

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01251

U.S. Patent No. 11,298,056

DECLARATION OF EUGENE E. WRIGHT, JR. MD

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS	2
IV.	SUMMARY OF OPINIONS	8
V.	LEGAL PRINCIPLES	8
A.	Claim Construction	9
B.	Anticipation	9
C.	Obviousness	10
VI.	OVERVIEW OF THE SCIENCE AND TECHNOLOGY AT ISSUE	13
A.	Diabetes	13
B.	Consequences of Hyperglycemia and Hypoglycemia	15
C.	Diabetes Interventions and Treatments	16
D.	Blood Sugar Monitoring	19
1.	Blood Glucose Monitors	19
2.	Continuous Glucose Monitors	20
E.	Overview of the 056 Patent	53
VII.	SOME OF MR. GROSS’ OPINIONS ARE NOT BASED ON, AND AT TIMES ARE CONTRADICTED BY, PRIOR ART, AND THEY APPEAR TO USE THE 056 PATENT AS A BLUEPRINT	59
A.	Person of Ordinary Skill in the Art	59
B.	Mr. Gross’ Opinions Are Not Based On Evidence Or Accurate Historical Facts, And Appear To Use The 056 Patent As A Blueprint	64
C.	Other Evidence Calls Into Question Mr. Gross’ Opinions	80
VIII.	OPINIONS ON CLAIM 1 UNDER GROUNDS 1 AND 2	83

A.	Claim Element [1.K]	84
B.	Claim Element [1.L].....	101
IX.	OPINIONS ON CLAIM 1 UNDER GROUND 3	104
A.	A POSITA Would Not Have Been Motivated To Combine Or Modify The Prior Art References Used In Ground 3.....	105
B.	Claim Element [1.I].....	111
C.	Claim Element [1.K]	119
D.	Claim Element [1.L].....	125
X.	OPINIONS ON CERTAIN DEPENDENT CLAIMS.....	127
A.	Claim 4	127
B.	Claim 21	131

I, Dr. Eugene E. Wright, Jr., do hereby declare as follows:

I. INTRODUCTION

1. I understand that Dexcom, Inc. (“Dexcom” or “Petitioner”) filed a petition for *inter partes* review against U.S. Patent No. 11,298,056 (the “056 patent”). I also understand that the Patent Trial and Appeal Board (the “PTAB” or “Board”) of the United States Patent and Trademark Office assigned case number IPR2023-01251 to the *inter partes* review proceeding.

2. I have been retained by Abbott Diabetes Care Inc. (“Abbott” or “Patent Owner”) through its attorneys to serve as an expert witness in this *inter partes* review proceeding.

3. I understand that the PTAB initiated *inter partes* review of the following claims of the 056 patent based on the following grounds:

- **Ground 1:** Whether claims 1-3, 5-8, 11, 12, 17-24, 26-28, or 30 are unpatentable as obvious in view of U.S. Pub. 2009/0085768 (Ex. 1012, Patel-2009) and Paradigm REAL-Time Documentation (Ex. 1011);
- **Ground 2:** Whether claims 4, 9, 10, 15, 16, and 25 are unpatentable as obvious in view of Patel-2009, Paradigm REAL-Time Documentation, and U.S. Patent No. 6,641,533 (Ex. 1017, Causey); and
- **Ground 3:** Whether claims 1-12, 14-18, 20-28, and 30 are unpatentable as obvious in view of U.S. Pub. 2008/0119705 (Ex. 1015, Patel-2008), U.S. Pub. 2006/0202859 (Ex. 1019, Mastrototaro), U.S. Pub. 2004/0122353 (Ex. 1023, Shahmirian), and Causey.

4. I have been asked to consider and respond to opinions expressed by Dexcom's expert, Mr. Brian Gross, in his declaration that was submitted with Dexcom's petition on August 1, 2023. I understand that Mr. Gross' declaration was assigned Exhibit No. 1008. I was also asked to provide my own opinions regarding the subject matter about which Mr. Gross opines, particularly from a clinical perspective, including a background on diabetes and monitoring devices, the scope and content of prior art that Mr. Gross relies on, and whether certain claims from the 056 patent are unpatentable based upon the grounds asserted in DexCom's Petition.

5. In this declaration, I do not address every opinion or statement expressed by Mr. Gross. This, however, should not be construed to mean that I agree with those opinions or statements, and I reserve the right to address them at a later time to the extent helpful or necessary, and to the extent permitted under the PTAB's rules. I also do not address every aspect of Grounds 1, 2, or 3 in this declaration, and that also should not be construed to mean that I agree with, or do not dispute, those unaddressed aspects.

II. BACKGROUND AND QUALIFICATIONS

6. Below is a summary of my background and qualifications. More information is set forth in my curriculum vitae, which I understand has been submitted as Exhibit No. 2014.

7. I earned a Bachelor of Science degree in Electrical Engineering from Princeton University in 1973. I earned a Doctor of Medicine degree from Duke University School of Medicine in 1978 and completed my internship and residency in Internal Medicine at Duke University Hospital in 1981. I am board certified in internal medicine by the American Board of Internal Medicine.

8. I am currently the Medical Director for the Performance Improvement South Piedmont Area Health Education Center (AHEC). I also hold appointments as Consulting Associate in the Department of Medicine of Duke University Medical Center.

9. From 2013 to 2018, I was a clinician and diabetologist for The CARE Clinic, which provides free quality health care to eligible, uninsured, low-income adults. I served as the primary care provider for people who had diabetes as one of their conditions.

10. I have served on several advisory boards in the field of diabetes treatment. These include the ADC Primary Care and Endocrine Advisory Board, the ADA/AHA Diabetes & Cardiovascular Disease Science Advisory Group and the Eli Lilly North American Diabetes Advisory Board. I have also served on the editorial boards for numerous scientific journals and publications, including Diabetes Technology and Therapeutics, Clinical Diabetes, UpToDate Endocrinology and Diabetes, and InforMed on Diabetes. From 2009 to 2022, I was also a member of

the planning committee of the Clinical Conference of the American Diabetes Association.

11. I am active in clinical research with a focus on diabetes diagnosis, treatment, and management. I have published more than two dozen articles in the field, including publications specifically on continuous glucose monitoring systems.

12. I have worked in the area of diabetes treatment for more than 40 years and have given numerous presentations at national and international meetings on the subject. These include presentations for the American Diabetes Association, the Diabetes Technology Society Meeting, and the World Diabetes Congress of the International Diabetes Federation.

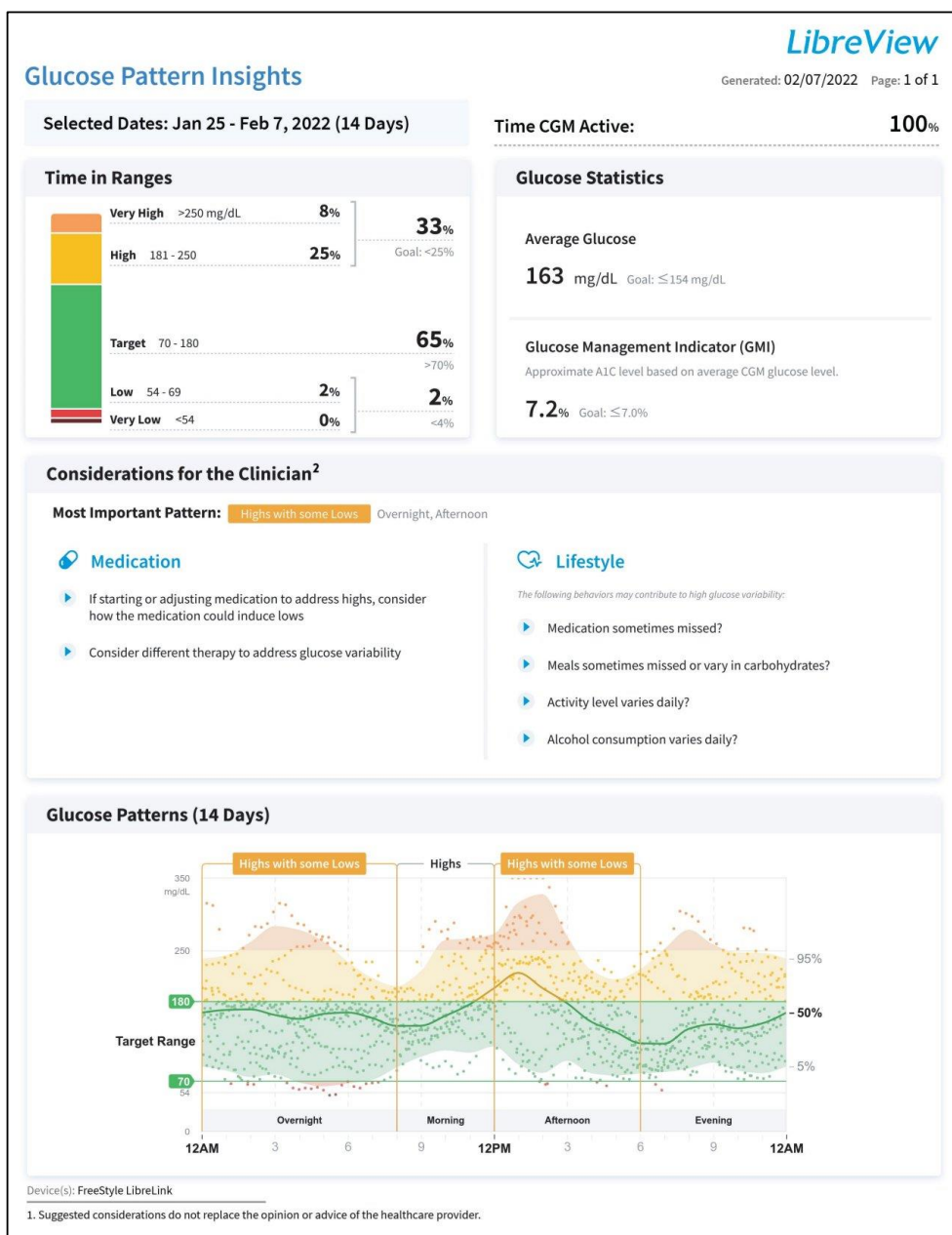
13. I am familiar with many commercially-available CGMs and insulin pumps. I've gained experience with and knowledge about them in several ways over the years, including by personally using and testing them, prescribing them for my patients, instructing patients on how to use them, staying abreast of developing technology in the field, attending conferences, conducting research, reviewing scholarship, writing scholarly works, and so forth.

