UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

In the *Inter Partes* Review of:

U.S. Patent No. 7,769,605

Filed: August 23, 2007

Issued: August 3, 2010

Inventors: Stephen J. Brown

Assignee: Robert Bosch Healthcare Systems, Inc.

Title: MULTIPLE PATIENT MONITORING SYSTEM FOR PROACTIVE HEALTH MANAGEMENT

Trial Number:

Attorney Docket No.: 12771.0106USW2

Panel: To Be Assigned

PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100

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On behalf of Medtronic, Inc. ("Medtronic") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review is respectfully requested for claims 1-9 of U.S. Patent No. 7,769,605 ("the '605 Patent") (Ex. 1001).

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Medtronic, Inc. is the real party-in-interest for petitioner.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '605 Patent is presently the subject of a patent infringement lawsuit brought by the successor-in-interest to purported assignee Health Hero Network, Inc., Robert Bosch Healthcare Systems, Inc. against Cardiocom, LLC captioned *Robert Bosch Healthcare Systems, Inc. v. Cardiocom, LLC, and Abbott Diabetes Care, Inc.*, United States District Court for the Eastern District of Texas, Case No.: 2:13-cv-349. Inclusive, there are two patent infringement lawsuits involving related patents:

Jurisdiction	**Case Number**	**Patent in suit**
Eastern District of Texas	2:13-cv-349	7,516,192; 7,587,469; 7,840,420; 7,769,605; 7,870,249; 7,921,186
Northern District of California	cv-12-03864	6,368,273; 6,968,375; 7,252,636; 7,941,327; 8,015,025; 8,140,663

The following concurrent and pending reexamination proceedings of patents related to the '605 Patent are pending with the U.S. Patent and Trademark Office:

Reexamination Control No.	**Patent No.**	**Type of Proceeding**	**Examiner**	**Status**
90/012,474	6,368,273	*Ex Parte*	Patel, Hetul B.	Granted, Pending
95/002,276 95/002,172	8,015,025	*Inter Partes*	Wehner, Cary Ellen	Granted, Pending (Merged)
95/002,237	6,968,375	*Inter Partes*	Patel, Hetul B.	Granted, Pending
95/002,178 95/002,221	8,140,663	*Inter Partes*	Patel, Hetul B.	Granted, Pending (Merged)
95/002,199	7,941,327	*Inter Partes*	Escalante, Ovidio	Granted, Pending
95/002,192 95/002,234	7,252,636	*Inter Partes*	Patel, Hetul B.	Granted, Pending (Merged)
90/013,104	7,252,636	*Ex Parte*	Patel, Hetul B.	Granted, Pending
90/013,105	8,140,663	*Ex Parte*	Salman, Ahmed	Granted, Pending
90/013,167	7,769,605	*Ex Parte*	TBD	Filed, Pending

In addition, U.S. Patent Nos. 7,921,186; 7,840,420; and 7,587,469 are the subject of *Inter Partes* Review proceedings, bearing control numbers IPR2013-00431, IPR2013-00449, and IPR2013-0451 (the "'451 IPR proceedings"), respectively. Trial was instituted in these proceedings on January 16, 2014. U.S. Patent No. 7,516,192 is the subject of two Petitions for *Inter Partes* Review, bearing control numbers IPR2013-00468 and IPR2013-00499. Trials were instituted and merged in these two proceedings on January 28, 2014 under the IPR2013-00468 proceeding.

The above *Inter Partes* Review proceedings were originally filed by Cardiocom. Medtronic acquired Cardiocom after Cardiocom filed the Petition for *Inter Partes* Review that resulted in institution of the '451 IPR proceeding. Cardiocom is now a wholly-owned subsidiary of Medtronic. Medtronic has been identified as a real party-in-interest in all of the above proceedings at the U.S. Patent Office. Additionally, a further proceeding, IPR2014-00436, was filed by Medtronic relating to the '469 patent on February 14, 2014, alongside a motion to join IPR2013-00451. That motion is pending.

C. Lead and Back-Up Counsel under 37 C.F.R. § 42.8(b)(3)

Pursuant to 27 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner provides the following designation of counsel, who consent to electronic service.

Lead Counsel	**Back-Up Counsel**
Daniel W. McDonald (Reg. No. 32,044) dmcdonald@merchantgould.com Postal and Hand-Delivery Address: MERCHANT & GOULD, P.C. 80 South 8th St., Suite 3200 Minneapolis, MN 55402 Telephone: (612) 336-4637 Fax: (612) 332-9081	Andrew J. Lagatta (Reg. No. 62,529) alagatta@merchantgould.com Postal and Hand-Delivery Address: MERCHANT & GOULD, P.C. 80 South 8th St., Suite 3200 Minneapolis, MN 55402 Telephone: (612) 371-5383 Fax: (612) 332-9081
Back-Up Counsel	**Back-Up Counsel**
William D. Schultz (pro hac vice to be filed) wschultz@merchantgould.com Postal and Hand-Delivery Address: MERCHANT & GOULD, P.C. 80 South 8th St., Suite 3200 Minneapolis, MN 55402 Telephone: (612) 336-4677	Thomas J. Leach (Reg. No. 53,188) tleach@merchantgould.com Postal and Hand-Delivery Address: MERCHANT & GOULD, P.C. 80 South 8th St., Suite 3200 Minneapolis, MN 55402 Telephone: (612) 336-4665 Fax: (612) 332-9081

Fax: (612) 332-9081	

Per 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel, above.

II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

Payment of $23,000.00 for the fees set forth in 37 C.F.R. § 42.15(a)(1-2) for this Petition for *Inter Partes* Review accompanies this request by way of credit card payment. Nine claims are challenged, so no excess claim fees are required. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to Deposit Account No. 13-2725.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. §§ 42.104

As set forth below and pursuant to 37 C.F.R. §§ 42.104, each requirement for *inter partes* review of the '605 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '605 Patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '605 Patent on the ground identified herein. More particularly, Petitioner certifies that: (1) Petitioner is not the owner of the

'605 Patent; (2) Petitioner has not filed a civil action challenging the validity of a claim of the '605 Patent; (3) this Petition is filed less than one year after the date on which the Petitioner, the Petitioner's real party-in-interest, or a privy of the Petitioner was served with a complaint alleging infringement of the '605 Patent; (4) the estoppel provisions of 35 U.S.C. § 315(e)(1) do not prohibit this *inter partes* review; and (5) the '605 Patent is a patent that is not described in section 3(n)(1) of the Leahy-Smith America Invents Act and so is available for this *inter partes* review, per 37 C.F.R. § 42.102(a)(2).

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that the Patent Trial and Appeal Board find claims 1-9 of the '605 Patent unpatentable.

1. Claims for Which Inter Partes review is Requested Under 37 C.F.R. § 42.104(b)(1)

Petitioner requests *inter partes* review of claims 1-9 of U.S. Patent No. 7,769,605.

2. The Specific Art and Statutory Ground(s) on Which the Challenge is Based Under 37 C.F.R. § 42.104(b)(2)

Inter partes review of the '605 Patent is requested in view of the following references: (1) U.S. Patent No. 5,827,180 ("Goodman"); (2) U.S. Patent No. 5,331,549 to Crawford ("Crawford"); (3) U.S. Patent No. 5,942,986 to Shabot ("Shabot"); (4) G.F. Groner et al., *An Introduction to the CLINFO Prototype Data*

Management and Analysis System, R-1541-NIH (1977) ("Groner"); (5) U.S. Patent No. 5,471,382 to Tallman ("Tallman"); (6) E. Chris Vincent et al., *The Effects of a Computer-Assisted Reminder System on Patient Compliance With Recommended Health Maintenance Procedures*, Proc. Annu. Symp. Comput. Appl. Med. Care. 1995:656-60 ("Vincent").

Each of the patents and publications listed above is prior art to the '605 Patent under pre-AIA 35 U.S.C. §§ 102(a), (b), or (e), as established in Section V(A), below.

Ground	Claim Numbers	Proposed statutory rejections
1	1, 3-9	Claims 1 and 3-9 are obvious under § 103(a) over Goodman in view of Shabot
2	2	Claim 2 is obvious under §103(a) over Goodman in view of Shabot, in further view of Vincent
3	1, 3-9	Claims 1 and 3-9 are obvious under § 103(a) over Goodman in view of Shabot and Crawford
4	2	Claim 2 is obvious under §103(a) over Goodman in view of Shabot and Crawford, in further view of Vincent
5	1, 3-9	Claims 1 and 3-9 are obvious under § 103(a) over Goodman in view of Shabot and Groner
6	2	Claim 2 is obvious under §103(a) over Goodman in view of Shabot and Groner in further view of Vincent
7	1, 3-9	Claims 1 and 3-9 are obvious under § 103(a) over Goodman in view of Shabot, Crawford and Tallman
8	2	Claim 2 is obvious under §103(a) in view of Goodman in view of Shabot, Crawford, and Tallman and in further view of Vincent.

3. How the Challenged Claims Are To Be Construed Under 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 42 C.F.R. § 42.100(b). The broadest reasonable interpretation in light of the specification for certain claim elements has already been determined at least on a preliminary basis in a related proceeding, *Cardiocom, LLC v. Robert Bosch Healthcare Sys., Inc.*, IPR2013-00439, Paper 26 (Jan. 16, 2014)(Decision Denying Institution of Inter Partes Review) (Ex. 1010). Therefore, Petitioner submits that, for the purposes of this proceeding, such phrases should be construed consistent with their interpretation in that decision unless stated otherwise herein. Specifically, "chart" should be construed to mean "information arranged in a form of one or more tables, graphs, or diagrams." *Id*. at 11. "Icon" should be construed to mean "a graphical representation of an underlying function or data." *Id*. at 12. In the Decision, all other claim terms in claims 1-9 were presumed to have their ordinary and customary meaning. *Id*.

4. How the Construed Claims are Unpatentable Under 37 C.F.R. § 42.104(b)(4)

An explanation of how construed claims 1-9 of the '605 Patent are unpatentable under the statutory grounds identified above, including the

identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section VI, below, in the form of claim charts.

5. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge raised, including identification of specific portions of the evidence that support the challenge, are provided in Section VI, below, in the form of claim charts. An Appendix of Exhibits identifying the exhibits is also attached. Pursuant to 37 C.F.R. § 42.63(a), Exhibit 1018 is a Declaration by Robert T. Stone, Ph.D. Regarding U.S. Patent No. 7,769,605 Under 37 C.F.R. § 42.63(a), attesting to, among other issues, the invalidity of claims 1-9 of the '605 Patent, reasons for intercombination of the references cited in this Petition, and supporting bases for the proposed grounds of unpatentability. (cited herein as "Stone Decl.")

6. One of Ordinary Skill in the Art at the Time of Invention

One of ordinary skill in the art at the time of the '605 Patent would have a bachelor's degree in Electrical Engineering or Computer Science, or its equivalent, and at least 2 years of experience with the design and programming of patient monitoring systems and at least 1 year of experience with the design or programming of networked systems. Ex. 1018, Stone Decl., ¶16.

IV. SUMMARY OF THE '605 PATENT

A. Description of the Alleged Invention of the '605 Patent

The '605 Patent generally relates to systems for monitoring a group of patients having a chronic disease or ongoing health condition. '605 Patent, Abstract. In particular, the '605 Patent includes features directed towards receiving health information from the patients' monitoring devices, calculating a control value from those measurements, generating a group overview chart to display those control values, and transmitting a supervisory message to the patient. '605 Patent, col. 3:26-4:15.

