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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESPIRONICS, INC.
Petitioner

v

ZOLL MEDICAL CORPORATION
Patent Owner

Patent
6,681,003

PETITION FOR INTER PARTES REVIEW

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List of Exhibits

Exhibit 1001.	U.S. Patent 6,681,003 to Linder et al.
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Exhibit 1003.	International Patent Publication No. WO 98/39061 to Owen et al.
Exhibit 1004.	U.S. Patent No. 5,474,574 to Payne et al.
Exhibit 1005.	U.S. Patent No. 6,564,797 to Mechlenburg et al.
Exhibit 1006.	U.S. Patent No. 5,078,134 to Heilman et al.
Exhibit 1007.	Expert Declaration of Dr. Igor Efimov, Ph.D, F.A.H.A., F.H.R.S.
Exhibit 1008.	Prosecution History of U.S. Application No. 09/624,275
Exhibit 1009.	Prosecution History of U.S. Application No. 10/197,159
Exhibit 1010.	U.S. Provisional Application No. 60/157,881

I. Introduction

Respironics, Inc. ("Petitioner") petitions for inter partes review of claims 1, 2, 4, 5, 8, 9, 16, 19, and 20 of U.S. Patent No. 6,681,003 ("the '003 patent") (Ex. 1001) ("challenged claims") assigned to ZOLL Medical Corporation ("Patent Owner") (Reel 018720, Frame 0288), in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.100 *et seq.* As set forth below, the challenged claims are unpatentable in light of prior art that the Office did not have before it during prosecution. Accordingly, Petitioner requests that the challenged claims be canceled as unpatentable.

II. Mandatory Notices

A. Real Parties-in-Interest

Respironics, Inc. is a wholly owned subsidiary of Philips Holdings USA, Inc., which is a wholly owned subsidiary of Koninklijke Philips N.V. ("KPNV"). Respironics, Inc. and KPNV are identified as the real parties-in-interest as required by 35 U.S.C. § 312(a)(2), 37 C.F.R. § 42.8(b)(1).

B. Related Matters

As required by 37 C.F.R. § 42.8(b)(2), Petitioner states that the '003 patent is asserted in a copending litigation captioned *ZOLL Medical Corp. v. Respironics, Inc.*, Case No. 12-1778-LPS (D. Del.) ("Related Litigation"). Patent Owner filed the Complaint against Petitioner on December 28, 2012, (Ex. 1002), asserting eight of the nine the claims challenged in this petition: 1, 2, 4, 5, 8, 16, 19 and 20.

C. Lead and Backup Counsel and Service Information

Lead Counsel	Backup Counsel
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III. Payment of Fees

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 06-0916.

IV. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the ’003 patent is available for inter partes review and that Petitioner is not barred or estopped from requesting inter partes review of the ’003 patent. This petition is timely filed within one year of the filing of the original Complaint against Petitioner in the Related Litigation.

V. Identification of Challenge

Pursuant to 37 C.F.R. § 42.104(b), Petitioner requests inter partes review of claims 1, 2, 4, 5, 8, 9, 16, 19, and 20 of the ’003 patent on the grounds set forth

below. In accordance with 37 C.F.R. § 42.104(b)(2), Petitioner requests inter partes review based on the grounds set forth below:

Ground	Challenged Claims	Statutory Basis for Challenge Under 35 U.S.C. §§ 102/103
1	1, 2, 4, 5, 8, 9, 16, 19, and 20	Anticipated under § 102(b) by International Patent Publication No. WO 98/39061 to Owen et al. ("Owen") (Ex. 1003)
2	1, 2, 4, 5, 8, 9, 16, 19, and 20	Anticipated under § 102(b) by U.S. Patent No. 5,474,574 to Payne et al. ("Payne") (Ex. 1004)
3	1, 4, 5, 8, 16, 19, and 20	Anticipated under § 102(e) by U.S. Patent No. 6,564,797 to Mechlenburg et al. ("Mechlenburg") (Ex. 1005)
4	1, 2, 4, 5, 8, 9, 16, 19, and 20	Anticipated under § 102(b) by U.S. Patent No. 5,078,134 to Heilman et al. ("Heilman") (Ex. 1006) or obvious under § 103(a) over Heilman in view of Owen (Ex. 1003)

Although any one of the grounds for challenge satisfies the threshold for the institution of trial, Petitioner respectfully requests the grant of this petition on all grounds for the following reasons:

Ground 1: Owen (Ex. 1003) provides the most detailed disclosure of a wearable device that interacts with a patient database for the storage and exchange of data and/or information.

Ground 2: Payne (Ex. 1004) discloses an alternative form of a "wearable medical device."

Ground 3: Mechlenburg (Ex. 1005) is an early patent related to a sleep apnea device similar to the device accused of infringement in the Related Litigation. It is only under the Patent Owner's construction of the challenged

claims, as evidenced in the complaint in the Related Litigation, that Mechlenburg discloses all the elements of the challenged claims. Accordingly, the Board's analysis of how the challenged claims might be applied to a sleep apnea device would be instructive on significant issues in the Related Litigation. Additionally, Mechlenburg provides the most detailed disclosure of the "patient compliance data." (Ex. 1006 at 4:63).

Ground 4: Heilman (Ex. 1006), which is assigned to Patent Owner, was not disclosed during prosecution of the '003 patent. A finding by the Board that the challenged claims are not patentable over Heilman would establish the first prong of an inequitable conduct claim under *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) ("'But-for' materiality means that the USPTO would not have allowed the claim over the undisclosed (or misrepresented) information."). Although Petitioner is free to bring an inequitable conduct claim in the Related Litigation, judicial efficiency weighs in favor of the Board determining "but for" materiality through its inter partes review of the challenged claims.

A. Proposed Claim Construction

For the purposes of inter partes review only, Petitioner submits that the terms of the challenged claims are to be given their broadest reasonable interpretation as understood by one of ordinary skill in the art in view of the

specification of the ’003 patent in accordance with 37 C.F.R. §§ 42.100(b) and 104(b) (3).

1. “Patient Compliance [and Use] Data”

Challenged claims 2 and 19 refer to “patient compliance data.” Claim 4 refers to “patient compliance and use data.” The specification makes clear that these terms should be construed to mean “data related to patient use.” *See* Expert Declaration of Dr. Igor Efimov (“Efimov Decl.”) at ¶¶ 17-19 (Ex. 1007).

Specifically, the specification provides that “[a]utomatic or manual transmission of results of analysis performed on the collected data . . . can then also be provided back to the patient or other physicians. . . . [*P*]atient *compliance and use data* can also be sent back to the central location for review by the physician or maintenance personnel . . . .” Ex. 1001 at 4:35-43 (emphasis added). The specification also states that “by reference to FIG. 6, the average wear time data for which the patient has worn the device can be analyzed to determine patient compliance.” *Id.* at 4:52-55. *See also id.* at 3:37-38. Finally, the specification indicates that “compliance and use data” can be analyzed “by the prescribing physician [to determine] if the device is not being used by the patient or is being used improperly.” *Id.* at 5:48-52. Thus, the claim term “patient compliance [and use] data” should be construed to mean “data related to patient use.”

2. “Information Database/Patient Database”

Challenged claims 1 and 2 refer to an "information database." Challenged claims 4, 8, 16, and 19 refer to a "patient database." The specification and claims make clear that these claim terms should be construed to mean "a storage location for data and/or information." Efimov Decl. at ¶¶ 20-22.

The specification repeatedly refers to the database as a storage location: *id.* at 2:62-63 ("recorded in an information database"); 4:17 ("collection of data in a database"); 5:37 ("database type gathering of information"); 8:6-8 ("Once the patient's baseline information has been recorded, this information must then be sent to the device manufacturer's database server via the modem."); 8:16-18 ("Preferably, the patient's database resides on the Lifecor's internet database server to receive the various patient information."); 9:8-12 ("In order to provide the patient information into the Lifecor's internet site database, the patient is prompted periodically, such as in [sic] the order of every 7 days, to connect his/her monitor to the modem for transfer of information to the database.").

Likewise, the claims make clear that the "patient database" is a "storage location for data or information." Claim 1 refers to "recording the patient medical information in an information database." *Id.* at 10:21-22. Claim 2 refers to "recording the patient medical information, device performance data and patient compliance data in an information database." *Id.* at 10:40-42. Claims 4 and 19 refer to "exchanging information between the medical device and the patient

database." *Id.* at 11:3-4. Thus, the claim terms "information database" and "patient" database should be construed to mean "a storage location for data and/or information."

3. Means-Plus-Function Terms

Several limitations in the challenged claims are set forth in means-plus-function format pursuant to 35 U.S.C. § 112(f). When construing a means-plus-function limitation, the claimed function must be identified first, and then the corresponding structure that actually performs the claimed function must be identified in the specification. *See Med. Instrumentation & Diagnostics Corp. v. Elektra AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003). A means-plus-function claim term is limited to the structures disclosed in the specification and equivalents. *Id.*

Pursuant to § 42.102(b)(3), the structure set forth in the specification,—to the extent any structure could be identified—is set forth in the table below. *See also* Efimov Decl. at ¶¶ 23-25.

Claim Term	Function	Structure	Exemplary Cites to '003 Patent
Storage means (Claim 1)	Store information	Memory	7:36-38; 7:44-46; 7:53-8:8; 9:16-17.
Storage means (Claim 2)	Store information	Memory	3:62-4:4; 7:36-38; 7:44-46; 7:53-8:8; 9:16-17.
Means for connecting the medical device to the communications	Connecting the medical device to the communications network	Internal or external modem or a base station with a modem, or other data transfer	Abstract; Figs. 1 and 2; 3:45-50; 5:9-13; 6:39-44; 8:10-17; 9:8-15; 8:22-24; 9:41-54.