14. As a physician, I have treated many people with diabetes (PWDs). I have helped PWDs select a CGM that is right for them and I have written prescriptions for many CGMs over the years. I work with my patients to help them

understand how diet, exercise, and medicine affects their glucose levels, and together we develop a plan for managing their diabetes.

15. Beginning in around 2015, I was also part of a group that helped develop a Glucose Patterns Insight Report (GPIR), which was intended to be a guided interpretation report of CGM data for the non-expert user. The group consisted of two other clinicians besides myself—Dr. Howard Wolpert of the Boston Medical Center and Dr. Kurt Midyett of the Midwest Pediatric Specialists, and also Gary Hayter and Matthew Novak of Abbott. The project was a multi-year project that, once completed in 2021, led to the incorporation of the GPIR into Abbott's LibreView product. An example of the GPIR is provided below¹:

¹ Available at <https://www.freestyleprovider.abbott/us-en/libreview.html>.



16. The GPIR was designed to provide the non-expert clinician with a quick, safe, and effective way to identify the most important patterns for clinical decision making when adjusting diabetes medications and to provide guidance on what changes to consider. We tested this on a small group of non-expert clinicians

and found that, compared with the standard AGP report, the clinicians were able to make a better and safer clinical decision in less time using the GPIR.

17. As explained in more detail below, I have reviewed GPIRs and other types of reports with many PWDs over the years. I have found such reports invaluable because they provide a perspective on how a PWD's lifestyle impacts their glucose levels, and vice versa, that is not readily obtainable from other sources.

III. PREVIOUS TESTIMONY, COMPENSATION, AND MATERIALS CONSIDERED

18. Over the past four years, I have testified as an expert at trial or by deposition in the following cases:

- *DexCom, Inc. v. Abbott Diabetes Care Inc. et al.*, C.A. No. 22-605-KAJ (D. Del.) (by deposition)

19. I am being compensated for my time spent on this matter at my usual and customary rate of \$650 per hour, including reimbursement for reasonable expenses. My compensation in no way depends on the opinions that I offer or on the outcome of this *inter partes* review proceeding or any other proceeding, and I have no financial interest in any such proceeding.

20. In preparing this declaration, I have relied upon my education, knowledge, skill, experience, and training. I have also considered the materials set forth in the Appendix or otherwise discussed in this declaration.

IV. SUMMARY OF OPINIONS

21. In my opinion:

- a. Many of Mr. Gross' opinions are unsupported, contradicted by the state of the art or the prior art at the time of the invention, and use the 056 patent as a blueprint to reconstruct the invention;
- b. Under Grounds 1 and 2, the combination of Patel-2009 and the Paradigm® REAL-Time documentation does not render claim 1 unpatentable because claim elements [1.K] and [1.L] are missing;
- c. Under Ground 3, a POSITA would not have been motivated to combine or modify Patel-2008, Mastrototaro, Shahmirian, and Causey, and therefore, claim 1 is not unpatentable;
- d. Under Ground 3, the combination of Patel-2008, Mastrototaro, Shahmirian, and Causey does not render claim 1 unpatentable because claim elements [1.I], [1.K], and [1.L] are missing;
- e. Under Grounds 1, 2, and 3, no dependent claim is unpatentable at least because claim 1 is not unpatentable; and
- f. Under Grounds 1, 2, and 3, at least dependent claims 4 and 21 are not unpatentable for reasons independent of claim 1 not being unpatentable.

V. LEGAL PRINCIPLES

22. I am neither an attorney nor a legal expert, and I am not purporting to provide any opinions regarding the correct legal standards to apply in this proceeding. I have been asked, however, to provide my opinions in the context of legal principles that have been provided to me by Abbott's counsel.

A. Claim Construction

23. I understand that patent claims are the numbered sentences at the end of a patent. The claims are intended to define, in words, the boundaries of the patent owner's rights. Each claim is considered on its own, and may cover more or less than another claim.

24. I understand that, before analyzing claims in view of prior art, the terms or elements of the claim must be construed. I further understand that claim terms are generally given their plain and ordinary meaning as would be understood by a person of ordinary skill in the art ("POSITA") at the time of the invention in the context of the entire disclosure of the patent, including other intrinsic evidence such as the prosecution history for the patent.

B. Anticipation

25. I understand that to anticipate a patent claim, each and every element of the claim, as properly construed, must be found either explicitly or inherently in a single prior art reference and arranged in the same manner as in the claim. Even if a prior art reference contains each and every element of a claim, the reference must be an enabling disclosure with enough information to enable a POSITA to reproduce the claimed invention without undue experimentation. For purposes of my declaration, I assume that Dexcom's references are prior art to the 056 patent.

C. Obviousness

26. I understand that a patent claim can be found unpatentable if the subject matter of the claim, as a whole, would have been obvious to a POSITA at the time of the invention. I further understand that obviousness is a question of law that requires underlying factual determinations of:

- The scope and content of the prior art;
- The differences, if any, between the prior art and each claim of the patent;
- The level of ordinary skill in the art at the time of the invention; and
- Any secondary considerations of non-obviousness.

27. I further understand that a claimed invention comprising several elements is not obvious merely because each of the elements may have been independently known in the prior art. Instead, I understand that to prove a claim would have been obvious, the challenger must demonstrate that a POSITA would have been motivated to combine or modify the prior art to achieve the claimed invention and had a reasonable expectation of successfully combining or modifying the prior art. I further understand that it is not enough to show that the prior art references *could* be combined.

28. I understand that the motivation to combine the prior art to arrive at the claimed invention cannot be based in whole or in part on the challenged patent in question. I further understand that the motivation to combine the prior art must be

supported by evidence or articulated explanation. I also understand that conclusory statements alone are insufficient, and any obviousness analysis must be supported by a reasoned explanation as to why a POSITA would have been motivated to combine the prior art in the manner proposed by the patent challenger.

29. I understand that it is impermissible to use the claimed invention, or disclosure of the subject patent, as an instruction manual or template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. In other words, I understand that one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to render obvious the claimed invention. As such, I understand that even if the collective prior art discloses all of the claim elements, it is important to consider whether there is any evidence, other than hindsight, indicating why a POSITA would combine the references in such a way as to arrive at the claimed invention.

30. I understand that a combination is more likely to be nonobvious when the prior art “teaches away” from the proposed combination. I understand that a prior art reference may be said to teach away when (1) a POSITA would be discouraged by the teachings of one prior art reference from combining a feature or teaching from another prior art reference; (2) a POSITA is led in a direction divergent from the claimed invention that is alleged to be obvious; or (3) the proposed combination would render the result inoperable.

