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

Case No 08-CP-38-826

ORIGINAL

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

FINAL BRIEF OF RESPONDENT

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STATEMENT OF ISSUES ON APPEAL

1 Did the trial court abuse its discretion in excluding the expert testimony of William Lively, Walter Daugherity, and Donna Wilkins under Rule 702, SCRE, where the testimony of each was unreliable under established case law and, in the case of Wilkins, the expert also was not qualified?

2 Did the trial court properly exclude affidavits of the Graves' computer experts filed after CAS Medical Systems, Inc ("CAS"), moved for summary judgment and in contradiction to those experts' previous deposition testimony on issues critical to the case?

3 Did the trial court properly grant summary judgment given the Graves' inability to show proximate cause?

4 Did the trial court properly grant summary judgment where the Graves' computer experts failed to identify the computer code defect that caused the alleged injury and those experts failed to support their hypothesis of a computer code defect by testing or any other valid computer engineering method?

RESPONDENT'S STATEMENT OF THE CASE

CAS largely agrees with the Graves' statement of the case with the following additions and corrections

The Graves' amended complaint, dated July 3, 2006, alleges causes of action for strict liability, negligence, breach of implied warranty, and wrongful death It appears that the Graves' appeal is limited to the adverse ruling as to their strict liability claim

Experts Walter Daugherity ("Daugherity") and William Lively ("Lively") are computer experts Expert Frank Painter ("Painter") is a biomedical engineer, but did give an opinion on the software used in the AMI Plus monitor It is an issue on appeal whether the multiple affidavits filed by Daugherity and Lively after CAS moved for summary judgment on March 6 2009, offer supplementation and clarification as represented by Appellants in their Statement of the Case or instead contradicted their earlier deposition testimony

CAS filed its amended motion to exclude experts on May 21, 2009, and filed with it an affidavit by computer expert Roger S Pressman ("Dr Pressman") In response to later affidavits by Daugherity dated April 17, 2009 and February 2, 2010, CAS filed supplemental affidavits of Dr Pressman, dated September 1, 2009 and February 3, 2010 Judge James Williams held a hearing for all pending motions on February 2, 2010 The Graves filed motions to exclude Dr Pressman's affidavit and strike him as an expert but those motions have not been argued or decided by the trial court

On March 3, 2010, CAS filed the affidavit of Sudden Infant Death Syndrome ('SIDS") expert Dr Carl E Hunt, M D ("Dr Hunt") The Graves filed no opposition to that affidavit

STATEMENT OF FACTS

I Introduction

India Graves died from SIDS during the early morning hours of Sunday, April 11, 2004 At the time of her death, India was attached to a CAS, AMI Plus ("AMI") infant breathing and heart rate monitor The Graves allege the monitor failed to alarm during India's approximately one hour decline The AMI was approved for marketing by the Food and Drug Administration ("FDA") (Painter Dep R p 975, lines 7-10), after a review of extensive documentation, including documentation of the AMI software development and testing (*See* Model 9700 Summary Software Verification Test Plan (listing the extensive number and the variety of tests of the software), R pp 1117-1127) The monitor worked properly before and after India's death, and the Graves' experts never triggered or recreated a malfunction in the device The Graves thus allege that the monitor's alarm function failed only coincident with the slow heart rate and slow breathing events that India experienced in the hour prior to her death

The log of patient events and monitor activities kept by the monitor, essentially like an airplane's "black box," shows the events India experienced An electronic recording in the monitor shows that a microphone in the monitor heard the alarm sound as it should have during India's decline Simply put, the machine's own record indicates it was functioning properly at the time of India's death

The Graves' causation expert, Dr Donna Wilkins ("Dr Wilkins"), opined that India would have survived had the alarm sounded and the parents stimulated her, but Dr Wilkins admitted she was not an expert in SIDS, could cite no medical authority for her opinion that India would have revived, and based her opinion on the incorrect understanding that India had similar events in the past from which she was revived CAS

filed affidavit testimony from Dr Carl Hunt ("Dr Hunt"), a long-time SIDS researcher, to the effect that there is no support for the notion that a SIDS death can be avoided by caregiver stimulation The trial court found under Rule 702, SCRE, that Dr Wilkins was not qualified to give her opinion and that her opinion was unreliable

Prior to CAS's motion for summary judgment, the Graves' computer experts Lively and Daugherity opined that the monitor failed to alarm due to a computer code writing error or "bug" in the code, but claimed poor code structure kept them from effectively testing to find the supposed error They also stated that the structure did not cause the malfunction After CAS moved for summary judgment based in part on the lack of proof of the device defect that caused the injury, these experts provided new opinions in the form of multiple affidavits where they reversed course and stated that the poor code structure *did* cause the failure [1] None of these opinions were proved through testing

CAS provided affidavit testimony from Dr Roger Pressman ("Dr Pressman"), recognized by Lively as an expert on the issues at hand Dr Pressman disagreed with the bulk of Daugherity's and Lively's claims The trial court struck Lively and Daugherity's post-motion affidavits under *Cothran v Brown*, 357 S C 210, 592 S E 2d 629 (2004), and excluded their affidavit and deposition opinions as unreliable under Rule 702, SCRE

Painter, the Graves' expert biomedical engineer, opined that the alarm failed due

[1] For ease of reference, CAS provides the following chronology as the opinions of the Graves' computer experts Daugherity and Lively Lively provided an affidavit of October 17, 2007 and was deposed on May 23, 2008 Daugherity was deposed on May 22, 2008 CAS filed its summary judgment motion on March 6, 2009 and its amended motion to exclude expert testimony on May 21, 2009 The motions were heard on February 2, 2010 Daugherity submitted affidavits dated April 17, 2009, February 2, 2010, and a letter dated March 1, 2010 Lively submitted additional affidavits dated March 11, 2009, March 13, 2009, and an undated supplement regarding spaghetti code

to a software error based on the Graves' claim that it failed and a questionable series of complaints supposedly related to the Graves' alleged alarm failure Painter never looked for the error or reproduced the alleged failure through testing, and agreed that his "external inputs" failure theory was an unproven hypothesis The court found Painter's opinion unreliable as well

II Detailed Facts Surrounding India Graves' Death

India Graves was one of premature triplets Premature infants have significant health challenges, including apnea of prematurity – breathing stoppage due to an underdeveloped brain After spending roughly two months in the neonatal intensive care unit, each triplet was discharged on an AMI breathing and heart rate monitor The AMI monitor is designed to alarm both audibly and with LED lights for "patient events," when the infant's heart rate or breathing do not reach certain set limits for longer than a set time period The AMI also alarms for "equipment events," most commonly if the leads connecting the infant to the monitor become loose or disconnected Loose lead alarms alert the caregiver that the infant is not being monitored, but are a constant headache for parents of increasingly mobile infants Caregivers are trained to stimulate children having breathing or heart rate events and to use mouth-to-mouth resuscitation if needed

Significant to this case are the monitor's internal microphone and the log of events that the monitor maintains in memory The monitor records or "logs" patient events, equipment events, and alarm activity The Graves correctly note that the log records if the microphone *does not* hear the alarm when it should, *i e* , during a patient or equipment event The Graves overlook, however, that the system also logs when the monitor's internal microphone *does* hear the alarm As testified by Scott Lambert, one of the creators of the AMI, alarm detection and logging, which is controlled by a separate

software section or module than the alarm function, is the express purpose of the microphone (*See e g*, Lambert Dep , R p 916, line 25-p 920, line 3, R p 927, line 17-p 929, line 8, R p 937, line 18-p 938, line 18, R p 939, lines 19-22, R p 940, line 23-p 942, line 23) An "alarm-heard" bar or indicator appears in an area of the patient events page of the printed version of the log called "Alarm Activity " Its location on the page corresponds with the tracing or "waveforms" of the patient events that triggered the alarm (*Id* at R p 932, line 16-p 936, line 16, Elliott Dep , R p 874, line 12-p 877, line 15) (*See* Monitor Events Log 4/1/04–4/12/04 waveform pages, R pp 1023-1059)

The monitor log of India's final hours shows not only declining heart rate and breathing leading to her death, but also shows that the microphone detected the alarm sounding as it should have, and only as it should have, for each of these events (Lambert Dep , R p 935, line 18-p 936, line 6) This system was specifically designed in part to help disprove erroneous alarm failure claims, which historically have been a problem in dealing with monitors (*Id* at R p 921, line 21-p 926, line 2)

If the microphone does not hear the primary front alarm when it should, it triggers a backup alarm located at the rear of the monitor If neither alarm is detected by the microphone when they should be, the monitor goes into failure mode, with all lights flashing and both alarms sounding (*Id* at R p 916, line 24-p 917, line 24) The monitor is designed to log these instances as well The log of India's decline does not reflect any such occurrences, only that the alarm sounded properly

Although Daylight Savings Time was in effect on April 11, 2004, the time entries on India's monitor for the morning of her death were in Eastern Standard Time Thus, the events leading to India's death actually began with a "heart slow" shortly after

2 39 56 AM DST rather than at 1 39 56 as reflected on the log (Monitor Events Log April 4/1/04–4/12/04 at R p 1020) The monitor log shows that it was powered down at 2 50 31 AM, or 3 50 31 AM DST *Id* The EMS run sheet shows that EMS received the call from 911 at 3 46 AM EMS arrived at 4 01 AM, and EMT Anita Kelly ("Kelly") took India to the EMS truck almost immediately after going upstairs (Kelly Dep , R p 901, line 19-p 903, line 3) After powering down on April 11 at 3 50 31 AM DST, the AMI was not powered up again until Monday, April 12 at 10 41 AM DST, when Steve Elliott of Ashby Medical, the company that leased the monitors to the Graves, checked the monitor and successfully ran the start-up, self-test on the monitor (Elliott Dep , R p 872, lines 12-23, Monitor Events Log, R p 1020)

