

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01251
U.S. Patent No. 11,298,056
Issued: April 12, 2022
Application No. 17/411,154
Filed: August 25, 2021

Title: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION
DETECTION AND PROCESSING

PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,298,056

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No.	Description
1001	U.S. Patent No. 11,298,056 (“the ’056 Patent”)
1002	Excerpts from Prosecution File History of U.S. Patent Application No. 17/411,154 (“Harper ’154 file history”)
1003	Excerpts from Prosecution File History of U.S. Patent Application No. 17/245,719 (“Harper ’719 file history”)
1004	Excerpts from Prosecution File History of U.S. Patent Application No. 16/228,910 (“Harper ’910 file history”)
1005	Excerpts from Prosecution File History of U.S. Patent Application No. 15/061,774 (“Harper ’774 file history”)
1006	Excerpts from Prosecution File History of U.S. Patent Application No. 13/925,694 (“Harper ’694 file history”)
1007	Excerpts from Prosecution File History of U.S. Patent Application No. 12/769,635 (“Harper ’635 file history”)
1008	Declaration of Brian Gross, dated July 24, 2023 (“Gross Decl.”)
1009	Curriculum Vitae of Brian Gross
1010	Affidavit of Nathaniel E. Frank-White (“Internet Archive Affidavit”)
1011	Exhibits A and B to Affidavit of Nathaniel E. Frank-White (“Paradigm® REAL-Time Archive”)
1012	U.S. Patent Application Publication No. 2009/0085768 to Patel et al. (“ <i>Patel</i> -2009”)
1013	Prosecution File History of U.S. Patent Application No. 12/056,651 (“ <i>Patel</i> -2009 file history”)
1014	U.S. Provisional Patent Application No. 60/976,886 (“ <i>Patel</i> -2009 provisional”)
1015	U.S. Patent Application Publication No. 2008/0119705 to Patel et al. (“ <i>Patel</i> -2008”)

1016	Excerpts from Prosecution File History of U.S. Patent Application No. 11/931,363 (“ <i>Patel</i> -2008 file history”)
1017	U.S. Patent No. 6,641,533 to Causey et al. (“ <i>Causey</i> ”)
1018	Excerpts from Prosecution File History of U.S. Patent Application No. 09/935,827 (“ <i>Causey</i> file history”)
1019	U.S. Patent Application Publication No. 2006/0202859 to Mastrototaro et al. (“ <i>Mastrototaro</i> ”)
1020	U.S. Patent Application 11/322,568 to Mastrototaro (“ <i>Mastrototaro</i> ’568 Application”)
1021	Excerpts from Prosecution File History of U.S. Patent Application No. 11/322,568 (“ <i>Mastrototaro</i> file history”)
1022	U.S. Patent Application 10/335,256 to Shahmirian et al. (“ <i>Shahmirian</i> ’568 Application”)
1023	U.S. Patent Application Publication No. 2004/0122353 to Shahmirian et al. (“ <i>Shahmirian</i> ”)
1024	Excerpts from Prosecution File History of U.S. Patent Application No. 10/335,256 (“ <i>Shahmirian</i> ’256 file history”)
1025	Geoffrey McGarraugh, <i>The Chemistry of Commercial Continuous Glucose Monitors</i> , Diabetes Technology & Therapeutics 11.S1 (2009)
1026	U.S. Patent Application Publication No. 2004/0193025 to Steil et al.
1027	C. Choleau et al., <i>Calibration of a Subcutaneous Amperometric Glucose Sensor Implanted for 7 Days in Diabetic Patients: Part 2. Superiority of the One-Point Calibration Method</i> , Biosensors and Bioelectronics 17.8 (2002)
1028	G. Velho et al., <i>In Vivo Calibration of a Subcutaneous Glucose Sensor for Determination of Subcutaneous Glucose Kinetics</i> , Diabetes, American Diabetes Association 1.3 (1988)

1029	John J. Mastrototaro, <i>The MiniMed Continuous Glucose Monitoring System</i> , Diabetes Technology & Therapeutics 2.1 (2000)
1030	U.S. Patent No. 6,424,847 to Mastrototaro et al.
1031	V. Poitout et al., <i>A Glucose Monitoring System for on line Estimation in Man of Blood Glucose Concentration Using a Miniaturized Glucose Sensor Implanted in the Subcutaneous Tissue and a Wearable Control Unit</i> , Diabetologia 36 (1993)
1032	U.S. Patent Application Publication No. 2006/0224109 to Steil et al.
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1039	Bruce Buckingham et al., <i>Real-Time Continuous Glucose Monitoring</i> , Current Opinion in Endocrinology, Diabetes & Obesity 14.4 (2007)
1040	Bruce Buckingham, M.D., <i>Clinical Overview of Continuous Glucose Monitoring</i> , Journal of Diabetes Science and Technology 2.2 (2008)
1041	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Paradigm Real Time System, Premarket Approval, dated April 7, 2006. Retrieved from

	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022S013 on July 21, 2023.
1042	Excerpts from Steven W. Smith, <i>The Scientist and Engineer's Guide to Digital Signal Processing</i> , California Technical Pub. (1997)
1043	B.A. Shenoi, <i>Introduction to Digital Signal Processing and Filter Design</i> , John Wiley & Sons (2006)
1044	Medtronic Inc., News Release: Medtronic Receives FDA Approval for World's First Insulin Pump with Real-Time Continuous Glucose Monitoring, dated April 13, 2006. Retrieved from https://web.archive.org/web/20060427084431/http://wwwp.medtronic.com:80/Newsroom/NewsReleaseDetails.do?itemId=1144875806140&lang=en_US on July 21, 2023.
1045	Marc D. Breton Ph.D. et al., <i>Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors</i> , Journal of Diabetes Science and Technology 2.3 (2008)
1046	Mark R. Burge, MD et al., <i>Continuous Glucose Monitoring: The Future of Diabetes Management</i> , Diabetes Spectrum 21.2 (2008)
1047	Adam Heller & Ben Feldman, <i>Electrochemical Glucose Sensors and Their Applications in Diabetes Management</i> , Chem. Rev. 108 (2008)
1048	U.S. Patent No. 5,391,250 to Cheney et al.
1049	List of Challenged Claims

MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

1. Real Party-In-Interest

Dexcom, Inc. is the sole real party-in-interest.

2. Related Matters

The '056 Patent (EX1001) has been asserted in the following litigation:

- *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, Case No. 1:23-cv-00239 (DED), filed March 3, 2023.

3. Lead And Back-Up Counsel, And Service Information

Lead Counsel	Back-up Counsel
John D. Vandenberg, Reg. No. 31,312 john.vandenberg@klarquist.com	Andrew M. Mason, Reg. No. 64,034 andrew.mason@klarquist.com Amy Haspel, Reg. No. 78,385 amy.haspel@klarquist.com Tucker T. Mottl, Reg. No. 74,763 tucker.mottl@klarquist.com
KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax)	

Petitioner consents to service via email at the above email addresses.

Pursuant to 37 C.F.R. § 42.10 (b), concurrently filed with this Petition is a Power of Attorney executed by Petitioner and appointing the above counsel.

Dexcom, Inc. (“Petitioner”) respectfully requests *inter partes* review (“IPR”) of claims 1-12, 14-28, and 30 of U.S. Patent 11,298,056 (“the ’056 patent,” EX1011), allegedly owned by Abbott Diabetes Care Inc. (“Patent Owner”). For the reasons set forth below, these claims should be found unpatentable and cancelled.

I. INTRODUCTION

The ’056 patent claims a glucose monitoring system in which a receiver unit wirelessly receives processed glucose sensor data and then displays that data in graph form. The supposed innovation is display of a data gap on the graph when there is an adverse condition (e.g., a communication error) and then later backfilling this gap upon correction of the adverse condition (e.g., communication being re-established). The ’056 patent illustrates the data gap feature and backfill in FIG. 7A and FIG. 7B, respectively:

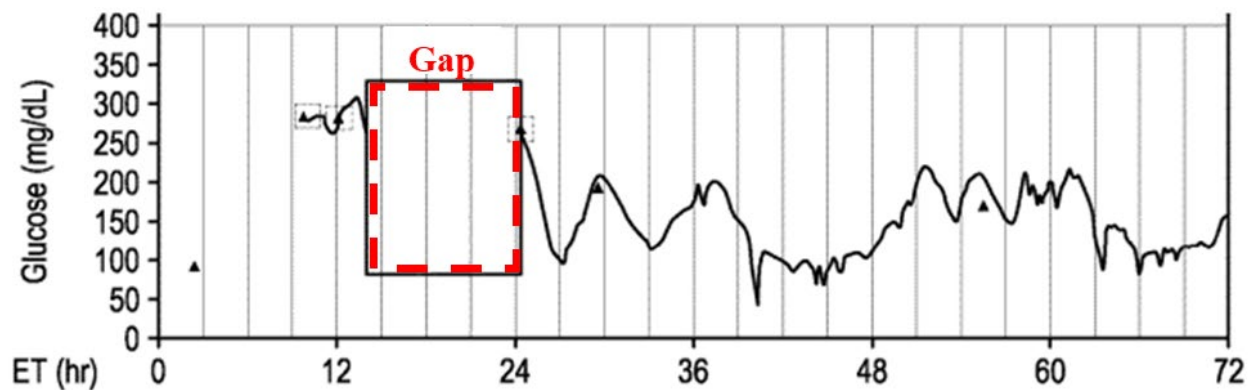


FIG. 7A

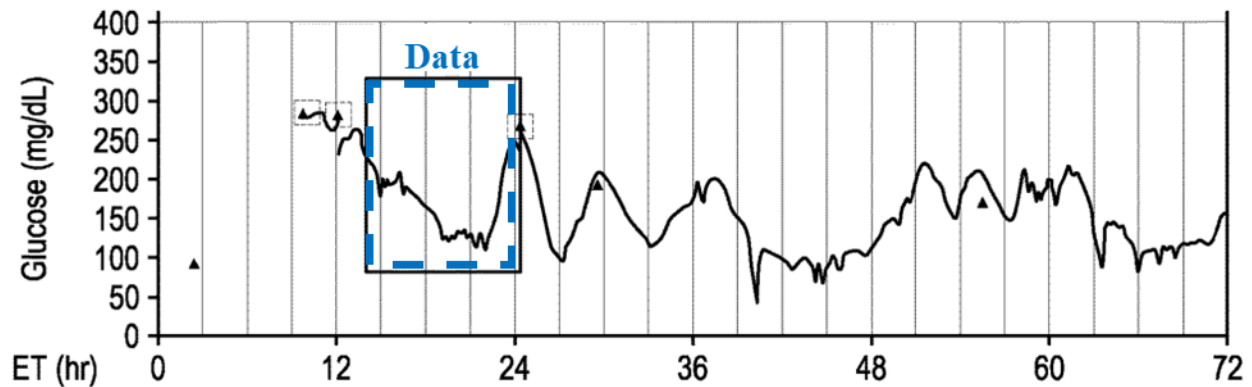
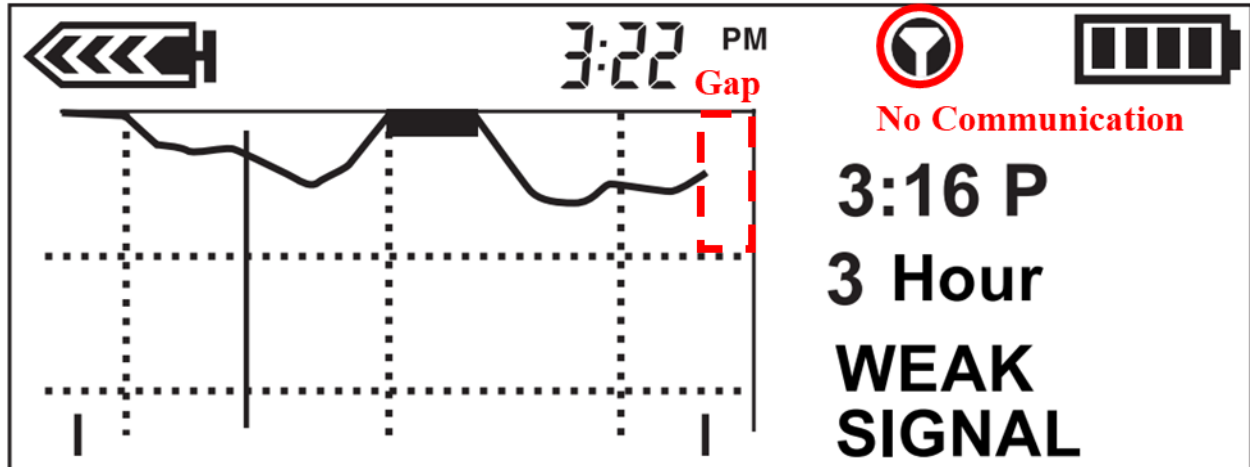


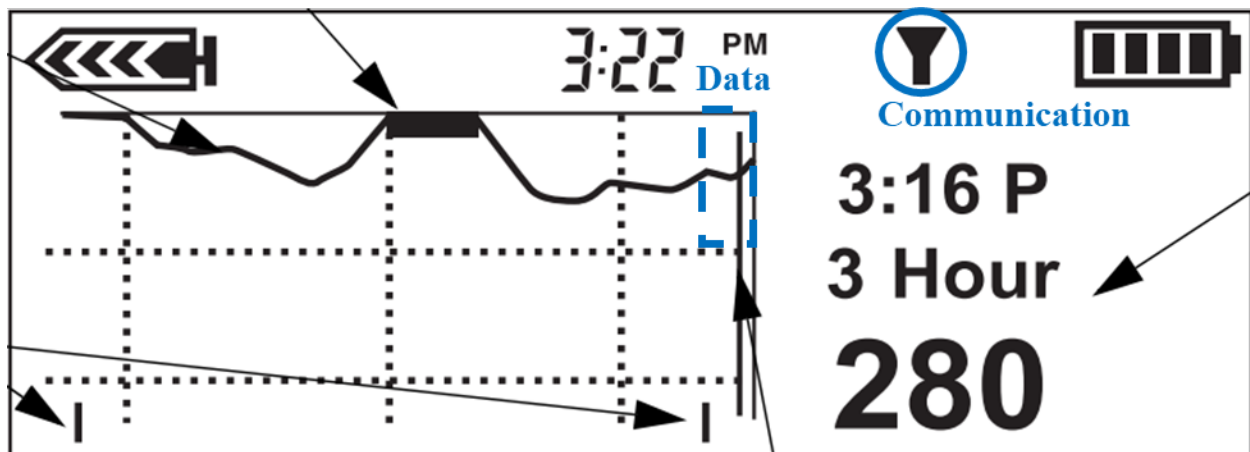
FIG. 7B

EX1001, Fig. 7A (annotated in red) & Fig. 7B (annotated in blue); *see also id.*, 12:26-39 & 12:47-13:5. However, this simplistic feature was well-known before the alleged invention and plainly described in the prior art.

Over a year earlier, a Medtronic user manual described the same backfill features in the same context of wirelessly monitoring and graphically displaying glucose sensor data, explaining that “even though your system is ‘out of range,’ continuous glucose monitoring (CGM) data can be re-populated.” EX1011 (“Paradigm® REAL-Time”), 8. It shows how prior to re-population (backfill) of data, a data gap is displayed:



EX1011, 8, 73 (excerpted; annotated in red). After communications resume, these data gaps are re-populated (backfilled):



Id., 8, 64 (excerpted; annotated in blue).

In a patent application with priority to October 2007, *Patel-2009* (EX1012), Medtronic disclosed storing calculated glucose values in a glucose sensor transceiver during failed communication and synchronizing these values from the transceiver to a monitoring device when communication is re-established. EX1012, [0086]. Together, *Patel-2009* and Paradigm® REAL-Time render obvious most claims; a

combination with a third Medtronic CGM publication, *Causey* (EX017), renders obvious the remaining claims.

Yet another Medtronic patent application with priority to October 2007, *Patel*-2008 (EX1015), disclosed a consumer electronic device (e.g., PDA/Smartphone) that displays a graph of glucose levels with missing data as a blank white space (i.e., a gap). EX1015, [0056-57], Fig. 7(a)/(b). *Patel*-2008 and other Medtronic prior art publications also render obvious all challenged claims, establishing a separate ground of unpatentability.

As explained below, skilled artisans would have implemented these features as described in Medtronic references, including *Patel*-2009 (EX1012) and *Patel*-2008 (EX1015), thus rendering obvious each challenged claim. *See infra* VII-VIII.

II. IDENTIFICATION OF CHALLENGE

A. Statement Of Relief Requested

Petitioner requests *inter partes* review of claims 1-12, 14-28, and 30 of the '056 patent on the following statutory grounds:

	Reference(s)	Basis	Claims
Ground 1	<i>Patel</i> -2009 (EX1012) and Paradigm® REAL-Time (EX1011)	35 U.S.C. § 103	1-3, 5-8, 11-12, 17-24, 26-28, 30
Ground 2	<i>Patel</i> -2009, Paradigm® REAL-Time, and <i>Causey</i> (EX1017)	35 U.S.C. § 103	4, 9-10, 15-16, 25

Ground 3	<i>Patel-2008</i> (EX1015), <i>Mastrototaro</i> (EX1019), <i>Shahmirian</i> (EX1023), and <i>Causey</i> (EX2017)	35 U.S.C. § 103	1-12, 14-18, 20-28, 30
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Sections VI-VIII present evidence of unpatentability and establish a reasonable likelihood that Petitioners will show each challenged claim is unpatentable.

Petitioner certifies that the '056 patent is available for IPR, and that Petitioner is not barred or estopped from requesting an IPR challenging the patent claims on the grounds identified in this petition.

Petitioner authorizes Account No. 02-4550 to be charged for any fees, including those enumerated in 37 C.F.R. § 42.15.

III. THE '056 PATENT

The '056 patent is titled “Methods and Systems for Early Signal Attenuation Detection and Processing” and issued from U.S. Application 17/411,154 on April 12, 2022.

A. Specification

The '056 patent describes an analyte monitoring system including a sensor unit, a data processing and transmitter unit, and a primary receiver unit. EX1001, 4:56-61; EX1008, ¶¶26-28.

The transmitter unit “receives analyte related sensor data” from the sensor and transmits this data to the receiver unit. EX1001, 11:27-37. The communication link between the transmitter and receiver is discussed as including various infrared, Bluetooth®, 802.11x, or other wireless communication protocols. *Id.*, 7:25-33, 9:15-22.

The '056 patent defines “analyte related sensor data” as including both “current signal received from the analyte sensor, as well as the current signal which has undergone ... processing routines” (e.g., filtering, clipping, digitizing, encoding, conditioning). *Id.*, 11:37-44, 14:21-23. Calibration applies “calibration data such as [a] sensitivity ratio” “to ensure the analyte related data signals ... are correctly converted to corresponding analyte levels,” but various conditions render calibration unsuitable. *Id.*, 10:62-66, 11:6-8, 12:54-61. The '056 patent describes that “when a scheduled calibration event fails ..., the output display of the processed, calibrated sensor data is disabled” resulting in a gap “where the analyte monitoring system **100** was not properly calibrated, [and] analyte related sensor data was not processed:”

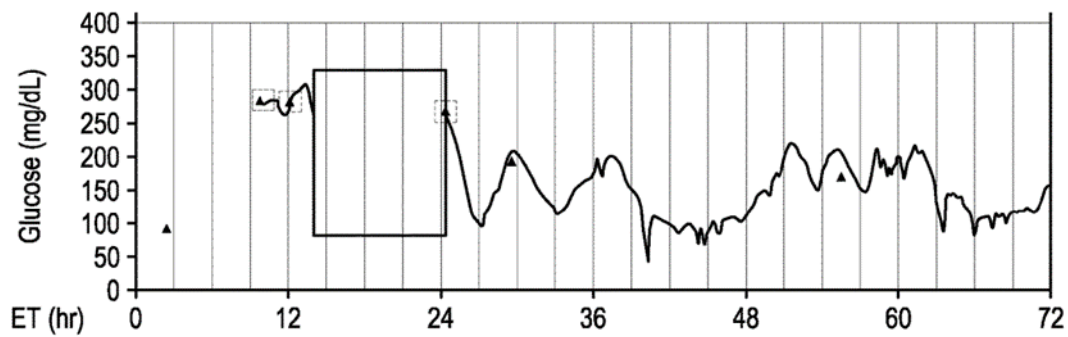


FIG. 7A

Id., 12:32-45, Fig. 7A. The '056 patent specification describes backfilling gaps by processing unprocessed sensor data with the sensitivity ratio from a subsequent calibration:

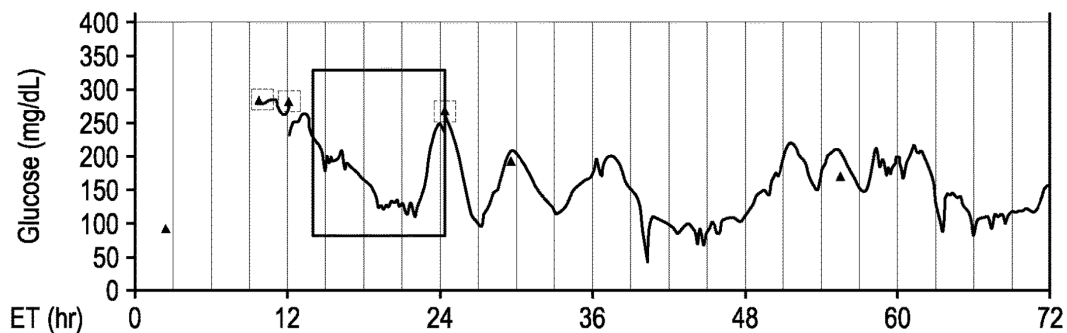


FIG. 7B

Id., 12:47-13:5, Fig. 7B.

B. Prosecution History

The '056 Patent issued from U.S. Patent Application 17/411,154 filed August 25, 2021 (EX1002), which claims priority to the April 29, 2009 filing of U.S. Provisional Application 61/173,600 through a series of continuation applications:

17/254,719 (EX1003); 16/228,910 (EX1004); 15/061,774 (EX1005); 13/925,694 (EX1006); and 12/769,635 (EX1007).

The only meaningful exchange during prosecution occurred with the initial U.S. Patent Application 12/769,635 (“the ’635 Application”) filed April 28, 2010, and focused on prior art rejections over U.S. Publications 2009/0033482 and 2009/0018424. EX1007, 76-84, 119-126. The ’635 Application was allowed because the examiner found that prior art did “not teach disabling output of sensor data during an adverse condition, where sensor data is still being stored and where the stored data is later retrieved and processed after the adverse condition is no longer present.” EX1007, 43. Prior art considered during prosecution of the ’635 Application did not include the *Patel*-2009 (EX1012), Paradigm® REAL-Time (EX1011), *Patel*-2008 (EX1015), *Causey* (EX1017), or *Mastrototaro* (EX1019) references relied on in this Petition. EX1007, 9-13, 85-100, 128-187, 203-216; *see infra* IX.A. Subsequent prosecution involved a Section 101 rejection (EX1006, 75-80), and double patenting rejections that were overcome with terminal disclaimers. EX1006, 35-41, 75-80; EX1005, 36-40; EX1004, 73-78; EX1003, 46-50; EX1002, 237-241.

C. Claims¹

The '056 patent's sole independent claim concerns a "glucose monitoring system for backfilling data gaps" displayed in a line graph of monitored glucose levels, wherein a data gap corresponds with detection of an adverse condition and is backfilled using data stored in transmitter memory during the adverse condition. EX1001, 15:24-16:20. The system includes a glucose sensor which samples biological fluid and provides data; a data processing and transmitter unit which stores, processes, and transmits sensor data; and a receiver unit which displays sensor data. *Id.*, 15:27-64. The transmitter and receiver units each have a processor, a memory, an RF ("radio frequency") transceiver, and various other components. *Id.*, 15:31-36, 15:52-54.

Dependent claims specify the adverse condition or relate to attributes and functions of the glucose monitoring system. *Id.*, 16:21-18:28.

IV. STATE OF THE ART AND LEVEL OF SKILL IN THE ART

A. State Of The Art

At least the following four features or concepts were well-known in the field of glucose monitoring. EX1008, ¶31.

¹ A claims listing is submitted as EX1049.

**1. Sensors With Working,
Reference, and Counter Electrodes**

The Background of the '056 patent admits that glucose monitoring systems “generally include[d]” sensors with “a two or three-electrode (work, reference and counter electrodes) configuration.” EX1001, 1:34-37. This is consistent with other publications, including a May 2009 article, which explained that a typical glucose sensor “includes three electrodes: a Gox working electrode, a counter electrode, and an Ag/AgCl reference electrode.” EX1025, S-19. For example, both *Patel*-2009 and *Patel*-2008 incorporate U.S. Patent 5,391,250 (EX1012, [0006]; EX1015, [0004]), which discloses manufacturing thin-film sensors with three electrodes, including “a reference electrode and a counter electrode.” EX1048, 5:6-16.

Therefore, skilled artisans were familiar with sensor configurations including working and counter electrodes. EX1008, ¶¶32-36, 54.

**2. Sensor Sensitivity Calibration
Data Was Used To Calibrate Sensors**

As early as 1988, it was recognized that “calibrating *in vivo* a subcutaneous glucose sensor” involved determining an “*in vivo* sensitivity coefficient” for the sensor and then using that coefficient “to determine from the sensor output an apparent subcutaneous glucose concentration.” EX1028, 227; *see also id.*, 228 (discussing the sensitivity coefficient as the “ratio between the decrease in the sensor current and the decrease in glucose concentration.”). Similarly, a 2002 article on

“Calibration of a subcutaneous amperometric glucose sensor...” explains how calibration procedures involved determining a “sensor sensitivity S ” that is then used to calibrate the sensor data. EX1027, 647; *see also id.*, 648 (“calibration of the system represents a crucial step” and further explaining determination and use of “sensor sensitivity S .”); EX1029, S-15; EX1030, 11:28-33 (explaining that “calibration involves calculating a calibration factor called a sensitivity ratio (SR)”).

Therefore, the POSITA understood that calibration data, in the context of monitoring glucose or other analytes, typically included sensitivity information for the sensor, e.g., the sensor sensitivity ratio (aka sensitivity coefficient). EX1008, ¶¶37-40, 54.

3. Microprocessor Computations

The '056 patent implicitly admits that skilled artisans knew how to perform signal processing by providing that sensor signals are processed (EX1001, 5:58-64, 11:37-44) without any details on how this is done. By 1993, the necessity of sampling, filtering, storing, and processing glucose sensor electrical current values before conversion to real-time glucose concentrations was well known. EX1031, 659, 661-662.

By the early to mid-2000's, Medtronic had developed more advanced procedures for smoothing, filtering, storing, and processing sensor electrical current signals. For example, a 2002 Medtronic patent described sampling electrical current

every 10 seconds and storing averaged sampling intervals in memory. EX1030, 8:42-60; *see also* EX1033, 1211 (describing the Medtronic Guardian RT's finite impulse filter). Additionally, a 2006 Medtronic publication described processing signals from analog current (I_{sig}) to digital sensor values (D_{sig}) stored in a buffer, prior to filtering and calibration. EX1032, [0230].

Therefore, POSITAs understood that continuous glucose monitoring systems included processors that processed and stored sensor data in memory, and also stored the resulting output in memory (e.g., processor cache, buffer, RAM). EX1008, ¶¶41-46, 54.

4. Bluetooth Communication

A January 2007 review of “Wireless connectivity for health and sports monitoring” found that most of the literature on healthcare monitoring and telemedicine related to the application of Bluetooth, described as a short-range cable replacement for device-to-device connections. EX1035, 286-87. Similarly, “A Survey on Wearable Biosensor Systems for Health Monitoring” presented at the International IEEE EMBS Conference in August 2008, studied 25 wearable biosensors and found that 10 used Bluetooth. EX1036, 4888-89.

Therefore, skilled artisans were familiar with implementing Bluetooth communication for short range device-to-device connections in health monitoring applications. EX1008, ¶¶47-49, 54.

B. Level Of Skill In The Art

In the 2009-2010 timeframe, the POSITA had a Bachelor of Science degree in biomedical engineering, or a similar field, such as electrical, or software, or computer engineering, and two years of industry experience or research working with medical devices and systems for measuring biomedical signals. Such systems might include those for determining levels of blood analytes, such as glucose, in a patient and transmitting indications of such levels to a receiving device for reporting the measurements. Additional education, such as a Master's degree could substitute for the industry experience, or vice versa. EX1008, ¶51.

The POSITA may be part of an interdisciplinary team with others having relevant experience and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals. EX1008, ¶52.

In addition to the state-of-the-art discussed above (*see supra* IV.A.1-4), POSITAs would have been aware of commercially available glucose monitoring systems (e.g., the Medtronic Paradigm® REAL-Time) through scientific journals and magazines. POSITAs would have known the importance of data reliability to glucose monitoring, including anticipating that errors (e.g., communication or calibration failures) would result in missing or inaccurate glucose data. POSITAs would have accounted for missing data using technical concepts known at the time,

including programming glucose monitoring systems to detect failures that result in data being unavailable for display (e.g., due to a calibration error or loss of communication), preserving this data in memory, regenerating it once the system recovered, and displaying regenerated data. EX1008, ¶¶54-61.

V. **CLAIM CONSTRUCTION**

For *inter partes* review, claim terms should be given their ordinary meaning to a person of ordinary skill in the art on the effective filing date, in view of the specification and file history. 83 Fed. Reg. 51340; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc). Unless otherwise expressly discussed, Petitioner applies the ordinary meaning of all claim terms. Petitioner does not, however, waive any argument in any litigation that claim terms in the '056 Patent have a particular meaning and/or are indefinite. Nor does Petitioner waive its right to raise additional issues of claim construction in any proceeding.

**VI. GROUND 1: CLAIMS 1-3, 5-8,
11-12, 17-24, 26-28 AND 30 ARE OBVIOUS OVER
PATEL-2009 IN VIEW OF PARADIGM® REAL-TIME**

A. Patel-2009 (EX1012) Is Prior Art

U.S. Publication 2009/0085768 to Patel (“*Patel-2009*”, EX1012) is prior art under at least 35 U.S.C. § 102(e) because its U.S. Patent Application 12/056,651 (EX1013) was filed on March 27, 2008, and contains materially identical disclosure.