The '605 Patent generally describes a system and method that involves collecting measurements from multiple patients ('605 Patent, col. 3:28-30; FIG. 1); processing the data to determine a "control value" for each patient ('605 Patent, col. 3:31-34; FIG. 6); storing the patient information in a database ('605 Patent, col. 3:58-59; FIGS. 2, 6); generating and displaying a "group overview chart" for the patients to display said control value ('605 Patent, col. 3:40-45; FIGS. 3, 6); and sending a telephone or electronic mail message to the patient based on the processed measurements ('605 Patent, col. 3:48-53FIGs. 6-8). *See also '605* Patent, claim 1.

B. Summary of the Prosecution of the '605 Patent

The patent application that issued as the '605 Patent was filed on Aug. 23, 2007 as U.S. Patent Application No. 11/843,727 (the "'727 Application"). The

original claims of the '727 application were different than those issued in the '605 Patent. For example, the originally filed claim 13 (later issued as claim 1 of the '605) recited:

> A system for monitoring a group of at least one individual regarding a health condition, comprising:
> a reception unit for receiving a corresponding set of measurements regarding said health condition from each individual of said group;
> a processing unit in communication with said reception unit for processing said corresponding set of measurements and identifying at least one individual based upon said processing of said corresponding set of measurements; and
> a transfer unit in communication with said processing unit, wherein said transfer unit communicates with said at least one individual.

Ex. 1011, '727 Application at 23. With the application, the Applicant filed an Information Disclosure Statement. Ex. 1012, Aug. 23, 2007 IDS.

The initial claims of the '727 application were rejected as unpatentable subject matter under 35 U.S.C. § 101, indefinite under § 112, and invalid under §§102 and 103. Ex. 1013, Dec. 22, 2008 Office Action at 2-9. The Applicant responded by cancelling claims 1-12 and adding a "display unit" element to claim 13, the sole remaining independent claim. Ex. 1014, March 25, 2009 Response and Amendment at 2. The display unit element required a group overview chart with a plurality of icons, each icon indicating a set of measurements for an individual. *Id*. The Applicant argued that prior art Fu and Chen lacked such a display. *Id*. at 4-5.

These amended claims were rejected over Fu and an article by A.M. Albiser titled *Intelligent Instrumentation in Diabetic Management*. Ex. 1015, July 24, 2009

Office Action at 2-4. The examiner found that the Albiser article disclosed the display unit and Fu disclosed all other elements of the purported invention. *Id*.

The Applicant attempted to overcome this rejection by narrowing the scope of the display unit with regard to unique icons (Ex. 1016, Sept. 24, 2009 Response at 2-5; *see also* Nov. 17, 2009 Request for Continued Examination) but the Examiner, instead, rewrote the independent claim 13 and marked it for allowance (Ex. 1017, April 16, 2010 Notice of Allowance).

The Examiner made significant changes to claim 13 in order to secure allowance. As detailed in the Notice of Allowance, the Examiner made the following changes (Examiner additions underlined):

> A system for monitoring a plurality of patients regarding a health condition, comprising:
> a reception unit for receiving a corresponding set of measurements regarding said health condition from each patient included in the plurality of patient [sic];
> a processing unit in communication with said reception unit for processing said corresponding set of measurements and identifying at least one patient included in the plurality of patient [sic] based upon said processing of said corresponding set of measurements;
> a database, the database being in communication with said processing unit, the database being configured for storing medical health history information for each patient included in the plurality of patients, wherein processing of said corresponding set of measurements by the processing unit includes evaluating said corresponding set of measurements against said stored medical health history information;
> a transfer unit in communication with said processing unit, wherein said transfer unit communicates with said at least one identified patient, said transfer unit being configured for transmitting a message for communicating with said at least one identified patient, the message being based upon said medical health history information

> and said processing of said corresponding set of measurements, the message being one of: a telephone message and an electronic mail message; and
> a display unit in communication with said processing unit, the display unit being configured for displaying a group overview chart, said group overview chart being generated by the processing unit based upon said processing and being provided to said display unit, said group overview chart including a plurality of data points, wherein each of the data points represents one corresponding patient included in the plurality of patients and indicates at least one control value for the one corresponding patient, the control value being indicative of the one corresponding patient's control over said health condition, the control value being based upon said corresponding set of measurements, each data point including an icon.

Ex. 1017, April 16, 2010 Notice of Allowance at 2-3.

The amendments and comments in the Notice of Allowance show that the Examiner allowed the claims based on monitoring a group of patients by using a group overview chart where each data point corresponds to a value and a patient, and furthermore based on a processing unit that evaluates a set of measurements against said stored medical health history information and a transfer unit configured for sending a message based on the processed measurements to a patient via a telephone message or an electronic mail message. Ex. 1017, April 16, 2010 Notice of Allowance at 2-3, 4.

C. Summary of the Prior Post-Grant Challenges

The '605 Patent and related U.S. Patent No. 7,840,420 ("the '420 patent") were the subject of prior petitions for inter partes review, bearing proceeding numbers IPR2013-00439 and IPR2013-00449, respectively. Both proceedings

alleged invalidity based on combinations prior art references including three references, Goodman, Crawford, and Tallman which form a portion of the grounds of challenge in the present petition.

In IPR2013-00449, the PTAB instituted trial on each of the claims of the related '420 patent based on combinations including Crawford, Tallman, and Goodman. Among other observations regarding the prior art in its order instituting trial, the Board indicated that "Petitioner has shown sufficiently that Crawford's overview display is a 'chart' having data points, each representing one patient and indicating a value for the patient (e.g., a warning situation) based on measurements for the patient, with each data point having an icon (image of a room)." Ex. 1009, IPR2013-00449, Paper 21 at p. 17.

In IPR2013-00439, the Board came to similar conclusions regarding the Crawford's disclosure of the group overview chart recited in claim 1 of the '605 Patent. *See, e.g.,* Ex. 1010, IPR2013-00439 ("the '439 IPR"), Paper 26 at p. 13. However, the Board did not institute an *inter partes* review of any of the asserted grounds, which all relied on either Crawford or Goodman in combination with other references. *Id*. at 8, 19. The Board's decision was based on a finding that neither Crawford nor Goodman disclosed the "evaluating" limitation of claim 1. In denying that petition, the Board concluded that the petitioner in the '439 IPR did not sufficiently show that "Crawford teaches a 'processing unit' for 'processing

said corresponding set of measurements,' where in the processing includes 'evaluating said corresponding set of measurements against said stored medical health history information,' as recited in independent claim 1." '439 IPR, paper 26 at 16. In making this determination the Board found that setting of default threshold values based on a patient's age (child, adult or senior) was not "medical health history of a patient." *Id*. at 15. The Board also found that Crawford did not meet the claim limitation because in Crawford "it is the *user* that selects the vital sign limits, not *a processing unit* in a system." *Id.* (emphasis in original).

The Board also found that Goodman did not disclose the "evaluating" limitation of claim 1. The Board found that while Goodman discloses generating a status report based on information contained in a patient record, there is no showing that there is an "evaluation performed in Goodman of a set of measurements against stored medical health history information." *Id*. at 18.

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '605 PATENT IS UNPATENTABLE UNDER 37 C.F.R. § 42.104(b)(4)

A. Identification of the References as Prior Art

U.S. Patent No. 5,827,180 to Goodman (Ex. 1002) was filed on November 26, 1997 and is a continuation of Ser. No. 518,783, filed on August 24, 1995, which is a continuation in part of Ser. No. 334,936, filed on November 7, 1994. Therefore, the earliest filing date of Goodman predates by nearly two years the

earliest claimed effective filing date of October 16, 1996 for the '605 Patent. Goodman therefore qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

U.S. Patent No. 5,942,986 to Shabot et al. (Ex. 1003) was filed on August 9, 1995, and issued on August 24, 1999. Therefore, the earliest filed date of Shabot predates by over one year the earliest claimed effective filing date of October 16, 1996 for the '605 Patent. Shabot therefore qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

E. Chris Vincent et al., *The Effects of a Computer-Assisted Reminder System on Patient Compliance With Recommended Health Maintenance Procedures*, Proc. Annu. Symp. Comput. Appl. Med. Care. 1995:656-60 (Ex. 1005) was published October, 1995. Vincent's publication predates the earliest claimed effective filing date for the '605 Patent. Therefore, Vincent is prior art to the '605 Patent under 35 U.S.C. § 102(a).

U.S. Patent No. 5,331,549 to Crawford (Ex. 1006) was filed on July 30, 1992 and issued on July 19, 1994. Crawford's publication predates the earliest claimed effective filing date for the '605 Patent by more than a year. Therefore, Crawford is prior art to the '605 Patent under 35 U.S.C. § 102(b). G.F. Groner et al., *An Introduction to the CLINFO Prototype Data Management and Analysis System*, R-1541-NIH (1977) (Ex. 1007) was published December, 1977. Groner's publication predates the earliest claimed effective filing date for the '605 Patent by

more than a year. Therefore, Groner is prior art to the '605 Patent under 35 U.S.C. § 102(b).

U.S. Patent No. 5,471,382 to Tallman (Ex. 1008) was filed on January 10, 1994 and issued on November 28, 1995. Tallman predates by over two years the earliest claimed effective filing date of October 16, 1996 for the '605 Patent. Tallman qualifies as prior art under pre-AIA 35 U.S.C. §§102(a) and 102(e).Shabot, Groner, and Vincent were not of record during prosecution of the '605 Patent. Tallman and Goodman were listed in the voluminous references cited in an IDS by the Applicant as reflected on the face of the '605 Patent. Crawford was discussed as background to the purported invention of the '605 Patent and was distinguished from the purported invention by differences irrelevant to the claims. None of the references was relied upon in any rejection of the claims.

B. Summary of Invalidity Arguments

The idea of displaying a chart of multiple patients' health values was not new in 1996. Similarly, the idea of sending messages to patients about their conditions via telephone or electronic mail was also not novel at that time. Health professionals had been using computers for decades by the time of the '605 Patent, and had been using automated telephone messages and electronic mail for years.

Concurrently, telehealth systems were developed in the 1990's that allowed for remote patient interaction, information gathering, and treatment. The '605

Patent represents one of many attempts to interact remotely with patients and allow healthcare professionals to effectively oversee a plurality of patients. It was not the first such attempt, and in fact contrary to Reasons for Allowance, it was not the first to display icons on a chart for patients or to communicate with automatic telephone messages or electronic mail. In fact, the description of the '605 Patent, itself, states that automated telephone systems to generate custom messages for recipients were well known in the art at the time. '605, col. 9:21-23.

The current Petition overcomes the deficiencies identified in the earlier '439 proceeding based on newly-cited art. In particular, Petitioner respectfully submits that the Shabot prior art reference submitted herewith discloses exactly the limitation found lacking by the Board in the '439 proceeding. In particular, Shabot discloses, among other limitations, both the display limitations leading to allowance of the '605 Patent and the limitation lacking from the '439 proceedings, namely that processing includes "evaluating said corresponding set of measurements against said stored medical health history information" as required by claim 1 of the '605 Patent. *See* Shabot at Fig. 2, col. 8:13-33; col. 9:3-6; col. 9:50-65 col. 10:29-11:50. Also, Crawford in fact suggests the "evaluating" limitation of claim 1, because Crawford explicitly teaches evaluating measurements against thresholds that are based on a patient's health history, which includes that patient's age. *See, e.g.,* Crawford, col. 2:34-39, 8:34-40.

