United States District Court,
D. Minnesota.

MEDTRONIC, INC.; and Medtronic, USA, Inc,
Plaintiffs.
v.
GUIDANT CORPORATION; Cardiac Pacemakers, Inc.; and Guidant Sales Corporation,
Defendants.
CARDIAC PACEMAKERS, INC.; and Guidant Sales Corporation,
Counterclaim Plaintiffs.
v.
MEDTRONIC,
INC.; and Counterclaim Defendant.

No. Civ.00-1473 MJD/JGL, Civ.00-2503 MJD/JGL

May 25, 2004.

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FN1. Please note that the enclosed opinion omits Mr. McBride's name from the "counsel" block.
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Court-Filed Expert Resumes

MEMORANDUM OF LAW & ORDER

DAVIS**, J.**

The following is a list of the names and addresses of counsel as well as the parties for whom they appeared.

I. INTRODUCTION

This matter is before the Court on the Parties' joint request for claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The Parties are Plaintiffs Medtronic, Inc., and Medtronic

USA, Inc., (collectively "Medtronic") and Defendants Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation (collectively "Guidant"). Cardiac Pacemakers, Inc., and Guidant Sales Corporation are also Counterclaim Plaintiffs and Medtronic, Inc., is the Counterclaim Defendant. At issue are claims from eight patents relating to atrial defibrillators. The eight patents are: U.S. Patent No. 5,207,219; U.S. Patent No. 5,282,836; U.S. Patent No. 5,265,600; U.S. Patent No. 5,549,641; U.S. Patent No. 5,441,519; U.S. Patent No. 5,674,249; U.S. Patent No. 5,645,569; and U.S. Patent No. 5,676,687. A ninth patent, U.S. Patent No. 5,490,862, was previously dismissed from this matter on summary judgment. *See* Medtronic, Inc. v. Guidant Corp., Civ. 00-1473 (MJD/JGL), No Civ. 00-1473, 2003 WL 21181103, at (D.Minn. May 16, 2003).

Guidant is the owner of the remaining patents in suit. In the instant lawsuit, Guidant alleges that Medtronic's Jewel AF and Gem III AT defibrillators infringe one or more of the more than fifty claims asserted from the eight patents.

II. BACKGROUND

The patents-in-suit describe technology related to the treatment of an irregular rhythm, or "arrhythmia," of the heart occurring in the atria. This technology is referred to as atrial defibrillation.

A. The Heart

The human heart is a muscular pump which pumps blood to the organs of the body. The heart is divided into four chambers: the top two chambers are referred to as the right and left atria, and the lower two chambers are referred to as the right and left ventricles. The right atrium receives and collects unoxygenated blood from the body and then pushes the unoxygenated blood to the right ventricle, which subsequently pumps to the lungs. The left atrium receives and collects oxygenated blood, which has passed through the lungs, and then delivers it to the left ventricle. The left ventricle pumps the oxygenated blood to the arteries, which deliver the blood to the body's organs.

The heart operates via electrical signals generated in the sinus node, which is a small bundle of nerves located in the right atrium. The sinus node is often referred to as the heart's natural pacemaker. The electrical impulse created in the sinus node travels via nerve fibers across the atria to a structure called the AV node, which is located in the middle of the heart. From the AV node, the electrical impulse travels to the ventricles.

As the electrical impulse generated in the sinus node spreads via nerve fibers across the atria, it changes, or "depolarizes," the electrical state of the atrial tissue, causing the atria to contract and force blood into the ventricles. Following a short delay, the electrical impulse travels to the ventricles, causing them to similarly depolarize and contract, forcing blood out of the ventricles and into the rest of the body. The heart then relaxes, or "repolarizes," with the atria repolarizing before the ventricles. If the heart functions as it should, the process then repeats itself. The electrical signals and pumping action of the atria and ventricles is a coordinated rhythmic action referred to as the "sinus rhythm."

An electrocardiogram, a recording of the heart's electrical impulses, has a characteristic form. By looking at an electrocardiogram, a physician can ascertain the functioning of the heart's electrical system. The wave forms seen on an electrocardiogram reflect heart activity, and are recorded as follows: P wave, Q wave, R wave, S wave, and T wave. The P wave corresponds to the electrical signal for the atria, which causes the depolarization and contraction of the atria. The R wave, also called the QRS complex, corresponds to the

depolarization and contraction of the ventricles. The T wave corresponds to the repolarization and relaxation of the ventricles. The ventricles relax in order to receive blood from the next heartbeat.

B. Arrhythmias of the Heart

Abnormal or irregular heart rhythms are referred to as arrhythmias, and can be characterized by changes observed on an electrocardiogram. Arrhythmias range in severity from benign arrhythmias, which may go unnoticed throughout a person's life, to severe arrhythmias that are fatal within minutes. Arrhythmias may occur in either the atria, the ventricles, or both.

A slow heartbeat is referred to as bradycardia. When a heart is experiencing bradycardia, the heart may beat too slowly to provide adequate amounts of blood to the body. A fast heartbeat is referred to as tachycardia. Some tachycardias are completely normal, such as when individuals raise their heart rates during exercise, while others can be life threatening. Atrial flutter is a rhythm disturbance that originates in the atria, and is characterized by a very high rate of organized depolarizations.

Fibrillation is characterized by a rapid, irregular, disorganized pattern of contraction. Atrial fibrillation is relatively benign; however, it can sometimes lead to dizziness, fainting, heart failure, or strokes. Some individuals go through life with atrial fibrillation and never notice any symptoms, but most are at least somewhat symptomatic.

Ventricular arrhythmias are generally more serious than atrial arrhythmias. Ventricular fibrillation can quickly kill an individual because the body's organs are not receiving blood and cease to function. An individual experiencing ventricular fibrillation can lose consciousness within seconds and die within minutes if not resuscitated.

C. Treatment of Arrhythmias

There are a variety of treatments for each type of arrhythmia, including drugs, pacemakers and defibrillators. Implantable electronic devices can be implanted surgically, and are basically electrical pulse generators designed to emit an electrical discharge at a specific voltage output at a specific time. The devices may perform one or more of three therapies. Pacing is the delivery of very low energy electrical pulses to the heart muscle. It augments the heart's own natural pacemaker, and can commonly treat bradycardia. Cardioversion, also known as atrial defibrillation, is the delivery of a high energy electrical pulse synchronized to the R wave. Defibrillation is characterized by delivery of an unsynchronized high energy shock to the heart muscles to revert ventricular fibrillation.

Electrical shocks delivered during a patient's T wave may have a pro-arrhythmic effect and make the arrhythmia worse. For example, a shock could convert a relatively stable tachycardia to a life threatening ventricular fibrillation. For that reason, the refractory period of the heart surrounding the T wave is referred to as the heart's vulnerable period. Thus, an electric shock is most often synchronized so that it coincides with the heart's R wave, signaling the contraction of the ventricles. Such a shock is generally referred to as a "cardioverting" shock, while an unsynchronized shock applied to terminate ventricular fibrillation is referred to as "defibrillating shock." Generally there is no need to synchronize a shock meant to treat ventricular fibrillation because the arrhythmia cannot get worse and the patient must be treated immediately.

Even with a synchronized shock, a pro-arrhythmic effect might occur if the T wave is very close to the next R wave, such as might occur when the patient has a very high tachycardia rate, and ventricular fibrillation

might be induced by the shock. In the event of such an occurrence, the patient would require another electrical shock to terminate the induced ventricular fibrillation.

D. The Accused Devices

As early as 1976, an implantable atrial defibrillator had been designed; however, Medtronic asserts that no devices having atrial defibrillation capabilities were commercialized in the United States until the release of Medtronic's Jewel AF 7250 and Gem III AT 7276 devices, the accused products in this matter. Both devices are dual chamber pacemaker/defibrillators and, according to Medtronic, derive from prior technologies, including Medtronic's series of pacemaker/defibrillators. Guidant asserts that the devices derive from the patents-in-suit.

E. InControl's Patents

In the early 1990s, InControl, Inc. ("InControl"), a small company in Redmond, Washington, began developing an implantable atrial defibrillator called the Metrix. Whether the patents at issue are limited to the design of the Metrix is a point of contention between the Parties.

Between 1992 and 1998, Medtronic evinced interest in licensing InControl's patents, or perhaps acquiring the company. Ultimately, neither came to pass. In 1998, Cardiac Pacemakers, Inc., now wholly owned by Guidant, purchased InControl's assets. InControl received over sixty patents related to the Metrix. Guidant currently asserts eight of those patents against Medtronic's Jewel AF and Gem III AT.

III. LEGAL STANDARD

A. General Claim Construction Principles

Interpretation of the terms used in a patent is a matter of law to be decided by the Court. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370 (1996). The *Markman* hearing is held to construe the meaning of claim language as a matter of law, not to make factual findings. The Court need only construe the disputed claim language "to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. American Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

When interpreting the claims of a patent, the Court begins with the ordinary meanings of claim terms. *See* Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed.Cir.2002). Claim terms are assigned their ordinary and accustomed meaning as understood by one of ordinary skill in the art. *Id*. Dictionaries, encyclopedias, and treatises can be useful resources to assist courts in determining the ordinary and customary meanings of claim terms. *Id*. The presumption in favor of ordinary definitions is rebutted when the patentee has acted as his or her own lexicographer by assigning definitions different from the normal definitions. *Id*. at 1204. In addition, dictionary definitions do not control when a patentee has "disavowed or disclaimed scope of coverage by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id*.

When interpreting claim language, the Court must also look to the intrinsic evidence of record: the claims, the specification, and the prosecution history. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The specification is the single best guide to the meaning of a disputed term, and may act as a dictionary defining a term expressly or by implication. *Id*. However, a patent is not necessarily limited to the embodiment or exemplary form described in the specification. *See* Tex. Digital, 308 F.3d at 1204. If the

meaning of the claim language would not be understood by one skilled in the art to be limited to the examples or embodiments delineated in the specification, it is improper to read such limitations into the claim. Id. at 1205. Thus, the Court first attempts to determine the ordinary meaning before comparing the ordinary meaning to the specification. Id. at 1204.

It is also improper to rely upon extrinsic evidence-evidence outside the claims, specification, and prosecution history-to vary or contradict the unambiguous meaning of the terms in the claim. *See* Vitronics, 90 F.3d at 1583. It is also improper to construe the claims with reference to the accused device. Neomagic Corp. v. Trident Microsys., Inc., 287 F.3d 1062, 1074 (Fed.Cir.2002).

B. Means-Plus-Function Claims

A claim element may be expressed as a means for performing a specified function without reciting the structure, material or acts in support thereof. 35 U.S.C. s. 112, para. 6. Such a "claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." *Id*. Whether an element of a claim is in means-plus-function form is a claim construction question. *See* Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360 (Fed.Cir.2000). Use of the term "means" creates a presumption that the element is to be construed in accordance with s. 112, para. 6, whereas the absence of the term "means" creates a presumption that the element is not to be construed in accordance with s. 112, para. 6. Kemco Sales, Inc., 208 F.3d at 1361. Means-plus-function claim terms are construed to cover only the structure disclosed in the patent's specification that performs the claimed function and equivalents of that disclosed structure. *CSS* Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1367 (Fed.Cir.2002).

1. The Function

The first step in construing means-plus-function language is to identify the function. *See* Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1208 (Fed.Cir.2002). The Court may not limit "a means-plus-function claim by adopting a function different from that explicitly recited in the claim." Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1258 (Fed.Cir.1999).

2. The Corresponding Structure

The second step in construing means-plus-function language is to identify corresponding structure in the written description necessary to perform the recited function. *See* Tex. Digital, 308 F.3d at 1208. "Section 112 paragraph 6 does not permit incorporation of structure from the written description beyond that necessary to perform the claimed function." Asyst Techs., Inc. v. Empak, Inc., 268 F.3d 1364, 1369-70 (Fed.Cir.2001) (internal quotation omitted).

The "[s]tructure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." Id. at 1370 (emphasis added) (internal quotation omitted). "Structural features that do not actually perform the recited function do not constitute corresponding structure and thus do not serve as claim limitations." *Id*. (citation omitted). However, "it is not necessary to claim in a patent every device required to enable the invention to be used." *Id*. at 1371 (internal quotation omitted).

IV. DISCUSSION

A. Introduction

As noted above, there are eight patents-in-suit. The Parties have addressed one representative claim from each patent in briefing and at the *Markman* hearing. The Court will address the claim construction of each representative claim. Because similar terms are repeated throughout the patents, and because many of the claims are dependent on other claims, determination of the claim construction for the representative claims will resolve most of the construction for the non-representative claims.

B. U.S. Patent No. 5,207,219 (" '219 Patent")

The '219 Patent relates to an atrial defibrillator and method for providing interval timing prior to cardioversion. It describes a way to determine when it is safe to cardiovert the atria based on the timing of contractions in the ventricles. Guidant has asserted six claims from the '219 Patent against Medtronic. The representative claim addressed at the *Markman* hearing was Claim 1, a means-plus-function claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator for providing cardioverting electrical energy to the atria of a human heart in need of cardioversion, said atrial defibrillator comprising:"

Guidant asserts that Medtronic ignores the word "comprising" in the Preamble. The Court notes that "[c]omprising is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344-45 (Fed.Cir.2003) (quotation omitted).

The interpretation of this Preamble is also governed by the interpretation of the phrase "applying said cardioverting electrical energy to the atria." The Parties' arguments regarding that language are set out later in the discussion of the Fourth Element of this claim. As explained fully in Part IV(B)(1)(e)(i), the Court concludes that the proper interpretation of this language requires that cardioverting electrical energy be applied toward the atria, rather than be substantially confined to the atria.