While Patel-2009 is prior art based on its March 2008 non-provisional filing date, its prior art status dates back to October 2, 2007, because Provisional Application 60/976,886 supports claim 1 and contains the same disclosures relied on in this Petition:

<i>Patel-2009 Claim 1</i>	Support in 60/976,886 Provisional
1. A telemetered characteristic sensor transceiver for exchanging data with at least one remote device, the transceiver comprising:	EX1014, p.9 [0007], p.31
a housing detachably coupled to a sensor located on a body of a user,	EX1014, p.19 [0050], p.20 [0051], p.21 [0054], p.50 Figs.1-2, p.52 Figs. 8A/B, p.56 Fig. 13, p. 61 Fig.18, p.31.
the sensor producing a signal indicative of a user characteristic;	EX1014, p.9 [0007], p.31.
a processor formed within the housing and in communication with the sensor for processing the signal produced by the sensor;	EX1014, p.9 [0007], p.10 [0013], p.31.
a transmitter coupled to the processor for transmitting data to at least one remote device;	EX1014, p.9 [0007], p.10 [0012], p.31.

a receiver coupled to the processor for receiving data from the at least one remote device;	EX1014, p.9 [0007], p.10 [0013], p.24 [0062], p. 31.
and a memory coupled to the processor for storing data,	EX1014, p.9 [0007], p.10 [0012], p.31.
wherein the processor performs calculations using at least one of the signal produced by the sensor, the data received from the at least one remote device and the data stored in the memory, and performs at least one of storing the calculations in the memory and transmitting the calculations to the at least one remote device through the transmitter.	EX1014, p.10 [0012], p. 31.

EX1008, ¶¶62-67; *see Medtronic, Inc. et al. v. Niazi Licensing Corp.*, IPR2018-00609, Paper 8 at 11 (PTAB Aug. 20, 2018) (“we determine *Dynamic Drinkware* requires the ... provisional to support just one claim in the ... patent”).

B. Paradigm® REAL-Time (EX1011) Is Prior Art

Paradigm® REAL-Time (EX1011)² consists of several pages published on the Medtronic Diabetes Website (www.medtronicdiabetes.com) at least by October 2007, thus making it prior art under § 102(b).

² Herein, “Paradigm® REAL-Time” refers to the webpages submitted as EX1011. “Paradigm® REAL-Time Product” refers to the product, which received FDA approval on April 7, 2006. (EXs1041, 1044)

In October 2007, as recorded by the Internet Archive (<https://web.archive.org>), the Medtronic Diabetes homepage prominently exhibited and linked to the Paradigm® REAL-Time product webpage, which included links to Features, Frequently Asked Questions, and User Guides:



EX1011, 17-20 (excerpted; annotated in red). The “Features” tab opened the Paradigm® REAL-Time “Features” webpage, which included a hyperlink to the Features & Benefits Fact Sheet:

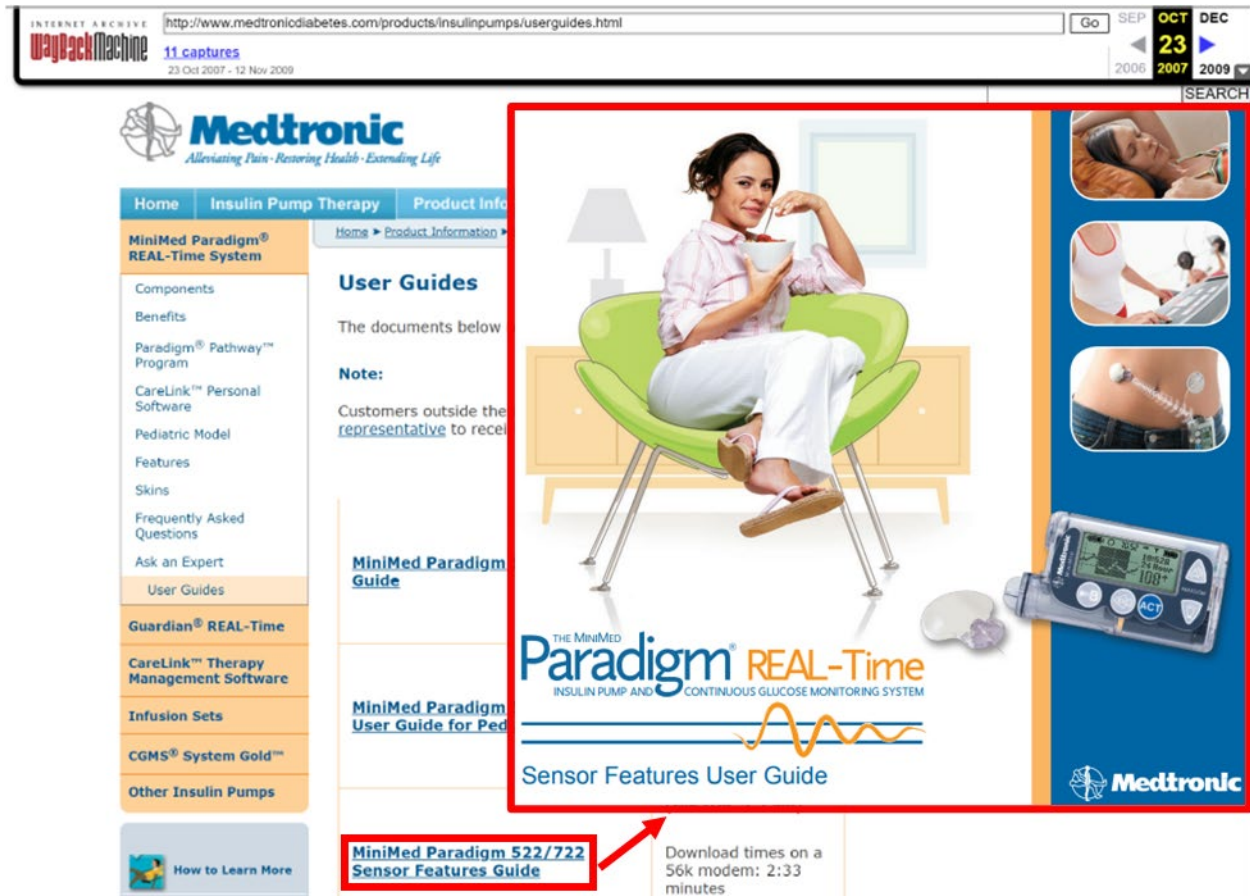
The screenshot shows the Medtronic website's 'Features' page for the MiniMed Paradigm® REAL-Time System. A red box highlights the 'Download the full features overview' link, which is a PDF file (42kb). Below this, a red box highlights a 'FACT SHEET' titled 'Features and Benefits MiniMed Paradigm® REAL-Time System*'. The fact sheet includes a 'now i can' logo and a table of features and benefits.

Feature	Specification	Benefit
Glucose Sensor	The glucose sensor is inserted, virtually painlessly, through the skin, usually in the stomach area. The glucose sensor sends an electronic signal measuring the amount of glucose in your interstitial fluid. Replace the glucose sensor every three days.	Measures your glucose levels continuously, as an addition to fingerstick measurements. Displays a five-minute average, 24 hours a day. Numerous studies have proven the accuracy of the sensor. ¹⁻⁴
Calibration	Calibrate your MiniMed Paradigm REAL-Time System at least once every 12 hours. In addition, make sure you always confirm with a fingerstick before making any adjustments in your therapy.	Simple and easy.

Id., 14-16 (excerpted; annotated in red). This Fact Sheet includes details on the MiniMed Paradigm® Insulin Pump (“Paradigm® Insulin Pump”), MiniLink™ Transmitter, glucose sensor, and glucose monitoring functionality of the Paradigm® REAL-Time System. *Id.*, 22-28.

The “Frequently Asked Questions” tab opened an FAQ webpage on various topics related to the Paradigm® REAL-Time Product. *Id.*, 5-13.

The “User Guides” tab opened a webpage with links to Paradigm® REAL-Time guides, including a “Sensor Features Guide”:



Id., 2-4 (excerpted; annotated in red). The Sensor Features Guide provides additional details on the Paradigm® System and glucose monitoring functionality. *Id.*, 29-105.

As discussed in the internet archive affidavit, each of these pages was archived within a single week from October 23 to 30, 2007. EX1010, ¶15; EX1011, 2, 5, 14, 22, 29. This affidavit establishes that Paradigm® REAL-Time is prior art under 35

U.S.C. § 102(b) as a printed publication that was publicly accessible by October 2007. *See, e.g., Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1374 (Fed. Cir. 2021) (noting USPTO and district court reliance on Wayback Machine to establish prior art public availability); *Crestron Elecs., Inc. v. Intuitive Bldg Controls, Inc.*, IPR2015-01460, Paper 14 at 12, 14 (PTAB Jan. 14, 2016); *Electronic Arts Inc. v. White Knuckle IP, LLC*, IPR2015-01595, Paper 38 at 11 (PTAB Jan. 12, 2017); MPEP § 2128 (II)(E). Public accessibility of Paradigm REAL-Time is further demonstrated by scientific journals and magazines, including a full-page advertisement in the November 2007 edition of the American Diabetes Association's Diabetes Forecast magazine that directed readers to the Medtronic Diabetes website (www.medtronicdiabetes.com). EXs1037-1040, 1046; EX1008, ¶¶55, 68-71.

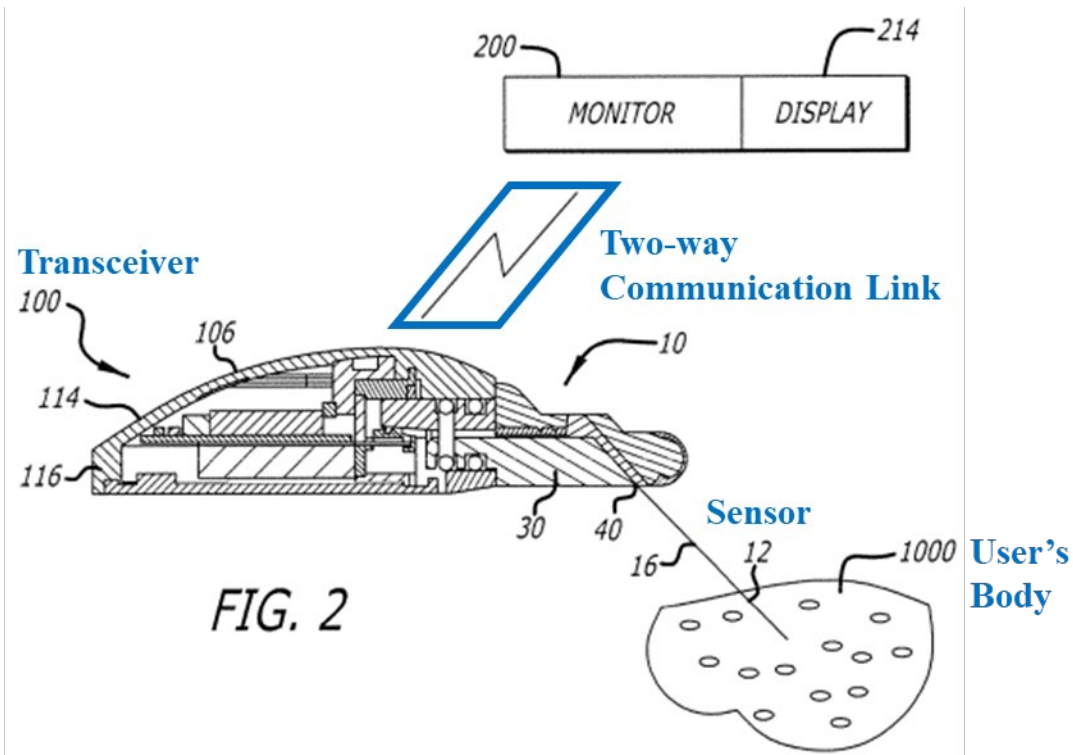
The Paradigm® REAL-Time reference constitutes a single publication because it describes a single product and was published on a common website. *Haliburton Energy Servs., Inc. v. Dynamic 3D Geosolutions LLC*, IPR2014-01186, Paper 13 at 15-18 (PTAB Jan. 12, 2015); *see also MacSports, Inc. v. Idea Nuevo, Inc.*, IPR2018-01006, Paper 6 at 8-9 (PTAB Nov. 13, 2018) (“[A] collection of webpages that describes a single product, from a single source, ... may properly be regarded as being a single printed publication.”). Indeed, the Board has considered Internet Archive captures from a single website as a single reference. *American*

Express Co. v. Harvey Lunenfeld, CBM2014-00050, Paper 51 at 49-51 (PTAB May 22, 2015).

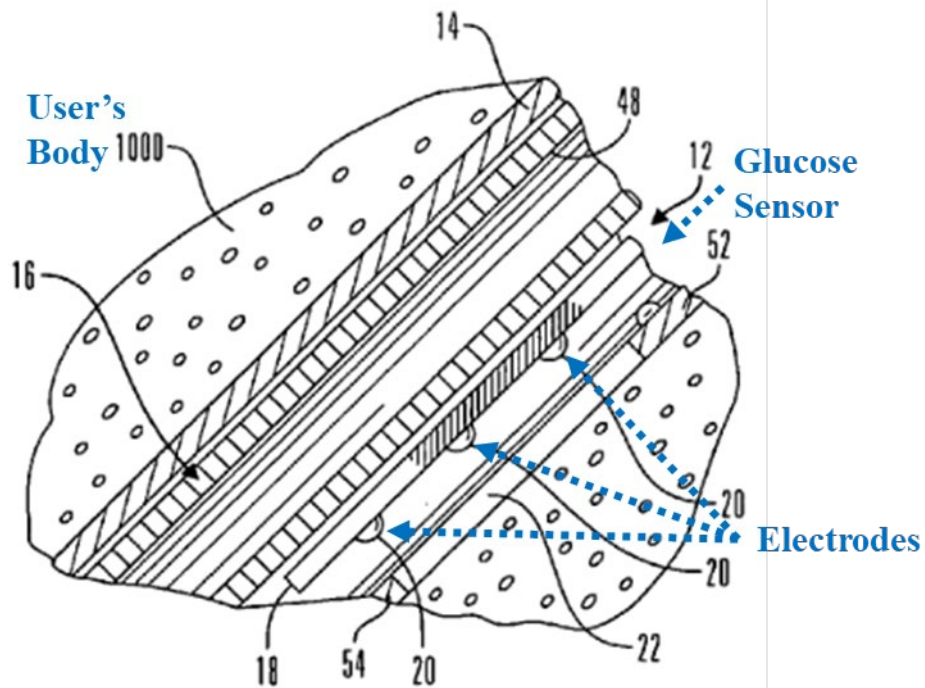
Alternatively, the Paradigm® REAL-Time reference is a collection of publications that “ordinarily skilled artisans would have considered ... together in order to gain a more complete understanding” of the corresponding Medtronic product. *Haliburton*, IPR2014-01186, Paper 13 at 19-20; *see also e.g., Samsung Elecs. Co. Ltd. v. Rosetta-Wireless Corp.*, IPR2016-00622, Paper 48 at 64-65 (PTAB August 21, 2017) (treating Internet Archive captures from a single website as “interrelated teachings that an ordinarily skilled artisan would have known to combine”); *L & P Prop. Mgmt. Co. v. Nat’l Prod. Inc.*, IPR2016-00475, Paper 27 at 23-25 (PTAB July 19, 2017) (same for printed instructions and online user guide).

C. Patel-2009 (EX1012)

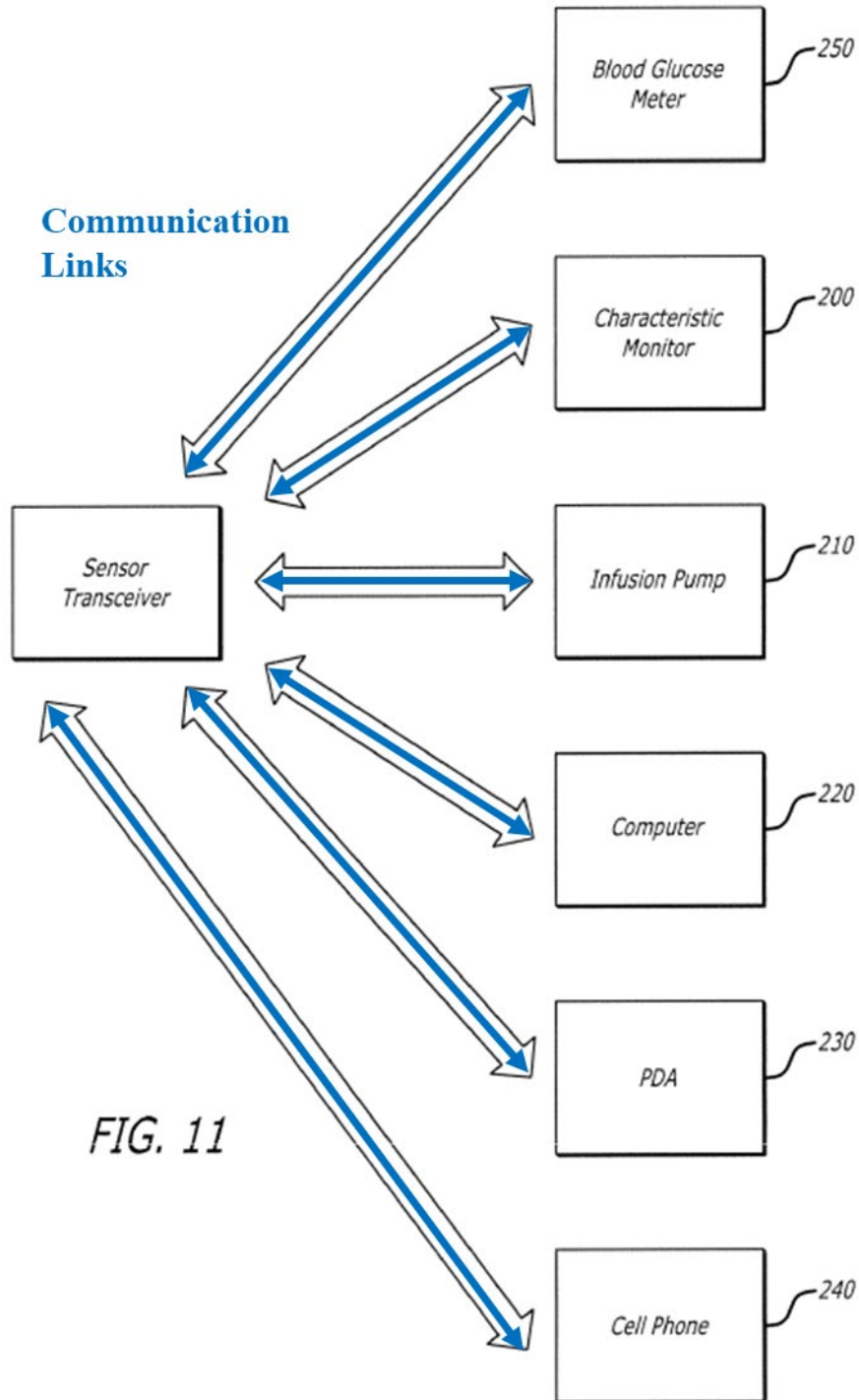
Patel-2009 (EX1012) discloses a transceiver (100) coupled to a subcutaneous glucose sensor (12) that exchanges data with a monitor over a two-way communication link:



EX1012, [0008-09], [0037], Fig. 2 (annotated in blue). The transceiver encompasses a processor that calibrates the sensor and calculates glucose values, a memory that stores these calculated glucose values, and a battery. *Id.*, [0008], [0013-14], [0058], [0061]; *see also* EX1014, [0051]. Sensor set (10) encompasses a subcutaneous sensor (12) which monitors glucose levels by exposing electrodes to bodily fluid:



EX1012, [0049-51], Fig. 6 (annotated in blue). The monitor displays glucose levels and trend graphs. *Id.*, [0066]. Finally, transceiver 100 maintains two-way communication with various devices, including monitor 200, infusion pump 210, PDA 230, cellular phone 240, and blood glucose meter 250 to exchange glucose values, calibration data, and other information:



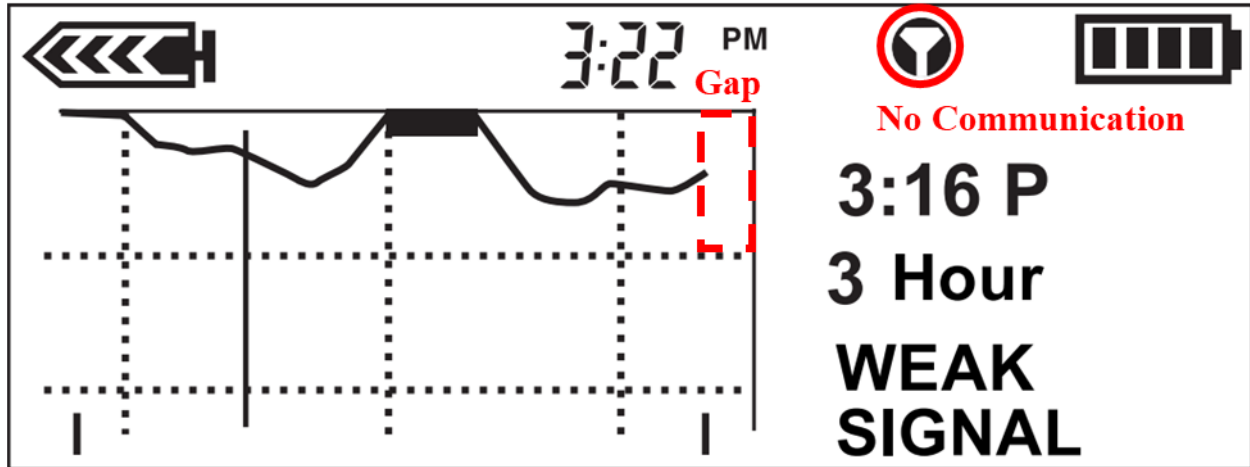
Id., [0042], [0075-76], [0084], Fig. 11 (annotated in blue). EX1008, ¶72.

Glucose values calculated during a loss of communication are synchronized from the transceiver to these remote devices when communication is re-established. EX1012, [0086]; EX1008, ¶73.

D. Paradigm® REAL-Time (EX1011)

Paradigm® REAL-Time (EX1011) discloses a continuous glucose monitoring system comprising Paradigm® Insulin Pump with a user display, MiniLink™ Transmitter, and glucose sensor components. EX1011, 9, 15, 18, 23-24, 37-38. The glucose sensor “measur[es] the amount of glucose in [] interstitial fluid” as an electronic signal, the MiniLink™ Transmitter “[r]eceives and processes signals from the glucose sensor and sends glucose values to the insulin pump through radio frequency (RF),” and the Paradigm® Insulin Pump displays 3 and 24-hour historical glucose graphs updated with average glucose readings every five minutes. *Id.*, 7-9, 15, 23-24, 64. EX1008, ¶74.

As long as continuous glucose data is transmitted from the transmitter to the insulin pump, continuous glucose monitoring (“CGM”) data is displayed on the insulin pump’s screen. EX1011, 7-8. When loss of communication from the transmitter to the insulin pump causes failed reception of glucose data, missed data is displayed as a gap:

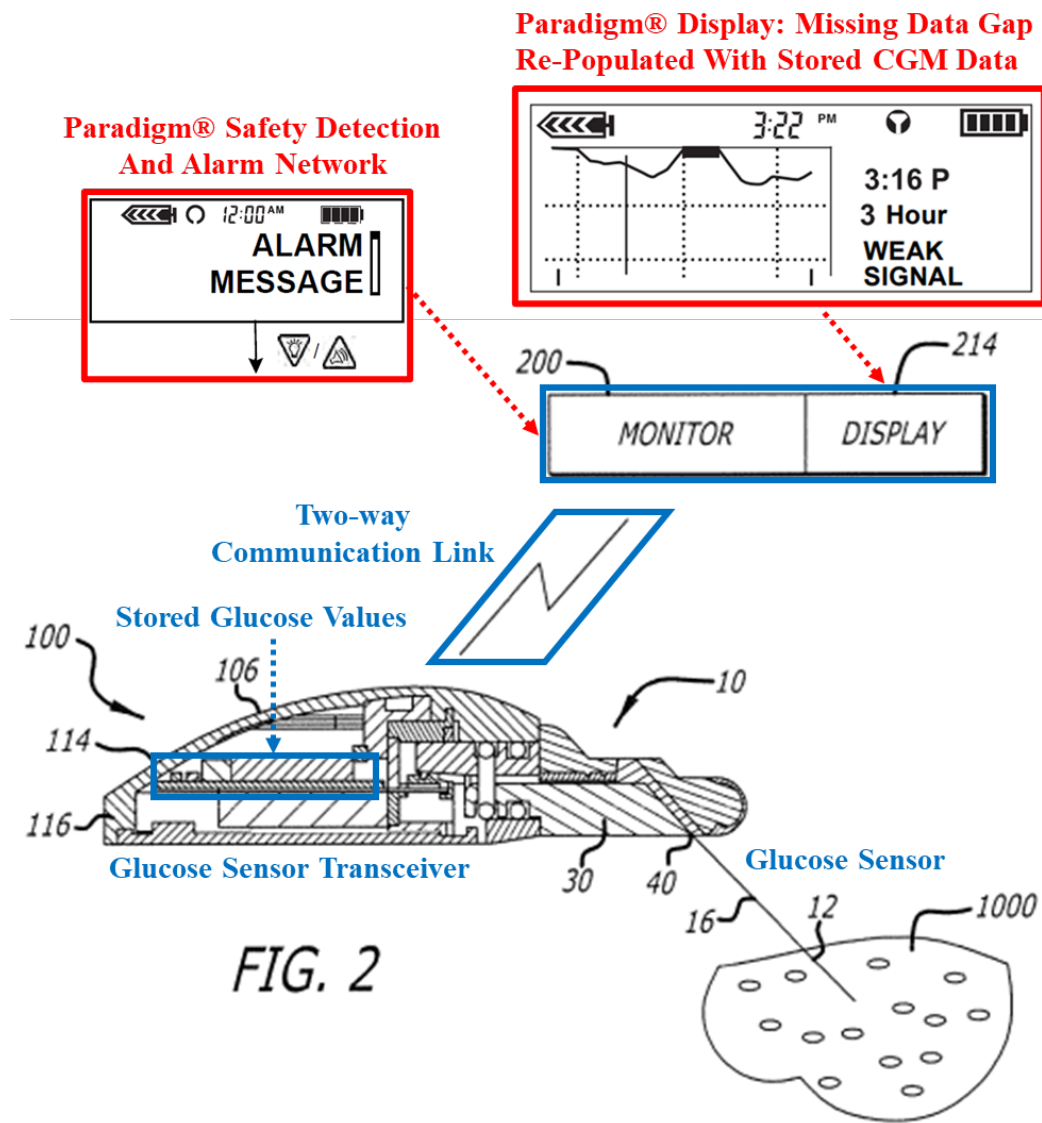


Id., 8, 43, 49, 73 (excerpted; annotated in red). The MiniLink™ Transmitter stores 40 minutes of glucose data that re-populates the insulin pump’s display of continuous glucose monitoring (CGM) data following correction of failed reception (e.g., when the transmitter and pump move within transmission range). *Id.*, 8. EX1008, ¶¶75-76.

E. Combination Of Patel-2009 And Paradigm® REAL-Time

Patel-2009 discloses a transceiver that calculates glucose values from sensor signals and stores calculated glucose values during failed communication, a monitor that graphs glucose values received from the transceiver, and the synchronization of glucose data when communication is re-established. EX1012, [0042], [0066], [0086]. The *Patel-2009/Paradigm* Combination incorporates Paradigm® REAL-Time’s “sophisticated network of safety checks and systems” that “detects anything unusual,” including failed receipt of glucose data (i.e., weak signal) and calibration errors. EX1011, 71-75. The *Patel-2009/Paradigm* Combination also incorporates

Paradigm® REAL-Time's display of missing "data gaps" when glucose data is not received because the transmitter is out-of-range or transmission fails due to interference, and the re-population of these gaps with glucose data stored in transmitter memory. *Id.*, 8, 10, 41, 73.



EX1012, Fig. 2 (annotated in blue for *Patel*-2009); EX1011, 72-73 (excerpted; annotated in red for Paradigm® REAL-Time). The *Patel*-2009/Paradigm Combination retains the subcutaneous glucose sensor and glucose sensor transceiver from *Patel*-2009. EX1012, [0008], [0041], [0049], [0051], [0084], [0086]. EX1008, ¶77.

By incorporating detection and display functionalities from Paradigm® REAL-Time, the *Patel*-2009/Paradigm Combination results in glucose graphs that accurately display the failed reception of glucose data. EX1011, 8, 71, 73. Then, when communication is re-established, the *Patel*-2009/Paradigm Combination re-populates gaps in continuous glucose monitoring data with glucose values synchronized from *Patel*-2009's glucose sensor transceiver. EX1012, [0086]; EX1011, 8. EX1008, ¶78.

1. Motivation To Combine And Expectation Of Success

Patel-2009 discloses displaying glucose trend graphs to a user and provides for specific advantages over previous glucose monitoring systems and preexisting glucose sensor transmitters, including a glucose sensor transceiver that calculates and stores glucose values during failed communication (e.g., when a monitoring device is not in proximity) and synchronization of calculated glucose values from the transceiver to the monitoring device when communication is re-established. EX1012, [0007], [0084], [0086]. However, *Patel*-2009 does not provide for glucose

graphs to convey that glucose data is missing during failed communication or to display glucose data that is synchronized when communication is re-established. *See Id.*, [0086]. EX1008, ¶79.

One purpose of continuous glucose monitoring is to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo glycemia by providing accurate glucose concentrations and trend information in real-time. EX1011, 15, 18, 23-27; EX1012, [0004], [0006]; *see also, e.g.*, EX1029; EX1037, 17; EXs1039-1040. Therefore, POSITAs would have been motivated to detect missing or inaccurate glucose data and convey as much accurate glucose information to a user as possible without providing inaccurate information. In particular, POSITAs would have been motivated to apply the advantages of *Patel-2009* to indicate when glucose data is missing and re-populate this display with accurate data synchronized when communication is re-established following failure. EX1012, [0086]. EX1008, ¶¶55, 60, 80.