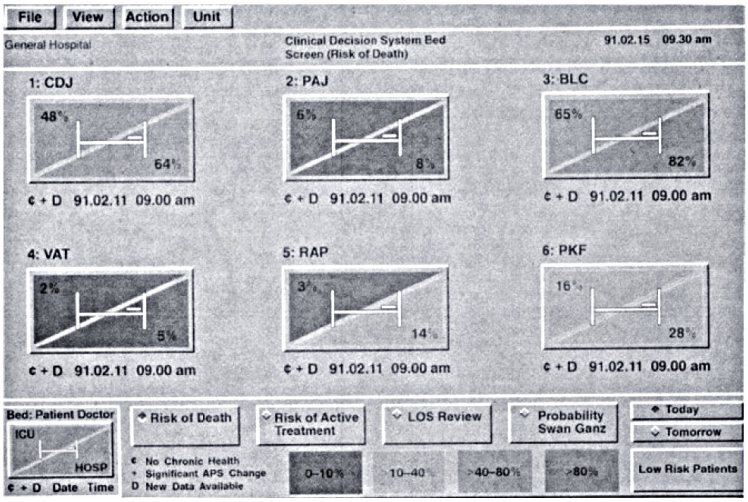
As outlined in the claim charts below, Goodman teaches automated communication with remote patients. In that system, a measurement device at the patient's home gathers data regarding health conditions; communicates the information to a host computer; the host computer processes the information; stores the information in a database; and communicates supervisory messages back to the patient through a modem or an electronic paging system. Stone Decl., ¶22, 35. Goodman also refers to communicating with patients via electronic mail. Given Goodman's disclosures of communicating supervisory messages and communicating with patients via electronic mail, it would be obvious to one of ordinary skill in the art to also use electronic mail for the supervisory automatic messages, as being a convenient and known set of prior art elements used to predictable, known effect. *Id*. Importantly for several dependent claims, Goodman also teaches the use of a home computer to receive supervisory messages and the use of a modem to receive health measurements at the host computer. *Id*.

With respect to the group overview chart recited in claim 1 of the '605 Patent, each of Shabot, Crawford, and Groner disclose showing multiple patient control values via icons on a chart. Shabot discloses a patient monitoring system that monitors patient statistics and a patient's medical health history in the patient's file to detect critical events. Stone Decl., ¶24; Shabot, col. 8:13-33, Fig. 2. Those critical events and other patient information can be sent to health professionals in

the form of a chart. Shabot, col. 11:39-50; col. 15:4-34, Figs. 10-12. Shabot discloses a processor that evaluates a set of patient measurements against stored medical health history information stored in a database of patient records, and identifies a patient based on that medical health history. Shabot, col. 6:13-47, 9:50-65. For example, Shabot discloses that the server workstation stores information in a patient's chart at database ("data archives 77"), and for certain alerting algorithms, compares new data with stored data to determine if there is an alert condition. *Id*., col. 6:36-47; col. 10:40-45. Figures 1 and 3 illustrate how the workstation server 69, as part of its processing, evaluates corresponding set of measurements against stored medical health history information. Shabot discloses collection of periodic data samples, such as from a ventilator, and employs algorithms that analyze current and past measurements to detect exception conditions. Shabot, col. 6:36-47; col. 9:50-67; 10:1-2; 10:46-67; 11:11-17.

Importantly, Shabot incorporates by reference the book *Decision Support Systems In Critical Care*, Ed. M. Michael Shabot and Reed Gardner (Springer-Verlag 1994) ("Shabot book"). Shabot, col. 12:10-22. The Shabot book discusses in depth the presentation of a display of patient status for a number of patients based on triage decisions for patients based on a risk of death, the display including information such as diagnosis and component scores for admission and chronic health issues (medical health history information). See, e.g., Ex. 1004 at pp. 251-

252 (Fig. 16.1). The *Decision Support Systems In Critical Care* book discloses the Apache III system that measures patient's vital signs, blood chemistry data, hemogram data and urine output data and compares it with a database from a large study to evaluate the patient's status. Ex. 1004at 245, Table 16.3. Based on this information, the Apache III system provides a graphical display of the beds in an ICU and color codes them based on the patient's measurements compared to historical data from other patients. Ex. 1004 at 251, Figure 16.1(A-C). This group overview chart provides management with a graphical representation of the status of the group of patients in the ICU:



Other charts disclosed in the Shabot book compare component scores of two patients, including acute and chronic conditions, with each data point represented as an icon. Shabot Book at 251-52.

Two additional articles incorporated by reference in Shabot, *Real-Time Wireless Decision Support Alerts on a Palmtop PDS*. M. Michael Shabot M.D. and

Mark LoBue (AMIA, Inc. 1995) ("Shabot Real-Time Article") (Ex. 1020) and *Inferencing Strategies for Automated ALERTS on Critically Abnormal Laboratory and Blood Gas Data* M. Michael Shabot M.D. et al. (SCAMC, Inc. 1989) ("Shabot Alerts Article")(Ex. 1021) describe collection of various clinical data using the overall system of Shabot, including blood gas, ventilator, urimeter, and other monitoring devices, as well as automation of recognition of abnormal laboratory and blood gas results. Stone Decl., ¶¶29-30.

In addition to Goodman and Shabot, Crawford shows a chart with each patient on a hospital floor as a room icon, with multiple rooms showing status data for patients' respiration, blood pressure, and the like:

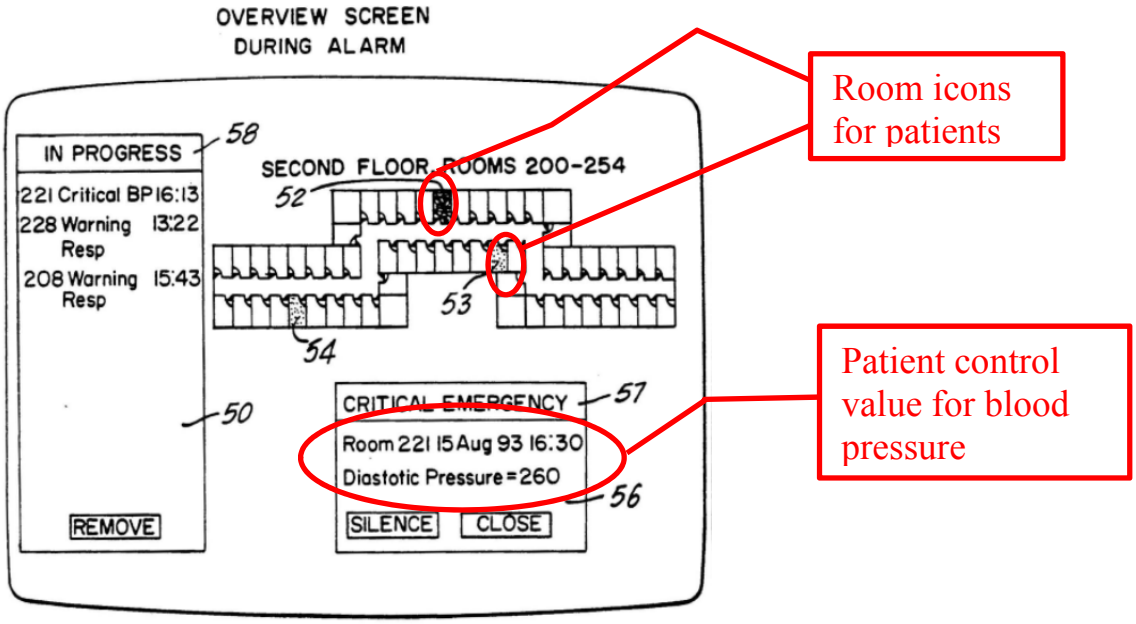


FIG. 3

The Board decided, in a copending IPR2013-00449, that "Crawford's overview display is a "chart" having data points, each representing one patient and indicating a value for the patient (e.g., a warning situation) based on measurements for the patient, with each data point having an icon (image of a room)." Ex. 1009 at p. 17.

The '605 Patent acknowledges the Crawford prior art, referring to Crawford's teaching of monitoring vital signs for multiple patients, storing that data in a central server and displaying it on monitors. '605 Patent, col. 2:39-3:3. The '605 alleges that Crawford is lacking because it requires a continuous connection and because its status calculation is limited to determining whether a patient is normal, in distress, or in an emergency state. '605 Patent, col. 2:61-66. The '605 argues that those limitations make Crawford "of little use to a clinician in managing the medical priorities of a group of patients who are not continually monitored in a healthcare facility." '605 Patent, col. 2:67-3:3. However, the claims of the '605 do not require a system to operate without a continuous connection or to provide more than three alarm states for patient status. *See '605* Patent, claims 1-9. In fact, nothing in the claims suggests that the claimed system must be useable for "managing the medical priorities of a group of patients who are not continually monitored in a healthcare facility." *Id*. In any event, as discussed below, the newly-cited Shabot reference teaches both continuous and non-continuous use, thereby

suggesting that analogous features could be used in both scenarios and providing a motivation to combine Shabot with both Crawford and Goodman.

Additionally, Groner, in a 1977 manual for using the CLINFO system, teaches users to create charts with graphical symbols for displaying patient health measurements. As an example, the authors explain how to create a graph showing patients' age versus their diabetes duration, with each symbol's location representing the corresponding value. Groner, p. 49. Additionally, in one chart, the authors specifically refer to showing "Control Glucose by Patient and by Hour." Groner, p. 50. The Groner publication specifically teaches users to create graphs with icons, like those above, for any set of data, including data like that found in the Glucose Control chart, which includes medical health history data (e.g., past glucose readings).

Additionally, as shown below, each of Tallman and Goodman teach systems for communicating with patients to gather medical information and transmit supervisory instructions to those patients. Tallman involves a system in which a nurse or other healthcare professional speaks to the patient on the phone; gathers medical information; and inputs it into the system; whereupon the system processes the information and generates a message for the nurse to convey to the patient. As noted by the '605 Patent, itself, automating the telephone message was well known in the art at the time of the alleged invention, so one of ordinary skill

would have known how to use the computer system to automatically generate the phone message. '605 Patent, col. 2:13-28. Such a step would be desirable because using the system to call patients removes the nurse from that rote duty and allows him or her to concentrate on more critical tasks. Furthermore, an automatic phone system can easily tell when the line is busy or no one answers and can reschedule the call without wasting valuable healthcare worker time. Stone Decl., ¶111.

Finally, for claim two, Vincent teaches a computer system that measures compliance of patients with supervisory messages, referred to in Vincent as Health Maintenance Recommendations. Vincent teaches that if a patient does not comply within a month of receiving a notice, that patient is marked as non-compliant.

Each of the prior art publications and patents are within the same field of art: computerized health care. As explained below, the publications and patents each suggest their intercombination, as does the general teachings within the art at the time of the invention.

VI. DETAILED EXPLANATION UNDER 37 C.F.R. §§ 42.104(b)

Below and in accordance with 37 C.F.R. §§ 42.104(b), an explanation of each proposed ground of unpatentability is provided. Grounds 1-8 are discussed and followed by a claim chart.

