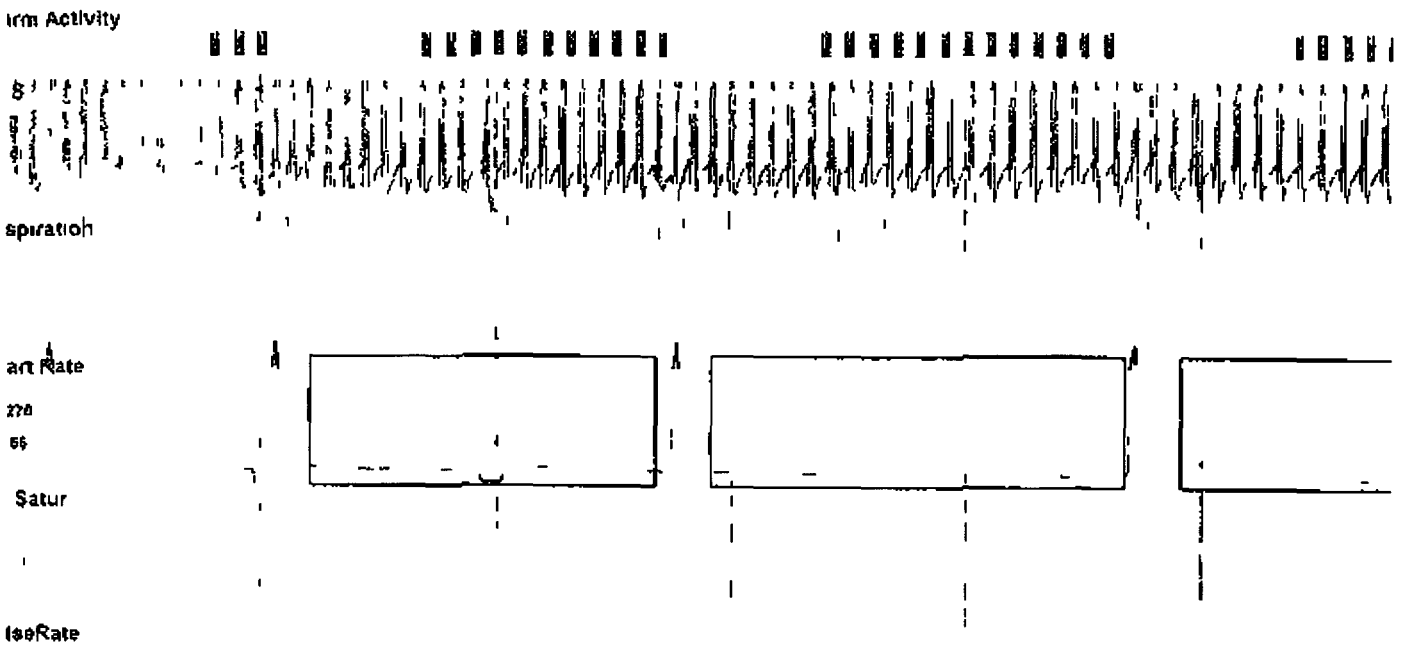

Alarm Activity
Respiration
Heart Rate
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62
Satur
PulseRate
44 57
#9 04/11 01 45 16 Heart Slow 8 secs UnReviewed
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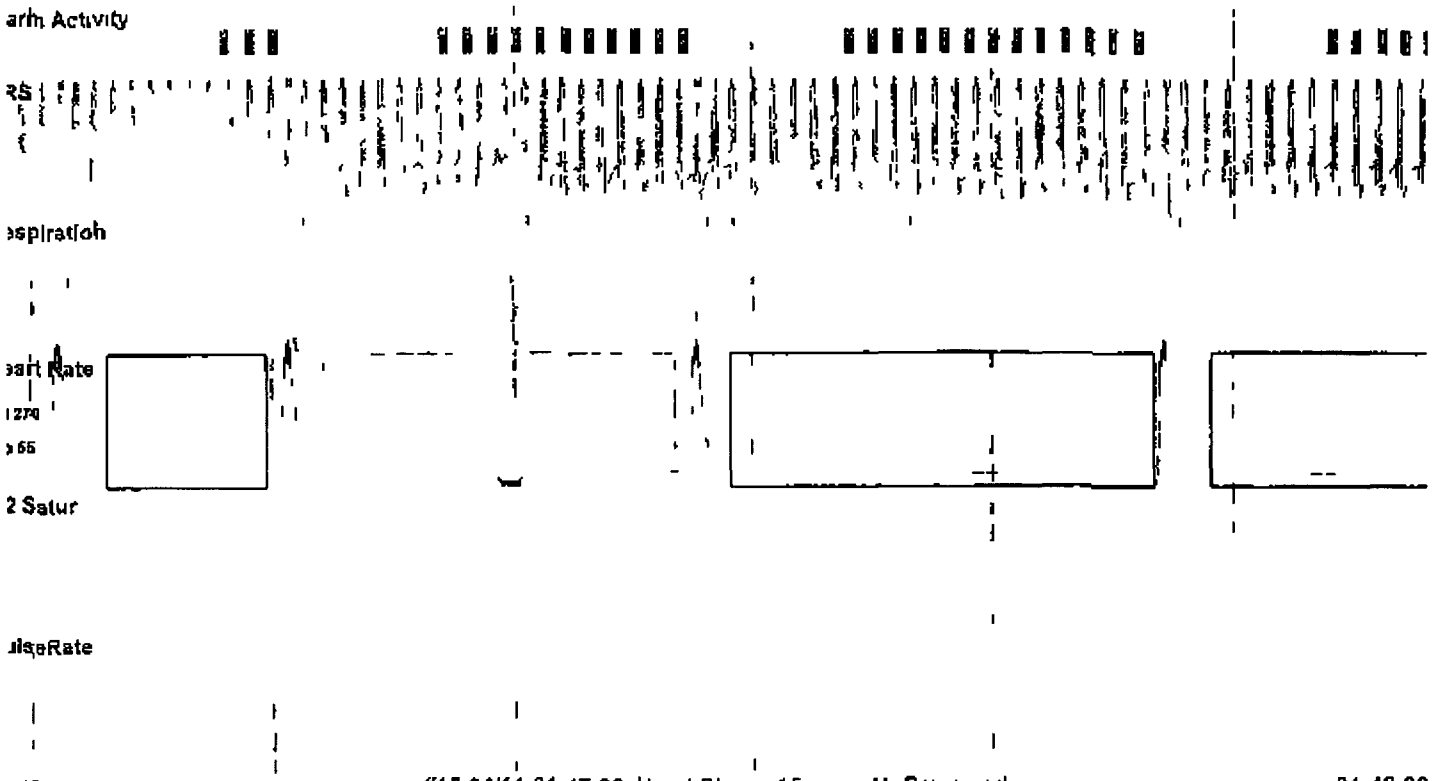

Alarm Activity
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01 45 58

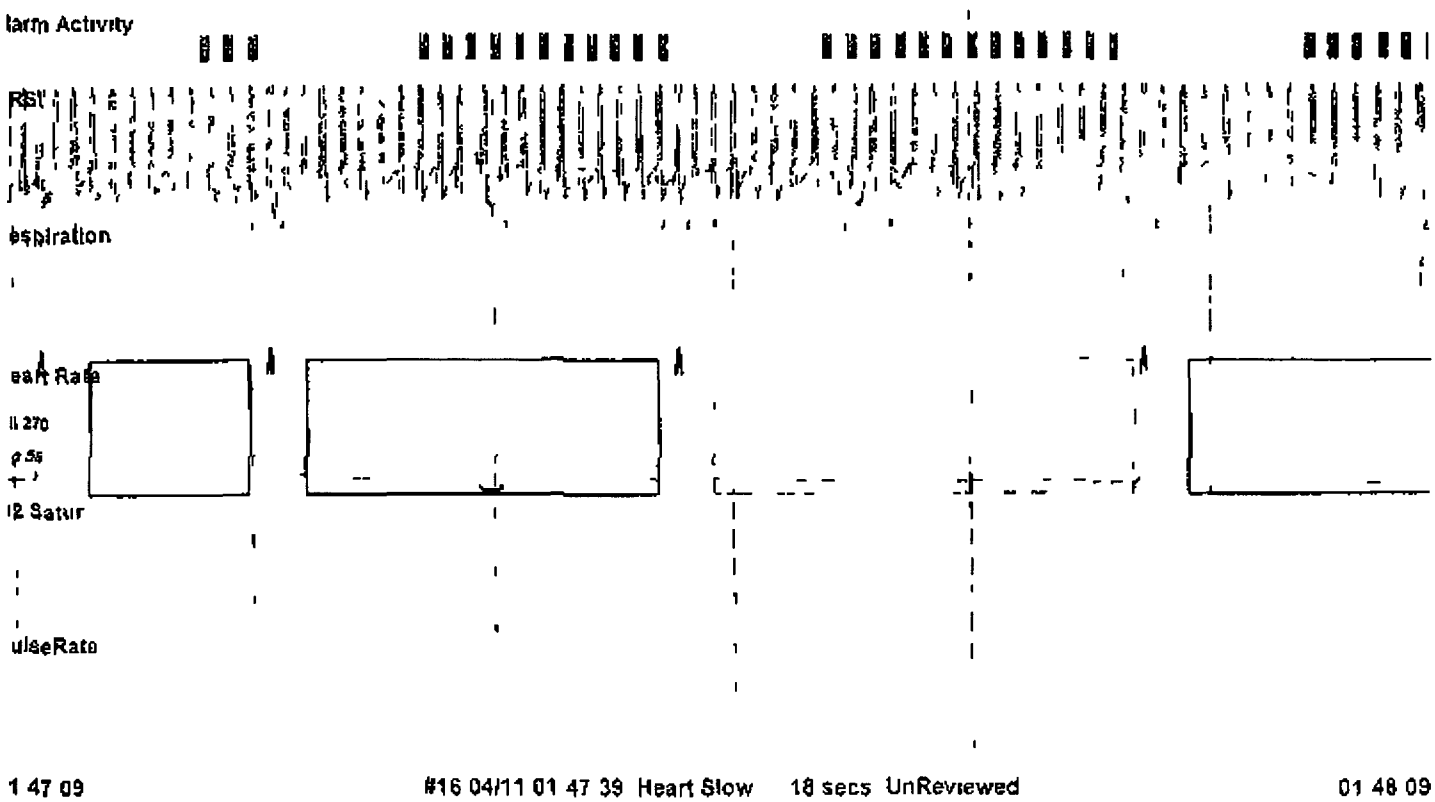

larm Activity
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1 45 22
#11 04/11 01 45 52 Heart Slow 6 secs UnReviewed
01 46 22

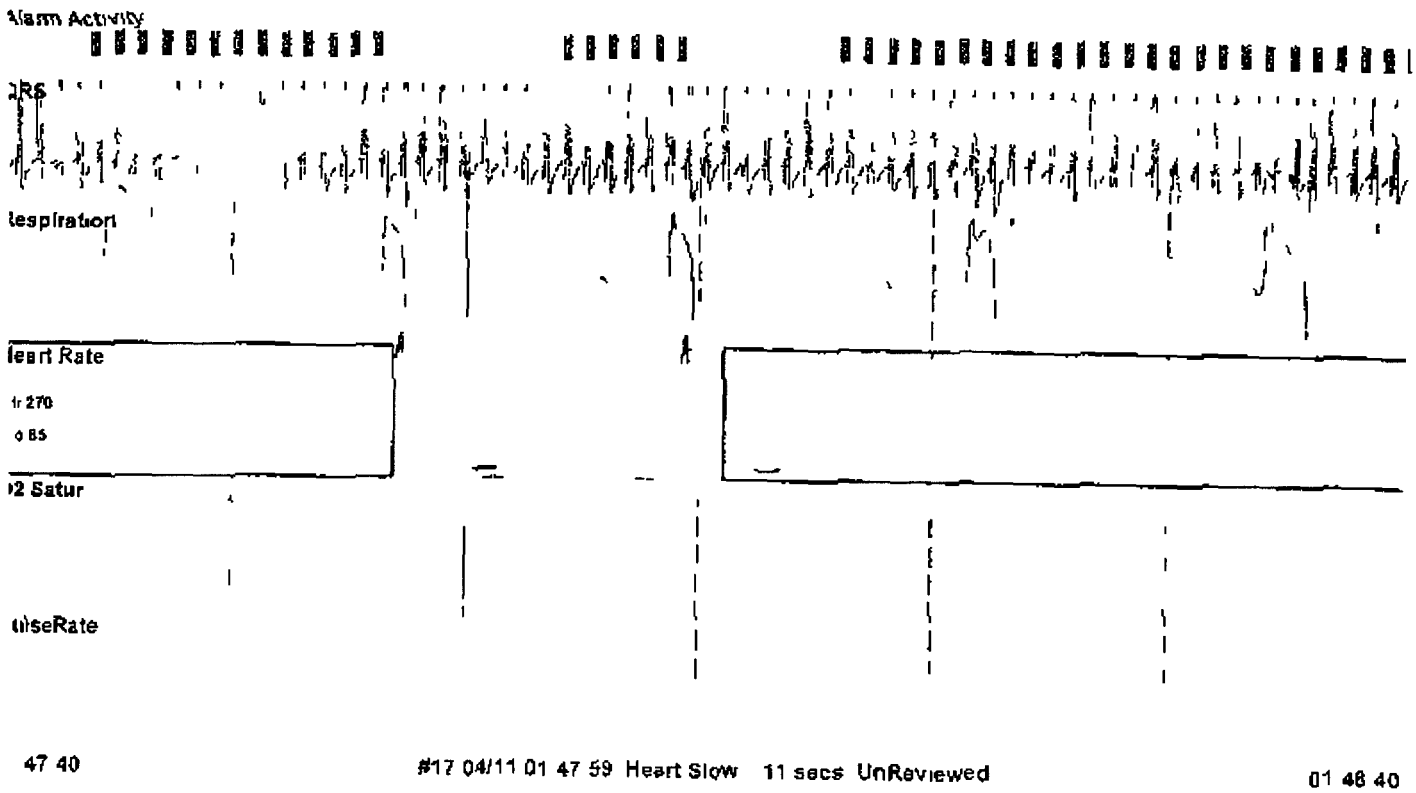

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01 47 02

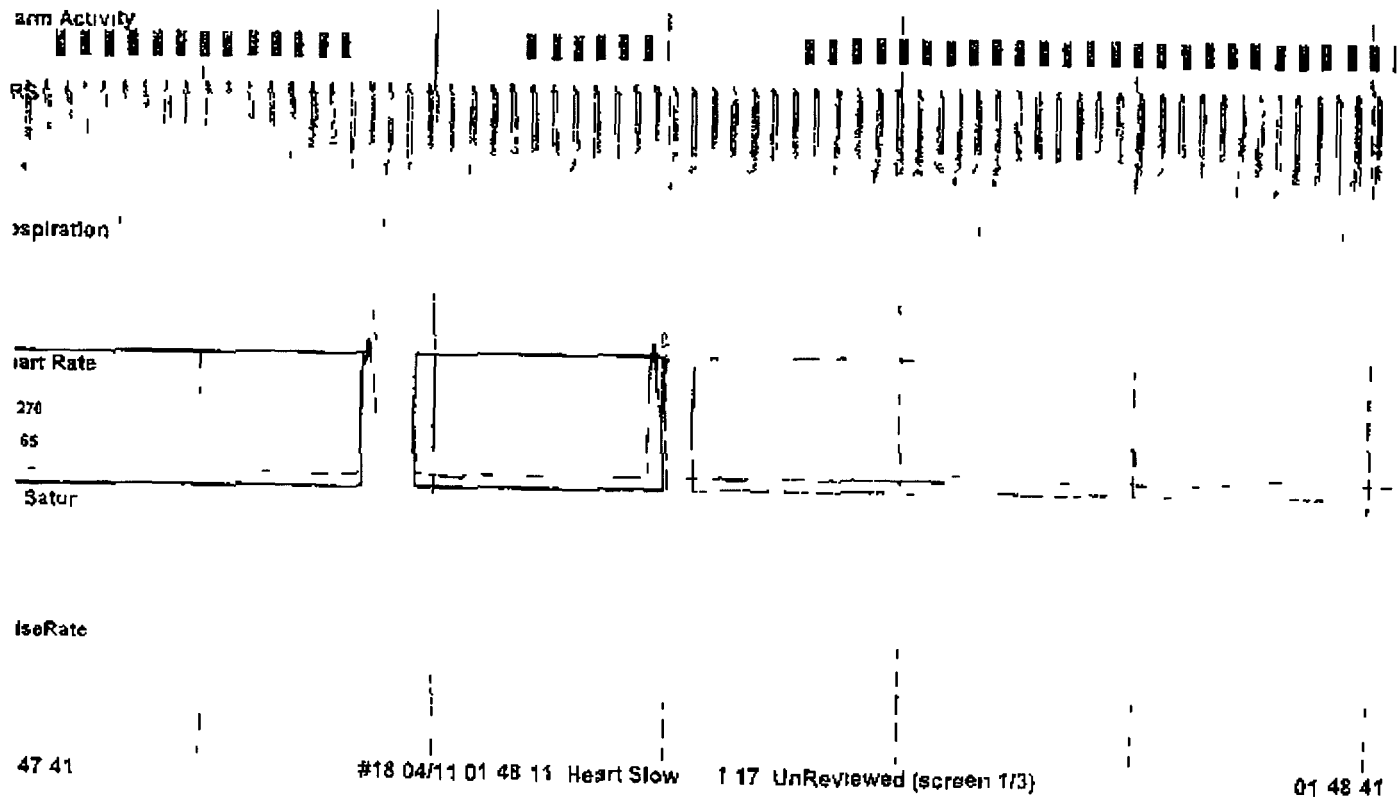

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01 47 03

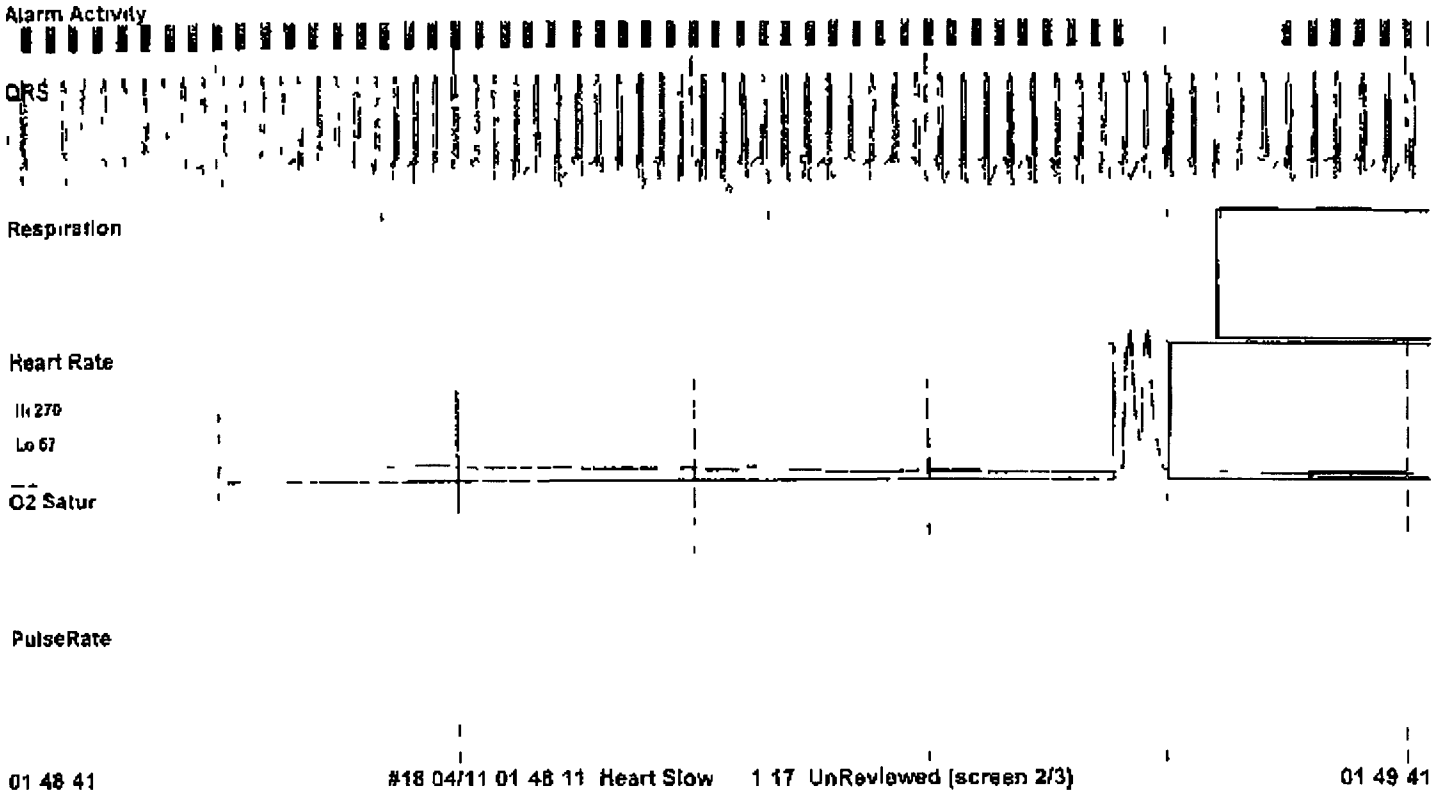

irm Activity
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01 48 08

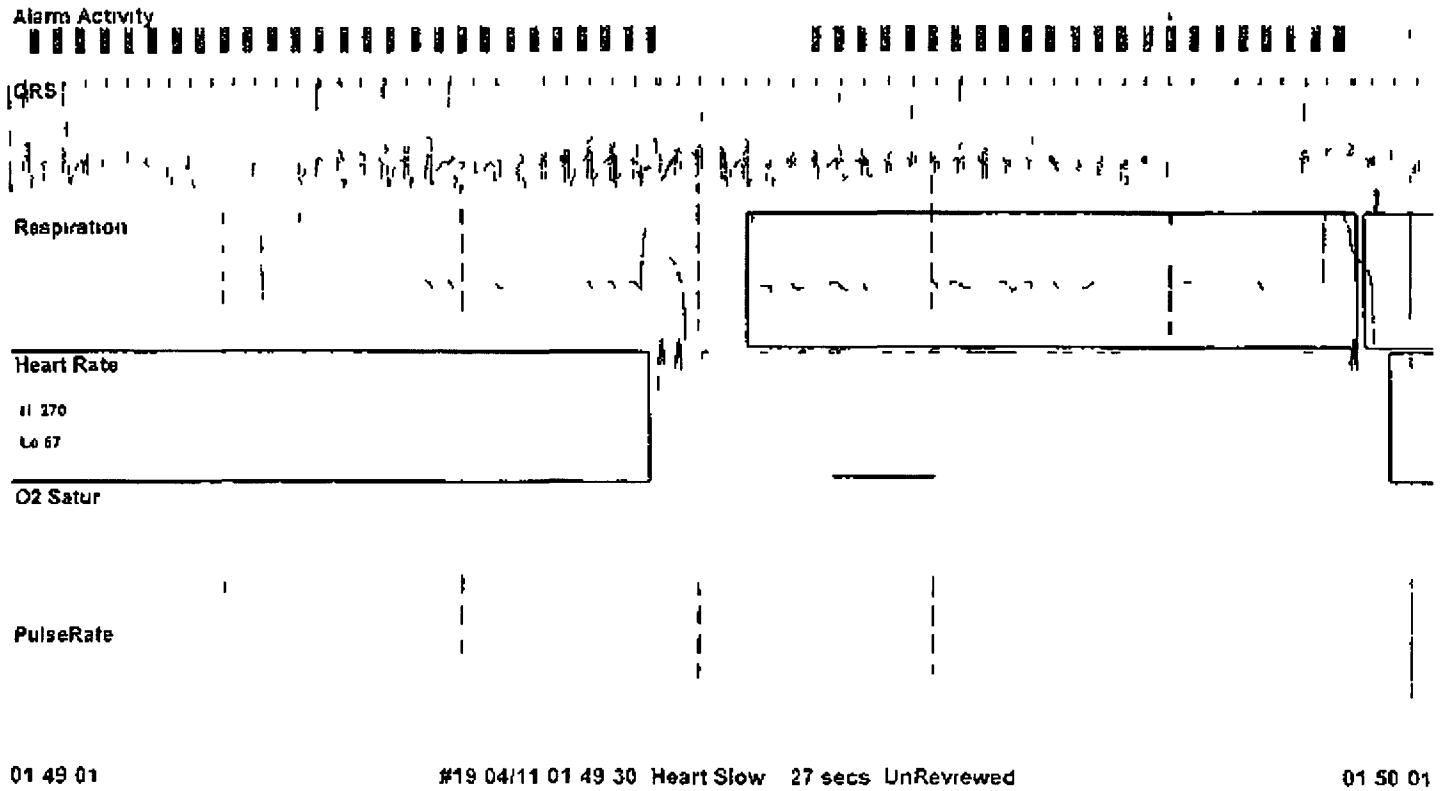

arm Activity
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eart Rate
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65
2 Satur
ulseRate
47 08
#15 04/11 01 47 22 Heart Slow 15 secs UnReviewed
01 48 08

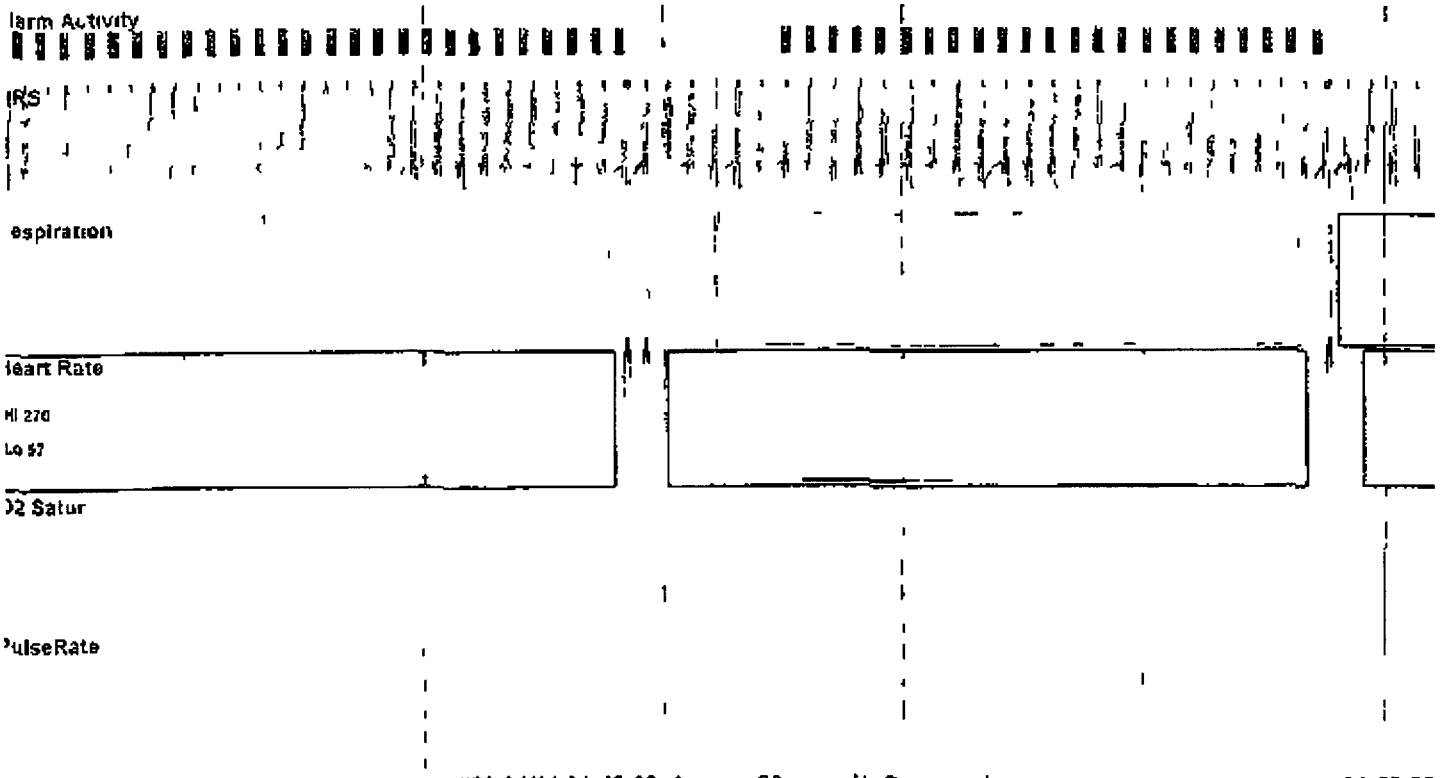

larm Activity
espiration
eart Rate
270
12 Satur
ulseRate
1 47 09
#16 04/11 01 47 39 Heart Slow 18 secs UnReviewed
01 48 09

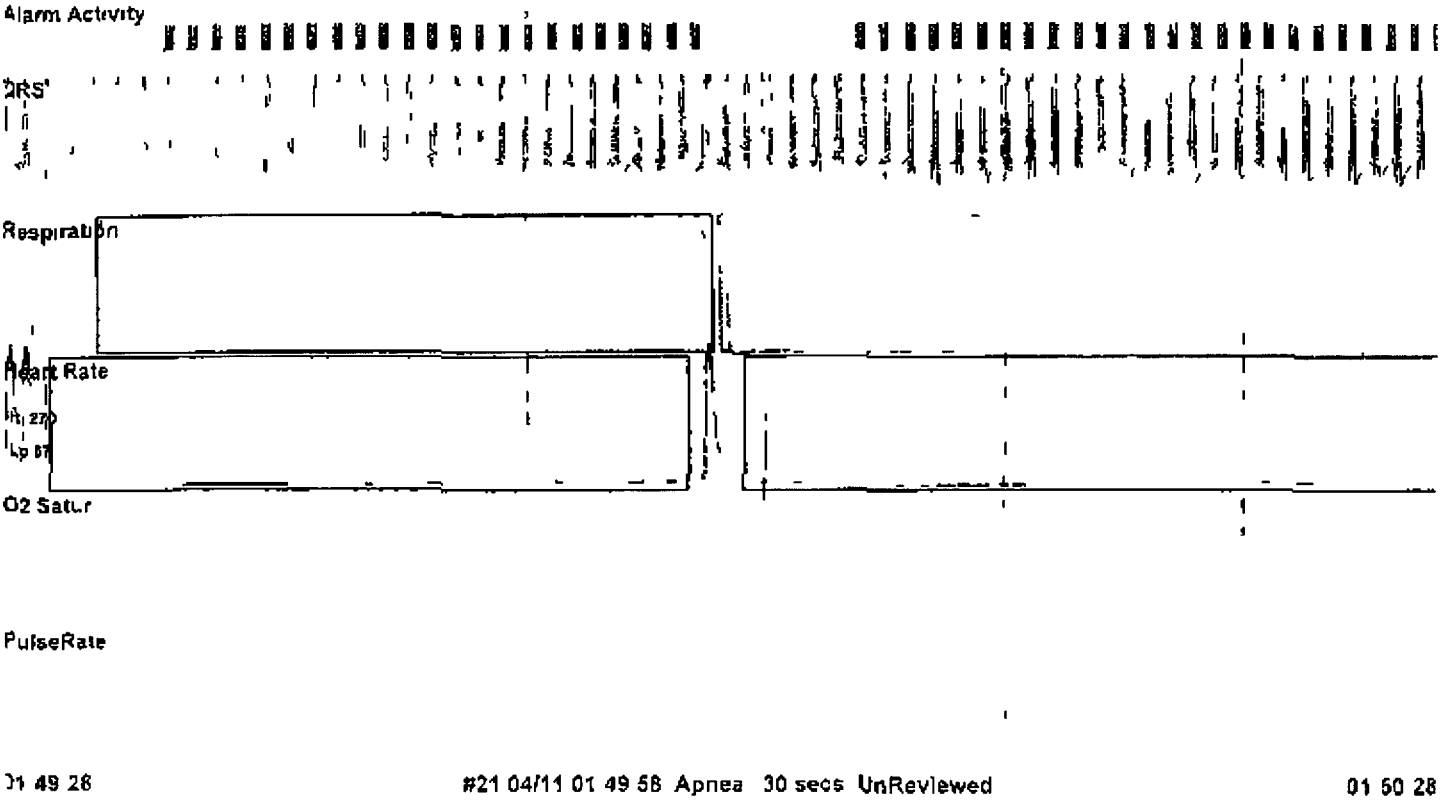

Alarm Activity
ECG
Respiration
Heart Rate
hi 270
lo 85
SpO2 Satur
PulseRate
47 40
#17 04/11 01 47 59 Heart Slow 11 secs UnReviewed
01 48 40


Alarm Activity
ECG
Respiration
Heart Rate
270
65
Satur
PulseRate
47 41
#18 04/11 01 48 11 Heart Slow 1 17 UnReviewed (screen 1/3)
01 48 41

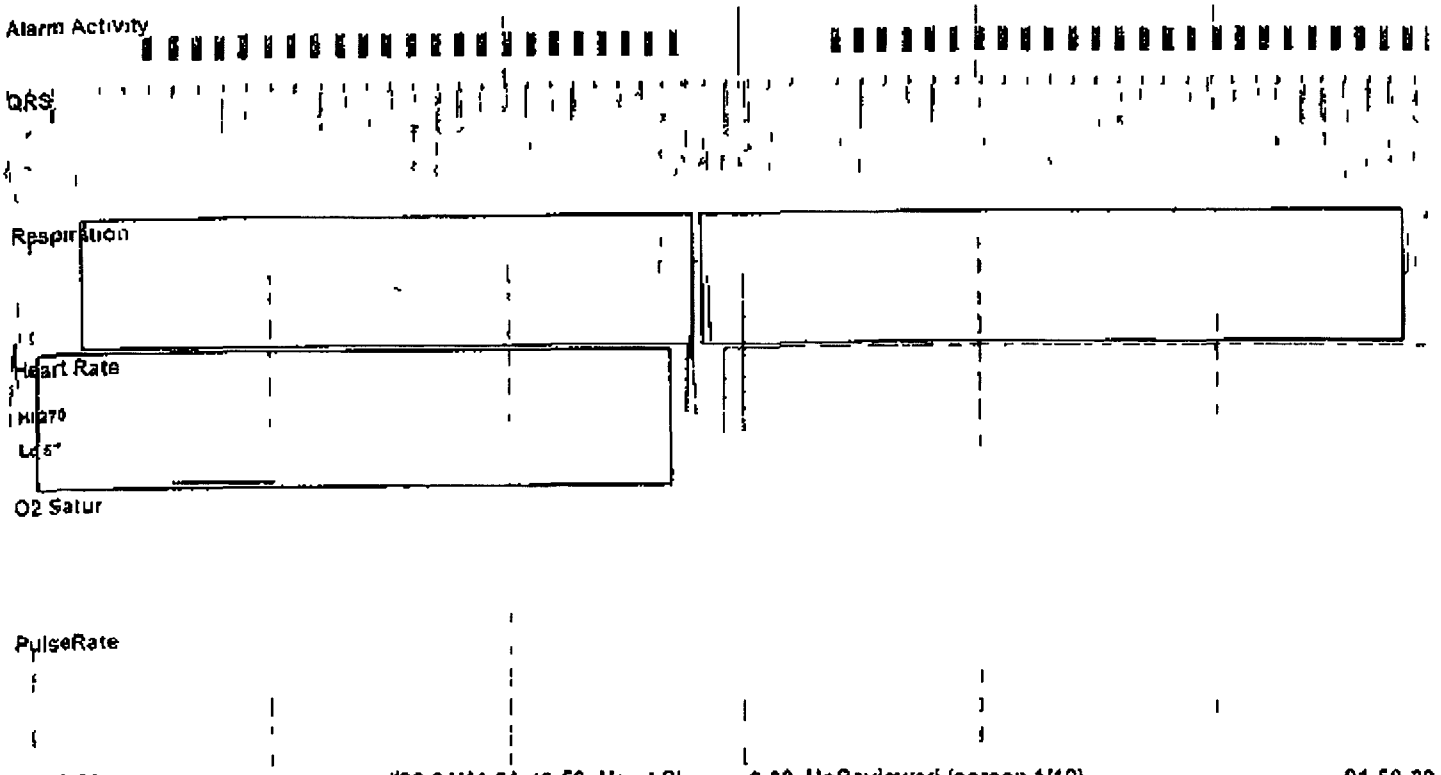

Alarm Activity
QRS
Respiration
Heart Rate
Hi 270
Lo 67
O2 Satur
PulseRate
01 48 41
#18 04/11 01 48 11 Heart Slow 1 17 UnReviewed (screen 2/3)
01 49 41


Alarm Activity
QRS
Respiration
Heart Rate
Hi 270
Lo 67
O2 Satur
PulseRate
01 49 01
#19 04/11 01 49 30 Heart Slow 27 secs UnReviewed
01 50 01

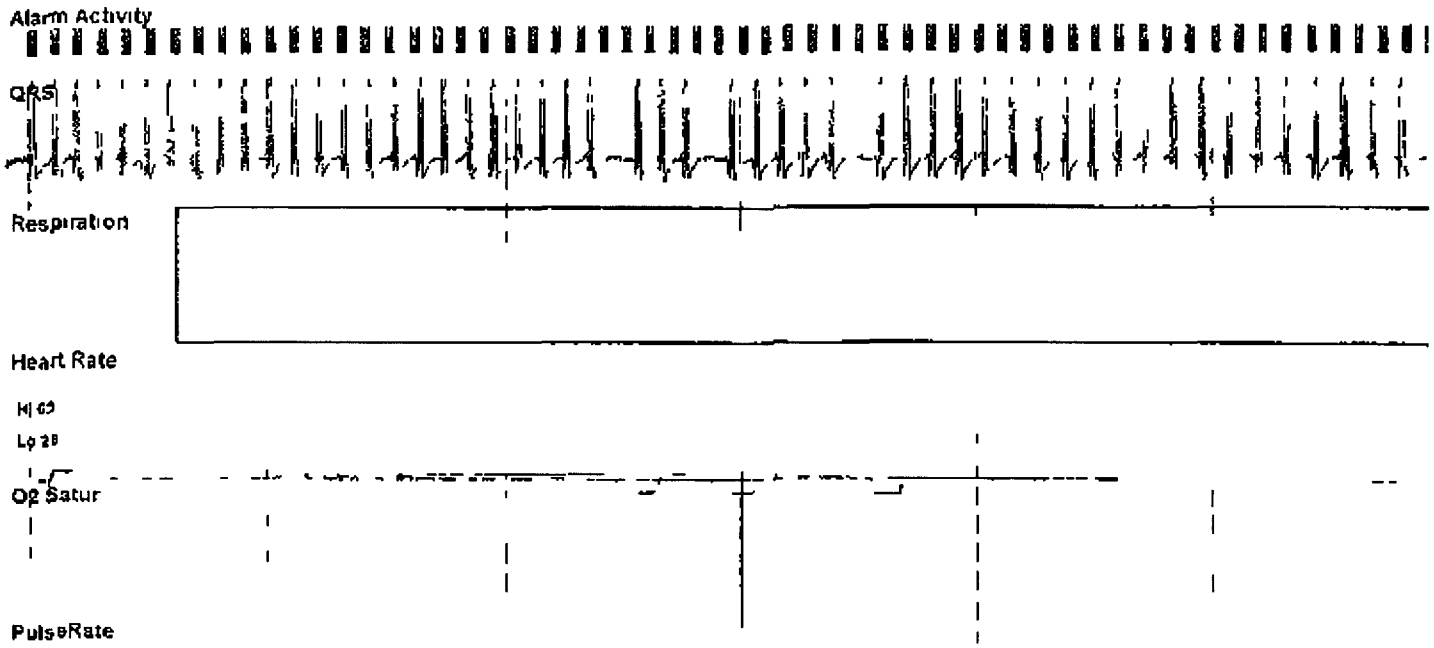

larm Activity
RS
espiration
leart Rate
Hi 270
Lo 57
)2 Satur
PulseRate
01 49 02
#20 04/11 01 49 32 Apnea 26 secs UnReviewed
01 50 02


Alarm Activity
2RS
Respiration
Heart Rate
Hi 270
Lo 57
O2 Satur
PulseRate
01 49 26
#21 04/11 01 49 58 Apnea 30 secs UnReviewed
01 50 28

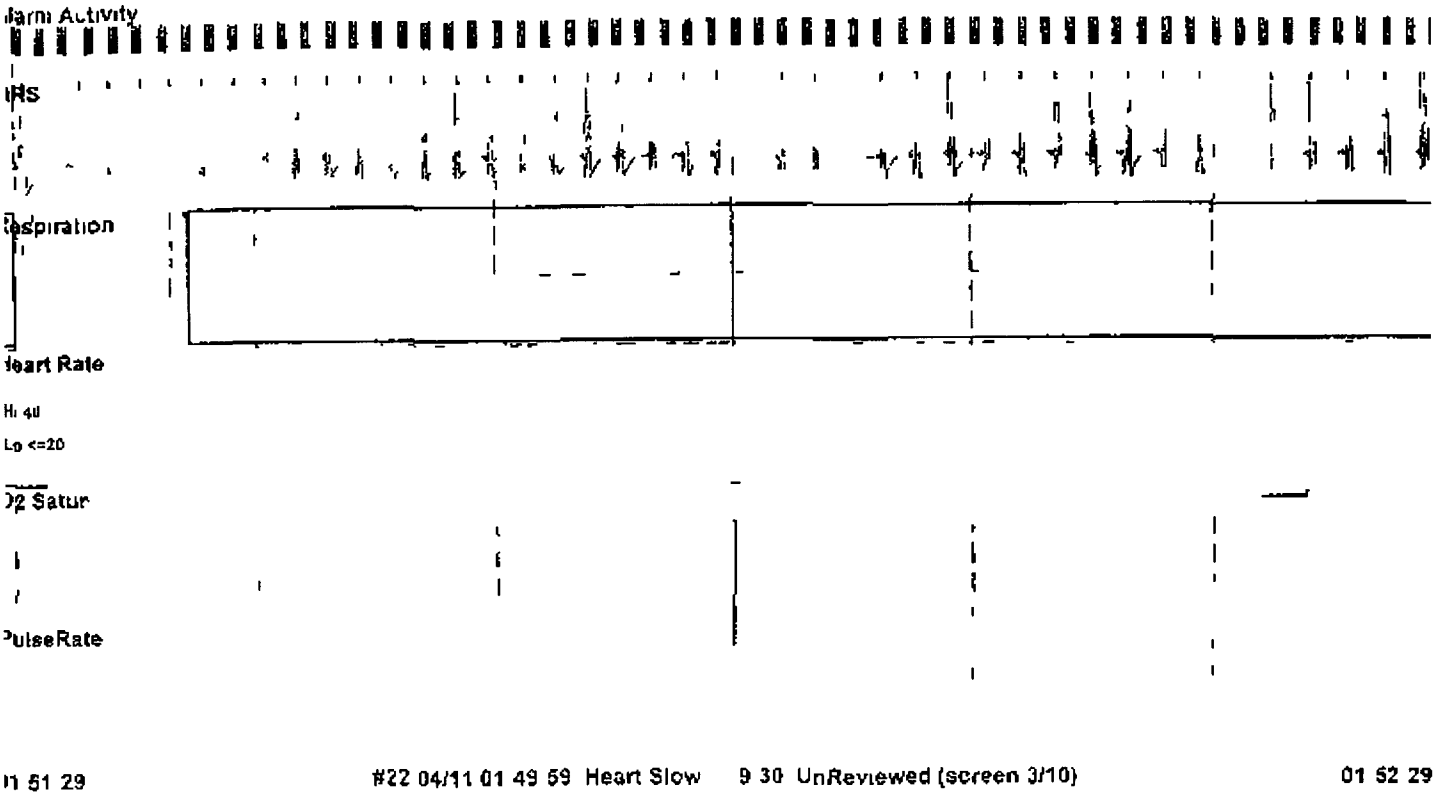
Graves,India PRMH 02140+



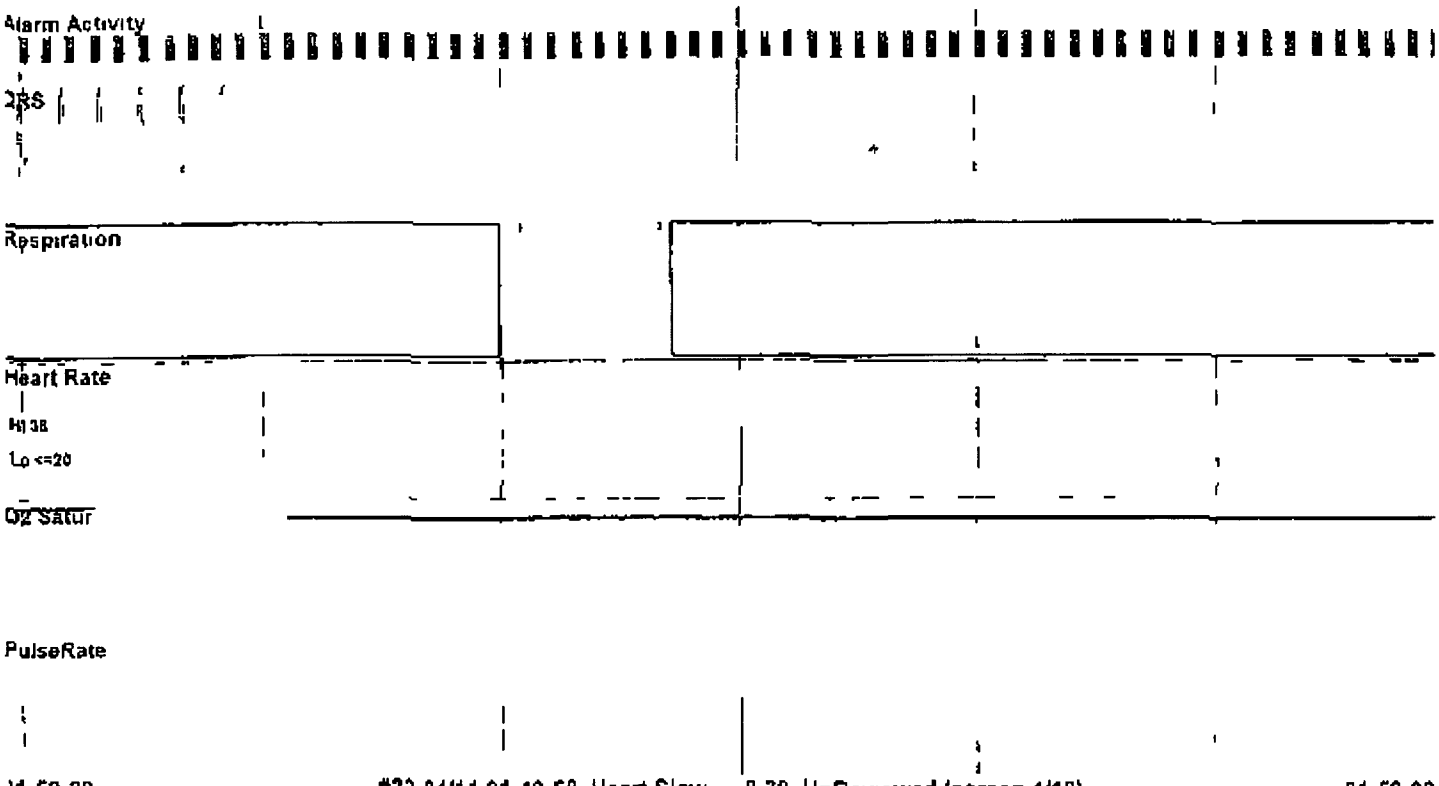
01 49 29 #22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 1/10) 01 50 29



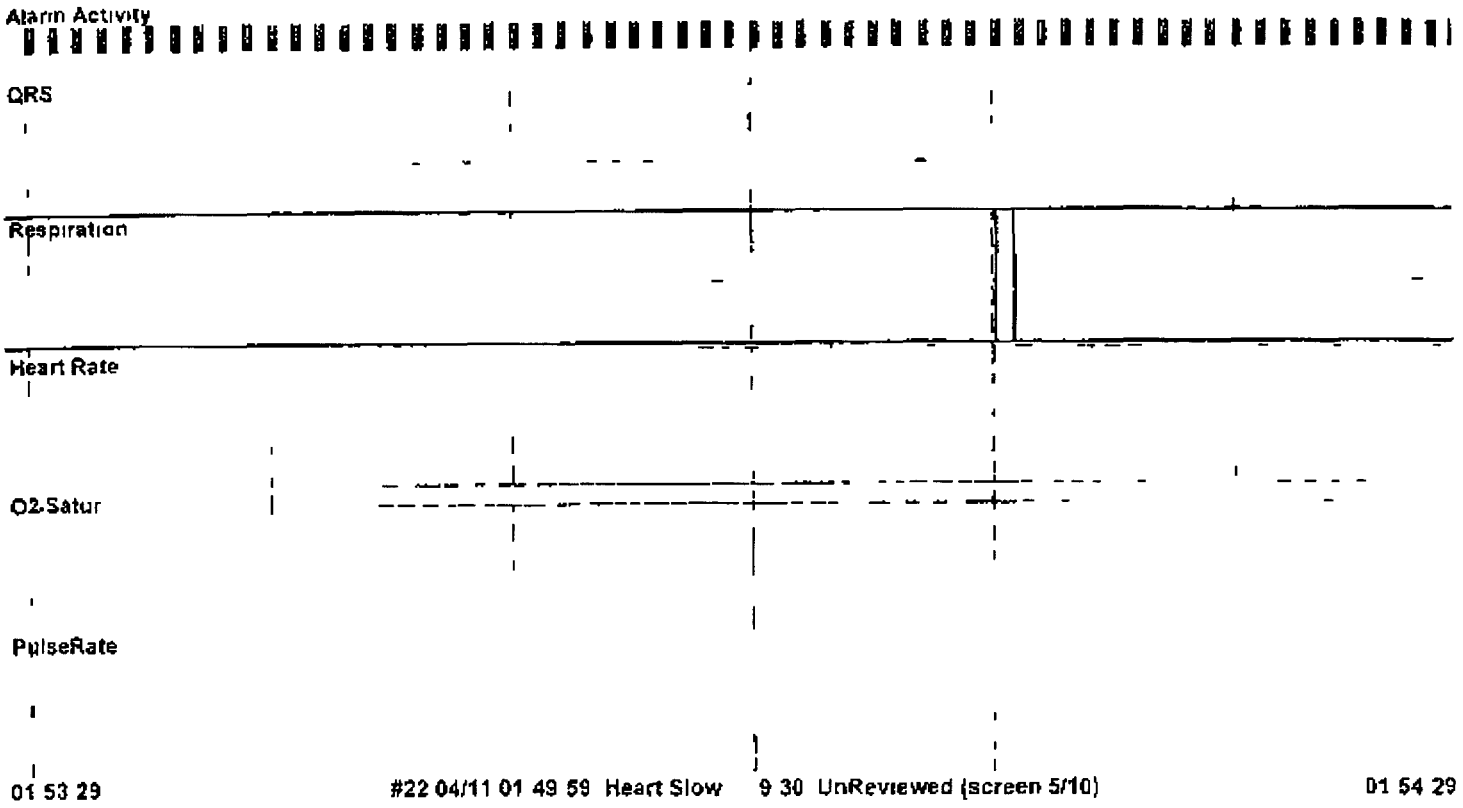
01 50 29 #22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 2/10) 01 51 29

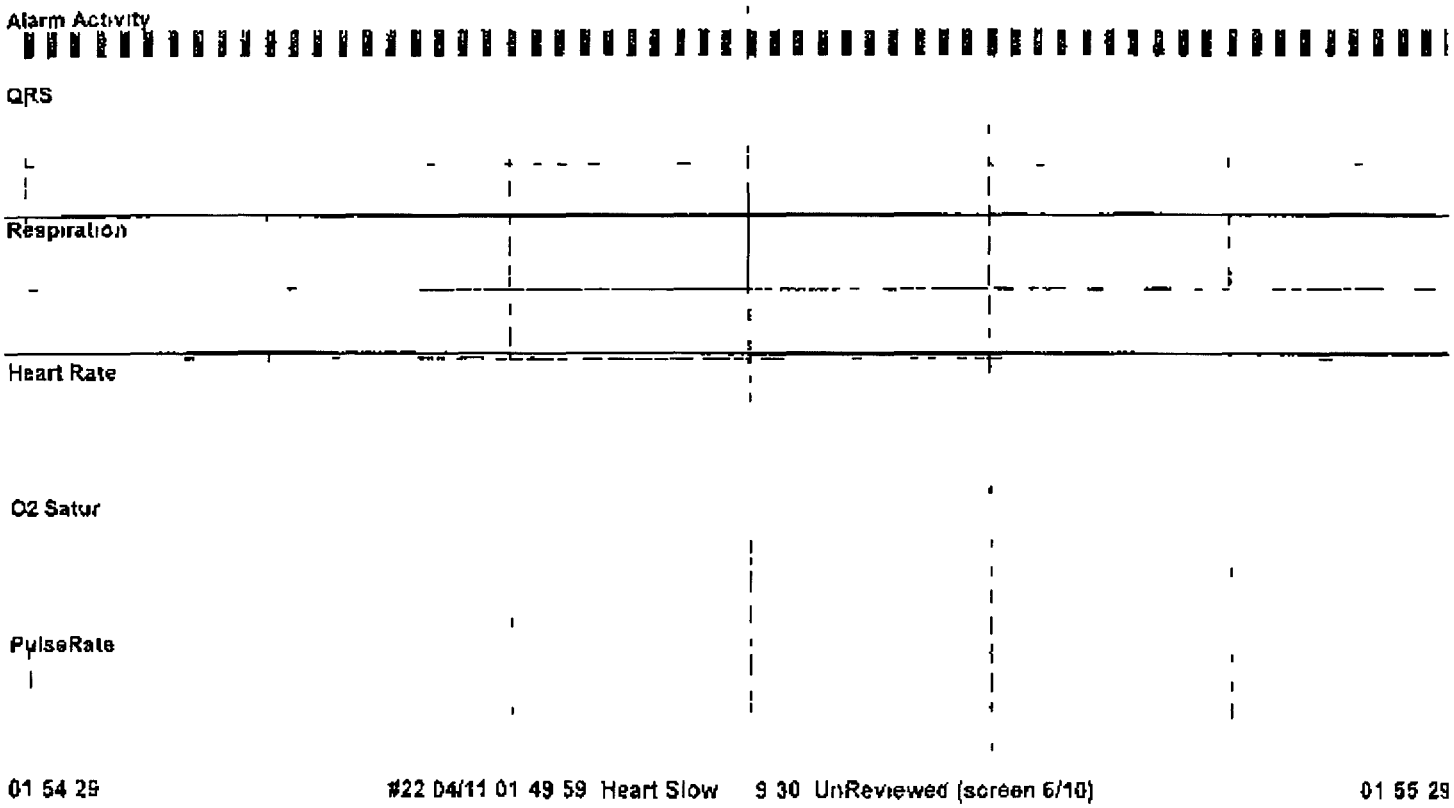


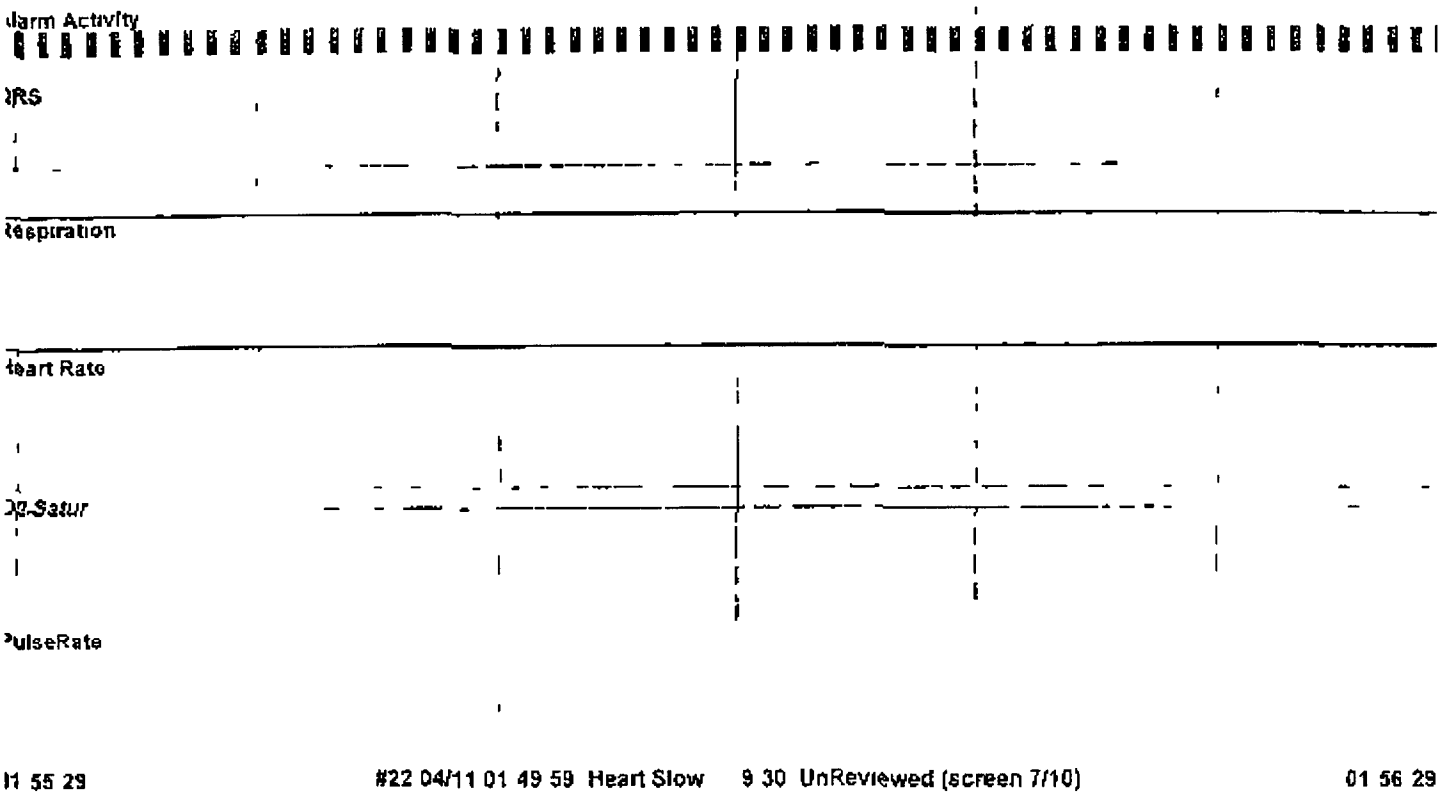
01 51 29 #22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 3/10) 01 52 29

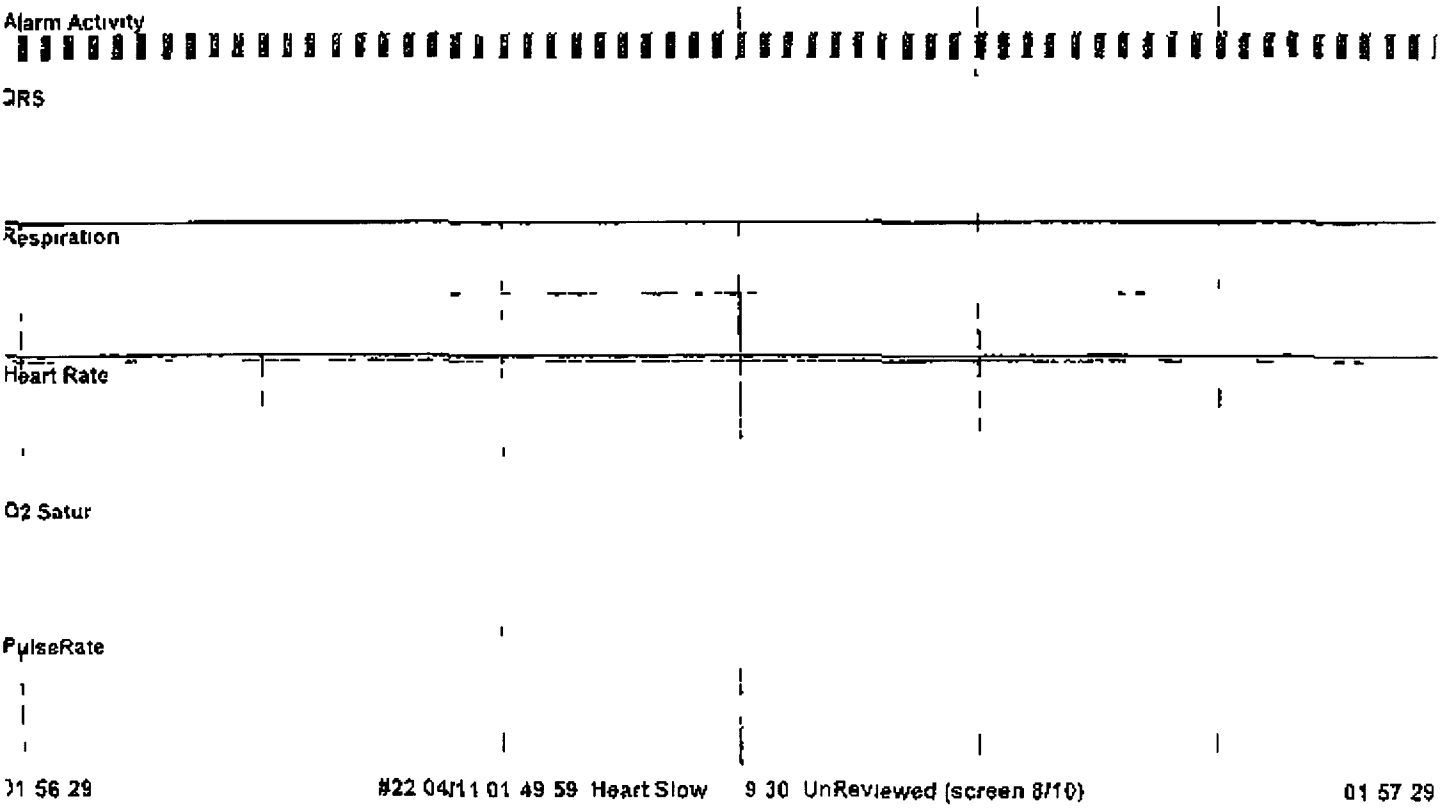


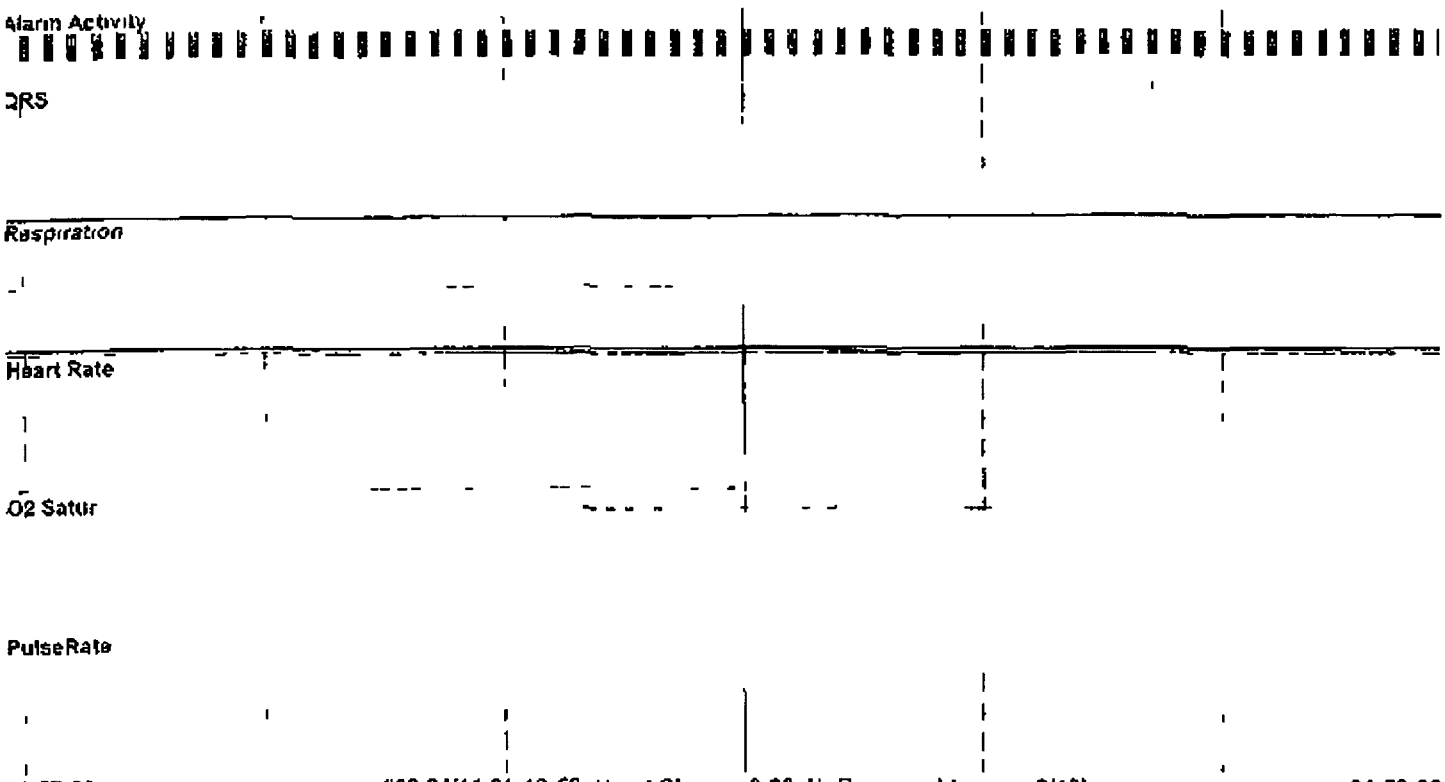
01 52 29 #22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 4/10) 01 53 29

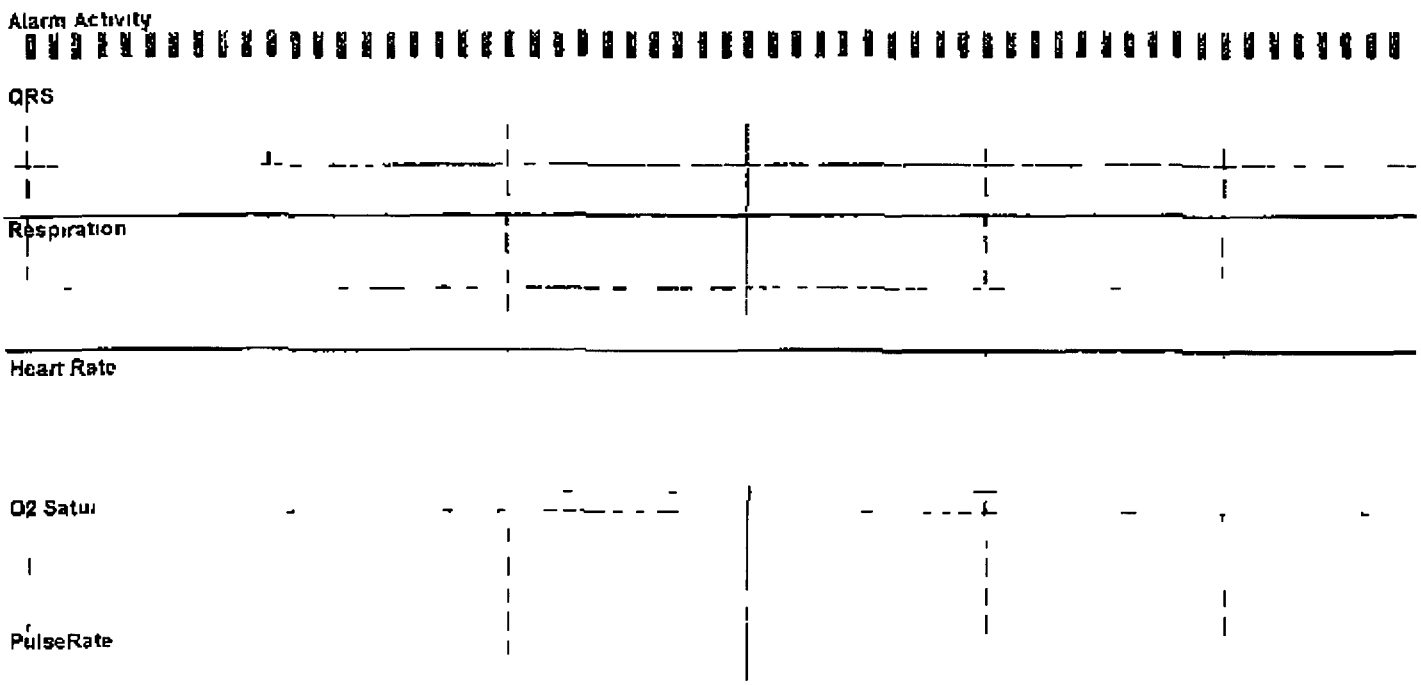

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 53 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 5/10)
01 54 29

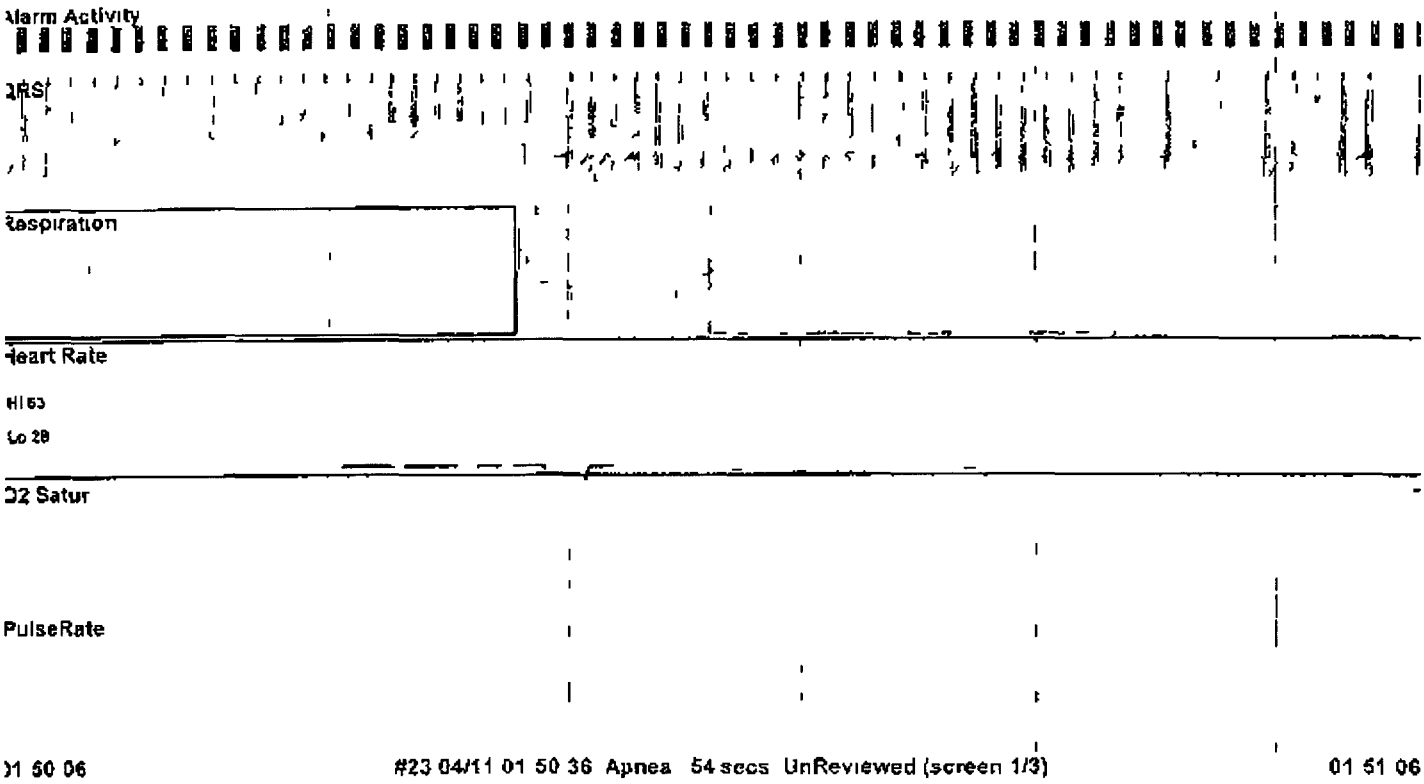

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 54 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 6/10)
01 55 29

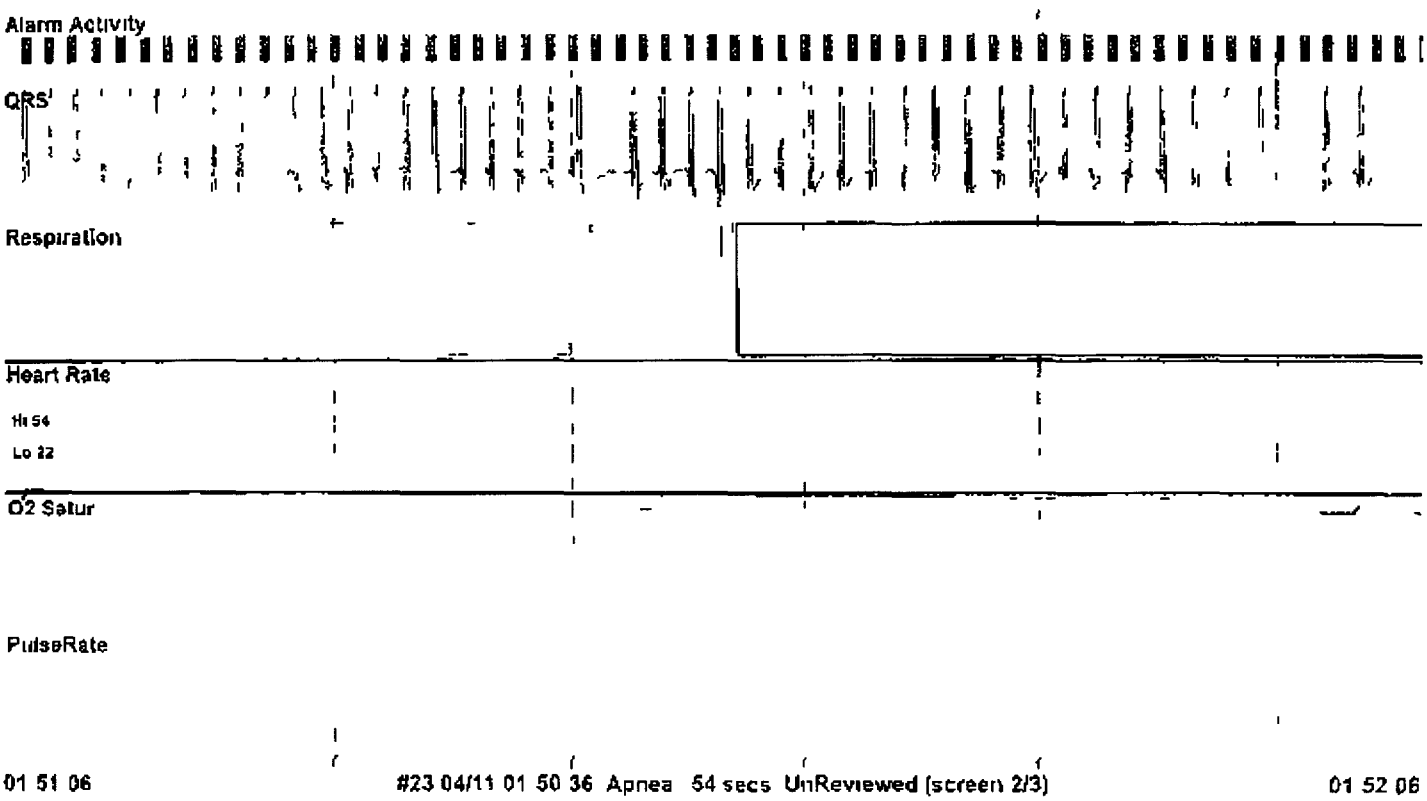

Alarm Activity
ECG
Respiration
Heart Rate
O2 Satur
PulseRate
01 55 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 7/10)
01 56 29

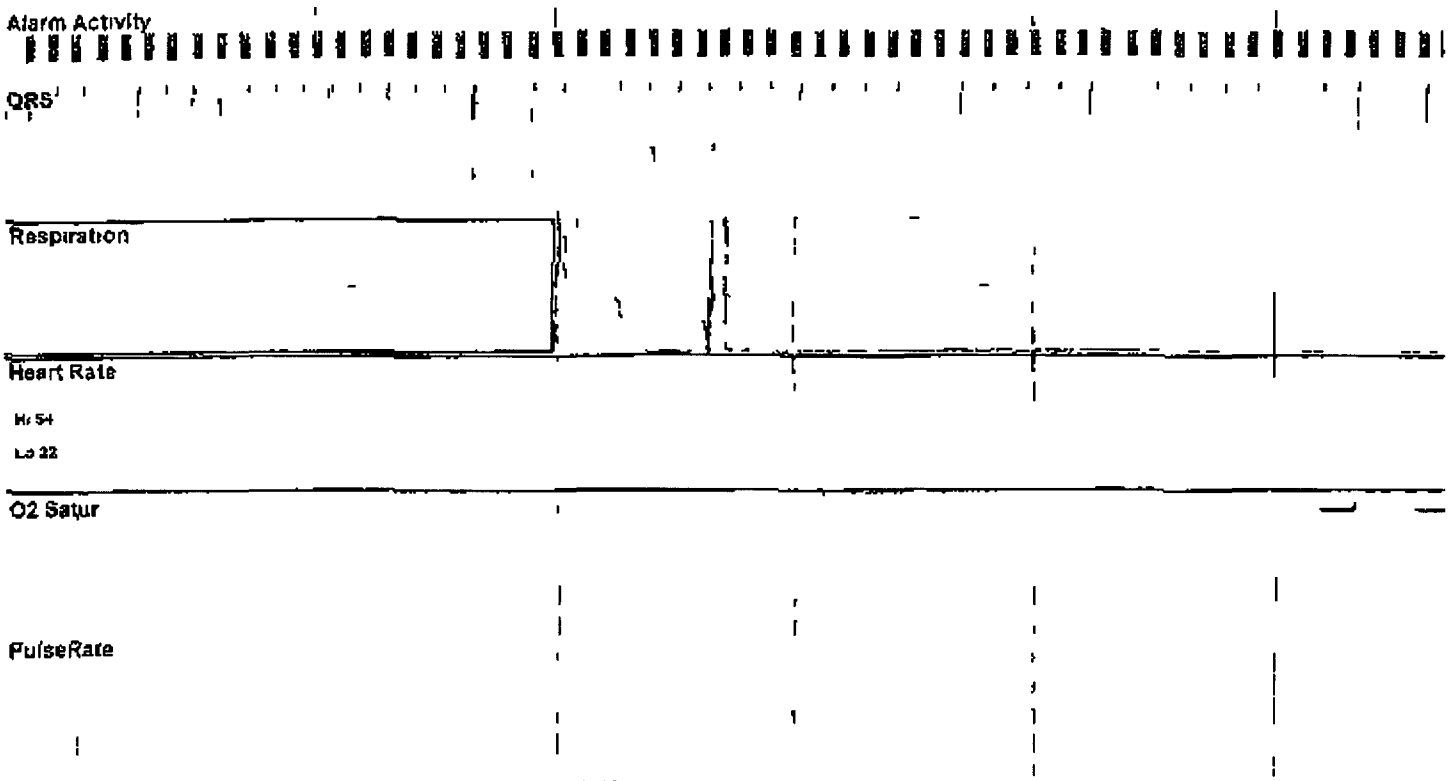

Alarm Activity
ECG
Respiration
Heart Rate
O2 Satur
PulseRate
01 56 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 8/10)
01 57 29