POSITAs would have naturally investigated Paradigm® REAL-Time because *Patel-2009* provides improvement to previous glucose monitoring systems, and Paradigm® REAL-Time was one of the leading continuous glucose monitoring systems of that time. EX1008, ¶84. POSITAs would have been especially motivated to combine Paradigm® REAL-Time with *Patel-2009* because they both relate to similar Medtronic continuous glucose monitoring systems as evidenced by their

visual similarity and common citation to Medtronic's U.S. Patent No. 6,554,798. EX1012, [0068-69], Fig. 1; EX1011, 32; EX1008, ¶¶81-83.

POSITAs would have expected to successfully combine Paradigm® REAL-Time with *Patel-2009* because *Patel-2009* discloses specific improvements over previous glucose monitoring systems like Paradigm® REAL-Time. EX1012, [0007], [0084-86]. POSITAs would have known how to modify *Patel-2009* to perform functions of Paradigm® REAL-Time, for example by modifying the programming of *Patel-2009*'s monitor or by importing programs from the Paradigm® Insulin Pump. EX1008, ¶¶56-57, 85.

F. Ground 1 Claim Mappings

As set out below, the *Patel-2009*/Paradigm Combination renders obvious claims 1-3, 5-8, 11-12, 17-24, 26-28 and 30. EX1008, ¶86.

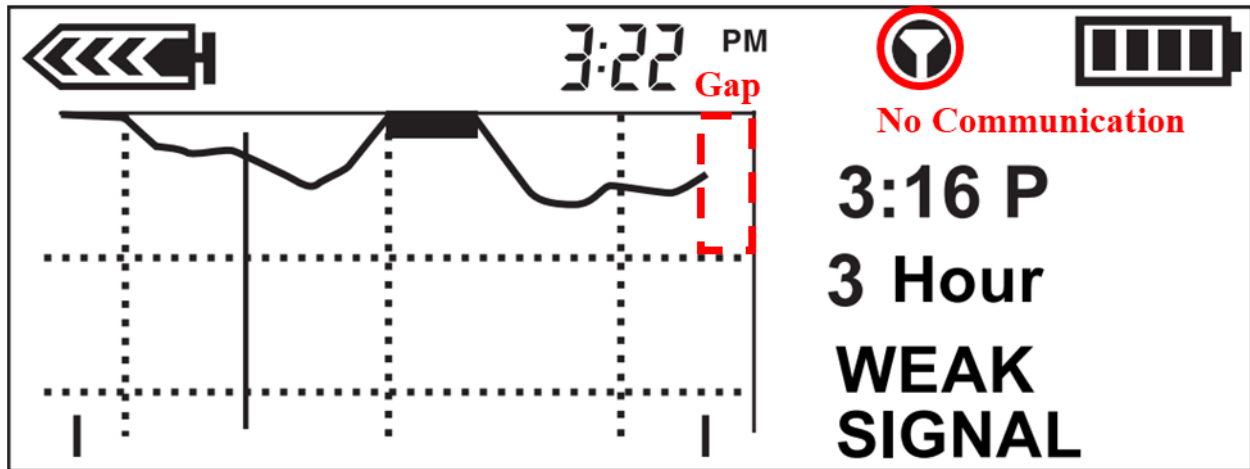
1. Claim 1

a) [1.A] (Preamble)

A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:
--

If the preamble is limiting, *Patel-2009* and Paradigm® REAL-Time both disclose CGM systems that display glucose levels to a user. EX1012, [0042], [0066]; EX1011, 15, 23-24, 37-38, 64. EX1008, ¶87.

Paradigm® REAL-Time discloses a graph that displays sensor glucose data points. EX1011, 64. When glucose data is not received (e.g., because “[t]ransmitter and insulin pump are too far apart”), this graph displays a corresponding gap in glucose values:



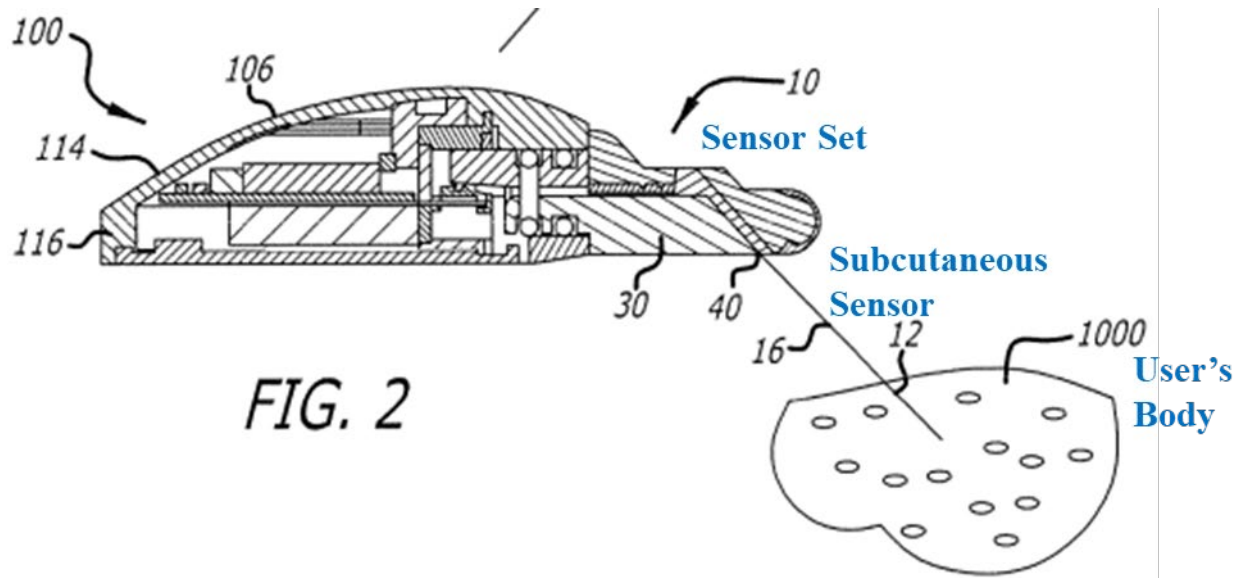
Id., 8, 73 (excerpted; annotated in red). EX1008, ¶88.

When out-of-range, the “transmitter holds 40 minutes worth of memory, so ... continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.” EX1011, 8. CGM data re-populates the last 40 minutes of missing glucose data so that gaps only remain in historical reports if the transmitter and pump are “out-of-range for longer than 40 minutes.” *Id.*; *see infra* VI.F.1.(k). EX1008, ¶89.

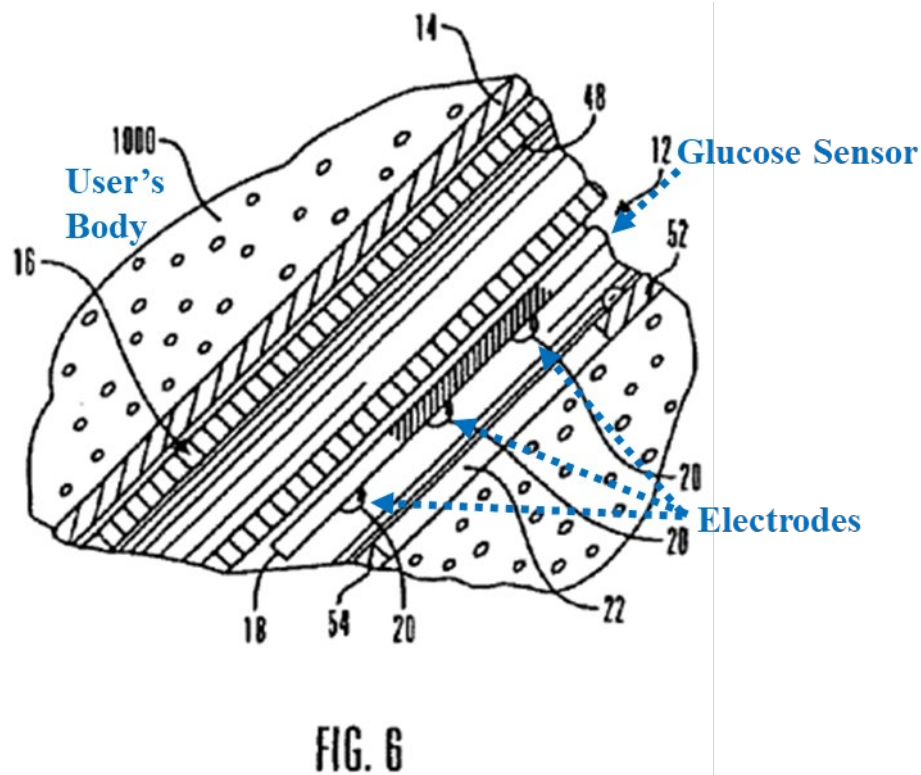
b) [1.B]

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user to provide sensor data;

Patel-2009 discloses percutaneous sensor set 10 with electrode-type sensor 12 placed below the skin in a user's body 1000:



EX1012, [0041], [0049], Fig. 2 (annotated in blue). Sensor 12 produces signals indicative of monitored glucose levels by exposing sensor electrodes 20 to the user's bodily fluids:



Id., [0008], [0038], [0049-51], Fig. 6 (annotated in blue). EX1008, ¶90.

Paradigm® REAL-Time also discloses a glucose sensor that “continuously measures glucose from [] subcutaneous tissue as an electronic signal.” EX1011, 38. This sensor is inserted through the skin, and “sends an electronic signal measuring the amount of glucose in [] interstitial fluid.” EX1011, 23. The sensor current signal (“Isig”) is reported in units of nanoamperes (nA) of current, for example 123.45 nA:

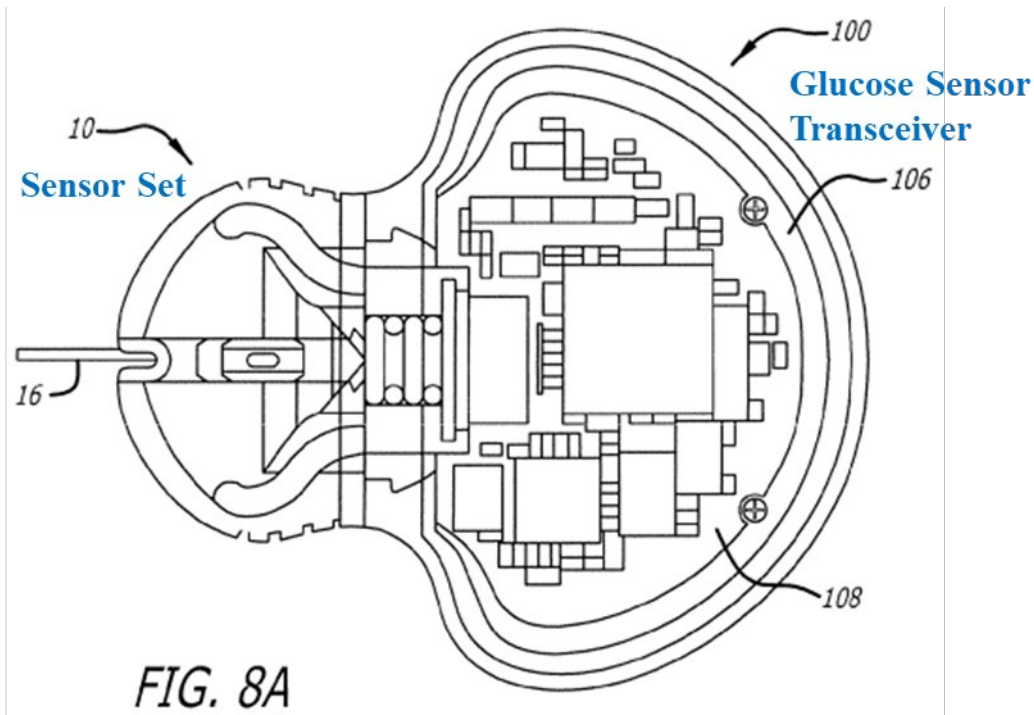
SENSOR STATUS	
Next Cal:	8:30A
Sensor Age:	2d 3h
Sensor Isig:	123.45
Transmtr Batt:	Good
Transmtr Ver:	1.1
Transmtr ID:	2111111
Pump S/N#:	2222222

Id., 63, 80 (excerpted; annotated in red). EX1008, ¶91.

c) [1.C]

a data processing and transmitter unit coupled to the glucose sensor, the data processing and transmitter unit comprising a power supply, a processor of the data processing and transmitter unit, memory of the data processing and transmitter unit, and a radio frequency transceiver of the data processing and transmitter unit, wherein the data processing and transmitter unit is configured to:

Patel-2009 discloses that “sensor set **10** is connected to the telemetered characteristic sensor transceiver **100**,” which satisfies the claimed “data processing and transmitter unit.” EX1012, [0072]. Figure 8A illustrates transceiver 100 coupled to sensor set 10:



Id., [0056], Fig. 8A (annotated in blue). The “sensor transceiver **100** includes ... Microprocessor **1120**, Digital to Analog Converter **1122**, Real Time Clock **1126**, EEPROM **1124**, RF Transceiver **1128**, and a battery **1130**, as well as other associated electronics such as an antenna.” *Id.*, [0058]; *see also id.*, [0008] (describing “transceiver comprising ... a processor ..., a transmitter ..., a receiver ..., and a memory coupled to the processor for storing data”) & [0056]; EX1014, [0051] (“The telemetered characteristic sensor transceiver 100 includes a housing 106 that supports a printed circuit board 108, batteries 110, antenna 112, and the cable 102 with the connector 104. The housing 106 may also support a processor for performing calculations and a memory for storing information.”) EX1008, ¶92.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter connects with a glucose sensor, has a rechargeable battery, and has memory that stores 40-minutes of glucose monitoring data. *See* EX1011, 8, 37, 51 (describing MiniLink™ Transmitter). EX1008, ¶93.

d) [1.D]

receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit; process the sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit; and

The *Patel*-2009 transceiver “perform[s] data calibration and sensor glucose value calculation” to “convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver.” EX1012, [0042], [0084], [0090]. The transceiver “calibrate[s] the sensor’s readings” with “calibration data” received from a remote device (e.g., a blood glucose meter). *Id.*, [0042], [0064], [0081], [0084]. Calibration is performed by running filtering and calibration algorithms. *Id.*, [0076]. Following calibration, *Patel*-2009 discloses that the transceiver “appropriately calculate[s] sensor glucose values using the calibrated sensor readings.” *Id.*, [0084]. The transceiver logs calculated glucose values and stores them in memory as glucose history. *Id.*, [0013], [0047], [0081], [0083], [0086]. EX1008, ¶94.

Patel-2009 discloses storing sensor data in memory at least during filtering, calibration, and calculation. *See supra* IV.A.3. POSITAs understood that the transceiver's processor stores sensor data in memory (e.g., processor cache, buffer, RAM) while filtering sensor signals, calibrating sensor readings, and calculating glucose values from calibrated sensor readings. EX1008, ¶¶46, 54, 95.

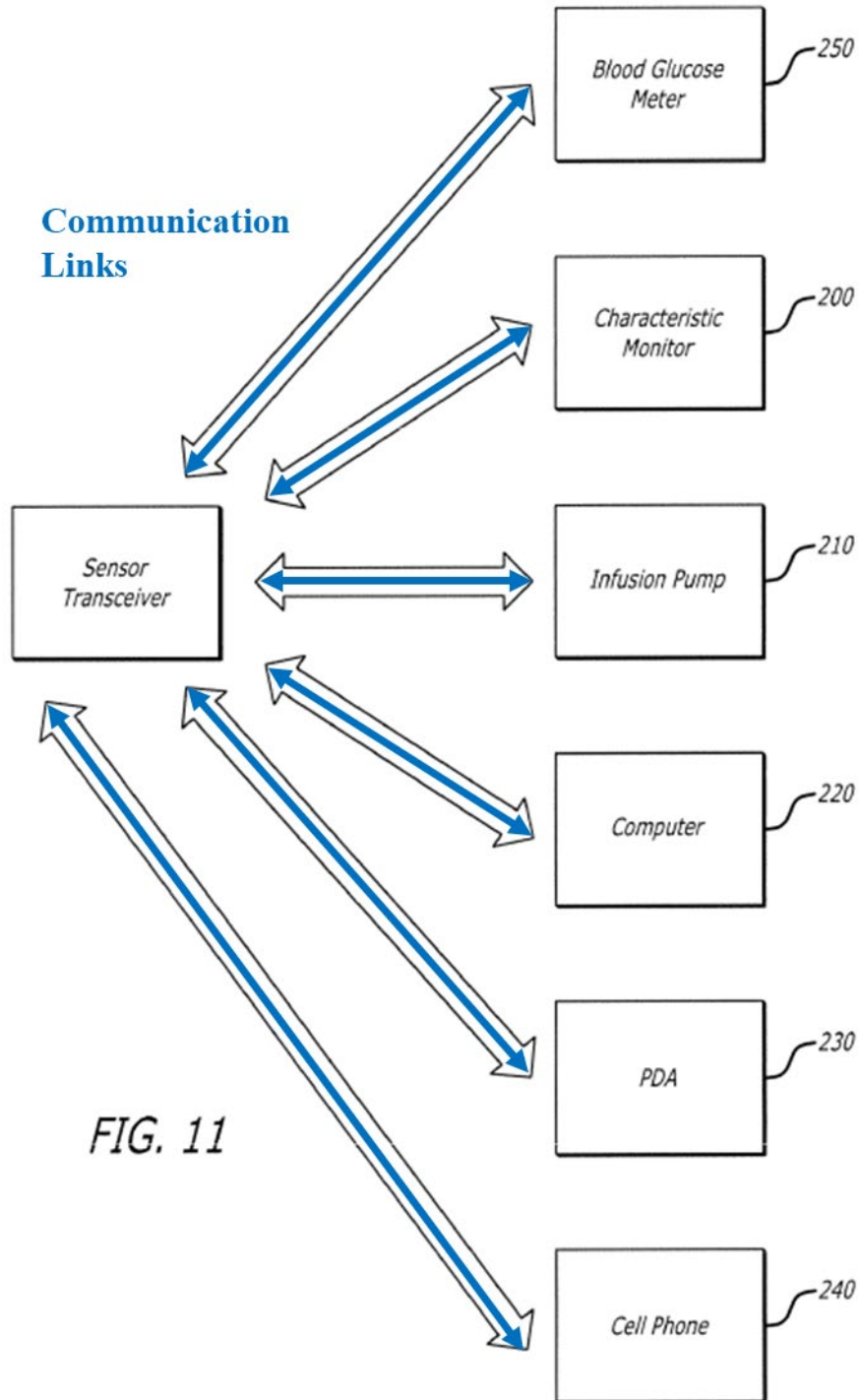
Paradigm® REAL-Time also discloses a calibration algorithm that uses meter blood glucose reference values (i.e., meter BG) to “align[] the glucose sensor ... so that continuous glucose monitoring (CGM) readings are representative of [] blood glucose level.” EX1011, 10, 37, 61-62, 75, 83. Glucose values are calculated following calibration. *Id.*, 61. EX1008, ¶96.

Patel-2009 and Paradigm® REAL-Time each disclose processing sensor signals with calibration data (e.g., reference values) and sensitivity coefficients associated with sensor sensitivity. POSITAs understood that calibration/calculation algorithms of *Patel-2009* and Paradigm® REAL-Time processed sensor readings with “data associated with a sensitivity of the glucose sensor” as calibration data in this context was understood to reflect the sensitivity of the glucose sensor. *See supra* IV.A.2; EX1008, ¶¶40, 54. For example, a 2008 article explained how the “calibration process must be repeated ... to correct for possible sensitivity changes.” EX1047, 2499 (explaining how different devices, including the Medtronic Guardian, updated calibration data throughout sensor life). EX1008, ¶97.

e) [1.E]

transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit; and

Patel-2009 provides that the transceiver transmits calculated glucose values to a monitor and other devices. EX1012, [0008], [0013], [0042], [0076]. The transceiver exchanges information over two-way wireless communication links:



Id., [0076], Fig. 11 (annotated in blue). The rate, frequency, and other attributes of communication links are configured according to configuration data exchanged with remote devices. *Id.*, [0012], [0082]. EX1008, ¶98.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter sends processed “glucose values to the insulin pump” using radio frequency transmission with a six-foot range. EX1011, 8, 23, 51; EX1008, ¶¶99.

POSITAs would have found it obvious to configure Bluetooth communication links in order to extend the compatibility, operating range, and usability of the system via a standardized, well-established wireless communication protocol. EX1008, ¶¶56, 61, 100; *see supra* IV.A.4. For example, Bluetooth would have been chosen for communication with computers, PDAs, and cell phones as disclosed in *Patel-2009*.

f) [1.F]

a receiver unit comprising a processor of the receiver unit, memory of the receiver unit, a radio frequency transceiver of the receiver unit, an antenna, and a display, wherein the receiver unit is configured to: receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data over the Bluetooth wireless communication link,

Patel-2009 discloses transmission of glucose data over two-way communication links to various devices with a display used to display glucose measurements, including infusion pumps, monitors, personal computers, PDAs, and cellular phones. EX1012, [0042], [0066], [0076], Figs. 2, 11; *see also supra* VI.F.1.(e). EX1008, ¶101.

Patel-2009 discloses various receivers that have a processor and receive glucose values with a transceiver and antenna. For example, *Patel-2009* discloses

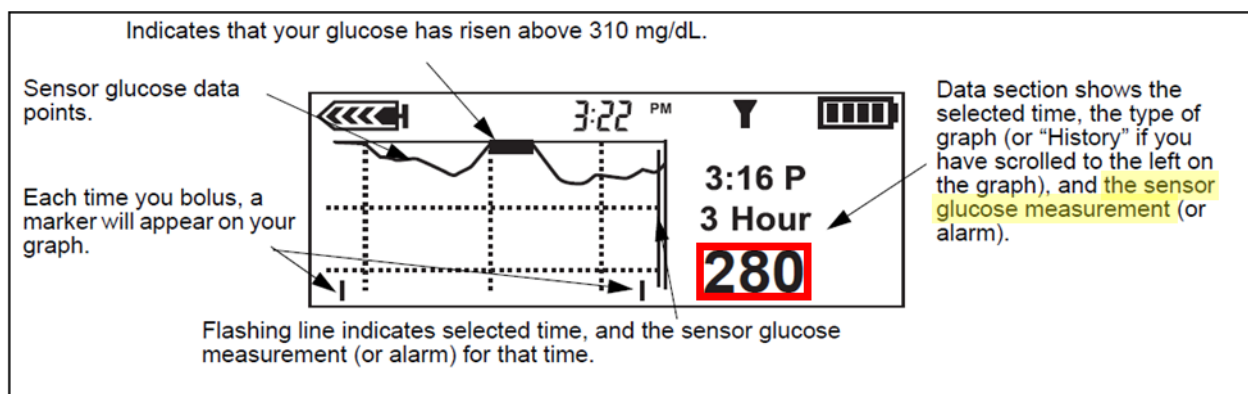
exchanging data with personal computer, personal digital assistant (PDA), or monitor. EX1012, [0043], [0045]. POSITAs would recognize that these devices have a processor and receive communications with an antenna and transceiver. EX1008, ¶¶61, 102; *see also* EX1011, 7-8, 23-26, 37, 43-50, 71 (monitoring device and function disclosed by Paradigm® REAL-Time); *infra* VIII.D.1.(f).

As discussed above, POSITAs would have found it obvious to configure communication links to use Bluetooth. EX1008, ¶¶56, 103-104; *see supra* IV.A.4, VI.F.1.(e).

g) [1.G]

output to the display of the receiver unit, a numerical value representing the processed sensor data,

Paradigm® REAL-Time discloses display of numerical sensor glucose values:



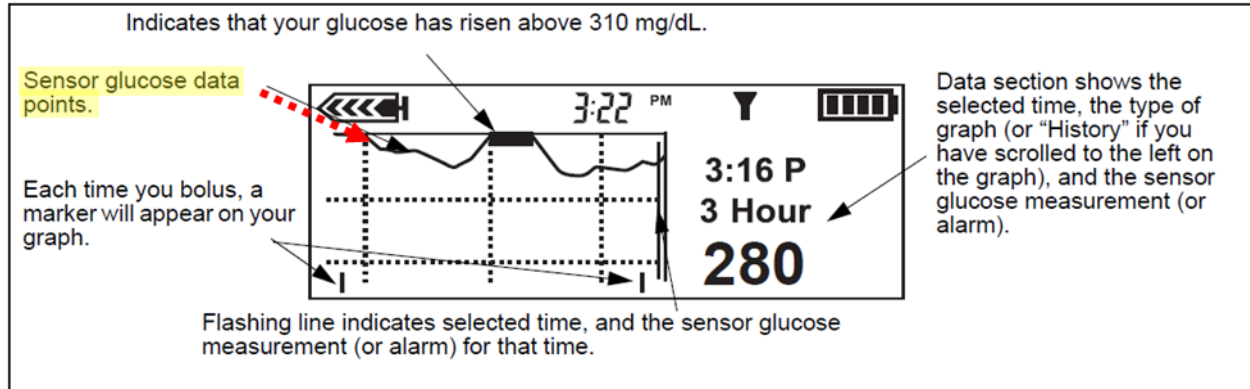
EX1011, 64 (excerpted; annotated in red; highlighted).

Patel-2009 also discloses display of glucose levels. EX1012, [0047], [0066]; EX1008, ¶105.

h) [1.H]

output to the display of the receiver unit, a first line graph that is a substantially continuous depiction of the processed sensor data over time,

Paradigm® REAL-Time discloses display of 3 and 24-hour glucose graphs with average sensor glucose values that update every five minutes:



EX1011, 7, 24, 64-65 (excerpted; annotated in red; highlighted); EX1008, ¶106.

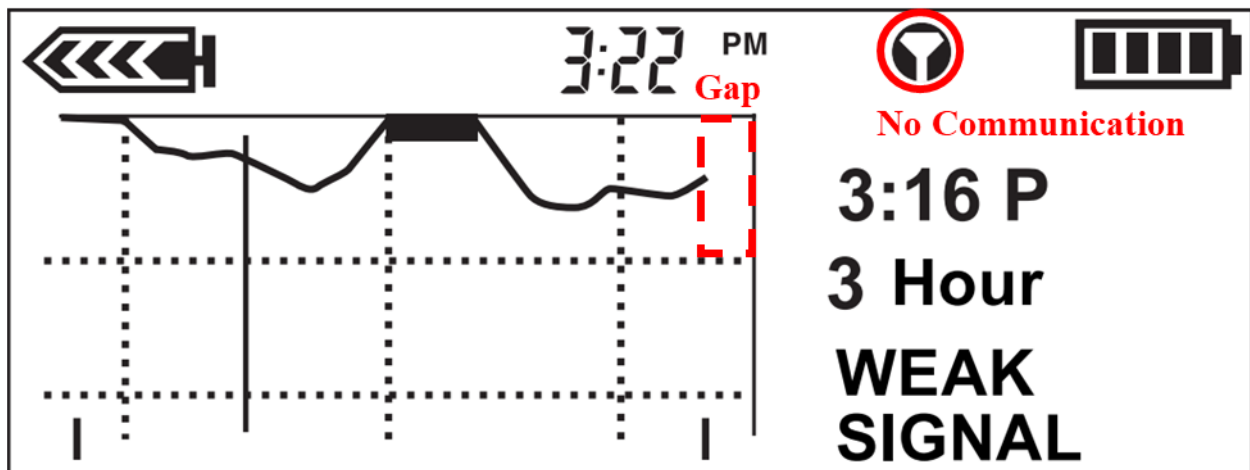
Patel-2009 also discloses display of glucose trends and graphs. EX1012, [0047], [0066]; EX1008, ¶107.

i) [1.I]

wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition;

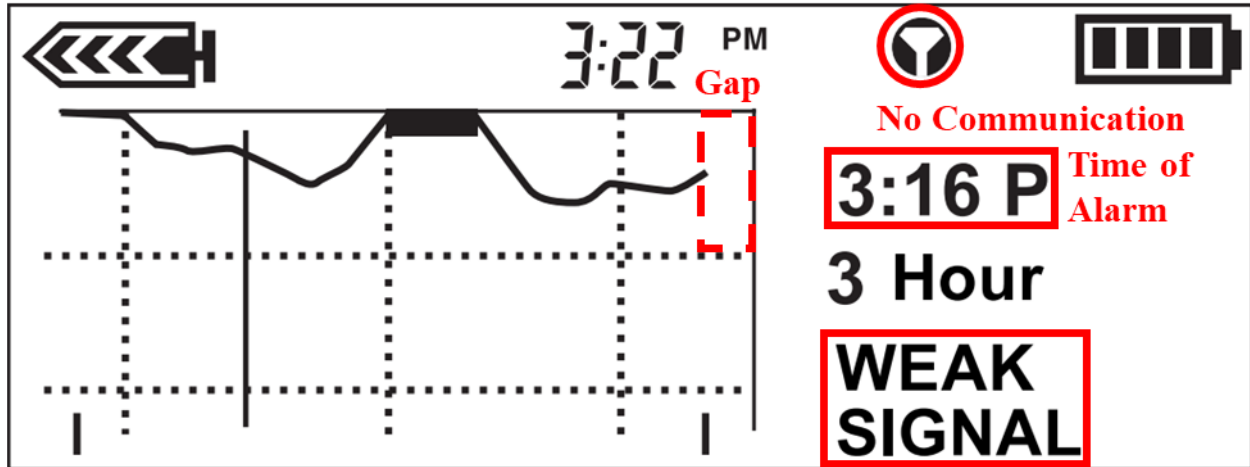
Paradigm® REAL-Time discloses “a sophisticated network of safety checks and systems” that “detects anything unusual” and provides notice of conditions requiring immediate attention, including weak signals and calibration errors. EX1011, 71, 73-76. For example, an (📶) icon changes to an (📶) icon when “the sensor is connected to the transmitter and [was] communicating with the pump” but this communication has been lost. *Id.*, 43. Lost communication causes “failed reception of continuous glucose monitoring (CGM) data.” *Id.*, 8. EX1008, ¶108.

“[W]hen the pump does not receive data,” the graph displays a “data gap:”



EX1011, 8, 73 (excerpted; annotated in red). If failed reception persists for 5-40 minutes as set in Missed Data,³ a “Weak Signal” alarm is triggered and shown on the graph “along with the time of the alarm:”

³ A “Lost Sensor” alarm is triggered after 40 minutes. EX1011, 73.