A. Ground 1 – Each of Claims 1 and 3-9 is Obvious over Goodman in view of Shabot

The combination of Goodman and Shabot teaches all elements of claims 1 and 3-9 of the '605 Patent. The comparison of this art with the claims of the '605 Patent is shown in more detail in the claim chart below. Goodman and Shabot each teach a system for monitoring the health conditions of a plurality of patients by gathering patient data, uploading that data to a central computer, and processing that data to gather useful information. Goodman, col. 2:52-67; Shabot, col. 6:16-65; col. 9:50-67; 10:1-2, 46-67; See "Critical Event Parameters" in Tables 2-3. Goodman teaches communication with a patient via telephone or electronic mail (col. 7:60-65) while Shabot discloses communication via a pager network. Shabot, col. 7:57-64; 9:66 -10:2; 11:28-36. Goodman discloses a reception unit within the host computer. Goodman, col. 2:52-67. Goodman teaches that the host computer functions as a central station for collecting, analyzing and routing data. *Id*. For example, the patient, prompted by a message, enters relevant physiological data, e.g., peak flow, etc., as directed by the treatment plan. *Id*. Shabot also teaches a reception unit (server workstation 69) for receiving a corresponding set of measurements from patients. Shabot, Fig. 3, col. 6:13-28. Shabot teaches, among other elements, the display unit and processing unit of claim 1, in particular in the Shabot book incorporated by reference, *Decision Support Systems In Critical Care*, Ed. M. Michael Shabot and Reed Gardner (Springer-Verlag 1994)) ("Shabot

Book") (Ex. 1004), at 245, 251-52. As noted in the charts below, Shabot discloses that the processing unit of claim 1 corresponds to the server workstation, which employs algorithms that import selected data from patient files or particular workstations to perform analysis on current and past data to determine if there is an alert. Stone Decl., ¶¶39-40. Shabot discloses a system wherein processing of said corresponding set of measurements by the processing unit includes evaluating said corresponding set of measurements against said stored medical health history. Shabot, col. 6:36-47.

The teachings of Goodman and Shabot would be combined by one of skill in the art based on teachings in the field of computerized health care at the time of the invention, as well as the references themselves. Within the general field of computerized healthcare, it was known at the time of the alleged invention to use computing technologies to assist in reducing the cost of healthcare, in particular by reducing the length of in-hospital stays. Stone Decl., ¶33. As such, outpatient management using the same technologies as were used for inpatient monitoring became more prevalent, and were desirable. *Id*. This is particularly the case for systems capable of monitoring multiple patients, which allowed for efficient patient monitoring by healthcare professionals and reduction of inpatient stays. *Id*.

At the same time (in the 1990's), computing systems, and in particular networking to in-home computing systems, were becoming more common and communication speeds using modems or other networking equipment were increasing, thereby enabling greater use of "connected" home devices such as personal computers. Stone Decl., ¶34. Improved graphics capabilities were available at the time as well, and were well known and readily integrable into healthcare devices. *Id*.

Both the Goodman and Shabot references describe systems for providing cost-effective healthcare by increasing the use of and capabilities of remote monitoring systems, and in particular remote monitoring systems that monitor patients over time (e.g., based on health history). Stone Decl., ¶31, 33. One of skill in the art would be motivated to provide features available in inpatient monitoring services to outpatients, and would look to computing technologies to enable and enhance such remote monitoring. Stone Decl., ¶34. Accordingly, one of skill in the art would recognize the value of incorporating features of Shabot, and other systems available for patient monitoring, into a remote monitoring system such as is disclosed in Goodman.

Addtionally, there are numerous teachings in both Goodman and Shabot which would suggest intercombination of the features of those references. For example, the Shabot Book indicates that Shabot system is intended to interface

with various systems, such as patient monitoring systems, using known techniques to obtain predictable results. *Id*. The computing systems of Goodman and Shabot each disclose use of standard protocols, such that the features of each reference would readily be intercombinable without change to the functionality of the systems disclosed, and with no technological hurdles to overcome. Stone Decl., ¶32. In particular, one of skill in the art would incorporate the displays of Shabot, as well as the comparison to health history data, into the monitoring system of Goodman to provide periodic reports to a primary provider, allowing that provider to determine if the patient is following a particular treatment. Stone Decl., ¶40-41.

Furthermore, because Goodman teaches that a primary provider may alter a patient's treatment, one of skill in the art would understand that such an alteration to a patient's treatment would occur based on an updated evaluation of a patient, and comparison of that evaluation to either stored medical health history information or a particular value, both of which are disclosed in Shabot. Stone Decl., ¶42-43. The disclosures of Goodman and Shabot (including the Shabot Book) to process patient data, using that patient information to generate status information, and generate a display allowing for reporting of that information was a known technique at the time of the references and thus, would readily be intercombined into such a remote monitoring system. This

would be recognized as increasing the efficiency of monitoring remote patients, and leading to predictable results of efficiently informing a caregiver of a patient's status. Stone Decl., ¶¶47-48.

Further, Goodman teaches that its host computer sends messages to the patient based on health history and processing via pager or modem. Specifically, Goodman uses a wireless device to communicate between the host computer and the patient with messages based upon medical health history information. Goodman, col. 5:64-6:15. Goodman also teaches that information could be communicated to a patient via electronic mail or telephone messages and discloses that the host computer would incorporate a message/mail server. Goodman, col. 7:66 -8:5. It would be obvious to one of ordinary skill in the art that the pager and modem messages disclosed by Goodman for transmitting health-related messages to patients were examples. One of ordinary skill would understand that the other means of communication disclosed by Goodman, telephone and electronic mail, were also known interchangeable methods to transfer messages to patients, since such other communication types were available for communication with remote computing systems. Stone Decl., ¶49.

Additionally, the Shabot book includes numerous instances suggesting extension of inpatient monitoring to outpatients, as well as integration of new computing technologies into medical monitoring systems. Specifically, Shabot

discloses that integrated patient records allows for data access at various locations, including home locations. Shabot Book at 7. Furthermore, Shabot Book repeatedly describes improved communication and graphic presentation capabilities being key in facilitating quick identification of abnormalities at an early stage, and to allow for online analysis of patients via computer networks. Stone Decl., ¶34. Accordingly, one of ordinary skill in the art would have recognized that the computerized display of a group overview chart disclosed in Shabot, would work well for managing remote patients and graphically displaying patient alerts to allow efficient monitoring and to facilitate patient contact. Stone Decl., ¶59. Furthermore, because both Goodman and Shabot disclose integrated databases of patient records (Goodman, col. 7:60-65; Shabot, col. 6:24-28, 6:48-52), Shabot suggests that either system would be well adapted to allow access to patient information at locations outside the hospital, including medical clinics or at the home, and could readily be adapted for use in a remote monitoring configuration. Stone Decl., ¶34, 38, 43; Shabot Book at 7.

Additionally, the suggestion in the Shabot book indicating the advantages of real-time graphic display features would suggest to one of ordinary skill in the art the advantages of a group overview chart as is disclosed in that reference, and would suggest its combination with distributed data systems to provide convenient, efficient monitoring of remote patients. Stone Decl., ¶25-28, 53-60.

Further, the group overview chart of Shabot represents a chart as would be known to one of skill in the art. *Id*.

Shabot also teaches that it would have been beneficial to combine the teachings of Shabot with Goodman to expand the types of patient health alerts to include alerts based data collected over time in addition to alerts based on real time measurements, thereby improving automation and efficiency in detecting health conditions of concern. Stone Decl., ¶¶45, 47. Shabot teaches storing patient heath history information and evaluating it with new patient measurements to obtain, for example, time-based information from which to evaluate complex-analysis alerts. Stone Decl., ¶45. For example, Shabot discloses an alert condition that occurs when a ventilator patient requires a sixty percent or greater oxygen level for more than four hours. *Id*.; Shabot, col. 6:36-47. This requires the new measurement to be evaluated against stored medical health history information, i.e. the past four or more hours of oxygen levels. One of ordinary skill in the art would have been motivated to combine the teachings of Shabot with Crawford and Goodman to expand detection of alerts to situations that account for past health history information to detect a critical situation, to assist healthcare professionals in enhancing patient care. Stone Decl., ¶¶45.

It would have been obvious to one of skill in the art to take the teachings of Shabot, regarding communicating with a physician, and communicate directly with the patient for such alerts that a patient could address directly, as is discussed in Goodman. Stone Decl., ¶¶49-52. Shabot teaches that in some cases automating the process can beneficially remove human error and time delays. Shabot, col. 7:26-29. One of skill in the art would have recognized that for conditions that can be addressed directly by the patient, such as taking medication, human error and time delays can be avoided by sending a message directly to the patient. Stone Decl., ¶¶49-52. This would have caused one of ordinary skill in the art look to how such medical monitoring systems communicated with those that needed the information, including doctors and patients. Stone Decl., ¶¶34, 49-52. Furthermore, if the teachings of Shabot were incorporated into the system of Goodman, it would be straightforward to incorporate communication with the patient, since Goodman is intended to provide outpatient remote monitoring of patients having chronic diseases. See Goodman, col. 2:36-41 ("Thus there is a need for a comprehensive outpatient management system which…allows 2-way information exchange between the provider and the patient and reduces the physician's burden of closely monitoring outpatient treatment.") Stone Decl., ¶¶33.

B. Ground 3 – Each of Claims 1 and 3-9 is Obvious over Goodman in view of Shabot and Crawford

The combination of Goodman, Shabot, and Crawford teaches all elements of claims 1 and 3-9 of the '605 Patent. The comparison of this art with the claims of the '605 Patent is shown in more detail in the claim chart below. Goodman, Shabot, and Crawford each teach a system for monitoring a plurality of patient's health conditions by gathering patient data, uploading that data to a central computer, and processing that data to gather useful information. Goodman, col. 2:52-67; Shabot, col. 6:16-28; Crawford, col. 1:6-8, 2:31-37. Crawford adds explicit disclosure of a group overview chart that displays icons representative of values associated with patient health assessments.

Since Goodman, Shabot, and Crawford are generally within the field of computerized health care, and in particular monitoring of patient populations, those references would have been available to one of skill in the art. Stone Decl., ¶¶22, 24, 80-82. Furthermore, the same advantages described in Section IV(A) above as existing within the field of computerized healthcare, and within Goodman and Shabot themselves, would extend to combination of Goodman and Shabot with Crawford, in particular (1) extending use of inpatient monitoring features to remote monitoring, and (2) incorporating new display and communications technologies to enhance the remote monitoring capabilities available. In particular, and as discussed in the '605 Patent, Crawford is

particularly related to monitoring of continuously-connected patients. *See* '605 Patent, col. 2:53-59. One of ordinary skill in the art would be motivated to look to medical informatics systems providing periodic or intermittent monitoring, such as in Shabot or Goodman, to find solutions to such shortcomings, to monitor wider populations of patients. Stone Decl., ¶¶33-34.

Additionally, Crawford supplies further motivation for intercombination with teachings from that reference. Regarding the "database unit" element, Crawford refers to storing patient measurement data at the server in a "single data storage" for reasons of efficiency. Stone Decl., ¶87; Crawford, col. 3:57-60. One of ordinary skill in the art would understand that "single data storage" as described in Crawford would generally mean a database. Stone Decl., ¶87. Crawford teaches storing medical alerts based on history in a database. Crawford, col. 9:49-59 (including explicit reference to database containing "room number, nature of alarm (warning, critical, off-line), date, time, and all sign values.") As such, Shabot would suggest that the Crawford database would readily be used for remote monitoring, and in particular remote monitoring of historical data relating to medical alerts.

Further, with limited resources and the incentive to make monitoring many patients easier, it would have been obvious to provide a display with a group overview chart where multiple patients can be quickly monitored at once.

Stone Decl., ¶¶33-34, 80-83. Crawford teaches a method of displaying patient data on a chart with icons based on control values and other options. Stone Decl., ¶87; Crawford, Fig. 3. Various other graphics and charts of different formats could be created, using data points for a plurality of patients, with each data point representing a single patient as was well known at the time of Crawford. Crawford, col. 5:2-6 ("The techniques of generating the program for the particular screen displays illustrated herein are techniques that are known to those skilled in the art who employ a process graphics software package such as InTouch.").

