### United States District Court District of Massachusetts

KONINKLIJKE PHILIPS ELECTRONICS )	
N.V., PHILIPS ELECTRONICS NORTH )	
AMERICA CORPORATION, )	
Plaintiffs, )	
)	
)	
v. )	Civil No.
)	10-11041-NMG
ZOLL MEDICAL CORPORATION )	
Defendant, )	
)	

#### MEMORANDUM & ORDER

GORTON, J.

#### I. Background

#### A. The Parties

On June 18, 2010, Philips Electronics North America

Corporation, a Delaware corporation with its principal place of business in Massachusetts, and its parent company Koninklijke

Philips Electronics N.V., a Dutch corporation with its principal place of business in the Netherlands, (collectively, "Philips")

filed a patent infringement suit against ZOLL Medical Corporation ("ZOLL"), a Massachusetts corporation with its principal place of business in Massachusetts.

Philips' complaint, in 15 counts, is for infringement of U.S. Patent No. 5,607,454, No. 5,721,482, No. 5,735,879, No. 5,749,905, No. 5,773,961, No. 5,800,460, No. 5,803,927, No. 5,836,978, No. 5,879,374, No. 6,047,212, No. 6,178,357, No.

6,304,783, No. 6,356,785, No. 6,441,582 and No. 6,871,093, which relate to components of automated external defibrillators ("AEDs"). Philips seeks a declaration that ZOLL is infringing the patents-in-suit, equitable relief, including an injunction, and monetary damages.

In a related, later-filed case, ZOLL brought suit against Philips for five counts of patent infringement of U.S. Patent No. 5,330,526, No. 5,391,187, No. 5,470,343, No. 5,575,807 and No. RE39,250, which also relate to components of defibrillators and supplemental products, including electrodes and power supplies. ZOLL seeks a declaration that Philips is infringing the ZOLL patents-in-suit, equitable relief, including an injunction, and damages. In August, 2011 the two cases were consolidated.

The parties submitted 35 claims for construction. The Court issued an order requesting that the parties narrow the claims for construction to 16. The Court conducted a Markman hearing on October 25, 2012 at which counsel offered arguments in support of their proposed claim construction of 15 disputed terms. The following is the Court's ruling with respect to those terms.

#### B. The Technology

1. Philips' '454, '879, '905, and '978 Patents
Six of Philip's patents ('454, '879, '905, '978, '212 and '927) are referred to as the "waveform patents" because they

 $<sup>^{\</sup>mathrm{I}}$  Hereinafter each patent will be referred to by its last three numbers.

relate to the electrical signal (or "waveform") that shocks the patient.

External defibrillators deliver energy to a patient's heart via electrodes applied to the surface of the patient's torso. Due to physiological differences among patients, the resistance to the flow of electricity through the tissue between the defibrillator electrodes and the patient's heart ("impedance") varies from patient to patient depending on the conductivity of their tissues. The intensity of the shock delivered to the heart by the defibrillator can also vary depending on that impedance. A shock that is effective to treat a low-impedance patient may not be effective to treat a high-impedance patient.

Prior art defibrillators required the operator to shock the patient first with an energy level appropriate for the average patient. If the first shock did not work, the operator could then raise the energy level and keep trying. The '454, '879, '905 and '978 patents overcome that problem by providing an external defibrillator that automatically compensates for the different levels of impedance in individual patients in real time by measuring the patient's impedence and adjusting the discharge accordingly.

#### 2. Philips' '212 Patent

The particular waveform described in the waveform patents above is "biphasic." With a biphasic waveform, the system flips

a switch midway to change from positive voltage to negative. Biphasic waveforms had been used in implanted defibrillators but until this patent there was no circuitry that could generate the biphasic waveform at the higher voltages required by external defibrillators. The '212 patent discloses a circuit that can deliver the biphasic waveform at the higher voltages required by an external defibrillator.

### 3. Philips' '374 and '460 Patents

The '374 and '460 patents ("the self test patents") cover an external defibrillator that can perform self tests to ensure it is functional and ready to use. Prior art external defibrillators were generally designed for hospitals where equipment is frequently tested and maintained. Portable defibrillators designed for a home or office are much less frequently tested and thus might not be functional when needed. The '374 and '460 patents disclose a defibrillator that conducts automatic self tests, some while switched "on" and others while switched "off." After the test, the defibrillator indicates the result "visually and audibly." The patents also describe a "system monitor" that performs the various functions of the self tests.