Thus, the Court concludes that the proper interpretation of the Preamble is as follows:

A device that may be implanted in a patient to treat atrial fibrillation by directing an electric shock toward the atria of the heart in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "first detecting means for detecting ventricular activations of the heart." The Parties agree that the function of this means-plus-function element is "detecting ventricular activations," and that the term "ventricular activation" can be simplified as "discrete R waves of the cardiac cycle." The Parties disagree on the corresponding structure. While Guidant asserts that the structure requires only a sense amplifier and an R wave detector, Medtronic asserts that "endocardial first lead 34 having closely spaced bi-polar electrodes 38 and 40 which are located in the right ventricle 12" are also part of the corresponding structure.

Medtronic argues that the lead is involved in detecting ventricular activations, because without the lead, there would be no detection of ventricular activation. It asserts that the sense amplifier does not do any detecting, but merely amplifies the sense that has already been detected. It also notes that the specifications refer to the electrodes and lead when describing the act of establishing contact with the ventricle and sensing ventricular activations. '219 Patent, at 4:52-55 ("The endocardial first lead 34 preferably comprises an endocardial bi-polar lead having electrodes 38 and 40 arranged for establishing electrical contact with the right ventricle 12 of the heart 10."); id. at 5:26-30 ("The first sense amplifier 50 and the R wave detector 52 form a first detecting means which together with the first lead 34 to which sense amplifier 50 is coupled, senses ventricular activations of the right ventricle 12.").

Guidant counters that the lead and electrodes merely enable detection by performing the function of establishing electrical contact with the ventricle to deliver electricity from the heart to the first detecting means. '219 Patent at 4:52-55. Under Federal Circuit precedent, enabling structures, such as the electrical outlet for a toaster, are not part of the corresponding structure. Asyst Techs., Inc. v. Empak, Inc., 268 F.3d 1364, 1371 (Fed.Cir.2001). Guidant also notes that at one point, when referring to the function of detecting, the patent refers only to the sense amplifier and the R wave detector: "The sense amplifier 50 and the R wave detector 52 continuously detect the occurrence of ventricular activations of the right ventricle 12. " '219 Patent, at 6:47-49.

Because the Parties agree that the function is "detecting ventricular activations," the Court need only determine what structure in the written description is necessary to perform the recited function. *See* Asyst Tech., 268 F.3d at 1370. The Court concludes that the corresponding structure which performs the function of detecting ventricular activations includes a sense amplifier, an R wave detector, a lead and electrodes (and their equivalents). *See* 35 U.S.C. s. 112, para. 6 (a means-plus-function claim "shall be construed to cover the corresponding structure ... described in the specification and equivalents thereof"). Contrary to Guidant's assertion, the lead and electrodes are clearly linked to the stated function of "detecting." The term "detect" means "to discover or determine the existence, presence, or fact of." *Webster's Ninth New Collegiate Dictionary* 345 (1990). The patent itself makes clear that a lead and electrodes perform this function. For example, the specification states: "The second sense amplifier 54 forms a second detecting means which, together with the first electrode 44 and second electrode 46 of the second lead 36 to which it is couple[d] detects atrial activity of the heart." '219 Patent, at 5:30-34. Thus, the lead and electrodes do more than enable the device to operate in order to detect, like the outlet enabling the toaster by providing power to the toaster. Instead, the lead and electrodes are part of the actual function of detecting: they sense the existence of ventricular activations and transmit those sensed signals to the sense amplifier and R wave detector for further processing.

The Court finds that the location of the electrodes is not part of the corresponding structure. The lead and electrodes are only necessary components of the structure in that they are able to detect ventricular activations, whether they are detected from a particular location, or by electrodes that are narrowly spaced or widely spaced. *See, e.g.,* Motorola, Inc. v. Vosi Techs., Inc., No. 01 C 4182, 2001 WL 1646559, at (N.D.Ill.Dec. 21, 2001) (holding that unless the physical location of the corresponding structure is necessary to perform the claimed function, the means is not construed "to require a particular placement" of the structure).

The Court concludes that the proper interpretation of the First Element of Claim 1 is as follows:

A sense amplifier, R wave detector, lead, and electrodes (or equivalent structure) for performing the function of detecting ventricular activations. "Ventricular activations" denotes R waves of the heart cardiac cycle which induce depolarizations of the ventricles (i.e. electrical events in the ventricles of the heart corresponding to ventricular contractions).

c. Second Element

The Second Element of Claim 1 is a "second detecting means for detecting atrial activity of the heart." The Parties agree that the function in this means-plus-function claim is "detecting atrial activity of the heart." The Parties dispute the meaning of the term "atrial activity." In addition, the Parties disagree regarding the components of the corresponding structure. The Parties do agree that "atrial" means "relating to an atrium" and "atria" means "plural of atrium."

i. Atrial Activity

The Parties dispute whether one skilled in the art would understand "atrial activity" to mean only electrical signals originating in the atria or all electrical signals that could possibly be detected in the atria.

Medtronic argues that, based on the language of the patent, "atrial activity" consists of all electrical signals in the atria, including any detectable R waves from the ventricles, and noise. Guidant, on the other hand, argues that "atrial activity" has an ordinary meaning to those skilled in the art. Guidant avers that "atrial activity" refers only to electrical events that occur in the atria, specifically both normal, organized depolarizations ("P waves") and abnormal, disorganized depolarizations, which occur during atrial fibrillation. In contrast to the term "atrial activation," which encompasses just P waves, the term "atrial activity" encompasses both complete activations, normal P waves, and incomplete or disorganized activations, abnormal electrical events, that exist during atrial fibrillation.

The Court agrees with Guidant. As Guidant notes, at the *Markman* hearing, Medtronic's expert, Dr. David Benditt, testified that the P wave represented "[t]he electrical signal for the atria." Tr. at 17:14-17. He also used the term "atrial activity" to refer to abnormal P waves existing during an atrial tachycardia. Tr. at 25:12-15.

Additionally, a treatise available at the time of the '219 Patent application states that "the external reading of normal atrial electrical activity was arbitrarily termed a P *wave* in the early days of electrocardiography." Stephen Scheidt, M.D., *Basic* Electrocardiography 6 (1986). The treatise also states that during atrial fibrillation, "[a]trial activity is seen as small, irregular undulations in the baseline [of a printout strip]." Id. at 95. In the context of the Scheidt treatise, the term "atrial activity" refers to electrical activity generated in the atria.

The Court concludes that contemporaneous literature available to one skilled in the art limits "atrial activity" to that activity either associated with a healthy P wave or with abnormal depolarizations such as occur during atrial fibrillation. There is nothing in the specification that alters this definition. Thus, the Court concludes that "atrial activity" means electrical events that occur in the atria.

ii. Structure

The Parties agree that the sense amplifier is part of the corresponding structure. Medtronic asserts that the corresponding structure also includes the following structure: "Intravascular second lead 36 having widely

spaced bi-polar atrial electrodes 44 and 46, sense amplifier 54, and analog-to-digital converter 60 that provides digitized data to microprocessor 62 'for further processing' by the atrial fibrillation detector, 70."

Guidant asserts that only a sense amplifier constitutes corresponding structure to detect atrial activity of the heart. It argues that the leads and electrodes merely enable the function of sensing by establishing electrical contact with the heart to pass electrical signals to the detecting means.

Guidant also argues that the analog-to-digital converter does not perform the function of detecting atrial activity. Instead, it performs the function of converting. It notes that the patent states, "The output of the second sense amplifier 54 is coupled to an analog to digital converter 60 which converts the analog signal representative of the atrial activity of the heart being detected to digital samples ..." '219 Patent at 5:39-43. According to Guidant, at the time of conversion, the sense amplifier has already detected the atrial activity and the converter is merely converting the analog signal into a digital signal.

The Court concludes that the corresponding structure which performs the function of detecting atrial activity of the heart includes a sense amplifier, a lead, electrodes, and an analog-to-digital converter.

As explained above in Part IV(B)(1)(b)(ii), the Court concludes that the lead and electrodes perform the function of detecting heart activity, but that the placement of the lead and electrodes is not a necessary part of the corresponding structure. The patent notes that electrodes 44 and 46 "provide bi-polar sensing of heart activity in the atria." '219 Patent at 5:7-9. Additionally, the patent states: "The second sense amplifier 54 forms a second detecting means which, together with the first electrode 44 and second electrode 46 of the second lead 36 to which it is couple[d] detects atrial activity of the heart." '219 Patent at 5:30-34.

Additionally, the Court concludes that the analog-to-digital converter performs part of the function of detecting, because converting the analog signal to a usable digital samples is an integral part of "discover[ing] or determin[ing] the existence, presence, or fact of" atrial activity. *See* id. at 5:40-44.

Thus, the Court concludes that the proper interpretation of the Second Element of Claim 1 is

A sense amplifier, an analog-to-digital converter, a lead, and electrodes (or equivalent structure) for performing the function of detecting atrial activity. "Atrial activity" refers to electrical events that occur in the atria.

d. Third Element

The Third Element of Claim 1 is an "atrial fibrillation detecting means responsive to said second detecting means for determining when the atria of the heart are in need of cardioversion ." This is a means-plus-function claim. The Parties agree that the function is determining when the atria are in need of cardioversion (i.e., are in atrial fibrillation) using the detected atrial activity. The Parties disagree on whether the corresponding structure must include a specific algorithm.

Medtronic argues that although 35 U.S.C. s. 112, para. 6, allows an inventor to avoid reciting structure in a means-plus-function claim itself, the statute does not allow the inventor to avoid describing specific structure altogether. *See* Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1381-82 (Fed.Cir.1999). If the inventor drafts the claim as a means-plus-function claim, the specification must provide the structure. "In a means-plus-function claim in which the disclosed structure is a computer, or microprocessor,

programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1362 (Fed.Cir.2003) (quoting WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 134849 (Fed.Cir.1999)). Thus, Medtronic asserts, the Court must determine the precise algorithm that is part of a recited structure that includes a microprocessor or computer program.

Medtronic further notes that the specification makes no disclosure as to what algorithm is to be used by the atrial fibrillation detector, other than references to co-pending applications that became U.S. Patent Nos. 5,282,837 (" '837 Patent") and 5,433,729 (" '729 Patent"). *See* '219 Patent, 5:45-50. The '837 and '729 Patents contain references to articles related to detection algorithms. The '837 Patent states:

There are many algorithms known in the art for processing such data to determine if fibrillation is present. One such algorithm is disclosed in a paper: Nitish V. Thakor, Yi-Sheng Zhu, and Kong-Yan Pan, "Ventricular Tachycardia and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm," IEEE Transactions on Biomedical Engineering, Vol. 37, No. 9, pp. 837-843, September, 1990.

'837 Patent at 10:45-51.

The '729 Patent states:

There are many algorithms known in the art for processing such data to determine if fibrillation is present. One such algorithm is disclosed in [the Thakor article]. Another such algorithm is disclosed in a paper: Janice Jenkins, Ki Hong Noh, Alain Guezennec, Thomas Bump, and Robert Arzbaecher, "Diagnosis of Atrial Fibrillation Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms," PACE, Vol. 11, pp. 622-631, May 1988.

'729 Patent at 10:13-24.

Medtronic asserts that the articles referenced in the '837 and '729 Patents ("Thakor and Jenkins articles") constitute corresponding structure in that they define the algorithms to be used by the atrial fibrillation detector of the microprocessor. While a patentee may not incorporate essential material, such as the corresponding structure, by reference to the substance of an article, a patentee can incorporate another United States patent or patent application and can rely on information disclosed by the title of an article stated in the patent. (Medtronic notes that at a later time it may argue that the '219 Patent is too vague to be valid, but at this point it simply argues that the algorithm is found in the articles.)

Guidant contends that the atrial fibrillation detector is described as a "functional stage" implemented by the microprocessor, and that one of skill in the art would understand this to mean that an atrial fibrillation detection algorithm is implemented by the microprocessor. '219 Patent at 5:51-57. Thus, Guidant contends that the specific details of the detection algorithm need not be explicitly described in the patent if such algorithms are known to one of skill in the art. For support, Guidant cites to a series of cases addressing whether a patent is invalid based on indefiniteness for the proposition that the law permits a generic disclosure of corresponding structure when the specific implementations are known to those in the art. *See, e.g.,* Intel Corp. v. VIA Tech., Inc., 319 F.3d 1357, 1367 (Fed.Cir.2003); S3, Inc. v. NVIDIA Corp., 259 F.3d 1364, 1371 (Fed.Cir.2001); Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1380 (Fed.Cir.1999).

While Guidant's proposition is generally true, "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1362 (Fed.Cir.2003) (quoting WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1348-49 (Fed.Cir.1999)).

The Court finds that the corresponding structure which performs the function of determining when the atria are in need of cardioversion using the detected atrial activity includes a microprocessor programmed to determine when the atria are in fibrillation. The Court agrees with Medtronic that a determination must be made as to the scope of the algorithms included as structure, and finds that the cited titles of the Thakor and Jenkins articles delimit the algorithms which comprise corresponding structure. *See* Tehrani, 331 F.3d at 1362.

The Federal Circuit recognizes that the opportunity to forgo identification of all structures in a means-plus-function claim is offset by the requirement that some structure be identified in the accompanying specification. WMS Gaming, 184 F.3d at 1348. Allowing the instant claim to include all possible algorithms which could be programmed into the microprocessor would expand the claim to cover an untenable number of algorithms. *See id.*

The Federal Circuit holds that corresponding structure may not be limited to details found in articles incorporated by reference, but that the structure may be found in the quoted titles of those articles if the "title alone [i]s sufficient to indicate to one skilled in the art the precise structure of the means recited in the specification." Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374, 1382 (Fed.Cir.1999). Additionally, when more than one algorithm is disclosed, the device does not need to perform every disclosed algorithm. Creo Prods., Inc. v. Presstek, Inc., 305 F.3d 1337, 1345 (Fed.Cir.2002)

Therefore, the Court concludes that the proper interpretation of "atrial fibrillation detecting means responsive to said second detecting means for determining when the atria of the heart are in need of cardioversion" is as follows:

A microprocessor programmed with one of the algorithms disclosed in Nitish V. Thakor, Yi-Sheng Zhu, and Kong-Yan Pan, Ventricular Tachycardia *and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm,* 37(9) IEEE Transactions on Biomedical Engineering, 837 (Sept.1990); and Janice Jenkins et al., *Diagnosis of* Atrial Fibrillation *Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms,* 11 PACE 622 (May 1988) (or equivalent structure), to use information derived from electrical events detected by the second detecting means, performing the function of determining whether the atria are in need of cardioversion (i.e. are in atrial fibrillation).

e. Fourth Element

The Fourth Element of Claim 1 is a "cardioverting means for applying said cardioverting electrical energy to the atria of the heart when the atria of the heart are in need of cardioversion and when the time between immediately successive ventricular activations is greater than a preselected minimum time interval."