Finally, in view of similar claims and much disclosure in common with the '605 Patent, the Board decided in IPR2013-00449 that Goodman would be combined with Crawford to teach the limitations of the related '420 Patent. Ex. 1009 at p. 22. As noted above, Shabot provides even more motivation to combine these references here.

Thus, the claimed invention would have been obvious in view of the combination of Goodman, Shabot, and Crawford. Moreover, there would have been multiple reasons to combine the references as claimed to display a group overview chart to easily monitor a group of patients, communicate with patients to gain efficiencies and reduce human error, and to expand the type of critical alerts that can be employed by using a patient's health history. Each of the

elements was known in prior art references in the field of the invention, and motivations to combine the teachings of these references existed in the art at the time of the invention, as well as within the references themselves. This motivation to combine the teachings of the references to obtain these efficiencies and enhanced capabilities is further supported by the fact that one of skill in the art would have understood that these features, when combined, would function in their expected ways. *Ecolab, Inc. v FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009). Further, the invention recited in the '605 Patent claims represents an obvious combination of such prior art elements, because each of the elements of those prior art references would maintain their respective properties or functions after being combined. Stone Decl., ¶¶81-88; *see Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008).

C. Ground 5 – Each of Claims 1 and 3-9 is Obvious over Goodman, Shabot and Groner.

The combination of Goodman, Shabot and Groner teaches all elements of claims 1 and 3-9 of the '605 Patent. The comparison of this art with the claims of the '605 Patent is shown in more detail in the claim chart below. Goodman, Shabot and Groner each deal directly with computerized patient monitoring and efficient patient data analysis. *See* Goodman, Abstract; Shabot, Abstract; Groner, pp. 1-2. Therefore, one of ordinary skill in the art at would consider these references to be in the same field of art, computerized health care, and

motivations in existence within that field (enhanced remote monitoring for cost-reduction and improved communications/graphics capabilities of computing systems, as noted in Section IV(A) above) would have suggested combining the teachings of Groner with the Goodman and Shabot references at the time of the invention of the '605 Patent.

In addition to the existing motivations in the field and in the Goodman and Shabot references, the group overview chart of Groner represents a further example chart for quickly depicting conditions of individuals and associated test values. Such a chart could be used in the systems of Goodman and Shabot to gain efficiencies and better manage a patient group's health conditions, or to lend additional precision to the graphical output, because Groner's graph is a precise representation of the actual value of the data. Stone Decl., ¶96-99. Such additional precision would be useful to a physician utilizing such a system to readily identify patients, and its integration would be straightforward. Stone Decl., ¶101. This additional feature would consequently be an obvious step from the teachings of Goodman or Shabot. Stone Decl., ¶¶100-102.

D. Ground 7 – Each of Claims 1 and 3-9 is Obvious over Crawford, Goodman, Shabot, and Tallman.

The combination of Goodman, Shabot, Crawford and Tallman teaches all elements of claims 1 and 3-9 of the '605 Patent. The comparison of this art with the claims of the '605 Patent is shown in more detail in the claim charts below.

For analogous reasons to those set forth in Section IV(A) above relating to Goodman, Shabot, and Crawford, it would be advantageous to incorporate the teachings of Tallman, which relates to efficient treatment of multiple patients. In particular, efficiencies would be gained by (1) increased remote communication between patients and caregivers, and (2) incorporating new display and communications technologies to enhance the remote monitoring capabilities available. These features are exactly of the type suggested by Tallman.

In particular, Tallman teaches transmitting healthcare messages back to the patient. Tallman, col. 34:34-54; FIGs 24, 67, 75-76. It would have been obviously beneficial to allow the Goodman system, as modified by the teachings of Shabot and Crawford, to send messages to remote patients via the additional methods taught by Tallman. Stone Decl.,¶¶106. Such messaging would allow patients to better manage their conditions. Stone Decl., ¶¶107.

Tallman also specifically teaches transmitting a communication (e.g., automatically initiating a call) to the selected patient, wherein said communication is transmitted to the selected patient via a telephone. Stone Decl., ¶¶110-111; Tallman, col. 34:34-54; FIGs. 24, 67, 75-76 (FIG. 24 showing system generated message to patient). In Tallman, the system prepares a narrative for the nurse to read to the patient over the phone related to the patient's condition. Tallman, FIG. 24.

As such, it would be obvious to one of ordinary skill in the art to deliver the messages of Tallman as automated telephone messages, since such a modification was known at the time of the '605 invention as a way to deliver a selected message. '605 Patent, col. 9:21-23 ("The programming of an automated call processing application to generate customized messages in this manner is well known in the art."). This would improve efficiency in healthcare by automating rote, non-healthcare tasks, and allow nurses to focus on nursing tasks. Stone Decl., ¶111.

In view of the phone call and pre-selected messages to be conveyed to a patient in Goodman and Tallman, it would be obvious to one of ordinary skill in the art for a system to send an automated telephone message with this same narrative message to the patient. Stone Decl., ¶¶34-35, 110-112. In addition, it would have been obvious for the system to send an electronic mail message with the narrative as prepared by the system, as such messages were well known alternative communication means at the time of the invention. Stone Decl. ¶¶34-35, 110-112. Furthermore, the '605 Patent itself recognizes that automated messaging systems were well-known in the art. *See* '605 Patent, col. 9:21-23.

Accordingly, one of ordinary skill in the art would have been motivated to combine the references to provide a group overview chart to allow for efficient management of multiple patients (Crawford, Shabot), using a processor

to evaluate stored health history to include a broader range of critical alerts (Shabot), and communicating with a patient via telephone or e-mail to reduce delay and errors (Goodman in view of Tallman and Shabot). Stone Decl., ¶112.

Finally, in view of similar claims and much common disclosure with the '605 Patent including phone and electronic mail messaging, the Board decided in IPR2013-00449 that Goodman would be combined with Crawford and Tallman to teach the limitations of the related '420 Patent. Ex. 1009 at p. 22. Shabot provides only more motivation to combine these references, as above.

E. Grounds 2, 4, 6 and 8 – Claim 2 is Obvious in further View of Vincent.

The combination of Grounds 1, 3, 5, and 7, in further view of Vincent, teaches all elements of claim 2 of the '605 Patent. The comparison of this art with the claims of the '605 Patent is shown in more detail in the claim charts below.

Vincent provides explicit discussion of calculating patient compliance based on time of data receipt and number of responses compared with an expected value, and teaches that calculating compliance and basing patient reminders on such compliance has a dramatic, positive impact on patient action. Vincent at 656-58. Accordingly, Vincent teaches the desirability of compliance calculations in health scenarios, and in particular for remote, computerized health systems. Thus, based on Vincent, one of ordinary skill in the art would

understand that another way to improve the systems of Crawford, Tallman, Goodman and Shabot (each of which suggest the desirability of greater efficiency in health care) would be to incorporate the teachings of Vincent to determine how many patients were complying with the supervisory messages and adjust those messages accordingly. Stone Decl., ¶¶74-79; 93-95; 114-116. Moreover, the combination would yield expected results. *Id*.

U.S. Pat. No. 7,769,605	**Proposed Grounds of Challenge**
1. A system for monitoring a plurality of patients regarding a health condition, comprising:	***Grounds 1-8:*** Goodman teaches monitoring one or more patients regarding a health condition. Goodman, col. 1:1-12 ("The invention relates to a system, methods and apparatus for monitoring a person's health, and more particularly to a comprehensive patient management system."); col. 4:8-12 ("For purposes of clarity only one patient node 2, and third party facility 3, and one health care provider 4 are illustrated in FIG. 1. However, it should be understood that there may be a plurality of patient nodes 2 and a plurality of health care providers 4 in communication with the third party facility 3.") (emphasis added). ***Grounds 1-8:*** Shabot teaches a system for monitoring a plurality of patients regarding a health condition. "The clinical information system monitors the patients and runs the alerting algorithms that make the decision to page. It consists of a commercially available computer network, namely, a CareVue 9000 System, available from the Hewlett-Packard Company. This system has a number of autonomous, but networked, computer workstations that execute software and supervise patient data for a large number of patients." Shabot, col. 5:42-49. ***Grounds 3-4, 7-8:*** Crawford teaches monitoring one or more patients regarding a health condition. "A medical monitoring system in which a plurality of vital signs monitors for a plurality of patients provide data on a continuing basis to a central server which in turn provides supervisory screen display that indicates

	the normal status or varying levels of alarm status of individual patients." (Crawford, Abstract.) "This invention relates to, in general, a supervisory system that monitors the vital signs of patients at home or in a health-care facility." (Crawford, col. 1:6-8.) "This invention gathers data on patient vital signs using portable bedside medical monitors. As the data is collected, it is sent to a central computer." (Crawford, col. 2:31-33.)(emphasis added)) ***Grounds 7-8:*** Tallman is directed to patient assessment of "health needs." Tallman, Abstract. Tallman states that "[t]he patient assessment component consists of a set of information tools which are used by health care professionals to assess patient conditions and assist in the selection of health care services and to help patients find appropriate care at the appropriate time." *Id*.
a reception unit for receiving a corresponding set of measurements regarding said health condition from each patient included in the plurality of patients;	***Grounds 1-8:*** Goodman teaches receiving corresponding sets of measurements regarding said health conditions from each patient included in the plurality of patients. Goodman, col. 2:52-67 ("The host computer, which is operated by a party other than the patient or health care provider, functions as a central station for collecting, analyzing and routing data…The patient is prompted by the message device to measure and enter relevant physiological data, e.g., peak flow, etc, as dictated by the treatment plan…These results can be transmitted to the facility and the health care provider.") Goodman specifically teaches that the health information is sent to the host computer 30 via modem. Goodman, col. 6:50-52; Goodman, col. 3:60-64 ("Each patient node 2 includes a data processor 10 and a message device 20. The data processor 10 is in communication with host computer 30 via communication line 31 and is used for downloading information to, and receiving information from, message device 20."); Goodman, col. 7:35-45 ("Accordingly, through the use of a custom interface to translate a signal of the medical device 70 corresponding to the measured parameter into a signal form acceptable to processor 10, the data obtained from basic medical devices 70, such as blood pressure, pulse, blood glucose meters, pulmonary function, cholesterol, etc., can be stored whenever the data is obtained, and then uploaded to the host computer 30 through the data processor 10 and/or message

	device 20. The design of such interfaces and the incorporation of such interfaces into devices 70 are straightforward and within the capabilities of those skilled in the art."); Goodman, col. 7:45-49 ("The host computer 30 receives data from the various information sources previously discussed, such as the message device 20, PHN compatible medical devices 70, the primary provider 4, and other health care facilities 5."). While Goodman refers to a single patient, it explicitly teaches using the system for a plurality of patients. Goodman, col. 4:8-12; col. 7:45-49. ***Grounds 1-8:*** Shabot teaches a server workstation 69 that includes a reception unit (i.e., for connection to local area networks 67, 75, as in FIG. 3) for receiving corresponding set of measurements regarding said health condition from each patient included in the plurality of patients. In Shabot, the reception unit is included in the server workstation 69, shown in FIG. 3. The server workstation receives a corresponding set of measurements regarding health conditions of patients. Shabot provides "[o]ne or more workstations also serves as a 'server' workstation, and can interface through a second network with a number of other computer systems and databases. Each workstation display received both continuous data inputs for certain patient statistics, e.g., pulse . . . ." Shabot, col. 5:49-61. "In particular, the server workstation provides an interface between the clinical information system and the other computer systems. Each time new data for a patient is reported to the clinical information system by an external computer (e.g., a blood gas computer or a clinical lab computer), that data is then distributed by the server workstation to the particular workstation corresponding to the patient. The data is then incorporated into the patient's chart. The server workstation also interfaces the clinical information system with an archives database (e.g., a computer mass storage device), so that patient data can be periodically stored in and retrieved from patient files maintained in the archives database." Shabot, col. 6:16-28. The patient data are collected from patients through workstations 59 and sent to and received by workstation 69. As shown in Fig. 3 below, data that is stored in the database is received to the workstation server 69, which interfaces with the data archives