Claim Term	Function	Structure	Exemplary Cites to '003 Patent
network (Claims 4 and 19)		technologies, and in the case of an implantable device, additionally including a transcutaneous transmitter	
Means for monitoring and storing [operations information of the medical device and patient compliance and use data / patient medical parameters, device performance data, and patient compliance data] (Claims 4 and 19)	1. Monitoring [operations information of the medical device and patient compliance and use data / patient medical parameters, device performance data, and patient compliance data]	Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	Abstract; 1:28-35; 2:31-36; 3:1-8; 9:33-35.
	2. Storing [operations information of the medical device and patient compliance and use data / patient medical parameters, device performance data, and patient compliance and use data]	Memory	3:62-4:4;; 7:36-38; 7:44-46; 9:16-17.
Means for connecting the patient database to the communication	Connecting the patient database to the communication network	Modem or other data transfer technologies	Figs. 1; 3:45-50; 5:9-25; 6:39-44; 6:62-66

Claim Term	Function	Structure	Exemplary Cites to '003 Patent
network (Claims 4 and 19)			
Means for exchanging information between the medical device and the patient database (Claims 4 and 19)	Exchanging information between the medical device and the patient database	Internal or external modem or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, additionally including a transcutaneous transmitter	Abstract; Figs. 1 and 2; 3:45-50; 5:9-13; 6:39-44; 8:10-17; 9:8-15; 8:22-24; 9:41-54
Means for transmitting the [medical device operations information and the patient compliance and use data / patient medical parameters, device performance data and patient compliance data] to the patient database via the communication[s] network (Claims 4 and 19)	Transmitting the [medical device operations information and the patient compliance and use data / patient medical parameters, device performance data and patient compliance data] to the patient database via the communication[s] network	Internal or external modem or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, additionally including a transcutaneous transmitter	Abstract; Figs. 1 and 2; 3:45-50; 5:9-13; 6:39-44; 8:10-17; 9:8-15; 8:22-24; 9:41-54
Means for monitoring an operating status of the medical	Monitoring an operating status of the medical device	Medical device (e.g., cardiac defibrillator, infusion pump,	2:31-36; 3:55-61; 4:66-5:4.

Claim Term	Function	Structure	Exemplary Cites to '003 Patent
device (Claim 5)		pacemaker)	
Means for transmitting patient medical information from the medical device to the patient database (Claim 8)	Transmitting patient medical information from the medical device to the patient database	Internal or external modem or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, additionally including a transcutaneous transmitter	Abstract; Figs. 1 and 2; 3:45-50; 5:9-13; 6:39-44; 8:10-17; 9:8-15; 8:22-24; 9:41-54
Means for monitoring battery status for a battery of the medical device (Claim 9)	Means for monitoring battery status	Medical device (e.g., cardiac defibrillator, infusion pump, pacemaker)	2:31-36
Means for accessing the patient database via the communication network (Claim 16)	Accessing the patient database via the communication network	Home or office computer	Abstract; Fig. 1; 3:50-53; 4:4-6; 5:30-32; 6:39-44; 6:62-66
Means for downloading device parameter software to the medical device from the communication network (Claim 19)	Downloading device parameter software to the medical device from the communication network	Internal or external modem or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, additionally including a	Abstract; Figs. 1 and 2; 3:45-50; 5:9-13; 6:39-44; 8:10-17; 9:8-15; 8:22-24; 9:41-54

Claim Term	Function	Structure	Exemplary Cites to '003 Patent
		transcutaneous transmitter	

B. Detailed Explanation of the Challenge

The claimed methods and systems recite a wearable medical device for monitoring and treating a patient, storing data related to the patient and to the device's operation, transmitting the data to a central database over a communications network. Healthcare providers, maintenance personnel, patients, or other individuals can access the database through a work or home computer. The claimed methods and systems were not new in 1999, as set forth below and in the Expert Declaration of Dr. Igor Efimov. *See* Efimov Decl. at ¶¶ 33-227

1. Owen Anticipates the Challenged Claims Under 35 U.S.C. § 102(b)

Owen discloses all the elements of the challenged claims. *See* Efimov Decl. at ¶¶ 33-80. Owen discloses a wearable defibrillator capable of monitoring a patient's heart condition and administering a defibrillating shock if needed by the patient. *See* Owen (Ex. 1003), 2:16-32; Figs. 1 and 2; claims 10 and 11. Owen's defibrillator monitors and stores patient medical information, information related to the operation of the device, and compliance information. *See id.* at 5:19-23; 34:15-16; 35:9-36:20; 52:14-23. The defibrillator exchanges information with a remote location, e.g., repository, doctor's office, or hospital, through an external

communications interface. *See id.* at 5:23-6:7. This functionality allows the defibrillator to be reprogrammed as needed based on information stored in the remote location. *See id.* at 7:20-24; 64:2-6. Owen's defibrillator comprises a non-contact interface that allows transmission of information while the defibrillator is being worn by the patient. *See id.* at 31:16-23.

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
1(pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	"A method of treating a patient for ventricular tachycardia using a wearable defibrillator includes monitoring the patient for a predetermined condition via one or more electrodes on the defibrillator . . . ." Abstract; 1:9-13; 6:29-7:6.
1(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	"The present invention is directed to . . . a personal wearable pacer/cardioverter/defibrillator which monitors a patient's condition, detects shockable or paceable arrhythmias, determines consciousness, and, in the case that the patient is determined to be unconscious, administers therapy to the patient." 1:9-13; Fig. 2; 7:11-19; 30:21-31.
1(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	"[D]efibrillator 10, includes housing 40 . . . [which] is preferably small enough to make the defibrillator portable and thus wearable . . . . [H]ousing 40 can comprise a belt, or the like, which a patient can wear around his or her waist, chest, etc." 30:21-31.
1(c) recording the patient medical information in a storage means of the medical device; **Structure for "storage means"**: memory	***Structure***: "memory block 57" 34:15-16. ***Function***: "Data logging memory block 57 stores both the operational history of defibrillator and information relating to the patient. . . . More specifically, data logging memory 57 stores . . . the patient's ECG before, during and after application of defibrillation energy . . . information concerning patient interaction with the defibrillator 10 . . . . In summary, data logging memory block essentially stores any information provided to, or transmitted from, defibrillator 10 over a predetermined span of time . . . ." 35:9-36:20; 5:19-23;

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
	34:15-16.
1(d) operatively connecting the medical device to a communications system;	"The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are transmitted, and over which external information is received . . . . The base station also includes an external interface, over which the defibrillation information and the patient information is transmitted to an external location, and over which the external information is received from the external location. By virtue of the foregoing arrangement, it is possible to transmit patient and defibrillation information from a defibrillator to a base station and from the base station to an external location, such as a central repository, doctor, hospital, etc." 5:23-6:7; 64:2-16.
1(e) transmitting the patient medical information to a health care provider by means of said communications system and recording the patient medical information in an information database; and	"Data retrieved by base station 2 from defibrillator 10 may be transmitted to central repository 9 via external data link 17. Central repository 9 preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients, all of whom use the same type of defibrillator." 14:2-6; Fig. 1; 5:32-6:3; 8:2-12; 31:8-21.
1(f) providing access to the patient medical information to individuals.	"Data retrieved by base station 2 from defibrillator 10 may be transmitted to a central repository 9 . . . [which] preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients . . . . A personal computer 19 is in communication with central repository 9. This personal computer may be used to analyze the patient and defibrillation information from the plurality of other patients . . . ." 14:2-12; 4:31-5:2; 5:32-6:14; 31:8-21.
2 (pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising	See claim element 1(pre) above for support.

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
the steps of:	
2(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	See claim element 1(a) above for support.
2(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(b) above for support.
2(c) recording the patient medical information, device performance data and patient compliance data in a storage means of the medical device; **Structure for "storage means"**: memory	***Structure***: "memory block 57" 34:15-16. ***Function***: "Data logging memory block 57 stores both the operational history of defibrillator and information relating to the patient. . . . the patient's ECG before, during and after application of defibrillation energy, . . . information concerning patient interaction with the defibrillator 10, . . . detected operational errors of defibrillator 10, . . . and patient parameters. These patient parameters include . . . electrode-to-skin impedance range which is used to determine whether the electrodes are not attached, or are improperly attached to the patient. . . . In summary, data logging memory block essentially stores any information provided to, or transmitted from, defibrillator 10 over a predetermined span of time . . . ." 35:9-36:20; 5:19-23; 34:15-16.
2(d) operatively connecting the medical device to a communications system;	See claim element 1(d) above for support.
2(e) transmitting the patient medical information, device performance data and patient compliance data	"[Claim] 50. A wearable defibrillator . . . comprising: an external interface, over which the patient information is transmitted to an external location . . . ." 77:17-20. "[Claim] 57. A wearable defibrillator according to Claim 50, wherein the external interface

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
to a health care provider by means of said communications system and	comprises a non-contact interface over which the patient information is transmitted to a personal computer." 79:9-11; 13:24-27; 31:18-21; 32:2-4; 33:25-31, Fig. 2.
2(f) recording the patient medical information, device performance data and patient compliance data in an information database,	"[T]he present invention is a method for reprogramming a defibrillator based on a central database of information relating to patients that use a type of defibrillator. The method includes collecting, in the *central database*, information relating to a plurality of patients that use the type of defibrillator, analyzing the information stored in the central database . . . ." 8:2-9. "Data retrieved by base station 2 from defibrillator 10 may be transmitted to central repository 9 via external data link 17. Central repository 9 preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients, all of whom use the same type of defibrillator. . . ." 14:2-12. See also claim elements 1(e), 2(c) and 2(e) above for support.
2(g) wherein said transmitting step is performed while the medical device is operatively connected to the patient for providing treatment to the patient; and	"Communications link 49 comprises a non-contact interface to personal computer 201 (see Figure 2), over which information may be transmitted between defibrillator 10 and personal computer 201 (see Figure 2) while defibrillator 10 is being worn by the patient or, if desired, at other times as well." 31:18-21; Fig. 2; 13:24-27; 79:9-11 ("[Claim] 50. A wearable defibrillator . . . comprising: an external interface, over which the patient information is transmitted to an external location . . . ."); 77:17-20("[Claim] 57. A wearable defibrillator according to Claim 50, wherein the external interface comprises a non-contact interface over which the patient information is transmitted to a personal computer.").