Id., 8, 49-50, 67, 73 (excerpted; annotated in red). The data gap corresponds with failed reception of glucose data, including the period (e.g., 10 minutes) before a Weak Signal alarm is triggered. *Id.*, 8, 73. EX1008, ¶¶58, 60, 109.

j) [1.J]

wherein, during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit;

Patel-2009 discloses that the transceiver calculates and stores glucose data during failed communication. EX1012, [0086]. EX1008, ¶110.

Paradigm® REAL-Time also discloses that the MiniLink™ Transmitter holds 40-minutes of glucose data in memory when the transmitter and insulin pump are out-of-range. EX1011, 8. EX1008, ¶111.

k) [1.K]

wherein the receiver unit is configured to output to the display, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled, and

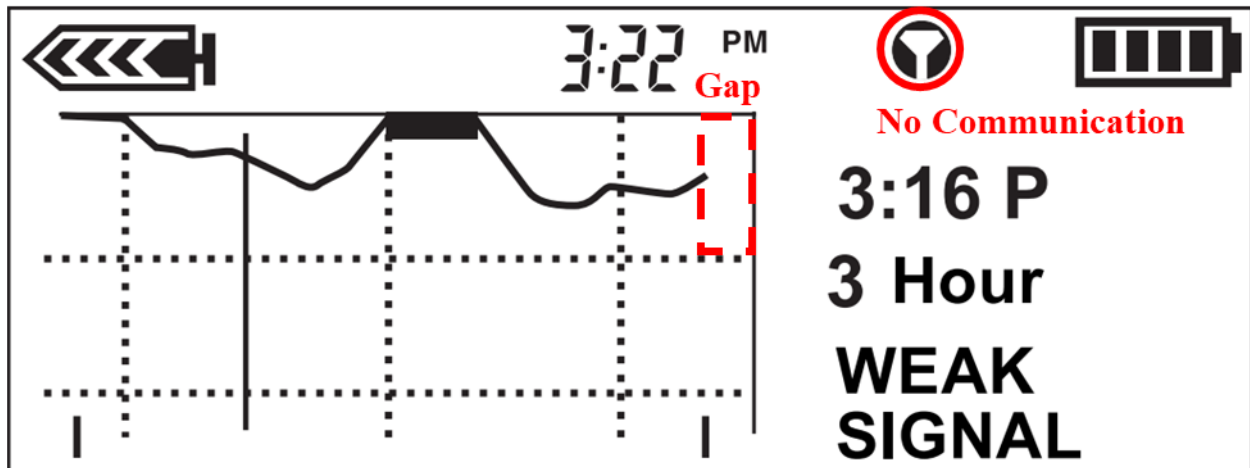
Paradigm® REAL-Time discloses that when the transmitter and insulin pump are out of transmission range, the “transmitter holds 40 minutes worth of memory, so ... continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.” EX1011, 8. If the “[t]ransmitter and insulin pump are out-of-range for longer than 40 minutes, only the last 40 minutes will be re-populated” and a data gap will persist for the remainder. *Id.* Thus, when transmission is out-of-range for less than 40 minutes, gaps in continuous glucose monitoring (CGM) data are entirely re-populated and do not persist in historical graphs. EX1011, 8. EX1008, ¶¶60, 112.

Patel-2009 also discloses that glucose values calculated during failed communication are synchronized from the transceiver to the monitoring device (e.g., infusion pump) when communication is re-established after being lost. EX1012, [0086]. EX1008, ¶¶60, 113.

D) [1.L]

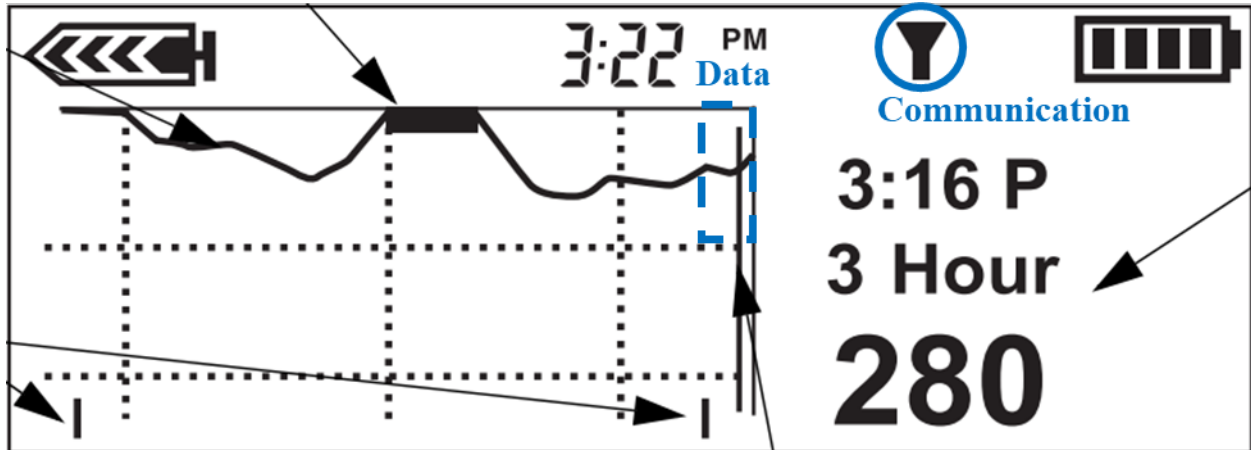
wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition.

Paradigm® REAL-Time illustrates a 3-hour glucose graph with a data gap during “failed reception of sensor data from the transmitter to the pump” while “communication is lost:”

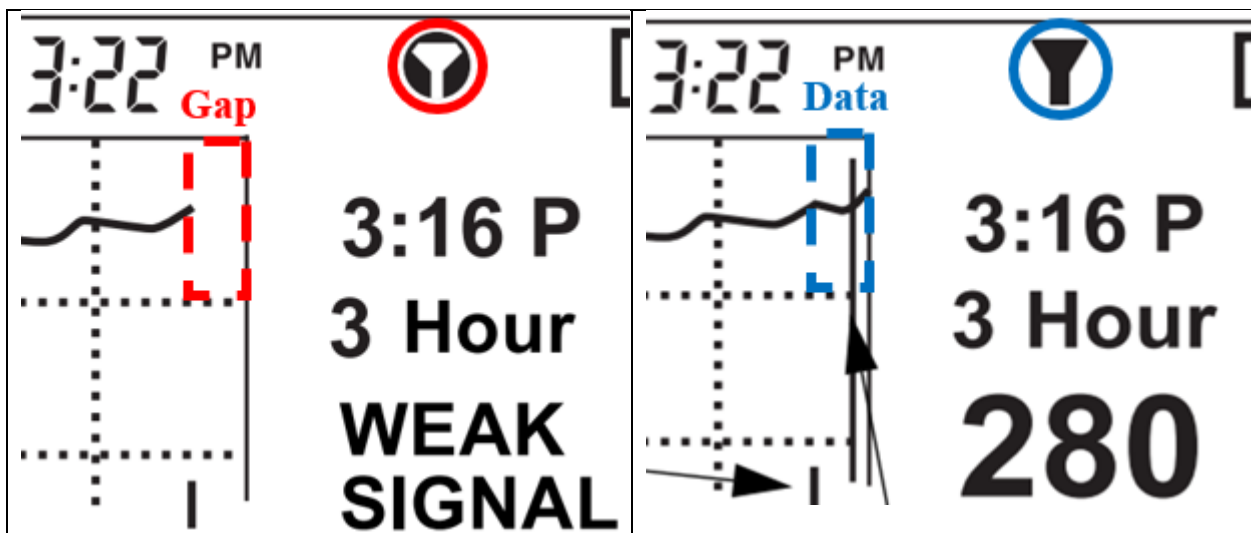


EX1011, 43, 49, 73 (excerpted; annotated in red); *see also supra* VI.F.1.(i). EX1008, ¶114.

A 3-hour graph is also illustrated plotting the same glucose data without a data gap and while the transmitter is communicating with the pump:



EX1011, 43, 64 (excerpted; annotated in blue); *see also supra* VI.F.1.(h). Paradigm® REAL-Time discloses that data gaps in continuous glucose monitoring (CGM) data are re-populated with glucose data stored by the transmitter such that these gaps do not appear in historical graphs. EX1011, 8; *see also supra* VI.F.1.(j)-(k). Comparing these two graphs, POSITAs would recognize that a data gap existing during reception failure is re-populated once communication is re-established:

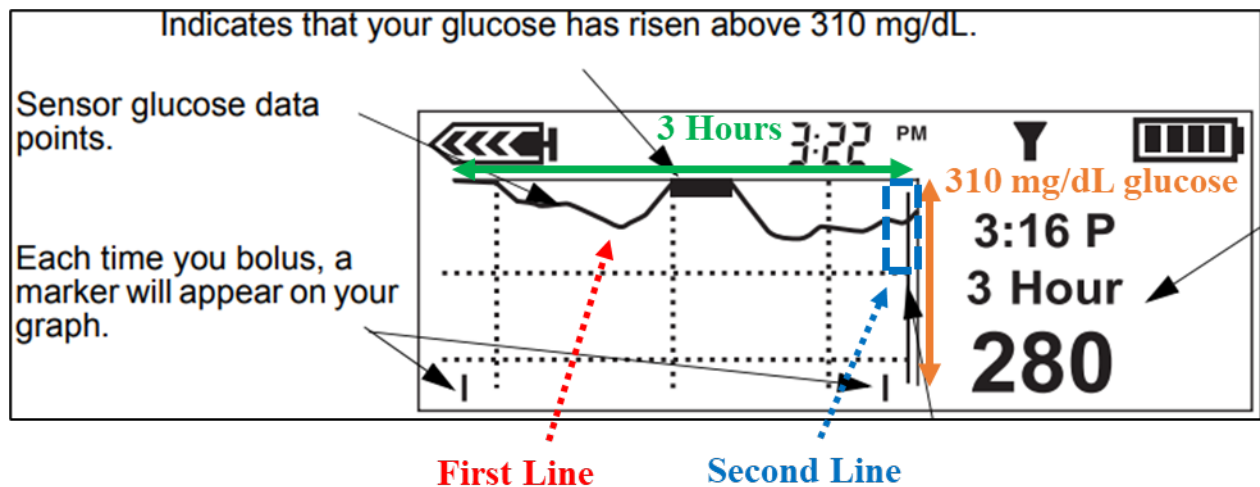


EX1011, 64 (excerpted; annotated in blue), 73 (excerpted; annotated in red). This re-populated data comprises a line from the beginning to the end of the data gap. *Id.*, 64, 73. EX1008, ¶¶60, 115

2. Claim 2

The glucose monitoring system of claim 1, wherein the first line graph and the second line graph are outputted to a same graph comprising a first axis having a time unit of measurement and a second axis having a glucose concentration unit of measurement.

Paradigm® REAL-Time discloses displaying graphs with glucose concentration on the vertical axis against 3 or 24 hours on the horizontal axis:



EX1011, 64 (excerpted; annotated in red, blue, green, orange); *see also supra* VI.F.1.(h). POSITAs would find it obvious to re-populate glucose data (i.e., the second line) to the same graph as original glucose data (i.e., the first line). EX1008, ¶¶60, 116; *see supra* VI.F.1.(k)-(l).

3. Claim 3

The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor communication error.

During glucose monitoring, an () icon indicates a loss of communication between the transmitter and the monitoring device (e.g., a pump with display). EX1011, 43. Communication is lost with both the transmitter and with the sensor. *Id.* Failed reception of glucose data results in a missing data gap and, eventually, a weak signal alarm. *Id.*, 8, 73; *see also supra* VI.F.1.(i). EX1008, ¶117.

Alternatively, if the term “sensor” is used to indicate the glucose sensor and transmitter collectively, a failed communication between the transmitter and the pump is also failed communication with the collective “sensor.” EX1008, ¶118. But if the term “sensor” only indicates the glucose sensor, than *Causey* discloses displaying updated glucose values following faulty or interrupted glucose readings. *See infra* VII.C.1.

4. Claims 5-6

5. The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the data processing and transmitter unit.

6. The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the receiver unit.

During glucose monitoring, an () icon indicates a loss of communication between the transmitter and the monitoring device (e.g., a pump with display).

EX1011, 43. This communication loss causes a missing data gap and, eventually, a Weak Signal alarm indicating “failed reception of sensor data from the transmitter to the pump.” *Id.*, 8, 49, 73; *see also supra* VI.F.1.(i). Paradigm® REAL-Time discloses failed communication when the transmitter and pump (monitoring device) are out of wireless transmission range and when devices (*e.g.*, cell phones, wireless networks) “interfere with [the] transmitter signal.” EX1011, 8, 10, 41. Out-of-range, interference, and other communication failures are associated with both the transmitter (transmission failure) and the pump (reception failure). EX1008, ¶¶58, 60, 119.

Additionally, POSITAs would recognize signal errors associated with either the transmitter or receiver as obvious causes of missing glucose data. EX1008, ¶119.

5. Claim 7

The glucose monitoring system of claim 1, wherein the adverse condition comprises a system malfunction associated with the data processing and transmitter unit or a system malfunction associated with the receiver unit.

Out-of-range, interference, and other problems with communication, transmission, and/or reception are malfunctions that result in missing glucose data. EX1008, ¶¶58, 60, 120; *see supra* VI.F.4.

Additionally, POSITAs would recognize transmitter and receiver malfunctions as an obvious cause of missing glucose data. EX1008, ¶120.

6. Claim 8

The glucose monitoring system of claim 1, wherein the adverse condition comprises an inability of the receiver unit to display or output at least a portion of the first line graph.

Paradigm® REAL-Time discloses displaying a gap when the pump does not receive glucose data (EX1011, 8, 73) because data cannot be displayed unless received. EX1008, ¶¶58, 60, 121; *see also infra* VI.F.9.

Additionally, POSITAs would recognize failed reception of glucose data as an obvious cause of the inability to display this data. EX1008, ¶121.

7. Claim 11

The glucose monitoring system of claim 1, wherein the adverse condition comprises a monitoring system failure condition.

Patel-2009 and Paradigm® REAL-Time both disclose monitoring systems composed of a glucose sensor, transceiver, and monitoring device. *See supra* VI.C-D. Therefore, problems with the sensor, transceiver, and/or monitor that result in failed reception of glucose data are system failures. *See supra* VI.F.3-5. EX1008, ¶¶58, 60, 122.

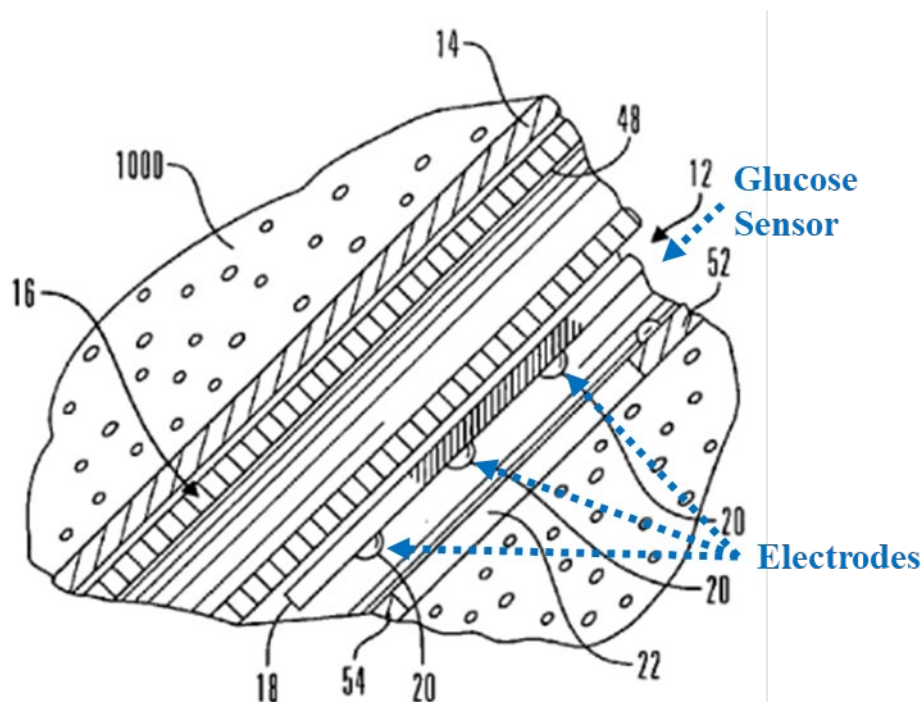
Alternatively, POSITAs would recognize monitoring system failures as an obvious cause of missing glucose data. EX1008, ¶123.

8. Claim 12

The glucose monitoring system of claim 1, wherein the glucose sensor comprises a working electrode and a counter electrode.

Patel-2009 incorporates U.S. Patent 5,391,250 (EX1012, [0006]), which discloses a glucose oxidase working electrode and a counter electrode. EX1048, 5:6-16; *see supra* IV.A.1.

Patel-2009 also discloses an electrode-type sensor 12 with sensor electrodes 20:



EX1012, [0041], [0049], [0051], Fig. 6 (annotated in blue). POSITAs would recognize that electrodes 20 include working and counter electrode. EX1008, ¶124; *see supra* IV.A.1.

9. Claim 17

The glucose monitoring system of claim 1, wherein the adverse condition comprises a data unavailability condition.

Paradigm® REAL-Time discloses that displaying a gap when the pump does not receive glucose data (EX1011, 8, 73) because data is unavailable for display unless received. EX1008, ¶¶58, 60, 125; *see also supra* VI.F.6.

Additionally, POSITAs would recognize failed reception of glucose data as an obvious cause of data unavailability. EX1008, ¶125.

10. Claim 18

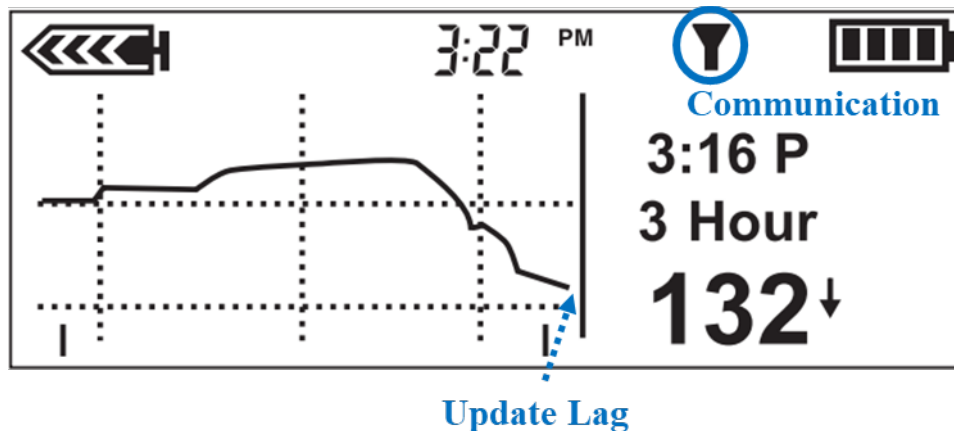
The glucose monitoring system of claim 1, wherein the receiver unit is further configured to display the second line graph immediately after the correction of the adverse condition.

Patel-2009 discloses that glucose data is synchronized from the transceiver to the monitoring device (e.g., infusion pump) “when communication is re-established” after being lost. EX1012, [0086]. POSITAs would have found it obvious to display glucose data when received. EX1008, ¶126.

11. Claim 19

The glucose monitoring system of claim 1, wherein the receiver unit is further configured to wait a predetermined period of time after the correction of the adverse condition before displaying the second line graph.

Paradigm® REAL-Time discloses updating glucose data every five minutes with a five-minute average. EX1011, 7, 24, 83; *see supra* VII.C.1.(h). This results in display of an update lag:



EX1011, 65 (excerpted; annotated in blue). POSITAs would recognize this lag as elapsed time since the most recent five-minute update. EX1008, ¶¶60, 127.

POSITAs would recognize that glucose data re-populated between five-minute updates is not displayed until the next update. EX1008, ¶128. Because updates occur every five minutes, the lag between synchronizing glucose data and Paradigm® REAL-Time's display of re-populated data is pre-determined when failed reception is corrected. EX1008, ¶44.

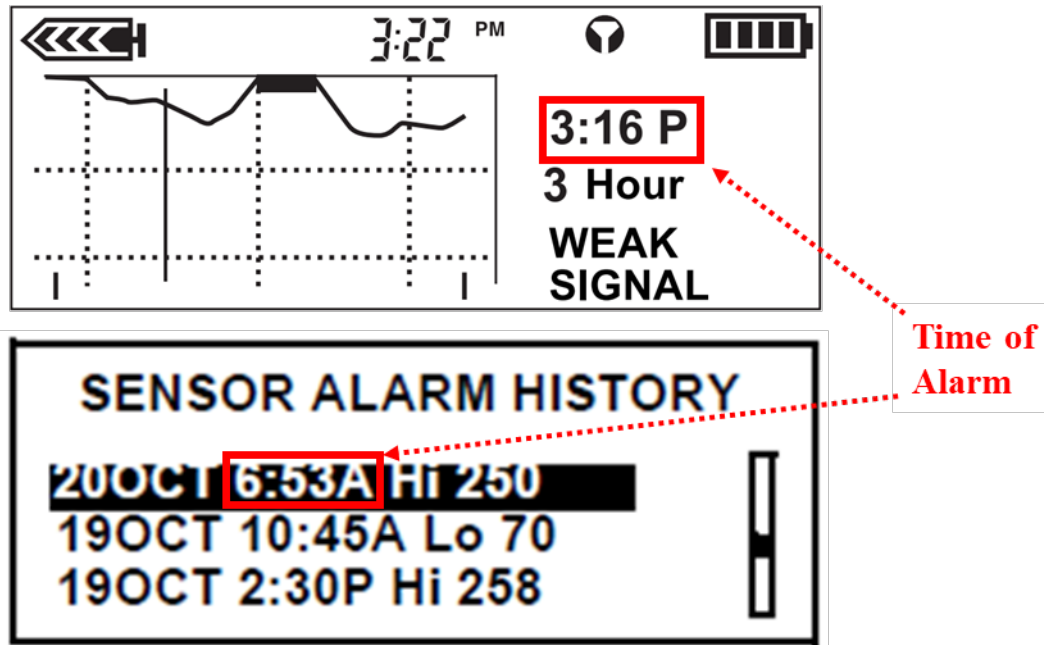
Alternatively, POSITAs would have found it obvious to wait a predetermined time (e.g., 10-minutes, two update cycles) before displaying re-populated glucose data. EX1008, ¶¶44, 60, 129; *see also* EX1008, ¶52 (noting that POSITAs would have consulted with clinicians).

12. Claim 20

The glucose monitoring system of claim 1, wherein the data processing and transmitter unit, the receiver unit, or both is further configured to store time information associated with the adverse condition.

Patel-2009 discloses exchanging glucose history according to a specified time interval. EX1012, [0012], [0084]. For example, glucose values calculated during a loss of communication are stored as glucose history and synchronized when communication is re-established. *Id.*, [0086]. Synchronizing stored glucose data associated with failed communication entails storing the time of failed communication. EX1008, ¶¶60, 130.

As an alternative basis, Paradigm® REAL-Time also discloses a data gap when “reception of sensor data from the transmitter to the pump” fails such that “the pump does not receive data.” EX1011, 8, 73; *see also supra* VI.F.1.(i). Weak signal and lost sensor alarms triggered after a period of time (5-40 minutes) are shown on the graph and saved in sensor alarm history “along with the time of the alarm.”

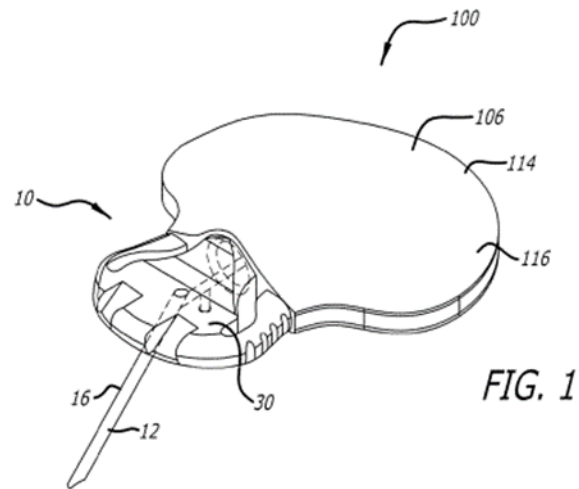


EX1011, 8, 49-50, 67 (excerpted; annotated in red), 73 (excerpted; annotated in red); *see also supra* VII.F.1.(i), n.3. Displaying data gaps and saving alarms associated with failed reception entails storing the time of failed reception. EX1008, ¶¶60, 131.

13. Claim 21

The glucose monitoring system of claim 1, wherein the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing.

Patel-2009 provides that transceiver 100 fits directly onto and is supported by sensor set 10 itself:

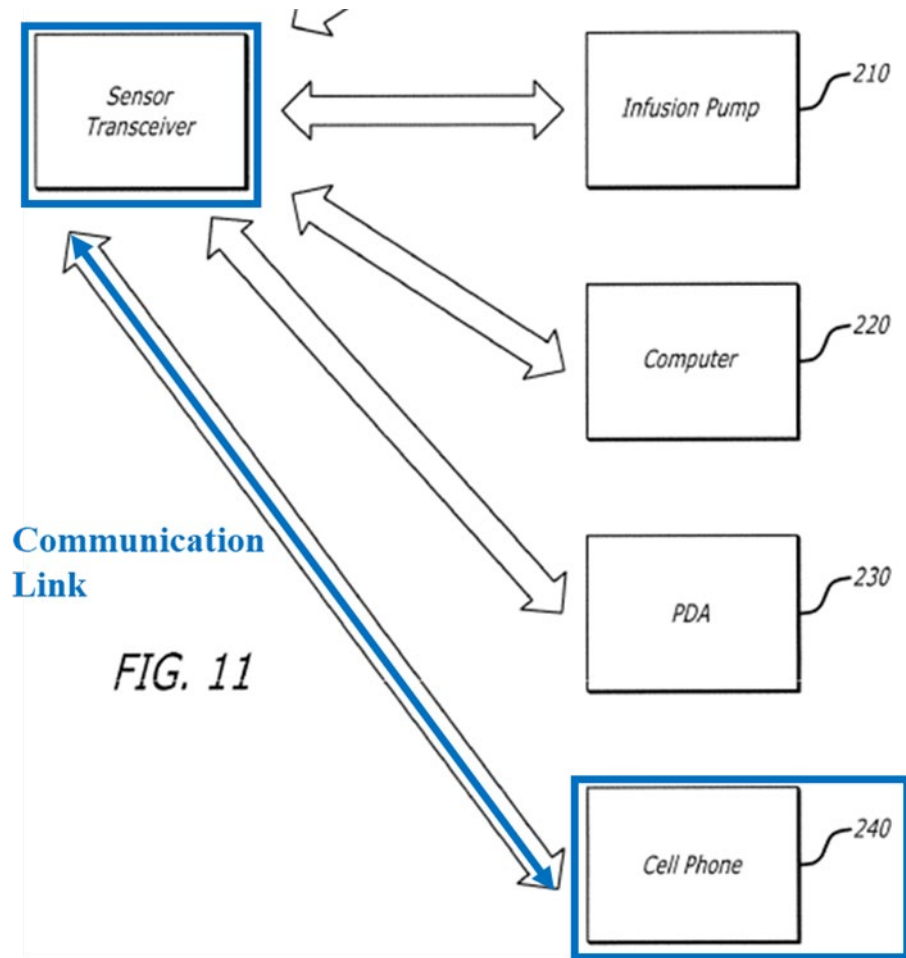


EX1012, [0056], [0059], Figs. 1-2; EX1008, ¶132.

14. Claim 22

The glucose monitoring system of claim 1, wherein the receiver unit comprises a mobile phone.

Patel-2009 discloses that the transceiver maintains two-way communication and sends glucose values to cellular phone 240:



EX1012, [0076], [0079], Fig. 11 (annotated in blue). EX1008, ¶133.

15. Claim 23

The glucose monitoring system of claim 1, wherein the time period associated with the adverse condition comprises at least one hour.

Patel-2009 provides that the transceiver logs calculated glucose values, stores glucose history, and synchronizes glucose data to various devices, including data calculated during communication failure. EX1012, [0047], [0081-83], [0086], Fig. 11. Glucose history encompasses a sensing period of 3-5 days. *Id.*, [0005]. EX1008, ¶¶45, 134.

16. Claim 24

The glucose monitoring system of claim 1, wherein the glucose monitoring system is further configured for periodic calibration, and wherein the calibration data is based at least in part on glucose reference data received after the portion of the glucose sensor has been positioned under the skin of the user.

Paradigm® REAL-Time discloses calibration after the sensor is inserted through the skin, “at least once every 12 hours” (i.e., periodically), using blood glucose reference values. EX1011, 10, 23, 47, 53, 61-62; EX1008, ¶135; *see also supra* VI.F.1.(d).

17. Claim 26

The glucose monitoring system of claim 24, wherein the glucose monitoring system is further configured for calibration twelve hours after the portion of the glucose sensor has been positioned under the skin of the user.

Paradigm® REAL-Time discloses initial calibration two hours after sensor insertion and recommends re-calibration more frequently than every 12 hours (e.g., three times a day). EX1011, 10, 61. A “Cal Reminder” is set as frequently as every 8 hours (i.e., 4 hours before calibration expires), and Paradigm® REAL-Time discloses setting a 2-hour Cal Reminder to request calibration every 10 hours. *Id.*, 47, 99. Re-calibration 10 hours after the 2-hour initial calibration occurs 12 hours after insertion. EX1008, ¶136.

18. Claim 27

The glucose monitoring system of claim 1, wherein the data processing and transmitter unit is configured to transition from a low-power mode to an operating mode, and wherein the data processing and transmitter unit consumes more power from the power supply in the operating mode than in the low-power mode.

Patel-2009 discloses that “the transceiver wakes up from a sleep mode prior to exchanging data” and is activated by circuitry that detects sensor connection, an on/off button, a magnetic swipe procedure, or an ultrasonic signal. EX1012, [0010], [0048], [0061], [0063], [0080]. The transceiver consumes more power when active. *Id.*, [0048], [0061], [0080]. EX1008, ¶137.

19. Claim 28

The glucose monitoring system of claim 1, wherein the power supply of the data processing and transmitter unit is configured to provide power for about three months of continuous operation.

Patel-2009 discloses transceiver batteries that provide power for 3 months to 2 years. EX1012, [0061]; EX1008, ¶138.

20. Claim 30

The glucose monitoring system of claim 1, wherein the glucose sensor is further configured to continuously sample the biological fluid of the user to provide the sensor data.

