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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.
Exhibit 1002.	Complaint in ZOLL Medical Corp. v. Respironics, Inc., Case No. 12-1778-LPS (D. Del.)
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.

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C. Lead and Backup Counsel and Service Information

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

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

partes review based on the grounds set forth below:

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

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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"

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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-plusfunction format pursuant to 35 U.S.C. § 112(f). When construing a means-plusfunction 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	Store information	Memory	7:36-38; 7:44-46;
(Claim 1)			7:53-8:8; 9:16-17.
Storage means	Store information	Memory	3:62-4:4; 7:36-38;
(Claim 2)			7:44-46; 7:53-8:8;
			9:16-17.
Means for	Connecting the	Internal or	Abstract; Figs. 1 and
connecting the	medical device to	external modem or	2; 3:45-50; 5:9-13;
medical device to	the	a base station with	6:39-44; 8:10-17;
the	communications	a modem, or other	9:8-15; 8:22-24;
communications	network	data transfer	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	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.
performance data, and patient compliance data] (Claims 4 and 19)	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	"A method of treating a patient for ventricular
monitoring patient	tachycardia using a wearable defibrillator includes
medical information for	monitoring the patient for a predetermined condition
the treatment of a patient,	via one or more electrodes on the defibrillator"
the method comprising	Abstract; 1:9-13; 6:29-7:6.
the steps of:	
1(a) providing a	"The present invention is directed to a personal
wearable medical device	wearable pacer/cardioverter/defibrillator which
for monitoring patient	monitors a patient's condition, detects shockable or
medical information and	paceable arrhythmias, determines consciousness, and,
treating the patient in	in the case that the patient is determined to be
response to a monitored	unconscious, administers therapy to the patient." 1:9-
medical condition;	13; Fig. 2; 7:11-19; 30:21-31.
1(b) operatively	"[D]efibrillator 10, includes housing 40 [which] is
connecting the medical	preferably small enough to make the defibrillator
device to the patient such	portable and thus wearable [H]ousing 40 can
that the medical device is	comprise a belt, or the like, which a patient can wear
worn by the patient;	around his or her waist, chest, etc." 30:21-31.
1(c) recording the	<i>Structure</i> : "memory block 57" 34:15-16.
patient medical	<i>Function</i> : "Data logging memory block 57 stores both
information in a storage	the operational history of defibrillator and information
means of the medical	relating to the patient More specifically, data
device;	logging memory 57 stores the patient's ECG
	before, during and after application of defibrillation
Structure for "storage	energy information concerning patient interaction
means": memory	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 	<i>Structure</i> : "memory block 57" 34:15-16. <i>Function</i> : "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	comprises a non-contact interface over which the
by means of said	patient information is transmitted to a personal
communications system	computer." 79:9-11; 13:24-27; 31:18-21; 32:2-4; 33:25-
and	31, Fig. 2.
2(f) recording the	"[T]he present invention is a method for
patient medical	reprogramming a defibrillator based on a central
information, device	database of information relating to patients that use a
performance data and	type of defibrillator. The method includes collecting, in
patient compliance data	the <i>central database</i> , information relating to a plurality
in an information	of patients that use the type of defibrillator, analyzing
database,	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	"Communications link 49 comprises a non-contact
transmitting step is	interface to personal computer 201 (see Figure 2), over
performed while the	which information may be transmitted between
medical device is	defibrillator 10 and personal computer 201 (see Figure
operatively connected to	2) while defibrillator 10 is being worn by the patient or,
the patient for providing	if desired, at other times as well." 31:18-21; Fig. 2;
treatment to the patient;	13:24-27; 79:9-11 ("[Claim] 50. A wearable
and	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. 4.(pre) A system for monitoring patient medical information and providing treatment to a patient, the system comprising: 	"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. "[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 <i>sensing</i> the patient's heart condition and of <i>delivering defibrillation</i> or pacing
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;	 condition and of <i>aetivering deportuation</i> of pacing impulses to the patient's heart when required." 8:17-27 (emphasis added); Figs. 1 and 2; 2:17-32; 12:24-30. "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; 4(c) means for	"External interface can comprise a modem link, a <i>network</i> 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. <i>See</i> Efimov Decl. at ¶ 52. <i>Structure</i> : "Base station" 5:23-6:7.

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
connecting the medical	<i>Function</i> : "The defibrillator also includes a base
device to the	station interface, over which the patient information
communication network;	and the defibrillation information are transmitted, and
Structure: Internal or	over which external information is received By
external modem or a base	virtue of the foregoing arrangement, it is possible to
station with a modem,	transmit patient and defibrillation information from a
and in the case of an	defibrillator to a base station and from the base station
implantable device,	to an external location, such as a central repository,
additionally including a	doctor, hospital, etc." 5:23-6:7; 65:10-18 ("The external
transcutaneous	interface in the base station can comprise a <i>modem</i> link,
transmitter	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 <i>central</i>
	<i>database</i> 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 <i>database</i> "
	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	1. Means for Monitoring:
monitoring and storing	Structure: "Defibrillator 10" (which includes
operations information of	diagnostics module 84) Fig. 8; 52:13-23.
the medical device and	Function: "[D]iagnostics module 84 performs
patient compliance and	diagnostics on defibrillator 10 related to the operation
use data;	and safety thereof prior to transmitting defibrillation
	energy to the patient In a case that diagnostics
1. Structure: Medical	module 84 detects operational defects as a result of
device (e.g., cardiac	these diagnostics, this information is stored in data
defibrillator, cardiac	logging memory block 57" 52:14-20.
monitor, infusion pump,	"[D]iagnostics module 84 also performs a plurality of
pacemaker)	diagnostics on defibrillator 10 to test defibrillator 10's