#### 4. Philips' '093 Patent

The '093 patent is directed to a defibrillator that includes an indicator (audible, visual or both) that reports whether the

defibrillator is functioning properly. The indicator can be activated automatically or in response to a "user-triggered inquiry."

#### 5. Philips' '785 Patent

The '785 patent is directed to a defibrillator that uses voice and visual prompts to instruct the user on how to perform CPR correctly because the steps of CPR are often forgotten, even by trained professionals. The covered defibrillator also monitors the heart rhythm of the patient to determine whether it is treatable by shock and, if so, prompts the rescuer to deliver CPR and follow the shock protocol.

#### 6. ZOLL's '187 Patent

The '187 patent is directed to a semi-automatic defibrillator which has an alarm. In previous defibrillators the alarm was activated by either the heart rate ("averaged QRS rate") or a shock advisory to indicate to the operator whether the electrocardiogram shows an abnormal heart rhythm of the sort that can be corrected by defibrillation shock. The '187 patent is directed to an alarm based on both of these inputs.

#### 7. ZOLL's '807 Patent

The '807 patent relates to a power supply that provides an "AC disconnect alarm." Because a defibrillator is used in emergency situations it is crucial that it is charged when needed. Thus, as the patent explains, "to ensure[] that a

battery of the defibrillator will not inadvertently be left uncharged" the power supply "produces an alarm when it is not connected to a source of AC power." Because this alarm would be distracting during actual emergencies, the alarm signal is only produced when the defibrillator is switched off.

#### 8. ZOLL's '250 Patent

The '250 patent is related to ZOLL's '526 patent and is directed to an "electrode package." Inside the package is a "conductor" that is

covered with a water based, conductive adhesive gel that contacts a patient's skin and electrically connects the electrode to the patient.

The package is an "envelope" formed from a sheet of material folded in half that opens like a book. It provides quick and easy access to the electrodes but also protects them when it is closed.

#### 9. ZOLL's '526 Patent

The '526 patent is related to the '250 patent and also concerns defibrillation electrodes. These electrodes are gel-covered discs that are placed on the patient's chest. This patent covers a gel arrangement with an electrical resistance that allows for effective shock treatment while also making it less likely that the patient will be burned.

#### III. Analysis

#### A. Principles of Claim Construction

In analyzing a patent infringement action, a Court must

1) determine the meaning and scope of the patent claims asserted
to be infringed and 2) compare the properly construed claims to
the infringing device. Markman v. Westview Instruments, Inc., 52

F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370

(1996). The first step, known as claim construction, is an issue
of law for the court to decide. Id. at 979. The second step is
determined by the finder of fact. Id.

The Court's responsibility in construing claims is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atl.

Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001). The meaning of the terms are initially discerned from three sources of intrinsic evidence: 1) the claims themselves, 2) the specification and 3) the prosecution history of the patent. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996).

The claims themselves define the scope of the patented invention. See Philips, 415 F.3d at 1312. Claim terms are generally given their "ordinary and customary meaning", which is the meaning that a person skilled in the art would attribute to the claim term. See id. at 1312-13. Even if a particular term

has an ordinary and customary meaning, however, a court may need to examine the patent as a whole to determine if that meaning controls. Id. at 1313 ("[A] person of ordinary skill in the art is deemed to read the claim term ... in the context of the entire patent..."); see also Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) (noting that a court cannot construe the ordinary meaning of a term "in a vacuum"). Ultimately, the correct construction will be one that "stays true to the claim language and most naturally aligns with the patent's description of the invention ...." Id. at 1316 (citation omitted).

The patent specification is

the single best guide to the meaning of a disputed term [because it may reveal] a special definition given to a claim term that differs from the meaning it would otherwise possess [or contain] an intentional disclaimer, or disavowal, of claim scope by the inventor.

Phillips v. AWK Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The Court should also consult the prosecution history to see how the inventor and PTO understood the patent and to ensure the patentee does not argue in favor of an interpretation it has disclaimed. Id. at 1317.

In the rare event that analysis of the intrinsic evidence does not resolve an ambiguity in a disputed claim term, the Court may turn to extrinsic evidence, such as inventor and expert testimony, treatises and technical writings. <u>Id.</u> at 1314.

Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence is afforded the greatest weight in determining what a person of ordinary skill would have understood a claim to mean. Id. at 1324.