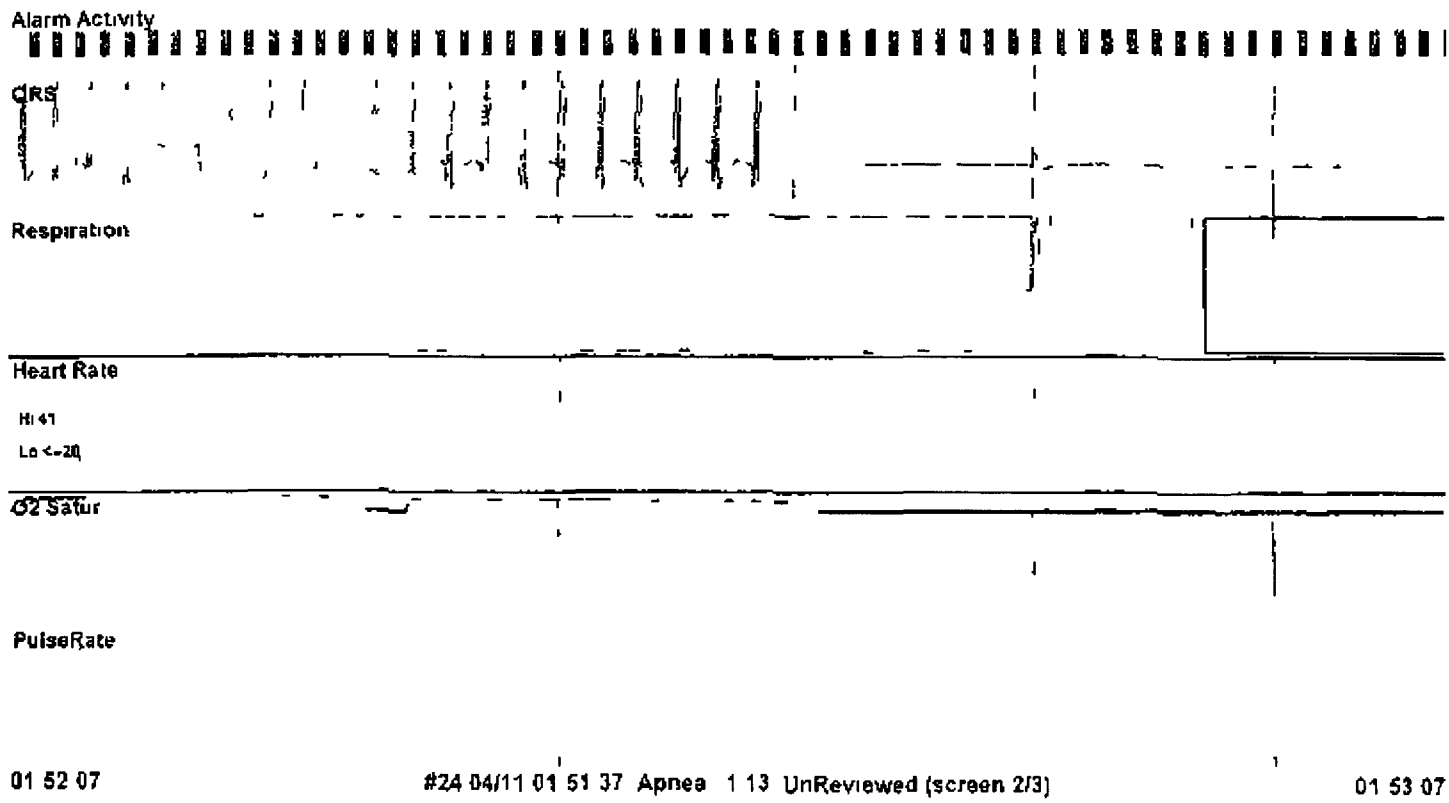

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 57 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 9/10)
01 58 29

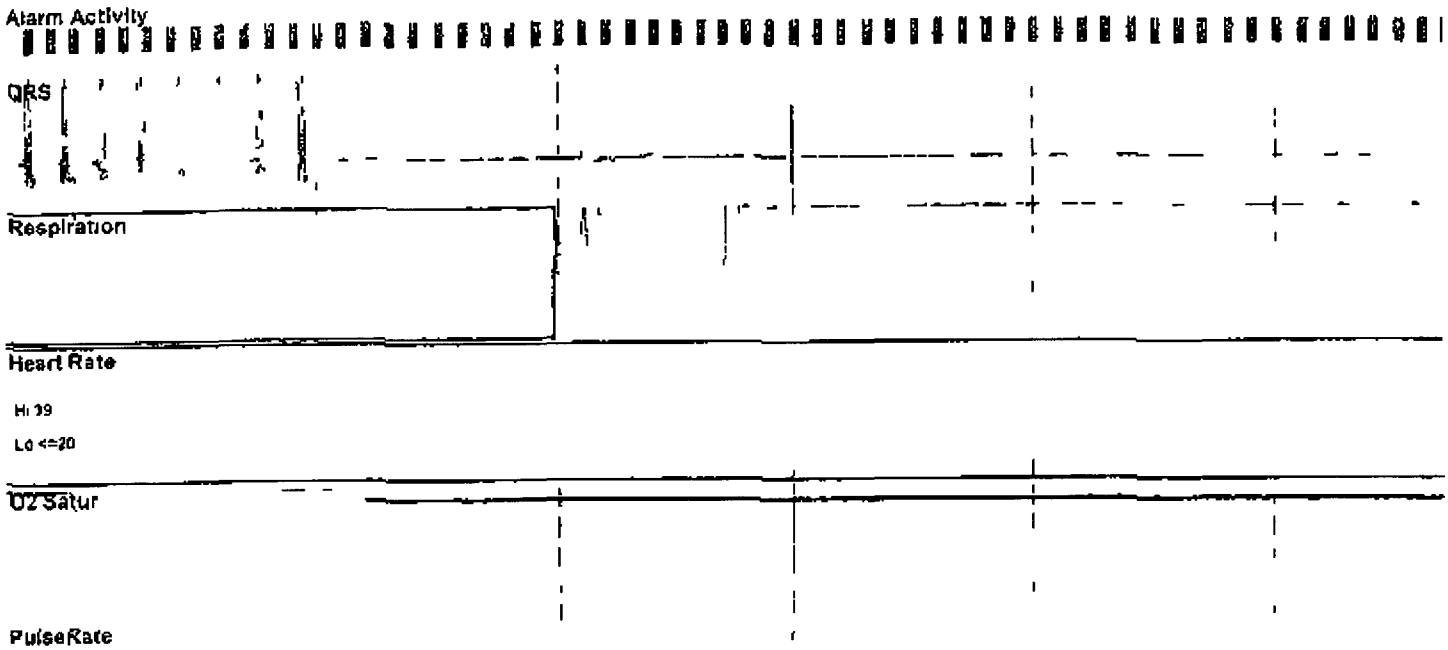

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 58 29
#22 04/11 01 49 59 Heart Slow 9 30 UnReviewed (screen 10/10)
01 59 28


Alarm Activity
QRS
Respiration
Heart Rate
Hi 63
Lo 28
O2 Satur
PulseRate
01 50 06
#23 04/11 01 50 36 Apnea 54 secs UnReviewed (screen 1/3)
01 51 06

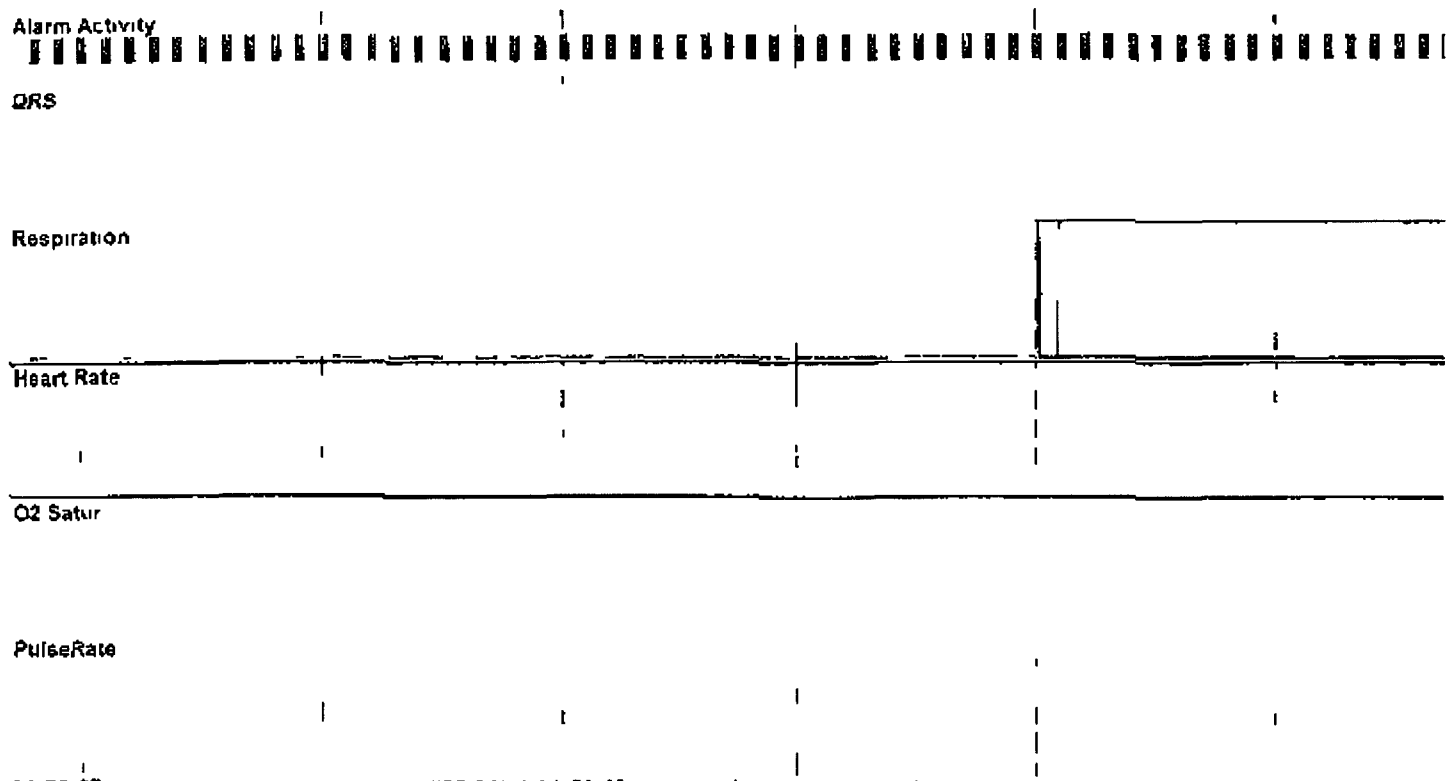

Alarm Activity
QRS
Respiration
Heart Rate
Hi 54
Lo 22
O2 Satur
PulseRate
01 51 06
#23 04/11 01 50 36 Apnea 54 secs UnReviewed (screen 2/3)
01 52 06


Alarm Activity
QRS
Respiration
Heart Rate
Hi 54
Lo 22
O2 Satur
PulseRate
01 51 07
#24 04/11 01 51 37 Apnea 1 13 UnReviewed (screen 1/3)
01 52 07

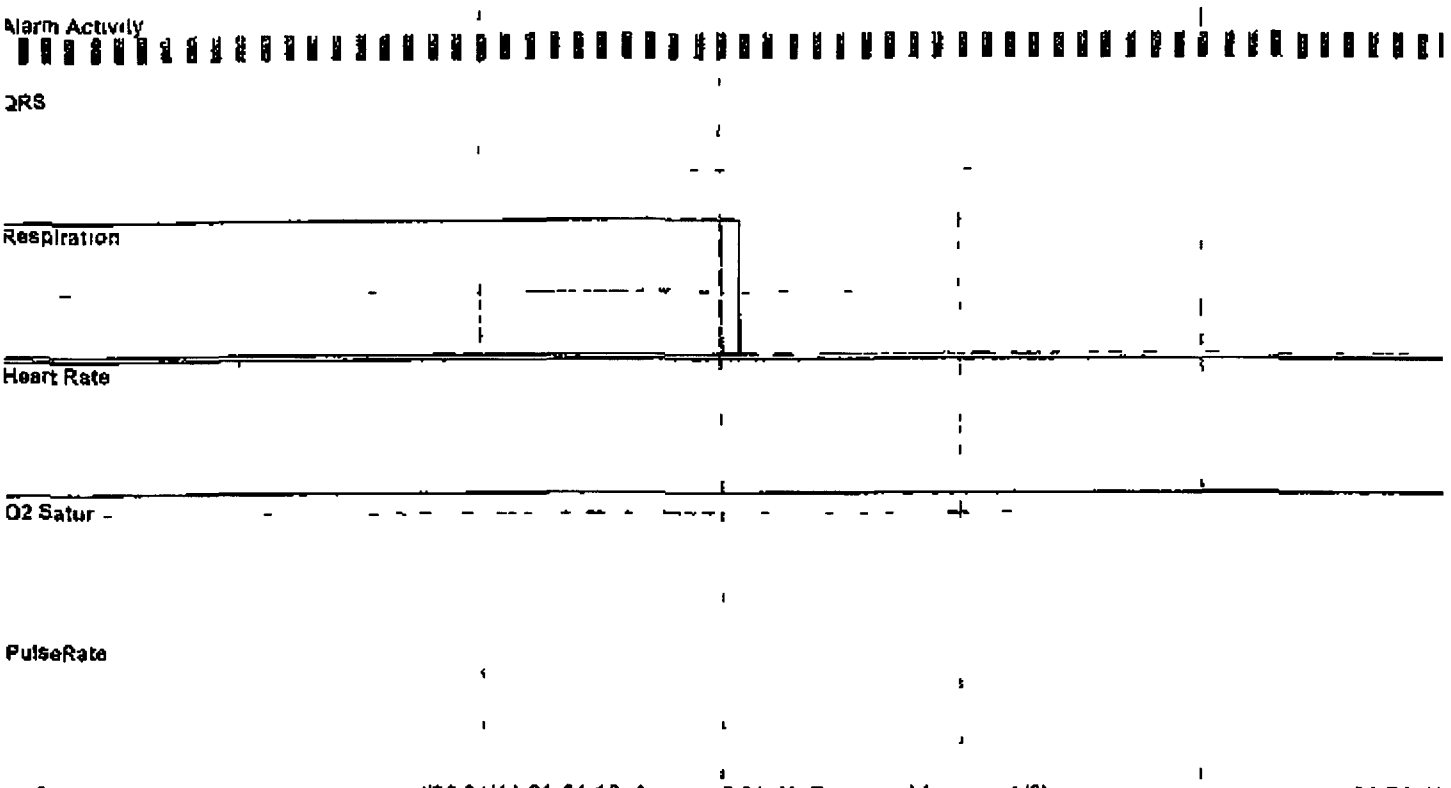

Alarm Activity
QRS
Respiration
Heart Rate
Hi 41
Lo <-20
O2 Satur
PulseRate
01 52 07
#24 04/11 01 51 37 Apnea 1 13 UnReviewed (screen 2/3)
01 53 07

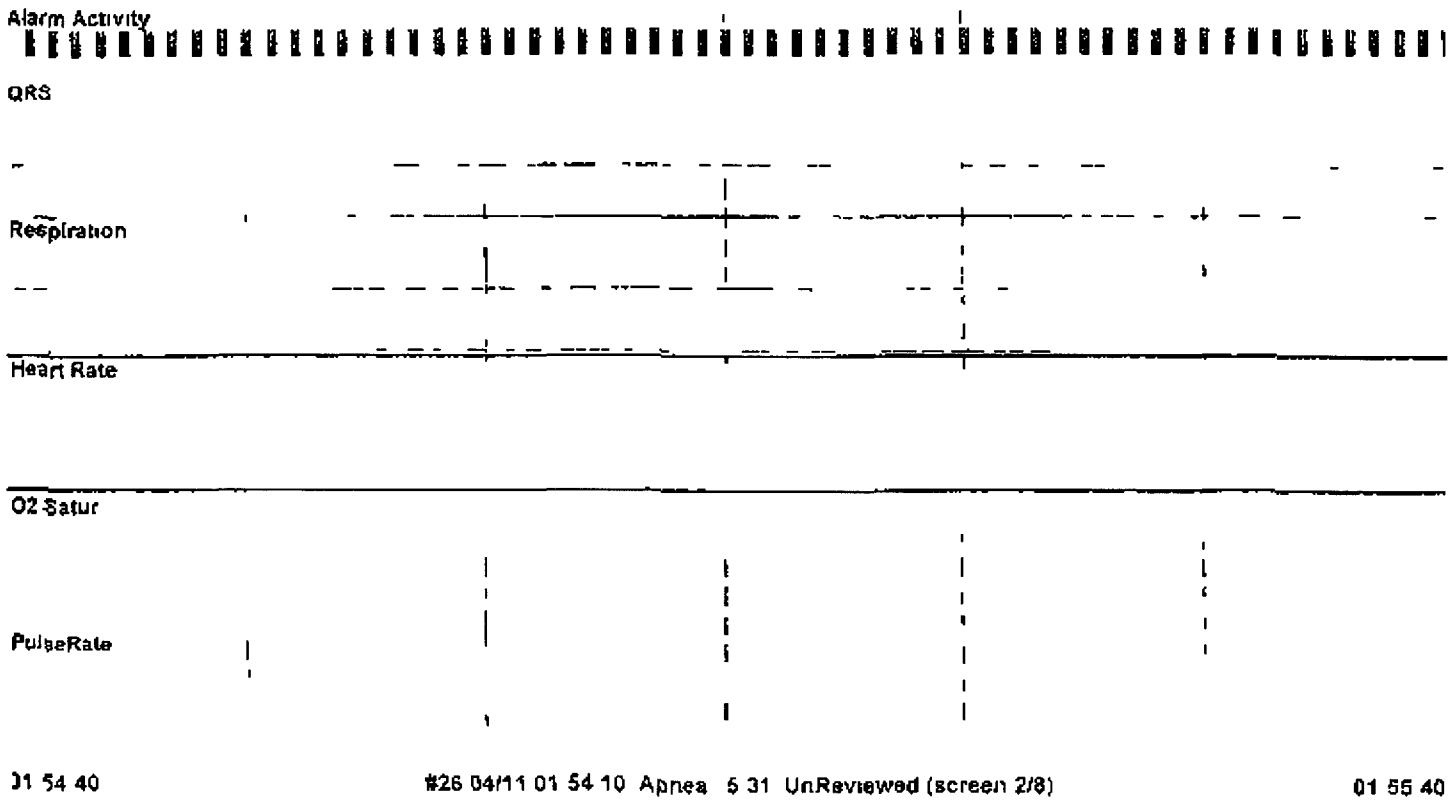


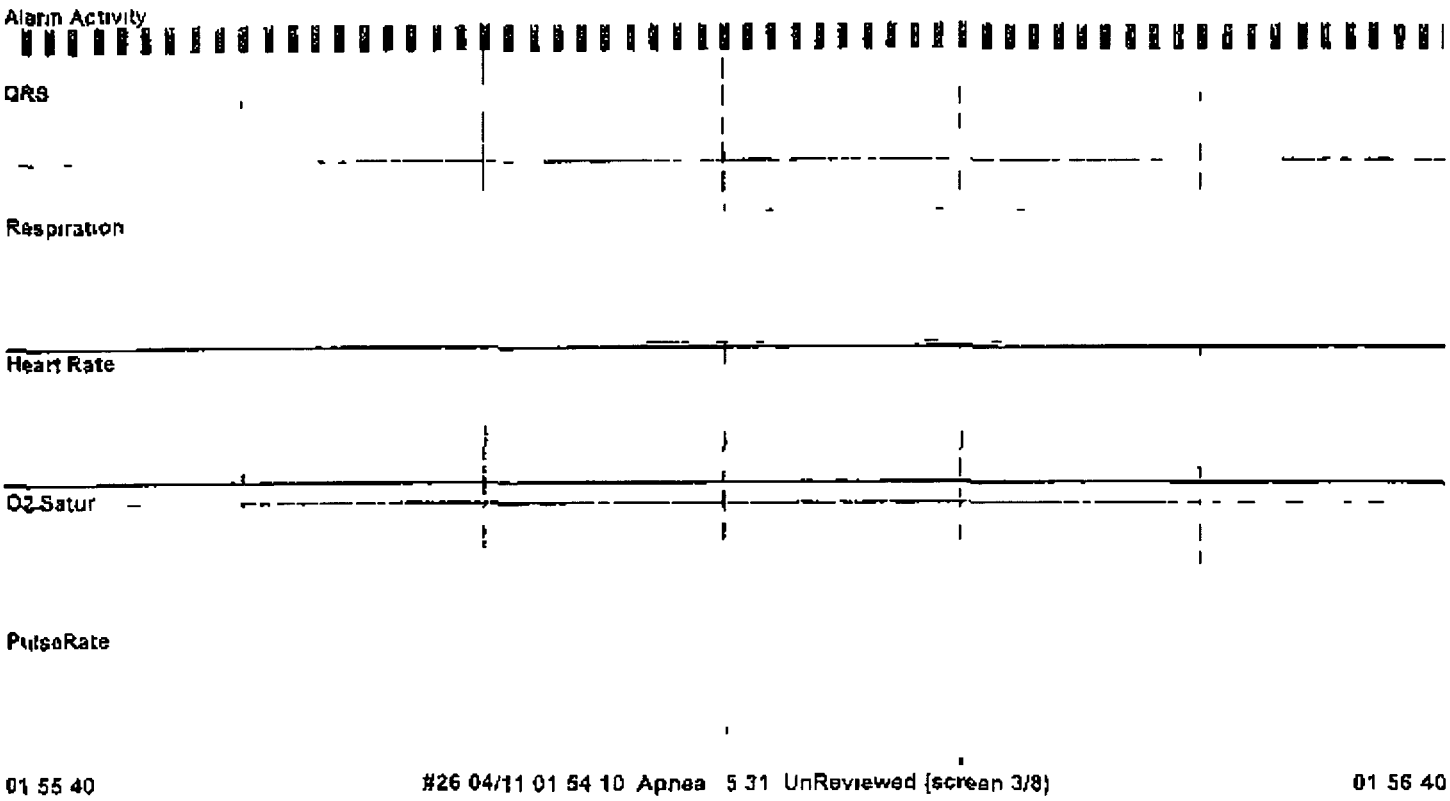
01 52 27 #25 04/11 01 52 57 Apnea 1 14 UnReviewed (screen 1/3) 01 53 27

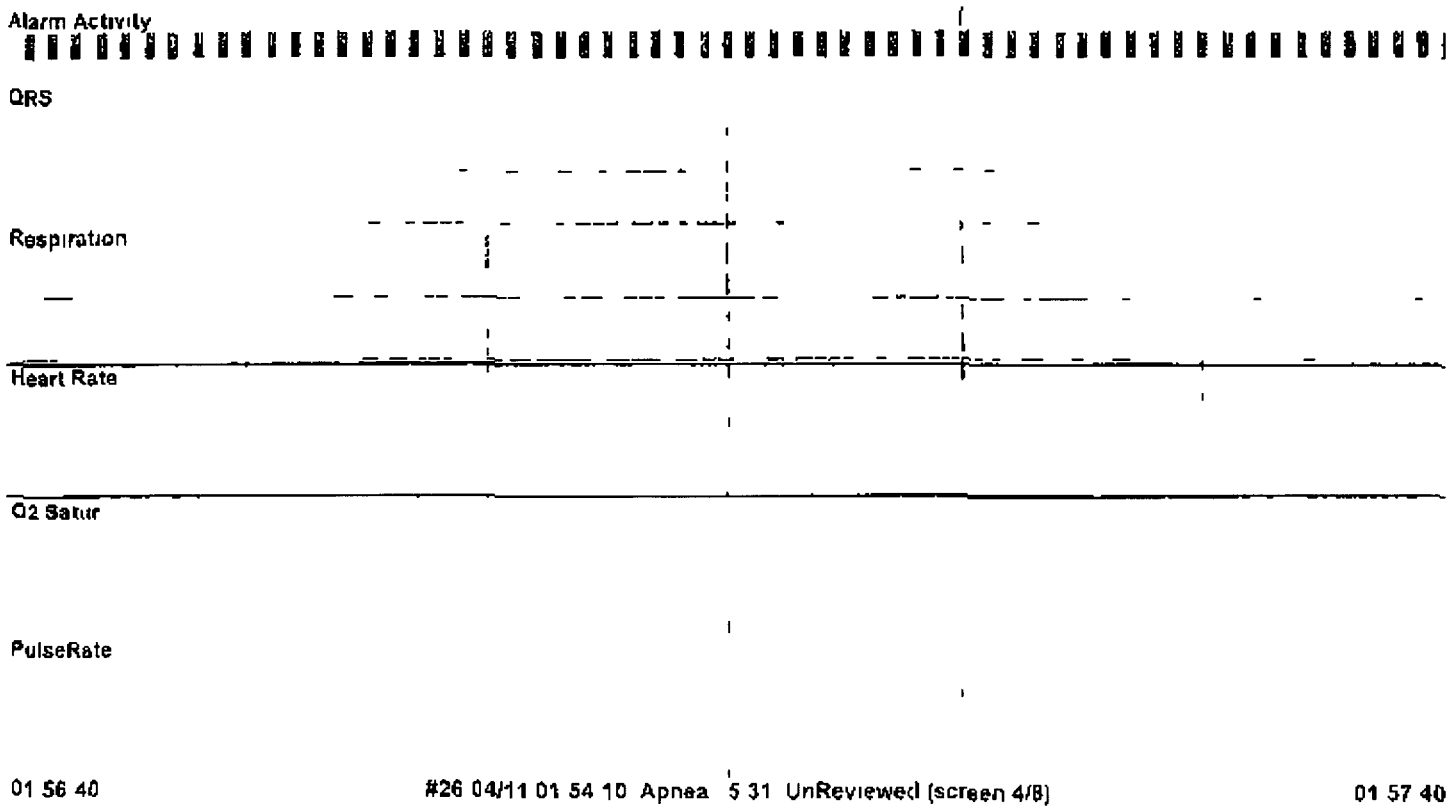


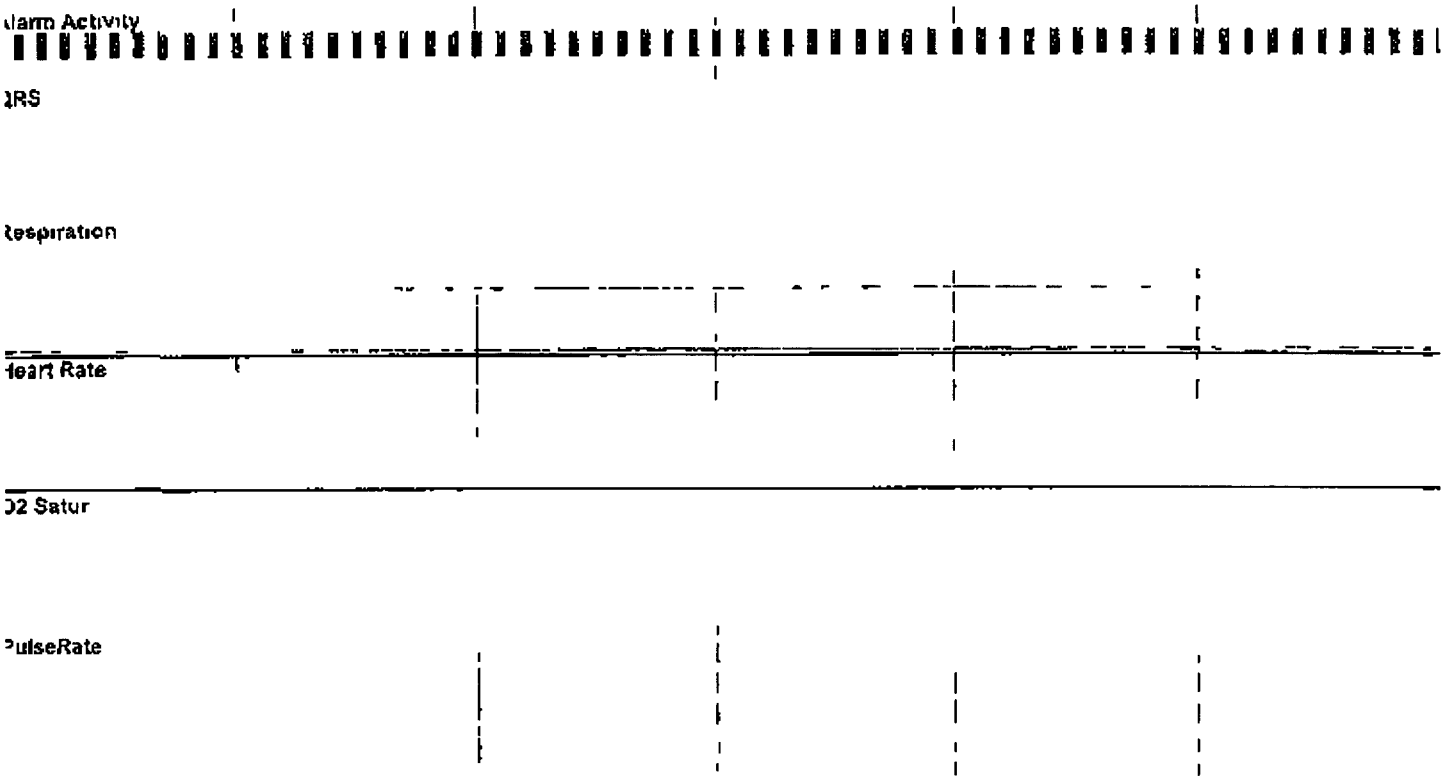
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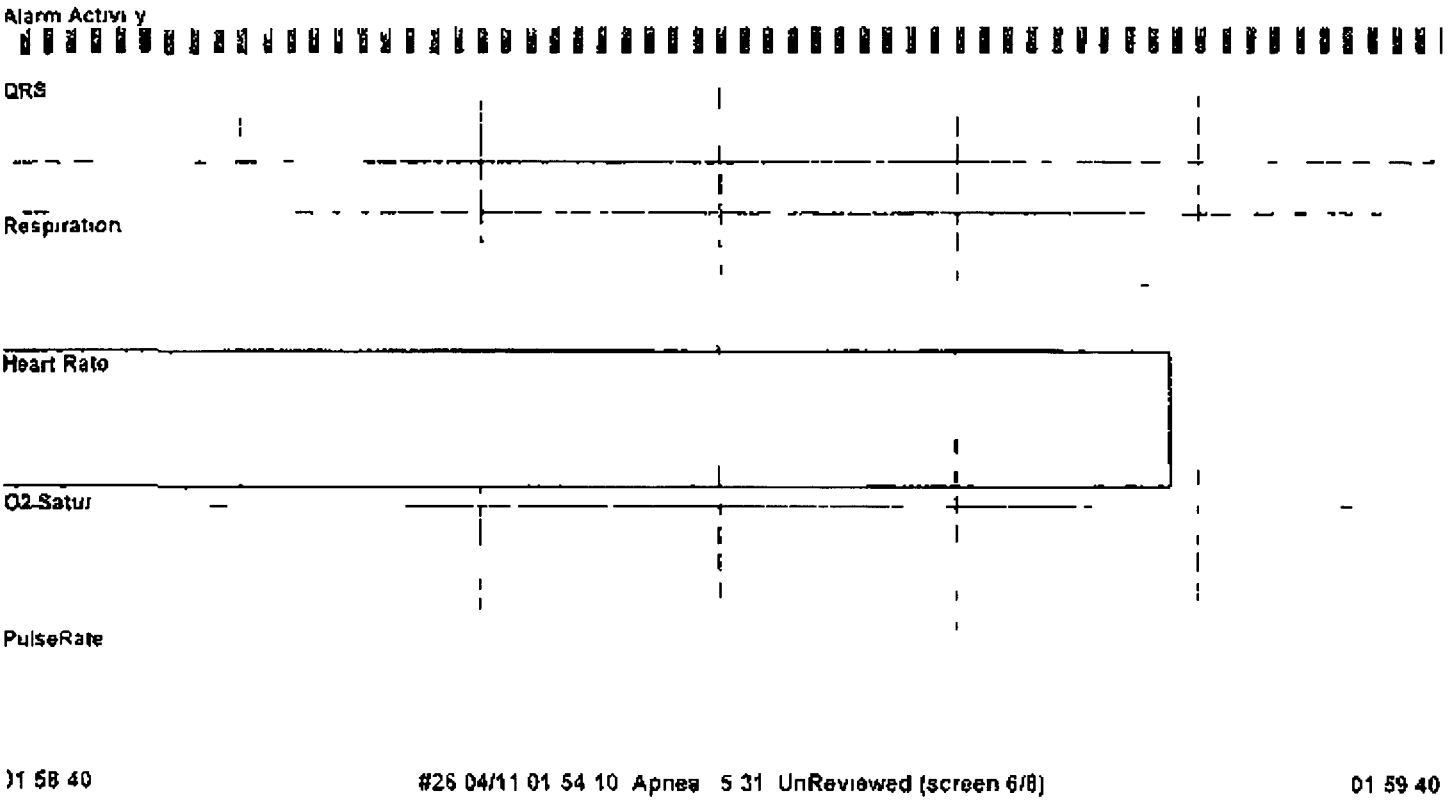

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 53 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 1/8)
01 54 40

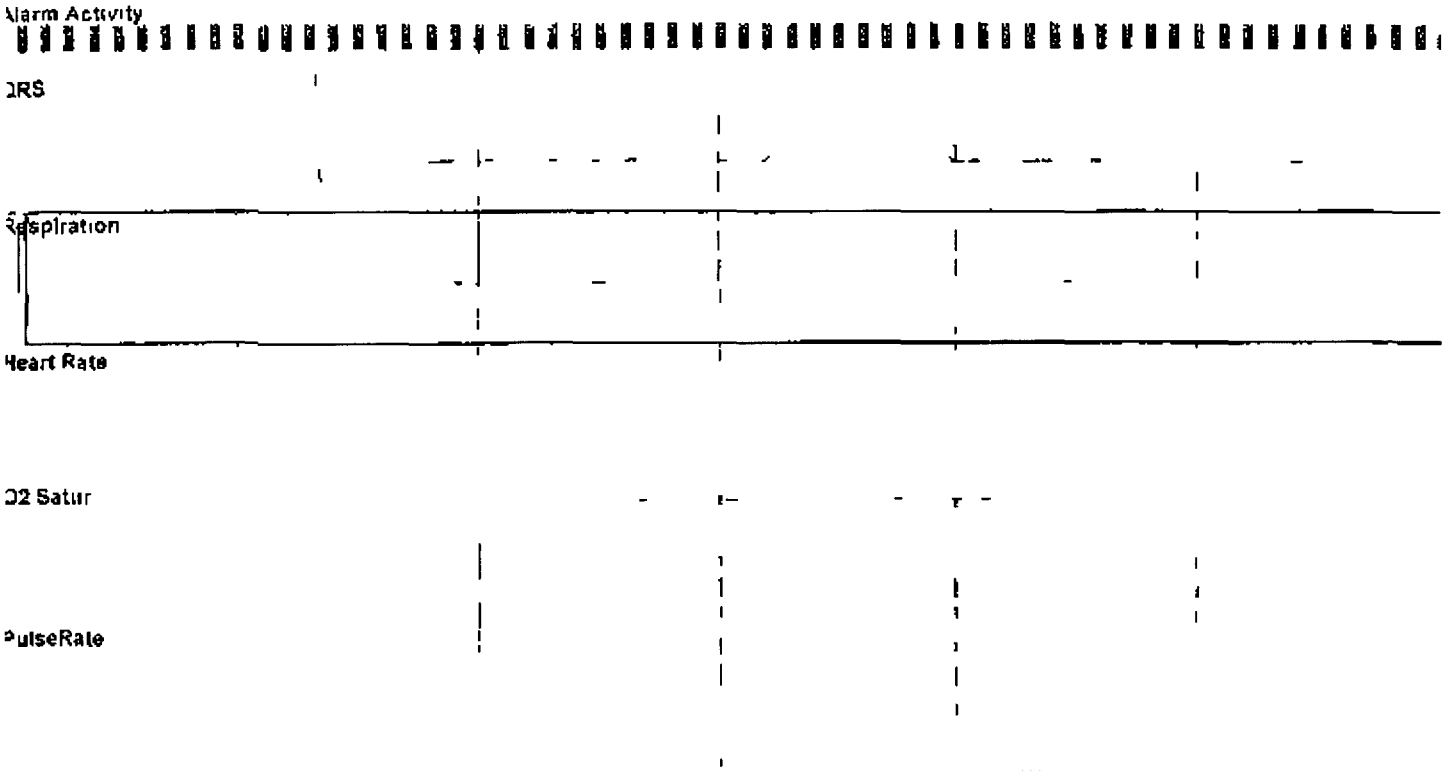

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 54 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 2/8)
01 55 40

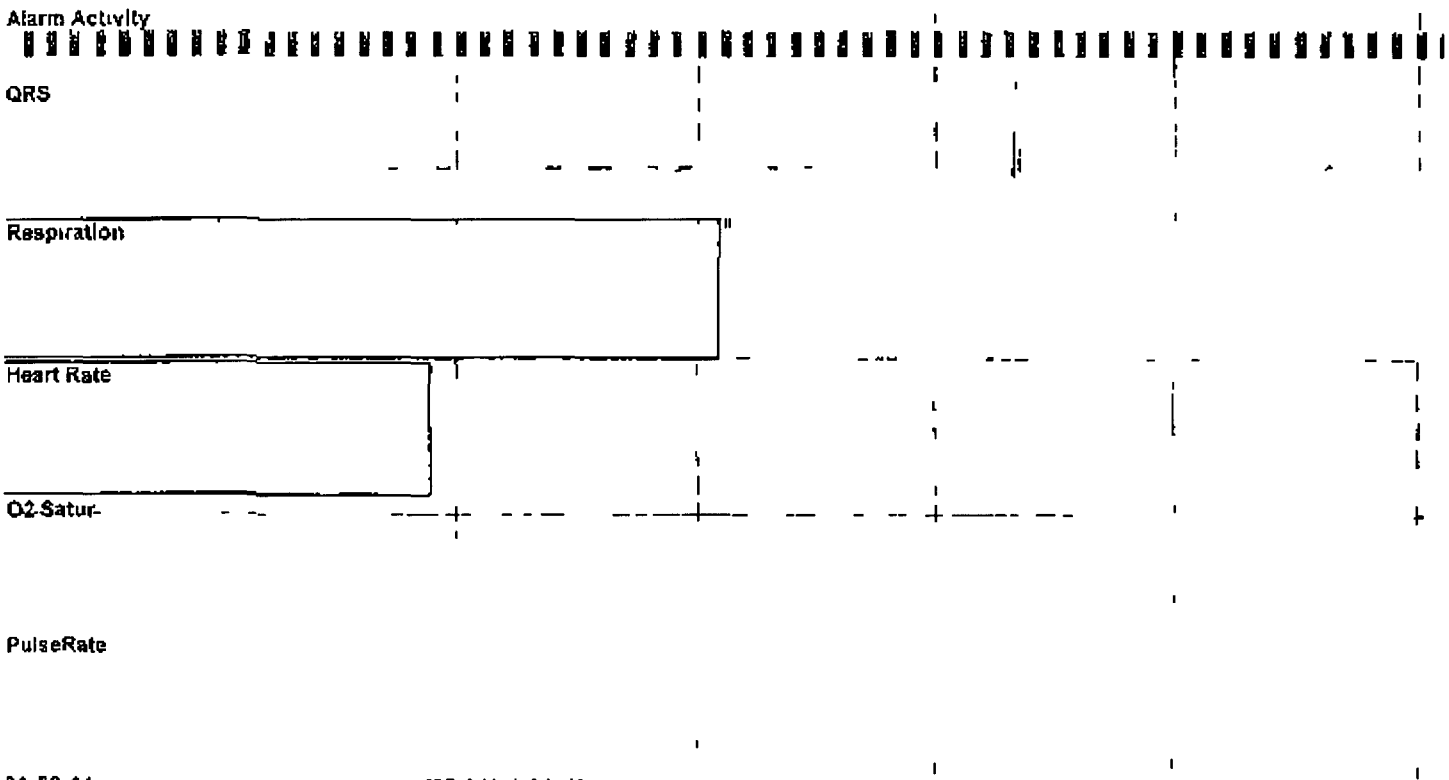

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 55 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 3/8)
01 56 40

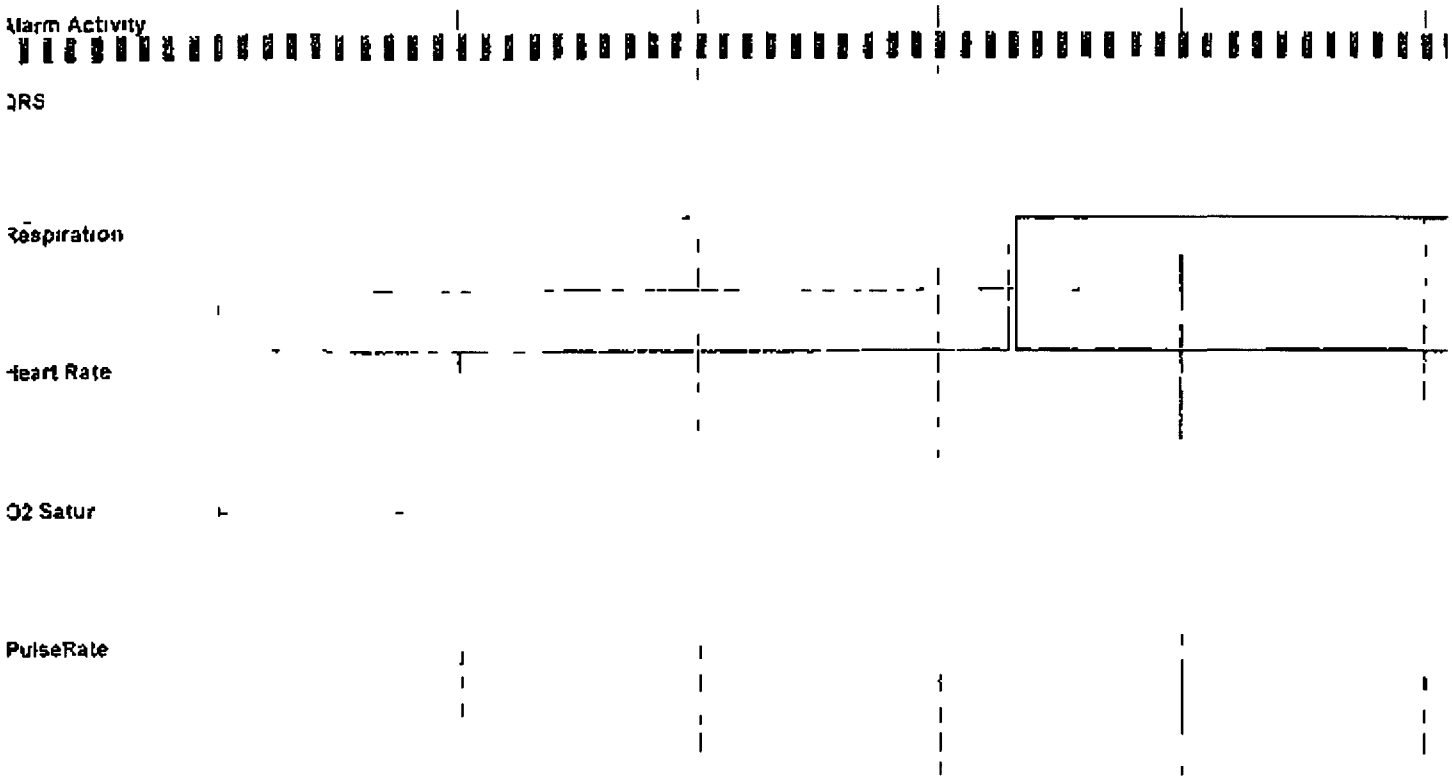

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 56 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 4/8)
01 57 40

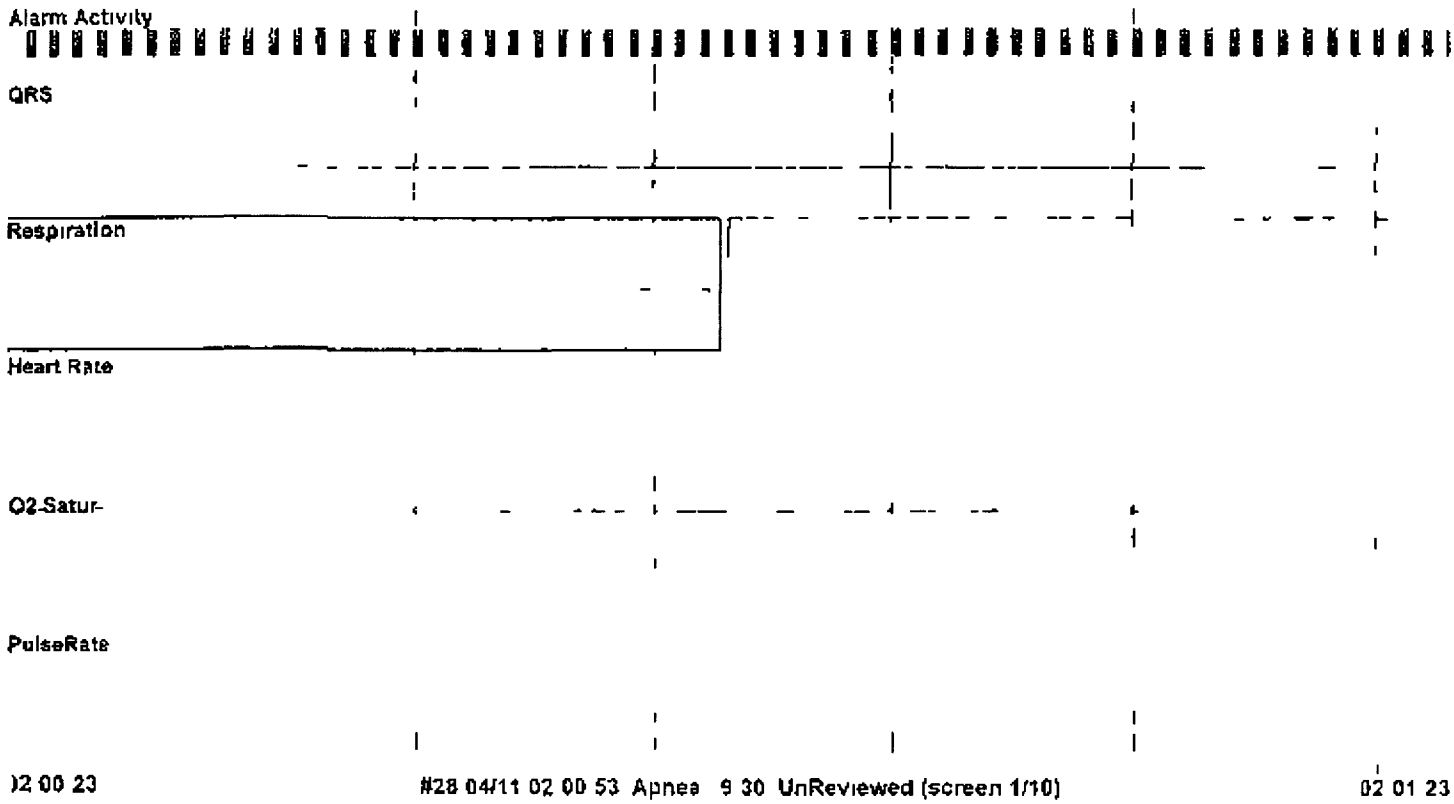

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 57 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 5/8)
01 58 40

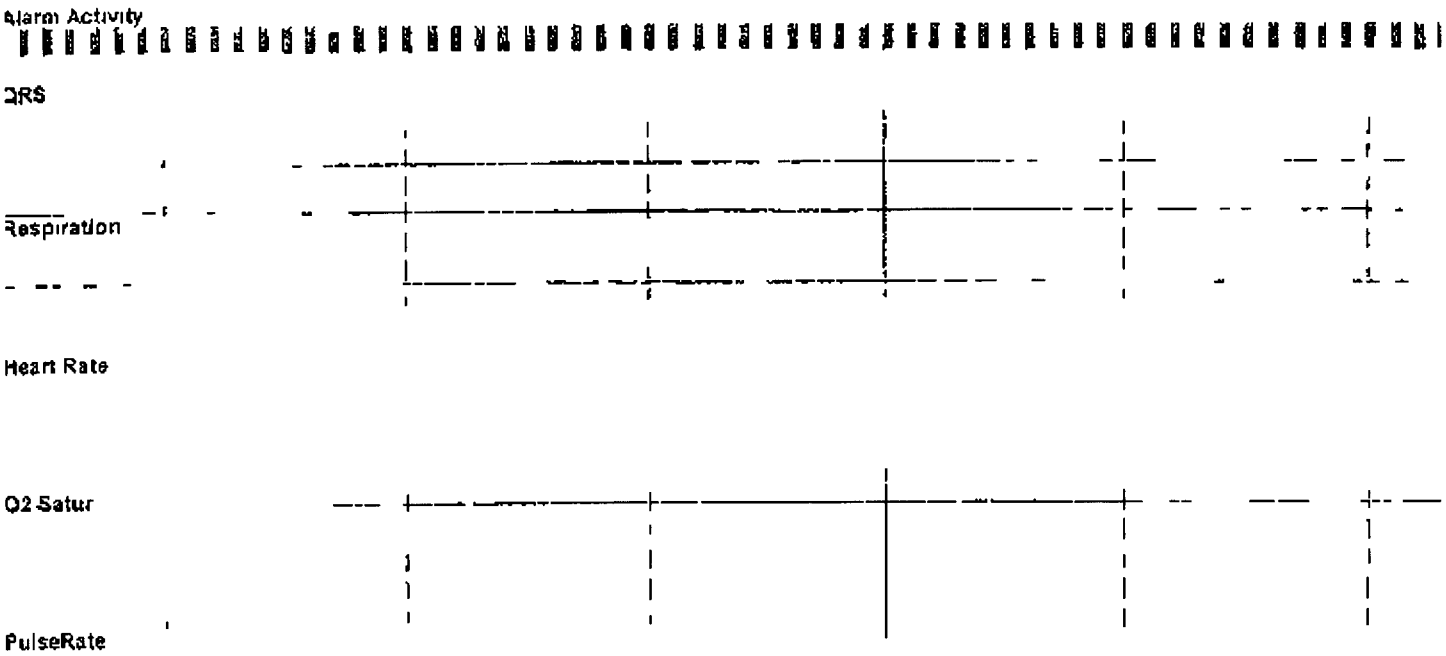

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 58 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 6/8)
01 59 40


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 59 40
#26 04/11 01 54 10 Apnea 5 31 UnReviewed (screen 7/8)
02 00 40

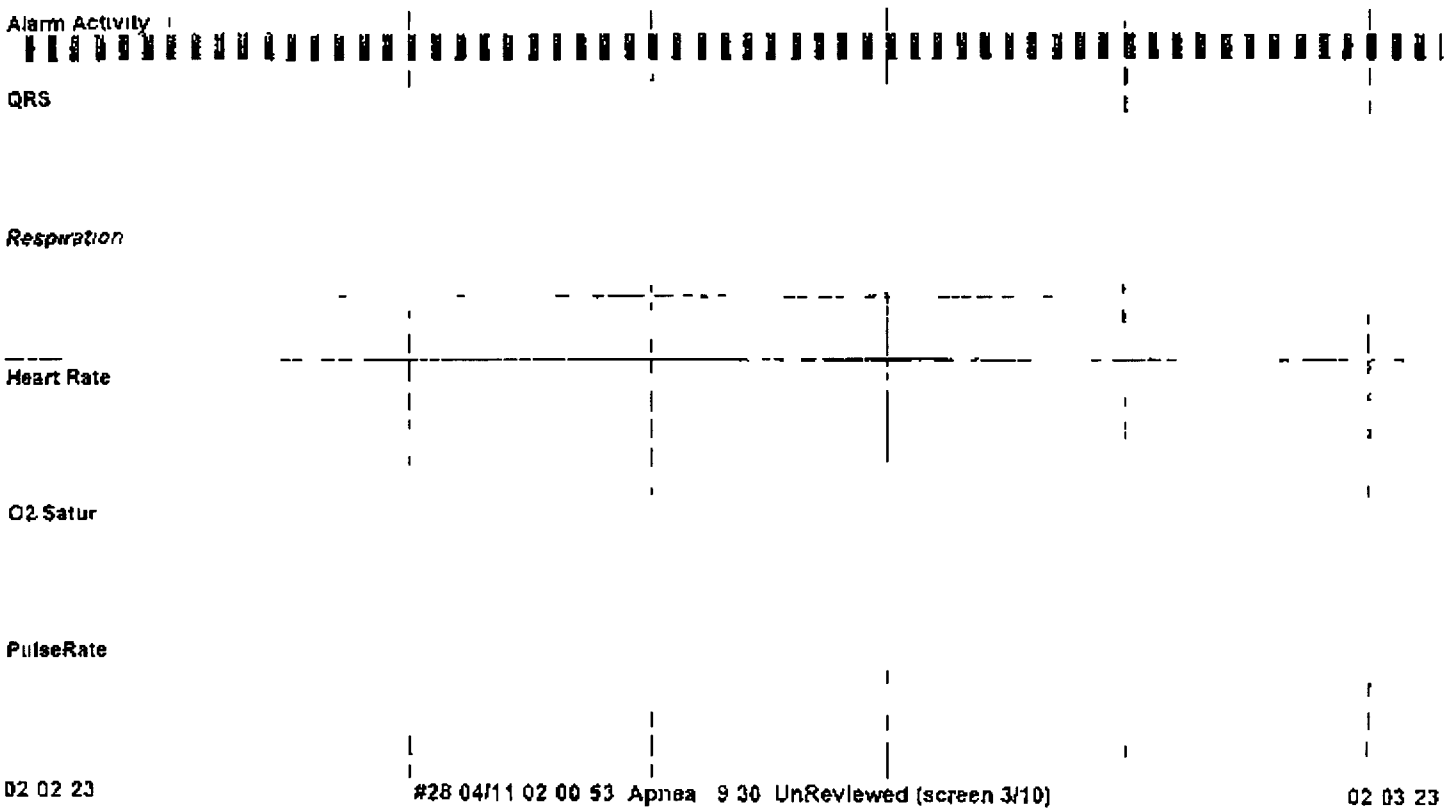

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
01 59 11
#27 04/11 01 59 41 Apnea 1 12 UnReviewed (screen 1/3)
02 00 11


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 00 11
#27 04/11 01 59 41 Apnea 1 12 UnReviewed (screen 2/3)
02 01 11

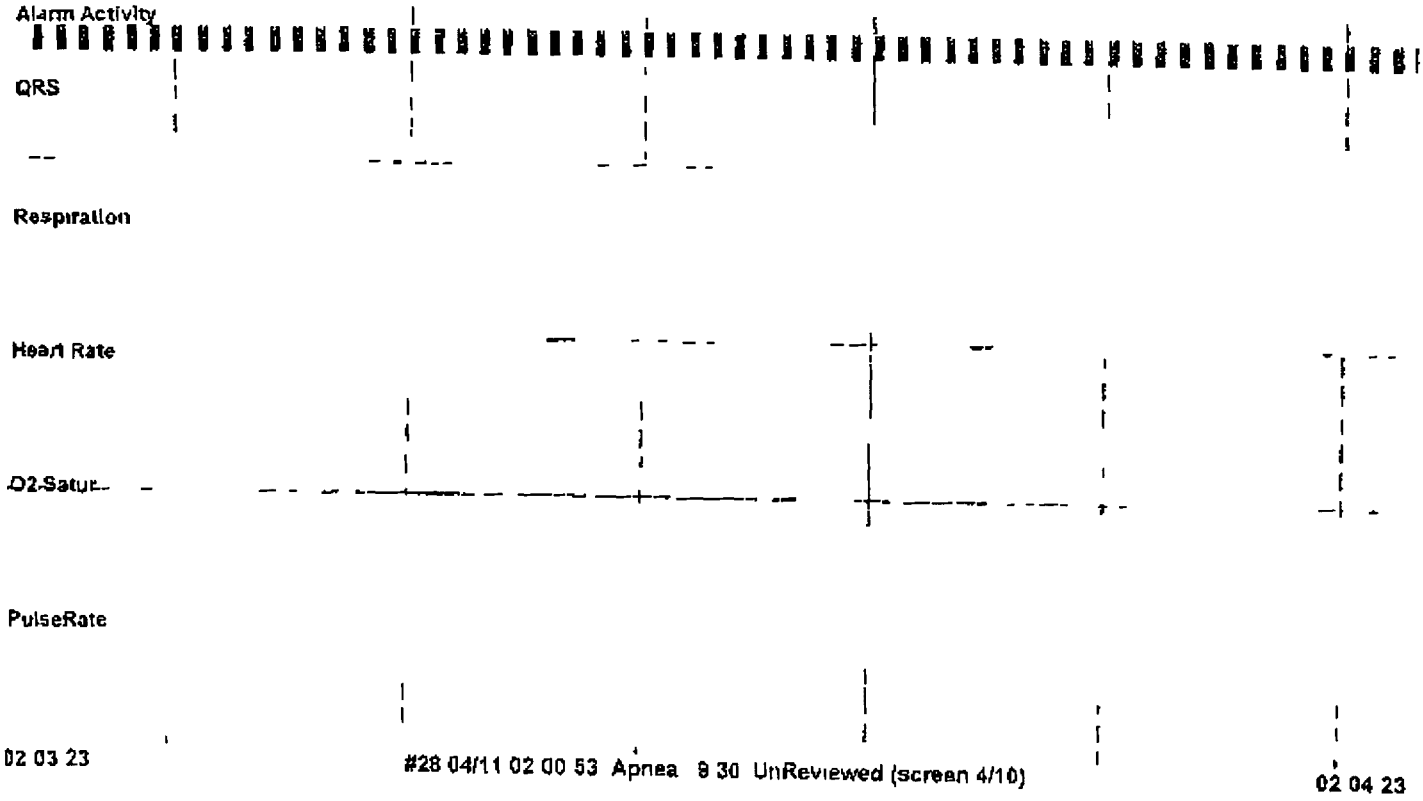

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 00 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 1/10)
02 01 23

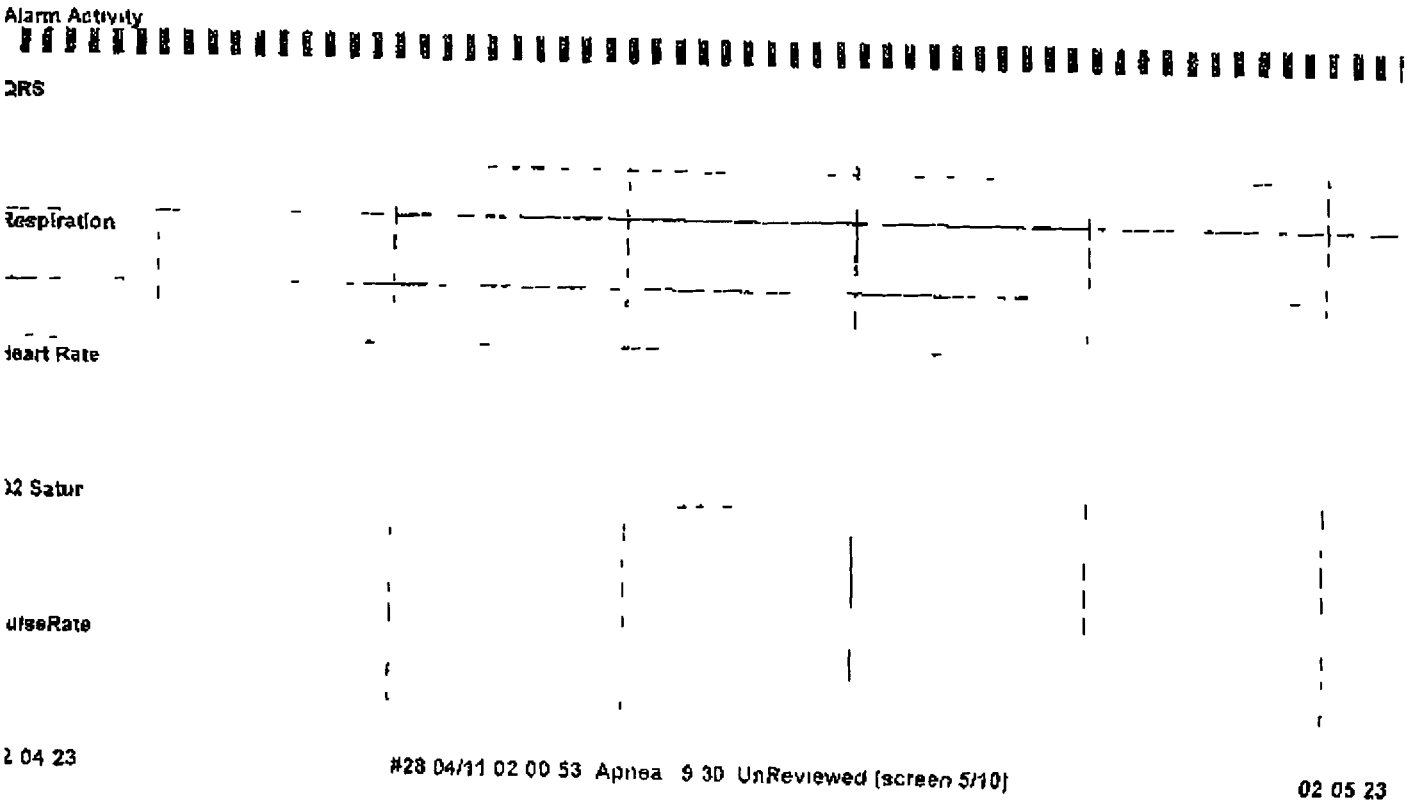


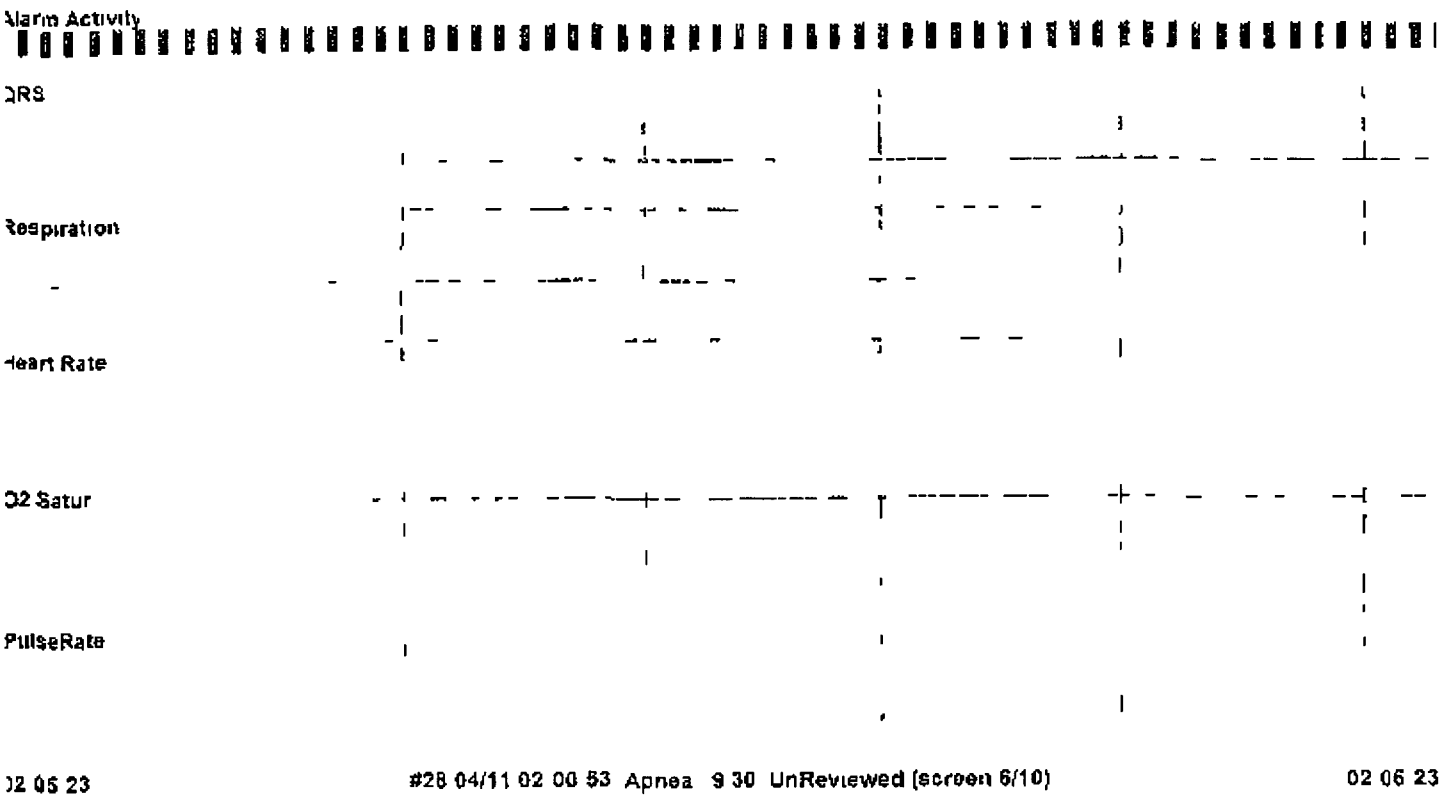
02 01 23 #28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 2/10) 02 02 23

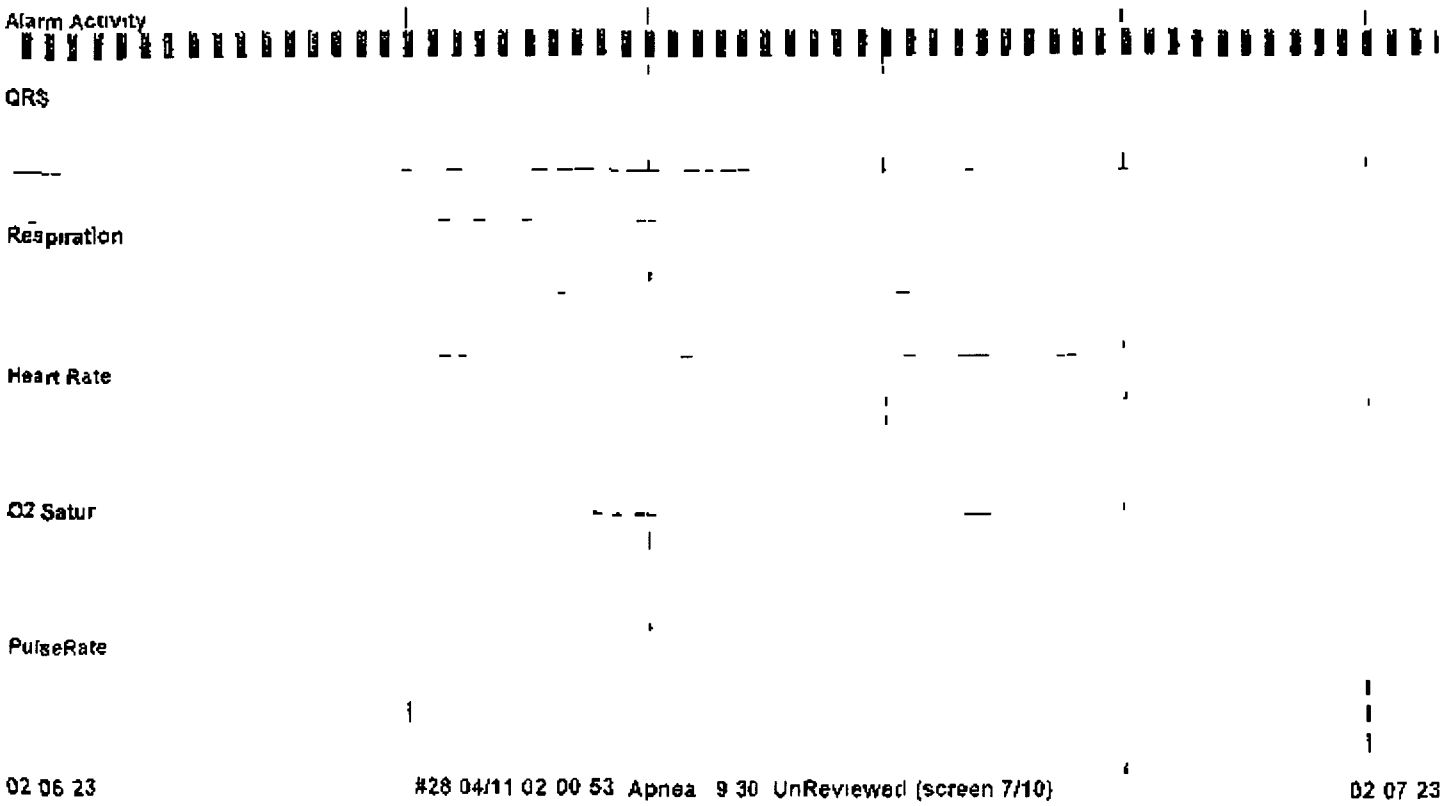


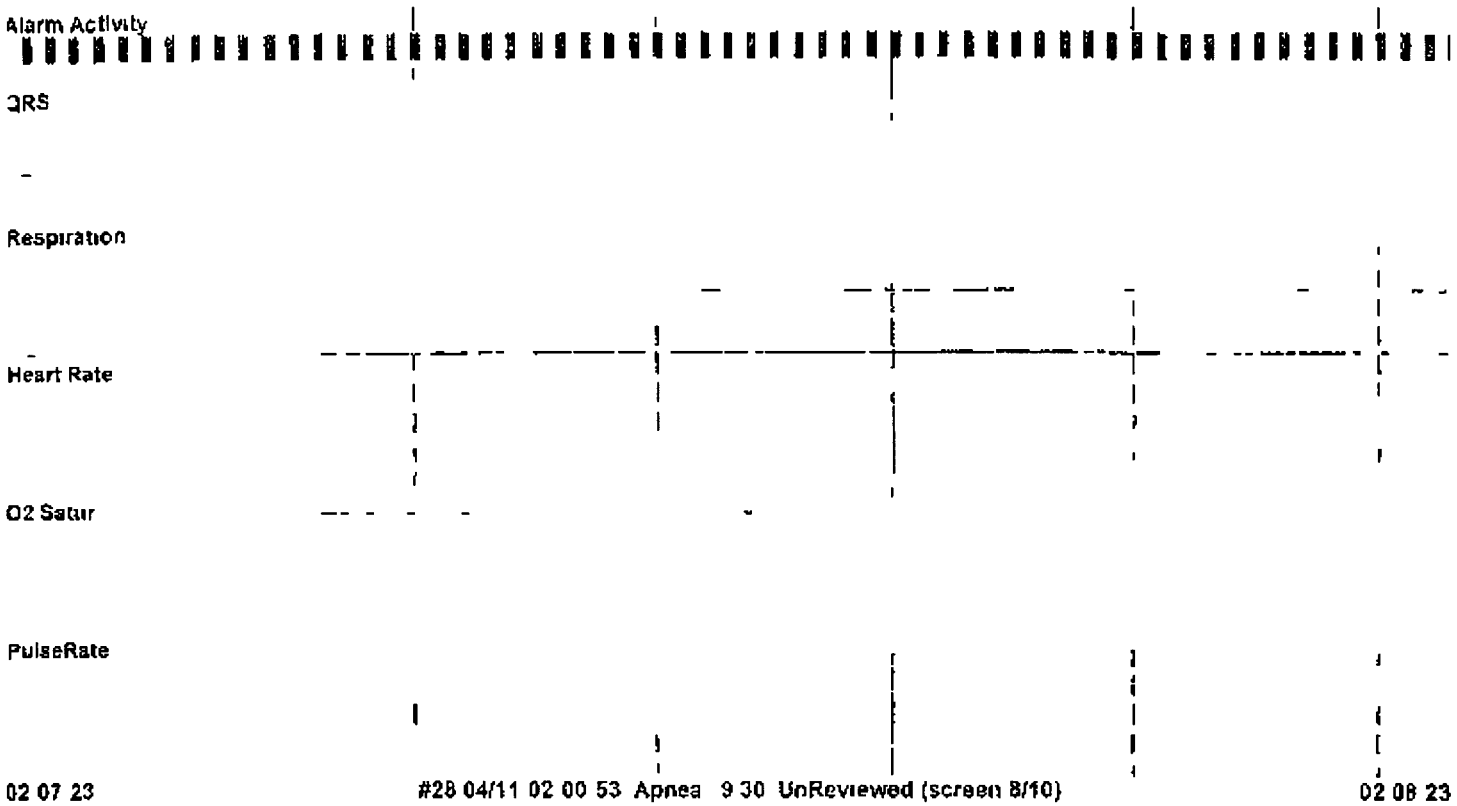
02 02 23 #28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 3/10) 02 03 23

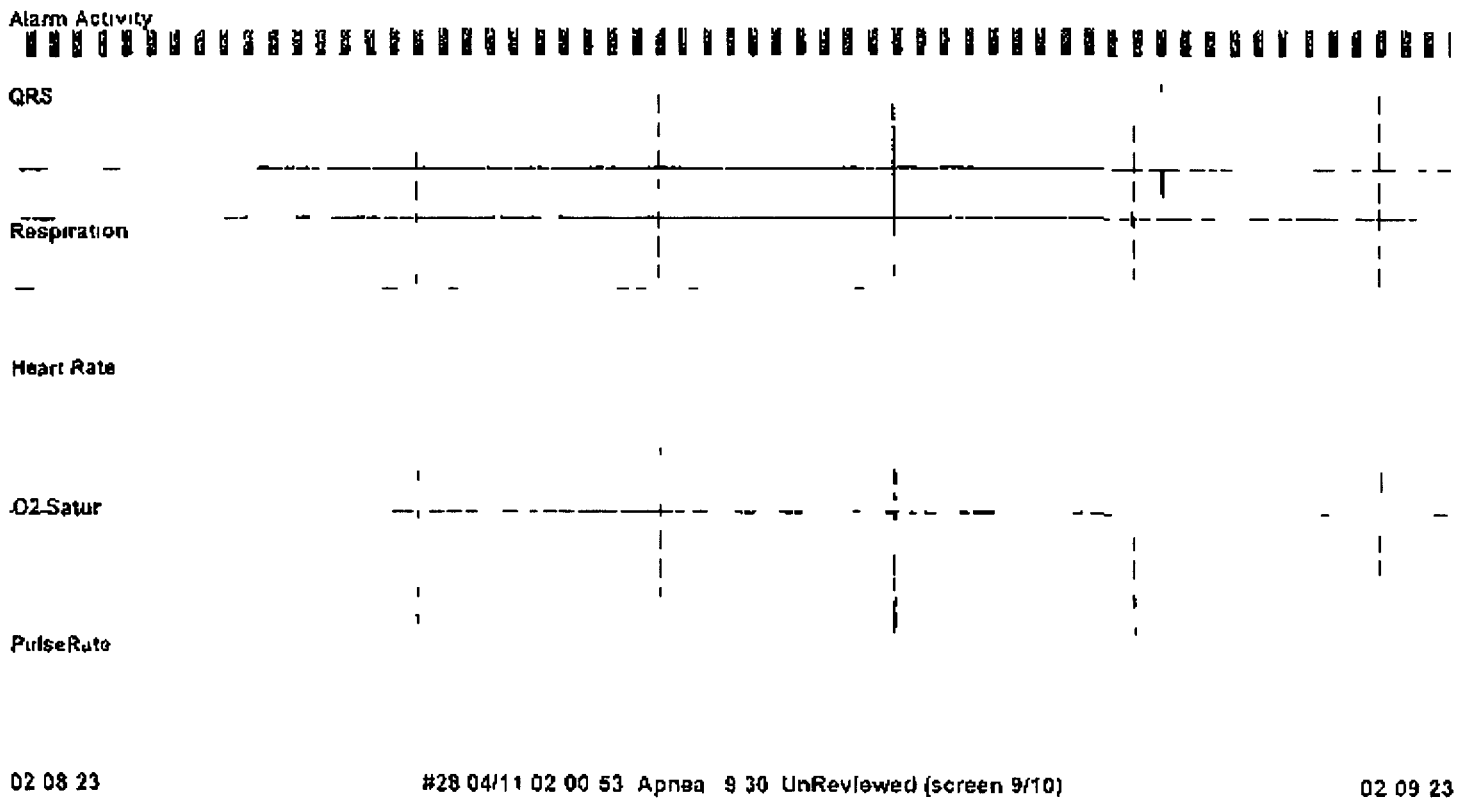

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 03 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 4/10)
02 04 23