Patel-2009 discloses that glucose values are calculated and provided on a continuous basis. EX1012, [0039], [0086]; EX1008, ¶139.

Paradigm® REAL-Time also discloses measuring “glucose levels continuously” with a glucose sensor “that continuously measures glucose from [] subcutaneous tissue as an electronic signal.” EX1011, 23, 38; EX1008, ¶140.

VII. GROUND 2: CLAIMS 4, 9-10, 15-16, AND 25 ARE OBVIOUS OVER PATEL-2009 AND PARADIGM® REAL-TIME IN VIEW OF CAUSEY

A. Causey (EX1017)

U.S. Patent 6,641,533 to *Causey* (EX1017) issued on November 4, 2003, and is prior art under at least 35 U.S.C. § 102(b).

Causey discloses a characteristic monitor 2200 that includes display 2208, microprocessor 2216, ROM 2204, and RAM 2206:

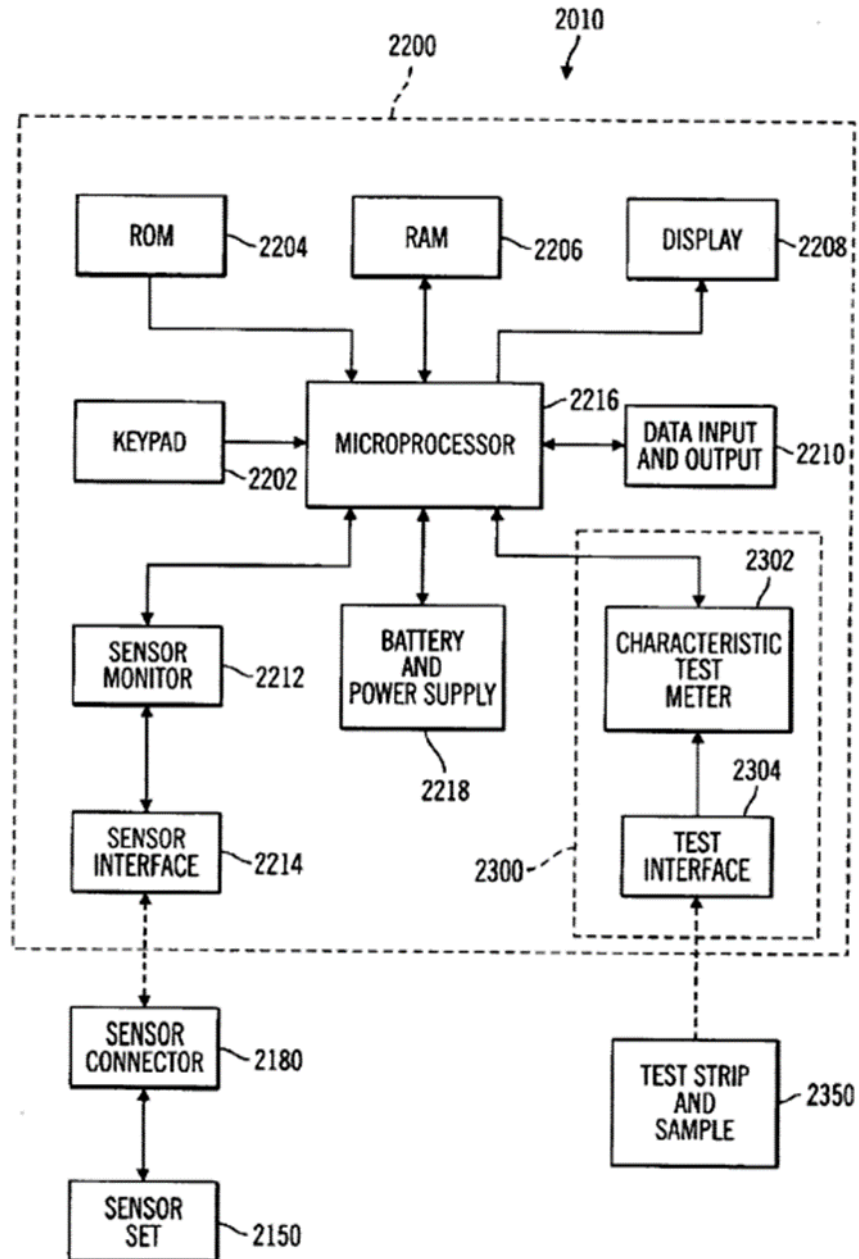


FIG. 30

EX1017, 15:17-25, Fig. 30. The monitor displays measurements received from sensor set 2150 via transmitter 2100:⁴

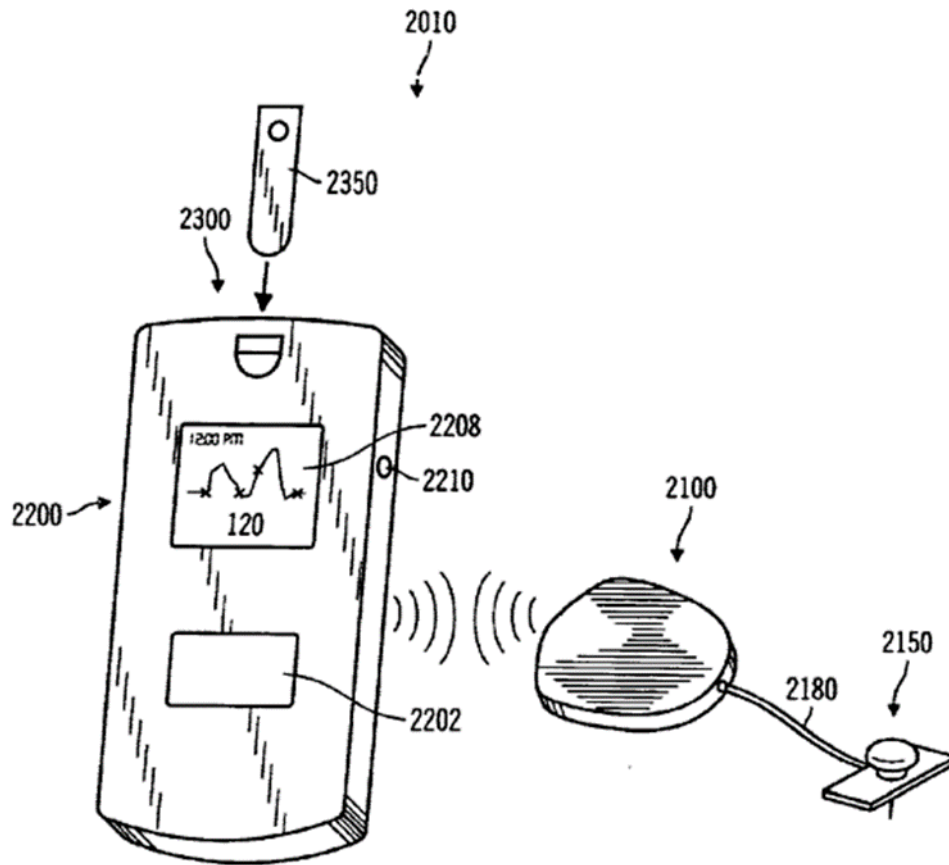


FIG. 31

EX1017, 15:43-47, Fig. 31. Sensor signals are monitored to determine when calibration should be performed or delayed due to sensor instability, rapidly changing glucose readings, extreme glucose values, faulty or interrupted data

⁴ Like *Patel-2009*, *Causey* provides that transmitter 2100 “includes a receiver for remote programming, calibration or data receipt.” EX1017, 14:14-17.

readings, and the like. EX1017, 22:18-45. The sensor monitor and microprocessor are controlled by programs stored in memory. *Id.*, 15:20-25. EX1008, ¶¶142-143.

The monitor displays average glucose levels and graphs of historical data. EX1017, 15:48-55. When the system is calibrated, the monitor updates “data as it was prior to [a] new calibration” (i.e., graphs of historical data) with newly calibrated data showing differences from before to after calibration. *Id.*, 15:59-65. EX1008, ¶144.

B. Combination Of Patel-2009, Paradigm® REAL-Time, And Causey

Causey discloses prompting or delaying calibration based on monitored data and updating graphs of historical glucose data with newly calibrated data. *See supra* VII.A.

Patel-2009 discloses “periodically read[ing] sensor data and run[ning] at least one of a calibration algorithm ... if needed.” EX1012, [0085]. Paradigm® Real-Time discloses “a Meter BG Now alarm when the sensor is ready for calibration.” EX1011, 59. By default, Paradigm® REAL-Time triggers a Meter BG Now alarm after 2 hours of sensor stabilization and every 12 hours thereafter. *Id.*, 61. Paradigm® Real-Time also discloses issuing calibration errors after a meter BG (blood glucose) reference is entered. *Id.*, 75. The addition of *Causey*’s monitoring and calibration programming expands the *Patel-2009/Paradigm* Combination to not only detect calibration errors but also to prompt or delay calibration based on sensor instability,

rapidly changing glucose, glucose level excursions, and faulty or interrupted glucose readings. *Id.*, 71, 75; EX1017, 22:18-45. EX1008, ¶¶145-147

The *Patel*-2009/Paradigm Combination displays a data gap when glucose data is not received and re-populates data gaps when glucose data is synchronized following failed communication. *See supra* VI.E, VI.F.1.(i), VI.F.1.(k)-(l). The addition of *Causey*'s functionality for updating graphs of historical glucose data with newly calibrated data expands the *Patel*-2009/Paradigm Combination to re-populate data gaps resulting from rapid glucose change, sensor instability, and other conditions affecting calibration. EX1017, 15:55-65. EX1008, ¶¶148-149.

1. **Motivation To Combine And Expectation Of Success**

POSITAs implementing the *Patel*-2009/Paradigm Combination to detect rapid glucose change, sensor instability, and other conditions affecting calibration (EX1011, 75) would have wanted to prompt or delay calibration and recalibration such that they occur at optimum times (*e.g.*, when blood glucose is 40-400 mg/dL and not changing rapidly). EX1011, 10, 61-62. *Patel*-2009 discusses advantages of “periodically read[ing] sensor data and run[ning] ... a calibration algorithm.” EX1012, [0085]. Paradigm® REAL-Time discloses a sophisticated detection network, issuance of a BG Now alarm to prompt calibration, and issuance of a calibration error when an entered blood glucose reference cannot be used for calibration. EX1011, 61, 75. Therefore, POSITAs would have been motivated to

incorporate *Causey*'s functionalities to prompt or delay calibration when warranted by sensor data. EX1017, 22:18-45; EX1008, ¶¶58, 60, 150-151.

POSITAs implementing the *Patel*-2009/Paradigm Combination to re-populate data gaps from failed reception would have also wanted to re-populate data gaps from calibration errors. As discussed with the *Patel*-2009/Paradigm Combination, POSITAs would have been motivated to detect missing or inaccurate glucose data and convey as much accurate glucose information as possible without providing inaccurate information. EX1008, ¶59; *see supra* VI.E.1. Therefore, POSITAs would have been motivated to expand the *Patel*-2009/Paradigm Combination to re-populate data gaps resulting from calibration error once the missing glucose data is calibrated as disclosed in *Causey*. EX1017, 15:55-65; EX1008, ¶¶55, 60, 152.

POSITAs would have specifically chosen to combine *Causey* with *Patel*-2009 and Paradigm® REAL-Time because they all relate to Medtronic continuous glucose monitoring systems and incorporate many of the same patents and applications. EX1017, 1:10, 1:57-63; EX1012, [0006], [0050], [0069]; EX1008, ¶¶153-154.

POSITAs would have expected to successfully combine *Causey* with the *Patel*-2009/Paradigm Combination for the same reasons discussed in Ground 1 (*see supra* VI.E.1) and because *Causey* discloses monitor control programs that are

stored in memory. EX1017, 15:20-25. POSITAs would have known how to modify the *Patel*-2009/Paradigm Combination to perform the functions disclosed in *Causey*, for example by modifying the code of *Patel*-2009's monitor or importing programs from *Causey*'s monitor. EX1008, ¶¶56-57, 155.

C. Ground 2 Claim Mappings

As set out below, the *Patel*-2009/Paradigm/*Causey* Combination renders obvious claims 4, 9-10, 14-16, and 25. EX1008, ¶156.

1. Claim 4

The glucose monitoring system of claim 1, wherein the adverse condition comprises a signal error associated with the glucose sensor.

Causey discloses monitoring sensor signals to detect faulty or interrupted glucose readings and prompting or delaying calibration based on these faulty or interrupted readings. EX1017, 22:28-45. When the system is calibrated, graphs of “data as it was prior to [a] new calibration” are updated with newly calibrated data showing differences from before to after calibration. *Id.*, 15:43-65. Thus, when data that was not calibrated and could not be displayed due to faulty or interrupted glucose readings becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 157.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following faulty or interrupted glucose readings and other sensor signal errors. EX1008, ¶158.

2. Claim 9

The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor instability condition.

Causey discloses monitoring sensor signals and delaying calibration until “sensor data readings are relatively stable.” EX1017, 22:28-36. When the system is calibrated, graphs of “data as it was prior to [a] new calibration” are updated with newly calibrated data showing differences from before to after calibration. *Id.*, 15:43-65. Thus, when data that was not calibrated and could not be displayed due to sensor instability becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 159.

Paradigm® REAL-Time also discloses sensor instability as a cause of calibration error. EX1011, 10, 75; EX1008, ¶160.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following sensor instability. EX1008, ¶161.

3. **Claim 10**

The glucose monitoring system of claim 1, wherein the adverse condition comprises a calibration failure condition.

Causey and Paradigm® REAL-Time disclose calibration errors due to sensor stabilization, rapidly changing glucose, blood glucose reference errors, and other conditions. EX1017, 22:28-45; EX1011, 10, 75. *Causey* discloses updating graphs of historical glucose data with newly calibrated data following calibration errors. *See supra* VII.C.2, *infra* VII.C.6-7. Thus, when data that was not calibrated and could not be displayed due to calibration error becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 162.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following calibration error. EX1008, ¶163.

4. **Claim 14**

The glucose monitoring system of claim 1, wherein the on body unit further comprises a temperature sensor, and wherein the adverse condition comprises a temperature measurement outside a predetermined range.

Patel-2009 “incorporate[s] by reference in its entirety” U.S. Patent Application 11/322,568 to Mastrototaro (EX1020). EX1012, [0040]. For the reasons discussed in Ground 3, *Patel*-2009 incorporates *Mastrototaro*’s temperature measurement disclosures (EX1019, [0042]) and would have been combined with

Causey to render obvious delaying calibration until temperature is within range and then displaying new glucose data in historical graphs once calibrated. EX1008, ¶¶59-60, 164-168; *see infra* VIII. B, VII.D.13.

5. Claim 15

The glucose monitoring system of claim 1, wherein the adverse condition comprises an analyte level exceeding a predetermined threshold.

Paradigm® REAL-Time discloses that calibration may only be performed when blood glucose is between 40 and 400 mg/dL. EX1011, 62. *Causey* discloses updating graphs of historical glucose data with newly calibrated data. EX1017, 15:43-65; *see also* 22:28-45 (disclosure of prompting calibration based on glucose excursions). Thus, when data that was not calibrated and could not be displayed due to glucose exceeding 400 mg/dL becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 169.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following glucose levels exceeding 400 mg/dL. EX1008, ¶170.

6. Claim 16

The glucose monitoring system of claim 1, wherein the adverse condition comprises a rate of change of an analyte level exceeding a predetermined threshold.

Paradigm® REAL-Time discloses rapidly changing glucose levels as a cause of calibration error. EX1011, 10, 61, 75. For example, Paradigm® REAL-Time indicates when glucose changes faster than 20 or 40 mg/dL in 20 minutes. *Id.*, 65-66. *Causey* discloses delaying calibration when glucose levels change too rapidly and updating graphs of historical glucose data with newly calibrated data. EX1017, 15:43-65, 22:28-45. Thus, when data that was not calibrated and could not be displayed due to glucose levels changing faster than 20 or 40 mg/dL over 20 minutes (*i.e.*, faster than 1 or 2 mg/dL per minute) becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 171.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following rapidly changing glucose. EX1008, ¶172.

7. Claim 25

The glucose monitoring system of claim 24, wherein the adverse condition comprises a signal error associated with the blood glucose reference data.

Paradigm® REAL-Time provides that blood glucose meter communications are interrupted by signal interference and that inaccurate, incorrect, and erroneous blood glucose readings are a cause of calibration error. EX1011, 10, 12, 41, 75. *Causey* discloses updating historical glucose data with newly calibrated data. EX1017, 15:43-65. Thus, when data that was not calibrated and could not be

displayed due to blood glucose reference signal error (e.g., interruption or interference with blood glucose meter signals) becomes calibrated, this newly calibrated glucose data re-populates historical glucose graphs. EX1008, ¶¶59-60, 173.

Alternatively, POSITAs would have found it obvious to update historical glucose graphs to display missing glucose data calibrated following blood glucose reference signal errors. EX1008, ¶174.

**VIII. GROUND 3: CLAIMS 1-12, 14-18, 20-28, AND 30 ARE OBVIOUS
OVER *PATEL*-2008 AND INCORPORATED REFERENCES**

A. *Patel*-2008 (EX1015)

U.S. Publication 2008/0119705 to Patel (“*Patel*-2008”, EX1015) is prior art under at least 35 U.S.C. § 102(a) and § 102(e) because it published on May 22, 2008, and its U.S. Application 11/931,363 (EX1016) was filed on October 31, 2007 and contains materially identical disclosure.

Patel-2008 teaches a system “for managing diabetes using a consumer electronic device [(“CED”)], including a medical device for taking a physiological reading of a user.” EX1015, [0006]. The medical device is a glucose monitoring device 120, including glucose sensor 130 and transmitter 125 for communicating readings to CED 100 (e.g., PDA/Smartphone):

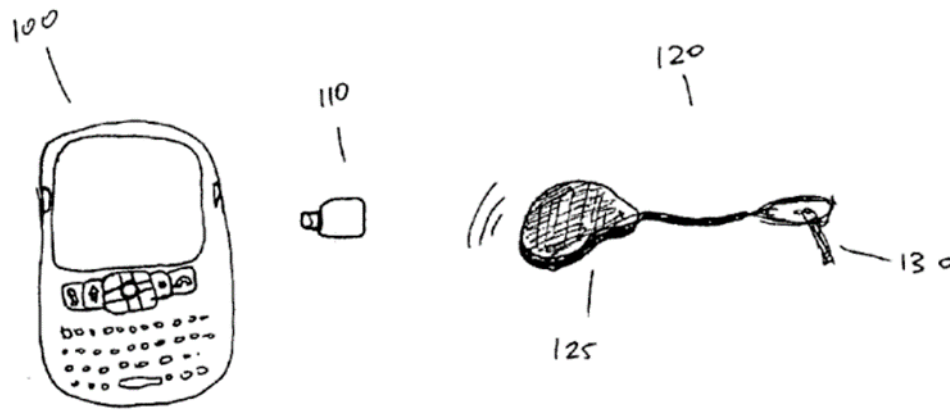
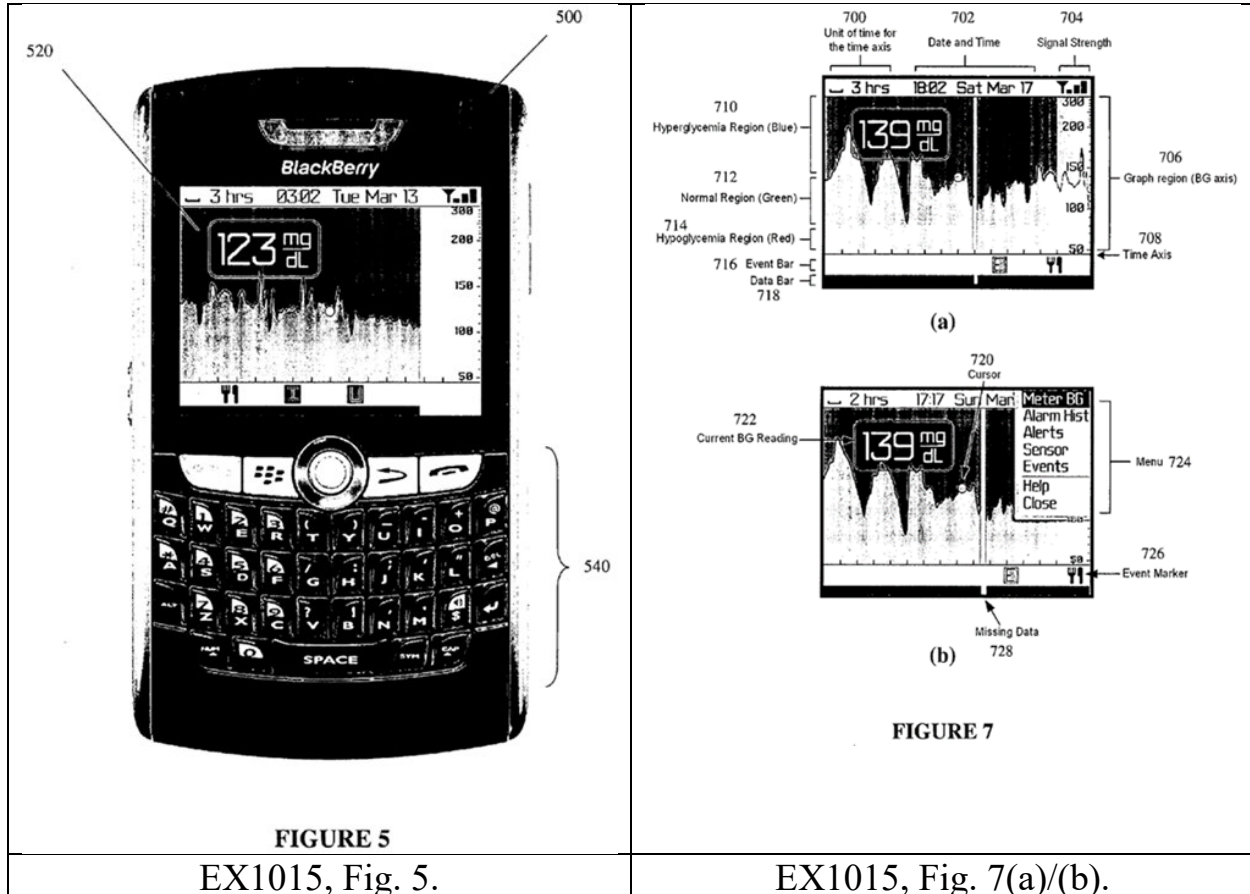


FIGURE 1

Id., [0006], [0033], Fig. 1. The glucose monitoring device and CED use a Bluetooth protocol to communicate directly or through connector 110. *Id.*, [0035], [0045]. *Patel-2008* “specifically incorporate[s] by reference” co-pending Application 11/322,568 to Mastrototaro (EX1020) as describing the glucose monitoring device; co-pending Application 10/335,256 to Shahmirian (EX1022) as describing the connector and “communication solutions;” and *Causey* (EX1017) as describing the CED. EX1015, [0033-35]. EX1008, ¶176.

The diabetes management system disclosed in *Patel-2008* “includes software for managing and processing data obtained by the [glucose monitoring] device.” EX1015, [0006]. This “software-based application includes a graphical user

interface for displaying data to a patient.” *Id.*, [0012]. Software 520 displays blood glucose levels 722, signal strength 704, and missing data 728:



Id., [0052], [0056-57]. EX1008, ¶177.

B. Incorporation Of Mastrototaro, Shahmirian, And Causey

Patel-2008 “specifically incorporate[s] by reference” the Mastrototaro Application (EX1020), the Shahmirian Application (EX1022), and *Causey* (EX1017), which were filed by Medtronic Minimed Inc., and are identified by patent or application number and by title. EX1015, [0033-35]. Both the Federal Circuit and PTAB have found similar language sufficient to incorporate co-pending

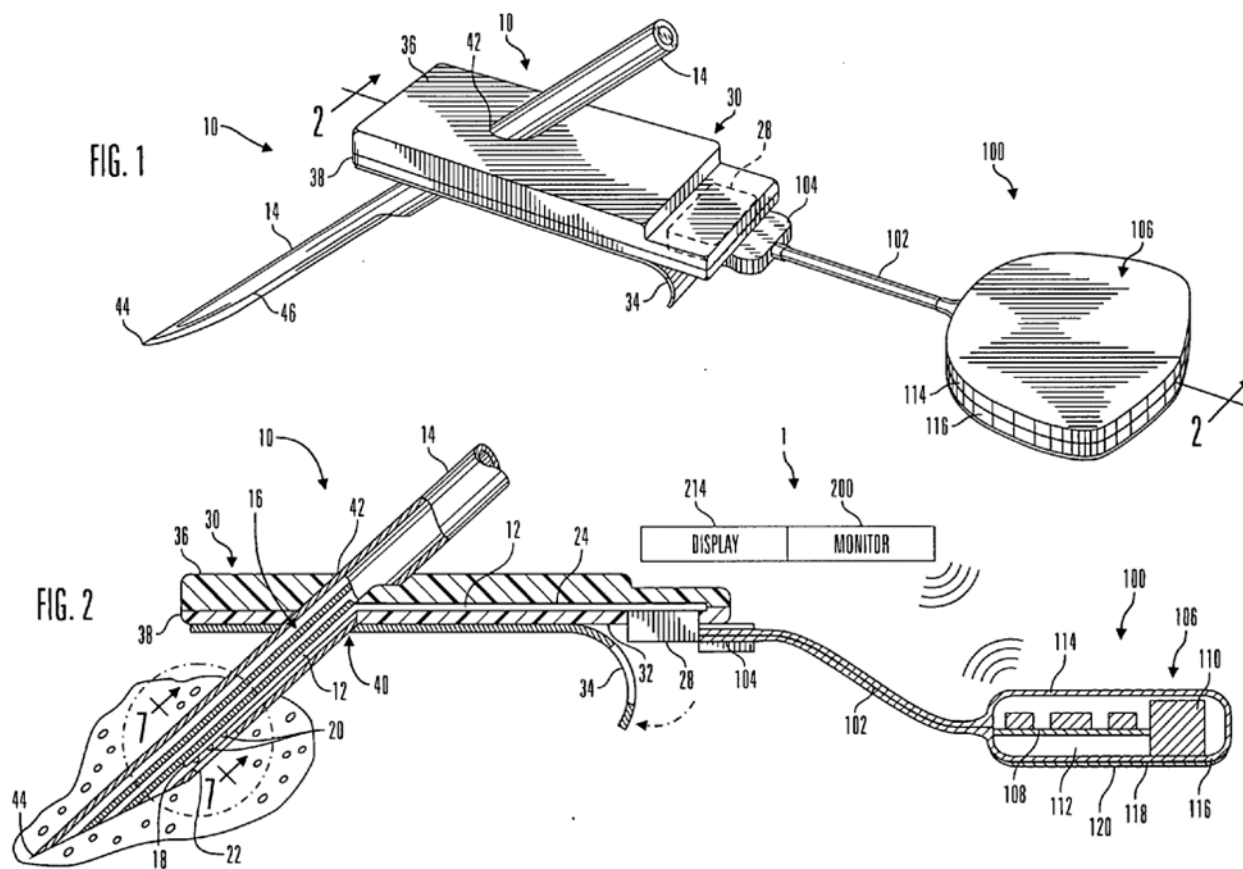
applications. *E.g.*, *Harari v. Lee*, 656 F.3d 1331, 1335 (Fed. Cir. 2011); *Google LLC v. Uniloc 2017 LLC*, IPR2020-00755, Paper 28 at 26-28 (PTAB Oct. 7, 2021) *aff'd*, 2023 WL 2847507 (Fed. Cir. Apr. 10, 2023). Therefore, the disclosures of *Mastrototaro* (EX1019), *Shahmirian* (EX1023), and *Causey* (EX1017) are “effectively part of [*Patel-2008*] as if [they] were explicitly contained therein.” *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018) (internal citation omitted); *see infra* VIII.B.1-2.

1. *Mastrototaro* (EX1019)

U.S. Publication 2006/0202859 to *Mastrototaro*⁵ (EX1019) published from U.S. Application 11/322,568 (EX1020) without amendment on September 14, 2006 (EX1021) and is prior art under at least 35 U.S.C. § 102(b).

Mastrototaro discloses a “telemetered characteristic monitor transmitter coupled to a sensor set,” adapted for use in subcutaneous tissue. EX1019, [0035]. In one embodiment, sensor set 10 and transmitter 100 are connected by cable 102 with a sensor connector 104:

⁵ *Mastrototaro* Publication 2006/0202859 has substantively identical disclosures to *Mastrototaro* Application 11/322,568. EX1008, ¶181. For convenience, the Petition cites to the *Mastrototaro* publication. *See Google* IPR2020-00755, Paper 28, at 27-28.



