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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA**

MASIMO CORPORATION, a  
California corporation,

*Plaintiff,*

v.

SOTERA WIRELESS, INC., a  
California corporation,

HON HAI PRECISION INDUSTRY  
CO., LTD., a Taiwan corporation,

*Defendants.*

Case No.: 3:19-cv-01100-BAS-NLS

**DECLARATION OF DR. GEORGE  
YANULIS IN SUPPORT OF  
DEFENDANTS' OPENING CLAIM  
CONSTRUCTION BRIEF**

Declaration of G. Yanulis, D.Eng.  
to Opening Claim Construction Brief

Case No. 3:19-CV-01100-BAS-NLS

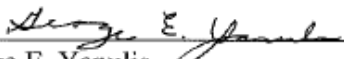
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1 I, Dr. George Yanulis, make this declaration as an independent expert  
 2 retained by Defendant Sotera Wireless, Inc. ("Sotera") in their lawsuit against  
 3 Plaintiff Masimo Corporation ("Masimo") to provide my expert opinion as to how  
 4 a Person Having Ordinary Skill in the Art ("PHOSITA") would understand certain  
 5 terms the parties have identified as of the filing date of the applicable patent. I  
 6 make this declaration either from my own personal knowledge, from documents  
 7 produced by the parties, from the files of Husch Blackwell LLP kept in the  
 8 ordinary course of business, or from publicly available documents, with which I  
 9 am familiar, as should be apparent from the context of my statements. I declare  
 10 under penalty of perjury under the laws of the United States of America that the  
 11 following is true and correct.

12 Dated: September 22, 2020

13   
 14 George E. Yanulis

15  
 16 **I. BACKGROUND AND QUALIFICATIONS**

17 1. I am a Medical Device Design and Development/Research Engineer. I  
 18 received my Bachelor of Arts in Pre-medicine degree in 1977 from Syracuse  
 19 University, which included a minor in Chemistry. Originally, I planned to go to  
 20 medical school, but I found that my interests aligned more closely to medical  
 21 devices than practicing medicine. So, I pivoted to biomedical engineering, and I  
 22 received a Masters' Degree in Biomedical Engineering from the University of  
 23 Virginia in 1981. I closely studied medical devices while in graduate school at  
 24 Virginia, including using preamplifiers to record evoked cortical signals to better  
 25 understand the etiology of Epilepsy.

26 2. For approximately the next two decades, my professional experience  
 27 included serving in the armed services as a 1<sup>st</sup> Lieutenant and Clinical Engineer for  
 28 the Air Force (stationed at the Malcolm Grow Medical Center, Andrews Air Force

Base), working as a Logistics Engineer for RCA, and conducting research within the education industry (at Syracuse, Alabama-Birmingham, Drexel, and the University of Pennsylvania). I was a Clinical Engineering Consultant involved with the Y2K Program at the Hospitals of the University of Pennsylvania from 1999–2000. Importantly, I continued as a research assistant at the University of Pittsburgh, but in 2002, I decided to pursue a doctorate. Even though I was leaving, my mentor at Pitt awarded me a Master of Science in Bioengineering for my research work rather than leave without a degree. I studied medical devices at Pitt, but also implantable devices, such as using elastomeric polymers to design artificial diaphragm muscles.

3. Still continuing my education, I received a Doctor of Engineering (D.Eng.) from Cleveland State University in 2008. For my Doctorate, I focused on Applied Biomedical Engineering. It was during my Doctorate that I developed a specialty in cardiovascular medical devices and treatments, with a focus on treating atrial fibrillation. At Cleveland State, we studied electrical stimulation (i.e., coupled pacing applied near the end of the T-wave, which represents the repolarization of the ventricles in electrocardiography to prevent rapid ventricle conduction during atrial fibrillation (AF)), and whether the benefits of coupled pacing could be used during persistent AF.

4. Since obtaining my D.Eng., I have taught the next generation of bright minds. From 2009-2013, I was an adjunct professor at the College of Staten Island teaching Engineering and Physics, and since 2015, I have been an Adjunct Professor at Temple University teaching Bioengineering, where I taught several courses involving medical device software and alarm limits, including a course in BioSignals, Bio Instrumentation, and Cardiac Systems.

5. However, my focus has been on clinical assessment of medical devices and monitoring systems. For example, I am currently involved in the research and development of a heart rate monitoring system based on my earlier

1 bench studies conducted related to my Doctoral research at the Cleveland Clinic  
 2 (2005-2008) and now with Medical Device Consulting, LLC (2016–Present). I  
 3 have consulted on heart bypass systems (2017-2018), and I served as a consultant  
 4 on several cardiac pacemaker device related cases, which involved monitoring  
 5 heart rate, pulse rate, and ECG. I was involved in reviewing critical monitoring  
 6 systems as both a member and peer reviewer of submitted manuscripts of the  
 7 association for the advancement of Medical Instrumentation (2012-present). At  
 8 Cleveland State, I was involved in the review of critical care monitoring systems  
 9 used for heart failure therapy patients both from 2005–2008, as part of my D.Eng.  
 10 and since 2014, as part of my research and the development of a heart monitoring  
 11 system. Further still, from 2015-2017, I was also involved in mentoring Temple  
 12 bio-engineering students in the design of critical care monitoring systems for both  
 13 a cardiac systems course and biomedical instrumentation design course. Finally, I  
 14 was involved in reviewing clinical care monitoring systems as a clinical engineer  
 15 with the USAF from 1987-1989.

16 6. I also have continued to study cardiovascular devices and other  
 17 medical devices as a consultant. Particularly, I collaborated with Data Science  
 18 Corporation to design a device that used a time elapsed interval between two  
 19 consecutive R-waves of the QRS heart signal (R-R interval) to potentially use on  
 20 heart failure therapy patients. I have assisted with 250 Cardiac Pacemaker Device  
 21 Implants on dogs to develop pacing algorithms for heart failure therapy patients.  
 22 Also, I have performed over 500 ECG signal detection sessions and cardiac  
 23 pressure-volume analysis on dogs. Further still, I have intensely studied Heart  
 24 Failure Cardiac Pressure/Flow Sensor Monitoring Systems.

25 7. Specifically related to pulse oximetry monitoring systems, I  
 26 conducted pulse oximetry research at the University of South Florida from 1996-  
 27 1997 under the direction of John E. Scharf, MD, who is an anesthesiologist  
 28 associated with the James A. Haley Veterans Hospital, Tampa, Florida. Also, my

1 Research and Development on the prototype development of a heart rate monitoring  
 2 system for Medical Device Consulting, LLC includes a means for monitoring both  
 3 oxygen saturation and pulse rate with over-the-counter portable sensing devices  
 4 (2016-present).

5 8. Lastly, I have written six peer-reviewed articles in this area and other  
 6 areas of medical device development. My publications from the last 10 years are  
 7 listed in my CV, which I have attached as Exhibit 1 to this declaration.

8 9. Thus, my background demonstrates an expertise and strong  
 9 understanding of medical devices and how they can improve the health of patients.

10 10. I am being compensated for my services and time spent on this matter  
 11 at my normal hourly rates, which include \$540 per hour for standard activities and  
 12 \$665 per hour for testimony. My compensation is not contingent on the outcome of  
 13 this matter or the content of my opinions, conclusions, or testimony.

## 14 **II. SUMMARY OF OPINIONS**

15 11. I understand that Masimo currently asserts nine patents: 9,788,735  
 16 (the “’735 Patent”) (JA1–41)<sup>1</sup>; 9,795,300 (the “’300 Patent”); 9,872,623 (the “’623  
 17 Patent”) (JA42–82); RE47,218 (the “RE218 Patent”); 10,213,108 (the “’108  
 18 Patent”) (JA83–122); RE47,244 (the “RE244 Patent”) (JA123–141); RE47,249  
 19 (the “RE249 Patent”) (JA142–160); RE47,353 (the “RE353 Patent”); and  
 20 10,255,994 (the “’994 Patent”) (JA161–265). I refer to these patents, collectively,  
 21 as the “Asserted Patents.”

22 12. The ’735 Patent, ’623 Patent, and ’108 Patent are related. Each list one  
 23 inventor, Ammar Al-Ali. The ’735 Patent and ’623 Patent are each a continuation  
 24 of patent application number 15/488,989 (i.e., the ’108 Patent), which itself is a  
 25 continuation of patent application no. 14/815,232. JA2, JA84, and JA43. Each  
 26

27 <sup>1</sup> I am informed the parties agreed to cite certain exhibits common to both parties’  
 28 positions—namely the patents in which the identified terms are found, in addition  
 to the file histories corresponding to said patents. I have used this common citation  
 format for these documents.

1 pertains to a mobile medical monitoring device designed to be worn on the patient,  
 2 preferable on or around the patient's wrist. I refer to these patents as the "Wearable  
 3 Patents." I note that the Wearable Patents also have similar specifications. I  
 4 understand the parties identify the following terms of most significance from the  
 5 Wearable Patents: Term No. 1 ("separate computing device"); Term No. 2  
 6 ("separate monitoring device"); Term No. 9 ("tail"). I also note there is one  
 7 additional patent, the '300 Patent, asserted in this matter that is also part of the  
 8 Wearable Patents family, but understand the parties do not identify any claim term  
 9 from the '300 Patent as one of the "most significant" terms at this stage of the  
 10 litigation.

11 13. The RE244 Patent and RE249 Patent are also related to one another.  
 12 Each is a continuation of patent application number 14/036,496, which  
 13 subsequently issued as U.S. Patent No. 8,847,740, which is not asserted in this  
 14 litigation. JA124, JA143. Each patent pertains to "[a]n alarm suspend system [that]  
 15 utilizes an alarm trigger responsive to physiological parameters and corresponding  
 16 limits on those parameters." JA124, JA143. I will refer to these patents as the  
 17 "Alarm Suspension Patents." I note that each of the abstracts of the Alarm  
 18 Suspension Patents are identical. *Id.* I understand the parties identify the following  
 19 terms of most significance from the Alarm Suspension Patents: Term No. 4  
 20 ("alarm delay or suspension period of time"); Term No. 5 ("the one or more  
 21 processors configured to electronically ... determine that the measurement of the  
 22 physiological parameter satisfies an alarm activation threshold"); Term No. 6  
 23 ("electronically initiating, using the patient monitoring device, the first parameter-  
 24 specific alarm delay or suspension period of time"); and Term No. 7 ("alarm hold  
 25 initiator"). I also note there is one additional patent, the RE353 Patent, asserted in  
 26 this matter that is also part of the Alarm Suspension Patents family, but understand  
 27 the parties do not identify any claim term from the RE353 Patent as one of the  
 28 "most significant" terms at this stage of the litigation.



1           14. The '994 Patent is not related to any other Asserted Patent. It pertains  
2 to simulating alarm notification delays, which are delays before notification of an  
3 active alarm is transmitted to a remote clinician or location. JA162. I refer to the  
4 '994 Patent as the "Alarm Notification Patent." I understand the parties identify  
5 only one term as most significant from the Alarm Notification Patent: Term No. 3  
6 ("alarm condition").

7           15. The RE218 Patent is not related to any other Asserted Patent. It is my  
8 understanding that the parties disagree as to certain terms of the RE218 Patent, but  
9 did not identify any of the terms of the RE218 Patent as one of the "most  
10 significant" terms at this stage of the litigation.

11           16. I have been asked to review the terms the parties have identified as  
12 requiring construction at this stage of the litigation, the construction each party  
13 proposes, the claims, specifications, and prosecution histories of the Asserted  
14 Patents, and the additional evidence the parties have identified as supporting their  
15 constructions. It is my opinion the constructions Defendants propose are supported  
16 by the claims and intrinsic evidence, as well as my knowledge and experience as a  
17 PHOSITA. In contrast, the constructions Masimo proposes exceed the boundaries  
18 of the specification and are incorrect.

19           17. I note that I have separately authored several declarations in support  
20 of Defendant Sotera's petitions for *Inter Partes Review* of the Asserted Patents. In  
21 these declarations, I opined the "plain meaning" of the patent terms was sufficient  
22 for purposes of the petition. For example, in my declaration supporting *Inter*  
23 *Partes Review* of the '623 Patent, I stated:

24                       Generally, the disputes as to claim interpretation are  
25                       irrelevant to the validity of the '623 patent because it is my  
26                       opinion that the '623 patent is invalid as obvious under  
27                       either party's proposed construction. As such, the Board  
28                       need not construe the claims and may give each and every  
                         term its plain and ordinary meaning because the claims are  
                         invalid under the plain and ordinary meaning.

1 Ex. 2 ('623 Patent IPR Decl.)<sup>2</sup>, ¶ 36.

2 18. This statement—or similar statement in the other declarations I  
3 authored in support of Sotera’s petitions for *Inter Partes Review*—does **not** mean it  
4 is my opinion any term the parties have identified in the district court litigation  
5 should be given its “plain meaning.” Rather, as I expressly state in the quoted text  
6 above, it was, and is, my opinion the Board need not construe the claims because  
7 the claims are invalid under *either party’s construction*. In other words, regardless  
8 of whether the Board accepted Masimo’s proposed construction (i.e., “plain  
9 meaning”) or adopts the construction I, and Sotera, propose—the patents are  
10 invalid as anticipated and/or rendered obvious because the prior art identified in  
11 the petitions reads on either interpretation.

12 19. In this litigation, however, we are concerned with more than the  
13 question of whether the Asserted Patents are invalid as obvious and/or anticipated.  
14 We must also consider questions of infringement, as well as invalidity under the  
15 doctrines of written description and indefiniteness. Here, properly construing the  
16 claim terms greatly matters. For example, Masimo proposes the term “separate  
17 computing device” (from the Wearable Patents) be given its plain meaning, but it  
18 contends the “plain meaning” of this term would encompass any device with a  
19 processor, such as an iPad, nursing station, server, or even a gaming system such  
20 as a PlayStation. The specification of the Wearable Patents, however, describes  
21 only a conventional bedside monitor with a wireless receiver module as the  
22 claimed “separate computing device.” Thus, if the Court construes the term  
23 “separate computing device” to have its plain meaning as advocated by Masimo,  
24 the parties must address whether the term is invalid because it lacks sufficient  
25 written description. This was not at issue in the petitions for *Inter Partes Review*.

26  
27 <sup>2</sup> To avoid duplicating exhibits for the court, I have worked with counsel to cite to  
28 exhibits to the Declaration of Dustin L. Taylor in support of Defendants’ Opening  
Claim Construction Brief. I have attached additional materials, such as my  
*curriculum vitae*, as exhibits to this declaration.

1 To be clear, I am ***not*** opining the terms should be given different meanings for  
2 purposes of invalidity than infringement. Rather, it is my opinion that under either  
3 proposed interpretation of the claim terms, the identified prior art renders the  
4 Asserted Patents invalid.

5 **III. MATERIALS CONSIDERED**

6 20. In forming my opinions below, I have considered and relied upon the  
7 use of the identified claim terms in the context of the claims, their use in the  
8 specification, and the prosecution history. Secondly, I have considered  
9 additional information, such as dictionary definitions. In each instance wherein I  
10 rely on this additional information, I have identified the information in the  
11 paragraphs below. In forming my opinions, I have examined these materials from  
12 the perspective of a PHOSITA, which I consider myself.