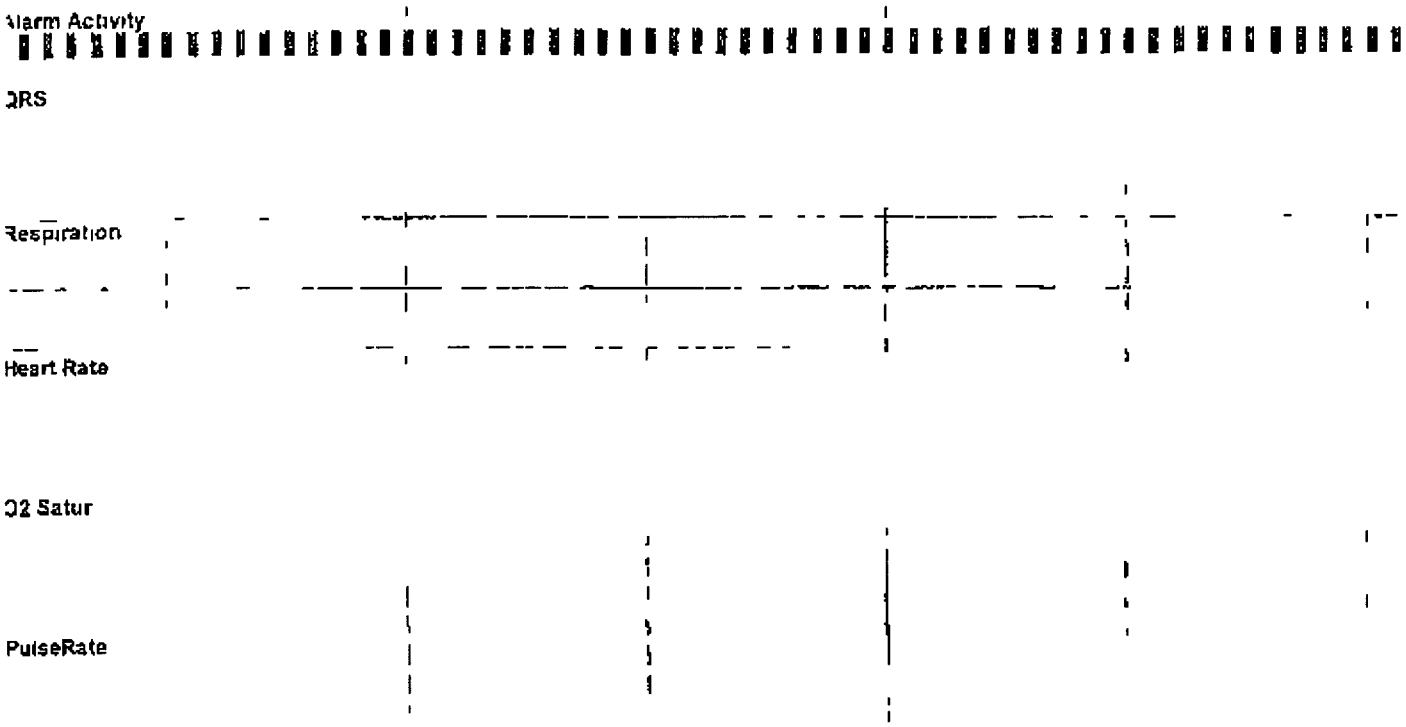

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
2 04 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 5/10)
02 05 23


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 06 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 6/10)
02 06 23

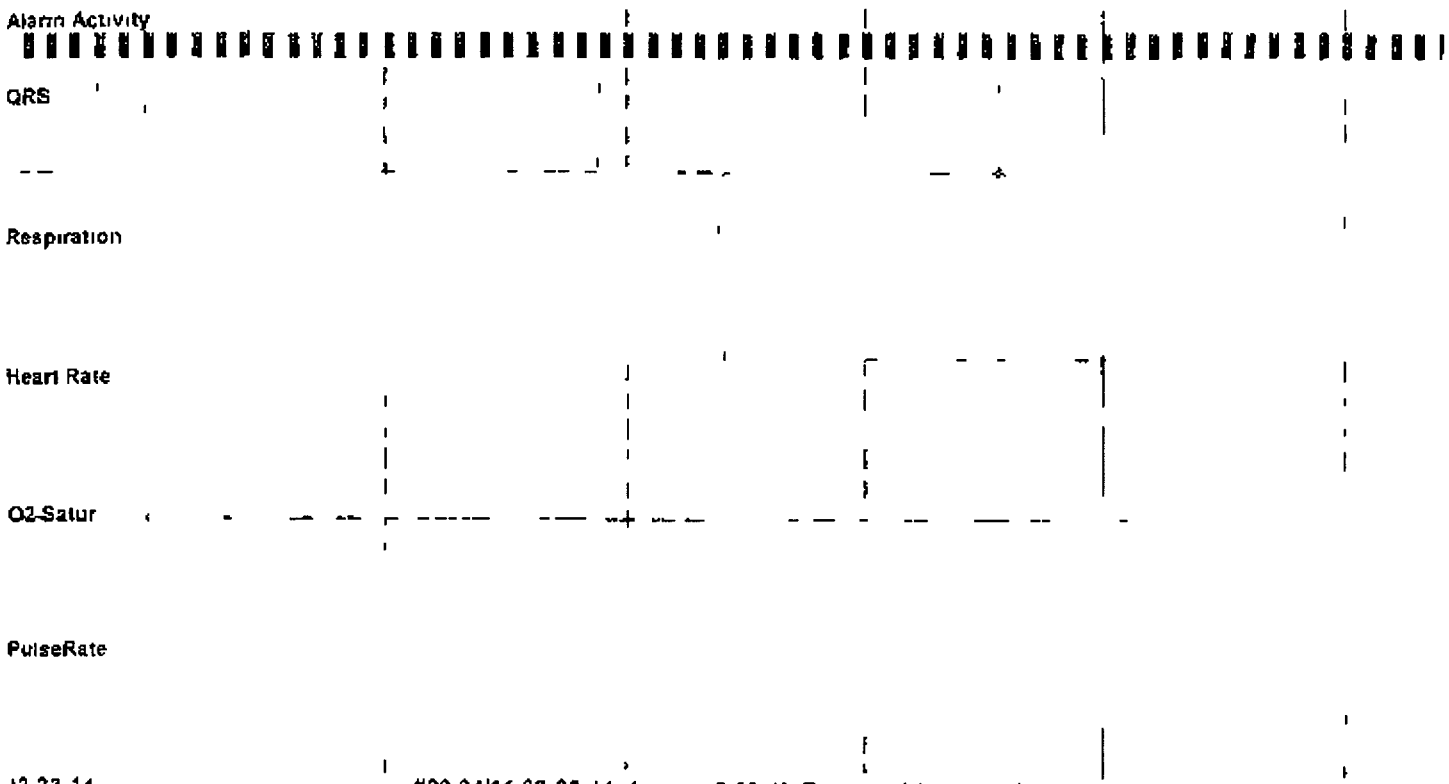

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 06 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 7/10)
02 07 23


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 07 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 8/10)
02 08 23

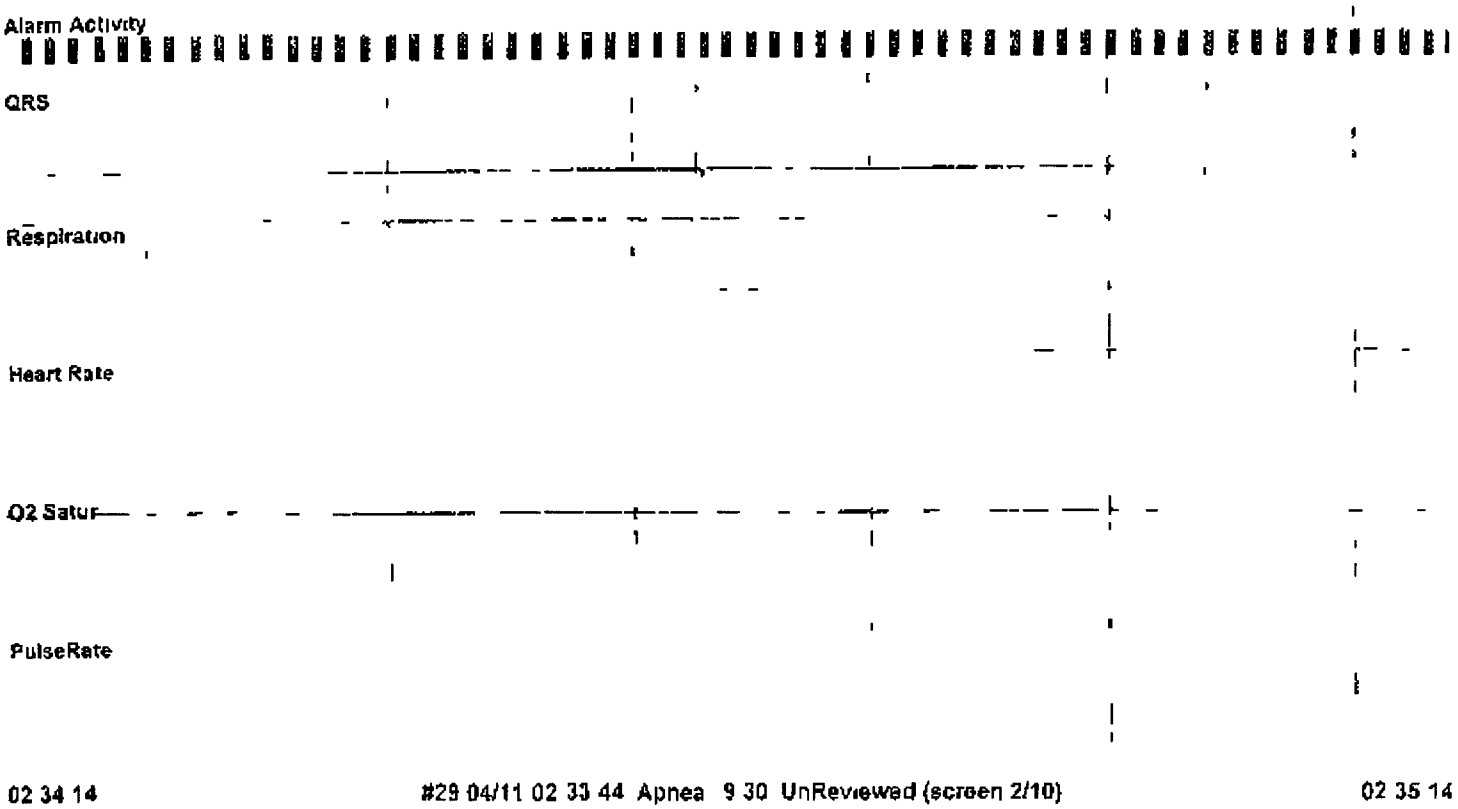

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 08 23
#28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 9/10)
02 09 23

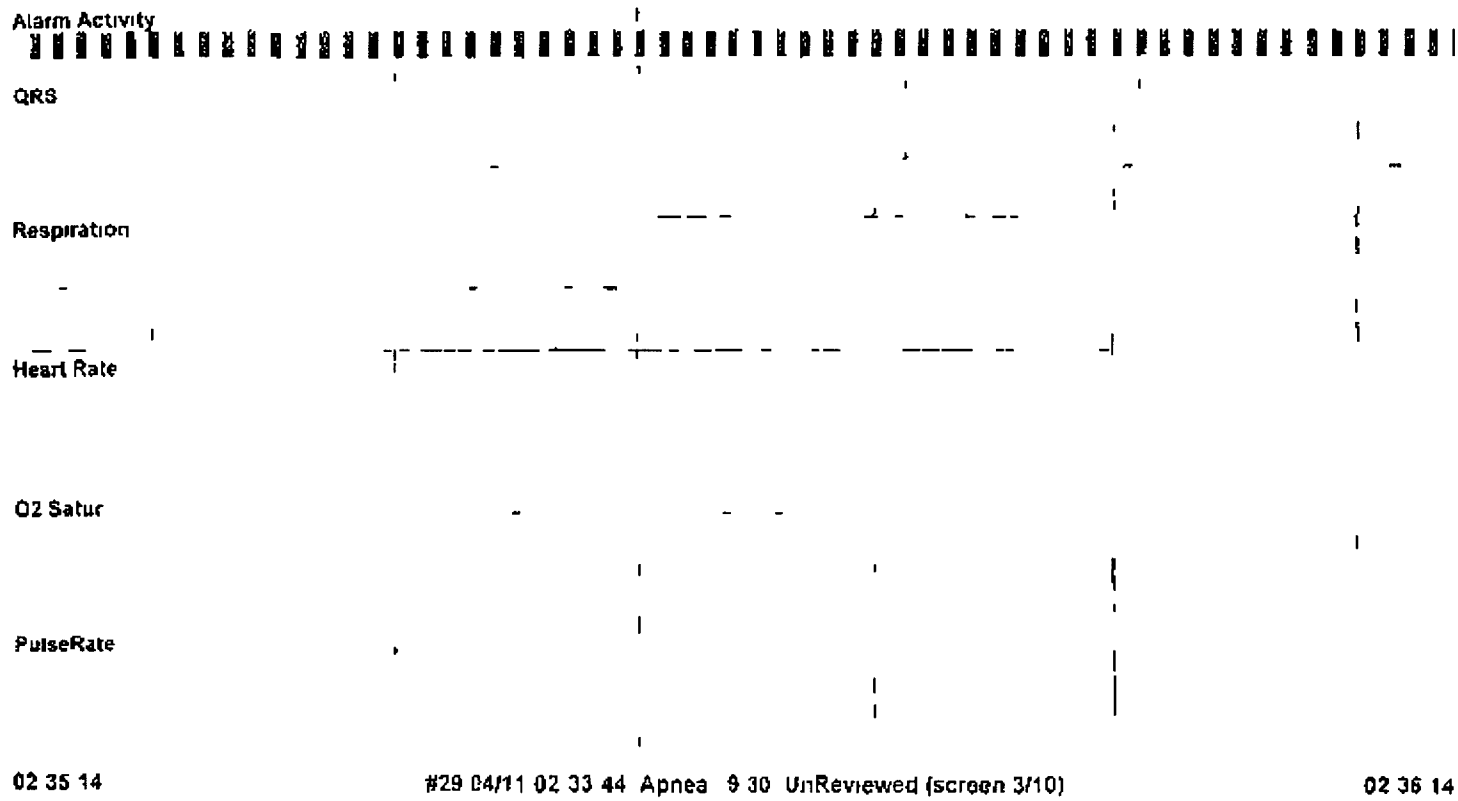


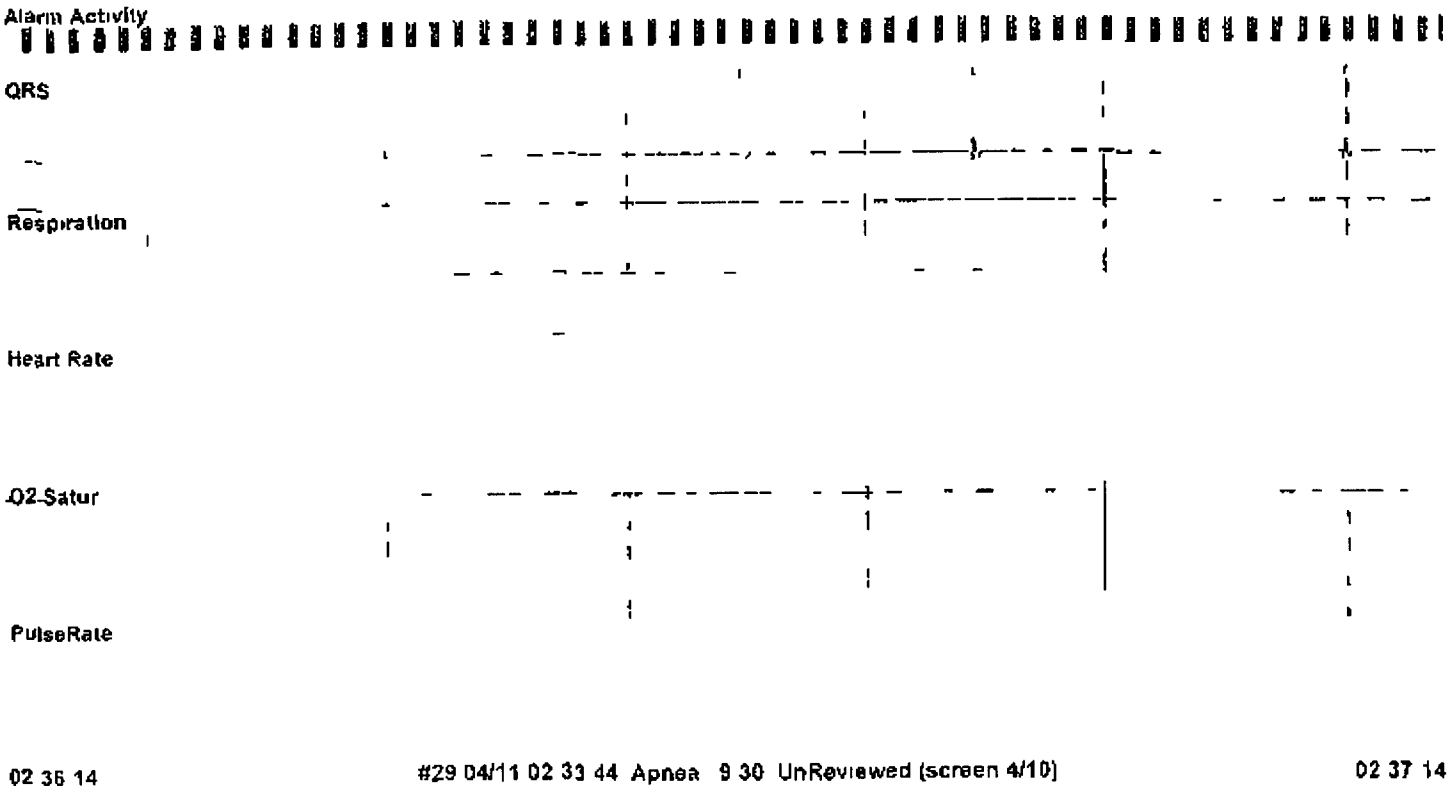
02 09 23 #28 04/11 02 00 53 Apnea 9 30 UnReviewed (screen 10/10) 02 10 22

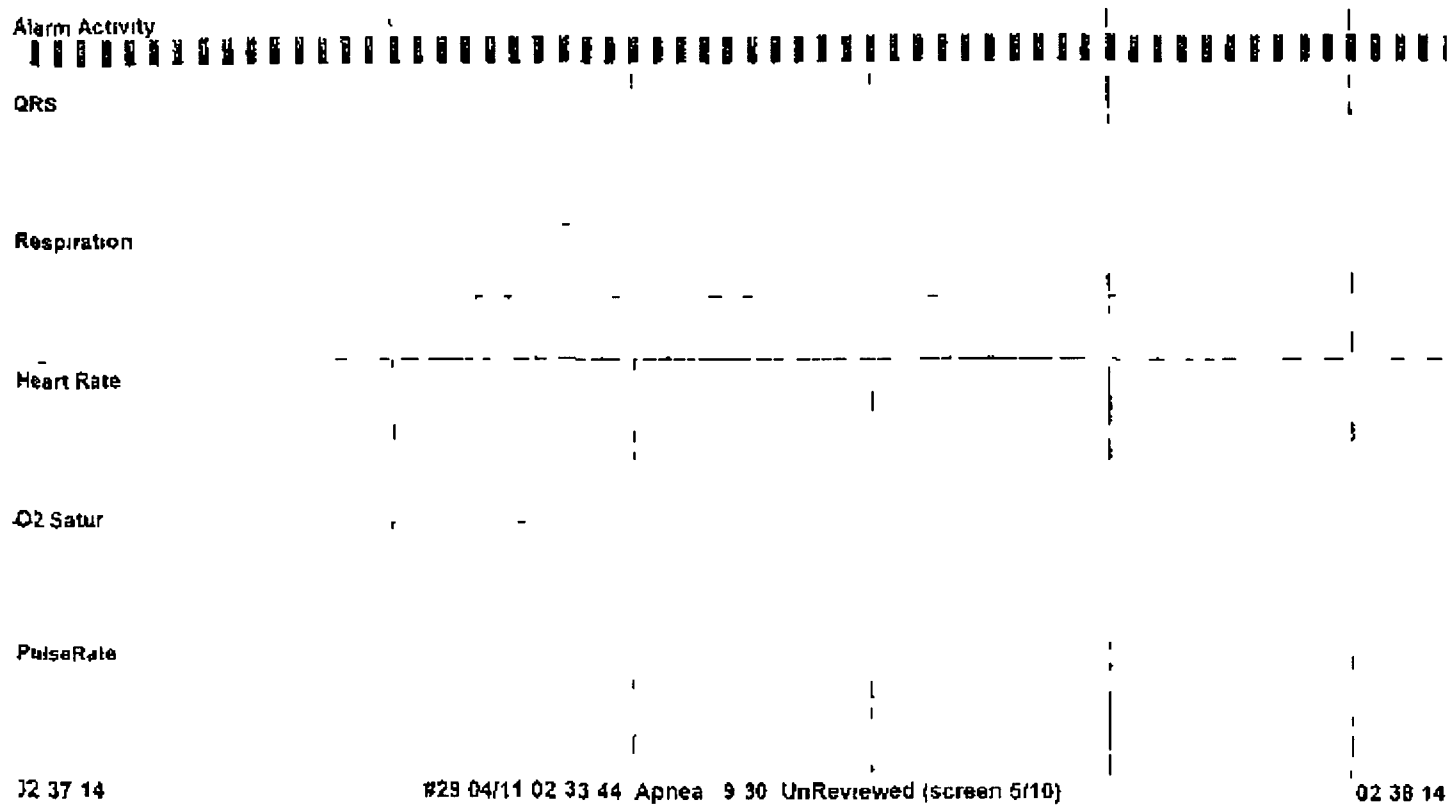


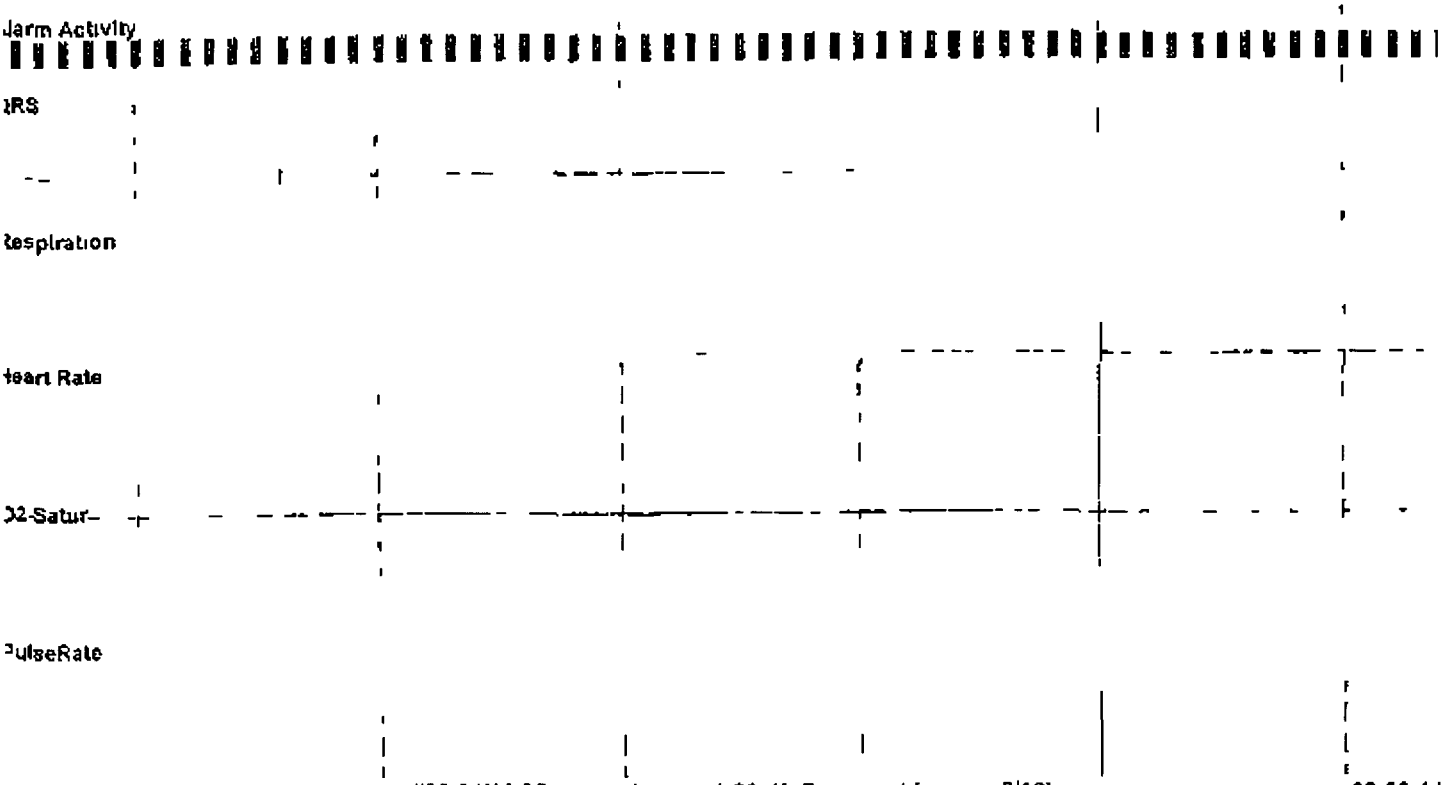
12 33 14 #29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 1/10) 02 34 14

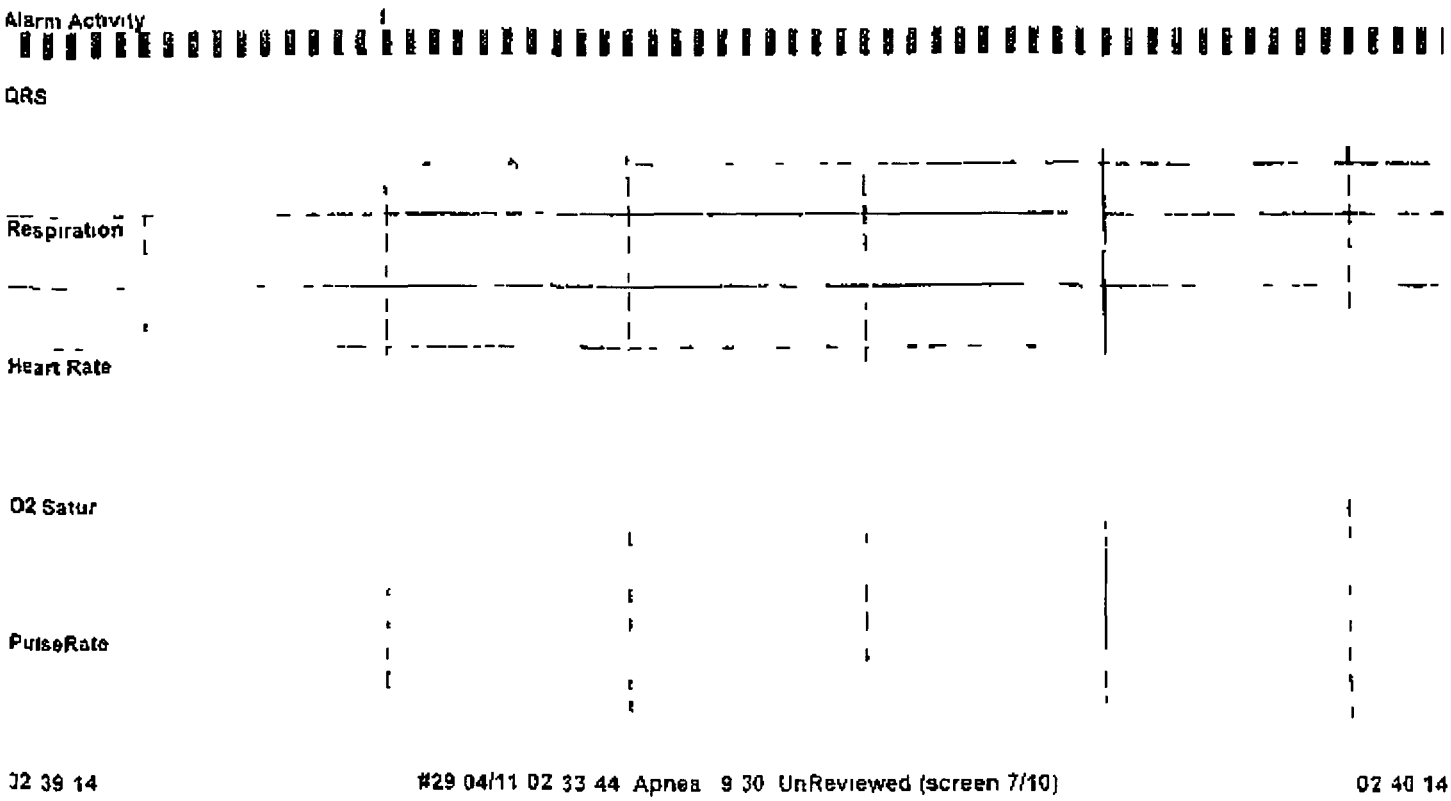

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 34 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 2/10)
02 35 14

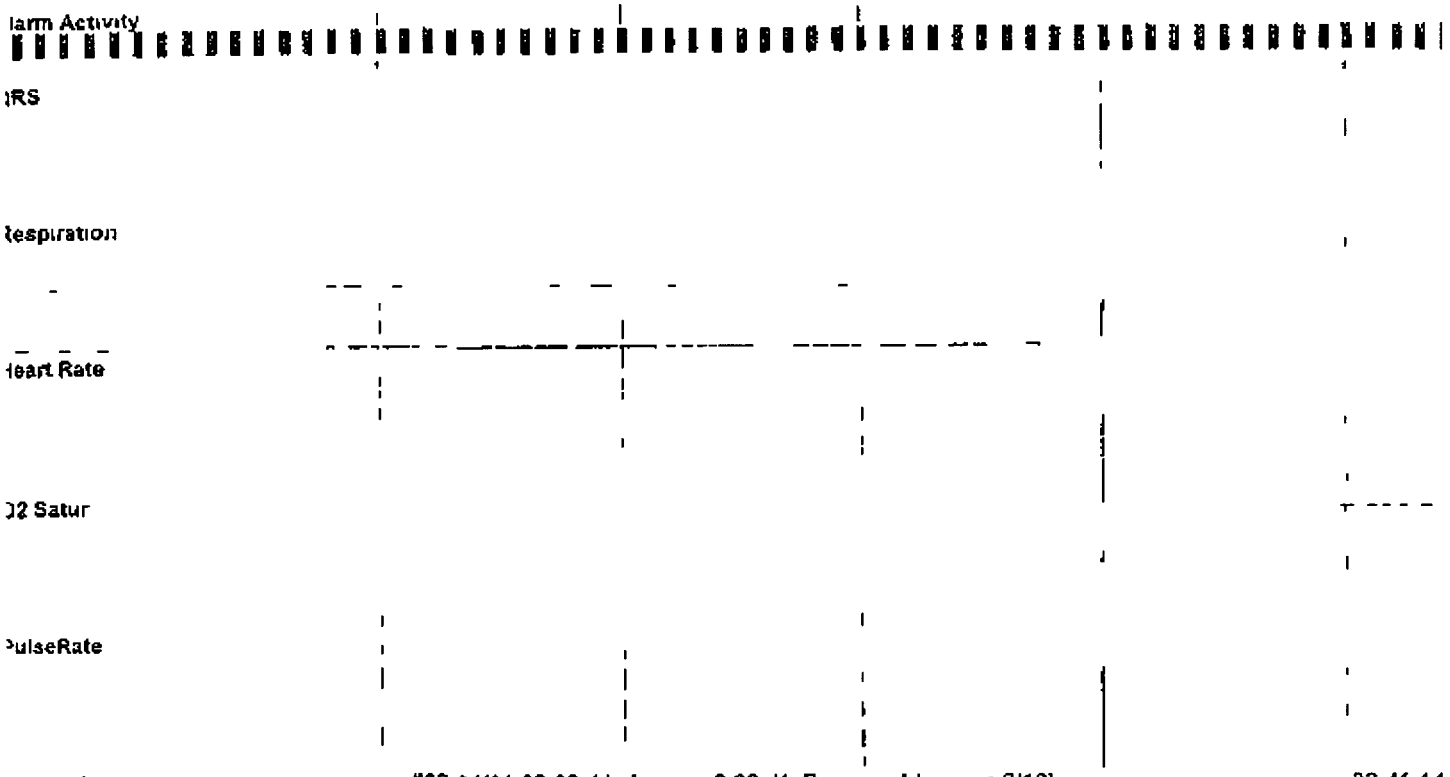

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 35 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 3/10)
02 36 14

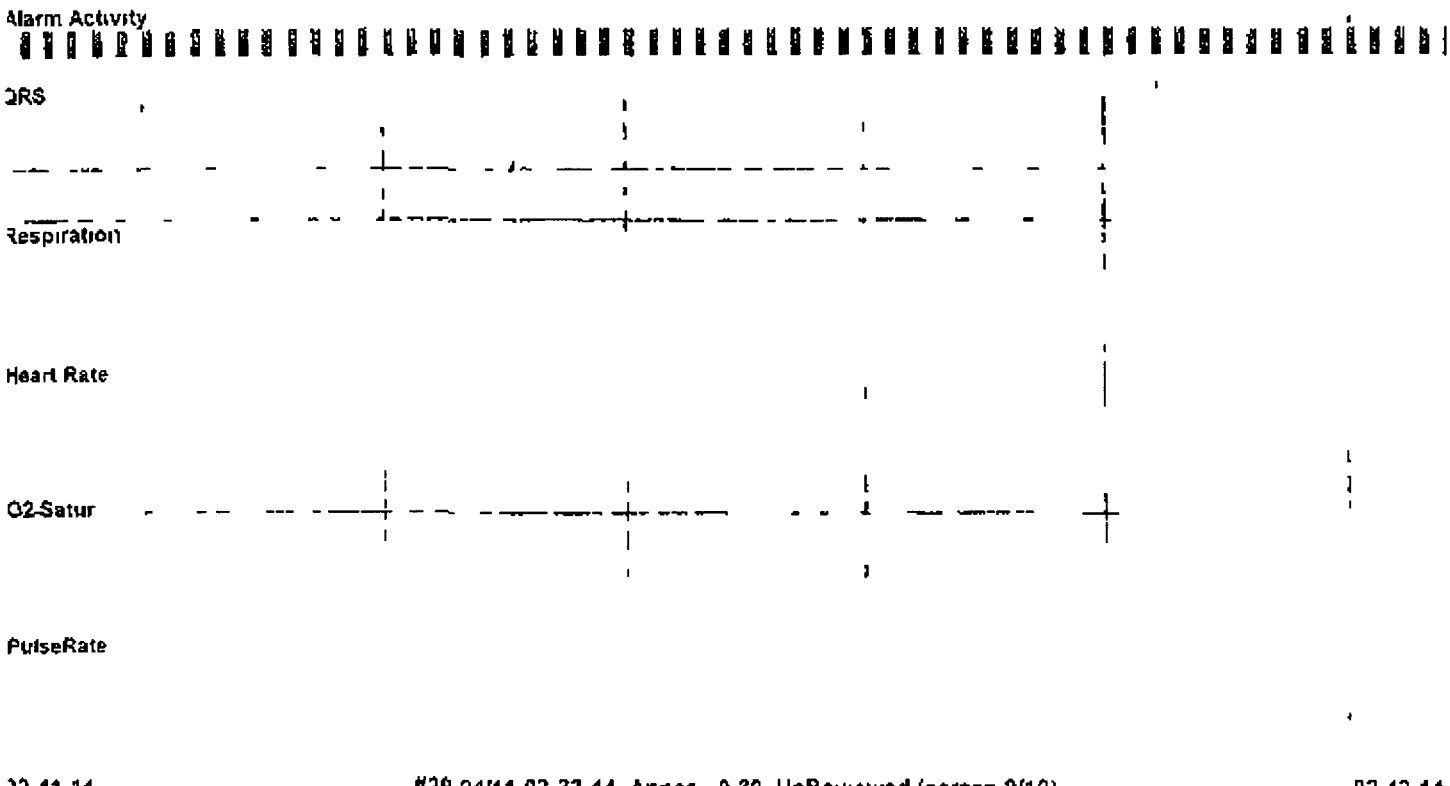

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 36 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 4/10)
02 37 14

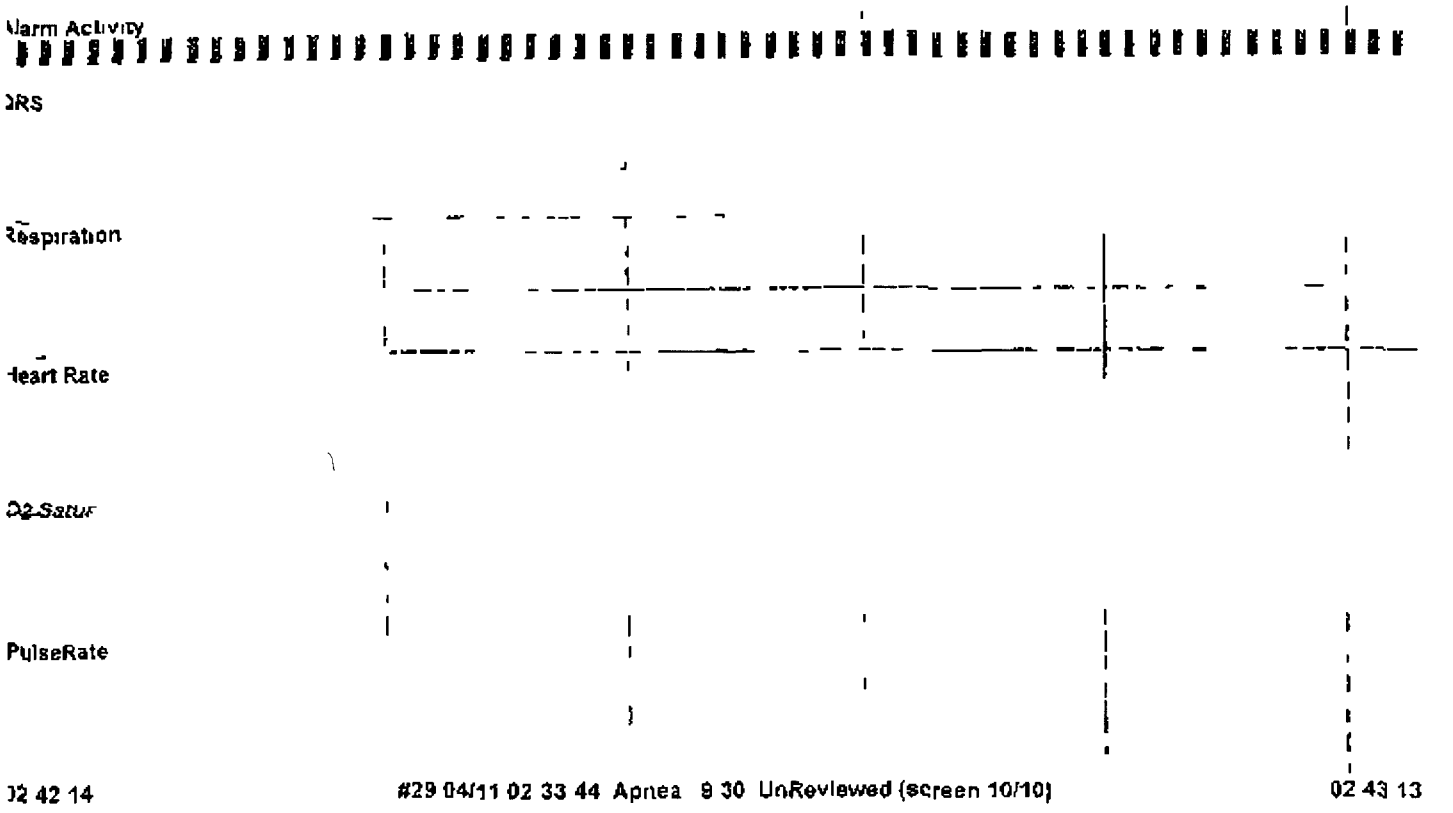

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 37 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 5/10)
02 38 14

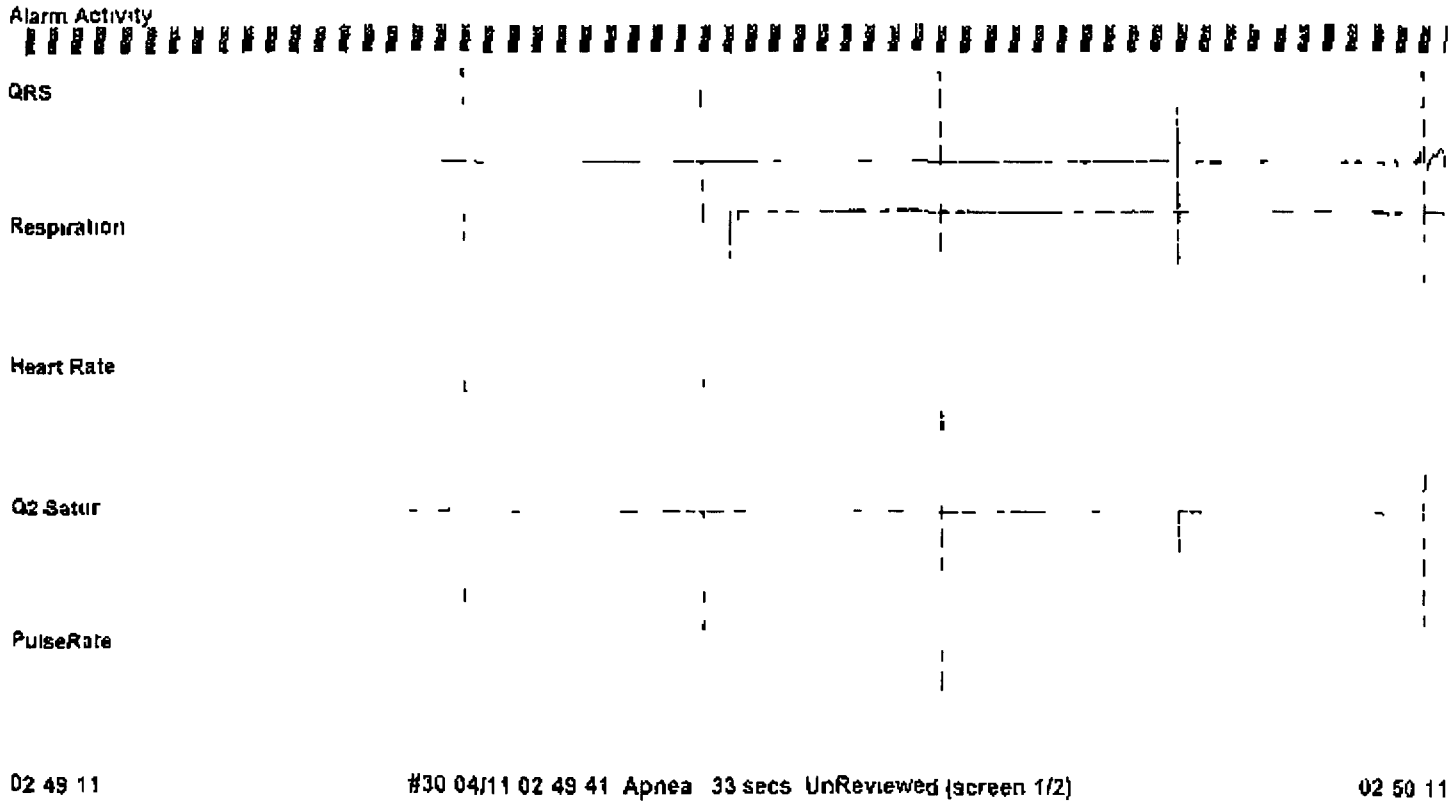

Alarm Activity
QRS
Respiration
Heart Rate
O2-Satur-
PulseRate
02 38 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 6/10)
02 39 14

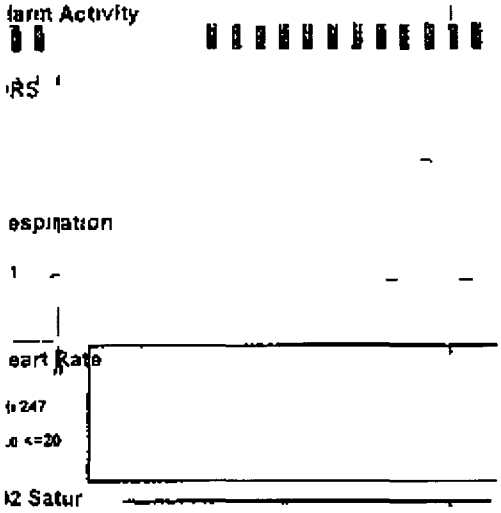

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 39 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 7/10)
02 40 14


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 40 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 8/10)
02 41 14

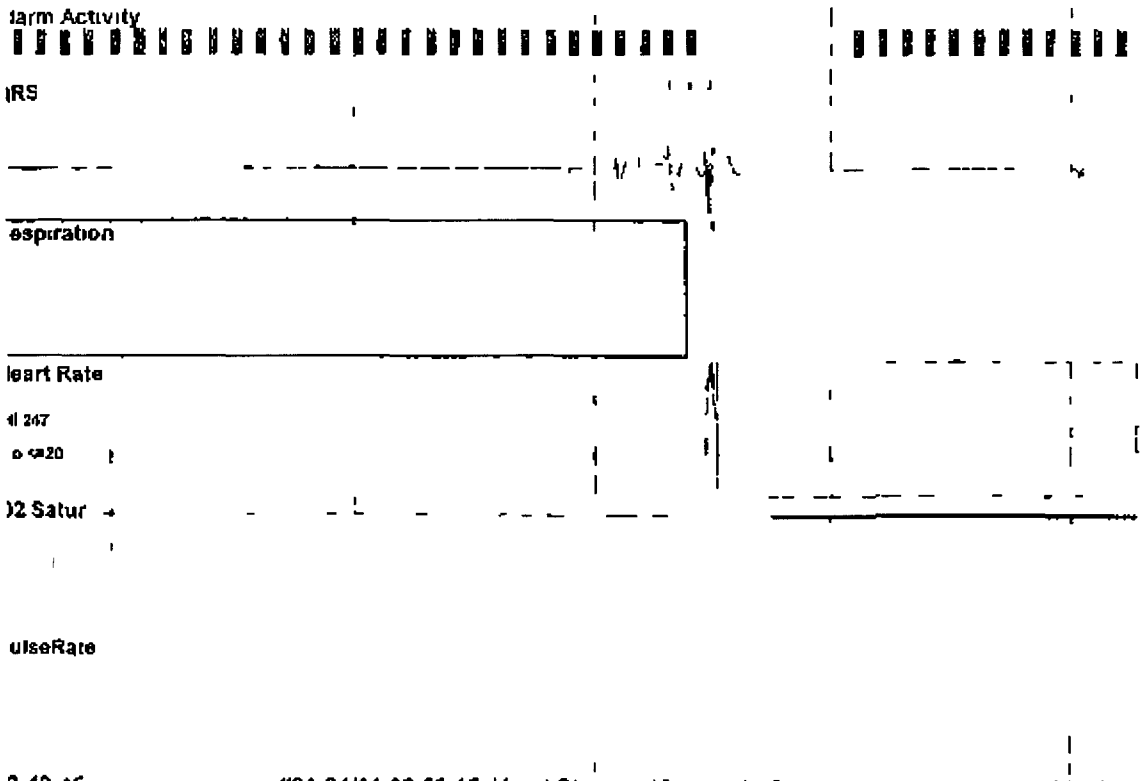

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 41 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 9/10)
02 42 14


Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 42 14
#29 04/11 02 33 44 Apnea 9 30 UnReviewed (screen 10/10)
02 43 13

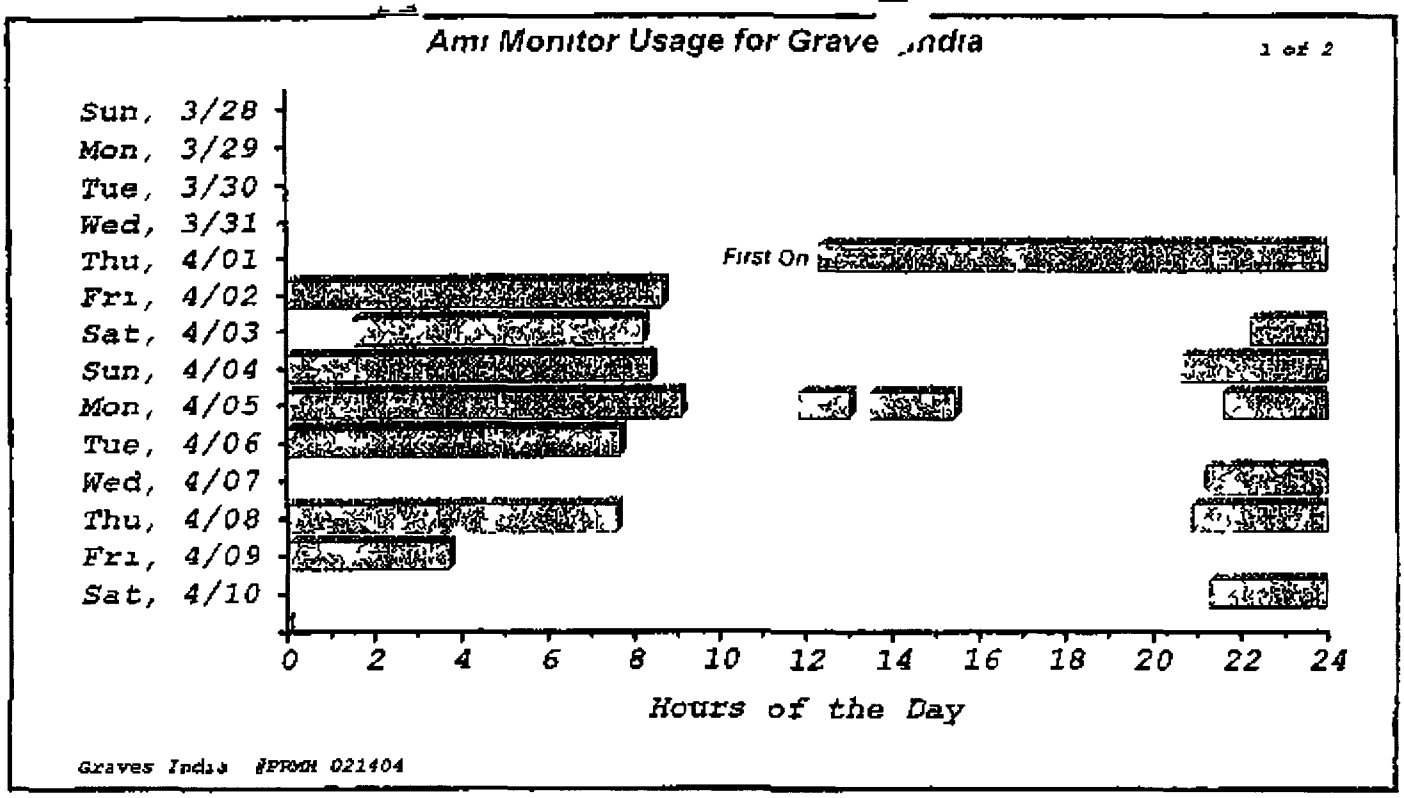

Alarm Activity
QRS
Respiration
Heart Rate
O2 Satur
PulseRate
02 49 11
#30 04/11 02 49 41 Apnea 33 secs UnReviewed (screen 1/2)
02 50 11



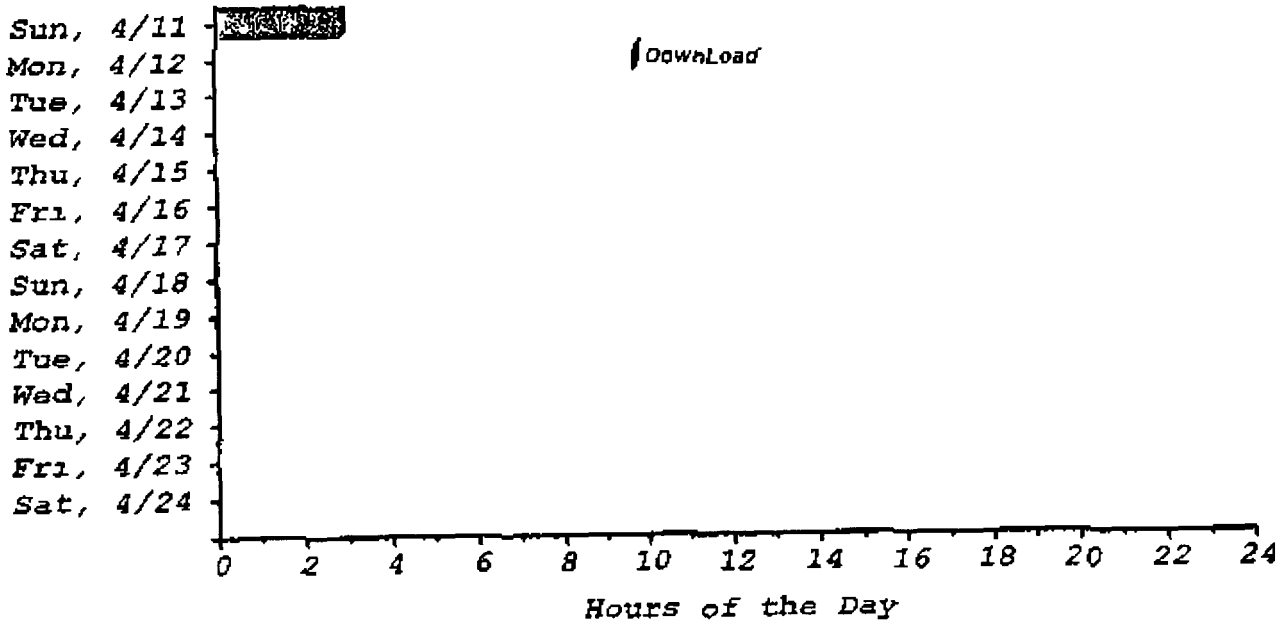
2 50 11 Apnea (scrn 2/2) 02 50 32



2 49 45 #31 04/11 02 50 15 Heart Slow 18 secs UnReviewed 02 50 33

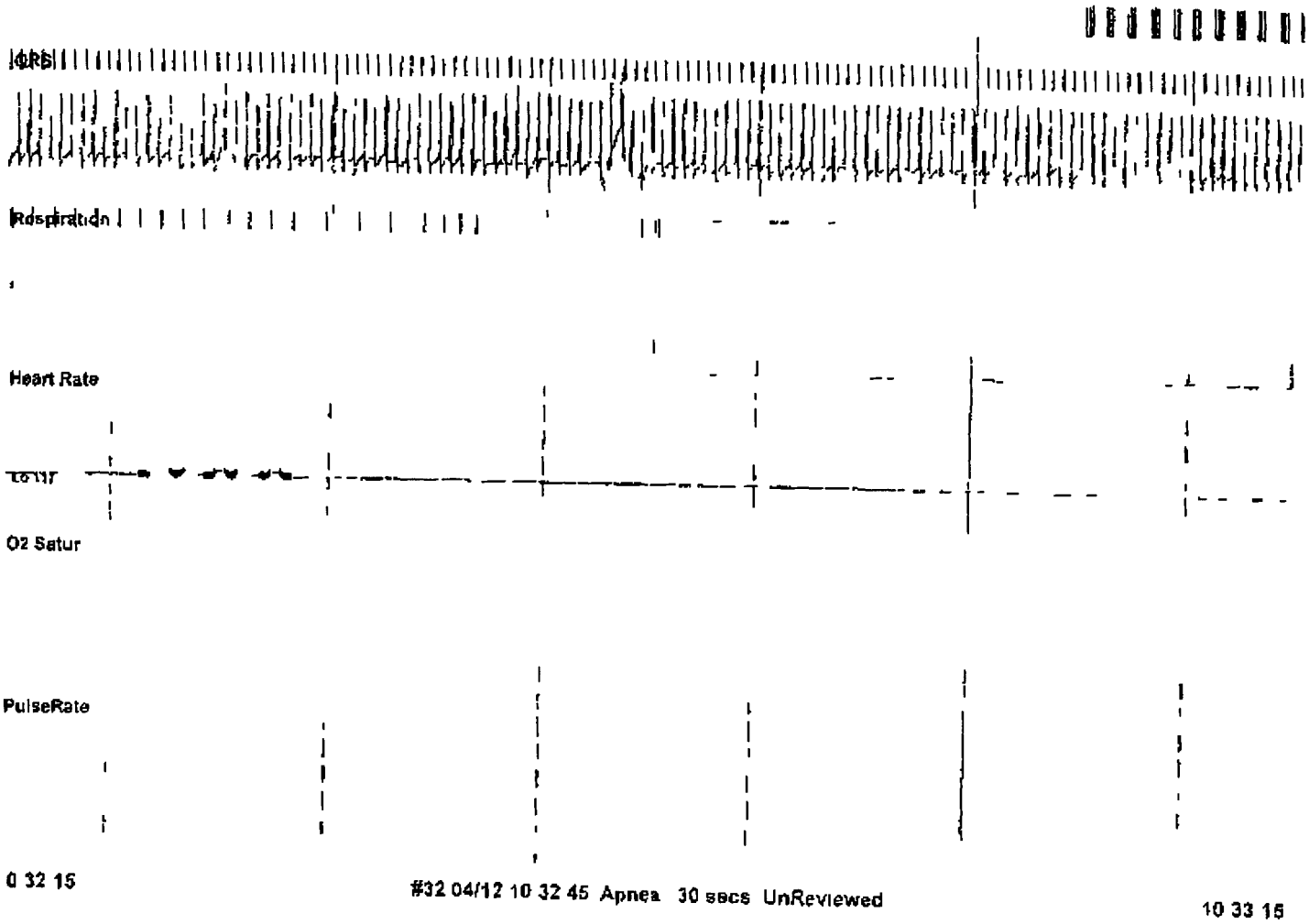

Ami Monitor Usage for Grave ndia
1 of 2
Sun, 3/28
Mon, 3/29
Tue, 3/30
Wed, 3/31
Thu, 4/01
Fri, 4/02
Sat, 4/03
Sun, 4/04
Mon, 4/05
Tue, 4/06
Wed, 4/07
Thu, 4/08
Fri, 4/09
Sat, 4/10
First On
0 2 4 6 8 10 12 14 16 18 20 22 24
Hours of the Day
Graves India EPROM 021404

Ami Monitor Usage for Grave_ ndia

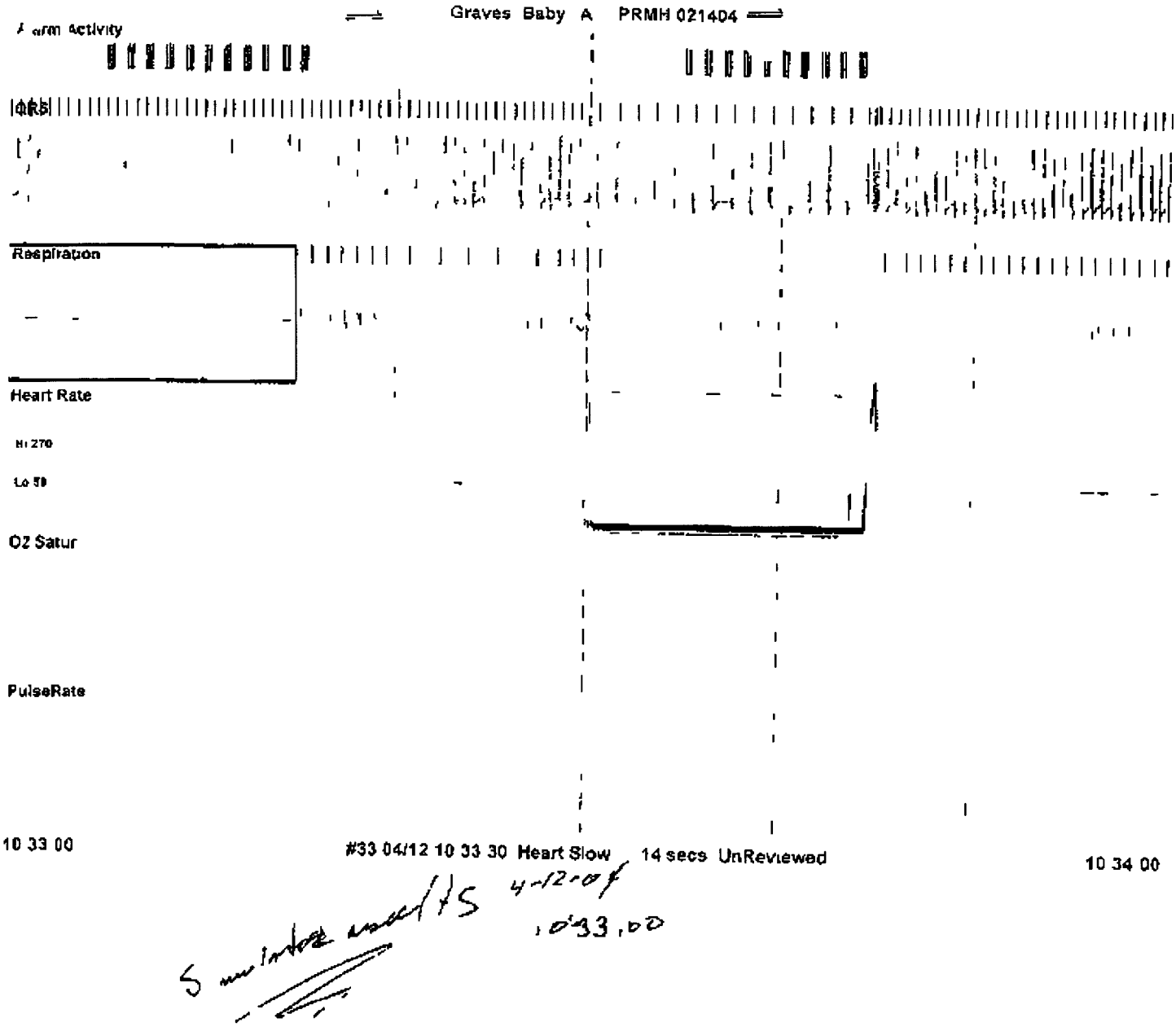


Graves India #PRMI 021404

Air Flow Activity — Graves Baby A PRMH 021404



Similar events 4-12-04 10 32 15



5 minutes used/15 4-12-04
10:33:00

```
 CCCCCC   DDDDDD    RRRRRR    HH   HH
CC        DD   DD   RR    R   HH   HH
CC        DD   DD   RRRRRRR   HHHHHHH
CC        DD   DD   RR  RR    HH   HH
 CCCCCC   DDDDDD    RR   RR   HH   HH
```

FOI RELEASABLE OUTPUT

LLW

User Name	LLW
Report Notes	2007 6566
Application	MAUDE QUERY (GUI)
Report Name	EVENT REPORT DETAIL LISTING
Report Description	DETAIL SUMMARY REPORT BOTH IN HOUSE & FOI FORMAT WILL BE GENERATED FROM THE INFORMATION OBTAINED ON THE MEDWATCH FORMS

22 OCT 2008
01 29

```
RRRRRR  EEEEEE PPPPPP   OOOOO  RRRRRR  TTTTTTTT  SSSSSS
RR   RR EE     PP   PP OO   OO RR   RR    TT     SS
RRRRRRR EEEE   PPPPPP  OO   OO RRRRRR     TT      SSSSS
RR  RR  EE     PP      OO   OO RR  RR     TT          SS
RR   RR EEEEEE PP       OOOOO  RR   RR    TT     SSSSSS
```

tabbies
PLAINTIFF'S EXHIBIT 8

MAUDE QUERY (GUI)

REPORT GENERATED FROM AD HOC SELECTION CRITERIA

Brand Name
AMI
AMI PLUS
AMI PLUS MONITOR

001065

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22-FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021160 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22-FEB 2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 15-JAN-2001

Event Description (B5)

Volun 28-FEB 2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR PLUS
Model *
Catalog *
Serial (*confidential*)
Lot *
Other ID: *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

001066

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 E INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Reporter Occupation(E3) NURSE
Reporter Name: ANNE WARD RN
Address 200 LOTHROP ST
PITTSBURGH PA 15213

Device Available for Evaluation R
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Recd 1 Recd Page 1 Rpt Page 1

001067

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

001068

Recd 1 Recd Page 2 Rpt Page 2

001069

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22-FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021161 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22-FEB 2001 Outcome Attribute to Event(B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 20 JAN-2001

Event Description (B5)

Volun 28-FEB 2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR PLUS
Model *
Catalog *
Serial (*confidential*)
Lot *
Other ID *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 EAST INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation Y
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) NURSE
Reporter Name ANNE WARD RN

Address 200 LOTHROP ST
PITTSBURGH PA 15213
Phone 412-647-3050

001071

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22-FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021162 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22 FEB-2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 25 JAN-2001

Event Description (B5)

Volun 28-FEB 2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR 2ND OCCURRENCE CAS CONFIRMED UNIT PATIENT READY AFTER THE INITIAL INSPECTION OF THE FIRST WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand	AMI
Device type	APNEA MONIOR PLUS
Model	*
Catalog	*
Serial	(*confidential*)
Lot	*
Other ID	*
Implant Date	NA
Explant Date	NA
Reprocessed & Reused	N/A

Mfr Name	CAS MEDICAL SYSTEMS INC
Address	44 E INDUSTRIAL RD
	BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation Y
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) NURSE

001072

Reporter Name ANNE WARD RN
Address 200 LOTHROP ST
PITTSBURGH PA 15213
Phone 412 647-3050

001073

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22-FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021163 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22 FEB 2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 12-DEC-2000

Event Description (B5)

Volun 28 FEB-2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR
Model *
Catalog *
Serial (*confidential*)
Lot *
Other ID *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 EAST INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation R
Is reporter a health professional?(B2) Y
Initial reporter also sent report to(B4)

Reporter Occupation(E3) NURSE
Reporter Name ANNE WARD RN

Address 200 LOTHROP ST
PITTSBURGH PA 15213
Phone 412-647 3050

001075

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22 FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021164 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22-FEB-2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 29 DEC 2000

Event Description (B5)

Volun 28 FEB-2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR PLUS
Model *
Catalog *
Serial (*confidential*)
Lot *
Other ID *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 E INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation Y
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) NURSE
Reporter Name ANNE WARD RN

Address 200 LOTHROP ST
PITTSBURGH PA 15213
Phone 412 647 3050

001077

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22 FEB-2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021165 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22 FEB-2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) 12 JAN-2001

Event Description (B5)

Volun 28 FEB 2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR PLUS
Model *
Catalog *
Serial (confidential*)
Lot *
Other ID *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 EAST INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation R
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) NURSE
Reporter Name ANNE WARD RN

Address 200 LOTHROP ST
PITTSBURGH PA 51213
Phone 412 647 3050

001079

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

22 FEB 2001

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1021166 Adverse Event(B1) N Product Problem(B1) Y
Date Received 22 FEB-2001 Outcome Attribute to Event(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Date(B3) *(error)

Event Description (B5)

Volun 28 FEB 2001 UNIT SHUT DOWN WITHOUT ALARM SOUNDING WATCHDOG ERROR

Concomitant Medical Products

DEVICE INFORMATION

Brand AMI
Device type APNEA MONITOR PLUS
Model *
Catalog *
Serial (*confidential*)
Lot *
Other ID *
Implant Date NA
Explant Date NA
Reprocessed & Reused N/A

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44E INDUSTRIAL RD
BRANFORD CT 06405

Device Operator LAY USER/PATIENT
Expiration Date *(error)

Device Available for Evaluation R
Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) NURSE
Reporter Name ANNE WARD RN

001080

Address 200 LOTHROP ST
PITTSBURGH PA 15213
Phone 412-647-3050

001081

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received
30-JUL-2002

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Report Number MW1025717 Adverse Event(B1) N Product Problem(B1) Y
Date Received 30-JUL-2002 Outcome Attribute to Event(B2)
Event Date(B3) 28 JUL-2002

Event Description (B5)

Volun 05 AUG 2002 APNEA MONITOR SHUT OFF DURING NIGHT WITH NO ALARM FAMILY UNABLE TO TURN MONITOR BACK ON MONITOR WAS EXCHANGED AND RETURNED TO MFR

Concomitant Medical Products

DEVICE INFORMATION

Brand	AMI
Device type	APNEA MONITOR
Model	AMI
Catalog	*
Serial	(*confidential*)
Lot	*
Other ID	*
Implant Date	*(error)
Explant Date	*(error)
Reprocessed & Reused	N/A

Mfr Name	CAS MEDICAL
Address	44 E INDUSTRIAL RD
	BRANFORD CT 06405

Device Operator LAY USER/PATIENT Device Available for Evaluation R
Expiration Date *(error) Is reporter a health professional?(E2) Y
Initial reporter also sent report to(E4)

Reporter Occupation(E3) OTHER HEALTH CARE PROFE

001082

Reporter Name *
Address 1818 S ROGERS
SPRINGFIELD MO 65804
Phone 417 888 7115

Recd 8 Recd Page 1 Rpt Page 9

001083

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

Mfr Report No 2244861 2001 00015 Mfr Name CAS MEDICAL SYSTEMS INC 09 APR-2001

Event Date(B3) UNK Event Report Type MALFUNCTION Adverse Event(B1) N Problem(B1) Y
Report Date(B4) *(error) Event Outcome(B2) OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date(F8) Reporter Occupation(E3) OTHER Event Location(F12)
Date Mfr Rec d(G4) 22 FEB-2001 Device Operator UNKNOWN Report Source(G3) DISTRIBUTOR

Product Code FLS(AN)-MONITOR APNEA FACILITY USE
Device Age(F9) Manufacture Date(H4) NOV 1999 Implant Date NA
Expiration Date NA Single Use(H5) N Explant Date NA
Device Usage(H8) U

Event Description (B5)

Mfr 18 APR-2001 DISTRIBUTOR ALLEGES THE MONITOR WILL NOT SOUND AN ALARM FOR FAST HEART RATE

Concomitant Medical Products NA

Mfr Name NELLCOR PURITAN BENNETT
Address 2800 NORTHWEST BLVD
PLYMOUTH MN 55441

Device Available for Evaluation Y
Device Evaluated by Manufacturer(H3) Device Not Returned to Manufacturer

Remedial Action(H7)
NA
Correction/Removal No(H9) NA

Additional Mfr Narrative(H10 & H11) 18 APR 2001 NA

Device Problems(F10)

DEVICE INFORMATION

Brand	AMI
Device type	BREATING FREQUENCY MONITOR
Model	9700A
Catalog	NA
Serial	(*confidential*)
Lot	NA
Other ID	RGA7370

Reprocessed & Reused N/A

001085

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

Internal Report No 555491 Facility Type HOME HEALTH AGENCY 24-SEP 2003

Event Date(B3) 10 SEP-2003 Event Report Type OTHER Adverse Event(B1) N Problem(B1) N
Report Date(B4) 23 SEP-2003 Event Outcome(B2)
Report Date(F8) 23-SEP 2003 Reporter Occupation(E3) Event Location(F12) HOME
Date Mfr Rec d(G4) Device Operator INVALID DATA Report Source(G3)

Manufacturer CAS MEDICAL SYSTEMS INC
Product Code NPF(AN) MONITOR APNEA HOME USE
Device Age(F9) * Manufacture Date(H4) Implant Date *(error)
Expiration Date NA Single Use(H5) Explant Date *(error)
Device Usage(H8)

Event Description (B5)

User 19-NOV-2004 APNEA MONITOR WAS SET UP IN 2003 AND MONITOR WAS EXCHANGED ON
THE FOLLOWING MONTH SEVEN DAYS LATER 3 FACILITY BECAME AWARE THAT THE PATIENT HAD EXPIRED 6 DAYS AGO THE FAMILY DID NOT NOTIFY FACILITY OF THE PATIENT S DEATH
6 DAYS LATER FACILITY SITEPICKED UP THE APNEA MONITOR THE DOWNLOAD FROM THE MONITOR REVEALED THAT MONITOR WAS TURNED ON FOR APPROXIMATELY 4 SECONDS AND TURNED BACK OFF INDICATING THAT THE PATIENT NEVER USED THE MONITOR THE SITE WAS UNABLE TO DOWNLOAD THE LOGGED INFORMATION FROM THE ORIGINAL MONITOR AND SENT IT BACK TO THE MANUFACTURER FOR THIS TO BE DONE THEY ARE AWAITING THE RESULTS

Concomitant Medical Products NOT KNOWN

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 EAST INDUSTRIAL ROAD
BRANFORD

Device Available for Evaluation R

Device Problems(F10)

DEVICE INFORMATION

Brand	AMI PLUS
Device type	APNEA MONITOR
Model	*
Catalog	*
Serial	(*confidential*)
Lot	*
Other ID	*

Reprocessed & Reused N/A

Recd 10 Recd Page 1 Rpt Page 11

001087

SORTED BY BRAND NAME CATALOG NUMBER DATE ENTERED
DATE OF EVENT DATE RECEIVED LOT NUMBER MANUFACTURER NAME MEDICAL

This output contains the medical device adverse event reports currently available to the public in accordance with the Freedom of Information Act and the requested search criteria Submission of a report does not constitute an admission that medical personnel user facility importer manufacturer or product caused or contributed to the event

Date Received

Mfr Report No 2244861-2007 00006 Mfr Name CAS MEDICAL SYSTEMS INC 14 AUG-2007

Event Date(B3) 01 JUL 2007 Event Report Type MALFUNCTION Adverse Event(B1) N Problem(B1) Y
Report Date(B4) 14-AUG 2007 Event Outcome(B2)
Report Date(F8) Reporter Occupation(E3) NOT APPLICABLE Event Location(F12)
Date Mfr Rec d(G4) 16 JUL 2007 Device Operator LAY USER/PATIENT Report Source(G3) DISTRIBUTOR

Product Code BZQ(AN) MONITOR BREATHING FREQUENCY
Device Age(F9) DA Manufacture Date(H4) 01-FEB 2006 Implant Date
Expiration Date Single Use(H5) N Explant Date
Device Usage(H8) R

Event Description (B5)

Mfr 21 DEC 2007 A PARENT/USER REPORTED TO THE HOME CARE DEALER THAT THE MONITORS AUDIO ALARM DID NOT FUNCTION THERE WAS NO MENTION OF A PROBLEM WITH THE UNIT NOT ACTUALLY MONITORING THE PATIENT CORRECTLY THE HOME CARE DEALER DID NOT WITNESS THE PROBLEM AND IT IS NOT SHOWN ON THE MEMORY DOWNLOAD EQUIPMENT ALARM

Concomitant Medical Products NA

Mfr Name CAS MEDICAL SYSTEMS INC
Address 44 E INDUSTRIAL RD
BRANFORD CT 06405

Device Available for Evaluation Y Returned to Manufacturer on 20-JUL 07
Device Evaluated by Manufacturer(H3) Yes Device Evaluated

Remedial Action(H7)
Correction/Removal No(H9)

Additional Mfr Narrative(H10 & H11)
21 DEC-2007 INITIAL EVAL PERFORMED TO CONFIRM OR REFUTE CLAIM THE ALARMS FUNCTIONED PROPERLY BUT WERE FOUND TO BE DIRTY

REPLACE AS PART OF ROUTING RECERTIFICATION/MAINTENANCE SEE SCANNED PAGES

Device Problems(P10)

DEVICE INFORMATION

Brand AMI PLUS MONITOR
Device type BREATHING FREQUENCY MONITOR
Model 9700B

001089

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Serial (*confidential*)
Lot NA
Other ID RGA7047

Reprocessed & Reused N

DHEC PATIENT CARE FORM

TRIP NO 2910

PATIENT IDENTIFICATION (Please Print)
LAST NAME (10–19): Graves
FIRST NAME (0–4, 45): Indo
MI: T
STREET (46–64): 1465 Spring Valley Dr
APT:
CITY (65–82): Cowpens
STATE (83–84): SC
ZIP CODE (85–94): 29330

DISPOSITION (110–111)
1 TREATED/TRANS
2 DOA AT SCENE
3 HOSPITAL ER
4 HOSPITAL OR ADM
5 PATIENT'S HOME
6 NURSING HOME
7 DR'S OFFICE
8 OUTPATIENT
9 PT REFUSED TREAT
10 EXPIRED AT SCENE

TYPE OF INCIDENT
TRAUMA: 1 MVA, 2 MCC, 3 MCS, 4 PED, 5 ASSAULT, 6 FALL, 7 FIRE, 8 INTERFACILITY, 9 OTHER
MEDICAL (113): 1 EMERGENCY, 2 OB, 3 CARDIAC, 4 PSYCH, 5 GI/GU, 6 RESP, 7 CVA, 8 OTHER

CALL TYPE
TO SCENE 14: 1 EMERGENT, 2 NONEMERGENT
ON SCENE (15): 1 URGENT, 2 NOT URGENT
FROM SCENE (16): 1 URGENT, 2 NON URGENT
COD: 3
CODE:

PATIENT STATUS

INCIDENT LOCATION
STREET OR HWY NAME OR NO.: 1465 Spring Valley Dr
CITY: Cowpens
STATE: SC
County (116–117): 42
Zip Code (118–122): 29330

SEX (104): Male / Female / Undetermined

RACE (105): White / Black / American Indian / Hispanic / Asian / Other

AGE (106–109): 003 — CHECK ONE: 1 YEARS / 2 MOS / 3 DAYS

SAFETY EQP (124): 1 Seatbelt / 2 Helmet / 3 Airbag / 4 Child Seat / 5 None / 6 Unknown