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
2(h) providing access to the patient medical information, device performance data and patient compliance data to individuals.	"Data retrieved by base station 2 from defibrillator 10 may be transmitted to a central repository 9 . . . [which] preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients . . . . A personal computer 19 is in communication with central repository 9. This personal computer may be used to analyze the patient and defibrillation information from the plurality of other patients . . . ." 14:2-12; 4:29-5:2; 5:32-6:14; 31:8-21.
4.(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	"[T]he invention features a long-term cardiac monitoring and defibrillation system that is wearable by a patient. The system includes at least two electrode arrays electrically connected to a portable defibrillator. . . . The electrode arrays comprise plural electrodes which are capable of *sensing* the patient's heart condition . . . and of *delivering defibrillation* or pacing impulses to the patient's heart when required." 8:17-27 (emphasis added); Figs. 1 and 2; 2:17-32; 12:24-30.
4(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	"The present invention is directed to a . . . personal wearable pacer/cardioverter/defibrillator which monitors a patient's condition, detects shockable or paceable arrhythmias . . . and, in the case that the patient is determined to be unconscious, administers therapy to the patient." 1:9-13; Fig. 2; 7:11-19; 30:21-31; 35:9-10 ("Data logging memory block 57 stores both the operational history of defibrillator and information relating to the patient.").
4(b) a communications network;	"External interface can comprise a modem link, a *network* connection, or the like, over which data may be transmitted to and from base station 2." 65:14-16; 85:6-7. Owen's disclosure of a "network connection" and of exchange of information of the defibrillator with a remote location necessarily discloses a communications network. *See* Efimov Decl. at ¶ 52.
4(c) means for	***Structure***: "Base station" 5:23-6:7.

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
connecting the medical device to the communication network; **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Function*:** "The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are transmitted, and over which external information is received . . . . By virtue of the foregoing arrangement, it is possible to transmit patient and defibrillation information from a defibrillator to a base station and from the base station to an external location, such as a central repository, doctor, hospital, etc." 5:23-6:7; 65:10-18 ("The external interface in the base station can comprise a *modem* link, a network connection, or the like over which data may be transmitted to and from base station 2." ; Figs. 1 and 2; 64:2-15.
4(d) a patient database;	"[T]he present invention is a method for reprogramming a defibrillator based on a *central database* of information relating to patients that use a type of defibrillator. The method includes collecting, in the central database, information relating to a plurality of patients that use the type of defibrillator, analyzing the information stored in the central *database* . . . ." 8:2-9 (emphasis added); 14:2-6 "Data retrieved by base station 2 from defibrillator 10 may be transmitted to central repository 9 . . . . *Central repository 9* preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients, all of whom use the same type of defibrillator." (Emphasis added).
4(e) means for monitoring and storing operations information of the medical device and patient compliance and use data; **1. Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	**1. <u>Means for Monitoring</u>:** ***Structure*:** "Defibrillator 10" (which includes diagnostics module 84) Fig. 8; 52:13-23. ***Function*:** "[D]iagnostics module 84 performs diagnostics on defibrillator 10 related to the operation and safety thereof prior to transmitting defibrillation energy to the patient. . . . In a case that diagnostics module 84 detects operational defects as a result of these diagnostics, this information is stored in data logging memory block 57 . . . ." 52:14-20. "[D]iagnostics module 84 also performs a plurality of diagnostics on defibrillator 10 to test defibrillator 10's

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
2. Structure: Memory	hardware. . . . Other tests include . . . electrodes-off-tests in which processor 109 confirms that electrodes are attached to the patient . . . .” 62:25-63:28; 14:30-32 (“Electrode harness 4 . . . can be worn for approximately 2 to 7 days or longer for a cumulative period of 1 week to 12 months. To this end, electrode harness 4 may include a means for defibrillator 10 to determine how long electrodes harness 4 has been connected thereto.); 31:28-32. **2. <u>Means for Storing</u>:** ***Structure*:** “memory block 57” 34:15-16. ***Function*:** “Data logging memory block 57 stores both the operational history of defibrillator and information relating to the patient. More specifically, data logging memory 57 stores . . . patient’s ECG before, during and after application of defibrillation energy . . . information concerning patient interaction with the defibrillator 10 . . . detected operational errors of defibrillator 10 . . . and patient parameters. These patient parameters include . . . electrode-to-skin impedance range which is used to determine whether the electrodes are not attached, or are improperly attached to the patient . . . . In summary, data logging memory block essentially stores any information provided to, or transmitted from, defibrillator 10 over a predetermined span of time . . . .” 35:9-36:20; 5:19-23; 52:14-23.
4(f) means for connecting the patient database to the communication network; and **Structure**: modem, or other data transfer technologies	***Structure*: “**External interface (modem embodiment)” and “external data link 17” 14:2-12; Fig. 2. ***Function*:** “Data retrieved by base station 2 from defibrillator 10 may be transmitted to central repository 9 *via* external data link 17. . . A personal computer 19 is in communication with central repository 9.” 14:2-12 (emphasis added); “External interface comprises a link to an external location such as a central repository (see Figure 1) . . . over which patient and defibrillation information is transmitted to the external source, and *over which the external information is received from the external source*. External interface can comprise a

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
	modem link, a network connection, or the like over which data may be transmitted *to* and from base station 2." 65:10-18 (emphasis added).
4(g) means for exchanging information between the medical device and the patient database, **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: "Base station" 5:23-6:7. ***Function***: "The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are *transmitted*, and over which external information is *received* . . . . The base station also includes an external interface, over which the defibrillation information and the patient information is *transmitted* to an external location, and over which the external information is *received* from the external location. By virtue of the foregoing arrangement, it is possible to transmit patient and defibrillation information from a defibrillator to a base station and from the base station to an external location, such as a central repository, doctor, hospital, etc." 5:23-6:7 (emphases added); 7:20-24; 64:2-6 ("[A] base station for use with the present invention includes a defibrillator interface, over which information is exchanged with the defibrillator, and an external interface over which information is exchanged with an external entity, such as central repository 9, a doctor's office, a hospital, etc.").
4(h) including means for transmitting the medical device operations information and the patient compliance and use data to the patient database via the communication network. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a	***Structure***: "Base station" 5:23-6:7. ***Function***: "The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are *transmitted*, and over which external information is received . . . The base station also includes an external interface, over which the defibrillation information and the patient information is *transmitted* to an external location, and over which the external information is received from the external location. By virtue of the foregoing arrangement, it is possible to transmit patient and defibrillation information from a defibrillator to a base station and from the base station to an external location, such as a central repository, doctor, hospital, etc." 5:23-6:7 (emphases added); 7:20-24; 64:2-6 ("[A] base

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
transcutaneous transmitter	station for use with the present invention includes a defibrillator interface, over which information is exchanged with the defibrillator, and an external interface over which information is exchanged with an external entity, such as central repository 9, a doctor's office, a hospital, etc.").
5. The system as recited in claim 4, further comprising means for monitoring an operating status of the medical device. **Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	***Structure*****:** Defibrillator 10 (which includes diagnostics module 84). Fig. 8; 52:13-23. ***Function*****: "**[D]iagnostics module 84 performs diagnostics on defibrillator 10 related to the operation and safety thereof prior to transmitting defibrillation energy to the patient. . . . In a case that diagnostics module 84 detects operational defects as a result of these diagnostics, this information is stored in data logging memory block 57 . . . . Such information also may be transmitted to base station 2 or personal computer 6." 52:14-23.
8. The system as recited in claim 4, wherein said means for exchanging information includes means for transmitting patient medical information from the medical device to the patient database. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: "Base station" 5:23-6:7. ***Function***: "The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are *transmitted*, and over which external information is *received* . . . . The base station also includes an external interface, over which the defibrillation information and the patient information is *transmitted* to an external location, and over which the external information is *received* from the external location. By virtue of the foregoing arrangement, it is possible to transmit patient and defibrillation information from a defibrillator to a base station and from the base station to an external location, such as a central repository, doctor, hospital, etc." 5:23-6:7 (emphases added); 7:20-24; 8:9-12; 64:2-6 ("[A] base station for use with the present invention includes a defibrillator interface, over which information is *exchanged* with the defibrillator, and an external interface over which information is exchanged with an external entity, such as central repository 9, a doctor's office, a hospital, etc." (emphasis added)).

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
9. The system as recited in claim 4, wherein said means for monitoring operations information includes means for monitoring battery status for a battery of the medical device.	Owen discloses that "diagnostics module 84 performs diagnostics on defibrillator 10 related to the operation and safety thereof prior to transmitting defibrillation energy to the patient. These diagnostics include diagnostics that are performed at power-on of defibrillator 10 in order to determine if there are operational defects therein." (52:13-16). Owen further discloses that it can run "[c]old start diagnostics [that] include . . . back up battery voltage tests. . . ." 63:1-8.
16. The system as recited in claim 8, further including means for accessing the patient database via the communication network, wherein medical personnel can analyze the patient medical information from a remote location. **Structure:** Home or office computer	***Structure*:** "Personal computer 19" Fig. 8; 14:2-12. ***Means*:** "Data retrieved by base station 2 from defibrillator 10 may be transmitted to central repository 9 via external data link 17. Central repository 9 preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients, all of whom use the same type of defibrillator. A personal computer 19 is in communication with central repository 9. This personal computer may be used to analyze the patient and defibrillation information received from the defibrillator 10 in view of corresponding information from the plurality of other patients." 14:2-12; 8:2-9.
19(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	See claim element 4(pre) above for support.
19(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the	See claim element 4(a) above for support.