Id., [0043], [0050], Figs. 1-2. The transmitter has a printed circuit board 108, batteries 110, antenna 112, sensor interface 122, and timers 126:

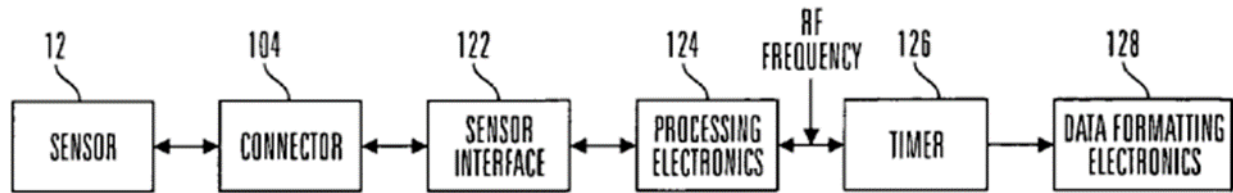
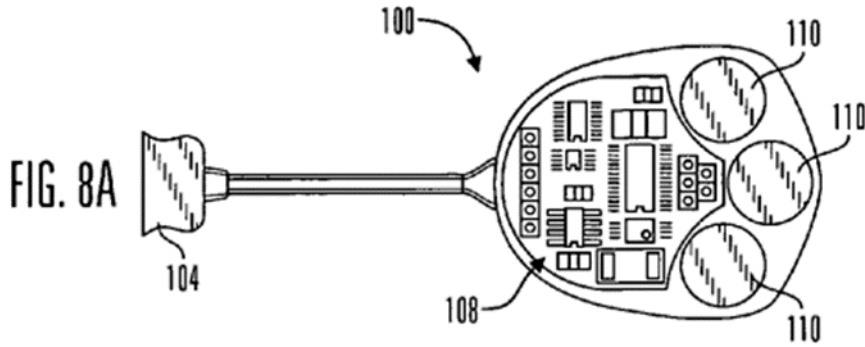
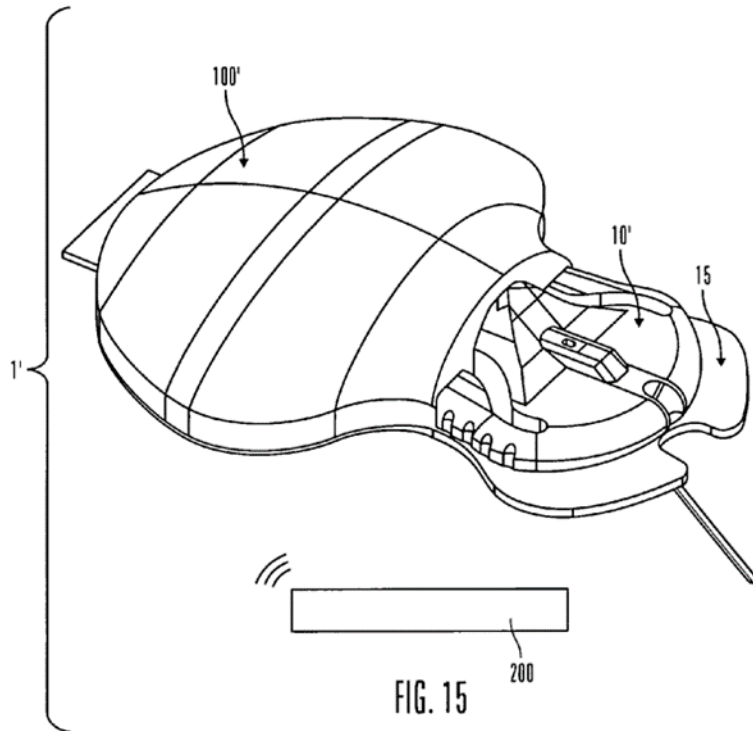


FIG. 8B

Id., [0051], [0054], Fig. 8(a)/(b). *Mastrototaro* also discloses sensor interface 122 connected directly to sensor 12 without a cable 102 or connector 104. *Id.*, [0050], [0054]. For example, transmitter 100' is directly connected to sensor set 10':



Id., [0050], [0054], Fig. 15. The printed circuit board has processing electronics 124 and formatting electronics 128. *Id.*, [0054]. For example, a circuit board with Microprocessor 1120, EEPROM 1126, RF Transceiver 1128, and battery 1130:

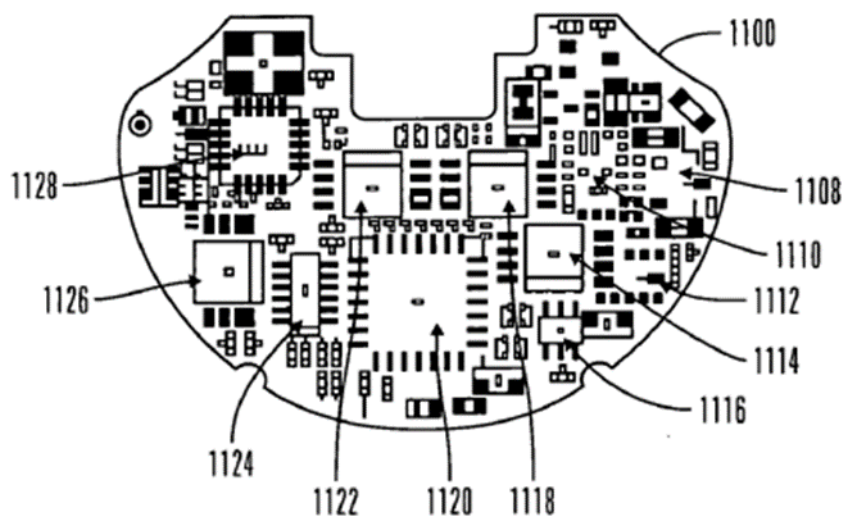


FIG. 19

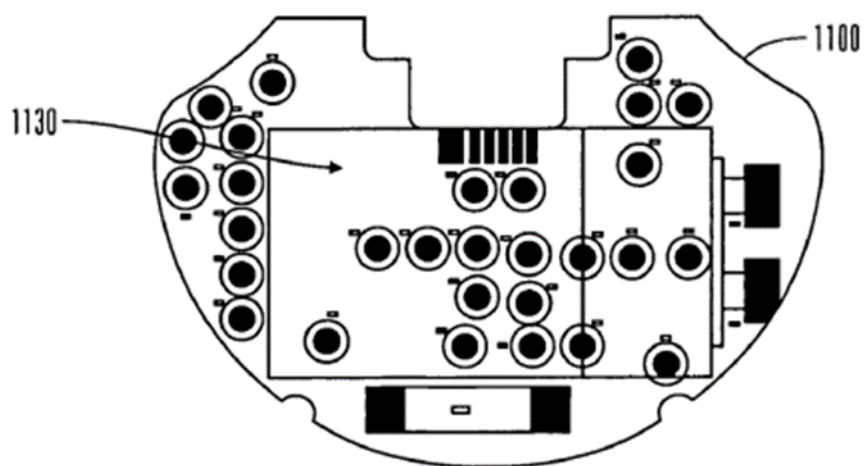


FIG. 20

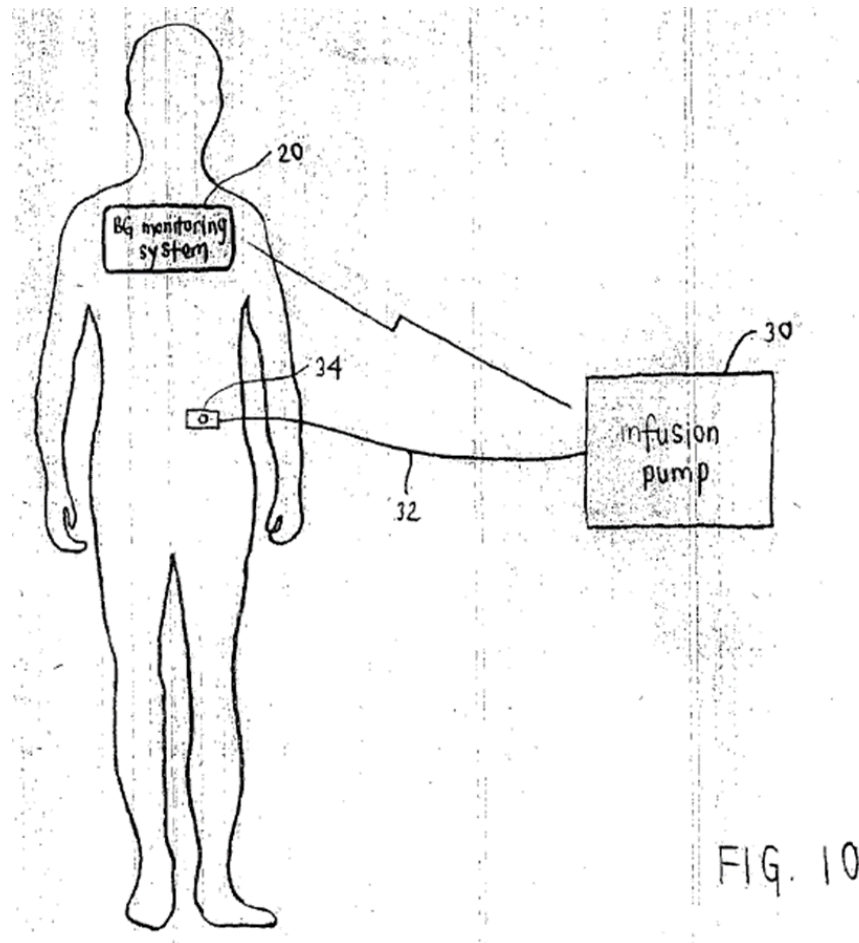
Id., [0054], Figs. 19-20. EX1008, ¶182.

2. **Shahmirian (EX1023)**

U.S. Publication 2004/0122353 to *Shahmirian*⁶ (EX1023) published from U.S. Application 10/335,256 (EX1022) without amendment on June 24, 2004 (EX1024) and is prior art under at least 35 U.S.C. § 102(b).

Shahmirian discloses a “BG (“Blood Glucose”) monitoring system 20 [that] communicate[s] with [an] infusion pump 30 using wireless modes of communication, such as radio frequency.”

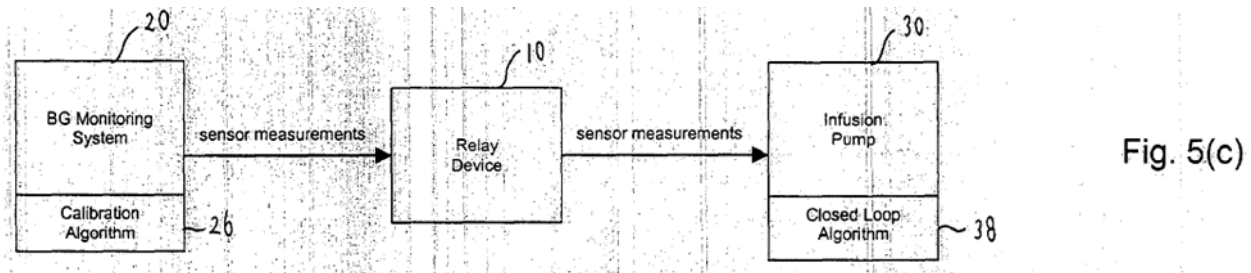
⁶ Like *Mastrototaro*, the Petition cites to *Shahmirian* publication 2004/0122353, which has substantively identical disclosure to *Shahmirian* application 10/335,256. EX1008, ¶185; *see also supra* n.5.



EX1023, [0081], Fig. 10. The infusion pump incorporates a relay device (e.g., transmitter and/or receiver) capable of both receiving and transmitting communications with the monitoring system in various formats, frequencies, and communication protocols—including Bluetooth. *Id.*, [0068], [0081], [0089]. EX1008, ¶186.

Shahmirian discloses bi-directional communication flowing between BG monitoring system 20 and infusion pump 30. EX1023, [0111]. These communications include transmission of sensor measurements processed by

calibration algorithm 26, which “resides with and is executed by the processor of the BG monitoring system 20 ... as shown in FIG. 5(c),” from the monitoring system (i.e., glucose sensor and transmitter) to infusion pump 30:

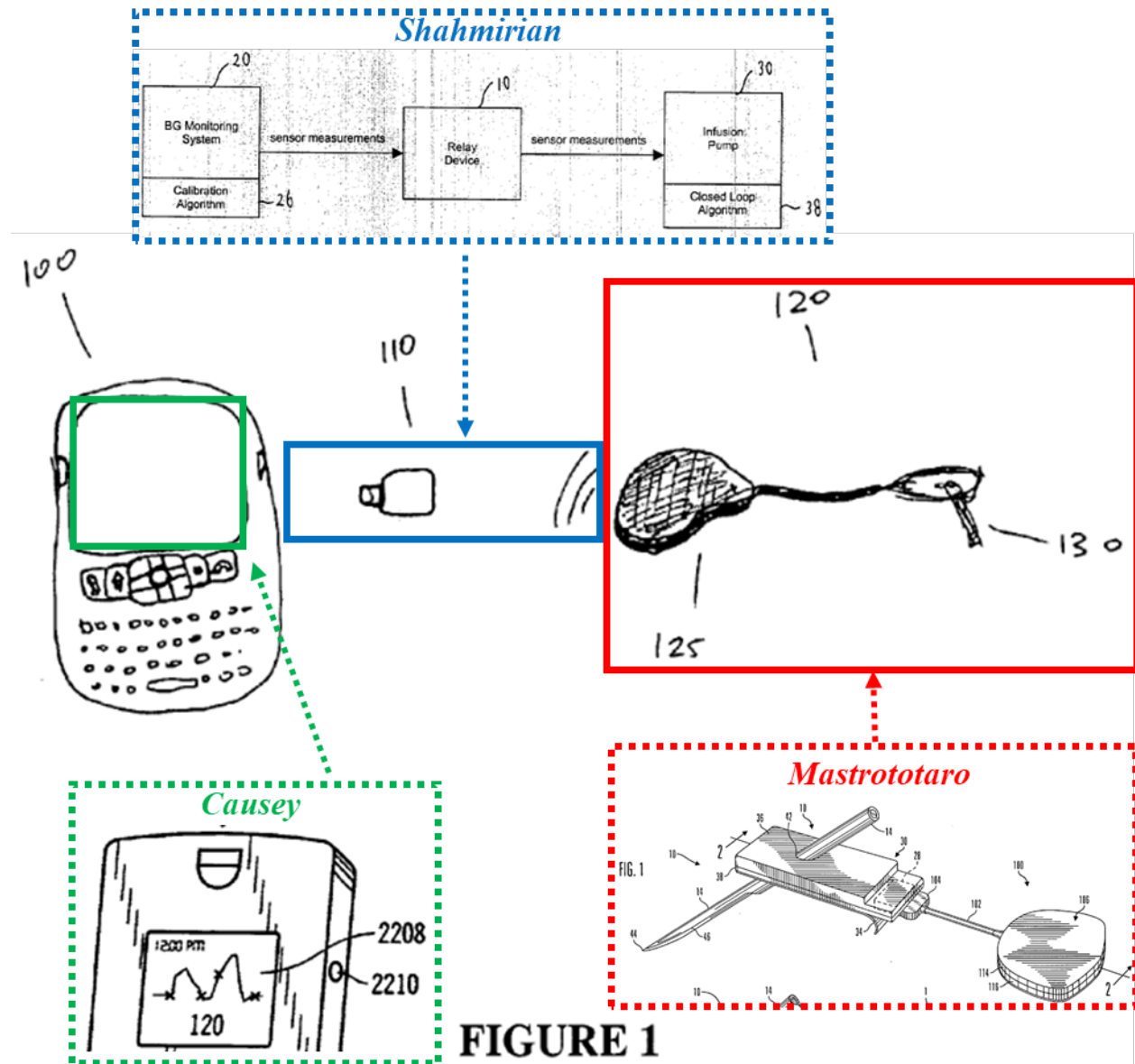


Id., [0106], Fig. 5(c). Communications also include signals from infusion pump 30 to BG monitoring system 20, including to “request information ... verify receipt of information, [and] echo information received.” *Id.*, [0111]. For example, “the infusion pump 30 indicates to the BG monitoring system 20 the most recent sensor data that the infusion pump 30 has received, and in response, the BG monitoring system 20 sends any additional sensor data that the BG monitoring system 20 has that has not been received by the infusion pump 30.” *Id.*, [0103]. The monitoring system stores raw glucose data and calibrated glucose measurements in memory. *Id.*, [0063]. EX1008, ¶187.

C. Combination, Motivation To Combine, And Expectation Of Success

Disclosures of *Mastrototaro*, *Shahmirian*, and *Causey* are incorporated into and are effectively part of *Patel-2008*. See *supra* VIII.B.

Alternatively, POSITAs would have been motivated to integrate the glucose sensor and transmitter in *Mastrototaro*, bi-directional communications of *Shahmirian*, and monitoring/display functionalities of *Causey* as expressly incorporated into the diabetes management system of *Patel-2008*:



EX1015, [0033-35], Fig. 1 (annotated in blue, green, red); EX1017, Fig. 31 (annotated in green); EX1019, Fig. 1 (annotated in red); EX1023, Fig. 5(c)

(annotated in blue). POSITAs would have been motivated to combine *Mastrototaro*, *Shahmirian*, and *Causey* with *Patel*-2008 because each is a Medtronic MiniMed continuous glucose monitoring component referenced by citation. *See Mastercard Int’l Inc. v. Stambler*, CBM2015-00044, Paper 32 at 35 (PTAB July 6, 2016) (citations support motivation to combine). *Patel*-2008 expressly states that “glucose monitoring device 120 ... [is] of the type described” in *Mastrototaro*, discusses communication protocols (including Bluetooth) associated with connector 110 of the type described in *Shahmirian*, and provides that CED 100 includes various PDA/Smartphones and other devices of the type described in *Causey*. EX1015, [0033-35]. EX1008, ¶190-192.

POSITAs would have expected to successfully combine *Mastrototaro*, *Shahmirian*, and *Causey* with *Patel*-2008 because each relates to components incorporated into the diabetes management system of *Patel*-2008. EX1015, [0033-35]; *see supra* VIII.B. POSITAs would have known how to program the CED of *Patel*-2008 to communicate with the telemetered transmitter of *Mastrototaro* using the bi-directional communications of *Shahmirian* over the Bluetooth connection disclosed in *Patel*-2008. Likewise, POSITAs would have known how to program the CED of *Patel*-2008 to perform the monitoring and display functions disclosed in *Causey*. *See supra* VII.B.1. EX1008, ¶¶56-57, 193.

D. Ground 3 Claim Mappings⁷

As set out below, *Patel-2008*, *Mastrototaro*, *Shahmirian*, *Causey* and their Combination disclose or render obvious each element of claims 1-12, 14-18, 20-28, and 30. EX1008, ¶194.

1. Claim 1

a) [1.A] (preamble)

If the preamble is limiting, *Patel-2008* discloses a diabetes management system composed of a glucose monitoring device and a CED that displays a graph of glucose levels. EX1015, [0006], [0033], [0052], [0056]. This graph shows a gap when no glucose data is received:

⁷ Claim language is recited in Grounds 1 and 2 (*supra* VI.F, VII.C) and EX1049.

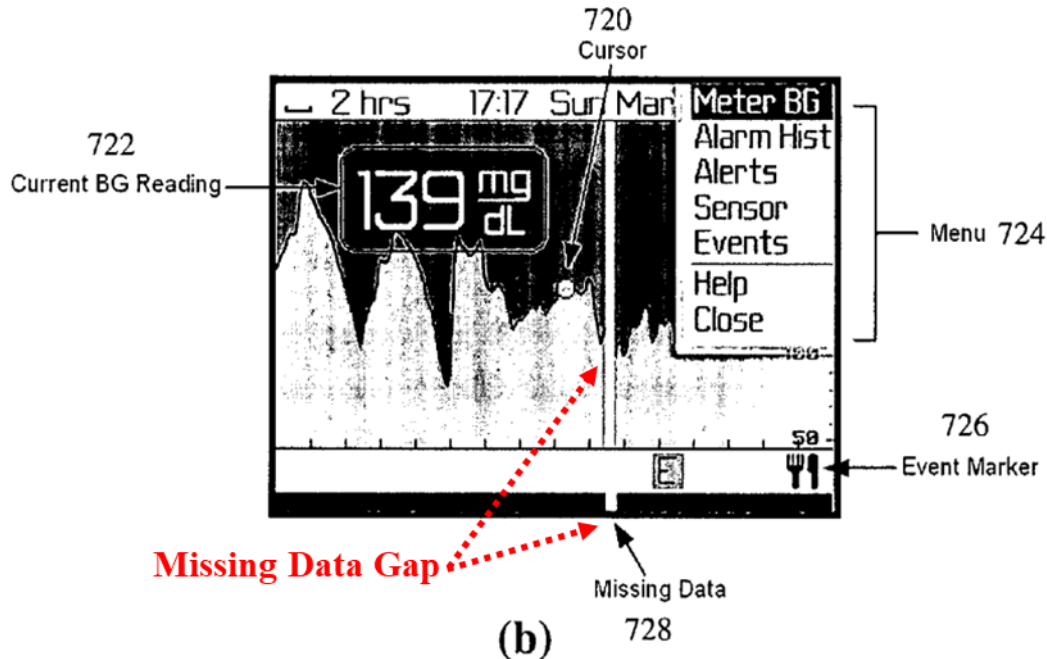


FIGURE 7

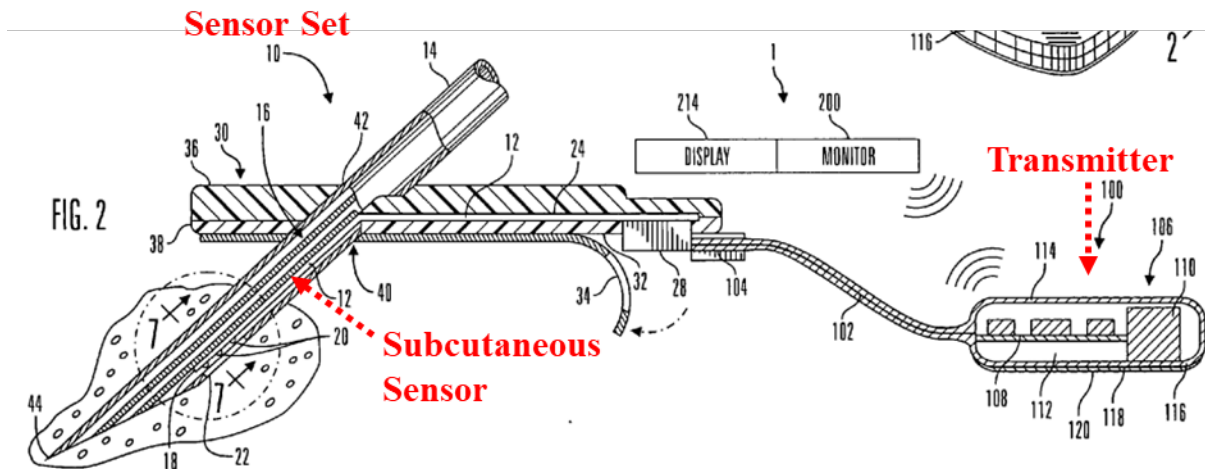
Id., [0057], Fig. 7(b) (annotated in red). EX1008, ¶195.

Shahmirian discloses storing raw and calibrated glucose data in memory of the BG monitoring system (e.g., glucose sensor and transmitter), retransmitting any sensor measurements not received by an insulin pump monitor, and displaying received measurements. *See infra* VIII.D.1.(j)-(k). EX1008, ¶196.

Therefore, POSITAs would have found it obvious to re-populate data gaps with retransmitted glucose data. *See infra* VIII.D.1.(l). EX1008, ¶197.

b) [1.B]

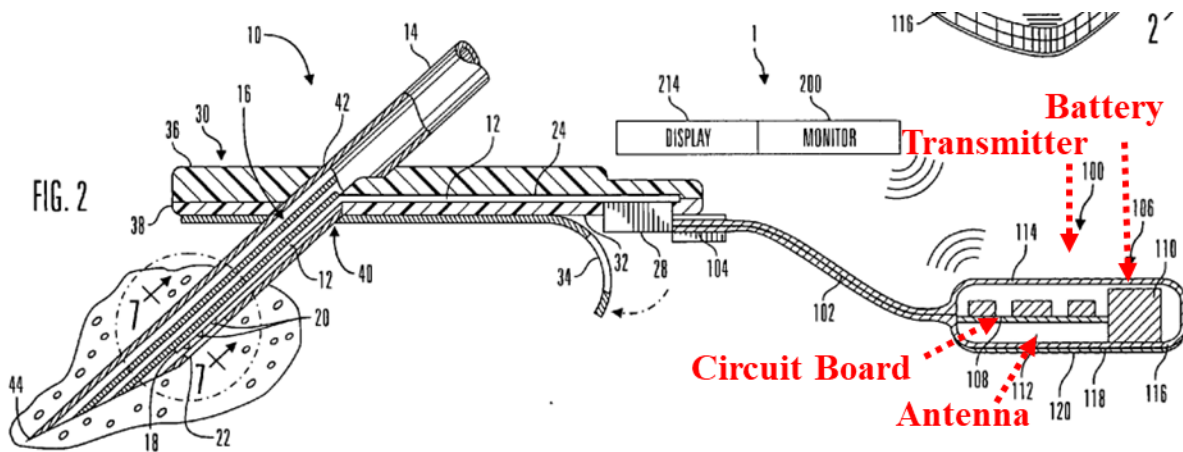
Mastrototaro discloses that subcutaneous sensor 12 of sensor set 10 exposes electrodes 20 to the user's bodily fluids:



EX1019, [0043], Fig. 2 (annotated in red). The sensor produces signals indicative of glucose concentration. *Id.*, [0007], [0041]. EX1008, ¶198.

c) [1.C]

Mastrototaro discloses transmitter 100 coupled to sensor set 10 by cable 102:



EX1019, [0050], Fig. 2 (annotated in red). Transmitter 100 includes printed circuit board 108, batteries 110, antenna 112, sensor interface 122, processing electronics 124, timers 126, and data formatting electronics 128. *Id.*, [0051] [0054].

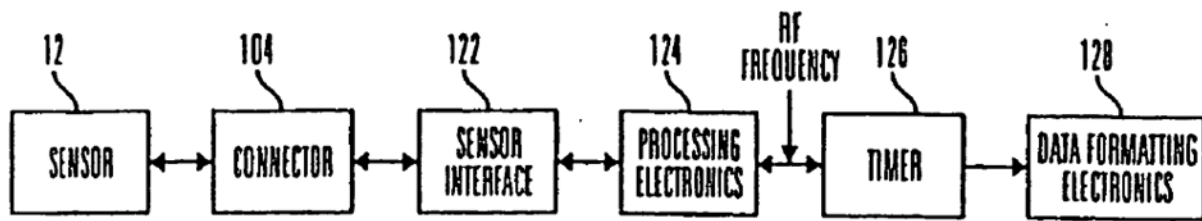
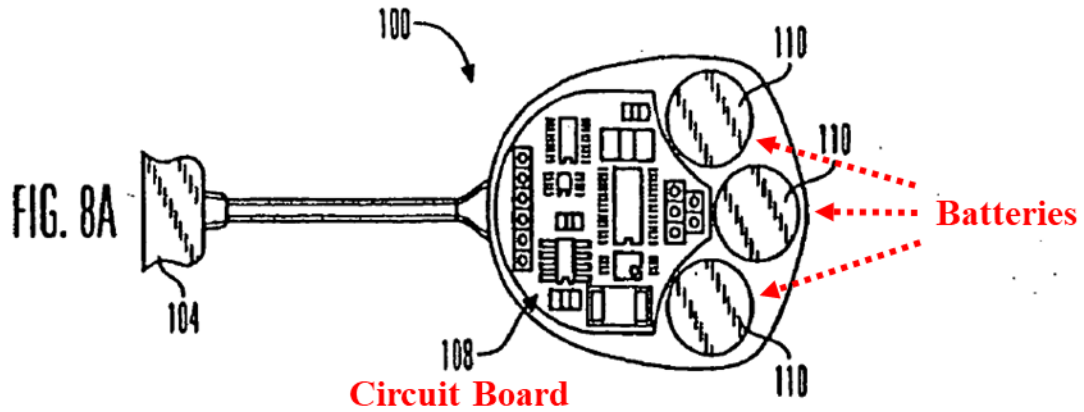
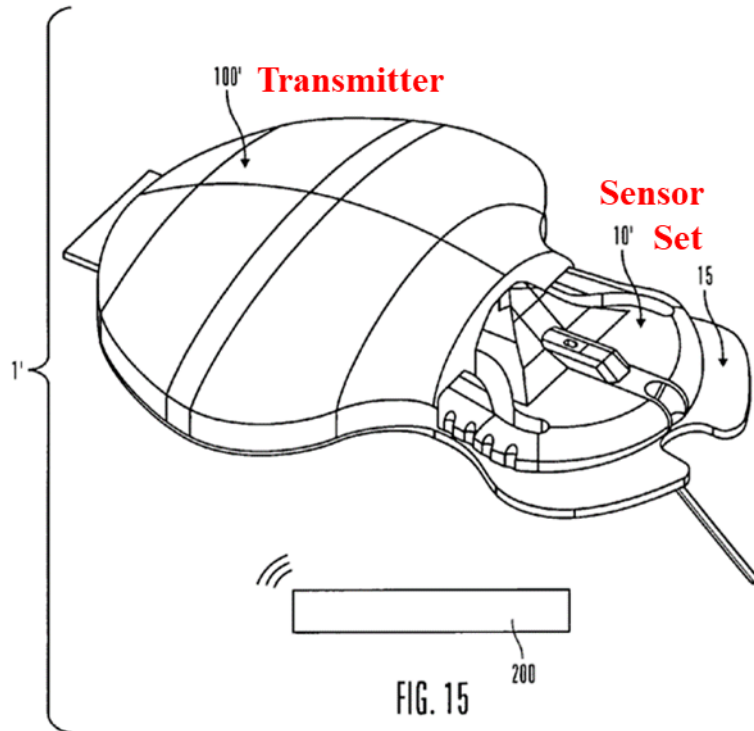


FIG. 8B

Id., Figs. 8(A)/(B) (annotated in red). *Mastrototaro* also discloses transmitter 100' and sensor set 10' modified for direct connection without a cable:



Id., [0050], Fig. 15 (annotated in red). Transmitter 100' includes a printed circuit board with microprocessor 1120, EEPROM 1126, RF Transceiver 1128, and battery 1130:

