IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CARDIONET, INC., :

Plaintiff,

and counterdefendant :

:

BRAEMAR MANUFACTURING, LLC,

Plaintiff

CIVIL ACTION No. 2:12-cv-2516

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THE SCOTTCARE CORPORATION, and AMBUCOR HEALTH SOLUTIONS,

INC.,

v.

:

Defendants, : and counterclaimants. :

MEMORANDUM OPINION

Tucker, C. J. October 08, 2014

Plaintiffs Cardionet, Inc. ("Cardionet") and Braemar Manufacturing, LLC ("Braemer") bring this patent infringement action against Defendants Scottcare Corporation ("Scottcare") and Ambucor Health Solutions ("Ambucor"), alleging that Scottcare and Ambucor infringed Cardionet's patents. Currently before the Court are the parties' claim construction briefs in which they seek to have the Court construe the patent pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). Upon consideration of the parties' submissions, and following a Markman hearing, the Court construes the disputed terms herein.

¹ Cardionet moved to amend its First Amended Complaint to add Braemar Manufacturing, LLC as co-party to the present action. Braemar was added to this suit on May 10, 2013. During the Markman Hearing, the only parties present were Cardionet and Scottcare.

I. Standard of Review for Claim Construction

In <u>Markman v. Westview Instruments, Inc.</u>, 517 U.S. 370 (1996), the Supreme Court held that the issue of claim construction is a question of law to be decided by the Court. Courts resolve the construction of claims before trial at what is now commonly referred to as a "<u>Markman</u> hearing." Once a court rules on the claim construction issues at the <u>Markman</u> hearing, cases may either settle or proceed to trial where the jury decides the factual question of whether an infringement occurred.

A court's claim construction analysis begins with the language of the claim itself, as the patentee specifically chose this language to describe his invention. Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001). The words of a claim "are generally given their ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303,1312-13 (Fed. Cir. 2005) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). If the claim language is clear, then a court may consider other intrinsic evidence, such as the specification and prosecution history, but only to determine whether such intrinsic evidence requires deviation from the clear language of the claim. Interactive Gift Express, 256 F.3d at 1331. A deviation may be necessary under two circumstances: (1) where the patentee has chosen to be his own lexicographer and defines terms in a manner other than their ordinary meaning; or (2) where the patentee has relinquished a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference. Id. (internal citations omitted).

However, if the meaning of a claim cannot be determined from a consideration of the totality of the intrinsic evidence, the court may consider extrinsic evidence. <u>Id.</u> Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. <u>Phillips</u>, 415 F.3d at 1317 (quoting <u>Markman</u>, 52 F.3d at 980). Nonetheless, a court should be hesitant to turn to extrinsic evidence for the purpose of claim construction. Relying on extrinsic evidence is "proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence . . . Such instances will rarely, if ever, occur." <u>Interactive Gift Express</u>, 256 F.3d at 1331 (internal citations and quotations omitted). Extrinsic evidence may never be used to contradict the terms in the claims themselves. Id.

II. The Patents

The five patents-in-suit are United States Patents Nos. 7,212,850 ('850 Patent), 7,907,996 ('996 Patent), 6,569,095 ('095 Patent), 7,587,237 ('237 Patent), and 7,941,207 ('207 Patent). These patents are directed to multiple aspects of electrocardiographic ("ECG") telemetry devices. ECG telemetry devices are monitors comprising one or more components that are used to monitor a patient's cardiac activity and detect cardiac irregularities, including transient and asymptomatic irregularities of which the patient may not be aware. The ECG telemetry devices transmit the cardiac data to a remote location for medical technicians to review. Cardionet asserts that, unlike prior art,² its patents work together with the common goal of accuracy and efficiency. That is, the patented inventions enable more accurate detection of cardiac

² Prior art in patent law is information that is available to the public as of the date of the claim invention, including information that could be obviously inferred. See In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions, 498 F. Supp. 28, 32 n.11 (E.D. Pa. 1980), aff'd 676 F.2d 51,55 (3d Cir. 1982).

irregularities at the device, as well as ensure that medically relevant information obtained during the ECG monitoring is efficiently processed and made available to medical personnel while minimizing waste of time and other resources (i.e. handling cost). Scottcare argues that Cardionet's patented inventions do not differ from the prior art of improved ambulatory cardiac monitor systems, specifically U.S. Patent No. 4, 333, 475 (the "Bock Patent"), and are therefore invalid. The parties dispute the proper construction of thirteen claim terms, which are described below.

a. '850 and 996 Patents

The '850 and '996 patents, both entitled "System And Method For Processing And Presenting Arrhythmia Information To Facilitate Heart Arrhythmia Identification And Treatment," disclose "systems and techniques relating to processing and presenting arrhythmia event information from physiological data." ('850 Patent at 1:18-20; '996 Patent at 1:23-25.) The patents are directed to methods and systems for effectively reporting information relating to atrial fibrillation events to medical practitioners to assist in treating heart arrhythmia. To enhance and simplify medical review by ensuring that the most relevant information is presented together, the '850 and '996 patents claim a novel way of pictographically presenting the information based on a human assessment of events.

The '850 claims at issue in this case are claims 1, 2, 5, 6, 20 and 31. The '996 claims at issue in this case are claims 1, 12, and 23. The parties present five disputed terms that the Court must construe:

³ The '996 Patent issued from a continuation of the application that led to the '850 patent. These patents share a common specification.