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
medical device is worn by the patient;	
19(b) a communications network;	See claim element 4(b) above for support.
19(c) means for connecting the medical device to the communication network;	See claim element 4(c) above for support.
19(d) a patient database;	See claim element 4(d) above for support.
19(e) means for connecting the patient database to the communication network;	See claim element 4(f) above for support.
19(f) means for monitoring and storing patient medical parameters, device performance data and patient compliance data;	See claim element 4(e) above for support.
19(g) means for exchanging information between the medical device and the patient database,	See claim element 4(g) above for support.
19(h) including means for transmitting the patient medical parameters, device performance data and patient compliance data to the patient database via the communications network; and	See claim element 4(h) above for support.
19. (i) means for downloading device parameter software to the medical device from the communications network.	***Structure***: "Base station" 5:23-6:7. ***Function***: "The defibrillator also includes a base station interface, over which the patient information and the defibrillation information are transmitted, and over which external information is received . . . . The

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
Structure: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	base station includes an external interface, over which the defibrillation information and patient information is[sic] transmitted to an external location, and over which the external information is received from the external location. . . . [T]he foregoing arrangement makes it possible to transmit external information from the base station to the defibrillator. This information can be used, e.g., to reprogram the defibrillator . . . ." 5:23-6:10; 8:2-16; 65:29-31; 67:14-26; 68:17-23; 94:25-95:4.
20. The system as recited in claim 19, wherein the device parameter software includes one or more of operations upgrade software, patient compliance guidelines or product maintenance information.	"As noted above, it is possible to reprogram defibrillator 10 and/or base station 2 with information received from the external location. In fact, it is even possible to use information received from defibrillator 10 to affect such reprogramming." 68:17-23; 8:2-16; 65:19-66:15; 67:14-26; 94:25-95:4.

2. Payne Anticipates the Challenged Claims Under 35 U.S.C. § 102(b)

Payne discloses all the elements of the challenged claims. *See* Efimov Decl. at ¶¶ 81-130. Payne discloses a wearable defibrillator capable of monitoring a patient's heart condition and administering a defibrillating shock if needed. *See* Payne (Ex. 1004), Figs. 1, 2 and 8; 4:9-11; 7:2-9. Payne's defibrillator can monitor patient medical information, *id.* at 7:10-12, and its own operation and run diagnostics to determine operational errors or proper use errors (such as failure to properly attach electrodes), *id.* at 11:40-12:2. Payne's system includes a bidirectional communication link that allows for transmission of information from

the defibrillator to an external unit and vice versa. *See id.* at 10:57-11:6. Such arrangement permits, for example, the external reprogramming of the defibrillator's microprocessor. *See id.* at 11:6-8. In embodiments in which the defibrillator moves with the patient, the bidirectional communications link is implemented as a two-way communication radio that allows data to be transmitted while the patient wears the device. *See id.* at 10:43-62; 10:63-65; 6:31-36. The information can be stored remotely, for example, in the external unit, and can be accessed by a doctor's office or hospital for evaluation and analysis. *See id.* at 9:5-26; 10:43-11:3; 11:34-39.

Challenged Claims	**Exemplary Cites to Payne (Ex. 1004)**
1(pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	"The present invention provides an integrated method . . . for monitoring, detecting, and treating conditions of ventricular fibrillation, ventricular tachycardia, and other associated conditions precipitated by the onset of electrical instabilities of the heart muscle." 20:42-46; 2:52-64.
1(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	"System 100 is an external cardiac monitor and cardioverter/defibrillator which is depicted connected to a patient 110. Through sensors, the system 100 monitors the signals from the patient's heart and automatically detects abnormal heart rhythms. . . . If therapy is necessary, the system 100 automatically delivers electrical and/or drug therapy in order to return the patient's heart to a normal cardiac rhythm." 4:7-19; 6:26-29 ("The signals could be audible tones, vibrations, or other signals discernible by the *wearer* and/or attendant." (emphasis added)); 7:2-4 ("FIG. 8 illustrates an additional ambulatory embodiment with the system 100 in a pack 240 which can be carried on a patient's back."); 7:7-9 ("[S]ystem 100 could also be

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
	divided into various components distributed in a vest or on a belt to be *worn* by the patient." (emphasis added)); Fig. 8.
1(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
1(c) recording the patient medical information in a storage means of the medical device; **Structure for "storage means"**: memory	***Structure***: Memory in microprocessor 120. 4:37-44. ***Function***: "[O]ne embodiment of the system 100 may also include optional data acquisition and storage components for continuous storage of ECG data which is acquired, stored, and displayed before, during, and following any episode or multi-episodes requiring electric pulse therapy. Furthermore, components for storing other data associated with an event such as, but not limited to the date and time of an event, the amount of energy delivered, and the response of the patient 110 to the delivered energy." 6:31-36.
1(d) operatively connecting the medical device to a communications system;	"One embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communication link 180 . . . ." 10:43-48; Fig. 1 (reference 180); 6:9-11.
1(e) transmitting the patient medical information to a health care provider by means of said communications system and recording the patient medical information in an information database; and	"[I]n addition to providing monitoring and electrical cardiac regulation, . . . the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180 . . . [which is] able to transmit and receive information relevant to the treatment of the patient 110. In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:43-62; 9:5-26; 11:34-39 ("The data which may be monitored through the external programming and monitoring unit 187 can be transferred to *other data storage devices*, including

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
	magnetic or hard data storage peripheral devices, a printer, the strip chart recorder 129, or other similar data recording means.)(Emphasis added).
1(f) providing access to the patient medical information to individuals.	"In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:57-62. "In addition to providing monitoring and electrical cardiac regulation, one embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180 . . . . The bidirectional communication link 180 is advantageously able to transmit and receive *information relevant to the treatment of the patient* 110." 10:43-59 (emphasis added); 11:9-14; 12:23-37.
2 (pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	See claim element 1(pre) above for support.
2(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	See claim element 1(a) above for support.
2(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
2(c) recording the patient medical information, device	***Structure***: Memory in microprocessor 120, 4:37-44, parameter memory 121, 8:61-63. ***Function***: "[I]n accordance with their knowledge of the

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
performance data and patient compliance data in a storage means of the medical device; **Structure for "storage means"**: memory	patient's condition, trained medical personnel are able to provide the proper inputs to the system 100 which serve to maximize the monitoring capability and the therapeutic effect of the system 100. Advantageously, these parameters are stored in the parameter memory 121." 8:58-63; 9:5-26; 6:31-36 ("[O]ne embodiment of the system 100 may also include optional data acquisition and storage components for continuous storage of ECG data which is acquired, stored, and displayed before, during, and following any episode or multi-episodes requiring electric pulse therapy. Furthermore, components for storing other data associated with an event such as, but not limited to the date and time of an event, the amount of energy delivered, and the response of the patient 110 to the delivered energy.") 6:17-22 ("The microprocessor 120 may also be connected to a real-time clock 190 via a bidirectional bus 192. The clock 190 allows the system 100 to maintain a 20 real-time account of the cardiac status of the patient 110 so that significant events may be labeled with the time and date at which they occurred for future analysis."); 10:67-11:3("Other useful information that may be transmitted includes the status of the system 100 itself in case any system malfunctions are observed, so that the physician is able to make a recommendation to correct the situation.").
2(d) operatively connecting the medical device to a communications system;	See claim element 1(d) above for support.
2(e) transmitting the patient medical information, device performance data and patient compliance data to a health care provider by means of said communications system	"In addition to providing monitoring and electrical cardiac regulation, one embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180 . . . . The bidirectional communication link 180 is advantageously able to transmit and receive

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
and	*information relevant to the treatment of the patient* 110." 10:43-59 (emphasis added); 10:67-11:3("Other useful information that may be transmitted includes the *status of the system* 100 itself in case any system malfunctions are observed, so that the physician is able to make a recommendation to correct the situation." (emphasis added)); 6:17-22 ("The microprocessor 120 may also be connected to a real-time clock 190 via a bidirectional bus 192. The clock 190 allows the system 100 to maintain a 20 real-time account of the cardiac status of the patient 110 so that significant events may be labeled with the time and date at which they occurred for future analysis."); 12:23-37.
2(f) recording the patient medical information, device performance data and patient compliance data in an information database**,**	"The data which may be monitored through the external programming and monitoring unit 187 can be transferred to other data storage devices, including magnetic or hard data storage peripheral devices, a printer, the strip chart recorder 129, or other similar data recording means." 11:34-39; 9:5-26; 10:43-62. See also claim elements 1(e), 2(c) and 2(e) above for support.
2(g) wherein said transmitting step is performed while the medical device is operatively connected to the patient for providing treatment to the patient; and	"In one embodiment the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis. In addition, the link 180 transmits *real time* ECG data to verify proper acquisition of the signals and proper attachment of the sensing electrodes 143-145. . . . Other useful information that may be transmitted includes the status of the system 100 itself in case any system malfunctions are observed, so that the physician is able to make a recommendation to correct the situation." 10:59-11:3; *See* Efimov Decl. at ¶ 98. "[O]ne embodiment of the system 100 may also include optional data acquisition and storage components for continuous storage of ECG data which is acquired, stored, *and displayed* before, *during*, and following any episode or multi-episodes requiring electric pulse therapy. . . ." 6:31-36 (emphasis added). "[W]herein the system 100 is embodied as an