SITE OF INCIDENT (125): 1 ROADWAY / 2 RESIDENCE / 3 INDUSTRIAL / 4 RECREATIONAL / 5 AGRICULTURAL / 6 OTHER

PRELIMINARY IMPRESSIONS (MARK NO MORE THAN 4) (126–137)
03 Seizure; 04 Diabetic; 011 Abrasion/Contusion; 13 Laceration; 03 Fracture; 04 Multi Trauma Shock; 10 Head Injury; 02 Spinal Injury; 06 Stroke; 05 GI Problem; 04 Respiratory Distress; 060 Cardiac Problems; 061 Cardiac Arrest; Other 009; Other

PRIMARY IMPRESSION (138–140): 009

TREATMENT PROCEDURES (141–174)
01 Dressing Applied; 02 Limb Splinted; 07 Spine Immobilized; 04 Neck Immobilized; 0 OB Assistance; 0F O/A Airway Used; 09 Oxygen Given; 08 Suction Used; 0 Antishock Trousers; 1 Airway Maintained; Antishock Treatment; 12 Artificial Resp; 13 Cardiac Massage; 14 Bleeding Controlled; Foil Applied; 15 Patient Restrained; 1 Other Treatments; 16 Ventilator

HCFA CODES (175–180)

SITE OF TRAUMA (181–189)
1 Head; 2 Face; 3 Neck; 4 Chest; Abdomen; Hip/Pelvis; Upper Extr; 8 Lower Extr; 9 Back

ADVANCED PROCEDURES (190–223)
1 EKG Monitored — Rhythm: NSR/STE — Time: 0463
2 First Defib Attempted — Watt Sec — Time
Post Defib — Rhythm
3 Second Defib Attempted — Watt Sec — Time
Post Defib — Rhythm
4 Third Defib Attempted — Watt Sec — Time
Post Defib — Rhythm
5 INTUBATED — 6 ET — Total # Attempts (224)
15 RSI — 16 DMA — 17 Cricothyrotomy
7 EXTERNAL PACING
8 BLOOD DRAWN — DEXTROSE BOLUS
9 IV START/ED/GAUGE — SOLUTION
RATE — IV TIME — IV VOLUME
9 IV START/ED/GAUGE — SOLUTION
RATE — IV TIME — IV VOLUME
11 IV ATTEMPTED — Total # — Reason
10 PLEURAL DECOMPRESSION — Time
11 INTRAOSSEOUS INF
12 AUTOMATIC DEFIB
13 PATIENT ASSISTED MEDS
Type — Route — Dose — Time

DRUGS USED (226–241)

DRUG	DOSE	TIME	DRUG	DOSE	TIME

REVISED TRAUMA SCORE
(243) EYES; (244) VERBAL; (245–246) GLASGOW; (247–249) SBP; 250–252 RR; PTS (254–256); 253 ANATOMICAL INJ: 1 YES 2 NO

VITAL SIGNS

BP	PULSE RATE	PULSE REG/IRREG	RESPIRATIONS RATE	RESP REG/IRREG	PUPIL	LEVEL OF CONSC	TIME
0	0	REG / IRREG	0	REG / IRREG	D	U	0403
/		REG / IRREG		REG / IRREG			
/		REG / IRREG		REG / IRREG			
/		REG / IRREG		REG / IRREG			
/		REG / IRREG		REG / IRREG			

G 0022 Graves v Richland Memorial et al 06 CP 38-421

EXPOSURE TO PT BODY FLUIDS? (256): 1 YES 2 NO
1st Responder (257): 1 YES Name: TRIC MD order recvd to DC — 2 NO

COMMENTS (INCLUDE CHIEF COMPLAINTS, OBSERVATIONS AT SCENE, RESPONSE TO STIMULI)

Upon Arrival Found PT pulseless, Apneic & Mother doing CPR. Pt was last seen 0 appx 1240 PM. Pt was seen 0 emergent on Thursday for cold/congestion. Pt was a 32 week product of multiple birth triplets. Pt was 15th baby. Pt was ill at birth, was on vent appx 1½ months & continued O2 with appx 2 months. Pt skin warm due to being wrapped in blankets. Pupils are fixed & dilated, eyes are glazed & appears Pt has cyanosis to hands/feet. BVM w/ O2 @ good breath sounds, EKG shows Asystole in all 3 leads. Resuscitation efforts discussed & family, TRMC contacted re DC efforts. Signs of trauma & pitch. Pt eyes/skin. Pt was on Apnea monitor & time negative Alarm showing loose lead & alarm. Mother stated baby was on her back every night & found

Patient Care Form effective (258): ED / ICU / OTHER Pt D/C'ed per MD order, Thursday. — See Page

TIME RECORD

RUN DATE (259–266): MONTH 04 DA 01 YEAR 04

Call Received (267–270)	0346
Crew Dispatched (271–274)	0346
En Route (275–278)	0350
Arrive Scene (279–282)	0401
Departed Scene (283–286)	0349
Arrive Destination (287–290)	

CAUSE OF DELAY

DHEC PERMIT NO. (291–295): 14904

RECEIVING AGENCY (296–299)

SENDING AGENCY (300–303)

PROVIDER TIME ZONE: 0 EST

ATTENDANT'S SIGNATURE & CERTIFICATION NO.: 8306127

PRINT ATTENDANT NAME (304–308): [illegible] 86628

ATTENDANT DRIVER (314–318):

RECEIVING NURSE OR PHYSICIAN: Dan D Cox

DHEC 1050 REV (01/2004) — EMS PROVIDER COPY — REPORT NO 9 [illegible]

"Ledalarm asm" Module With
GOTO Statements Highlighted

```
$PROCESSOR(233)
$NODEBUG
$SYMLEN

NAME  LEDALARM_TICK

,  ,,,  ,  ,  , ,       ,,, ,               ,,,, ,,  ,,,,

        REINING International  Ltd    (c) 1993-1996
,
                          FILE  ledalarm asm
,
                   MODULE NAME  alarm_tick

        functional description  called by ms_int to do
                                microphone detection of alarms
                                alarms
                                all led flash
                                service led
,                               blinking of memfull led
                                blinking of batt led
,                               rest of leds on/off

,              input arguments  none

              output arguments  none
,
,,         ,    ,  , ,    ,,,,,,,      , ,,    ,,

  28-NOV-01 mar release V13 00 memful led blink during modem connection
,
  18-Jun-97 sal corrected on test to set alarm detect counter when zero
, 06-May-97 sal corrected on test to set zero bit to prevent rollover
  02-May-97 sal added initial setting of alarm_detection_counter at
startup
, 01-May-97 sal corrected on test to check for zero to prevent rollover
  29-Apr-97 sal added zero check before dec during on test to fix off
time
  28-Apr-97 sal added 10 min mic off time and multiple alarm on checks
  08-Oct-96 sal added alarm activation for shorted battery
, 08-Apr-96 wgc added fast pulse for battery very low
, 05-Apr-96 wgc changed lowbatt warning to once every 5 seconds
                changed lowbatt alarm to all other leds off -
                don't do pulses
  22-Mar-96 wgc service_flash_flag should not touch alarm
  18-Mar-96 wgc added timeout_alarm_flag
  01-Mar-96 wgc added toohigh
, 15-Feb-96 wgc changed 1 alarm failure to service led blink from flash
  22-Jan-96 wgc added lowbatt_beep_flag
  18-Jan-96 wgc very low batt is no longer also service alarm
, 12-Jan-96 wgc changed microphone_detection_off "on" from 1 to 0ffH
  11-Jan-96 wgc don t do solid alarm unless both alarm1 and 2 failed
```

```
  08-Jan-96 wgc changed microphone_detect_off_flag to variable cleared
                only by protocol
  04-Jan-96 wgc changed service caution_flag to variable cleared
,               only upon actively setting new limits
, 04-Jan-96 wgc do solid alarm if either alarm1 or 2 failed
  15-Dec-95 wgc added wu_openbatt_flag to audible alarmlist
                do not treat mic_off as special in de flag setting
, 14-Dec-95 wgc fixed non debug branches
  02-Nov-95 wgc changed alarm caution/pulse total comparisons
                from equality in on_pulse
, 11-Oct-95 wgc moved blinkctr_service, blinkctr_memfull
,               to external space
, 29-Sep-95 wgc added microphone_detect_off_flag
, 29-Sep-95 wgc added alarm solid/pulse indicators
  21-Sep-95 wgc revised to match specs for alarm failures
  27-Jun-95 wgc revised for protocol array of led/alarm status
  16-Jun-95 wgc revised for a2d version of microphone
  12-Jun-95 wgc revised false positive microphone detection
  08-Jun-95 wgc revised for new powerup display
  02-Jun-95 wgc revised for all led flash
                service led flash
,               memfull led flash
,               very low batt is also service alarm
  24-Apr-95 wgc pulsed alarms missed first 1 second'
  02-Mar-95 wgc release V06 00 for testing
, 15-Aug-94 wgc release V00 0 for testing

      ,  ,                ,

$ INCLUDE (model inc)

$ INCLUDE (  \  \inc\defines inc)
$ INCLUDE (  \  \inc\portdefs inc)
$ INCLUDE (  \  \inc\db_flags inc)

,,,, , ,    ,  ,,,,,,,,,,, ,, ,,,,,,, ,,,,  ,

      PUBLIC     ledalarm_tick
      PUBLIC     ledalarm_startup

        EXTRN   leds_off
        EXTRN   leds_off_exceptlowbatt
        EXTRN   get_hl_via_de
        EXTRN   put_hl_via_de

            EXTDATA alarm_detection_count
            EXTDATA alarm_pulse_count
            EXTDATA blinkctr_lowbatt
            EXTDATA blinkctr_memfull
            EXTDATA blinkctr_service
            EXTDATA microphone_detection_off
            EXTDATA off_failed_count
            EXTDATA pulsectr_qrsled
            EXTDATA pulsectr_respled
```

```
            EXTDATA service_caution

          EXTBIT  alarm1_flag
          EXTBIT  alarm1_failed_flag
          EXTBIT  alarm2_flag
          EXTBIT  alarm2_failed_flag
          EXTBIT  alarmR_flag
             EXTBIT      alarm_caution_flag
             EXTBIT      alarm_click_flag
             EXTBIT      alarm_pulse_flag
             EXTBIT      alarm_pulse_this_second_flag
             EXTBIT      alarm_solid_flag
             EXTBIT      alarm_solid_this_second_flag
             EXTBIT      click_flag
          EXTBIT  false_alarm_flag
             EXTBIT      led_apnea_flag
             EXTBIT      led_hrh_flag
             EXTBIT      led_hrl_flag
             EXTBIT      led_ll_flag
          EXTBIT  led_lowbatt_flag
          EXTBIT  led_memfull_flag
          EXTBIT  led_qrs_flag
          EXTBIT  led_resp_flag
          EXTBIT  led_service_flag
          EXTBIT  lowbatt_beep_flag
             EXTBIT  modem_LED_flag                    V13 00 * MAR *
             EXTBIT      memfull_flash_flag
             EXTBIT      memfull_on_flag
          EXTBIT  mic_on_flag
             EXTBIT      pulse_qrsled_flag
             EXTBIT      pulse_respled_flag
             EXTBIT      service_alarm_flag
           EXTBIT  service_blink_flag
             EXTBIT      service_flash_flag
             EXTBIT      service_warning_flag
             EXTBIT      timeout_alarm_flag
             EXTBIT      wu_apnea_central_flag
             EXTBIT      wu_highbatt_flag
             EXTBIT      wu_hrh_flag
             EXTBIT      wu_hrl_flag
             EXTBIT      wu_ll_flag
             EXTBIT      wu_lowbatt_flag
             EXTBIT      wu_openbatt_flag
             EXTBIT      wu_power_flag
             EXTBIT      wu_shortedbatt_flag
             EXTBIT      wu_verylowbatt_flag

$IF     (MODEL9700)
$ELSE
     EXTBIT      wu_apnea_mixed_flag
     EXTBIT      wu_apnea_obstructive_flag
     EXTBIT      wu_lb_flag
$ENDIF
```

```
@@CODE      CSEG

     ,                                  ,,, ,         ,,     ,

ledalarm_startup
        bt      timeout_alarm_flag $onsolid
        bt      click_flag $onclick
        btclr   alarm_solid_flag $need_off
        br      startoff

ledalarm_tick
        call    !alarm_tick
        br      detection

                                           ,,      ,   ,,,

alarm_tick
        bt      wu_verylowbatt_flag,$onfastpulse

        bf      alarm1_failed_flag,$notforced
        bt      alarm2_failed_flag,$onsolid
notforced
        bt      service_alarm_flag $onsolid
        bt      wu_power_flag $onsolid
        bt      wu_ll_flag $onsolid
        bt      wu_openbatt_flag $onsolid
        bt      wu_highbatt_flag $onsolid
        bt  wu_shortedbatt_flag $onsolid
        bt      timeout_alarm_flag $onsolid

$IF     (MODEL9700)
$ELSE
        bt      wu_lb_flag $onsolid
$ENDIF
        bt      wu_apnea_central_flag $onpulse
        bt      wu_hrh_flag $onpulse
        bt      wu_hrl_flag $onpulse
$IF     (MODEL9700)
$ELSE
        bt      wu_apnea_mixed_flag $onpulse
        bt      wu_apnea_obstructive_flag,$onpulse
$ENDIF

        mov     a !service_caution
        or      a,a
        bne     $oncaution

        bt      lowbatt_beep_flag $oncaution

        bt      click_flag,$onclick

        btclr   alarm_solid_flag $need_off
        bt      alarm_pulse_flag $need_off
```

```
        bt      alarm_caution_flag,$need_off
        bt      alarm_click_flag $need_off
        br      alarmoff

need_off
        clr1    alarm_pulse_flag
        clr1    alarm_caution_flag
        clr1    alarm_click_flag
        br      startoff

onsolid
        clr1    alarm_click_flag
        clr1    alarm_caution_flag
        clr1    alarm_pulse_flag
        bt      alarm_solid_flag $alarmon
        set1    alarm_solid_flag
        br      starton

onclick
        set1    alarm_click_flag
        br      starton

onfastpulse
        clr1    alarm_caution_flag
        clr1    alarm_solid_flag
        clr1    alarm_click_flag
        bf      alarm_pulse_flag $startpulse

        movw    ax alarm_pulse_count
        incw    ax
        movw    alarm_pulse_count ax

        cmpw    ax #ALARM_PULSE_ON
        bl      $alarmon
        be      $startoff

        cmpw    ax #ALARM_PULSE_TOTAL/2
        bnl     $startpulse
        br      alarmoff

onpulse
        clr1    alarm_caution_flag
        br      $shared
oncaution
        set1    alarm_caution_flag
```

```
shared
        clr1    alarm_solid_flag
        clr1    alarm_click_flag
        bf      alarm_pulse_flag,$startpulse

        movw    ax alarm_pulse_count
        incw    ax
        movw    alarm_pulse_count ax

        cmpw    ax #ALARM_PULSE_ON
        bl      $alarmon
        be      $startoff

        cmpw    ax,#ALARM_CAUTION_TOTAL
        bnl     $startpulse

        bt      alarm_caution_flag $alarmoff

        cmpw    ax,#ALARM_PULSE_TOTAL
        bl      $alarmoff

''''''''''''''' ''

startpulse
        set1    alarm_pulse_flag
        movw    alarm_pulse_count,#0
starton
        mov     a #ALARM_PULSE_ON
        mov     'alarm_detection_count a
alarmon
        ALARMR_ON
        set1    alarmR_flag
        ALARM1_ON
        set1    alarm1_flag
        bt      false_alarm_flag $use_2
        bt      alarm2_failed_flag $use_2
        bt      alarm1_failed_flag $use_2
        br      $alarmdone

use_2
        ALARM2_ON
        set1    alarm2_flag
        br      $alarmdone

   '

startoff
        mov     a #0
        sub     a #ALARM_DETECTION_DELAY
        mov     'alarm_detection_count,a
alarmoff
        ALARM1_OFF
        ALARM2_OFF
        ALARMR_OFF
```

```
        clr1    alarm1_flag
        clr1    alarm2_flag
        clr1    alarmR_flag

                ,

alarmdone
        clr1    click_flag
        ret

,,,, ,,    ,,,,,       ,     ,     ,                    ,,
    ,,,
          ,                    ,         ,,,,,,,,,,,,,,

detection
        bt      false_alarm_flag $detect_done_jump     ,already failed
        bt      alarm1_failed_flag $detect_2_jump

        mov     a 'alarm_detection_count
        bt      a 7 $off_test_cont

on_test_cont

      or    a,a
      bne   $not_zero
      mov   a #ALARM_PULSE_ON
      mov   'alarm_detection_count a
not_zero
        dec     a
        mov     'alarm_detection_count a
        cmp a,#20                   ALARM_PULSE_ON - ALARM_DETECTION_DELAY
        bl      $here1
        br  $detect_done_jump
here1
        mov     a 'microphone_detection_off
        cmp     a #0FFH
        be      $detect_done_jump
        bt      mic_on_flag,$setdetect_done_jump
        mov a,'alarm_detection_count
      cmp   a #1
        bne $detect_done_jump

$IF     (MICOFF)
$ELSE
        set1    alarm1_failed_flag
        ALARM2_ON
        set1    alarm2_flag
      mov   a #ALARM_PULSE_ON
      mov   'alarm_detection_count a
$ENDIF
detect_done_jump
        br      detect_done
setdetect_done_jump
      br    setdetect_done
```

```
detect_2_jump
      br    detect_2

''''''''''''''' ' '''''' '

off_test_cont
        inc     a
        mov     !alarm_detection_count a
        bne     $detect_done_jump

        sub     a,#ALARM_DETECTION_DELAY
        mov     !alarm_detection_count,a

        mov     a,!microphone_detection_off
        cmp     a,#0FFH
        be      $not_failed
        bf      mic_on_flag $not_failed

$IF     (MICOFF)
$ELSE
        mov     a,!off_failed_count+0
        inc     a
        mov     !off_failed_count+0 a
        bne $detect_done

        mov a,!off_failed_count+1
        inc a
        mov !off_failed_count+1 a

        cmp     a,#OFF_FAILURE_COUNTS
        bl      $detect_done

        set1    false_alarm_flag
        br      detect2_failed
$ENDIF

not_failed
        mov     a #0
        mov     !off_failed_count+0,a
        mov !off_failed_count+1 a
        br      $detect_done

''''''''''''     ' ' '''''

detect_2
        bt      alarm2_failed_flag $detect_done          already failed
        mov     a !alarm_detection_count
        bt      a 7 $off_test_cont

     or    a a
     bne   $non_zero
     mov   a #ALARM_PULSE_ON
     mov   !alarm_detection_count a
non_zero
```

```
        dec     a
        mov     'alarm_detection_count,a
        cmp a #20                   ,ALARM_PULSE_ON - ALARM_DETECTION_DELAY
        bl      $here2
        br  $detect_done
here2
        mov     a,'microphone_detection_off
        cmp     a #0FFH
        be      $detect_done
        bt      mic_on_flag $setdetect_done

      mov   a,'alarm_detection_count
      cmp   a #1
      bne   $detect_done
$IF     (MICOFF)
$ELSE
        set1    alarm2_failed_flag
        ALARM1_ON
        set1    alarm1_flag
detect2_failed
      movw  hl #LED_BLINK_TOTAL
        call    'put_hl_blinkctr_service
$ENDIF
        br      detect_done

, ,  ,,,,,, , ,,

setdetect_done

      bt      alarm_solid_flag $detectsolid
        set1    alarm_pulse_this_second_flag
        br      detect_done

detectsolid
        set1    alarm_solid_this_second_flag

  ,,,       ,,,,,

detect_done

        ,
    ,         ,,          ,,,              ,,,,
,,, , , ,, ,,, ,,,     ,,,, ,,    , ,,,,,,,,,,,  ,    ,,,

                                                  do leds
        bf      wu_verylowbatt_flag,$notlowbatt_led_only
        br      'leds_off_exceptlowbatt

notlowbatt_led_only
        bt      false_alarm_flag,$flash_all
        bf      alarm1_failed_flag $try_service_led
        bf      alarm2_failed_flag $try_service_led

flash_all
```

```
        call    'incw_blinkctr_service
        cmpw    ax #LED_FLASH_TOTAL
        bnl     $all_led_on
        cmpw    ax,#LED_FLASH_ON
        bnl     $all_led_off
        ret

all_led_off
        br      'leds_off

all_led_on
        call    'put_0_blinkctr_service
        mov     'ADR_LED_APNEA_ON,a
        mov     'ADR_LED_HRH_ON a
        mov     'ADR_LED_HRL_ON,a
        mov     'ADR_LED_LOOSE_ON,a
        mov     'ADR_LED_LOWBATT_ON a
        mov     'ADR_LED_MEMFULL_ON a
        mov     'ADR_LED_QRS_ON,a
        mov     'ADR_LED_RESP_ON a
        clr1    MONITOR_LED
        set1    led_apnea_flag
        set1    led_hrh_flag
        set1    led_hrl_flag
        set1    led_ll_flag
        set1    led_lowbatt_flag
        set1    led_memfull_flag
        set1    led_qrs_flag
        set1    led_resp_flag
        set1    led_service_flag
        ret

;;;    ;;;;;;;;;;;

try_service_led
        bt      alarm1_failed_flag $service_led_blink
        bt      alarm2_failed_flag $service_led_blink

        bt      service_flash_flag,$service_led_flash
        mov     a 'service_caution
        or      a a
        bne     $service_led_flash
        bt      service_warning_flag $service_led_flash
        bt      service_alarm_flag,$service_led_on
         bt      wu_verylowbatt_flag,$service_led_on
        bt      wu_shortedbatt_flag,$service_led_on
        bt      wu_openbatt_flag,$service_led_on
        bt      wu_highbatt_flag,$service_led_on
        br      service_led_off

service_led_blink
        call    'incw_blinkctr_service
        cmpw    ax,#LED_BLINK_TOTAL+1
        bnl     $start_service_led_on
```

```
        cmpw    ax #LED_BLINK_ON
        br      service_led_shared

service_led_flash
        call    'incw_blinkctr_service
        cmpw    ax #LED_FLASH_TOTAL+1
        bnl     $start_service_led_on
        cmpw    ax #LED_FLASH_ON
service_led_shared
        bl      $service_led_on
service_led_off
        set1    MONITOR_LED              LED_SERVICE_OFF
        clr1    led_service_flag
        br      service_led_done

start_service_led_on
        call    'put_0_blinkctr_service
service_led_on
        clr1    MONITOR_LED             ,LED_SERVICE_ON
        set1    led_service_flag

service_led_done
        bt      modem_LED_flag $modem_led_flash           V13 00 * MAR
*  if flag set goto modem_led_flash
        bt      memfull_flash_flag $memfull_led_flash
        bt      memfull_on_flag $memfull_led_on
        br      memfull_led_off

modem_led_flash                                                ,V13 00 *
MAR *
        call    'incw_blinkctr_memfull                  ,  If modem is
connected
        cmpw    ax,#60+1                                  ,,
blink memfull led 10 times/second
        bnl     $start_memfull_flash_on                    100msec
on/100msec off
        cmpw    ax,#30
        bl      $memfull_led_on
           br          $memfull_led_off

memfull_led_flash
        call    'incw_blinkctr_memfull
        cmpw    ax,#LED_FLASH_TOTAL+1
        bnl     $start_memfull_flash_on
        cmpw    ax,#LED_FLASH_ON
        bl      $memfull_led_on
memfull_led_off
        mov     'ADR_LED_MEMFULL_OFF a
        clr1    led_memfull_flag
        br      memfull_led_done

start_memfull_flash_on
     movw  hl #0
     movw  de #blinkctr_memfull
```

```
        callf   'put_hl_via_de
memfull_led_on
        mov     'ADR_LED_MEMFULL_ON a
        set1    led_memfull_flag
memfull_led_done



        bf      wu_lowbatt_flag $lowbatt_led_off

      movw  ax blinkctr_lowbatt
        incw    ax
      movw  blinkctr_lowbatt ax
        cmpw    ax #LED_BLINK_TOTAL+1     was  cmpw
ax #LED_FLASH_TOTAL+1
        bnl     $start_lowbattflash_on
        cmpw    ax #LED_BLINK_ON          was  cmpw    ax #LED_FLASH_ON
        bl      $lowbatt_led_on
lowbatt_led_off
        mov     'ADR_LED_LOWBATT_OFF a
        clr1    led_lowbatt_flag
        br      lowbatt_done

start_lowbattflash_on
      movw  blinkctr_lowbatt #0
lowbatt_led_on
        mov     'ADR_LED_LOWBATT_ON a
        set1    led_lowbatt_flag

lowbatt_done

           ,

      mov     a 'pulsectr_qrsled
        or      a a
        be      $qrsled_off
      dec     a
      mov     'pulsectr_qrsled a
        be      $qrsled_off

        mov     'ADR_LED_QRS_ON,a
        set1    led_qrs_flag
        br      $qrsled_done

qrsled_off
        mov     'ADR_LED_QRS_OFF a
        clr1    led_qrs_flag

qrsled_done

,,, ,, ,,,,,,,,,,,,

      mov     a 'pulsectr_respled
        or      a,a
```

```
        be      $respled_off
      dec     a
      mov     !pulsectr_respled a
        be      $respled_off

        mov     !ADR_LED_RESP_ON a
        set1    led_resp_flag
        br      $respled_done

respled_off
        mov     !ADR_LED_RESP_OFF a
        clr1    led_resp_flag

respled_done

'

        bf      led_apnea_flag $a_off

        mov     !ADR_LED_APNEA_ON a
        set1    led_apnea_flag
        br      a_done

a_off
        mov     !ADR_LED_APNEA_OFF a
        clr1    led_apnea_flag

a_done

 ''       '

        bf      led_hrh_flag,$hrh_off

        mov     !ADR_LED_HRH_ON a
        set1    led_hrh_flag
        br      hrh_done

hrh_off
        mov     !ADR_LED_HRH_OFF a
        clr1    led_hrh_flag

hrh_done

          '

        bf      led_hrl_flag $hrl_off

        mov     !ADR_LED_HRL_ON,a
        set1    led_hrl_flag
        br      hrl_done

hrl_off
        mov     !ADR_LED_HRL_OFF a
        clr1    led_hrl_flag
```

```
hrl_done

          ,   ,, ,

        bf      led_ll_flag,$ll_off

        mov     'ADR_LED_LOOSE_ON a
        set1    led_ll_flag
        br      ll_done

ll_off
        mov     'ADR_LED_LOOSE_OFF,a
        clr1    led_ll_flag

ll_done



        ret

                                          ,

incw_blinkctr_memfull
      movw  de #blinkctr_memfull
        br      inc_shared
incw_blinkctr_service
      movw  de #blinkctr_service
inc_shared
        callf   'get_hl_via_de
        incw    hl
        callf   'put_hl_via_de
        movw    ax hl
        ret

put_0_blinkctr_service
      movw  hl #0
put_hl_blinkctr_service
      movw  de #blinkctr_service
        callf   'put_hl_via_de
        ret

   ,  ,    ,                  ,

      END
```

Other Modules With
GOTO Statements Highlighted

```
/CLKINT/BATT_PRO ASM          br      'lowpower_immediate
/CLKINT/BATT_PRO ASM          br      'lowpower
/CLKINT/BATT_PRO ASM          br      shorted_done
/CLKINT/BATT_PRO ASM          br  open_done
/CLKINT/BATT_PRO ASM          br      open_done
/CLKINT/BATT_PRO ASM          br      shared
/CLKINT/BATT_PRO ASM          br      try_low
/CLKINT/BATT_PRO ASM          br      try_high
/CLKINT/BPM ASM          br       $loop
/CLKINT/BPM ASM          br       $loop_by16
/CLKINT/CLK_300 ASM          br      done2
/CLKINT/CLK_300 ASM          br      $done_xmit
/CLKINT/CLK_300 ASM          br      skipdebugmin
/CLKINT/CLK_300 ASM          br      $mic_done
/CLKINT/CLK_300 ASM          br      is_off
/CLKINT/CLK_300 ASM          br      is_off
/CLKINT/CLK_300 ASM          br      is_off
/CLKINT/CLK_300 ASM          br      done_stagger
/CLKINT/CLK_300 ASM          br      done_stagger
/CLKINT/CLK_300 ASM          br      done_stagger
/CLKINT/CLK_300 ASM          br      freqsave
/CLKINT/CLK_300 ASM          br      done_stagger
/CLKINT/CLK_300 ASM          br      $done_stagger
/CLKINT/CLK_300 ASM          br      $done_stagger
/CLKINT/CLK_300 ASM          br      $done_stagger
/CLKINT/CLK_300 ASM          br      shared
/CLKINT/CLK_300 ASM          br      not284
/CLKINT/CLK_300 ASM          br      not284
/CLKINT/CLK_300 ASM          br      $done_284
/CLKINT/CONT_PRO ASM          br      state_exit
/CLKINT/CONT_PRO ASM          br      state5_exit
/CLKINT/CONT_PRO ASM          br      state_exit
/CLKINT/CONT_PRO ASM          br      exit
/CLKINT/CONT_PRO ASM          br      $state_1
/CLKINT/CONT_PRO ASM          br      shared_compress
/CLKINT/CONT_PRO ASM          br      shared_compress
/CLKINT/CONT_PRO ASM          br      shared_compress
/CLKINT/CONT_PRO ASM          br      shared_compress
/CLKINT/CONT_PRO ASM          br      exitshared
/CLKINT/CONT_PRO ASM          br      do_save_loop
/CLKINT/CONT_PRO ASM          br      make_space
/CLKINT/CONT_PRO ASM          br      make_space
/CLKINT/CONT_PRO ASM          br      remove
/CLKINT/CONT_PRO ASM          br      pos_loop
/CLKINT/DE_PROC ASM   br    $aclogoff
/CLKINT/DE_PROC ASM   br    $hhlogoff
/CLKINT/DE_PROC ASM   br    $hllogoff
/CLKINT/DE_PROC ASM   br    $o2logoff
/CLKINT/DE_PROC ASM          br      next_state
/CLKINT/DE_PROC ASM          br      next_state
/CLKINT/DE_PROC ASM          br      state_restarted
/CLKINT/DE_PROC ASM          br      next_state
/CLKINT/DE_PROC ASM          br      to_cont
/CLKINT/DE_PROC ASM          br      next_state
```

```
/CLKINT/DE_PROC ASM          br      next_state
/CLKINT/DZ_TICK ASM          br      wasloose
/CLKINT/DZ_TICK ASM          br      common
/CLKINT/DZ_TICK ASM          br      skip_1
/CLKINT/DZ_TICK ASM          br      skip_2
/CLKINT/DZ_TICK ASM          br      skip_3
/CLKINT/DZ_TICK ASM          br      dowave1_part3
/CLKINT/DZ_TICK ASM          br      dowave3
/CLKINT/DZ_TICK ASM          br      save_bump_shared
/CLKINT/DZ_TICK ASM          br      save_bump_shared
/CLKINT/DZ_TICK ASM          br      skip_peak3
/CLKINT/DZ_TICK ASM          br      skip_peak3
/CLKINT/DZ_TICK ASM          br      skip_peak3
/CLKINT/DZ_TICK ASM          br      rejoinsigh
/CLKINT/DZ_TICK ASM          br      rejoinsigh
/CLKINT/DZ_TICK ASM          br      failed_3
/CLKINT/DZ_TICK ASM          br      dowave3
/CLKINT/DZ_TICK ASM          br      over_bump
/CLKINT/DZ_TICK ASM          br      over_bump
/CLKINT/DZ_TICK ASM          br      setup_inhalationshared
/CLKINT/DZ_TICK ASM          br      rejoinpeaksigh
/CLKINT/DZ_TICK ASM          br      rejoinpeaksigh
/CLKINT/DZ_TICK ASM          br      shared_w2
/CLKINT/DZ_TICK ASM          br      rejoinvalleysigh
/CLKINT/DZ_TICK ASM          br      rejoinvalleysigh
/CLKINT/DZ_TICK ASM          br      shared_w3
/CLKINT/DZ_TICK ASM          br      'gotaresp
/CLKINT/ECG_PEAK ASM          br      ok
/CLKINT/ECG_TICK ASM          br      common
/CLKINT/GOTAQRS1 ASM          br      setstatus
/CLKINT/GOTAQRS1 ASM          br      setstatus
/CLKINT/GOTAQRS1 ASM          br      slow_off
/CLKINT/GOTAQRS1 ASM          br      slow_off
/CLKINT/GOTAQRS1 ASM  br    $slow_off
/CLKINT/GOTARESP ASM          br      cont
/CLKINT/GOTARESP ASM          br      cont
/CLKINT/HR_COMPU ASM          br      gotbpm
/CLKINT/HR_COMPU ASM          br      gotbpm
/CLKINT/HR_PROC ASM          br      reset_brady
/CLKINT/HR_PROC ASM          br      done_slow_r
/CLKINT/KEYS_TIC ASM          br      $reset_newstate
/CLKINT/KEYS_TIC ASM          br      $reset_newstate
/CLKINT/KEYS_TIC ASM          br      $power_newstate
/CLKINT/KEYS_TIC ASM          br      powershared
/CLKINT/KEYS_TIC ASM          br      $power_newstate
/CLKINT/KEYS_TIC ASM          br      $down_newstate
/CLKINT/KEYS_TIC ASM          br      $down_newstate
/CLKINT/KEYS_TIC ASM          br      $downshared
/CLKINT/KEYS_TIC ASM          br      $down_newstate
/CLKINT/KEYS_TIC ASM          br      $enter_newstate
/CLKINT/KEYS_TIC ASM          br      $enter_newstate
/CLKINT/KEYS_TIC ASM          br      $mode_newstate
/CLKINT/KEYS_TIC ASM          br      $mode_newstate
/CLKINT/KEYS_TIC ASM          br      $up_newstate
```

```
/CLKINT/KEYS_TIC ASM          br      $up_newstate
/CLKINT/KEYS_TIC ASM          br      $upshared
/CLKINT/KEYS_TIC ASM          br      $up_newstate
/CLKINT/MEMFULL ASM         br      nowarning
/CLKINT/RESET ASM         br      'start_sq_display_timer
/CLKINT/RESP_TIC ASM          br      $do_pb
/CLKINT/RESP_TIC ASM          br      $do_pb
/CLKINT/RESP_TIC ASM          br      $do_8
/CLKINT/RESP_TIC ASM          br      $inc_state
/CLKINT/RESP_TIC ASM          br      $inc_state
/CLKINT/RESP_TIC ASM          br      $inc_state
/CLKINT/RESP_TIC ASM          br  $reset_state
/CLKINT/RESP_TIC ASM          br      $new_state
/CLKINT/RESP_TIC ASM          br      $new_state
/CLKINT/RESP_TIC ASM          br  $reset_state
/CLKINT/RR_COMPU ASM          br      got_rate
/CLKINT/RR_COMPU ASM          br      got_rate
/CLKINT/RR_COMPU ASM          br      got_rate
/CLKINT/RR_PROC ASM         br      'rr_compute
/CLKINT/RWF_INDE ASM          br      $loop
/CLKINT/RWF_INDE ASM          br      $shared
/CLKINT/RWF_PROC ASM          br      common
/CLKINT/ST_ALARM ASM          br      start_timer
/CLKINT/ST_ALARM ASM          br      nextstate
/CLKINT/ST_ALARM ASM          br      nextstate
/CLKINT/ST_ALARM ASM          br      start_timer
/CLKINT/ST_ALARM ASM          br      nextstate
/CLKINT/ST_ALARM ASM          br      nextstate
/CLKINT/ST_ALARM ASM          br      nextstate
/CLKINT/ST_DISPL ASM          br      'set_state
/CLKINT/ST_DISPL ASM          br      shared_0_20
/CLKINT/ST_DISPL ASM          br      shared_0_20
/CLKINT/ST_DISPL ASM          br      shared_0_20
/CLKINT/ST_DISPL ASM          br      shared_0_20
/CLKINT/ST_DISPL ASM          br      shared
/CLKINT/ST_DISPL ASM          br      state7_15
/CLKINT/ST_DISPL ASM          br      dodata
/CLKINT/ST_DISPL ASM          br      state20
/CLKINT/ST_DISPL ASM          br      'inc_state
/CLKINT/ST_DISPL ASM          br      buildsub2
/CLKINT/ST_DISPL ASM          br      buildapnea
/CLKINT/ST_DISPL ASM          br      buildhrf
/CLKINT/ST_DISPL ASM          br      buildhrs
/CLKINT/ST_DISPL ASM          br      buildsub
/CLKINT/ST_DISPL ASM          br      buildsub
/CLKINT/ST_DISPL ASM          br      buildsub
/CLKINT/ST_DISPL ASM          br      shared
/CLKINT/ST_DISPL ASM          br      buildsub2
/CLKINT/ST_LEDS ASM         br      $state_18
/CLKINT/ST_LEDS ASM         br      start_timer
/CLKINT/ST_LEDS ASM         br      start_timer
/CLKINT/ST_LEDS ASM         br      start_timer
/CLKINT/ST_LEDS ASM         br      start_timer
/CLKINT/ST_LEDS ASM         br      start_timer
```

```
/CLKINT/ST_LEDS ASM          br      start_timer
/CLKINT/ST_LEDS ASM          br      start_timer
/CLKINT/ST_LEDS ASM          br      start_timer
/CLKINT/ST_LEDS ASM          br      start_timer
/CLKINT/Z0_PROC ASM          br      cont
/CLKINT/Z0_PROC ASM          br      cont
/CLKINT/Z0_PROC ASM          br      stillbad
/COMM/COMM ASM          br      'main_comm_return
/COMM/COMM ASM          br      goto
/COMM/CS_IDLE ASM          br      'main_comm_return
/COMM/C_S_INIT ASM          br      'protocol_start
/COMM/C_S_INIT ASM          br      'main_comm_return
/HDW/DISPLAY ASM          br      $shared
/HDW/Poweroff asm          br      $self1
/HDW/XMIT_STR ASM          br      $loop
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      init_shared
/INT/INIT_MOD ASM          br      'modem_off
/INT/INIT_MOD ASM          br      $loop1
/INT/INIT_MOD ASM          br      $loop1
/INT/INIT_MOD ASM          br      $loop1
/INT/INIT_MOD ASM          br      $loop1
/INT/INIT_MOD ASM          br      $loop1
/INT/Modem_in asm          br      'init_modem_int
/INT/Modem_in asm          br      $loop1
/INT/Modem_in asm          br      $loop1
/INT/Modem_in asm          br      $loop2
/INT/Modem_in asm          br      $loop2
/INT/Modem_in asm          br      $loop2
/INT/Modem_in asm          br      full
/INT/RCV_INT ASM          br      quit
/INT/RTC_INT ASM      br    $ok
/MISC/ADD_COMP ASM          br      $gotone
/MISC/ADD_COMP ASM          br      $loopr
/MISC/A_L_OFF ASM          br      common
/MISC/B_TO_DA2 ASM          br      addzero
/MISC/B_TO_D_R ASM          br      'a_to_da_r
/MISC/Clrdata asm          br      $wt_loop1
/MISC/I_TO_DA ASM          br      $loop3
/MISC/LOG_DATE ASM          br      'add_to_compliancelog
/MISC/LOG_NAME ASM          br      'add_to_compliancelog
/MISC/LOG_NUMB ASM          br      'add_to_compliancelog
/MISC/LOG_SETU ASM          br      'add_to_compliancelog
/MISC/MENUDISP ASM          br      hl
/MISC/READKEY ASM          br      d0
/MISC/READKEY ASM          br      d0
/MISC/READKEY ASM          br      d0
/MISC/SPACEFIL ASM          br      loop
/MISC/START_EL ASM          br      shared
/MISC/START_EL ASM          br      shared
```

```
/MISC/START_EL ASM          br      shared
/MISC/START_EL ASM          br      shared
/MISC/XFER_EVE ASM          br      $shared
/POWER/10M_SAVE ASM          br      ok
/POWER/10M_SAVE ASM          br      restart
/POWER/COMPRESS ASM          br      down6to2
/POWER/COMPRESS ASM          br      down6to2
/POWER/COMPRESS ASM          br      down4to2
/POWER/COMPRESS ASM          br      up8from2
/POWER/COMPRESS ASM          br      store8
/POWER/COMPRESS ASM          br      loop8
/POWER/COMPRESS ASM          br      loop6
/POWER/COMPRESS ASM          br      $store4
/POWER/COMPRESS ASM          br      loop4
/POWER/COMPRESS ASM          br      store2
/POWER/COMPRESS ASM          br      loop2
/POWER/COMPRESS ASM          br      shared8
/POWER/COMPRESS ASM          br      shared6
/POWER/COMPRESS ASM          br      shared6
/POWER/COMPRESS ASM          br      shared4
/POWER/COMPRESS ASM          br      shared2
/POWER/COMPRESS ASM          br      shared4
/POWER/COMPRESS ASM          br      shared4
/POWER/COMPRESS ASM          br      shared6
/POWER/COMPRESS ASM          br      shared2
/POWER/COMPRESS ASM          br      shared4
/POWER/COMPRESS ASM          br      shared6
/POWER/COMPRESS ASM          br      gp_shared
/POWER/DE_SAVE ASM          br      done
/POWER/DE_SAVE ASM          br      cc_loop
/POWER/DE_SAVE ASM          br      mp_loop
/POWER/DE_SAVE ASM          br      delfifo
/POWER/DE_SAVE ASM          br      any
/POWER/DE_SAVE ASM          br      any
/POWER/DE_SAVE ASM          br      any
/POWER/DE_SAVE ASM          br      any
/POWER/DE_SAVE ASM          br      any
/POWER/DE_SAVE ASM          br      $prior_loop_noswap
/POWER/DE_SAVE ASM          br      completedelete
/POWER/DE_SAVE ASM          br      $window_loop_noswap
/POWER/DE_SAVE ASM          br      $fifo_loop_noswap
/POWER/DE_SETUP ASM          br      nowindows
/POWER/DE_SETUP ASM          br      loopcont
/POWER/DE_SETUP ASM          br      windows_part2
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      loop
/POWER/DE_SETUP ASM          br      shared_
/POWER/DE_SETUP ASM          br      nw_loop
/POWER/INIT_232 ASM          br      $shared
/POWER/INIT_232 ASM          br      $shared
```

```
 /POWER/IS_POWER ASM          br      'pulse_power_off
 /POWER/IS_POWER ASM          br      'pulse_power_off
 /POWER/IS_POWER ASM          br      'pulse_power_off
 /POWER/IS_POWER ASM          br      'checksum_ram
 /POWER/LEGAL_CH ASM          br      $do_nonlimits
 /POWER/LEGAL_CH ASM          br      $badshared
 /POWER/LEGAL_CH ASM          br      $fix3rd          ,hl=ptr1 de=
ptr3 c=size
 /POWER/LEGAL_CH ASM          br      $fix3rd           hl=ptr1 de=
ptr2,c=size
 /POWER/LEGAL_CH ASM          br      $loop2
 /POWER/POWERUP ASM          br      runtime_startwd
 /POWER/POWERUP ASM          br      runtime_cont
 /POWER/POWERUP ASM          br      shared3'
 /POWER/POWERUP ASM          br      $self
 /POWER/POWERUP ASM          br      'comm
 /POWER/POWERUP ASM          br      $skipdsp
 /POWER/POWERUP ASM    br    runtime_loop
 /POWER/POWERUP ASM          br      runtime_loop'
 /POWER/POWERUP ASM          br      'add_to_compliancelog
 /POWER/POWERUP ASM          br      'is_powerkeys
 /POWER/RAMTEST ASM          br      ramtest3
 /POWER/RAMTEST ASM          br      r3_loop1
 /POWER/RAMTEST ASM          br      r3_loop2
 /POWER/RWF_SAVE ASM          br      debug_shared
 /POWER/WARN_DSP ASM          br      'display_off
 /PROTO/AUTODIAL ASM          br      return
 /PROTO/AUTODIAL ASM          br      retry_maybe
 /PROTO/AUTODIAL ASM          br      retry_maybe
 /PROTO/AUTODIAL ASM          br      retry_maybe
 /PROTO/AUTODIAL ASM          br      return
 /PROTO/AUTODIAL ASM          br      'main_comm_return
 /PROTO/AUTODIAL ASM          br      newdate_done
 /PROTO/AUTODIAL ASM          br      'save_nextdatetime
 /PROTO/AUTODIAL ASM          br      newdate_done
 /PROTO/AUTOMENU ASM          br      'protocol_start
 /PROTO/GETPACKE ASM          br      $dataloop
 /PROTO/INITPACK ASM          br      $loop
 /PROTO/PC_10MIN ASM          br      loop
 /PROTO/PC_COMPL ASM          br      $nomore
 /PROTO/PC_COMPL ASM          br      get_nondelete
 /PROTO/PC_COMPL ASM          br      $get_delete
 /PROTO/PC_COMPL ASM          br      'add_to_compliancelog
 /PROTO/PC_CONT ASM          br      loop
 /PROTO/PC_EVENT ASM          br      'nomore
 /PROTO/PC_EVENT ASM          br      get_nondelete
 /PROTO/PC_EVENT ASM          br      c_cont
 /PROTO/PC_EVENT ASM          br      c_cont2
 /PROTO/PC_EVENT ASM          br      get_delete
 /PROTO/PC_EVENT ASM          br      'put_hl_via_de
 /PROTO/PC_WAVEF ASM          br      shared
 /PROTO/PC_WAVEF ASM          br      shared
 /PROTO/PC_WAVEF ASM          br      shared
 /PROTO/PC_WAVEF ASM          br      shared
```

```
/PROTO/PC_WAVEF ASM          br      shared
/PROTO/PC_WAVEF ASM          br      loop
/PROTO/PD_10MIN ASM          br      goodrtn
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $doit
/PROTO/PD_WAVEF ASM          br      $loop
/PROTO/PD_WAVEF ASM          br      fail
/PROTO/PD_WAVEF ASM          br      $doit_loop
/PROTO/PD_WAVEF ASM          br      $donext
/PROTO/PD_WAVEF ASM          br      mp_loop
/PROTO/PROTORTN ASM          br      'main_comm_return
/PROTO/PS_DUMP ASM          br      $shared
/PROTO/PS_DUMP ASM          br      $bl_loop
/PROTO/PS_DUMP ASM          br      loop
/PROTO/PS_FRSTC ASM          br      'point_to_cont_data
/PROTO/PS_PACK ASM          br      big_loop
/PROTO/PWDATTIM ASM          br      both
/PROTO/PWLIMITS ASM          br      chkrange
/PROTO/PWLIMITS ASM          br      reply
/PROTO/PWLIMITS ASM          br      crloop2
/PROTO/PW_MODEM ASM          br      reply
/PROTO/PW_SETUP ASM          br      checkaux
/PROTO/PW_SETUP ASM          br      reply
/PROTO/P_DATA ASM          br      shared
/PROTO/P_MEMUSE ASM          br      shared
/PROTO/SENDPACK ASM          br      badrtn
/SETUP/SETUPMOD ASM          br      $wait
/SETUP/SETUPMOD ASM          br      done
/SETUP/SS_CODE ASM          br      $sc_wait
/SETUP/SS_CODE ASM          br      $sc_loop
/SETUP/SS_CODE ASM          br      $sc_loop
/SETUP/SS_CODE ASM          br      $shared
/SETUP/SS_CODE ASM          br      $sc_loop
/SETUP/SS_CODE ASM          br      'ss_loop
/SETUP/SS_GETAN ASM          br      $an_wait
/SETUP/SS_GETAN ASM          br      $an_loop
/SETUP/SS_GETAN ASM          br      $an_loop
/SETUP/SS_GETAN ASM          br      $incshared
/SETUP/SS_GETAN ASM          br      $shared
/SETUP/SS_GETAN ASM          br      $decshared
/SETUP/SS_GETAN ASM          br      'an_loop
/SETUP/SS_WAITK ASM          br      shared
/SETUP/SS_WAITK ASM          br      skip
/SETUP/SU_AUX ASM          br      'display_linecontinue
/SETUP/SU_DATET ASM          br      $change
/SETUP/SU_DATET ASM          br      $wait
/SETUP/SU_DATET ASM          br      $year_show
/SETUP/SU_DATET ASM          br      $year_show
/SETUP/SU_DATET ASM          br      $useit
/SETUP/SU_DATET ASM          br      $wait
```

```
/SETUP/SU_DATET ASM          br      $show
/SETUP/SU_DATET ASM          br      $show
/SETUP/SU_DATET ASM          br      $show
/SETUP/SU_LIMIT ASM          br      rejoin
/SETUP/SU_LIMIT ASM          br      wait
/SETUP/SU_LIMIT ASM          br      $skip1
/SETUP/SU_LIMIT ASM          br      loop
/SETUP/SU_LIMIT ASM          br      dodec1
/SETUP/SU_LIMIT ASM          br      pointshared
/SETUP/SU_PATIE ASM          br      $resp2_done
/SETUP/SU_PATIE ASM          br      $brady_done
/SETUP/SU_PATIE ASM    br    $ox1_done   ,    v11 10
/SETUP/SU_PATIE ASM    br    $ox1_loop
/SETUP/SU_PATIE ASM          br      'start_new_patient
/SETUP/SU_PATIE ASM          br      aux_set_shared
/SETUP/SU_PATIE ASM          br      aux_set_shared
/SETUP/SU_PATIE ASM          br      $aux_loop
/SETUP/SU_PRIOR ASM          br      $do_p_line2
/SETUP/SU_PRIOR ASM          br      $do_fixed_line2
/SETUP/SU_PRIOR ASM          br    $do_pa
/SETUP/SU_PRIOR ASM          br      'exit
/SETUP/SU_PRIOR ASM          br      $pa_loop
/SETUP/SU_PRIOR ASM          br      $pa_loop
```

Model 9700 Summary Software Verification Test Plan

Revision 09

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Project Manager :		4/12/96
Lead Sftw Engineer		4/12/96
Ind. Sftw. Engineer		4/12/96
Q.A. Engineer		4/15/96

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1.0 INTRODUCTION

This test plan is a summary of the software verification testing performed on the Model 9700 Apnea Monitor Software.

2.0 OBJECTIVE

The objective of these tests is to identify and correct as many errors in the software as possible and to verify that the software performs as specified and designed.

3.0 TEST ITEMS

3.1 Software Revision Level

The system software revision level to be tested is 9.0 The revision date for each module tested will be recorded in the Model 9700 Summary Software Verification Test Report.

3.2 Equipment Required

AMI Model 9700 Apnea Monitor
RD 5000 Heart Rate/Respiration Simulator
AMI 8310 Heart Rate/Respiration Simulator
Cardiovascular Artifact Generator
2 Power Supplies
HP 54501A Oscilloscope
Voltmeter
Personal Computer
Model 9700 Report Generator Software

4.0 APPLICABLE DOCUMENTS

AMI Software Development Protocol

Model 9700 Software Requirements Specification

Model 9700 Software Design Specification

Model 9700 Design Verification Test (DVT) Plan

Model 9700 Source Code Listing

Model 9700 Requirements Traceability Matrix

Model 9700 Product Change Notices (PCN's)

Standards Document for NEC 78k Series Programming

Individual module and integration test plans per Table 2

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5.0 TEST APPROACH

The software has undergone extensive system testing and debug per the Model 9700 DVT (i.e. system test). All known software errors identified during this testing have have been identified and corrected. Formal software testing as defined by this plan as well as system regression testing as identified in the Model 9700 DVT will now begin.

A review of the software criticality was performed by determining the effects of a single point software error assuming that there are no simultaneous hardware failures. Any software function (requirement) that could result in a missed or delayed audible alarm, due to an error in the software used to perform that function, was determined to have a major level of concern. All other potential errors of software functions such as false alarm, safety feature disabled, missed or delayed warning alarm, visual indicator disabled, loss of communications, loss of data, and incorrect data recording were determined to have a minor level of concern. Each software requirement was analyzed. The level of concern of each software requirement was determined. The same level of concern for each software requirement was then assigned to each module that is used to perform the requirement. Thus criticality was used to determine the level of test required for each function and module.

All software modules will be static tested by performing code walk throughs. Code walk throughs will be the only sub-system tests required for modules with a minor level of concern as shown in Table 1. Participation in these walk throughs will be required by the lead software engineer, the software quality engineer and an independent software engineer. These reviews will consist of but not be limited to adherence to coding standards (Standards Document for NEC 78k Series Programming, accuracy of the header description and revision tracking, functional performance versus specifications, and robustness including boundary conditions.

Following completion of the code walk throughs, all modules with a major level of concern (i.e. safety related) will be tested using the test techniques defined in Table 2. Details and rationale for this testing are included in the individual module and integration verification test plans for these modules.

6.0 PASS/FAIL CRITERIA

All errors identified as a result of this software testing will be assessed as to the error's effect on safety and performance. All errors which could impact the safety of the patient must be corrected. All errors which would cause the monitor to not meet requirements must also be corrected. All other errors will be reviewed and will only be changed if there is clearly no other potential effect that could result from changing the software.

The software testing will have been successfully completed once the tests detailed in the test approach section have been performed, the regression tests detailed in the Model 9700 DVT plan have been completed, and all required error corrections have been implemented.

7.0 REGRESSION TEST CRITERIA

All modules in which error corrections were made will repeat the module walk throughs. If the module is a major level of concern, all module testing related integration testing and related system regression testing will be repeated.

8.0 DELIVERABLES

Model 9700 Summary Software Verification Test Report

Model 9700 Source Code Listing (including revision history)

PCN File (Documentation of all product changes)

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TABLE 1		
Module	Level of Concern	Module Tests
10m_dele.asm	Minor	Walk Through
10m_save.asm	Minor	Walk Through
a2d_int.asm	Minor	Walk Through
add_24.asm	Minor	Walk Through
add_comp.asm	Minor	Walk Through
add5mins.asm	Minor	Walk Through
autodial.asm	Minor	Walk Through
automenu.asm	Minor	Walk Through
aux_proc.asm	Minor	Walk Through
a_l_off.asm	Minor	Walk Through
b3_to_da.asm	Minor	Walk Through
b_to_da.asm	Minor	Walk Through
b_to_da2.asm	Minor	Walk Through
b_to_d_r.asm	Minor	Walk Through
b_to_ha.asm	Minor	Walk Through
clrdata.asm	Minor	Walk Through
cmp_24.asm	Minor	Walk Through
cmp_tone.asm	Minor	Walk Through
cnvdt.asm	Minor	Walk Through
comm.asm	Minor	Walk Through
compress.asm	Minor	Walk Through
cont_pro.asm	Minor	Walk Through
copy.asm	Minor	Walk Through
copynons.asm	Minor	Walk Through
copystri.asm	Minor	Walk Through
cs_idle.asm	Minor	Walk Through
cs_ram.asm	Minor	Walk Through
cs_table.asm	Minor	Walk Through
c_m_baud.asm	Minor	Walk Through
c_m_recv.asm	Minor	Walk Through
c_s_init.asm	Minor	Walk Through
defaults.asm	Minor	Walk Through
de_alloc.asm	Minor	Walk Through
de_proc.asm	Minor	Walk Through
de_save.asm	Minor	Walk Through
de_setup.asm	Minor	Walk Through
dio_int.asm	Minor	Walk Through
display.asm	Minor	Walk Through
divaxde.asm	Minor	Walk Through
div_24.asm	Minor	Walk Through
do_idle.asm	Minor	Walk Through
elog_sec.asm	Minor	Walk Through
end_sp.asm	Minor	Walk Through
freq_int.asm	Minor	Walk Through
ga_apnea.asm	Minor	Walk Through
ga_hrf.asm	Minor	Walk Through
ga_hrs.asm	Minor	Walk Through

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TABLE 1		
Module	Level of Concern	Module Tests
gethlde.asm	Minor	Walk Through
getpacke.asm	Minor	Walk Through
get_dpm.asm	Minor	Walk Through
get_rtc.asm	Minor	Walk Through
gr_apnea.asm	Minor	Walk Through
gr_hrf.asm	Minor	Walk Through
gr_hrs.asm	Minor	Walk Through
gr_o2.asm	Minor	Walk Through
g_aux1.asm	Minor	Walk Through
g_aux2.asm	Minor	Walk Through
g_aux3.asm	Minor	Walk Through
g_bmode.asm	Minor	Walk Through
g_m_baud.asm	Minor	Walk Through
g_m_comp.asm	Minor	Walk Through
g_m_dela.asm	Minor	Walk Through
g_m_rate.asm	Minor	Walk Through
g_m_retr.asm	Minor	Walk Through
g_pa_ca.asm	Minor	Walk Through
g_pa_hrf.asm	Minor	Walk Through
g_pa_hrs.asm	Minor	Walk Through
g_pa_o2.asm	Minor	Walk Through
g_ptype.asm	Minor	Walk Through
mctime.asm	Minor	Walk Through
mutcomm.asm	Minor	Walk Through
mutpack.asm	Minor	Walk Through
mutport.asm	Minor	Walk Through
mut_232.asm	Minor	Walk Through
mut_mod.asm	Minor	Walk Through
mut_rtc.asm	Minor	Walk Through
nsdigit.asm	Minor	Walk Through
nsithex.asm	Minor	Walk Through
nsitpmn.asm	Minor	Walk Through
ns_power.asm	Minor	Walk Through
s_to_da.asm	Minor	Walk Through
s_to_d_r.asm	Minor	Walk Through
keys_rtc.asm	Minor	Walk Through
legal_ch.asm	Minor	Walk Through
lith_pro.asm	Minor	Walk Through
log_date.asm	Minor	Walk Through
log_init.asm	Minor	Walk Through
log_limt.asm	Minor	Walk Through
log_name.asm	Minor	Walk Through
log_numb.asm	Minor	Walk Through
log_setu.asm	Minor	Walk Through
memfull.asm	Minor	Walk Through
menudisp.asm	Minor	Walk Through
messages.asm	Minor	Walk Through

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TABLE 1		
Module	Level of Concern	Module Tests
modemoff.asm	Minor	Walk Through
modem_m.asm	Minor	Walk Through
mulaxbc.asm	Minor	Walk Through
op_qts.asm	Minor	Walk Through
op_resp.asm	Minor	Walk Through
pb_sec.asm	Minor	Walk Through
pc_10mun.asm	Minor	Walk Through
pc_compl.asm	Minor	Walk Through
pc_cont.asm	Minor	Walk Through
pc_event.asm	Minor	Walk Through
pc_wavef.asm	Minor	Walk Through
pd_10mun.asm	Minor	Walk Through
pd_compl.asm	Minor	Walk Through
pd_cont.asm	Minor	Walk Through
pd_event.asm	Minor	Walk Through
pd_pb.asm	Minor	Walk Through
pd_wavef.asm	Minor	Walk Through
poweroff.asm	Minor	Walk Through
powerup.asm	Minor	Walk Through
protocol.asm	Minor	Walk Through
protorpl.asm	Minor	Walk Through
protortn.asm	Minor	Walk Through
ps_clkdis.asm	Minor	Walk Through
ps_dump.asm	Minor	Walk Through
ps_eof.asm	Minor	Walk Through
ps_frstc.asm	Minor	Walk Through
ps_nxtc.asm	Minor	Walk Through
ps_pack.asm	Minor	Walk Through
ps_putc.asm	Minor	Walk Through
pulse_ti.asm	Minor	Walk Through
puthldr.asm	Minor	Walk Through
pwdattim.asm	Minor	Walk Through
pwlimits.asm	Minor	Walk Through
pwsecrty.asm	Minor	Walk Through
pw_modem.asm	Minor	Walk Through
pw_rs232.asm	Minor	Walk Through
pw_setup.asm	Minor	Walk Through
p_anopts.asm	Minor	Walk Through
p_bad.asm	Minor	Walk Through
p_clear.asm	Minor	Walk Through
p_data.asm	Minor	Walk Through
p_dateti.asm	Minor	Walk Through
p_ledalm.asm	Minor	Walk Through
p_lumits.asm	Minor	Walk Through
p_memory.asm	Minor	Walk Through
p_memuse.asm	Minor	Walk Through
p_mic.asm	Minor	Walk Through

TABLE 1		
Module	Level of Concern	Module Tests
p_modem.asm	Minor	Walk Through
p_monmo.asm	Minor	Walk Through
p_reset.asm	Minor	Walk Through
p_rt.asm	Minor	Walk Through
p_secty.asm	Minor	Walk Through
p_setup.asm	Minor	Walk Through
p_signal.asm	Minor	Walk Through
p_versio.asm	Minor	Walk Through
p_watchd.asm	Minor	Walk Through
q_and_a.asm	Minor	Walk Through
ramtest.asm	Minor	Walk Through
rcv_ch.asm	Minor	Walk Through
rcv_mt.asm	Minor	Walk Through
readkey.asm	Minor	Walk Through
readtime.asm	Minor	Walk Through
reset.asm	Minor	Walk Through
reteq.asm	Minor	Walk Through
reme.asm	Minor	Walk Through
romtest.asm	Minor	Walk Through
rr_compu.asm	Minor	Walk Through
rr_proc.asm	Minor	Walk Through
rtc_int.asm	Minor	Walk Through
rwf_mde.asm	Minor	Walk Through
rwf_proc.asm	Minor	Walk Through
rwf_save.asm	Minor	Walk Through
sa_apnea.asm	Minor	Walk Through
sa_hrf.asm	Minor	Walk Through
sa_hrs.asm	Minor	Walk Through
sendpack.asm	Minor	Walk Through
setdatim.asm	Minor	Walk Through
setP6.asm	Minor	Walk Through
setPM6.asm	Minor	Walk Through
setummod.asm	Minor	Walk Through
set_rtc.asm	Minor	Walk Through
spacefil.asm	Minor	Walk Through
sq_build.asm	Minor	Walk Through
sq_dsp.asm	Minor	Walk Through
sq_sec.asm	Minor	Walk Through
sq_start.asm	Minor	Walk Through
sr_apnea.asm	Minor	Walk Through
sr_hrf.asm	Minor	Walk Through
sr_hrs.asm	Minor	Walk Through
sr_o2.asm	Minor	Walk Through
ss_code.asm	Minor	Walk Through
ss_getan.asm	Minor	Walk Through
ss_wartk.asm	Minor	Walk Through
startpat.asm	Minor	Walk Through

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TABLE 1		
Module	Level of Concern	Module Tests
start_el.asm	Minor	Walk Through
start_sp.asm	Minor	Walk Through
st_alarm.asm	Minor	Walk Through
st_displ.asm	Minor	Walk Through
st_leds.asm	Minor	Walk Through
sub_24.asm	Minor	Walk Through
sumpacke.asm	Minor	Walk Through
su_aux.asm	Minor	Walk Through
su_baud.asm	Minor	Walk Through
su_datet.asm	Minor	Walk Through
su_lmit.asm	Minor	Walk Through
su_pabe.asm	Minor	Walk Through
su_prior.asm	Minor	Walk Through
s_anc1.asm	Minor	Walk Through
s_anc2.asm	Minor	Walk Through
s_anc3.asm	Minor	Walk Through
s_bmode.asm	Minor	Walk Through
s_m_band.asm	Minor	Walk Through
s_m_comp.asm	Minor	Walk Through
s_m_date.asm	Minor	Walk Through
s_m_dela.asm	Minor	Walk Through
s_m_phon.asm	Minor	Walk Through
s_m_rate.asm	Minor	Walk Through
s_m_retr.asm	Minor	Walk Through
s_name.asm	Minor	Walk Through
s_number.asm	Minor	Walk Through
s_pa_ca.asm	Minor	Walk Through
s_pa_hrf.asm	Minor	Walk Through
s_pa_hrs.asm	Minor	Walk Through
s_pa_o2.asm	Minor	Walk Through
s_ptype.asm	Minor	Walk Through
s_scode.asm	Minor	Walk Through
toupper.asm	Minor	Walk Through
vectors.asm	Minor	Walk Through
wantclk.asm	Minor	Walk Through
warm_dsp.asm	Minor	Walk Through
watchdog.asm	Minor	Walk Through
writetim.asm	Minor	Walk Through
wuf_ap_c.asm	Minor	Walk Through
wuf_high.asm	Minor	Walk Through
wuf_hrh.asm	Minor	Walk Through
wuf_hrl.asm	Minor	Walk Through
wuf_lith.asm	Minor	Walk Through
wuf_ll.asm	Minor	Walk Through
wuf_lowb.asm	Minor	Walk Through
wuf_open.asm	Minor	Walk Through
wuf_shor.asm	Minor	Walk Through

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TABLE 1		
Module	Level of Concern	Module Tests
wnf_vlow.asm	Minor	Walk Through
wnn_aper.asm	Minor	Walk Through
wnn_high.asm	Minor	Walk Through
wnn_hrhr.asm	Minor	Walk Through
wnn_hrlr.asm	Minor	Walk Through
wnn_lith.asm	Minor	Walk Through
wnn_lowh.asm	Minor	Walk Through
wnn_open.asm	Minor	Walk Through
wnn_shor.asm	Minor	Walk Through
wnp_grs.asm	Minor	Walk Through
wnp_resp.asm	Minor	Walk Through
xfer_eve.asm	Minor	Walk Through
xmit_ch.asm	Minor	Walk Through
xmit_int.asm	Minor	Walk Through
xmit_str.asm	Minor	Walk Through

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TABLE 2

Module	Level of Concern	Module Tests	Integration Tests
batt_pro.asm	Major	WT & EXH	
bom.asm	Major	WT & BVA	
clk_300.asm	Major	WT & EXH	
dz_rail.asm	Major	WT & EXH	
dz_tick.asm	Major	WT	BB
ecg_int.asm	Major	WT & EXH	
ecg_peak.asm	Major	WT & EXH	
ecg_tick.asm	Major	WT	BB
gotaqrs1.asm	Major	WT & EXH	
gotaresp.asm	Major	WT & EXH	
hb_tick.asm	Major	WT & EXH	
hr_compu.asm	Major	WT & BVA	
hr_proc.asm	Major	WT & EXH	
ledalarm.asm	Major	WT & EXH	
resp_tic.asm	Major	WT & EXH	
rr0_proc.asm	Major	WT & EXH	
wm_apca.asm	Major	WT & BB	
wm_hrha.asm	Major	WT & BB	
wm_hrla.asm	Major	WT & BB	
wm_ll.asm	Major	WT & BB	
wm_vlow.asm	Major	WT & BB	

KEY
BB = Black Box
BVA = Boundary Value Analysis
EXH = Exhaustive
WT = Walk Through

NO CV 71591

JAMIE SMITH, Individually and as Next Friend of KORTNEY SMITH, a Minor,	§	IN THE DISTRICT COURT
Plaintiff,	§	
vs	§	
	§	LIBERTY COUNTY, TEXAS
CAS MEDICAL SYSTEMS, INC , and J & B MEDICAL ENTERPRISES, INC ,	§	
Defendants	§	253RD JUDICIAL DISTRICT

NELLCOR'S MOTION TO STRIKE THE EXPERT TESTIMONY OF PLAINTIFF'S RETAINED SOFTWARE DEFECT EXPERTS

TO THE HONORABLE JUDGE OF SAID COURT

Defendants Nellcor Puritan Bennett L.L C Mallinckrodt, Inc and Covidien Inc (collectively referred to as "Nellcor") file this Motion to Strike the Expert Testimony of Plaintiff's Retained Software Defect Experts Frank Painter William Lively and Walter Daugherity (collectively referred to as Plaintiff's Retained Software Experts) and would respectfully show the Court the following

I.

SUMMARY OF THE ARGUMENT

Plaintiff's Retained Software Experts seek to opine that an alleged software defect caused Kortney Smith s apnea monitor to fail to alarm for a loose lead condition [1] Plaintiff's Retained Software Experts concede that they have no objective evidence that such a defect could even occur as is required to provide a reliable expert opinion under Texas law Plaintiff's Retained Software Experts admit that, based on their testing of the Ami monitor software the

[1] Causation is an essential element for each and every one of Plaintiff's causes of action To the extent the Court grants this Motion Nellcor is entitled to judgment as a matter of law on each and every one of Plaintiff's claims

261595v2

EXHIBIT D

software alarmed appropriately for conditions including for all loose lead conditions Thus Plaintiff's Retained Software Experts admit that they are unable to reproduce or even locate the alleged software bug in the source code that would cause an Ami monitor to fail to alarm for a loose lead condition The unreliability of Plaintiff's Retained Software Experts opinions is best summarized in the following testimony

> **Q All right. Now with respect to – is it fair to say, sir, that you, sitting here today, based upon all the facts and information that you know in this case, can neither prove or disprove the existence of a software glitch or a software bug that played any part in the events of the evening in question? Is that fair to say?**
>
> **A Yes**

See October 16 2007 Deposition of Walter Daugherty at 147 20-148 2 attached as Exhibit A

> **Q Can you show me – can you point me to anything, any software bug or glitch, in the programming of the monitor at issue that you can show played a part in the alleged outcome in this case?**
>
> **A No**
>
> **Q You would agree, then sir, that you can neither prove nor disprove the existence of a software bug or glitch in the Ami monitor product line at issue in this case, true?**
>
> **Mr Hastings Form.**
>
> **Q Do you agree with that?**
>
> **A True**

See November 8 2007 Deposition of William Lively at 16 13-17 12 attached as Exhibit B

> **Q You have had in your possession at some point, as I understand it, an exemplar device?**
>
> **A Yes**

Q How long was it in your possession?

A About two weeks

Q Did you test it?

A I did.

Q Did it perform according to your expectations?

A It did

Q Okay How did you test it, by the way?

A I got a simulator and turned it on and ran through as many different variations of input as I could do.

Q Did it alarm as intended by the manufacturer?

A Yes

Q Okay Always alarmed when an alarmable event occurred, true?

A Yes.

See October 26 2007 Deposition of Frank Painter, at 5 4-6 5 attached as Exhibit C"

The testimony of each of Plaintiff's Retained Software Experts is clear positive and direct They have no objective evidence of a software defect as alleged by Plaintiff's in this case as is required by Texas law They have provided no scientific literature that supports their purported opinion that a software defect exists with the Ami monitor used by Plaintiff Finally each of Plaintiff's Retained Software Experts admits that they cannot rule out the possibility that Plaintiff's allegation in this case is an erroneous report (i e that the alarm was actually sounding when Plaintiff alleges it was not) as is required by Texas law Thus, the testimony of Plaintiff's Retained Software Experts is nothing more than subjective belief or unsupported speculation,

which is not grounded in any scientific method or procedure Accordingly Nellcor seeks to exclude all of the purported testimony of Plaintiff's Retained Software Experts

II

ARGUMENTS & AUTHORITIES

The trial court may admit expert testimony [i]f scientific technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue TEX R EVID 702 For expert testimony to be admissible, the proponent has the burden to establish that (1) the expert is qualified to render an opinion on the subject matter; (2) the testimony is relevant to the issues in the case and (3) it is reliable TEX R. EVID 702 *E I du Pont de Nemours & Co v Robinson* 923 S W 2d 549 556 (Tex 1995)

Expert testimony is unreliable if it is not grounded in scientific method or procedure and is no more than subjective belief or speculation *Volkswagon of Am. Inc v Ramirez* 159 S W 3d 897 904 (Tex 2004) Expert testimony is also unreliable if there is too great of an analytical gap between the data and the opinion proffered *Gammill v Jack Williams Chevrolet, Inc* 972 S W 2d 713, 726-27 (Tex 1998) (stating that the trial court was not required "to admit opinion evidence which is connected to the existing data only by the *ipse dixit* of the expert ")

In determining the reliability of an expert's opinion in 1995 the Texas Supreme Court outlined a six-factor test for evaluating the reliability of expert testimony *Robinson* 923 S W 2d at 557 Nellcor will evaluate each of the relevant factors below More recently the Texas Supreme Court has re-emphasized the importance of applying these factors *Volkswagen*, 159 S W 2d at 905-906 (holding that under the *Robinson* factors an expert's testimony was unreliable because the expert failed to conduct tests cite studies, or perform calculations" in support of his theory)

A PLAINTIFF'S RETAINED SOFTWARE EXPERTS' OPINION REGARDING A SOFTWARE BUG CAUSING A FAILURE TO ALARM FOR A LOOSE LEAD CONDITION IS UNRELIABLE, THEREFORE IT IS INADMISSIBLE

(1) PLAINTIFF'S RETAINED SOFTWARE EXPERTS HAVE NO OBJECTIVE EVIDENCE THAT SOFTWARE BUG EXISTS

The Texas Supreme Court has held that proof of a product defect requires competent expert testimony and objective proof of a product defect *Nissan Motor Company Ltd v Armstrong*, 145 S W 3d 131, 137 (Tex 2004), *Ford Motor Co v Ridgway*, 135 S W 3d 598, 601 (Tex 2004) (holding that a specific defect must be identified by competent evidence and other possible causes must be ruled out)

All of Plaintiff's Retained Software Experts admit that they have no objective proof of a software defect with the Ami monitor They have been unable to reproduce the alleged defect or even locate the alleged software defect in the software source code *See* Ex A at 10 11-25 and 147 20-148 2 (Professor Daugherity stating that he has been unable to duplicate the alleged defect alleged in this case and that the Ami monitor alarmed appropriately at all times) Ex B at 18 14–25 110 8–13 and 116 4–17 12 (Professor Lively stating that the Ami monitor he tested always alarmed appropriately and that Plaintiff's experts have been 'unable to find the alleged software defect in the source code), *see also* Ex C at 5 4–6 5 (Frank Painter stating that the Ami monitor he tested always alarmed appropriately)

Compounding the problem for Plaintiff's Retained Software Experts is the fact that the monitor at issue in this case passed all subsequent post-incident testing including for the exact defect (a loose lead condition) alleged in this case and appropriately alarmed for all other conditions as well *See* May 10, 2007 Deposition of Gary Santos at 71 3 84 22, attached as Exhibit D' Moreover none of the Plaintiff's retained experts can rule out, with any reliable scientific analysis an erroneous report from the parents (i e , that the monitor was alarming when

the parents said it was not) *Robinson* 923 S W 2d at 559 (holding that an expert s opinion is not reliable if the expert fails to rule out other causes) (citations omitted)

(2) **PLAINTIFF'S RETAINED SOFTWARE EXPERTS' OPINIONS REGARDING AN ALLEGED SOFTWARE DEFECT FAILS EVERY RELIABILITY FACTOR OUTLINED IN *ROBINSON***

In determining the reliability of an expert s opinion the Texas Supreme Court outlined the following six factors for reliability in *Robinson*

(1) the extent to which the theory has been or can be tested,

(2) the extent to which the technique relies upon the subjective interpretation of the expert

(3) whether the theory has been subjected to peer review and/or publication

(4) the technique's potential rate of error,

(5) whether the underlying theory or technique has been generally accepted as valid by the relevant scientific community, and

(6) the non-judicial uses which have been made of the theory or technique

Robinson 923 S W 2d at 557

Plaintiff's Retained Software Experts opinion regarding an alleged software defect fails each and every reliability factor outlined in *Robinson*

As for the first factor (testability), Plaintiff's Retained Software Experts tested their software defect theory—and Plaintiff's Retained Software Experts' theories were proven false every time That is Plaintiff's Retained Software Experts tested an exemplar monitor in an attempt to prove their software defect theory The apnea monitor alarmed appropriately each and every time Plaintiff's Retained Software Experts tested it Ex A at 10·11-25, 147 20-148 2 Ex B at 18 14-25 110 8-13 116 4-117 12, Ex C at 5 4-6 5 Thus, each one of Plaintiff's Retained Software Experts concedes that they could not either prove or disprove their software theory

The unreliability of Plaintiff's Retained Software Experts software defect theory is further clarified by the fact that J&B Medical and two other retained software experts (Software CPR and Dr Bruce Barkolow) performed testing on Ami monitors and those Ami monitors also alarmed appropriately every time This factor weighs against the admissibility of Plaintiff's Retained Software Experts' opinions

As for the second factor (subjective interpretation), the opinion of Plaintiff's Retained Software Experts is completely subjective Because Plaintiff's Retained Software Experts is not based on any objective facts there is nothing that Nellcor can test (or even review) in an attempt to confirm or disprove the purported opinions of Plaintiff's Retained Software Experts Accordingly this factor also weighs against the admissibility of Plaintiff's Retained Software Experts opinions

As for the third factor (peer review or publication) there is not a single peer reviewed article or publication that states that an unverified, undefined and non-reproducible software defect proves a software defect exists in a medical device Accordingly this factor also clearly weighs against the admissibility of the opinions from Plaintiff's Retained Software Experts

The fourth factor (potential rate of error) does not help Plaintiff Since Plaintiff's Retained Software Experts only have their subjective opinions there is no established rate of error In fact, Nellcor would argue that the testing of Plaintiff's Retained Software Experts confirms that the potential rates of error for their opinions are 100% Every test Plaintiff's Retained Software Experts performed in an attempt to confirm their theory in fact rejected their theory Morevover, testing by J&B Medical, Software CPR and Dr Bruce Barkolow also

indicates that the potential rate of error is 100% for the purported opinions of Plaintiff's Retained Software Experts Accordingly, this factor also weighs against the admissibility of their opinion

The fifth factor (general acceptance by the scientific community of the underlying technique) also weighs against the admissibility of the Plaintiff's Retained Software Experts opinion Professor Lively testified that software Engineers locate software bugs by performing one or more of the following validation techniques black box testing white box testing, boundary tests, and a structured code walk-through Ex B at 50 14-52 15 Plaintiff's Retained Software Experts have performed none of these scientific techniques to reach there purported opinions *Id.*

The sixth factor (non-judicial uses which have been made of the theory) also weighs against admissibility Plaintiff's Retained Software Experts formulated their opinion after being retained by the Plaintiff in this lawsuit. Plaintiff's Retained Software Experts have not published their alleged findings in any scientific journal or article and have not used their opinions for any non-judicial purpose Accordingly this factor also weighs against the admissibility of their purported opinion

The Texas Supreme Court has held that competent expert testimony (including **the identity of a specific defect** and **objective proof**) that a defect caused the injury in question is required in products liability cases *Nissan Motor Co Ltd. v Armstrong* 145 S W 3d 131 137 (Tex 2004) *Ford Motor Co v Ridgway*, 135 S W 3d at 598 601 (Tex 2004) In this case none of Plaintiff's Retained Software Experts have been able to identify a specific defect that would cause an Ami monitor to fail to alarm for a loose lead condition as alleged by Plaintiff Moreover, Plaintiff's Retained Software Experts have no objective proof that a software defect does in fact exist Accordingly all of the opinions of Plaintiff's Retained Software Experts must

be excluded as subjective belief or speculation because none of their opinions are grounded in any type of scientific method or procedure *Volkswagen of Am. Inc* 159 S W 2d at 904, *Gammill* 972 S W 2d at 726 27 *Robinson*, 923 S W 2d at 557

IV

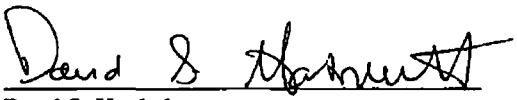
CONCLUSION & PRAYER

After several months of testing and spending hundreds of thousands of dollars testing Ami apnea monitors for an alleged defect, all of the experts in this case agree on one thing—none of them can reproduce verify confirm, or identify a defect that would cause an Ami apnea monitor to fail to alarm for a loose lead condition as reported by the Plaintiff in this case Moreover none of the experts can rule out an erroneous report by the Plaintiff (i e , the monitor was alarming when Plaintiff says it was not) In fact the Ami Plus has an internal microphone that confirms that an audible alarm sounds as appropriate In this case the download from the Ami monitor confirms that the microphone heard the audible alarm sounding at all times relevant to this lawsuit

With respect to th.s motion, Plaintiff's Retained Software Defect Experts admit that they have no objective scientifically valid evidence that an alleged defect exists as is required by Texas law Plaintiff's Retained Software Experts have provided nothing that Nellcor can test, verify validate, or even look at to confirm that a software defect does in fact exist in this case Therefore Nellcor respectfully requests that the Court grant this Motion and prohibit Plaintiff's Retained Software Experts from testifying that an alleged software defect exists or caused the Ami apnea monitor to fail to alarm as is alleged in this case

Respectfully Submitted

SHOOK, HARDY & BACON L L P



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CERTIFICATE OF SERVICE

I the undersigned attorney, hereby certify that I served a copy of the foregoing document to the attorney/parties listed below on this the 23rd day of January, 2008, via Certified Mail/Return Receipt Requested

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SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

SOFTWARECPR® AMI AND AMI PLUS TECHNICAL ASSESSMENT REPORT

September 12, 2007

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SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY LLC

Introduction

Purpose

This report documents the results of an assessment focusing on the Ami and Ami Plus Infant Central Apnea/Heart Rate monitor The focus of the assessment was to determine if Nellcor/MKG acted reasonably in the design and development of the Ami and Ami Plus monitors In addition, SoftwareCPR® was retained to perform and independent analysis to determine whether there is a reasonable basis to conclude that a software bug caused the "Lapse Lead" audio alarm to fail to function between the hours of 12 04 AM to 02 13 AM on October 13 2005 in the Ami Plus monitor (SN 30200355)

Sponsor

SoftwareCPR® was retained by Boyd Hoekel and David S. Hartnett of Shook, Hardy & Bacon LLP Houston TX.