The Parties agree that the function in this means-plus-function element is applying a cardioverting shock to the atria when the atria are in need of cardioversion and when the time between immediately successive ventricular activations is greater than a preselected minimum time interval. The Parties dispute what it

means to apply cardioverting shock "to the atria" and what components constitute the corresponding structure.

i. "To the Atria"

Medtronic asserts that the cardioverting energy must be substantially confined to the atria, and that any cardioverting energy passing through the ventricles must be minimized or reduced. Guidant asserts that cardioverting energy may pass through the ventricles and other anatomy when applying cardioverting energy to the atria without departing from the claim.

Medtronic focuses its argument on how the cardioverting energy is applied to the atria, contending that the patent revolves around a "unique shocking vector." It argues that "to the atria" means that cardioverting energy is applied directly to the atria, rather than traveling through other tissue before reaching the atria. (Medtronic asserts that the ordinary meaning of "to the atria" might result in an absurd meaning, so it argues that the energy must be "substantially" confined to the atria.)

Medtronic asserts that because the '219 Patent, and all of the patents in the case, describe devices that do not have the ability to detect or shock the ventricles, the focus of the inventions is the prevention of ventricular fibrillation. Medtronic argues that the patents demonstrate that ventricular fibrillation is avoided by reducing "the amount of the electrical energy which is passed through the ventricles during cardioversion of the atria," and by placing electrodes so that the electrical shock is substantially confined to the atria. '219 Patent at 2:22-32, 5:12-19; '836 Patent at 2:23-34, 5:50-57; '600 Patent at 2:25-36, 5:45-52.

Guidant focuses on the term "to apply" found in the claim to support is argument regarding the term "to." The element describes a "cardioverting means for applying said cardioverting electrical energy to the atria." It argues that the ordinary meaning of the term "to apply" means "to bring into action." *Webster's Ninth New Collegiate Dictionary* 97 (1990). It asserts that "to" is "used as a function word to indicate movement or an action or condition suggestive of movement toward a place, person, or thing reached." Id. at 1238. Thus, Guidant contends that a correct interpretation requires that the cardioverting energy is brought into action and directed toward the atria.

Guidant emphasizes that the element uses the term "when" and notes that the U.S. Patent Office recognized that the "when" clause is the principal contribution of the inventions claimed in the '219 Patent. The Patent Office found, "There is no teaching in the prior art of record for supplying cardioverting means which, when necessary, cardiovert the atria when the time between immediately successive ventricular activations is greater than a preselected minimum time interval." Notice of Allowability, at 2, Guidant Exh. 49.

Guidant also notes that the '219 Patent uses the term "applying cardioverting electrical energy to the atria" when describing an alternative embodiment: the use of an invention with an external electrode system that passes as much energy through the ventricles as it does through the atria. '219 Patent at 8:35-43. During transthoracic defibrillation in humans, only four percent of the transthoracic current actually transverses the heart. *See* Bruce B. Lerman & O. Carlton Deale, *Relation Between Transcardiac and Transthoracic Current During* Defibrillation *in Humans,* 67(6) Circulation Research 1420 (Dec.1990). Thus, Medtronic's interpretation of the element is inconsistent with the specification.

The Court first examines the explicitly recited function, and then searches for the structure in the specification that is necessary to perform that function. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314,

1330 (Fed.Cir.2003). As a starting point, the Court must determine the ordinary meaning of the claim terms. Medtronic does not provide the Court with definitions for the words "apply" and "to." However, the Court determines that Guidant's proffered dictionary provides a definition for the word "to" that seems in concert with Medtronic's interpretation of that word.

The Court can find nothing in the specification or claim language that counsels against adopting the ordinary meaning of the word "applying." In this case, the Court finds that the definition which best fits the claim is "to bring into action."

The Court agrees with Guidant that the definition of "applying ... cardioverting energy to the atria" means that energy is directed toward the atria. Medtronic improperly imports limitations from the preferred embodiment to come to its conclusion that cardioverting energy must go only to the atria. The claim does not include any language which limits the application of energy only to energy applied *directly* to the atria. Moreover, the claim also does not say that energy is to be applied *only* to the atria, or that energy must *not* be applied to the ventricles. The fact that the preferred embodiment places the electrodes in such a way so as to limit the flow of electricity to the ventricles is not dispositive. This invention teaches technology having the unique feature of timing the cardioversion. *See* '219 Patent at 2:66-3:4 (stating that the invention reduces the risk of inducing ventricular fibrillation by "interval timing prior to applying the cardioverting or defibrillating electrical energy"). Moreover, it is improper to limit claim construction based on the "perceived 'purpose" of the invention. Rather, the Court should "interpret claims according to their plain language unless the patentee has chosen to be his own lexicographer in the specification or has clearly disclaimed coverage during prosecution." E-Pass Tech., Inc. v. 3COM Corp., 343 F.3d 1364, 1370 (Fed.Cir.2003).

While the preferred embodiment states that the electrodes are placed so as to "substantially confine" the cardioverting energy to the atria, that placement is not what is explicitly claimed in the claim language. To require such a limitation would be to improperly import limitations that are not in the claim. *See* Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1362-63 (Fed.Cir.2003) (holding that the lower court improperly imported a limitation from the specification when it interpreted a claim to describe "automatic measuring" when the claim only stated "measuring").

The Court notes that its finding is consistent with Federal Circuit precedent. In interpreting a patent in which liquid had to flow "to" the second pumping means, the Federal Circuit held that "the 'to' limitation requires only that the liquid move from the filter 'in a pathway with a destination of the second pumping means' and does not preclude the fluid from passing through intervening components." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1458-59 (Fed.Cir.1998). Thus, "to the atria" means that the electric shock must be directed toward the destination of the atria, but that the electric shock may pass through the ventricles on its way toward the atria.

ii. Structure: Lead and Electrodes

The structure associated with this claim is a "cardioverting means." Medtronic argues that leads and the precise placement of the leads and electrodes are structure which is clearly linked to the function. It asserts that if the electrodes and lead were not present, no cardioverting electrical energy would reach the atria. Thus, they must be part of the corresponding structure. *See* '219 Patent at 5:9-11 ("The first electrode 44 together with the second electrode 46 further provide for the delivery of defibrillating electrical energy to the atria."). (Medtronic asserts that the same argument applies to the all of the patents. *See* '519 Patent at

3:38-41; '836 Patent at 5:47-49; '600 Patent at 5:42-44; '641 Patent, 4:66-5:2; '569 Patent at 3:32-34; and '687 Patent at 3:66-4:2.)

Medtronic asserts that under its ordinary meaning, "applying" must include the electrodes placed to deliver energy "to the atria," because the specification states: "The first electrode 44 and the second electrode 46 further provide for the delivery of defibrillating electrical energy to the atria." '219 Patent at 5:9-11.

Guidant argues that Medtronic cannot identify anything in the intrinsic record of the '219 Patent that associates the electrodes to the function of "applying." Instead, Guidant asserts that the lead and electrodes are associated with the function of "delivering ." '219 Patent at 5:9-11 ("The first electrode 44 and the second electrode 46 further provide for the delivery of defibrillating electrical energy to the atria.").

The Court concludes that the lead and electrodes are clearly identified as structure associated with the function of applying cardioverting electrical energy to the atria. Under the Court's definition of the phrase "applying said cardioverting electrical energy to the atria," this element's function requires directing an electric shock toward the atria of the heart, with the atria as the destination of that shock. Thus, delivering the shock to the atria is part of the function of applying-the shock is directed toward the atria by traveling over the lead and through the electrodes.

Additionally, the specification states that "to provide a controlled discharge output of electrical energy when required to the atria of the heart ... the discharge circuit 76 is coupled to the first electrode 44 and the second electrode 46 of the lead 36 for applying the cardioverting or defibrillating electrical energy to the atria." Id. at 6:38-43. Thus, the Court agrees with Medtronic that the electrodes and lead are part of the structure associated with this claim.

The Court does not agree, however, that the location of the electrodes as described in the preferred embodiment is required by the claim. Medtronic asserts that the placement of the electrodes is important in order to avoid sending electrical energy to the ventricles and to insure that the electrodes sense all electrical signals that could be detected in the atria. Based on the Court's earlier interpretation of "to the atria" and "atrial activity," Medtronic's argument fails.

The Court concludes that the corresponding structure which performs the function of applying cardioverting energy to the atria consists of a charger and storage capacitor circuit, a discharge circuit, lead, electrodes, and a microprocessor programmed to perform the function of causing the discharge circuit and storage capacitor to pass an electric shock toward the atria. The Court also concludes that the corresponding structure to the function of determining when the time between immediately successive ventricular activations is greater than a preselected minimum time interval consists of a microprocessor which is programmed to determine that the time between two consecutive R waves (the R-R interval) is greater than a preselected minimum R-R time interval.

Thus, the correct interpretation of the Fourth Element of Claim is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of causing the discharge circuit and storage capacitor circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm when the microprocessor determines that the time between two consecutive R waves (the R-R interval) is greater than a preselected minimum R-R time interval.

C. U.S. Patent No. 5,282,836 (" '836 Patent")

The '836 Patent relates to an atrial defibrillator and method for providing pre-cardioversion pacing. It provides a method of stabilizing the heart rate of a heart in atrial fibrillation by pacing the ventricles at a steady rate before the device cardioverts the atria. Guidant has asserted ten claims from the '836 Patent against Medtronic. The Parties addressed Claim 1, a means-plus-function claim, as the representative claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator for providing cardioverting electrical energy to the atria of a human heart in need of cardioversion, said atrial defibrillator comprising."

This language is identical to the language in the Preamble to Claim 1 of the '219 Patent, and the Parties agree that it should be interpreted in the same manner. Accordingly, the Court concludes that the correct interpretation of the Preamble of Claim 1 is

A device that may be implanted in a patient to treat atrial fibrillation by directing an electric shock toward the atria of the heart in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "first detecting means for detecting atrial activity of the heart." This element is almost identical to the "second detecting means" element of Claim 1 of the '219 Patent, and the Parties proffer the same arguments regarding the interpretation of this claim. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(c) applies to this element as well. Accordingly, the Court concludes that the correct interpretation of the First Element of Claim 1 is

A sense amplifier, an analog-to-digital converter, a lead, and electrodes (or equivalent structure) for performing the function of detecting atrial activity. "Atrial activity" refers to electrical events that occur in the atria.

c. Second Element

The Second Element of Claim 1 is an "atrial fibrillation detecting means responsive to said first detecting means for determining when the atria of the heart are in need of cardioversion ." This element is almost identical to the Third Element of Claim 1 of the '219 Patent, and the Parties proffer the same arguments regarding the interpretation of this claim. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(d) applies to this element as well.

Accordingly, the Court concludes that the correct interpretation of the Second Element of Claim 1 is

A microprocessor programmed with one of the algorithms disclosed in Nitish V. Thakor, Yi-Sheng Zhu,

and Kong-Yan Pan, Ventricular Tachycardia *and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm,* 37(9) IEEE Transactions on Biomedical Engineering, 837 (Sept.1990); and Janice Jenkins et al., *Diagnosis of* Atrial Fibrillation *Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms,* 11 PACE 622 (May 1988) (or equivalent structure), to use information derived from electrical events detected by the first detecting means, performing the function of determining whether the atria are in need of cardioversion (i.e. are in atrial fibrillation).

d. Third Element

The Third Element of Claim 1 is a "stabilizing means responsive to said atrial fibrillation detecting means for stabilizing the cardiac rate of the heart when the atria of the heart are in need of cardioversion." This is a means-plus-function claim. The function is stabilizing the cardiac rate of the heart when the atria of the heart are in need of cardioversion.

i. "Stabilizing the Cardiac Rate"

The Parties agree that "stabilizing the cardiac rate" means "establishing a steady ventricular cardiac rate." The ordinary meaning of stabilize is "to hold steady: as ... to limit fluctuations of." *Webster's Ninth New Collegiate Dictionary* 1146 (1990). However, Medtronic goes on to argue that this term also means that the steady ventricular rate must be "impervious to perturbations." At the *Markman* hearing, Medtronic argued that its interpretation of "stablizing" was consistent with Guidant's interpretation. Tr. at 178:18-19. However, Medtronic's proffered construction would require that fluctuations be totally eliminated. "Eliminate" is not the same as "limit." Guidant's interpretation better reflects the true meaning of this element. Thus, the element requires that fluctuations are limited, not that they are eliminated.

ii. Structure

The Parties also dispute what structure corresponds to the function of stabilizing the cardiac rate of the heart when the atria of the heart are in need of cardioversion. They agree that the structure associated with the stabilizing means includes at least a pacing output circuit.

Medtronic argues that the structure consists of "the pacer output circuit 78 together with the timer 64, average rate stage 66 and counter 63." It further argues that if there is a microprocessor base in a means-plus-function claim, then the corresponding structure is limited to the specific algorithm disclosed for meeting the function of the claim, in this case, the specific algorithms disclosed for establishing a steady cardiac rate.

The patent states the following:

[T]he pacer output circuit 78 together with the timer 64, average rate stage 66 and counter 68 form a cardiac rate stabilizer 63 for stabilizing the cardiac rate of the heart when the atria are in need of cardioversion and before cardioverting electrical energy is applied to the atria.