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
	ambulatory monitor and cardioverter/defibrillator device, the bi-directional communications link may be implemented as a two-way radio, or other device which is capable of transmitting and receiving radio signals . . . . [T]he bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:43-62; 10:63-65.
2(h) providing access to the patient medical information, device performance data and patient compliance data to individuals.	"In one embodiment the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis. In addition, the link 180 transmits real time ECG data to verify proper acquisition of the signals and proper attachment of the sensing electrodes 143-145. . . . Other useful information that may be transmitted includes the status of the system 100 itself in case any system malfunctions are observed, so that the physician is able to make a recommendation to correct the situation." 10:59-11:3. "In addition to providing monitoring and electrical cardiac regulation, one embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180 . . . . The bidirectional communication link 180 is advantageously able to transmit and receive information relevant to the treatment of the patient 110." 10:43-59.
4.(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	"The present invention is an external cardiac monitor and cardioverter/defibrillator system . . . .[T]he system automatically delivers or withholds therapy according to parameters preferably selected through programming by the physician." 2:18-25; 2:52-64; Fig. 3.
4(a) a wearable medical device for monitoring and storing medical parameters and treating	"System 100 is an external cardiac monitor and cardioverter/defibrillator which is depicted connected to a patient 110. . . . [T]he system 100 monitors the signals from the patient's heart . . . . If therapy is

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	necessary, the system 100 automatically delivers electrical and/or drug therapy in order to return the patient's heart to a normal cardiac rhythm. The system 100 as described may be implemented as an ambulatory or portable monitor and cardioverter/defibrillator device." 4:8-23; 6:26-29; 7:2-4 ("FIG. 8 illustrates an additional ambulatory embodiment with the system 100 in a pack 240 which can be carried on a patient's back."); 7:7-9 ("[S]ystem 100 could also be divided into various components distributed in a vest or on a belt to be *worn* by the patient."(emphasis added)). ("[O]ne embodiment of the system 100 may also include optional data acquisition and storage components for continuous storage of ECG data which is acquired, stored, and displayed before, during, and following any episode or multi-episodes requiring electric pulse therapy. Furthermore, components for storing other data associated with an event such as, but not limited to the date and time of an event, the amount of energy delivered, and the response of the patient 110 to the delivered energy.") 6:31-36
4(b) a communications network;	"The bidirectional communication link 180 . . . able to transmit and receive information relevant to the treatment of the patient 110. In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:57-62; 6:9-12 ("The communication link 180 is adapted to connect to a system external programming and monitoring unit 187 via signal lines 185."); Fig. 1.
4(c) means for connecting the medical device to the communication network; **Structure**: internal or external modem or base station with a modem, and in the case of an	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving radio signals). 10:43-56. ***Function***: "The microprocessor 120 is further connected to a bidirectional communication link 180 via signal lines 182. The communication link may comprise, for example, a two way-radio

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
implantable device, including a transcutaneous transmitter.	transmitter/receiver, a telephone modem, or any other bidirectional communication means which are appropriate to transmit information relating to the cardiac status of the patient 110. The bidirectional communication link 180 is adapted to *connect* to a system external programming and monitoring unit 187 via signal lines 185." 6:3-12 (emphasis added); 10:57-62.
4(d) a patient database;	"[I]n addition to providing monitoring and electrical cardiac regulation, one embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. . . . In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:43-62; 2:28-30 (The microprocessor obtains *data* from signals provided by one or more ECG sensors, and a plurality of optional secondary sensors." (emphasis added)); 11:34-39 ("[T]he data which may be monitored through the external programming and monitoring unit 187 can be transferred to *other* data storage devices." (emphasis added)).
4(e) means for monitoring and storing operations information of the medical device and patient compliance and use data; **1. Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	**1. <u>Means for Monitoring</u>**: ***Structure***: System 100 "an external cardiac monitor and cardioverter/defibrillator . . . ." 4:9-11. ***Function***: "[O]nce the power is supplied to the system 100 . . . an internal systems diagnostics check is performed in a process block 305. The internal diagnostics execute system checks on functions such as battery life . . . the status of the charging capacitor within the cardioverter/defibrillator circuitry 130, and the status of the electrodes 143-145." 11:43-52; 6:19-23 ("The clock 190 allows the system 100 to maintain a real-time account of the cardiac status of the patient 110 so that significant events may be labeled with the time and date at which they occurred for future analysis."); 6:31-36; 11:30-34; 12:31-33; Fig. 3A (references 305 and 308).

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
2. Structure: Memory	**2. <u>Means for Storing</u>**: ***Structure***: Memory in microprocessor 120. 4:37-44. ***Function***: See claim element 2(c) above for support. *See also* 4:37-44; Fig. 1 (reference 120).
4(f) means for connecting the patient database to the communication network; and **Structure**: modem, or other data transfer technologies	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving radio signals) 10:43-56. ***Function***: "In order to externally program and monitor the system 100, the external programming and monitoring unit 187 may be employed at the hospital end of the bidirectional communication link 180." 11:9-12. "The bidirectional communication link 180 is adapted to *connect* to a system external programming and monitoring unit 187 via signal lines 185." 6:10-12 (emphasis added).
4(g) means for exchanging information between the medical device and the patient database, **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter.	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving radio signals). 10:43-56. ***Function***: "The bidirectional communication link 180 is advantageously able to *transmit and receive* information relevant to the treatment of the patient 110. In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis. In addition, the link 180 transmits real time ECG data to verify proper acquisition of the signals, and proper attachment of the sending electrodes 143-145. . . . Other useful information that may be transmitted includes the *status of the system* 100 itself in case any system malfunctions are observed, so that the physician is able to make a recommendation to correct the situation." 10:57-11:3 (emphases added); 6:19-23. Furthermore, the bidirectional communications link 180 can receive information from a remote location such as a doctor's

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
	office or hospital." 10:57-11:6 (emphasis added). 6:9-12 ("The communication link 180 is adapted to connect to a system external programming and monitoring unit 187 via signal lines 185."); Fig. 1.
4(h) including means for transmitting the medical device operations information and the patient compliance and use data to the patient database via the communication network. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving radio signals). 10:43-56. ***Function***: "The bidirectional communication link 180 is advantageously able to *transmit* and receive information relevant to the treatment of the patient 110. In one embodiment, the bidirectional communication link 180 *transmits* patient information to the corresponding doctor's office or hospital for evaluation and analysis. In addition, the link 180 *transmits* real time ECG data to verify proper acquisition of the signals, and proper attachment of the sending electrodes 143-145. . . . Other useful information that may be transmitted includes the status of the system 100 itself in case any system malfunctions are observed . . . . Furthermore, the bidirectional communications link 180 can receive information from a remote location such as a doctor's office or hospital." 10:57-11:6 (emphasis added); 6:9-12 ("The communication link 180 is adapted to connect to a system external programming and monitoring unit 187 via signal lines 185."); Fig. 1.
5. The system as recited in claim 4, further comprising means for monitoring an operating status of the medical device. **Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump,	***Structure***: System 100 "an external cardiac monitor and cardioverter/defibrillator . . . ." 4:9-11. ***Function***: "[O]nce the power is supplied to the system 100 . . . an internal systems diagnostics check is performed in a process block 305. The internal diagnostics execute system checks on functions such as battery life . . . the status of the charging capacitor within the cardioverter/defibrillator circuitry 130, and the status of the electrodes 143-145." 11:43-52; 11:30-34; 12:31-33; Fig. 3A (references 305 and 308).

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
pacemaker)	
8. The system as recited in claim 4, wherein said means for exchanging information includes means for transmitting patient medical information from the medical device to the patient database. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving radio signals). 10:43-56 ***Function***: "[O]ne embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180. . . . The bidirectional communication link 180 is able to *transmit* and *receive information relevant to the treatment of the patient 110*. In one embodiment, the bidirectional communication link 180 *transmits* patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:43-62 (emphases added)."The communication link 180 is adapted to connect to a system external programming and monitoring unit 187 via signal lines 185." 6:9-12; Fig. 1.
9. The system as recited in claim 4, wherein said means for monitoring operations information includes means for monitoring battery status for a battery of the medical device. **Structure:** Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	***Structure***: System 100 "an external cardiac monitor and cardioverter/defibrillator . . . ." 4:9-11. ***Function***: "[O]nce the power is supplied to the system 100 . . . an internal systems diagnostics check is performed in a process block 305. The internal diagnostics execute system checks on functions such as battery life . . . the status of the charging capacitor within the cardioverter/defibrillator circuitry 130, and the status of the electrodes 143-145." 11:43-52; 6:19-23 ("The clock 190 allows the system 100 to maintain a real-time account of the cardiac status of the patient 110 so that significant events may be labeled with the time and date at which they occurred for future analysis."); 6:31-36; 11:30-34; 12:31-33; Fig. 3A (references 305 and 308).
16. The system as recited in claim 8, further	***Structure***: "personal computer or custom computer." 11:9-12.

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
including means for accessing the patient database via the communication network, wherein medical personnel can analyze the patient medical information from a remote location. **Structure:** Home or office computer	***Function***: **"**In order to externally program and monitor the system 100, the external programming and monitoring unit 187 may be employed at the hospital end of the bidirectional communication link 180. For example, a personal computer or custom computer designed for this task may be employed as the external programming and monitoring unit 187. . . . It should be noted that the external programming unit 187 may also be incorporated within the control and display unit 144 or as an additional host computer system which may be coupled with the microprocessor 120." 11:9-33; 10:56-62; "[O]ne embodiment of the system 100 of the present invention is capable of communicating with a physician or other trained medical personnel from a remote location. This may be accomplished by means of the bidirectional communications link 180. . . .[,] able to transmit and receive information relevant to the treatment of the patient 110. In one embodiment, the bidirectional communication link 180 transmits patient information to the corresponding doctor's office or hospital for evaluation and analysis." 10:43-62.
19(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	See claim element 4(pre) above for support.
19(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn	See claim element 4(a) above for support.