31. I understand that, in relation to analyzing a patent claim for obviousness, one must consider certain objective evidence that might suggest the claim is not obvious, which are often referred to as secondary considerations of non-obviousness. These considerations include commercial success, copying, long-felt but unresolved needs, failure of others to solve the problem, unexpected results, and whether the invention was made independently by others at the same time of the invention. I understand that such evidence can outweigh other evidence that might otherwise tend to show obviousness. I further understand that there must be a nexus between the secondary consideration and the claimed inventions' novel features for the secondary consideration to have probative value.

32. I understand that a hypothetical POSITA is considered to have the normal skills and knowledge of a person in a certain technical field, as of the time of the invention at issue. I understand that factors that may be considered in determining the level of ordinary skill in the art include: (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field.

VI. OVERVIEW OF THE SCIENCE AND TECHNOLOGY AT ISSUE

33. In this section, I provide a background on diabetes, products and techniques for managing and treating diabetes, and an overview of CGMs and some of their features. This will provide a framework for my opinions that follow.

A. Diabetes

34. The term “diabetes mellitus” (hereinafter, “diabetes”) rather than referring to a single disease or condition, actually describes a number of separate conditions with different causes and prognoses. But each of these differing types of diabetes share one primary feature: high blood sugar or “hyperglycemia.”

35. In an individual without diabetes, specialized cells in the pancreas called “ β cells” make and release insulin to appropriately regulate the body’s use and storage of glucose. Simply put, insulin is what allows the body’s cells to use glucose as fuel. In a PWD, the body cannot make enough insulin and/or cannot use the insulin it does make well enough to maintain a normal blood sugar level (“euglycemia”), leading to a build-up of excess glucose in the blood.

36. In people with Type 1 Diabetes, the body’s immune system views the pancreas’s β cells as a threat, and destroys them over a few weeks, months, or even years, eventually completely cutting off the body’s natural supply of insulin. In people with Type 2 Diabetes, the body’s ability to use insulin is diminished (commonly referred to as “insulin-resistance”) and, over time, the insulin produced

by the β cells becomes insufficient to maintain euglycemia. Other types of diabetes can be caused by, for example, a temporary increase in insulin-resistance during pregnancy (Gestational Diabetes), damage to the pancreas by another disease such as pancreatitis (Type 3c Diabetes), or a more gradual development of autoantibodies against pancreatic cells, insulin, or pancreatic enzymes (Latent Autoimmune Diabetes in Adults, or “LADA”). Regardless of the type of diabetes or its underlying cause, treating the condition requires some combination of supplementing the body’s own insulin production and/or improving the body’s ability to utilize insulin.

37. However, many of these interventions increase the risk of low blood sugar or “hypoglycemia.” When blood sugar drops into the hypoglycemic range, the patient may experience a wide range of symptoms ranging from confusion, agitation, and feeling shaky to seizures, coma, or even death. The typical hypoglycemia treatment rule we teach is the “15-15 Rule”: consume 15 grams of carbohydrates (preferably something that is quickly absorbed such as juice or glucose tablets) and wait 15 minutes to watch how blood glucose responds before consuming another serving if necessary. Left untreated, mild hypoglycemia can progress to severe hypoglycemia, where the PWD requires the assistance of others to take corrective action. In these cases, the PWD may need to be treated with glucagon, a hormone that stimulates the liver to release stored glucose into the blood stream, that is administered via injection or a dry nasal spray.

38. Just as there are important differences across the various types of diabetes, people diagnosed with a particular type of diabetes are not a monolith. The latest National Diabetes Statistics Report indicates that 38.4 million people in the United States live with diabetes, including about 38.1 million adults aged 18 or older. (Ex. 2028 (CDC, National Diabetes Statistics Report) at 1.) Depending on a number of factors including the PWD's age, sex, pregnancy, and comorbidities, different treatment approaches and different treatment goals may be appropriate. For example, due to the increased possibility for pregnancy complications from hyperglycemia, a pregnant woman's target blood sugar range is likely to be lower, with more risk of moderate hypoglycemia tolerated, when compared to others her age or even her pre-pregnancy-self. On the other end of the spectrum, in older or medically fragile PWDs for whom the acute complications of low blood glucose represent the greater danger, more time spent slightly hyperglycemic can be considered appropriate to minimize the risk of hypoglycemia.

B. Consequences of Hyperglycemia and Hypoglycemia

39. Both hyperglycemia and hypoglycemia can result in acute danger and chronic complications for PWDs.

40. With prolonged hyperglycemia, elevated levels of glucose in the blood damage the tissue of various body systems over time (months to years). This damage can impact the eyes (diabetic retinopathy, decreased vision, blindness), the kidneys

(diabetic nephropathy), the heart and blood vessels (cardiovascular disease, heart attack, stroke, peripheral artery disease), the nerves (diabetic neuropathy), and the body's extremities such as the feet (infections, sores, amputation).

41. In the short term (hours to days), high blood glucose can trigger a hyperglycemic crisis—such as diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome—which requires emergency care, potential hospitalization, and can lead to death. Similarly, acute hypoglycemia may result in the PWD having a seizure, falling into a coma, or dying if the crisis is not treated quickly enough (within minutes). Based on CDC data, in 2020, the rates of adult emergency department visits for hyperglycemic crisis was about 267,000 visits (11.4 per 1,000 adults with diabetes) and for hypoglycemic crisis was about 202,000 visits (8.6 per 1,000 adults with diabetes). (Ex. 2028 (CDC, National Diabetes Statistics Report) at 12.) The number of hypoglycemic crises may be underreported, however, because many episodes are either treated at home or result in the PWD dying in bed. (*See* Ex. 1040 at 1 (noting that “[s]eventy-five percent of hypoglycemic seizures occur at night”).)

C. Diabetes Interventions and Treatments

42. Across all of the illnesses and conditions I have seen over my years as a physician, diabetes is unique in that nearly all of the interventions used to treat diabetes are managed by the PWD or their loved ones. As physicians, we can provide guidance to PWDs on how to manage their diabetes, use various tests to track its

progression, and write prescriptions for the medications and tools they need. A typical PWD may see their primary care physician quarterly and may see a specialist doctor annually to help manage their diabetes—or more frequently if the PWD is dealing with comorbidities or complications. But because there are so many factors that can impact blood sugar, and because blood sugar can vary widely over the course of a single day, it is up to PWDs to determine and implement the appropriate interventions every single day.

43. Interventions to treat diabetes fall into two general categories: behavioral interventions and medication interventions. For individuals whose bodies still produce their own insulin, it is sometimes possible to improve insulin sensitivity—and in doing so improve glycemic control—solely through behavior interventions including dietary changes and increased exercise or physical activity. There are also various classes of medication that can help the body to increase the amount of insulin secreted by the pancreas (i.e., secretagogues such as glimepiride and gliclazide), to use the body's naturally produced insulin more efficiently (i.e., insulin sensitizers), or to increase the amount of glucose filtered out of the blood by the kidneys. For all PWDs with Type 1 Diabetes, and for some with Type 2 and other less common types of diabetes, insulin injections² are necessary.

² In addition to injectable insulin, inhalable insulin has recently become available, but is much less widely used.

44. The goal of modern insulin therapy is to match as closely as possible what the body would do naturally. In essence, the PWD takes over the role of their own pancreas and tries to emulate how it would behave given all of the data available to them. There are currently multiple types of insulin available to PWDs, with different pharmacokinetic/pharmacodynamic profiles depending on which of the pancreas's functions the PWD is trying to match. For example, "ultrarapid" insulin Fiasp first enters the bloodstream in about 2.5 minutes and continues to impact blood sugar for around five hours total, while "long-acting" insulin Lantus is designed to provide a steady level of insulin up to 24 hours from a single injection. The most commonly used insulins for insulin pump therapy—"fast-acting" insulins Novolog and Humalog—have a peak effect one hour after injection or infusion, and last about two to four hours. There are also various dual-peak, pre-mixed insulins available that combine the features of fast-acting and long-acting insulins.

45. The term basal insulin refers to insulin taken to supplement or replace the body's round-the-clock secretion of insulin. In administering basal insulin, PWDs typically either take one to two shots of a long-acting insulin per day at fixed intervals or utilize an insulin pump that provides small amounts of a faster acting insulin spread out over the entire day. In contrast, bolus insulin refers to ultra-rapid or fast-acting insulin taken to supplement or replace the body's response to stimulus that would otherwise cause blood glucose to rise quickly, such as a meal.

46. Importantly, there is no instantaneous way to lower blood glucose: all insulins reach peak efficacy at some point in the future from when they are taken. And there is no way to arrest the effect of insulin once it has been injected: it will continue to work to lower blood glucose for the full time it is active in the body.

D. Blood Sugar Monitoring

47. In order to manage diabetes on a daily basis and track its progression over time, tools have been developed, such as blood glucose monitors (BGM) and continuous glucose monitors (CGM), that provide PWDs and their doctors with data and information about blood sugar levels.