EMT Kelly had no reason to doubt the accuracy of the monitor log showing the monitor was powered down around 3 50 AM DST, about ten minutes before she got there (Kelly Dep , R p 912, lines 7-13) Mrs Graves did not believe that she had turned the monitor off Both of the Graves testified that they saw it with the lights on but not audibly alarming Mr Graves testified that he examined it with one of the EMTs Kelly denied that she looked at it with him and said the other EMT remained in the truck after they brought India out from the house (Kelly Dep , R p 906, line 18-p 907, line 18, R p 904, line 22-p 905, line 1) Kelly could only say she should have looked at the monitor (*id* at R p 913, lines 13-22), not whether she actually did examine it (*Id* at R p 914, lines 16-19 *See also id* at R p 909, line 15-p 910, line 2) None of the narrative entry on her run sheet is in quotes, so she was unable to say what she was told that morning or what she observed first hand (*Id* at R p 911, lines 1-19)

India's monitor has never failed to operate at any other time After successfully

starting and testing the monitor the day after India died, Elliott removed the monitor from the Graves' home and downloaded the log (Elliott Dep , R p 872, line 12-p 873, line 4) Elliott then sent the monitor to CAS, which also found it to be operating properly and returned it to Ashby India's monitor had been used by others before her and, after receiving it back from CAS, Ashby put the monitor back into service, where it remained and operated without problem until it was pulled from inventory as a result of this suit (*Id* at R p 881, line 11-p 882, line 4) Elliot's company had approximately 100 AMI monitors (*Id* at R p 879, lines 14-16) He has had no other complaint of an alarm not sounding (*id* at R p 879, line 17-p 880, line 9) and has never heard of a situation where an AMI monitor failed to log an alarm failure (*Id* at R p 878, lines 8-23)

The Graves testified that the monitor worked before the night of India's death (T Graves Dep , R p 896, lines 10-18, K Graves Dep , R p 899, lines 3-12) When Mrs Graves powered the monitor up the night India died, it properly ran through its self-test (T Graves Dep R p 894, line 25-p 895, line 11) She remembers hearing a low battery alarm that night and the log reflects also that someone responded to a loose lead alarm that evening by turning the monitor off and back on (Monitor Events Log April 4/1/04–4/12/04 at All Study Logs p 2, R p 1020) After India's death, the Graves allowed their two surviving triplets to continue to be monitored by their CAS AMI monitors (A Simmons Dep , R p 1002, lines 19-22)

Daugherity characterized as monitor failures several log entries of "front alarm not heard" and "rear alarm not heard" from the March log of India's monitor Lambert reviewed these events and noted that each was preceded by an active alarm and each was followed by the monitor being powered down, which had to be done by a caregiver

From these facts and from the fact that the monitor successfully self-tested on each start-up, it was his opinion that one or both alarms, depending on the entry, were being muffled while the caregiver attended to India (Lambert Dep , Appendix p 1, line 22-p 7, line 2) Daugherity apparently did not take the events surrounding these entries into account, and claimed the alarm could not be muffled, but had to admit that, like his other opinions, he had not tested this claim (Daugherity Dep , R p 833, line 5-p 835, line 19, R p 836, lines 16-24)

Mrs Graves' sister, April Simmons, the only other adult in the house that night (Simmons Dep , R p 999, lines 13-17), was sleeping in a downstairs bedroom (*id* at R p 992, lines 13-14), and woke up when she heard Mrs Graves screaming (*Id* at R p 993, lines 10-11) When she got upstairs, Mrs Graves had already unhooked India from the monitor, had placed India on the bed, and had begun CPR (*Id* at R p 995, lines 4-12, R p 996, lines 12-24, R p 997, lines 4-11, R p 998, lines 12-18) Simmons could not see the monitor because it was under the bassinet, and she never looked at the monitor thereafter (*Id* at R p 997, line 12-p 998, line 8) Simmons thought she would have heard the alarm had it sounded (*id* at R p 994, lines 16-20), but, again, was sleeping and on another floor of the house Ms Simmons often helped her sister tend to the triplets In accordance with Mr Lambert's observation about the alarm not heard entries, Ms Simmons habitually turned the monitors off during loose lead alarms before re-establishing the connection between the child and the monitor (*Id* at R p 1000, line 14-p 1001, line 6)

III The Graves' Causation Expert

Dr Wilkins is a neonatal specialist in Muncie, Indiana She was the Graves' specially retained expert on proximate cause, offered as an expert in SIDS to testify that

India likely would have been revived by her parents had the alarm sounded Despite her designation, Dr Wilkins denied that she was a SIDS expert (Wilkins Dep , R p 1007, lines 24-25)

Dr Wilkins had some exposure to the subject of SIDS in medical school and medical journals she subscribes to occasionally included articles on the subject, but she has never researched SIDS in a clinic, in the laboratory, or through a literature study Dr Wilkins did no research on SIDS before offering her opinion in this case, nor did she confer with any peer or expert on SIDS (*Id* at R p 1005, line 23-p 1007, line 23) Dr Wilkins did not identify a single study or article supporting her conclusion that an infant who otherwise would be a SIDS victim can be revived through stimulation or any other means (*Id* at R p 1005, lines 19-22) Dr Wilkins' opinion is inconsistent with what she tells caregivers in her practice, which is that a monitor will not necessarily save their child (*id* at R p 1008, line 19-p 1009, line 20), because "there's no proof that a monitor is going to prevent a SIDS " (*Id* at R p 1008, lines 13-14) Despite her opinion here, she knew that no one has connected apparent near death events (ALTEs") in children to SIDS (*id* at R p 1004, line 12-p 1005, line 18), so there is no medical evidence that a SIDS death can be avoided by intervention Finally, Dr Wilkins' opinion was based on the erroneous belief that India had been revived from prior events In fact, India had experienced no significant prior events, as testified by a pediatric pulmonologist who interpreted India's logs in consultation with India's pediatrician (Dr Jane Gwinn Dep , R p 886, lines 5-18, R p 887, lines 2-14, R p 23, line 22-p 26, line 5)

In response to Dr Gwinn's testimony, CAS filed the affidavit of Dr Hunt, a long-time SIDS researcher, who confirmed that there is no medical research supporting the

idea that India more likely than not would have survived her SIDS event under any circumstances (Hunt Aff ¶¶ 6-12, R pp 598-599)

Judge Williams excluded Dr Wilkins' opinions based both on lack of qualifications and lack of reliability

IV The Graves' Computer Experts

The Graves' two computer experts, Daugherity and Lively, worked together in an attempt to find a defect in the code that caused the monitor alarm not to sound CAS deposed them in May of 2008 after being assured by counsel that they had reached their full conclusions in the case

At that time, Lively and Daugherity testified that although they considered the "defect" in the monitor to be disorganized computer code, which they sometimes called "spaghetti code," they said that this was not the problem which caused the alleged malfunction, but only made the problem more difficult to find and repair (Daugherity Dep , R p 856, line 18-p 858, line 22, Lively Dep , R p 952, lines 11-18) They further testified that the problem causing the malfunction was a portion of code that had been miswritten, a computer "bug" that they had not located (Daugherity Dep , R p 856, line 18-p 858, line 22, Lively Dep , R p 952, line 19-p 953, line 18)

When asked in his deposition about a type of instruction in the code known as unconditional branch instructions or "GoTo" statements, Daugherity said that they were not the cause of the alarm failure but made "it harder to test and maintain and to find and fix bugs "[2] (Daugherity Dep , R p 852, lines 5-20) Daugherity hypothesized that a

[2] Understanding how GoTo statements work is not required to understand the expert claims in this case In general, however, GoTo statements are instructions in the code that cause a signal passing though the code to branch to another portion of the code They

particular input to the code triggered a malfunction but phrased this only as a possibility, not a probability (*See, e g*, R p 829, line 9-p 830, line 4)

These experts and Painter all tried to make an exemplar monitor malfunction but were unable to do so (*Id* at R p 846, lines 2-23, Painter Dep , R p 968, lines 1-12) They made no attempt to test the code itself to prove their hypothesis that there was a computer coding error that could cause the alarm to not sound The experts criticized the extensive testing performed on the software before FDA approval but gave no support for their criticism A forensic computer company, Software CPR, also extensively examined the code, which it found to be well organized, and tested it for many hours without a failure (Software CPR AMI and AMI Plus Technical Assessment Report, R pp 1139-1151)

The experts concluded that the AMI software has a defect based on their opinion of the general code structure, allegedly similar complaints[3], and the Graves' claim that it failed

They thus did not make a determination that India s alarm failed, they began their analysis with that assumption They have not published or sought peer review for their method of determining a software error through anecdotal evidence There is no literature that supports this approach Their opinion of a code error is not supported by testing, nor were the experts able to calculate rates of error for their opinions These

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are also referred to as "unconditional branch instructions " (Daugherity Dep , R p 849, lines 9-21)

[3] These complaints are not in the record below The Graves attached as Exhibit 8 to their October 23, 2009, memorandum a series of complaints ("Maude Reports") most of which are unrelated static electricity complaints (Elliott Dep , R p 883, line 10-p 884, line 8, Daugherity Dep , R p 848, lines 11-16) There is a 2007 complaint of a faulty alarm but as is shown on that document, the problem turned out to be dirty alarm speakers (*See* Maude Reports, R p 1088)

experts ignored parts of the record that did not fit their theory, such as the log kept by the monitor Additionally, although the reporting of a complaint to the FDA does not signify its validity (Painter Dep , R p 976, line 3-p 977, line 4), Daugherity in forming his opinion relied on the complaints as valid (Daugherity Dep , R p 831, lines 7-10), and Lively did not know whether they were valid or not, although he conceded that was important for him to know (Lively Dep , R p 955, lines 2-10) Neither the Graves nor their experts made any effort to show that the number of complaints was statistically significant with respect to the number of monitors in use or how the complaints as to the AMI compared to complaints relating to other brands of monitors The Graves made no showing that the complaints were substantially similar to the evidence in this case, nor did they show that the experts reasonably relied on them