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
	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. Means for Storing:
2. Structure : 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 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	<i>Structure</i> : "External interface (modem embodiment)"
connecting the patient	and "external data link 17" 14:2-12; Fig. 2.
database to the	Function: "Data retrieved by base station 2 from
communication network;	defibrillator 10 may be transmitted to central repository
and	9 via external data link 17 A personal computer 19
	is in communication with central repository 9." 14:2-12
Structure: modem, or	(emphasis added); "External interface comprises a link
other data transfer	to an external location such as a central repository (see
technologies	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	<i>Structure</i> : "Base station" 5:23-6:7.
exchanging information	<i>Function</i> : "The defibrillator also includes a base
between the medical	station interface, over which the patient information
device and the patient	and the defibrillation information are <i>transmitted</i> , and
database,	over which external information is <i>received</i> The
	base station also includes an external interface, over
Structure: Internal or	which the defibrillation information and the patient
external modem or a base	information is <i>transmitted</i> to an external location, and
station with a modem,	over which the external information is <i>received</i> from
and in the case of an	the external location. By virtue of the foregoing
implantable device,	arrangement, it is possible to transmit patient and
additionally including a	defibrillation information from a defibrillator to a base
transcutaneous	station and from the base station to an external location,
transmitter	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	<i>Structure</i> : "Base station" 5:23-6:7.
transmitting the medical	<i>Function</i> : "The defibrillator also includes a base
device operations	station interface, over which the patient information
information and the	and the defibrillation information are <i>transmitted</i> , and
patient compliance and	over which external information is received The
use data to the patient	base station also includes an external interface, over
database via the	which the defibrillation information and the patient
communication network.	information is <i>transmitted</i> to an external location, and
Store stores Later 1	over which the external information is received from
Structure: Internal or	the external location. By virtue of the foregoing
external modem or a base	arrangement, it is possible to transmit patient and
station with a modem,	defibrillation information from a defibrillator to a base
and in the case of an	station and from the base station to an external location,
implantable device,	such as a central repository, doctor, hospital, etc." 5:23-
additionally including a	6:7 (emphases added); 7:20-24; 64:2-6 ("[A] base

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
transcutaneous	station for use with the present invention includes a
transmitter	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	Structure: Defibrillator 10 (which includes diagnostics
in claim 4, further	module 84). Fig. 8; 52:13-23.
comprising means for	Function: "[D]iagnostics module 84 performs
monitoring an operating	diagnostics on defibrillator 10 related to the operation
status of the medical	and safety thereof prior to transmitting defibrillation
device.	energy to the patient In a case that diagnostics
Structure: Medical	module 84 detects operational defects as a result of
device (e.g., cardiac	these diagnostics, this information is stored in data
defibrillator, cardiac	logging memory block 57 Such information also
monitor, infusion pump,	may be transmitted to base station 2 or personal
pacemaker)	computer 6." 52:14-23.
8. The system as recited	<i>Structure</i> : "Base station" 5:23-6:7.
in claim 4, wherein said	<i>Function</i> : "The defibrillator also includes a base
means for exchanging	station interface, over which the patient information
information includes	and the defibrillation information are <i>transmitted</i> , and
means for transmitting	over which external information is <i>received</i> The
patient medical	base station also includes an external interface, over
information from the	which the defibrillation information and the patient
medical device to the	information is <i>transmitted</i> to an external location, and
patient database.	over which the external information is <i>received</i> from
	the external location. By virtue of the foregoing
Structure: Internal or	arrangement, it is possible to transmit patient and
external modem or a base	defibrillation information from a defibrillator to a base
station with a modem,	station and from the base station to an external location,
and in the case of an	such as a central repository, doctor, hospital, etc." 5:23-
implantable device,	6:7 (emphases added); 7:20-24; 8:9-12; 64:2-6 ("[A]
additionally including a	base station for use with the present invention includes
transcutaneous	a defibrillator interface, over which information is
transmitter	<i>exchanged</i> 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	Owen discloses that "diagnostics module 84 performs
in claim 4, wherein said	diagnostics on defibrillator 10 related to the operation
means for monitoring	and safety thereof prior to transmitting defibrillation
operations information	energy to the patient. These diagnostics include
includes means for	diagnostics that are performed at power-on of
monitoring battery status	defibrillator 10 in order to determine if there are
for a battery of the	operational defects therein." (52:13-16). Owen further
medical device.	discloses that it can run "[c]old start diagnostics [that]
	include back up battery voltage tests" 63:1-8.
16. The system as recited	Structure: "Personal computer 19" Fig. 8; 14:2-12.
in claim 8, further	Means: "Data retrieved by base station 2 from
including means for	defibrillator 10 may be transmitted to central repository
accessing the patient	9 via external data link 17. Central repository 9
database via the	preferably stores this data, together with patient and
communication network,	defibrillation information corresponding to a plurality
wherein medical	of other patients, all of whom use the same type of
personnel can analyze the	defibrillator. A personal computer 19 is in
patient medical	communication with central repository 9. This personal
information from a	computer may be used to analyze the patient and
remote location.	defibrillation information received from the
Structure: Home or	defibrillator 10 in view of corresponding information
office computer	from the plurality of other patients." 14:2-12; 8:2-9.
19(pre) A system for	See claim element 4(pre) above for support.
monitoring patient	
medical information and	
providing treatment to a	
patient, the system	
comprising:	
19(a) a wearable	See claim element 4(a) above for support.
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	