#### B. Disputed Terms

1. Monitoring/monitoring. . .during (Philips' '454, '879, '905, '978 Patents)

The dispute centers on whether monitoring must occur continuously throughout the discharge step, as ZOLL contends, or only one or more times during the discharge step, as Philips' contends.

ZOLL requests that the Court adopt the ordinary meaning of monitoring, which it asserts, has a notion of "ongoingness."

ZOLL argues that because the "discharge step" (construed below) takes place over time, "monitoring" must also occur over a period time and cannot be only a single measurement during the step.

ZOLL further asserts that the '454 patent actually distinguishes prior art models because they merely "measured" patient impedance and did not continually monitor impedance in "real time." As a result, ZOLL requests that the Court construe the term as "sampling on a regular or ongoing basis" because this definition is the term's ordinary meaning according to the American Heritage Dictionary.

Philips, however, argues that ZOLL's reliance on a single dictionary definition ignores the intrinsic evidence. As a

result, Philips requests that the Court adopt the construction that the United States District Court for the Western District of Washington selected in construing "monitoring" as "measuring... one or more times." Koninklijke Philips Elec.s NV v. Defibtech LLC, 397 F. Supp. 2d 1257 (W.D. Wash. 2005).

The <u>Difibtech</u> Court noted that "monitoring" and "measuring" are both used in related Philips patents. Generally, using different terms raises an inference that the terms have different meanings, but that inference is not determinative. <u>Desper Prods.</u>, <u>Inc.</u> v. <u>QSound Labs, Inc.</u>, 157 F.3d 1325, 1337 n. 3 (Fed. Cir. 1998). The <u>Difibtech</u> Court concluded that because "both measuring and monitoring occur during periods of time" in the Philips patents, there is "little reason to assume that one term excludes single measurements and one does not." <u>Defibtech</u> 397 F. Supp. 2d at 1264. As a result, the Court construed "monitoring" during the discharge step to require only a "single measurement." <u>Id.</u>

The <u>Defibtech</u> Court determined that if "monitoring" were construed as covering only a single measurement, it would require reading out preferred embodiments. Reading out preferred embodiments is an approach that is "rarely, if ever, correct."

<u>Vitronics Corp.</u> v. <u>Conceptronic, Inc.</u>, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Each of the six waveform patents, discloses an invention the preferred embodiment of which has three "aspects."

Depending on the patient's impedance, one of the three aspects requires only a single measurement. As a result, the patent must cover single measurements as well as ongoing monitoring.

Accordingly, this Court adopts the construction "measuring . . . one or more times."

#### 2. The discharge step/the discharging step

ZOLL requests that the Court construe "discharge step" to make clear that it is "not a test pulse to measure patient impedance." The Court believes that by requesting the addition of that negative limitation to the claim term, ZOLL is proposing that the Court resolve an infringement question during claim construction. Doing so would contradict the purpose of a Markman hearing because "the role of the district court in construing claims" is not to "read limitations into the claims to obviate factual questions of infringement." Am. Piledriving Equip. v. Geoquip, Inc. 637 F.3d 1324, 1331 (Fed. Cir. 2011). Here, the Court declines to adopt ZOLL's construction. Instead, the Court adopts the plain meaning of the term and construes it to mean "the step of discharging the energy source."

The Court notes, however, that during prosecution the patentee equated "discharge" with "shock" in describing prior art. That suggests that the "discharge step" was not intended to describe every possible delivery of energy from the energy source.

### 3. Plurality of electronic switches (Philips' '212 Patent)

Philips requests that the Court adopt the same construction of this term as did the Court in <u>Defibtech II</u>, which limited the term to the "five-switch configuration disclosed in the specification." Koninklijke Philips Elect. NV v. Defibtech LLC, CO3-1322JLR, 2005 WL 3500783, at \*4 (W.D. Wash. Dec. 21, 2005) (Defibtech II). Philips asserts that both the patent examiner and the applicants understood a "plurality of electronic switches" to refer to the five-switch circuit in Figure 11.

In <u>Defibtech II</u> the court held that although the patentee disavowed the prior art five-switch configuration contained in the Swanson patent, the "inventors did not...expressly limit the invention to the five-switch configuration that they disclosed in their patent application." 2005 WL 3500783 at \*3. At the <u>Markman</u> hearing in the present case both parties agreed that the statements made during prosecution of the '212 patent do not meet the standard for a "clear and unmistakable" surrender necessary to reject the ordinary meaning. <u>Omega Eng'g, Inc. v. Raytek</u> <u>Corp.</u>, 334 F.3d 1314, 1323-26 (Fed. Cir. 2003). In <u>Defibtech II</u> the Court relied on extrinsic evidence including an expert declaration and inventor testimony to reach the conclusion that "plurality of switches" could only cover the five switch configuration contained in Figure 11. Neither of those pieces of extrinsic evidence are, however, before this Court which

therefore declines to adopt that construction.