- 1. "pictographically presenting" (appearing in '850 claims 1, 2, 5, 6, 20 and 31; and '996 claims 1 and 12)
- 2. "heart rate trend" (appearing in '850 claims 1, 2, 5, 6, and 20, 31; and '996 claims 1, 12, and 23)
- 3. "measure of correlation" (appearing in '850 claims 1 and 20)
- 4. "selectively presenting the information" (appearing in '850 claims 1 and 20)
- 5. "subset" (appearing in '996 claims 1, 12, and 23)

b. '095 Patent

The '095 Patent, entitled "Adaptive Selection of a Warning Limit in Patient Monitoring," claims techniques for remotely monitoring a patient using a device that continuously monitors the patient. This device also generates a warning signal when the patient's physiological characteristic, such as a heart rate, exceeds the acceptable limits.

The '095 claims at issue in this case are claims 1, 9, 11, and 15. The parties present three disputed terms that the Court must construe:

- 1. "selecting a revised warning limit" (appearing in claims 1 and 11)
- 2. "physiological characteristic" (appearing in claims 1, 9, and 11)
- 3. "warning signal" (appearing in claims 1, 11 and 15)

c. **'237 Patent**

The '237 Patent, entitled "Biological Signal Management," discloses systems and techniques for analyzing and handling biological signals for medical purposes, such as a patient's cardiac signal. From a remote location, medical personnel analyze biological signals prior to handling, which reduces the volume of data requiring handling. This system both minimizes handling costs and ensures that relevant information is not lost.

The '237 claims at issue in this case are claims 1, 22, 23, 25, 26, and 37. The parties present three disputed terms that the Court must construe:

- 1. "measure of merit" (appearing in claims 1, 22, 23, 25, and 37)
- 2. "merit criterion" (appearing in claims 1, 22, 25, 26, and 37)
- 3. "discarding information" (appearing in claims 1, 22, 25, and 37)

d. '207 Patent

The '207 Patent, entitled "Cardiac Monitoring," discloses devices and techniques for monitoring cardiac activity. Specifically, the devices and techniques collect information describing variability in heart beats and determine whether that variability is indicative of an atrial fibrillation or atrial flutter (collectively "AF") event.

The '207 claims at issue in this case are claims 1 and 13. The parties present two disputed terms that the Court must construe:

- 1. "ventricular beat detector" (appearing in claim 1)
- 2. "when the absolute difference between the first time and the second time grows" (appearing in claim 13)

III. Claims Construction Analysis

The Court will now turn to the construction of each of the disputed claims.

1. Pictographically presenting

CARDIONET'S CONSTRUCTION	SCOTTCARE'S CONSTRUCTION
This term does not require construction beyond its ordinary meaning as used in	"presenting data in a graph as discrete values and not as a continuous
the patent	waveform"

The construction of this term depends upon whether the intrinsic evidence of the '850 and '996 patents requires deviation from the clear language of the asserted claims. The Court agrees

with Cardionet's assertion that the term "pictographically presenting" has a plain and ordinary meaning in the context of both patents and accordingly does not need to be construed. The plain meaning of the term is to present pictographically, that is, using pictures and/or graphs.

However, Scottcare contends that the term is limited by the patents' specification and prosecution histories and therefore must be construed within the context of these limitations. According to Scottcare, its proposed construction for "pictographically presenting" is supported by Figures 2 and 4 of the specification, which "present data in a graph as discrete values and not as a continuous waveform." Furthermore, Scottcare contends that the United States Patent and Trademark Office ("PTO") understood the '886 patent to cover the arrangement shown in Figures 2 and 4 and that during the prosecution of the '996 patent the patentee disclaimed presenting data as a continuous waveform when distinguishing its claims from prior art. The Court finds Scottcare's arguments to be unconvincing.

Firstly, Scottcare's attempt to limit the claim to disclosed embodiments in the specification is patently incorrect. To be sure, the Federal Circuit has repeatedly admonished that claims should not be limited to the disclosed embodiments, even if the specification only discloses a single embodiment. Woods v. DeAngelo Marine Exhaust, Inc., 692 F.3d 1272,1283 (Fed. Cir. 2012). While the Court acknowledges that "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply," Phillips, 415 F.3d at 1323, the specification for both patents repeatedly reference that Figures 2 and 4 are two examples of pictographically presenting, but that "to pictographically present such data, however, a graph is not required." ('850 Patent, 4:6-7; '996 Patent, 4:3-4). Additionally, the specification also notes that Figures 2

and 4 "could be modified to show continuous heart rate trend rather than specific instances of this trend." ('850 Patent, 5:58-61; '996 Patent 5:51-54.) Hence, limiting "pictographically presenting" to a graph of discrete values is also inconsistent with the claim language when read in the context of the specification.

"A patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." Purdue Pharma L.P. v. Endo Pharms. Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). "Although prosecution history can be a useful tool for interpreting claim terms, it cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter." Schwing GmbH v. Putzmeister Aktiengesellschaft, 305 F.3d 1318, 1324 (Fed. Cir. 2002). Additionally, the statements or disavowals must directly address the disputed terms. See IMS Tech., Inc. v. Haas Automation Inc., 206 F.3d 1422, 1439 (Fed. Cir. 2000). Only where these conditions are met, and where the evidence in the prosecution history does not contradict the language of the claims, is it proper for the Court to consider such evidence in determining the correct interpretation.

Here, Scottcare seeks to narrow the scope of the claims based on the prosecution histories of the '850 and '996 patents, but fails to point to a single statement that amounts to an explicit disavowal of claim scope in making any necessary amendments. Moreover, the locus of the arguments during the prosecution histories of both patents had nothing to do with the "continuous versus discrete" distinction, as suggested by Scottcare. During the prosecution history of the '850 patent, the patentee did not address the Bock Patent or Figure 7 of the Bock Patent, nor did he deliberately disavow any claim scope so as to limit "pictographically

presenting" to "discrete, non-continuous waveform." Scottcare's reliance on the PTO's remarks alone is insufficient, especially where the patentee does not respond to such remarks. (See Office Action Summary for '850 Patent dated May 11, 2006 at p. 2-3.) There was also no explicit disavowal of claim scope during the prosecution history of '996. To overcome the PTO's Bock reference, the patentees amended the claim to merely distinguish the invention from the prior art of Bock. In doing so, the patentee noted that Bock's waveform does not show a "a range of heart rates" and "heart rate average." (See Am. In Reply To Action Of December 8, 2009, at p.15.) However, this statement did not amount to a disavowal but mere distinction from prior art.