13 **IV. LEGAL STANDARDS**

14 21. I am not an attorney and will not offer opinions on the law. I have  
15 been informed by counsel of at least some of the legal standards for claim  
16 construction, identified below, which I have employed in forming my opinions that  
17 are recited in this declaration.

18 22. I have been informed by counsel that infringement is a two-step  
19 inquiry: first the meaning of the terms and scope of the patent must be determined,  
20 and only then can a factfinder apply the construed claims to the accused device or  
21 system. Counsel has also explained to me that the objective in claim construction is  
22 to determine what a given claim term would mean to a person of ordinary skill in  
23 the field at the time of the patent's earliest priority date. I have also been informed  
24 that, if a claim term has a commonly understood meaning to those in the field, then  
25 that plain meaning is how the claim term should be construed in the absence of  
26 evidence to the contrary.

27 23. I have been informed by counsel that evidence to the contrary may be  
28 either intrinsic evidence (evidence contained within the prosecution history of the

1 patent itself) or extrinsic evidence (everything else, such as dictionary definitions).  
2 I have been informed that the strongest evidence of a claim term's meaning is the  
3 words of the claim itself, followed by any definition or explanation given in the  
4 patent's specification, followed by any definition or explanation given in the  
5 patent's prosecution history. I have been informed that other claims, either asserted  
6 or unasserted, can also be valuable sources for claim construction. For example,  
7 differences among claims can be a useful guide in understanding a claim term's  
8 meaning.

9 24. I have been informed by counsel that extrinsic evidence is evidence  
10 from outside the patent's prosecution history, which may include expert testimony,  
11 other literature defining the term or terms, and the like. I have been informed by  
12 counsel that dictionary definitions are also extrinsic evidence, although they may  
13 be used to inform what the plain and ordinary meaning of a claim term is.

14 25. I have been informed by counsel that some terms may be written in  
15 "means-plus-function" format and that this is sometimes referred to as "Section  
16 112, paragraph 6" terms. I am informed that "means-plus-function" claiming  
17 allows a patentee to draft a claim term by describing the function that is performed  
18 without reciting the structure that performs the described function. In exchange, I  
19 am informed, the patentee must describe the structure in the specification. I am told  
20 if the structure is a "general purpose" processor, the patentee must also provide in  
21 the specification an algorithm by which the processor can be programmed to  
22 perform the recited function.

23 26. Counsel has informed me that when the claim term uses the language  
24 "means for," and then recites the function, there is a rebuttable presumption that  
25 the term is a "means-plus-function" term. Counsel has also informed me that when  
26 the claim does not use the "means for" language, there is a presumption that the  
27 term is not a "means-plus-function" term, but that this presumption can be  
28 overcome by a showing that the claim term does not recite sufficient structure for

1 performing the function.

2 27. I have been informed by counsel that a patent specification must  
3 conclude with one or more claims particularly pointing out and distinctly claiming  
4 the subject matter which the applicant regards as his or her invention. To be  
5 definite, the boundaries of the claim, as construed by the court, must inform with  
6 “reasonable certainty” a PHOSITA about the scope of the invention, based on the  
7 language of the claim, the specification, and the prosecution history, as well as the  
8 PHOSITA’s knowledge of the relevant field of art. If the meaning of a claim is  
9 discernable, even where reasonable persons may disagree, the claim is sufficiently  
10 clear to be definite. I have been advised that it is among the duties of a Patent  
11 Examiner at the U.S. Patent and Trademark Office to examine the claims of patent  
12 applications for compliance with the requirement of definiteness.

13 28. I am informed that several of the Asserted Patents are “reissue”  
14 patents. I am informed that a patentee may not introduce new matter into the  
15 application for reissue. I am also informed that when a patentee requests a  
16 “reissue,” the patentee must provide a declaration that specifies every difference  
17 between the original and reissue claims. I have further been informed that under  
18 the “original patent rule” a broadening reissue patent claim must have clearly and  
19 unequivocally been disclosed in the original patent, and it must be clear from the  
20 original patent that the invention recited in the reissue claims was intended to have  
21 been covered by the original patent.

22 **V. PERSON HAVING ORDINARY SKILL IN THE ART**

23 29. As noted above, I have reviewed the Asserted Patents, their  
24 prosecution history, and the other materials identified in the Materials Considered  
25 from the perspective of a PHOSITA.

26 30. I have been informed that the following five factors inform the  
27 analysis for determining the level of ordinary skill in the art: (1) type of problems  
28 encountered in the art; (2) prior art solutions to those problems; (3) rapidity with

1 which innovations are made; (4) sophistication of the technology; and (5)  
 2 educational level of active workers in the field. *In re GPAC Inc.*, 57 F.3d 1573,  
 3 1579 (Fed. Cir. 1995). I apply these factors in the section below in providing my  
 4 opinion as to the level of one having ordinary skill in the art.

5 31. Using these factors, it is my opinion that a PHOSITA during the time  
 6 of the filing of the patent applications (March 2002 being the filing of the earliest  
 7 application) would be a person having at least a B.S. degree in electrical or  
 8 biomedical engineering or a related field, with at least two (2) years' experience  
 9 designing patient monitoring systems. If the person has a higher level of education,  
 10 such as a Masters' degree, less work experience could be acceptable, and vice  
 11 versa. It is my opinion that a PHOSITA would be the same for each of the Asserted  
 12 Patents.

13 32. I have knowledge relevant to what a person having ordinary skill in  
 14 the art at the time of the invention would understand and do. In 2002, at the  
 15 priority date of the Wearable Patents, which have the earliest priority date of any of  
 16 the Asserted Patents, I had 20 years of experience in this field and was a  
 17 PHOSITA.

## 18 **VI. THE WEARABLE PATENTS (THE '108, '735, AND '623 PATENTS)**

19 33. I understand the parties have identified the following terms from the  
 20 Wearable Patents as the "most significant": (1) separate computing device (Term  
 21 No. 1); (2) separate monitoring device (Term No. 2); and "tail" (Term No. 9). I  
 22 discuss the meaning a PHOSITA would understand these terms to have, in view of  
 23 the specification and prosecution history, in the paragraphs below.

24 34. I further understand that although the parties originally identified the  
 25 term "side" (from Claims 1 and 17 of the '623 Patent, Claims 1, 17, 19 and 21 of  
 26 the '108 Patent, Claim 20 of the '735 Patent, and Claim 19 of the '300 Patent),  
 27 Defendants have agreed the term should be given its plain and ordinary meaning  
 28 and no additional construction is necessary. I have therefore not considered the

1 meaning of the term “side” at this time.

2 **A. Overview of the Wearable Patents**

3 35. As I discuss above, the specifications of the ’108 Patent, ’735 Patent,  
4 and ’623 Patents are similar. Thus, for the sake of simplicity, I cite only to the ’108  
5 Patent, from which the ’735 Patent and ’623 Patent depend, in this section.

6 36. The Wearable Patents are directed to “provid[ing] a communications  
7 adapter that is plug-compatible with existing sensors and monitors and that  
8 implements a wireless link replacement for the cable.” JA115, 2:31–35.

9 37. Specifically, the Wearable Patents teach that in the prior art,  
10 monitoring of patient vital signs (e.g., measurements of blood oxygen, blood  
11 pressure, EKG, etc.) “typically requires a sensor in contact with a patient **and a**  
12 **cable connecting the sensor to a monitoring device.**” *Id.* at 1:37-41 (emphasis  
13 added). This “monitoring device” receives and processes a detector signal from a  
14 physiological sensor “to provide, typically, a numerical readout of the patient’s  
15 oxygen saturation, a numerical readout of pulse rate, and audible indicator or  
16 “beep” that occurs in response to each arterial pulse.” *Id.* at 1:52-56. This is  
17 consistent with my knowledge and experience with bedside monitoring equipment  
18 as of 2002. The sensor transmits a signal to a separate bedside monitor, which  
19 processes the signal to provide and display the physiological measurements of the  
20 patient.

21 38. The Wearable Patents further teach that “[c]onventional physiological  
22 measurement systems are limited by the patient cable connection between sensor  
23 and monitor.” *Id.* at 2:19-21. Specifically, the “patient must be located in the  
24 immediate vicinity of the monitor” and “patient relocation requires either  
25 disconnection of monitoring equipment and a corresponding loss of measurements  
26 or an awkward simultaneous movement of patient equipment and cables.” *Id.* at  
27 2:22–25. Although the Wearable Patents teach that other “[v]arious devices have  
28 been proposed or implemented to provide wireless communication links between



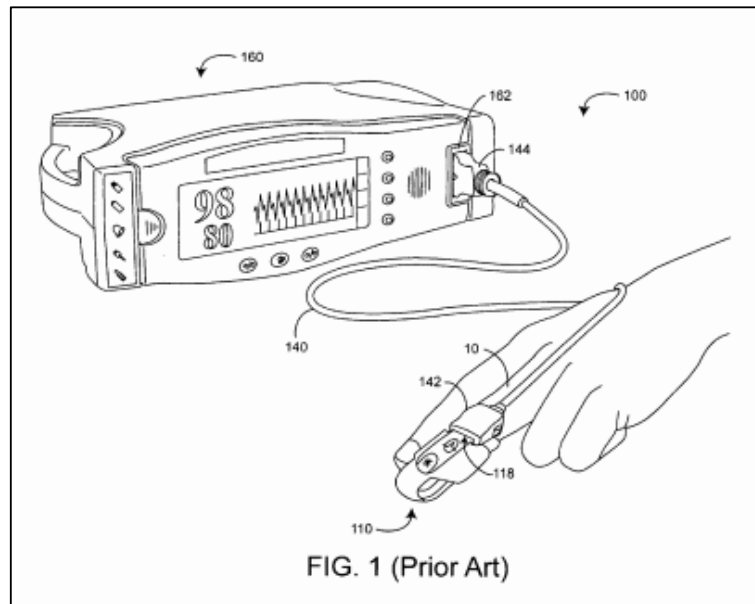
1 sensors and monitors,” these devices “are incapable of working with the large  
 2 installed base of existing monitors and sensors, requiring caregivers and medical  
 3 institutions to suffer expensive wireless upgrades.” JA115, 2:25–31. Thus, the  
 4 Wearable Patents teach existing equipment—including the conventional bedside  
 5 monitors—are to be used with the disclosed inventions. Indeed, the Wearable  
 6 Patents expressly state the purpose of the invention is “to provide a  
 7 communications adapter that is plug-compatible both with **existing sensors and**  
 8 **monitors** and that implements a wireless link replacement for the patient cable.”  
 9 *Id.* at 2:28–35 (emphasis added).

10 39. I understand that Masimo has additional patents, not asserted in this  
 11 litigation but to which all the Wearable Patents claim priority, that claim both a  
 12 wireless transmitter module and the plug-compatible receiver unit. *See* Ex. 3, U.S.  
 13 Patent No. 6,850,788 (the “’788 Patent”). I note that Claim 1 of the ’788 Patent  
 14 claims not only the wireless transmitter and the wireless receiver, but also a plug  
 15 compatible interface that connects to a bedside monitor via a sensor port of the  
 16 monitor. Claim 17 even claims a “conventional monitor connector” that “is also  
 17 capable of communicating with said sensor through conventional cabling,” further  
 18 supporting the purpose of the invention: providing an adapter that connects  
 19 existing sensors and conventional bedside monitors.

20 40. The Background of the ’108 patent explains the conventional  
 21 technology explaining that a pulse oximetry sensor 110 connects to a monitor 160  
 22 using a cable 140. JA115, 1:42-56.

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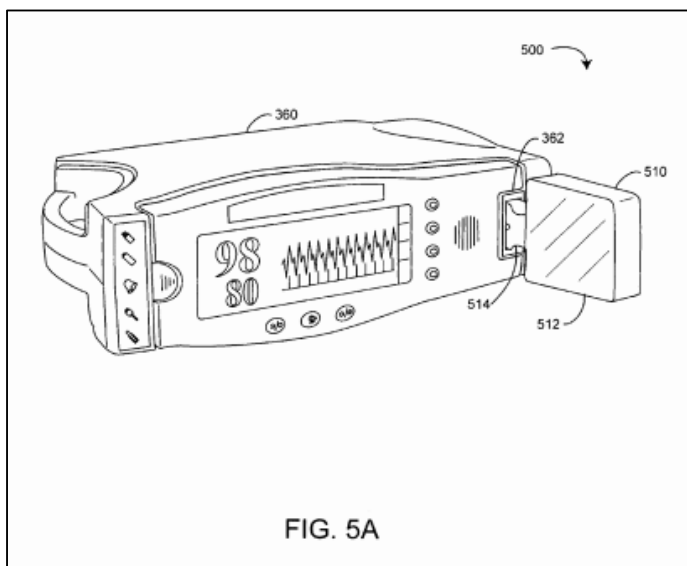
JA98.

41. As a PHOSITA, I can attest that most patient monitoring at the priority date of the Wearable Patents (2002) occurred via wired connections between sensors attached to a patient's body and a bedside monitor. However, wireless monitoring of medical parameters did exist long before 2002. The specifications of the Wearable Patents agree that previous wireless solutions existed before the applications for the first Wearable Patent was filed. JA115, 2:28–30. Thus, Masimo didn't invent the wireless transmission of medical data.

42. Returning to the specification, immediately after explaining the state of the prior art, the specification explains that this wired connection between a patient sensor and a *monitor* is limiting. *Id.* at 2:22–25. As stated above, Masimo admits that other wireless solutions have been proposed, but all are too expensive and require replacement of existing monitors. *Id.* at 2:25–31. Then, Masimo provides its solution: a plug-compatible adapter that works with existing sensors and *existing monitors* that *replaces* the patient cable 140 shown in FIG. 1. *Id.* at 2:31–35. The remainder of the “Summary of the Invention” describes the

1 combined transmitter and receiver system originally invented in 2002. JA115-116,  
2 2:39–3:60.

3 43. Throughout the remainder of the specification, the specifications of  
4 the Wearable Patents describe the combined receiver transmitter system. The  
5 specifications again explain how the system replaces a conventional patient cable,  
6 and advantageously is plug-compatible with a conventional monitor 300, plugging  
7 into the monitor 300 in “a similar manner as to the patient cable.” JA116, 4:51–54,  
8 JA116–117, 4:65–5:2. The monitor module 500, shown below plugging directly  
9 into the conventional monitor, emulates the signals transmitted by the patient  
10 cable, replaces the patient cable, and “adapt[s] an *existing wired . . . system into a*  
11 *wireless . . . system.*” JA116–117, 4:65–5:10 (emphasis added).



22 JA103.

23 44. The specifications of the Wearable Patents thus inform a PHOSITA  
24 that the claimed system is intended to convert a conventional wired monitor into a  
25 wireless monitor without the need to replace the entire system.

26 45. An extremely similar development occurred at approximately the  
27 same time with personal computers. From approximately 2000-2009, most PCs  
28

1 used an Ethernet cord to connect to the Internet. Unlike now, most PCs did not  
 2 include a “built-in” wireless network card because very few wireless networks  
 3 existed. Eventually, wireless networks started to become more affordable and more  
 4 commonplace. New PCs started to include built-in wireless network cards, but  
 5 most consumers did not want to buy a whole new laptop just to support wireless  
 6 Internet. So, network companies started offering after-market wireless network  
 7 cards. One of the most common versions was a wireless network card that plugged  
 8 into a USB port of a standard PC. A person would plug in the wireless network  
 9 card into the USB, thereby converting the laptop into a computer that was able to  
 10 connect to a wireless network.