Based on Daugherity's and Lively's testimony that the cause of the alleged malfunction was an error in the code that they could not identify, and the lack of qualified reliable medical testimony as to causation, CAS moved for summary judgment on March 6, 2009 On March 12, 2009, the Graves submitted a "supplemental affidavit of Lively, the first of five post-motion affidavits from Lively and Daugherity The essence of these affidavits was that, contrary to their prior testimony, the experts' opinion now was that, instead of a miswritten line of code being the problem, the structure of the code itself, and the use of GoTo statements in particular, caused the failure In addition, Daugherity reneged on his earlier testimony that he could not say the logging function had malfunctioned, opining in his April 17, 2009, affidavit, again without any supporting testing, that it was "certain that the logs are not reliable " (Daugherity Aff ¶ 24, R p 551)

V Frank Painter

Frank Painter, a biomedical engineer, examined the AMI monitor but did not critically examine the code or look for a defect in it (Painter Dep , R p 968, lines 21-25, R p 967, lines 10-13) Painter believed that a software failure in the monitor was induced by a combination of inputs to the monitor (*id* at R p 969, line 22-p 970, line 3), but had no idea what those inputs might be (*See, e g , id* at R p 971, lines 1-10, R p 972, lines 2-23) Painter agreed that his theory of external inputs causing the monitor to fail was no more that an unproven hypothetical (*Id* at R p 973, line 20-p 974, line 9)

Painter could never make the monitor malfunction (*id* at R p 968, lines 1-12), and thus any testing he performed failed to support his hypothesis Painter instead based his opinion of a software failure on the same unproven complaints about the monitor's operation as discussed above, and the Graves' claim that it failed [4] In creating his complaint collection, Painter lumped together a number of different types of alleged failures without regard for whether they could be causally related, his approach being to include all complaints unless proven to not be software claims (*See e g , id* at R p 989, lines 5-8) Even so, Painter admitted that at least some of the complaints he and the other experts relied on were more likely hardware problems and for others he could not tell the most likely cause (*See e g , id* at R p 986, line 4-p 989, line 8) Again, these complaints are not in the record below

Painter claimed he had identified a failure trend from his collection of undifferentiated complaints, but never addressed the significance of the fact that the last complaint he identified was early in 2005 (*id* at R p 982, lines 21-23), more than three

[4] These complaints were reported to the FDA by CAS or its predecessor, Mallinckrodt, as required by federal regulation FDA has taken no action as a result of these complaints

years before his July 10, 2008, deposition and more than five years before the Graves' final briefing and affidavits to the trial court [5] Since then the only alarm complaint in the record proved to be from a dirty alarm speaker (*See* Maude Report, R p 1088)

Painter had no idea how many AMI monitors were in the market (*id* at R p 982, line 24-p 983, line 2) and so could not calculate a rate of complaint He did not know the percentage of complaints on the AMI compared with other brands of monitors (*Id* at R p 983, lines 3-10) He also did not know the rate of error in his opinion (*id* at R p 984, lines 14-18) because "this is mostly just my understanding based on my particular background and experience as an engineer" (*Id* at R p 984, line 14-p 985, line 3) Painter has published no peer reviewed or other article of the method of analysis he used here and admitted that his testimony found no support in any learned treatise (*Id* at R p 985, lines 4-7)

Because he did not analyze the software, Painter was not qualified to describe the detailed operation of it, and in fact had a limited understanding of the monitor Among other errors, Painter suggested in his 2007 affidavit and in his deposition that the same software module that triggers the alarm controls the microphone and log (*See e g*, Painter Aff ¶ 17, R p 556 (actual affidavit paragraphs are unnumbered)) The logging system is actually controlled by a different software module (Lambert Dep , R p 942, lines 11-23) Painter did not understand prior to his deposition the critical fact that the monitor logs showed that the microphone has detected the audible alarms (Painter Dep , R p 978, line 19-p 979, line 5) Despite educating himself about this during the deposition and despite having only a hypothetical opinion as to a defect in the software,

[5] Painter also claimed that there had to be additional complaints for several years (*id* at R p 981, line 22-p 982, line 23), but the Graves never produced any

Painter simply chose to believe the Graves that the alarm did not sound over the monitor log showing that it did (*Id* at R p 978, lines 1-18, R p 980, lines 3-15)

The court excluded the Painter opinions under Rule 702, SCRE

VI Dr Roger Pressman

CAS filed the affidavits of Dr Pressman in response to the Graves' computer opinions (R pp 579-588) Dr Pressman is a well-known computer engineering educator and author (Pressman CV, R pp 613-614) Indeed, Lively acknowledged that he relied on Dr Pressman's text to inform his opinions for this case (Lively Dep , R p 944, line 19-p 945, line 3, R p 946, line 21-p 947, line 19), and in teaching code testing (*Id* at R p 947, line 25-p 949, line 20) Among other things, Pressman pointed out that the Graves' computer experts had by their methodology constructed a hypothesis but had not tested to prove it, as is required in software engineering (Pressman Aff ¶¶ 4 0-7 0, 14 0, R p 580, R pp 582-583) Daugherity and Lively offered no rebutting support for their discredited methodology Pressman also described the "decades old debate within the computer science and software engineering communities" regarding the use of GoTo statements and explained that in assembler language (also called "assembly," the language in the AMI monitor), GoTo statements are used frequently, and that avoiding GoTo statements may create rather than avoid errors This is consistent with Daugherity's deposition testimony but contrary to Daugherity's later affidavit opinions

After allowing the Graves an extensive opportunity to respond to CAS's motions to strike the expert affidavits and for summary judgment, the trial court granted CAS's motion to strike the later filed affidavits of Daugherity and Lively as contradicting critical sworn testimony to avoid summary judgment under *Cothran v Brown*, 357 S C 210, 592

S E 2d 629 (2004) The trial court also found that either version of the computer experts' opinions as well as Wilkins' and Painter's opinions did not meet the reliability factors enunciated in *State v Council*, 335 S C 1, 515 S E 2d 508 (2004), and granted summary judgment to CAS based on the Graves' failure to present a question of fact for trial as to either the existence of a defect in the AMI monitor or proximate cause

ARGUMENT

I Summary of Arguments

The trial court properly granted summary judgment because the Graves failed to prove proximate cause and failed to prove a defect As our Supreme Court held recently in *Watson v Ford Motor Co* , Op No 27686 (re-filed Sept 13, 2010), a defect must be proven, and cannot be shown by circumstantial evidence

The Graves also failed to demonstrate proximate cause, *i e* , that some defect in the monitor was the cause of India Graves' SIDS death The Graves' causation witness, Dr Wilkins, was by her own admission not an expert on SIDS, and her testimony that India Graves would have survived if stimulated was properly found unreliable by the trial court under Rule 702, SCRE Her opinion has not been peer-reviewed or otherwise published, there is no research supporting the opinion, the opinion was based on an incorrect medical history, and the opinion is contradicted by Dr Wilkins' statements to her own patients' caregivers Arguments by the Graves that Dr Wilkins' testimony was presented as "differential diagnosis" are raised for the first time in this appeal and not supported by the record In contrast to the Graves' causation witness, the expert witness for CAS testified by affidavit that there is no evidence that any home monitoring system can prevent sudden infant death, and even continuous hospital surveillance may be insufficient to prevent death due to SIDS Because the Graves failed to show causation,

the trial court appropriately awarded summary judgment to CAS

The Graves also failed to establish a defect The testimony of computer experts Drs Lively and Daugherity was scientific in nature, as admitted by the Graves in the trial court, and therefore subject to the reliability factors enunciated in *State v Council* The trial court properly excluded the testimony under the *Council* factors because the experts cited no supporting authority for their methodology of reliance on anecdotal evidence rather than testing, the experts lacked authoritative support for their assertions, and the experts lacked objectivity While the Graves argue that the opinions of Drs Lively and Daugherity are the result of "reasoning to the best inference," this theory is untenable and is raised for the first time on this appeal at any rate

The testimony of the Graves' other defect expert, biomedical engineer Frank Painter, was also properly excluded by the trial court as lacking an objective basis or other indicia of reliability Finally, the Court correctly excluded affidavits filed by Drs Lively and Daugherity after CAS moved for summary judgment below The later affidavit testimony of the computer experts materially changed the witnesses' testimony, by purporting to identify a deficiency when earlier deposition testimony by the experts made clear that they had been unable to find the alleged defect The experts' post-motion opinions were properly excluded by the trial court under *Cothran v Brown*

The Graves failed to meet their burden of showing that a defect existed in the monitor, and failed to show that, even if a defect had existed, the defect would have been a proximate cause of India Graves' death, and the trial court properly granted summary judgment in favor of CAS

II The trial court properly excluded the Graves' experts, given the unreliability of their opinions and given Dr Wilkins' lack of SIDS qualifications

A Standard of Review

The qualification of a witness as an expert is a matter largely within the trial court's discretion and will not be reversed absent an abuse of that discretion *Gooding v St Francis Xavier Hosp*, 326 S C 248, 252, 487 S E 2d 596, 598 (1997) "An abuse of discretion occurs when the trial court's decision is based upon an error of law or upon factual findings that are without evidentiary support" *Fields v J Haynes Waters Builders Inc*, 376 S C 545, 555, 658 S E 2d 80, 85-86 (2008) Here, the trial court carefully considered the summary judgment record before it and reached a well-reasoned result that is supported by the record and South Carolina law

B The trial court recognized its role as gatekeeper under Rule 702, SCRE, in disallowing the Graves' experts' opinions