1. Blood Glucose Monitors

48. Due to the multitude of factors that can impact blood glucose and the potential for acute complications, it is important for PWDs to be able to determine their current glucose level. Blood glucose monitors allow the PWD to test their glucose level using a disposable strip that accepts a small drop of blood obtained by lancing the finger. The test strip is inserted into the monitor, which typically activates it, after which the PWD applies a drop of blood to the strip. After a short while, the monitor provides a numerical value for the PWD's blood glucose concentration.

49. The first blood glucose test strip was the Dextrostix, which was developed in 1965. (Ex. 2017 (ADA, Role of Continuous Glucose Monitoring in

Diabetes Treatment) at 3.) The PWD placed a large drop of blood onto the test strip, and after about 60 seconds, the blood washed away and the color of the test strip changed. (*Id.*) The color was then compared to a chart to estimate qualitatively³ how much glucose was present in the blood sample. (*Id.*)

50. Shortly thereafter, in the 1970s, the first blood glucose meter was developed using the Dextrostix. (*Id.*) Although the accuracy was poor, it opened the door to potential home use for BGMs and ways in which PWDs could self-monitor. (*Id.*) By the mid-1980s, BGMs had become more accurate, cheaper, and required little blood to operate. The technology continued to improve through the 1990s and the early 2000s. (*Id.*)

2. Continuous Glucose Monitors

51. Rather than measuring blood glucose intermittently at single moments in time, CGM systems were developed in which the glucose concentration in interstitial fluid is sampled on an ongoing basis. Generally speaking, for most CGMs, these measurements are taken by a sensor that is inserted subcutaneously,

³ Ex. 2017 notes that “[t]he generated color was then compared to a chart on the bottle for a *semi-quantitative* assessment of blood glucose.” (Ex. 2017 at 3.) In my opinion, the comparison to a color chart was more qualitative in nature, although the conclusion from the comparison could also be considered semi-quantitative.

with new replacement sensors inserted from between every few days to once every two weeks.⁴ (*See* Ex. 1039 at 1.)

52. The sensor can be inserted into the subcutaneous region using an inserter (which is sometimes referred to as an applicator). (Ex. 1039 at 1.) The sensor is held in place on the PWD's skin with adhesive. For example, the glucose sensor is usually fastened to a mount or a base that is placed onto the PWD's skin with the inserter, and then the mount or base is held in place on the skin with adhesive. Glucose sensors for most CGMs are electrochemical—they have an enzyme, glucose oxidase, that reacts with glucose and oxygen in the interstitial fluid, which causes an electrical current to develop on the sensor. (Ex. 1039 at 1.) Electronics continuously sample the electrical current on the sensor and convert the current into digital data. The data is then converted to glucose concentration values through a process known as calibration. The glucose concentration values are ultimately displayed to the PWD.

53. The conversion from digital sensor data to glucose concentration values can take place in the CGM transmitter or in the receiver. (Ex. 1019 (Mastrototaro) at [0035].) For example, the CGM transmitter can convert the sensor data into glucose concentration values and then transmit those values wirelessly to a receiver.

⁴ Sensionics' Eversense CGM is surgically implanted and can last a few months.

Alternatively, the CGM transmitter can transmit the sensor data to the receiver, and then the receiver can convert the data into glucose concentration values. (Ex. 1019 (Mastrototaro) at [0035].)

54. There is also software that can receive glucose data from a CGM (or BGM), as well as other types of glucose-related information, such as diet, exercise, and insulin dosing, and generate offline reports in several different formats, including the glucose patterns insight report that I helped develop. As I explain in more detail below, reports generated by such software are invaluable for PWDs and their physicians to develop a plan for managing and treating diabetes, and to uncover insights that would not be available from day-to-day use of CGMs alone.

55. The first CGM was developed by Medtronic MiniMed, called the CGMS, and it was approved by the FDA in 1999. (Ex. 2017 at 3; Ex. 2025 at 6.) It had a sensor that lasted for three days. (Ex. 2017 at 3.) The system did not display or otherwise provide glucose data to the PWD during those three days. (*Id.*; Ex. 2025 at 6.) Instead, once the sensor session ended, a physician would download the data from the device and review it retrospectively with the PWD. (Ex. 2017 at 3.) This is referred to as “blinded” use of a CGM. Medtronic’s product that followed, called the CGMS Gold, was also retrospective only. (Ex. 2025 at 6.)

56. As counsel has explained to me, the priority date for the 056 patent is in 2009 and, thus, 2009 is the relevant timeframe for evaluating the scope and

content of the prior art and any motivation to combine or modify the prior art. As of 2009, not that many commercial CGMs existed.

57. The three major CGM manufacturers at the time were Medtronic, DexCom, and Abbott (and remain so today). As mentioned above, Medtronic had two early retrospective-only CGMs. Medtronic then released the Guardian REAL-Time CGM, which was the first CGM that displayed readings to the user in real-time. (Ex. 2025 at 6.) Shortly after launching the Guardian, Medtronic made the Guardian's CGM components compatible with the Paradigm insulin pump as an optional add-on feature. (*See* Ex. 1011 at 13, 37, 83.) When the Paradigm insulin pump included the CGM components, Medtronic referred to it as the Paradigm® REAL-Time System, which is the subject of Exhibit 1011. (*See* Ex. 1011 generally.)⁵

58. By 2009, DexCom had released three commercial CGM products: (i) the Short Term Sensor, or STS; (ii) the STS-7, which was a 7-day version of the STS (also referred to as the "SEVEN"); and (iii) the SEVEN Plus. (Ex. 2025 at 8.) As of that time, Abbott had released its FreeStyle Navigator CGM. (*Id.*)⁶

⁵ My understanding is that Medtronic also released the iPro in 2008, but that system was used by physicians for blinded studies only. (*See* Ex. 2025 at 6.)

⁶ Other CGMs were developed in the relevant timeframe, such as the GlucoWatch Biographer from Cygnus, but they were not commercially successful. Thus, most of my discussion focuses on CGMs from Medtronic, DexCom, and Abbott, as these have been the leading manufacturers of CGMs over the years.

59. Since 2009, each of Medtronic, DexCom, and Abbott have released several additional CGM systems, including, for example, the Medtronic iPro 2, Enlite, Guardian 3, and Guardian 4 systems; the DexCom G4 Platinum, G5 Mobile, G6, and G7 CGM systems; and the Abbott FreeStyle Libre 14-day, Libre 2, and Libre 3 systems. (*See, e.g.*, Ex. 2025 at 6, 8, 11; Ex. 2026 at 4-5; Ex. 2029 at 1.)⁷

60. CGMs have come a long way since they were first developed. Some now have the capability to interface with an insulin pump and automatically control the delivery of insulin, thereby simulating the natural production of insulin by the pancreas. These types of systems are referred to as Automated Insulin Delivery (AID) systems or closed-loop systems.

61. There is a large body of scholarship written about different features and characteristics of CGMs. A review of all of these features and characteristics is beyond the scope of this declaration. However, there are certain features and characteristics that I highlight and discuss below because they are particularly relevant to the opinions later in this declaration.

⁷ At least Abbott and DexCom have released other systems as well, such as Abbott's Libre Pro and DexCom's G6 Pro, Pro Q, and ONE. There have also been slightly different versions of each CGM released in European markets. For purposes of this declaration, I am not attempting to provide a comprehensive list of every CGM. Rather, the point is that many additional CGMs have been released since 2009.

a. Disposable vs. Reusable Transmitters

62. In the 2009 timeframe, glucose sensors lasted for about 3-7 days depending on the particular CGM. (Ex. 2025 at 6, 8, 11.) Transmitters, on the other hand, were reusable and could be used many times with different sensors. Therefore, CGM sensors and transmitters were sold separately. The PWD would insert a glucose sensor beneath their skin using an inserter, and then connect a transmitter to the sensor. Once the sensor expired, the PWD removed both from their skin, discarded the sensor, inserted a new sensor beneath their skin, and then connected the transmitter to the new sensor.