Challenged Claims	Exemplary Cites to Owen (Ex. 1003)
medical device is worn by	
the patient;	
19(b) a communications	See claim element 4(b) above for support.
network;	
19(c) means for	See claim element 4(c) above for support.
connecting the medical	
device to the	
communication network;	
19(d) a patient database;	See claim element 4(d) above for support.
19(e) means for	See claim element 4(f) above for support.
connecting the patient	
database to the	
communication network;	
19(f) means for	See claim element 4(e) above for support.
monitoring and storing	
patient medical	
parameters, device	
performance data and patient compliance data;	
19(g) means for	See claim element 4(g) above for support.
exchanging information	see chann chement 4(g) above for support.
between the medical	
device and the patient	
database,	
19(h) including means	See claim element 4(h) above for support.
for transmitting the	
patient medical	
parameters, device	
performance data and	
patient compliance data	
to the patient database via	
the communications	
network; and	
19. (i) means for	<i>Structure</i> : "Base station" 5:23-6:7.
downloading device	<i>Function</i> : "The defibrillator also includes a base
parameter software to the	station interface, over which the patient information
medical device from the	and the defibrillation information are transmitted, and
communications network.	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 <i>wearer</i> 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 <i>worn</i> by the patient." (emphasis added)); Fig. 8.
1(b) operatively connecting the medical device to the patient such	See claim element 1(a) above for support.
that the medical device is worn by the patient;	
1(c) recording the patient medical information in a storage means of the medical	<i>Structure</i> : Memory in microprocessor 120. 4:37-44. <i>Function</i> : "[O]ne embodiment of the system 100 may also include optional data acquisition and storage components for continuous storage of ECG data which
device;	is acquired, stored, and displayed before, during, and following any episode or multi-episodes requiring
Structure for "storage means": memory	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 <i>other data storage devices</i> , 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	See claim element 1(pre) above for support.
monitoring patient	
medical information for	
the treatment of a	
patient, the method	
comprising the steps of:	
2(a) providing a	See claim element 1(a) above for support.
wearable medical device	
for monitoring patient	
medical information and	
treating the patient in	
response to a monitored	
medical condition;	Sag alaim alamant 1(a) above for support
2(b) operatively connecting the medical	See claim element 1(a) above for support.
device to the patient such	
that the medical device is	
worn by the patient;	
2(c) recording the	<i>Structure</i> : Memory in microprocessor 120, 4:37-44,
patient medical	parameter memory 121, 8:61-63.
information, device	Parameter memory 121, 0.01 00.
	<i>Function</i> : "[I]n accordance with their knowledge of the

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
performance data and	patient's condition, trained medical personnel are able
patient compliance data	to provide the proper inputs to the system 100 which
in a storage means of the	serve to maximize the monitoring capability and the
medical device;	therapeutic effect of the system 100. Advantageously,
Structure for "storage	these parameters are stored in the parameter memory
means": 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	See claim element 1(d) above for support.
connecting the medical	
device to a	
communications system;	
2(e) transmitting the	"In addition to providing monitoring and electrical
patient medical	cardiac regulation, one embodiment of the system 100
information, device	of the present invention is capable of communicating
performance data and	with a physician or other trained medical personnel
patient compliance data	from a remote location. This may be accomplished by
to a health care provider	means of the bidirectional communications link
by means of said	180 The bidirectional communication link 180 is
communications system	advantageously able to transmit and receive

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
and	<i>information relevant to the treatment of the patient</i> 110." 10:43-59 (emphasis added); 10:67-11:3("Other useful information that may be transmitted includes the <i>status of the system</i> 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 <i>real</i> <i>time</i> 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; <i>See</i> 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, <i>and displayed</i> before, <i>during</i> , 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	"In one embodiment the bidirectional communication
the patient medical	link 180 transmits patient information to the
information, device	corresponding doctor's office or hospital for evaluation
performance data and	and analysis. In addition, the link 180 transmits real
patient compliance data	time ECG data to verify proper acquisition of the
to individuals.	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	"The present invention is an external cardiac monitor
monitoring patient	and cardioverter/defibrillator system[T]he system
medical information and	automatically delivers or withholds therapy according
providing treatment to a	to parameters preferably selected through programming
patient, the system	by the physician." 2:18-25; 2:52-64; Fig. 3.
comprising:	
4(a) a wearable medical	"System 100 is an external cardiac monitor and
device for monitoring	cardioverter/defibrillator which is depicted connected
and storing medical	to a patient 110 [T]he system 100 monitors the
parameters and treating	signals from the patient's heart If therapy is