	77. Shabot, Fig. 3, col. 12:30-35. ***Grounds 3-4, 7-8:*** Crawford teaches a reception unit (Adapter I/O Interface 15) for receiving corresponding sets of measurements regarding said health conditions from each patient included in the plurality of patients. Crawford, col. 3:32-34 ("As shown in FIG. 1, a plurality of vital sign monitors 12 are coupled through converters 14 to a central server 16."); Crawford, col. 4:11-16 ("The output of [the vital signs monitor] converter 14 is transmitted in digital form over a two wire data grade telephone cable to an RS485 adapter at the input of the central server 16. In a preferred embodiment, a card is employed which has sixteen RS485 adapters on it as an input/output interface 15 to the CPU 12.") In Crawford, the reception unit is the "Adaptor I/O Interface 15" of Figure 1.
a processing unit in communication with said reception unit for processing said corresponding set of measurements and identifying at least one patient included in the plurality of patients based upon said processing of said corresponding set of measurements;	***Grounds 1-8:*** Shabot discloses a processing unit (server workstation 69, which includes a processing unit). "The present invention provides a critical event notification system that . . . permits review of a patient's diagnostic information, lab results, chart, or other data, automatically, by computer or similar equipment." Shabot, col. 2:27-31 (emphasis added). Shabot discloses processing said corresponding set of measurement and identifying at least one patient included in the plurality of patients based upon said processing of said corresponding set of measurements. "When the server workstation detects a critical event for a particular patient, either via a critical event flag (e.g., abnormal measurement data) or via the existence an exception condition (periodic patient file analysis), it automatically and immediately pages the responsible physician or physicians. To do this, the server workstation formulates an alphanumeric message that (1) ***identifies the patient and preliminary diagnosis*** (the medical ailment of the patient), (2) the particular critical event that has occurred and other critical alphanumeric information related to that critical event, and (3) provides the physician with the name of the responsible nurse at the hospital and a telephone number by which the physician can contact the nurse." Shabot, col. 6:60 – col. 7:5.

	The alerting algorithms review the data to determine if a "critical event flag" has been placed in the data by the hospital lab. Shabot, col. 6:29-36. The server workstation also employs algorithms that periodically import selected data from patient files or particular workstations . . . in order to perform more complex analysis, e.g., the detection of 'exception conditions.'" Shabot, col. 6:36-40. ***Grounds 3-4, 7-8:*** Crawford teaches a processing unit (central server 16) in communication with said reception unit (adapter I/O interface 15) for processing said corresponding set of measurement and identifying at least one patient included in the plurality of patients based upon said processing of said corresponding set of measurements. Crawford teaches that the server 16 receives and processes information for a plurality of patients, identifying those patients by room number and name. Specifically, Crawford teaches a system for comparing measurements to preset values to determine if a patient is in an emergency state. Crawford, col. 2:34-39 ("Using the computer, users can examine the current or past vital signs of any patient simply by selecting the patient's room from a geographic facility map displayed on a computer screen (CRT). The system will also alert users when the monitored signs of any supervised patient go above or below preset limits."); Crawford, col. 2:67-3:2 ("The system's abilities to display and graph all past readings (taken 24 hours a day) makes the analysis of vital signs and medical trends much more effective and accurate.") As shown above, Crawford teaches that the processing unit is in communication with the vital signs monitor via a reception means. Crawford, col. 3:32-34; 4:11-16; Crawford, FIG. 1 (showing Adaptor I/O Interface 15" in communication with "CPU 17").
a database, the database being in communication with said processing unit, the database being	***Grounds 1-8:*** Goodman teaches the use of a database connected to the host computer 30 that stores medical health history information for each of a plurality of patients. Goodman, col. 7:60-65 ("Though appropriate software, the host computer 30 provides a variety of other network-related functions including communications, network management, database manager, error/reliability manager and message/mail manager."); Goodman, col. 11:59-62 ("It is contemplated however, that the

configured for storing medical health history information for each patient included in the plurality of patients,	prescription information is at some point provided to host computer 30 and to the filling facility 90 for electronic storage in respective databases.") Goodman, col. 13:42-46 ("Based upon the subject's reported clinical status, the primary provider may, for example, alter the patient's treatment regime. These changes are transmitted to the third party, where the patient's database is updated."). ***Grounds 1-8:*** Shabot discloses a database (data archives 77) wherein the database is in communication with the processing unit (see, e.g., Fig. 3). "Each time new data for a patient is reported to the clinical information system by an external computer (e.g., a blood gas computer or a clinical lab computer), that data is then distributed by the server workstation to the particular workstation corresponding to the patient. The data is then incorporated into the patient's chart. The server workstation also interfaces the clinical information system with an archives database (e.g., a computer mass storage device), so that patient data can be periodically stored in and retrieved from patient files maintained in the archives database." Shabot, col. 6:18-28. "As indicated by the block 43 of FIG. 2, the particular workstation dedicated to each patient displays both the just-mentioned samples of the continuous data, and also new lab data sent to it from the server workstation, as part of the patients' files. These files are periodically stored in a mass storage device, which act as a data archives." Shabot, col. 10:40-45. ***Grounds 3-4, 7-8:*** Crawford teaches a system with a database ("data storage 20") wherein the database being in communication with said processing unit (See FIG. 1, above, communicatively connected to CPU 17). The database of Crawford is configured for storing medical health history information for each patient included in the plurality of patients. Crawford, col. 2:57-59 ("Patient data is stored at regular intervals, allowing future retrieval of readings, and detailed medical trend analysis."); Crawford, col. 3:45-57 ("A data storage 20 is employed to store data so that it can be retrieved and reviewed for analysis that is deemed appropriate."); Crawford, col. 3:57-60 ("It is more efficient for there to be a single data storage 20 which stores all the information in the system.") Crawford also teaches storing medical alerts based on history in a database. Crawford, col.

	9:49-59 ("D. Add data storage logic for data and alarms: 1. Signs database shall contain patient name, room number (221a for first bed in room 221, 221b for second bed, etc.), date, time, and all sign values. 2. Signs will be stored to disk every fifteen minutes. 3. Alarms (Notification States 1-3) database shall contain room number, nature of alarm (warning, critical, off-line), date, time, and all sign values. 4. Alarms will be stored in the alarms database as they occur.")
wherein processing of said corresponding set of measurements by the processing unit includes evaluating said corresponding set of measurements against said stored medical health history information;	***Grounds 1-8:*** Shabot teaches a system wherein processing of said corresponding set of measurements by the processing unit includes evaluating said corresponding set of measurements against said stored medical health history information. "Periodically, alerting algorithms are employed by the workstation to determine the existence of an "exception" condition, an operation indicated by the parallelogram 51. The term "exception condition" refers to complex conditions that can be ascertained by a review of different data, representing the same or different parameters. As examples, one exception condition used in connection with a patient on a ventilator is whether the patient has required levels of oxygen ventilation of greater than 60% oxygen composition for over four hours duration. This type of condition cannot in the preferred embodiment be determined from just instantaneous data provided from directly from the ventilator, and so, patient files are periodically reviewed to look at several, time-spanned data entries representing oxygen composition. In fact, as mentioned, review of this data is triggered anytime new data is received. For example, if continuous data provided from the ventilator to the particular workstation has been sampled once each hour, then as each new data is received, the four most-recent ventilator data samples may be examined each hour to determine whether the exception conditions have been met (in the preferred embodiment, ventilator data is updated as often as once per minute)." Shabot, col. 10:46-67. "[T]he server workstation also employs algorithms that periodically import selected data from patient files or particular workstations, as a logical unit of work, in order to perform more complex analysis, e.g., the detection of "exception conditions." For example, one exception condition is the state of a ventilator

	patient requiring a sixty percent or greater oxygen level for more than four hours. This type of analysis cannot be performed upon instantaneous measurements, such as upon only one data measurement obtained from hospital lab and distributed by the server workstation, and so, the analysis is performed on a periodic basis." Shabot, col. 6:36-47. "When the server workstation detects a critical event for a particular patient, either via a critical event flag (e.g., abnormal measurement data) or via the existence an exception condition (periodic patient file analysis), it automatically and immediately pages the responsible physician or physicians." Shabot, col. 6:60-65. "Critical event detection can also be accomplished by programming the server workstation with alerting algorithms that look at the numerical value of each parameter to compare it to an associated number, instead of comparing the quantities in the "HL7" format with the alphanumeric quantity In this latter example, there would be no need for the lab assistant to insert a critical event tag into the "HL7" format message, but the critical event would be directly determined using numerical data within the "HL7" format message. In fact, automated review of this nature is implemented for determination of some exception conditions, e.g., some exception condition review is automatically triggered upon arrival of certain new data, such as from a ventilator. It is well within the skill of one familiar with computer systems to construct an alerting algorithm of this type…Irrespective of the manner in which a critical event is determined to exist, the clinical information system both stores the periodic information in the patient's file, and also proceeds to formulate a pager message," Shabot, col. 9:50-67; 10:1-2; See "Critical Event Parameters" in Tables 2-3. Table 4 of Shabot lists exception conditions, such as "urine output < 0.3 cc/kg/hr and patient not admitted in renal failure . . . systolic blood pressure < 80 mm Hg and patient has no pulmonary artery catheter Systolic blood pressure < 80 mm Hg and pulmonary artery wedge pressure < 10 mm Hg." Shabot, col. 11:11-17 (emphasis in original).
a transfer unit	***Grounds 1-8:*** Goodman teaches that the host computer sends

in communication with said processing unit, wherein said transfer unit communicates with said at least one identified patient, said transfer unit being configured for transmitting a message for communicating with said at least one identified patient, the message being based upon said medical health history information and said processing of said corresponding set of measurements, the message being one of: a telephone message and an electronic mail message; and	messages to the patient based on health history and processing via pager or modem. Specifically, Goodman uses a wireless device to communicate between the host computer and the patient with messages based upon medical health history information. Goodman, col. 5:64-6:15 ("FIG. 4a shows a further embodiment of the PHN 1 wherein the host computer 30 is in communication with a wireless carrier 60 to provide medication reminders and messaging capabilities for patients who own/lease paging devices 61. Wireless carrier 60 thus receives instructions form host computer 30 to deliver particular messages to specific patients 2 at predetermined times. Wireless carrier 60 then "telephones" the patient's pager 61 in a conventional manner, or under control of an automatic operator and delivers the message, activating the pager 61 alarm mechanism. The patient 2 then responds to the pager alarm by pressing the switch. For paging devices 61 having 2-way communication, pressing the switch can provide an acknowledgement of the message delivered, which can be recorded by the wireless carrier 61 as compliance information, which information is then communicated to the host computer 30. Thus, the wireless carrier 60 functions as the data processor 10 and the paging device 61 performs the messaging functions of the message device 20."); Goodman, col. 3:60-64. Goodman also teaches that information could be communicated to a patient via electronic mail or telephone messages and discloses that the host computer would incorporate a message/mail server. Goodman, col. 7:66-8:5 ("[i]n place of the host computer 30, one or more employees/representatives of the third party 3 may collect information, generate and maintain a record of information pertaining to a patient's health and transmit information either directly or indirectly to the patient 2, health care provider 4, or other location via telephone, facsimile transmission, electronic mail, or other communication means."); Goodman, col. 7:60-65. ***Grounds 1-8:*** Shabot discloses a transfer unit in communication with the processing unit, wherein the transfer unit (the "Starlink" paging network) communicates with a nurse associated with a patient. The transfer unit (the "Starlink" paging network) is configured for transmitting a message for communicating with the nurse associated with a patient, where the message is based