'836 Patent at 7:21-26. Medtronic asserts that this portion of the patent indicates that the average rate stage is part of the structure associated with the stabilizing means.

Guidant argues that the "average rate stage" is not necessary for performing the function of stabilizing because the pacing rate may be a programmed rate rather than an average rate, and therefore, the average

rate stage is not necessary corresponding structure for the stabilizing means.

To support its argument that an average rate stage is not required, Guidant cites the portion of the specification which states that "[t]he cardiac rate in which the ventricles are paced ... may be the average rate in the absence of pacing, or a programmed rate, or another calculated rate." '836 Patent at 10:21-24. Thus, according to Guidant, the patent clearly allows for alternative methods for setting the stabilizing rate, and the "average rate stage" is not necessary structure.

The Court agrees with Guidant that the "average rate stage" is not necessary structure. While it is true that an average rate stage is identified as structure in the preferred embodiments, the Court finds that it is improper to limit the structure to require the inclusion of an average rate stage. The portion of the specification cited by Guidant supports this conclusion. The "average cardiac rate in the absence of pacing." '836 Patent at 10:22-23, refers to the "average rate stage" described in the preferred embodiments. The "preprogrammed rate, or another calculated rate" cited by Guidant refers to other ways in which stabilizing can be achieved. The patent clearly identifies alternative methods of setting the pacing rate. The schematic drawings accompanying the patent merely state: "determine pacing rate." *See* '836 Patent, figs. 2-4. Neither the drawings nor the specification state that the rate must be determined by the average rate stage. While the average rate stage is the focus of the preferred embodiments, neither the claim nor the specification state that the determination of the pacing rate must be made by using the average rate stage. In fact, the specification states that an appropriate pacing rate may be a rate that corresponds to the average cardiac rate, not that it must be such a rate. *See* id. at 7:65-67.

The unique feature of this patent is the ability to stabilize the heart through pacing the ventricles before applying the cardioverting shock. The specification states that this can be achieved by one of three methods. It would be improper to import the limitation that the stabilizing means must include an average rate stage. *See* Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1258-59 (Fed.Cir.1999) (finding that when multiple embodiments in the specification correspond to the claimed function, it is improper to limit the claim element, and that the claim should be read to "embrace each of those embodiments").

Thus, the Court finds that the structure associated with the function of stabilizing the cardiac rate of the heart when the atria of the heart are in need of cardioversion includes a microprocessor programmed either to a certain cardiac rate, or to determine the average cardiac rate, and a pacer output circuit.

Thus, the correct interpretation of the Third Element of Claim 1 is

A pacer output circuit and a microprocessor programmed either to a certain cardiac rate, or to determine the average cardiac rate, and a pacer output circuit (or equivalent structure) for performing the function of establishing a steady cardiac rate in the ventricles after detecting atrial fibrillation.

e. Fourth Element

The Fourth Element of Claim 1 is a "cardioverting means for applying the cardioverting electrical energy to the atria of the heart after said stabilizing means has stabilized the cardiac rate for a predetermined number of cardiac cycles." This is a means-plus-function claim. The function is applying the cardioverting electrical energy to the atria of the heart after said stabilizing means has stabilized the cardiac rate for a predetermined number of cardiac cycles. The Parties agree that "cardioverting means" and "to the atria" should be interpreted in the same way as they were in Claim 1 of the '219 Patent.

The patentee has acted as its own lexicographer regarding the term "cardiac cycle." The patent states, "As used herein, the term 'cardiac cycle' denotes the period of heart activity which begins with each ventricular activation (R wave) of the heart." '836 Patent at 4:61-63. At the *Markman* hearing, Medtronic noted that the definition does not state when a cardiac cycle ends, and stated that "for purposes of this argument, we will assume that where one cycle starts, the previous cycle ends. So, R wave to R wave is a single cardiac cycle ..." Tr. at 174:4-6. Guidant does not take issue with this interpretation. Thus, the Court concludes that a "cardiac cycle" runs from the beginning of one R wave to the beginning of the next R wave.

i. "Predetermined Number of Cardiac Cycles"

The crux of the Parties' dispute regarding this element is the meaning of the term "predetermined number of cardiac cycles." Specifically, Medtronic argues that the ordinary meaning of the word "cycles" and the specification support an interpretation requiring more than one cardiac cycle. Guidant, on the other hand, proffers a definition in which "cardiac cycles" encompasses both the singular and the plural of the word "cycle." Guidant argues that under the rules of grammar, a plural noun may refer to a set that includes only one item. For support, Guidant relies on Astra Aktiebolag v. Andrx Pharm., Inc., 222 F.Supp.2d 423, 469 (S.D.N.Y.2002).

The plural form of a word "pertain[s] to more than one." *The Random House College Dictionary* 1022 (rev. ed.1982). Thus, the ordinary meaning of the word "cycles" means more than one cycle. At the *Markman* hearing, Guidant argued: "Just as it is appropriate to say 'one or more apples' and grammatically incorrect to say 'one or more apple,' it would have been incorrect for the claim to recite 'a predetermined number of cardiac cycle." ' Guidant Exh. 67 at GR08.14. Guidant's argument is misplaced. The claim does not state "one or more cardiac cycles." Had the claim included that language, there would be no question that the claim was intended to include the singular.

The Court finds that the instant patent can be distinguished from the patents at issue in *Astra,* the case relied upon by Guidant, because the *Astra* patents stated that the inventions required "one or more layers of materials," and "one or more layers comprising materials." Astra, 222 F.Supp.2d at 469. The *Astra* court found that even though the term "materials" was used, the patents were clearly intended to include the singular, and that the plural form was merely used to "comply with grammatical correctness." *Id*. This is not the case with the '836 Patent: the patentee did not state "one or more cardiac cycles." Therefore, unless the specification clearly indicates that "cardiac cycles" was intended to include the singular, the ordinary meaning will control.

As discussed above, the specification includes three different preferred embodiments. All the embodiments state that pacing is conducted for "consecutive" cardiac cycles. *See* '836 Patent, 8:35-36; 9 :5-6, 29. The term "consecutive" implies that pacing for more than one cardiac cycle is required for stabilizing the cardiac rate of the heart before shock. The Court is aware that it may not limit the claim language by importing limitations from the specification. *See* Tex. Digital Sys., Inc. v. Telegenix. Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002). The Court merely cites this specification language to demonstrate that in the context of the patent, the ordinary meaning of the word "cycles" makes sense. *See* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998).

Guidant also argues that the use of the open variable "N" in figures two through four of the patent indicates that any number of cardiac cycles may be chosen, including one. The Court agrees with Guidant that "N" is

an open ended variable, and that "N" does not necessarily imply that any certain number of cardiac cycles must be employed. However, the Court does not agree that in the context of this patent, "N" can represent only one. The ordinary meaning of the "cycles" precludes that interpretation, and the intrinsic evidence supports this ordinary meaning.

ii. Structure

The Parties agree that the structure associated with this claim includes at least a charger and storage capacitor circuit, a discharge circuit, and a microprocessor. Medtronic argues that the electrodes should also be included as structure. *See* '836 Patent 5 :47-49 (stating that electrodes 44 and 46 "provide for the delivery of defibrillating electrical energy to the atria"). For the reasons explained in the discussion regarding the Fourth Element of Claim 1 of the '219 Patent. Section IV(B)(1)(e), the Court concludes that the lead and electrodes are part of the corresponding structure. *See also* '836 Patent at 7:12-15 ("The discharge circuit 76 is coupled to the first electrode 44 and the second electrode 46 of the second lead 36. This permits the application of the cardioverting or defibrillating electrical energy to the atria.")

Thus, the correct interpretation of Fourth Element of Claim 1 is

A charger and storage capacitor circuit, a discharge circuit, lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of causing the discharge circuit and storage capacitor circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm after the 'stabilizing means' has established a steady cardiac rate in the ventricles by pacing the ventricles for a preselected number, greater than one, of cardiac cycles, the number of cardiac cycles being set at before the shock is given. A 'cardiac cycle' as defined in the specification denotes 'the period of heart activity which begins with each ventricular activation (R-wave) of the heart. Each ventricular activation signals the beginning of one cardiac cycle and the end of the preceding cycle.

D. U.S. Patent No. 5,265,600 (" '600 Patent")

The '600 Patent relates to an atrial defibrillator and method for providing post-cardioversion pacing: pacing to lower the ventricular rate after the cardioverting shock. Guidant has asserted eight claims from the '600 Patent against Medtronic. The representative claim addressed by the Parties is Claim 1, a means-plus-function claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator for applying cardioverting electrical energy to the atria of a human heart in need of cardioversion and thereafter gradually returning the cardiac rate of the heart to a normal cardiac rate, said atrial defibrillator comprising." Both parties agree the preamble should be interpreted in a manner similar to the preamble to Claim 1 of the '219 Patent, and rely on the same arguments. For the "gradually returning" language, Guidant directs the Court to its argument regarding the Fourth Element of Claim 1 of the '600 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(a) and Part IV(D)(1)(e) applies to this element.

Thus, the Court concludes that the correct interpretation of the Preamble to Claim 1 is

A device that may be implanted in a patient to treat atrial fibrillation by directing an electric shock toward the atria of the heart in order to restore the atria to a normal rhythm. After the electric shock, the device paces the ventricles to gradually return the heart rate to a preselected lower rate. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "first detecting means for detecting atrial activity of the heart." The Parties agree that this element should be interpreted in the same way as similar language found in the Second Element of Claim 1 of the '219 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(c) applies to this element as well.

Thus, the correct interpretation of the First Element of Claim 1 is

A sense amplifier, an analog-to-digital converter, a lead, and electrodes (or equivalent structure) for performing the function of detecting atrial activity. "Atrial activity" refers to electrical events that occur in the atria.

c. Second Element

The Second Element of Claim 1 is an "atrial defibrillation detecting means, responsive to said first detecting means, for determining when the atria of the heart are in need of cardioversion ." The Parties agree that this claim contains a typographical error. The claim should describe an atrial fibrillation detecting means, not a defibrillation detecting means. The Parties agree that this element should be interpreted in the same way as similar language was interpreted in the Third Element of Claim 1 of the '219 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(d) applies to this element as well.

Thus, the correct interpretation of the Second Element of Claim 1 is

A microprocessor programmed with one of the algorithms disclosed in Nitish V. Thakor, Yi-Sheng Zhu, and Kong-Yan Pan, Ventricular Tachycardia *and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm,* 37(9) IEEE Transactions on Biomedical Engineering, 837 (Sept.1990); and Janice Jenkins et al., *Diagnosis of* Atrial Fibrillation *Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms,* 11 PACE 622 (May 1988) (or equivalent structure), to use information derived from electrical events detected by the first detecting means, performing the function of determining whether the atria are in need of cardioversion (i.e. are in atrial fibrillation).

d. Third Element

The Third Element of Claim 1 is a "cardioverting means responsive to said atrial fibrillation detecting means for applying the cardioverting electrical energy to the atria of the heart when the atria are in need of cardioversion." The Parties agree that terms from this element should be interpreted in the same way as similar terms from the Fourth Element of Claim 1 of the '219 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(e) applies to this element as well. For the reasons explained in the

discussion regarding the Fourth Element of Claim 1 of the '219 Patent, the Court concludes that the lead and electrodes are part of the corresponding structure. *See also* '600 Patent at 5:42-44 ("The first electrode 44 and the second electrode 46 further provide for the delivery of defibrillating electrical energy to the atria."); 7:9-12 ("The discharge circuit 76 is coupled to the first electrode 44 and the second electrode 46 of the second lead 36. This permits the application of the cardioverting or defibrillating electrical energy to the atria.")

Thus, the correct interpretation of the Third Element of Claim 1 is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of causing the discharge circuit and storage capacitor circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm when the heart is in atrial fibrillation.

e. Fourth Element

The Fourth Element of Claim 1 is a "pacing means for pacing the ventricles of the heart at a controlled decreasing rate from a base rate to a final rate lower than said base rate after said cardioverting means applies said cardioverting electrical energy to the atria of the heart." This is a means-plus-function element. The function is pacing the ventricles of the heart at a controlled decreasing rate from a base rate to a final rate lower than said base rate after said cardioverting means applies said cardioverting electrical energy to the atria of the heart. The Parties dispute the meaning of the terms "base rate" and "after." The Parties also dispute what structure corresponds to this pacing means.

i. "Base Rate"

The Parties agree that the term "base rate" does not have an ordinary meaning. Medtronic asserts that the base rate is calculated according to the preshock rate, whereas Guidant argues that the rate may be calculated or it may be programmed.

The Parties agree that "base rate" is the rate at which the first post-shock pacing pulse is delivered, which is a rate greater than the final lower rate, and is the rate from which the controlled decrease in pacing occurs. Medtronic Exh. 40; Tr. 214:1-10. The Parties disagree about how the base rate number is derived. Medtronic asserts that "base rate" is defined as any rate higher than the normal heart rate, determined as a function of the heart rate prior to cardioversion. It asserts that only under its definition would the device appropriately respond to a sudden reduction in cardiac rate.

Guidant argues that under Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1372 (Fed.Cir.2003), it is appropriate to parse out the words of the term to arrive at an ordinary meaning. In doing so, Guidant argues that "base" means "the starting point or line for an action or undertaking." *Webster's Ninth New Collegiate Dictionary* 133 (1990). The Parties agree that the ordinary meaning of "rate" is "pacing rate." Thus, Guidant argues that "base rate" means the rate at which ventricular pacing starts, which is higher than a preselected lower rate where the pacing ends up.

Guidant asserts that Claim 1 does not state that the base rate is a determined or calculated value, as opposed to a programmed value. The claim does not mention the calculation or determination of the base rate.