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
by the patient;	
19(b) a communications network;	See claim element 4(b) above for support.
19(c) means for connecting the medical device to the communication network;	See claim element 4(c) above for support.
19(d) a patient database;	See claim element 4(d) above for support.
19(e) means for connecting the patient database to the communication network;	See claim element 4(f) above for support.
19(f) means for monitoring and storing patient medical parameters, device performance data and patient compliance data;	See claim element 4(e) above for support.
19(g) means for exchanging information between the medical device and the patient database,	See claim element 4(g) above for support.
19(h) including means for transmitting the patient medical parameters, device performance data and patient compliance data to the patient database via the communications network; and	See claim element 4(h) above for support.
19(i) means for downloading device parameter software to the medical device from the	***Structure***: Bidirectional communication link 180 (which can be implemented as a telephone modem device or as a two-way communication radio, or other device which is capable of transmitting and receiving

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
communications network. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	radio signals). 10:43-56. ***Function***: "The bidirectional communication link 180 is adapted to connect to a system external programming and monitoring unit 187 via signal lines 185." 6:10-12. "The bidirectional communication link 180 can *receive* information from a remote location such as a doctor's office or hospital. 11:4-7 (emphasis added); 8:64-9:14 ("In one embodiment, the system 100 includes additional programming features such as 'batch processing' . . . [which] allows a physician to set individual program settings into the external programming unit 187 and, after the program is satisfactory, *download* the program to the system 100." (emphasis added)); 9:5-16.
20. The system as recited in claim 19, wherein the device parameter software includes one or more of operations upgrade software, patient compliance guidelines or product maintenance information.	"In one embodiment, the system 100 includes additional programming features such as "batch processing . . . [which] allows a physician to set individual program settings into the external programming unit 187 and, after the program is satisfactory, download the program to the system 100." 8:64-9:14; 9:5-16.

3. Mechlenburg Anticipates Challenged Claims 1, 4, 5, 8, 16, 19 and 20 Under 35 U.S.C. § 102(e)

Mechlenburg is an early patent related to the commercial product that Patent Owner accuses Petitioner of infringing in the Related Litigation. Patent Owner's assertion of the '003 Patent against the accused product suggests a broad interpretation of the challenged claims such that they are anticipated by Mechlenburg. In this context, Mechlenburg anticipates challenged claims 1, 4, 5, 8, 16, 19 and 20. *See* Efimov Decl. at ¶¶ 131-165.

Mechlenburg discloses a variable pressure device used to provide a positive pressure therapy to a patient with certain respiratory conditions. *See* Mechlenburg (Ex. 1005), 3:56-61. The device can be connected to a patient through a patient interface device such as a nasal/oral mask, total face mask, or nasal cannula. *See id.* at 4:64-67. The variable pressure therapy systems include a sensor that detects the conditions of the patient so that the pressure provided can be controlled based on the detected conditions. *See id.* at 4:26-29. The variable pressure device has a control unit that can monitor and store patient medical information, patient compliance information, and information related to the proper operation of the device. *See id.* at 4:57-64; 5:39-49; 6:9-18. Mechlenburg also discloses a communication network that connects one or more variable pressure devices with one or more remote locations, enabling the caregiver to monitor various aspects of the patient's treatment and adjust the operating parameters of the device if needed. *See id.* at Fig. 3; 5:54-58; 6:40-43; 6:60-7:10.

Challenged Claims	**Exemplary Cites to Mechlenburg (Ex. 1005)**
1(pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	"[A] method of treating and monitoring the treatment of a breathing disorder . . . that includes the steps of: (1) providing a device that administers a pressure therapy to a patient and includes an interactive capability, (2) causing the device to provide information to the patient, such as questions or symbols, and (3) acquiring, via the device, information from the patient, such as responses to the questions or reactions to the symbols presented." 3:10-16. The tests that are disclosed in Mechlenburg are used to determine whether the patient is experiencing symptoms associated with

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
	certain respiratory conditions such as sleep apnea. *See, e.g.*, 1:52-2:4; claims 2-4.
1(a) providing a wearable medical device[1] for monitoring patient medical information and treating the patient in response to a monitored medical condition;	"According to one embodiment of the present invention [A] patient interface device 44, such as a nasal mask, nasal/oral mask, total face mask, nasal cannula, trachea tube, or any other suitable device connects the patient to breathing circuit 40." 4:64-67; Fig. 1 (references 30, 40, 42 and 44)
1(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
1(c) recording the patient medical information in a storage means of the medical device; **Structure for "storage means"**: memory	***Structure***: Control unit 42 (which includes memory) 5:45-49 ***Function***: "Control unit 42 can also include a suitable amount of memory for storing information necessary to carry out these functions, such as sufficient *memory to store* indicia to present to the user and the responses thereto." 5:45-49; 5:63-6:1. As explained above, the tests that are disclosed in Mechlenburg are used to determine whether the patient is experiencing symptoms associated with certain respiratory conditions such as sleep apnea. *See, e.g.*, 1:52-2:4. ("Memory 54 functions as an extended memory supplementing the memory that

[1] In the context of this petition, the claim terms are entitled to their "broadest reasonable construction." 37 C.F.R. § 42.100(b). In the Related Litigation, the claim terms will be given their "broadest reasonable construction" but only "in light of the specification and prosecution of the patent in which [they] appear." *See Phillips v. AWH Corp*., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Thus, the term "wearable medical device," for example, would be construed more narrowly in the Related Litigation based on the specification and prosecution history. While Mechlenburg is anticipatory in the context of this petition, it would not be anticipatory in the Related Litigation.

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
	is provided in control unit 42 . . . [and] can be used to store, for example, additional tests to provide to the patient, and extended amount of results input from the patient and/or the scores associated with the results provided by the patient.")(emphasis added).
1(d) operatively connecting the medical device to a communications system;	"In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is transmitted to and/or received from the interactive pressure support system 30 and/or remote locations." 6:60-67; Fig. 3; 5:54-58.
1(e) transmitting the patient medical information to a health care provider by means of said communications system and recording the patient medical information in an information database; and	"In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is transmitted to and/or received from the interactive pressure support system 30 and/or remote locations. . . . Communications system 66 is any communication network that transmits data from one location to another. For example, communication system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote location 68 via modems . . . . Remote locations 68 are any device capable of communication with the interactive pressure support system 30. Typically, a remote location is acomputer located at the care giver and/or test administrator." 6:60-7:12. "Depending on the desired operation of the interactive system, the test score, the results of the test, and/or other data, . . . are stored in control unit 42 and/or memory 54 in step 78 for later retrieval and/or transmission to a remote location in step 80; or steps 78 and 80 are performed immediately upon completion of the test with the test results being sent immediately to a remote location, such as remote locations 68 or *a processing system* in communication system 66." 7:54-

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
	63. The database in Mechlenburg may be located in the processing system in communications system 66 or in remote location 68, as Mechlenburg describes both locations as having the ability to collect and process data or information . Such functionality necessarily discloses storing the information to preserve it until the necessary or desired processing is complete. As such, these are locations "for the storage of information" and therefore disclose the "information database." *See* Efimov Decl. at ¶ 137.
1(f) providing access to the patient medical information to individuals.	"Remote locations 68 are any device capable of communicating with the interactive pressure support system 30. Typically, a remote location is a computer located at the care giver and/or test administrator. In an exemplary embodiment of the present invention, the user at the remote location *downloads* data from the interactive pressure support system 30 and/or base stations in communication system 66 that collect data from the interactive pressure support systems so that this information can be used to monitor the condition of the patient." 7:10-19(emphasis added). "Depending on the desired operation of the interactive system, the test score, the results of the test, and/or other data, . . . are stored in control unit 42 and/or memory 54 in step 78 for later retrieval and/or transmission to a remote location in step 80; or steps 78 and 80 are performed immediately upon completion of the test with the test results being sent immediately to a remote location, such as remote locations 68 or a processing system in communication system 66." 7:54-63.
4.(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	"[T]he present invention provides a system that performs two functions: (1) it provides a treatment to the patient to correct a disorder suffered by the patient, such as a pressure support device to treat OSA, and (2) it provides an interactive function so that the caregiver can periodically monitor the effectiveness of the treatment by having the patient complete a test intended to measure the patient's condition using the

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
	same device used to treat the patient." 8:9-20; 3:6-25; 4:57-64. As explained above, the tests that are disclosed in Mechlenburg are used to determine whether the patient is experiencing symptoms associated with certain respiratory conditions such as sleep apnea. *See, e.g.*, 1:52-2:4; claims 2-4.
4(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
4(b) a communications network;	"FIG. 3 is a schematic diagram of a *communication network* 60 that includes interactive pressure support system 30 of the present invention." 6:58-60 (emphasis added); Fig. 3; claim 21.
4(c) means for connecting the medical device to the communication network; **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Modem 6:60-7:10 ***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is transmitted to and/or received from the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with *the interactive pressure support systems 30 communicating with remote locations 68 via modems*, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10 (emphasis added); Fig. 3; 5:54-58.
4(d) a patient database;	See claim element 1(e) above for support.

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
4(e) means for monitoring and storing operations information of the medical device and patient compliance and use data; **1. Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker) **2. Structure**: Memory	**1. <u>Means for Monitoring</u>**: ***Structure***: Pressure support system 30, which includes control unit 42. 4:57-64. ***Function***: "According to one embodiment of the present invention, control unit 42 performs the patient monitoring function and controls the pressure provided to the patient as discussed above in conjunction with pressure control unit 38. . . . [C]ontrol unit 42 can perform other functions, such as monitoring use of the pressure generating system (patient compliance), running diagnostics routines and providing error/warning indications." 4:57-64. **2. <u>Means for Storing</u>**: ***Structure***: Memory 5:39-49 ***Function***: "Control unit 42 is any suitable device that can perform the functions discussed above with respect to pressure generating systems 32 and the input/output functions of interactive system 34. . . . Control unit 42 can also include a suitable amount of memory for storing information necessary to carry out these functions, such as sufficient memory to store the indicia to present to the user and the responses thereto." 5:39-49; 6:9-18.
4(f) means for connecting the patient database to the communication network; and **Structure**: modem, or other data transfer technologies	***Structure***: Modem 6:60-7:10 ***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is transmitted to and/or received from the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote locations 68 via modems, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10; Fig. 3; 5:54-58.
4(g) means for	***Structure***: Modem 6:60-7:10

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
exchanging information between the medical device and the patient database, **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is *transmitted to and/or received from* the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote locations 68 via modems, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10 (emphasis added); Fig. 3; 5:54-58.
4(h) including means for transmitting the medical device operations information and the patient compliance and use data to the patient database via the communication network. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Modem 6:60-7:10 ***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is *transmitted to* and/or received from the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote locations 68 via modems, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10 (emphasis added); Fig. 3; 5:54-58; 7:20-29.