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
the patient in response to	necessary, the system 100 automatically delivers
a monitored medical	electrical and/or drug therapy in order to return the
condition, the medical	patient's heart to a normal cardiac rhythm. The system
device operatively	100 as described may be implemented as an ambulatory
attachable to the patient	or portable monitor and cardioverter/defibrillator
such that the medical	device." 4:8-23; 6:26-29; 7:2-4 ("FIG. 8 illustrates an
device is worn by the	additional ambulatory embodiment with the system 100
patient;	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 <i>worn</i> 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	"The bidirectional communication link 180 able to
network;	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	Structure: Bidirectional communication link 180
connecting the medical	(which can be implemented as a telephone modem
device to the	device or as a two-way communication radio, or other
communication network;	device which is capable of transmitting and receiving
	radio signals). 10:43-56.
Structure: internal or	<i>Function</i> : "The microprocessor 120 is further
external modem or base	connected to a bidirectional communication link 180
station with a modem,	via signal lines 182. The communication link may
and in the case of an	comprise, for example, a two way-radio

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
implantable device,	transmitter/receiver, a telephone modem, or any other
including a	bidirectional communication means which are
transcutaneous	appropriate to transmit information relating to the
transmitter.	cardiac status of the patient 110. The bidirectional
	communication link 180 is adapted to <i>connect</i> 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 <i>data</i> 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 <i>other</i> data storage devices." (emphasis added)).
4(e) means for	1. Means for Monitoring:
monitoring and storing	<i>Structure</i> : System 100 "an external cardiac monitor
operations information	and cardioverter/defibrillator" 4:9-11.
of the medical device	<i>Function</i> : "[O]nce the power is supplied to the system
and patient compliance	100 an internal systems diagnostics check is
and use data;	performed in a process block 305. The internal
	diagnostics execute system checks on functions such as
1. Structure : Medical	battery life the status of the charging capacitor
device (e.g., cardiac	within the cardioverter/defibrillator circuitry 130, and
defibrillator, cardiac	the status of the electrodes 143-145." 11:43-52; 6:19-23
monitor, infusion pump,	("The clock 190 allows the system 100 to maintain a
pacemaker)	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> :
	<i>Structure</i> : Memory in microprocessor 120. 4:37-44.
	<i>Function</i> : See claim element 2(c) above for support.
	See also 4:37-44; Fig. 1 (reference 120).
4(f) means for	Structure: Bidirectional communication link 180
connecting the patient	(which can be implemented as a telephone modem
database to the	device or as a two-way communication radio, or other
communication network;	device which is capable of transmitting and receiving
and	radio signals) 10:43-56.
	<i>Function</i> : "In order to externally program and monitor
Structure: modem, or	the system 100, the external programming and
other data transfer	monitoring unit 187 may be employed at the hospital
technologies	end of the bidirectional communication link 180." 11:9-
	12. "The bidirectional communication link 180 is
	adapted to <i>connect</i> to a system external programming
	and monitoring unit 187 via signal lines 185." 6:10-12
	(emphasis added).
4(g) means for	Structure: Bidirectional communication link 180
exchanging information	(which can be implemented as a telephone modem
between the medical	device or as a two-way communication radio, or other
device and the patient	device which is capable of transmitting and receiving
database,	radio signals). 10:43-56.
	<i>Function:</i> "The bidirectional communication link 180
Structure: Internal or	is advantageously able to transmit and receive
external modem or a	information relevant to the treatment of the patient 110.
base station with a	In one embodiment, the bidirectional communication
modem, and in the case	link 180 transmits patient information to the
of an implantable device,	corresponding doctor's office or hospital for evaluation
additionally including a	and analysis. In addition, the link 180 transmits real
transcutaneous	time ECG data to verify proper acquisition of the
transmitter.	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	<i>Structure</i> : Bidirectional communication link 180
transmitting the medical	(which can be implemented as a telephone modem
device operations	device or as a two-way communication radio, or other
information and the	device which is capable of transmitting and receiving
patient compliance and	radio signals). 10:43-56.
use data to the patient	<i>Function:</i> "The bidirectional communication link 180
database via the	is advantageously able to <i>transmit</i> and receive
communication network.	information relevant to the treatment of the patient 110.
	In one embodiment, the bidirectional communication
Structure: Internal or	link 180 <i>transmits</i> patient information to the
external modem or a	corresponding doctor's office or hospital for evaluation
base station with a	and analysis. In addition, the link 180 <i>transmits</i> real
modem, and in the case	time ECG data to verify proper acquisition of the
of an implantable device,	signals, and proper attachment of the sending
additionally including a	electrodes 143-145 Other useful information that
transcutaneous	may be transmitted includes the status of the system
transmitter	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	<i>Structure</i> : System 100 "an external cardiac monitor
in claim 4, further	and cardioverter/defibrillator" 4:9-11.
comprising means for	<i>Function</i> : "[O]nce the power is supplied to the system
monitoring an operating	100 an internal systems diagnostics check is
status of the medical	performed in a process block 305. The internal
device.	diagnostics execute system checks on functions such as
Structure: Medical	battery life the status of the charging capacitor
device (e.g., cardiac	within the cardioverter/defibrillator circuitry 130, and
defibrillator, cardiac	the status of the electrodes 143-145." 11:43-52; 11:30-
monitor, infusion pump,	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 	<i>Structure</i> : 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 <i>Function</i> : "[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 <i>transmit</i> and <i>receive information relevant to the</i> <i>treatment of the patient 110</i> . In one embodiment, the bidirectional communication link 180 <i>transmits</i> 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	<i>Structure</i> : "personal computer or custom computer." 11:9-12.