Approach

SoftwareCPR® reviewed Nellcor/MKG Ami and Ami Plus design history documentation including

- ☐ requirements
- ☐ specifications
- ☐ risk/hazard analysis,
- ☐ traceability matrices
- ☐ software source code
- ☐ verification & validation procedures and results,
- ☐ Engineering Change Notices/Orders
- ☐ MDRs
- ☐ Regulatory submission documentation including analysis of the need to resubmit for changes.

In addition, SoftwareCPR® performed testing on an Ami Plus monitor to independently assess software behaviors under various stress conditions

This assessment focused on key elements that are likely to be important to whether a software bug may have contributed to the alleged event

Performed by

Alan Kusmitz and Brian Pate of SoftwareCPR® performed this assessment

Alan Kusmitz is Founder of SoftwareCPR® He was co-chair with an FDA representative for development of the Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report *Medical Device Risk Software Risk Management* and on the executive board and working group for development of AAMI SW68 *Medical Device Software – Software life cycle processes* He has provided internal training at FDA and Health Canada on Software Validation and Software Risk Management. He is a Lead Instructor for public AAMI/FDA Software Courses and instructor for AAMI Quality System Regulation and Design Control courses He is a frequent national and international speaker on Medical Device Compliance and Risk Management. Further information can be found in his CV included as Attachment 1

Brian Pate of SoftwareCPR® has over twenty years of experience in the design and development of real time, embedded software systems for medical devices He has worked for several major medical device manufacturers including Johnson & Johnson, Baxter Healthcare and GE Medical Systems In these positions he was personally involved in the development of ten different medical devices containing software He was a member of the Association for the Advancement of Medical Instrumentation (AAMI) working group that developed the Technical Information Report *Medical Device Risk Software Risk Management* Further information can be found in his CV included as Attachment 2

Current CVs are attached as exhibits to this report for further information and also posted in the credentials section of www.softwarecpr.com.

Prepared by

This report was prepared by Alan Kusmitz and Brian Pate of SoftwareCPR®

Scope

The assessment was limited to a review of the Ami and Ami Plus design documentation released in the 1995 to 2000 timeframe The assessment does not address changes to the design following December 2000 with the following exceptions

- ☐ Software source code changes for versions 11 11 11 12, 12 00 13 00 14 00 and 15 00 were examined.
- ☐ Special testing was performed on an Ami Plus monitor with version 13 00 software

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Documents/ Materials Reviewed

The following documents were reviewed. SoftwareCPR® reserves the right to modify or amend the conclusions of this report if additional design history materials are made available in the future or if additional testing is performed.

1) Model 9700 Heart Rate/Respiration Monitor Hazard Analysis (001465)
2) Model 9700 Heart Rate/Respiration Monitor Requirements Traceability Matrix (001065)
3) Model 9700 Heart Rate/Respiration Monitor System Requirements Specification (000677)
4) Model 9700 Heart Rate/Respiration Monitor Hardware Requirements Specification (001513)
5) Model 9700 Heart Rate/Respiration Monitor Failure Modes and Effects Analysis (001513)
6) AMI 9700 Software Requirements Specification (001047)
7) AMI 9700 Software Design Specifications (001096)
8) AMI 9700 Software Hazard Analysis (001084)
9) Model 9700 Heart Rate/Respiration Monitor Pilot Build Design Verification Report (000857)
10) Model 9700 Module Verification Test Plans and Test Reports RESP_TIC (001305) LEDALARM (001298), HR_PROC (001292) HB_TICK (001286), GOTAQRS1 (001280) BATT_PRO (001271) HR_COMPU (001265) BPM (001259) ECG_INIT (001252) Z0_PROC (001246) WUN_VLOW (001241), WUN_OPEN (001235), WUN_LL (001229) WUN_HRLA (001223) WUN_HRHA (001218), WUN_HIGH (001212) WUN_APCA (001207)
11) Model 9700 ECG1 Integration Verification Test Plan (001312)
12) Model 9700 ECG2 Integration Verification Test Plan (001320)
13) Model 9700 RESP Integration Verification Test Plan (001328)
14) Software Review Reports (000998 through 001008)
15) Software Audit Verification and Results (001009)
16) Electrical Design Review Report (000808)
17) Industrial and Mechanical Design Review Report (000816)
18) Ami 510(k) Submission
19) Regulatory Documentation for the Ami Plus Infant Central Apnea/Heart Rate Monitor
20) Software Quality Assurance Plan (Y-09-007676-002A)
21) Ami Plus Software Hazard Analysis (Y 02-007676-03A)
22) Ami Plus Summary Software Verification Test Plan (Y-09 007676-00A)
23) Ami Plus Summary Software Verification Test Report (Y-09-007676-01A)
24) Ami Plus Software Design Verification Test Plan (Y 10-007676-00A)
25) Ami Plus Software Design Verification Test Report (Y 10-007676-01A)
26) Ami Plus Software Development Plan (Y-02-007676-01A)
27) Source code Versions 11 11 11 12 13 00 14 00 and 15 00
28) Monitor log file SMITHKORTNEY 20051015 cas
29) CAS Technical report 2126 for Serial # 30200355 dated 8/20/04
30) CAS QA Final Test and Inspection Ami 9700 Series Monitors for Serial # Y30200355 dated 8/20/04
31) J& B Ami/Ami Plus bench test report for serial # Y30200355(R) 7/7/06

Summary of Opinions

SoftwareCPR® performed a variety of reviews and testing related to the Arm and Arm Plus The remainder of this report provides facts and analysis followed by more detailed SoftwareCPR® opinions As a summary

- The comprehensiveness, clarity and level of detail of the requirements and design specifications as well as the structure and relationship between requirements and design documents appeared adequate for software development, software test design, and FDA submission purposes
- The software was well structured. Use of assembly language can be appropriate for a small embedded system such as this Assembly language can, and has been used, to develop safe and effective software for many medical devices.
- The safety architecture and risk management is impressive due to its inclusion of a variety of strong risk control measures for both direct and indirect causes with high levels of independence and cross checking at the hardware, software, and system level
- Nellcor/MKG testing appears to adequately address system requirements and risk control measures White box testing at the unit and integration level for critical modules to augment structured walkthroughs and black box testing is a reasonable practice.
- Clearance of the 510(k) by FDA is clear indication of the adequacy of the submission unless the submission was inaccurate or misleading Our review of the 510(k) and other development and V&V documentation did not uncover any evidence of inaccurate or misleading information.
- The design control documentation/design history file for the Arm Plus through Version 11 11 appears to be properly updated to reflect the changes made. The changes do not appear to affect the system, software or safety architecture and are mainly to the user interface and external monitor interfaces The functional and design specifications for these changes indicate that the changes were minor in scope. There is evidence of specific testing of the changes made as well as regression testing.
- Nellcor/MKG properly applied the FDA guidance in their decision to not submit a 510(k) for Arm Plus.
- The fact that the monitor in question passed CAS J&B and device self tests before and after the alleged incident indicates that it is unlikely that there was a hardware component failure and added to the body of evidence that the software alarm handling logic functioned properly
- Independent SoftwareCPR® simulation and testing did not uncover any evidence of a software defect and this together with review of the safety architecture risk control measures, Nellcor/MKG testing and other items mentioned above lead us to our opinion that the existence of a latent software defect that would cause the alleged event is unlikely
- Given the safety architecture and multiple independent risk control measures and no evidence of an overriding software defect failure of the alarm to occur would require multiple simultaneous points of failure. This together with the fact that our additional independent testing to simulate the event did not uncover a software defect lead us to conclude that there is no reasonable objective evidence to conclude the alarm did not occur

Assessment Detail

Ami Release

Design Inputs

Analysis

1) Requirements were developed at the system level for hardware and software
2) Design Specifications contain very detailed description of software

SoftwareCPR® Opinion

- The comprehensiveness, clarity and level of detail of the requirements and design specifications as well as the structure and relationship between requirements and design documents appeared adequate for software development, test design, and FDA compliance purposes

Design and Code Reviews

Analysis

1) Just over 300 source code files organized into 12 descriptive folders
2) Critical software modules were designated for detailed code walkthroughs
3) Electrical, Industrial, and Mechanical design reviews were planned, conducted and outputs from the review were instituted.
4) Major project reviews were conducted at versions 6 7 and 8 with changes folded into version 9
5) Structured walkthroughs were performed for code and included an independent reviewer
6) Module and file naming mapped to functionality and variable names were unique and meaningful relative to the functionality
7) The software was written in assembly language.

SoftwareCPR® Opinion

- The software was well structured Use of assembly language can be appropriate for a small embedded system such as this Assembly language can, and has been used, to develop safe and effective software for many medical devices
- Use of structured code walkthroughs is an effective verification method for assembly language to augment various forms of dynamic testing
- Requiring participation of an independent reviewer in code walkthroughs adds a level of rigor to this process

Safety Architecture / Risk Management

Analysis

1) The System Hazard Analysis analyzes a large number of failure modes using a Fault Tree Analysis methodology including several causal paths for the field issue in questions For example on page 5 the clinical effect is 'No alarm during alarm condition This result lists numerous causes each of which are analyzed and decomposed to mitigations
2) The circuit has independent hardware alarm channels from processor to each claxon (Alarm 1 and Alarm 2) Signals are active low thus inadvertent grounding of signal would result in activating the alarm. Alarm claxons are physically located on separate sides of the instrument and one is facing the front while the other faces the rear adding another form of independence.
3) A microphone monitors when alarm is active to verify sound pressure output The microphone also monitors when alarm is not active to verify there is no unintentional sound pressure output
4) In software, each alarm is controlled by an independent bit addressable port eliminating the possibility that an unintentional write would disable both alarms. (Software Design Specification [Y-02-007676 00A] Section 5 2.5 Source Code file \INC\PORTDEFS.INC)
5) Alarm audio alarm LEDs and alarm logging are handled separately once Loose Lead is detected.
6) Ami/Ami Plus software is written in assembly language There are no third

party libraries linked so the Ami development team was in control of the lifecycle for all software.

7) There is an independent time base check in the software using the real time clock IC. (Software Design Specification [Y 02-007676-00A] Section 6 1 4 7 Source Code file: \INT\RTC_INT.ASM)
8) Watchdog is pulsed from idle loop rather then dependent on any complex interrupt trigger (Software Design Specification [Y-02-007676-00A] Section 5 1 13 Source Code file \INT\RTC_INT.ASM)
9) The software is designed with a chronological log file collection of events and log file functionality was tested as part of V&V activities
10) The design avoids complex multitasking only implementing one background and one foreground process.
11) The hazard analysis addresses risk control measures for predictable potential causes for specific hazards and for potential failures that result in unpredictable behavior

SoftwareCPR® Opinion

- The safety architecture and risk management is impressive due to its inclusion of a variety of strong risk control measures for both direct and indirect causes with high levels of independence and cross checking at the hardware software, and system level

Testing

Analysis

1) System level verification test is detailed and maps to the system requirements
2) Clear test plan for critical software modules
3) Testing included white box and black box testing including boundary testing.
4) The traceability matrix indicates that all requirements were tested
5) All risk control measures were included in the requirements and tested.

SoftwareCPR® Opinion

- Testing appears to adequately address system requirements and risk control measures
- White box testing at the unit and integration level for critical modules to augment structured walkthroughs and black box testing is a reasonable practice.

510(k) Submission

Analysis

1) The 510(k) was submitted to and cleared by FDA, for the original AMI release to the field.
2) The 510(k) submission included extensive documentation of the software and its verification and validation as well as other general elements required in 510(k) submissions.
3) 510(k) submissions provide FDA information to allow FDA reviewers to determine substantial equivalence to previously marketed devices.
4) Upon submission of a 510(k) FDA can reject the submission (Refuse to File) if the submission does not include the elements required by regulation or if not provided in an appropriate form.
5) FDA reviewers can ask questions and request any additional information they believe is needed to make their decision.

SoftwareCPR® Opinion

- The 510(k) submission contained extensive software information and other required elements generally acceptable in 510(k) submissions and in some areas more detailed and comprehensive than may have been required.
- Clearance of the 510(k) by FDA is clear indication of the adequacy of the submission unless the submission was inaccurate or misleading Our review of the 510(k) and other development and V&V documentation did not uncover any evidence of inaccurate or misleading information.

Ami Plus Release

Documentation

Analysis

1) SoftwareCPR® reviewed all ECNs from 1/98 to 12/00 to understand changes and design artifacts created to release the changes Identified the following design control documents supporting release Customer Requirements Specification (Y-01 102555 00A) Software Development Plan (Y 02 007676 01A) Software Quality Assurance Plan (Y-09-007676 02A) Summary Software Verification Test Plan (Y-09-007676-00A) Software Config Mgmt Plan (Y-02-007676-02A) System Requirements Specification (Y 24 006385 00A) Hardware Requirements Specification (Y 24 006414-00A) Hardware Design Spec (Y 02-006413 00A) Software Design Spec (Y 02-007676-00A), Software Reqmts Spec (Y-02-007675-00A) Hardware Risk Analysis (Y 05-101970 01A) Software Risk Analysis (Y-05-007676-03A) Ami Software Risk Analysis (Y 05 007676-00A) NEC 78K Series Programming (Y-02-007676-04A) Hardware DVT Plan (Y 10-100374-00B), Software DVT Plan (Y 10-007676-00A) Traceability Matrix (Y 39 006122-00A) User Manual (Y 14-006432 00A), Clinician Manual (Y 14 006434-00A), Inspection Process (Y 11-006124-XXX) Schematic CKT ASSY Main, 9700 (Y 31 006118 XXX) Test Spec Model Ami Final Test (L-00-007817-000), Ami Test Station Cal Process (L-13-007893 000) Test Station Design Spec, Ami Monitor (L-00-007893-000) Test File, Ami Plus Final Test (Y 28 102611 00A) Model 9700 Monitor ATE Test Sys Val (Y 26-102613 00A), Ami Test Station Cal. Process (L-12-007893-00A)
2) The DHF inventory indicates that a technical design review report was issued on May 23 2000

SoftwareCPR® Opinion

- The design control documentation/ design history file appears to be properly updated to reflect the changes made.
- The changes do not appear to affect the system, software, or safety architecture and are mainly to the user interface and external monitor interfaces The functional and design specifications for these changes indicate that the changes were minor in scope.

Testing

Analysis

1) The Software Design Verification Test Plan (Y 10-007676-00A) states that the purpose of the testing is to "verify that these software modifications have been correctly implemented and to verify that software routines related and unrelated, have not been compromised
2) Section 4 17 states that the 'factory-automated test will be run on each test unit to verify that the software changes have not affected normal functionality" This is accomplished using the Model 9700 Final Test and Inspection Process (Y 20 006122-00A)

SoftwareCPR® Opinion

- There is evidence of specific testing of the changes made as well as regression testing of core functionality using production software in the Ami and Ami Plus monitors

Documentation Related to Decision to Not File new 510(k)	Analysis 1) SoftwareCPR® reviewed the document titled "Regulatory Documentation for the Ami Plus Infant Central Apnea/Heart Rate Monitor' dated 5/22/2000 2) SoftwareCPR® reviewed all ECNs from 1998 until release of Ami Plus 3) SoftwareCPR® reviewed verification and validation results for Ami Plus. 4) FDA does not require new 510(k) submissions for all device changes 5) FDA requires new 510(k) submissions for changes that impact safety and effectiveness and provides a guidance to assist manufacturers in determining what changes warrant a new 510(k) 6) Nellcor/MKG used the FDA guidance in performing their analysis as demonstrated in the document listed above. 7) FDA guidance documents are not regulatory requirements and are subject to interpretation and alternative methods to meeting the underlying regulatory requirement. SoftwareCPR® Opinion ➢ Nellcor/MKG properly applied the FDA guidance in their decision to not submit a 510(k) ➢ Our review of the individual ECNs did not uncover any changes likely to impact the safety and effectiveness of the device or its intended use or claims ➢ The results of design verification and validation activities do not appear to raise new issues of safety and effectiveness.

MDR Review

Review of Records Analysis

1) We were provided forty MDRs and the service report associated with each event from 1998 through 2000 time period to review Our understanding is that these forty represent all the MDRs from the period of 1998 to 2000 and that all of these MDRs are associated with the Ami monitor Our understanding is that there were no MDRs in the period of 1998 to 2000 for the Ami Plus monitor
2) Twenty seven of the forty events were investigated and tied to a root-cause of hardware, accessory misuse/damage or testing. Of the four assigned the problem trend code, 9057 (No Loose Lead Alarm) a clear root-cause was identified and corrected.
3) Thirteen of the forty MDRs reported problems but after investigation could not be duplicated. In many cases, the accessories in use at the time of the reported incident were not returned for investigation.
4) At the time of this assessment, the monitor downloads (log files) were not available for review
5) According to the Nellcor/MKG Access database, there were approximately 4500 Ami and Ami Plus monitors in field as of late 2000

SoftwareCPR® Opinion

- The information contained in the files did not identify any additional information that would lead us to add or revise the design of the independent test protocol
- The thirteen events that could not be duplicated do not have a clear root-cause established and therefore there is always the possibility that software could be the cause. However there are many possible explanations for these MDRs besides a software defect, including, but not limited to
  - problems with electrodes or cables
  - use of unapproved accessories
  - misuse
  - obstructive apnea
  - monitor picking up maternal breathing
  - short duration event and audible alarm not heard
  - misinterpretation of events by user
  - unqualified test technician (at distributor)
- Given the range of possible reasons for "could not duplicate' types of MDRs these thirteen MDRs out of 4500 home use apnea monitors do not provide any clues to a software defect with Loose Lead alarm handling and does not indicate a clear trend.

Review of Event Log and related information for field issue in question

Event Log	Analysis 1) There were long periods of Loose Lead alarms prior to the period of time where two Loose Lead alarms are alleged to have not worked It is our understanding that there are approximately 71 hours leading up to the event where proper alarm handling is not disputed. 2) According to the log, two very long periods of Loose Lead occur a) 33 minutes and 45 seconds period of Loose Lead at 12 04 AM on 10/13/05 and b) 95 minutes and 12 seconds of Loose Lead at 12 38 AM on 10/13/05 3) Again, our understanding from the depositions in the case is that during these two periods of Loose Lead alarm it is alleged that No audible alarm occurred "Loose Lead" LED did not illuminate 4) The log file from the device indicates that the loose lead alarm was triggered and that no A1 or A2 failures were detected. 5) The monitor was powered off at the exact second (2 13 40 AM) that the second period of Loose Lead alarm ended. SoftwareCPR® Opinion ➢ We have a high degree of confidence that the log file is accurate based on the original verification and validation testing, the alarms that appear to have occurred in the 71 hours leading up to the event and our independent testing of the loose lead alarm and log file functionality
Test records for monitor in question	Analysis 1) The Ami Plus monitor in question was tested at CAS prior to shipment on 8/20/04 The two CAS tests performed prior to shipment to J&B (Technical report 2126 and QA Final Test and Inspection Ami 9700 Series monitors for Serial # Y30200355 dated 8/20/04) verified both human and equipment alarms including a simulation of a loose lead condition. The monitor generated the audible and visual loose lead alarm. 2) Self-tests were analyzed from download files from the monitor in question. The download files contain no "A1 or A2 codes which are intended to indicate a failure of alarm 1 alarm 2, and/or the microphone. 3) J& B performed a bench test on the returned device involved in the alleged incident on 7/7/06 (Ami/Ami Plus bench test report for serial # Y30200355(R)) that verified both human and equipment alarms including a simulation of a loose lead condition The monitor generated the audible and visual loose lead alarm SoftwareCPR® Opinion ➢ Based on the reported results of this testing it is unlikely that a hardware component failure was related to the alleged incident In addition, the results of these tests further increase our confidence that the software loose lead alarm handling logic functioned properly

Special Testing performed by SoftwareCPR®

Reproduction of "Monitor State"

Analysis

1) SoftwareCPR® created five test cases in an attempt to reproduce the events preceding the alleged event. Over 73 hours of testing was conducted, with patient events (Tachycardia, Bradycardia Apnea) and equipment events (Loose Lead) simulated to mimic as closely as possible the "state" of the monitor in question on October 13 2005 The audible alarm annunciation was verified to occur for all 248 events simulated (159 Loose Lead events, 37 Tachycardia events, 45 Bradycardia events, and 7 Apnea events).
2) Two test cases were created to stress the software handling of Loose Lead events by crossing boundaries with Loose Lead measurement and memory allocation for events In all cases, the audible alarm annunciation was verified to occur
3) One test case was created to check for proper operation of risk control measures associated with detection of alarm annunciator failures and microphone failures In each case the monitor responded as specified with proper risk control measures
4) SoftwareCPR® independently executed these test cases on the version of software in question and no software defect was uncovered as a result of this testing.

SoftwareCPR® s independently developed Special Test Protocol for the Arm Plus Monitor containing the test cases mentioned above, the test results, and log file from the testing are provided as Attachment 3 to this report

SoftwareCPR® Opinion

- This testing is a significant simulation of the conditions present during the time period of the alleged event and is a significant challenge regarding proper software operation
- The results of this testing are a significant factor that contributes to our increased confidence that no latent software defect exists related to the loose lead alarm handling.

SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY LLC

DHEC PATIENT CARE FORM

TRIP NO 2816

PATIENT IDENTIFICATION | **DISPOSITION** | **TYPE OF INCIDENT** | **CALL TYPE** | **PATIENT STATUS**

LAST NAME: Graves | FIRST NAME: India | MI: ST

STREET: 1465 Spangle Valley Dr | APT #:

CITY: Orangeburg | STATE: SC | ZIP CODE: 29115

TYPE OF INCIDENT: TRAUMA (112) | MEDICAL (119)

CALL TYPE: TO SCENE (114) — 1 EMERGENT, 2 NON-EMERGENT | ON SCENE (115) — 1 URGENT, 2 NON URGENT | FROM SCENE (116) — 1 URGENT, 2 NON URGENT

CODE: 3

INCIDENT LOCATION

NAME OR NO: 1465 Spangle Valley Dr

CITY: Orangeburg SC

County (117 118): 38 | Zip Code (119-123):

SEX (104) | RACE (105) | AGE (106-108)

SEX: 2 Female

RACE: 3 Black

AGE: 13 — CHECK ONE: 12/ 1-85 MOS DA / 3 DAYS

SAFETY EQP (124) | **SITE OF INCIDENT (125)**

SAFETY EQP: 1 Seat Belt | 2 Helmets | 3 Child Seat | 5 Air Bag

SITE OF INCIDENT: 1 ROADWAY | 2 RESIDENCE | 3 RECREATIONAL | 4 AGRICULTURAL | 5 INDUSTRIAL | 6 OTHER

PRELIMINARY IMPRESSIONS (MARK NO MORE THAN 4) (126-137)

004 Diabetic | 011 Abnormal/Cardiac Conditions | 013 Laceration | 023 Fracture | 024 Multi-trauma/Shock | 030 Head Injury | 032 Spinal Injury | 034 Stroke | 051 G.I. Problems | 054 Respiratory Distress | 060 Cardiac Problem | 063 Cardiac Arrest | Other | Other

PRIMARY IMPRESSION (138-140)

TREATMENT PROCEDURES (141-174)

01 Dressing Applied | 02 Limb Splinted | 03 Spine Immobilized | 04 Neck Immobilized | 05 OB Assistance | 06 Oral Airway Used | 07 Oxygen Given | 08 Suction Used | 09 Antishock Trousers | 10 Arterial Tourniquet | 11 Antishock Treatment | 12 Artificial Resp. | 13 Cardiac Massage | 14 Bleeding Controlled | 15 Cold Application | 16 Patient Restrained | 17 Other Use Comment | 18 Ventilator

MCFA CODES (175-180)

ADVANCED PROCEDURES (190-223)

DRUGS USED (226-241)

DRUG | DOSE | TIME | ROUTE

SITE OF TRAUMA (181-189)

1 Head | 2 Face | 3 Neck | 4 Chest | Abdomen | Hip/Pelvis | Upper Extr | 8 Lower Extr | 9 Back

REVISED TRAUMA SCORE

GCS: (240) EYES _____ (243) VERBAL _____ (244) MOTOR _____ (245-248) GCS/GSW _____

(247-248) SBP _____ (250-252) RR _____

RTS (254-255)

(253) ANATOMICAL INJ 1 YES 2 NO

VITAL SIGNS

BP	PULSE	RESPIRATIONS	PUPILS	LEVEL OF CONSC	TIME
0	RATE 0 REG IRREG	RATE 0 REG IRREG	D	U	0903
/	REG IRREG	REG IRREG	E U A V P		
/	REG IRREG	REG IRREG			
/	REG IRREG	REG IRREG			
/	REG IRREG	REG IRREG			

EXPOSURE TO PT's BODY FLUIDS? (258) 1 YES 2 NO

1st Responder (257) 1 YES Name: TRMC MD ORDER FOLLOW * DE 2 NO

G 0022 Graves v Richland Memorial, et al 06-CP 35-421

COMMENTS (INCLUDE CHIEF COMPLAINTS, OBSERVATIONS AT SCENE, RESPONSE TO STIMULI)

Upon Arrival Found pt outside, Appx 2 months. Pt was last seen @ appx 12:40 pm. Pt was seen @ Emergency on Thursday for cold/congestion. Pt was a 35 week product of multiple birth triplets. Pt was 1st baby. Pt was 1 lbs 6 ozs. Was to have been born Appx 1½ months & continued @ birth. Appx 2 months. Pt skin warm dry to touch wrapped in blankets, Pupils are Equal & dilated eyes are closed in appearance. Pt has cyanosis to hands/feet. Even & good breath sounds. EKG shows Asystole in all 3 leads. Resuscitative efforts discussed & Family TRMC contacted to DC efforts @ Signs of trauma @ pt at this time. Pt was on Apnea monitor @ time of Alarm showing lower heart rate @ Alarm. Mother states baby was on her back when discovered. Then

Patient Care Form Letter (256) 1 ED 2 ICU 3 OTHER Pt to Peds DC care made Thursday. See Page 2

TIME RECORD

RUN DATE (259-266): MONTH 04 DAY 27 YEAR 04

Call Received (267-270)	0346
Unit Dispatched (271-274)	0346
Unit En Route (275-278)	0351
Arrive Scene (279-282)	0401
Depart Scene (283-286)	0407
Arrive Destination (287-290)	0409

CAUSE OF DELAY

DHEC PERMIT NO. (291-295)

RECEIVING AGENCY (296-299)

SENDING AGENCY (300-303)

PROVIDER TIME OPTIONAL

ATTENDANT'S SIGNATURE & CERTIFICATION NO.

PRIMARY ATTENDANT (304-312)

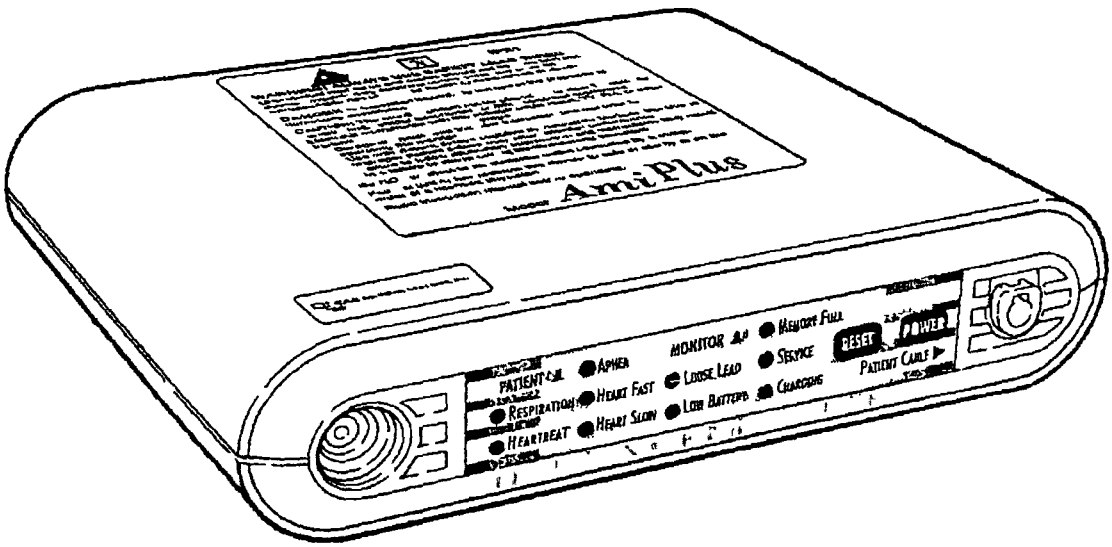
ATTENDANT/DRIVER (313-321)

ATTENDING PHYSICIAN

DHEC 1050 REV (01/200- EMS PROVIDER COPY REPORT NO (10

Ami® and Ami® Plus

Infant Central Apnea/Heart Rate Monitors



SAMPLE

ASHBY MEDICAL
123 Centrum Drive Suite 1
IRMO SC 29063
(803) 781 5302 (800) 229 7561

SAMPLE

Caregiver s Manual
21 02 0117 Rev 03 06/02

CAS MEDICAL SYSTEMS INC
TECHNOLOGY APPLIED TO MEDICINE

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Section 1

Warnings

Warnings

The following warnings appear throughout this manual. For more information on a specific warning, see the section referenced in the warning.

WARNING
The monitor may not be able to detect all episodes of inadequate breathing. Refer to Section 3.

WARNING
Caregivers must closely watch patients who are subject to obstructive apnea. Refer to Section 3.

WARNING
Federal Law restricts this device to sale or use by or on the order of a licensed physician. Refer to Section 3.

WARNING
Not to be used in an explosive atmosphere. Refer to Section 3.

WARNING
The monitor may sometimes detect false breathing signals called artifacts. Refer to Section 3.

WARNING
Children at risk of seizures need to be closely watched to protect them from obstructive apnea during a seizure. Ask your physician for specific instructions on what to do if your child has a seizure. Refer to Section 3.

WARNING
The *Ami* and *Ami Plus* monitors may be affected by electromagnetic interference from household appliances for example static from a television set This interference may keep the monitor from working properly Refer to Section 4

WARNING
If at any point the monitor alarm is not loud enough to get your attention do not leave your child unattended Refer to Section 7

WARNING
All directions in the *Connecting The Monitor* section must be followed carefully Refer to Section 8

WARNING
To reduce the risk of strangulation do not leave loose or unconnected wires in the infant s crib Make sure that wires are routed away from the child s head Refer to Section 8

WARNING
During an equipment alarm (except Low Battery Caution) the monitor cannot sound any human alarms because of the equipment problem Therefore during an equipment alarm (except Low Battery Caution) someone must watch the patient until the equipment problem has been corrected Refer to Section 8

WARNING
If the monitor s modem is in use the monitor must be disconnected from the phone lines before you can use the phone Refer to Section 9

WARNING
When the monitor is not working someone must watch the child at all times Refer to Section 10

WARNING
If detergent is not fully rinsed out of the electrode belt the patient may get a skin rash Refer to Section 13

Section 2

Introduction

ntroduction

This book explains what apnea is and how the *4mi* and *4mi Plus* monitors detect it It also explains how to setup the monitor respond to monitor alarms and care for the monitor

It is important that you read and understand all of the information in this book It is important that you also share this information with anyone who will care for your child

This book

- Explains what apnea is and how the monitor detects it
- Describes the monitor and its features
- Shows how to connect the monitor to your child
- Discusses how to respond to monitor alarms
- Explains how to care for the monitor and what to do if you have a problem with the monitor

If you have questions or problems with the monitor that are not answered in this book ask your doctor or homecare dealer for help

Follow directions given to you by your doctor or homecare dealer

In this manual the following conventions are used

WARNING
Directions that warn of conditions that put the baby or caregiver at risk

CAUTION
Directions that help you avoid damaging your monitor or losing data

Note Directions that make it easier to use your monitor

Section 3

Apnea Monitoring

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Apnea Monitoring

Apnea is a medical term meaning a time when a person stops breathing Central apnea occurs when a person does not make an effort to breath Your doctor has prescribed this monitor to help protect your child from the dangers of an apnea event All babies experience short harmless periods of apnea Some babies especially premature ones have longer periods that can be harmful

Your doctor has probably spoken to you about the monitor and how it may help your child The monitor when used according to its directions is intended to alert you when your child experiences central apnea It is very important that you immediately respond to all of the monitor s alarms

Everyone caring for the child must know how to respond to the monitor s alarms

Everyone caring for the child must know CPR (Cardiopulmonary Resuscitation) for infants If you have not received CPR training ask your doctor or homecare dealer about how to get certified training

The *Ami* and *Ami Plus* monitors are intended to detect central apnea through a process called impedance monitoring As your child s chest expands and contracts during breathing the chest s movement causes a change in the signal between the electrodes which the monitor senses When central apnea happens the child stops breathing and the chest does not expand or contract When the monitor detects that the chest is not moving the alarm sounds The monitor does not interfere with your child s breathing

WARNING
The monitor may not be able to detect all episodes of inadequate breathing

The *Ami* and *Ami Plus* monitors also detect your child s heart rate with the same electrodes used to detect breathing A heart rate alarm will sound when the heart rate is outside the set alarm limits A heart rate alarm may sound when inadequate breathing occurs

WARNING
Caregivers must closely watch patients who are subject to obstructive apnea

Obstructive apnea is when the child tries to breathe but the air does not reach the lungs due to a blockage in the airway The blockage can be caused by soft tissues in the child s throat blocking the trachea or windpipe If the child has a cold tonsillitis enlarged adenoids or other respiratory

problems blockage from soft tissue can occur The *Infant* and *Infant Plus* monitors are *not* intended to detect obstructive apnea

A child s chest can still expand and contract even when the airway is blocked The Apnea alarm may not sound because it may still detect false breathing signals If this occurs a Heart Slow alarm may sound since the child s heart rate will drop Children who suffer from these respiratory problems must be watched closely to protect them from obstructive apnea

WARNING
Federal Law restricts this device to sale or use by or on the order of a licensed physician

WARNING
Not to be used in an explosive atmosphere

Do not allow any person or pets to sleep with a monitored child Movements by people or by pets may cause your child to move The monitor may interpret this movement as breathing from your child and may not alarm properly

CAUTION
Do not rely on the monitor while the child is subject to being jostled (use of baby swing car travel over rough roads etc) This type of motion may prevent any impedance monitor from properly detecting breathing or heart rate

WARNING
The monitor may sometimes detect false breathing signals called artifact

An apnea alarm may be delayed or not occur at all if the child stops breathing but the monitor detects false breathing signals If this happens a Heart Slow alarm will sound if your child s heart rate drops

WARNING
Children at risk of seizures need to be closely watched to protect them from obstructive apnea during a seizure Ask your physician for specific instructions on what to do if your child has a seizure

Section 4

Electromagnetic Interference

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Electromagnetic Interference

WARNING
The *4mi* and *4mi Plus* monitors may be affected by electromagnetic interference (EMI) from household appliances for example static from a television set This interference may keep the monitor from working properly

The monitor is an electronic device Electronic devices can be affected by electrical interference from household appliances Loose electrodes can cause electromagnetic interference Although interference is unlikely no device is completely immune The monitor was tested and conforms to industry guidelines

The monitor should not be operated near

- television sets
- citizens band and amateur radios
- microwave ovens
- paging transmitters
- radio/TV station transmitters
- emergency vehicle two way radios
- air conditioners
- radio controlled toys
- hand held transceivers (i e walkie talkies security emergency)
- Electronic Article Surveillance (EAS) (found in many stores as security devices)
- cordless or cellular telephones
- food processors
- wireless computer links communications/data transmitters
- other *Ami* or *Ami Plus* monitors (4 ft minimum separation)

Using the monitor near these appliances may cause the monitor to fail to alarm To prevent this move the appliance as far away as possible from the monitor Watch the Respiration and Heartbeat lights on the monitor Compare with baby s breathing and pulse If they do not match it may be due to electromagnetic interference Carefully watch the child and call the homecare dealer for assistance

The monitor should not share electrical outlets with any of these appliances. This may cause electrical interference with the monitor and cause the monitor to fail to alarm.

Electrostatic Discharge

Electrostatic Discharge (ESD) is the small electric shock caused by static electricity. ESD happens when you touch an object like the monitor after walking across a carpeted floor when the weather is cool and dry. Touching a wall or the crib before handling the monitored child or the *Arm* Monitor can prevent this. Whenever possible, use cotton bed sheets for the baby and a fabric softener in the laundry. The use of a spray Static Guard in carpeted floor areas can help the minimize this type of interference.

Section 5

Description of the Monitor

Description of the Monitor

The *Ann* and *Ann Plus* monitors are meant to be used in the home in a hospital or on family outings Your doctor should have told you when to use the monitor If you are unsure when to use the monitor use it all the time (except when bathing your child) but ask your doctor for more specific directions

The outlet for the patient cable is on the monitor s front panel

There are two buttons on the front panel of the monitor These buttons are marked Reset and Power

The front panel of the monitor also has warning lights and other indicators of the monitor s operating status

When lit green lights show that the monitor is properly connected and that it is detecting breathing and heartbeats

Red lights show an alarm condition or an equipment problem These red lights tell you why an alarm sounds

There are ten lights on the front of the monitor

APNEA — Red light shows that there has been an episode of central apnea

HEART FAST — Red light shows that the heart is beating faster than the set limits

HEART SLOW — Red light shows that the heart is beating slower than the set limits

LOOSE LEAD — Red light shows that a wire electrode belt or patient cable is loose or disconnected

SERVICE — Red light shows that the monitor is in need of servicing by a licensed provider

LOW BATTERY — A constant red light shows that there is not enough power to properly operate the monitor A flashing light shows that the monitor has enough battery power to operate properly for at least 60 minutes

MEMORY FULL — The monitor s memory stores information that will be used by your doctor A constant red light shows that this memory is full A flashing light shows that data has been lost Call your homecare dealer if this light comes on

RESPIRATION — Green light shows that the monitor is detecting breathing

HEARTBEAT — Green light shows that the monitor is detecting a heartbeat

CHARGING — Green light shows that power is being supplied from an AC outlet and the battery is being charged

Front Panel

Figure 5 1
Front Panel

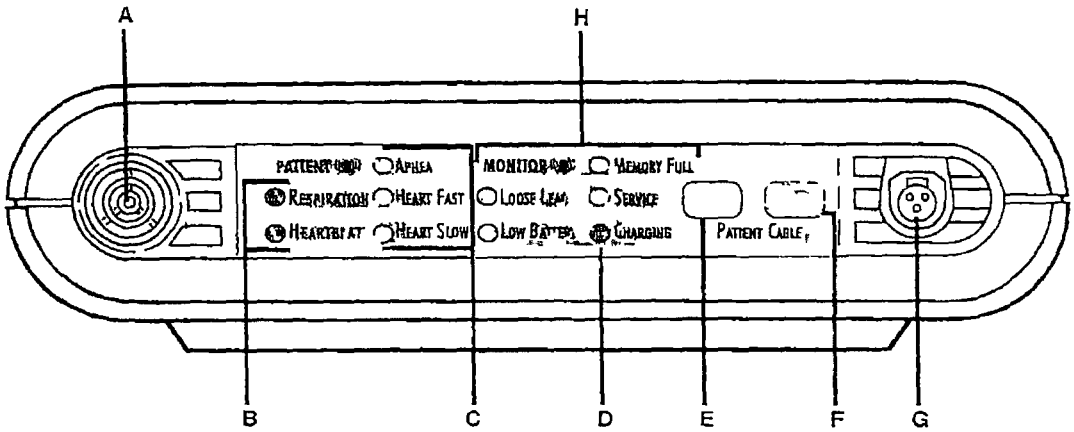


Table 5 1
Description of Front Panel

A	Audible alarm output Do not put anything in front of this opening
B	Respiration and Heartbeat lights Green lights blink once with each detected breath or heartbeat
C	Human Alarm lights Red lights come on when the monitor detects breathing effort or heart rate outside the alarm limits set by your doctor
D	Charging light The green Charging light shows that power is being supplied from an AC outlet and the battery is charging
E	RESET Button Use to turn off alarm lights after the problem is corrected Also use with the Power button to turn the monitor off
F	POWER Button Use to turn the monitor on
G	Patient Connector Use to connect the monitor to the patient cable
H	Equipment Alarm lights Indicate an equipment alarm event

Back Panel

Figure 5-2
Back Panel

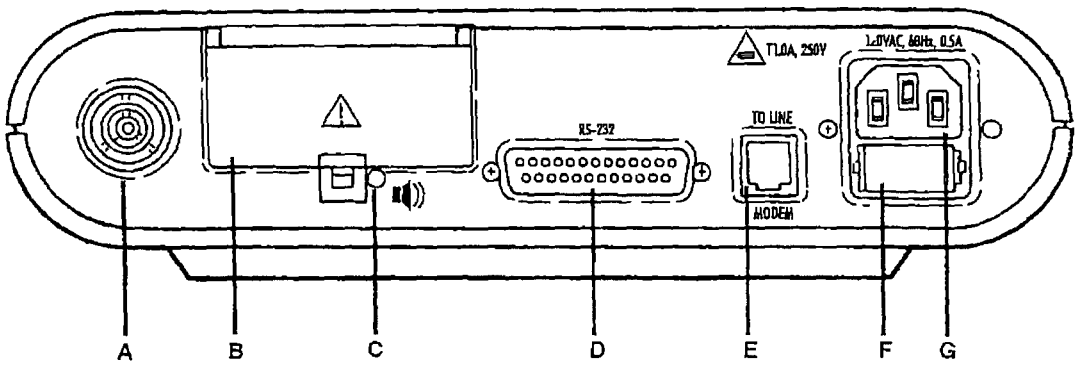


Table 5-2
Description of Back Panel

A	Audible alarm output Do not put anything in front of this opening
B	Battery compartment
C	Remote alarm output
D	Interface connector (RS 232)
E	Telephone connector
F	Fuse holder
G	Power cord connector

Bottom Panel

Figure 5-3
Bottom Panel

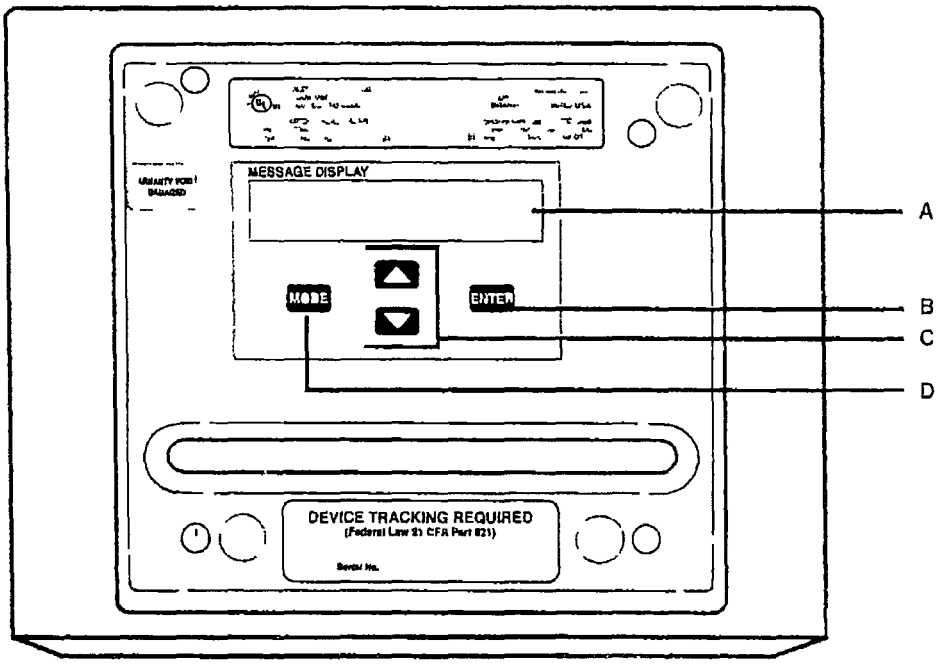


Table 5-3
Description of Bottom Panel

A	Message display
B	ENTER button
C	Up and down arrow keys
D	MODE button

The bottom panel of the monitor has a message display and control panel. The control panel has four buttons that are used by your dealer to enter information. If your dealer instructs you to use the control panel buttons, follow instructions carefully.

abels

Each monitor includes labels explaining the monitor s features and information needed to operate this device safely A sample label is shown below

Figure 5-4
Sample Label

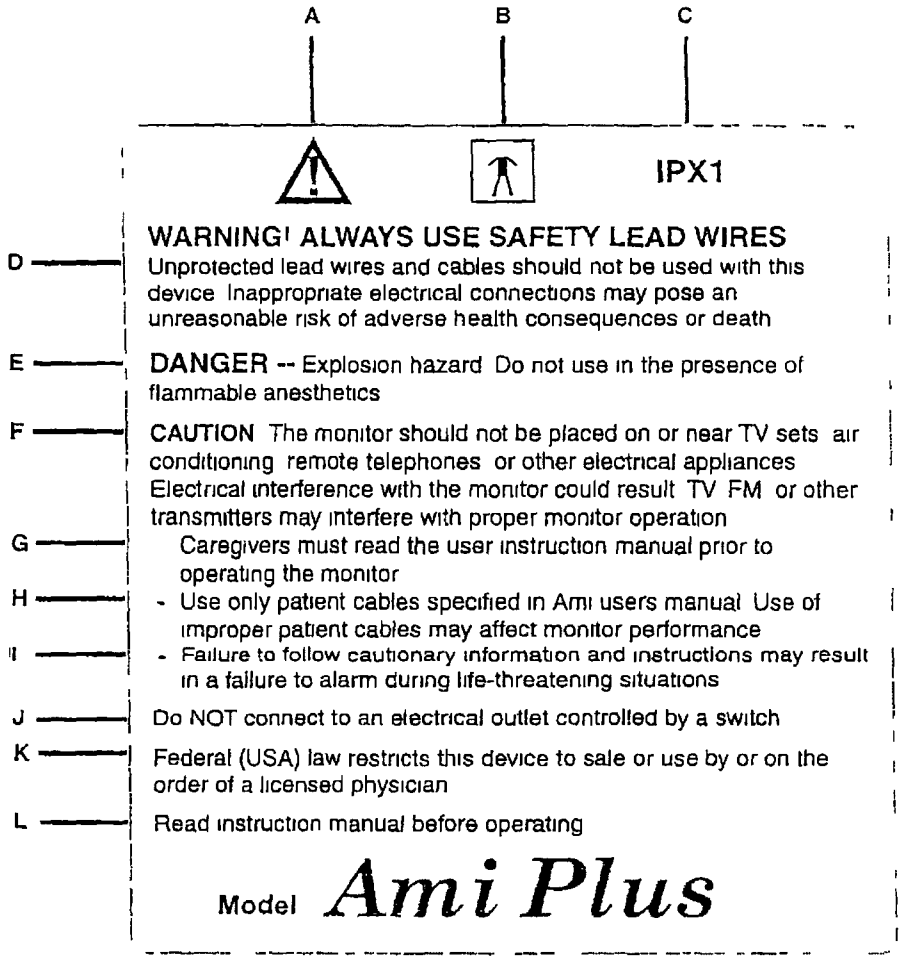


Table 5 4
Description of Label

A	Attention It is important that you read and understand all of the information in this manual along with any other documentation that came with the monitor
B	The monitor meets the IEC 601 1 standard (an international safety standard) for Type BF Equipment Type BF Equipment is constructed so the patient is protected from hazardous electrical currents
C	The monitor is enclosed in a case to protect against dripping water
D	Unprotected lead wires and cables should not be used with this device Inappropriate electrical connections may pose an unreasonable risk of adverse health consequences or death
E	Not to be used in an explosive atmosphere for example where a high amount of oxygen or flammable gas is present
F	The monitor may be subject to electrical interference if used near certain household appliances Refer to Section 4 for more information
G	The caregiver must read and understand the entire *Caregiver s Manual* before using the monitor The caregiver must share this information with anyone who will care for the child
H	Only accessories provided by your homecare dealer may be used with the monitor Using other accessories may cause the monitor to not work properly Refer to Section 6 for more information
I	The monitor may not alarm properly if cautionary information and instructions are not followed Refer to Section 10 for more information
J	Do not connect the monitor to an electrical outlet controlled by a switch
K	US Federal law restricts the sale or use of the *Ami* and *Ami Plus* monitors without a prescription from a licensed physician
L	Read the instruction manual and all documentation before operating the monitor

Section 6

Accessories

21-02-0117 Rev 03 06/02

Accessories

The accessories for the *Ami* and *Ami Plus* monitors include electrodes patient belt lead wires patient cable power cord remote alarm modem modem cable oximeter direct connect cables and a carrying case

The following accessories are needed to use the monitor

- Electrodes
- Lead Wires
- Patient Cable
- Patient Belt
- Power Cord

Carbon Electrodes

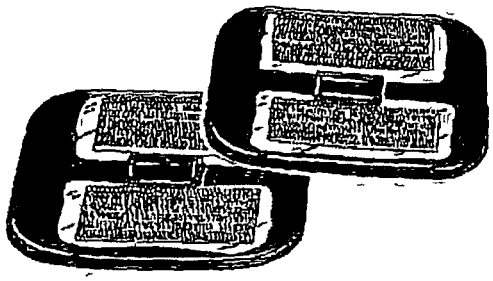
The black electrode pads pick up the breathing effort and heartbeat signals from the baby

Rinse the flat sides of the pads with water each day Do not use soap or detergent on the pads because both interfere with breath and heart beat signals

Your homecare dealer may give you other types of electrodes Your homecare dealer will instruct you in their proper application

It is important that any type of pre-gelled electrodes are used before the manufacturer s expiration date Before the electrodes are used check to see if they have become dried out or damaged during storage Dried-out or damaged electrodes may not properly detect the baby s breathing effort and heartbeat and may prevent an alarm from being detected

Figure 6-1
Carbon Electrodes

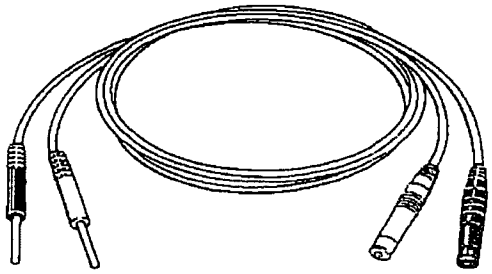


Lead Wires

The lead wires carry the breathing effort and heartbeat signals from the electrodes to the patient cable Always hold the lead wires by the plastic ends when you are connecting or disconnecting them Never pull on the lead wires cord because you can damage the wires inside the leads

New lead wires come joined together When you connect the child to the monitor pull gently to separate the leads as much as you need to

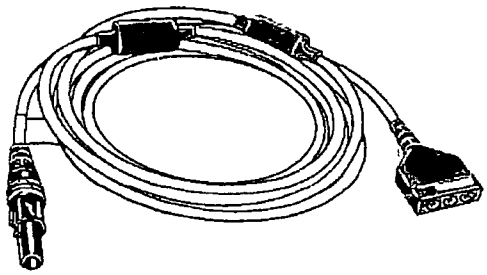
Figure 6-2
Lead Wires



Patient Cable

The patient cable carries the breathing effort and heartbeat signals from t lead wires to the monitor Hold the patient cable at the ends when you u connecting or disconnecting Never pull on the cable s cord because you may damage the wires inside

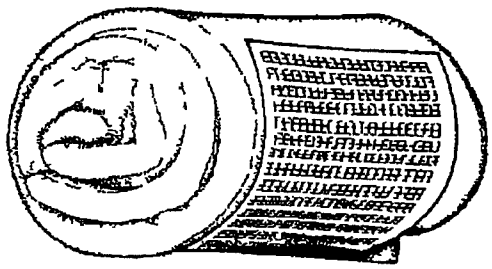
Figure 6-3
Patient Cable



Patient Belt

The belt is made of soft foam and is used to hold the electrodes to the infant s chest The belt is fastened around the infant s chest with a velc strap

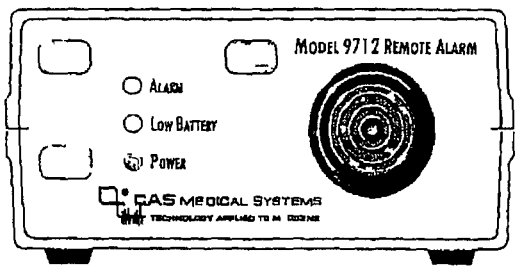
Figure 6-4
Patient Belt



Remote Alarm

The remote alarm allows monitoring up to 100 feet from your baby. The remote alarm will sound anytime the monitor alarms. The Alarm light will also come on. The alarm will sound if the monitor becomes disconnected from the remote alarm or if the monitor's Power button is pressed without pressing the Reset button first.

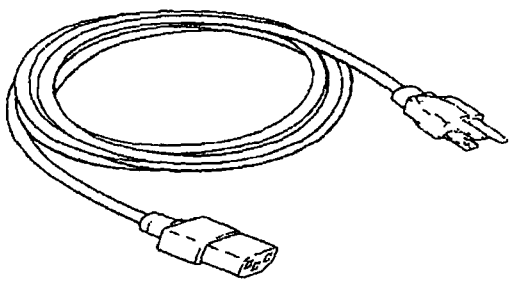
Figure 6-5
Remote Alarm



Power Cord

A standard AC power cord which connects the monitor to an electrical outlet.

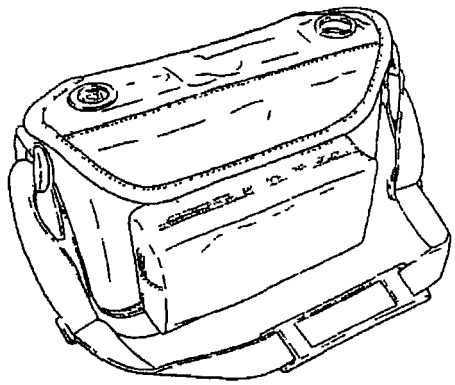
Figure 6-6
Power Cord



Carrying Case

This case holds the monitor patient cables and electrodes when you need t take the baby and monitor out of the home

Figure 6-7
Carrying Case



Modem Cable

The modem is a standard feature of the *Ami Plus* monitors It sends information from the monitor through telephone lines to a computer at another location If the monitor has a modem there will be a label reading Modem on the back of the monitor, below the modem jack The modem cable connects the monitor to a phone jack to transmit information from the monitor to an outside source

Oximeter

The oximeter is a separate device that can be used with the *Ami* or *Ami Pl* monitors to record oxygen saturation levels in the blood and pulse rate

If an oximeter is used with the monitor your homecare dealer will instru you on how to properly use the oximeter The monitor does not alarm for oxygen saturation the oximeter may alarm for low oxygen saturation

Section 7

Using the Monitor

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Using the Monitor

Plugging in the Monitor

Plug the socket end of the power cord into the power cord connector on the back of the monitor

Plug the other end of the cord into a wall outlet If the integrity of the earth ground connection is in doubt the monitor should be operated on battery power

The Charging light will only illuminate when the monitor is plugged in If the monitor is plugged in and the Charging light is not on check the connection to both the monitor and the electrical outlet If the light does not come on call your homecare dealer

Note Keep the monitor plugged in whenever possible

Figure 7-1
Connecting the Monitor to the Power Cord

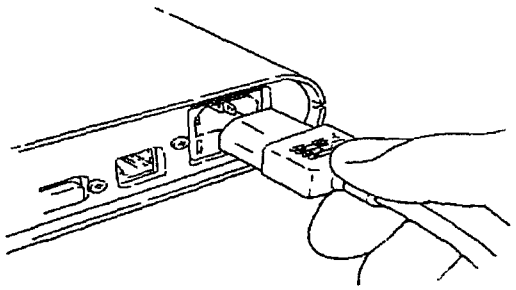
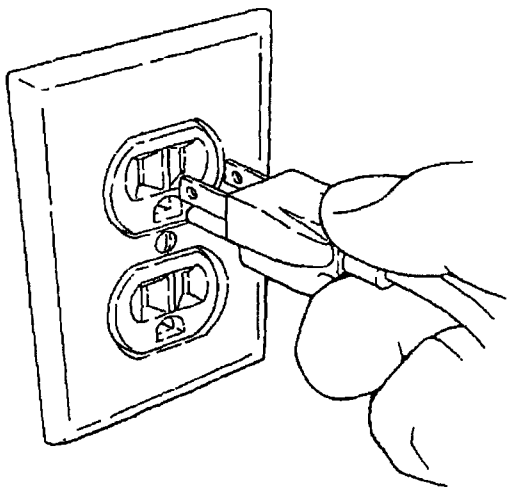


Figure 7-2
Connecting the Power Cord to the Wall Outlet



System Check

When the *Ami* or *Ami Plus* monitor is first turned on it runs through a system check to make sure the monitor is working properly

During this check the monitor s alarm will beep and all the monitor s lights except the Charging light will flash individually The Charging light will not flash during the system check.

If you do not hear the monitor s alarm beep turn the monitor off and repe it the system check If you do not hear the alarm beep call your homecare dealer for further assistance

When the system check is over look to see if an alarm light is on If so follow the instructions in Section 10 to fix the problem

Note The monitor should be turned off and on daily so that it can run through the system check. It is best to do this when the baby is awake The monitor should always be used when the baby is sleeping or according to instructions from your physician

Using the Monitor Effectively

The *Ami* and *Ami Plus* monitors are effective only if the alarms can be heard Before connecting the monitor to your child you need to test how well the alarms can be heard in every location of the home

1 Put the monitor where it will be used most

2 Plug the monitor into a wall outlet. Do not connect the monitor to the baby

3 Turn the monitor on. All lights will illuminate as the monitor runs through a system check. A Loose Lead alarm will sound

4 Go to each part of the home and see if you can hear the alarm Try to do the things you will normally do If you will be running water turn on the water If the TV will be on turn on the TV If you will be vacuuming turn on the vacuum

WARNING
If at any point during this test the monitor is not loud enough to get your attention do not leave your child unattended while you are in this room.

A remote alarm for the *Ami* and *Ami Plus* monitors is available This alarm allows you to hear the monitor alarms from farther away If you think the remote alarm is necessary one can be obtained from your homecare dealer

If you are using a remote alarm, repeat the test above using the remote alarm so it can be placed in the best position You must make sure that you can respond to an event immediately after its first alarm It is especially important to consider this when using the remote alarm

Section 8

Connecting The Monitor

Connecting The Monitor

This section will discuss how to set up the *Ami* and *Ami Plus* monitoring systems It is very important that all information in this section is read and understood

WARNING
All directions in this section must be followed carefully

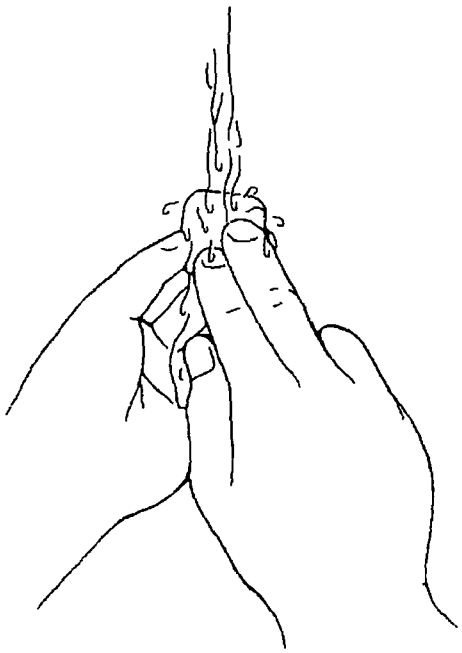
Note Use only soap and water to clean the child s skin where the electrodes will be placed The skin must be free of lotion and powders If the child s skin is not clean in this area the monitor may not operate properly

Use of electrodes may result in an allergic or chemical reaction with your child s skin If redness or skin irritation is noticed contact your home care provider

Periodic placement of the electrodes in different locations may prevent or reduce the occurrence of skin irritation

1 Rub the flat side of the electrodes under warm running water for at least one minute Dry the electrodes before using them

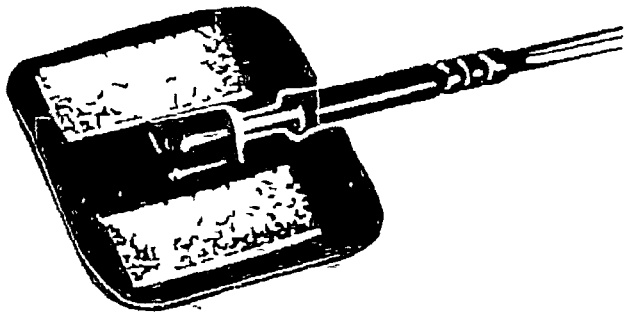
Figure 8-1
Rinse Electrodes



2 Connect the electrodes to the lead wires

Plug the metal tips of the lead wires into the electrodes Be sure you push the lead wire tips in all the way

Figure 8-2
Electrode with Lead wire

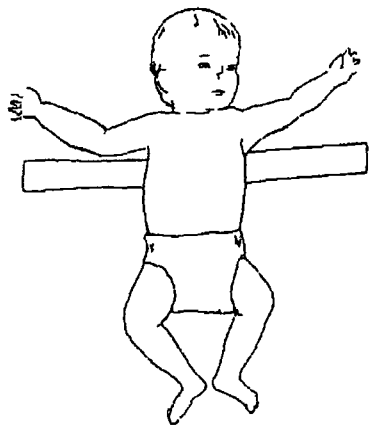


3 Lay the belt on a flat surface

Lay the child down with the child s back on the belt

It is important to place the electrodes correctly The best place is with each armpit near the bottom rib as shown in Figure 8-3 If you must place them somewhere else make certain they are on the child rib cage on opposite sides of the chest If you imagine a line going from one electrode to the other that line must seem to go through th center of the child s chest

Figure 8-3
Belt Placement



4 Place the electrodes on the belt with the Velcro side down

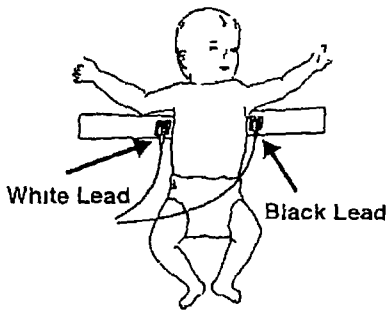
Lay the electrode pads on the belt so that when the belt is wrapped around the child the pads will be in the correct place Place the pad with the white end on the *child s* right Place the pad with the black end on the *child s* left

The pads should be in line with the armpit and down toward the bottom rib

Separate the wires as much as needed

CAUTION
If the electrodes are touching each other an improper signal will be sent to the monitor

Figure 8-4
Electrode Placement

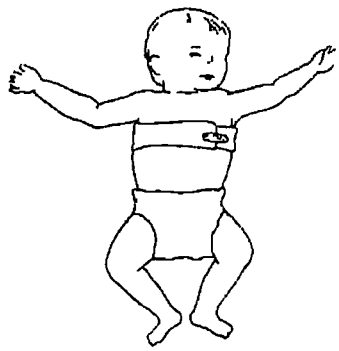


5 Wrap the belt snugly but not tightly around the patient's chest. Close the belt and fasten it with the velcro strip.

The belt needs to be snug but not too tight. It should be possible to slide one finger under the belt after it is closed.

Be sure that the belt does not overlap and block one of the electrodes. If necessary remove the belt, then cut it to make it shorter.

Figure 8 5
Wrapped Belt

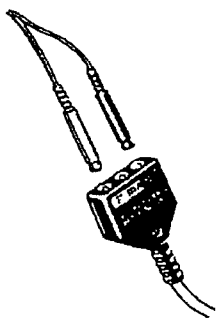


6 If an oximeter is being used, your homecare dealer will tell you how to place the oximeter sensor.

7 Connect the lead wires to the patient cable.

The white connector on the lead wire goes into the hole with the white mark on the patient cable. The black connector goes into the hole with the black mark. Push the connectors until they snap firmly into the cable. These connections fit tightly.

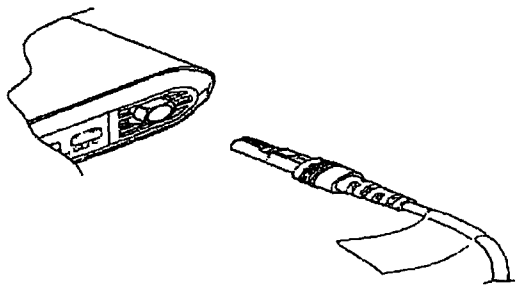
Figure 8-6
Lead Wires and Patient Cable



8 Connect the patient cable to the monitor

Plug the patient cable into the patient cable jack on the front of the monitor Be sure it is firmly in place The cable slips in only if you have the button on the end of the cable facing up To remove the cable from the monitor press the button at the end of the cable and pull straight out

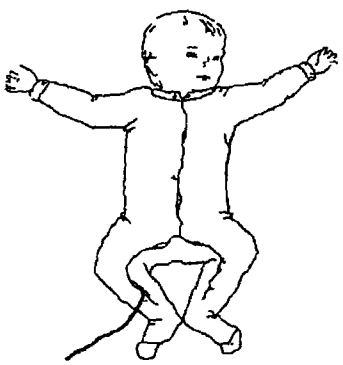
Figure 8 7
Patient Cable and Monitor



Be sure the lead wires and patient cable are away from the child s head and neck You can put a sleeper over the cable and lead wires with the patient cable coming out near your child s foot, as shown in Figure 8 8 Or you can tape the cable to your child s ankle your doctor or home-care dealer have a special tape that will not harm your child s skin

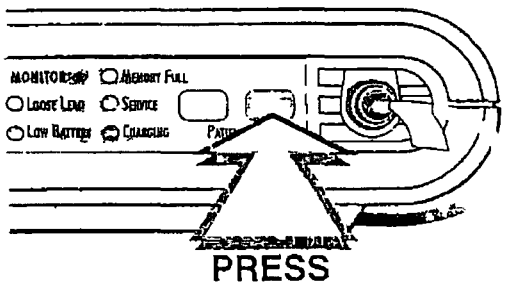
WARNING
To reduce the risk of strangulation do not leave loose or unconnected wires in the infant s crib Make sure that wires are routed away from the child s head

Figure 8-8
Baby and Sleeper



9 Turn monitor on by pressing the power button

Figure 8-9
Power



All lights except the Charging light will illuminate as the monitor runs through a system check.

When the system check is over make sure the green indicator lights are blinking showing that the electrodes are firmly connected and the monitor is receiving signals If the electrodes are not firmly connected the indicator marked Loose Lead will light up and an audible alarm will sound

If you have been instructed to use the Signal Quality indicator turn the monitor over and check the quality rating The connection rating describes the quality of the belt electrodes lead wires and patient cable connections The signal rating describes the quality of the respiration effort and heart rate signals If the rating is Best or Good the signal and connection qualities are acceptable If the rating is poor you may be instructed to follow the Signal Quality instructions in the Section 11 to reduce the potential for false alarms

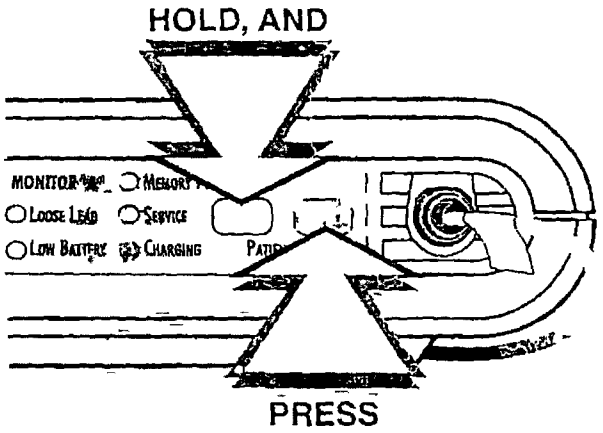
WARNING
During an equipment alarm (except Low Battery caution) the monitor cannot sound any human alarms because of the equipment problem Therefore during an equipment alarm (except Low Battery caution) someone must watch the patient until the equipment problem has been corrected

To turn the monitor off press and hold the RESET button then press the POWER button at the same time

After a delay of up to 30 seconds the monitor will signal that it has powered down with an audible double beep

After the beep the monitor may be turned on again

Figure 8-10
Turning the Monitor Off



Section 9

Auxiliary Connections

Auxiliary Connections

Figure 9-1
Auxiliary Connections

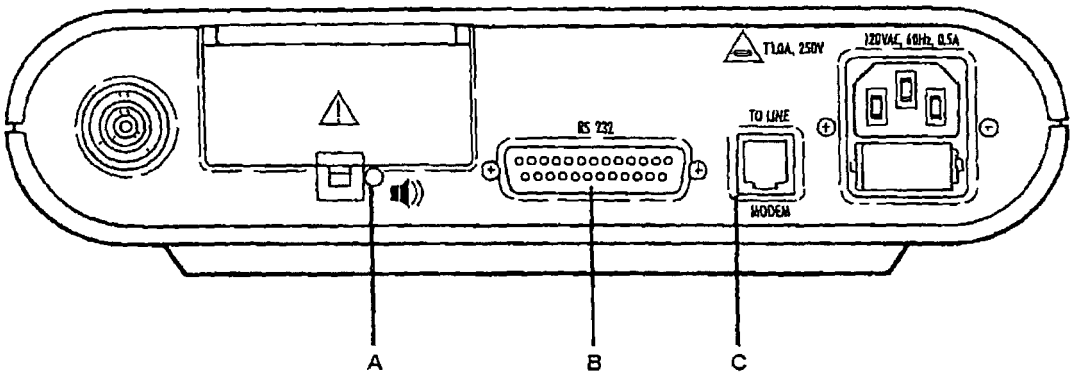


Table 9-1
Description of Auxiliary Connections

A	REMOTE ALARM — Plug the small end of the remote alarm cable into the remote alarm output jack
B	AUXILIARY INPUTS/ DATA OUTPUT — Plug the monitor end of the cable into the interface connector
C	MODEM — The modem cable is plugged into the monitor s telephone connector like a telephone cord Insert the cable with the tab facing down until you feel it click The other end of the cable is plugged into your telephone outlet **Note** The internal modem always answers phone calls on the first ring Therefore only connect the modem cable when instructed by your doctor or homecare dealer or when you expect the monitor to send or receive data To unplug the modem cable press the tab and pull out **WARNING** When the monitor s modem is in use the monitor must be disconnected from the phone lines before you can use the phone

CAUTION
When monitoring a patient make sure AC power is connected to the monitor whenever the phone line is connected to the monitor via a modem.

When you are monitoring a patient and the monitor is connected via modem to the phone lines the monitor may not accurately detect heartbeat when the phone rings and the AC power cord is not connected to the monitor. Without AC power during use with a modem the monitor may detect an extra heartbeat or miss a heartbeat during each ring.

Section 10

Alarms

Alarms

The monitor will sound an alarm when it detects a problem with your child s breathing or heart rate or with the equipment You must respond to all alarms at once Your child needs careful and prompt care when an alarm sounds The monitor warns you of a problem but you must correct the problem

All caregivers of a monitored child must receive CPR (Cardiopulmonary Resuscitation) training for infants If you or any other caregiver has not received this training you must contact your doctor or home health care provider as soon as possible to receive this training

The monitor will sound an alarm for two reasons When the monitor detects a problem with the child s breathing or heart rate it will signal a human alarm When the monitor detects a problem with the equipment it will signal an equipment alarm

You must make sure that you can respond to an event immediately after its first alarm It is especially important to consider this when using the remote alarm

The first thing to remember when answering an alarm is to *always check the child first*

Human Alarms

Human alarms warn you that the monitor has detected apnea fast heart rate or a slow heart rate For human alarms you must respond as you have been trained Your doctor and homecare dealer can help you get the proper training

Apnea

An Apnea alarm tells you that the monitor did not detect suitable breathing from your child

If your child is not breathing follow your doctor s instructions

When the monitor detects suitable breathing the alarm sound will stop The red Apnea light will stay on until you press the RESET button

Heart Fast

A Heart Fast alarm tells you that your child s heart is beating faster than the high heart rate alarm limit

If this alarm sounds follow your doctor s instructions

When the heart rate comes down below the alarm limit the alarm sound will stop The red Heart Fast light will stay on until you press the RESET button

Heart Slow

A Heart Slow alarm tells you that your child s heart is beating slowe the low heart rate alarm limit

If this alarm sounds follow your doctor s instructions

When the heart rate is above the alarm limit the alarm sound will stop red Heart Slow light will stay on until you press the RESET button

Equipment Alarms

Equipment alarms warn you of possible problems with the equipmen

Most equipment alarms produce a continuous audible alarm for the duration of the event

The first thing to remember when answering an alarm is to *always ch the child first*

If the alarm is from an equipment problem, check the front display to why the monitor s alarm is sounding

Low Battery

The red Low Battery light is constantly lit and the audible alarm beep twice each second when the battery does not have enough power for th monitor to work properly

The red Low Battery light flashes when battery power is low but the monitor will still work properly

To correct a Low Battery alarm, plug the monitor into an AC elect outlet

The green Charging light should light

If the monitor is plugged in at all times the monitor should not indic it Low Battery alarms

If the monitor is plugged into a wall outlet and power is lost the monit can operate up to 20 hours if the monitor s battery is fully charged

Loose Leads

A Loose Lead alarm will sound constantly if there is a poor or loose connection between the child and the monitor

If you have a Loose Lead alarm, do the following

Check the lead wire and patient cable connections to be sure they are ti

Electrodes to lead wires,

Lead wires to patient cable and

Patient cable to patient cable jack

Check the electrodes

Are they in the right place?

Is the belt snug enough?

Are the electrodes clean? They should not have any lotion, powder or oil on them

Try new electrodes

Check the lead wires

Are they tightly connected to the electrodes and patient cable?

Try a new set of lead wires

Check the patient cable

Is the patient cable tightly connected to the monitor?

Try a new patient cable

If these steps do not work, call your homecare dealer immediately for assistance

When the problem is corrected, the monitor will turn the alarm off but the Loose Lead light will stay on until the RESET button is pressed

Memory Full

The monitor will light a red Memory Full light when its memory is almost full. The audible alarm will not sound.

If you have a Memory Full alarm

Follow the instructions your doctor or homecare dealer gave you, or

Call your doctor or homecare dealer for instructions

Service

A Service alarm warns you of a problem with the monitor.

To fix a service alarm

Hold in the RESET button and turn the monitor off

Make sure nothing is blocking the audible alarms

Wait 30 seconds. The monitor will sound a double beep

Turn the monitor back on again

If the problem is corrected, no alarm will sound.

If the alarm problem is not corrected, the service alarm will sound again.

If this happens, *do not use the monitor*. Turn the monitor off and call your homecare dealer immediately. A caregiver should personally monitor the child.

All Lights Flashing

All lights will flash if both audio alarms are not working

If this happens *do not use the monitor* Turn the monitor off and call your homecare dealer immediately

WARNING
When the monitor is not working someone must watch the child at all times

If you cannot fix the equipment problem consult your homecare dealer or your physician Always remember to watch your child closely during an equipment problem

Section 11

Troubleshooting and Error Messages

21 02 0117 Rev 03 06/02

Troubleshooting

If you have a problem with a false alarm or other monitor alarm and need assistance this troubleshooting guide may help Always watch the child during an equipment problem

FALSE APNEA ALARM

Frequent apnea alarms when the child is breathing normally

Possible Cause	Possible Solution
Child may be breathing shallowly	Check electrode placement
The belt may be too loose around the child s chest	Tighten the belt but do not over tighten

FALSE HEART SLOW ALARMS

Frequent heart slow alarms when the child has a heart rate above the set limit

Possible Cause	Possible Solution
The electrodes may be dirty	Rinse the electrodes under running water
The child may have lotion or powder on the skin under the electrodes	Clean the child s skin with soap and water, rinse well and dry
The child may have outgrown the Heart Slow limit	Ask your doctor about the prescribed Heart Slow limit
The belt may be too loose around the child s chest	Tighten the belt but do not over tighten
The patient may be too small for electrodes used with a belt	Call your homecare dealer

LOW BATTERY ALARM

Possible Cause	Possible Solution
The battery needs to be recharged	Plug the power cord into the monitor and then into the wall outlet
	Keep the power cord plugged in whenever possible

NO CHARGING LIGHT

Possible Cause	Possible Solution
Improper connection	Check the connection to the electrical outlet and to the monitor
Monitor may need to be serviced	Call your homecare dealer

MEMORY FULL INDICATOR

Possible Cause	Possible Solution
The monitor s memory is full	Call your homecare dealer

LOOSE LEAD ALARMS

Shows a disconnected or broken piece of equipment.