As Guidant notes, although overcoming the "sudden reduction in cardiac rate" that may result from applying

cardioverting electrical energy to the atria is an advantage of the invention, "[a]dvantages described in the body of the specification, if not included in the claims, are not per se limitations to the claimed invention." Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1301 (Fed.Cir.2003) (citation omitted).

The Court agrees with Guidant The claim refers only to a "base rate," not a method for determining the base rate. For support, Medtronic cites to the referred embodiment of the '600 Patent. The Court will not rely on these portions of the specification because it is inappropriate to import limitations from the preferred embodiment into claim construction. *See* Tex, Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002). Medtronic also cites to the background portion of the specification and the prosecution history to support its argument that it proffered interpretation of "base rate" is consistent with the perceived purpose of the claimed invention which is to avoid the problems associated with a sudden reduction in cardiac rate following successful cardioversion or defibrillation. The Court should not limit its claim construction based on the perceived purpose of the invention. *See* E-Pass Techs., Inc. v. 3COM Corp ., 343 F.3d 1364, 1370 (Fed.Cir.2003). Therefore, Medtronic's proposed limits will not be included in the Court's claim construction.

Thus, the proper interpretation of "base rate" is the rate at which ventricular pacing starts. The rate is higher than a preselected lower rate.

ii. "After"

The Fourth Element of Claim 1 is a "pacing means for pacing the ventricles of the heart at a controlled decreasing rate from a base rate to a final rate lower than said base rate *after* said cardioverting means applies said cardioverting electrical energy to the atria of the heart." (emphasis added).

Medtronic argues that the ordinary meaning of "after" is "subsequent in time," which is an "unbounded term." It argues that the term must be bounded, otherwise the pacing could begin days after the cardioversion. Thus, the ordinary meaning of the term "after" cannot be used. *See* Combined Sys., Inc. v. Defense Tech. Corp. of America, 350 F.3d 1207, 1215 (Fed.Cir.2003) (noting that it is incorrect to rely exclusively on a dictionary definition or to allow a dictionary definition to overcome the clear language of the patent). Instead, Medtronic asserts that "after" means that the pacing must be initiated in time to avoid a sudden reduction in cardiac rate after shocking the atria.

To support its definition, Medtronic relies on the perceived purpose of the patent: preventing a sudden reduction in cardiac rate. It relies on the prosecution history of the '600 Patent in which the patentees explained how the invention differed from the prior art:

None of the cited references describe or suggest in any way the adverse effects of such a sudden reduction in cardiac rate following successful cardioversion of the atria and hence do not show, describe, or even suggest an implantable atrial defibrillator or method having structure or function for overcoming such a circumstance.

'600 Patent Amendment at 10-11, Medtronic Exh. 12.

Guidant argues that nothing in the patent states that the pacing must be initiated in time sufficient to prevent sudden reduction. In fact, the invention has a purpose other than preventing a sudden reduction in cardiac rate following cardioversion: avoiding bradycardia.

Guidant asserts that although the ordinary meaning of "after" is "following in time or place," *Webster's Ninth New Collegiate Dictionary* 62 (1990), "after" is not an unbounded term as understood by those skilled in the art. It contends in the context of this patent, "after" means that the pacing does not occur until the microprocessor determines that the shock was successful in stopping atrial fibrillation.

The Court agrees with Guidant. The Court cannot rely solely on the ordinary dictionary meaning when that meaning contradicts the patent language. Combined Sys., Inc. v. Defense Tech. Corp. of America, 350 F.3d 1207, 1215 (Fed.Cir.2003). As Guidant notes, when describing the steps that occur to start the pacing, the preferred embodiment indicates that the pacing occurs when the microprocessor determines that the shock was successful in stopping atrial fibrillation. The preferred embodiment states:

When the atrial fibrillation detector 70 determines in step 128 that the cardioversion of the atria was successful in arresting the atrial fibrillation, the microprocessor proceeds to step 134. In step 134, the microprocessor resets and starts timer 64.

At this time, the atrial defibrillator 32 has begun the first post-cardioversion pacing interval which is the aforementioned base interval and the timer is timing the base interval. The next three steps, namely steps 136, 138, and 140 implement a demand mode of pacing of the type well known in the pacing art and more specifically, a VVI pacing mode of the ventricles.

'600 Patent at 8:44-55. *See also* id. fig. 2.

Additionally, in the preferred embodiment, pacing may not occur for eight to fifteen seconds after the cardioverting electrical energy is applied to the atria. The '600 Patent incorporates by reference the algorithms denoted by the Jenkins and Thakor article titles. *See* '600 Patent at 7:34-38; '837 Patent at 10:45-51; '729 Patent at 10:13-24.

Medtronic's construction of the term "after" would not cover the embodiment found in the '600 Patent, because it would exclude embodiments in which pacing occurs after the microprocessor analyzes fifteen seconds worth of data to determine whether the cardioversion shock was successful. *See, e.g.,* Janice Jenkins, et al., *Diagnosis of* Atrial Fibrillation *Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms,* 11 PACE 622, 623-24 (May 1988). Guidant asserts, and Medtronic does not dispute, that if the device waits for fifteen seconds worth of data, it will not begin pacing of the ventricle in time to avoid a sudden reduction in cardiac rate. Medtronic's proposed definition of "after" would exclude the preferred embodiment of the device. "[C]onstruing a claim to exclude a preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support." Invitrogen Corp. v. Biocrest Mfg., 327 F.3d 1364, 1369 (Fed.Cir.2003) (internal quotation omitted). Medtronic does not present such "highly persuasive" evidence. Thus, the Court concludes that "after" means that the pacing occurs when the microprocessor determines that the shock was successful in stopping atrial fibrillation.

iii. Structure

The Parties agree that the structure that corresponds to this pacing means includes at least a pacer and a microprocessor. However, Medtronic asserts that the microprocessor must be limited to the algorithms set forth in the patent, and that a lead is part of the corresponding structure. Medtronic argues that, because the only algorithms set forth in the patent with respect to base rate are algorithms for determining base rate as a

function of the cardiac rate before cardioversion, those algorithms must be part of the structure.

Guidant argues that the corresponding structure for the pacing means is the pacer and the microprocessor programmed to implement that pacing. It asserts that the particular algorithms noted by Medtronic are not part of the structure of the pacing means. Instead, the algorithms are part of the structure of the base interval determining means, used to calculate the base rate in one of the preferred embodiments. However, the algorithms do not perform the function of pacing.

The Court agrees with Guidant. As explained above, the base rate is not necessarily a calculated rate, it may be programmed. Thus, the algorithms used for calculating the rate are not a necessary part of the corresponding structure for this element.

The Court also determines that a lead and electrodes are a necessary part of the corresponding structure because they apply or deliver the pacing shock to the heart, which is part of the function of pacing. '600 Patent at 7:15-18 ("The pacer output circuit 78 is coupled to electrodes 38 and 40 of lead 34 for applying the pacing electrical energy to the right ventricle 12.").

Thus, the correct interpretation of the Fourth Element of Claim 1 is

A pacer output circuit, a lead, electrodes, and a microprocessor (or equivalent structure) for performing the function of pacing the ventricle at a rate that is higher than a preselected lower rate when the microprocessor determines that the shock was successful in stopping atrial fibrillation. The microprocessor is programmed to control the pacing rate by gradually decreasing the pacing rate from the higher rate to the preselected lower rate. Pacing is the delivery of a relatively small amount of stimulating energy to induce a contraction of a heart chamber.

E. U.S. Patent No. 5,549,641 (" '641 Patent")

The '641 Patent relates to an atrial fibrillation type selective cardioverter and method. The patent describes a claimed improvement to existing atrial defibrillators. Guidant has asserted 9 claims from the '641 Patent against Medtronic. The Parties focused on Claim 15 as the representative claim, a means-plus-function claim.

The Parties' main dispute is whether the patent should be construed to only be able to classify two types of atrial fibrillation, as described in the preferred embodiment. The Parties also dispute the meaning of the term "corresponding" therapy. The Parties disagree regarding whether the device must be able to measure cardiac cycle lengths less than 75 milliseconds.

1. Claim 15

a. Preamble

The Preamble to Claim 15 is "[a]n atrial defibrillator comprising:" The Parties agree that the Preamble should be interpreted in line with the identical terms found in the Preamble to the '219 Patent. Thus, the correct interpretation of the Preamble to Claim 15 is

A device for treating atrial fibrillation in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 15 is a "criteria establishing means for providing a respective different criteria for each of different types of atrial fibrillation." This is a means-plus-function element.

The Parties disagree regarding the corresponding structure for the "criteria establishing means." Medtronic argues that, in order to establish structure, the Court should look to the specification. Medtronic asserts that Guidant cannot omit to disclose the structure and then claim that someone of ordinary skill in the art could write any program to satisfy criteria establishing means. According to Medtronic, the only structure identified in the patent as establishing criteria is a memory already programmed to identify Type 1 atrial fibrillation as an atrial rhythm with a cardiac cycle length less than 150 milliseconds but greater than 75 milliseconds and Type 2 atrial fibrillation as an atrial cardiac cycle length of less than 75 milliseconds. '641 Patent at 7:24-31, 7:55-61 8:5-9. Because this is the only program disclosed in the '641 specification, Medtronic argues that it is the only description that satisfies the patent applicant's obligation under 35 U.S.C. s. 112, para. 6.

Both parties agree that the corresponding structure is memory, but, according to Guidant, Medtronic incorrectly includes the specific numerical values of the atrial cardiac cycle length ranges stored in the memory of the preferred embodiment. (Guidant notes that Medtronic states that it is not arguing that the specific numerical values are part of the function of the "criteria establishing means" element, Tr. at 254:24-255:1, thus, for the values to be included, Medtronic must be arguing that they are "corresponding structure." 35 U.S.C. s. 122, para. 6.)

Guidant argues that Medtronic improperly imports the numerical limitations from the preferred embodiment into the claim construction. The Court agrees with Guidant and concludes that because this element would have connoted sufficient structure to one of ordinary skill in the art at the time of the patent, the specific numerical criteria recited in the specification do not need to be imported into the definition of the corresponding structure.

The Court notes that the claim language itself does not provide any numerical limits. Additionally, the specification does not describe the numerical values until after the patentees had "complete[d] the identification of the various structural elements within the [atrial cardioverter/defibrillator]. " '641 Patent at 6:36-54 (completing identification of structural elements); 6:55-65, 7:53-8:18 (describing numerical values). Also, the specification discloses that other criteria, such as measurements using "correlation functions," may be used, '641 Patent 10 :14-18. For example, atrial fibrillation may be classified by cycle lengths or cycle length variability. Finally, Medtronic's claim construction excludes the preferred embodiment, which permits atrial arrhythmia type classification criteria, such as atrial cardiac cycle lengths, to be programmed and changed by a physician. *See* '641 Patent at 6:11-17.

Thus, the correct interpretation of the Second Element of Claim 15 is

Memory (or equivalent structure) for performing the function of providing different criteria for distinguishing different types of disorganized atrial rhythms by using atrial cardiac cycle length, atrial cardiac cycle length and atrial cardiac cycle length variability, correlation functions, or operating parameters programmed by an external controller.

c. Second Element

The Second Element of Claim 15 is "a sensor for sensing activity of at least one of the atria of a heart to provide an electrogram signal." This is not a means-plus-function element, because it recites structure but does not use the means language.

Both Parties agree that the element describes a sensor that senses electrical events of at least one of the atria; however, Medtronic asserts that the sensor must sense "all electrical signals" because, under the doctrine of claim differentiation, Claim 16 must be interpreted more narrowly than Claim 15. Claim 16 describes "[a]n atrial defibrillator as defined in claim 15 wherein said sensor includes means for sensing localized activity of the [sic] at least one of the atria of the heart." Thus, Medtronic asserts that the sensor in Claim 15 must sense more than just localized activity.

Guidant responds that the doctrine of claim differentiation does not mean that the structures disclosed in the specification needed to perform Claim 15 and Claim 16 must be different. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed.Cir.1991) (holding that "a means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure.")

As Guidant notes, Medtronic contradicts the claim language when it requires that the sensor collect *all* of the activity during the atrial cardiac cycle. The specification does not state that the sensor must sense all electrical events in the atria or must collect all electrical signals.

The Court agrees with Guidant and further refers to its analysis of the term "atrial activity" in Part IV(B)(1)(c)(i). Thus, the correct interpretation of the Second Element of Claim 15 is

A device ("sensor") that senses electrical events in at least one of the atria and provides data regarding the electrical events.

d. Third Element

The Third Element of Claim 15 is a "therapy means for providing a corresponding therapy to the heart for each of said different types of atrial fibrillation." This is a means-plus-function element. The Parties disagree regarding whether each corresponding therapy must be different from each other corresponding therapy. They also disagree regarding the corresponding structure.

i. "Corresponding"

Medtronic asserts that a different therapy must be provided for each type of atrial fibrillation for several reasons. It asserts that the first column of the specification teaches away from a "single therapy regimen." '641 Patent 5 :1-67. Medtronic also asserts that, when addressing two claims of the '641 Patent that were never issued, the patentee represented to the United States PTO that "corresponding therapy" carried the same meaning as "different therapy:"

Claims 1 and 34 have been slightly amended to make explicit that which was originally implicit by claim interpretation. More specifically, it is respectfully submitted that claims 5 and 34, when originally read in light of the clear intent of the specification, defined an atrial cardiovertor/ defibrillator and method respectively wherein a different corresponding therapy is provided for atrial flutter and atrial fibrillation.

Nowhere is it even suggested in the instant specification that atrial flutter and atrial fibrillation may be treated with the same therapy. Hence, the inclusion of the word "different" at line 7 of claim 1 and the inclusion of the words "respective different" at line 10 of claim 34 do not add any new limitations to these claims.

Response to Final Rejection at 4-5, Medtronic Exh. 13. Medtronic also notes that the patentee distinguished its invention from prior art by noting that the prior art "*does not teach* a different therapy for each condition." Id. at 5, Medtronic Exh. 13 (emphasis in original).