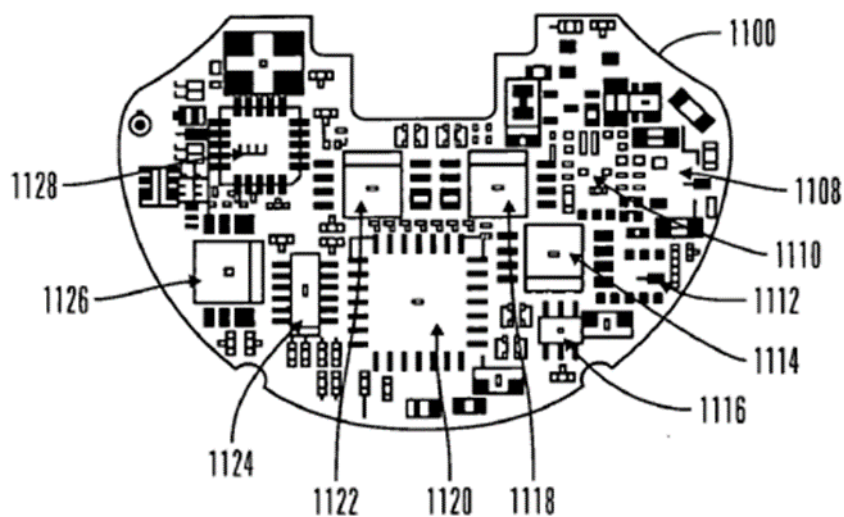


FIG. 19

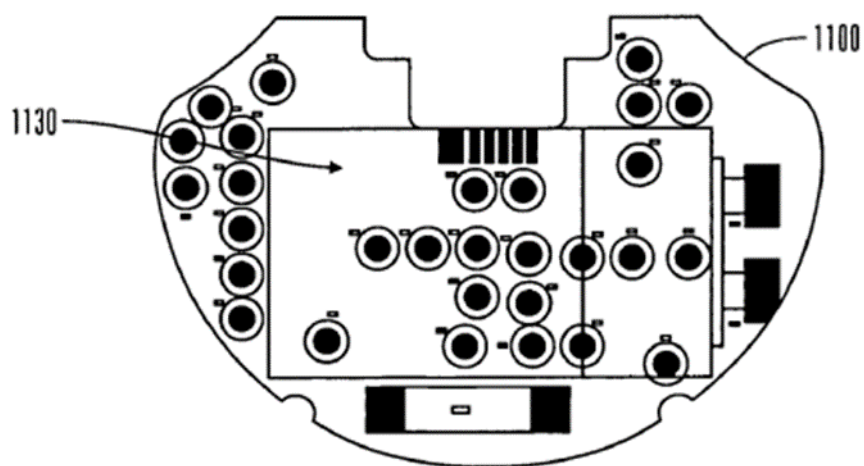
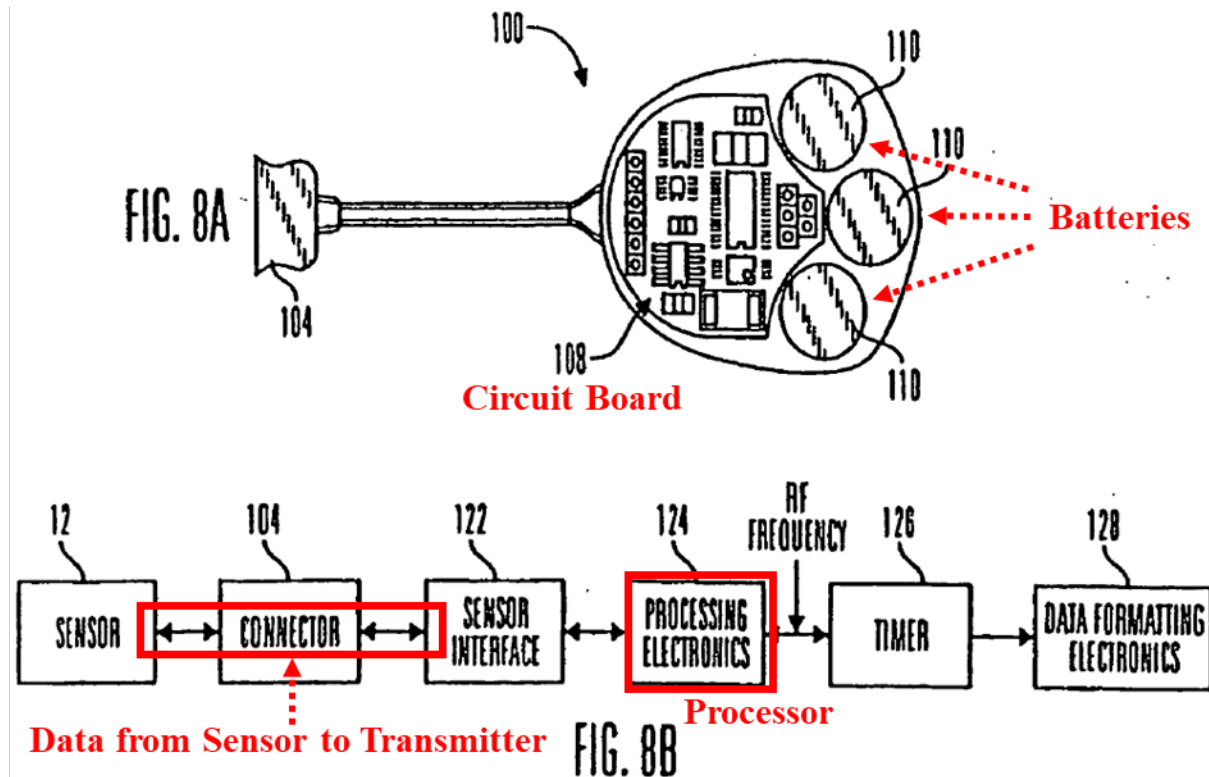


FIG. 20

Id., [0054], Figs. 19, 20. EX1008, ¶199.

d) [1.D]

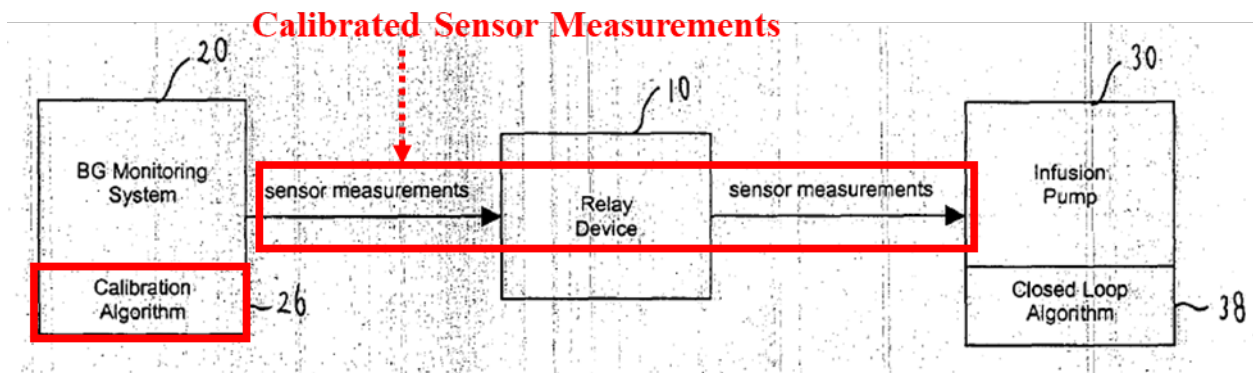
Mastrototaro discloses that transmitter 100 receives glucose data from sensor set 10 (including sensor 12) and processes signals with a processor (e.g., processing electronics 124, microprocessor 1120):



EX1019, [0007], [0041], Fig. 8B (annotated in red). *Mastrototaro* provides for calibration of the sensor set using data received by the transmitter. *Id.*, [0035]. EX1008, ¶200.

Shahmirian provides that the monitoring system receives calibration data, including blood glucose reference readings. EX1023, [0064]. The monitoring

system's processor executes a calibration algorithm to convert sensor data into calibrated sensor measurements:



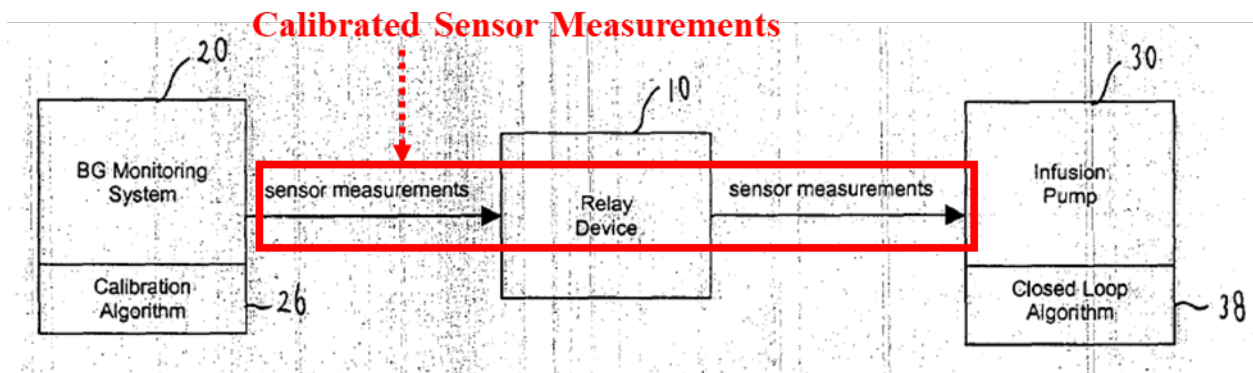
Id., [0015], [0104], [0106], Fig. 5(c) (annotated in red). POSITAs understood that *Shahmirian*'s calibration algorithm processed sensor data with "data associated with a sensitivity of the glucose sensor." EX1008, ¶¶40, 54, 201-202; *see also supra* IV.A.2, VII.F.1.(d).

Shahmirian discloses that the BG monitoring system (e.g., glucose sensor and transmitter) stores raw glucose data and calibrated glucose measurements in memory. EX1023, [0063]. EX1008, ¶203.

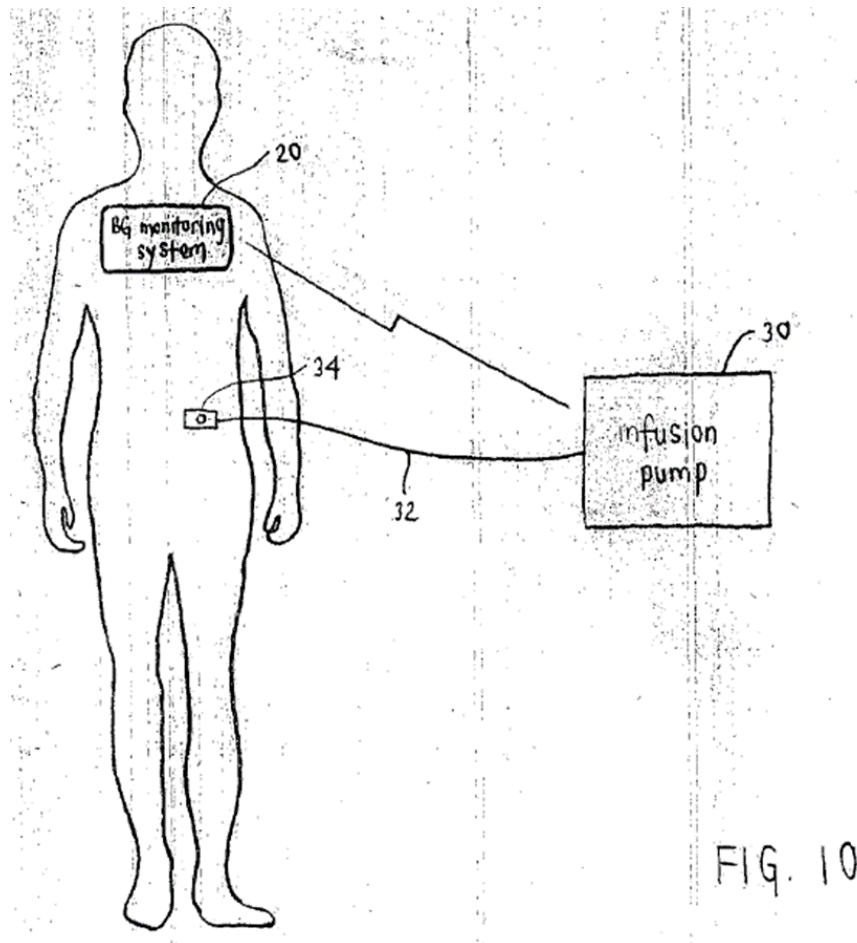
e) [1.E]

Patel-2008 incorporates the connector and communication solutions described in *Shahmirian* and discloses that the glucose monitoring system and CED communicate directly over Bluetooth. EX1015, [0035], [0045]. *Shahmirian* discloses that the monitoring system includes a transmitter and/or receiver (i.e., a transceiver) for communicating with external devices, like the infusion pump.

EX1023, [0061]. Communications include “[c]alibrated sensor measurements ... sent from the BG monitoring system 20 through the relay device 10 to the infusion pump 30:”



Id., [0106], Fig. 5(c) (annotated in red). *Shahmirian* discloses the relay device incorporated into the infusion pump such that monitoring system 20 and infusion pump 30 communicate wirelessly using radio frequency, including over Bluetooth:

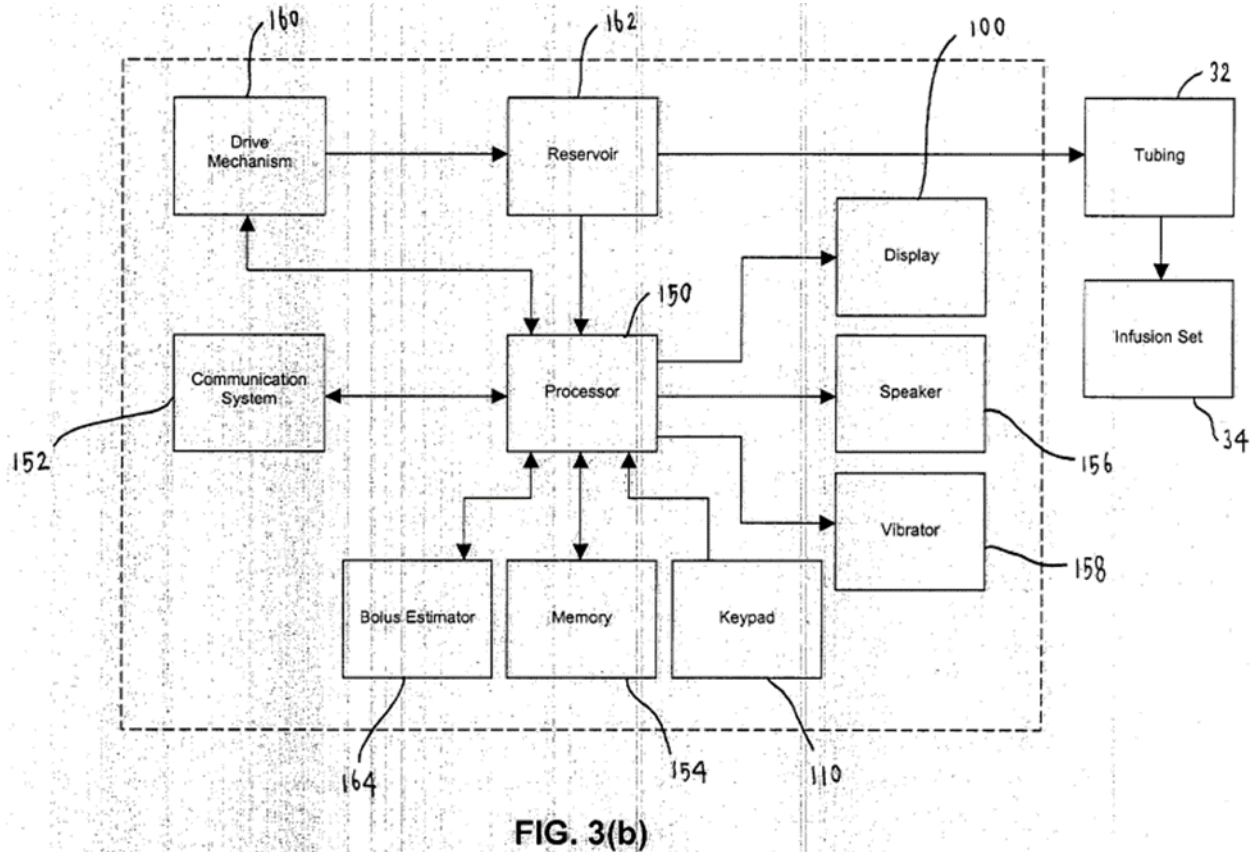


Id., [0081], [0089], Fig. 10. *Shahmirian* thereby provides direct Bluetooth communication between the glucose monitoring device and CED as disclosed in *Patel-2008*. EX1015, [0045]; EX1008, ¶¶61, 204-205; *see also supra* IV.A.4.

f) **[1.F]**

Shahmirian discloses that infusion pump 30 receives calibrated glucose measurements over Bluetooth. *See supra* VIII.D.1.(e). Infusion pump 30 includes display 100, processor 150, internal memory device 154, communication system 152

with a transmitter and/or receiver (i.e., a transceiver), and antenna 268 as disclosed with communications board 265:



EX1023, [0066-67], [0069], [0080], Fig. 3(b). The infusion pump uses the transceiver (i.e., transmitter and/or receiver) for radio frequency communication with external devices over a particular frequency and communication protocol, including Bluetooth. *Id.*, [0067], [0089]; *see supra* VIII.D.1.(e), IV.A.4. EX1008, ¶¶61, 206.

In addition, *Causey* also discloses a monitoring device used to display glucose graphs and levels. EX1017, 13:52-59, 14:20-23, 15:3-17. The monitor includes display 2208, microprocessor 2216, ROM 2204, and RAM 2206:

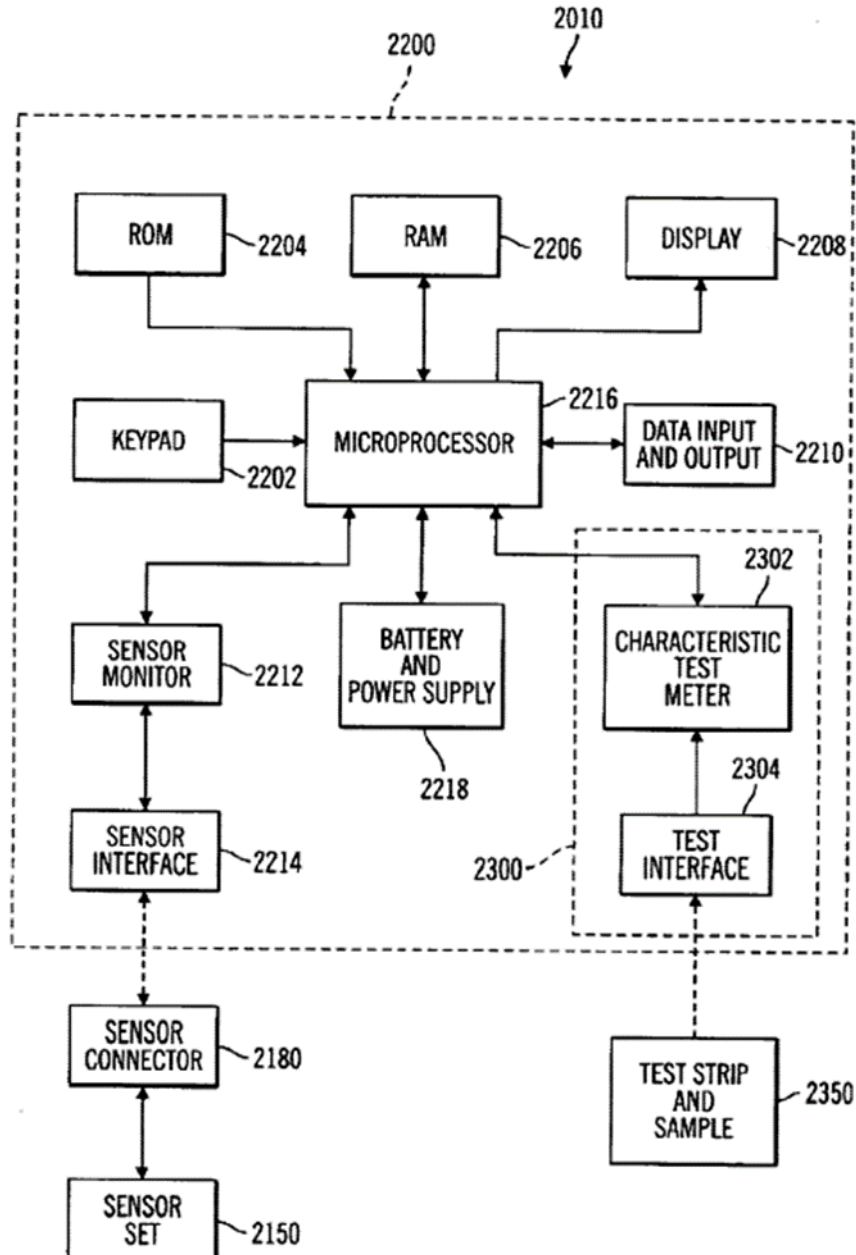


FIG. 30

Id., 15:17-25, Fig. 30. The monitor receives glucose measurements as wireless RF signals from transmitter 2100:

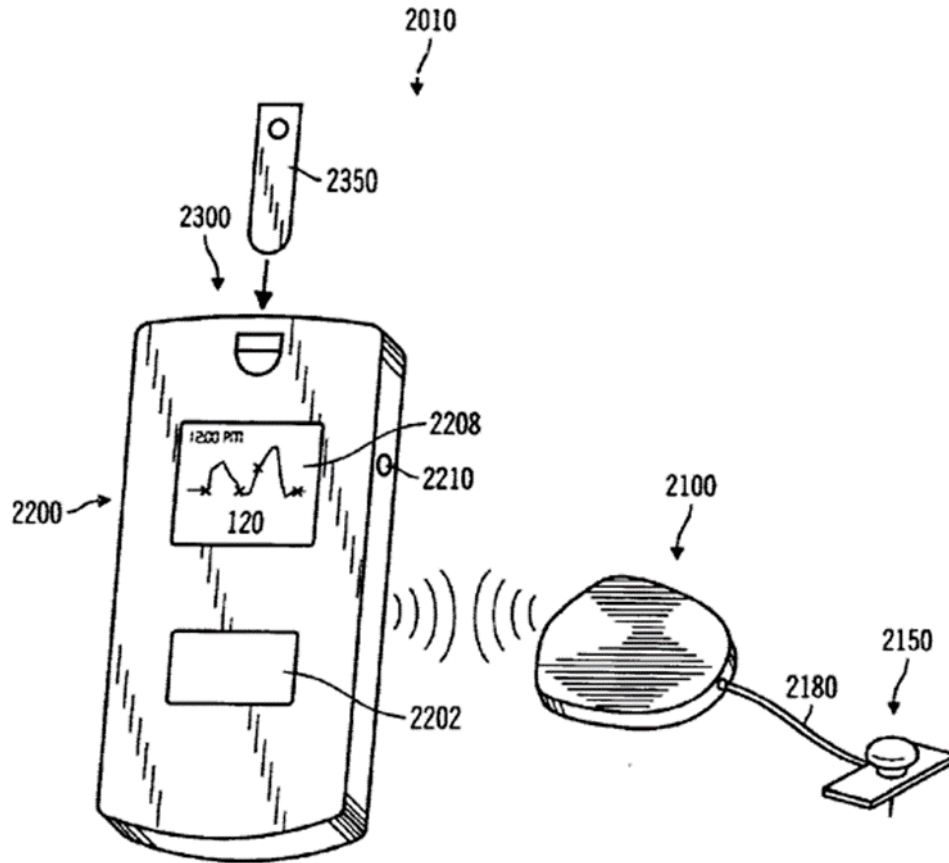


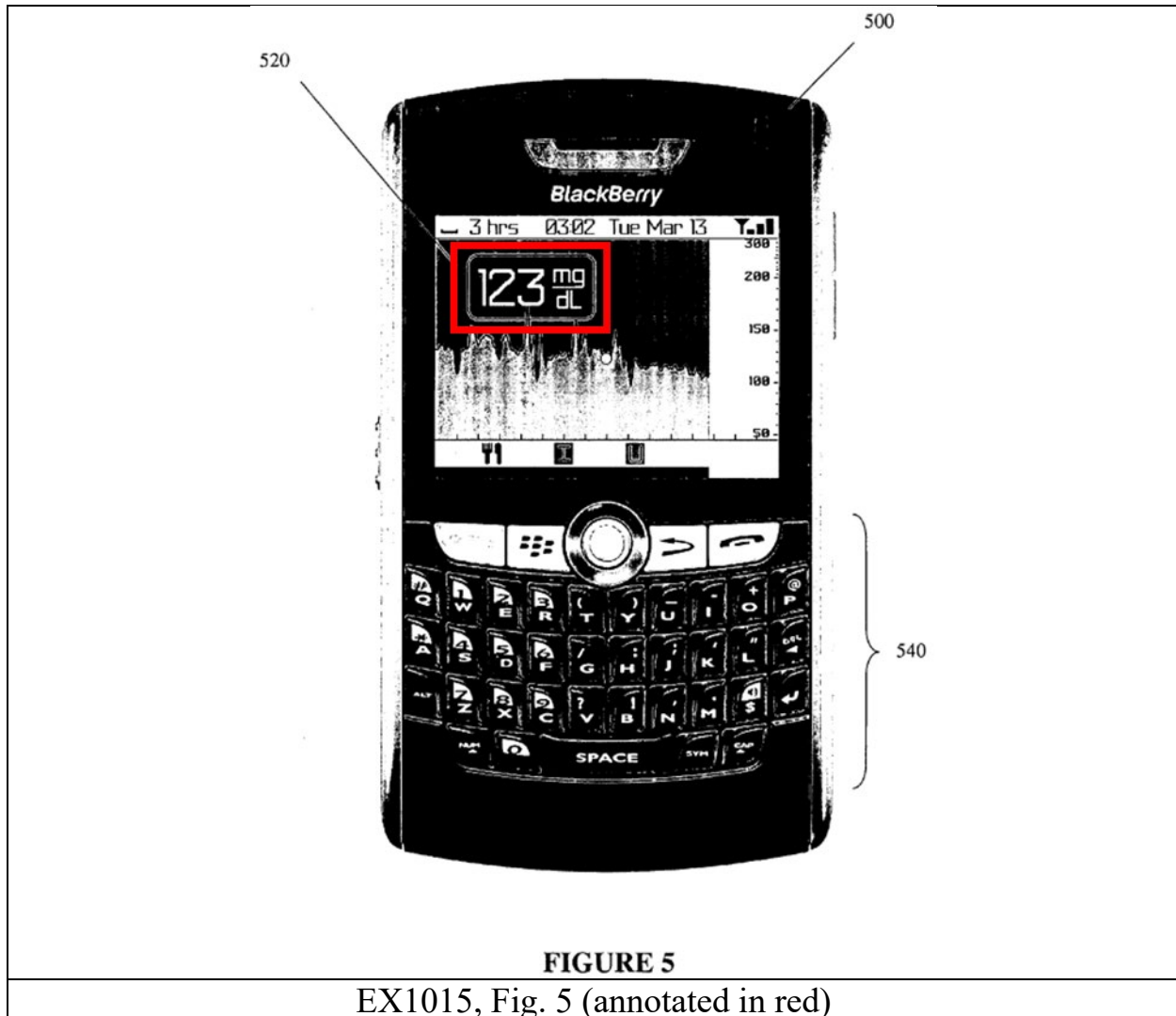
FIG. 31

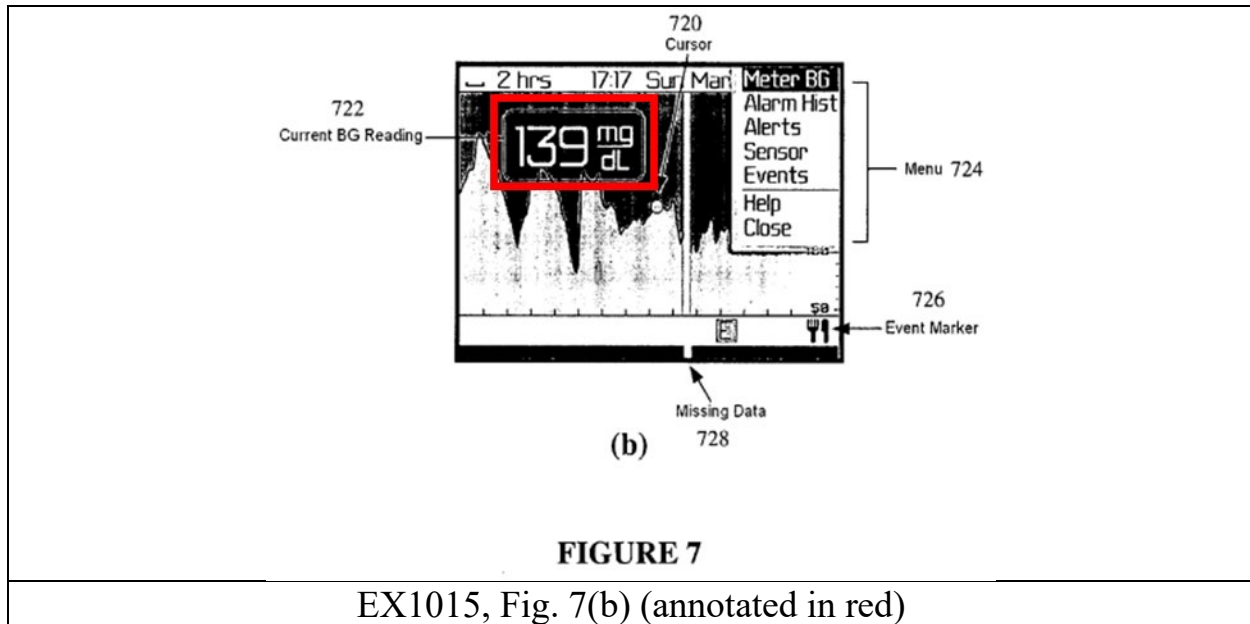
Id., 13:52-56, 17:28-31, Fig. 31. POSITAs would recognize that communications are sent and received by an antenna and RF transceiver. EX1008, ¶¶61, 207.