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
including means for	<i>Function</i> : "In order to externally program and monitor
accessing the patient	the system 100, the external programming and
database via the	monitoring unit 187 may be employed at the hospital
communication network,	end of the bidirectional communication link 180. For
wherein medical	example, a personal computer or custom computer
personnel can analyze	designed for this task may be employed as the external
the patient medical	programming and monitoring unit 187 It should be
information from a	noted that the external programming unit 187 may also
remote location.	be incorporated within the control and display unit 144
	or as an additional host computer system which may be
Structure: Home or	coupled with the microprocessor 120." 11:9-33; 10:56-
office computer	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	See claim element 4(pre) above for support.
monitoring patient	
medical information and	
providing treatment to a	
patient, the system	
comprising:	See alaim alament 4(a) above for summert
19(a) a wearable medical device for	See claim element 4(a) above for support.
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	
medical device is worth	

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

Challenged Claims	Exemplary Cites to Payne (Ex. 1004)
communications	radio signals). 10:43-56.
network.	<i>Function</i> : "The bidirectional communication link 180
Structure: Internal or	is adapted to connect to a system external programming
external modem or a	and monitoring unit 187 via signal lines 185." 6:10-12.
base station with a	"The bidirectional communication link 180 can receive
modem, and in the case	information from a remote location such as a doctor's
of an implantable device,	office or hospital. 11:4-7 (emphasis added); 8:64-9:14
additionally including a	("In one embodiment, the system 100 includes
transcutaneous	additional programming features such as 'batch
transmitter	processing' [which] allows a physician to set
	individual program settings into the external
	programming unit 187 and, after the program is
	satisfactory, <i>download</i> the program to the system 100."
	(emphasis added)); 9:5-16.
20. The system as recited	"In one embodiment, the system 100 includes
in claim 19, wherein the	additional programming features such as "batch
device parameter	processing [which] allows a physician to set
software includes one or	individual program settings into the external
more of operations	programming unit 187 and, after the program is
upgrade software, patient	satisfactory, download the program to the system 100."
compliance guidelines or	8:64-9:14; 9:5-16.
product maintenance	
information.	
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	"[A] method of treating and monitoring the treatment of
monitoring patient	a breathing disorder that includes the steps of:
medical information for	(1) providing a device that administers a pressure
the treatment of a	therapy to a patient and includes an interactive
patient, the method	capability, (2) causing the device to provide information
comprising the steps of:	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. <i>See</i> , <i>e.g.</i> , 1:52-2:4; claims 2-4.
 1(a) providing a wearable medical device¹ 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 	<i>Structure</i> : Control unit 42 (which includes memory) 5:45-49 <i>Function</i> : "Control unit 42 can also include a suitable amount of memory for storing information necessary to carry out these functions, such as sufficient <i>memory to</i> <i>store</i> 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. <i>See, e.g.</i> , 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	"In the illustrated network, a number of interactive
connecting the medical	pressure support systems 30 communicate via
device to a	communication links 62 and 64 and communications
communications	system 66 to one or more locations 68. Communications
system;	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	"In the illustrated network, a number of interactive
patient medical	pressure support systems 30 communicate via
information to a health	communication links 62 and 64 and communications
care provider by means	system 66 to one or more locations 68. Communications
of said communications	links 62 and 64 can be hard wired or wireless so long as
system and recording	information is transmitted to and/or received from the
the patient medical	interactive pressure support system 30 and/or remote
information in an	locations Communications system 66 is any
information database;	communication network that transmits data from one
and	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	"Remote locations 68 are any device capable of
to the patient medical	communicating with the interactive pressure support
information to	system 30. Typically, a remote location is a computer
individuals.	located at the care giver and/or test administrator. In an
	exemplary embodiment of the present invention, the
	user at the remote location <i>downloads</i> 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	"[T]he present invention provides a system that
monitoring patient	performs two functions: (1) it provides a treatment to
medical information and	the patient to correct a disorder suffered by the patient,
providing treatment to a	such as a pressure support device to treat OSA, and
patient, the system	(2) it provides an interactive function so that the
comprising:	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,
	<i>e.g.</i> , 1:52-2:4; claims 2-4.
4(a) a wearable	See claim element 1(a) above for support.
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;	
4(b) a communications	"FIG. 3 is a schematic diagram of a <i>communication</i>
network;	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	<i>Structure</i> : Modem 6:60-7:10
connecting the medical	<i>Function</i> : "In the illustrated network, a number of
device to the	interactive pressure support systems 30 communicate
communication	via communication links 62 and 64 and communications
network;	system 66 to one or more locations 68. Communications
	links 62 and 64 can be hard wired or wireless so long as
Structure: Internal or	information is transmitted to and/or received from the
external modem or a	interactive pressure support system 30 and/or remote
base station with a	locations [C]ommunications system 66 can be a
modem, and in the case	conventional telephone or computer network with <i>the</i>
of an implantable	interactive pressure support systems 30 communicating
device, additionally	with remote locations 68 via modems, a satellite based
including a	system, a fiber optic/optical system, a microwave
transcutaneous	system or any combination thereof." 6:60-7:10
transmitter	(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	1. Means for Monitoring:
monitoring and storing	<i>Structure</i> : Pressure support system 30, which includes
operations information	control unit 42. 4:57-64.
of the medical device	<i>Function</i> : "According to one embodiment of the present
and patient compliance	invention, control unit 42 performs the patient
and use data;	monitoring function and controls the pressure provided
	to the patient as discussed above in conjunction with
1. Structure : Medical	pressure control unit 38 [C]ontrol unit 42 can
device (e.g., cardiac	perform other functions, such as monitoring use of the
defibrillator, cardiac	pressure generating system (patient compliance),
monitor, infusion pump,	running diagnostics routines and providing
pacemaker)	error/warning indications." 4:57-64.
	2. <u>Means for Storing</u> :
2. Structure : Memory	<i>Structure</i> : Memory 5:39-49
	<i>Function</i> : "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	<i>Structure</i> : Modem 6:60-7:10
connecting the patient	<i>Function</i> : "In the illustrated network, a number of
database to the	interactive pressure support systems 30 communicate
communication	via communication links 62 and 64 and communications
network; and	system 66 to one or more locations 68. Communications
Structure: modem, or	links 62 and 64 can be hard wired or wireless so long as
other data transfer	information is transmitted to and/or received from the
technologies	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	<i>Structure</i> : Modem 6:60-7:10