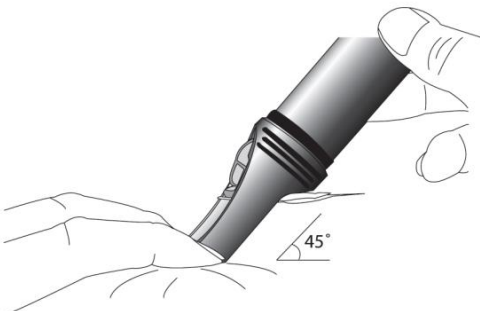
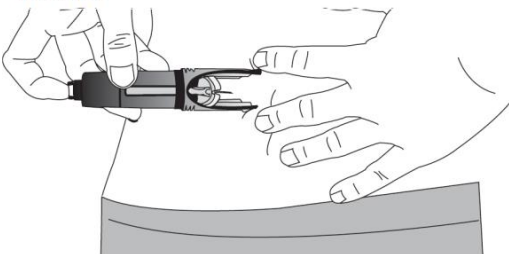
63. For example, the Medtronic MiniLink Transmitter that was used with the Paradigm® REAL-Time System contained “a non-replaceable, rechargeable battery that [the user could] recharge as needed with the charger.” (Ex. 1011 at 51.) “A fully charged transmitter battery will generally work more than 14 days without recharging.” (*Id.* at 52.) A picture of the MiniLink Transmitter is shown below.



MiniLink
Transmitter

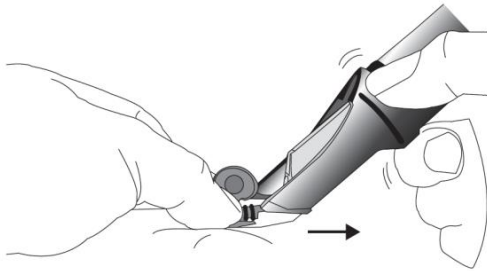
(Ex. 1011 at 51.)

64. The Medtronic Paradigm® User Guide explains that “[t]he sensor is inserted through the skin with an insertion device called the Sen-serter® and placed in the fatty layer under the skin.” (Ex. 1011 at 53.) The User Guide provides 14 steps for inserting the sensor. (*Id.* at 55-58.) Steps 8-14 are reproduced below.

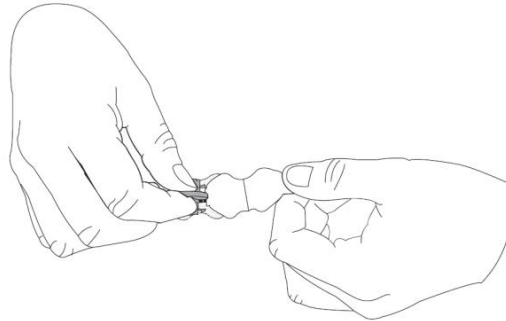
8 Rest the Sen-serter legs flat on skin so the Sen-serter is at a <i>45 degree angle or more</i> to the insertion site. Place two fingers of your other hand on the Sen-serter legs to maintain the correct angle. NOTE - <i>Bleeding can occur if you insert the sensor at an angle less than 45 degrees.</i> 	9 Turn the white button to unlock the Sen-serter. Press the white button to insert the sensor. If the sensor is not fully inserted, it can be manually pushed into place before removing the introducer needle. 
10 Make sure the sensor is inserted and flush with your skin.	

(Ex. 1011 at 56.)

11 While holding the sensor in place, gently slide the Sen-serter away from the sensor. Do not twist, bend or lift the Sen-serter while removing from the sensor.

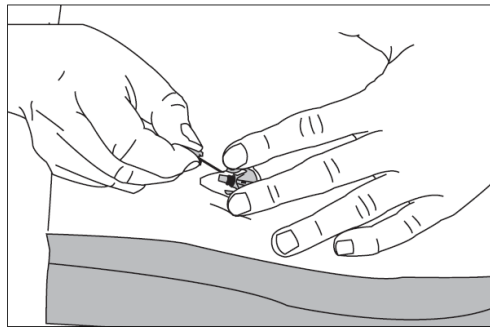


12 Holding the sensor in place, remove the white paper from the adhesive pad. Press adhesive against your skin.



(Ex. 1011 at 57.)

13 Hold the sensor with two fingers on the base, and gently remove the introducer needle. Do NOT rotate the introducer needle when removing. Dispose of the needle in sharps container.



14 Wait 5 minutes after insertion before connecting the transmitter to the sensor. Make sure that the site is not bleeding before connection. If bleeding occurs apply pressure using a sterile gauze or clean cloth for 3 minutes.

When bleeding stops, attach the transmitter to the sensor.

Caution: If bleeding does NOT stop, DO NOT connect the transmitter to the sensor.

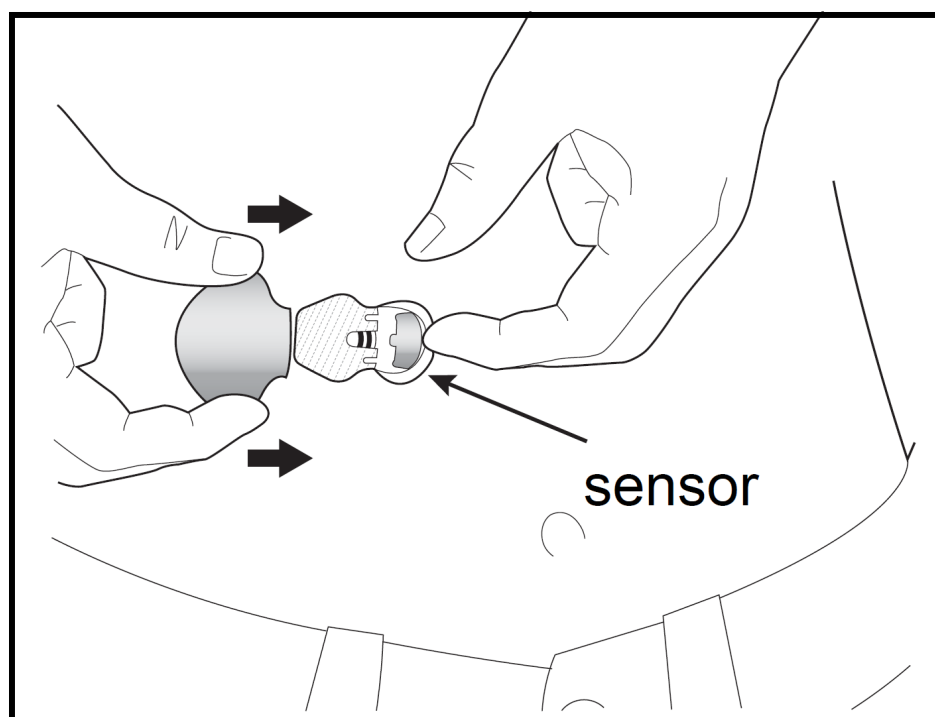
- a.** Remove the sensor and discard.
- b.** Reapply pressure using a sterile gauze or a clean cloth until the bleeding stops.
- c.** Insert a new sensor in a different location.

(Ex. 1011 at 58.)

65. As shown above, the glucose sensor was connected to a base that was held on the PWD's skin with adhesive. (Ex. 1011 at 57-58.) After removing the

introducer needle, the PWD waited “5 minutes after insertion before connecting the transmitter to the sensor.” (Ex. 1011 at 58.) This was to “[m]ake sure that the site is not bleeding before connection.” (*Id.*)

66. Once five minutes passed and/or the site was no longer bleeding, the PWD connected the transmitter to the sensor. To do so, the Paradigm® User Guide instructed the PWD to “[h]old the transmitter ... to line up the two notches on both sides with the flexible side arms of the sensor.” (Ex. 1011 at 59.) “The transmitter’s flat side with the label should face the skin.” (*Id.*) Then, “[s]lide the transmitter onto the sensor and push in firmly until the flexible side arms of the sensor ‘click’ into the notches on both sides of the transmitter.” (*Id.*) This is shown below.



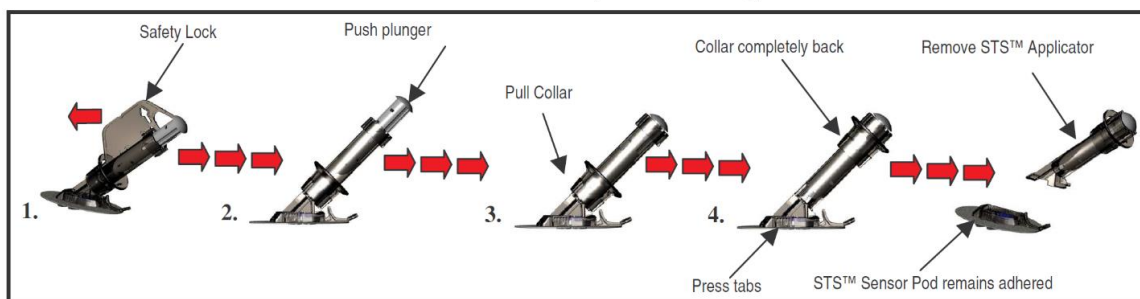
(Ex. 1011 at 59.)