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
5. The system as recited in claim 4, further comprising means for monitoring an operating status of the medical device. **Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	***Structure***: Pressure support system 30, which includes control unit 42. 4:57-64. ***Function***: See claim element 4(e)(1) above for support.
8. The system as recited in claim 4, wherein said means for exchanging information includes means for transmitting patient medical information from the medical device to the patient database. **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Modem 6:60-7:10 ***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is *transmitted to* and/or received from the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote locations 68 via modems, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10 (emphasis added); Fig. 3; 1:52-54; 5:54-58; 7:13-20.
16. The system as recited in claim 8, further including means for accessing the patient database via the communication network, wherein medical personnel can analyze the patient	***Structure***: Computer 7:10-19 ***Function*:** "Remote locations 68 are any device capable of communicating with the interactive pressure support system 30. Typically, a remote location is a computer located at the care giver and/or test administrator. In an exemplary embodiment of the present invention, the user at the remote location downloads data from the interactive pressure support system 30 and/or base stations in communication system 66 that collect data

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
medical information from a remote location. **Structure:** Home or office computer	from the interactive pressure support systems so that this information can be used to monitor the condition of the patient." 7:10-19; Fig. 3 (Remote location A and remote location B). *See also* claim element 1(e) above for support.
19(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	See claim element 4(pre) above for support.
19(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
19(b) a communications network;	See claim element 4(b) for support.
19(c) means for connecting the medical device to the communication network;	See claim element 4(c) for support.
19(d) a patient database;	See claim element 4(d) above for support.
19(e) means for connecting the patient database to the communication network;	See claim element 4(f) above for support.

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
19(f) means for monitoring and storing patient medical parameters, device performance data and patient compliance data;	See claim element 4(e) above for support.
19(g) means for exchanging information between the medical device and the patient database,	See claim element 4(g) above for support.
19(h) including means for transmitting the patient medical parameters, device performance data and patient compliance data to the patient database via the communications network; and	See claim element 4(h) above for support.
19. (i) means for downloading device parameter software to the medical device from the communications network **Structure**: Internal or external modem or a base station with a modem, and in the case of an implantable device, additionally including a transcutaneous transmitter	***Structure***: Modem 6:60-7:10 ***Function***: "In the illustrated network, a number of interactive pressure support systems 30 communicate via communication links 62 and 64 and communications system 66 to one or more locations 68. Communications links 62 and 64 can be hard wired or wireless so long as information is *transmitted to and/or received from* the interactive pressure support system 30 and/or remote locations. . . . [C]ommunications system 66 can be a conventional telephone or computer network with the interactive pressure support systems 30 communicating with remote locations 68 via modems, a satellite based system, a fiber optic/optical system, a microwave system or any combination thereof." 6:60-7:10 (emphasis added); Fig. 3; 5:54-58; 6:40-43 ("In addition, the operating parameters of the therapy device can be controlled and altered to meet the specific needs of that patient as well as the patient's condition changes.").

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
20. The system as recited in claim 19, wherein the device parameter software includes one or more of operations upgrade software, patient compliance guidelines or product maintenance information.	"Control unit 42 is any suitable device that can perform the functions discussed above with respect to pressure generating system 32 and the input/output functions of interactive system 34. . . . [I]nteractive system 34 also includes a communication unit 52 . . . [which] provides the interactive system with the capability of transmitting information to and/or receiving information from an external device. In addition, communication unit 52 allows the operating parameters of the therapy device to be monitored, *controlled*, or both from an external device." 5:39-59 (emphasis added); 6:40-43 ("In addition, the operating parameters of the therapy device can be controlled and altered to meet the specific needs of that patient as well as the patient's condition changes.").

4. Heilman Anticipates the Challenged Claims Under 35 U.S.C. § 102(b) or Renders Obvious the Challenged Claims Under § 103(a) in View of Owen

Heilman anticipates and/or renders obvious all the elements of the challenged claims. *See* Efimov Decl. at ¶¶ 166-226. Heilman discloses a wearable defibrillator capable of monitoring a patient's heart condition and administering a defibrillating shock if needed by the patient. *See* Heilman (Ex. 1006), 2:35-43; 2:65-3:2; 6:4-16. Heilman's defibrillator can monitor and store patient data, background operation, system events, communication with the maintenance subsystem, self-checks of the system, and electrode functioning. *See id.* at 8:17-25. Heilman discloses that the defibrillator may further comprise a maintenance system or module that can provide system memory in which the memory from the wearable device may be "dumped." *See id.* 9:23-28. The maintenance system can

also provide a link between the device and a telephone line. *See id.* at 9:1-16. The defibrillator comprises an RF link and antenna, which allow for wireless communication with the maintenance system, and therefore would permit communication and information exchange while the patient is wearing the device. *See id.* Heilman also discloses that certain tasks, such as charging the defibrillator may be carried out while the patient is wearing the defibrillator. *See id.* at 9:7-11. The data collected may be also transmitted through a suitable telephone link to health care personnel for problem solving and advice on correct device operation. *Id.* at Abstract. Heilman discloses an "information database/patient database": "In Fig. 1, reference 162 is a microprocessor and system memory. . . . The system memory preferably is large compared with the belt memory, allowing it to store more of the patient's electrocardiogram and other data." *Id.* at 9:18-25. *See also* Efimov Decl. at ¶¶ 172-173, 194-195.

Alternatively, the challenged claims are unpatentable as obvious over Heilman, in view of Owen. It would have been obvious to one of skill in the art to modify Heilman to include a database as disclosed in Owen. Both Owen and Heilman are directed to solving the same problem, i.e., provide suitable monitoring and treatment of patients with cardiac problems (and in potential need of defibrillation) without hindering the day-to-day lifestyle when the patient is located outside the hospital or care giving facility, and providing means to record data, and

to transmit the data to remote health care personnel for problem solving and advising on correct device operation. Thus, it would have been obvious to modify Heilman, which provides for data transmission over a phone line to include a database as disclosed by Owen to ensure proper functioning of the device and appropriate treatment.

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
1(pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	"The present invention provides a system and means whereby susceptible patients may be substantially protected from arrhythmic death including a portable patient-worn external pacemaker/defibrillator that is comfortable to wear yet has the capability of *continuously monitoring* the patient for potentially lethal arrhythmias and *delivering* corrective electrical pulses quickly and appropriately in the event that such arrhythmia occurs." 2:35-43 (emphasis added); 2:65-3:2; 6:4-16.
1(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	See claim element 1 (pre) above for support. See also "[D]evice 10 may be worn over a comfortable undergarment 34, such as a T-shirt . . . . Attachments 38, such as patches of loop and pile Velcro-type fabric, may be provided between belt 14, strap 18 and the undergarment." 6:27-33; 2:35-43; Figs. 4, 7, 8 and 17.
1(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
1(c) recording the patient medical information in a storage means of the medical device; **Structure for "storage means"**: memory	***Structure***: "System memory 118" 8:17-25 ***Function***: "The microprocessor [116], in conjunction with a system memory 118, performs all functions necessary for patient monitoring, time keeping and background operation, recording of arrhythmias and system events, communication with the maintenance subsystem 12, control of treatment sequences, self-checks of system and electrode functioning, and

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
	monitoring of status switches 120 and 122. The microprocessor and memory together constitute essential elements of the pulse generator 24. . . . " 8:17-27.
1(d) operatively connecting the medical device to a communications system;	"The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:4-16; 3:11-22; 5:47-55. "The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . Communication with the belt is through an RF link 156 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160. . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:4-28; 3:11-22; 5:47-55.
1(e) transmitting the patient medical information to a health care provider by means of said communications system and recording the patient medical information in an information database; and	**Anticipation** "It is a further object of the invention to provide different types of system monitoring means to maximize safety, efficacy and reliability of the patient-worn device. Such monitoring means may include . . . means to *record memory contents of the patient-worn device*. . . ." 3:11-22; 3:2-6; 9:17-18 ("Reference 162 is a microprocessor and system memory");9:22-27 ("The system memory preferably is large compared with the belt memory, allowing it to store more of the patient's electrocardiogram and other data. The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone."). **Obviousness** Heilman suggest the storage of information and transmission of vital data to remote healthcare personnel for problem solving and advising on correct device operation. *See, e.g.,* 3:17-21. Owen, in turn, teaches the use of a central repository for the same purpose: "[d]ata

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
	retrieved . . . from defibrillator 10 may be transmitted to a central repository 9 . . . [which] preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients . . . . A personal computer 19 is in communication with central repository 9. This personal computer may be used to analyze the patient and defibrillation information from the plurality of other patients . . . .” Owen at 14:2-12. Thus, it would have been obvious to modify Heilman at the time of the invention to include a database for the storage of the information collected from patient and the medical device as taught by Owen, for example, to record and maintain the collected data in a database, such as to allow healthcare providers or patients access to analyze patient data, use data, etc. for patient treatment.
1(f) providing access to the patient medical information to individuals.	“It is a further object of the invention to provide different types of system monitoring means to maximize safety, efficacy and reliability of the patient-worn device. Such monitoring means may include means to . . . *transmit* vital data to remote health care personnel for problem solving and advising on correct device operation.” 3:11-22; 3:22-26.
2 (pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:	See claim element 1(pre) above for support.
2(a) providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;	See claim element 1(a) above for support.
2(b) operatively connecting the medical device to the patient such that the medical device is worn by the patient;	See claim element 1(a) above for support.
2(c) recording the patient	***Structure***: “System memory 118” 8:17-25