In <u>Defibtech II</u>, Philips argued contrary to its current position, noting that to construe the "plurality of electronic switches" to cover only the five switch embodiment is

contrary to the plain, ordinary definition of the word plurality, which means two or more. 'Plurality' does not mean 'only five' or 'five or more.'

This Court agrees. Because the ordinary meaning of plurality is clear to a jury, the term does not require construction.

### 4. Prior to any attempted use of the defibrillator (Philips' '374 Patent)

The parties dispute the meaning of "attempted use" and thus disagree over when the self test must occur. The parties do agree that self tests performed while the defibrillator is turned off fall within the scope of the applicable claims. The contested issue is, however, whether "prior to any attempted use" includes self tests that are performed after the defibrillator is turned on but before attempted use to treat a patient. Philips asserts that the self test must be performed before the defibrillator is turned on. Zoll proposes a construction in which the self test can occur at any point after the defibrillator is turned on but before it is used to treat a patient. This Court agrees with the <u>Defibtech</u> Court that

It makes little difference what the phrase 'prior to any attempted use' means, because the claims in which it appears impose modifications that resolve the parties' disputes.

397 2d. at 1268. As a result, the Court will examine the precise use of the term in each of the Claims in which the term appears.

Claim 41 teaches a "periodic test signal generator." Claim
42 states that the test signal will be generated "periodically."
According to the "detailed description of the preferred
embodiment" in the '374 Patent these periodic self-tests occur
daily, weekly or monthly, even when the defibrillator is turned
off. Thus, "by their nature, these tests occur before any use of
the defibrillator, including merely turning the device on." Id.
1269. As a result, the Defibtech court construed the term when
used in Claims 41 and 42 to mean "prior to any attempted use of
the defibrillator, even non-therapeutic uses." Although this
Court is persuaded by the same reasoning adopted in Defibtech, it
prefers the more easily understood construction "prior to an
operator turning on the defibrillator."

In Claim 67 the language requires that the generation of a test signal occur "without human intervention." As a result, that language must also refer to one of the periodic self-tests and the status indication must occur prior to turning on the defibrillator. Thus, the Court adopts the same construction as in Claims 41 and 42 where "prior to any attempted use" means "prior to an operator turning on the defibrillator."

Claims 1 and 67 require a different construction. Claim 1 does not indicate which of the multiple types of self-test in the

'374 Patent is required. Claim 1 does not require all of the tests, instead, it requires only one. As the <u>Defibtech</u> Court described, a defibrillator that was designed to conduct a "run time" test and to monitor the defibrillator "continually" would not reveal its status before it was turned on, even though turning it on is a "use." <u>Id.</u> at 1269. Similarly, a defibrillator that could conduct a manual self-test could not indicate its status prior to such a test, even though this test is itself a "use." <u>Id.</u> Thus, it is clear that Philips' proposed construction "prior to an operator turning on the defibrillator" does not accurately express the meaning of this term.

#### The Defibtech court found that

the only "uses" of the defibrillator for which the invention of Claim 1 would *invariably* have means to provide an indication of pre-use status are uses in treating a patient.

In the case of a defibrillator capable of running a randomly selected self-test the device would only be guaranteed to "indicate status before anyone used it to treat a patient, but not necessarily before other uses." <a href="Id">Id</a>. It is clear, therefore, that in some instances "prior to any attempted use" means "prior to use to treat a patient." In the case of a defibrillator with means to perform a run-time test, however, the term means "prior to an operator turning on the defibrillator." Therefore, with respect to these Claims, the Court adopts the construction "prior to any attempted"

use of the defibrillator to treat a patient, and in some cases prior to an operator turning on the defibrillator."

"automatically in response to a predetermined event or condition." This Claim includes at least one kind of selftest but does not include the "periodic" self-tests. This Court agrees with the reasoning in <a href="Defibtech">Defibtech</a> that if the test is a "run-time" test the status could not be indicated before the defibrillator was turned on. <a href="Id.">Id.</a> As a result, the Court applies the same construction as in Claim 1.