	upon the medical health history information and the processing of the corresponding set of measurements. The message is a telephone message. "It is presently contemplated that this system will also provide for two-way communication, such that using the keyboard 33 of the 'Palmtop' device 27, the physician can issue orders which are then transmitted in the reverse direction, e.g., to a paging or cellular radio network, via modem, page or radio link to the clinical information system, and to the pertinent workstation where the orders can be displayed to the nurse responsible for the patient." Shabot, col. 7:57-64. "Irrespective of the manner in which a critical event is determined to exist, the clinical information system both stores the periodic information in the patient's file, and also proceeds to formulate a pager message," Shabot, col. 9:66 -10:2. "Once a critical event is detected, software run by the server workstation is used to compile an alphanumeric pager message (as indicated by the parallelogram 45) and obtain a PIN for each physician to whom the message is to be sent. Once the message is formulated, it along with each physician PIN is sent to the "Starlink" paging network via modem, which causes the physician(s) to be paged and the alphanumeric message to be transmitted to them." Shabot, col. 11:28-36. "That is to say, a decision to page an individual (a physician in the case of the preferred embodiment) is made automatically by the system, and does not require a direct human decision. As can be seen therefore, the present invention permits reduction in the number of pages by controlling paging directly in response to automatically detected critical events." Shabot, col. 2:33-36. ***For Grounds 7-8:*** Tallman teaches transmitting a communication (e.g., initiating a call to patient) to the selected patient, wherein said communication is transmitted to the selected patient via a telephone message. See e.g., Tallman, Fig. 6 (showing options for a nurse to begin a phone call with patient); Abstract; Fig. 24 (showing transmitting a message to a patient via textual interaction); Fig. 67, Figs. 75-76, associated description.

	More specifically, Tallman states the following steps relating to a callback: "Select the appropriate callback item from the Worklist window. Click the Perform button to open the Perform Callback Window. Read the information presented in the Call Summary window. Display and read the Patient Chart and Self Care Instructions windows. Dial the Call Phone number shown in the Perform Callback window. If you reach the caller, make the appropriate inquiries regarding their condition, then type a description of the callback in the Resolution text box and mark the Call Result successful by clicking the Success radio button." Tallman, col. 34:34-54. As shown in Figure 24, for example, the system of Tallman prepares a narrative (i.e., the communication to the patient) for the nurse to read to the patient over the phone related to the patient's health condition. (See e.g., Fig. 24 ("Message to Patient.").) See also, Tallman, Figs. 4A-4E (showing question flows presented to a patient relating to adult back pain); Fig. 76 ("Your answers to our questions indicate that it is highly unlikely that you have a condition that would benefit from an appointment with a physician.").
a display unit in communication with said processing unit, the display unit being configured for displaying a group overview chart, said group overview chart being generated by the processing unit based upon said processing and being	***Grounds 1-8:*** Shabot discloses a display unit for displaying a chart for at least one patient. The chart is generated by the processing unit based on the processing. "The present invention provides a critical event notification system that . . . permits review of a patient's diagnostic information, lab results, chart, or other data, automatically, by computer or similar equipment." Shabot, col. 2:27-31. The Background of Shabot discloses workstations that enable the display of various types of data side-by-side for review and to periodically store the data as an electronic "chart" or as part of the patient record. Shabot, col. 1:16-22. Additionally, Shabot discloses a workstation display screen that shows a patient's chart. Shabot, col. 6:1-7; 10:40-44. Shabot discloses that its system is for monitoring a plurality of patients. Additionally, the HP CareVue 9000, disclosed by Shabot, is configured to monitor a large number of patients."The clinical information system monitors the

provided to said display unit, said group overview chart including a plurality of data points, wherein each of the data points represents one corresponding patient included in the plurality of patients and indicates at least one control value for the one corresponding patient, the control value being indicative of the one corresponding patient's control over said health condition, the control value being based upon said corresponding set of measurements, each data point including an icon.	patients and runs the alerting algorithms that make the decision to page." Shabot, col. 5:42-43. Shabot discloses analyzing data for critical events, such as values above or below a predetermined level. "In this example, the measurement parameter would be calcium level, and there could be many such parameters carried by the data, for example, phosphorus, oxygen, urea, nitrogen and/or magnesium levels. Each of these can be analyzed with respect to a critical event, e.g., when concentration of one of these elements falls above or below a predetermined level or between a range of values." Shabot, col. 3:4-11. "When the server workstation detects a critical event for a particular patient, either via a critical event flag (e.g., abnormal measurement data) or via the existence an exception condition (periodic patient file analysis), it automatically and immediately pages the responsible physician or physicians." Shabot, col. 6:60-65. The Shabot book discloses the server workstation as an Apache III system that measures patient's vital signs, blood chemistry data, hemogram data and urine output data and compares it with a database from a large study to evaluate the patient's status. Shabot book, p. 245, Table 16.3. The display disclosed in that book includes information such as diagnosis and component scores for admission and chronic health issues, which constitutes medical health history information. Shabot Book, at pp. 251-252 (Fig. 16.1). The display chart provides the APACHE III risk of ICU and hospital death for all patients in a six bed ICU. Shabot Book at 251. The data points on the charts disclosed in the Shabot Book indicate a control value for each patient that represents, among other things, the risk of death, risk of active treatment, and probability of discharge alive for each patient. Shabot Book, at 251-52. Additional charts in the Shabot book display comparative data points on a single screen to compare two patients. Shabot Book, at 251-52. The data includes component scores for admission, acute physiology, and chronic health, with mortality trends presented graphically. Each of the data points on the graphical chart is represented by an icon (triangle and circle provided) and

	indicates the patient's risk of mortality. Shabot Book at 251-52. The charts in the Apache III system are "designed to provide real-time clinical information . . . to support the effective treatment and management of critically ill medical and surgical patients." Shabot Book, at 247. Each of the six patients represented is identified by a data point that is represented by a color coded icon that is coded by risk of death range. *Id.* The graphical display in the chart represents beds in an ICU with color codes based on the patient's measurements compared to historical data, including the patient's past medical health history. Shabot Book, at 251, Figure 16.1(A-C). For example, Figures 16.1(A) and 16.1(B) include legend that displays color codes (displayed as icons as further discussed below) for "No Chronic Health", "Significant APS Change," and "New Data Available", each of which shows an evaluation of past medical health history with current or corresponding set of measurements. Shabot Book, Figs. 16.1(A), (B); p. 259. Further, the system is interfaced with clinical laboratory information systems; patient monitoring systems, and the hospital's admission, discharge, and transfer system. Shabot Book, at 249. Additionally, the clinical decision support module provides risk predictions for individual patients and displays detailed information and trends on selected patients. Shabot Book, at 248. As another example, Figure 16.1(C) teaches charting the patient's medical health history over time (day 1, 2, 3, 4, 5, today on the x axis of the chart). The display disclosed in that book includes information such as diagnosis and component scores for admission and chronic health issues, which constitutes medical health history information. Shabot Book, at pp. 251-252 (Fig. 16.1). The group overview chart in the Shabot Book includes a plurality of data points in at least two forms. First, the charts in Figure 16.1(A) and 16.1(B) discloses six data points. Shabot Book, at 251-52. Each of the data points represents one corresponding patient. *Id.* The chart in Figure 16.1(C) represents two patients in a side-by-side graphs. Shabot Book, at 252. The graphs include data points that represent that corresponding patient. *Id.* The data points on the charts listed in the Shabot Book indicate a control value for each patient that represents, among other

	things, the risk of death, risk of active treatment, and probability of discharge alive for each patient. Shabot Book, at 251-52. The information in the charts indicates a patient's control over a health condition (e.g., by color) based on the corresponding set of measurements. "Patients at high risk of death will be indicated in red, those at intermediate risk in yellow and those at low risk in green." Shabot Book, at 251. The Shabot Book discloses a chart that provides further insight into the clinical details for two patients. Shabot Book, at 251-52. As shown above, the chart displays comparative data points on a single screen to compare two patients. Shabot Book, at 251-52. The data includes component scores for admission and current acute physiology as well as chronic health. *Id.* Mortality risk trends are presented graphically. *Id.* The Shabot Book discloses that mortality is influenced by variables, including the degree of physiologic deviation from normal and chronic health conditions. Shabot Book, at 243. Additional data related to mortality is set forth in Table 16.3. Shabot Book, at 244-45; Table 16.3. The Shabot Book discloses three group overview charts. Figures 16.1(A) and 16.1(B) disclose that "[p]atients are represented by a stylized bed symbol." Shabot Book, at 250. As discussed above, one of ordinary skill in the art at the time of the invention of the '605 patent would have defined "icon" as "a graphical representation of an underlying function or data." Based on that construction, the "stylized bed symbol constitutes an icon because it is a graphical representation of an underlying data." Further, the data points disclosed in Figure 16.1 (C) also include an icon. Each of the data points on the graphical chart is represented by an icon (triangle and circle provided) and indicates the patient's risk of mortality. Shabot Book, at 251-52. ***Grounds 3-4, 7-8:*** Crawford teaches generating and displaying a chart (Fig. 3) via a display (e.g., screen display 18), said chart having a plurality of data points / icons (e.g., plurality of selectable patient rooms shown on chart). Crawford, col. 5:38-51. In Crawford, each of said data points, or room icons, represents one corresponding patient and indicates at least one value for the one corresponding patient (e.g., each patient room indicates whether patient is at a warning situation or not based on monitored values for that patient). Crawford, Fig. 3; col. 5:38-51.