11 46. The Wearable Patents teach this same concept applied to medical  
 12 monitors. Hospitals didn’t want to replace perfectly acceptable, very expensive  
 13 bedside monitors in order to make the monitors wireless. The Wearable Patents  
 14 acknowledge this need and teach the equivalent of a USB network card plugged  
 15 into the sensor port of a conventional bedside monitor.

16 47. Thus, the original problem to be solved and the original scope of the  
 17 Wearable Patent’s parent application was a transmitter that wirelessly transmitted  
 18 data to a plug-compatible receiver connected to the sensor port of an existing,  
 19 conventional bedside monitor. The existence of a bedside monitor was *critical* to  
 20 the technology disclosed by the Wearable Patents because the entire problem to be  
 21 solved was making a conventional bedside monitor wireless *without having to*  
 22 *replace the conventional bedside monitor*. Thus, a PHOSITA reading the  
 23 Wearable Patents would understand that any claimed invention related to this  
 24 specification and problem statement would advance the specification’s stated goal:  
 25 namely, to convert a conventional, non-wireless, bedside monitor into a wireless-  
 26 capable device without having to replace it.

27  
 28

**B. Opinions Regarding the Proper Construction of Claim Terms in the Wearable Patent Family.**

**1. Term No. 1: “separate computing device”**

48. It is my opinion that a PHOSITA would understand the term “separate computing device” to mean “a conventional bedside monitor.”

49. As I explained above, the first step in understanding claim term scope and construction is to look at the claim language itself. In, for example, the ’735 Patent, the claim language says:

*wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to a separate computing device configured to display, on a remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter.*

JA39, 18:11–18 (emphasis added).

50. To a PHOSITA, the claim context explains that the “separate computing device” is wirelessly connected to the claimed “body worn portable patient monitoring device.” Also, the claim context explains the separating monitoring device is configured to display received measurements from the patient monitoring device on a remote display. Thus, the claim language informs a PHOSITA only that the claimed “separate computing device” wirelessly receives data from the patient monitoring device and is configured to display measurements on a display.

51. The ’623 Patent uses very similar language. Specifically, Claim 1 of the ’623 Patent says:

*wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and*

JA78, 13:65–14:3 (emphasis added). Claim 17 also recites:

1                    *wirelessly transmit a transmit signal indicative of the*  
 2                    *measurements of oxygen saturation and pulse rate to a*  
 3                    *separate computing device configured to display the*  
                   *measurements of oxygen saturation and pulse rate;*

4                    JA79, 16:58-62 (emphasis added).

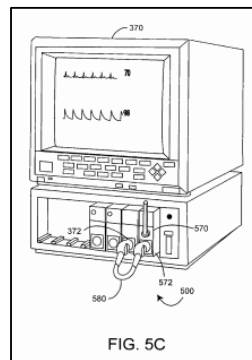
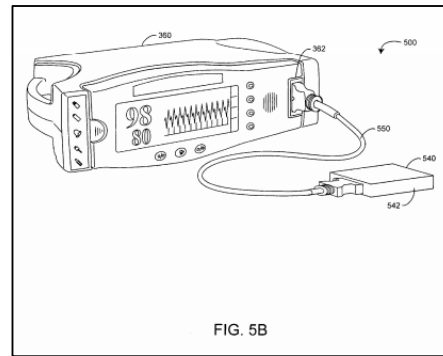
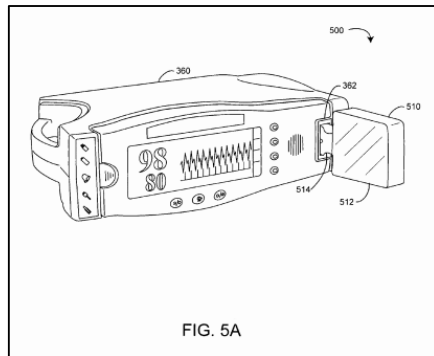
5                    52. A PHOSITA would understand the '735 Patent and '623 Patent claim  
 6                    language in which "separate computing device" is used to require the "separate  
 7                    computing device" to be able to receive signals that are indicative of physiological  
 8                    information (e.g., oxygen saturation, pulse rate, etc.) and to display the  
 9                    physiological measurements. It is my opinion that a PHOSITA would understand a  
 10                    "separate computing device" that met these requirements to not be any "computing  
 11                    device" under the broad plain meaning, but rather to be a conventional bedside  
 12                    monitor.

13                    53. A PHOSITA would understand the specifications to support this  
 14                    understanding. As noted above in my "Overview of the Wearable Patents" section,  
 15                    the '735 Patent and '623 Patent teach the conventional bedside monitor processes  
 16                    the signal to provide "a numerical readout of pulse rate, and audible indicator or  
 17                    'beep' that occurs in response to each arterial pulse." JA31, 1:55-59; JA72, 1:55-  
 18                    59. The specifications teach the disclosed inventions are intended to work with  
 19                    existing sensors and monitors and not require "medical institutions to suffer  
 20                    expensive wireless upgrades." JA31, 2:25-38; JA72, 2:25-38.

21                    54. The term "separate computing device" is not used in either the '735  
 22                    Patent or the '623 Patent. Indeed, at no point does the specification of the '735  
 23                    Patent or '623 Patent ever discuss wirelessly communicating information  
 24                    indicating physiological information with anything other than the dedicated  
 25                    receiver unit that connects to (and receives power from, for that matter) a  
 26                    conventional bedside monitor. *See e.g.*, JA32-33, 4:62-5:34, JA34, 7:31-8:3,  
 27                    JA34-35, 8:50-10:3, JA35, 10:23-45, JA36, 11:33-55, *id.* at 12:36-63. The  
 28                    specification even calls the receiver module a "monitor module." *See e.g.*, JA30

(Fig. 14). There would be no question that a PHOSITA would understand that the sensor module, worn by a patient, communicates with one thing and one thing only: a dedicated receiver that plugs into a conventional bedside *monitor*.

55. The Wearable Patents teach three embodiments of the special receiver unit, and all three embodiments connect to a conventional bedside monitor. *See e.g.*, JA33, 5:62–6:34, JA19–21 (FIGs. 5A-C).



56. As such, the specification only supports a system where the body worn unit communicates wirelessly with a dedicated received unit (i.e., monitor module) which plugs into a conventional bedside monitor. I have been informed by counsel that a continuation application may not add new matter not disclosed in the original specification. I have been informed by counsel that a specification cannot always support expansive claim language and satisfy the written description requirement. I have also been informed by counsel that disclosure of a species in a parent application cannot always provided adequate written description support for

1 claims to the genus in a child application.

2 57. That the conventional monitor may be augmented by including an  
3 adapter to allow wireless communication does not change that the “separate  
4 computing device” or “separate monitoring device” to which the physiological  
5 information is transmitted to be displayed is a conventional bedside monitor any  
6 more than adding a wireless USB adapter to a PC changes the PC.

7 58. Every example of signals representing physiological information  
8 transmitted from the wearable patient sensor in the specifications identifies only  
9 the conventional bedside monitor or the wireless adapter that is plug-compatible  
10 with the conventional bedside monitor as the recipient of the transmitted signal.

11 59. For example, at Column 4, lines 47 through 51, the ’735 Patent and  
12 ’623 Patent state: “The communications adapter 300 communicates patient data  
13 derived from a sensor 310 between the sensor module 400, which is located  
14 proximate a patient 20 and the monitor module 500, which is located proximate a  
15 monitor 360.” JA32, 4:50–54; JA73, 4:50–54. This disclosure thus informs a  
16 PHOSITA that information derived from the patient-worn sensor is transmitted  
17 only to the monitor module, which is connected to the monitor 360. The ’735  
18 Patent and ’623 Patents teach the “monitor 360” is a conventional monitor. *See*  
19 *e.g.*, JA33, 5:1–2 (“As shown in FIG. 3, the monitor module 500 is advantageously  
20 plug-compatible with a conventional monitor 360.”).

21 60. I further understand that Mr. Goldberg agreed these patents teach  
22 “monitor 360” is a conventional monitor.

23 Q And then in Figure 3, we have a monitor, which is labeled  
24 360; is that correct?

25 A We do, yes.

26 Q And it's described in the specification in Column 4, line  
27 63: “The sensor module 400 outputs a drive signal to the  
28 sensor 310 and inputs a sensor signal from the sensor 310 in  
an equivalent manner as a conventional monitor 360.” Do  
you see that?



1 A I see those words, yes.

2 Q Okay. So the patent specification is describing 360 as the  
3 conventional monitor, correct?

4 A The words describe the 360 as a conventional monitor,  
5 yes.

6 Ex. A, Goldberg Dep. Tr., 54:3–18. Thus, a PHOSITA would understand the  
7 specifications of the '735 Patent and '623 Patent to teach the signal containing  
8 physiological information is transmitted to the conventional monitor 360 through  
9 the use of the disclosed wireless adapter.

10 61. Similarly, at column 7, lines 30 through 35, the specifications teach:

11 FIG. 7 illustrates a monitor module 500 having a receive  
12 antenna 770, a receiver 710, a decoder 720, a waveform  
13 processor 730 and a monitor interface 750. A receive signal  
14 712 is coupled from the receive antenna 770, which  
15 provides wireless communications to a corresponding  
16 transmit antenna 670 (FIG. 6), as described above. The  
17 receiver 710 inputs the receive signal 712, which  
18 corresponds to the transmit signal 654 (FIG. 6), a described  
19 above.

20 JA34, 7:31–36; JA75, 7:30-35.

21 62. At Column 6, the specifications teach the components of Figure 6  
22 relate to the patient-worn device (i.e., what is Claimed by the '735 and '623  
23 Patents):

24 FIG. 6 illustrates a sensor module 400 having a sensor  
25 interface 610, a signal processor 630, an encoder 640, a  
26 transmitter 650 and a transmitting antenna 670. A  
27 physiological sensor 310 provides an input sensor signal  
28 612 at the sensor connector 318. . . . [T]he transmitter 650  
inputs a baseband signal 642 that is responsive to the sensor  
signal 612. The transmitter 650 modulates the baseband  
signal 642 with a carrier to generate a transmit signal 654. .  
The transmit signal 654 is coupled to the transmit antenna  
670, which provides wireless communications to a  
corresponding receive antenna 770 (FIG. 7), as described  
below.

JA33, 6:37–58; JA74, 6:37–58.

63. Collectively, these portions of the specifications inform a PHOSITA  
that information (transmit signal 654) indicating physiological measurements of a



1 patient are transmitted from the patient-worn device via transmitter 650 and  
 2 transmit antenna 670 to the receive antenna 770, which is connected to a  
 3 conventional monitor 360. This is thus another example wherein information is  
 4 transmitted to a conventional bedside monitor.

5 64. At column 8, lines 30 through 54, the specifications teach yet another  
 6 example, similar to the teachings at column 6, lines 34 through 56 and column 7,  
 7 lines 30 through 35, wherein information indicating physiological measurements of  
 8 a patient are transmitted to the wireless adapter, which is connected to a  
 9 conventional bedside monitor. *See e.g.*, JA34, 8:32–49.

10 65. I understand Masimo contends “separate computing device” should  
 11 not be construed and instead given its plain meaning. I disagree. A PHOSITA  
 12 would understand the “plain meaning” of a “separate computing device” to mean  
 13 basically any computer or any digital device having a processor. This broad  
 14 interpretation could include a smartphone, a laptop, a PC, a bedside monitor, a  
 15 server, a gaming system, a nursing station, or countless other devices having a  
 16 processor.

17 66. I have been informed by counsel, however, that claims should be  
 18 construed to maintain the validity of the claims. I have also been informed by  
 19 counsel that claims must be supported by the written description in order to be  
 20 valid. Here, the written description does not support the broad, plain meaning  
 21 discussed above.

22 67. As discussed in the paragraphs above, a PHOSITA would understand  
 23 the teachings of the ’735 Patent and ’623 Patent to only disclose wireless  
 24 transmission of data to a dedicated receiver unit that connects to a bedside monitor,  
 25 wherein the components are capable of receiving signals indicative of a patient’s  
 26 physiological information, processing such information to obtain the physiological  
 27 measurements, and displaying such information. A PHOSITA would therefore  
 28 understand the specification does not support the broader “plain meaning” of

1 “separate computing device” because not all computing devices (e.g., nursing  
2 stations, iPad, server, laptop, video game consoles, etc.) have these capabilities.

3 68. I understand Masimo may argue “conventional bedside monitor”  
4 cannot be the correct construction because the purpose of the invention is to  
5 modify conventional machines, such as the bedside monitor, to receive wireless  
6 communications from the patient worn monitor. It is nevertheless my opinion that  
7 “separate computing device” is properly construed as a “conventional bedside  
8 monitor” because the device that displays the patient’s physiological monitor is the  
9 conventional bedside monitor. A PHOSITA, reading the claims and specifications  
10 of the ’735 Patent and ’623 Patent, would understand wireless module described in  
11 the specifications could be used only with the conventional bedside monitor.

12 69. As such, a PHOSITA would understand that the term “separate  
13 computing device” requires a construction and means “a conventional bedside  
14 monitor.”

## 15 2. Term No. 2: “separate monitoring device”

16 70. I understand the parties also identified the term “separate monitoring  
17 device” as the “most significant” and requiring construction. The term “separate  
18 monitoring device” appears in Claims 1, 16 through 19, and 22 of the ’108 Patent.  
19 As discussed above, the ’108 Patent shares a similar specification with the ’735  
20 Patent and ’623 Patent. Moreover, the claims of the ’108 Patent also use the term  
21 “separate monitoring device” only to discuss the transmission of “information  
22 indicative of the measurements of oxygen saturation and pulse rate to a **separate**  
23 **monitoring device** configured to receive the information indicative of the  
24 measurements of oxygen saturation and pulse rate.” *See* JA121, 13:50–55. I  
25 therefore incorporate my analysis in Section VI.B.1 as if fully set forth herein, and  
26 it is my opinion that a PHOSITA would understand the term “separate monitoring  
27 device” to require construction and mean “a conventional bedside monitor” for the  
28 same reasons discussed above.

1           71. In addition to those reasons, I further believe “separate monitoring  
2 device” is properly construed to mean a “conventional bedside monitor” because  
3 the claim specifically requires a “monitoring device.” It is my opinion that a  
4 PHOSITA would understand a “monitoring device” only to refer to a conventional  
5 bedside monitor.

6           72. Other than the Abstract (which was amended to match Claim 1 when  
7 the ’108 Patent was filed), the specification of the ’108 Patent never uses the term  
8 “separate monitoring device.” The specification does, however, use the term  
9 “monitoring device” when describing a conventional bedside monitor. Specifically,  
10 the ’108 Patent states:

11           Each of these physiological parameters typically requires a  
12 sensor in contact with a patient and a cable connecting the  
13 sensor to a **monitoring device**. . . . The monitor 160 has a  
14 socket 162 that accepts a patient cable plug 144. The patient  
15 cable 140 transmits an LED drive signal 252 (FIG. 2) from  
16 the monitor 160 to the sensor 252 and a resulting detector  
17 signal 254 (FIG. 2) from the sensor 110 to the monitor 160.  
The monitor 160 processes the detector signal 254 (FIG. 2)  
to provide, typically, a numerical readout of the patient’s  
oxygen saturation, a numerical readout of pulse rate, and an  
audible indicator or “beep” that occurs in response to each  
arterial pulse.