Possible Cause	Possible Solution
The belt may be too loose around the child s chest	Tighten the belt but do not over tighten
The lead wires may be disconnected	Check the lead wires at the electrode end and at the patient cable to be sure they are connected securely
The patient cable may be disconnected	Check the patient cable jack on the monitor to be sure it is plugged in securely
The lead wires may be broken	Replace the lead wires
The electrodes may be old	Replace the electrodes
The child may have lotion or powder on the skin	Clean the child s skin with soap and water rinse well and dry
The electrodes may be dirty	Rinse the electrodes under running water
The electrodes may not be placed correctly	Place electrodes according to instructions
The patient may be too small for electrodes used with a belt	Call your homecare dealer

FALSE HEART FAST ALARM

Frequent heart fast alarms when the child s heart is beating normally

Possible Cause	Possible Solution
The alarm limit may be set too low	Call your homecare dealer
The patient may be too small for electrodes used with a belt	Call your homecare dealer

SERVICE ALARMS

Shows a problem with the monitor

Possible Cause	Possible Solution
The monitor is in need of service by authorized personnel	Call your homecare dealer

SIGNAL QUALITY

Possible Cause	Possible Solution
The belt may be too loose around the child s chest	Tighten the belt but do not over tighten
The child may have lotion or powder on the skin under the electrodes	Clean the child s skin with soap and water rinse well and dry
The electrodes may be dirty	Rinse the electrodes under running water
The electrodes may not be placed correctly	Place electrodes according to instructions
The electrodes may be old	Replace the electrodes

Error Messages

The *Ami* and *Ami Plus* monitors display two error messages on the monitor's LCD display

Replace Battery

The Replace Battery error message may be displayed when the Service light is flashing

When the Replace Battery message is displayed contact your homecare dealer to have the monitor serviced

Loose Connection

The Loose Connection error message will be displayed when a Loose Lead alarm sounds

When the Loose Connection error message is displayed follow the directions for a Loose Lead alarm

Section 12

Power

21 02 0117 Rev 03 06/02

Power

The *Ami* and *Ami Plus* monitors can be connected to a standard household electrical outlet in the United States

Do not connect the monitor to an electrical outlet controlled by a switch

Do not connect the monitor to an electrical outlet through a power strip

Inside each monitor is a rechargeable battery When the monitor is plugged into an electrical outlet the battery charges With a charged battery the monitor can be used where electrical outlets are not available The battery will charge fully within five hours A fully charged battery will power the monitor for 20 hours before needing to be recharged

Section 13

Taking Care of Your Monitor

21-02 0117 Rev 03 06/02

Taking Care of Your Monitor

Your monitor and its accessories may be cleaned to keep them in good working order. You must follow the guidelines for cleaning in this book. If you have any questions about cleaning or maintaining your monitor or its accessories, please contact your homecare dealer.

CAUTION
Do not soak the monitor or allow moisture to get inside. Do not use solvent or abrasive cleaners on any monitor equipment or accessories.

Use a damp cloth to clean the monitor. Only your homecare dealer should disinfect the monitor.

The electrodes may be rinsed daily on the flat side with running water.

The belt should be hand washed.

- Remove the electrodes before washing.
- Use lukewarm water and mild detergent.
- Do not use bleach.
- The belt must be air dried. It cannot be dried in an automatic dryer.

WARNING
If detergent is not fully rinsed out of the electrode belt, the patient may get a skin rash.

The lead wires and patient cable may be cleaned if necessary by wiping them with a soft, damp cloth.

Inspect the monitor's cables and lead wires each day. If they look worn or have any noticeable breaks or kinks, replace the cables or lead wires.

Section 14

Maintenance

Maintenance

If your monitor should need service please call your homecare dealer. Your monitor may only be serviced by certified personnel. Do not attempt to open the monitor case to make repairs.

Section 15

Summary

NEWBERRY PATHOLOGY ASSOCIATES, P A
185 Executive Drive, P O Box 839
Newberry, S C 29108
Phone (803) 276-0201
1-888-446-9898
Fax (803) 276-0208

NECROPSY REPORT **FA04-223**
NAME **INDIA A. GRAVES**
TYPE OF AUTOPSY **Complete**

AGE **3-MONTHS** RACE **BLACK** SEX **FEMALE** D O B **12/30/37**

PROSECTORS **JANICE ROSS, M.D** COUNTY **ORANGEBURG**

DIED on **4/11/04** AUTOPSIED **4/11//04** at **11 00 AM**

FINAL NECROPSY DIAGNOSIS

1 **NO ANOMALIES**

2 **NO EVIDENCE OF TRAUMA**

MANNER OF DEATH **NATURAL**

PROBABLE CAUSE AND MECHANISM OF DEATH		INTERVAL
SUDDEN INFANT DEATH SYNDROME	-	**MINUTES**

JER ajg
4/12/04

CASE HISTORY

This 3-month old black female infant who was one of triplets was found unresponsive by her mother at approximately 3 00 AM on 04/11/04 The baby had last been seen alive at 12 40 AM that same date She was born on 12/30/03 and has some respiratory problems and a "heart murmur" She was seen by a local physician on 04/10/04 for "congestion" and thrush

The body was brought to this prosector for autopsy

EXTERNAL EXAMINATION The body is received clothed in a diaper and a one-piece shortsleeved T-shirt She measures 18 ½ inches from crown to heel, 14 inches from crown to rump The head circumference is 14 ½ inches The chest circumference is 13 ¾ inches Abdominal circumference is 14 inches The foot length is 3 1/8th inches The ear length is 1 ½ inches and she weighs 7 pounds 13 ounces The hair is scant and black The eyes are brown No conjunctival petechiae are present. The oral and nasal cavities are without excessive fluid. The frenulae are intact

Examination of the neck, chest and abdomen is unremarkable except for a slight hernia which is reducible in the umbilicus

Examination of the upper extremities is unremarkable

Examination of the lower extremities is unremarkable

Examination of the back is unremarkable The genitalia are those of an infantile female

DISSECTION The usual Y-shaped incision is made The panniculus of the chest and abdomen show no contusions The abdominal cavity, pleural cavities and pericardial sac contain no excessive fluid

The structures of the anterior neck maintain symmetry The hyoid bone is intact The trachea and larynx are patent.

DESCRIPTION OF INTERNAL ORGANS

THYROID The thyroid gland weighs 1 grams It maintains symmetry of its firm tan parenchyma

DESCRIPTION OF INTERNAL ORGANS, Continued:

THYMUS The thymus gland weighs 18 grams It maintains its usual yellowish-tan nodular parenchyma

HEART The heart weighs 22 grams The coronary arteries maintain their usual positions and relationships The myocardium is reddish-brown and firm The valves are grossly unremarkable

LUNGS The right lung weighs 38 grams The left lung weighs 26 grams The arterial trees are patent The tracheobronchial trees are patent The parenchyma is pinkish-gray and soft

LIVER. The liver weighs 144 grams Its capsule is smooth and glistening Sections show purplish-red parenchyma

GALLBLADDER AND DUCTS Without significant pathology

SPLEEN The spleen weighs 12 grams Its capsule is smooth and glistening Sections show purplish-red parenchyma

PANCREAS The pancreas weighs 8 grams It maintains its usual yellowish-tan nodular parenchyma

ADRENAL GLANDS The adrenal glands together weigh 4 grams They maintain their usual positions and relationships and are otherwise unremarkable

KIDNEYS The right kidney weighs 16 grams The left kidney weighs 18 grams Their capsules strip with ease to show lobulated cortical surfaces Sections show the usual cortical medullary ratios bilaterally

URETERS AND URINARY BLADDER Without significant pathology

FEMALE REPRODUCTIVE TRACT The uterus, tubes and ovaries are symmetrical and immature

GI TRACT The GI tract is unremarkable The stomach contains 1 cc of a brown thick liquid.

MUSCULOSKELETAL SYSTEM Without significant pathology

DESCRIPTION OF INTERNAL ORGANS, Continued:

CENTRAL NERVOUS SYSTEM The scalp is reflected No contusions are seen The calvarium is removed as is the brain The brain maintains symmetry of the cerebrum, cerebellum, pons and medulla Sections show the gray and white matter in the usual anatomic design for age The blood vessels at the base of the brain are patent.

CASE SUMMARY

This autopsy was done upon the request of and after due authorization by the Orangeburg County Coroner in the Newberry County Memorial Hospital Morgue on 4/10/04 at approximately 11 00 AM

Autopsy findings include no evidence for trauma and no anomalies

Sections of all organs demonstrate the before mentioned findings Specimens are drawn for toxicological analysis

The opinion rendered here is without knowledge of toxicological results If a positive analysis is submitted to this prosector, an amended opinion may be necessary

It is therefore the opinion of this prosector after review of the history and autopsy findings on this victim that the cause of death Sudden Infant Death Syndrome The manner of death is natural

Janice E Ross, M D
Forensic Pathologist

JER.ajg
4/12/04

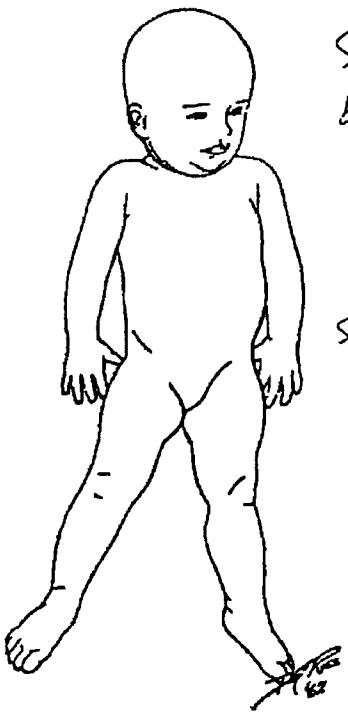
NAME India Graves FA04-223

MICROSCOPIC EXAMINATION

THYROID	There is no pathological finding
THYMUS	There is no pathological finding
HEART	There is no pathological finding
LUNGS	There is no pathological finding, There is mild congestion present
LIVER.	There is no pathological finding
KIDNEYS	There is no pathological finding
SPLEEN	There is no pathological finding
PANCREAS	There is no pathological finding
ADRENAL(S)	There is no pathological finding
BRAIN	There is no pathological finding

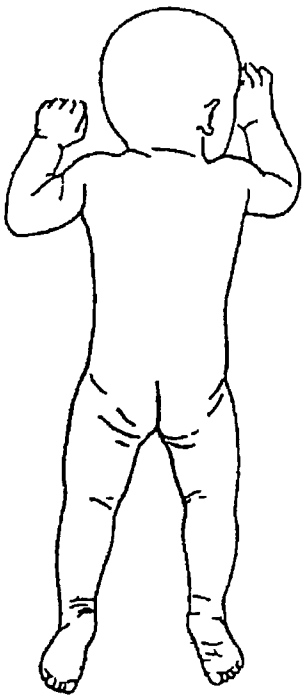
Name Indira Ryanne Graves Autopsy No FA04223

Color _____ Age _____ Sex _____ Date 4-11-04



Scat black hair
brow eye
Freckles chest

Slight lesion -
buttocks





1/4" nodule



CH 18½
CR 14
HC 14½
CC 13¾
AC 14
FL 3⅛
EL 1½
Wt 7' 13

NAME OF DECEDENT INDIA A GRAVES

AUTOPSY NUMBER. FA04-223 RACE BLACK AGE 3 MOS SEX. FEMALE

PATHOLOGIST(S) JANICE E ROSS,M.D

FORENSIC CASE INFORMATION

Caller's Name DAVID FARR Caller's Phone# **533-5842**

Address **1665 SPRING VALLEY CIRCLE** County **ORANGEBURG**
ORANGEBURG, SC

Date and time of injury at Location

Date and time of death **4/11/04** at Location

CIRCUMSTANCES OF DEATH

3 MONTH OLD, ONE OF TRIPLETS HAS HAD SOME RESPIRATORY PROBLEMS AND HEART MURMUR. SEEN BY LMD YESTERDAY FOR THRUSH AND MINOR SYMPTOMS

LAST SEEN ABOUT 12 40 AM 4/11/04 ALIVE FOUND LATER THAT AM UNRESPONSIVE SLEEPING IN A BASSINET BY THE PARENTS BED
MEDICAL HISTORY

DR. CASTLE

AU ORIZATION FOR CORONER S AUTOPSY

I, David P. Zorn, duly authorized Coroner, or duly authorized representative of the Coroner of Orangeburg County, SC, do hereby authorize Joel S Sexton, M D , Pathologist, Newberry County Memorial Hospital, to perform a complete examination of the body and head of said patient with the object of establishing the cause and manner of death Authority is also granted to remove unexposed tissues and parts for preservation and study, to include research and pituitary hormone replacement, or to otherwise dispose of these tissues in a proper and suitable manner

April 11, 2004 (Date)

David P Zorn (Signature of person authorizing autopsy)

THE FOLLOWING INFORMATION IS NEEDED TO EXPEDITE EXAMINATION AND REPORTS

Name of Coroner Lamonta Marshall Phone # 533-5842 (Office)

Address P.O. Drawer 9000 Orangeburg, S.C. 29116 496-5273 (Home)

Person to whom bill should be sent Orangeburg County Coroner

The body will be transported to Newberry Hospital by Paul Simmons Simmons Funeral Home (Undertaking firm or Auth Person)

If person(s) transporting the body do not plan to wait the body will be picked up by _____ (Name of authorized person(s))

PERTINENT INFORMATION CONCERNING PATIENT

Name India Iyana Graves Age 3 months DOB 12-30 2003 Sex F Race B

Home address 1665 Spring Valley Circle Orangeburg, S.C. 29115

Date of injury _____ Time of injury _____ Location _____

Date of death April 11, 2004 Time of death approx. 3:00 A.M. Location 1665 Spring Valley Circle Orangeburg, S.C. 29115

Chemical analysis requested in addition to what is routinely done by SLED (alcohol & drug screen) _____

Suspected mode of death SIDS

* ALL BODIES MUST BEAR IDENTIFICATION TAGS FIRMLY TIED TO ANKLE OR TOE *

(Please complete reverse side of form)

Address where body was found 1665 Spring Valley Circle Orangeburg SC 29115

Type of premises Residence
(Farm home pond parking lot, etc)

Occupation of Decedent —
(If farmer or farm worker, specify type of commodity produced)

Decedent found by Jara S. Greaves Date & Time

Address 1665 Spring Valley Circle, Orbg, SC Relationship to Decedent Mother

Decedent last seen by Jara S. Greaves Date & Time 9-11 2004 approx 3:40 P.M.

Address 1665 Spring Valley Circle, Orbg, SC Relationship to Decedent Mother

Activity Decedent engaged in at time of death Sleeping

What position was decedent in when found (lying on back right or left side, abdomen sitting, or other)? Laying on Back

Is position of decedent natural looking? ✓ Yes ___ No

Was decedent clothed, partially clothed, or unclothed--Type of Clothing

Sleepwear

Was decedent's body temperature Hot ___ Warm ___ Cool ✓ Cold ___ when found?

Is blood on decedent? Yes ___ No ✓, Coming from Mouth ___, Nose ___, Ears ___

Is rigor present in jaw ___ neck ___ abdomen ___, arms ___, legs ___?

Is there blood or blood spatters on floor ___ walls ___, furniture ___ and/or appliances ___ around or near the decedent (explain) None

e there any electrical appliances or electrical wires near or around decedent? No

Are there any alcohol bottles around or near decedent? No Quantity ___

Name of investigating officer Deputy Logan

Department OCSO Phone # 534 3550

(IF ~~THIS IS A HOMICIDE, DO NOT COMPLETE THE ITEMS BELOW~~)

MEDICAL HISTORY

Name of family doctor (or last doctor seen) Dr. Castle Pediatrician & Dr. Charles Kilgore Phone # 803-360-6363

Address Columbia, SC

Date of last visit April 6, 2004 Purpose of visit Cold, Skin Rash, Thrush

Diagnosis at last visit " " "

Medication prescribed Amoxycillin, Keplan, Zantac, Hydrocortisone Cream

Does decedent have any history of drug and/or alcohol problems? Yes ___ No ✓

Was decedent involved in any type of accident or incident within the past year or so that might have caused treatable or non-treatable type injuries (Explain) No

Other Medical History available Premature, Multiple birth with problems associated, decedent has been sickly since Birth

• PLEASE COMPLETE ALL INFORMATION THIS SIDE AND REVERSE SIDE AND SEND WITH BODY

NAME OF DECEDENT INDIA A. GRAVES DATE 4/11/04

AUTOPSY NUMBER FA04-223 RACE BLACK AGE 3 MOS SEX FEMALE

PATHOLOGIST(S) JANICE E ROSS,M.D

AUTOPSY WORKSHEET

RIGOR-	--
LIVIDITY	--
m	**HEIGHT**
7 LBS. 13 OZ#	**WEIGHT**
HEAD trauma	--
442g	**Brain**
	Skull fractures
	Other
NECK trauma	--
g	Thyroid gland
18 g	Thymus
	Vocal cords
CHEST trauma	--
	Pericardium
22 g	**Heart**
38 g	**R. Lung**
26 g	**L Lung**
ABDOMEN trauma	--
	Diaphragm
144g	**Liver**
12g	**Spleen**
8g	**Pancreas**
	Lymph nodes
4g	Adrenal glands TOGETHER
16g	**R. Kidney**
18g	**L. Kidney**
0 cc	**Urine**
	Bladder
	Genitalia
GI TRACT	Appendix present?YES
1 CCcc	**Stomach contents BROWN LIQUID**
UPPER Ext trauma	
	Scars
	Other
LOWER Ext trauma	--
	Scars
	Other
BACK trauma	--
	Scars
	Other

NEWBERRY PATHOLOGY ASSOCIATES, P.A.
185 Executive Drive, P O Box 839
Newberry, S C 29108
Phone (803) 276-0201
1-888-446-9898
Fax (803) 276-0208

NECROPSY REPORT **FA04-223**
NAME **INDIA A. GRAVES**
TYPE OF Autopsy Complete

AGE **3 MONTHS** RACE **BLACK** SEX **FEMALE** SSN D O B **12/30/03**

PROSECTOR(S) **JANICE E ROSS,M.D** COUNTY **ORANGEBURG**

INJURED on at DIED on **4/11/04** at AUTOPSIED on **4/11/04** at **11 00AM**

FINAL NECROPSY DIAGNOSIS

NO ANAMOLIES

NO EVIDENCE OF TRAUMA

MANNER OF DEATH **SIDS**

PROBABLE CAUSE AND MECHANISM OF DEATH INTERVAL

SIDS

DUE TO _____

DUE TO _____

DUE TO _____

NAME OF DECEDENT INDIA A. GRAVES

AUTOPSY NUMBER FA04-223 RACE BLACK AGE 3 MOS SEX FEMALE

PATHOLOGIST(S) JANICE E ROSS,M.D

Date of Death 4/11/04 County of Death ORANGEBURG

27 PART I Enter the diseases injuries or complication that causes the death. Do not enter the mode of dying, such as *cardiac or respiratory arrest* shock or heart failure List only one cause on each line — Approximate Interval Between Onset and Death

IMMEDIATE CAUSE (Final) A. SUDDEN INFANT DEATH SYNDROME

DUE TO (OR AS A CONSEQUENCE OF)

B _____

DUE TO (OR AS A CONSEQUENCE OF)

C _____

DUE TO (OR AS A CONSEQUENCE OF)

D _____

DUE TO (OR AS A CONSEQUENCE OF)

PART II. Other significant conditions contributing to death but not resulting in the underlying Causes given at Part I. — 28a. Autopsy *Yes or No* YES — 28b WERE AUTOPSY FINDINGS CONSIDERED IN DETERMING CAUSE OF DEATH? *YES OR NO* YES

29 MANNER OF DEATH — 30a. DATE OF INJURY — 30b TIME OF INJURY — 30c. INJURY AT WORK — 30d. DESCRIBE HOW INJURY OCCURRED

X Natural ____ Pending Investigation ____ Accident ____ Suicide ____ Homicide ____ could not be determined

30e. PLACE OF INJURY – At home, farm, street, factory office 30f LOCATION (Street and Number of Rural Number City or Town, State, building etc (Specify)

Janice E Ross, M.D	_____ Signature	Forensic Pathologist Title	Newberry Pathology Associates 185 Executive Dr Newberry S C 29108
Joel S Sexton, M.D	_____ Signature	Forensic Pathologist Title	Newberry Pathology Associates 185 Executive Dr Newberry S C 29108
Inas Z. Yacoub, M.D	_____ Signature	Forensic Pathologist Title	Newberry Pathology Associates 185 Executive Dr Newberry S C 29108

Date Signed 4/11/04

NAME OF DECEDENT INDIA A. GRAVES

AUTOPSY NUMBER. FA04-223 RACE BLACK AGE 3 MOS SEX FEMALE

PATHOLOGIST(S) JANICE E ROSS,M.D

QTY	ITEM	DESCRIPTION
	SHIRT OR T-SHIRT	
1	UNDERSHIRT	ONE-PIECE SHORT-SLEEVE WHITE
____	PANTS OR SHORTS	
	SKIRT OR DRESS	
	BELT	
	BRA	
	UNDERWEAR	
	SOCKS	
	SHOES	
1 PR	EARRINGS	YELLOW METAL STUDS
1	BLANKET	YELLOW,PINK/GREE/WHITE/BLUE

MISCELLANEOUS ITEMS RECEIVED WITH THE BODY

DOLLARS 1S 5S 10S 20S 50S 100S =

CHANGE PENNIES NICKLES DIMES QUARTER =

TOTAL

PRINT NAME JOEL S SEXTON, M.D FOR NEWBERRY PATHOLOGY

PRINT NAME INAS Z YACOUB, M.D FOR NEWBERRY PATHOLOGY PRINT

NAME JANICE E ROSS, M.D FOR NEWBERRY PATHOLOGY

EVIDENCE TRANSFERRED TO Paul A Simmons DATE 4-11-04 TIME

PRINT NAME PAUL A SIMMONS

REPRESENTING

PHONE#

NAME OF DECEDENT INDIA A GRAVES

AUTOPSY NUMBER FA04-223 RACE BLACK AGE 3 MOS SEX FEMALE

PATHOLOGIST(S) JANICE E ROSS,M.D

EVIDENCE TRANSFER FORM

The following listed items were transferred at NEWBERRY PATHOLOGY ASSOCIATES, Newberry, S C 29108

Qty	Toxicology
-	Grey top test tube(s) of blood from distal aorta
-	Grey top test tube(s) of blood from chest cavity
1	Grey top test tube(s) of blood from heart
-	Grey top test tube(s) of chest fluid
1	Red top test tube BILE
-	Red top test tube VITREOUS
-	Bottle URINE
-	Bottle BLOOD
1	Bottle GASTRIC
1	Bottle tissue—BRAIN
1	Bottle tissue—LIVER
-	Medication(s)
	SEROLOGY
-	Lavender top test tube(s) BLOOD
	EVIDENCE TRANSFERRED BY _____
	Joel S Sexton, M.D , Inas Yacoub, M.D or Janice E Ross, M D
	EVIDENCE TRANSFERRED TO
	PRINT NAME Laurie Shuler Signature Laurie Shuler
	DATE 4-12-04
	REPRESENTING SLED
	(Name) **(Phone#)**

SOUTH CAROLINA LAW ENFORCEMENT DIVISION
FORENSIC SERVICES LABORATORY REPORT

MARK SANFORD
Governor

ROBERT M STEWART
Chief

TOXICOLOGY DEPARTMENT

November 19 2004
SLED Lab No L04-03690
Your Case No Not Listed
Incident Date 04/11/04
(V) Graves, India Ayanna

Coroner Samuetta Marshall
Orangeburg County Coroner's Office
PO Drawer 9000
Orangeburg, SC 29116

This is an official report of the South Carolina Law Enforcement Division Forensic Services Laboratory and is to be used in connection with an official criminal investigation. These examinations were conducted under your assurance that no previous examinations of person(s) or evidence submitted in this case have been or will be conducted by any other laboratory or agency

Robert M. Stewart, Chief
South Carolina Law Enforcement Division

RECEIVED
NOV 29 2004

ITEMS OF EVIDENCE

Item 1 Blood labeled India A Graves FA04-223"

RESULTS

Negative for volatiles in blood (includes Ethanol Methanol Isopropanol, Acetone, Acetaldehyde threshold 0 01 % w/v)

Chlorpheniramine found in blood Insufficient sample for quantitation

Methorphan found in blood Insufficient sample for quantitation

Negative screen for Acetaminophen
Urine threshold 10 0 mg/L blood threshold 10 0 mg/L

Negative screen for Barbiturates
(Secobarbital et al)
Urine threshold 0 2 mg/L blood threshold 0 075 mg/L

Negative screen for Benzodiazepines
(Oxazepam Nordiazepam et al)
Urine threshold 0 2 mg/L blood threshold 0 05 mg/L

Negative screen for Cocaine and/or Cocaine metabolites
(Cocaine, Benzoylecgonine et al)
Urine threshold 0 3 mg/L blood threshold 0 1 mg/L

Negative screen for Salicylates
Urine threshold 50 0 mg/L, blood threshold 50 0 mg/L

Insufficient sample for further analysis

Item 2 Bile

RESULTS

No analysis performed

Item 3 Gastric

RESULTS

Insufficient sample for analysis

Item 4 Brain

RESULTS

Less than 0 20 mg/Kg Methorphan found in brain tissue

0 04 mg/Kg Chlorpheniramine found in brain tissue

Item 5 Liver

RESULTS

Less than 0 20 mg/Kg Methorphan found in liver tissue

Less than 0 20 mg/Kg Methorphinan found in liver tissue

0 20 mg/Kg Chlorpheniramine found in liver tissue

Forensic Toxicologist

Robert M Sears, DFTCB

RMS/dlj

cc Dr Janice Ross

Biological specimens processed for testing which are not consumed during analysis will be maintained for 180 days from the completion date of the analysis and then destroyed unless otherwise notified

4416 Broad River Road, P O Box 21398 Columbia South Carolina 29221 1398 Phone (803) 896 7300

Microbiology Report

Newberry County Memorial Hospital

Name	GRAVES INDIA	Specimen	1500	Status	Final
Patient ID	FA04 223	Source	BLOOD	Collected	4/11/2004
ard/Rm	/	Ward of Iso	AUT	Attd Phys	

1 Staphylococcus capitis subspecies capitis Status Final

1 **S capitis capit**

Drug	MIC	Interps	Drug	MIC	Interps
Amox/K Clav (c d)	<=4/2				
Ampicillin	8	BLAC			
Cefazolin	<=2				
Cefotaxime (c e)	<=8				
Ciprofloxacin	<=1	S			
Clarithromycin	<=0 25	S			
Clindamycin	<=0 25	S			
Erythromycin	<=0.25	S			
Gentamicin	>8	R			
Imipenem (c)	<=4				
Nitrofurantoin	<=32				
Oxacillin	<=0 5	N/R			
Penicillin	>8	BLAC			
Rifampin	<=1	S			
Tetracycline	<=2	S			
Trimeth/Sulfa	<=2/38	S			
Vancomycin	<=2	S			

S = Susceptible
I = Intermediate
R = Resistant
MIC = mcg/ml (mg/L)

N/R = Not Reported
— = Not Tested
TFG = Thymidine-dependent strain

Blank = Data not available, or drug not advisable or tested
ESBL = Extended spectrum beta-lactamase
Blac = Beta-lactamase positive

R = Resistance due to extended spectrum beta-lactamases (ESBL)
ESBL? = Suspected ESBL. Confirmatory tests needed to differentiate ESBL from other beta-lactamases.
IB = Inducible Beta-lactamase Appears in place of Susceptible* with species known to possess inducible beta-lactamases potentially they may become resistant to all beta-lactam drugs Monitoring of patients during/after therapy is recommended Avoid other/combined beta-lactam drugs

For blood and CSF isolates a beta-lactamase test is recommended for Enterococcus species

(a) Use maximum doses of drug with an aminoglycoside for P aeruginosa in patients with granulocytopenia or serious infections
(b) Breakpoints based on parenteral dose The cefuroxime axetil (PO) breakpoints for Enterobacteriaceae and staphylococci are <8=S 8-16=I >16=R, and for S pneumoniae are <2=S 2=I 2=R.
(c) Refer to the penicillin interpretation when an interpretation is not reported for streptococci
(d) Refer to the penicillin interpretation for non beta-lactamase producing enterococci
(e) Breakpoints are based on S pneumoniae isolated from patients with meningitis Breakpoints are <2=S 2=I >2=R for non-meningitis infections.

Interpretive breakpoints are based on NCCLS M100-S13 Jan 2003. Sparfloxacin (for Gram negative isolates) and moxifloxacin are based on FDA approved breakpoints

Name	GRAVES INDIA	Specimen	1500	Status	Final
Patient ID	FA04-223	Source	BLOOD	Collected	4/11/2004
Ward/Rm	/	Ward of Iso	AUT	Req Phys	JANICE E ROSS MD

Printed 4/14/2004 10 08 36 AM

Tech

Laboratory Director
PO Box 219
Bridgeville, PA 15017
(412) 220-2300 Phone
(412) 220-0784 Fax

04/20/2004

Date Collected	00/00/0000	Date Recvd	04/19/2004	Birth Date	12/30/2003
Submittor	Sexton Joel MD			Cond of Spec	S
Filter Paper	1963656	Baby's Name	GRAVES INDIA	Sex	U
Newborn ID	2107828	AKA Name			
Accession No	2004092747	Med Rec No			
Mother's Name				Physician	ROSS JANICE

Autopsy Specimen Report

Screening Test	Outcome
Acylcarnitine Profile	Within Normal Limits
Congenital Adrenal Hyperplasia	Within Normal Limits

Comments

Newborn Screening Laboratory Report

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 06/15/1998
Event Type Death **Patient Outcome** Death Other
Manufacturer Narrative
Na

Event Description
Nellcor puritan bennett rec'd a call from rptr on 06/15/1998 Rptr called to report a infant death on 06/15/1998 with allegation of no apnea alarm Infant turned blue and taken to the hosp

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 75

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section G)*	NELLCOR PURITAN BENNETT, INC 2800 Northwest Blvd Minneapolis MN 55441 2625
Manufacturer Contact	Andrew Radford 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500 ext 3781
Device Event Key	172953
MDR Report Key	177867
Event Key	167181
Report Number	2183157-1998-00111
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	07/15/1998
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/16/1998
Is This An Adverse Event Report?	Yes

Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	373719-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	07/02/1998
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	06/15/1998
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	02/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-480875	6/15/1998

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
MEMORY BEFORE SHIPPING UNIT

Serial Number	Text Date
L 480875	6/15/1998

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
HAVEN'T DOWNLOADED THE UNIT ADVISED THEM TO DL W/O CLEARING

Serial Number	Text Date
L-480875	6/15/1998

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
FAX # 318-424 9206

Serial Number	Text Date
L 480875	6/15/1998

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
NO ALARM FOR APNEA

Serial Number	Text Date
L 480875	6/15/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
30 BABY TURNED BLUE AND WAS TAKEN TO THE HOSPITAL

Serial Number	Text Date
L 480875	9/22/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
UPDATED PER EN 121535 AND ADDED P/N Y 100465 00A S/N 974

Serial Number	Text Date
L 480875	9/22/1998

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
WAS COMPLETELY TESTED DURING RECALL. SEE REQUEST 370065 003

Serial Number	Text Date
L-480875	9/22/1998

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
DOWNLOADED AND REPORT FORWARDED TO PRODUCT MONITORING MONITOR

Serial Number	Text Date
L 480875	9/22/1998

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
AND AUDIBLE ALARM WHEN TESTED AT 10 AND 30 SECONDS MONITOR WAS

Serial Number	Text Date
L-480875	9/22/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
UNABLE TO DUPLICATE NO ALARM FOR APNEA MONITOR HAD AN APNEA LED

Serial Number	Text Date
L 480875	10/14/1998

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 480875	10/14/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9075	APN MTR DEATH

Text Detail
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL

Serial Number	Request Numb	Line Date	Product Numb	Trend Code Symptom	Observer Code Symptom
L 480875	370065	5/27/1998	L 9700A	9103	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	
L 480875	373719	6/15/1998	L 9700A	9075	

001240

Short Text	Customer Nam	RMA Type	Customer Phone	Text Seq Numb
5/98 AMI RCL ECG NOISE	RED BALL ME	CA	0	1
APN MTR DEATH	RED BALL ME	WR	3184248393	1
APN MTR DEATH	RED BALL ME	WR	3184248393	1
APN MTR DEATH	RED BALL ME	WR	3184248393	1
APN MTR DEATH	RED BALL ME	WR	3184248393	2
APN MTR DEATH	RED BALL ME	WR	3184248393	2
APN MTR DEATH	RED BALL ME	WR	3184248393	2
APN MTR DEATH	RED BALL ME	WR	3184248393	3
APN MTR DEATH	RED BALL ME	WR	3184248393	3
APN MTR DEATH	RED BALL ME	WR	3184248393	4
APN MTR DEATH	RED BALL ME	WR	3184248393	4
APN MTR DEATH	RED BALL ME	WR	3184248393	5

001241

Text Detail
UPDATED PER EN 121535 AND ADDED P/N Y 100465-00A S/N 974
30 BABY TURNED BLUE AND WAS TAKEN TO THE HOSPITAL
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL
UNABLE TO DUPLICATE NO ALARM FOR APNEA MONITOR HAD AN APNEA LED
AND AUDIBLE ALARM WHEN TESTED AT 10 AND 30 SECONDS MONITOR WAS
NO ALARM FOR APNEA
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
DOWNLOADED AND REPORT FORWARDED TO PRODUCT MONITORING MONITOR
FAX # 318 424 9206
HAVEN T DOWNLOADED THE UNIT ADVISED THEM TO DL W/O CLEARING
WAS COMPLETELY TESTED DURING RECALL SEE REQUEST 370065-003
MEMORY BEFORE SHIPPING UNIT

001242

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 11/02/1998
Event Type Malfunction
Manufacturer Narrative
Na

Event Description
Nellcor puritan bennett rec d a call from facility on 11/02/1998 Facility called to report the following problem incorrect brady alarms led without audible alarm or delayed audible alarm Found during testing

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 77

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer *(Section G)*	NELLCOR PURITAN BENNETT, INC 2800 Northwest Blvd Minneapolis MN 55441 2625
Manufacturer Contact	Andrew Radford 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500 ext 3781
Device Event Key	194946
MDR Report Key	200690
Event Key	188541
Report Number	2183157-1998-00229
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Health Professional
Reporter Occupation	RESPIRATORY THERAPIST
Type of Report	Initial
Report Date	12/01/1998
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/01/1998
Is This An Adverse Event Report?	No

Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	398591-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	11/05/1998
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	na
Event Location	Not Applicable
Date Manufacturer Received	11/02/1998
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	03/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 480346	4/28/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
000	APN MTR DUPLICATE REQUEST

Text Detail
UPDATE

Serial Number	Text Date
L-480346	9/22/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
REWORKED PER EN 121535 AND ADDED P/N Y 100465-00A S/N 967

Serial Number	Text Date
L-480346	9/22/1998

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
000	APN MTR DUPLICATE REQUEST

Text Detail

Serial Number	Text Date
L 480346	9/22/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
000	APN MTR DUPLICATE REQUEST

Text Detail
UNIT WAS UPDATED ON REQUEST 370063 006

Serial Number	Text Date
L-480346	11/2/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Text Detail
ODD HIGH PITCHED NOISE ON ALL THE TIME

Serial Number	Text Date
L-480346	11/5/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Text Detail
RECD 11-04 98 NO ACC RECD

Serial Number	Text Date
L 480346	12/31/1998

Product Number	Text Seq Numbe
L 9700A	7

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Text Detail
AM OFF 8 30 AM 12/30

Serial Number	Text Date
L-480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	6	FAILURE PART# Y 100465-00A LOT# YW4027 BURN IN ON 12/29 8 30

Serial Number	Text Date
L 480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	5	REPLACED WITH S/N 1894 TO CORRECT NO HEARTRATE DETECTION

Serial Number	Text Date
L 480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	L 006118 00A LOT# NCR30869 SCRAPPED NOTCH FILTER S/N 967 AND

Serial Number	Text Date
L 480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	WITH S/N BAA02189 TO CORRECT HIGH PITCHED NOISE FAILURE PART#

Serial Number	Text Date
L-480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	AT POWER UP SCRAPPED CIRCUIT BOARD S/N BAA00557 AND REPLACED

Serial Number	Text Date
L 480346	12/31/1998

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	NO HEART RATE HEART SLOW ALARM ON VERIFIED HIGH PITCHED NOISE

Serial Number	Text Date
L 480346	1/15/1999

Trend Code Symptom	Short Text
4204	APN MTR ALARM, VOL/TONE/QUALITY

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
TO CORRECT THE REPORTED PROBLEM TREND AND REPORT TO CAB

Serial Number	Text Date
L-480346	1/15/1999

Trend Code Symptom	Short Text
4204	APN MTR ALARM VOL/TONE/QUALITY

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED CIRCUIT BOARD

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 480346	365503	4/28/1998	L 9700A	000	
L 480346	365503	4/28/1998	L 9700A	000	
L 480346	365503	4/28/1998	L 9700A	000	
L 480346	370063	5/27/1998	L 9700A	9103	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L-480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	
L 480346	398591	11/2/1998	L 9700A	4204	

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HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR DUPLICATE REQUEST	NORTHWEST MEDICAL	S	0	1
APN MTR DUPLICATE REQUEST	NORTHWEST MEDICAL	S	0	1
APN MTR DUPLICATE REQUEST	NORTHWEST MEDICAL	S	0	2
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	1
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM, VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	3
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	4
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	5
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	6
APN MTR ALARM VOL/TONE/QUALITY	NORTHWEST MEDICAL	WR	9075630073	7

001250

Text Detail
UNIT WAS UPDATED ON REQUEST 370063 006
UPDATE
REWORKED PER EN 121535 AND ADDED P/N Y 100465 00A S/N 967
NO HEART RATE HEART SLOW ALARM ON VERIFIED HIGH PITCHED NOISE
ODD HIGH PITCHED NOISE ON ALL THE TIME
RECD 11 04 98 NO ACC RECD
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED CIRCUIT BOARD
AT POWER UP SCRAPPED CIRCUIT BOARD S/N BAA00557 AND REPLACED
TO CORRECT THE REPORTED PROBLEM TREND AND REPORT TO CAB
WITH S/N BAA02189 TO CORRECT HIGH PITCHED NOISE FAILURE PART#
L 006118 00A LOT# NCR30869 SCRAPPED NOTCH FILTER S/N 967 AND
REPLACED WITH S/N 1894 TO CORRECT NO HEARTRATE DETECTION
FAILURE PART# Y 100465 00A LOT# YW4027 BURN IN ON 12/29 8 30
AM OFF 8 30 AM 12/30

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATORY MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 01/04/1999
Event Type Malfunction **Patient Outcome** Other
Event Description
Nellcor puritan bennett received the following information Alarm stopped in the middle of study

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

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Brand Name	9700 HEART/RESPIRATORY MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 78

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section G)*	NELLCOR PURITAN BENNETT, INC 2800 Northwest Blvd Minneapolis MN 55441 2625
Manufacturer Contact	Andrew Radford 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500 ext 3781
Device Event Key	202743
MDR Report Key	208908
Event Key	196074
Report Number	2183157-1999-00023
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/03/1999
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/03/1999
Is This An Adverse Event Report?	No

Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	408126-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	01/12/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Event Location	Not Applicable
Date Manufacturer Received	01/04/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	09/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

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DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-481435	1/4/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	ALARM STOPPED IN THE MIDDLE OF STUDY

Serial Number	Text Date
L-481435	1/12/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	ACC RECD PATIENT CABLE PWR CORD

Serial Number	Text Date
L-481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	IN AN APNEA NARM WITH NO PROBLEMS 24 HOURS BURN IN COMPLETE

Serial Number	Text Date
L-481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	AVAILABLE TO CONFIRM REPORTED PROBLEM MONITOR RAN FOR 15 HOURS

Serial Number	Text Date
L-481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	POOL PER CRAIG

Serial Number	Text Date
L 481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
MONITOR DOWNLOADED AND FORWARED TO REGULATORY WITH NO DATA

Serial Number	Text Date
L-481435	1/29/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 481435	408126	1/4/1999	L 9700A	4202	
L-481435	408126	1/4/1999	L 9700A	4202	
L 481435	408126	1/4/1999	L 9700A	4202	
L 481435	408126	1/4/1999	L 9700A	4202	
L-481435	408126	1/4/1999	L 9700A	4202	
L-481435	408126	1/4/1999	L 9700A	4202	
L 481435	408126	1/4/1999	L 9700A	4202	
L 481435	408126	1/4/1999	L 9700A	4202	

001257

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	1
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	1
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	1
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	1
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	1
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	2
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	2
APN MTR ALARM ON INTERMITTENTLY	ALT FIELD MARKETING	L	6126943510	3

001258

Text Detail
ACC RECD PATIENT CABLE PWR CORD
ALARM STOPPED IN THE MIDDLE OF STUDY
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL
MONITOR DOWNLOADED AND FORWARED TO REGULATORY WITH NO DATA
POOL PER CRAIG
AVAILABLE TO CONFIRM REPORTED PROBLEM MONITOR RAN FOR 15 HOURS
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
IN AN APNEA NARM WITH NO PROBLEMS 24 HOURS BURN IN COMPLETE

001259

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 01/27/1999
Event Type Malfunction **Patient Outcome** Other,
Event Description
Nellcor puritan bennett received a call on 1/27/1999 Source called to report the following problem parents stated the monitor had an apnea led without an alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 79

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section G)*	NELLCOR PURITAN BENNETT, INC 2800 Northwest Blvd Minneapolis MN 55441 2625
Manufacturer Contact	Andrew Radford 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500 ext 3781
Device Event Key	205893
MDR Report Key	212171
Event Key	199103
Report Number	2183157-1999-00049
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/24/1999

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	02/25/1999
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes

Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	412868-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	02/02/1999
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	na
Event Location	Not Applicable
Date Manufacturer Received	01/27/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	11/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

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DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 481634	1/27/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
TEST AS A PRECAUTION

Serial Number	Text Date
L 481634	1/27/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
ALARM DOWNLOAD SHOWED NO VERIFICATION TESTED OK BY HOMECARE

Serial Number	Text Date
L 481634	1/27/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
PARENTS COMPLAINED THAT THEY FOUND THE APNEA ON W/O AN AUDIBLE

Serial Number	Text Date
L 481634	2/2/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
RECD 2 1 99 NO ACC RECD

Serial Number	Text Date
L-481634	2/12/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
WITH UNIT PASSED ALL TESTING

Serial Number	Text Date
L 481634	2/12/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
FLUCTUATE TEST NO INFORMATION IN DOWNLOAD NO PROBLEM FOUND

Serial Number	Text Date
L-481634	2/12/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
LITHIUM BATTERY 3 67 VDC NICAD BATTERY 5 52 VDC PASSED

Serial Number	Text Date
L 481634	2/17/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 481634	2/17/1999

Trend Code Symptom	Short Text
9047	APN MTR FALSE APNEA ALARM (NO PU)

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	
L 481634	412868	1/27/1999	L 9700A	9047	

001265

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phon	Text Seq Numb
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	1
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	1
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	1
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	1
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	2
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	2
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	2
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	3
APN MTR FALSE APNEA ALARM (NO PU)	ELKHART GENERAL HOME	WR	2192966448	3

001266

Text Detail
COULD NOT REPRODUCE THE CUSTOMERS COMMENT AT OUR LOCATION FINAL
LITHIUM BATTERY 3 67 VDC NICAD BATTERY 5 52 VDC PASSED
PARENTS COMPLAINED THAT THEY FOUND THE APNEA ON W/O AN AUDIBLE
RECD 2 1 99 NO ACC RECD
ALARM DOWNLOAD SHOWED NO VERIFICATION TESTED OK BY HOMECARE
FLUCTUATE TEST NO INFORMATION IN DOWNLOAD NO PROBLEM FOUND
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
TEST AS A PRECAUTION
WITH UNIT PASSED ALL TESTING

001267

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 07/29/1999
Event Type Malfunction **Patient Outcome** Other
Event Description
Nellcor puritan bennett received a call from rep of facility on 7/29/1999 Facility called to report the following problem no heart rate slow alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 81

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 06/01/1997

Manufacturer *(Section F)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441 2625

Manufacturer *(Section D)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441 2625

Manufacturer *(Section G)* NELLCOR PURITAN BENNETT INC
2800 Northwest Blvd
Minneapolis MN 55441 2625

Manufacturer Contact Andrew Radford
2800 Northwest Blvd
Plymouth MN 55441
(612) 694 -3500 ext 3781

Device Event Key 231282

MDR Report Key 238676

Event Key 223919

Report Number 2183157-1999-00192

Device Sequence Number 1

Product Code FLS

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 08/26/1999

1 **Device Was Involved in the Event**

1 **Patient Was Involved in the Event**

Date FDA Received 08/30/1999

Is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	445982-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	08/04/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	07/29/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	12/01/1997
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 480539	8/21/1998

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
UPDATED PER EN 121535 AND ADDED P/N Y 100465 00A S/N 368

Serial Number	Text Date
L 480539	7/23/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
UNIT NOT PICKING UP LOW HR ALARM DURING BENCH TEST WARRANTY

Serial Number	Text Date
L-480539	7/23/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
TITLE PLEASE

Serial Number	Text Date
L-480539	8/10/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
MNTS AND INCOMPLETE

Serial Number	Text Date
L-480539	8/10/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
RECD 8 3-99 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING IN

Serial Number	Text Date
L 480539	8/13/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
TEST AND RETURN? CS

Serial Number	Text Date
L-480539	8/13/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	MONITOR PASSED AUTOMATED FINAL TEST NO PROBLEMS FOUND OK TO

Serial Number	Text Date
L 480539	8/13/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	CALL CUSTOMER OK TO TEST AND RETURN UNDER WARRANTY?

Serial Number	Text Date
L-480539	8/18/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	ADVISED OF TEST RESULTS OK TO RETURN

Serial Number	Text Date
L 480539	8/31/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L-480539	8/31/1999

Trend Code Symptom	Short Text
9055	APN MTR NO HEART RATE SLOW ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 480539	370055	5/27/1998	L 9700A	9103	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	
L 480539	445982	7/23/1999	L 9700A	9055	

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HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phon	Text Seq Numb
5/98 AMI RCL ECG NOISE	MERCY HOME RESPIRATORY	CA	0	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	1
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	2
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	2
APN MTR NO HEART RATE SLOW ALARM	ALLIANCE MEDICAL SERVICE	WR	5152801568	2

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Text Detail
UPDATED PER EN 121535 AND ADDED P/N Y 100465 00A S/N 368
ADVISED OF TEST RESULTS OK TO RETURN
CALL CUSTOMER OK TO TEST AND RETURN UNDER WARRANTY?
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL
MONITOR PASSED AUTOMATED FINAL TEST NO PROBLEMS FOUND OK TO
RECD 8 3 99 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING IN
TITLE PLEASE
UNIT NOT PICKING UP LOW HR ALARM DURING BENCH TEST WARRANTY
MNTS AND INCOMPLETE
TEST AND RETURN? CS
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

001275

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 11/12/1999
Event Type Malfunction **Patient Outcome** Other,
Event Description
Mfr received a call from representative of facility on 11/12/1999 Facility called to report the following problems alarm of service is intermittent

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 82

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	267063
MDR Report Key	275916
Event Key	258702
Report Number	2183157-2000-00122
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	UNKNOWN
Type of Report	Initial
Report Date	04/27/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	04/28/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	Other
Device MODEL Number	9700

OTHER Device ID Number	466834-005
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/21/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	11/12/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	09/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 495063	11/29/1999

Trend Code Symptom	Short Text
512	APN MTR RETURN FO SERVICE

Product Number	Text Seq Numbe
L 9700-S	1

Text Detail
EUROPEAN RGA#-830001 004 RETURN FOR SERVICE.

Serial Number	Text Date
L 495063	12/3/1999

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe
L 9700-S	2

Text Detail
CUSTOMER COMPLAINT DON'T APPEAR TEXTS IN THE SCREEN

Serial Number	Text Date
L-495063	12/3/1999

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe
L 9700-S	1

Text Detail
EURO RETURNS SEE RQST # 830001 004

Serial Number	Text Date
L-495063	12/3/1999

Trend Code Symptom	Short Text
512	APN MTR RETURN FO SERVICE

Product Number	Text Seq Numbe
L 9700-S	1

Text Detail
SEE RQST # 466834-001 THRU 005 FOR EVALUATION AND REPAIRS

Serial Number	Text Date
L-495063	1/20/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe
L 9700-S	2

Text Detail
DUE TO S/N ALREADY IN INVENTORY

Serial Number	Text Date
L-495063	1/20/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe
L 9700-S	1

Text Detail
RECD 12 20 99 W/ CASE PWR CORD PT CABLE UNIT WAS UNRECEIVABLE

Serial Number	Text Date
L 495063	1/28/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe	Text Detail
L 9700-S	2	P/N L-006255-032 LOT #Y26816

Serial Number	Text Date
L-495063	1/28/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	VERIFIED CUSTOMERS COMMENT FOUND C235 TO BE BAD REPLACED C235

Serial Number	Text Date
L 495063	2/1/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe	Text Detail
L 9700-S	2	TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED

Serial Number	Text Date
L 495063	2/1/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	CONFIRMED CUSTOMER STATEMENT REPLACED C235 ON MAIN BOARD

Serial Number	Text Date
L-495063	2/1/2000

Trend Code Symptom	Short Text
9108	APN MTR DISPLAY MALFUNCTION

Product Number	Text Seq Numbe	Text Detail
L 9700-S	3	TO CAB

Serial Number	Text Date
L-495063	9/4/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP RETURN FOR SERVICE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	2	DEN BOSCH NETHERLANDS

Serial Number	Text Date
L-495063	9/4/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP RETURN FOR SERVICE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	RETURN FOR REPAIR RGA # 830033 1 AFTER REPAIR SEND BACK TO MALL

Serial Number	Text Date
L 495063	9/5/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP RETURN FOR SERVICE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	TRANSFERED TO REQUEST 513375-004

Serial Number	Text Date
L 495063	9/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	EURO SERVICE RETURNS TECH SERVICE TO EVALUATE AND REPAIR

Serial Number	Text Date
L 495063	9/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	5	SEE RQST 513155-004

Serial Number	Text Date
L-495063	9/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	4	PLEASE RETURN UNIT TO MALL DEN BOSCH NETHERLANDS

Serial Number	Text Date
L 495063	9/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	3	THERE IS NO TEST (THE TEST DON T APPEAR)BATTERY IS WRONG

Serial Number	Text Date
L 495063	9/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	2	ORIGINAL TEXT

Serial Number	Text Date
L-495063	10/5/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	1	RECD CASE PWR CORD PT CABLE

Serial Number	Text Date
L 495063	10/9/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	2	PER DEVIATION D00-111 10/09/00 MAR

Serial Number	Text Date
L 495063	10/9/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	1	VERIFIED CUSTOMERS COMMENT UNIT WON'T POWER UP WILL BE CORRECTED

Serial Number	Text Date
L 495063	11/2/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	1	FINAL REVIEW BY RC 10/28/00

Serial Number	Text Date
L-495063	11/7/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700-S	2	MAIN CIRCUIT BOARD TO CORRECT THE REPORTED PROBLEM TREND AND

Serial Number	Text Date
L 495063	11/7/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700 S	1	THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED C235 ON THE

Serial Number	Text Date
L-495063	11/7/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number
L 9700-S

Text Seq Numbe
3

Text Detail
REPORT TO CAB

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 495063	465773	11/29/1999	L 9700-S	512	
L 495063	465773	11/29/1999	L 9700 S	512	
L 495063	466834	12/3/1999	L 9700 S	9108	
L 495063	466834	12/3/1999	L 9700-S	9108	
L 495063	466834	12/3/1999	L 9700 S	9108	
L 495063	466834	12/3/1999	L 9700 S	9108	
L 495063	466834	12/3/1999	L 9700 S	9108	
L-495063	466834	12/3/1999	L 9700-S	9108	
L-495063	466834	12/3/1999	L 9700-S	9108	
L 495063	466834	12/3/1999	L 9700 S	9108	
L 495063	466834	12/3/1999	L 9700-S	9108	
L 495063	513155	9/4/2000	L 9700 S	512	
L-495063	513155	9/4/2000	L-9700-S	512	
L 495063	513155	9/4/2000	L 9700 S	512	
L-495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L 495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700-S	4243	
L 495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700-S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L-495063	513375	9/5/2000	L 9700 S	4243	
L 495063	513375	9/5/2000	L 9700 S	4243	

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HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phon	Text Seq Numb
APN MTR RETURN FO SERVICE	NELLCOR PURITAN BENNETT	SR	0	1
APN MTR RETURN FO SERVICE	NELLCOR PURITAN BENNETT	SR	0	1
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR DISPLAY MALFUNCTION	NELLCOR PURITAN BENNETT	WR	0	3
APN MTR DLRTS/CHECK FOR PROPER OP RET	NELLCOR PURITAN BENNETT	SNC	0	1
APN MTR DLRTS/CHECK FOR PROPER OP RET	NELLCOR PURITAN BENNETT	SNC	0	1
APN MTR DLRTS/CHECK FOR PROPER OP RET	NELLCOR PURITAN BENNETT	SNC	0	2
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	1
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	2
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	3
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	3
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	4
APN MTR CALIBRATION TEST FAILURE	NELLCOR PURITAN BENNETT	WR	0	5

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Text Detail
EUROPEAN RGA# 830001 004 RETURN FOR SERVICE
SEE RQST # 466834 001 THRU 005 FOR EVALUATION AND REPAIRS
CONFIRMED CUSTOMER STATEMENT REPLACED C235 ON MAIN BOARD
EURO RETURNS SEE RQST # 830001 004
RECD 12 20 99 W/ CASE, PWR CORD PT CABLE UNIT WAS UNRECEIVABLE
VERIFIED CUSTOMERS COMMENT FOUND C235 TO BE BAD REPLACED C235
CUSTOMER COMPLAINT DON T APPEAR TEXTS IN THE SCREEN
DUE TO S/N ALREADY IN INVENTORY
P/N L 006255 032 LOT #Y26816
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED
TO CAB
TRANSFERED TO REQUEST 513375 004
RETURN FOR REPAIR RGA # 830033 1 AFTER REPAIR SEND BACK TO MALL
DEN BOSCH NETHERLANDS
EURO SERVICE RETURNS TECH SERVICE TO EVALUATE AND REPAIR
FINAL REVIEW BY RC 10/28/00
RECD CASE PWR CORD PT CABLE
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED C235 ON THE
VERIFIED CUSTOMERS COMMENT UNIT WON T POWER UP WILL BE CORRECTED
MAIN CIRCUIT BOARD TO CORRECT THE REPORTED PROBLEM TREND AND
ORIGINAL TEXT
PER DEVIATION D00 111 10/09/00 MAR
THERE IS NO TEST (THE TEST DON T APPEAR)BATTERY IS WRONG
REPORT TO CAB
PLEASE RETURN UNIT TO MALL DEN BOSCH NETHERLANDS
SEE RQST 513155 004

001286

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700

Event Type Malfunction **Patient Outcome** Other,

Event Description

Nellcor puritan bennett received a call from a representative on 11/29/1999 Representative called to report the following problem patient turned blue while on monitor Parent stated unit did not alarm

Manufacturer Narrative

Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 83

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	249098
MDR Report Key	257231
Event Key	241101
Report Number	2183157-1999-00319
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	12/29/1999

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	12/30/1999
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700

OTHER Device ID Number	464315-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/01/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	11/29/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	12/01/1997
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-480565	9/23/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
REWORKED PER EN 121535 AND ADDED P/N Y 100465-00A S/N 993

Serial Number	Text Date
L 480565	2/4/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
507	APN MTR ADMINISTRATIVE RETURN

Text Detail
UNIT TO BE RETURNED FOR CREDIT

Serial Number	Text Date
L 480565	2/16/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
507	APN MTR ADMINISTRATIVE RETURN

Text Detail
PASSED ALL TESTING CAS 2/12/99 POOL

Serial Number	Text Date
L-480565	11/30/1999

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
UNIT DID NOT ALARM FIRST MONITOR 10-22

Serial Number	Text Date
L-480565	11/30/1999

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
PATIENT MATHEW RUCKERS WENT BLUE WHILE ON MONITOR PARENT STATED

Serial Number	Text Date
L-480565	12/1/1999

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
INCOMPLETE AND THEN IN MNPR

Serial Number	Text Date
L-480565	12/1/1999

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
RECD 11 24-99 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING

Serial Number	Text Date
L 480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	4

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
AND RETURN PER STEVE ELLIOTT

Serial Number	Text Date
L-480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
48 HOURS UNIT PASSED ALL TESTING OK TO TEST UNDER WARRANTY

Serial Number	Text Date
L-480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
HOURS IN APNEA CONDITION UNIT PICKED UP APNEA ALARM FOR FULL

Serial Number	Text Date
L 480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
UNABLE TO VERIFY UNIT NOT ALARMING FOR APNEA RAN UNIT FOR 48

Serial Number	Text Date
L 480565	12/30/1999

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 480565	370068	5/27/1998	L 9700A	9103	
L-480565	414076	2/4/1999	L 9700A	507	
L-480565	414076	2/4/1999	L 9700A	507	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	
L-480565	464315	11/29/1999	L REF9700A	9053	
L 480565	464315	11/29/1999	L REF9700A	9053	

001292

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
5/98 AMI RCL ECG NOISE	PROFESSIONAL HOME HEALTH	CA	0	1
APN MTR ADMINISTRATIVE RETURN	PROFESSIONAL HOME HEALTH	WC	7858254400	1
APN MTR ADMINISTRATIVE RETURN	PROFESSIONAL HOME HEALTH	WC	7858254400	1
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	1
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	1
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	1
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	1
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	2
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	2
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	2
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	2
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	3
APN MTR NO APNEA ALARM	AHR MEDICAL REPS	WR	8034346392	4

001293

Text Detail
REWORKED PER EN 121535 AND ADDED P/N Y 100465 00A S/N 993
PASSED ALL TESTING CAS 2/12/99 POOL
UNIT TO BE RETURNED FOR CREDIT
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL
PATIENT MATHEW RUCKERS WENT BLUE WHILE ON MONITOR PARENT STATED
RECD 11 24 99 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING
UNABLE TO VERIFY UNIT NOT ALARMING FOR APNEA RAN UNIT FOR 48
HOURS IN APNEA CONDITION UNIT PICKED UP APNEA ALARM FOR FULL
INCOMPLETE AND THEN IN MNPR
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
UNIT DID NOT ALARM FIRST MONITOR 10-22
48 HOURS UNIT PASSED ALL TESTING OK TO TEST UNDER WARRANTY
AND RETURN PER STEVE ELLIOTT

001294

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 12/02/1999
Event Type Malfunction **Patient Outcome** Other
Event Description
Nellcor puritan bennett received a call from a representative of user facility on 12/02/1999 User facility called to report the following problems no loose lead alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 85

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	249785
MDR Report Key	257947
Event Key	241765
Report Number	2183157-2000-00001
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	01/03/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	01/04/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	466537-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/07/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	12/02/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	11/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-481844	12/8/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
INVENTORY

Serial Number	Text Date
L 481844	12/8/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
RECD 12 7 99 NO ACC UNIT WAS UNRECEIVABLE DUE TO S/N ALREADY IN

Serial Number	Text Date
L 481844	12/13/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
PATIENT CABLE CONNECTOR BROKEN CUSTOMER OPEN UP MONITOR TO TRY

Serial Number	Text Date
L 481844	12/13/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
TO FEX IT

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
REPLACED AND THE UNIT RETURNED TO HIM WITH CONVERSATION WITH

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CUSTOMER DOES NOT WANT THE BOARDS REPLACED BUT WANTS THE PC JACK

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CUSTOMER WILL BE CHARGED $100 00 FOR TESTING AND REPLACEMENT OF

Serial Number	Text Date
L-481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
VERIFIED PIN FROM PATIENT CABLE STUCK INSIDE PC JACK UNIT WILL

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
PC JACK

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
RANDY HOYT TECH SUPPORT MANAGER IT WAS DECIDED THE CUSTOMER

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
SPOKE WITH AL ON 12/16/99 AND GAVE HIM AN ESTIMATE OF OF $650 00

Serial Number	Text Date
L-481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
FOR REPLACEMENT OF MAIN CKT BOARD AND MODEM BOARD HE STATED HE

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
WILL ASSUME ALL LIABILITY FOR THE MONITOR SEE LETTER MAILED TO

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CUSTOMER FILED WITH THE HARD COPY OF REQUEST

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
WILL CALL BACK WITH AN ANSWER

Serial Number	Text Date
L 481844	12/22/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
BE PROCESSED AS AN OPEN UNIT LEFT MESSAGE FOR AL ON 12/15/99

Serial Number	Text Date
L 481844	12/30/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CORRECT THE REPORTED PROBLEM TREND AND REPORT TO CAB

Serial Number	Text Date
L 481844	12/30/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED PC JACK TO

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 481844	466537	12/2/1999	L-9700A	9057	
L-481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L-481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L-481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L-9700A	9057	
L 481844	466537	12/2/1999	L-9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	
L 481844	466537	12/2/1999	L 9700A	9057	

001301

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	3
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	3
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	4
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	4
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	5
APN MTR NO LEAD ALARM	RESPIRATORY THERAPY	SR	8008244127	5

001302

Text Detail
CUSTOMER DOES NOT WANT THE BOARDS REPLACED BUT WANTS THE PC JACK
CUSTOMER WILL BE CHARGED $100 00 FOR TESTING AND REPLACEMENT OF
PATIENT CABLE CONNECTOR BROKEN CUSTOMER OPEN UP MONITOR TO TRY
RECD 12 7 99 NO ACC UNIT WAS UNRECEIVABLE DUE TO S/N ALREADY IN
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED PC JACK TO
VERIFIED PIN FROM PATIENT CABLE STUCK INSIDE PC JACK UNIT WILL
BE PROCESSED AS AN OPEN UNIT LEFT MESSAGE FOR AL ON 12/15/99
CORRECT THE REPORTED PROBLEM TREND AND REPORT TO CAB
INVENTORY
PC JACK
REPLACED AND THE UNIT RETURNED TO HIM WITH CONVERSATION WITH
TO FEX IT
RANDY HOYT TECH SUPPORT MANAGER IT WAS DECIDED THE CUSTOMER
SPOKE WITH AL ON 12/16/99 AND GAVE HIM AN ESTIMATE OF OF $650 00
FOR REPLACEMENT OF MAIN CKT BOARD AND MODEM BOARD HE STATED HE
WILL ASSUME ALL LIABILITY FOR THE MONITOR SEE LETTER MAILED TO
CUSTOMER FILED WITH THE HARD COPY OF REQUEST
WILL CALL BACK WITH AN ANSWER

001303

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 12/02/1999
Event Type Malfunction **Patient Outcome** Other
Event Description
Nellcor puritan bennett received a call from a representative on 12/02/1999 Representative called to report the following problem no lead alarm Pt cable connector broken inside pt cable jack Customers opened unit to try to fix it

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT P4

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	249111
MDR Report Key	257244
Event Key	241114
Report Number	2183157 1999-00328
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	12/29/1999

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	12/30/1999
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	466537-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	12/08/1999
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	12/02/1999
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	12/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 481693	12/7/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM, FAILED TO

Text Detail
NO ACC

Serial Number	Text Date
L 481693	12/13/1999

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail

Serial Number	Text Date
L-481693	12/13/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail

Serial Number	Text Date
L 481693	12/13/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
NO LOOSE LEAD ALARM

Serial Number	Text Date
L 481693	12/29/1999

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CORRECT NO LOOSE LEAD ALARM FAILURE

Serial Number	Text Date
L-481693	12/29/1999

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MAIN CKT BOARD S/N BAA02213 AND REPLACED WITH S/N BAA03835 TO

Serial Number	Text Date
L 481693	12/29/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
AND HEARTBEAT UNABLE TO VERIFY TO COMPONENT LEVEL SCRAPPED

Serial Number	Text Date
L 481693	12/29/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
VERIFIED NO LOOSE LEAD ALARM MONITOR CONTINUES TO DETECT RESP

Serial Number	Text Date
L 481693	1/27/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
TROUBLESHOOT DOWN TO COMPONENT LEVEL TREND AND REPORT TO CAB

Serial Number	Text Date
L-481693	1/27/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CIRCUIT BOARD TO CORRECT THE REPORTED PROBLEM UNABLE TO

Serial Number	Text Date
L 481693	1/27/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED PLACED MAIN

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L-481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L 481693	466537	12/2/1999	L 9700A	4201	
L-481693	466537	12/2/1999	L 9700A	4201	

001309

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	1
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	2
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	3
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	3
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	3
APN MTR ALARM FAILED TO	RESPIRATORY THERAPY	SR	8008244127	4

001310

Text Detail
NO ACC
NO LOOSE LEAD ALARM
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACED PLACED MAIN
VERIFIED NO LOOSE LEAD ALARM MONITOR CONTINUES TO DETECT RESP
AND HEARTBEAT UNABLE TO VERIFY TO COMPONENT LEVEL SCRAPPED
CIRCUIT BOARD TO CORRECT THE REPORTED PROBLEM UNABLE TO
MAIN CKT BOARD S/N BAA02213 AND REPLACED WITH S/N BAA03835 TO
TROUBLESHOOT DOWN TO COMPONENT LEVEL TREND AND REPORT TO CAB
CORRECT NO LOOSE LEAD ALARM FAILURE

001311

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 03/24/2000
Event Type Malfunction **Patient Outcome** Other
Manufacturer Narrative
Na

Event Description
Nellcor puritan bennett rec d a call from a representative of the user facility on 03/24/2000 User facility called to report the following problem no loose lead alarm

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 86

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	267182
MDR Report Key	276043
Event Key	258819
Report Number	2183157-2000-00121
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial Followup
Report Date	04/14/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	04/27/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	485480-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	03/29/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	03/24/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	12/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-481615	3/24/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
NO LOOSE LEAD ALARM FLAT RATE 100 00

Serial Number	Text Date
L-481615	3/29/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
NO ACC

Serial Number	Text Date
L 481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	7

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
5 2-00

Serial Number	Text Date
L 481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	6

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CORRECT NO LOOSE LEAD ALARM FAILURE REPLACED BATTERY CT

Serial Number	Text Date
L-481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
REPLACED MAIN CIRCUIT BOARD S/N BAA01575 WITH S/N BAE00489 TO

Serial Number	Text Date
L-481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
OF $450 00 APPROVED PER JOHN FOR MAIN CIRCUIT BOARD REPLACEMENT

Serial Number	Text Date
L 481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
TO COMPONENT LEVEL MAIN CIRCUIT BOARD TO BE REPLACED ESTIMATE

Serial Number	Text Date
L-481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CONTINUES TO DETECT RESP AND HEARTRATE UNABLE TO TROUBLESHOOT

Serial Number	Text Date
L 481615	5/2/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
VERIFIED NO LOOSE LEAD ALARM WITH PATIENT CABLE DISCONNECTED

Serial Number	Text Date
L 481615	6/14/2000

Product Number	Text Seq Numbe
L-9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
THE REPORTED PROBLEM TREND AND REPORT TO CAB

Serial Number	Text Date
L-481615	6/14/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
BOARD (UNABLE TO TROUBLE SHOOT TO COMPONENT LEVEL) TO CORRECT

Serial Number	Text Date
L-481615	6/14/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACE MAIN CIRCUIT

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L-481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L-481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L-481615	485480	3/24/2000	L 9700A	9057	
L-481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	
L 481615	485480	3/24/2000	L 9700A	9057	

001317

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	1
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	1
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	1
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	1
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	2
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	2
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	3
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	3
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	4
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	5
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	6
APN MTR NO LEAD ALARM	LIFE HOME HEALTHCARE SERV	SR	4129205433	7

001318

Text Detail
NO ACC
NO LOOSE LEAD ALARM FLAT RATE 100 00
THE CUSTOMERS STATEMENT WAS CONFIRMED REPLACE MAIN CIRCUIT
VERIFIED NO LOOSE LEAD ALARM WITH PATIENT CABLE DISCONNECTED
BOARD (UNABLE TO TROUBLE SHOOT TO COMPONENT LEVEL) TO CORRECT
CONTINUES TO DETECT RESP AND HEARTRATE UNABLE TO TROUBLESHOOT
THE REPORTED PROBLEM TREND AND REPORT TO CAB
TO COMPONENT LEVEL MAIN CIRCUIT BOARD TO BE REPLACED ESTIMATE
OF $450 00 APPROVED PER JOHN FOR MAIN CIRCUIT BOARD REPLACEMENT
REPLACED MAIN CIRCUIT BOARD S/N BAA01575 WITH S/N BAE00489 TO
CORRECT NO LOOSE LEAD ALARM FAILURE REPLACED BATTERY CT
5 2 00

001319

Adverse Event Report

NELLCOR PURITAN BENNETT LP10 VOLUME VENTILATOR

back to search results

Model Number 9700
Event Date 04/10/2000
Event Type Malfunction **Patient Outcome** Other

Event Description
Nellcor puritan bennett received a call from a rep of facility on 4/10/2000 Facility called to report the following problem no alarm for apnea

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	LP10 VOLUME VENTILATOR
Type of Device	VOLUME VENTILATOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No

EXHIBIT 87

Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth , MN 55441 (612) 694 -3500
Device Event Key	269104
MDR Report Key	278015
Event Key	260714
Report Number	2183157-2000-00140
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial Followup
Report Date	05/08/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	05/10/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700
OTHER Device ID Number	488117-001

Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	04/18/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	04/10/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	11/01/1999
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

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DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-482994	4/10/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
SETTINGS NO PATIENT HARM REPORTED

Serial Number	Text Date
L 482994	4/10/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
ALARMS REPORT SHOWS APNEAS OCCURING THAT MATCH ALARM NOT LOG

Serial Number	Text Date
L 482994	4/10/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
VERIFYING IN HOUSE DEALER WAS RESPONDING TO MEMORY FULL LED W/O

Serial Number	Text Date
L-482994	4/10/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
NO ALARM FOR APNEA AMI SET AT 20 SIMULATOR SET AT 25? WHEN

Serial Number	Text Date
L-482994	4/18/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
RECD 4-17 00 W/ DISK

Serial Number	Text Date
L-482994	6/30/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
FOR RETURN

Serial Number	Text Date
L 482994	6/30/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
CONSECUTIVE TIMES WITH NO PROBLEMS COULD NOT DUPLICATE REASON

Serial Number	Text Date
L 482994	6/30/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
RAN WITH MONITOR SETTINGS AT 20 AND SIMULATOR AT 25 FOR TEN

Serial Number	Text Date
L 482994	7/6/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
LEFT MESSAGE WITH DARREL.

Serial Number	Text Date
L 482994	7/10/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
UPDATED PER DEV DOO-111

Serial Number	Text Date
L 482994	7/10/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
SPOKE WITH DARREL HE INDICATED IT WAS OK TO RETURN MONITOR

Serial Number	Text Date
L-482994	8/14/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 482994	8/14/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 05/11/2000
Event Type Malfunction **Patient Outcome** Other,
Event Description
Nellcor puntan bennett received a call from rep of the user facility on 05/11 The rep called to report the following problem no audible alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 90

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth , MN 55441 (612) 694 -3500
Device Event Key	274416
MDR Report Key	283575
Event Key	266001
Report Number	2183157-2000-00197
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	06/21/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	06/21/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700

OTHER Device ID Number	492916-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	05/18/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	05/11/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	08/01/1999
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-482765	12/22/1999

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
SUPER GLUE PATIENT CABLE PLEASE CHECK AND CALL WITH ESTIMATE

Serial Number	Text Date
L 482765	12/22/1999

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
PATIENTS MOTHER TRIPPED OVER PATIENT CABLE AND THEN TRIED TO

Serial Number	Text Date
L-482765	1/4/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
LOANER/RENTAL RETURN

Serial Number	Text Date
L-482765	1/26/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
SCRAPPED GLUE OFF OF CASE AND REPLACED BROKEN PC JACK UNIT

Serial Number	Text Date
L 482765	1/26/2000

Trend Code Symptom	Short Text
512	APN MTR DLRTS/CHECK FOR PROPER OP

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
WILL GO INTO POOL INVENTORY

Serial Number	Text Date
L 482765	5/10/2000

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Product Number	Text Seq Numbe
L REF9700A	2

Text Detail

Serial Number	Text Date
L 482765	5/10/2000

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Product Number	Text Seq Numbe
L REF9700A	1

Text Detail
NO AUDIBLE ALARM

Serial Number	Text Date
L 482765	5/18/2000

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
LOANER NEEDS TO GO IN LOANER POOL

Serial Number	Text Date
L 482765	7/5/2000

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MARY RAYMOND FOR HER RECORDS

Serial Number	Text Date
L-482765	7/5/2000

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MARY WOULD LIKE TO KNOW IF YOU FOUND ANYTHING WRONG PLEASE CALL

Serial Number	Text Date
L-482765	7/20/2000

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
LEFT MESSAGE WITH MARY THAT THE CLAIM OF NO AUDIBLE ALARM COULD

Serial Number	Text Date
L-482765	7/20/2000

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
NOT BE DUPLICATED SEVERAL EVENTS WERE SIMLULATED AND THE

Serial Number	Text Date
L 482765	7/20/2000

Product Number	Text Seq Numbe
L REF9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MONITOR ALARMED EVERY TIME

Serial Number	Text Date
L-482765	10/6/2000

Product Number	Text Seq Numbe
L REF9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
REPLACED BATTERY UPDATED PER DEVIATION D00 111

Serial Number	Text Date
L 482765	10/9/2000

Product Number	Text Seq Numbe
L REF9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L-482765	10/9/2000

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Product Number	Text Seq Numbe
L REF9700A	1

Text Detail
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 482765	469806	12/22/1999	L 9700A	512	
L 482765	469806	12/22/1999	L 9700A	512	
L 482765	469806	12/22/1999	L 9700A	512	
L 482765	469806	12/22/1999	L 9700A	512	
L 482765	469806	12/22/1999	L 9700A	512	
L 482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L-482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L-482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L-482765	492916	5/10/2000	L REF9700A	4201	
L 482765	492916	5/10/2000	L REF9700A	4201	
L-482765	492916	5/10/2000	L REF9700A	4201	

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Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR DLRTS/CHECK FOR PROPER OP	SLEEP DIAGNOSTIC CENTERS	L	9126911300	1
APN MTR DLRTS/CHECK FOR PROPER OP	SLEEP DIAGNOSTIC CENTERS	L	9126911300	1
APN MTR DLRTS/CHECK FOR PROPER OP	SLEEP DIAGNOSTIC CENTERS	L	9126911300	1
APN MTR DLRTS/CHECK FOR PROPER OP	SLEEP DIAGNOSTIC CENTERS	L	9126911300	2
APN MTR DLRTS/CHECK FOR PROPER OP	SLEEP DIAGNOSTIC CENTERS	L	9126911300	2
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	1
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	2
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	2
APN MTR ALARM FAILED TO	ARY RAYMOND	L	9017632260	2
APN MTR ALARM, FAILED TO	ARY RAYMOND	L	9017632260	2
APN MTR ALARM, FAILED TO	ARY RAYMOND	L	9017632260	3

001332

Text Detail
LOANER/RENTAL RETURN
PATIENTS MOTHER TRIPPED OVER PATIENT CABLE AND THEN TRIED TO
SCRAPPED GLUE OFF OF CASE AND REPLACED BROKEN PC JACK UNIT
SUPER GLUE PATIENT CABLE PLEASE CHECK AND CALL WITH ESTIMATE
WILL GO INTO POOL INVENTORY
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO
LEFT MESSAGE WITH MARY THAT THE CLAIM OF NO AUDIBLE ALARM COULD
LOANER NEEDS TO GO IN LOANER POOL
MARY WOULD LIKE TO KNOW IF YOU FOUND ANYTHING WRONG PLEASE CALL
NO AUDIBLE ALARM
REPLACED BATTERY UPDATED PER DEVIATION D00 111
FURTHER CORRECTIVE ACTION
MARY RAYMOND FOR HER RECORDS
NOT BE DUPLICATED SEVERAL EVENTS WERE SIMLULATED AND THE
MONITOR ALARMED EVERY TIME

001333

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 06/26/2000
Event Type Malfunction **Patient Outcome** Other,
Event Description
Nellcor puritan bennett received a call from representative of the user facility on 06/26 The user facility called to report the following problem audible alarm turns off when unit is touched/moved

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 91

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	277158
MDR Report Key	286418
Event Key	268713
Report Number	2183157-2000-00228
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	07/17/2000

***1* Device Was Involved In the Event**

***1* Patient Was Involved in the Event**

Date FDA Received	07/17/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	501231-002
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/30/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	06/26/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	01/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-480766	11/16/1998

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
RECD 10-30-98

Serial Number	Text Date
L 480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	8

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
SERVICE ALARM WHEN POSITIONED CORRECTLY MONITOR FUNCTIONS

Serial Number	Text Date
L 480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	7

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
UP CYCLE GASKETS FOR ALARMS WAS IN WRONG POSITION CREATING

Serial Number	Text Date
L-480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	6

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
BURN IN 1/19 6 30 AM REJECT F/T SERVICE LED FOLLOWING POWER

Serial Number	Text Date
L 480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
SERVICE LED TRIED 2 TIMES AT BURN IN BI ON 1/15 ' 00 PM OFF

Serial Number	Text Date
L-480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
PART# Y 006118-00A LOT# NCR30869 BI ON 12/28/98 7 45 AM REJECT

Serial Number	Text Date
L 480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
WITH NEW BOARD S/N BAA02579 TO CORRECT SERVICE LED FAILURE

Serial Number	Text Date
L 480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
REJ 1 SEC SERVICE LED ON POWER UP REPLACED BOARD S/N BAA00924

Serial Number	Text Date
L-480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
UPDATED PE REN 1215335 AND ADDED P/N Y 100465-00A S/N 1836 I/P

Serial Number	Text Date
L-480766	2/4/1999

Product Number	Text Seq Numbe
L 9700A	9

Trend Code Symptom	Short Text
9103	5/98 AMI RCL ECG NOISE

Text Detail
CORRECTLY

Serial Number	Text Date
L-480766	3/10/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Text Detail
FLASHING SERVICE ALARM TIME & DATE WERE SCRAMBLED TRIED

Serial Number	Text Date
L 480766	3/10/1999

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Text Detail
CLEARING MEMORY NOT BLOCKING ALARMS

Serial Number	Text Date
L 480766	3/12/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Text Detail
NO ACC RECD

Serial Number	Text Date
L 480766	3/15/1999

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Text Detail
UNIT GETTING SERVICE LIGHTS OFTEN DIRECTED BONNIE TO DOWNLOAD

Serial Number	Text Date
L 480766	3/15/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TO SEE WHY IT KEEPS GETTING THE LIGHTS, SHE SAID SHE D SPOKEN TO

Serial Number	Text Date
L 480766	3/15/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	SUSAN ABOUT THIS PREVIOUSLY

Serial Number	Text Date
L 480766	4/7/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	DOWNLOAD STATES LITHIUM BATTERY LOW BATTERY VOLTAGE APPROX 5 0

Serial Number	Text Date
L 480766	4/7/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	VDC AT ARRIVAL BATTERY WILL BE CHARGED AND MONITOR RUN FOR 24

Serial Number	Text Date
L-480766	4/7/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	HOURS LITHIUM BATTERY CHARGED TO 5 48 VDC NO PROBLEMS FOUND

Serial Number	Text Date
L-480766	4/7/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	WITH MONITOR

Serial Number	Text Date
L 480766	4/9/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TEST AND VERIFIED OPERATION RECHARGED LITHIUM BATTERY NO

Serial Number	Text Date
L-480766	4/9/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L-480766	4/9/1999

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	COULD NOT REPRODUCE CUSTOMER COMPLAINT AT OUR LOCATION FINAL

Serial Number	Text Date
L-480766	6/8/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	FLASHING SERVICE LED NO OTHER INFO

Serial Number	Text Date
L 480766	6/15/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	NO ACC

Serial Number	Text Date
L 480766	6/29/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	BE CHARGED AND VOLTAGE CHECKED TO ENSURE PROPER LEVEL. MONITOR

Serial Number	Text Date
L 480766	6/29/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	WILL RUN FOR 48 HOURS TO ENSURE PROPER OPERATION

Serial Number	Text Date
L 480766	6/29/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	DOWNLOADING APPEARS TO BE A LOW BATTERY SITUATION BATTERY WILL

Serial Number	Text Date
L-480766	6/29/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	CALL CUSTOMER OK TO TEST AND RETURN?