	The at least one underlying value indicative of a warning is based upon a corresponding set of measurements related to a health condition. *Id*. ("As shown in FIG. 3, showing, Room 221, shown at reference number 52, has a critical blood pressure out of limits situation which occurred at 16:30 hours. Similarly, Room 228, shown as reference number 53, has a warning out of limits situation (less serious than critical) with respect to the patient's respiration and that occurred at 13:22 hours. Room 208, shown at reference number 54, has a warning out of limits respiration problem that occurred at 15:43 hours. On the same FIG. 3 screen, the Critical Emergency window 6 provides somewhat more detailed information concerning the critical situation in Room 221 and in particular shows that the blood pressure problem is that diastolic pressure is at 260."); see also Crawford, col. 6:64-7:2 ("Thus the overview screen of FIGS. 2 and 3 provides a real time indication that there is an emergency, where it is occurring, how severe the emergency is (that is, whether it is at a warning level or a critical level) and which type of vital sign function is out of line. The overview screen also provides a geographic presentation of where the emergency is.") Crawford teaches a display ("screen display 18") in communication with the processing unit and useable to display the chart of Fig. 3. Crawford, col. 3:38-43. ("At the central server 16, a screen display 18 is provided and is a critical part of the system of this invention. The screen display is what provides the appropriate selected information to facilitate response to various out of normal range conditions.") Each data point (e.g., patient) is represented by an icon (e.g., room icon). For example, Crawford states, "[i]n addition the iconography of the display provides a particularly useful presentation of information to those who must monitor the situation leading to a more immediate recognition of where a warning situation exists, what the nature of it is likely to be and what individuals are involved." Crawford, col. 8:11-16, Fig. 3. "[W]e interpret 'chart' to mean information arranged in the form of one or more tables, graphs, or diagrams. Petitioner has shown sufficiently that Crawford's overview display is a "chart" having data points, each representing one patient and indicating a value for the patient (e.g., a warning situation) based on measurements

	for the patient, with each data point having an icon (image of a room), as recited in claim 1." *Decision instituting trial*, IPR2013-00449, p. 17. ***Grounds 5-6:*** Groner teaches generating and displaying a chart (Fig. III-8) via a display, said chart having a plurality of data points (e.g., scatter plot with various data points), wherein each of said data points represents one corresponding patient (e.g., each point represents a diabetes patient). In particular, Groner states that Fig. III-8 is "[a] scatter plot of age vs. duration of diabetes." Thus, each data point on the scatter plot represents a patient with diabetes. Groner, p. 49. As shown above, each data point indicates at least one value for the one corresponding patient, each data point including a symbol (circular dot), the at least one value being based upon a corresponding set of measurements related to a health condition (e.g., age and duration of diabetes per patient). This element is also taught at Fig. III-10, which is a chart illustrating "all of the hourly *glucose* (control glucose) values for each of the first 20 patients." Groner, p. 50. Groner teaches the system user how to create such charts and how to plot them on graphs like those shown in Fig. III-8, above. *See* Groner, pp. 47-57.
2. The system of claim 1, wherein said processing unit determines compliance based upon a time of receipt of said set of corresponding set of measurements and a number of corresponding sets of measurements compared with	***For Grounds 2, 4, 6, and 8:*** Vincent teaches a computer system that determines compliance based on receipt (or lack of receipt) of health measurements and by comparing the number of measurements received to a prescribed number. Vincent, p. 656 ("Data from the visit worksheets and initial questionnaires are entered into the program's database by clerical staff. The clerk also prints the daily worksheets, monthly patient reminder letters, and periodic physician performance reports. Patients with HMR's that are due are mailed up to two reminder letters. If after one month the HMR is not performed, the patient is recorded by the system as a 'non-responder' for that HMR."); *See also* Vincent, p. 656 ("In June of 1993 we implemented a computer-assisted reminder system in the outpatient clinic of an 18 resident family practice training program."); Vincent, p. 657 TABLE 1 (showing "Physician and Patient Compliance at Beginning and End of Study Period" based on response rates to Health Maintenance Recommendations).

a prescribed number.	
3. The system of claim 1, further comprising a device in communication with said reception unit.	***Grounds 1-8:*** Goodman teaches the use of a "data processor" to act as a transfer device for communicating with the reception unit within the host computer. Goodman col. 3:60-64; col. 6:50-52. Through the data processor 10, the reception unit is in communication with remote monitoring devices that gather health testing. Goodman, col. 7:22-28 ("In a preferred embodiment as shown in FIG. 5, the data processor 10 is adapted to accept information input 71 from a medical device 70 that is network compatible. Tracking patient response to medical treatments outside of a health care setting (hospital, hospital, doctor office, clinic) require patients to monitor their blood pressure, blood sugar, pulse rate and other important physiological parameters.") ***Grounds 1-8:*** Shabot teaches a device (ventilators 81, urimeters 83, Merlin Monitors 85) in communication with the reception unit. See Fig. 4. "The patients 79 are monitored by three different devices, including ventilators 81, urimeters 83 and Merlin monitors 85." Shabot, col. 12:39-41; *see also* 4:31-35. The devices are in communication with the server workstation of Shabot via digital interfaces and networks coupled to the server workstation. Shabot, col. 12:46-53. ***Grounds 3-4, 7-8:*** Crawford teaches a remote vital signs monitor 12 in communication with the reception unit. Crawford, col. 3:32-34; col. 4:11-16. In Crawford, the reception unit is the "Adaptor I/O Interface 15" in communication with the "Vital Signs Monitor 12" via the "Converter 14" of Figure 1.
4. The system of claim 3, wherein said device is one of a remote monitoring system or an electronic logbook.	***Grounds 1-8:*** Goodman teaches the use of a "data processor" to act as a transfer device for communicating with the reception unit within the host computer. Goodman col. 3:60-64; col. 6:50-52. Through the data processor 10, the reception unit is in communication with remote monitoring devices that gather health testing. Goodman, col. 7:22-28. ***Grounds 1-8:*** Shabot discloses that the measurement data are sent over a network, which means the device is one of a remote monitoring system. "Since the format of this data and its

	transmission does not necessarily match the format accepted by the CareVue 9000 system, a digital interface 87 is constructed to adapt the transmission of information from the ventilators 81 to a uniform format that is placed upon a third network 93 that is coupled to the server workstation 69. Likewise, data from urimeters 83 must also pass through an interface 89 to place information on the network." Shabot, col. 12:46-53. ***Grounds 3-4, 7-8:*** Crawford teaches a remote vital signs monitor 12 in communication with the reception unit. Crawford, col. 3:32-34; 4:11-16. In Crawford, the reception unit is the "Adaptor I/O Interface 15" in communication with the "Vital Signs Monitor 12" via the "Converter 14" of Figure 1.
5. The system of claim 4, further comprising a response device in communication with said transfer unit.	***Grounds 1-8:*** Goodman teaches the data processor 10 both sends information to and receives messages from the host computer, either through the messaging device, or directly on the data processor. Goodman, col. 5:29-41 ("In a further embodiment, the message device 20 can be enhanced to incorporate two-way message capability when coupled to data processor 10. For example, by adding one or more switches 24 (two are shown in FIG. 2), patients can respond to query-type messages, enhancing the ability of providers 4 to track the status of their patients 12. The electronics required to provide the two-way message capability over wire-based coupling and radio frequency based coupling are well known to those skilled in the art. Advantageously, providing the switches 24 on message device 20 ensures that the stored data can be uploaded to the host computer. Alternatively, the switches 24 could be located on processor 10."); Goodman, col. 5:57-63 ("In a further embodiment of data processor 10, a patient-owned computer such as a personal computer (or workstation) or personal digital assistant could be used in place of a dedicated data processor, provided that the host computer 30 is provided access to the personal computer and can establish communications therewith in a similar manner as the data processor 10 described herein."); Goodman, col. 10:43-56 ("In this context, the message device 20 is preferably a personal digital assistant. Use of a personal digital assistant having suitable programming capabilities facilitates portability. Further, with appropriate ancillary equipment, a communication link can be established with the primary provider

	4 so that results can be sent to the provider via facsimile or e-mail. In a further preferred embodiment, the message device 20 is configured by means known to those skilled in the art such that the algorithm can be programmed into the message device 20 at the third party facility 3 or remotely via the various communication links previously described in this specification. If the message device 20 is remotely programmable, the primary provider 4 or the third party facility 3 can conveniently modify the treatment algorithm as appropriate.").
6. The system of claim 5, wherein said response device is at least one of a personal computer, a network terminal, a television, a personal digital assistant, or a video game system.	***Grounds 1-8:*** Goodman teaches the data processor 10 may be a personal computer and that the message device for sending and receiving messages should be a personal digital assistant. Goodman, col. 5:57-63; 10:43-56.
7. The system as claimed in claim 1, wherein said reception unit is a modem.	***Grounds 1-8:*** Goodman teaches that the health information is sent to the host computer 30 via modem. Goodman, col. 6:50-52. As explained above, it is inherent that the receiving device at the host computer is also a modem. ***Grounds 1-8:*** Shabot discloses a modem ("the internal modem 23 which is used to report critical events to the pager network and page physicians." Shabot, col. 12:33-35). It would be obvious to use modem 23 in the reception unit. Further, Shabot discloses using the modem to receive messages as part of two-way communication from a remote device. Shabot, col. 7:57-64.
8. The system as claimed in claim 7, wherein said processing unit	***Grounds 1-8:*** Goodman teaches that the host computer acts as a server. Goodman col. 7:63-65; 7:60-65. ***Grounds 1-8:*** FIG 3 and the specification of Shabot disclose wherein the processing unit is a server (server workstation 69). ***Grounds 3-4, 7-8:*** Crawford teaches that the processing unit, in

is a server.	communication with the vital signs monitor via a reception means, may be a server. Crawford, col. 3:32-34; 4:11-16.
9. The system as claimed in claim 8, wherein said display unit is a workstation.	***Grounds 1-8:*** Shabot discloses wherein the display unit is a workstation. "Each workstation display receives both continuous data inputs for certain patient statistics, e.g., pulse, and also periodic data, for example, representing lab results, such as enzyme production, drug levels, blood cell counts, etc., when they are available." Shabot, col. 5:55-60. ***Grounds 3-4, 7-8:*** Crawford teaches that data may be displayed at either the server or at remote workstations. Crawford, col. 2:56-57; 5:13-17. ***Grounds 5-6:*** Groner teaches the display of charts relating to patient control values on a terminal attached to a server. Groner, pp. 16-17 (describing the use of an "Ann Arbor Terminal" for viewing and entering data.) One of ordinary skill in the art at the time of invention would recognize that a workstation may perform all the tasks of a terminal, and is an obvious replacement such a terminal. Therefore, given the teaching of Groner, a workstation display unit is an obvious step.

VII. CONCLUSION

For the foregoing reasons, *inter partes* review of claims 1-9 of U.S. Patent No. 7,769,605 is respectfully requested.

Respectfully submitted,

Attorneys for Petitioner,
MERCHANT & GOULD, P.C.

Medtronic, Inc.

BY: /Andrew J. Lagatta/
Daniel W. McDonald, Reg. No. 32,044
Andrew J. Lagatta, Reg. No. 62,529

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William D. Schultz, *pro hac vice* forthcoming
Thomas J. Leach, Reg. No. 53,188
80 South 8th St., Suite 3200
Minneapolis, MN 55402
Telephone: (612) 332-5300
Fax: (612) 332-9081

CERTIFICATE OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on the 6th day of March, 2014, a complete and entire copy of this Petition for *Inter Partes* Review Under 37 C.F.R. §42.100, the associated Appendix of Exhibits, Exhibits 1001-1021, and Petitioner's Power of Attorney were provided via Federal Express, postage prepaid, to the Patent Owner by serving the correspondence address of record for the '605 Patent, as well as litigation counsel for the copending lawsuit captioned in the foregoing Petition (litigation counsel also served by e-mail):

Attorney(s) of Record
Attn: Paul Maginot
Maginot Moore & Beck LLP
One Indiana Square, Suite 2200
Indianapolis, IN 46204

Litigation Counsel
Attn: Chris R. Ottenweller
Orrick, Herrington & Sutcliffe
1000 Marsh Road
Menlo Park, CA 94025

Robert Bosch Healthcare Systems, Inc.
Attn: Anthony Serventi
2400 Geng Road, Suite 200
Palo Alto, CA 94303

Respectfully submitted,
MERCHANT & GOULD P.C.

BY: /Andrew J. Lagatta/
Daniel W. McDonald, Reg. No. 32,044
Andrew J. Lagatta, Reg. No. 62,529
80 South 8th St., Suite 3200
Minneapolis, MN 55402
Telephone: (612) 332-5300
Fax: (612) 332-9081