18           JA115, 1:37–56 (emphasis added).

19           73. Thus, the specification informs a PHOSITA the “monitoring device”  
20 to which the sensor is connected is a conventional monitor 160. As discussed  
21 above, although the ’108 Patent teaches the use of a wireless adapter to replace the  
22 cable connecting the sensor to the conventional monitor, a PHOSITA would  
23 understand the data is still transmitted to a conventional bedside monitor.

24           74. Thus, for all the reasons discussed in Sections VI.B.1 and VI.B.2  
25 herein, it is my opinion a PHOSITA would understand that the term “separate  
26 monitoring device” requires a construction and means “a conventional bedside  
27 monitor.”  
28

1                   **3. Term No. 3: “tail”**

2           75. It is my opinion a PHOSITA would not understand either the '623  
3 Patent or the '108 Patent to inform what is the scope of the term with any sort of  
4 reasonable specificity.

5           76. Initially, I note a PHOSITA would have no idea what a “tail” is in the  
6 context of a medical device. This is not a term of art, and it is not a term with  
7 which I am familiar from my substantial experience in the industry. It is therefore  
8 my opinion the term “tail” does not have a plain and ordinary meaning within the  
9 field of medical devices.

10          77. The specifications of the '623 Patent and '108 Patent do not inform a  
11 PHOSITA what constitutes a “tail.” The specifications do not define the term  
12 “tail.” Instead, the term appears only once, when the specifications state: “[i]n an  
13 alternative embodiment, the sensor 310 may have a tail (not shown) that connects  
14 directly to the wrist-mounted module 410, eliminating the auxiliary cable 420.”  
15 JA74, 5:45–47; JA117, 5:43-45. This disclosure primarily informs a PHOSITA  
16 what a “tail” is *not*, namely an auxiliary cable 420.

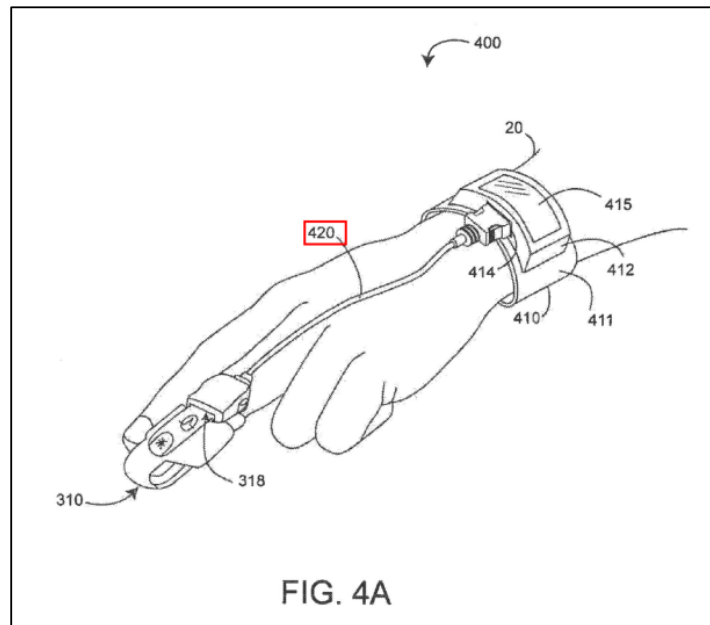
17          78. While the specifications provide little information regarding what  
18 constitutes a “tail,” the specifications provide ample information regarding what is  
19 an “auxiliary cable.” Specifically, the specifications teach:

20                   Fig. 4A illustrates a wrist-mounted module 410 having a  
21 wrist strap 411, a case 412 and an auxiliary cable 420. . . .  
22 The auxiliary cable 420 mates to a sensor connector 318 and  
23 a module connector 414, providing a wired link between a  
conventional sensor 310 and the wrist-mounted module 410.  
Alternatively, the auxiliary cable 420 is directly wired to the  
sensor module 400.

24 JA74, 5:29–39; JA117, 5:33-37.

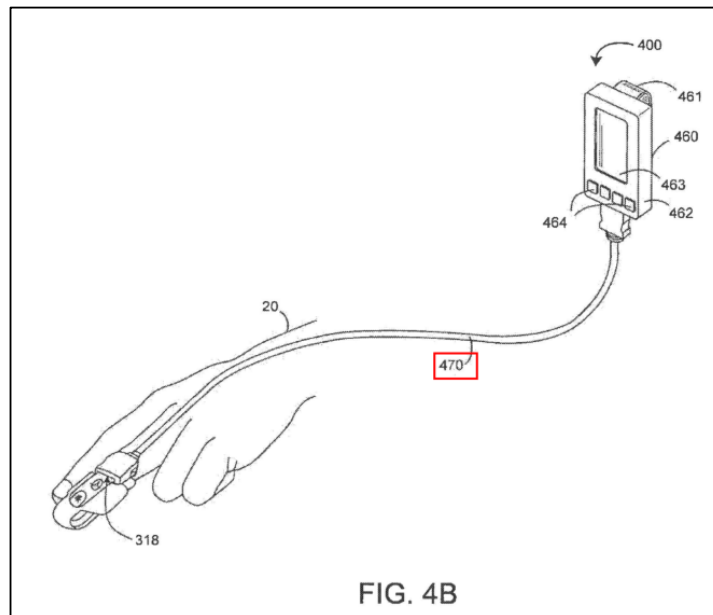
25          79. The auxiliary cable 420 is also shown in Figure 4A.

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27  
28



JA58; JA101.

80. A functionally identical cable, auxiliary cable 470, is also shown in Figure 4B:



JA59; JA102; *see also* JA74, 5:51–54 (“The auxiliary cable 470 mates to the sensor connector 317 and functions as for the auxiliary cable 420 (FIG. 4A),

1 described above.); JA117, 5:48-52 (same).

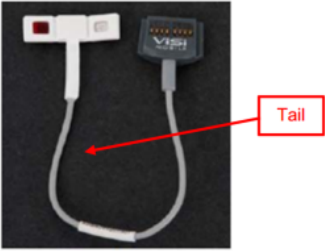
2 81. A PHOSITA would understand the specification to unambiguously  
3 teach a “tail,” whatever the term means, is *not* an auxiliary cable and thus is not  
4 something that either: 1) provides a wired link between a conventional sensor 310  
5 and the wrist-mounted module 410 by mating to sensor and module connectors; or  
6 2) is directly wired to the sensor module 400.

7 82. I understand Masimo proposes the term “tail” is not indefinite and be  
8 construed to mean “a cable integral to the sensor.” I disagree. It is my opinion that  
9 the claims and specifications of the ’623 Patent and ’108 Patent do not provide  
10 sufficient detail to support such a construction. As discussed above, the  
11 specifications primarily inform a PHOSITA what a “tail,” which, again, is a term  
12 that is not used in the medical field, is not.

13 83. In addition, a PHOSITA would understand the term “cable” and “tail”  
14 to be used interchangeably in the claims of the patents without distinguishing what  
15 differences exist between the terms. Both Claim 2 and Claim 5 of the ’108 Patent  
16 depend from Claim 1. Claim 2 requires “the wired connection from the pulse  
17 oximetry sensor to the first sensor port is provided at least in part via a tail of the  
18 pulse oximetry sensor.” JA121, 13:55–58. Claim 5 of the ’108 Patent also requires  
19 “a cable providing the wired connection from the pulse oximetry sensor to the first  
20 sensor port.” *Id.* at 14:1-2. Thus, a PHOSITA reading these two claim limitations  
21 would understand both limitations to describe a component that provides a wired  
22 connection from the pulse oximetry sensor to the “first sensor port,” but one  
23 component to be called a “tail” and another a “cable” without distinguishing what  
24 differences, if any, exist between the components. Providing further complication,  
25 Claim 2 of the ’623 Patent requires the “tail” to “compris[e] a cable extending  
26 from the pulse oximetry sensor to the first sensor port of the housing.” JA78, 14:7–  
27 9. But, the specification explains that the tail *replaces* the cable. The system either  
28 includes a cable or a tail, not both. A PHOSITA would thus not understand how

the tail *cannot be* a cable but can also *comprise* a cable, or *what* differences, if any, a “tail” would have from a “cable,” despite the specification distinguishing a “tail” from the “auxiliary cable.”

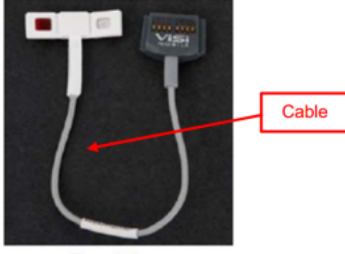
84. I further understand that Masimo itself identifies the same component as meeting both the “cable” and “tail” limitations discussed above. Specifically, in Exhibit G to Masimo’s Amended Infringement Contentions, Masimo identified the Sotera component below as the claimed “tail” as required by Claim 2 of the ’108 Patent:

Claim 2	
The portable patient monitoring device of claim 1,	See Claim 1.
wherein the wired connection from the pulse oximetry sensor to the first sensor port is provided at least in part via a tail of the pulse oximetry sensor.	<p>The wired connection from the pulse oximetry sensor of the ViSi Mobile Thumb Sensor to the first sensor port of the ViSi Mobile Monitor is provided at least in part via a tail of the pulse oximetry sensor.</p>  <p><b>Thumb Sensor</b></p> <p>ViSi Mobile Monitoring System User Manual at 66 (MAS0008343-0008584).</p> <p>See SOTERA 00004717-00004724; SOTERA 00005233-00005240; SOTERA 00005241-00005248; SOTERA 00029744.</p>

Ex. H at 46.

85. For Claim 5, however, Sotera identified the same component as the claimed “cable”:



<b>Claim 5</b>	See Claim 1.
The portable patient monitoring device of claim 1 further comprising:	
a cable providing the wired connection from the pulse oximetry sensor to the first sensor port.	The ViSi Mobile Thumb Sensor includes a cable providing wired connection from the pulse oximetry sensor to the first sensor port of the ViSi Mobile Monitor.
	 <p data-bbox="738 619 868 640"><b>Thumb Sensor</b></p> <p data-bbox="657 640 1250 661">ViSi Mobile Monitoring System User Manual at 66 (MAS0008343-0008584).</p> <p data-bbox="657 682 1437 724">See SOTERA 00004717-00004724; SOTERA 00005233-00005240; SOTERA 00005241-00005248; SOTERA 00029744.</p>

Ex. H at 50.

86. To the extent a PHOSITA did understand a “tail” to be a “cable integral to the sensor,” a PHOSITA would not understand Masimo’s identical identification of the same component to provide any delineation between what constitutes a tail and a cable.

## **VII. THE ALARM SUSPENSION PATENTS (THE RE244 PATENT AND RE249 PATENT)**

### **A. Overview of the Alarm Suspension Patents**

87. I understand the parties have identified the following terms of most significance from the Alarm Suspension Patents: Term No. 4 (“alarm delay or suspension period of time” (RE244 patent, Claims 1, 6-8, 13, 18, 19, and 25)); Term No. 5 (“the one or more processors configured to electronically . . . determine that the measurement of the physiological parameter satisfies an alarm activation threshold” (RE244 patent, Claim 1)); Term No. 6 (“electronically initiating, using the patient monitoring device, the first parameter-specific alarm delay or suspension period of time” (RE244 patent, Claim 13)); and Term No. 7 (“alarm hold initiator” (RE249 patent, Claims 1, 8, 13, 18, and 19)).

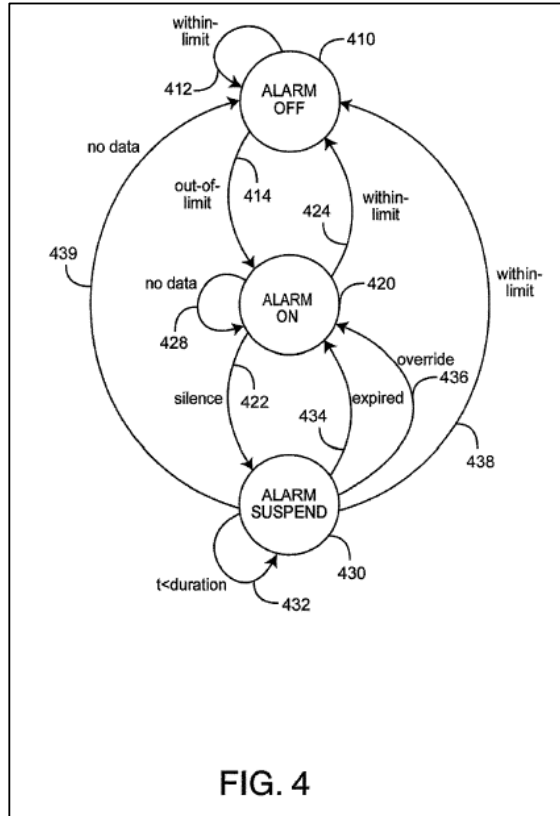
88. The specification of the Alarm Suspension Patents teach a multi-



1 physiological patient monitor that monitors physiological parameters, including  
 2 oxygen saturation (SpO<sub>2</sub>) and pulse rate measured by a pulse oximeter, and other  
 3 blood constituents including carboxyhemoglobin (HbCO), methemoglobin  
 4 (HbMet) and total hemoglobin (Hbt). *See e.g.*, JA124, Abstract, JA136, 1:40-51,  
 5 *id.* at 2:23–32, JA137, 4:30–36. Like any conventional physiological monitor,  
 6 alarms are triggered by “out-of-limit parameters” (i.e., a measured parameter  
 7 exceeds an alarm threshold). JA124, Abstract, JA136, 2:18–20, 2:61-64, JA137,  
 8 4:42–46, 5:42–44, 5:51–53, JA137–138, 5:66–6:4. Also, like any conventional  
 9 physiological monitor, alarms may be audible and/or visual. JA136, 2:21–23,  
 10 JA137, 4:42–53, 5:44-50; JA138, 6:4-5. The point is, of course, to alert medical  
 11 personnel that a particular patient vital sign is of concern and may require further  
 12 medical attention.

13 89. The Alarm Suspension Patents teach that once an alarm is triggered or  
 14 activated, an alarm silence button or other suspend initiator may be actuated to  
 15 temporarily suspend or deactivate an alarm (i.e., silence audible alarms) for a  
 16 period of time. *Id.*, JA124, Abstract, JA136, 2:33-36, JA137, 3:1-4, 3:30-32, 3:58-  
 17 60, 4:46-48, JA138, 5:38-41, 5:53-60, 6:5-10. “A timer tracks the duration of the  
 18 suspended alarm and is initiated by actuation of an alarm silence button.” JA137,  
 19 3:3-4. Alarm suspension times correspond to parameters “partitioned according to  
 20 treatment time, i.e., the relative length of time it takes for a person to respond to  
 21 medical treatment for a parameter measurement outside of the predetermined  
 22 limits.” JA136, 2:64-67; *see also* JA124, Abstract, JA137, 3:6-19, 3:28-65, 4:58-  
 23 65, JA138, 6:23-36. Each “alarm suspend period is typically long enough to give a  
 24 caregiver sufficient time to intervene with appropriate patient treatment yet short  
 25 enough to ensure that patient health is not endangered if intervention is  
 26 ineffective.” JA136, 2:38-42. In other words, when a given parameter triggers an  
 27 alarm, the alarm suspension period of time will correspond to the amount of time it  
 28 typically takes to treat that condition.