Serial Number	Text Date
L-480766	6/29/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	BATTERY LOW ALARM AND SERVICE ALARM SCRAMBLED DATA WITH

Serial Number	Text Date
L-480766	7/2/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	BATTERIES PASS RUN DOWN TESTING

Serial Number	Text Date
L 480766	7/2/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	ADVISED BONNIE OF TEST RESULTS OK TO RETURN AS LONG AS

Serial Number	Text Date
L 480766	7/9/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	CUSTOMER

Serial Number	Text Date
L 480766	7/9/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	FURTHER CORRECTIVE ACTION RECHARGED BATTERY AND RETURNED TO

Serial Number	Text Date
L-480766	7/9/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO

Serial Number	Text Date
L 480766	8/16/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	REQUEST WILL BE CLOSED DUE TO AGE WDP X3633

Serial Number	Text Date
L 480766	8/16/1999

Trend Code Symptom	Short Text
4200	APN MTR ALARM ON CONSTANTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	CANNOT VERIFY THIS PART HAS BEEN RECEIVED OR REPAIRED THIS

Serial Number	Text Date
L-480766	6/26/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	AUDIBLE ALARM TURNS OFF WHEN UNIT IS TOUCHED/MOVED

Serial Number	Text Date
L 480766	6/30/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	NO ACC

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	UNABLE TO VERIFY AUDIBLE ALARM TURNING OFF WHEN UNIT IS TOUCHED

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	OR MOVED UNIT DID HAVE FLASHING SERVICE LED DUE TO LOW LITHIUM

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	BATTERY VOLTAGE SPOKE WITH CARY SYCKS ON 7 11 00 HE OK D

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	RECERTIFICATION ON UNIT FOR $150 00 REPLACED BATTERY TO

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	5	CORRECT FLASHING SERVICE LED UNIT UPDATED PER DEVIATION

Serial Number	Text Date
L 480766	7/11/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	6	D00-111 CT 7 11-00

Serial Number	Text Date
L 480766	7/14/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	FINAL REVIEW BY CAS 7/14/00

Serial Number	Text Date
L 480766	7/17/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

Serial Number	Text Date
L-480766	7/17/2000

Trend Code Symptom	Short Text
4202	APN MTR ALARM ON INTERMITTENTLY

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L-480766	11/27/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
RECERT FLAT RATE 150 00

Serial Number	Text Date
L-480766	12/7/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
NO ACC

Serial Number	Text Date
L 480766	1/12/2001

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
PERFORMED RECERT REPLACED BATTERY ALSO UPDATED PER DEVIATION

Serial Number	Text Date
L 480766	1/12/2001

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
THIS PRODUCT LINE WAS SOLD TO CAS MEDICAL BRANFORD CT

Serial Number	Text Date
L-480766	1/12/2001

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
COMPLAINT HANDLING AND INVESTIGATION WILL BE PERFORMED AT THEIR

Serial Number	Text Date
L 480766	1/12/2001

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
D00-111 DEH 12 13-00 FINAL REVIEW BY MR 01/11/01

Serial Number	Text Date
L 480766	1/12/2001

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9094	APN MTR RECERTIFICATION

Text Detail
LOCATION

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L-480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L-480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	370063	11/2/1998	L 9700A	9103	
L 480766	420946	3/10/1999	L 9700A	4200	
L-480766	420946	3/10/1999	L 9700A	4200	
L 480766	420946	3/10/1999	L 9700A	4200	
L 480766	420946	3/10/1999	L 9700A	4200	
L 480766	420946	3/10/1999	L 9700A	4200	
L-480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L-480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L 480766	421035	3/10/1999	L 9700A	4202	
L-480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	

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Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	1
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	1
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	2
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	3
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	4
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	5
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	6
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	7
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	8
5/98 AMI RCL ECG NOISE	NORTHWEST MEDICAL	CA	0	9
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075630073	3
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	1
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	2
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	3
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	3
APN MTR ALARM ON INTERMITTENTLY	NORTHWEST MEDICAL	WR	9075630073	4
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	1
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	2
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	2

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Text Detail
RECD 10-30-98
UPDATED PE REN 1215335 AND ADDED P/N Y 100465 00A S/N 1836 I/P
REJ 1 SEC SERVICE LED ON POWER UP REPLACED BOARD S/N BAA00924
WITH NEW BOARD S/N BAA02579 TO CORRECT SERVICE LED FAILURE
PART# Y 006118 00A LOT# NCR30869 BI ON 12/28/98 7 45 AM REJECT
SERVICE LED TRIED 2 TIMES AT BURN IN BI ON 1/15 1 00 PM OFF
BURN IN 1/19 6 30 AM REJECT F/T SERVICE LED FOLLOWING POWER
UP CYCLE GASKETS FOR ALARMS WAS IN WRONG POSITION CREATING
SERVICE ALARM WHEN POSITIONED CORRECTLY MONITOR FUNCTIONS
CORRECTLY
CANNOT VERIFY THIS PART HAS BEEN RECEIVED OR REPAIRED THIS
UNIT GETTING SERVICE LIGHTS OFTEN DIRECTED BONNIE TO DOWNLOAD
REQUEST WILL BE CLOSED DUE TO AGE WDP X3633
TO SEE WHY IT KEEPS GETTING THE LIGHTS SHE SAID SHE'D SPOKEN TO
SUSAN ABOUT THIS PREVIOUSLY
COULD NOT REPRODUCE CUSTOMER COMPLAINT AT OUR LOCATION FINAL
DOWNLOAD STATES LITHIUM BATTERY LOW BATTERY VOLTAGE APPROX 5 0
FLASHING SERVICE ALARM TIME & DATE WERE SCRAMBLED TRIED
NO ACC RECD
CLEARING MEMORY, NOT BLOCKING ALARMS
TEST AND VERIFIED OPERATION RECHARGED LITHIUM BATTERY NO
VDC AT ARRIVAL BATTERY WILL BE CHARGED AND MONITOR RUN FOR 24
FURTHER CORRECTIVE ACTION
HOURS LITHIUM BATTERY CHARGED TO 5 48 VDC NO PROBLEMS FOUND
WITH MONITOR
ADVISED BONNIE OF TEST RESULTS OK TO RETURN AS LONG AS
BATTERY LOW ALARM AND SERVICE ALARM SCRAMBLED DATA WITH
CALL CUSTOMER OK TO TEST AND RETURN?
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO
FLASHING SERVICE LED NO OTHER INFO
NO ACC
BATTERIES PASS RUN DOWN TESTING
DOWNLOADING APPEARS TO BE A LOW BATTERY SITUATION BATTERY WILL

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HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L 480766	438766	6/8/1999	L 9700A	4200	
L-480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L-480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L-480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	501231	6/26/2000	L 9700A	4202	
L 480766	526173	11/27/2000	L 9700A	9094	
L 480766	526173	11/27/2000	L 9700A	9094	
L-480766	526173	11/27/2000	L 9700A	9094	
L-480766	526173	11/27/2000	L 9700A	9094	
L-480766	526173	11/27/2000	L 9700A	9094	
L 480766	526173	11/27/2000	L 9700A	9094	
L 480766	526173	11/27/2000	L 9700A	9094	

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Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	2
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	3
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	3
APN MTR ALARM ON CONSTANTLY	NORTHWEST MEDICAL	WR	9075626710	4
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	2
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	2
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	3
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	4
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	5
APN MTR ALARM ON INTERMITTENTLY	PROCARE HOME MEDICAL INC	SR	9072740770	6
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	1
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	1
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	1
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	1
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	2
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	2
APN MTR RECERTIFICATION	PROCARE HOME MEDICAL INC	PM	9072740770	3

001349

Text Detail
FURTHER CORRECTIVE ACTION RECHARGED BATTERY AND RETURNED TO
BE CHARGED AND VOLTAGE CHECKED TO ENSURE PROPER LEVEL MONITOR
CUSTOMER
WILL RUN FOR 48 HOURS TO ENSURE PROPER OPERATION
AUDIBLE ALARM TURNS OFF WHEN UNIT IS TOUCHED/MOVED
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL
FINAL REVIEW BY CAS 7/14/00
NO ACC
UNABLE TO VERIFY AUDIBLE ALARM TURNING OFF WHEN UNIT IS TOUCHED
OR MOVED UNIT DID HAVE FLASHING SERVICE LED DUE TO LOW LITHIUM
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
BATTERY VOLTAGE SPOKE WITH CARY SYCKS ON 7 11 00 HE OK'D
RECERTIFICATION ON UNIT FOR $150 00 REPLACED BATTERY TO
CORRECT FLASHING SERVICE LED UNIT UPDATED PER DEVIATION
D00-111 CT 7 11 00
NO ACC
PERFORMED RECERT REPLACED BATTERY ALSO UPDATED PER DEVIATION
RECERT FLAT RATE 150 00
THIS PRODUCT LINE WAS SOLD TO CAS MEDICAL BRANFORD CT
COMPLAINT HANDLING AND INVESTIGATION WILL BE PERFORMED AT THEIR
D00-111 DEH 12 13 00 FINAL REVIEW BY MR 01/11/01
LOCATION

001350

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 06/30/2000
Event Type Malfunction **Patient Outcome** Other,
Event Description
Nellcor puritan bennett received a call from rep of the user facility on 6/30 User facility called to report the following problem unit will not alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained In Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 92

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Minneapolis MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	279297
MDR Report Key	288608
Event Key	270822
Report Number	2183157-2000-00233
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	07/28/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	08/01/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700

OTHER Device ID Number	502238-003
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	07/12/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	06/30/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	02/01/2000
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-483418	7/3/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
UNIT WILL NOT ALARM RECERT IF NEEDED OK FOR $150

Serial Number	Text Date
L 483418	7/12/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
NO ACC

Serial Number	Text Date
L-483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
7 26-00 CT

Serial Number	Text Date
L-483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
DETECTING VARIOUS ALARMS LEFT MESSAGE FOR SOPHIA GRIMM ON

Serial Number	Text Date
L-483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
PER DEVIATION D00 111 CT 7 26-00

Serial Number	Text Date
L-483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
ANY ALARMS NOT BEING HEARD RAN UNIT FOR 48 HOURS WITH MONITOR

Serial Number	Text Date
L 483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
OK TO TEST AND RETURN MONITOR PER SOPHIA GRIMM UNIT UPDATED

Serial Number	Text Date
L-483418	7/26/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
COULD NOT VERIFY UNIT WILL NOT ALARM DOWNLOAD DOES NOT STATE

Serial Number	Text Date
L 483418	7/27/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
FINAL REVIEW BY CAS 7/27/00

Serial Number	Text Date
L 483418	7/31/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L-483418	7/31/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9058	APN MTR NO MONITOR ALARM

Text Detail
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	
L-483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L-9700A	9058	
L-483418	502238	6/30/2000	L 9700A	9058	
L 483418	502238	6/30/2000	L 9700A	9058	

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HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	1
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	2
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	2
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	2
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	3
APN MTR NO MONITOR ALARM	VNA HOME MEDICAL EQUIPME	WR	3024522932	4

001357

Text Detail
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL
COULD NOT VERIFY UNIT WILL NOT ALARM DOWNLOAD DOES NOT STATE
FINAL REVIEW BY CAS 7/27/00
NO ACC
OK TO TEST AND RETURN MONITOR PER SOPHIA GRIMM UNIT UPDATED
UNIT WILL NOT ALARM RECERT IF NEEDED OK FOR $150
ANY ALARMS NOT BEING HEARD RAN UNIT FOR 48 HOURS WITH MONITOR
PER DEVIATION D00-111 CT 7 26-00
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
DETECTING VARIOUS ALARMS LEFT MESSAGE FOR SOPHIA GRIMM ON
7 26-00 CT

001358

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/REPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 08/29/2000
Event Type Malfunction **Patient Outcome** Other
Event Description
During svc of the unit a no apnea alarm condition was found Replaced main circuit board to correct the failure mode

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/REPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 94

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 06/01/1997

Manufacturer *(Section F)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441

Manufacturer *(Section D)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441

Manufacturer Contact Randy Hoyt
2800 Northwest Blvd
Plymouth , MN 55441
(612) 694 -3500

Device Event Key 287123

MDR Report Key 296625

Event Key 278603

Report Number 2183157-2000-00294

Device Sequence Number 1

Product Code FLS

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 09/11/2000

1 **Device Was Involved in the Event**

1 **Patient Was Involved in the Event**

Date FDA Received 09/13/2000

Is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator UNKNOWN

Device MODEL Number 9700

OTHER Device ID Number	504491-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	07/21/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	08/29/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	07/01/1998
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 481059	3/29/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
UNIT WILL NOT TURN ON

Serial Number	Text Date
L-481059	4/3/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
NO ACC

Serial Number	Text Date
L-481059	5/31/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
VERIFIED UNIT WOULD NOT POWER UP UNDER AC TALKED TO SAM

Serial Number	Text Date
L-481059	5/31/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
HAYWARD ON 5 31 00 GAVE ESTIMATE OF $450 00 SAM STATED THAT

Serial Number	Text Date
L-481059	5/31/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
JANNIE BALL WILL CALL BACK WITH DECISION

Serial Number	Text Date
L-481059	6/26/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
UNIT UPDATED PER DEVIATION D00-111 CT 6-26-00

Serial Number	Text Date
L 481059	6/26/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
UNIT TO BE REPAIRED AT NO COST TO CUSTOMER PER ANN HANSON

Serial Number	Text Date
L 481059	6/26/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
REPLACED SW1 ON MAIN CIRCUIT BOARD TO CORRECT POWER UP FAILURE

Serial Number	Text Date
L 481059	6/30/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
FINAL REVIEW BY BJ 6/29/00

Serial Number	Text Date
L 481059	7/5/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED

Serial Number	Text Date
L 481059	7/5/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
TO CAB

Serial Number	Text Date
L-481059	7/5/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED SW1 ON MAIN CIRCUIT BOARD

Serial Number	Text Date
L 481059	7/17/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
MNPR FOR REVIEW

Serial Number	Text Date
L 481059	7/17/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
$100 00 ANNUAL TEST CALL JANIE WITH ADDITION EST PROBLEM DESC

Serial Number	Text Date
L 481059	7/17/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
WHEN PROBLEM DESCRIPTION ARRIVES ENTER INTO PRMS AND ROUTE TO

Serial Number	Text Date
L 481059	7/17/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
W/UNIT

Serial Number	Text Date
L 481059	7/20/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
FAILS SECTION 5 CONTINUES TO PICK UP RESP BEATS

Serial Number	Text Date
L-481059	7/21/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
RECD 7 20-00 UNIT WAS UNRECEIVABLE DUE TO REQ BEING IN MNTS AND

Serial Number	Text Date
L 481059	7/21/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
THEN IN MNPR

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
BOARD REPLACEMENT 9/01/00

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
S/N BEU00583 9/15/00 MAR

Serial Number	Text Date
L-481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
REPLACED MAIN BOARD WITH P/N Y 101205 00A LOT # Y39082 BOARD

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
UPDATED UNIT PER D00-111 8/29/00 MAR

Serial Number	Text Date
L-481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
THE TIME RAN UNIT OVERNIGHT AND COULD NOT DUPLICAT RECOMEND

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
APNEA REPLACED Q15 AND RETESTED 8/29/00 MAR

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
VERIFIED CUSTOMERS COMMENT PICKS UP RESP BEATS WHILE SIMULATING

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
UNIT STILL HAS ERRATIC RESP SIGNAL BUT FUNCTION PROPERLY MOST OF

Serial Number	Text Date
L 481059	9/15/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail

Serial Number	Text Date
L-481059	9/25/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
CAB

Serial Number	Text Date
L 481059	9/25/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD

Serial Number	Text Date
L 481059	9/25/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
FINAL REVIEW BY MR 9/22/00

Serial Number	Text Date
L-481059	9/25/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9053	APN MTR NO APNEA ALARM

Text Detail
TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 481059	486212	3/29/2000	L 9700A	122	
L-481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	486212	3/29/2000	L 9700A	122	
L 481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L-481059	504491	7/17/2000	L 9700A	9053	
L 481059	504491	7/17/2000	L 9700A	9053	

001367

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phone	Text Seq Numb
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	1
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	2
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	2
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	2
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	3
APN MTR WON T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	3
APN MTR WON'T TURN ON	BAPTIST HOME MEDICAL	SR	9013738485	3
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	1
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	2
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	2
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	2
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	2
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	2
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	3
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	3
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	3
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	4
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	4
APN MTR NO APNEA ALARM	BAPTIST HOME MEDICAL	WR	9013738485	5

001368

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED SW1 ON MAIN CIRCUIT BOARD
FINAL REVIEW BY BJ 6/29/00
NO ACC
UNIT TO BE REPAIRED AT NO COST TO CUSTOMER PER ANN HANSON
UNIT WILL NOT TURN ON
VERIFIED UNIT WOULD NOT POWER UP UNDER AC TALKED TO SAM
HAYWARD ON 5-31 00 GAVE ESTIMATE OF $450 00 SAM STATED THAT
REPLACED SW1 ON MAIN CIRCUIT BOARD TO CORRECT POWER UP FAILURE
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED
JANNIE BALL WILL CALL BACK WITH DECISION
TO CAB
UNIT UPDATED PER DEVIATION D00 111 CT 6 26-00
$100 00 ANNUAL TEST CALL JANIE WITH ADDITION EST PROBLEM DESC
CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD
FAILS SECTION 5 CONTINUES TO PICK UP RESP BEATS
FINAL REVIEW BY MR 9/22/00
RECD 7 20-00 UNIT WAS UNRECEIVABLE DUE TO REQ BEING IN MNTS AND
UNIT STILL HAS ERRATIC RESP SIGNAL BUT FUNCTION PROPERLY MOST OF
VERIFIED CUSTOMERS COMMENT PICKS UP RESP BEATS WHILE SIMULATING
WHEN PROBLEM DESCRIPTION ARRIVES ENTER INTO PRMS AND ROUTE TO
APNEA REPLACED Q15 AND RETESTED 8/29/00 MAR
MNPR FOR REVIEW
THE TIME RAN UNIT OVERNIGHT AND COULD NOT DUPLICAT RECOMEND
THEN IN MNPR
TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO
W/UNIT
BOARD REPLACEMENT 9/01/00
CAB
UPDATED UNIT PER D00 111 8/29/00 MAR
REPLACED MAIN BOARD WITH P/N Y 101205 00A LOT # Y39082 BOARD
S/N BEU00583 9/15/00 MAR

001369

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 08/31/2000
Event Type Malfunction **Patient Outcome** Other
Event Description
During service of the unit a no lead alarm condition was found Replaced main circuit board to correct the failure mode

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 95

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441 2625
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441 2625
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	287117
MDR Report Key	296619
Event Key	278597
Report Number	2183157-2000-00293
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	09/11/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	09/13/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700

OTHER Device ID Number	500622-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	06/26/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	08/31/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	05/01/1999
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L 482350	8/2/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
W/O CORRECTING CONDITION

Serial Number	Text Date
L 482350	8/2/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
SERIVICE LED FLASHES NO AUDIBLE ALARM(FOR LED) TURNED OFF/ON

Serial Number	Text Date
L 482350	8/6/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
RECD PWR CORD (MISC) PT CABLE (F)

Serial Number	Text Date
L 482350	9/1/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
PATIENT CABLE PASSED SERVICE TESTING DATECODE 12/98 CT

Serial Number	Text Date
L 482350	9/1/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
VERIFIED NO AUDIBLE REAR ALARM WHICH CAUSES SERVICE LED FRONT

Serial Number	Text Date
L-482350	9/1/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
ALARM WORKS CORRECTLY CAS

Serial Number	Text Date
L 482350	9/1/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
REPLACED REAR AUDIBLE ALARM

Serial Number	Text Date
L-482350	9/2/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
TO CAB

Serial Number	Text Date
L 482350	9/2/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED REAR ALARM

Serial Number	Text Date
L 482350	9/2/1999

Trend Code Symptom	Short Text
9046	APN MTR ERROR LIGHT ON/ERROR COND

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED

Serial Number	Text Date
L 482350	6/21/2000

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
FAILED IMPEDENCE TESTING CUSTOMER QUOTED 450 00

Serial Number	Text Date
L 482350	6/26/2000

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
NO ACC

Serial Number	Text Date
L-482350	8/31/2000

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
UPDATED PER DEV D00-111 8/31/00 MAR

Serial Number	Text Date
L-482350	9/7/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
REPLACED BATTERY

Serial Number	Text Date
L 482350	9/7/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
VERIFIED CUSTOMERS COMMENT UNIT WOULD NOT ALARM DURING A LOOSE

Serial Number	Text Date
L 482350	9/7/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
LEAD CONDITION REPLACED MAIN BOARD S/N BAA02887 WITH

Serial Number	Text Date
L 482350	9/7/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
S/N BAE00660 8/31/00 MAR

Serial Number	Text Date
L 482350	9/8/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CAB

Serial Number	Text Date
L 482350	9/8/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD

Serial Number	Text Date
L 482350	9/8/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
9057	APN MTR NO LEAD ALARM

Text Detail
TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 482350	447281	8/2/1999	L 9700A	9046	
L-482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L-482350	447281	8/2/1999	L 9700A	9046	
L-482350	447281	8/2/1999	L 9700A	9046	
L 482350	447281	8/2/1999	L 9700A	9046	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	
L-482350	500622	6/21/2000	L 9700A	9057	
L 482350	500622	6/21/2000	L 9700A	9057	

001376

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phon	Text Seq Numb
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	1
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	1
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	1
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	1
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	1
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	2
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	2
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	2
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	3
APN MTR ERROR LIGHT ON/ERROR COND	MIDSTATE MEDICAL OXYGEN	WR	9314339719	3
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	1
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	2
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	2
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	3
APN MTR NO LEAD ALARM	MID STATE MEDICAL OXYGEN	SR	9314339719	3

001377

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED REAR ALARM
PATIENT CABLE PASSED SERVICE TESTING DATECODE 12/98 CT
RECD PWR CORD (MISC) PT CABLE (F)
SERIVICE LED FLASHES NO AUDIBLE ALARM(FOR LED) TURNED OFF/ON
VERIFIED NO AUDIBLE REAR ALARM WHICH CAUSES SERVICE LED FRONT
ALARM WORKS CORRECTLY CAS
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED
W/O CORRECTING CONDITION
REPLACED REAR AUDIBLE ALARM
TO CAB
CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD
FAILED IMPEDENCE TESTING CUSTOMER QUOTED 450 00
NO ACC
REPLACED BATTERY
UPDATED PER DEV D00 111 8/31/00 MAR
VERIFIED CUSTOMERS COMMENT UNIT WOULD NOT ALARM DURING A LOOSE
LEAD CONDITION REPLACED MAIN BOARD S/N BAA02887 WITH
TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO
CAB
S/N BAE00660 8/31/00 MAR

001378

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 09/01/2000
Event Type Malfunction **Patient Outcome** Other
Manufacturer Narrative
Na

Event Description
Nellcor puritan bennett received a call from representative of facility on 09/01
Facility called to report the following problem no apnea alarm

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 96

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 06/01/1997

Manufacturer *(Section F)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441

Manufacturer *(Section D)* NELLCOR PURITAN BENNETT
2800 Northwest Blvd
Plymouth MN 55441

Manufacturer Contact Randy Hoyt
2800 Northwest Blvd
Plymouth MN 55441
(612) 694 -3500

Device Event Key 289489

MDR Report Key 299065

Event Key 280951

Report Number 2183157-2000-00330

Device Sequence Number 1

Product Code FLS

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Other

Remedial Action Other

Type of Report Initial

Report Date 09/29/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 10/02/2000

Is This An Adverse Event Report? No

Is This A Product Problem Report? Yes

Device Operator UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	513104-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	09/07/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Event Location	Not Applicable
Date Manufacturer Received	09/29/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	07/01/1999
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-482564	2/25/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
WONT TURN ON

Serial Number	Text Date
L 482564	3/6/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
RECD 2 29-00 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING

Serial Number	Text Date
L-482564	3/6/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
INCOMPLETE

Serial Number	Text Date
L-482564	3/15/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
REPLACED C235 ON MAIN CKT BOARD TO CORRECT POWER UP

Serial Number	Text Date
L 482564	3/16/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
TO CAB

Serial Number	Text Date
L-482564	3/16/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
122	APN MTR WON'T TURN ON

Text Detail
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED

Serial Number	Text Date
L 482564	3/16/2000

Product Number	Text Seq Numbe
L-9700A	1

Trend Code Symptom	Short Text
122	APN MTR WON T TURN ON

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED C235ON MAIN BOARD

Serial Number	Text Date
L-482564	8/1/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	WERE NOT BLOCKED LOGS NOT AVAILABLE

Serial Number	Text Date
L 482564	8/1/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	$100 00 OK D PO # RS8100A

Serial Number	Text Date
L 482564	8/1/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	SERVICE LIGHT COMES ON AFTER APNEA ALARM DURING TESTING ALARMS

Serial Number	Text Date
L-482564	8/3/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	NO ACC

Serial Number	Text Date
L 482564	8/16/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	VERIFIED FLASHING SERVICE LED AFTER ALARMS FRONT AND REAR

Serial Number	Text Date
L 482564	8/16/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	ALARMS NOT BEING HEARD REPLACED M1 ON MAIN CIRCUIT BOARD TO

Serial Number	Text Date
L 482564	8/16/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	CORRECT FLASHING SERVICE LED FAILURE UNIT UPDATED PER

Serial Number	Text Date
L-482564	8/16/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe
L 9700A	4

Text Detail
DEVIATION D00-111 REPAIRS DONE AT NO CHARGE TO CUSTOMER CT

Serial Number	Text Date
L-482564	8/16/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe
L 9700A	5

Text Detail
8-16-00

Serial Number	Text Date
L 482564	8/22/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
TO CAB

Serial Number	Text Date
L 482564	8/22/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED M1 ON MAIN CIRCUIT BOARD

Serial Number	Text Date
L 482564	8/22/2000

Trend Code Symptom	Short Text
9080	APN MTR CONSTANT SERVICE LIGHT

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED

Serial Number	Text Date
L-482564	9/1/2000

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
NO APNEA ALARM UNIT UNDER WARRANTY

Serial Number	Text Date
L 482564	9/7/2000

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
RECD 9-6-00 UNIT WAS UNRECEIVABLE DUE TO REQ BEING INCOMPLETE

Serial Number	Text Date
L-482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	8

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
UNIT BACK TO CUSTOMER 9/29/00 MAR

Serial Number	Text Date
L-482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CALLED CUSTOMER 9/29/00 SPOKE WITH RANDY SMITH AND HE SAID THAT

Serial Number	Text Date
L-482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
HE COULD NOT GET ANY INFORMATION ON CUSTOMERS COMPLANT AND THAT

Serial Number	Text Date
L 482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THE PATIENT CABLES AND LEAD WIRES ARE STRIPPED FROM UNIT WHEN

Serial Number	Text Date
L-482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
4201	APN MTR ALARM, FAILED TO

Text Detail
THEY COME IN HE GETS A NOTE OF THE COMPLANT AND CALLS IT IN

Serial Number	Text Date
L 482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	5

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
I DOWN LOADED STUDY 9/29/00 INFORMATION SHOWS UNIT FUNCTIONED

Serial Number	Text Date
L 482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	7

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CAME ON AND APNEA LED CAME ON RECOMEND FREE UPGRADES AND SEND

Serial Number	Text Date
L-482564	9/29/2000

Product Number	Text Seq Numbe
L 9700A	6

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
PROPERLY AND WHEN I TESTED UNIT SIMULATING APNEA AUDIBLE ALARM

Serial Number	Text Date
L-482564	10/5/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO

Serial Number	Text Date
L 482564	10/5/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
REPLACED BATTERY PER WARRANTY UPDATED PER DEVIATION D00-111

Serial Number	Text Date
L 482564	10/5/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
FURTHER CORRECTIVE ACTION

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L-482564	480540	2/25/2000	L 9700A	122	
L 482564	480540	2/25/2000	L 9700A	122	
L 482564	480540	2/25/2000	L 9700A	122	
L 482564	480540	2/25/2000	L 9700A	122	
L 482564	480540	2/25/2000	L 9700A	122	
L-482564	480540	2/25/2000	L 9700A	122	
L 482564	480540	2/25/2000	L 9700A	122	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L-482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	507338	8/1/2000	L 9700A	9080	
L 482564	513104	9/1/2000	L 9700A	4201	
L-482564	513104	9/1/2000	L 9700A	4201	
L-482564	513104	9/1/2000	L 9700A	4201	
L-482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	
L 482564	513104	9/1/2000	L 9700A	4201	

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HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR WON'T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	2
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	2
APN MTR WON T TURN ON	PROCARE HOME MEDICAL INC	WR	9072740770	3
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	1
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	2
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	2
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	2
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	3
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	3
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	3
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	4
APN MTR CONSTANT SERVICE LIGHT	PROCARE HOME MEDICAL INC	SR	9072740770	5
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	1
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	2
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	2
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	3
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	4
APN MTR ALARM, FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	5
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	6
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	7
APN MTR ALARM FAILED TO	PROCARE HOME MEDICAL INC	WR	9072740770	8

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Text Detail
CONFIRMED CUSTOMER STATEMENT REPLACED C235ON MAIN BOARD
RECD 2 29-00 NO ACC UNIT WAS UNRECEIVABLE DUE TO REQ BEING
REPLACED C235 ON MAIN CKT BOARD TO CORRECT POWER UP
WONT TURN ON
INCOMPLETE
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED
TO CAB
CONFIRMED CUSTOMER STATEMENT REPLACED M1 ON MAIN CIRCUIT BOARD
NO ACC
SERVICE LIGHT COMES ON AFTER APNEA ALARM DURING TESTING ALARMS
VERIFIED FLASHING SERVICE LED AFTER ALARMS FRONT AND REAR
ALARMS NOT BEING HEARD REPLACED M1 ON MAIN CIRCUIT BOARD TO
TO CORRECT THE PROBLEM THIS PART WILL BE TRENDED AND REPORTED
WERE NOT BLOCKED LOGS NOT AVAILABLE
$100 00 OK D PO # RS8100A
CORRECT FLASHING SERVICE LED FAILURE UNIT UPDATED PER
TO CAB
DEVIATION D00-111 REPAIRS DONE AT NO CHARGE TO CUSTOMER CT
8 16 00
CALLED CUSTOMER 9/29/00 SPOKE WITH RANDY SMITH AND HE SAID THAT
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO
NO APNEA ALARM UNIT UNDER WARRANTY
RECD 9 6 00 UNIT WAS UNRECEIVABLE DUE TO REQ BEING INCOMPLETE
REPLACED BATTERY PER WARRANTY UPDATED PER DEVIATION D00 111
FURTHER CORRECTIVE ACTION
HE COULD NOT GET ANY INFORMATION ON CUSTOMERS COMPLANT AND THAT
THE PATIENT CABLES AND LEAD WIRES ARE STRIPPED FROM UNIT WHEN
THEY COME IN HE GETS A NOTE OF THE COMPLANT AND CALLS IT IN
I DOWN LOADED STUDY 9/29/00 INFORMATION SHOWS UNIT FUNCTIONED
PROPERLY AND WHEN I TESTED UNIT SIMULATING APNEA AUDIBLE ALARM
CAME ON AND APNEA LED CAME ON RECOMEND FREE UPGRADES AND SEND
UNIT BACK TO CUSTOMER 9/29/00 MAR

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Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 09/19/2000
Event Type Malfunction **Patient Outcome** Other,

Event Description
Nellcor puritan bennett received a call from representative of ahr medical reps on 09/19 Ahr medical reps called to report the following problem unit is alarming when it should not and isn t alarming when it should No pt harm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting, enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 99

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	291766
MDR Report Key	301461
Event Key	283213
Report Number	2183157-2000-00353
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	BIOMEDICAL ENGINEER
Type of Report	Initial
Report Date	10/17/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	10/18/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	515830-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	09/25/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Event Location	Not Applicable
Date Manufacturer Received	09/19/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	06/01/2000
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29 2007

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Center for Devices and Radiological Health / CDRH

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
Y 30200214	9/20/2000

Product Number	Text Seq Numbe
Y 9700B	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
SHOULD BE NO PATIENT HARM

Serial Number	Text Date
Y 30200214	9/20/2000

Product Number	Text Seq Numbe
Y 9700B	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
UNIT IS ALARMING WHEN IT SHOULD NOT AND ISN'T ALARMING WHEN IT

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	8

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THEIR BOX OF CABLES BEFOR USING THEM 10/02/00 MAR

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CALLED STEVE 9/26/00 HE SAID THE REASON THEY PULLED UNIT OUT OF

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THE FIELD WAS THEY WERE GETTING ALOT OF HEART SLOW ALARMS AND

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THE STUDY THAT I DOWN LOADED WAS FROM THEIR SIMULATER THEY DID

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	4

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
NOT SEND THEIR PATIENT CABLE OR LEAD WIRES BACK I ASKED THEM IF

Serial Number	Text Date
Y-30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	5

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
THEY HAD USED THE SAME PATIENT CABLE AND LEAD WIRES WHEN THEY

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	7

Trend Code Symptom	Short Text
4201	APN MTR ALARM, FAILED TO

Text Detail
THROWN IN WITH THERE OTHER CABLES I ADVISED THEM TO GO THROUGH

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	9

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
TESTED UNIT ON BENCH SEVERAL DAYS CREATING HEAR SLOW ALARMS AND

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	10

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
APNEA ALARMS UNIT FUNCTIONED PROPERLY COULD NOT DUPLICATE

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	11

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
CUSTOMERS DISCREPANCY 10/02/00 MAR

Serial Number	Text Date
Y 30200214	10/2/2000

Product Number	Text Seq Numbe
Y 9700B	6

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
TESTED UNIT HE DID NOT KNOW HE TOLD ME THAT THE CABLES WERE

Serial Number	Text Date
Y 30200214	10/5/2000

Product Number	Text Seq Numbe
Y 9700B	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
REPLACED PC JACK PER WARRANTY

Serial Number	Text Date
Y 30200214	10/5/2000

Product Number	Text Seq Numbe
Y 9700B	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO

Serial Number	Text Date
Y 30200214	10/5/2000

Product Number	Text Seq Numbe
Y 9700B	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
UPDATED US WITH 1 MEG RESISTOR UNIT PASSED FUNCTIONAL TESTING

Serial Number	Text Date
Y 30200214	10/5/2000

Product Number	Text Seq Numbe
Y 9700B	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
FURTHER CORRECTIVE ACTION

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y-30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	
Y 30200214	515830	9/19/2000	Y 9700B	4201	

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Text Detail
CALLED STEVE 9/26/00 HE SAID THE REASON THEY PULLED UNIT OUT OF
COULD NOT DUPLICATE CUSTOMER STATEMENT AT THIS LOCATION NO
UNIT IS ALARMING WHEN IT SHOULD NOT AND ISN'T ALARMING WHEN IT
UPDATED US WITH 1 MEG RESISTOR UNIT PASSED FUNCTIONAL TESTING
FURTHER CORRECTIVE ACTION
REPLACED PC JACK PER WARRANTY
SHOULD BE NO PATIENT HARM
THE FIELD WAS THEY WERE GETTING ALOT OF HEART SLOW ALARMS AND
THE STUDY THAT I DOWN LOADED WAS FROM THEIR SIMULATER THEY DID
NOT SEND THEIR PATIENT CABLE OR LEAD WIRES BACK I ASKED THEM IF
THEY HAD USED THE SAME PATIENT CABLE AND LEAD WIRES WHEN THEY
TESTED UNIT HE DID NOT KNOW HE TOLD ME THAT THE CABLES WERE
THROWN IN WITH THERE OTHER CABLES I ADVISED THEM TO GO THROUGH
THEIR BOX OF CABLES BEFOR USING THEM 10/02/00 MAR
TESTED UNIT ON BENCH SEVERAL DAYS CREATING HEAR SLOW ALARMS AND
APNEA ALARMS UNIT FUNCTIONED PROPERLY COULD NOT DUPLICATE
CUSTOMERS DISCREPANCY 10/02/00 MAR

001397

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART RATE/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 09/29/2000
Event Type Malfunction **Patient Outcome** Other
Event Description
Nellcor puritan bennett rec d a call from a rep to report the following problem intermittent lead alarm

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART RATE/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972
Baseline Shelf Life Information	No

EXHIBIT 101

Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	291958
MDR Report Key	301652
Event Key	283401
Report Number	2183157-2000-00361
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	10/18/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received	10/19/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN
Device MODEL Number	9700

OTHER Device ID Number	517736 004
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	10/05/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	09/29/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	11/01/1999
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29, 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-482971	6/9/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	DIDNT PASS 1ST STEP OF BENCH TEST WARRANTY

Serial Number	Text Date
L 482971	6/15/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	NO ACC

Serial Number	Text Date
L 482971	7/19/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	H R SLOW ALARM NO HEART BEAT LED LITE UP 7/6/00 KV REPLACED

Serial Number	Text Date
L 482971	7/19/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	U31 ON MAIN CIRCUIT BOARD TO CORRECT ABOVE FAILURE 7/17/00 KV

Serial Number	Text Date
L 482971	7/19/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	TESTED PER DOO 115 7/18/00 KV FINAL REVIEW BY CAS 7/19/00

Serial Number	Text Date
L-482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	THE PARTS USED WILL BE TRENDED AND REPORTED TO CAB

Serial Number	Text Date
L-482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	CONFIRMED THE CUSTOMERS STATEMENT

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	VERIFIED NO HEARTBEAT DETECTION LOOSE WIRES ON NOTCH FILTER

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	REPLACED U31 RESOLDERED LOOSE WIRES ON NOTCH FILTER AND UPDATED

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	RESOLDERED ALL LOOSE CONNECTIONS ON NOTCH FILTER AND REPLACED

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	PER DEV D00-011 TO CORRECT THE PROBLEM

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	4	UNIT UPDATED PER DEVIATION D00-111 CT 7 6 00

Serial Number	Text Date
L 482971	7/24/2000

Trend Code Symptom	Short Text
4243	APN MTR CALIBRATION TEST FAILURE

Product Number	Text Seq Numbe	Text Detail
L 9700A	3	U31 TO CORRECT HEARBEAT DETECTION FAILURE

Serial Number	Text Date
L-482971	9/29/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
FUNCTIONAL TEST UNIT UNDER WARRANTY

Serial Number	Text Date
L 482971	10/5/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
NO ACC

Serial Number	Text Date
L 482971	10/11/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	1

Text Detail
DURING FUNCTIONAL TEST UNIT HAD INTERMITTENT HEART SLOW ALARMS

Serial Number	Text Date
L-482971	10/11/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	2

Text Detail
AND NO LEAD ALARM WHEN PATIENT CABLE WAS DISCONNECTED

Serial Number	Text Date
L 482971	10/11/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
REPLACING MAIN BOARD WITH P/N Y 101205-00A LT# Y39082 BOARD

Serial Number	Text Date
L 482971	10/11/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	4

Text Detail
S/N BEU00498 10/11/00 MAR

Serial Number	Text Date
L 482971	10/16/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe
L 9700A	3

Text Detail
CAB

Serial Number	Text Date
L-482971	10/16/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD

Serial Number	Text Date
L 482971	10/16/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	1	FINAL REVIEW BY MR 10/13/00

Serial Number	Text Date
L 482971	10/16/2000

Trend Code Symptom	Short Text
9051	APN MTR INTERMIT LEAD ALARM

Product Number	Text Seq Numbe	Text Detail
L 9700A	2	TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L-9700A	4243	
L-482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L-482971	498655	6/9/2000	L 9700A	4243	
L-482971	498655	6/9/2000	L 9700A	4243	
L-482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L 482971	498655	6/9/2000	L 9700A	4243	
L-482971	498655	6/9/2000	L 9700A	4243	
L-482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	
L-482971	517736	9/29/2000	L 9700A	9051	
L 482971	517736	9/29/2000	L 9700A	9051	

001405

HISTORY BY SERIAL NUMBER 9/6/2007

Short Text	Customer Name	RMA Type	Customer Pho	Text Seq Numb
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	1
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	1
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	1
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	1
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	1
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	2
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	2
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	2
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	3
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	3
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	3
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	4
APN MTR CALIBRATION TEST FAILURE	NURSES UNLIMITED HEALTH	WR	8004608118	4
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	1
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	1
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	1
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	1
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	1
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	2
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	2
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	3
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	3
APN MTR INTERMIT LEAD ALARM	NURSES UNLIMITED HEALTH	WR	9155505041	4

001406

Text Detail
CONFIRMED THE CUSTOMERS STATEMENT
DIDNT PASS 1ST STEP OF BENCH TEST WARRANTY
H R SLOW ALARM NO HEART BEAT LED LITE UP 7/6/00 KV REPLACED
NO ACC
VERIFIED NO HEARTBEAT DETECTION LOOSE WIRES ON NOTCH FILTER
REPLACED U31 RESOLDERED LOOSE WIRES ON NOTCH FILTER AND UPDATED
RESOLDERED ALL LOOSE CONNECTIONS ON NOTCH FILTER AND REPLACED
U31 ON MAIN CIRCUIT BOARD TO CORRECT ABOVE FAILURE 7/17/00 KV
PER DEV D00-011 TO CORRECT THE PROBLEM
TESTED PER DOO 115 7/18/00 KV FINAL REVIEW BY CAS 7/19/00
U31 TO CORRECT HEARBEAT DETECTION FAILURE
UNIT UPDATED PER DEVIATION D00 111 CT 7 6 00
THE PARTS USED WILL BE TRENDED AND REPORTED TO CAB
CONFIRMED THE CUSTOMER STATEMENT WE REPLACED THE CIRCUIT BOARD
DURING FUNCTIONAL TEST UNIT HAD INTERMITTENT HEART SLOW ALARMS
FINAL REVIEW BY MR 10/13/00
FUNCTIONAL TEST UNIT UNDER WARRANTY
NO ACC
AND NO LEAD ALARM WHEN PATIENT CABLE WAS DISCONNECTED
TO REPAIR THE UNIT THIS PART WILL BE TRENDED AND REPORTED TO CAB
REPLACING MAIN BOARD WITH P/N Y 101205-00A LT# Y39082 BOARD S/N BEU00498 10/11/00 MAR

001407

Adverse Event Report

NELLCOR PURITAN BENNETT 9700 HEART/RESPIRATION MONITOR BREATHING FREQUENCY MONITOR

back to search results

Model Number 9700
Event Date 10/25/2000
Event Type Malfunction **Patient Outcome** Other

Event Description
Nellcor puritan bennett received a call from representative from the facility The facility called to report the following problem when leads are removed from the baby the unit does not alarm Unit continues to detect heart and resp

Manufacturer Narrative
Na

Search Alerts/Recalls (Contained in Enforcement Reports)
(After selecting enter device information to search Alerts/Recalls)

new search | submit an adverse event report

Brand Name	9700 HEART/RESPIRATION MONITOR
Type of Device	BREATHING FREQUENCY MONITOR
Baseline Brand Name	HEART RATE/RESPIRATION MONITOR
Baseline Generic Name	APNEA MONITOR
Baseline Catalogue Number	NA
Baseline Model Number	9700
Baseline Device Family	BREATHING FREQUENCY MONITOR
Baseline Device 510(K) Number	K961972

EXHIBIT 103

Baseline Shelf Life Information	No
Is Baseline PMA Number Provided?	No
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	06/01/1997
Manufacturer *(Section F)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer *(Section D)*	NELLCOR PURITAN BENNETT 2800 Northwest Blvd Plymouth MN 55441
Manufacturer Contact	Randy Hoyt 2800 Northwest Blvd Plymouth MN 55441 (612) 694 -3500
Device Event Key	296743
MDR Report Key	306638
Event Key	288159
Report Number	2183157-2000-00419
Device Sequence Number	1
Product Code	FLS
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	RESPIRATORY THERAPIST
Type of Report	Initial
Report Date	11/21/2000
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	11/21/2000
Is This An Adverse Event Report?	No
Is This A Product Problem Report?	Yes
Device Operator	UNKNOWN

Device MODEL Number	9700
OTHER Device ID Number	521725-001
Was Device Available For Evaluation?	Device Not Returned To Manufacturer
Date Returned to Manufacturer	11/01/2000
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	na
Date Manufacturer Received	10/25/2000
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	04/01/2000
Is The Device Single Use?	No
Is the Device an Implant?	No
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on June 29 2007

DETAIL REPORT BY SERIAL NUMBER

Serial Number	Text Date
L-483676	10/25/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
PLEASE DOWNLOAD AND SAVE

Serial Number	Text Date
L 483676	10/25/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MONITOR WAS ON WHEN LEADS TAKEN OFF BABY UNIT DID NOT ALARM

Serial Number	Text Date
L 483676	11/1/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
RECD PWR CORD PT CABLE

Serial Number	Text Date
L-483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
UNIVERISITY HOSPITAL

Serial Number	Text Date
L 483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
11/13 SPOKE WITH DAVE TOLD DAVE INITIAL TESTING COUNLD NOT

Serial Number	Text Date
L-483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
11/15 SPOKE WITH NOEL DEBARDELABEN (39358) RECOMMENDED THE UNIT

Serial Number	Text Date
L 483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
BE TESTED IN THE HOME UNKNOWNS ELECTRONIC SECURITY SYSTEM

Serial Number	Text Date
L-483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
DUPLICATE THE REPORTED PROBLEM

Serial Number	Text Date
L-483676	11/21/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
PT'S DOCTOR JOSEPH DECHRISTOPHARO SUSAN CATS NURSE

Serial Number	Text Date
L 483676	11/28/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
SUPPORTING DATA (PRODUCT MONITORING)

Serial Number	Text Date
L 483676	11/28/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
VIDEO AND DISK RECIEVED FROM HOMECARE DEALER FILED WITH

Serial Number	Text Date
L 483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
COULD NOT DULPLICATE CUSTOMERS DISCREPANCY DURING BENCH TESTING

Serial Number	Text Date
L 483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
REPLACED BATTERY DUE TO PREVENTIVE MAINTANANCE UPDATED UNIT PER

Serial Number	Text Date
L 483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
DEVIATION D00-111 11/29/00 MAR

Serial Number	Text Date
L-483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
UNIT FUNCTIONED PROPERLY PUT UNIT INTO BURN IN FOR 48 HOURS UNIT

Serial Number	Text Date
L 483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	3

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
FUNCTIONED PROPERLY TESTED UNIT WITH CUSTOMERS PATIENT CABLE AND

Serial Number	Text Date
L 483676	11/29/2000

Product Number	Text Seq Numbe
L 9700A	4

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
MONITOR FUNCTIONED PROPERLY 11/29/00 MAR

Serial Number	Text Date
L 483676	12/8/2000

Product Number	Text Seq Numbe
L 9700A	2

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION

Serial Number	Text Date
L 483676	12/8/2000

Product Number	Text Seq Numbe
L 9700A	1

Trend Code Symptom	Short Text
4201	APN MTR ALARM FAILED TO

Text Detail
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL

HISTORY BY SERIAL NUMBER

9/6/2007

Serial Number	Request Numb	Line Date	Product Numb	Trend Cod	Observer Code
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L-483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L-483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L-483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L 483676	521725	10/25/2000	L 9700A	4201	
L-483676	521725	10/25/2000	L 9700A	4201	

001414

Short Text	Customer Name	RMA Type	Customer Phor	Text Seq Numb
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	1
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	2
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	3
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	3
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	4
APN MTR ALARM FAILED TO	CONTINUED CARE LONG	WR	6316948787	4

001415

Text Detail
11/13 SPOKE WITH DAVE TOLD DAVE INITIAL TESTING COUNLD NOT
11/15 SPOKE WITH NOEL DEBARDELABEN (39358) RECOMMENDED THE UNIT
COULD NOT DULPLICATE CUSTOMERS DISCREPANCY DURING BENCH TESTING
COULD NOT REPRODUCE CUSTOMERS COMMENT AT OUR LOCATION FINAL
MONITOR WAS ON WHEN LEADS TAKEN OFF BABY UNIT DID NOT ALARM
RECD PWR CORD PT CABLE
REPLACED BATTERY DUE TO PREVENTIVE MAINTANANCE UPDATED UNIT PER
VIDEO AND DISK RECIEVED FROM HOMECARE DEALER FILED WITH
BE TESTED IN THE HOME UNKNOWNS ELECTRONIC SECURITY SYSTEM
DEVIATION D00-111 11/29/00 MAR
DUPLICATE THE REPORTED PROBLEM
PLEASE DOWNLOAD AND SAVE
SUPPORTING DATA (PRODUCT MONITORING)
TEST AND VERIFIED OPERATION NO FURTHER CORRECTIVE ACTION
UNIT FUNCTIONED PROPERLY PUT UNIT INTO BURN IN FOR 48 HOURS UNIT
FUNCTIONED PROPERLY TESTED UNIT WITH CUSTOMERS PATIENT CABLE AND
PT S DOCTOR JOSEPH DECHRISTOPHARO SUSAN CATS NURSE
MONITOR FUNCTIONED PROPERLY 11/29/00 MAR
UNIVERISITY HOSPITAL

001416

MedWatch
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: 8/31/01 See OMB statement on reverse

Mfr report #: 2244861200100009

MF/Dist report #:

FDA Use Only

A. Patient information

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

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 ____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☒ other MALFUNCTION

Date of event (mo/day/yr): UNK

4. Date of this report (mo/day/yr): 03/09/01

Describe event or problem

Dealer reports monitor did not alarm for Fast Heart Rate

Relevant tests/laboratory data, including dates

Device not returned to manufacturer for evaluation

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

#1 NA

#2

3. Therapy dates (if unknown, give duration) from/to (or 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)

#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
UNK

6. model # ~~500EXL~~ 9700A (9/20/01)

catalog # NA

serial # 282588

lot # NA

other # RGA7104

5 Expiration date (mo/day/yr): UNK

7 If implanted give date (mo/day/yr): UNK

8. If explanted, give date (mo/day/yr): UNK

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☒ no ☐ returned to manufacturer on NA (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

NA

E. Initial reporter

1 Name & address

Home Health Resources
111 N Ewing St
Lancaster OH 43130

phone # 740-654-7171

032422

2. Health professional? ☐ yes ☒ no

3. Occupation: Distributor

4 Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

EXHIBIT 104

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.

ıcation and Device
ıience 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
Public Health Service Food and Drug Administration

to guidelines for specific instructions

Page 2 of 2

FDA Use Only

or use by user facility/distributor–devices only

ck one
user facility ☐ distributor

2. UF/Dist report number

r facility or distributor name/address

dact person

5 Phone Number

le user facility or distributo
ame aware of event
day/yr)

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

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

proximate
s of device

10 Ev nt problem codes (refer to coding manual)
patient code
device code

eport sent to FDA?
es ____ (mo/day/yr)
o

port sent to manufacturer?
es ____ (mo/day/yr)
o

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

icturer name/address

H. Device manufacturers only

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

2. If follow-up, what type? NA
☐ 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
(mo/yr)
UNK

5. Labeled for single us ?
☐ 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 na

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

032423

All manufacturers

ntact office – name/address (& mfring site for devices)
.S Medical Systems Inc.
E. Industrial Rd
ınford CT 06405
te CAS purchased product line after this
vice was manufactured from.
ilcor Purban Bennett
00 Northwest Blvd
rmouth 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 ____

ate received by manufacturer
(mo/day/yr)
/08/01

IND protocol #
A

Type of report (check all that apply)
5-day ☐ 15-d y
10-day ☐ periodic
Initial ☐ follow-up # ____

Mfr report number
24 1200100009

5
(A) NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

8. Adverse event term(s)
NA

...ated reporting burden for this collection of information has been estimated to average ... per response, including the time for reviewing instructions, searching existing data sources, ...ering and maintaining the dat needed, and completing and reviewing the collection of infor... on. Send comments regarding this burden estimat or any other aspect of this collection of ...mation, including suggestions for reducing this burden to:

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Please DO NOT RETURN th... form to this address.

Form 3500A back

CAS Medical Systems, Inc

RGA #

Find Record

DATE ISSUED 2/7/01

USTOMER HOME HEALTH RESOURCES CUSTOMER#

MODEL AMI W/MODEM SERIAL # 482586 # OF TIMES RETURNED

PART # 01 05 0163 WARRANTY No

CUSTOMER COMMENTS FALSE ALARM FOR SLOW HEART RATE DIDN T ALARM FOR FAST HEART RATE

REPAIR SECTION

PART2 PART3 # PART4 # PART5 #

REPAIR COMMENTS Monitor not returned as of 4/16/01

INVESTIGATION MDR filed 3/9/01 (#00009) due to alleged complaint wording

CLOSED BY R Jeffrey DATE CLOSED 4/16/01

032424

✓ DATE FEB 8 2001

CAS MEDICAL SYSTEMS, INC
REFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

PRODUCT COMPLAINT # 7104

INSTRUCTIONS:
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION.

A.

ORIGINATED BY EM
DATE OF THIS REPORT 2-8-01
PRODUCT AM1
LOT/SERIAL # 482586
QUANTITY

CUSTOMER NAME: Home Health Resources
ADDRESS. 111 N Ewing St
Lancaster, OH 43130
COMPLAINANT Vicki Thompson
PHONE. 740-654-7171

DETAIL OF COMPLAINT

False Alarm for Slow heart rate
Didn't alarm for fast heart rate

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

_VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 7104
COPY OF WRITTEN RESPONSE ATTACHED
OTHER

_VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O #)
NOTIFIED

B

DATE RECEIVED AT QA 2/8/01 ASSIGNED TO TASTY QA
FOR ✓ INVESTIGATION
CORRECTIVE ACTION RESPONSE DUE DATE. / /
QA COMMENTS TO ASSIGNEE.

INVESTIGATION RESULTS (NOTE FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT.)

See Access Data Base

REASON FOR NO INVESTIGATION

AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION

See attached

REPLY TO COMPLAINANT

YES NO REASON FOR NO REPLY

036520

CLOSE OUT

SIGNATURE RO Barker DATE 5/17/02

CAS MEDICAL SYSTEMS, INC.

DATE 02/07/01

SHIP TO 6349
HOME HEALTH RESOURCES
111 NORTH EWING ST
LANCASTER, OH 43130

ATTN ACCOUNTS PAYABLE

DATE NOTIFIED	DATE RECEIVED	CUST PO	DELIVER	SALESMAN	TAX
02-07-01					DY

WEIGHT	TERMS	SHIP VIA
	2% 10 N 30	

LIN#	PART# DESCRIPTION	QTY RETURNED
1	PART# 01-05-0 63 UNIT MONITOR W MODEM Under Warranty NO REASONS RETURNED RE NON-WARRANTY, 2-20-01, 1602 SN 7F2586 SCHED I & E DTY 02-07-31 1 FALSE ALARM FOR SLOW HEART RATE DITN' ALARM FOR FAST PER RT RATE	

036521

CAS Medical Systems, Inc.

7104

DATE ISSUED: 2/7/01

CUSTOMER: HOME HEALTH RESOURCES

CUSTOMER #:

MODEL: AMI W/MODEM

SERIAL #: 482586

RETURN #:

PART #: 01-05-0163

WARRANTY: No

CUSTOMER COMMENTS: FALSE ALARM FOR SLOW HEART RATE. DIDN'T ALARM FOR FAST HEART RATE.

REPAIR SECTION

PART2 #: PART3 #: PART4 #: PART5 #:

REPAIR COMMENTS: Monitor not returned as of 4/16/01

INVESTIGATION: MDR filed 3/9/01 (#00009) due to alleged complaint wording

CLOSED BY: R.

DATE CLOSED: 4/16/01

Monitor w/ Get return?

036522

Copy

MEDWATCH

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

Mfr report #: 2244861200100021

USFDAst report #:

FDA Use Only

A. Patient information

Patient identifier	2. Age at time of event / or Date of birth.	3. Sex	4 Weight
UNK	UNK / UNK	UNK ☐ female ☐ male	UNK 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 ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: MALFUNCTION

Date of event (mo/day/yr): 04/00/01

4 Date of this report (mo/day/yr): 05/29/01

Describe event or problem

Distributor reports that the monitor is not giving an LED for slow heart indications. There is also a report that the audible alarm is sporadic

Relevant tests/laboratory data, including dates

UNK

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

UNK

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) (mo/day/yr or 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)

#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: UNK

5. Expiration date (mo/day/yr): NA

6

model # 9700A

catalog # NA

serial # 483734

lot # NA

other # RGA8790

7 If implanted, give date (mo/day/yr): NA

8 If explanted, give date (mo/day/yr): NA

9 Device available for evaluation? (Do not send to FDA)

☒ yes ☐ no ☐ returned to manufacturer on 05/01/01 (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

NA

E. Initial reporter

1 Name & address:

Consolidated Health Systems
1501 Riverside Dr Suite350
Chattanooga TN 37406

032479

phone # 423-629-1251 X3521

2 Health professional? ☐ yes ☒ no

3 Occupation: Distributor

4 Initial reporter also sent report to FDA – ☐ yes ☐ no ☒ unk

EXHIBIT 108

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.

dication and Device
perience Report
ntinued)

uidelines 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.

.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
☐ use facility ☐ distributor

2. UF/Dist report number

User facility or distributor name/address

c tact p rson

5 Phone Number

Date user facility or distributor became aw re of event (mo/day/yr)

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

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

Approximate age of device

10 Event problem codes (refer to coding manual)
patient code
device code

Report nt to FDA?
☐ yes ____ (mo/day/yr)
☐ no

Report sent to manufacturer?
☐ yes ____ (mo/day/yr)
☐ no

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

ufa tu er name/addre s

G. All manufacturers

Contact office – name/address (& mfring site for devices)

CAS Medical Systems Inc
44 E Industrial Rd
Branford CT 06405
NOTE CAS purchased product line after manufacture of monitor 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 (mo/day/yr)
4/26/01

5 (A)NDA # NA
IND # MA
PLA # NA
pre-1938 ☐ yes
OTC product ☐ yes

If IND protocol #
NA

7 Type f report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☒ initial ☐ follow up # ____

8 Adverse event term(s)
NA

9 report number
861200100021

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 (mo/yr)
04/10/00

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 NA

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

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

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

NA

032480

T publ reporting urden for hi collec on of nformation has been estimated to average one-hour pe esponse includi g th time for reviewi g tructions, searching existing data sources, gath and maintain ng th data needed and mplet and reviewing the collection of infor- mati Send omments regarding his burde stimate or ny othe pect of this collection of mati n, including uggestions for reduci g this burd to

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, D.C. 20201

An gency may not conduct or sponsor and person is not required to respond to, collectio of information unle it displays currently valid OMB control umber

Please DO NOT RETURN this form to this address.

FDA Form 3500A b ck

CAS Medical Systems, Inc.

8790

DATE ISSUED: 4/26/01

CUSTOMER: CONSOLIDATED HEALTH SYSTEMS

CUSTOMER #: 6994

MODEL: AMI W/MODEM

SERIAL #: 483734

PART #: 01 05-0163

WARRANTY: No

CUSTOMER COMMENTS: BENCH TEST #2 STEP #4 NOT GIVING LED ON SLOW HEART LED AUDIBLE ALARM SPARATIC RECERT

REPAIR SECTION

PART #: 15 01 0335 1 | 2 0275, 03 08 0 | 21 01 1001

REPAIR COMMENTS: No repair necessary Fully tested and made necessary updates

INVESTIGATION: Complaint could not be confirmed All testing showed the monitor to perform correctly Updated and recertified Filed MDR 00021 5/29/01

CLOSED BY: R Jeffrey

DATE CLOSED: 5/29/01

032481

CAS MEDICAL SYSTEMS, INC

SERVICE REPORT

SECTION A Procedure Number

RGA # or S/O # 8790 CUSTOMER CONSOLIDATED HEALTH SYSTEM

MODEL # 9700A WINDOWS SERIAL # 483734

DATE RECEIVED 5-1-01 ESTIMATE REQUIRED ☐ Do not perform work until estimate is approved

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

☐ Complaint: NOT CALIBRATED ON SLOW HEART LED. AUDIBLE ALARM SPORADIC

INITIAL FINDINGS

Has the customers stated complaint been verified? ☐ YES ☑ NO

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

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

UPDATED PER DEVIATION DOC-111, INSTALLED ECN 5554; REPLACED BATTERY PER RECERT,

ECN Update # 5554

032482

	Rec.	2Min	Final	Total
TECH	CLM		ACH	
DATE	5-11-01		5-11-01	Time
REPAIR TIME	1/2		1/2	1

Date to QA: 5-11-01

QA DATA SHEET
FORM 21-04-0218
REVISION # 01
EFFECTIVE 3/15/01

AMI PLUS (9700) QA FINAL TEST AND INSPECTION

1 SCOPE

To confirm AMI PLUS (9700) monitor operates to its full intent and conforms to CAS Medical test specifications

SERIAL # 483734 RGA # 8790

2 TEST EQUIPMENT REQUIRED
Aequitron 8310 simulator
EdenTec 2301 multi function tester

3 DATA REQUIRED
3 1 EMI label, drawing # 21 01-0932
3 2 Modem label, drawing # 21-01-0871
3 3 Serial number label, drawing # 21-01-0884
3 4 Device tracking label, drawing # 21-01-0931
3 5 Service label, drawing # 21-01-0935

	PASS	FAIL
4 TEST SHEET INSPECTION		
4 1 Review and confirm all test data is complete and conforms to test data specifications	✓	
5 INSPECT UNIT FOR LABELING Ref. Manufacturing Process # 03-08-0360 Rev 01		
5 1 EMI label, Ref page 15 figure 16 for location and drawing #21-01-0932 Rev 00 for content	✓	
5.2 Modem label, Ref page 15 figure 16 for location and drawing #21-01 0871 Rev 00 for content.	✓	
5.3 Serial #/Device Tracking label, Ref Page 16 Figure 17 for location and drawings #21-01-0884 and #21 01-0931 Rev 00 for content.	✓	
5 4 Service label, Ref Page 16, figure 17 for location and drawing # 21 01 0935 Rev 00 for content.	✓	

032483

	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		
CONNECT DC POWER CONVERTER AND PATIENT CABLE TO UNIT UNDER TEST CONNECT PATIENT CABLE (RA/LA) TO 8310 SIMULATOR AND VERIFY THE FOLLOWING		
7 1 Power-up unit under test	✓	
A) LED lights strobes through self-test.	✓	
B) LCD display strobes through self-test Parameters	✓	
C) Alarm will sound at both front and rear panel locations	✓	
D) With patient leads disconnected from monitor the front panel alarm will turn on.	✓	

8 OPERATIONAL TEST

WITH MONITOR UNDER TEST STILL CONNECTED TO 8310 SIMULATOR, SET THE DEFALT VALUES TO THE SIMULATOR. (REF CHART A.)

SIMULATOR SETTINGS

DEFAULT VALUES				TEST VALUES
165 BPM/1 mV				165 BPM/1 mV
RESPIRATION 30\B/M				RESPIRATION 00\B/M

CHART A

032484

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 Lead loose LED remains on.	✓	___
D) Press reset to turn Lead loose LED off	✓	___

8 2 Disconnect the Aequitron 8310 from unit under test and connect the EdenTec 2301 as required, and power unit up Set simulator settings to 60 BPM/40 RESP

A) Press APNEA button on simulator The alarm turns on along with APNEA LED	✓	___
B) Press APNEA button again after 20 seconds audio alarm turns off but APNEA LED remains on.	✓	___

8 3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously) and wait approximately 30 seconds for chirp At the bottom side of unit you will find the LCD display with monitor and patient settings Press the ⇧ and enter button at the saine 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 5-15-01

FAIL
☐ Reason for rejection._____

QA Inspector_____ Date_____

Correction made_____

QA Inspector_____ Date_____

032485

EPORT Single Run Summary
CHNICAL REPORT f2126
=P'AL NUMBER 483734 TEST RESULTS PASSED

VISION 1.2 *Ami w/Modem, Final Test*
ST DATE 5/11/01

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

NELLCOR
PURITAN
BENNETT

TIME	TEST	TEST DESCRIPTION	STATUS
2 36 25 PM	1	Initial Power Up	PASSED
2 36 25 PM	2	Version & Serial Number Verification	PASSED
2 37 01 PM	3	Time & Date	PASSED
2 37 37 PM	4	Patient Setup	PASSED
2 37 47 PM	5	Patient Limits	PASSED
2 37 54 PM	6	Access Code	PASSED
2 38 28 PM	7	O2 Desat	PASSED
2 39 46 PM	8	Signal Quality Indicator	PASSED
2 42 37 PM	9	Resp Detect min, mid, and max	PASSED
2 43 47 PM	10	ECG Crosstalk	PASSED
2 47 35 PM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
2 51 40 PM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
2 52 47 PM	13	Apnea Alarm ECG = RESP	PASSED
2 53 33 PM	14	Human Alarm Condition - Heart Slow	PASSED
2 54 36 PM	15	Human Alarm Condition - Apnea	PASSED
2 56 38 PM	16	Power Alert Function	PASSED
2 56 45 PM	17	WatchDog Test	PASSED
3 00 20 PM	18	Data Transfer & Recording Verification	PASSED

032486

ERATOR Andrew Hamblin STATION ID 1 RUN ID 706 PAGE 1

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

MEDWATCH
FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities distributors and manufacturers for MANDATORY reporting

Page 1 of 2

Mfr report #: 2244861200100015
User facility report #:
FDA Use Only

A. Patient information

1 Patient identifier	2 Age at time of event: / Date of birth	3 Sex	4 Weight
UNK In confidence	UNK UNK	UNK ☐ female ☐ male	UNK 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 (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: MALFUNCTION

3 Date of event (mo/day/yr): UNK

4 Date of this report (mo/day/yr): 04/11/01

5 Describe event or problem

DISTRIBUTOR ALLEGES THE MONITOR WILL NOT SOUND AN ALARM FOR FAST HEART RATE

6 Relevant tests/laboratory data, including dates

DEVICE NOT RETURNED FOR TESTING AND EVALUATION

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

UNK

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) (from/to or 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)

#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: AMI

2 Type of device: BREATING 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: UNK

5 Expiration date (mo/day/yr): NA

6
- model #: 9700A
- catalog #: NA
- serial #: 482847
- lot #: NA
- other #: RGA7370

7 If implanted, give date (mo/day/yr): NA

8 If explanted, give date (mo/day/yr): NA

9 Device available for evaluation? (Do not send to FDA)
☒ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

NA

E. Initial reporter

1 Name & address:

PRO CARE
709 NORTHWAY DR.
ANCHORAGE AK 99508

phone #: 907 274 0770

032469

2 Health professional? ☐ yes ☒ no

3 Occupation: DISTRIBUTOR

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.

PLEASE TYPE OR USE BLACK INK

EXHIBIT 107

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

r to guidelines for specific instructions

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

4 Contact person

5 Phone Number

6 Date user facility or distributor 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 R port sent to FDA?
☐ yes _____ (mo/day/yr)
☐ no

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

13 R port sent t ma ufacturer?
☐ yes _____ (mo/day/yr)
☐ no

14 Manufacturer name/address

G. All manufacturers

1 Contact office – name/address (& mfring site for devices)
CAS MEDICAL SYSTEMS INC
44 E INDUSTRIAL RD
BRANFORD CT 06405
Note CAS purchased product line after this device was manufactured by
NELLCOR PURITAN BENNETT
2800 NORTHWEST BLVD
PLYNOUTH 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

4 Date received by manufacturer (mo/day/yr)
02/22/01

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)

9 Mfr report number
2244861200100015

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 (mo/yr)
11/09/99

5 Labeled for singl u ?
☐ 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 NA

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

9 If action reported to FDA under 21 USC 360l(f) list correction/removal reporting number:
NA

10 ☐ Additional manufacturer narrati and/or 11 ☐ Corrected data
NA

032470

public reporting burde for this collecti of information has been estimated to average ho nour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the coll tion of infon mation, and comments regarding this burden estimate or any othe aspect of this collection of inf rmation, including suggestions for reducing this bur en to:

DHH Reports Clearance Officer
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building room 53 -H
200 Independence Avenue, W
Washington D.C 2020

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

Please DO NOT RETURN th s form t this addre

FDA Form 3500A back

ENTERED

CAS MEDICAL SYSTEMS, INC
REFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

PRODUCT COMPLAINT # 7370

INSTRUCTIONS:
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION.

6026

B3 160379

A.

ORIGINATED BY DC
DATE OF THIS REPORT 2/22/01
PRODUCT Ami L9700A
LOT/SERIAL # 482847
QUANTITY 1

CUSTOMER NAME. Pro Care
ADDRESS. 709 Northway Dr
Anchorage AK 99508
COMPLAINANT Randy
PHONE 907-274-0770

DETAIL OF COMPLAINT

Monitor will not get a fast heart rate alarm — NO alarm when in fast heart rate mode

P.O RS22201A

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

_VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 7370
COPY OF WRITTEN RESPONSE ATTACHED
OTHER.

_VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O #)
NOTIFIED

B.

DATE RECEIVED AT QA. / /
FOR. _____ INVESTIGATION _____
QA COMMENTS TO ASSIGNEE:

ASSIGNED TO
CORRECTIVE ACTION RESPONSE DUE DATE. / /

INVESTIGATION RESULTS (NOTE. FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT.)

See Spreadsheet & Data base

REASON FOR NO INVESTIGATION

AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION.

see Data Base

038823

REPLY TO COMPLAINANT
✓ YES NO

REASON FOR NO REPLY

CLOSE OUT
SIGNATURE

DATE. 5/29/02

AS Medical Systems, Inc.

Find Record

RGA # 7370

DATE ISSUED 2/22/01

CUSTOMER PROCARE HOME MEDICAL

CUSTOMER#

MODEL AMI W/MODEM SERIAL # 482847

OF TIMES RETURNED

PART # 01 05 0163 WARRANTY No

CUSTOMER COMMENTS: MONITOR WILL NOT GET A FAST HEART RATE ALARM. —

REPAIR SECTION

PART 2 # 03 08 0314 PART 3 # 28 02 0402 PART 4 # 28-02 0328 PART 5 #

REPAIR COMMENTS: Performed recertification ECN 5554 update updated per DOO-111 CND the problem.

INVESTIGATION: Testing could not conform the problem as stated All testing passed MDR# 00015 was sent in 4/11/01

CLOSED BY R Jeffrey DATE CLOSED 4/23/01

032471

[redacted]

PAGE 1 OF 1

DATE 03/07/01

ACKNOWLEDGEMENT
/370

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

ATTN ACCOUNTS PAYABLE

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

ATTN RECEIVING

BE NOTIFIED	DATE RECEIVED	[illegible]	BUYER	SALESMAN	TAX
[illegible]	[illegible]	[illegible]	[illegible]	1	0%

WEIGHT	TERMS	SHIP VIA
	2%-10 N 30	UPS

		QTY RETURNED
1	PART# 01-05-0163 AMI MONITOR W MODEM Under Warranty NO REASONS RETURNED 99 NON WARRANTY, 501-0-50-1 1602 SN 48L847 SCHED-DATE QTY 02-28-01 1 MONITOR WILL NOT GIVE A FAST HEART RATE ALARM *03-07-01* UPDATE THEIR IS NO ALARM AT ALL WHEN IN FAST HEART RATE MODE'	

Updated
3/7/01

038824

LOCATE RETURN

CT7370

482847

NOT WARRANTED

NEEDS RECERTIFICATION

INSPECTION

Unspected

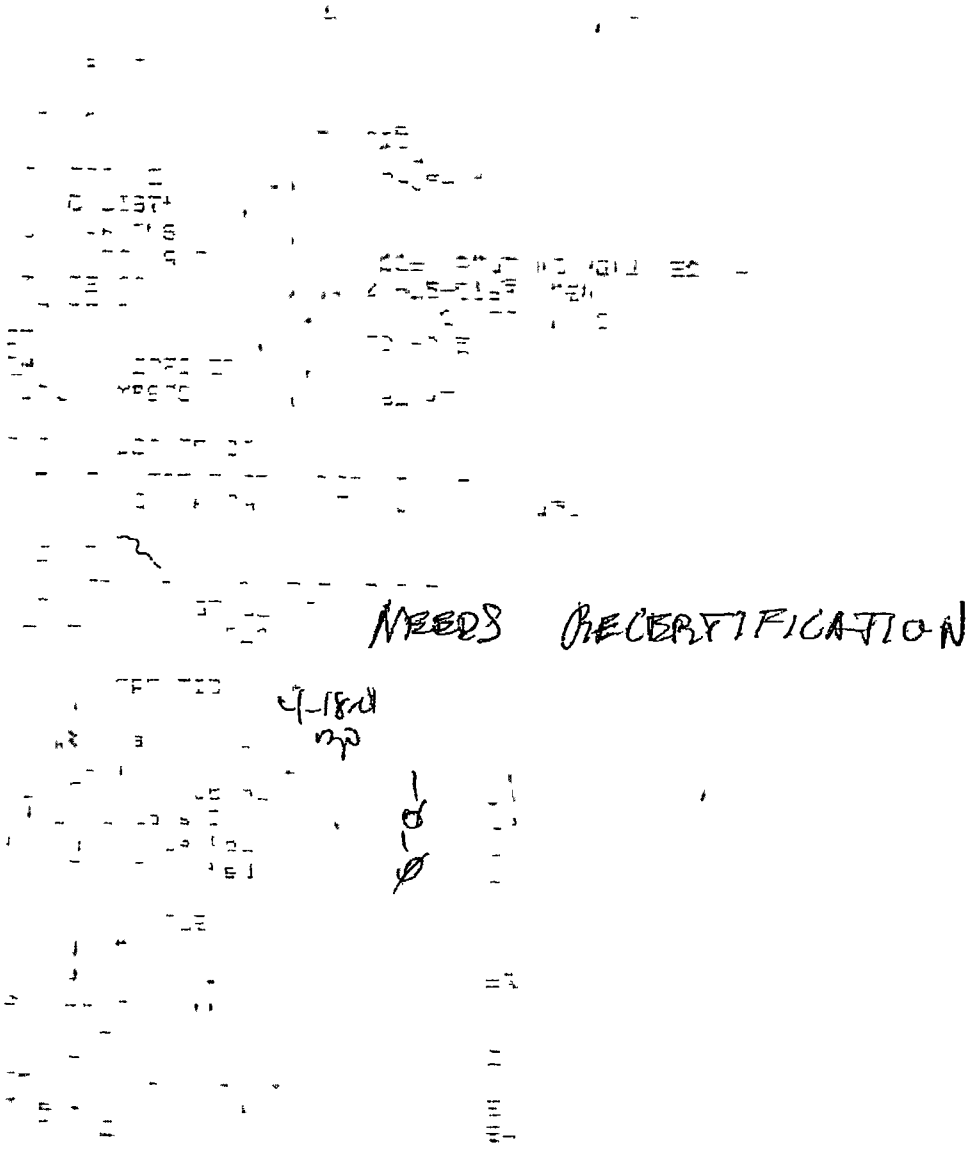
Loss Qty

Qty Accepted

Qty Rejected

RD* DS2220HA
CMB
8/28/01

032472



032473

CAS MEDICAL SYSTEMS, INC **SERVICE REPORT**

Complaint? YES ☐ NO ☐

SECTION A **Procedure Number**

RGA # 7370 CUSTOMER PROCARE HOME MEDICAL

MODEL # 9700A W.MODEM SERIAL # 482847

DATE RECEIVED 03-05-01 ESTIMATE REQUIRED ☐ DO NOT PREFORM WORK UNTIL ESTIMATE IS APPROVED

SECTION B

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

CHARGER		SPO2 SENSOR		TEMP PROBE	
BATTERY		PATIENT CABLE		AC LINE CORD	
				CARRYING CASE	

Cuff and size					
Leak Test Results of cuffs					

RECEIVED CONDITION: External ☐ If damaged describe _____

Internal ☐ _____

~~NEEDS UPDATE~~ ACH 4-18-01

TECH SERVICE FINDINGS/SERVICE

☑ RECERTIFICATION	☐ PATIENT JACK DEFECTIVE	~~WILL NOT GET A FAST HEART ATTACK~~ ACH 4-18-01
☐ BATTERY DEFECTIVE	☐ BATTERY JACK DEFECTIVE	☐ BEEPER DEFECTIVE
☐ CALIBRATION REQUIRED	☐ CHARGER DEFECTIVE	☐ CHARGER JACK DEFECTIVE
☐ CPU DEFECTIVE RAM/ROM	☐ PREVENTITIVE MAINTENANCE	☐ LED DEFECTIVE
☐ COULD NOT DUPLICATE PROBLEM	☐ PUMP DEFECTIVE	☐ SPO2 SENSOR DEFECTIVE
☐ SWITCH DEFECTIVE	☐ TEMP PROBE DEFECTIVE	☐ VALVE LEAKS/DEFECTIVE
☑ ECN UPDATE # 5554	☐ ENGEERING REQUESTED	☐ QA REQUESTED

OTHER REPAIRS UPDATED PER DEVIATION D00-111;

REPAIR TIME 1

Date to QA 4-18-01

TECH Candace Stanley ACH 4-18-01

DATE 4-5-01

032474

TEST RESULTS: PASSED

CAS Medical Systems Inc Form 21-04 0027 Rev 08

QA DATA SHEET
FORM 21-04-0218
REVISION # 01
EFFECTIVE 3/15/01

AMI PLUS (9700) QA FINAL TEST AND INSPECTION

1 SCOPE

To confirm AMI PLUS (9700) monitor operates to its full intent and conforms to CAS Medical test specifications.