### 5. Test signal (Philips' '374, '460 Patents)

The dispute surrounding the construction of "test signal" also relates to the <u>Defibtech</u> court's prior construction of the term. In that case, the court acknowledged that the patent claims are "inconsistent" in the use of the term "test signal." <u>Id.</u> at 1267. As a result, the court construed most instances of "test signal" to mean "a signal associated with testing," but in some instances found that "additional claim language limits the term to a 'signal that initiates testing'." <u>Id.</u> ZOLL requests that the Court adopt the <u>Defibtech</u> Court's construction while Philips argues that "a signal associated with testing" is the better construction because it is one that "a jury can apply uniformly across the board, yet still

be understood within the context of each claim."

The <u>Defibtech</u> court found that the claims in the '460 and '374 patents fell into three classes. <u>Id.</u> First, in claims that "expressly disclose one or more self-tests performed 'in response' to the test signal or other stimuli", "the test signal is a signal that initiates a test, not one that performs it." <u>Id.</u> Second, in claims where the test signal is generated by the system monitor, the test signal is also one that initiates testing. <u>Id.</u> Finally, in the third category where the test signals are neither used to initiate self-testing nor generated by the system monitor, the "test signal" is simply "a signal associated with testing." <u>Id.</u> Thus, although "signal associated with testing" applies in the third category, the other two categories require the additional limitation of "a signal that initiates testing."

While generally "the same claim term used in the same patent 'carries the same construed meaning'" this rule applies only if the court is not "otherwise compelled."

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003). Here, this Court agrees with the ruling in Defibtech that the limitations in several of the claims require the court to reach two different constructions of "test signal." As a result, the Court construes this term

to mean the following:

Construction	Patent	Claims
"A signal that initiates testing"	<b>`</b> 374	22, 25-27, 42, 44-45, 51-52, 61-62, 64-65, 67-69, 71-72
"A signal that initiates testing"	<b>'</b> 460	1-6
"A signal associated with testing"	<b>`</b> 374	1-6, 10, 21, 34-37, 41, 43

# 6. A heart rate alarm circuit in which the inputs comprise an averaged QRS rate and the shock advisory indication (ZOLL's '187 Patent)

The Summary of the Invention in ZOLL's '187 Patent states that it features "an alarm driven by both a heart rate detector and a fibrillation/tachycardia advisory algorithm." This distinction sets the '187 patent apart from prior art in which alarms were based on only one of those inputs. Philips requests that the word "both" be added to the claim construction to make this distinction clear. The Court finds, however, that the claim language is already clear that both inputs are required and is capable of being understood correctly by the jury. As a result, the Court declines to construe this term.

7. Generate an alarm when the monitoring circuitry determines that the external power connection is not connected to a source of external power and that the medical device to which the power supply may be connected is not turned on/Generating an alarm when the external power connection is not connected to the external power source and the medical device is not

### turned on (ZOLL's '807 Patent)

Philips argues that the alarm circuitry is configured to generate an alarm "as a result of" the monitoring circuitry determining that the device is both not connected to external power and not turned on. Philips asserts, therefore, that unless the Court construes "when" to mean "as a result of" the causal connection will not be clear to the jury.

The Court finds that the patent does not, however, require that the alarm actually be triggered by the two events but only that the alarm function when the two events occur. Thus, if the power supply is connected to AC power and the defibrillator is turned on the power supply will be prevented from activating the alarm. Because the patent language already makes this relationship clear the Court declines to construe it further.

8. A method of supplying power from an external power source to a battery-powered medical device for charging a battery of the medical device and operating the medical device (ZOLL's '807 Patent)

Philips requests that the Court construe the claim language to add the words "by a power supply" to make "the method of supplying power" clear to the jury. This Court, however, agrees with ZOLL that the inclusion is unnecessary. The language in Claim 15 already indicates that "the method of supplying power" includes "providing a power supply." As a result, the additional inclusion is superfluous and the Court declines to construe this term.

### 9. Power supply (ZOLL's '807 Patent)

ZOLL argues that "power supply" is a common term that requires no construction. This Court agrees with Philips, however, that the term requires construction to improve juror comprehension but declines to adopt Philips' proposed construction, particularly the inclusion of the words "connects to a source of AC power." That language is too narrow to address the actual invention. For example, Claim 1 recites a "connection for bringing external power into the power supply." Such language suggests that the power supply does not always connect directly to a source of AC power. Instead, the Court relies on the patent specification to adopt the construction "a unit that connects to a device and that supplies power to the device."