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

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

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
medical information	from the interactive pressure support systems so that this
from a remote location.	information can be used to monitor the condition of the
	patient." 7:10-19; Fig. 3 (Remote location A and remote
Structure: Home or	location B). See also claim element 1(e) above for
office computer	support.
19(pre) A system for	See claim element 4(pre) above for support.
monitoring patient	
medical information and	
providing treatment to a	
patient, the system	
comprising:	
19(a) a wearable	See claim element 1(a) above for support.
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;	
19(b) a	See claim element 4(b) for support.
communications	see chann chement 4(0) for support.
network;	
19(c) means for	See claim element 4(c) for support.
connecting the medical	
device to the	
communication	
network;	
19(d) a patient	See claim element 4(d) above for support.
database;	
19(e) means for	See claim element 4(f) above for support.
connecting the patient	
database to the	
communication	
network;	

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

Challenged Claims	Exemplary Cites to Mechlenburg (Ex. 1005)
20. The system as	"Control unit 42 is any suitable device that can perform
recited in claim 19,	the functions discussed above with respect to pressure
wherein the device	generating system 32 and the input/output functions of
parameter software	interactive system 34 [I]nteractive system 34 also
includes one or more of	includes a communication unit 52 [which] provides
operations upgrade	the interactive system with the capability of transmitting
software, patient	information to and/or receiving information from an
compliance guidelines	external device. In addition, communication unit 52
or product maintenance	allows the operating parameters of the therapy device to
information.	be monitored, <i>controlled</i> , 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	"The present invention provides a system and means
monitoring patient medical	whereby susceptible patients may be substantially
information for the treatment	protected from arrhythmic death including a portable
of a patient, the method	patient-worn external pacemaker/defibrillator that is
comprising the steps of:	comfortable to wear yet has the capability of
	<i>continuously monitoring</i> the patient for potentially lethal
	arrhythmias and <i>delivering</i> 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	See claim element 1 (pre) above for support. See also
medical device for monitoring	"[D]evice 10 may be worn over a comfortable
patient medical information	undergarment 34, such as a T-shirt Attachments 38,
and treating the patient in	such as patches of loop and pile Velcro-type fabric, may
response to a monitored	be provided between belt 14, strap 18 and the
medical condition;	undergarment." 6:27-33; 2:35-43; Figs. 4, 7, 8 and 17.
1(b) operatively connecting	See claim element 1(a) above for support.
the medical device to the	
patient such that the medical	
device is worn by the patient;	
1(c) recording the patient	<i>Structure</i> : "System memory 118" 8:17-25
medical information in a	<i>Function</i> : "The microprocessor [116], in conjunction
storage means of the medical	with a system memory 118, performs all functions
device;	necessary for patient monitoring, time keeping and
	background operation, recording of arrhythmias and
Structure for "storage	system events, communication with the maintenance
means": memory	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 main functions of the maintenance subsystem are
the medical device to a	to provide a communications link, for example
communications system;	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;
1(a) transmitting the notiont	3:11-22; 5:47-55.
1(e) transmitting the patient medical information to a	Anticipation "It is a further object of the invention to provide different
health care provider by means	types of system monitoring means to maximize safety,
of said communications	efficacy and reliability of the patient-worn device. Such
system and recording the	monitoring means may include means to <i>record</i>
patient medical information in	memory contents of the patient-worn device" 3:11-
an information database; and	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)
1(f) providing access to the patient medical information to individuals.	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. "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 <i>transmit</i> vital data to remote health care personnel for problem solving and advising on correct device operation." 3:11-
 2 (pre) A method of monitoring patient medical information for the treatment of a patient, the method comprising 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; 2(b) operatively connecting the medical device to the patient such that the medical 	22; 3:22-26. See claim element 1(pre) above for support. See claim element 1(a) above for support. See claim element 1(a) above for support.
device is worn by the patient;2(c) recording the patient	<i>Structure</i> : "System memory 118" 8:17-25