Accordingly, the Court need not construe "pictographically presenting" because the term is not affected by the specification or the prosecution history.

2. Heart Rate Trend

CARDIONET'S CONSTRUCTION	SCOTTCARE'S CONSTRUCTION
Information relating to heart rate over the defined time period.	Numerical values for an average heart rate over a period of time.
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Cardionet's proposed construction of "heart rate trend" follows the explicit language of the asserted claims:

"pictographically presenting, using a common time scale, **information regarding** heart rate data during a defined time period and regarding duration of atrial fibrillation activity, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden . . ." ('850 Patent, 6:8-14.) (emphasis added).

"based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, **information regarding the heart rate data** for the multiple time intervals **during a defined time period** in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the

defined time period such **that heart rate trend** is presented with atrial fibrillation burden " ('996 Patent, 6:7-15.) (emphasis added).

Hence, the phrase "heart rate trend" stands in place of the other phrase, "information regarding heart rate data." The invention and exemplary embodiments (Figures 2 and 4) disclosed in the specification make clear that "information regarding heart rate data" may be shown through the display of various types of data which, taken together, may constitute heart rate trend, including average heart rates, heart rate ranges, and standard deviations.

While Scottcare attempts to limit "heart rate trend" to displaying "average heart rate," and nothing else, Cardionet argues that its construction does not rigidly limit heart rate trend to just a depiction of average heart rate, but may include other types of data such as heart rate ranges and standard deviations. Scottcare contends that "heart rate trend" should be limited to "numerical values" because the disputed term is discussed only in the context of Figures 2 and 4, which present the trend as numerical values for an average heart rate over a period of time. Additionally, Scottcare reasserts that the prosecution histories of the '850 and '996 patents prevent a construction that includes presenting data as a continuous waveform.

The Court rejects Scottcare's proposed construction for two reasons. Firstly, where the express language of the specification clearly defines the claim term, the Court will not add language that may be unduly limiting and confusing to the jury. Scottcare admits that heart rate trend is not limited to average heart rate, so the Court finds no reason to limit the term to suggest otherwise. Secondly, to the extent Scottcare attempts to narrowly construe the term on the same grounds asserted in favor of its construction for "pictographically presenting," the Court rejects these arguments for the same reasons stated above. Accordingly, the Court will construe "heart rate trend" in the manner proposed by Cardionet.

3. Measure of Correlation

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
This term does not require construction beyond its ordinary	A numerical value representing a comparison between the first
meaning as used in the patent.	data set with a second data set

Cardionet contends that "measure of correlation" does not require construction because the terms "measure" and "correlation" are ordinary terms with plain meanings. While the Court does not dispute that the meaning of the two terms – "measure" and "correlation" – standing alone is clear, the same cannot be said for when the terms are combined to create the single phrase "measure of correlation." In fact, Cardionet fails to provide the Court with a clear understanding of this phrase in the context of the claim language. However, the claim language – both asserted and unasserted – makes clear that the term "measure of correlation" is a "numerical value representing a comparison between the first data set with a second data set," as proposed by Scottcare.

Where the claim language is unclear, the specification becomes the "single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315. Here, the specification of the '850 patent makes clear that the "measure of correlation" is a "numerical value" when describing how the processing system determines when to generate a report for review by a medical practitioner. For example, determining a "measure of correlation" includes "determining whether a correlation measure exceeds and/or equals a predetermined correlation parameter or whether a correlation measure is less than and/or equals that parameter." ('850 Patent at 3:36-39.) The specification further states that a graph is generated when "if more than 50% of the ten minute flags (generated at 302) match events identified by a CVT (at 303) – a correlation (with respect

to the time period at issue) indicating a high positive predictivity for the identification of AF events. If this 50% threshold is not met, then the system does not generate a graph." <u>Id.</u> at 3:53-58. Additionally, while asserted claims 1 and 20 do not impose the limitation of requiring "numerical values," unasserted claims 10, 22, 35, 39, 41, and 43⁴ all recite "if the measure of correlation matches or exceeds at least one predetermined value." (<u>Id.</u> at 6:49-12:48.)

Accordingly, the Court adopts Scottcare's position that "[i]f 'measure of correlation' was not a numerical value, it could not 'match or exceed' a predetermined value." (Def.'s Claim Construction Br. 12.)

The Court also finds that the asserted claim language supports Scottcare's proposed construction. Asserted claims 1 and 20 read, in pertinent part, as follows:

"wherein presenting information comprises selectively presenting the information based on a **measure of correlation** between the **identified atrial fibrillation events** and **human-assessments of at least a portion of the identified atrial fibrillation events.**" ('850 Patent, claim 1 at 6:15-19.) (emphasis added)

"wherein presenting information comprises selectively presenting the information based on a **measure of correlation** between the **identified atrial fibrillation events** and **human-assessments of at least a portion of the identified atrial fibrillation events.**" ('850 Patent, claim 20 at 7:56-59.) (emphasis added)

This language makes clear that the "measure of correlation" is between two sets of data – (1) "identified atrial fibrillation events;" and (2) "a human assessment of at least a portion of the identified atrial fibrillation events." Cardionet's assertion that "the measure of correlation is not between two data sets, but rather between a set of 'events' and 'human assessments'" is unavailing. (Pl.'s Claim Construction Br. 15.) Cardionet may label these two data sets in whatever manner it chooses to, but the fact remains that the claim

⁴ These claims are also independent claims.

language clearly refers to the "measure of correlation" involving a first and second set of information. This is further supported by the specification. (See '850 Patent, claim 20 at 4:46-52) ("[T]he CVT analyzes this data and reports whether arrhythmia events have occurred, thereby generating a second group of data. The processing system then determines (at 602), based on comparing time stamps associated with each group of data, at least one measure of correlation between the first group of data and the second group of data."). Heavily relying on the written description and claim language, the Court finds that "measure of correlation" is a numerical value representing a comparison between the first data set with a second data set.