90. “The timer retriggers the audible alarm after the timed duration has lapsed/expired.” JA137, 3:4-6; *see also* JA124, Abstract, JA136, 2:37-38, JA138, 5:59-60, 6:9-12. Figure 4 illustrates the alarm suspend method:



JA134. The alarm suspension method operates independently for each measured parameter. JA138, 5:66-6:1. As shown in Figure 4, an alarm is suspended for a pre-determined duration after the alarm is triggered as a result of an out-of-limit parameter and in response to a “silence request.” *Id.*, 6:1-22. When the suspend duration expires, the alarms are reactivated. *Id.*, 6:10-12.

## **B. Opinions Regarding the Proper Construction of Claim Terms in the Alarm Suspension Patents.**

### **1. Term No. 4: “alarm delay or suspension period of time.”**

91. A PHOSITA in patient monitoring systems undoubtedly understands that an “alarm delay” is a fundamentally different concept than an “alarm

1 suspension.”

2 92. A PHOSITA would know that an alarm suspension, in the medical  
3 field, is akin to a snooze button—it silences or suspends an *active* alarm. In other  
4 words, a sensor measures a patient’s vital signs, a monitor finds those vital signs to  
5 be out-of-limits, and the monitor triggers an alarm, usually both audibly and  
6 visually. The Alarm Suspension Patents confirm this, as discussed above and  
7 further below.

8 93. This really isn’t much different than an alarm clock. For example,  
9 when a set of parameters results in a triggered alarm (e.g., because the current time  
10 is equal to a set wakeup time), the alarm makes an audible sound (e.g., beeping,  
11 music, etc.) and a visual indication (e.g., flashing numbers). In response to that  
12 alarm, a person can snooze the alarm by pressing a button (the snooze button).  
13 Subsequently, the alarm will reactivate after the snooze duration (e.g., 9 minutes).  
14 Alarm suspensions embody a very similar concept – a triggered alarm can be  
15 “snoozed” (i.e., silenced) for a predetermined period of time so that a doctor or  
16 nurse can address the medical issue without being bothered by a blaring alarm that  
17 might distract the doctor or nurse while providing medical treatment. But  
18 importantly, an alarm suspension silences or snoozes an alarm *that has already*  
19 *been triggered* due to out-of-limit parameter readings.

20 94. In contrast, a pre-alarm delay is an amount of time that a bedside  
21 monitor waits *before actually* triggering *the alarm* to ensure that any out-of-limit  
22 parameter readings are out-of-limit more than just temporarily. In other words, pre-  
23 alarm delays verify out-of-limit parameters and prevent false alarms. When  
24 properly used, a pre-alarm delay won’t trigger an alarm that isn’t medically  
25 significant.

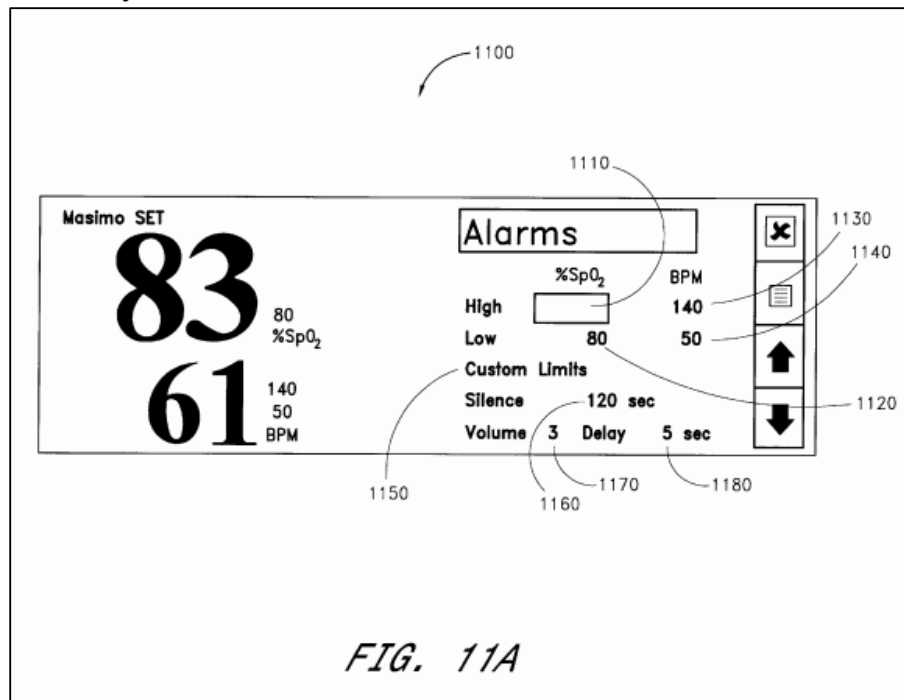
26 95. Generally, when designing alarms for medical monitoring devices, a  
27 primary goal is the reduction of false alarms that do not represent clinical  
28 significance or do not require caregiver intervention. Multiple false alarms can

1 result in alarm fatigue to a caregiver, resulting in true alarms going unnoticed and  
 2 caregivers failing to provide timely medical intervention for true alarm conditions.  
 3 In other words, medical staff become numb to too many alarms going off when  
 4 time-and-again, after responding to the alarm, the patient's safety was not in  
 5 danger. Consider a person's oxygen saturation. Generally, oxygen saturation is  
 6 typically measured using a non-invasive light-based sensor worn on a patient's  
 7 finger. Sometimes, due to patient movement, the sensor may erroneously find an  
 8 incorrect oxygen saturation reading due to a phenomenon known in the art as  
 9 "motion artifact." The motion artifact is a fleeting error, usually corrected within a  
 10 few seconds. Rather than trigger an alarm in response to the motion artifact,  
 11 medical devices began "delaying" the triggering of an alarm for a few seconds to  
 12 ensure that the out-of-limit reading wasn't just a momentary false alarm. Thus, a  
 13 system implementing a pre-alarm delay must first find that a parameter value  
 14 exceeds a threshold *and that the parameter exceeds the threshold for the entire*  
 15 *alarm delay period of time* before triggering an alarm at all. In other words, a pre-  
 16 alarm delay *is an alarm triggering parameter*.

17 96. Thus, it should be clear how fundamentally different alarm  
 18 suspensions and alarm delays really are. Pre-alarm delays are a period of time  
 19 *before* an alarm is triggered at all to ensure its clinical significance before alerting  
 20 medical personnel, whereas an alarm suspension is a period of time to silence an  
 21 alarm *after* an alarm is triggered and medical personnel are attending the patient.

22 97. In fact, the inventor of the Alarm Suspension Patents, Mr. Joe Kiani  
 23 agrees with me in a previously filed patent. Ex. C (U.S. Patent No. 6,658,276).  
 24 Mr. Kiani himself said that there is a difference between alarm silence durations  
 25 and pre-alarm delay durations. Silence durations are suspend durations—as the  
 26 specification of the Alarm Suspension Patents clearly demonstrates. Mr. Kiani  
 27 even explained in U.S. Patent No. 6,658,276 that alarm silence/suspension periods  
 28 are triggered by pressing a silence button and mute already triggered alarms. *Id.* at

13:1–20. Indeed, the silence duration 1160 is illustrated as being 120 seconds whereas a delay duration 1180 is shown to be five seconds.



98. These terms have two different and well-understood meanings in the art. Neither of these concepts are new nor were they new at the priority date of the Alarm Suspension Patents. A PHOSITA would have been familiar with both pre-alarm delays and alarm suspensions in 2008 and long before that. For example, U.S. Patent No. 3,608,545 to Novack, which was filed in 1968, discloses different alarm delay times for various combinations of pulse rate and ECG measurements, with long alarm delay times for measurements that are more susceptible to being a result of artifact and thus a false alarm, and short delay times for measurements that are more likely indicative of a dangerous condition requiring immediate medical treatment. Ex. 4 (3,608,545) at 5:13–63; *see also* Ex. 5, U.S. Patent No. 5,253,645 to Friedman (1991) (applying a delay time to SpO<sub>2</sub> alarms to prevent false alarms during portion of blood pressure cuff inflation/deflation cycle) (Ex. 5, 4:14-29); U.S. Patent No. 6,816,266 to Varshneya (2002) (teaches setting different

1 alarm delay times for heart rate and respiration measurements in infants and adults)  
 2 (Ex. 6, 33:42-50); U.S. Patent No. 5,865,736 to Baker (1997) (disclosing activation  
 3 of an alarm *only when* a measured physiological is outside of set limits for a certain  
 4 time period) (Ex. 7, Abstract, 1:54-63, 3:18-55, 5:29-37, 5:42-56, Fig. 3); U.S.  
 5 Patent Publication No. 2009/0247851 to Batchelder (2009) (disclosing an alarm  
 6 management system that utilizes an algorithm to generate an alarm based on the  
 7 combination of the amount by which a physiological parameter exceeds a threshold  
 8 and the amount of time in which the physiological parameter exceeds the  
 9 threshold) (Ex. 8, Abstract, [0015], [0024], [0030]-[0032]); U.S. Patent No.  
 10 8,792,949 to Baker (2009) (disclosing a pre-alarm delay implemented by an  
 11 algorithm or “predetermined delay periods” that only generate an alarm if a  
 12 measured parameter still exceeds an alarm threshold after waiting the delay period)  
 13 (Ex. 9, Abstract, 1:48-57, 11:53-65, 12:32-45, 14:1-16:15). In all of these prior art  
 14 patents, the pre-alarm delays are *part of* the criteria required to activate an alarm,  
 15 i.e., no alarm is ever generated unless **both** the threshold is exceeded **and** the alarm  
 16 delay period has passed. Alarm suspensions, on the other hand, have also been  
 17 well-known in the art to prevent distraction to a caregiver in the clinical  
 18 environment and to prevent false alarms occurring as a result of short-term  
 19 procedures on a patient. *See* U.S. Patent No. 5,920,263 to Huttenhoff (1998) (Ex.  
 20 10, 2:6-12; 32-37); U.S. Patent No. 6,510,344 to Halpern (2000) (Ex. 11, 1:28-49);  
 21 *see also* U.S. Patent No. 8,130,105 to Kiani (2006) (Ex. 12, 12:47-59); Kiani (Ex.  
 22 C, 13:1-6). As discussed below, Masimo distinguished the prior art on the basis  
 23 that the Alarm Suspension Patents claim “parameter-specific” alarm suspensions.<sup>3</sup>

24 99. Knowing this context and the clear, unequivocal differences between  
 25 alarm suspension and pre-alarm delay, a PHOSITA would read the Alarm  
 26 Suspension Patents and instantly recognize that they are directed to alarm

27  
 28 <sup>3</sup> However, it should be noted that parameter-specific alarm suspension periods of  
 time were also known prior to the priority date of the Alarm Suspension Patents.

1 suspension, and *not* alarm delays. For example, the abstract of the RE244 patent  
 2 mentions that audible alarms respond to an alarm trigger and that an alarm  
 3 suspension occurs in response to a user pressing a silence button. JA124, Abstract.  
 4 But most importantly, the patent discusses the relationship between different alarm  
 5 suspension periods of time and fast and slow *treatment* times. JA124, Abstract;  
 6 JA136, 2:38–42. The Alarm Suspension Patents explain that a treatment time is the  
 7 amount of time necessary for a caregiver to intervene and address the out-of-limit  
 8 parameters that triggered an alarm. *Id.* The Alarm Suspension Patents even give  
 9 some examples of medical treatments and interventions, such as applying an  
 10 oxygen mask when a patient has low oxygen saturation or injection of methylene  
 11 blue when high methemoglobin is detected. JA136, 2:45–55. A PHOSITA would  
 12 recognize these medical treatments as actions taken by a medical caregiver in  
 13 response to an alarm condition, not something that occurs before an alarm is  
 14 triggered. A PHOSITA would equally recognize that these treatments would never  
 15 occur *before* an alarm was triggered.

16 100. The remainder of the specification only confirms that the patentee  
 17 disclosed parameter specific alarm *suspensions*. Importantly, the specification  
 18 always describes an alarm being triggered before an alarm suspension period of  
 19 time begins. JA124, Abstract, JA136, 2:33-36, JA137, 3:1-2, 3:31-32, 3:58-60,  
 20 4:46-48, 4:58-60, JA138, 5:51-58, 6:3-10. The specification uses the term  
 21 “suspend” synonymously with “silence” and “deactivating.” *Id.* Even after a  
 22 suspension period ends, the specification describes the alarm as “resuming” or  
 23 “retriggering” or “reactivating.” JA136, 2:37-38, JA137, 3:4-7, 3:22-23, 3:34-36,  
 24 3:65-4:1, JA138, 6:9-14. A PHOSITA need look no further than FIG. 4, which  
 25 shows the envisioned method. As shown in FIG. 4 and described by the  
 26 specification, the alarm *first* triggers after comparing a measured value to alarm  
 27 limits, then a user presses a button to silence the audible portion of an active alarm,  
 28 the system suspends the audible alarm for the suspend period of time, and then the



1 system reactivates the audible alarm if the parameter is still outside of the alarm  
2 limits after the suspend duration elapses. JA138, 5:66–6:23, JA134 (FIG. 4).

3 101. Nor does the specification disclose any embodiment where an alarm is  
4 not automatically generated when a physiological parameter is outside of an alarm  
5 limit or threshold. JA124, Abstract, JA136, 2:18-20, JA136–137, 2:67–3:1, JA137,  
6 3:28–31, 4:42–46, JA138, 5:51–53, 6:1–5, JA139, 7:16–18.

7 102. Even as originally claimed before reissue, the claims disclosed this  
8 process that involves first the triggering of an alarm upon a determination it is  
9 outside of set limits, then reception of user input to begin an alarm suspension, and  
10 then suspending the active alarm for a period of time. JA3766, U.S. Patent No.  
11 9,153,121, Claim 1.

12 103. The specification refers to “alarm delays” in a single sentence, and  
13 they are described as something different than an “alarm suspension” and not  
14 parameter-specific. “Other alarm features apply to both slow treatment and fast  
15 treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds  
16 applies to all enabled parameters.” JA138, 6:38–40. Assuming that these “alarm  
17 delays” are “pre-alarm delays” (no definition or description of what “alarm delays”  
18 are is provided in the specification), because the “alarm delays” are referred to as  
19 “other alarm features” immediately after describing alarm suspensions for slow  
20 and fast treatment parameters, a PHOSITA would understand the “alarm delay” to  
21 be something different than an “alarm suspension.” Additionally, the “alarm delay”  
22 is described as “appl[ying] to all enabled parameters,” so in contrast to the  
23 described alarm suspension time periods that are specific to each parameter, the  
24 alarm delay times apply equally to all measured parameters (i.e., the alarm delay  
25 times are not parameter-specific).