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
medical information, device	<i>Function</i> : "The microprocessor, in conjunction with a
performance data and patient	system memory 118, performs all functions necessary for
compliance data in a storage	patient monitoring, <i>time keeping</i> and background
means of the medical device;	operation, recording of <i>arrhythmias</i> and system events,
	communication with the maintenance subsystem 12,
	control of treatment sequences, self-checks of system and
Structure for "storage	electrode functioning, and monitoring of status switches
means": memory	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	See claim element 1(d) above for support.
the medical device to a	
communications system;	
2(e) transmitting the patient	"The microprocessor, in conjunction with a system
medical information, device	memory 118, performs all functions necessary for patient
performance data and patient	monitoring, time keeping and background operation,
compliance data to a health	recording of arrhythmias and system events,
care provider by means of said	communication with the maintenance subsystem 12,
communications system and	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	See claim elements 1(e), 2(c) and 2(e) above for support.
medical information, device	
performance data and patient	
compliance data in an	
information database,	
2(g) wherein said	"The main functions of the maintenance subsystem are to
transmitting step is performed	provide a communications link, for example between
while the medical device is	the belt and a telephone line Communication with
operatively connected to the	the belt is through an RF link 156 and an antenna 158.
patient for providing treatment	Communication with a telephone line is through a
to the patient; and	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. <i>See</i> Efimov Decl. at ¶185.
2(h) providing access to the	See claim elements 1(f), 2(c) and 2(e) above for support.
patient medical information,	
device performance data and	
patient compliance data to	
individuals.	
4.(pre) A system for	See claim elements 1(pre) above for support.
monitoring patient medical	
information and providing treatment to a patient, the	
system comprising:	
4(a) a wearable medical	See claim elements 1(a) and 1(b) above for support.
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;	
4(b) a communications	"The main functions of the maintenance subsystem are to
network;	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	<i>Structure</i> : "RF link" or "Modem 159" 9:12-16
medical device to the	<i>Function</i> : "The main functions of the maintenance subsystem are to provide a communications link, for
communication network;	example between the belt and a telephone line
Structure : internal or external	Communication with the belt is through an RF link 156

Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
modem, or a base station with	and an antenna 158. Communication with a telephone
a modem, or other data	line is through a telephone dialer and modem 159 and a
transfer technologies, and in	built-in speaker phone 160 The belt memory may be
the case of an implantable	periodically 'dumped' into the maintenance system for
device, including a	storage and eventual relay to a physician via telephone."
transcutaneous transmitter.	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
	record and mantain the concerca data in a dataodoc, buch

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	1. Means for Monitoring:
and storing operations	<i>Structure</i> : Patient-worn defibrillator, which includes
information of the medical	sensors and a microprocessor 8:5-25.
device and patient compliance	Function: "A set of sensors (monitoring means) is used
and use data;	to gather information as to the patient's condition
	The microprocessor, in conjunction with a system
1. Structure: Medical device	memory 118, performs all functions necessary for patient
(e.g., cardiac defibrillator,	monitoring, self-checks of system and electrode
cardiac monitor, infusion	functioning, and monitoring of status switches 120 and
pump, pacemaker)	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. Structure: Memory	microprocessor that the device is in place on a patient."). 2. <u>Means for Storing</u> :
2. Structure. Memory	Structure: "system memory 118" 8:17-24
	<i>Function:</i> "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	<i>Structure</i> : "RF link" or "Modem 159" 9:12-16
patient database to the	<i>Function</i> : "Communication with the belt is through an
communication network; and	RF link 156 and an antenna 158. Communication with a
	telephone line is through a telephone dialer and modem
Structure: modem, or other	159 and a built-in speaker phone 160 The belt
data transfer technologies	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	<i>Structure</i> : "RF link" or "Modem 159" 9:12-16
information between the	<i>Function</i> : "A servicing subsystem is provided for the
medical device and the patient	harness or vest and may be used to interface with the
database,	harness or vest and also to communicate with remote
Structure: internal or external	health care personnel through a suitable telephone link."
modem, or a base station with	Abstract; 3:11-22; 9:4-16 ("Communication with a
a modem, or other data	telephone line is through a telephone dialer and <i>modem</i>
transfer technologies, and in	159 and a built-in speaker phone 160"). See also the
the case of an implantable	discussion of claim elements 4(c) and 4(f).
device, including a	
transcutaneous transmitter.	
4(h) including means for	See claim element 4(c), 4(d), 4(f) and 4(g) above for
transmitting the medical	support.
device operations information	
and the patient compliance and	
use data to the patient database	
via the communication	
network.	
5. The system as recited in	<i>Structure</i> : Wearable defibrillator with microprocessor
claim 4, further comprising	116. See 8:17-25.
means for monitoring an	<i>Function</i> : "[M]icroprocessor [116], in conjunction with
operating status of the medical	a system memory 118, performs all functions necessary
device.	for patient monitoring, time keeping and background
Structure: Medical device	operation, recording of arrhythmias and system events,
(e.g., cardiac defibrillator,	communication with the maintenance subsystem 12,
cardiac monitor, infusion	control of treatment sequences, <i>self-checks of system and</i>
pump, pacemaker)	electrode functioning, and monitoring of status switches
	120 and 122." 8:17-25 (emphasis added); 3:11-22.
8. The system as recited in	See claim elements 4(g) and 4(h) above for support.
claim 4, wherein said means	
for exchanging information	
includes means for	
transmitting patient medical	
information from the medical	
device to the patient database.	Characterize Wessenhle 1. Claritheter (d.)
9. The system as recited in	<i>Structure</i> : Wearable defibrillator with microprocessor
claim 4, wherein said means	116. 8:17-25.
for monitoring operations	