Medtronic asserts that the above language demonstrates that "corresponding" means providing a different therapy for each different type of atrial fibrillation. It notes that a patentee's statements made during prosecution or reexamination of a patent may create a binding definition for a patent term, and that the definition is relevant to the interpretation of that term in every other claim in the patent. CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1158 (Fed.Cir.1997); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995).

In contrast, Guidant asserts that "corresponding" should be given its ordinary meaning, which does not require that the therapies be different from one another. As Guidant asserts, "different" and "corresponding" have distinct meanings. "Different" means

1: partly or totally unlike in nature, form, or quality: DISSIMILAR <could hardly be more [different]> ... 2: not the same as a: DISTINCT <[different] age groups> b: VARIOUS <[different] members of the class> c: ANOTHER <did not like the TV program so switched to a [different] channel> 3: UNUSUAL, SPECIAL <she was [different] and superior>.

Webster's Ninth New Collegiate Dictionary 353 (1990). "Corresponding" means "having or participating in the same relationship (as kind, degree, position, correspondence, or function) esp. with regard to the same or like wholes ... [or] RELATED, ACCOMPANYING <all rights carry with them [corresponding] responsibilities ... >." *Id*. at 293. Thus, the Court concludes that under the ordinary meaning of "corresponding," while there must be a therapy that corresponds to a particular classified arrhythmia, there is no requirement that each corresponding therapy be different from the others.

This ordinary meaning is not contradicted by the specification or the prosecution history of the patent. The statements from the Response to Final Rejection cited by Medtronic were made with respect to two claims that used the word "different" in describing the therapy provided. Medtronic Exh. 13 at 2-3. These claims were never issued. Significantly, when the cited sentences are put in context, it is apparent that the applicants were not distinguishing between different types therapies for different types of atrial fibrillation. *See* Response to Final Rejection at 4-5, Medtronic Exh. 13. Instead, the applicants were pointing out that, unlike prior art, their patent distinguished between atrial flutter and atrial fibrillation when providing therapy. *Id*. The patentee argued that adding the word "different" to the term "corresponding therapy" did not change the meaning of the term in that case because the corresponding therapy for atrial flutter is different than the corresponding therapy for atrial fibrillation. The patentee did not address whether the corresponding therapies for different types of atrial fibrillation were different from one another. Thus, the patentee's statements do not constitute a clear and unequivocal disavowal of claim scope with respect to therapies for different types of atrial fibrillation. *See, e.g.,* Omega Eng'g, Inc. v. Raytek Corp, 334 F.3d 1314, 1325 (Fed.Cir.2003); Teleflex, Inc. v. Ficosa North America Corp. 299 F.3d 1313, 1327 (Fed.Cir.2002).

Finally, the Court notes that Medtronic's requirement that the therapy means be different and distinct from one another excludes the preferred embodiment, which allows the device to be programmed by the doctor. *See* '641 Patent at 6:11-17.

ii. Structure

The Parties agree that the corresponding structure includes at least a charger and storage capacitor circuit and a discharge circuit. Medtronic alone asserts that particularly placed electrodes and particular numerical ranges for the therapies are also part of the structure, while Guidant alone asserts that a microprocessor is part of the structure.

Medtronic argues that, as in the other patents at issue, the electrodes are used for delivering cardioverting electrical energy to the atria. It also argues that the language is similar to the language used in the '249 patent, in which Guidant admitted that the electrodes were part of the means for applying energy to the atria.

Guidant argues that Medtronic erred in including the electrodes into the corresponding structure, because the electrodes only deliver electrical energy; they do not provide a corresponding therapy. '641 Patent at 4:66-5:2 ("The first electrode 40 together with the second electrode 42 provide for the delivery of cardioverting/defibrillating electrical energy to the atria, in a manner to be described subsequently."). Guidant cites to the following section of the patent as evidence that the electrodes are not part of the necessary structure for applying the therapy: "To apply this therapy, the capacitor of circuit 88 is charged as previously described, and the charge delivery and energy control 65 causes the discharge circuit 90 to discharge the capacitor in timed relation to a sensed R wave, as previously described." Id. at 7:65-8:-2. While it is true that the foregoing sentence does not explicitly mention to the terms "electrodes" or "lead," it does state that the therapy is applied as stated and "*as previously described*." The phrase "as previously described" indicates that the therapy is applied as described in the following sentence: "The discharge circuit 90 discharges the capacitor of circuit 88 for a controlled period of time to provide the application of cardioverting energy to the atria across electrodes 40 and 42 of lead 34." Id. at 7:46-49. As stated in the quoted sentence, and as explained in previous sections of this Opinion, the electrodes and lead are included in the corresponding structure for applying cardioverting energy to the atria. *See* Part IV(B)(1)(e)(ii); *see also* '641 Patent at 6:44-46 ("To that end, the discharge circuit 90 is coupled to electrodes 40 and 42 of the intravascular lead 34 for applying the cardioverting or defibrillating electrical energy to the atria."). Thus, the Court concludes that the lead and electrodes are part of the corresponding structure for this element.

Medtronic also argues that the specific numerical values for corresponding therapies, as provided in the preferred embodiment, are part of the structure. *See* WMS Gaming, Inc. v. Int'l Tech., 184 F.3d 1339, 1349 (Fed.Cir.1999); Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1361-62 (Fed.Cir.2003).

Guidant rejects Medtronic's argument that, because the contents of the memory are "programable," the corresponding structure must include the contents of the memory. The Court agrees with Guidant. The cases cited by Medtronic address the situation in which the corresponding structure was a general purpose microprocessor programmed to execute a novel algorithm. WMS Gaming, Inc. v. Int'l Tech., 184 F.3d 1339, 1349 (Fed.Cir.1999); Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1361-62 (Fed.Cir.2003). In contrast, in this case the structure is memory used to store variable ("programmable") data. Medtronic has not cited a case holding that numerical values stored in electronic memory constitute structure corresponding to a means-plus-function element.

Finally, the microprocessor is part of the corresponding structure. The microprocessor is specified at 5:49-56, and controls the charging delivery of the cardioverting energy.

Thus the correct interpretation of the Third Element of Claim 15 is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of providing a particular type of treatment to the heart for each of the different types of disorganized atrial rhythms.

e. Fourth Element

The Fourth Element of Claim 15 is a "classifying means responsive to said electrogram signal and said criteria establishing means for identifying one of said types of atrial fibrillation and causing said therapy means to provide the therapy to the heart corresponding to said identified one of said types of atrial fibrillation." This is a means-plus-function element. The Parties disagree regarding the term "responsive," and offer the same arguments regarding the inclusion of specific numerical values in the corresponding structure as they did regarding the Third Element of Claim 15 of this patent.

Guidant asserts that Medtronic again improperly limits the claim element to classifying atrial fibrillations have cycle lengths in only two ranges, and improperly states that the atrial defibrillator must be able to detect intervals of less than 75 milliseconds. Additionally, it asserts that Medtronic's decision to specify that the corresponding structure includes the memory is redundant because the establishing means, first element, is the memory. Thus, Medtronic's interpretation requires the memory to be responsive to itself. Guidant also argues that Medtronic's inclusion of the cycle length determining stage and the average cycle length determining stage is unnecessary. Although stages are listed in the preferred embodiment, they are not necessary for performing the classifying function. The specification notes that the invention could use atrial cardiac cycle length, atrial cardiac cycle length variability, or correlation functions. '641 Patent, 10:5-18. It asserts that a correlation function is a comparison of two signals from two locations in the atria, which does not require cycle length or average cycle length in order to use a correlation function.

The Court agrees with Guidant. As explained in the discussion of the First Element of Claim 15 of this patent, because atrial cardiac cycle length is not necessary for performing the function of classifying, the specific numerical values cited by Medtronic are not part of the corresponding structure.

Additionally, the Court concludes that the microprocessor must be part of the corresponding structure because it performs the function of comparing electrical signals from the atria against the criteria data stored in the memory in order to classify a particular atrial arrhythmia and provide corresponding therapy. *See, e.g.,* '641 Patent at 6:66-7:2 ("At predetermined times, determined by the first timer 61, the atrial arrhythmia detector 64 is activated to determine if an atrial arrhythmic episode is occurring in the atria, and to classify the arrhythmia if one is present."). In describing the function of classifying, the patent repeatedly states that the microprocessor interacts with the memory, the criteria establishing means. *See, e.g.,* '641 Patent at 7:14-15, 7:24-25, 7:52-53, 8:3-5.

Thus, the correct interpretation of the Fourth Element of Claim 15 is

An atrial arrhythmia detector of a microprocessor programmed to use the data provided by the sensor

regarding electrical events in the atria and the criteria for distinguishing different types of disorganized atrial rhythms found in the memory (or equivalent structure) to perform the function of distinguishing the types of disorganized atrial fibrillation and causing the related treatment to be provided.

F. U.S. Patent No. 5,441,519 (" '519 Patent")

The '519 Patent relates to an implantable defibrillator having delayed intervention therapy. Guidant has asserted 2 claims from the '519 patent against Medtronic. The Parties have addressed Claim 1 as the representative claim, a means-plus-function claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator for applying cardioverting electrical energy to the atria of a human heart in need of cardioversion, said atrial defibrillator comprising:" The Parties agree that this language should be interpreted in the same manner as the Preamble to Claim 1 of the '219 patent. Thus, the correct interpretation of the Preamble of Claim 1 is

A device that may be implanted in a patient to treat atrial fibrillation by directing an electric shock toward the atria in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "sensing means for sensing electrical activity of the heart." Guidant asserts that the term "electrical activity" should be interpreted as a general reference to electrical events in the heart.

Both Parties agree that the corresponding structure to the "sensing means" includes electrodes. However, Medtronic asserts that the electrodes must be located in a particular way: "widely spaced" and "located in the great cardiac vein 23 and the superior vena cava 20." Medtronic's claim construction is in accordance with its prior arguments, particularly its argument regarding the inclusion of the location of the lead and electrodes in the Second Element of Claim 1 of the '219 Patent.

Medtronic asserts that the claimed function requires sensing an amount and type of electrical activity that the electrode configuration disclosed in the preferred embodiment is able to sense; however, this method of construction is backwards. *See* Omega Eng'g v. Rayteck Corp., 334 F.3d 1314, 1330 (Fed.Cir.2003). The Court must first determine the function before it turns to the structure. In this case, the function is sensing electrical activity, not sensing a particular amount and type of electrical activity. The patent states that the electrodes perform the function of sensing: "Electrodes 44 and 46 of lead 34 sense atrial activity of the heart ... [e]lectrodes 38 and 40 sense R waves of the heart ... [and][e]lectrode 44 together with either electrode 38 or electrode 40 also sense R waves of the heart ..." '519 Patent at 3:38-45.

The locational restrictions are not part of the claim because they are not necessary to perform the claimed function. *See, e.g.,* Motorola, Inc. v. Vosi Techs., Inc., No. 01 C 4182, 2001 WL 1646559, at (N.D.Ill.Dec. 21, 2001) (noting that unless the physical location of the corresponding structure is necessary to perform the claimed function, the means is not construed "to require a particular placement" of the structure). The only necessary limitations on the electrodes are those limitations required in order for the structure to be able to

sense electrical activity of the heart. The electrodes can sense electrical activity wherever they are located on or around the heart. Thus, electrodes, but not their location, are necessary structure.

The Court also concludes that a sense amplifier, an analog-to-digital converter, and leads are part of the corresponding structure. The Court does not view the First Element of Claim 1 in isolation from the other elements of the claim. Hockerson-Halberstadt, Inc. v. Converse Inc., 183 F.3d 1369, 1374 (Fed.Cir.1999) ("Proper claim construction ... demands interpretation of the entire claim in context, not a single element in isolation."). The Second Element of this claim describes an "atrial fibrillation detecting means responsive to said sensed electrical activity of the heart for detecting if the heart is in atrial fibrillation." Thus, together, the First and Second Elements denote structures that sense electrical activity of the heart and convey that information to the microprocessor in a usable form so that it can determine if the atria are in fibrillation. While the specification explicitly uses the term "sense" when describing the function of the electrodes and does not use that term when describing leads, the Court concludes that, when the First and Second Elements are read together, leads are necessary structure for Claim 1. The lead conveys the electrical signals from the electrodes toward the microprocessor which is a necessary part of the combined functions of sensing and detecting. Additionally, while, again, the specification for the '519 Patent does not explicitly use the term "sense" or "detect" to describe the function of the analog-to-digital converter or the sense amplifier (in contrast to, for example, the '219 Patent), the Court concludes that these components, and their leads, are necessary parts of the structure for performing the combined functions of sensing and detecting. These components are necessary for the combined function of perceiving electrical activity of the heart and conveying it in a usable form to the microprocessor to determine the existence of atrial fibrillation.

Thus, the correct interpretation of the First Element of Claim 1 is

Electrodes, leads, an analog-to-digital converter, and a sense amplifier (or equivalent structure) perform the function of sensing electrical events of the heart.

c. Second Element

The Second Element describes an "atrial fibrillation detecting means responsive to said sensed electrical activity of the heart for detecting if the heart is in atrial fibrillation and providing a first detect signal upon detecting atrial fibrillation." This is a means-plus-function element.

Medtronic asserts that the atrial fibrillation detector of the microprocessor is implemented according to the two patent applications incorporated by reference into the '519, United States Patent No. 5,522,852 (" '852") and United States Patent No. 5,486,199 (" '199"):

The atria fibrillation detector may be implemented as disclosed in copending U.S. application Ser. No. 08/233,251 filed Apr. 26, 1994, in the names of Harley White and Joseph Bocek, for "SELECTIVE CARDIAC ACTIVITY ANALYSIS ATRIAL FIBRILLATION DETECTION SYSTEM AND METHOD AND ATRIAL DEFIBRILLATOR UTILIZING SAME", and/or copending U .S. application Ser. No. 08/278,055, filed Jul. 20, 1994, in the names Jaeho Kim and Harley White, for "SYSTEM AND METHOD FOR REDUCING FALSE POSITIVES IN ATRIAL FIBRILLATION DETECTION", which applications are assigned to the assignee of the present invention and incorporated herein by reference.