The Rule 702, SCRE, issues in this case are governed by the recent case of *Watson v Ford Motor Co*, Op No 26786 (re-filed Sept 13, 2010), and the several cases leading up to it, including *State v Council* In *State v Council*, the court recognized the gatekeeper role of the trial judge in determining the reliability of scientific expert testimony before allowing the jury to hear it That court found that DNA evidence used for identification was reliable based on application of "several factors, including" the following four factors

> (1) the publications and peer review of the technique, (2) prior application of the method to the type of evidence involved in the case, (3) the quality control procedures used to ensure reliability, and (4) the consistency of the method with recognized scientific laws and procedures

Id at 19, 515 S E 2d at 517 (citing *State v Ford*, 301 S C 485, 392 S E 2d 781 (1990))

In *State v White*, 382 S C 265, 676 S E 2d 684 (2009), the court made clear that

the trial court's gatekeeping role extended to testimony of technical and experiential experts as well as to opinions of scientific experts Finally, in *Watson v Ford*,[6] the court made clear that expert opinion is required in cases "where a factual issue must be resolved with scientific, technical or any specialized knowledge "

The *Watson* court's application of the *Council* "scientific" factors to an engineering expert, Anderson, is instructive here Anderson's opinion was that electromagnetic interference ("EMI") had caused an automobile cruise control to malfunction, resulting in a wreck The trial court had allowed his testimony after determining that he was qualified as an expert but without examining the reliability of his opinions On appeal, the court rejected the idea that Anderson's opinions were technical rather than scientific so as not to be subject to the same scrutiny as scientific opinions and proceeded to apply the *Council* factors to determine reliability In so doing, the court found that his opinions "were based on scientific principles and theories," *Watson v Ford* n 3, but may have been mindful as well of the admonition in *Kumho Tire Co v Carmichael* 526 U S 137 (1999), regarding expert testimony based on scientific as opposed to technical, or other specialized knowledge

> There is no clear line that divides the one from the others Disciplines such as engineering rest upon scientific knowledge Pure scientific theory itself may depend for its development upon observation and properly engineered machinery And conceptual efforts to distinguish the two are unlikely to produce clear legal lines capable of application in particular cases

526 U S at 148

The court found that the substance of Anderson's opinions was not reliable

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[6] Although *Watson* is not cited in their Appellants' Brief, the Graves' counsel were also counsel in *Watson* and made essentially the same arguments there that they make here

because his opinions had not been peer reviewed, he had not published papers on his theories, he could not determine exactly where the EMI originated or what part of the system it affected, he had not tested his theory and admitted it was not possible to do so, he could not replicate the alleged failure and, although not dispositive under South Carolina law, his theory had been rejected by the scientific community The essence of the court's ruling was that a hypothesis without evidence tending to prove it renders the opinion unreliable

The trial court in this case properly applied *Watson v Ford* and its predecessor cases to find that the Graves' expert opinions were not reliable The Graves did not meet their burden of demonstrating the reliability of their experts' opinions

C Dr Wilkins' Opinions Were Neither Qualified Nor Reliable

The Graves bore the burden of proving that the alleged defect was the proximate cause of India's death *Small v Pioneer Mach* , 329 S C 448, 494 S E 2d 835, 842 (Ct App 1997) (under any products liability theory of recovery, plaintiff must establish a product defect was proximate cause of injury sustained) The survivability of what would otherwise be a SIDS death unquestionably is a medical issue "beyond the ordinary knowledge of the jury, thus requiring an expert to explain the matter to the jury " *Watson v Ford* The Graves offered Dr Wilkins as their only evidence that India would have survived had the alarm sounded, assuming it did not

1 The Graves waived the argument raised in support of the reliability of Wilkins' opinion

The Graves make only one argument as to the reliability of Dr Wilkins' opinion – that it is a reliable differential diagnosis This argument was neither raised to nor ruled on by the trial court The Graves thus cannot raise this argument on appeal and it should

not be considered by this court *I On Inc v Town of Mt Pleasant*, 338 S C 406, 422, 526 S E 2d 716, 724 (2000)

2 Dr Wilkins is not a SIDS expert and her opinion was without support beyond her own say-so

Dr Wilkins admitted that she is not an expert in SIDS (Wilkins Dep , R p 1007, lines 24-25) Her experience with SIDS is limited to coverage in a course in medical school and some reading in professional journals Her opinion that India's death could have been avoided by early intervention is unsupported by any medical authority, and she made no effort to determine if it was supported before voicing her opinion or after CAS challenged her opinion before the trial court In short, her opinion was supported only by her own say-so

Although not reflected in its order, the trial court also had before it uncontradicted evidence that Dr Wilkins' opinion had not been published or peer-reviewed, and that her opinion was in fact contrary to accepted medical understanding, as shown by the affidavit of Dr Hunt, a SIDS researcher Dr Hunt confirmed what Dr Wilkins tells her patients' caregivers, that "[t]here is no medical evidence that any home infant monitor on the market can prevent sudden unexpected death in infants" (Hunt Aff ¶ 7, R p 598, Wilkins Dep , R p 1005, lines 19-22) Dr Hunt also stated that the data suggests that infants destined to die of SIDS will die "regardless of the timeliness of resuscitation, in other words that SIDS infants are non-resuscitatable" (R p 599) He also pointed out the correlation between this and "reports of infants who have died of SIDS while under continuous surveillance in inpatient hospital settings" *Id* Dr Hunt also provided follow-up on several older SIDS articles (the newest dating from 1993) that the Graves filed with the court As noted by Dr Hunt, it had been hoped that the use of home

monitors would help avoid SIDS deaths but "[t]he clear consensus then [when the articles were published] was that there is no evidence that home monitors save lives (prevent SIDS), and there has been no subsequent evidence to the contrary" (*Id* at ¶¶ 10-11, R p 599) Finally, Dr Hunt pointed out that no study has confirmed the failure of any home monitor alarm (*Id* at ¶ 12, R p 599)

The trial court also had before it substantial evidence that Dr Wilkins' litigation opinion was contrary to views she expressed in her medical practice as to the survivability of a true SIDS event as opposed to surviving an ALTE, which has not been medically linked to SIDS Finally, the court had before it uncontradicted evidence that Dr Wilkins misunderstood India's medical history when basing her opinion on the understanding that India had survived prior significant events In fact, India had experienced no such prior events

In short, beyond her admitted lack of qualifications, Dr Wilkins' testimony is without any medical basis, is contrary to current medical understanding, and relied on an incorrect patient history It has no indicia of reliability and was properly excluded by the trial court

3 The trial court applied the proper standards in reviewing and ultimately excluding Dr Wilkins' opinions

Should the court find that the Graves have not waived their argument raised in support of Dr Wilkins' testimony, the argument also fails on its merits The Graves argue without any support that medicine is not science and that the *Council* factors thus cannot be used to test the reliability of her testimony They offer no definition of "science" nor do they provide any explanation of why Dr Wilkins' testimony is not scientific Moreover, they argued to the trial court that Dr Wilkins "understands the

medical science necessary to make an opinion in this case " Brief in Support of Experts n 1, 3/1/10 Webster's definition of science includes "knowledge possessed or attained through study or practice," or "knowledge obtained and tested through use of the scientific method " Webster's Third New International Dictionary, 2032 (Philip Babcock Gove et al eds 1993) Beyond this apt description of medical research, the very case on which the Graves rely for their argument that differential diagnosis is a valid methodology describes it as "a standard *scientific technique* of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated " *Westberry v Gislaved Gummi AB*, 178 F 3d 257, 262 (4th Cir 1999) (emphasis added)

The gatekeeping role applies to all expert testimony, scientific or technical *State v White*, 382 S C 265, 270, 676 S E 2d 684, 686 (2009) (citing *Kuhmo Tire*) Whether one considers the testimony scientific or not, the *Council* factors provide a useful framework for analyzing Dr Wilkins' testimony and the Graves fail to explain why they should not be applied here

The Graves' differential diagnosis argument also inaccurately characterizes Wilkins' opinion as a diagnosis Dr Wilkins herself recognized she did not make a diagnosis (Wilkins Dep , R p 1010, line 2-p 1011, line 15)

A differential diagnosis is not a guess or a choosing of sides The cases speak in terms of a "*reliable* differential diagnosis," one where, among other things, the expert "must provide reasons for rejecting alternative hypotheses using scientific methods and procedures" and the elimination of those hypotheses must be founded on more than "subjective beliefs or unsupported speculation " *Clausen v M/V New Clarisa*, 339 F 3d 1049, 1058 (9th Cir 2003) (quoting *Claar v Burlington N R R Co* , 29 F 3d 499, 502

(9th Cir 1994)) To the extent one can apply a differential diagnosis framework to Dr Wilkins' opinion, one finds no indicia of reliability She employed no scientific method or procedure and gave no valid basis for rejecting the hypothesis that India would have died in any event She pointed to no research, nor is there anything in Dr Wilkins' own experience, training or education to support her opinion Moreover, the bases of her opinion were, as shown, medically and factually wrong, and inconsistent with her deposition testimony that there is no medical science linking ALTEs to SIDS

Dr Wilkins' opinion was neither a diagnosis nor was it reliable Her opinion is classic *ipsi dixit* and was properly excluded by the trial court

D The trial court properly excluded Daugherity's and Lively's opinions

1 The Graves abandoned the argument that Daugherity's and Lively's opinions were not scientific

The Graves at one point questioned whether the computer expert opinions were scientific (Plaintiffs' Supplemental Memorandum, October 23, 2009, R pp 219-223), but later abandoned the issue Indeed, the Graves' appeal argument that the trial court erred in applying *State v Council* to the testimony of their computer experts because their testimony was not scientific is directly contrary to what they told the trial court at the hearing on February 4, 2010

> But [computer code] literally, Judge, is a science and a language that I'm not adequate to explain And so, I think we have, judge, a battle of scientific experts that I know aren't talking over your head, but Judge, they are talking way over my head