67. DexCom's products also included reusable transmitters except for its newest product, the G7, which was released in 2023. DexCom referred to the mount or base that was installed on the PWD's skin as a "sensor pod." (*See, e.g.*, Ex. 2001 at 6 ("The STS Transmitter is a reusable device that snaps into the STS Sensor Pod and wirelessly sends glucose information measured by your STS-7 Sensor to the STS Receiver."), 8 ("STS Sensor Pod": "The small base adhered to your abdomen that holds the STS Transmitter in place. The STS Sensor Pod and STS Transmitter are all that remain on your skin during each STS-7 Sensor wear period.").) The sensor pod included a sensor and was held on the PWD's skin with adhesive. (Ex. 2001 at 20-21.)

STEP 1- Inserting a New STS™ Sensor

Choose a site on your abdomen (belly) to put the Sensor that is a flat area and where you don't have any scarring or rough patches of skin and clean the site with an alcohol swab. Remove the adhesive backing from the STS™ Sensor Pod and place the STS™ Sensor on the selected site.

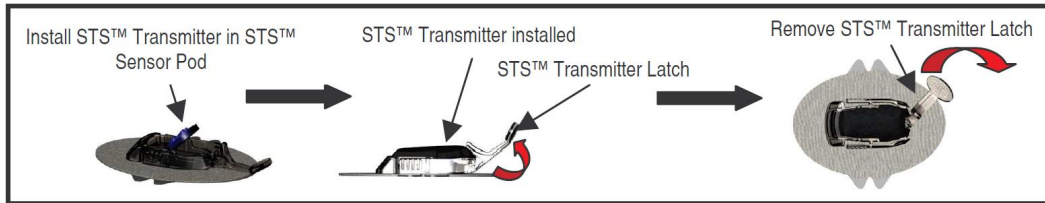
1. Pull the safety lock out from the Applicator.
2. Place 2 fingers under the collar, with your thumb on the plunger, and push the plunger down completely.
3. At the same time that you are pushing the plunger down, pull the collar back completely until you hear a click.
4. Press the tabs on the sides of the STS™ Sensor Pod and pull out the STS™ Applicator.



(Ex. 2019 at 1.) After the sensor was inserted and the sensor pod was adhered to the PWD's skin, the transmitter was installed in the pod.

STEP 2- Installing Your STS™ Transmitter

- Place the STS™ Transmitter into the STS™ Sensor Pod with the flat side facing down.
- Pull the STS™ Transmitter Latch up onto the STS™ Transmitter to snap it into place.
- Remove the STS™ Transmitter Latch by holding the end of the latch and quickly twisting off the latch away from your body.



(Ex. 2019 at 2.)

68. DexCom's other products also used a two-piece architecture in which a reusable transmitter connected to a sensor after the sensor was inserted beneath the PWD's skin. (Ex. 2030 (SEVEN Plus Users Guide) at 48-51; Ex. 2002 (G4 Platinum User's Guide) at 62-67; Ex. 2031 (G5 Mobile User Guide) at 86-93; Ex. 2020 (G6 CGM User Guide) at 75-83).

69. In the G6 User Guide, the sensor pod is referred to as a "transmitter holder." The G6 applicator included the transmitter holder with a sensor.

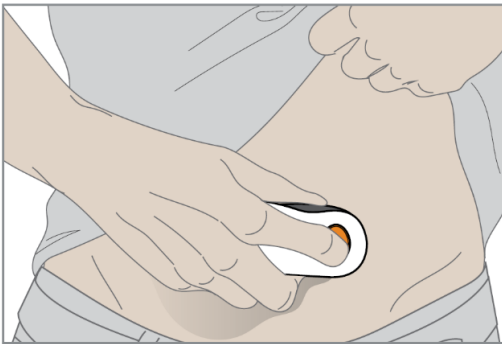
What you see	What it's called	What it does
The diagram shows a G6 applicator, which is a small, curved device used to insert the sensor wire under the skin. A circular inset provides a magnified view of the sensor wire being inserted. Labels include 'Applicator' pointing to the main device and 'Sensor (inside)' pointing to the wire within the skin.	Applicator with built-in sensor	Applicator helps you insert the sensor wire under your skin. Sensor gets your glucose information.

(Ex. 2020 at 47.)

70. Using the applicator, the PWD inserted the sensor beneath their skin while adhering the transmitter holder to their body.

STEP
8 of 10

Insert Sensor

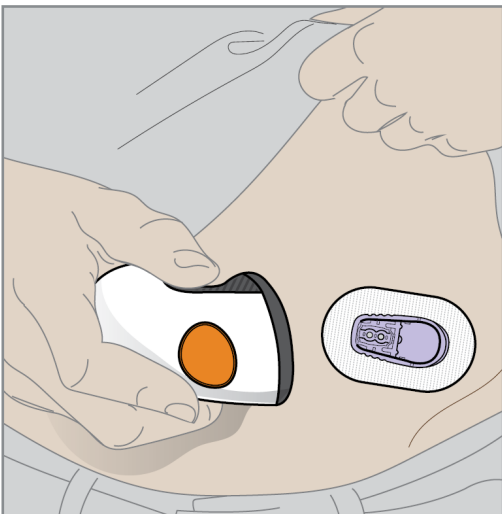


Push and release button to insert sensor.

(Ex. 2020 at 79.)

STEP
9 of 10

Insert Sensor



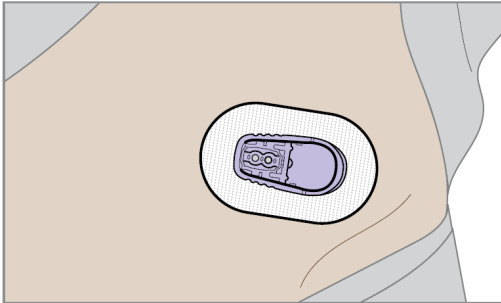
Remove applicator.

Throw out applicator following local guidelines for disposal of blood-contacting components.

(Ex. 2020 at 80.)

STEP
10 of 10

Insert Sensor



What's left on you?

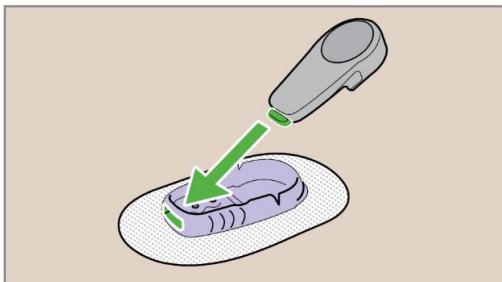
- Sensor wire
- Transmitter holder
- You've successfully inserted the sensor!

(Ex. 2020 at 80.)

71. The PWD then connected the reusable transmitter to the sensor by snapping the transmitter into the transmitter holder.

STEP
3 of 5

Attach Transmitter

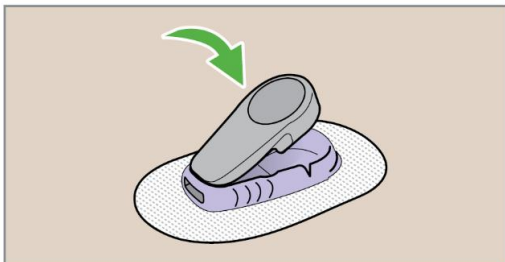


Slide transmitter tab into the slot at the narrow end of the holder.

(Ex. 2020 at 82.)

STEP
4 of 5

Attach Transmitter



Press the wide end of the transmitter until it clicks into the holder.

(Ex. 2020 at 83.)

72. Abbott's FreeStyle Navigator also included a reusable transmitter that was installed in a mount to connect to the glucose sensor.

Steps

- 1. Attach the transmitter to the sensor support mount.**



Fig. 1

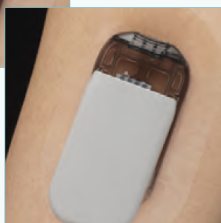


Fig. 2

Do This

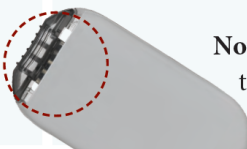
- a. Position the transmitter over the sensor support mount so that the battery side faces the mount.
- b. Lower the transmitter onto the mount.

Note: It helps to position the transmitter's connector directly over the *round part of the "keyhole"* (Fig. 1) as you lower the transmitter.