Patel-2008 also discloses a CED (e.g., PDA/Smartphone) that obtains glucose monitoring data over Bluetooth, then stores and displays this data. EX1015, [0045], [0047]. EX1008, ¶208.

g) [1.G]

Patel-2008 discloses that the CED displays glucose data, including numerical glucose values:

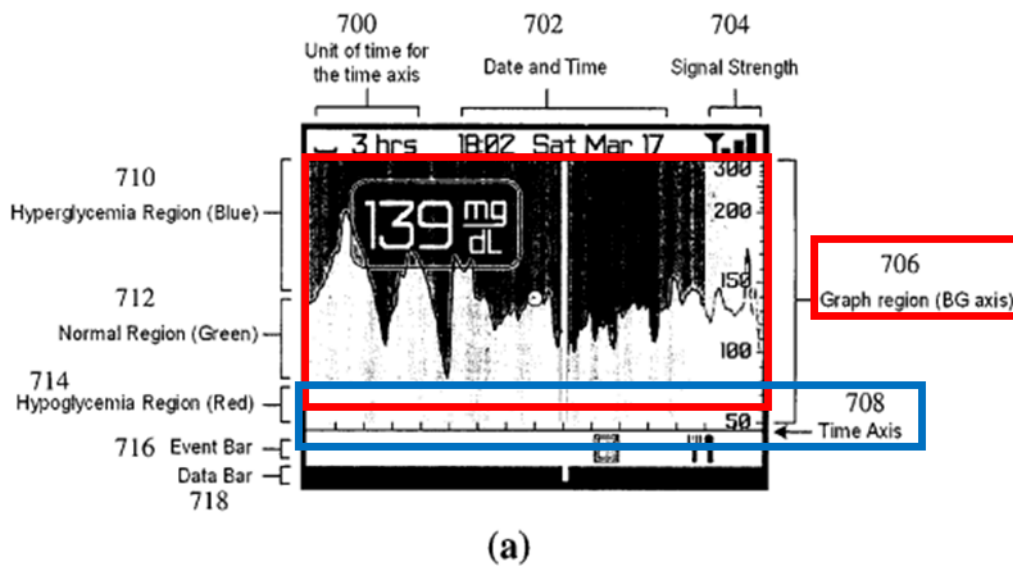




EX1015, [0047], [0052], [0057]; EX1008, ¶209.

h) [1.H]

Patel-2008 discloses software that displays glucose levels on axis 706 against time on axis 708:



EX1015, [0056], Fig. 7(a) (annotated in red, blue); EX1008, ¶210.

i) [1.I]

Patel-2008 discloses detecting failed reception of sensor data and indicating missing data with “a blank white space during the time no data was received:”

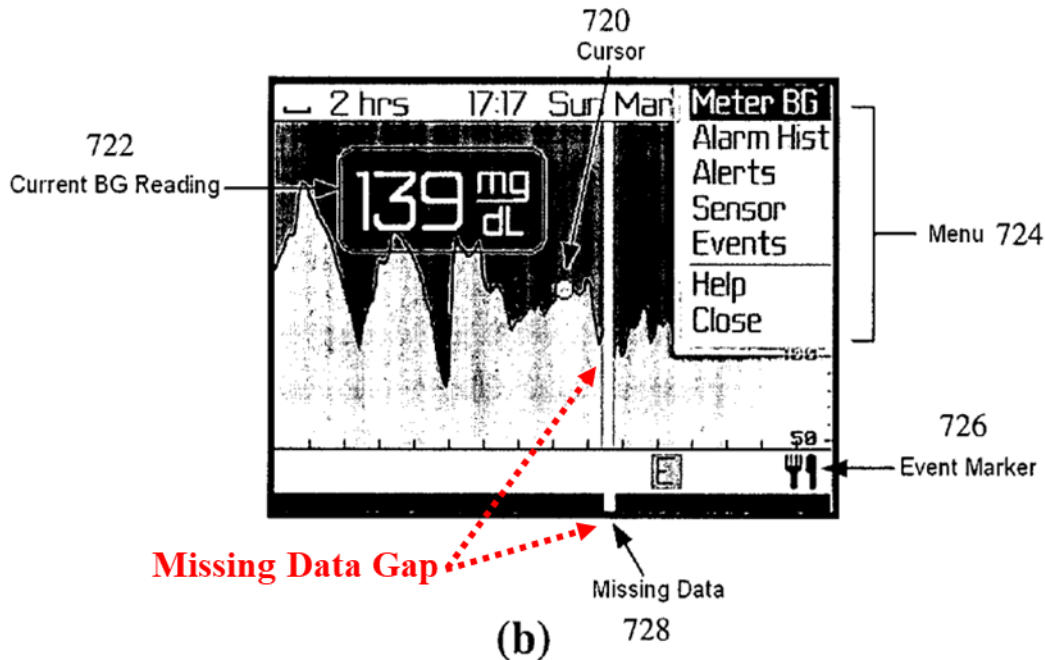


FIGURE 7

EX1015, [0057], Fig. 7(b) (annotated in red). Conditions associated with out-of-range (i.e., extreme) glucose readings and sensor calibration are also detected. *Id.*, [0044]. EX1008, ¶¶60, 211.

Shahmirian and *Causey* detect additional adverse conditions. *Shahmirian* discloses verifying receipt of sensor data by echoing it back to the transmitter to detect missing or inaccurate data. EX1023, [0102], [0111]. *Causey* discloses monitoring sensor data signals to determine conditions like rapidly changing,

extreme, faulty, or interrupted glucose data and prompting or delaying calibration accordingly. EX1017, 22:28-45. EX1008, ¶¶60, 212.

j) [1.J]

Shahmirian discloses that raw and calibrated glucose data is stored in transmitter memory and that sensor data not received by the pump is retransmitted from the transmitter. EX1023, [0063] [0102-103], [0111]. Data is stored during failed reception because the same missing glucose data is retransmitted. EX1008, ¶¶55-56, 60, 213.

k) [1.K]

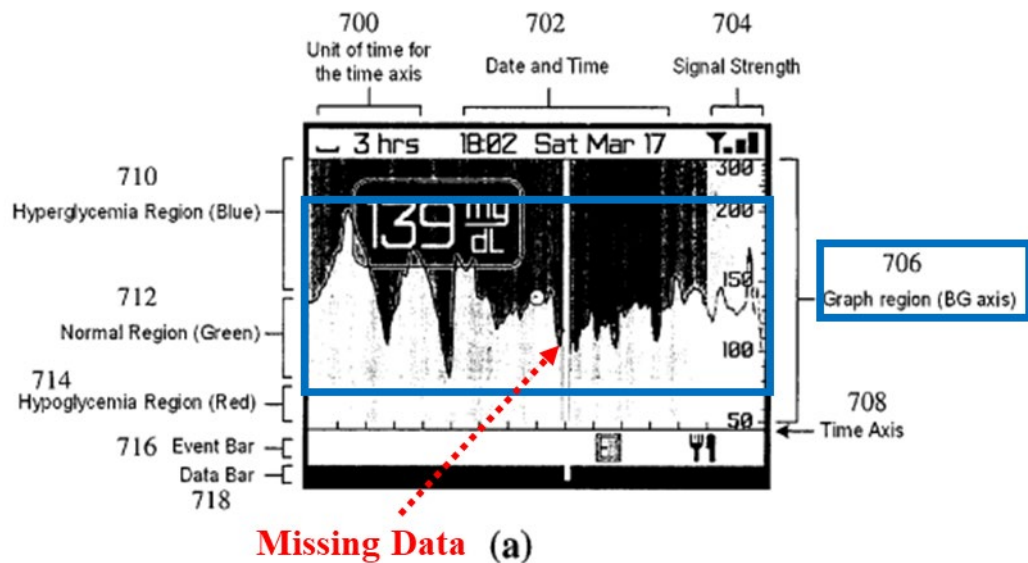
Shahmirian discloses retransmission of glucose data not received. Receipt of sensor data is verified by echoing it back to the transmitter. EX1023, [0102], [0111]. “[T]he infusion pump 30 indicates to the BG monitoring system 20 the most recent sensor data that the infusion pump 30 has received, and in response, the BG monitoring system 20 sends any additional sensor data that the BG monitoring system 20 has that has not been received by the infusion pump 30.” *Id.*, [0103]. “Once the sensor data is received, ... the most recent sensor measurement” is displayed. EX1023, [0103]. EX1008, ¶214.

Causey also discloses updating display of glucose data to show newly calibrated glucose values and differences with previously displayed data. EX1017, 15:59-65. EX1008, ¶215.

Additionally, POSITAs would recognize that retransmission or calibration of previously missing glucose data and the display of this data would fill in associated missing data gaps. EX1008, ¶¶58-60, 216. Alternatively, considering *Shahmirian* and *Causey*'s disclosures, POSITAs would have found it obvious to re-populate glucose data gaps with retransmitted or newly calibrated data following failed communication or calibration. EX1008, ¶¶58-60, 216

D) [1.L]

Patel-2008 discloses a glucose line graph with a missing data gap:



EX1015, [0057], Fig. 7(a) (annotated in red, blue). EX1008, ¶217.

POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated. EX1008, ¶¶60, 218.

2. Claim 2

Claim 2 is disclosed. *See supra* VIII.D.1.(h). EX1008, ¶219.

3. Claim 3

Patel-2008 provides that the glucose monitoring device includes a glucose transmitter and a sensor. EX1015, [0033]. When glucose data is not received, a missing data gap is displayed. *See supra* VIII.D.1.(i). Loss of communication between the monitor and transmitter also interrupts communication with the sensor and with the collective glucose monitoring device. *See supra* VI.F.3. EX1008, ¶¶58, 60, 220.

Alternatively, POSITAs would recognize a sensor communication error as an obvious cause of missing glucose data. EX1008, ¶ 221.

4. Claim 4

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data calibrated following faulty or interrupted glucose readings and other sensor signal errors. *See supra* VII.C.1. EX1008, ¶¶222-223.

5. Claims 5-6

Patel-2008 discloses displaying a missing data gap when glucose data is not communicated from the transmitter to the monitor of a diabetes monitoring system. *See supra* VIII.D.1.(i). Communication failures are associated with the transmitter, monitor, or both. *See supra* VI.C.4. EX1008, ¶¶58, 60, 224.

Alternatively, POSITAs would recognize transmission and reception errors as obvious causes of missing glucose data. EX1008, ¶225.

6. Claim 7

Missing glucose data from failed reception is a malfunction associated with the transmitter, monitor, or both. *See supra* VIII.D.5, VI.F.4-5. EX1008, ¶¶58, 60, 226.

Alternatively, POSITAs would recognize transmitter and/or receiver malfunctions as an obvious cause of missing data. EX1008, ¶227.

7. Claim 8

Patel-2008 discloses displaying a missing data gap when glucose data is not received (EX1015, [0057]) because data cannot be displayed unless received. EX1008, ¶¶58, 60, 228; *see supra* VIII.D.1.(i), *infra* VIII.D.15; *see also supra* VI.C.6.

Alternatively, POSITAs would recognize the failed reception of glucose data as an obvious cause of the inability to display this data. EX1008, ¶229

8. Claim 9

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data calibrated following sensor instability. *See supra* VII.C.2. EX1008, ¶¶230-232.

9. Claim 10

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data calibrated following calibration error. *See supra* VII.C.3. EX1008, ¶¶233-234.

10. Claim 11

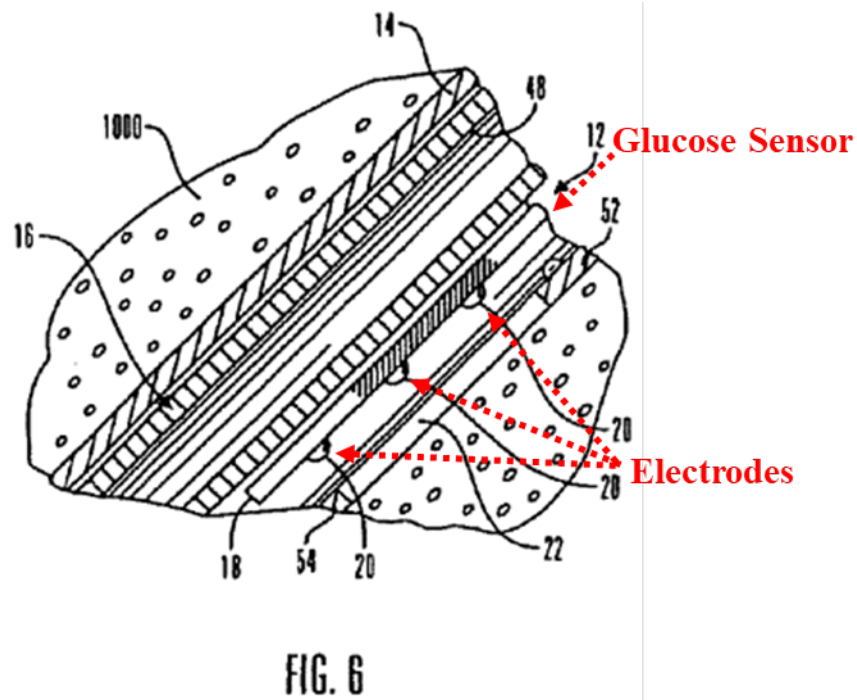
Patel-2008 discloses a diabetes management system composed of a glucose monitoring device, which includes a glucose sensor and transmitter, and a CED. *See supra* VIII.A. Failures and malfunctions associated with the sensor, transmitter, or monitor are monitoring system failures. *See supra* VIII.D.3, VIII.D.5-6, VI.F.7. EX1008, ¶¶58, 60, 235-236.

Alternatively, POSITAs would recognize a monitoring system failure as an obvious cause of missing glucose data. EX1008, ¶237.

11. Claim 12

Patel-2008 incorporates U.S. Patent 5,391,250 (EX1015, [0004]), which discloses a glucose oxidase working electrode and a counter electrode. EX1048, 5:6-16.

Mastrototaro also discloses sensor 12 with sensor electrodes 20:



EX1019, [0043], Fig. 6 (annotated in red). POSITAs would recognize that electrodes 20 include working and counter electrodes. EX1008, ¶238; *see supra* IV.A.1.

12. Claim 14

Mastrototaro discloses that sensor set 10 monitors temperature and uses the relationship between glucose sensor activity and temperature to determine sensor calibration. EX1019, [0042]; *see also* EX1023, [0052]. EX1008, ¶239.

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data following calibration. EX1017, 15:43-65; *see supra* VII.A. EX1008, ¶240.

POSITAs would have found it obvious to delay calibration until temperature is within range and update historical glucose graphs to display missing glucose data following calibration delayed due to out-of-range temperature. EX1008, ¶241.

13. Claim 15

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data calibrated following glucose level excursions. *See supra* VII.C.5. EX1008, ¶¶242-243.

14. Claim 16

Causey discloses or renders obvious updating historical glucose graphs to display missing glucose data calibrated following rapid glucose change. *See supra* VII.C.6. EX1008, ¶¶244-245.

15. Claim 17

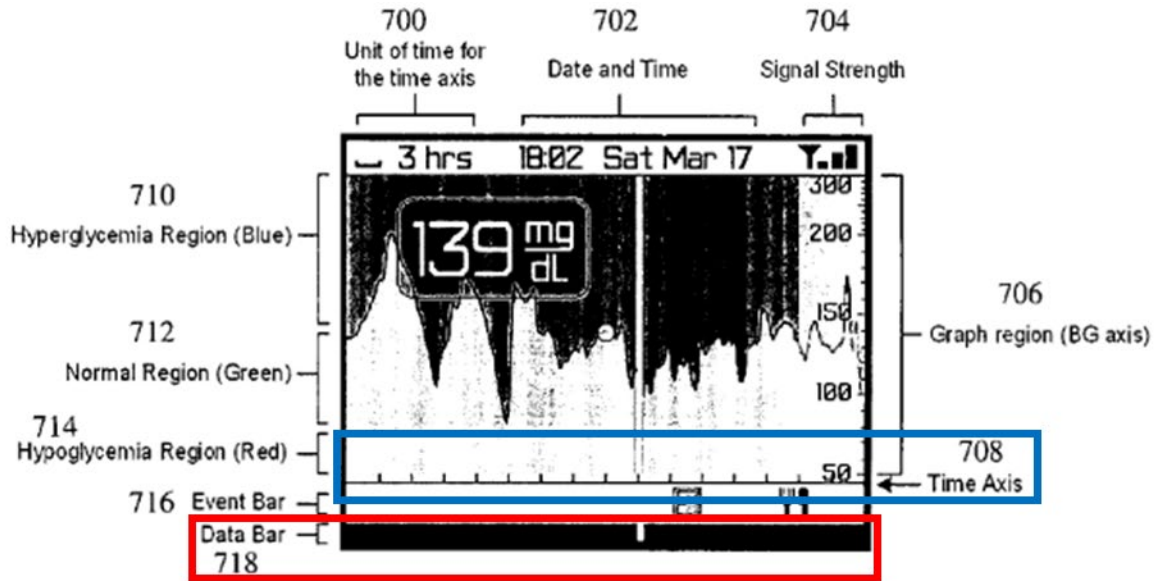
Patel-2008 discloses displaying a missing data gap when glucose data is unavailable because it was not received. *See supra* VIII.D.1.(i). EX1008, ¶¶58, 60, 246.

16. Claim 18

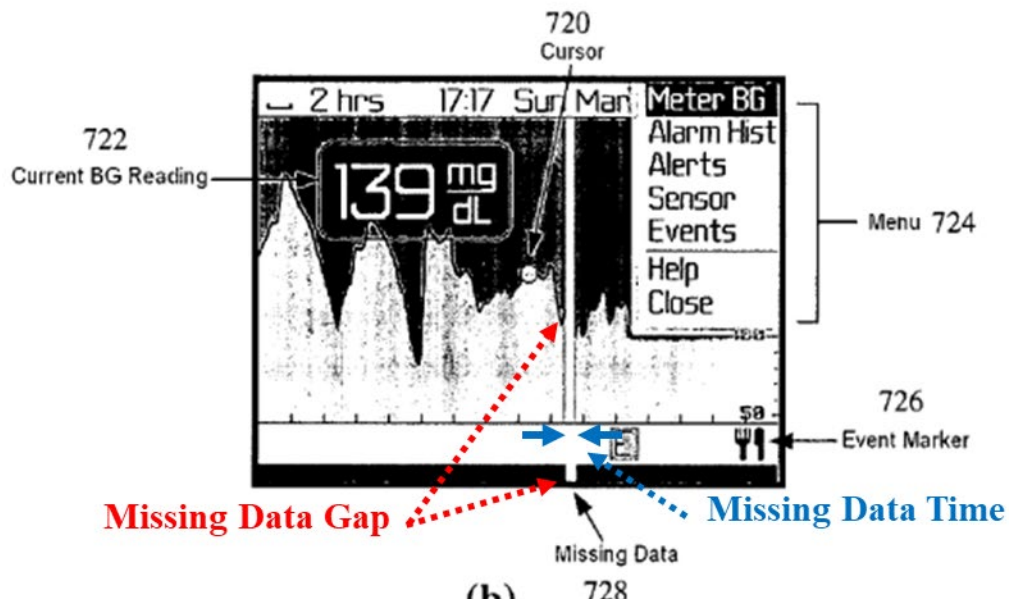
Shahmirian discloses that “[o]nce the sensor data is received, ... the most recent sensor measurement” is displayed. EX1023, [0103]; EX1008, ¶247.

17. Claim 20

Patel-2008 discloses a glucose graph which identifies “the time no data was received” with a blank white space (i.e., data gap) 728 graphed against data bar 718 and time axis 708:



(a)



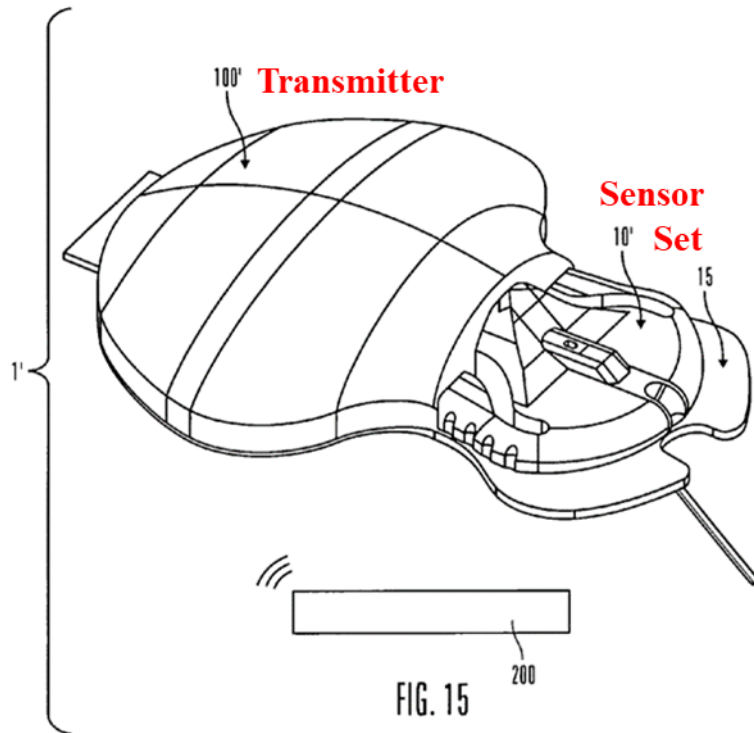
(b)

FIGURE 7

EX1015, [0056-57], Fig. 7(a)/(b) (annotated in red, blue); *see also* VIII.D.1.(i). At least data bar 718 stores the time of failed glucose data reception. EX1008, ¶¶60, 248-249.

18. Claim 21

Mastrototaro provides that transmitter 100' fits directly onto and is supported by sensor set 10' itself:



EX1019, [0050], Fig. 15 (annotated in red). Indeed, *Mastrototaro* discloses discarding the transmitter and directly connected sensor set together after the 3-to-5-day use period. EX1019, [0050]. EX1008, ¶250.

19. Claim 22

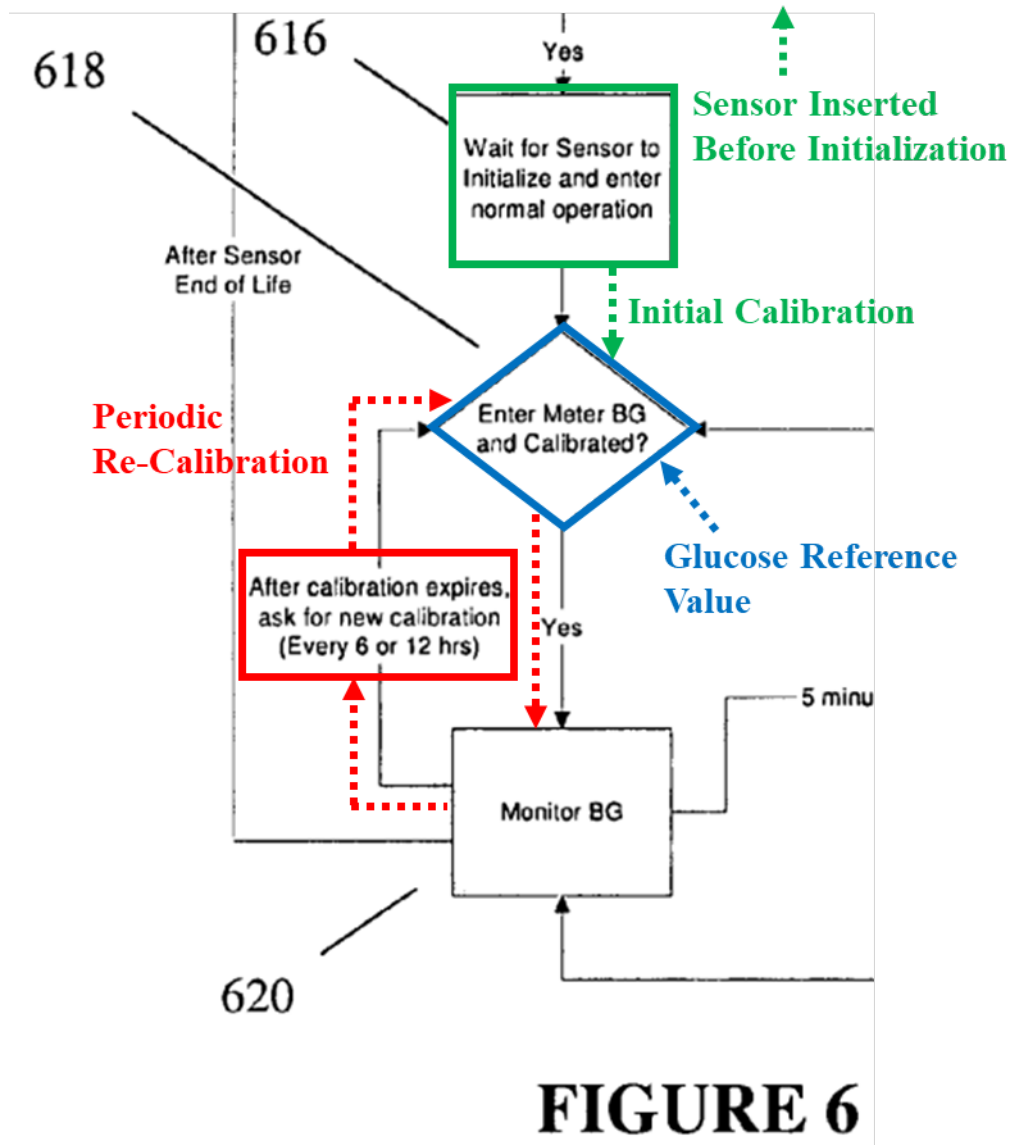
Patel-2008 discloses a PDA/Smartphone (e.g., Blackberry, Apple iPhone) as the CED, and that glucose monitoring software operates on “Windows CE, Windows Mobile, ... iPhone Operating System.” EX1015, [0034], [0039]; EX1008, ¶251.

20. Claim 23

Shahmirian discloses storage of raw and calibrated glucose data. EX1023, [0063]. POSITAs would have found it obvious to install sufficient memory and store over one hour of glucose data. EX1008, ¶¶45, 252.

21. Claim 24

Patel-2008 provides that glucose sensors are periodically re-calibrated with blood glucose reference values (step 618) after being inserted and initialized (step 616) and once glucose monitoring is active (step 620):



EX1015, [0054-0055], [0059], Fig. 6 (annotated in red, blue, green). EX1008, ¶253.

22. Claim 25

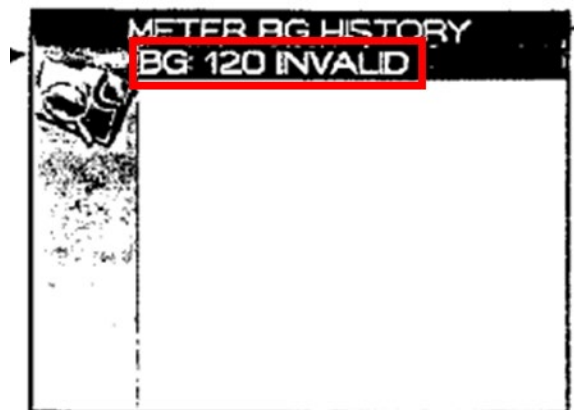
Causey discloses event and trend triggered calibration prompts (e.g., “faulty or interrupted data readings, or the like”) and updating historical glucose data with newly calibrated data. EX1017, 15:43-65; 22:28-45. Therefore, *Causey* renders obvious updating historical glucose graphs to display missing glucose data calibrated

following blood glucose reference error, including faulty or interrupted blood glucose signals. *See supra* VII.C.7. EX1008, ¶¶254-255.

In addition, *Shahmirian* also discloses “a BG reference reading utilizing a BG meter ..., which then transmits the BG reference reading to the BG monitoring system.” (EX1023, [0064].)

Furthermore, *Patel-2008* also discloses invalid blood glucose reference readings:

904



EX1015, Fig. 9 (annotated in red).

23. Claim 26

When using a new sensor, *Patel-2008* discloses calibration with a BG (blood glucose) reading, that this reading should be obtained every 12 hours, and that it may only be required once. EX1015, [0059].

Additionally, *Mastrototaro* also discloses omitting the sensor initialization sequence that reduces sensor stabilization from several hours to one hour or less when stabilization time is not a factor. EX1019, [0060]. Without the initialization (EX1015, [0054] (step 616)), *Patel-2008* discloses asking for calibration after 12 hours. EX1015, [0055]; *see also supra* VIII.D.21. EX1008, ¶256.

24. Claim 27

Mastrototaro discloses circuitry for the transmitter to detect connection with the sensor set and a sensor on/off button (e.g., power switch 1112), each to conserve power when the sensor is disconnected or turned off. EX1019, [0041], [0055]; EX1008, ¶257.

25. Claim 28

Mastrototaro discloses transmitter batteries that provide power for 3 months to 2 years. EX1019, [0055]; EX1008, ¶258.

26. Claim 30

Patel-2008 discloses that “glucose sensor **130** is a continuous glucose sensor capable of taking readings from a user on a continuous ... basis throughout the day.” EX1015, [0038]. EX1008, ¶259.

Mastrototaro and *Shahmirian* also disclose that sensor readings may be provided on a continuous basis. EX1019, [0035]; EX1023, [0052], [0060]. EX1008, ¶259.

IX. DISCRETIONARY CONSIDERATIONS

A. § 325 (d)

Neither art nor argument advanced by the Petition is substantially similar to those previously before the office. *See Advanced Bionics, LLC. v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-9 (PTAB Feb. 13, 2020). Paradigm® REAL-Time, *Patel-2008*, *Causey*, and *Mastrototaro* were not before the examiner. EX1001, 1-7. Although *Shahmirian* and *Patel-2009* were among 700 references submitted via IDS, neither was relied on or discussed by the Examiner. *Amazon.com, Inc. v. M2M Sols. LLC*, IPR2019-01205, Paper 14 at 16 (PTAB Jan. 27, 2020) (“a reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor” of exercising discretion under § 325(d)) (internal citations omitted). Moreover, *Patel-2009* was submitted more than a decade into prosecution when the Examiner’s office action and allowance

only considered double patenting. EX1002, 237-241. Finally, prosecution focused on U.S. Publications to Hayter and Kamath, not on the combinations and arguments in this Petition. *See supra* III.B.

B. § 314 (a)

At this time, § 314(a) does not favor exercising discretion because a Rule 26(f) scheduling conference has yet to occur and trial date has not been set.

X. CONCLUSION

Petitioner requests institution for claims 1-12, 14-28, and 30, on the Grounds specified in this petition.

Respectfully submitted,

August 1, 2023

By: /John D. Vandenberg/
John D. Vandenberg, Reg. No. 31,312
john.vandenberg@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Petitioner

**CERTIFICATE OF COMPLIANCE WITH
TYPE-VOLUME LIMITATION PURSUANT TO 37 C.F.R. § 42.24**

This brief complies with the type-volume limitation of 37 C.F.R. § 42.2
(a)(1)(i).

The brief contains 13,921 words, excluding the parts of the brief exempted by
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By: /John D. Vandenberg/
John D. Vandenberg, Reg. No. 31,312
john.vandenberg@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Petitioner

CERTIFICATE OF SERVICE
IN COMPLIANCE WITH 37 C.F.R. § 42.6 (E)(4)

The undersigned certifies that the **Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056 and Exhibits 1001 – 1049** were served on August 1, 2023, via **Federal Express** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

One LLP - ADC
Alana Fredericks
23 Corporate Plaza, Suite 150
Newport Beach, CA 92660

A copy of the Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056 only was served on litigation counsel for Patent Owner via email to:

ADC-MNAT@morrisnichols.com
MHM-ADC@mcandrews-ip.com

By: /John D. Vandenberg/
John D. Vandenberg, Reg. No. 31,312
john.vandenberg@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Petitioner