'519 Patent at 4:39-53.

As explained in Section IV(B)(1)(d), "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1362 (Fed.Cir.2003) (quoting WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1348-49 (Fed.Cir.1999)). A patent applicant can incorporate copending patent applications by reference. Thus, the Court concludes that the corresponding structure is a microprocessor programmed according to the systems disclosed in the '852 Patent and/or the '199 Patent.

Thus, the correct interpretation of the Second Element of Claim 1 is

A microprocessor programmed with one or more of the systems disclosed in United States Patent No. 5,522,852 and/or United States Patent No. 5,486,199 (1) to use information derived from electrical events sensed by the sensing means and (2) to determine whether the atria are in fibrillation (or equivalent structure) for performing the function of detecting if the atria are in fibrillation and providing an atrial fibrillation detect signal.

d. Third Element

The Third Element describes a "timing means for timing a delay time period responsive to said first detect signal and providing a time-out signal upon timing said delay time period."

Guidant argues that the corresponding structure for timing and providing a time-out signal is a timer, but not the microprocessor. Medtronic does not specifically address this element.

The Court agrees that the microprocessor is not included. The timer performs the actual function of timing, while the microprocessor merely initiates the timer. *See, e.g.,* '519 Patent at 6:18-24 ("If atrial fibrillation is detected in step 114, the microprocessor sets and starts timer 76 in step 116 for timing a delay time period.... During the time in which the timer 76 performs its timing of the delay time period ...").

The Parties do not explicitly address the structure necessary for providing a time-out signal upon timing the delay time period. The Court concludes that the timer provides the necessary structure. '519 Patent at 6:37 ("After the timer 76 times-out, another data acquisition is performed in step 120 ...").

Thus, the correct interpretation of the Third Element of Claim 1 is

A timer (or equivalent structure) for performing the function of responding to the atrial fibrillation detect signal by timing a delay time period that delays the start of therapy intervention and of providing a time-out signal upon timing said delay time period.

e. Fourth Element

The Fourth Element of Claim 1 is "said atrial fibrillation detection means being further responsive to said time-out signal for redetecting for atrial fibrillation of the heart and providing a second detect signal upon redetecting atrial fibrillation." The Parties agree that the ordinary meaning of "redetecting" is "detecting again," but disagree regarding whether this term requires the second detection to be in the same manner as the first detection.

Medtronic asserts that "redetecting for atrial fibrillation" means performing an atrial fibrillation detection

process once again. Thus, it reasons, the device performs, for a second time, whatever functions were necessary to first detect whether atrial fibrillation is present. It asserts that the patent specification states that two complete atrial fibrillation detection processes, separated by a delay time, are performed. '519 Patent at 6:37-40. It argues that the claim does not merely require "partially redetecting," but rather requires "redetecting." Thus, a complete atrial fibrillation detection process must occur.

Guidant argues that Medtronic's argument fails because, although one microprocessor is used for the initial detection of atrial fibrillation as well as for the detection of a continuing episode of atrial fibrillation, the patent does not require that the exact same process be used for both. It asserts that the argument is particularly flawed because the characteristics of the onset of atrial fibrillation may not be the same as those of an atrial fibrillation that has continued for the duration of the delay time period.

The Court agrees with Medtronic. The claim language of Claim 1 requires that the initial detection of atrial fibrillation and the redetection be performed in the same manner, because the claim uses the word "said." '519 Patent at 8:17-19 ("said atrial fibrillation detection means ... for redetecting for atrial fibrillation"). The term "said" is a word commonly used in patent claims and it is used to refer back to a particular previous element. *See, e.g.,* Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1339 (Fed.Cir.2003). Thus, in this case, the Fourth Element is referring back to the atrial fibrillation detection means described in the second element.

As explained in Section IV(B)(1)(d), because the claim element is in a means-plus-function format, it must be construed to cover the microprocessor and corresponding algorithms disclosed in the specification for performing the atrial fibrillation detection function. Tehrani v. Hamilton Med., Inc., 331 F.3d 1355, 1362 (Fed.Cir.2003). The specification states that "redetecting for atrial fibrillation" is performed "as previously described," which means in the same manner as the initial detection. '519 Patent, at 6:37-40 ("After the timer 76 times-out, another data acquisition is performed in step 120, and the atrial fibrillation detector 70 thereafter again determines if the atria are in fibrillation in step 122, *as previously described*.") (emphasis added).

Medtronic also asserts that the redetecting step cannot be coextensive or coterminous with the time delay. Relying on Claim 6 of the '519 Patent, Medtronic asserts that the sequence is "detection, timed delay, redetection, applying electrical energy to the atria," thus, the redetecting step cannot begin before the time delay expires. *See* '519 Patent at 8:52-54 (stating that the fourth step in the method is "redetecting for atrial fibrillation of the heart after the delay time period is completed and responsive to said sensed electrical activity"). Medtronic also argues that the portion of the specification allowing for an alternative embodiment employing continuous detection of atrial fibrillation is not an alternative embodiment, but rather is a modification of the claim language.

The Court disagrees. The alternative embodiment clearly allows for detection to occur during the delay time period. '519 Patent at 7:51-53 ("For example, the present invention may also be employed to advantage in defibrillators which continuously monitor heart activity for possible fibrillation.") In the alternative embodiment, the functions of detecting, timing a delay, and then redetecting are performed in the same sequence as in the preferred embodiment; however, the continuous detection simply would run concurrently with the timing of the delay. This alternative embodiment is not an attempted modification of the claim language because it does not contradict the claim language.

Thus, the correct interpretation of the Fourth Element of Claim 1 is

The microprocessor programmed with one of the systems disclosed in United States Patent No. 5,522,852 and/or United States Patent No. 5,486,199 (or equivalent structure), as described in the Second Element of Claim 1 of the '519 patent, responds to the signal provided at the end of the time delay period by determining whether atrial fibrillation is present and if it is present, the microprocessor provides another atrial fibrillation detect signal. The claimed function requires that a second atrial fibrillation detection process ('redetecting') be performed by analyzing the same amount and type of 'sensed electrical activity' as the first atrial fibrillation detection process.

f. Fifth Element

The Fifth Element describes a "cardioverting means responsive to said second detect signal provided by said atrial fibrillation detecting means for applying cardioverting electrical energy to the atria of the heart." The Parties agree this claim should be interpreted in a manner similar to the corresponding language in the Fourth Element of Claim 1 of the '219 Patent.

This element is almost identical to the Third Element of Claim 1 of the '600 Patent and the Parties proffer similar arguments. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the interpretation adopted in Part IV(B)(1)(e) applies to this element as well.

The correct interpretation of the Fifth Element of Claim 1 is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of responding to the atrial fibrillation detect signal at the end of the time delay period by causing the charger and storage capacitor circuit and the discharge circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm.

G. U.S. Patent No. 5,674,249 (" '249 Patent")

The '249 Patent relates to an atrial defibrillation system having a portable communication device. Guidant has asserted 8 claims from the '249 Patent against Medtronic. The Parties addressed Claim 10 as the representative claim, a means-plus-function claim.

The Parties only cursorily addressed the Preamble or Elements 1, 2, 3, 6, 9, and 10 in their briefs or during the *Markman* hearing. Therefore, the Court's interpretation of those elements is based on those interpretations, its review of the Parties' submissions regarding other elements, the ordinary meanings of key terms, the intrinsic evidence, and the Court's reasoning found elsewhere in this Opinion.

1. Claim 10

a. Preamble

The Preamble describes "[a]n atrial defibrillation system comprising:"

The correct interpretation of the Preamble is

An atrial defibrillation system that includes but is not limited to the following elements:

b. First Element

The First Element is "an implantable atrial defibrillator including."

Like the term "comprising," "including" "is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Amgen Inc. v. Hoechst Marion Roussel. Inc., 314 F.3d 1313, 1344-45 (Fed.Cir.2003) (quotation omitted). Thus, the correct interpretation of the Third Element of Claim 10 is

A device that may be implanted in a patient to treat atrial fibrillation in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements.

c. Second Element

The Second Element is "an atrial fibrillation detector."
The correct interpretation of the Second Element of Claim 10 is

A device that determines whether the atria are in fibrillation.

d. Third Element

The Third Element is "an atrial cardioverter, and."
The correct interpretation of the Third Element of Claim 10 is

A device that provides an electric shock that passes through the atria to restore the atria to a normal rhythm.

e. Fourth Element

The Fourth Element describes "electrodes attached to the atrial cardioverter; and." Unlike most of the previous elements, this is not a means-plus-function element.

Guidant interprets the element in the following manner: "The implantable defibrillator has electrodes that are attached to the atrial cardioverter." Medtronic's interprets the element as "[a]n atrial cardioverter with atrial electrodes capable of delivery cardioverting electrical energy."

Medtronic asserts that the electrodes must be placed in the atria because they are part of the structure of cardioverting atria. It notes that Claim 1 has limitation of having electrode means for sensing atrial activity of the heart and applying cardioverting electrical energy to the atria of the heart.

Guidant asserts that Medtronic improperly requires the electrodes to be atrial electrodes. The Court agrees with Guidant. The electrodes do not have to be located in any particular place: they merely have to be attached to the atrial cardioverter. Additionally, this is not a means-plus-function claim. The structure is simply that which is described in the element, and the element does not state that the electrodes are placed in the atria.

Thus, the correct interpretation of the Fourth Element of Claim 10 is

The implantable defibrillator has electrodes that are attached to the atrial cardioverter.

f. Fifth Element

The Fifth Element is "a portable external communication device dimensioned to be hand-held and including an RF transmitter for transmitting a command signal to the implantable defibrillator." The Parties disagree regarding the definition of "portable."

Guidant asserts that Medtronic's construction improperly omits the requirement of portability. To be portable means "capable of being carried or moved about." *Webster's Ninth New Collegiate Dictionary* 916 (1990). Thus, the correct interpretation of the Fifth Element of Claim 10 is

The implantable defibrillation system also includes an external device located outside the body of the patient. The external device is small enough to be held and carried by the patient in one hand and to be used while the patient is holding it. It has a component (a 'transmitter') for sending a command signal via radio waves to be the implantable defibrillator. The command signal is meant to cause the implantable defibrillator to start a predetermined operation.

g. Sixth Element

The Sixth Element is "the implantable defibrillator including a receiver for receiving the command signal." The correct interpretation of the Sixth Element of Claim 10 is

The implantable defibrillator has a component (a 'receiver') for receiving the command signal.

h. Seventh Element

The Seventh Element of Claim 1 is an "activation means responsive to receipt of the command signal for activating the atrial fibrillation detector and the atrial cardioverter if the atrial fibrillation detector detects atrial fibrillation." This is a means-plus-function element. The Parties disagree whether the atrial fibrillation detector must be inactive before it receives the command signal.

Medtronic argues that this element requires that the atrial fibrillation detector be inactive before it is activated, because the plain meaning of "activate" is to make something active that wasn't active before. Thus, it argues that the claim is not addressing an automatic defibrillator continuously operating without input from the patient. It asserts that the claim language and the specification addresses a device in which the intervention sequence is initiated by the patient's command.

Guidant argues than nothing in the claim language requires that the atrial fibrillation detector be deactivated or inactive before responding to the command signal. It asserts that, when the element is read in its entirety, it means that in response to the receipt of a command signal from the external, hand-held device, the cardioverter will shock the patient if the atrial fibrillation detector detects atrial fibrillation. According to Guidant, it is the combination of the atrial fibrillation detector and the atrial cardioverter that is activated in response to the command signal. It argues that this combination can be activated even if the atrial fibrillation detector was already active. Medtronic has isolated one feature of the preferred embodiment, in which the patient has sole control over whether he will receive a shock or not.

The Court agrees with Guidant. Additionally, Medtronic's construction ignores the "combined automatic and

patient activated mode." In this mode, detection and cardioversion may occur automatically or when requested by the patient. '249 Patent at 6:59-65. In the combined mode, the atrial fibrillation detector is not maintained in a deactivated state in the absence of the command signal. Instead, it may be activated by the automatic mechanism and the patient would then receive the shock without the command signal. Thus, the atrial fibrillation detector is already active when a command signal is received.

The correct interpretation of the Seventh Element of Claim 10 is

The implantable defibrillator has a microprocessor (or equivalent structure) programmed to act on receipt of the command signal from the external device and perform the function of shocking the atria to restore them to a normal rhythm if the atria are in fibrillation.

i. Eighth Element

The Eighth Element of the claim describes a "means for generating an acknowledgment message responsive to the receiver receiving the command signal." The Parties disagree regarding the content of the acknowledgment message.

Guidant argues that Medtronic's proposed construction erroneously adds the requirement that the acknowledgment signal contain information regarding receipt of the command signal. Guidant asserts that the claim does not limit what the acknowledgment message must include in the message.

The Court agrees with Medtronic. The patent states that the acknowledgment signal initiates an indicator which "provides positive feed-back for the patient ... Hence, the patent will positively know if the command was received and is being acted upon by the implanted device 30." '249 Patent at 4:66 -5:3. Thus, the acknowledgment signal must contain information regarding the receipt of the command signal and the initiation of the task. Additionally, the message would have no purpose if it did not contain information regarding the receipt or initiation.

Thus, the proper interpretation of the Eighth Element of Claim 10 is

A microprocessor (or equivalent structure) programmed to perform the function of creating an acknowledgment signal, which contains information regarding receipt of the command signal by the implantable atrial defibrillator and initiation of the commanded task, in response to the implantable defibrillator receiving the command signal sent from the external device.

j. Ninth Element

The Ninth Element describes "an RF transmitter for transmitting the acknowledgment message to the external communication device, and ."