Result: *The transmitter fits flush against the mount and slides smoothly back and forth on the guide rails.*

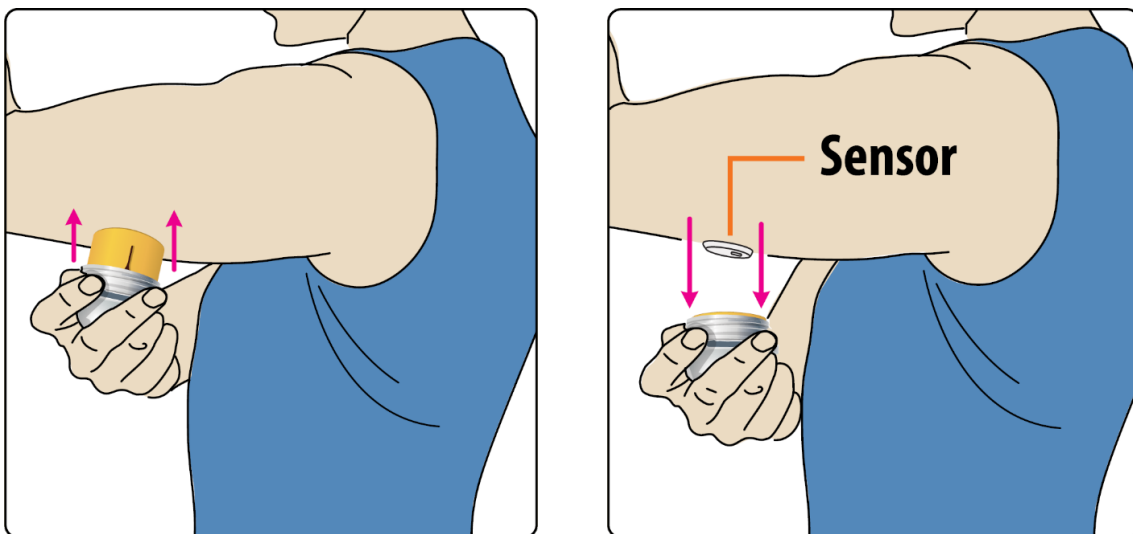
- c. Hold the transmitter between your forefinger and thumb and slide the transmitter until it clicks into place. Apply firm pressure as you slide the transmitter into place. (Fig. 2)

Note: It is normal to see a gap between the transmitter and the support mount towards the top.



(Ex. 2021 at 58.)

73. Abbott changed course with its FreeStyle Libre products. Instead of a reusable transmitter that connects to a new sensor for each glucose monitoring session, the FreeStyle Libre products feature a disposable transmitter unit, which is sometimes referred to as an “on-body unit” or an “on-body electronics unit.” The transmitter unit includes a single integrated housing in which a glucose sensor is pre-connected to electronics. The transmitter unit is loaded in an inserter and, in one step, the PWD inserts a portion of the glucose sensor beneath their skin while the transmitter unit is adhered to their body. This is shown, for example, in the FreeStyle Libre 3 User’s Manual.



(Ex. 2022 at 39.)

74. The FreeStyle Libre sensors last for about 14 days. (Ex. 2022 at 189.)

Once the 14 days have ended, the PWD removes the transmitter unit from their body, discards it, and installs a new one.

Removing Your Sensor	
Step	Action
1	 Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion. Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.
2	Discard the used Sensor following directions from your health care professional. See <i>Maintenance and Disposal</i> section. When you are ready to apply a new Sensor, follow the instructions in <i>Applying Your Sensor</i> and <i>Starting Your Sensor</i> sections. If you removed your last Sensor before it ended, go to "Start New Sensor"))) in the menu to start the new one. You will be prompted to confirm that you would like to start a new Sensor. Note: After removing your Sensor you may observe a slight bump at the insertion site. This goes away quickly, usually in a day or two.

(Ex. 2022 at 125.)

b. Accuracy

75. There are different metrics and methods by which to assess the accuracy of a CGM. Some of these are the mean absolute relative difference (MARD), precision absolute relative deviation (PARD), and the Clarke-Error Grid (EGA). MARD tends to be one of the more common metrics to assess accuracy. MARD is the difference between a person's CGM readings and matched blood glucose reference measurements taken at the same time. (Ex. 2026 at 8.) The lower the MARD value is, the more accurate the CGM system is. (Ex. 2017 at 10 (“Lower MARD values indicate greater device accuracy”).)

76. As of 2009, commercially-available CGMs had MARD values that generally ranged between about 15% to 25%. One article, for example, lists the MARD for the Medtronic Guardian as 17.2%, the DexCom STS as 26%, and the DexCom SEVEN-Plus as 16%. (Ex. 2026 at 4-5.)

77. As mentioned earlier, the Medtronic Paradigm® REAL-Time system was an insulin pump that used the CGM components from the Medtronic Guardian. Near the end of the Paradigm® User Guide, which is part of Exhibit 1011, there is a chapter on “Sensor accuracy.” This chapter details a study in which “YSI measurements (taken every half hour) were paired with the corresponding Guardian RT reading (taken every 5 minutes).” (Ex. 1011 at 85.) The study found that the

MARD for the Guardian sensor was about 19.7% and had a bias⁸ of about -15 mg/dL. (Ex. 1011 at 85.) From an accuracy perspective, the Medtronic Paradigm® REAL-Time system was not very accurate in my opinion.

78. Poor accuracy was initially a barrier to adopting CGMs. For example, one article explains:

Compared to SMBG, whose MARD falls between 5% and 10%, the low accuracy (i.e., elevated MARD) of these “first generation” CGM systems represented one of the major barrier for the early adoption of these devices by both users, who felt unsafe in adopting CGM, and many leading diabetologists, whose reluctance to integrate CGM sensors in the daily diabetes management greatly limited the spreading of this technology.

(Ex. 2016 at 3.)

79. Current CGMs are now far more accurate. One example is the FreeStyle Libre 3 (“FSL3”), which is offered by Abbott Diabetes Care. The MARD for the FSL3 has been measured as low as 7.9%. (Ex. 2026 at 5.)

⁸ Sensor bias is similar to MARD, but with directionality. For example, a bias of -15 mg/dL means that, on average, the CGM readings are 15 mg/dL below the user’s actual glucose readings.

c. Adjunctive vs. Non-Adjunctive Use

80. CGMs are medical devices that require FDA approval before they can be sold in the United States. A CGM can be approved for adjunctive use or non-adjunctive use.

81. Adjunctive use means that the glucose information provided by the CGM is not reliable or accurate enough, and therefore the CGM is not cleared by the FDA, for making treatment decisions, including for calculating insulin doses. Instead, a blood glucose measurement is needed for therapy decisions and insulin calculations. As of 2009, all CGMs were approved by the FDA for adjunctive use only. (Ex. 2016 at 6.) As one article explains, this was because CGMs were too inaccurate for non-adjunctive use:

Until a few years ago [as of 2019], all CGM devices for personal use were approved to be used in adjunct to SMBG, i.e., before making the treatment decisions patients were required to check CGM readings by confirmatory fingersticks. Indeed, as described in Section “History of CGM Sensors,” past CGM sensors suffered from accuracy problems due to plasma-interstitium kinetics, imperfect calibrations, compression artefacts and sensitivity to interfering substances, such as acetaminophen.

(Ex. 2016 at 6.)

82. For example, a User’s Guide for DexCom’s STS-7 System explains:

- This device is not designed to replace a blood glucose meter. The STS-7 System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the STS-7 System. You must confirm with a blood glucose meter before making therapeutic adjustments.

(Ex. 2001 at 7.) The Medtronic Paradigm® REAL-Time system had the same restrictions:

Does the MiniMed Paradigm REAL-Time System replace fingerstick measurements?

No. You still need to use your blood glucose meter to confirm a continuous glucose monitoring (CGM) reading before treating and to calibrate the CGM system. The FDA has approved REAL-Time CGM with conservative labeling, so fingerstick measurements are still required before therapy adjustments are made.

(Ex. 1011 at 10; *see also* Ex. 1011 at 15 (“A confirmatory fingerstick using a standard blood glucose meter is required prior to making self-management or therapy decisions.”).)

83. Non-adjunctive use means that the glucose information provided by the CGM is reliable and accurate enough to be used for making treatment decisions, including calculating insulin doses, without the need for confirmatory fingerstick measurements. For a CGM to be approved for non-adjunctive use, it must comply with rigorous requirements under the FDA’s guidelines, which can be found at 21 C.F.R. § 862.1355. As one article explains, the first time the FDA approved a CGM for non-adjunctive use was in 2016:

Thanks to recent technological developments and enhancement of signal processing algorithms, the accuracy of CGM sensors has been remarkably improved during the last years, reaching the range of accuracy performance of SMBG devices (MARD <10%). These improvements led to the regulatory approval of CGM nonadjunctive use, i.e., the use of CGM readings to make treatment decisions without confirmatory fingersticks, whose safety and effectiveness have been proved by simulations [8] and a randomized non-inferiority clinical trial [33]. From 2014 to 2015, three CGM sensors received the nonadjunctive label in Europe: the FreeStyle Navigator II, the FreeStyle Libre and the Dexcom G5 Mobile. The approval of nonadjunctive use by the FDA came a couple of years later: the Dexcom G5 Mobile obtained the approval in 2016, followed by the FreeStyle Libre in 2017 and the Dexcom G6 in 2018.