4. Selectively Presenting the Information

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
This term does not require construction beyond its ordinary	A processing system determining whether to present information or
meaning as used in the patent.	not present information based on a numerical value

Cardionet does not advance a construction of the term "selectively presenting the information," other than to say that it should be given its ordinary meaning. On the other hand, Scottcare construes "selectively presenting the information" as "a processing system determining whether to present information or not present information based on a numerical value." Scottcare's proposed construction imports three separate limitations into the claim: (1) requiring that the selection be done by a "processing system;" (2) requiring that "selectively presenting" be limited to a single selection – whether or not to present; and (3) requiring that the selection be based on a "numerical value." The Court will assess each limitation.

First, the intrinsic record does not support requiring that the information be selectively presented by "a processing system." Unquestionably, the preamble of claims 1 and 20 refer to a "a machine-implemented method." (See '850 Patent, 6:4; 7:40-45.) While the Court does not reject Scottcare's position that the respective preambles implicate a method implemented by a machine or machine-readable product, construction of the disputed term turns on whether this limitation in the preamble applies to every aspect of the claim method, including the step of "selectively presenting the information." See Uship Intellectual Props., LLC v. United States, 714 F.3d 1311, 1314-1315 (Fed. Cir. May 8, 2013) (concluding that a limitation in the preamble does not raise a presumption that every step of the claimed method must be restricted to that limitation). In looking to the intrinsic record for guidance, the Court finds no justification for requiring that "selectively presenting the information" be done by a machine. Although the disclosed embodiments are described and illustrated as using a processing system, the specification clearly states, "other embodiments are within the scope of the following claims." ('850 Patent, 5:51-52.) As such, the Court will not read limitations from the specification into the claims. ⁵

Next, the plain and ordinary meaning of the term "selectively presenting the information" is essentially "whether to present information or not present information." Cardionet's contention that the term is not limited to whether or not to present information, but also encompasses *what* information is presented, as well as *how* the information is presented is too

⁵ Defense counsel argues that permitting the selection to be done by a human being makes it too similar to prior art and thereby eliminates the novelty of the device (Tr. of Markman Hr'g, May 1, 2013, at 113:4-8). However, the claimed novelty is not that the patented invention uses a machine to present information to medical practitioners, but that the methods and systems by which such information is monitored and reviewed is more accurate and efficient.

broad. When read in the context of the intrinsic record, the term clearly refers to the determination of whether information will be generated for review by a medical practitioner.

Lastly, "selectively presenting the information" is necessarily "based on a numerical value" given the Court's construction of "measure of correlation." Hence, the Court will adopt the latter language of Scottcare's proposed construction. As such, "selectively presenting the information" will be construed as "determining whether to present information or not present information based on a numerical value."

5. Subset

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
A set consisting of elements of a	A set that is less than all the
given set that can be the same as	elements of a given set.
the given set or smaller	

The point of dispute between Cardionet and Scottcare is whether a "subset" of a set can contain all of the members of that set (as Cardionet contends) or whether a subset must contain fewer than all of the members of the set of which it is a subset (as Scottcare contends). Neither party suggests that the disputed term has a "plain and ordinary meaning." Moreover, the meaning of the term is not clear from a plain reading of the claim. Therefore, the Court turns to remaining intrinsic evidence, and even some extrinsic evidence, to aid in the construction of the term.

Cardionet contends that the intrinsic record supports its proposed construction of "subset," arguing that nothing in the written description states that all data cannot be reported to the technician. According to Cardionet, asserted claims 1, 12, and 23 minimizes the data received by the CVT by sending a "subset of the identified atrial fibrillation events." ('996

Patent, 6:7-8.) However, while the subset does not have to include the physiological data for each identified event, the subset must report data associated with the most significant events identified. (See '996 Patent, 4:37-41.) To the contrary, Scottcare contends that Cardionet's proposed construction is inconsistent with the specification when read in the context of the claimed invention. According to Scottcare, permitting the CVT to review all the data, rather than a subset of the data, directly contradicts the claimed novelty of "achiev[ing] increased accuracy in the presentation of information relating to the arrhythmia information while minimizing the data that the CVT reviews." ('996 Patent, 4:56-59.) The Court agrees with Scottcare.

A clear reading of the specification, in the context of the invention, indicates that "subset" is a set that is less than all the elements of a given set. While the Court takes note of the disputed term's construction in the scientific and mathematical world — as including proper and improper subset — such a construction is not the plain and ordinary meaning to a person in the art of the '996 patent or a layperson. More importantly, Cardionet's proposed construction of "subset" contradicts the intrinsic record when understanding the claim in the context of the claimed invention. During the Markman Hearing, Cardionet's counsel repeatedly referred to the '850 and '996 patents involving a method of efficiency, whereby time and resources would be saved. Yet, the proposed construction offered by Cardionet essentially abandons this concept of efficiency and suggests that every step of the "monitor and review" stage involves all data.

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⁶ Cardionet does not suggest that its proposed construction is the plain meaning to an ordinary person skilled in the art of the patent-in-issue. Instead, Cardionet offers expert testimony regarding the mathematical use of the term. Because the Court does not find the need to rely on extrinsic evidence given the intrinsic record, the Court will not consider this evidence.