information includes means for monitoring battery status for a battery of the medical device.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.Structure: Hedical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)See claim element 4(d) above for support. See Efimov Decl. at ¶¶ 211-212.16. The system as recited in claim 8, further including means for accessing the patient database via the communication network, wherein medical patient database via the communication from a remote location.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 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 connectingSee claim element 4(c) above for support.	Challenged Claims	Exemplary Cites to Heilman (Ex. 1006)
for a battery of the medical device.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 (e.g., cardiac defibrillator, cardiae monitor, infusion pump, pacemaker)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.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 is worn by the patient;See claim element 4(b) above in support.19(b) a communicationsSee claim element 4(b) above in support.	information includes means	
device.worn device. Such monitoring means may include means to check battery status of the device" 3:11-22 (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)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.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 element 4(b) above in support.19(b) a communicationsSee claim element 4(b) above in support.	for monitoring battery status	provide different types of system monitoring means to
Structure: Medical device (e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)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.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 element 4(b) above in support.19(b) a communicationsSee claim element 4(b) above in support.	for a battery of the medical	maximize safety, efficacy and reliability of the patient-
(e.g., cardiac defibrillator, cardiac monitor, infusion pump, pacemaker)(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.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 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.	device.	worn device. Such monitoring means may include
cardiac monitor, infusion pump, pacemaker)See claim element 4(d) above for support. See Efimov Decl. at ¶ 211-212.16. 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.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(pre) A system for monitoring 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 4(b) above in support.	Structure: Medical device	means to check battery status of the device " 3:11-22
pump, pacemaker)See claim element 4(d) above for support. See Efimov16. 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.See claim element 4(d) above for support. See Efimov Decl. at ¶¶ 211-212.Structure: Home or office computerSee claim element 4(pre) 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 medical parameters and treating the patient in response to a monitored medical condition, the medical device operatively attachable to the patient;See claim element 4(b) above in support.19(b) a communications network;See claim element 4(b) above in support.	(e.g., cardiac defibrillator,	(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.See claim element 4(d) above for support. See Efimov Decl. at ¶ 211-212.Structure: Home or office computerSee claim element 4(pre) above for support.See Claim element 4(pre) 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 is wom by the patient;See claim element 4(b) above in support.19(b) a communications network;See claim element 4(b) above in support.	cardiac monitor, infusion	
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.Decl. at ¶¶ 211-212.Structure: Home or office computerDecl. 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 is worn by the patient;See claim element 4(b) above in support.19(b) a communications network;See claim element 4(b) above in support.	pump, pacemaker)	
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monitoring patient medical information and providing treatment to a patient, the system comprising:See claim elements 1(a) 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 4(b) above in support.	–	
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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;1119(b) a communications network;See claim element 4(b) above in support.		
storing medical parametersand treating the patient inresponse to a monitoredmedical condition, the medicaldevice operatively attachableto the patient such that themedical device is worn by thepatient;19(b) a communicationsnetwork;		See claim elements 1(a) above for support.
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;19(b) a communications network;See claim element 4(b) above in support.	-	
response to a monitored medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient; 19(b) a communications network;	• -	
medical condition, the medical device operatively attachable to the patient such that the medical device is worn by the patient;19(b) a communications network;See claim element 4(b) above in support.		
device operatively attachable to the patient such that the medical device is worn by the patient;19(b) a communications network;See claim element 4(b) above in support.	-	
to the patient such that the medical device is worn by the patient;19(b) a communications network;See claim element 4(b) above in support.		
medical device is worn by the patient;19(b) a communications network;See claim element 4(b) above in support.		
patient;19(b) a communications network;See claim element 4(b) above in support.	-	
19(b) a communications network;See claim element 4(b) above in support.		
network;	1	See claim element 4(b) above in support
		See claim element 4(c) above for support.
the medical device to the	_	

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

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,

Denne Walt

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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

was served upon the below-listed counsel of record by Federal Express:

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ZOLL Medical Corporation c/o Lando & Anastasi, LLP One Main Street, Suite 1100 Cambridge MA 02142 Date: May 31, 2013

By: _ pluine h alet

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