(Transcript of Hearing 2/4/10, R p 290, lines 3-5, R p 293, lines 3-6 (emphasis added)) Further, in their final memorandum to the court, dated March 1, 2010, the Graves argued, "A careful reading of the deposition testimony and subsequent affidavits shows the Defendant is not only wrong, but clearly *does not understand the science* involved in

these complex facts " (Brief Supporting the Testimony of the Plaintiff's Experts, R pp 53-54 (emphasis added)) Thus, when the trial court issued its order this issue was no longer before it, and there are no findings on it The Graves did not raise this issue in their Rule 59(e), SCRCP motion, and it is therefore not preserved for review by this Court *I On Inc v Town of Mt Pleasant*, 338 S C 406, 422, 526 S E 2d 716, 724 (2000)

The argument that the Graves' computer expert opinions should have been examined by the trial court as opinions the result of "reasoning to the best inference" is also new and was not ruled on by the trial court In their October 23, 2009, memorandum, where they argued that the opinions were not scientific for purposes of *State v Council* and *State v White*, the Graves offered the trial court no framework by which to analyze the expert opinions They refer in that memorandum to their July 15, 2009, memorandum opposing exclusion of the experts A review of that memorandum reveals other arguments but not the one they advance here This argument was neither raised nor ruled on below and is thus improperly raised for the first time here

2 The trial court was correct in applying the *Council* factors

The *State v Council* inquiries fit the opinions offered to the court here and were properly applied Not only did the Graves tell the trial court the computer issues were scientific, but the arguments supporting the application of the *Council* factors in *Watson* to Dr Wilkins apply with equal force to Daugherity's and Lively's testimony Moreover, the court had before it Dr Pressman's uncontradicted opinion that the scientific method of testing to prove a hypothesis is required in computer engineering, thus rendering appropriate at least that portion of the *Council* inquiry (Pressman Aff ¶¶ 4 0–7 0, 13 0–14 0, R pp 580-582) The Graves offer no cogent reason why the *Council* standards

should not have been applied by the trial court

3 Daugherity's and Lively's opinions were properly excluded under *Council*

The Graves do not argue that either the deposition or the affidavit versions of their computer expert opinions can survive application of the *Council* factors and thus have waived that issue as well A brief review of the application of those factors shows why the opinions fail that inquiry

The experts' methodology of relying on unproven anecdotal complaints rather than directed testing of the suspect code paths has not been published or peer reviewed, has not been shown to have been applied before to computer software, and has significant quality control issues Among these problems is that none of the complaints, the method, or the conclusions have been tested Further, these experts considered part, rather than all, of the evidence, and their opinions are unsupported by the literature in their field Their opinions that the code is *per se* unreliable due to use of GoTo statements and its alleged spaghetti code structure is likewise unpublished, not peer reviewed, not shown to have been applied before, is subject to similar quality control issues, and, again, has no support in the literature, which states for example that although GoTo statements can cause issues, properly used they can make software perform better (R pp 1826-1830) (noting that GoTo's use in "C" language (a different language than Assembly, the language used in the monitor) *can* but will not always undermine the code and recognizing the benefits of using GoTo statements in "C" language in certain instances) (*See also* Pressman Aff ¶¶ 9 0–12 0, R pp 581-582)

In analyzing the reliability of an expert's testimony, the "key question" is "whether it can be (and has been) tested " *Daubert v Merrell Dow Pharms* , 509 U S

579, 593 (1993) South Carolina cases are in accord *See e g Watson v Ford Motor Co* Like the expert in *Watson*, Daugherity and Lively contend that the code could not be tested to find the problem they claim exists In fact, no code of any complexity can be exhaustively tested (*see e g* , General Principles of Software Validation Final Guidance, R p 1825), but testing to find a specific problem is a different matter Dr Pressman's affidavit points out that a test directed to the alleged defect should be fairly easy to construct (Pressman Aff ¶11 0, R p 582) No expert identified by the Graves cited any authority that directed testing would not work (*See* Pressman Second Supplemental Aff ¶¶ 5 0–9 0, R pp 587-588) Indeed, in his deposition in the *Smith* case, Lively said he could test the software for the defect in the same manner Pressman advocated (*Compare* Lively Dep (*Smith*), R p 963, line 14-p 965, line 4, *with* Pressman Aff (9/1/09) ¶ 9 0, R p 585 (both advocating black box and white box testing))

4 The experts' opinions are also untenable under a best inference review

To reliably reason to the best inference, an expert

> must provide objective reasons for eliminating alternative causes Furthermore, the inference to the best explanation must first be in the range of possible causes, there must be some independent evidence that the cause identified is of the type that could have been the cause But more than mere possibility, an inference to the best explanation for the cause of an accident must eliminate other possible sources as highly improbable, and must demonstrate that the cause identified is highly probable

Bitler v AO Smith Corp 400 F 3d 1227,1237-38 (10th Cir 2004), *see also Clausen v M/V New Carissa* 339 F 3d 1049, 1058 (9th Cir 2003) ("The expert must provide reasons for rejecting alternative hypotheses 'using scientific methods and procedures' and the elimination of those hypotheses must be founded on more than 'subjective beliefs or unsupported speculation '") (*quoting Claar v Burlington N R R Co* , 29 F 3d 499, 502

(9th Cir 1994)) The Graves' experts' analyses do not meet this requirement Their reasons for accepting the Graves' claims over the monitor log were not objective An expert's job is to prove a failure, not start with the assumption of a failure and use that as a basis for his opinion, and such an opinion is excludable as unhelpful to the jury under Rule 702, SCRE *See e g Clark v Takata Corp* , 192 F 3d 750, 757 (7th Cir 1999) ("Simply put, an expert does not assist the trier of fact if he starts his analysis based on the assumption the product failed (the very question he was called upon to resolve) ") Such an opinion should also be excluded as invading the province of the jury *State v Morgan*, 326 S C 503, 485 S E 2d 112 (Ct App 1997) (reversed in part by *State v White*, 382 S C 265, 273, 676 S E 2d 684, 688 (2009) (Assessment of witness credibility is for the trier of fact, not for experts)

These experts also formed their conclusions without understanding the log showed that the alarm was actually heard, and refused to re-assess their opinions after learning this Instead Daugherity changed his opinion of the log to suit their prior conclusion, and Painter simply chose to believe the Graves over the log Moreover, the experts had no basis on which to rule out misreporting by the Graves The experts' reliance on a group of other, unverified complaints about AMI monitors (making the similarity of them to the Graves' alleged failure unclear at best) was likewise not objective Daugherity and Lively incorrectly thought or ignored whether the complaints were proven failures Furthermore, the court did not find the complaints to be deserving of reliance under Rule 703, SCRE *Jamison v Morris*, 385 S C 215, 228 684 S E 2d 168, 175 (2009) Finally, the experts conducted their analyses based on partial information and the misunderstanding that the EMT saw the monitor lighted but not

alarming

The experts' willingness to impugn the software without understanding the product, without meeting the software engineering standard of testing, and in the face of extensive testing contradicting their opinions further underscores the unreliability of their reasoning to an inference as urged by the Graves Finally, as argued elsewhere, the opinions were rendered subjective and unreliable by the experts' selective use of facts rather than the entire record to arrive at their opinions

The Graves argue that, under *Bitler* testing was not required, but in that case an explosion confirmed that a failure occurred and the alleged failure mechanism was a well-known problem Testing thus was not required to prove the underlying failure or potential cause In the instant case, however, the fact of a failure is far from certain, nor is there a recognized mode of failure if one assumes the alarm failed The *Bitler* court likely would *require* that the Graves' computer expert opinions be proved by testing "When an expert proposes a theory that modifies otherwise well-established knowledge we would expect the importance of testing as a factor in determining reliability to be at its highest" *Bitler* at 1235

With no indicia of reliability, the trial court properly excluded Daugherity's and Lively's opinions

E The trial court properly excluded Painter's testimony

CAS did not question the general qualifications of the Graves' expert biomedical engineer, Frank Painter Painter offered two basic opinions in this case (1) that the monitor failed on the night India died, and (2) that the monitor software is defective in some manner

1 Painter's opinion that there was a failure lacks any objective basis

Painter admitted at deposition that his opinion that the monitor failed on April 11, 2004, was based solely on the Graves' testimony that it failed (Painter Dep , R p 990, lines 15-17) He came to this opinion before being aware that the monitor recorded the alarm sounding (*Id* at R p 978, line 19-p 979, line 5) When he learned this during his deposition, he acknowledged that either the log was wrong or the Graves were wrong (*id* at R p 978, lines 1-15), but simply chose to believe the Graves over the monitor log (*Id* at R p 978, line 16-p 979, line 12) This subjective opinion meets no recognized requirement of a reliable expert opinion and the trial court properly exercised its discretion in excluding it

2 Painter's opinion contains no indicia of reliability

Painter's opinion that the software in the monitor is defective was based on complaints received by CAS and the prior owner of the AMI product line and on his subjective decision to accept the Graves' testimony that the alarm did not sound To show admissibility of other similar events, "[a] plaintiff must present a factual foundation for the court to determine that the other accidents were substantially similar to the accident at issue " *Watson v Ford Motor Co* Although the court advised the Graves that they needed to make a showing of reliability (Transcript 2/4/10, R p 358, line 18-p 360, line 2), they never sought to show that these complaints were admissible evidence, or that their expert could rely on these complaints under Rule 703, SCRE "Under Rule 703, SCRE, an expert may rely on inadmissible evidence if the trial judge 'examines the reliability of the inadmissible evidence and excludes opinions not deserving of reliance in the specific instance and/or those that rely on grossly unreliable data '" *Jamison v*

Morris, 385 S C 215, 228 684 S E 2d 168, 175 (2009) (citing Kaye, Bernstein and Mnookin, *The New Wigmore Expert Evidence* § 3 6 1a (2004)) Indeed, Painter admitted that he included complaints unless he had enough information to exclude them (Painter Dep , R p 989, lines 5-8), an approach contrary to what evidentiary law requires *Watson v Ford*