⁷ The Court's construction does not limit the technician from requesting additional data, outside of the data sent for review, as stated in the specification. (See '996 Patent, 3:25-31.)

Additionally, federal circuit precedence makes clear that where the patentee intends to deviate from the ordinary and accustomed meaning of a claim term, such intent must be clear.

See e.g., SuperGuide Corp. v. DirectTV Enters., 358 F.3d 870, 874-75 (Fed. Cir. 2004) (noting that there is a "heavy presumption that terms used in claims mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.")

The manner in which Cardionet seeks to construe "subset" deviates from the plain meaning of the term and there is nothing in the intrinsic record that clearly supports this construction.

Accordingly, the Court adopts Scottcare's construction, as it defines the term as "a set that is less than all the elements of a given set."

6. Selecting a Revised Warning Limit

CARDIONET'S CONSTRUCTION	SCOTTCARE'S CONSTRUCTION
This term does not require	Initially selecting a revised
construction beyond its ordinary	warning limit without human
meaning as used in the patent	input.

While it is a district court's duty to construe disputed claims, part of this duty is to determine the extent to which construction is even necessary. Here, there is no need to construe the self-explanatory phrase "selecting a revised warning limit." Although Scottcare offers a proposed construction, it fails for several reasons. First, the intrinsic record makes clear that "selecting" can be performed in a number ways, including by a human. (See '095 Patent at 2:7-9) ("The present approach is fully compatible with adjustments to warning limits made by medical personnel.")

Next, Scottcare's proposed construction runs afoul of Federal Circuit precedent regarding claim differentiation. "Under the doctrine of claim differentiation, dependent claims are

presumed to be of narrower scope than the independent claims from which they depend." <u>AK</u>

<u>Steel Corp. v. Sollac & Ugine</u>, 344 F.3d 1234, 1242 (Fed. Cir. 2003). Claim 1 of the '095 patent states the following:

1. A method of monitoring a patient, comprising the steps establishing a current warning limit for a physiological characteristic of the patient; providing a sensor for the physiological characteristic; measuring a measured value of the physiological characteristic of the patient using the sensor; comparing the measured value and the current warning limit, and generating a warning signal responsive to the step of comparing; and selecting a revised warning limit responsive to at least one of the three steps of providing and measuring.

('095 Patent, 6:55-66.) (emphasis added). Claim 10, a dependent claim, narrows claim 1 to exclude human intervention by stating, "The method of claim 1, wherein the step of **selecting is performed without human intervention**." ('095 Patent, 7:33-34.) (emphasis added). Hence, the express language of claim 10 makes clear that the step of "selecting a revised warning limit" as described in claim 1 is so broad as to include human intervention.

Lastly, adding the term "initially" to "selecting a revised warning limit" also runs afoul of claim differentiation. Scottcare contends that, based on the specification, the warning limit is initially made without human intervention and then a human may subsequently review the revised warning limit to be certain that it is realistic. (See Tr. of Markman Hr'g, May 1, 2013, at 148:4-7) (see also '095 patent at 2:1-14.) However, the Court will not read limitations from the specification in the claim when the express claim language clearly states otherwise. Claim 2, a claim dependent upon claim 1, states, "[t]he method of claim 1, including an additional step, after the step of selecting, of a human being reviewing a revised limit." Hence, claim 2 includes an additional limitation that is not present in claim 1 – that is, a human reviewing the revising

warning limit after it has been selected to ensure accuracy. However, Scottcare's proposed construction of claim 1 attempts to restrict the claimed method as described in claim 2. As already stated, this type of claim construction is inconsistent with the canons of claim differentiation and is therefore rejected.

Finding no reason to deviate from the plain and ordinary meaning of "selecting a revised warning limit," the Court will not construe this term.

7. Physiological Characteristic

CARDIONET'S CONSTRUCTION	SCOTTCARE'S CONSTRUCTION
A physiological state measurable using a sensor, such as heartbeat rate, respiration rate, blood pressure, and the like	Plain and ordinary meaning (of or relating to human physiology)

While "physiological characteristic" may have a plain and ordinary meaning – that being, of or relating to human physiology or a physiological state, Cardionet's proposed construction describes the scope of the term within the context of the actual invention. According to Cardionet, construing "physiological characteristic" in the manner it is used within the intrinsic record is necessary where there is a potential ambiguity in the claim language. The relevant portions of claims 1, 9, and 11 are: "providing a sensor for the physiological characteristic" and "measuring a measured value of the physiological characteristic of the patient using the sensor." ('095 Patent, 6:60-63). Cardionet suggests that, based on this language, jurors may be confused about what is actually being measured – the physiological characteristic itself or the measured value in the measuring step of the claim. Hence, its proposed construction seeks to clarify this ambiguity by extracting language directly from the claim language and specification to provide

jurors with concrete examples of "physiological characteristics" within the context of the invention.

Scottcare does not refute that Cardionet's proposed construction comes directly from the intrinsic record, but simply argues that any confusion or potential ambiguities can be resolved during the patent tutorial or general discussion of the technology. The Court finds such resolution to be insufficient. Where there is a potential ambiguity regarding the context in which a term is used, the Court has a duty to resolve such an issue rather than leave it for the jury to decide. Moreover, even where a term may have a plain and ordinary meaning, such meaning must also involve the scope of the term when used in the context of surrounding words in the claim. See ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003) ("While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered in determining the ordinary and plain meaning of the terms."). Hence, the potential ambiguity regarding "physiological characteristic" and "measuring a measured valued" must be resolved; and because Cardionet's construction is consistent with the intrinsic record and more helpful to the jury, the Court will adopt it.

8. Warning Signal

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
A signal that alerts a user, such as a patient, or a person at the central unit	Plain and ordinary meaning – a signal that warns.