26 104. Also, the specification distinguishes “alarm limits” from “alarm  
27 suspensions.” JA136-137, 2:61-3:13, 3:30-32, 4:49-63, JA138, 5:51-54, 5:66-6:23,  
28 6:33-40. An alarm limit is a condition that must be satisfied to trigger an alarm.



1 JA138, 5:51-53. A PHOSITA understands an alarm delay as part of an alarm limit,  
 2 because it is something that must be satisfied to trigger an alarm. In other words,  
 3 the specification does not support any conclusion other than out-of-limit  
 4 parameters automatically generate alarms and alarm suspensions only occur *after*  
 5 an alarm has been triggered.

6 105. Turning to the claim language, the disputed term is an “alarm delay or  
 7 suspension period of time.” However, it is important to analyze claim context here  
 8 because the claim actually says *parameter-specific* alarm delay or suspension  
 9 period of time. Yet, the specification only describes a parameter specific alarm  
 10 *suspension* time. As noted above, the specification specifically notes that alarm  
 11 delays are the same for “all enabled parameter,” thereby describing alarm delays  
 12 are parameter independent. Thus, the specification of the Alarm Suspension  
 13 Patents only supports the conclusion that the parameter specific alarm delay or  
 14 suspension time means a period of time in which an active alarm is paused (i.e., an  
 15 alarm suspension). If the claims were construed any broader, then again, the claims  
 16 would lack written description from the specification, rendering the claims invalid,  
 17 and I have been counseled to construe the claims to avoid invalidity.

18 106. Construing the claims to mean a period of time in which an active  
 19 alarm is paused, as Sotera has proposed, comports not only with the clear teachings  
 20 of the specification, but also the very purpose of the technology disclosed by the  
 21 Alarm Suspension Patents. The specification teaches that “alarm suspend period  
 22 [that] is typically long enough to give a caregiver sufficient time to intervene with  
 23 appropriate patient treatment yet short enough to ensure that patient health is not  
 24 endangered if intervention is ineffective.” JA136, 2:38-42; *see also id.*, 2:45-67;  
 25 JA137, 3:6-13, 3:28-42, 4:58-4:1, JA138, 5:60-65, 6:23-36, JA139, 7:26-32. The  
 26 parameter-specific durations of time are related to *treatment* times, which as I  
 27 mentioned above, would be understood by a PHOSITA to mean the time it takes to  
 28 address physiological parameters that triggered an alarm. If the term is construed to

1 cover pre-alarm delays, the stated purpose and advantages of the claimed invention  
 2 would not make any sense because the purpose of pre-alarm delays is to *prevent* an  
 3 alarm from triggering at all if the physiological parameter only briefly exceeds an  
 4 alarm threshold. Conversely, the purpose of alarm suspensions is to prevent  
 5 distraction to a caregiver during medical intervention *after* an alarm has already  
 6 been triggered.

7 107. In contrast, Masimo proposed a construction broad enough to cover  
 8 both pre-alarm delays and alarm suspensions. Yet a PHOSITA would not agree  
 9 with this construction after having read the specification.

10 108. Finally, I note that the Alarm Suspension Patents are all “reissue”  
 11 patents. I have been informed by counsel that the Alarm Suspension Patents are  
 12 “broadening reissue” patents, meaning the claim scope is broader than the original  
 13 patent they reissued from. After having reviewed the prosecution history of the  
 14 Alarm Suspension Patents and specifically the “Reissue Declaration,” it seems that  
 15 Masimo wanted to broaden their claim to amend the claims to “recite a  
 16 noninvasive physiological sensor that does not necessarily include a plurality of  
 17 light emitting diodes and at least one detector.” JA3890. And yet, it seems that  
 18 Masimo has attempted to broaden the claims much further than that. It also  
 19 removed the requirement that user input (e.g., pressing the silence button) to  
 20 initiate the alarm suspension period of time and also removed the requirement that  
 21 an alarm trigger before initiation of the alarm suspension period of time. A  
 22 PHOSITA would recognize that these additional broadening statements are  
 23 unrelated to the physiological sensor’s infrastructure and composition have nothing  
 24 to do with whether the sensor has a light emitter or detector. The omission of those  
 25 claim elements relates specifically to the functions of the processor, not the  
 26 hardware comprising the claimed physiological sensor.

27 109. I have been informed by counsel that a Reissue Applicant is required  
 28 to notify the USPTO of all broadening changes made to the claims in the Reissue

1 Declaration, yet I see no further disclosure from Masimo in the prosecution  
 2 history. It also appears from the prosecution history of the RE244 patent that the  
 3 Examiner very clearly interpreted the claim language as Sotera proposes and how I  
 4 have explained above (as an alarm suspension and not a pre-alarm delay). For  
 5 example, the Examiner, in interpreting the prior art, mentioned that it was known  
 6 to use a suspension period of time before *retriggering* an alarm. JA3951-3953.  
 7 Specifically, he found U.S. Patent Pub. 2008/0281168 (“Gibson”) and U.S. Patent  
 8 Pub. 2008/0255438 (“Saidara”) both taught suspension of active alarms. JA3951.  
 9 (“As explained in paragraphs [0181] a parameter specific silence button can be  
 10 pressed which will silence a current alarm.”); JA3952 (“The examiner determines  
 11 that the teachings of Saidara shows that it was well known to set different delay  
 12 periods (after an alarm has been triggered) before an alarm will be retriggered.”)  
 13 Thus, as expected, a PHOSITA (the Examiner) interpreted these claims to only  
 14 cover parameter-specific alarm suspension periods or a period of time in which an  
 15 **active** alarm is paused. Indeed, an untriggered alarm cannot be retriggered.  
 16 Moreover, Masimo successfully argued around these rejections on the basis that  
 17 Gibson and Saidara do not disclose *parameter-specific* suspensions of active  
 18 alarms for different physiological parameters, but never distinguished the prior art  
 19 on the basis that the amended claims are directed to delaying an alarm before it is  
 20 initially generated as it argues now. JA3953-3954; JA4382-4384.

21 110. In summary, all the intrinsic evidence clearly relates to post-alarm  
 22 suspensions, and not pre-alarm delays (as Masimo proposes). The claimed alarm  
 23 delay or suspension period of time clearly relates to a period of time in which an  
 24 active alarm is paused, and this claim term is unrelated to pre-alarm delays

25 **2. Term No. 5: “the one or more processors configured to**  
 26 **electronically ... determine that the measurement of the**  
 27  
 28

**physiological parameter satisfies an alarm activation threshold”**

111. A PHOSITA would certainly know what a processor is, generally. Also, a PHOSITA would generally understand what is meant by “determine that the measurement of the physiological parameter satisfies an alarm activation threshold.” However, a PHOSITA would know that an off-the-shelf, general-purpose processor would not be able to “determine that the measurement of the physiological parameter satisfies an alarm activation threshold.” Instead, a PHOSITA would know that the processor would have to be specially programmed in order to accomplish this function.

112. While the concept of determining “that the measurement of the physiological parameter satisfies an alarm activation threshold” is generally understandable as an abstract concept, the specifics of *how* the processor determines “that the measurement of the physiological parameter satisfies an alarm activation threshold” are unclear to me and would be unclear to a PHOSITA. For example, a PHOSITA might ask “does the ‘determination’ involve a comparison?”, “is the ‘determination’ made by an algorithm instead?” “what does ‘satisfy’ mean (exceed?, equal to? lower than?)”, “what is the output from this determination?”, “does an alarm trigger in response to determining that the measurement of the physiological parameter satisfies an alarm activation threshold?”, or “why does the processor perform this step at all?” The claim language fails to answer any of these questions.

113. For example, the claims recite a portion of an algorithm to be implemented by the claimed “one or more processors.” According to Claim 1 of the RE244 Patent, the one or more processors first determine a measurement for a physiological parameter, then determines that the measurement of the physiological parameter satisfies a threshold, then initiates a suspension period of time, and then activates an alarm at the expiration of the suspension period of time.

1 The claim does not explain what the result of the determination that the  
 2 measurement of the physiological parameter satisfies an alarm activation threshold  
 3 is, and how that determination relates to the other claim limitations. As written the  
 4 determination that the measurement of the physiological parameter appears  
 5 completely inconsequential; it has no bearing on any other claimed function of the  
 6 one or more processors. It would seem, based on the claim language, that the one  
 7 or more processors determined that the measurement of the physiological  
 8 parameter satisfies a threshold for no reason. That would make no sense to a  
 9 PHOSITA because people of skill in the art do not program processors to make  
 10 determinations for absolutely no reason. In fact, the next limitation in the claim,  
 11 “the one or more processors configured to electronically . . . initiate a parameter-  
 12 specific alarm delay or suspension period of time . . .,” is not connected to the  
 13 “determining” limitation at all and it is not clear from the claim language how  
 14 these two functions relate to each other.

15 114. Thus, a PHOSITA would conclude that something is missing from the  
 16 claim because surely the one or more processors are determining that the  
 17 measurement of the physiological parameter of the alarm activation threshold for  
 18 no reason. But, the claimed threshold is an alarm **activation** threshold. A  
 19 PHOSITA would conclude that the algorithm necessary to cause the processor to  
 20 “determine that the measurement of the physiological parameter satisfies an alarm  
 21 activation threshold” is not taught by the claim language itself, and a PHOSITA  
 22 would have to look to the specification to find that algorithm.

23 115. I have been informed by counsel that claim language can omit an  
 24 algorithm when claimed as a “mean-plus-function” claim limitation. Counsel has  
 25 informed me that a “means-plus-function” claim limitation occurs when the claims  
 26 recite function without reciting sufficient structure for performing that function,  
 27 and that, in the context of computing-implemented functions, the missing structure  
 28 is a specific computer algorithm for performing the function. That is exactly the

1 case here. As I explained above, the claims recite a vague, abstract function, but  
 2 not a specific algorithm for performing that function. However, the specification  
 3 does disclose that specific algorithm.

4 116. The specification defines the algorithm that determines “that the  
 5 measurement of the physiological parameter satisfies an alarm activation  
 6 threshold” in FIGS. 3 and 4. Looking to FIG. 4 and it’s corresponding description,  
 7 a person of skill would learn that determining “that the measurement of the  
 8 physiological parameter satisfies an alarm activation threshold” involves an  
 9 initially off alarm that triggers (both audibly and visually) upon measured  
 10 parameter having out-of-limit values. JA138, 5:66–6:5. In other words,  
 11 determining “that the measurement of the physiological parameter satisfies an  
 12 alarm activation threshold” involves a processor programmed to activate an alarm  
 13 upon determining that the measurement of the physiological parameter is outside  
 14 of predetermined limits. The specification answers all the questions unanswered by  
 15 the claim; it defines the algorithm, the inputs of the algorithm, and most  
 16 importantly, the outputs – an activated alarm. Thus, the determination is not done  
 17 for no reason, as one of skill would originally suspect; instead, it is done to  
 18 determine when to activate an alarm. FIG. 3 shows the same algorithm—“As  
 19 shown in FIG. 3, measured parameters 312 are compared 310 to default or user-  
 20 specified limits 314. An out-of-limit condition 318 triggers an alarm.” JA138,  
 21 5:51–53. Nothing in the specification teaches an algorithm or anything else that  
 22 even suggests the processor can be programmed to *not* activate an alarm upon a  
 23 determination a parameter is outside of set limits or has exceeded an alarm  
 24 activation threshold.

25 117. Inclusion of the activated alarm into this unspecific function of the  
 26 claimed one or more processors completely makes sense in the context of the full  
 27 specification. As I explained above in detail, the specification is related to  
 28 silencing or pausing active alarms so that a medical caregiver can provide medical

1 treatment without alarms blaring in their ears. Meanwhile, the claimed step after  
 2 the “determine that the measurement of the physiological parameter satisfies an  
 3 alarm activation threshold” step is the initiating the alarm suspension step. A  
 4 PHOSITA would understand that this step is referring to the initiation of  
 5 suspension period that silences an *active* alarm. Yet, the claim language omits the  
 6 express language requiring of the alarm before initiation of the alarm suspension  
 7 period of time. A person cannot suspend an alarm that is not active, so a PHOSITA  
 8 would expect an alarm triggering function. The algorithms disclosed in FIGS. 3  
 9 and 4 and referenced by the means-plus-function claim limitation “the one or more  
 10 processors configured to electronically... determine that the measurement of the  
 11 physiological parameter satisfies an alarm activation threshold” invokes that  
 12 algorithm that triggers an alarm.

13 118. So, in conclusion, a PHOSITA would read the limitation “the one or  
 14 more processors configured to electronically . . . determine that the measurement  
 15 of the physiological parameter satisfies an alarm activation threshold” and know  
 16 that a general-purpose computer cannot perform this function without additional  
 17 programming. A PHOSITA would look to the specification to understand how to  
 18 program it. And, after referencing the specification, a PHOSITA would learn the  
 19 algorithm necessary to implement the function that determines “that the  
 20 measurement of the physiological parameter satisfies an alarm activation  
 21 threshold” and understand that the function involves a processor programmed to  
 22 active an alarm upon determination that the measurement of the physiological  
 23 parameter is outside predetermined limits.

24 119. Alternatively, if the claim term is not found to be a means-plus-  
 25 function term, my analysis above still applies. The RE244 patent only teaches  
 26 automatic activation of an alarm when a physiological parameter is outside of set  
 27 limits. In view of all of the intrinsic evidence, it is my opinion that a PHOSITA  
 28 would understand this term to mean “the one or more processors determine that the



1 measurement of the physiological parameter is outside of predetermined limits,  
2 resulting in activation of an alarm.”

3 **3. Term No. 6: “electronically initiating, using the patient**  
4 **monitoring device, the first parameter-specific alarm delay**  
5 **or suspension period of time”**

6 120. Claim 13 of the RE244 Patent is very similar to Claim 1, but Claim 13  
7 is a method claim. However, the same general function is claimed in both claims:  
8 determine a measurement for a physiological parameter, determine that the  
9 measurement of the physiological parameter satisfies a threshold, initiate a  
10 suspension period of time, and activate an alarm at the expiration of the suspension  
11 period of time. However, like the above, a PHOSITA would not understand how or  
12 why the suspension period of time is initiated. For example, a PHOSITA would not  
13 understand what caused the initiation – why did the initiation occur?

14 121. Again, the specification fills in the gaps of the claims. Throughout the  
15 specification, the specification explains that an alarm suspension period of time  
16 initiates in response to user input, namely through the pressing of an alarm silence  
17 button. JA137, 4:46-48 (“The controls 140 include an alarm silence button 144 that  
18 is pressed to temporarily suspend out-of-limit parameter alarms and system alarms,  
19 such as low battery.”); 4:58-60 (“The alarm silence button 144 is pressed to  
20 temporarily suspend audible alarms.”); JA138, 5:52-56 (“An alarm suspend 328 is  
21 user-initiated by a silence request 322. This may be a press of a silence button 144  
22 (FIG. 1) on a monitor front panel 110 (FIG. 1).”); 6:5-10 (“A user can request to  
23 silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example.  
24 The silence request 422 suspends the alarm 430 which turns off audible alarms but,  
25 in an embodiment, does not deactivate visual alarms”).