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
medical information, device performance data and patient compliance data in a storage means of the medical device; **Structure for "storage means"**: memory	***Function***: "The microprocessor, in conjunction with a system memory 118, performs all functions necessary for patient monitoring, *time keeping* and background operation, recording of *arrhythmias* and system events, communication with the maintenance subsystem 12, control of treatment sequences, *self-checks of system* and electrode functioning, and monitoring of status switches 120 and 122." 8:17-25 (emphases added); 8:62-65 ("An 'on patient' sensor (switch 122) may be provided to inform the microprocessor that the device is in place on a patient.").
2(d) operatively connecting the medical device to a communications system;	See claim element 1(d) above for support.
2(e) transmitting the patient medical information, device performance data and patient compliance data to a health care provider by means of said communications system and	"The microprocessor, in conjunction with a system memory 118, performs all functions necessary for patient monitoring, time keeping and background operation, recording of arrhythmias and system events, communication with the maintenance subsystem 12, control of treatment sequences, self-checks of system and electrode functioning, and monitoring of status switches 120 and 122." 8:17-25(emphasis added); 9:1-16("The maintenance subsystem 12 . . . . provide[s] . . . a communications link, for example between the belt and a telephone line . . . . The belt memory may be periodically dumped into the maintenance system for storage and eventual relay to a physician via telephone."
2(f) recording the patient medical information, device performance data and patient compliance data in an information database,	See claim elements 1(e), 2(c) and 2(e) above for support.
2(g) wherein said transmitting step is performed while the medical device is operatively connected to the patient for providing treatment to the patient; and	"The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . Communication with the belt is *through an RF link* 156 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
	phone . . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:4-16; 3:6-10; 8:62-65. *See* Efimov Decl. at ¶185.
2(h) providing access to the patient medical information, device performance data and patient compliance data to individuals.	See claim elements 1(f), 2(c) and 2(e) above for support.
4.(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	See claim elements 1(pre) above for support.
4(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	See claim elements 1(a) and 1(b) above for support.
4(b) a communications network;	"The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . Communication with the belt is through an RF link 156 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160. . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:4-28.
4(c) means for connecting the medical device to the communication network; **Structure**: internal or external	***Structure***: "RF link" or "Modem 159" 9:12-16 ***Function***: "The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . Communication with the belt is through an RF link 156

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
modem, or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, including a transcutaneous transmitter.	and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160. . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:4-16; 3:11-22.
4(d) a patient database;	**Anticipation** "It is a further object of the invention to provide different types of system monitoring means to maximize safety, efficacy and reliability of the patient-worn device. Such monitoring means may include . . . means to *record memory contents of the patient-worn device*. . . ." 3:11-22; Abstract; 3:2-6; 9:17-18 ("Reference 162 is a microprocessor and system memory"); 9:22-27 ("The system memory preferably is large compared with the belt memory, allowing it to store more of the patient's electrocardiogram and other data. The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone."). **Obviousness** Heilman suggest the storage of information and transmission of vital data to remote healthcare personnel for problem solving and advising on correct device operation. *See, e.g.,* 3:17-21. Owen, in turn, teaches the use of a central repository for the same purpose: "[d]ata retrieved . . . from defibrillator 10 may be transmitted to a central repository 9 . . . [which] preferably stores this data, together with patient and defibrillation information corresponding to a plurality of other patients . . . . A personal computer 19 is in communication with central repository 9. This personal computer may be used to analyze the patient and defibrillation information from the plurality of other patients . . . ." Owen at 14:2-12. Thus, it would have been obvious to modify Heilman at the time of the invention to include a database for the storage of the information collected from patient and the medical device as taught by Owen, for example, to record and maintain the collected data in a database, such

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
	as to allow healthcare providers or patients access to analyze patient data, use data, etc. for patient treatment.
4(e) means for monitoring and storing operations information of the medical device and patient compliance and use data; **1. Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker) **2. Structure**: Memory	**1. <u>Means for Monitoring</u>**: ***Structure***: Patient-worn defibrillator, which includes sensors and a microprocessor 8:5-25. ***Function*:** "A set of sensors (monitoring means) is used to gather information as to the patient's condition. . . . The microprocessor, in conjunction with a system memory 118, performs all functions necessary for patient monitoring, . . . self-checks of system and electrode functioning, and monitoring of status switches 120 and 122." 8:5-25; 3:11-22; 8:62-65 ("An 'on patient' sensor (switch 122) may be provided to inform the microprocessor that the device is in place on a patient."). **2. <u>Means for Storing</u>**: ***Structure***: "system memory 118" 8:17-24 ***Function*:** "A set of sensors (monitoring means) is used to gather information as to the patient's condition. . . . The signals from the sensors are amplified and conditioned . . . . The conditioned signals are applied to microprocessor 116. The microprocessor, in conjunction with a system memory 118, performs all functions necessary for patient monitoring, time keeping and background operation, recording of arrhythmias and system events . . . ." 8:5-25; 3:11-22; 8:62-65
4(f) means for connecting the patient database to the communication network; and **Structure**: modem, or other data transfer technologies	***Structure***: "RF link" or "Modem 159" 9:12-16 ***Function***: "Communication with the belt is through an RF link 156 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160. . . . The belt memory may be periodically 'dumped' into the maintenance system for storage and eventual relay to a physician via telephone." 9:12-28; Abstract ("A servicing subsystem is provided for the harness or vest and may be used to . . . communicate with remote health care personnel through a suitable telephone link."); 9:17-18 ("Reference 162 is a microprocessor and system memory")

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
4(g) means for exchanging information between the medical device and the patient database, **Structure**: internal or external modem, or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, including a transcutaneous transmitter.	***Structure***: "RF link" or "Modem 159" 9:12-16 ***Function***: "A servicing subsystem is provided for the harness or vest and may be used to interface with the harness or vest . . . and also to communicate with remote health care personnel through a suitable telephone link." Abstract; 3:11-22; 9:4-16 ("Communication with a telephone line is through a telephone dialer and *modem* 159 and a built-in speaker phone 160"). See also the discussion of claim elements 4(c) and 4(f).
4(h) including means for transmitting the medical device operations information and the patient compliance and use data to the patient database via the communication network.	See claim element 4(c), 4(d), 4(f) and 4(g) above for support.
5. The system as recited in claim 4, further comprising means for monitoring an operating status of the medical device. **Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	***Structure***: Wearable defibrillator with microprocessor 116. See 8:17-25. ***Function***: "[M]icroprocessor [116], in conjunction with a system memory 118, performs all functions necessary for patient monitoring, time keeping and background operation, recording of arrhythmias and system events, communication with the maintenance subsystem 12, control of treatment sequences, *self-checks of system and electrode functioning, and monitoring of status switches* 120 and 122." 8:17-25 (emphasis added); 3:11-22.
8. The system as recited in claim 4, wherein said means for exchanging information includes means for transmitting patient medical information from the medical device to the patient database.	See claim elements 4(g) and 4(h) above for support.
9. The system as recited in claim 4, wherein said means for monitoring operations	***Structure***: Wearable defibrillator with microprocessor 116. 8:17-25.

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
information includes means for monitoring battery status for a battery of the medical device. **Structure**: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)	***Function*:** "It is a further object of the invention to provide different types of system monitoring means to maximize safety, efficacy and reliability of the patient-worn device. Such monitoring means may include . . . *means to check battery status of the device* . . . ." 3:11-22 (emphasis added); 8:17-25.
16. The system as recited in claim 8, further including means for accessing the patient database via the communication network, wherein medical personnel can analyze the patient medical information from a remote location. **Structure:** Home or office computer	See claim element 4(d) above for support. See Efimov Decl. at ¶¶ 211-212.
19(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising:	See claim element 4(pre) above for support.
19(a) a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;	See claim elements 1(a) above for support.
19(b) a communications network;	See claim element 4(b) above in support.
19(c) means for connecting the medical device to the	See claim element 4(c) above for support.

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
communication network;	
19(d) a patient database;	See claim element 4(d) above for support.
19(e) means for connecting the patient database to the communication network;	See claim element 4(f) above for support.
19(f) means for monitoring and storing patient medical parameters, device performance data and patient compliance data;	See claim element 4(e) above for support.
19(g) means for exchanging information between the medical device and the patient database,	See claim element 4(g) above for support.
19(h) including means for transmitting the patient medical parameters, device performance data and patient compliance data to the patient database via the communications network; and	See claim element 4(h) above for support.
19(i) means for downloading device parameter software to the medical device from the communications network. **Structure**: internal or external modem, or a base station with a modem, or other data transfer technologies, and in the case of an implantable device, including a transcutaneous transmitter	***Structure***: "Modem 159" or "RF link 156" 9:14-16 ***Function***: "The main functions of the maintenance subsystem are to provide . . . a communications link, for example between the belt and a telephone line. . . . Communication with the belt is through an RF link 156 and an antenna 158. Communication with a telephone line is through a telephone dialer and modem 159 and a built-in speaker phone 160. . . ." 9:4-16; 3:11-22; 5:46-55 ("There is provided a patient-wearable automatic electric heart therapy device such as device 10 . . . and a maintenance subsystem or module 12 on which the respective therapy device can be mounted when not in use on a patient, effectively to service, *program* and charge the device." (emphasis added)).
20. The system as recited in claim 19, wherein the device parameter software includes	See claim element 19(i) above for support.

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
one or more of operations upgrade software, patient compliance guidelines or product maintenance information.	

VI. Conclusion

For the reasons set forth above, Petitioner submits that the challenged claims are unpatentable. Accordingly, Petitioner respectfully requests that the Board grant this petition for inter partes review and institute trial.

Date: May 31, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I, Denise W. DeFranco, certify that on this 31st day of May, 2013, a copy of

PETITION FOR INTER PARTES REVIEW

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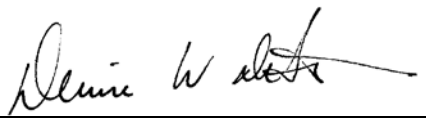
By: 

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