The Court will forgo construing "warning signal" and apply its plain and ordinary meaning – that is, a signal that warns or alerts. Although Cardionet's proposed construction is consistent with the intrinsic record, Cardionet does not offer any reason why the plain meaning

needs to be clarified, so as to explain who the signal alerts. Although the Court permitted Cardionet to further clarify "physiological characteristic," despite its plain and ordinary meaning, that determination was based on the potential ambiguity regarding the context of the term given the surrounding claim language. Here, no such issue exists and therefore the Court will refrain from offering a construction beyond its plain meaning.

9. Measure of Merit

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
Valuation applied to a particular purpose	A value associated with a cardiac event, where such value is determined from the severity of the cardiac event and the noise of the signal that includes the cardiac event

When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls. See Phillips, 415 F.3d at 1321 (Fed. Cir. 2005) ("[T]he specification 'acts as a dictionary when it expressly defines terms used in the claims") (quoting Vitronics Corp., 90 F.3d at 1582). Here, the patentee explicitly defined "measure of merit" as a "valuation of an event when applied to a particular purpose." ('237 Patent, 8:44-46.) Scottcare contends that this definition should not be controlling because it lacks clarity. The Court disagrees. When reading the patentee's definition in the context of the patent and, more importantly, with the surrounding claim language, the Court finds that the definition provides the required clarity, deliberateness, and precision needed for claim terms. See In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir.1994) ("Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision."). Scottcare's construction, on the other hand, attempts to import the limitations of the disclosed embodiments

into the claim language, which the Court has countlessly rejected. Thus, finding that the patentee clearly defines "measure of merit" in the specification, the Court will construe the disputed term pursuant to Cardionet's definition.

10. Merit Criterion

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
Criteria for determining whether information describing an event may be transmitted	A threshold for a category that determines whether an event can be classified as in the category.

The construction of "merit criterion" turns on whether the term refers to classifying information into a category (as proposed by Scottcare) or transmitting information into a category (as proposed by Cardionet). The Court turns to the intrinsic record to determine the meaning of the disputed claim within the context of the invention.

The '237 patent is generally directed to methods of filtering information into different groups based on identifying characteristics and transmitting a portion of this information to the cardiac monitoring center for review by a medical practitioner. Claim 1 provides an example of how "merit criterion" is used in the context of the classification and transmission method steps:

at the electrocardiographic monitoring instrumentation, classifying the events into two or more categories based on cardiac conditions indicated by the information describing each event;

at the electrocardiographic monitoring instrumentation, determining a measure of merit of the information describing each event, wherein the measure of merit embodies a severity of the cardiac condition associated with the event and an amount of noise in the information describing the event;

comparing, at the electrocardiopgrahic monitoring instrumentation, the measure of merit of information describing each event with a first merit criterion;

transmitting, for medical purposes, information describing a first proper subset of the events **in a first of the categories that have merits meeting the first merit criterion** from the electrocardiographic monitoring instrumentation to a remote medical receiver, wherein the remote medical receiver is not located at the same site at the electrocardiographic monitoring instrumentation;

at the electrocardiographic monitoring instrumentation, discarding information describing a second proper subset of the events in the first of the categories that have measures of merit that fail to meet the first merit criterion

('237 Patent, 15:21-45) (emphasis added). This three-step cycle of comparing, transmitting, and discarding is repeated a second time; thereby increasing the average relevance of data. (<u>Id.</u> at 15:46-62). In lay terms, the process can be summarized as follows:

Method	Description	
Step		
1.	Events are identified and then classified based on identifying characteristics as described in Table 1 of the specification. These identifying characteristics can be used to identify the specific cardiac event, i.e. tachycardia, bradycardia, atrial fibrillation, etc.	
2.	The device performing process determines a measure of merit of the identified events – also known as a valuation of an event when applied to a particular purpose.	
3.	Each classified event's measure of merit is compared with a first merit criterion to determine if the event is meritorious or, otherwise, good data.	
4.	Based on method step 3, if the classified event is meritorious, it is moved from the "first of the categories" into a first proper subset and be transmitted to a remote medical received. However, if the classified event is not meritorious, it is moved from the "first of the categories" into a second proper subset	
	and be discarded.	

A clear understanding of the claimed method indicates that information is classified into groups based on certain attributes that relate to specific cardiac conditions; given a diagnostic value (measure of merit); and then transmitted or discarded based on a comparison between the diagnostic value and merit criterion. Hence, the method step of categorizing information is based on cardiac condition, and the method step of transmitting (or discarding) information is

based on a "merit criterion." The claim expressly states that the classified events (based on cardiac condition) are "in the first of the categories" regardless of whether these events meet the "merit criterion." (See id., 15:31-45.) However, the identified (and already categorized) event is transmitted to the remote medical receiver from the device if it meets the merit criterion. Based on the plain language of the claim and specification, it is clear that "merit criterion" does not refer to categorizing or classifying information into the groups, but refers to transmitting or discarding information based on its relevancy. As Cardionet suggests, Scottcare's proposed construction of the term, as well as its explanation of the invention, conflates two method steps (classifying and transmitting) into one. This reading of the term is inconsistent with the intrinsic record and is therefore rejected.

Accordingly, the Court will construe merit criterion as criteria for determining whether information describing an event may be transmitted. This construction is supported by the claim language and specification.