26 122. Every single teaching regarding suspend initiation taught by the  
27 specification requires user input. Technically, the specification always teaches that  
28 the user input is always a button except for one passing mention of an “other

1 suspend initiator.” The specification states, “Advantageously, an alarm suspend  
 2 system provides a parameter-dependent variation in the alarm suspend duration, as  
 3 described below, utilizing a common silence button or other suspend initiator.”  
 4 Yet, a PHOSITA would still understand this ambiguous “other suspend initiator”  
 5 as just another means of user input different from a button, such as a switch or a  
 6 touchscreen selection. A PHOSITA would not understand this ambiguous term to  
 7 mean “data” or a “flag,” as suggested by Masimo’s expert. Ex. A, Goldberg Dep.  
 8 Tr., 130:129:24–131:4. Indeed, the *algorithms* disclosed by FIGs. 3–4 both require  
 9 user input to initiate the alarm suspension after an activated alarm sounds. JA138,  
 10 5:53–58; 6:5–10. So, any suggestion that this “other suspend initiator” is anything  
 11 other than a component in which a user may request an alarm suspension is quickly  
 12 dispelled by the method taught by the Alarm Suspension Patents.

13 123. Even if we were to trust Mr. Goldberg that “other suspend initiator”  
 14 could encompass something that does not require user input, then a PHOSITA  
 15 would be completely in the dark as to how such a system would work. After an  
 16 alarm is activated, a PHOSITA would not know how to program a processor that  
 17 automatically initiates alarm suspensions after alarm activation. There is simply no  
 18 enablement for a system that gives alarm suspension control to anything other than  
 19 the user. Would it be in response to somehow detecting that the doctor or caregiver  
 20 is in the same room as the active alarm? Would it somehow be able to tell that the  
 21 doctor is providing care to the patient? The specification does not explain *how* such  
 22 an embodiment would function. I would need to experiment a great deal to create a  
 23 system that automatically suspends active alarms, especially in a way that would  
 24 not compromise patient safety and endanger the lives and health of patients. The  
 25 entire purpose of an alarm is to alert medical personnel to a health issue likely  
 26 requiring medical attention. If the processor could simply suspend an alarm  
 27 without user intervention, the purpose of the alarm is entirely undermined.

28 124. Thus, a PHOSITA would read this claim limitation and know that

1 alarm suspension initiation initiates due to or in response to the input of a user. A  
 2 PHOSITA would obviously be familiar with “a common silence button,” as the  
 3 RE244 Patent calls it because these silence buttons were ubiquitously used by  
 4 medical monitors in any modern medical setting, even in 2008, the priority date of  
 5 the Alarm Suspension Patents. *See* Ex. C, U.S. Patent No. 6,658,276, Fig. 2A,  
 6 4:40-49 (depicting “alarm silence button 230”). A reading of the specification  
 7 would confirm this understanding for a PHOSITA.

8 125. While additional evidence isn’t required because the claims and  
 9 specification so clearly require user input initiation of an alarm suspension, the  
 10 prosecution history further affirms the requirement that user input initiate the alarm  
 11 suspension period of time.

12 126. First, I note that during prosecution of U.S. Patent No. 9,153,121,  
 13 from which all the Alarm Suspension Patents reissued, the applicant included a  
 14 claim limitation specifying the input for alarm initiation. Specifically, the claims  
 15 recited:

16 activating an alarm in response to determining an alarm  
 17 activation threshold has been satisfied by the physiological  
 parameter measurement;

18 receiving an alarm suspension indication; and

19 in response to receiving the alarm suspension indication,  
 20 suspending the alarm for the indicated parameter-specific  
 alarm suspension period of time

21 127. The claims as originally filed were far clearer in terms of input and  
 22 output of the various claimed method steps. First, the alarm was activated.  
 23 Subsequently, an alarm suspension indication was received. Finally, in response to  
 24 receiving that alarm suspension indication, the alarm was suspended. The original  
 25 patent clarified what initiated the alarm suspension – it was the reception of an  
 26 alarm suspension indication. As the claims stand in the Reissue Patent, nothing is  
 27 received to initiate the alarm suspension.

28 128. I have been informed by counsel that Reissue Patents must survive a

1 heightened standard regarding support from the written description. Counsel has  
 2 told me that it must appear from the face of the instrument that what is covered by  
 3 the reissue was intended to be covered and secured by the original patent. The  
 4 original patent never intended to claim anything other than a system that suspended  
 5 active alarms for various period of time in response to a user pressing a button or  
 6 some other user input. The original patent never suggested that “data” or a “flag”  
 7 could trigger initiation of an alarm suspension period of time. Indeed, a data-  
 8 controlled, automatic system for suspending alarms would be illogical and rejected  
 9 by the medical community because it would lead to true alarm conditions to go  
 10 unnoticed by medical personnel.

11 129. Furthermore, the claims of the original patent clearly indicate that an  
 12 “alarm suspend indication” is required to suspend and alarm. The specification  
 13 only supports user input, via the pressing of a silence button, as the claimed “alarm  
 14 suspend indication.” Especially given the heightened nature of Reissue patents, this  
 15 claim limitation clearly requires user input to initiate the alarm suspension. Any  
 16 suggestion to the contrary would not be plainly covered and secured by the original  
 17 patent.

#### 18 4. Term No. 7: “alarm hold initiator”

19 130. For all the reasons discussed above, initiating the alarm suspension  
 20 requires user input. Consistently, the Alarm Suspension Patents describe the  
 21 initiating user input as the press of a silence button.

22 131. However, Claim 1 of the RE249 Patent claims an “alarm hold  
 23 initiator.” I do not recognize this term, and neither would any other PHOSITA.  
 24 Although the term “initiator,” by itself, is known, “initiator” in combination with  
 25 “alarm hold” is not. This is not a term of art or a term that has meaning within the  
 26 art. Alarm “holds” are not even a term of art or a term having a specific meaning  
 27 with the art of medical devices, let alone an alarm hold initiator. As such, I have  
 28 been informed by counsel that the specification is required to provide a definition

1 for this term.

2 132. The specification does not provide a special definition for this term. In  
3 fact, the specification never even uses this term. The specification doesn't even use  
4 the word "hold," let alone "alarm hold" or "alarm hold initiator."

5 133. The specification does use the phrases "a common silence button or  
6 other suspend initiator" and a "user-initiated silence request." These are the only  
7 ways identified in the specification to initiate an alarm suspension. I discussed this  
8 sentence quite a bit above, and in this context, it would seem that a suspend  
9 initiator is something other than a button, but very similar to one. A PHOSITA  
10 would understand this sentence as suggesting that alarm suspensions occur using  
11 user inputs, like a silence button or something similar (e.g., a switch, a  
12 touchscreen, a mouse click). Even so, this is my best guess simply based on the  
13 context that an "other suspend initiator" is at least akin to a common silence  
14 button. Also, all the disclosed algorithms for alarm suspension include a step of  
15 receiving user input. JA138, 5:52-56; 6:1-10, FIGs. 3-4.

16 134. Even so, the phrase "or other suspend initiator" is a far cry from an  
17 express definition of an ambiguous term not recognizable in the art. Furthermore,  
18 that still doesn't explain what an alarm **hold** initiator is. Is it the same as an alarm  
19 suspend initiator? Something different? A PHOSITA would not know for certain.

20 135. As I said above, the only reasonably discernable thing disclosed in the  
21 specification that initiates an alarm suspension is a silence button, and "other  
22 suspend initiator" would be understood by a PHOSITA as some other traditional  
23 user input, like a switch or touchscreen. So, while this term is not reasonably  
24 understandable to a PHOSITA, the only part of the specification that could  
25 arguably be tied to this claim term is the silence button or other user actuated input  
26 means (i.e., "other suspend initiator) because that is all that is disclosed in the  
27 specification that can initiate an alarm suspension. But, I shouldn't have to guess  
28 when it comes to patent scope – I understand patent law to require certainty and

1 definiteness. Masimo's patent has not provided that here.

2 136. Regardless of whether the term is indefinite or a user-actuated silence  
3 button or other suspend initiator, it certainly isn't data, as suggested by Masimo.  
4 The RE249 Patent discusses data but never in reference to that which triggers the  
5 alarm suspension. The only data discussed is digital data input to the DSP from the  
6 physiological sensors and data received by the instrument manager for displaying  
7 of parameter measurements. JA138, 5:20-34. The patentee knew how to describe  
8 data, and did so with ease, yet never described the initiator that initiates the alarm  
9 suspension as data. That was *only* described as user input.

10 137. To the extent Masimo argues that user inputs generate signals that can  
11 be expressed as data, then I would agree with them. But Masimo's construction is  
12 not limited to signals generated by a user pressing a button or other user input. It's  
13 broad enough to cover *any* data. Frankly, the specification does not support such a  
14 construction, especially under the Original Patent Rule.

15 138. In summary, a PHOSITA would not understand the term "alarm hold  
16 initiator" without a definition from the specification because it is not a term of art  
17 or a term that has plain meaning within the medical field. Furthermore, the  
18 specification does not define this term; it merely uses a different term (suspend  
19 initiator) in a confusing manner that, at best, suggests another user input  
20 mechanism similar to a button. Regardless, the initiator is certainly not data  
21 because the patent does not support a system that suspends alarms without user  
22 input.

## 23 **VIII. THE ALARM NOTIFICATION PATENT (THE '994 PATENT)**

### 24 **A. Overview of the Alarm Notification Patent**

25 139. The '994 Patent is 104 pages and includes 43 figures and 76 columns  
26 of text. It broadly teaches ways to detect the presence of a medical device,  
27 clinician, and/or patient, take some location-based action (e.g., changing the  
28 configuration of a medical device or transmitting notification of an event to a

1 specified individual based on their location), facilitate communication between  
 2 medical monitoring devices using a medical communication protocol translator,  
 3 simulate alarm criteria, and simulate alarm notification delay times. JA228, 2:20–  
 4 5:26.

5 140. The eight claims of the '994 Patent, however, pertain only to the  
 6 simulation of alarm notification delays. Thus, although it seems oppressively large,  
 7 the vast majority of the '994 Patent specification is not relevant to discerning the  
 8 meaning of the terms of the claims.

9 141. The specification discusses such simulation of alarm notification  
 10 delays at column 71, line 11, wherein the specification teaches:

11 In addition to simulating alarm criteria, as described herein, the  
 12 reporting module can also simulate the effect of other  
 13 configuration changes in the bedside patient monitoring devices  
 14 and/or a central patient monitoring station. For example, the  
 15 reporting module can simulate the effect of different alarm  
 16 notification delay times.

16 JA263, 71:11–16.

17 142. A PHOSITA would understand this disclosure—by using the words  
 18 “in addition to”, “also”, and “other configuration changes”—to teach the disclosure  
 19 beginning at column 71, line 11 was different from the simulation of alarm criteria.

20 **B. Opinions Regarding the Proper Construction of the Term in the**  
 21 **Alarm Notification Patent.**

22 143. The parties identify one claim term in the '994 Patent as the “most  
 23 significant” at this stage of the litigation. That term is term number 3, “alarm  
 24 condition,” which is used in Claims 1 and 5 of the '994 Patent.

25 144. It is my opinion that a PHOSITA would understand the term “alarm  
 26 condition” to mean “a patient condition that satisfies all alarm criteria resulting in a  
 27 triggered alert.”  
 28



1           145. The '994 Patent specification teaches medical monitoring devices for  
 2 monitoring physiological parameters such as blood oxygen saturation, pulse rate,  
 3 blood pressure, and many others:

4                   are often programmed with alarm limits to automatically  
 5 detect when a physiological parameter has a value that is,  
 6 for example, outside the range of values considered safe or  
 7 healthy for that particular physiological parameter. In some  
 8 embodiments, when such an alarm condition is detected,  
 9 various actions can be taken. For example, the bedside  
 10 medical monitor can emit an audible or visual alarm. In  
 11 addition, in some cases, after the alarm condition has  
 12 persisted for some set amount of time (e.g., 5 sec.), the alarm  
 13 condition can be displayed at, for example, a central patient  
 14 monitoring station, as described herein. Moreover, if the  
 15 alarm condition continues to persist for some set amount of  
 16 time (e.g., 10 sec.), the clinician assigned to care for the  
 17 patient who is experiencing the alarm condition can be  
 18 notified by, for example, a pager or other notification  
 19 device.

20 JA258, 61:52–62:3.

21           146. A PHOSITA would understand this disclosure to teach two things.  
 22 First, when an alarm condition is detected, the bedside monitor can emit an audible  
 23 or visual alarm (i.e., triggers an alarm). As I discuss in the paragraphs below,  
 24 although the specification uses permissive language (i.e., “can emit”), a PHOSITA  
 25 would understand the specification in its entirety to teach only that an alarm  
 26 condition will trigger some type of alarm (e.g., audible, visual, reduced audible,  
 27 etc.). Second, after the alarm condition has persisted for some time, and the alarm  
 28 has thus been sounding or visually displayed for some time, **notification** of that  
 alarm can be transmitted to locations outside the range of the bedside monitor  
 alarm.

1           147. My opinion is further supported by the next portion of the  
 2 specification, which states:

3                   The number of detected alarm conditions is, of course,  
 4 dependent upon the settings for the alarm criteria that  
 5 indicate an alarm condition. In some embodiments, such  
 6 alarm criteria can include a threshold value, which may  
 7 indicate the boundary between values for a physiological  
 8 parameter that are considered safe or normal, and those that

are considered to indicate a medical condition which may require attention from a clinician.

JA258, 62:4–12.

148. A PHOSITA would understand this disclosure to teach an alarm condition is not detected until *all* alarm criteria are satisfied. Indeed, as discussed more fully in the paragraphs below, the '994 Patent teaches the possibility of multiple alarm criteria. *See e.g.*, JA260, 65:34–38 (“Other types of alarm criteria can also be used.”); JA259, 64:36–37 (“If the alarm criteria are satisfied, then an alarm can be generated, as described herein.”). A PHOSITA would understand the use of the plural “are satisfied” to require the existence of more than one criterion. Indeed, the word “criteria” is plural. If the inventors of the '994 Patent intended to inform a PHOSITA there was a limit of only one requirement to create an alarm condition, the inventors could have used the proper singular form “criterion.”

149. I understand Masimo contends this term does not require any construction and should be given its plain and ordinary meaning. I further understand that, in the alternative, Masimo contends this term should be construed to mean “a measurement of a physiological parameter that is outside set limits.” For the reasons below, I disagree.

150. Initially, I understand Masimo asserts functionality by Sotera related to pre-alarm delays—i.e., delays before an alarm sounds or is visually displayed on the ViSi Mobile monitor—infringes the '994 Patent. For example, I understand in its amended infringement contentions, Masimo makes the following contention for the claim limitation that includes the claim language “the one or more processors further configured to detect an alarm condition for the physiological parameter and delay a notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time”:

For example, based on the alarm limits shown in the tables below, the ViSi Mobile Monitor determines whether the measurement of oxygen saturation satisfies an alarm activation threshold. In

1 addition to Auto Set, the ViSi Mobile Monitor can determine, for  
 2 example, whether the measurement of oxygen saturation satisfies  
 3 a default limit, factory default limit, or other alarm limit. When  
 4 the measurement of oxygen saturation satisfies an alarm  
 5 activation threshold, an annunciation delay of 60 seconds is  
 6 initiated.