# 10. Envelope comprising a sheet of material (ZOLL's $^\prime$ 250 Patent)

The underlying dispute over the two claim terms in the '250 patent relates to whether the "envelope" must be fully enclosed. ZOLL asserts that the term should be given its "ordinary meaning" and thus does not require construction. Philips, on the other hand, relies on the purpose of the invention to argue that an envelope must be an "enclosure." This Court agrees with Philips and construes the term to mean "a sheet of material that forms an enclosure."

Claim 1 teaches that the envelope has a releasable "seal" that forms a "sealed first compartment" and allows the electrodes

to be "isolated from an external environment." This isolation is described as necessary to "prevent[] the adhesive gel from drying out." The Court is persuaded that if the envelope did not "enclose" the electrodes, the gel would dry out and the invention would not work as described. As a result, the Court finds that the "envelope" is an enclosure.

#### 11. Seal (ZOLL's '250 Patent)

This term is closely related to the "envelope" construed in the proceeding section. ZOLL argues that the seal need only provide a "barrier" that serves as "something that closes the envelope by joining parts of it together." This construction, however, ignores the purpose of the invention. As Philips points out, a porous barrier could still join the parts together but would not serve the purpose of the invention. If the seal is not airtight, it will not "isolate the electrode from the external environment" as the patent requires.

Further, the '250 patent uses the terms "seal" and "barrier" differently. For example, in Claim 13 the "gasket" that allows the wires that connect to the electrode to pass through the envelope is described as a "barrier element". Because the gasket allows items to pass through, it is not airtight. That word choice suggests that the patentee chose the term "seal" to distinguish from other non-airtight barriers within the same invention. The seal is also repeatedly described as a "heat

seal", which is further evidence that it is intended to be airtight. As a result, the Court construes "seal" to mean an "airtight barrier."

12. A concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a  $50\Omega$  resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than  $1\Omega$  when a 200 Joule defibrillation pulse is discharged into the series circuit (ZOLL's '526 Patent)

ZOLL asserts that no construction is needed. Philips, responds however, that Claim 1 of the '526 patent is indefinite because there is no explanation "for how one skilled in the art would choose specific testing conditions to determine whether the resistance of a given gel electrode is 'greater than  $1\Omega'$ ." A term is indefinite where the product "might or might not infringe depending on its usage in changing circumstances." Geneva Pharms. Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1384 (Fed. Cir. 2003).

According to Philips, gel electrodes are tested under the industry standards for defibrillators set by the Association for Advancement of Medical Instrumentation (AAMI). These standards include a variety of test conditions including the temperature of the gel, the amount of time the gel has been exposed to air (humidity) and the number of shocks delivered through the gel. The '526 patent does not, however, specify the test conditions

necessary to determine whether the claim limitation is met. Philips conducted testing under a variety of temperature conditions. At 35° centigrade ("C") the resistance did not exceed  $1\Omega$  but at 15C it did. Thus, depending on the temperature, the same gel electrode may or may not infringe Claim 1. Philips also conducted tests with varying degrees of dryness in the electrode gel and number of shocks to the electrode and elicited results that both did and did not infringe Claim 1.

ZOLL contends that the testing conditions are apparent to a skilled artisan who would know that when testing conditions are not specified the tests should be conducted at room temperature, shortly after removing the electrodes from their packaging and without performing numerous previous shocks. Furthermore, ZOLL argues that Philips fails to mention that the AAMI standards do not include any requisite parameters and thus describe as much as the '526 patent does. Finally, ZOLL asserts that descriptions of electrode resistance tests that do not include those parameters are commonly described in the technical literature.

Patent claims must state with particularity the subject matter which the applicant regards as his invention. 35 U.S.C. § 112. That definiteness requirement serves a public notice function and ensures that patent claims will be "sufficiently precise to permit a potential competitor to determine whether or not he is infringing." Amgen Inc. v. Hoechst Marion Roussel,

Inc., 314 F.3d 1313, 1342 (Fed Cir. 2003) (internal quotation omitted).