11. Discarding Information

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
Not transmitting information from	Plain and ordinary meaning –
the electrocardiographic	deleting information
monitoring instrumentation to the	
remote medical receiver	

The point of dispute between the parties is whether "discarding information" is broadly defined as "not transmitting" (as proposed by Cardionet) or more narrowly defined as simply "deleting" (as proposed by Scottcare). For the Court to properly construe the disputed term, the claim must not be read in a vacuum, but in the context of the entire patent, including the specification and prosecution history. See Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather,

we must look . . . in the context of the written description and the prosecution history.") (quoting DeMarini Sports, Inc. v. Worth, 239 F.3d 1314, 1324 (Fed. Cir. 2001). Interestingly, both parties suggest that "discarding information" has a plain meaning. However, the meaning of "discarding information" when read in the context of the claimed invention is not clear. Cardionet contends that the patentee understood "discarding information" to mean not transmitting information from the monitoring device to the remote monitoring center. According to Cardionet, this construction is supported by the patent's primary objective and prosecution history. With respect to the patent's primary objective, Cardionet states the following:

The specification makes clear that one purpose of the invention is to minimize data handling costs, which includes the amount of information for medical review, while minimizing the possibility that important information is lost. For example, the specification explains that events may be associated with time spans by creating a data structure (i.e. storing in memory) The merit of that event may then be compared with the merit of other events in the same category to determine which events get transmitted. Thus, in this embodiment, all events are stored, but not all events are transmitted. The very next paragraph explains the advantages of such a system and technique, including that "the volume of data often should be reduced to minimize data handling costs. At the same, relevant information should not be lost."

(See Pl.'s Claim Construction Br. 27.)

Scottcare, on the other hand, contends that the plain meaning of "discard" is to delete, and that the intrinsic record supports such construction based on the patentee's failure to explicitly define the term beyond its customary use. In looking to the specification, Scottcare contends that the patentee's failure to expressly define "discarding" as "not transmitting" indicates that such a construction was not contemplated. Scottcare also contends that Figure 11

⁸ Cardionet implies that "discarding information" has a plain meaning when stating, ""[a]lthough 'discarding' is a seemingly common word, in this particular instance, a construction is necessary because the specification does not use the term 'discarding' in necessarily the same manner that a layperson might use that term in everyday speech." (Pl.'s Claim Construction Br. 26)

supports its construction of "discarding information, suggesting that even if it is unclear whether the discarded information is stored on the device the mere fact that such information may never be retrieved or becomes difficult to retrieve equates to the information being deleted. (See Tr. of Markman Hr'g, May 1, 2013, at 30:2-8,18-20.) The Court is not persuaded by Scottcare's arguments for the following reasons.

Certainly, the Court does not have to apply the patentee's special definition to a term where such definition does not appear with "reasonable clarity, deliberateness, and precision."

See In re Paulsen, 30 F.3d at 1480. However, even where the patentee does not explicitly define the claim term, thereby requiring that the term be given its plain and ordinary meaning; the Court still has a duty to apply the plain meaning within the context of the claim invention, rather than in a vacuum. As such, the mere fact that the specification does not expressly define "discarding information" as "not transmitting information" is not dispositive. The more important question is whether the proposed construction is consistent when read in the context of the entire patent. Scottcare does not suggest that the specification explicitly defines the disputed term as deleting information, but contends that the relative difficulty in retrieving discarded information from the device makes it clear that the only reasonable meaning of the term is that the information is deleted. The Court disagrees. To define discarding information as deleted information even where such information may be later retrieved is misleading and confusing. Moreover, the Court will not unduly limit a claim term by adding language not supported by the specification. As

such, the Court rejects Scottcare's limiting construction and will apply the construction Cardionet offers. ⁹

12. Ventricular Beat Detector

PLAINTIFF'S CONSTRUCTION	DEFENDANT'S CONSTRUCTION
Hardware and/or software running on a processor that identifies ventricular beats	Hardware and/or software running on a processor that identifies ventricular beats and distinguishes such beats from other irregular beats and from regular beats

The parties agree that ventricular beat detector includes at least "hardware and/or software running on a processor that identifies ventricular beats." Thus, the only dispute between the parties is whether Scottcare's addition of the limitation "and distinguishes such beats from other irregular beats and from regular beats" is proper. Because the parties already provide a joint construction for "ventricular beat," Scottcare's additional language is unduly redundant and potentially confusing. Accordingly, "ventricular beat detector" is defined as hardware and/or software running on a processor that identifies ventricular beats.

⁹ Cardionet and Scottcare also suggest that the prosecution history of the '237 patent support its respective constructions. However, the Court is not entirely persuaded by either party's argument. Moreover, the prosecution history of the '237 patent has no bearing on the construction of "discarding information," as the patentee's remarks in no way address the interpretation of "discarding information" in the context of the '237 patent. Instead, the patentee's remarks address the '237 patent's method of classifying and then transmitting or discarding information based on cardiac conditions, thereby distinguishing it from the prior art of the Nau patent. (See Am. In Reply To

based on cardiac conditions, thereby distinguishing it from the prior art of the Nau patent. (See Am. In Reply To Action of March 19, 2007, at pp.11-12.) Although the patentee references the term "discarded" and even discusses how information is "discarded" with respect to the Nau patent, the patentee is silent as to what he understands the term "discarded" to mean with respect to the '237 Patent.

¹⁰ The parties jointly construe ventricular beat as "premature, irregular ventricular beats that interrupt the normal heart rhythm." (See Joint Claim Construction Chart, at p. 17.)