SERIAL # 482847 RGA # 7370

2 TEST EQUIPMENT REQUIRED
Aequitron 8310 simulator
EdenTec 2301 multi function tester

3 DATA REQUIRED
3 1 EMI label, drawing # 21-01-0932
3 2 Modem label, drawing # 21-01-0871
3 3 Serial number label, drawing # 21-01-0884
3 4 Device tracking label, drawing # 21-01-0931
3 5 Service label, drawing # 21-01-0935

	PASS	FAIL
4 TEST SHEET INSPECTION		
4 1 Review and confirm all test data is complete and conforms to test data specifications.	✓	
5 INSPECT UNIT FOR LABELING Ref. Manufacturing Process # 03-08-0360 Rev 01		
5 1 **EMI label**, Ref page 15 figure 16 for location and drawing #21 01-0932 Rev 00 for content.	✓	
5 2 **Modem label**, Ref page 15 figure 16 for location and drawing #21-01-0871 Rev 00 for content.	✓	
5 3 **Serial #/Device Tracking label**, Ref. Page 16 Figure 17 for location and drawings #21-01-0884 and #21-01-0931 Rev 00 for content	✓	
5 4 **Service label**, Ref Page 16 figure 17 for location and drawing # 21 01-0935 Rev 00 for content	✓	

032475

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 Lead loose LED remains on.	✓	____
D) Press reset to turn Lead loose LED off.	✓	____

8.2 Disconnect the Aequitron 8310 from unit under test and connect the EdenTec 2301 as required, and power unit up Set simulator settings to 60 BPM/40 RESP

A) Press APNEA button on simulator The alarm turns on along with APNEA LED	✓	____
B) Press APNEA button again after 20 seconds audio alarm turns off but APNEA LED remains on.	✓	____

8 3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously) and wait approximately 30 seconds for chirp 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 4-18-01

FAIL
☐ Reason for rejection _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

032476

AMI 9700 Deviation D00-111 Parts List

Qty	Part Number	Description
	01-05-0174	9700 Software
	03 11-0040	9700G German Software
	03-11-0041	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	16-04-0085	0 1ufd cap (C235)
	29 01-0218	Feet, case
	28-02-0275	Foot-Rubber (square)

RGA # 7370

S/N 482847

Date 4-5-01

Other Parts Used

Qty	Part Number	Description
1	03 08-0317	BATTERY ASSY
1	28-02-0402	GASKET
1	28-02-0328	DUST CAP
1	21-01-1055	LABEL
1	21-01-1001	WARNING LABEL

032477

REPORT Single Run Summary
TECHNICAL REPORT #2126
SERIAL NUMBER 482847 TEST RESULTS PASSED

VISION 1 2 *Ami w/Modem, Final Test*
TEST DATE 4/18/01

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

NELLCOR
PURITAN
BENNETT

TIME	TEST	TEST DESCRIPTION	STATUS
9 35 28 AM	1	Initial Power Up	PASSED
9 35 28 AM	2	Version & Serial Number Verification	PASSED
9 35 39 AM	3	Time & Date	PASSED
9 36 14 AM	4	Patient Setup	PASSED
9 36 24 AM	5	Patient Limits	PASSED
9 36 30 AM	6	Access Code	PASSED
9 37 04 AM	7	O2 Desat	PASSED
9 38 21 AM	8	Signal Quality Indicator	PASSED
9 41 08 AM	9	Resp Detect min, mid, and max	PASSED
9 42 20 AM	10	ECG Crosstalk	PASSED
9 46 13 AM	11	ECG Detect mm, mid, max Rate & Amplitude	PASSED
9 50 27 AM	12	Reverse Leads, ECG Detect mm, mid, max Rate & Amp	PASSED
9 51 34 AM	13	Apnea Alarm ECG = RESP	PASSED
9 52 20 AM	14	Human Alarm Condition - Heart Slow	PASSED
9 53 23 AM	15	Human Alarm Condition - Apnea	PASSED
9 55 28 AM	16	Power Alert Function	PASSED
9 55 34 AM	17	WatchDog Test	PASSED
9 59 57 AM	18	Data Transfer & Recording Verification	PASSED

032478

OPERATOR Andrew Hamblin STATION ID 1 RUN ID 393 PAGE 1

MEDWATCH

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: 6/30/01
See OMB statement on reverse.

MFR report #: 2244861200100031

FDA Use Only

Patient information

Patient identifier: K

2. Age at time of event: UNK or Date of birth: UNK

3. Sex: UNK ☐ female ☐ male

4. Weight: UNK lbs or UNK kgs

confidence

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 (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other

Date of event (mo/day/yr): 07/00/01

Date of this report (mo/day/yr): 08/03/01

Describe event or problem

stributor reports that the alarm is intermittant when running on mulation

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.)

NA

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) (from/to or 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)
#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 (mo/day/yr): NA

6.
model # 9700A
catalog # NA
serial # 482387
lot # NA
other # RGA9886

7. If implanted, give date (mo/day/yr): NA

8. If explanted, give date (mo/day/yr): NA

9. Device available for evaluation? (Do not send to FDA)
☒ yes ☐ no ☐ returned to manufacturer on 07/12/01 (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)
NA

E. Initial reporter

1. Name & address:
Procare Home Medical
709 Northway Dr
Anchorage AK 99508

phone # 907 274 0770

032495

2. Health professional? ☐ yes ☒ no

3. Occupation: Dealer

4. Initial report to FDA: ☐ yes ☐ no ☒ unk

EXHIBIT 109

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.

dication and Device
perience Report
itio nd)

r uidelines 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

heck one
☐ user facility ☐ distributor

2. UF/Dist report number

iser facility or distributor name/address

ontact person

5 Phone Number

late user facility or distributor became aware of vent (mo/day/yr)

7 Type of report
☐ initial
☐ follow up # ___

8 Date of this report (mo/day/yr)

pproximate ge of device

10 Event p oblem codes (refer to coding manual)
patient code
device code

R port sent to FDA?
yes ___ (mo/day/yr)
no

Report sent t manufa turer?
yes ___ (mo/day/yr)
no

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

ufacturer n me/addre s

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 d te (mo/yr)
06/02/99

5 Labeled for single use?
☐ yes ☒ no

6 Evaluation codes (refer to coding manual)
method 10 – 33 – – –
results 708 – – – –
conclusions 72 – – – –

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 360i(f) list correction/removal reporting number
NA

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

NA

. All manufacturers

Contact office – name/address (& mfrng site for devices)
AS Medical Systems Inc
4 East Industrial Rd
ranford CT 06405
ote CAS purchased product line after this
evice was manufactured from
ellcor Puritan Bennett
800 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 ___

Date received by manufacturer (mo/day/yr)
07/10/01

5
(A)NDA # NA
IND # ___
PLA # ___
pre-1938 ☐ yes
OTC product ☐ yes

If IND protocol #
NA

Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ period c
☒ initial ☐ follow up # ___

6. Adverse event term(s)
NA

port number
4486120010003 1

032496

public reporting burden thi ollection of Informatio has bee stimated to average re- er pe response, including the tim for revi wing instructions, searching existing data sources, tlering and maintaining the data needed, and compl ting and reviewing the coll ction of infor- tion. Sen comment regard ng this burde stimate any other aspect of thi colle tion of formation, including gestions for redu ng thi burde inc

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H Humphrey Building, Room 531-H
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

DA F rm 3500A b k

CAS Medical Systems, Inc.

9886

DATE ISSUED: 7/10/01

CUSTOMER: PROCARE HOME MEDICAL

CUSTOMER #: 6628

MODEL: AMI W/MODEM

SERIAL #: 482387

PART #: 01 05 0163

WARRANTY: No

CUSTOMER COMMENTS: INTERMITTENT ALARM WHEN RUNNING THROUGH SIMULATION

REPAIR SECTION

1 0335 16 04-0 | 2 0275, 28 02 0 | 28 02-0328 | 1 1055, 21-01 1

REPAIR COMMENTS: UPDATED PER DEVIATION DOO 111 INSTALLED ECN 5554 PASSED ALL FUNCTIONAL TESTS

INVESTIGATIONS: BATTERY DATED 3/01 514/3687 CUSTOMERS COMPLAINT WAS NOT VERIFIED DUE TO THE NATURE OF THE COMPLAINT MDR 00031 WAS SENT 8/3/01

CLOSED BY: R JEFFREY

DATE CLOSED: 8/3/01

032497

✓ ENTERED JUL 11 2001

3 MEDICAL SYSTEMS, INC
REFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

PRODUCT COMPLAINT # 9886

INSTRUCTIONS
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION. Cust #161628

A.

ORIGINATED BY MJJ
DATE OF THIS REPORT 7-10-06
PRODUCT L-9700A
LOT/SERIAL # ~~482387~~ 482387
QUANTITY 1 @ 21501

CUSTOMER NAME: PRocare Home Medical
ADDRESS 709 Northway DR
Anchorage, ALASKA 99508
COMPLAINANT Bondy
PHONE 907-274-0770

DETAIL OF COMPLAINT

Intermittent Alarm when running
Through Simulation

Purchase Order # R571001A

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

_VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 9886
COPY OF WRITTEN RESPONSE ATTACHED
OTHER:

_VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O #)
NOTIFIED

B

DATE RECEIVED AT QA 7/11/01
ASSIGNED TO TSG QA
FOR ✓ INVESTIGATION
CORRECTIVE ACTION RESPONSE DUE DATE / /
QA COMMENTS TO ASSIGNEE

INVESTIGATION RESULTS (NOTE. FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT)

See Access DB

REASON FOR NO INVESTIGATION

AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION

MDR # 000381 Sent 8/3/01

REPLY TO COMPLAINANT

014141

YES NO REASON FOR NO REPLY

CLOSE OUT
SIGNATURE
DATE 8-3-01

CAS MEDICAL SYSTEMS INC
TECHNOLOGY APPLIED TO MEDICINE

SERVICE REPORT

SECTION A Procedure Number

RGA # 9886 CUSTOMER PORTABLE HOME MEDICAL

MODEL # 97cc A W/MODEM SERIAL # 482387

DATE RECEIVED 7-12-01 ESTIMATE REQUIRED ☐ Do not perform work until estimate is approved

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					
Glass/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification ☐ Preventative Maintenance ☐ Data Download

☑ Complaint: INTERMITTENT ALARM WHEN RUNNING THROUGH SIMULATION

INITIAL FINDINGS

BATTERY DATED, 3/01, 514/3687;

Has the customers stated complaint been verified? ☐ YES ☑ NO

Warranty (Y/N) [N] PO Number Obtained (Y/N) [Y] PO # _____

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

UPDATED PER DEVIATION DEC-111; INSTALLED ECN 5554; PASSED ALL FUNCTIONAL TESTS;

032498

ECN Update # 5554

	Rec.	2Min.	Final	
TECH	CLH		CLH	Total Time
DATE	7-25-01		7-26-01	
REPAIR TIME	1/2		1/2	1

Date to QA: 7-26-01

CAS Medical Systems Inc Form 21-04-0027 Rev 10

REPORT Single Run Summary

TECHNICAL REPORT #126

IAL NUMBER 482387 TEST RESULTS PASSED

REVISION 1 2 *Amt w/Modem Fmal Test*

TEST DATE 7/26/01 MODEL NUMBER L-9700A

PART NUMBER Y-006122 10A

NELLCOR PURITAN BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
7 11 20 AM	1	Initial Power Up	PASSED
7 11 20 AM	2	Version & Serial Number Verification	PASSED
7 11 59 AM	3	Time & Date	PASSED
7 12 22 AM	4	Patient Setup	PASSED
7 12 47 AM	5	Patient Limits	PASSED
7 12 55 AM	6	Access Code	PASSED
7 13 29 AM	7	O2 Desat	PASSED
7 14 47 AM	8	Signal Quality Indicator	PASSED
7 17 36 AM	9	Resp Detect min, mid, and max	PASSED
7 18 47 AM	10	ECG Crosstalk	PASSED
7 22 38 AM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
7 26 40 AM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
7 27 48 AM	13	Apnea Alarm ECG = RESP	PASSED
7 28 35 AM	14	Human Alarm Condition - Heart Slow	PASSED
7 29 38 AM	15	Human Alarm Condition - Apnea	PASSED
7 37 39 AM	16	Power Alert Function	PASSED
7 37 47 AM	17	WatchDog Test	PASSED
7 41 27 AM	18	Data Transfer & Recording Verification	PASSED

032499

OPERATOR Andrew Hamblin STATION ID 1 RUN ID 82 PAGE 1

AMI 9700X Parts Used List

Qty	Part Number	Description
1	01-05-0174	9700 Software
0	03-11-0040	9700G German Software
0	03-11-0041	9700S Spanish Software
2	15-01-0335	IC 74AC00 (U23 & U28)
1	16-04-0085	0 1ufd cap (C235)
1	29-01-0218	Feet case
1	28-02-0275	Foot-Rubber (square)
1	28-02-0402	Remote Alarm Gasket

RGA # 9886

S/N 482387

Date 7-25-01

Other Parts Used

Qty	Part Number	Description
	03-08-0314	Battery Assembly
1	28 02 0328	CAP DUST 25 PIN
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
	22-01-0187	Patient Cable Jack
	17-08-0123	1Meg Resistor AMI Plus

032500

QA DATA SHEET
FORM 21-04-0220
REVISION # 01
EFFECTIVE 5/23/01

AMI 9700 SERIES QA FINAL TEST AND INSPECTION

1 SCOPE

To confirm AMI (9700) monitor operates to its full intent and conforms to CAS Medical test specifications

SERIAL # 482387
WORK ORDER #
RGA # 9886

2 TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 LABEL DRAWINGS REQUIRED
3 1 EMI label, drawing # 21-01-0932
3.2 Modem label, drawing # 21-01-0871
3 3 Serial number label, drawing # 21-01-0884
3 4 Device tracking label, drawing # 21-01-0931
3 5 Service label, drawing # 21-01-0935
3 6 AMI Distributed by label, drawing # 21-01-1112

	PASS	FAIL
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.	✓	
5 INSPECT UNIT FOR LABELING Ref. Manufacturing Process # 03-08-0360		
5 1 EMI label, Ref page 15 figure 16 for location and drawing #21 01-0932 Rev 00 for content.	✓	
5 2 Modem label, Ref. page 15 figure 16 for location and drawing #21-01-0871 Rev 00 for content.	✓	
5 3 Serial #/Device Tracking label, Ref. Page 16 Figure 17 for location and drawings #21-01 0884 and #21-01-0931 Rev 00 for content.	✓	
5 4 Service label, Ref. Page 16 figure 17 for location and drawing # 21-01-0935 Rev 00 for content.	✓	

032501

	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		
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 strobes through self-test	✓	
B) LCD display strobes through self-test Parameters	✓	
C) Alarm will sound at both front and rear panel locations	✓	
D) With patient leads disconnected from monitor the front panel alarm will turn on.	✓	
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.	✓	

032502

8.3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously), and wait approximately 30 seconds for chirp 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 BB

Date 7-26-01

FAIL
☐ Reason for rejection _____

QA Inspector _____ Date: _____

Correction made _____

QA Inspector _____ Date: _____

032503

TECHNOLOGY APPLIED TO MED
44 EAST INDUSTRIAL RD • BRANFORD
203-488-6055 • FAX 203-488-94

Serial Number ✓

DATE 07/12/01

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

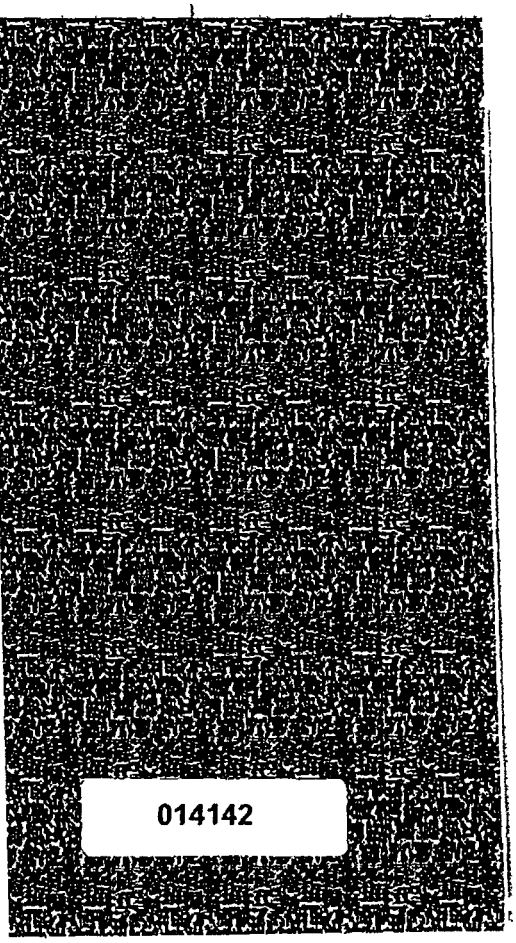
ATTN ACCOUNTS PAYABLE

SHIP TO

DATE NOTIFIED	DATE RECEIVED	CUST PO#	COVER	SALESMAN	TAX
07-10-01		RMA71001A1	RANDY		04

FREIGHT	TERMS	
	2%-10 N 30	

LI#	PART# DESC	QTY RETURNED
1	PART# 01 05-016 AMI MONITOR W MODEM Under Warranty: NO REASON RETURNED 98 NON-WARRANTY, 501-0-50), 160' SN: 482387 SCHED-DATE QTY 07-10-01 1 INTERMITTENT ALARM WHEN RUNNING THROUGH SIMULATION PO# APPROVLS UP TO $195 00 /MJJ	



CHECK OFF

SIMULATOR USED: Edentec Model 2301 R# 9584

SERIAL # 482387 TECHNICIAN AS DATE 7/6/01

R# 9686

☐	Power On Self Test	Pass ✓	Fail ___
☐	Battery Charger Operation	Pass ✓	Fail ___
☐	Lead Alarms	Pass ✓	Fail ___
☐	Heart Slow Alarm	Pass ✓	Fail ___
☐	Heart Fast Alarm	Pass ✓	Fail ___
☐	Apnea Alarm	Pass ___	Fail ✓

External Condition of Monitor: ___ New / ✓ Good / ___ Fair / ___ Poo

Explain(scratch/location) _____

ProCare Label Intact ✓ Yes / ___ No

Comments delayed apnea alarm

014150

CUSTOMER RETURN TRAVELLER

**** RECEIVING ****

RECEIVER#	30016
CR# LI#	CR9886 1
DATE RECEIVED	07-12-01
PACKING LIST#	00
NO OF CARTONS	1
CUST# CUST NAME	6628 PROCARE HOME MEDICAL
PART# REV00	01-05-0163 REV
DESCRIPTION	AMI MONITOR W MODEM
ACCT#	500-0-50-1
QUANTITY RECEIVED	1
SERIAL NUMBERS	482387

RETURN CODES/REASONS

98 NON-WARRANTY, 501-0-50-1, 1603

COMMENTS

INTERMITTENT ALARM WHEN
RUNNING THROUGH
SIMULATION PO# APPROVES
UP TO $195 00 /MJJ

**** INSPECTION ****

Date of Inspection 7-26-01
Inspector's Initials BB
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

014149

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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.

Mfr report #: 2244861200100032

MFR/Dist report #:

FDA Use Only

A. Patient information

Patient identifier	2. Age at time of event / Date of birth	3. Sex	4. Weight
NK	UNK / UNK	☐ UNK ☐ female ☐ male	UNK lbs / 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 (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other

5. Date of event (mo/day/yr): 07/00/01

6. Date of this report (mo/day/yr): 08/10/01

Describe event or problem

Home care dealer reports monitor is unable to alarm for apnea during the self test function

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
   #1 NA
   #2

3. Therapy dates (if unknown, give duration) (from/to or 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)
   #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)
   – –

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: Unk

5. Expiration date (mo/day/yr): NA

6.
   model # 9700A
   catalog # NA
   serial # 481752
   lot # NA
   other # RGA9921

7. If implanted, give date (mo/day/yr): NA

8. If explanted, give date (mo/day/yr): NA

9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☒ no ☐ returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)
    NA

E. Initial reporter

1. Name & address:
   Community Care Services
   900 Easton Ave
   Suite 22
   Somerset NJ 08873

   032504

Phone #: 732 993 1010

2. Health professional? ☐ yes ☒ no

3. Occupation: Dealer

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☒ unk

EXHIBIT 110

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.

dication and Device
perience Report
ntinued)
uidelines 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 d Drug Administratio

Page 2 of 2

FDA Use Only

For use by user facility/distributor–devices only

heck one
☐ user facility ☐ distributor

2. UF/Dist report number

Jser facility or distributor name/address

ontact person

5 Phone Number

Date user facility or distributor ɔecams aware of event (mo/day/yr)

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

8 Date of this report (mo/day/yr)

Approximate age of device

10 Event problem codes (refer to coding manual)
patient code
device code

Report sent to FDA?
] yes ___ (mo/d yr)
] no

Report sent to manufacturer?
] yes ___ (mo/day/yr)
] no

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

ufacturer 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 (mo/yr)
02/10/99

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 360i(f) list correction/removal reporting number
NA

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

5. All manufacturers

Contact office – name/address (& mfring site for devices)
CAS Medical Systems Inc
14 E Industrial Rd
Branford CT 06405
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 (mo/day/yr)
07/12/01

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

9 Mfr report number
361200100032

032505

re publ reporting b rden for this collectio of information has b en estimated to averag one- nou per esponse including the tim for re iewing instructions, searching ɛxisting ata sources, gathering an maintaining the d ta needs and compl ting and reviewing the collection of i fo mat Send comments regarding this burden estimate any other aspect of this llection of inf rmation incl di g suggestion for reducing this burd to

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Pleas DO NOT RETURN thi form to this address

FDA F rm 3500A back

ENTERED JUL 16 2001

EDICAL SYSTEMS INC
RENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

DUCT PLAINT # 9921

INSTRUCTIONS.
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION. Cust #5968

ORIGINATED BY MJJ
DATE OF THIS REPORT 7-12-01
PRODUCT 9700 A
LOT/SERIAL # 481752
QUANTITY 1

CUSTOMER NAME Community Care Service
ADDRESS 900 Easton Ave Suite 22
Somerset, N.J. 08873
COMPLAINANT matt
PHONE 732 993 1010 EXT. 105

DETAIL OF COMPLAINT

Mimics heartbeat light unable To apnea alarm during
Approves up To 19500 Selftest

Purchase Order # 005591

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 9921
COPY OF WRITTEN RESPONSE ATTACHED
OTHER

VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O #)
NOTIFIED

DATE RECEIVED AT QA. 7/16/01 ASSIGNED TO TEST QA
FOR V INVESTIGATION
CORRECTIVE ACTION RESPONSE DUE DATE / /
QA COMMENTS TO ASSIGNEE

INVESTIGATION RESULTS (NOTE. FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT.)

REASON FOR NO INVESTIGATION.

AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION.

MDR # 00032 filed 8/9/01 (mfg date 2/10/99)
1-31-02 Issue closed (See Emails) Probably never a valid complaint as it turns out

032506

R V TO COMPLAINANT
YES NO

REASON FOR NO REPLY

CLOSE OUT
SIGNATURE

DATE 1-31-02

ffrey, Ron

	Clark Don
ıject	RE RGA 9921 never returned?
portance	High

ın This is a new situation (serious type complaint where cust. fixes but we cannot confirm validity) ease try to find out if they 1 Checked the alarms 2 How checked 3 Found an alarm problem ıd 4 What they did about it Thanks

ın Jeffrey
rector of Regulatory Affairs
AS Medical Systems Inc
I E Industrial Rd
anford CT 06405 USA
ffrey@casmed com

Don asked for
Now 11-15-01

—Original Message—
om Clark Don
ent Thursday November 08 2001 12 10 PM
ı Jeffrey Ron
ubject RE RGA 9921 - never returned?

n I just talked to Matt and they will not be returning this monitor he said they were able to fix it ıemselves

on

—Original Message—
rom Jeffrey Ron
ent Monday November 05 2001 7 39 AM
o Clark Don
ubject RGA 9921 - never returned?

ıon - Can you find out why it hasn't (or if) this unit will return?

ron Jeffrey
)irector of Regulatory Affairs
CAS Medical Systems Inc
44 E Industrial Rd
Branford CT 06405 USA
jeffrey@casmed com

032507

CAS MEDICAL SYSTEMS INC
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL RD BRANFORD CT 06405
203-488-6056 FAX 203-488-9438

DATE 11/21/01

CUSTOMER RETURNS

ACKNOWLEDGEMENT
9921

SOLD TO 5960
COMMUNITY CARE SERVICES
900 EASTON AVE
SUITE 22
SOMERSET NJ 08873

ATTN ACCOUNTS PAYABLE

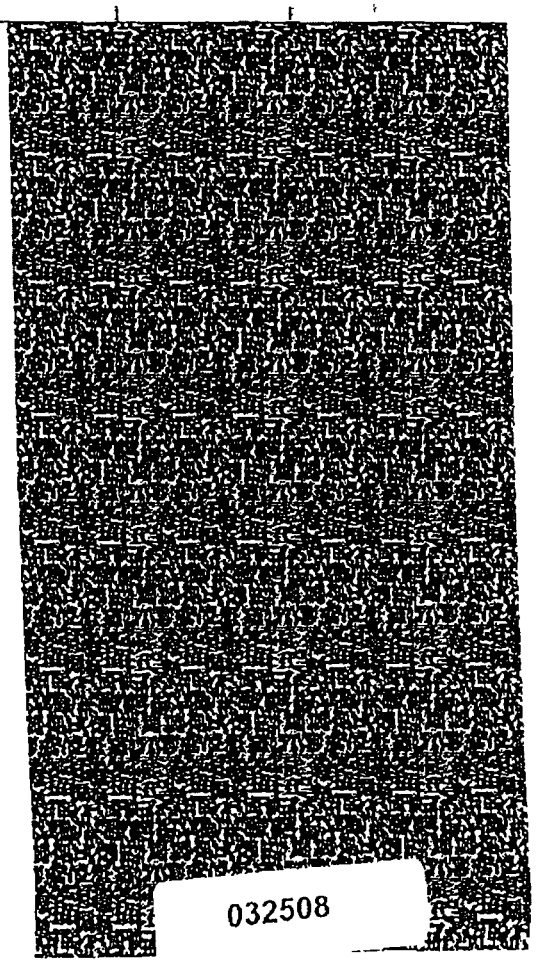
SHIP TO 5960
COMMUNITY CARE SERVICES
900 EASTON AVE
SUITE 22
SOMERSET NJ 0873

ATTN RECEIVING

NOTIFIED	DATE RECEIVED	CUST PO#	BUYER	SALESMAN	TAX
7-12 01		005591	MATT	1	0%

FREIGHT	TERMS	SHIP-VIA
	2%-10 N 30	UPS

#	PART# DESC	QTY RET	UNIT PRICE
1	PART# 01-05-0163 APNEA MONITOR W MODEM Under Warranty NO REASONS RETURNED 19 NON WARRANTY, 301-0-50-1 1002 SN 40752 SCHED-DATE OTH NUMEROUS HEARTBEAT LIGHT UNABLE TO APNEA ALARM DURING SELF TEST APPROVED UP TO $195.00 PO#005591 /MAJ *11-8 01*MONITOR WILL NOT BE RETURNED TO CAS FOR SERVICE THIS COMPLAINT WAS NOT VALID MATT IS NO LONGER WITH THEIR COMPANY DENISE SAID THAT SHE HAD NO RECORD OF THE COMPLAINT WE TOOK FROM MATT IN JULY		



MEDWATCH

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

MFR report #: 2244861200100033

FDA Use Only

A. Patient information

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

n 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 ____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other ____

Date of event (mo/day/yr): 07/00/01

Date of this report (mo/day/yr): 08/16/01

Describe event or problem

Dealer reports that the monitor would not alarm when used on a patient. No patient harm as monitor was removed from patient. Monitor claimed to not work on a bench top simulator either

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
#1 NA
#2

3. Therapy dates (if unknown give duration) (from/to (or 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)
#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 (mo/day/yr): NA

6. model # 9700A
catalog # NA
serial # 482606
lot # NA
other # RGA10003

7. If implanted give date (mo/day/yr): NA

8. If explanted give date (mo/day/yr): NA

9. Device available for evaluation? (Do not send to FDA)
☒ yes ☐ no ☐ returned to manufacturer on 07/24/01 (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)
NA

E. Initial reporter

1. Name & address:
Home Care Supply
2155 Interstate 10 East
Beaumont TX 77701

phone #: 409-835-3939

032509

2. Health professional? ☐ yes ☒ no

3. Occupation: DEALER

4. Initial report to FDA? ☐ yes ☐ no ☒ unk

EXHIBIT

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.

dication and Device
perience Report
ntinued)

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

...idelines for specific instructions

Page ___ of 2

FDA Use Only

...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 (mo/day/yr)

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

8 Date of this report (mo/day/yr)

Approximate age of device

10 Event problem codes (refer to coding manual)
patient code
device code

Report sent to FDA?
yes ___ (mo/day/yr)
no

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

Report sent to manufacturer?
yes ___ (mo/day/yr)
no

...facture 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 (mo/yr)
07/27/99

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 360i(f) list correction/removal reporting number

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

NA

...All manufacturers

Contact office – name/address (& mfring site for devices)

AS Medical Systems Inc
4 E Industrial Rd
ranford CT 06410
lote CAS purchased product line after this
evice was manufactured from
lellcor Puritan Bennett
800 Northwest Blvd
lymouth MN 55441

2. Phone number

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

Date received by manufacturer (mo/day/yr)
07/17/01

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

If IND protocol #
NA

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
2. 91200100033

032510

...public report...ed...er this co...lection of information has been estimated to average ...hour per response, including the ...me for reviewing instructions searching existing data sources, ...ath...rin...and co...mpleting and reviewing the collection of ...formation. Send comments regarding this burden estimate or any other aspect of this collection of ...formation, ...cluding suggestions for reducing this burden to ...

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Please DO NOT RETURN this form to this address

FDA Form 3500A back

ENTERED JUL 1 8 2001

CAS MEDICAL SYSTEMS, INC
REFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

PRODUCT COMPLAINT # 10003 #6892

INSTRUCTIONS.
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION.

A.

ORIGINATED BY MAJ
DATE OF THIS REPORT 7/17/01
PRODUCT 9700A
LOT/SERIAL # 482606
QUANTITY 1

CUSTOMER NAME Home Care Supply
ADDRESS 2155 IH-10 East
Beaumont, TX 77701
COMPLAINANT Darryl
PHONE 409/ 835-3939

DETAIL OF COMPLAINT
Apnea will not alarm - from even bench top tester. Was used on a patient - no patient harm Darryl recognized it was not working and removed the monitor
PO RP238501 Monitor was DC - Darryl picked it up from the patient and called CAS

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE) Approval for $195

_ VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 10,003
COPY OF WRITTEN RESPONSE ATTACHED
OTHER:

Red Tag
Attn: Ron Jeffcoat

_ VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O # _____)
NOTIFIED _____

B.

DATE RECEIVED AT QA 7/18/01 ASSIGNED TO TEST QA
FOR ✓ INVESTIGATION _____ CORRECTIVE ACTION RESPONSE DUE DATE / /
QA COMMENTS TO ASSIGNEE _____

INVESTIGATION RESULTS (NOTE. FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT.)

See Access DB

REASON FOR NO INVESTIGATION _____ AUTHORIZED BY _____

CORRECTIVE ACTION AND DISPOSITION.

See Access DB
3 @ 8/14/01
MFG date - 7/27/99
RMA # 00033 Sent 8/16/01

014198

REPLY TO COMPLAINANT
YES NO REASON FOR NO REPLY _____

CLOSE OUT
SIGNATURE _____ DATE 8/16/01

CAS Medical Systems, Inc.

10003

7/17/01

CUSTOMER: HOME CARE SUPPLY

6892

MODEL: AMI W/MODEM

SERIAL: 482606

PART: 01 05-0163

No

CUSTOMER COMMENTS: APNEA WILL NOT ALARM EVEN FROM BENCHTOP TESTER WAS USED ON A PATIENT NO PATIENT HARM BECAUSE MONITOR WAS REMOVED WHEN IT WAS REALIZED IT WAS NOT WORKING

REPAIR SECTION

PART: 28 02 0402 PART 3 #: 28 02 0328 PART: 21 01 1055 PART: 21 01 1001

REPAIR COMMENTS: INSTALLED ECN 5554 PASSED ALL FUNCTIONAL TESTS

INVESTIGATION: MONITOR GIVES APNEA ALARM UNDER ANY CONDITION COULD NOT DUPLICATE PROBLEM BATTERY DATED 8/00 11 11 VERSION MDR # 00033 FILED 8/16/01

CLOSED BY: R JEFFREY

DATE CLOSED: 8/16/01

032511

CAS MEDICAL SYSTEMS, INC

SERVICE REPORT

SECTION A Procedure Number

A # or S/O # 10003 CUSTOMER Home Care Supply

MODEL # 9700A SERIAL # 482606

DATE RECEIVED 7-24-01 ESTIMATE REQUIRED ☐ Do not perform work until estimate is approved

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			

Trade and Size					
Loss/Replace					

CUSTOMER REQUEST/COMPLAINT

☐ Recertification ☐ Preventative Maintenance ☐ Data Download

☑ Complaint Apnea will not alarm - even from bench top testers. Was used on a patient - no harm because Darryl recognized it wasn't working and removed the monitor. monitor was discontinued Darryl picked it up from the patient and called CAS.

INITIAL FINDINGS

Monitor gives an apnea alarm under any condition could not duplicate problem time 7 24-01 : BATTERY DATED 8/00 III VERSION

as the customers stated complaint been verified? ☐ YES ☑ NO

Warranty (Y/N) N PO Number Obtained (Y/N) Y PO # BP-2385-01

☑ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

INSTALLED ECN 5554 ; PASSED ALL FUNCTIONAL TESTS ;

032512

ECN Update # 5554

	Rec	2Mth	Final	
TECH	CLH		CLH	Total Time
DATE	7-25-01		7-25-01	
REPAIR TIME	½		½	1

Date to QA: 7-25-01

AMI 9700X Parts Used List

Qty	Part Number	Description
	01-05-0174	9700 Software
	03-11 0040	9700G German Software
	03 11 0041	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	16-04-0085	0 1ufd cap (C235)
	29-01-0218	Feet, case
	28-02-0275	Foot-Rubber (square)
1	28-02-0402	Remote Alarm Gasket

RGA # 1ce83

S/N 4826ce

Date 7-25-01

Other Parts Used

Qty	Part Number	Description
	03-08 0314	Battery Assembly
1	28 02-0328	CAP DUST 25 PIN
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 01-0187	Patient Cable Jack
	17 08-0123	1Meg Resistor AMI Plus

032513

EPORT Single Run Summary

CHNICAL REPORT #2126

AL NUMBER 482606 TEST RESULTS PASSED

VISION 1 2 *Ami w/Modem, Final Test*

ST DATE 7/25/01

MODEL NUMBER L-9700A

PART NUMBER Y-006122 10A

NELLCOR PURITAN BENNETT

TIME	TEST	TEST DESCRIPTION	STATUS
3 11 43 PM	1	Initial Power Up	PASSED
3 11 44 PM	2	Version & Serial Number Verification	PASSED
3 12 23 PM	3	Time & Date	PASSED
3 12 46 PM	4	Patient Setup	PASSED
3 13 11 PM	5	Patient Limits	PASSED
3 13 19 PM	6	Access Code	PASSED
3 13 53 PM	7	O2 Desat	PASSED
3 15 12 PM	8	Signal Quality Indicator	PASSED
3 18 06 PM	9	Resp Detect min, mid, and max	PASSED
3 19 16 PM	10	ECG Crosstalk	PASSED
3 23 08 PM	11	ECG Detect min, mid max Rate & Amplitude	PASSED
7 14 PM	12	Reverse Leads ECG Detect min, mid, max Rate & Amp	PASSED
3 28 22 PM	13	Apnea Alarm ECG = RESP	PASSED
3 29 07 PM	14	Human Alarm Condition - Heart Slow	PASSED
3 29 57 PM	15	Human Alarm Condition - Apnea	PASSED
3 50 18 PM	16	Power Alert Function	PASSED
3 50 24 PM	17	WatchDog Test	PASSED
3 54 26 PM	18	Data Transfer & Recording Verification	PASSED

032514

PERATOR. Andrew Hamblin STATION ID 1 RUN ID 80 PAGE 1

QA DATA SHEET
FORM 21-0d-0220
REVISION # 01
EFFECTIVE 5/23/01

AMI 9700 SERIES QA FINAL TEST AND INSPECTION

1 SCOPE

To confirm AMI (9700) monitor operates to its full intent and conforms to CAS Medical test specifications

SERIAL # #82606
WORK ORDER #
RGA # 10003

2 TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 LABEL DRAWINGS REQUIRED
3 1 EMI label, drawing # 21-01-0932
3.2 Modem label, drawing # 21-01-0871
3.3 Serial number label, drawing # 21-01-0884
3 4 Device tracking label, drawing # 21-01-0931
3 5 Service label, drawing # 21-01-0935
3 6 AMI Distributed by label, drawing # 21-01-1112

	PASS	FAIL
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	✓	
5 INSPECT UNIT FOR LABELING Ref Manufacturing Process # 03-08-0360		
5 1 EMI label, Ref. page 15 figure 16 for location and drawing #21-01-0932 Rev 00 for content.	✓	
5.2 Modem label, Ref page 15 figure 16 for location and drawing #21-01-0871 Rev 00 for content	✓	
5 3 Serial #/Device Tracking label, Ref Page 16 Figure 17 for location and drawings #21-01-0884 and #21-01-0931 Rev 00 for content.	✓	
5 4 Service label, Ref Page 16 figure 17 for location and drawing # 21-01-0935 Rev 00 for content.	✓	

032515

	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

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

	PASS	FAIL
7 1 Power-up unit under test.		
A) LED lights strobes through self-test.	✓	
B) LCD display strobes through self-test Parameters	✓	
C) Alarm will sound at both front and rear panel locations	✓	
D) With patient leads disconnected from monitor the front panel alarm will turn on.	✓	

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.	✓	

032516

8.3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously), and wait approximately 30 seconds for chirp 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 CD

Date 7-26-01

FAIL
☐ Reason for rejection._____

QA Inspector _____ Date_____

Correction made._____

QA Inspector _____ Date_____

032517

CAS MEDICAL SYSTEMS INC.
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL RD • BRANFORD, CT 06405
203-488-6056 FAX 203-488-9438

DATE

CUSTOMER RETURNS

SHIP TO 6892
HOME CARE SUPPLY
2155 INTERSTATE 10 EAST
BEAUMONT, TEXAS 77701

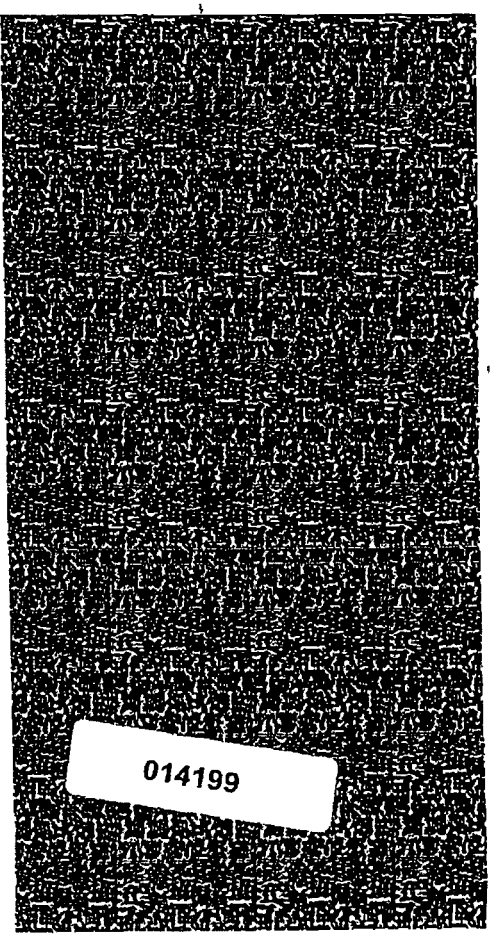
ATTN ACCOUNTS PAYABLE

SHIP TO

DATE NOTIFIED	DATE RECEIVED	CUST PO#	BUYER	SALESMAN	TAX
07-17-01		RP-2385-01	DARRYL		0%

FREIGHT	TERMS
	2%-10,N-30

LI#	PART# DESC	QTY RETURNED
1	PART# U -05-0163 AM MONITOR W MODEM Under Warranty NO REASON RETURNED 98 NON-WARRANTY, 501-0-50-1 1003 SN 49264L SCHED-DATE QTY 07-17-01 1 APNEA WILL NOT ALARM- EVEN FROM BENCHTOP TESTER WAS USED ON A PATIENT-NO PATIENT HARM BECAUSE DARRYL RECOGNIZED IT WAS NOT WORKING AND REMOVED THE MONITOR MONITOR WAS DISCONTINUED DARRYL PICKED IT UP FROM THE PATIENT AND COLLECT CAS PO#RP 2385-01 THIS PO IS APPRVD FOR $195.00 ATTENTION RON JEFFREY RED TAG	



CUSTOMER RETURN TRAVELLER

RECEIVING ****

!ECEIVER#	30333
R# LI#	CR10003 1
)ATE RECEIVED	07-24-01
)ACKING LIST#	00
!O OF CARTONS	1
UST# CUST NAME	6892 HOME CARE SUPPLY
)ART# REV00	01-05-0163 REV
)ESCRIPTION	AMI MONITOR W MODEM
!CCT#	500-0-50-1
!UANTITY RECEIVED	1
)ERIAL NUMBERS	482606

!ETURN CODES/REASONS

98 NON-WARRANTY, 501-0-50-1, 1603

OMMENTS

APNEA WILL NOT ALARM-
VEN FROM BENCHTOP
TESTER WAS USED ON A
)ATIENT-NO PATIENT HARM
BECAUSE DARRYL RECOGNIZED
IT WAS NOT WORKING AND
REMOVED THE MONITOR
ITOR WAS DISCONTINUED
ARRYL PICKED IT UP FROM
HE PATIENT AND CALLED
CAS PO#RP-2385-01
THIS PO IS APPRVD FOR
$195 00
ATTENTION RON JEFFREY
RED TAG

**** INSPECTION ****

Date of Inspection	7-26-01
Inspector's Initials	LO
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

014200

MEDWATCH

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

Mfr report # 2244861200100036

MFR/dist report #

FDA use Only

Patient information

Patient identifier	2. Age at time of event: / or Date of birth	3. Sex	4. Weight
NK	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)

Outcomes attributed to adverse event (check all that apply)

☐ death ____ (mo/da/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other ____

Date of event (mo/da/yr)	Date of this report (mo/da/yr)
07/00/01	08/27/01

Describe event or problem

Dealer reports that the service LED flashes once every five seconds and there is a failure of the audible alarm

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) (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)	8 Event reappeared after reintroduction
#1 NA	#1 NA	#1 ☐ yes ☐ no ☒ doesn't apply
#2	#2	#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 (mo/da/yr): NA

6
model # 9700A
catalog # NA
serial # ~~3200268~~ 30200268 8/27/01
lot # NA
other # RGA9817

7 If implanted give date (mo/da/yr): NA

8 If explanted, give date (mo/da/yr): NA

9 Device available for evaluation? (Do not send to FDA)
☒ yes ☐ no ☐ returned to manufacturer on 08/08/01 (mo/da/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

NA

E. Initial reporter

1 Name & address	phone #	2 Health professional?	3 Occupation	4 Initial report also report to FDA
Best Care Medical Equipment 711 West 17th St. Suite C7 Costa Mesa CA 92627 032518	949-645-6047	☐ yes ☒ no	Dealer	☐ yes ☐ no ☒ unk

EXHIBIT 112

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.

dication and Device
perience Report
tinued)

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 ood nd Drug Administration

idelines for specific instructions

Page 2 of 2

FDA Use Only

For use by user facility/distributor–devices only

heck one
☐ user facility ☐ distributor

2. UF/Dist report number

ser facility or distributor name/address

ontact person

5 Phone Number

ate user facility or distributor ecame aware of event (mo/day/yr)

7 Type of report
☐ Initial
☐ follow-up # ____

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

pproximate ge of device

10 Event problem codes (refer to coding manual)
patient code ____ – ____ – ____
device code ____ – ____ – ____

Report sent to FDA?
yes ____ (mo/day/yr)
no

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

Report sent to manufacturer?
yes ____ (mo/day/yr)
no

ufacturer 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 (mo/yr)
UNK

5 Labeled for single use?
☐ yes ☒ no

6 Evaluation codes (refer to coding manual)

method	10	33		
results	710	414		
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 360h(f) list correction/removal reporting number

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

NA

All manufacturers

Contact office – name/address (& mfring site for devices)
AS Medical Systems Inc
4 E Industrial Rd
Branford CT 06405
Attn Ron Jeffrey
Note CAS purchased product line after this device was manufactured from.
Delicor Puritan Bennett
800 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 (mo/day/yr)
07/27/01

5 (A)NDA # NA
IND # ____
PLA # ____
pre 1938 ☐ yes
OTC product ☐ yes

If IND protocol #
NA

Type of r port (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☒ Initial ☐ follow-up # ____

8 Adverse event term(s)
NA

M eport number
2 361200100036

032519

public reporting burden for this collection of information has be stimated to average one hour per response including the time for reviewing instructions arching existing dat sources, athering and maint ain th data needed, nd completing and reviewi g the collection f information. Send comment regarding this burden estimate any other aspect of this collection of nformation, cludin suggestions for reducing this burden t

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building Room 531-H
200 Independence Avenue S.W
Wa hington, D C. 20201

An pe cy may no conduct or sponsor, and person i not required to respon to collection of information unless it displays currently valid OMB control number

Please DO NOT RETURN this form to this address

DA Form 3500A back

Medical Systems, Inc.

9817

DATE: 7/27/01

CUSTOMER: BEST CARE MEDICAL

CUST #: 7751

MODEL: AMI W/MODEM

SERIAL #: 3200268

PART #: 01 05 0163

WARRANTY: No

CUSTOMER COMMENTS: SERVICE LED FLASHES ONCE EVERY FIVE SECONDS FAILURE OF AUDIBLE ALARM
ALERT RON JEFFREY

REPAIR CODES

2 0402 28 02 0 | 21-01 1004 | 21 01 1009 | 28 02 0316

REPAIR COMMENTS: FRONT ALARM OUTPUT DID NOT QUITE MEET SPECIFICATIONS REPLACED FRONT ALARM INSTALLED ECN 5554 PASSED ALL FUNCTIONAL TESTS

INVESTIGATION: DUPLICATED FLASHING SERVICE ALARM BY REMOVING AND INSERTING THE PATIENT CABLE FROM THE MONITOR SINCE THIS WAS A MONITOR CONDITION NOT A PATIENT CONDITION NO AUDIO ALARM IS HEARD MDR # 00036 sent 8/27/01

CLOSED BY: R Jeffrey

DATE CLOSED: 8/27/01

032520

SERVICE REPORT

SECTION A Procedure Number

GA # or S/O # 9817 CUSTOMER Best Care Medical

MODEL # 9700B SERIAL # 30200268

DATE RECEIVED 8-8-01 ESTIMATE REQUIRED ☐ Do not perform work until estimate is approved

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

☑ Complaint Service LED flashes once every five seconds - failure of audible alarm.

INITIAL FINDINGS

Duplicated flashing service light by removing and inserting the patient cable from the monitor. Since this was a monitor condition not a patient condition, no audio alarm is heard

Has the customers stated complaint been verified? ☑ YES ☐ NO

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

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

Front alarm output did not quite meet specification Replaced front alarm Passed functional tests INSTALLED ECN 5554: PASSED ALL FINAL TESTS

ECN Update # 5554

032521

	Rec.	2Min	Final	
TECH	[illegible]		[illegible]	Total
DATE	8-23-01		8-23-01	Time
PAIR TIME	.5		½	1

Date to QA: 8-23-01

8 3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously) and wait approximately 30 seconds for chirp 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 LD

Date 8-24-01

FAIL ☐ Reason for rejection _____

QA Inspector _____ Date _____

Correction made _____

QA Inspector _____ Date _____

032522

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 strobes through self-test.	✓	____
B) LCD display strobes through self-test Parameters	✓	____
C) Alarm will sound at both front and rear panel locations	✓	____
D) With patient leads disconnected from monitor the front panel alarm will turn on.	✓	____

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.	✓	____

032523

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 02

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

1 SCOPE

To confirm that an AMI 9700 Series monitor operates to its full intent and conforms to CAS Medical test specifications

SERIAL # 30200218
WORK ORDER #
RGA # 9817

2 TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 DRAWINGS REQUIRED
3 1 EMI label drawing # 21-01-0932
3 2 Modem label drawing # 21-01-0871
3 3 Serial number label drawing # 21-01-0884
3 4 Device tracking label drawing # 21-01-0931
3 5 Service label drawing # 21-01-0935

	PASS	FAIL
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 Ref. Manufacturing Process Sheet # 03-08-0360		
5 1 EMI label, Ref process sheet for location and drawing #21 01-0932 for content.	✓	
5.2 Modem label Ref process sheet for location and drawing #21-01-0871 for content.	✓	
5 3 Serial #/Device Tracking label, Ref process sheet for location and drawings #21 01-0884 and #21-01-0931 for content.	✓	
5 4 Service label, Ref process sheet for location and drawing # 21 01-0935 for content.	✓	
	PASS	FAIL
6 VISUAL INSPECTION	✓	
6 1 Inspect AMI Plus monitor for workmanship	✓	
6.2 Inspect labels for legibility	✓	
6.3 Is monitor clean?		

032524

7 FUNCTIONAL SELF TEST

REPORT Single Run Summary

TECHNICAL REPORT #2126

IAL NUMBER 30200268 TEST RESULTS PASSED

REVISION 1 1 *Amt Plus w/Modem, Final Test*

TEST DATE 8/23/01 MODEL NUMBER Y 9700B

PART NUMBER Y-006122-00B

NELLCOR PURITAN BENNETT.

TIME	TEST	TEST DESCRIPTION	STATUS
4 26 32 PM	1	Initial Power Up	PASSED
4 26 32 PM	2	Version & Serial Number Verification	PASSED
4 27 13 PM	3	Time & Date	PASSED
4 27 49 PM	4	Patient Setup	PASSED
4 28 00 PM	5	Patient Limits	PASSED
4 28 08 PM	6	Access Code	PASSED
4 28 42 PM	7	O2 Desat	PASSED
4 30 00 PM	8	Signal Quality Indicator	PASSED
4 32 49 PM	9	Resp Detect min, mid, and max	PASSED
4 34 00 PM	10	ECG Crosstalk	PASSED
4 37 55 PM	11	ECG Detect min, mid max Rate & Amplitude	PASSED
42 00 PM	12	Reverse Leads ECG Detect min, mid max Rate & Amp	PASSED
4 43 08 PM	13	Apnea Alarm ECG = RESP	PASSED
4 43 54 PM	14	Human Alarm Condition - Heart Slow	PASSED
4 44 58 PM	15	Human Alarm Condition - Apnea	PASSED
4 51 02 PM	16	4 2 VDC +/- 100mV Verification	PASSED
4 51 10 PM	17	WatchDog Test	PASSED
4 56 41 PM	18	Data Transfer & Recording Verification	PASSED

032525

OPERATOR Andrew Hamblin STATION ID 1 RUN ID 66 PAGE 1

AMI 9700X Parts Used List

Qty	Part Number	Description
	01 05-0174	9700 Software
	03-11-0040	9700G German Software
	03-11-0041	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	16-04-0085	0 1ufd cap (C235)
	29-01-0218	Feet, case
	28-02-0275	Foot-Rubber (square)
1	28-02-0402	Remote Alarm Gasket

RGA # 9817

S/N 30200268

Date 8-23-01

Other Parts Used

Qty	Part Number	Description
	03-08-0314	Battery Assembly
1	28-02-0328	CAP DUST 25 PIN
	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
	22-01-0187	Patient Cable Jack
	17 08-0123	1Meg Resistor - AMI Plus
1	28-02-0316	Sonalarm assy

032526

ENTERED AUG 3 2001

AS MEDICAL SYSTEMS, INC
EFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

PRODUCT COMPLAINT # 9817

INSTRUCTIONS.
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B.
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION. 7751

A

ORIGINATED BY Dominick
DATE OF THIS REPORT 7/22/01
PRODUCT 9200
LOT/SERIAL # 20200268
QUANTITY 1

CUSTOMER NAME. Best Care Medical Equip
ADDRESS 211 West 17th Suite C7
Costa Mesa Ca 92627
COMPLAINANT
PHONE: 949-645-6047

DETAIL OF COMPLAINT
Service LED flashes once every five seconds - failure of audible alarm

Purchase Order # 7/27/01 Bob

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

_VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
ISSUED RGA # 9817
COPY OF WRITTEN RESPONSE ATTACHED
OTHER:

_VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
CORRECT PRODUCT SENT (S/O #)
NOTIFIED

B

DATE RECEIVED AT QA 8/3/01 ASSIGNED TO TEST QA
FOR ✓ INVESTIGATION CORRECTIVE ACTION RESPONSE DUE DATE / /
QA COMMENTS TO ASSIGNEE

INVESTIGATION RESULTS (NOTE: FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT)

See access DB

REASON FOR NO INVESTIGATION

AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION.

~~Hold~~ 8/20/01 MDR # 00036 Sent 8/28/01

014403

REPLY TO COMPLAINANT

YES NO REASON FOR NO REPLY

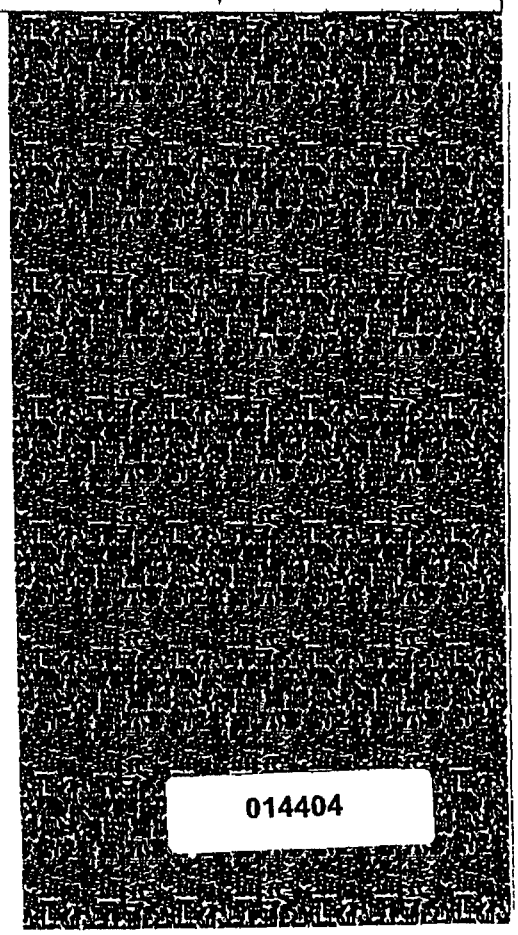
CLOSE OUT

SIGNATURE

DATE 8/22/01

LAB MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
44 EAST INDUSTRIAL RD • BRANFORD, CT 06405
203-488-6056 • FAX 203-488-9438

DATE 08/27/01



CUSTOMER RETURN TRAVELLER

*** RECEIVING ****

'ECEIVER#	30679
R# LI#	CR9817 1
)ATE RECEIVED.	08-08-01
'ACKING LIST#	00
)O OF CARTONS	1
UST# CUST NAME	7751 BEST CARE MEDICAL
)ART# REV00	01-05-0163 REV
)ESCRIPTION	AMI MONITOR W MODEM
)CCT#	500-0-50-1
)UANTITY RECEIVED	1
)ERIAL NUMBERS	Y-30200268

)ETURN CODES/REASONS

)8 NON-WARRANTY, 501-0-50-1, 1603

OMMENTS

)ERVICE LED FLASHES
)NCE EVERY FIVE SECONDS-
-AILURE OF AUDIBLE ALARM
*RED TAG
*NOTIFY RON JEFFREY

ccn 8-23-01

MONITOR FUNCTIONAL TESTED

$100

* INSPECTION ****

ate of Inspection	8-24-01
Inspector's Initials	VD
)QL 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

014405

Preliminary Study Report | **Ami Apnea Monitor** | **Summary Report**

« Patient Information »

		Hernandez, Salvador	HER
Gender	[None]	Gestational	40 weeks
Birth Date	08/23/01	Study Age	0 0 weeks

« Study Ends »

Ami Monitor	08/23/01 Thu	12 33.23	
Rep Gen PC	08/23/01 Thu	15 32 07	[At Time Of Transfer]

« Monitor Setup »

Aux 1 Signal	O2 Satur	HR Slow Mode	5 Second Delay
Aux 2 Signal	PulseRate	Event Capture	FIFO Full Dura
Aux 3 Signal	Position		

« Monitor Limits »

Apnea Alarm	20 Sec	Apnea Log	15 Sec
Heart Slow	80 BPM	Heart Slow	80 BPM
Heart Fast	225 BPM	Heart Fast	225 BPM
		Desaturation	85 % Sat

« Recorded Events »

Monitor Logs	8 of 2000	Study Start	07/27/01 Fri 11 36
Patient Logs	2 of 2000	Study Period	3 Weeks 6 Days
Event Waves	0 0% Filled	Monitor Time	9 Mins 30 Secs [0 0%]

« Recorded Waveforms »

No Waveforms Available

« Events Counted »

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

« Modem Answer Only »

« System Version »

Serial Numb	30200268	Ami Monitor	11 11 31 JAN-00
Access Code	[NONE]	Report Generator	01 1a 19-Mar 99

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

014409

Nellcor Puritan Bennett — Ami Apnea Monitor — All Study Logs

	Date	Time	Event Type	
< 1 >	07/27	10:52.16	Monitor Powered Up	
< 2 >	07/27	11 36 12	New Recording Start	
< 3 >	07/27	11 36.29	Monitor Powered Down	
< 4 >	07/27	11 38 10	Monitor Powered Up	
1	07/27	11 42.19	Loose Lead	1 Sec
2	07/27	11 42 19	Loose Lead	1 Sec
< 5 >	07/27	11 42.20	Front Alarm Not Heard	
< 6 >	07/27	11 46 56	Monitor Powered Down	
< 7 >	08/23	12:32:31	Monitor Powered Up	
< 8 >	08/23	12.32.58	Detection Disabled	
<Ami>	08/23	12.33 23	Received 8 Monitor Logs	
	08/23	12 33 23	Received 2 Patient Logs	

Event Count Totals

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

Copyright (c) 1997 98 Nellcor Puritan Bennett, Inc

014410

Nellcor Puritan Bennett — Ami Apnea Monitoring Periods

Previous Recording Session Cleared

07/27	11 36 12	thru 07/27	11 36 29	17 Secs
07/27	11 38 10	thru 07/27	11 46 56	8 Mins 46 Secs
08/23	12.32 31	thru 08/23	12 32 58	27 Secs

Duration of the Study Period Was	3 Weeks 6 Days
Total Time Monitor Was Recording	9 Mins 30 Secs
Total Time Monitor Was Turned Off	3 Weeks 6 Days
% of Study Period Monitor Was On	0 0%

Copyright (c) 1997 98 Nellcor Puritan Bennett, Inc

014411

MEDWATCH
MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities distributors and manufacturers for MANDATORY reporting

Page 1 of 2

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

MFR report #: 2244861200100042
User/Dist report #:
FDA Use Only

A. Patient information

Patient identifier	2. Age at time of event: UNK or Date of birth: UNK	3. Sex: UNK ☐ female ☐ male	4. Weight: UNK lbs or ___ kgs
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 ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

Date of event (mo/day/yr): 08/00/01

Date of this report (mo/day/yr): 10/12/01

Describe event or problem

In-house service report confirms the dealers report that the monitor's audible alarm has not worked at the time that the service LED was flashing

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

#1 NA

#2

3. Therapy dates (if unknown give duration) from/to (or 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)

#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 (mo/day/yr): NA

6

model # 9700A

catalog # NA

serial # 483351

lot # NA

other # RGA10196

7 If implanted give date (mo/day/yr): NA

8 If explanted, give date (mo/day/yr): NA

9 Device available for evaluation? (Do not send to FDA)

☒ yes ☐ no ☐ returned to manufacturer on 09/19/01 (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

NA

E. Initial reporter

1 Name & address

Home Care Supply
18227 Ammi Trail
Houston TX 77066

phone # 281-448 7299

032527

2. Health professional? ☐ yes ☒ no

3 Occupation: Dealer

4 Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

EXHIBIT 113

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

dication and Device
perience Report
ntinued)

r 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
P blt Health Servic Food and Drug Administration

Page 2 of 2

FDA Use Only

I Use by user facility/distributor-devices only

heck one
☐ user facility ☐ distributor

2. UF/Dist report number

ser facility or distributor name/address

ontact person

5 Phone Number

ate user facility or distributor ecame aware of event (mo/day/yr)

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

8 Date of this report (mo/day/yr)

Approximate ge of device

10 Event problem codes (refer to coding manual)
patient code
device code

Report sent to FDA?
☐ yes ____ (mo/day/yr)
☐ no

Report sent to manufacturer?
☐ yes ____ (mo/day/yr)
☐ no

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

Manufacturer name/addr ss

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 (mo/yr)
02/04/00

5 Labeled for single use?
☐ yes ☒ no

6. E aluation codes (refer to coding manual)

method	10	33		
results	120	137		
conclusions	54			

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 360l(f) list correction/removal reporting number
NA

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

NA

All manufacturers

Contact office – name/address (& mfring site for devices)
AS Medical Systems Inc
14 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

3 Report s urce (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consume
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☒ other
Dealer

Date received by manufacturer (mo/day/yr)
10/05/01

5 (A) NDA # NA
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

If IND protocol #
NA

7 Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☒ initial ☐ follow-up # ____

8 Adverse ev nt term(s)
NA

9 Mf report number
2? 4861200100042

032528

public report g burden for this ollection of information as been estimate to average one per response, including the time for reviewing instruct ns, searching existing data sourc s, gathering and maintaining th data ne ded, and completing d reviewing the collection of information. Send comments regarding this burde estimat or any other aspect f this collection of information, including suggestions for reducing this burde to

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aperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
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 displays currently valid OMB control umber

Please DO NOT RETURN this form to this add ess

FDA Form 3500A back

10196

8/24/01

CUSTOMER: HOME CARE SUPPLY

8230

MODEL: AMI W/MODEM

SERIAL: 483351

PART: 01-05-0163

WARRANTY: No

CUSTOMER COMMENTS: SERVICE LIGHT WAS FLASHING WITH NO AUDIO ALARM INDICATES A FAILED AUDIBLE ALARM

REPAIR ACTION

PART: 1 0335, 16 04 0

PART: 2 0275, 28 02 0

PART: 3-0314 28 02-

PART: 5, 21 01 1001 0

REPAIR COMMENTS: UPDATED PER DEVIATION DOO 111 INSTALLED ECN 5554 REPLACED TOP AND BOTTOM ENCLOSURE RECERT TO MEET MFG SPECIFICATIONS REPLACED FUSE SONALARM LITHIUM 3 679 PASSED ALL FUNCTIONAL TESTS UNIT OK

INVESTIGATION: BATTERY DATED 2/00 NEEDS RECERT DUT TO OUTDATED BATTERY ALSO NEEDS SONALARM AND TOP AND BOTTOM ENCLOSURE Likely that cleaning fluid cracked case Alarm probably drew too much current blowing fuses needing replacement MDR# 00042 sent 10/12/01

CLOSED BY: R Jeffrey

DATE CLOSED: 10/12/01

032529

ENTERED JG 2 4 2001

S MEDIGAL SYSTEMS, INC
REFERENCE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

Angela – Watch for S.R Notify me if there is an alarm problem found – Don

OLUCT MPLAINT # 10196

INSTRUCTIONS
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION. &.

ORIGINATED BY Dominick
DATE OF THIS REPORT 8/24/01
PRODUCT Ami
LOT/SERIAL # 483351
QUANTITY 1

CUSTOMER NAME Home Care
ADDRESS 18227 Round T
Houston Tx 77066
COMPLAINANT Winston
PHONE 281-448-72

DETAIL OF COMPLAINT

Service LED was flashing, with no audio alarm. a failed Audible Alarm.

PO - RP - 050564-39

ACTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

- ☐ VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
- ☐ VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
- ☐ ISSUED RGA # 10196
- ☐ CORRECT PRODUCT SENT (S/O # _____)
- ☐ COPY OF WRITTEN RESPONSE ATTACHED
- ☐ NOTIFIED _____
- ☐ OTHER: _____

DATE RECEIVED AT QA 8/24/01 ASSIGNED TO TEST V QA
FOR ✓ INVESTIGATION _____ CORRECTIVE ACTION RESPONSE DUE DATE. / /
QA COMMENTS TO ASSIGNEE _____

INVESTIGATION RESULTS (NOTE FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT)
No indication that malfunction could cause or contribute to an adverse event Complaint does not necessarily mean that had an apnea (or Respiratory) event occurred an alarm would not have sounded @ 9/21/01

REASON FOR NO INVESTIGATION — AUTHORIZED BY

CORRECTIVE ACTION AND DISPOSITION

'LY TO COMPLAINANT
☐YES ☐ NO REASON FOR NO REPLY _____

CAS 002399

CLOSE OUT
SIGNATURE _____ DATE. _____

SERVICE REPORT

SECTION A Procedure Number

RGA # or S/O # 10196 CUSTOMER HOME CARE SUPPLY

MODEL # 9700A W/MODEM SERIAL # 483351

DATE RECEIVED 9-19-01 ESTIMATE REQUIRED ☐ Do not perform work until estimate is approved

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

☒ Complaint: YELLOW LED WAS FLASHING WITH NO AUDIO ALARM (INDICATES A FAILED AUDIBLE ALARM)

INITIAL FINDINGS

BATTERY DATED 2/00; MONITOR NEEDS RECERTIFICATION DUE TO OUT DATED BATTERY; ALSO NEEDS A SPKR ASSY; ALSO NEEDS A TOP & BOTTOM ENCLOSURE;

Has the customers stated complaint been verified? ☑ YES ☐ NO

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

☐ QA Required ☐ Engineering Required ☐ Sales Required

SERVICE FINDINGS/OTHER SERVICE PERFORMED

UPDATED PER DEVIATION DEV-111; INSTALLED ECN 5554; REPLACED TOP & BOTTOM ENCLOSURE; RECERTIFIED TO MEET MANUFACTURERS SPECIFICATIONS; REPLACED FUSE; REPLACED SPKR ASSY; PASSED ALL FUNCTIONAL LITHIUM 3.6V TESTS; PASSED ALL FINAL TESTS;

ECN Update # 5554

032530

	Rec.	2Min	Final	Total
TECH	CLH		CLH	
DATE	9-28-01		10-5-01	Time
REPAIR TIME	½		½	1

Date to QA: 10-5-01

CAS Medical Systems Inc Form 21-04-0027 Rev 6

CAS MEDICAL SYSTEMS, INC

QA DATA SHEET
FORM 21-04-0220
REVISION 02
PAGE 1 OF 3

QA FINAL TEST AND INSPECTION
AMI 9700 SERIES MONITORS

1 SCOPE

To confirm that an AMI 9700 Series monitor operates to its full intent and conforms to CAS Medical test specifications

SERIAL # 483351
WORK ORDER # _____
RGA # 10196

2 TEST EQUIPMENT REQUIRED
EdenTec 2301 multi function tester

3 DRAWINGS REQUIRED
3 1 EMI label, drawing # 21-01-0932
3 2 Modem label, drawing # 21-01-0871
3 3 Serial number label drawing # 21-01-0884
3 4 Device tracking label drawing # 21-01-0931
3 5 Service label, drawing # 21-01-0935

	PASS	FAIL
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 Ref Manufacturing Process Sheet # 03-08-0360		
5 1 EMI label Ref process sheet for location and drawing #21-01-0932 for content.	✓	___
5 2 Modem label Ref process sheet for location and drawing #21 01-0871 for content.	✓	___
5 3 Serial #/Device Tracking label, Ref process sheet for location and drawings #21-01-0884 and #21 01 0931 for content.	✓	___
5 4 Service label, Ref process sheet for location and drawing # 21-01-0935 for content.	✓	___
	PASS	FAIL
6 VISUAL INSPECTION		
6 1 Inspect AMI Plus monitor for workmanship	✓	
6 2 Inspect labels for legibility	✓	
6 3 Is monitor clean?	✓	___

032531

7 FUNCTIONAL SELF TEST

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 strobes through self-test.	✓	
B) LCD display strobes through self-test Parameters	✓	
C) Alarm will sound at both front and rear panel locations	✓	
D) With patient leads disconnected from monitor the front panel alarm will turn on	✓	

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	✓	

032532

8.3 CLEARING MEMORY

Turn unit under test off (press reset & power simultaneously) and wait approximately 30 seconds for chirp. 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 10-10-01

FAIL

☐ Reason for rejection. _____

_____

QA Inspector: _____ Date _____

Correction made _____

_____

QA Inspector _____ Date _____

032533

AMI 9700X Parts Used List

Qty	Part Number	Description
1	01-05-0174	9700 Software
0	03-11-0040	9700G German Software
0	03 11-0041	9700S Spanish Software
2	15-01-0335	IC 74AC00 (U23 & U28)
1	16-04-0085	0 1ufd cap (C235)
1	29 01-0218	Feet, case
1	28-02-0275	Foot Rubber (square)
1	28 02-0402	Remote Alarm Gasket

RGA # 10191

S/N 483351

Date 9-28-01

Other Parts Used

Qty	Part Number	Description
1	03-08-0314	Battery Assembly
1	28 02-0328	CAP DUST 25 PIN
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
	22-01 0187	Patient Cable Jack
	17-08 0123	1Meg Resistor AMI Plus
1	09-01 0024	Fuse

032534

AMI 9700 Deviation D00-111 Parts List

Qty	Part Number	Description
	01-05-0174	9700 Software
	03 11-0040	9700G German Software
	03 11-0041	9700S Spanish Software
	15-01-0335	IC 74AC00 (U23 & U28)
	16-04-0085	0 1ufd cap (C235)
	29-01-0218	Feet, case
	28-02-0275	Foot-Rubber (square)

RGA # 10196

S/N 483351

Date 9-28-01

Other Parts Used

Qty	Part Number	Description
4	29-01-0218	FEET, CASE
1	28 02-0275	FOOT, RUBBER
1	21-06-0004	SWITCH, OVERLAY, FRONT
1	21-06-0001	SWITCH, OVERLAY, LCD
1	28-02-0279	LCD GASKET
1	28-02-0277	AC GASKET
1	28-02-0280	MODEM GASKET
[illegible]	[illegible]	[illegible] Qty 4-24-01
1	21-01-0848	DEVICE TRACKING LABEL
1	21-01-0870	MODEM LABEL

1 21-01-0886 SERVICE LABEL

1 28-02-0274 FOAM SHIELDING DB25 (RS 232

1 21-01-0177 LABEL CAUTION & UL ICSA

1 29-01-0213 ENCLOSURE, BOTTOM

1 29-01-0217 TCP ENCLOSURE

1 21-01-0849 LABEL, EMI, ENGLISH

032535

REPORT Single Run Summary

TECHNICAL REPORT #2126

SERIAL NUMBER 483351 TEST RESULTS PASSED

REVISION 1 2 *Ami w/Modem, Final Test*

TEST DATE 10/ 5/01 MODEL NUMBER L-9700A

PART NUMBER Y-006122 10A

NELLCOR PURITAN BENNETT

TIME	TEST	TEST DESCRIPTION	STATUS
11 58 32 AM	1	Initial Power Up	PASSED
11 58 32 AM	2	Version & Serial Number Verification	PASSED
11 59 11 AM	3	Time & Date	PASSED
11 59 46 AM	4	Patient Setup	PASSED
11 59 58 AM	5	Patient Limits	PASSED
12 00 05 PM	6	Access Code	PASSED
12 00 39 PM	7	O2 Desat	PASSED
12 01 57 PM	8	Signal Quality Indicator	PASSED
12 04 48 PM	9	Resp Detect min, mid, and max	PASSED
12 05 59 PM	10	ECG Crosstalk	PASSED
12 09 55 PM	11	ECG Detect min, mid, max Rate & Amplitude	PASSED
12 14 03 PM	12	Reverse Leads, ECG Detect min, mid, max Rate & Amp	PASSED
12 15 11 PM	13	Apnea Alarm ECG = RESP	PASSED
12 15 56 PM	14	Human Alarm Condition - Heart Slow	PASSED
12 16 46 PM	15	Human Alarm Condition - Apnea	PASSED
12 48 48 PM	16	Power Alert Function	PASSED
12 48 57 PM	17	WatchDog Test	PASSED
12 53 43 PM	18	Data Transfer & Recording Verification	PASSED

032536

OPERATOR Andrew Hamblin STATION ID 1 RUN ID 490 PAGE 1

✓ ENTERED AUG 2 4 2001

YSTEMS, INC
CE QSP2009

QA DATA SHEET

PRODUCT COMPLAINT FORM

1 10196

INSTRUCTIONS
1. ORIGINATOR COMPLETES SECTION A.
2. SEND TO QA MANAGER TO COMPLETE SECTION B
3. INJURY TYPE OF COMPLAINTS NEED IMMEDIATE ACTION. 8230

IATED BY Dominick
OF THIS REPORT 8/24/01
UCT Ami
ERIAL # 483351
NTITY 1

CUSTOMER NAME Home Care Supply
ADDRESS 18227 Round Trail
Houston TX 77066
COMPLAINANT Winston
PHONE 281-448-7299

AIL OF COMPLAINT
Service LED was flashing with no audio Alarm. An electric failed Audible Alarm

PO - RP - 050564-39

CTION TAKEN THUS FAR (CHECK AS APPROPRIATE)

- ☐ VERIFIED ORDER ENTERED CORRECTLY (PICKING ERROR)
- ☐ VERIFIED ORDER ENTERED INCORRECTLY (ORDER ENTRY ERROR)
- ☐ ISSUED RGA # 10196
- ☐ CORRECT PRODUCT SENT (S/O # _____)
- ☐ COPY OF WRITTEN RESPONSE ATTACHED
- ☐ NOTIFIED _____
- ☐ OTHER _____

DATE RECEIVED AT QA 8/24/01 ASSIGNED TO TEST V QA
FOR ✓ INVESTIGATION _____ CORRECTIVE ACTION RESPONSE DUE DATE 1 1
QA COMMENTS TO ASSIGNEE _____

INVESTIGATION RESULTS (NOTE FOR SERVICE COMPLAINTS ATTACH COPY OF SERVICE REPORT)
No indication that malfunction could cause or contribute to an adverse event Complaint does not necessarily mean that had an apnea (or respiratory) event occurred an alarm would not have sounded @ 9/21/01 In light of the findings at Service, (alarm needed replacement) an RGA is now required → @ 10/12/01

REASON FOR NO INVESTIGATION _____ AUTHORIZED BY _____

CORRECTIVE ACTION AND DISPOSITION
RMDR # 00042 Sent 10/12/01 @

032537

REPLY TO COMPLAINANT
☐ YES ☐ NO REASON FOR NO REPLY _____

CLOSE OUT _____ DATE 10/12/01

EDICAL SYSTEMS INC FORM 21-04-0045 REV 03

B woodley asked why alarm was replaced
It is speculated that alarm draws too much
current, thus blows the fuse

A number of case parts bay replaced probably due
to cracking from certain cleany fluids applied
by the dealer or user.

10/12/01

032538