Proof of indefiniteness of patent claims, enough to render a patent invalid, is met where an accused infringer shows, by clear and convincing evidence, that a skilled artisan could not discern the bounds of the claim "based upon the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). The bar is high: "a claim is not indefinite merely because its scope is not ascertainable from the face of the claims." Amgen, 314 F.3d at 1342. Instead, it must be "insolubly ambiguous" such that "reasonable efforts at claim construction prove futile." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2010). Indeed,

Even if it is a formidable task to understand a claim, and the result not unanimously accepted, as long as the boundaries of a claim may be understood it is sufficiently clear to avoid invalidity for indefiniteness.

Invitogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1383 (Fed. Cir. 2005) (internal quotation omitted); see also Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1379 (Fed. Cir. 2001) ("Provided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of the claims does not

render the claims indefinite.").

Although it is true that "the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction," Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (citation omitted), there are several reasons to defer rulings on indefiniteness until the summary judgment stage, CSB-Syst. Int'l Inc. v. SAP Am., Inc., No. 10-2156, 2011 WL 3240838, at \*17-18 (E.D. Pa. July 28, 2011). Those reasons include the fact that an allegedly infringing party must prove indefiniteness by "clear and convincing proof" to overcome the statutory presumption of validity and that

unlike a Markman proceeding that gives meaning to patent claims, indefiniteness invalidates the claims entirely. As such, this dispositive effect is more appropriately tackled at summary judgment.

Id. at \*18 (citing numerous instances in which courts elected to defer indefiniteness until summary judgment).

This is not a case where a defense of indefiniteness is based upon claims which, on their face, are so vague that they cannot reasonably be interpreted but rather is a case where the relevant claims can be construed but are alleged to be indefinite as applied. Compare Am. Med. Systs., Inc. v. Biolitec, Inc., 666 F. Supp. 2d. 216, 223 (D. Mass. 2009) (construing a claim as indefinite where claim language was subject to "multiple conflicting interpretations"); with Takeda Pharm. Co. v. Handa

Pharms., LLC, 2012 WL 1243109, at \*16 (N.D. Cal. Apr. 11, 2012) (deferring indefiniteness until summary judgment because whether a skilled artisan could determine relevant amounts without undue experimentation was a "largely factual" inquiry). Here, the parties' respective experts offer extrinsic evidence as to whether the disclosure of the patent is sufficient to allow a person of ordinary skill to identify the relevant testing conditions necessary to determine whether the electrode infringes. This "battle of the experts" is not, therefore, properly decided at the claim construction phase.

The Court declines to construe this term. Philips is not, however, foreclosed from challenging the validity of this claim for indefiniteness at summary judgment.

# 13. User-triggered inquiry/user-triggered indicator (Philips' '093 Patent)

The parties agree on the plain and ordinary meaning of "user-triggered." ZOLL, however, requests that the Court add "regardless of whether the defibrillation capability is active or not" to its construction. To support this additional limitation, ZOLL points to the patent specification which contrasts the invention with prior art defibrillators because "the present invention" permits "the user-initiated inquiry to be carried out whether or not the defibrillator is turned on." Philips responds that defibrillation capability is not dependent upon whether the defibrillator is turned on. The Court agrees with Philips and

construes this term according to its ordinary meaning.

# 14. Detailed [audio] instructions (Philips' '785 Patent)

The dispute over this term relates to the level of "detail" the instructions require. The parties agree that the construction of this term should be informed by the prosecution history. The original application recited "prompts" and "instructions" but not "detailed instructions" and was thus rejected because such terms were broad enough to encompass the "sound or flashing light pacing signals" in the prior Lurie patent. In response, the applicants amended their application to include "detailed instructions."

Philips requests that the Court adopt the construction

[audio] instructions that prescribe a sequence of steps for reviving a patient, such as (1) deliver a number of chest compressions, (2) deliver a certain number of breaths, (3) deliver a certain number of therapeutic shocks, (4) call 911, and/or (5) clear the patient's airway.

To reach that proposed construction, Philips relies on a statement made by the applicants in response to the original patent application rejection that:

Various forms of detailed instructions are provided in the referenced sections of the written description, including, for example, prompting the caregiver to: deliver a number of chest compressions, deliver a certain number of breaths, deliver a certain number of therapeutic shocks, call 911, and/or clear the patient's airway. This level of instruction is not disclosed in Lurie.

ZOLL responds that the inclusion of the words "such as" in Philips' proposed construction "improperly requires the fact-finder to decide subjectively how detailed an instruction must be." This Court agrees and rejects that construction.

ZOLL, instead, requests that the Court adopt the construction

[audio] instructions that prescribe a sequence of CPR steps, including the number of times a particular step is to be taken (if the step is to be repeated).