13. When the absolute difference between the first time and the second time grows

DEFENDANT'S CONSTRUCTION
This term cannot be construed, because the term is indefinite and
therefore fails to comply with 35
U.S.C. § 112 ¶2
1

Cardionet and Scottcare dispute whether the term "when the absolute difference between the first time and second time grows" has a plain and ordinary meaning to a person skilled in the art of the '207 Patent. While the Court acknowledges that the language is somewhat confusing when read alone; a person of ordinary skill in the relevant art would reasonably understand the phrase when read in the context of the entire intrinsic record. This claim term is construed in the context of claim 13, which reads as follows:

13. A method comprising:

receiving information describing a timing of heart beats of an individual; determining a first time between a first heart beat and a second heart beat of the individual, wherein the second heart beat follows immediately after the first heart beat;

determining a second time between the second heart beat and a third heart beat of the individual, wherein the third heart beat follows immediately after the second heart beat;

determining a factor reflecting the difference between the first time and the second time, wherein the factor is lowest when the first time is close to the second time, and

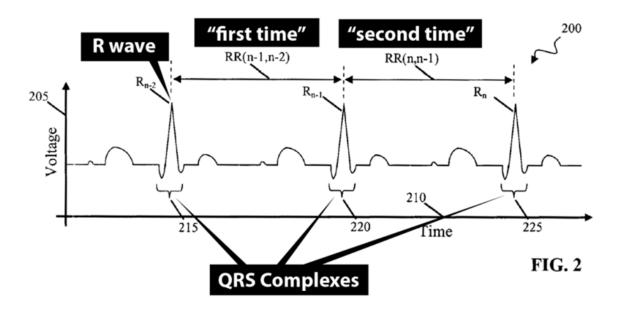
the factor increases non-linearly when the absolute difference between the first time and the second time grows; and

identifying at least one of an atrial fibrillation event and an atrial flutter event of the individual based on the factor.

('207 Patent at 13:14-31) (emphasis added).

As shown below, Figure 2 of the '207 patent demonstrates how to determine the absolute difference between the first time and second time. An ECG signal shows three consecutive heart beats, i.e. QRS Complexes. The "first time" and "second time" are determined by measuring the

time between the "R wave" of each beat, referred to as the "R to R interval." The "first time" and the "second time" correspond to the R to R intervals labeled as "RR(n-1, n-2)" and "RR(n, n-1)." That is, the measure between the patient's first and second heart beat is the "first time," and the measure between the patient's second and third heart beat is the "second time."



Once the "first time" and "second time" are determined, claim 13 indicates that a "factor" may be calculated based on how close or distant these two measures are. For instance, if the "first time" and "second time" are close, meaning the measurement between the consecutive heart beats are rhythmic and regular, then the absolute difference between them would be small and, consequently, the "factor" would have a low value. Conversely, if the "first time" and the "second time" are further apart, meaning the measurement between the consecutive heart beats are no longer rhythmic but irregular, then the absolute difference between them would be larger and, therefore, the factor would increase.

Cardionet contends, and this Court agrees, that claim 13 involves a functional or mathematical relationship between variables "first time," otherwise referred to as "A," and "second time," otherwise referred to as "B," which are related to the factor. ¹¹ That is, A and B are not single numerical values, as suggested by Cardionet, but changeable numerical values which reflect the progression of the individual's heart beat. Hence, as the absolute difference between A and B is small, the factor is also small; and as the absolute difference between A and B grows, the factor also grows nonlinearly. By performing the method steps of claim 13, many factors may be calculated to determine non-linear behavior. A plain reading of the disputed term, in the context of the entire claim, describes this relationship between the absolute difference and the factor.

Scottcare argues that the term, "when the absolute difference between the first time and second time grows," cannot be construed because it is indefinite and therefore fails to comply with 35 U.S.C. § 112. 12 According to Scottcare, claim 13 defines "first time" and "second time" as a single numerical value. Scottcare then concludes that an absolute difference between a first time (i.e., a first numerical value) and a second time (i.e., a second numerical value) is a single positive value, which cannot grow. (See Def.'s Claim Construction Br. 24.) However, Scottcare's interpretation is unavailing.

Cardionet uses the mathematical equation $x = y^2$ to describe the relationship between the absolute difference and the factor. (See Pl.'s Resp. Br. 21.)

^{12 35} U.S.C. § 112(a) requires that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." Subsection b of the statute further requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."

Construing "first time" and "second time" as single numerical values, rather than variables, renders claim 13 (the independent claim) narrower than claim 17 (the dependent claim), which repeats the step of determining the absolute difference between a first time and a second time to calculate multiple factors. Such an outcome runs afoul the principles of claim differentiation. Because claim 17 is dependent upon claim 13, claim 13 encompasses claim 17 and can therefore cover multiple calculations of first and second time pairs. Additionally, although the Court's decision does not weigh heavily on parties' expert testimony, it is worth noting that Scottcare's expert testified that it is possible for "first time" and "second time" to be variables, rather than single numerical values. Hence, the fact that Scottcare, or its expert, merely disagrees with the interpretation proposed by Cardionet does not render a term insolubly ambiguous. Indefiniteness must be proven by clear and convincing evidence, and the Court does not find that such legal standard has been met. Thus, the Court agrees with Cardionet that the term does not require construction beyond its ordinary meaning as used in the patent.

IV. Conclusion

Based on the foregoing reasons, the Court will construe the disputed terms as follows:

- 1. **pictographically presenting** need not be construed beyond its plain and ordinary meaning;
- 2. **heart rate trend** means information relating to heart rate over the defined time period;
- 3. **measure of correlation** means a numerical value representing a comparison between the first data set with a second data set;
- 4. **selectively presenting the information** means determining whether to present information or not present information based on a numerical value;
- 5. **subset** means a set that is less than all the elements of a given set;

- 6. **selecting a revised warning limit** need not be construed beyond its plain and ordinary meaning;
- 7. **physiological characteristic** means a physiological state measurable using a sensor, such as heartbeat rate, respiration rate, blood pressure, and the like;
- 8. warning signal need not be construed beyond its plain and ordinary meaning;
- 9. **measure of merit** means valuation applied to a particular purpose;
- 10. **merit criterion** means criteria for determining whether information describing an event may be transmitted;
- 11. **discarding information** means not transmitting information from the electrocardiographic monitoring instrumentation to the remote medical receiver;
- 12. **ventricular beat detector** means hardware and/or software running on a processor that identifies ventricular beats; and
- 13. when the absolute difference between the first time and second time grows need not be construed beyond its plain and ordinary meaning.

An appropriate Order follows.