6 Ex. H (Pls. Am. Infringement Contentions), 16.

7 151. What Masimo identifies is actually a pre-alarm delay; i.e., a period of  
 8 time in which a physiological parameter must be outside of set limits before an  
 9 alarm will activate, which, as discussed below, is not what the '994 Patent teaches  
 10 is an "alarm notification delay time." Indeed, such pre-alarm delays were well-  
 11 known in the art well before the application for the '994 Patent was filed. For  
 12 example, I describe multiple examples of prior art in paragraph 98 above that use  
 13 pre-alarm delays.

14 152. Instead of a delay before an alarm is triggered at the bedside monitor,  
 15 the '994 Patent teaches an "alarm notification delay" is the time between when the  
 16 alarm condition is detected at a bedside monitor and when notification of the alarm  
 17 is sent to a remote location, such as to a clinician or a central monitoring station.  
 18 Specifically, the '994 Patent teaches:

19 As discussed herein, in some embodiments, when an alarm  
 20 condition is detected, bedside patient monitors may be configured  
 21 to wait until a predetermined alarm notification delay time has  
 22 elapsed before transmitting notification of the alarm event to  
 23 either a clinician or to a central monitoring station. In addition,  
 24 the central monitoring station can likewise be configured to wait  
 25 until a predetermined alarm notification delay time has elapsed  
 26 before actually transmitting a notification of the detected alarm to  
 27 a clinician by, for example, a page or other notification method.

28 JA263, 71:16–26.

153. Shortly after, the '994 Patent similarly teaches:

For example, an alarm notification event may be a notification by

1 a bedside patient monitor to a central monitoring station of an  
 2 alarm condition. In this case, the first alarm notification delay  
 3 time could be measured as the elapsed time between when an  
 4 alarm condition was detected at the bedside monitor and when  
 5 notification of the alarm was sent to the central monitoring  
 6 station. In addition, an alarm notification event may be a  
 7 notification from a patient monitoring device to a clinician of an  
 8 alarm condition. In this case, the first alarm notification delay  
 9 time can be measured as the elapsed time between when an alarm  
 10 condition was detected and when the clinician was notified.

11 *Id.* at 71:46–57.

12 154. A PHOSITA would understand both these disclosures to teach an  
 13 “alarm notification delay” is not a delay before an alarm is triggered at the bedside  
 14 monitor, but a delay before notification of that alarm is transmitted to a remote  
 15 location. There is absolutely no disclosure of an “alarm notification delay” used  
 16 before an alarm is triggered at the bedside monitor.

17 155. Masimo’s confusion regarding the differences between a pre-alarm  
 18 delay and an alarm notification delay seemingly seeps into Masimo’s proposed  
 19 construction for the term “alarm condition.” I understand Masimo proposes the  
 20 term be construed to mean: “a measurement of a physiological parameter that is  
 21 outside set limits.” What Masimo defines as an “alarm condition” is in fact an  
 22 alarm criterion. The ’994 Patent teaches

23 The number of detected alarm conditions is, of course, dependent  
 24 upon the settings for the alarm criteria that indicate an alarm  
 25 condition. In some embodiments, such alarm criteria can include  
 26 a threshold value, which may indicate the boundary between  
 27 values for a physiological parameter that are considered safe or  
 28 normal, and those that are considered to indicate a medical  
 condition which may require attention from a clinician.

JA258, 62:4–11.

156. A PHOSITA would understand this disclosure to expressly teach a  
 threshold value “which may indicate the boundary between values for a

1 physiological parameter that are considered safe or normal, and those that are  
 2 considered to indicate a medical condition which may require attention from a  
 3 clinician” is the same as “a measurement of a physiological parameter that is  
 4 outside set limits” (i.e., Masimo’s proposed construction), and is an example of  
 5 “such alarm criteria.” I therefore disagree with Masimo’s proposed construction for  
 6 “alarm condition” because the ’994 Patent teaches this is an alarm criterion, which  
 7 although may indicate an alarm condition, is not itself an alarm condition.

8 157. A PHOSITA would understand the ’994 Patent to teach the potential  
 9 use of multiple alarm criteria and that an alarm condition will exist only when all  
 10 such criteria are met. Indeed, the word “criteria” is plural whereas “criterion” is  
 11 singular. The specification teaches “[i]n some embodiments, the alarm criteria  
 12 includes multiple threshold values that define, for example, an enclosed range of  
 13 safe or normal values for the physiological parameter. **Other types of alarm**  
 14 **criteria can also be used.**” JA260, 65:34–38 (emphasis added). As discussed  
 15 above in paragraph 98, the use of pre-alarm delays was well known in the art and a  
 16 PHOSITA would readily understand a pre-alarm delay would be an alarm criteria.

17 158. At column 63, lines 51 through 56, the specification refers to “a  
 18 relatively small adjustment to alarm criteria (e.g., an alarm threshold value) . . . .”  
 19 By using “e.g.” instead of “i.e.,” the patentee indicates not only are there multiple  
 20 alarm criteria, but that “an alarm threshold value” is merely one such criterion.  
 21 Similarly, at column 64, lines 36 through 37, the specification teaches “[i]f the  
 22 alarm criteria are satisfied, then an alarm can be generated, as described herein.”  
 23 JA259, 64:36–37. Here, the use of “the” and “are” in the phrase “the alarm criteria  
 24 are satisfied” again teach there are multiple alarm criteria. A PHOSITA would  
 25 understand these disclosures to teach “a measurement of a physiological parameter  
 26 that is outside set limits” is one type of alarm criteria, and that multiple alarm  
 27 criteria may be used.

28 159. At my deposition, I was asked regarding the difference between

1 “multiple alarm criteria” and “all alarm criteria.” The above description illustrates  
 2 this difference. “All” requires the full set of criteria to be satisfied before an alarm  
 3 condition will exist, whereas “multiple” would allow an alarm condition to exist so  
 4 long as more than one alarm criterion was met. For example, an alarm system  
 5 could be designed and implemented to have the following criteria for the SpO<sub>2</sub>  
 6 parameter: (1) blood oxygen saturation percentage below 89%; (2) blood oxygen  
 7 saturation percentage remains below lower limit for 10 seconds; and (3) another  
 8 physiological indicator (e.g., respiration rate) also changes while the blood oxygen  
 9 saturation percentage is below the lower limit. Under the teachings of the ’994  
 10 Patent (i.e., “all criteria”), an alarm condition would not exist until all three criteria  
 11 were met. Under an understanding of “multiple criteria”, as I was asked during my  
 12 deposition, an alarm condition would exist only if more than one criterion was met  
 13 (i.e., criteria numbers 1 and 3, 1 and 2, 2 and 3, etc.) By requiring “all” criteria to  
 14 be met, the ’994 Patent allows for the system described above.

15 160. Of course, “all” and “multiple” can be the same, and “all” can also  
 16 refer to “one”. In that instance, there would be no practicable difference between  
 17 “alarm criteria” and “alarm condition” because once the sole criterion was met, an  
 18 alarm condition would occur. The ’994 Patent allows for both designs, however,  
 19 and a PHOSITA would understand the use of multiple criteria, which is expressly  
 20 allowed for by the ’994 Patent, would distinguish between “alarm criteria” (which  
 21 precede or give rise to an alarm condition) and an “alarm condition”, which exists  
 22 only once all alarm criteria are met.

23 161. In another example, a PHOSITA would understand a system could be  
 24 designed to have only the first criterion described above (blood oxygen saturation  
 25 percentage below 89%). In this situation, if the single criterion is met, “all” criteria  
 26 are met and an alarm condition would exist. A PHOSITA would understand the  
 27 teachings of the ’994 Patent in this way. By stating “[t]he number of detected  
 28 alarm conditions is, of course, dependent upon the settings for the alarm criteria

1 that indicate an alarm condition,” JA258, 62:4–6, the ’994 Patent informs a  
 2 PHOSITA that “all” can be multiple or “one”.

3 162. During my deposition, I was directed to column 39 of the ’994 Patent,  
 4 beginning at line 29. Here, the ’994 Patent states “the patient monitoring device  
 5 1400 could automatically create some type of report, such as a report of all alarm  
 6 conditions that have been registered by that monitor over a predetermined period  
 7 of time.” JA247, 39:27–31. This disclosure does not undermine my opinion that  
 8 the ’994 Patent teaches an alarm condition exists only when “all” criteria are met.  
 9 Here, the ’994 Patent is discussing multiple alarm conditions over a period of time.  
 10 Thus, in the example above, all three criteria could be satisfied—giving rise to an  
 11 alarm condition—multiple times in 24 hours, a week, or a month.

12 163. Only when all alarm criteria are satisfied, however, will an alarm  
 13 condition exist. The ’994 Patent specification expressly teaches “[t]he number of  
 14 detected alarm conditions is, of course, dependent upon the settings for the alarm  
 15 criteria that indicate an alarm condition.” JA258, 62:4–6; *see also* JA260, 65:24–  
 16 26 (“At block 3104, the physiological parameter data is analyzed to identify alarm  
 17 conditions **based upon a first set of alarm criteria**. The alarm criteria can be  
 18 configurable so as to modify the physiological conditions that will trigger an  
 19 alarm”).

20 164. Once an alarm condition exists, the bedside monitor will trigger an  
 21 alarm. The specification teaches “[i]f the alarm criteria are satisfied, then an alarm  
 22 can be generated as described herein.” JA259, 64:36–37. Similarly, at column 61,  
 23 lines 59 through 62, the specification teaches “when such an alarm condition is  
 24 detected, various actions can be taken. For example, the bedside monitor can emit  
 25 an audible or visual alarm.” JA258, 61:59–62. At column 65, the specification  
 26 teaches “[t]he alarm criteria can be configurable so as to modify the physiological  
 27 conditions **that will trigger an alarm**.” JA260, 65:26–27. A PHOSITA would  
 28 thus understand the ’994 Patent specification to teach a connection between the



1 alarm criteria, which may be singular or plural, and triggering of an alarm. Once  
 2 the alarm criteria are met, an alarm condition exists and an alarm or alert is  
 3 triggered.

4 165. A PHOSITA would understand the triggered alarm may take several  
 5 forms, such as audible, reduced-volume audible, and/or visual. *See e.g.*, JA258,  
 6 61:61–62 (“For example, the bedside medical monitor can emit an audible **or**  
 7 visual alarm.”); JA247, 39:32–51 (“For example, if the patient monitoring device  
 8 1400 detects an alarm condition while the clinician is already in proximity to the  
 9 monitoring device, then it may emit no audible alarm or a lower-volume audible  
 10 alarm.”). Although the specification uses permissive language (e.g., “can emit”), a  
 11 PHOSITA would understand this to refer to the option to disclose various types of  
 12 alarms. Thus, the bedside monitor can emit an audible alarm, it can emit a reduced-  
 13 volume audible alarm if the clinician is detected as being present, or it can emit a  
 14 visual alarm. In no instance, however, does the ’994 Patent teach the bedside  
 15 monitor does not emit any type of alarm whatsoever when an alarm condition is  
 16 detected.

17 166. A PHOSITA would understand Figure 4, and the corresponding  
 18 description, to further teach an alarm condition will result in a triggered alert.  
 19 Specifically, Figure 4 teaches the monitor receives physiological information at  
 20 step 404, and—in the next step 405—determines whether an “alarm condition or  
 21 alert has occurred.” JA175; *see also* JA235, 15: 7–14. Thus, not only does the  
 22 specification use the terms “alarm condition or alert” interchangeably, but the  
 23 description of Figure 4 uses “alarm condition” (denoted at 405) to refer to **both**  
 24 “alarm condition” **and** “alert,” again showing an alarm condition **is** an alert.  
 25 JA175. Furthermore, I understand Masimo’s expert, Mr. Goldberg, testified that  
 26 when a value for a physiological parameter is outside of a safe range (i.e., what  
 27 Masimo identifies as an alarm condition), the bedside medical monitor emits an  
 28 audible or visual alarm:

1 Q: So when a value for a physiological parameter is outside of a  
 2 safe range, one action that can be taken is that the bedside medical  
 3 monitor can emit an audio or visual alarm, correct?

4 A: That's the way I read it, yes.

5 Ex. A, 95:15–19. I agree with Mr. Goldberg that the specification teaches the  
 6 bedside monitor emits an alarm—which may be audible, visual, or some other  
 7 form—when an alarm condition is detected.

8 167. Importantly, the 994 Patent repeatedly teaches clinicians are notified  
 9 of alarm conditions, which occurs only after the bedside monitor has triggered the  
 10 alarm. JA233, 11:37–52, JA235, 16:43–48, JA236, 17:2–8, 18:22–30, JA243-244,  
 11 32:63–33:20, JA244, 34:13–33, JA247, 39:38–57, JA249, 44:21–60. If  
 12 Defendants' proposed construction was incorrect—and an alarm condition did not  
 13 “result[] in a triggered alarm”—then there would be nothing of which to notify  
 14 clinicians. Moreover, Masimo's proposed construction, wherein an alarm condition  
 15 does not result in a triggered alarm but clinicians are nevertheless notified of alarm  
 16 conditions, is contrary to the state purpose of the claims, “to reduce a frequency of  
 17 alarms from a physiological monitoring system” (Claims 1-4) and “reducing a  
 18 frequency of alarms” (Claims 5-8).

19 168. To the extent Masimo contends an “alarm condition” does **not** result  
 20 in a triggered alert because the “alarm notification delay” is the delay before which  
 21 an alert is triggered in response to an alarm condition, I disagree. The '994 Patent  
 22 teaches an “alarm notification delay” is not a delay between the onset of an alarm  
 23 condition and the triggering of an audible or visual alert at the bedside monitor, but  
 24 rather the elapsed time between alarm condition and transmission of notification,  
 25 not merely annunciation of the alarm condition at the bedside monitor.  
 26 Specifically, the specification provides two examples of an “alarm notification  
 27 delay” at column 71, lines 46 through 57:  
 28

For example, an alarm notification event may be a notification by a bedside patient monitor to a central monitoring station of an alarm condition. In this case, the first alarm notification delay time could be measured as the elapsed time between when an alarm condition was detected at the bedside monitor and when notification of the alarm was sent to the central monitoring station. In addition, an alarm notification event may be a notification from a patient monitoring device to a clinician of an alarm condition. In this case, the first alarm notification delay time can be measured as the elapsed time between when an alarm condition was detected and when the clinician was notified.

JA263, 71:46–57

169. Thus, in both examples, the “notification delay” is measured as the elapsed time between when an alarm condition was detected and transmission of the notification to a remote location—the central monitoring station or the clinician—not between when the alarm condition was detected and the bedside monitor emits an audible or a visual alarm.

170. As such, a PHOSITA would understand the term “alarm condition” means “a patient condition that satisfies all alarm criteria resulting in a triggered alert.”

## **IX. CONCLUSION**

171. In light of the foregoing, it is my opinion the constructions of the seven “most significant” terms identified by the parties are properly construed to have the meanings Defendants propose. It is my opinion such proposals are consistent with the teachings of the patent claims and specifications, as well as the prosecution history, as a PHOSITA would understand these disclosures. It is further my opinion that the additional evidence I identify in the paragraphs above further corroborates Defendants’ proposed constructions.

172. All of my opinions stated above are based upon my review of the documents listed in my section Materials Considered. I reserve the right to supplement and/or amend my opinions based on additional information that I receive.