Had they been able to make a Rule 703, SCRE, showing, the inadmissible complaints would not be evidence of a failure, but only an explanation of how the expert reached his determination The rule does not render admissible otherwise inadmissible hearsay *Jones v Doe* 372 S C 53, 62-63, 640 S E 2d 514, 519 (Ct App 2006)

Moreover, none of these complaints has been proven and many of them are clearly different than the complaint in this case Painter admitted that at least some of the complaints were more likely hardware problems and as to others he could not tell whether the alleged malfunction was caused by hardware or software (*See e g* , Painter Dep , R p 986, line 4-p 989, line 8) Most importantly, Painter had not located the alleged defect (*id* at R p 967, lines 20-22), nor had he established what combination of inputs could trigger the alleged defect (*Id* at R p 972, lines 5-8) Painter thus could not say that causation in any of the complaints was similar to causation in the Graves' alleged failure This opinion was insufficient to prove the allegation of a defect

Indeed, Painter admitted that he did no more than construct a hypothesis (*Id* at R p 973, line 20-p 974, line 9) He did not examine the code for defects (*id* at R p 969, lines 6-11), and conducted no experimentation that confirmed his hypothesis (*Id* at R p 968, lines 9-12) The monitor operated properly in the little testing he did (*Id* at R p 968, lines 1-12) Painter relied only on his own training and cited no authority that

supports his method or his conclusion (*Id* at R p 984, line 21-p 985, line 7) His method does not lend itself to determining a rate of error *Id* Painter cited no prior publication where he or anyone else has employed his method in other situations *Id*

Further, Painter made no efforts to conduct any kind of quality control relating to his opinion For example, beyond relying on unproven complaints, Painter did not determine the statistical significance of the number of complaints in connection with the number of AMI monitors in use He also did not know how the number of complaints regarding the AMI monitors compared with those experienced by other monitor models or manufacturers (*Id* at R p 982, line 24-p 983, line 10) For the same reasons, Painter's opinion is unreliable when examined under any other reasonable test of reliability

Like the opinions of Daugherity and Lively, Painter's opinion is no more than an unproven suspicion Such an opinion is "speculative, theoretical, and hypothetical" and amounts only to "guesses and speculation" *Jackson v Bermuda Sands Inc*, 383 S C 11, 17-18, 677 S E 2d 612, 616 (2009) The trial court thus properly exercised its discretion in excluding Painter's testimony

F The trial court also properly excluded the expert testimony under Rule 403, SCRE

"Unfair prejudice means an undue tendency to suggest [a] decision on an improper basis" *State v Holland* 385 S C 159, 171, 682 S E 2d 898, 904 (Ct App 2009) (quoting *State v Gilchrist*, 329 S C 621, 627, 496 S E 2d 424, 427 (Ct App 1998)) The determination of whether the danger of unfair prejudice outweighs the probative value of evidence must be based on the entire record and will turn on the facts of each case *Id* (quoting *State v Lyles*, 379 S C 328, 338, 665 S E 2d 201, 206 (Ct

App 2008)) This Court reviews a trial court's decision regarding the admissibility of evidence under Rule 403 pursuant to the abuse of discretion standard and must give great deference to the trial court's judgment *Id*

Even if otherwise admissible, the prejudicial effect of computer experts' testimony, based as it was on the Graves' say-so, unproven and unrelated complaints, and hypotheses rather than proof, outweighed its probative value and was properly excluded as an exercise of the court's discretion The prejudice inherent in Dr Wilkins' opinions, based on incorrect facts her own say-so likewise outweighed any probative value and was properly excluded

III The trial court properly excluded affidavits of Daugherity and Lively filed after CAS moved for summary judgment because those affidavits contradicted the experts' deposition testimony on issues critical to the case

A Daugherity and Lively changed their opinions after CAS filed its summary judgment motion

Considerations for whether an affidavit should be excluded as a sham are found in the case of *Cothran v Brown*, 357 S C 210, 592 S E 2d 629 (2004) Those considerations are (1) whether explanation is offered for the contradictory statements, (2) the importance to the litigation of the facts about which there is contradiction, (3) whether the non-movant had access to this fact prior to the previous sworn testimony, (4) the frequency and degree of variation between statements in the previous sworn testimony and statements made in the later affidavit, and (5) whether the previous sworn testimony indicates the witness was confused at the time *Id* at 218, 592 S E 2d at 633 Although the striking of an affidavit is not favored, see *id*, when reviewed in light of the *Cothran* guidelines, there can be no doubt that the trial court correctly excluded the later-filed expert affidavits in this case

The Graves argue only that there is no contradiction between the depositions and affidavits Recognizing that the expert testimony failed to show the defect that caused the harm, an essential element of proof in their case, the Graves had to come up with new expert opinions to survive summary judgment The experts do not claim that they did not have access to all of the needed information in advance of their depositions nor do they claim any confusion, however, the later-filed affidavits vary from the earlier deposition testimony on all significant issues

B Daugherity and Lively gave testimony in an earlier case that is similar to their deposition testimony here and contrary to the statements provided in the later-filed affidavits

Daugherity and Lively were previously named as experts in a case against CAS pending in Texas, *Smith v CAS Medical Systems Inc et al* That case alleged that a loose lead alarm failed to sound, leading to brain damage in an infant because the infant allegedly was not being monitored while having an event Daugherity and Lively were deposed in that case in November, 2008 They gave essentially the same testimony that they gave when deposed in this case in May of 2009, that an error or "bug" in the code caused the alarm not fail, but that they had not located that bug because the structure of the software, which they subjectively dubbed "spaghetti code," made it impossible to test exhaustively For example

> Q , really, **your issue with spaghetti code is in part that if a problem is reported, it's very difficult to find the source for that problem, right?**
>
> A **Right**

(Daugherity Dep (*Smith*), R p 863, lines 20-24) (Emphasis added) (*See also id* at R p 861, line 14-p 862, line 10, R p 864, lines 7-12) As a result, Daugherity conceded he could not prove or disprove the existence of the *legal defect* that being the error or

glitch that caused the alleged failure

> Q Okay And you've ruled out hardware And essentially with respect to software, **you've simply been unable to determine or haven't spent the time to ascertain whether or not, in fact, there is a defect in the software in that module which controls the loose-lead alarm, true?**
>
> A **True It's impossible because of the astronomical number of paths through the code**

(*Id* at R p 865, lines 14-21) (Emphasis added)

> 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**

(*Id* at R p 868, line 20-p 869, line 2 *See also id* at R p 860, lines 1-6, R p 866, line 13-p 867, line 7) Nowhere in his deposition did Daugherity say the structure of the code caused a failure, nor did he even mention GoTo statements, which he claims are the primary problem with the code in his post-*Graves* deposition affidavits

Daugherity's deposition testimony in the instant case was the same as in *Smith* The Graves quote from Daugherity's deposition by selecting two ambiguous exchanges Aware during the deposition of these unclear exchanges, at the very end of the deposition counsel for CAS had Daugherity clarify his opinions on the code in an exchange free of ambiguity

> BY MR DuBOSE
>
> Q I want to make sure I understand one thing you told him directly in the context of what we've been talking about this afternoon **Assuming the correctness of your testimony that this code is too convoluted -- spaghetti code, to use your term -- as I understand your testimony,**

that in and of itself would not cause the alarm to fail It was a bug within the code that would have had to cause the alarm to actually not sound when it should have Do I understand that -- did I get that right?

A **Yes, that's correct**

Q **But it's the bug and not the spaghetti code itself that actually causes the computer to malfunction?**

A **That's correct**

Q Okay **And so you could have spaghetti code that's much worse than this, but if it managed to be perfectly written without a bug in it, then it would function fine?**

A **Yes, and that's possible with simple devices** But when you get to code that's the size **it's impossible to test thoroughly enough** to rely on

Q **But getting back to my question, it's the bug that is the cause of the malfunction in a computer –**

A **That's –**

Q **-- not the method, the general method in which the code is structured?**

A **That's correct**

Q Okay

A But good design leads to fewer bugs Poor design leads to more bugs

MR DuBOSE I don't have anything further Thank you

MR WINSLOW I guess we're done

(Daugherity Dep , R p 856, line 18-p 858, line 22) (emphasis added) Moreover, Daugherity was fully prepared to testify (*id* at R p 827, line 18-p 828, line 5), and gave his complete opinions during the deposition (*Id* at R p 853, line 21-p 855, line 12) Daugherity also stated in *Smith* that all of his opinions and bases for them had been

covered (Daugherity Dep (*Smith*), R p 870, lines 6-14)

1 Daugherity's first affidavit sought to change his deposition testimony in material ways

In his first affidavit, Daugherity directly contradicted his deposition opinion that a bug in the code caused the alarm not to sound and that GoTo statements in the code and the code structure generally were not the cause of the alleged failure, but only made the bug harder to find His new opinion was that the use of GoTo statements in the AMI monitor code created a "structural error" in the code as a whole (Daugherity Aff ¶ 16, R p 549)[7] Daugherity contended that the structural error rather than a bug within the code caused the monitor alarm to malfunction (*Id* at ¶¶ 16, 19-22, R p 549-550) The term "structural error" was new, and the opinion that an error in the structure of the code could cause a malfunction directly contradicted his deposition testimony

Daugherity's affidavit includes other contradictions At his deposition, Daugherity was certain that the alleged malfunction of the monitor was the result of a computer "bug," a portion of the code that had been miswritten Spaghetti code made the problem more difficult to find, but the bug itself had to be located to find the problem in the code that caused the malfunction (*Id* at R p 832, lines 16-24 *See also id* at R p 856, line 20-p 857, line 20, R p 20, lines 1-16 (emphasis added))