The correct interpretation of the Ninth Element of Claim 10 is

The implantable atrial defibrillator has a component (a "transmitter") for sending via radio waves the acknowledgment message created by the microprocessor to the external device.

k. Tenth Element

The Tenth Element describes "the external communication device further including a receiver for receiving the acknowledgment message and an indicator for providing a perceptible indication responsive to receipt of the acknowledgment message." The correct interpretation of the Tenth Element of Claim 10 is

The external device has a component (a "receiver") for receiving the acknowledgment message sent by the implantable defibrillator and a component (an "indicator") for making the patient aware that the acknowledgment message was received.

H. U.S. Patent No. 5,645,569 (" '569 Patent")

The '569 Patent relates to a post-atrial cardioversion atrial pacing and method. The invention is an implantable atrial defibrillator with the ability to provide atrial pacing after cardioversion, in order to prevent reversion to atrial fibrillation. Guidant has asserted eight claims from the '569 Patent against Medtronic. The Parties have addressed Claim 1 as the representative claim, a means-plus-function claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator comprising." The Parties agree that Preamble should be interpreted in the same way as the Preamble to the '219 Patent. Thus, the correct interpretation of the Preamble to Claim 1 is

A device that may be implanted in a patient to treat atrial fibrillation in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "[c]ardioverting means for applying cardioverting electrical energy to [sic] atria of a heart when the atria are in need of cardioversion." The Parties agree that the language in this element should be interpreted in a similar manner as the equivalent language in the Fourth Element of Claim 1 of the '219 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence, and concludes that the interpretation found Part IV(B)(1)(e) applies. Thus, the correct interpretation of the First Element of Claim 1 is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of causing the discharge circuit and capacitor circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm when the heart is in atrial fibrillation.

c. Second Element

The Second Element of Claim 1 is a "pacing means for pacing the atria of the heart responsive to and immediately after each application of cardioverting electrical energy to the atria of the heart by the cardioverting means." This is a means-plus-function element. The function is pacing the atria of the heart responsive to and immediately after each application of cardioverting electrical energy to the atria of the heart by the cardioverting means. The Parties dispute the meaning of the terms "responsive to" and "immediately after."

i. "Responsive to"

Medtronic asserts that "responsive to" means that the atrial pacing is enabled by and coordinated with the application of cardioverting electrical energy to the atria. If further argues that there is no pre-cardioversion atrial pacing disclosed in the '569 Patent. First, it avers that the ordinary meaning of atrial pacing "responsive to" the atrial shock suggests that the atrial pacing is enabled by the atrial shock. Thus, the element does not describe a return to an atrial pacing regimen in operation prior to the interruption for application of the atrial shock. Second, Medtronic notes that the specification states that the pacer is not enabled until after the cardioverting shock. '569 Patent at 6:10-15 ("After applying the cardioverting electrical energy to the atria, the microprocessor 60 ... enables the pacer 92 which has been programmed into an AAI or DDD modality.... This begins the post-cardioversion atrial pacing of the heart."). Third, Medtronic argues that the prosecution history of the '569 Patent supports its position. It asserts that in order to distinguish the atrial pacing in the '569 Patent from the '524 Patent (the Rahul/Mehra Patent), the patent applicant committed itself to the definition of "responsive to" advocated by Medtronic.

Guidant asserts that the ordinary meaning of "response" is "something constituting a reply or a reaction: as ... the output of a transducer or detecting device resulting from a given input." *Webster's Ninth New Collegiate Dictionary* 1005 (1990). Thus, Guidant reasons that the correct construction of "responsive to" is that the pacing is coordinated to the discharge of the electrical shock that terminates the atrial fibrillation; however, it asserts that its interpretation does not bar any interpretation that includes a return to an atrial pacing mode used before the shock was given. The Court agrees with Guidant.

The claim language does not preclude a return to an atrial pacing mode in use prior to the cardioverting shock being delivered, if indeed such pacing was present. The '569 Patent does not mention pre-cardioverting pacing at all. The '569 Patent describes a device that provides atrial demand pacing during a finite period of time after cardioversion. *See* '569 Patent at 6:40-43. It would be improper to limit the claim to preclude a return to some pre-cardioverting pace.

Thus, the ordinary meaning of "responsive" and the specification do not require the limits proffered by Medtronic. However, that does not end the Court's inquiry. The Parties also dispute whether certain amendments made during prosecution of the '569 Patent limited the patent to pacing only at a pace other than any pre-cardioverting pace. The amendments at issue was made to overcome rejection in light of a preexisting patent, the Rahul/Mehra Patent. During prosecution of the '569 Patent, the inventor added the term "responsive to" to Claim 1 after it was rejected in light of the Rahul/Mehra Patent. At that time, the inventor stated the following:

Rahul does not describe or suggest that responsive to and immediately after each application of cardioverting electrical energy to the atria, the atria should be paced. Further, Rahul does not suggest any coordination between atrial pacing and cardioverting therapies.

Amendment and Response at 4, Medtronic Exh. 17. The Court has examined both the Rahul/Mehra Patent and the prosecution history of the '569 Patent, and concludes that this intrinsic evidence does not limit the post-cardioversion pacing to a rate other than any pre-cardioversion setting, if indeed one is present. The cited language does not demonstrate the patentee's desire to limit the application of post-cardioverting pacing to any specific rate, or to bar any pre-cardioversion pacing. Rather, the patentee was discussing the impetus for beginning post-cardioversion pacing, not the rate of the pacing. The discussion focused on the

fact that the post-cardioversion pacing represented by the '569 Patent is begun as a reaction to the application of cardioverting energy. The patentee did not address at what rate the post-cardioversion pacing would occur or whether pre-cardioversion pacing was permitted. There was no clear disavowal of the ability to pace at any pre-cardioverting rate. Therefore, it would be improper for the Court to so limit the claim. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325 (Fed.Cir.2003).

ii. "Immediately After"

Medtronic asserts that "immediately after" means "without any events between the application of cardioverting energy to the atria and the enabling of the atrial pacing." Medtronic argues that, according to its dictionary, "immediately" means "[w]ithout intermediary." *American Heritage Dictionary* 643 (2d college ed.1982). Medtronic argues that the Parties agree that the ordinary meaning of the term "immediately" prohibits an intermediary or intervening event, such as a ventricular pacing pulse supplied by the device, between shock and the initiation of atrial pacing.

Guidant argues that within the context of pacing the atria, "immediately" means pacing as soon as it would be effective within the first heart cycle after the cardioversion shock is applied. Guidant asserts that this definition is appropriate because one of ordinary skill in the art would know that events take place in both the heart and the device between applying the shock and enabling the pacing, such as restoration of normal atrial activity and repolarization. For support, Guidant cites language in the '569 Patent itself:

After applying the cardioverting electrical energy to the atria, the microprocessor 60, through the disable stage 63, enables the pacer 92 which has been preprogrammed.... This begins the post-cardioversion atrial pacing of the heart. The pacing of the heart continues, preferably at a rate greater than a bradycardia pacing rate, for a finite time until the occurrence of a predetermined event.

'569 Patent at 6:11-18.

Guidant asserts that the reason for pacing "immediately after" the cardioverting shock is to eliminate the time required to confirm whether the shock was successful in restoring normal cardiac activity. However, the Court cannot limit its claim construction based on the perceived purpose of the invention. *See* E-Pass Techs., Inc. v. 3COM Corp., 343 F.3d 1364, 1370 (Fed.Cir.2003).

The Court agrees with Medtronic. The cited language says nothing about waiting to determine the results of cardioversion. In addition, the specification states that the pacing begins "immediately after each cardioversion attempt, " '569 Patent at 6:22-23, not immediately after each *successful* cardioversion attempt. Moreover, the claim itself says nothing about waiting to determine the success of the cardioversion.

Medtronic also asserts that the claimed atrial pacing must be performed after every application of cardioverting energy. The ordinary meaning of the word "each" is "every one of two or more considered individually or one by one." *The Random House College Dictionary* 414 (rev. ed.1982). The specification and claim language do not change this ordinary meaning. Therefore, the Court will include the word "every" in its interpretation of this claim.

iii. Structure

Guidant argues that the structure associated with the pacing means includes a dual chamber ventricular and atrial pacer or single chamber atrial pacer, and a microprocessor. Medtronic argues that, in addition to the

pacer, the following are also structure associated with the pacing means: memories that store operating instructions, leads and electrodes, and a disable (enable) stage 63. The Court agrees that the leads and electrodes are included in the structure. *See* '569 Patent at 3:48-50 ("The electrodes 48 and 50 are closely spaced apart ... for pacing the atria."). Although the patent does not explicitly state that the lead is used in pacing, it implicitly teaches that the lead is part of the corresponding structure. It states, "The pacer 92 is coupled to the electrodes 48 and 50 to provide single site pacing of the atria. One output of the pacer 92 is also coupled to electrode 41 for providing, in the alternative, dual site pacing of the atria in combination with either electrode 48 or electrode 50." Id. at 5:15-19. The pacer is "coupled" to the electrodes by the lead. *See* id. Figure; 3:45-48.

The Court concludes that the memories and the disable (enable) stage are not part of the corresponding structure. The memories receive and store operating instructions; they do not pace. '569 Patent at 4:36-42. The disable (enable) stage enables the pacer, it does not pace. Id. at 6:11-14.

Thus, the correct interpretation of the Second Element of Claim 1 is

A pacer, lead, electrodes, and a microprocessor (or equivalent structure) for performing the function of pacing the atria coordinated to the discharge of the electric shock. This claimed function requires that the atria be paced 'immediately after' the application of electrical energy to the atria-i.e., without any events between the application of cardioverting energy to the atria and the enabling of the atrial pacing. The claimed function also requires that the claimed atria pacing be performed after 'each' or every application of cardioverting electrical energy.

I. U.S. Patent No. 5,676,687 (" '687 Patent")

The '687 Patent is a continuation-in-part of the '569 Patent, and relates to post-atrial cardioversion at a high atrial pacing rate with a gradual rate return. Guidant has asserted six claims from the '687 Patent against Medtronic. The Parties have chosen Claim 1 as the representative claim, a means-plus-function claim.

1. Claim 1

a. Preamble

The Preamble to Claim 1 describes "[a]n implantable atrial defibrillator comprising." The Parties agree that the Preamble should be interpreted in the same way as the Preamble to the '219 Patent, and the Preamble to the '569 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the correct interpretation of the Preamble to Claim 1 is

A device that may be implanted in a patient to treat atrial fibrillation in order to restore the atria to a normal rhythm. The device includes but is not limited to the following elements:

b. First Element

The First Element of Claim 1 is a "cardioverting means for applying cardioverting electrical energy to [sic] atria of a heart when the atria are in need of cardioversion." The Parties agree that the language in this element should be interpreted similarly to the corresponding language in the Fourth Element of Claim 1 of the '219 Patent. The Court has reviewed the Parties' submissions, the ordinary meanings of key terms, and the intrinsic evidence and concludes that the correct interpretation of the First Element of Claim 1 is

A charger and storage capacitor circuit, a discharge circuit, a lead, electrodes, and a microprocessor (or equivalent structure) programmed to perform the function of causing the discharge circuit and capacitor circuit to direct an electric shock toward the atria to restore the atria to a normal rhythm when the heart is in atrial fibrillation.

c. Second Element

The Second Element of Claim 1 is a "pacing means for pacing the atria of the heart immediately after application of cardioverting electrical energy to the atria of the heart and including rate control for commencing the pacing at a relatively high first rate and gradually reducing the rate to a lower second rate." This is a means-plus-function claim. The function is pacing the atria of the heart immediately after application of cardioverting electrical energy to the atria of the heart and including rate control for commencing the pacing at a relatively high first rate and gradually reducing the rate to a lower second rate.

i. Disputed Terms

The Parties dispute the meaning of the term "immediately after." The Parties proffer the same arguments regarding the term that they proffered regarding the '569 Patent. The Parties agree that the language should be interpreted in the same way as it was interpreted in the Second Element of Claim 1 of the '569 Patent. As discussed in Part IV(H)(1)(c)(ii), "immediately after" means that there are no intervening events between the application of cardioverting energy to the atria and the enabling of the atrial pacing

Medtronic argues that the "relatively high first rate" must be a rate well above a bradycardia rate. Medtronic extracts this limitation from the preferred embodiment of the '687 Patent. *See* '687 Patent at 6:58-62. The Court finds that importing this limitation would improperly limit claim construction based on a limitation in the preferred embodiment. *See* Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002). The Court declines to do so. There is nothing in the claim language that requires that the first pacing rate be above the bradycardia rate. Thus, Medtronic's proffered limitation will not be included in the Court's claim construction.

ii. Structure

The Parties agree that the structure corresponding to the function of pacing the atria of the heart includes at least a pacer and a microprocessor. Medtronic, however, would also include memories which store operating instructions, leads, electrodes, a rate control, and a disable (enable) stage. For the reasons explained in the discussion of structure of the Second Element of Claim 1 of the '569 Patent, the Court concludes that while the lead and electrodes are components of the corresponding structure, the memories and disable (enable) stage are not.

Moreover, the Court finds that the pacing rate control is structure clearly associated with the pacing function. First, the claim itself states that rate control is part of the pacing means. Second, the specification identifies the rate control as structure associated with the pacing function: it controls the pacing rate. '687 Patent at 6:58-62.

Thus, the correct interpretation of the Second Element of Claim 1 is

A pacer, lead, electrodes, a microprocessor and rate control (or equivalent structure) for performing the

function of pacing the atria and commencing the pacing at a relatively high first rate and then gradually reducing the rate to a lower second rate. This claimed function also requires that the atria be paced 'immediately after' the application of electrical energy to the atria-i.e., without any events between the application of cardioverting energy to the atria and the enabling of the atrial pacing.

For the reasons stated, IT IS HEREBY ORDERED:

The claims of the patents at issue in this case should be construed in a manner consistent with the definitions set forth by the Court in this Memorandum of Law & Order.