That construction is based on the series of diagrams in Figures 3-17 that the applicants submitted as part of the amended patent application. ZOLL argues that each of those figures "shows a process by which a user is prompted to administer a CPR step a particular number of times." This Court, however, agrees with Philips' contention that the figures are meant only to be illustrative and were not intended to represent all of the invention's functions. Thus, the Court declines to find that the "detailed instructions" must include the specific number of times a step should be repeated.

Furthermore, as the patentee's statements in prosecution quoted above indicate, the "detailed instructions" were intended to include "deliver[ing] a certain number of therapeutic shocks." In fact, several of the flow charts in the figures that ZOLL seeks to rely upon even include a step that asks whether a particular number of "consecutive shocks have been delivered."

At oral argument the parties agreed that the defibrillation shock is not a "CPR step." As a result, ZOLL's construction fails to make clear to the jury that the detailed instructions include both CPR and the invention's core function of providing defibrillator shocks. To address that concern, the Court adopts the construction "[audio] instructions that prescribe a sequence of steps for reviving a patient, including CPR and defibrillation shocks."

# 15. Synchronized audible [visual] prompts (Philips' '785 Patent)

Both parties agree that "synchronized" should be construed to mean that the prompts correspond to steps of the "detailed instructions." Philips requests that the Court construe this term as "audible/visual prompts corresponding to the time at which the step should be performed." ZOLL asserts that "the step" should instead be construed as "a particular step" because otherwise Philips' construction is ambiguous as to which step corresponds to which time. ZOLL's argument is unavailing because no portion of the patent specification requires the additional limitation of "a particular step." Instead, the specification states that "the rate of flashing of the visual prompt may correspond to the timing at which the step, such as CPR, is to be performed." (emphasis added). As a result, the Court adopts Philip's proposed construction.

In accordance with the foregoing,

1) "Monitoring/monitoring. . .during" means:

"measuring . . . one or more times";

- 2) "The discharge step/the discharging step" means
  - "the step of discharging the energy source";
- The Court declines to construe the term "plurality of electronic switches";
- 4) "Prior to any attempted use of the defibrillator" means

"prior to any attempted use of the defibrillator to treat a patient, and in some cases prior to an operator turning on the defibrillator" or " prior to an operator turning on the defibrillator";

5) "Test signal" means

"a signal that initiates testing" in some claims, and in others, "a signal associated with testing,"

Construction	Patent	Claims
"A signal that initiates testing"	<b>`</b> 374	22, 25-27, 42, 44-45, 51-52, 61-62, 64-65, 67-69, 71-72
"A signal that initiates testing"	<b>'</b> 460	1-6
"A signal associated with testing"	<b>`</b> 374	1-6, 10, 21, 34-37, 41, 43

6) The Court declines to construe the term "A heart

- rate alarm circuit in which the inputs comprise an averaged QRS rate and the shock advisory indication";
- 7) The Court **declines to construe** the term "Generate an alarm when the monitoring circuitry determines that the external power connection is not connected to a source of external power and that the medical device to which the power supply may be connected is not turned on/Generating an alarm when the external power connection is not connected to the external power source and the medical device is not turned on";
- 8) The Court **declines to construe** the term "A method of supplying power from an external power source to a battery-powered medical device for charging a battery of the medical device and operating the medical device";
- 9) "Power supply" means
  - "a unit that connects to a device and that supplies power to the device";
- 10) "Envelope comprising a sheet of material" means
  - "a sheet of material that forms an enclosure";
- 11) "Seal" means

#### "airtight barrier";

- 12) The Court **declines to construe** the term "A concentration of an electrolyte that produces a combination series resistance of two of said electrodes, when measured with the electrodes configured in a series circuit with a  $50\Omega$  resistance, and with the electrolytic gel layer of each electrode in contact with that of the other electrode, that is greater than  $1\Omega$  when a 200 Joule defibrillation pulse is discharged into the series circuit";
- 13) "User-triggered inquiry/user-triggered indicator" means

"an inquiry that the user may trigger"/ "an indicator that the user may trigger";

14) "Detailed [audio] instructions" means

"[audio] instructions that prescribe a sequence of steps for reviving a patient, including CPR and defibrillation shocks";

15) "Synchronized audible [visual] prompts" means

"audible/visual prompts corresponding to the time at which the step should be performed".

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated November 26, 2012