Although at deposition he claimed that the code was too complicated to examine in its entirety, in his affidavit Daugherity stated that he has examined the code for errors or bugs "and none has been found " (Daugherity Aff ¶ 17, R p 549) This also contradicted what counsel had written the court on April 3, 2009, to the effect that Daugherity had found some of the errors but needed more time to find the rest

[7] This Daugherity affidavit was supplied without paragraph numbers but numbers are used here to simplify navigation through the affidavit

(Transcript 2/4/10, R p 295, line 14-p 296, line 18, Winslow letter April 3, 2009, R p 1013) At deposition, Daugherity did not testify that the structure of the code could cause a failure, nor did he say use of GoTo statements could cause a failure

In his deposition, Daugherity discussed that GoTo statements were not favored by some code writers but then clearly stated that, in this code, even if excessive, they would not cause the alleged malfunction, they just made the bug harder to locate

> Q Is that another way of saving that they didn't cause the problem here to the extent that there might have been one, they just make it harder to find the problem if there is one?
>
> A That's right

(Daugherity Dep , R p 852, lines 13-17 *See also id* at R p 851, line 21-p 852, line 12)

Daugherity recognized that NEC, the manufacturer of the processor used in the AMI, specifically allowed the use of GoTo statements and that they were an "option" in writing code for that processor *(Id* at R p 849, line 9-p 850, line 7) He further testified that in places GoTo statements could make the code ' a lot simpler," and that it was not "a hard and fast rule" that GoTo statements rendered code unstructured, but he did advocate limited use of them *(Id* at R p 850, line 2-p 851, line 16) Daugherity also testified that the use of Assembly language was proper for this application (Daugherity Dep , R p 847, lines 16-19) In paragraph 21 of his affidavit, however, Daugherity made a 180 degree turn when he stated "These GoTo statements are defective and not fit for use with this device " (R p 550)

Daugherity's affidavit offered as his exhibits 5 and 6 excerpts from two texts that he characterized as "recognition of the dangers of GoTo statements and their effects," but

these texts both cover writing in a computer language called "C" The authors do not discuss whether GoTo statements are appropriate in Assembly language Moreover, both of these authorities allow for the use of GoTo statements at times (*See e g* "C By Dissection, R p 1829, *see also* excerpt from Knuth, "Structured Programming with go to Statements," 1974, R p 1838) ("What I am really doing is striving for a reasonably well balanced viewpoint about the proper role of GoTo statements I argue for the elimination of GoTo's in certain cases and for their introduction in others")) Knuth also notes that a writer named Dijkstra, relied on by both Daugherity and Lively, "recently wrote the following 'Please don't fall into the trap of believing that I am terribly dogmatic about (the GoTo statement) I have the uncomfortable feeling that others are making a religion out of it " *Id* Since GoTo statements can be harmful only if misused, the blanket statement by Daugherity that they not be used at all is overbroad and fails, once again, to identify the defect that caused the alleged failure

In short, Daugherity contradicted his deposition testimony regarding the appropriateness of using GoTo statements in the monitor software, cited texts that did not support his opinion, and failed to advise the trial court that there is, at a minimum, a substantial split in authority regarding the use of GoTo statements

2 Daugherity fully examined the code prior to giving his deposition testimony in this case

Although Daugherity repeated acknowledged in *Smith* that he could not identify the cause of the alleged failure, in the eight months between that deposition and the experts' depositions in this case, Daugherity's and Lively's opinions did not change, although they clearly had the time to do more work Moreover, at the *Smith* deposition, Daugherity had before him the very printout of the code that by affidavit he claimed

shows the errors on its face

> Q In front of you here on the table, is that --
> is that the printout of the code for the AMI --
> A Yes
> Q -- medical device?

(Daugherity Dep (*Smith*), R p 862, lines 11-14) The GoTo statements Daugherity by affidavit identified as defects (*see* "Ledalarm asm with GoTo Statements Highlighted," R pp 1093-1107),[8] appear on numerous pages of the code print-out, so Daugherity had to have seen them when he was diagramming the code, as he did[9] before his deposition in the *Smith* case (*See* Flow Chart, R p 1017) [10]

Instead, the exhibit "Ledalarm asm Module with GOTO Statements Highlighted," never appeared in the record before Daugherity attached it to his April 17, 2009, affidavit (Daugherity Aff , R pp 546-552) It is not in the *Smith* record and it did not appear in this case until after CAS moved for summary judgment Only in response to that motion did Daugherity need to discover the GoTo statement was the cause of all of the problems and highlight them on the code print-out

Daugherity offered no explanation why, in reviewing and diagramming the code initially for *Smith* and during his depositions in this case, where he said he was fully prepared to be deposed and gave all of his opinions, he never gave this essential opinion,

---

[8] The Graves' Exhibit 4 begins with an unsworn statement by Daugherity It is essentially the same as portions of his contested affidavits

[9] Daugherity and Lively designated *all* of the unconditional branching statements in the monitor code defective without benefit of any testing to determine if any one or all of them actually work properly, rendering their affidavit opinions unproven hypothesis and thus unreliable under SCRE 702 (*See* "Other Modules with GoTo Statements Highlighted," R pp 1108-1116)

[10] The convoluted flow chart is a rough draft (Daugherty Dep , R p 825, line 22-p 826, line 3), and could be simplified (Pressman Supp Aff ¶¶ 2 0–3 0, R p 584, Lively Dep R p 950, line 19-p 951, line 8)

the opinion that was the very purpose of the depositions Nowhere in either deposition did Daugherity say the faulty design was the most likely cause of the alleged alarm failure, as he later attested To the contrary, as shown, he repeatedly said the design was not the causative defect, but just made that defect harder to find, and that he had not found the cause Daugherity also offered no explanation of how he came to his GoTo revelation after so long In Daugherity's post-deposition affidavits the trial court was faced with new opinions promulgated without explanation to avoid summary judgment The court properly struck them under *Cothran v Brown*, 357 S C 210, 592 S E 2d 629 (2004)

3 Daugherity reversed his testimony on the monitor log

At deposition, Daugherity testified that he could not say more likely than not that the logging function ever malfunctioned (Daugherity Dep , R p 838, lines 14-21) In paragraph 25 of his affidavit, however, with the pressure of summary judgment upon the Graves, Daugherity's opinions changed to "it is certain that the logs are not reliable " (R p 551) He did not base this on new information from further study or from testing of the code, the only new factor was his new opinion that the unstructured architecture of the code as a whole caused malfunctions

4 Daugherity's affidavit opinion was rendered on short notice

The Graves argue without citation that Daugherity labored over his new opinion for a year At the March 17, 2009, hearing the Graves were given 30 days to provide any additional expert opinions On April 3, 2009, the Graves wrote the court asking for an extension of the 30 days, telling the court that their experts were busy with final exams, and stating further

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

(Winslow Letter to Court, April 3, 2009, R p 1013) When the court did not grant the requested extension, the Graves had to provide an opinion in less than 14 days The result was Daugherity's first affidavit, dated April 17, 2009 Not only did what Daugherity write in the affidavit contradict his deposition testimony, as shown, but it also contradicted what counsel advised the court about the work the experts were doing Daugherity did not "pull out bad code" nor did he test the software Instead, he highlighted one specific instruction in the written version of code each time it appeared and constructed an argument to support what he had done If these GoTo statements were truly a problem, Daugherity's work in highlighting the GoTo statements in the code is something he reasonably would have done before his November 2008 deposition in the *Smith* case Since highlighting them could have only taken a matter of minutes, this could not have been the work counsel told the court he had begun but needed up to three more months to complete The court expressed concern about this inconsistency at the February 2, 2010, hearing (R p 295, line 14-p 296, line 18), but the Graves failed to offer any explanation for it

In his second affidavit, dated February 2, 2010, Daugherity repeated his changed opinions set forth in his original affidavit and tried to bolster his claim that the code was untestable by taking part of Dr Pressman's text book out of context (Daugherity Aff 2/2/10 at ¶ 5, R p 565, Pressman Suppl Aff 2/3/10 at ¶¶ 2 0–9 0, R pp 586-588) Most notable in this affidavit, however, is Daugherity's advocacy against CAS,

repeatedly calling it "clearly negligent," "incredibly negligent," and characterizing its conduct in not finding the alleged error, which Daugherity also has not found, as "deplorable " The trial judge noted the fact that Daugherity had crossed the line from objective expert to biased advocate (Order, R pp 1, 7) Daugherity also was impermissibly stating legal conclusions *See, e g , Hermitage Indus v Schwerman Trucking Co* , 814 F Supp 484, 485 (D S C 1993)

5 Daugherity's third affidavit added further inconsistency

As Exhibit 6 to their March 1, 2010, memorandum, the Graves provided the court with a third affidavit from Daugherity (R pp 595-597) In this affidavit, Daugherity retracted earlier opinions regarding the alleged failure of the logging function of the monitor, spaghetti code, and GoTo statements, and failed to explain how his two opinions are actually the same In his third affidavit, Daugherity wrote that it is "*possible* that the logging function might not be called ," that raw events "*may not* have been handled properly after logging," and that the events "*may be* unreliable if the device did not create the log according to the specification " Daugherity offered no indication of the degree of likelihood of one, much less all, of these failures actually occurring *Id* Although not discussed in the orders on appeal, these new opinions are not stated with sufficient certainty to be admissible, leaving the trial court with no admissible opinion (or inconsistent and thus inadmissible opinions) that the logging operation of the monitor malfunctioned

6 Lively's affidavit changed his testimony

Lively also sought to change his deposition testimony by way of later affidavit He said at deposition that use of GoTo statements caused the code to be spaghetti code (Lively Dep , R p 958, lines 5-7), but rejected the idea that the spaghetti code structure

caused the alleged alarm failure He stated instead that there had to be a software failure, an error in the code, that was causing the malfunction (*Id* at R p 952, line 8-p 593, line 12) Rather than the structure causing the malfunction, he complained only that it "is preventing me from finding the problem and fixing the code " (*Id* at R p 952, lines 11-18)[11] Lively had not looked for nor had he found the alleged software error, nor had anyone else found it to his knowledge (*Id* at R p 952, line 18, R p 956, line 16-p 957, line 1) In the *Smith* case, Lively likewise testified that they had not found any specific problem in the code that cause the alleged alarm failure (Lively Dep (*Smith*), R p 960, line 13-p 961, line 12)

After CAS filed its summary judgment motion, however, Lively contradicted his deposition testimony, for the first time making statements such as "[m]y review of the relevant material has led to my opinion that the 'spaghetti code' is a direct cause for the alarm to malfunction " (Lively Aff 3/13/09, ¶ 12, R p 576) These claims, repeated throughout his affidavits, contradict not only his specific deposition opinion that spaghetti code only made the error harder to find, but also cannot be reconciled with his deposition admission that he and Daugherity had not found the software error causing the supposed malfunction

The Graves citation to Lively's general deposition statements that the software is the problem and that there was error in that part of the design misses the point That general testimony insufficiently identifies the defect that caused the injury, just as

[11] Contrary to what the Graves argue on appeal, Lively did not say at page 144 of his deposition that GoTo statements ' allow the signal to travel an erroneous pathway " Instead, he said that they "cause me to branch throughout the program" which is a comment only about structure, not erroneously traveled pathways (R p 958, lines 8-10)

testimony that "the brake system failed" would be inadequate evidence of an alleged auto brake defect Both experts did consistently claim the problem was the code, but when pressed to identify what one might call the *legal defect*, the specific error that caused the alleged failure, they first testified that they knew there was a code writing error, that the problem causing the alleged malfunction was not the structure of the code or GoTo statements, and that they had not found the cause Like Daugherity, after CAS filed its summary judgment motion, Lively's opinions turned 180 degrees

Faced with Daugherity's and Lively's unexplained course reversal in response to CAS's summary judgment motion, the trial court appropriately excluded the experts' affidavits under *Cothran*

IV The Court Properly Granted Summary Judgment

A The Graves failed to present admissible evidence of proximate cause

As in *Watson* after exclusion of the Graves' experts, the trial court was left with no facts to support a judgment Although the Graves' allegation of an alarm failure remained, there was no proof of a defect, and most critically, in light of the exclusion of Dr Wilkins' unreliable opinion, no evidence as to causation Indeed, the lack of admissible causation testimony mandated summary judgment even if the expert testimony as to the monitor software had been allowed

B The Graves cannot prove a defect in the AMI monitor solely by circumstantial evidence

The Graves concede that no South Carolina case supports their claim that they can prove a product design defect by circumstantial evidence In *Watson v Ford*, the Court first implicitly rejected proof of a defect by testimony other than expert opinion, making clear that expert testimony is *required* "where a factual issue must be resolved with

scientific, technical, or any other specialized knowledge" The court went on to hold more explicitly "Without such [expert] testimony, respondents failed to present a case for products liability We find that the mere occurrence of an accident or existence of an alleged product malfunction does not establish the liability of a product manufacturer" *Watson v Ford* *Watson* thus rejected the circumstantial evidence argument made by the Graves' counsel in that case, and here, and rejected as well the idea that a strict liability version of *res ipsa loquitor* might be recognized The Graves' claim of a design defect required reliable expert testimony of a specific defect and could not be proved by circumstantial evidence

The ruling in *Watson* was not novel In *Shelton v LS&K Inc*, 374 S C 294, 648 S E 2d 307 (2007), the court found that the plaintiff failed to prove her case that a Burger King parking lot landscape design was defective when she offered no expert testimony on proper placement of trees and other design elements for pedestrian safety Certainly the issue of software design is vastly more complicated than the location of trees at a Burger King and must be proven by reliable expert testimony, particularly where not only the cause of the alleged malfunction, but the very question of whether a malfunction occurred, is at issue

Other cases hold likewise In *Sunvillas Home Owners Ass n v Square D Co*, 301 S C 330, 391 S E 2d 868 (Ct App 1990), the court upheld a directed verdict for the allegedly negligent manufacturer–defendant on the issue of whether its circuit breaker failed due to a defect, explaining "Sunvillas' expert did not identify a *specific defect* in the circuit breaker which was the result of a manufacturing error by Square D At most the jury would be left to speculate how Square D failed to exercise due care" 301 S C at

334, 391 S E 2d at 870 (emphasis added) Submission of this products liability case under a strict liability on nothing but circumstantial evidence would likewise require a jury to speculate as to the defect and, in this case, as to claim of failure, as well

Moreover the Graves's circumstantial evidence is largely inadmissible The Graves argue that six items of supposed circumstantial evidence support their claim even assuming the proper exclusion of what they term their experts' "specific defect claims " CAS does not dispute that the monitor was set up properly and that it had power Beyond that, however, the Graves rely primarily on what they apparently consider to be portions of their expert Daugherity's testimony that are not particular to identification of the defect, specifically the structure of the code so as to allegedly be subject to "external interrupt events," Daugherity's exclusion of other possible causes, and Daugherity's "reliable opinion" as to how the monitor log could show that the alarm sounded even if it did not

The Graves' reliance on this testimony overlooks that CAS objected to and the trial court excluded *all* of Daugherity's opinions as unreliable and his affidavit testimony as running afoul of *Cothran v Brown* Like the experts excluded in *Watson*, Daugherity (as well as the other experts) were not offered for general testimony on how the monitor software worked They were offered to testify that the monitor was defective and how it was defective Any general opinions they had were necessarily informed by these specific conclusions The Graves do not and cannot explain how the opinions could be properly excluded yet still support a circumstantial evidence case

The Graves seem to argue in favor of a rule that would admit an expert's negative comments about a product even where that expert could not meet the threshold obligation

of identifying a defect or the test of reliability The danger of allowing one clothed with the authority of an expert to malign a product, in essence testifying without proof of an actual defect, about what *might* happen, violates at least Rules 401 and 403, SCRE One need to look no further than the passages quoted by the Graves to see that Daugherity's and Painter's external events testimony was by their own admission strictly a possibility and not more likely to happen than not Nowhere did any expert identify a condition where an external event more likely than not did or even could interrupt the processing CAS has found no precedent that would exclude an expert's opinions as unreliable yet allow into evidence the faulty reasoning by which he arrived at his conclusion Additionally, Daugherity's analysis excluding other possible causes was, as shown above, deeply flawed

Stripped of the excluded testimony of the experts, the inconclusive testimony of the other witness in the house, and the testimony of the EMT who did not remember what she saw, the circumstantial evidence case boils down to the Graves' claim that the alarm malfunctioned This is merely the product failure allegation of the complaint, which under Rule 56, SCRCP, and settled law is not sufficient support for an opposition to a Rule 56 motion *George v Empire Fire & Marine Ins Co* , 344 S C 582, 593, 545 S E 2d 500, 505 (2001) (party opposing summary judgment cannot simply rest on mere allegations or denials contained in pleadings) Assuming the Graves' claim can be considered, however, it is evidence only of whether there was a failure, not the cause of the failure

In *Sunvillas* (unlike here) there was no doubt that the product failed The issue was whether the failure was due to a defect While *Sunvillas* involved a claim only of

negligence, its proof of defect requirement would apply equally if not more so to the Graves' claims of strict liability and breach of warranty With the plaintiffs unable to identify the alleged defect that caused the injury, a jury is left to speculate whether that defect exists *Jackson v Bermuda Sands Inc* , 383 S C 11, 17, 677 S E 2d 612, 616-17 (Ct App 2009) (where alleged defect not proved by scientific testing, opinions "amount to mere speculation and conjecture ") *See also Disher v Synthes*, 371 F Supp 2d 764, 770 (D S C 2005) (applying S C law) ("Speculative or conclusory allegations of defective design do not, as a matter of law, establish the existence of a defect ")

C The Graves failed to show feasible alternative design

The Graves bore the burden of proving by expert testimony there was a feasible alternative design available, but their experts failed to advance a feasible alternative design *Branham v Ford Motor Co* , Op No 26860 (Filed August 16, 2010), *see also Watson v Ford Motor Co* (expert's testimony regarding feasible alternative design "lacked any scientific basis and contained no indicia of reliability")

In *Watson*, expert Anderson's alternative design testimony was found unreliable because he could not explain how his proposed design would fit within the automobile cruise control system at issue, offered no model comparison, and failed to provide evidence of claimed economic feasibility In the instant case, the experts' proposed alternative design is no more than an untested assertion that CAS should exchange the allegedly defective software for working, structured software Here, much like in *Watson*, the experts do not address compatibility of the proposed software with the existing monitor processor, the cost of a new processor if needed for compatibility, and, if needed, whether a new processor would be compatible with the remainder of the monitor Although the experts have given an estimate of the cost of writing new

software, they do not estimate the cost of recall and reinstallation in the thousands of monitors that are in use The Graves have not shown the feasibility of their proposed alternative design, rendering the expert testimony on this subject unreliable and thus inadmissible

CONCLUSION

For the reasons stated in the trial court's Orders, and the reasons stated above, including the numerous additional sustaining grounds, the Orders of the trial court excluding the Graves' expert opinions, striking their affidavits, and granting summary judgment to CAS Medical Systems, Inc , should be affirmed

Respectfully submitted, this 22nd day of December, 2010

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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

Case No 08-CP-38-826

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vs

CAS MEDICAL SYSTEMS, INC — Respondent

CERTIFICATE OF COUNSEL

The undersigned hereby certifies that this Final Brief of Respondent complies with Rule 211 (b), SCAR

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CERTIFICATE OF SERVICE

I do hereby certify that I have this 22nd day of December, 2010, caused the foregoing **Final Brief of Respondent** to be served via U S mail, postage prepaid, on Appellants counsel of record at the address shown below

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