(Ex. 2016 at 6.)

d. Historical Reports

84. As I noted above, the first two CGMs approved by the FDA, which were manufactured by Medtronic, were retrospective only, or “blinded.” This means that the PWD wore the CGM for a period of time (~3 days) without knowing or seeing the data that it was collecting. Once the sensor expired, the PWD took the CGM to their physician, who would download the data from the CGM and analyze it retrospectively.

85. Once CGMs became real-time, the PWD could see the information that was being collected on a display unit (i.e., receiver unit). Typically, glucose information was displayed numerically and/or graphically. The information was also stored and available for download, for example, to a computer that could run much more powerful diabetes management software than was capable of being run on the CGM receiver.

86. CGMs are tools that were designed to change behavior. They do not treat diabetes or make the PWD's disease get better. Instead, they help PWDs understand details about their body that are not readily available. In the 2009 timeframe (and even so today), one of the primary uses of a CGM was to collect, organize, analyze, and summarize glucose data to transform it into actionable information.

87. Most diabetes management software accepts not only CGM data, but also related information such as information about the PWD's diet, exercise, and insulin doses. The software can analyze large amounts of this data and information and then detect patterns and trends that would not otherwise be discernable. This information is then used to generate different types historical reports, which can be saved, printed, emailed, and/or shared with treating physicians. Historical reports were and remain critical tools for clinicians to help PWDs manage their diabetes.

88. I have personally reviewed thousands of reports over the years. They are useful for conveying a lot of information to the PWD and helping them understand how their daily choices are impacting their blood sugar levels.

89. Exhibit 1039 (dated 2007) lists a few different diabetes management software applications that were available at that time, which included Abbott's FreeStyle CoPilot, DexCom's DM Consumer Data Manager, and Medtronic's Carelink personal software. (*See* Ex. 1039 at 3.) As that article explains:

There is a tremendous amount of information in the reports generated from real-time continuous glucose monitoring. As healthcare providers, we have found the reports generated by the CareLink software from MiniMed particularly helpful since these reports integrate the information from the insulin infusion pump with home glucose monitoring and their continuous glucose monitoring data. As it is known when a meal bolus is given, the software allows synchronization of blood glucose levels in the hours before and after a meal bolus, even if the meal is given at variable times over multiple days. The 'Daily Detail' report graphically shows continuous glucose monitoring data (including alarms), insulin pump data and carbohydrate intake. We have found this report particularly helpful in identifying problems with the carbohydrate to insulin ratio, a 'missed meal bolus', overtreatment of hypoglycemia and inappropriate suspension of the basal rate.

(Ex. 1039 at 7.)

90. Exhibit 1040 also provides a nice summary of the importance of historical reports for diabetes management:

Retrospective analysis of uploaded RT-CGM data allows the patient to recognize glucose trends, to make changes to basal rates, carbohydrate-to-insulin ratios, and insulin sensitivity for correction dose, and to modify their food choices and responses to activity. Retrospective analysis of downloaded data is the primary tool the health care provider has in making recommendations to the patient wearing a RT-CGM.

(Ex. 1040 at 4.)

91. As noted above, Medtronic's diabetes management software was called CareLink. Exhibit 1011 includes several frequently asked questions (FAQs) that were apparently on Medtronic's website in 2007, some of which relate to CareLink. (See Ex. 1011 at 6-13.) One FAQ states: "Why should I use CareLink Personal Software?" (Ex. 1011 at 11.) The response states:

Understanding the effects of insulin dosage, eating habits, exercise routine, and medication on glucose levels is the key to improving your diabetes control. Seeing this cause-and-effect relationship in chart, graph, and table formats allows you to better identify patterns and problems that will help you figure out the root cause of your low and high blood glucose levels. With CareLink Personal software, you are empowered to effectively maximize your therapy by working with your healthcare professional to reach your individual goals.

(Ex. 1011 at 11.)

92. Exhibit 2007 is the CareLink Personal Software Getting Started Guide (“CareLink Guide”). The CareLink Guide explains that the CareLink software “goes beyond meter software or logbooks to give you and your healthcare provider clearer insight into your personal glucose patterns for improved therapy management.” (Ex. 2007 at 1.) The software was a “free online tool that allows the discovery of patterns and problems that meter software and logbooks would not uncover.” (Ex. 2007 at 3.) Among its many benefits, the CareLink software allowed PWDs to:

- Have greater control by understanding the effects of insulin, carbohydrates and exercise on [their] glucose levels
- Effectively maximize [their] therapy by easily identifying patterns and problems
- Work more productively with [their] healthcare provider by sharing detailed reports in order to make therapy and lifestyle changes
- Get the full picture with continuous glucose monitoring data by revealing more low or high glucose patterns than fingerstick data

(Ex. 2007 at 3.)

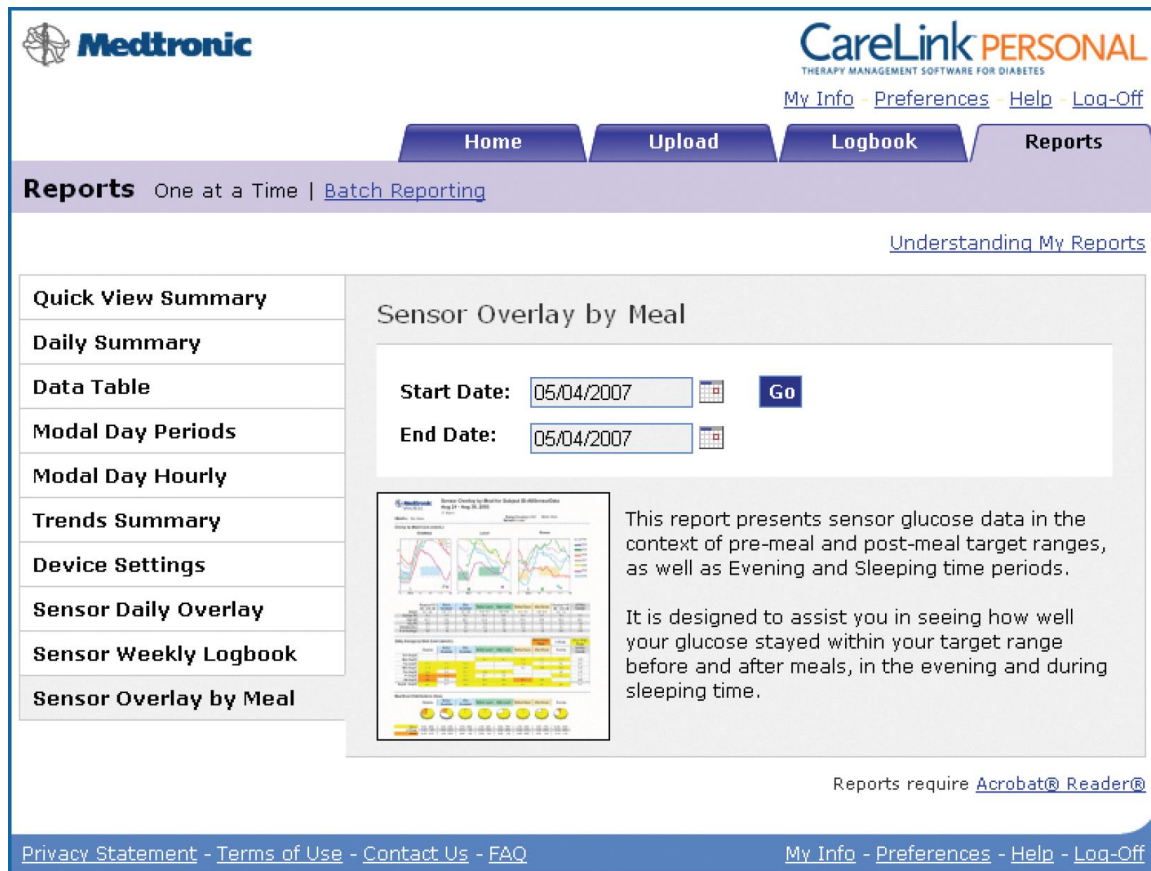
93. The CareLink software made it easy to share historical reports with healthcare providers. The CareLink Guide explains:

As an added benefit, CareLink Personal software is designed so it can integrate with CareLink Pro software for healthcare providers. You can easily and quickly upload your latest device data to our secure site, and if your provider has CareLink Pro software, he/she can download your device data in advance of your office visit. You and your provider both save time, enabling you to focus fully on getting the best therapy results

(Ex. 2007 at 3.)

94. The CareLink software could generate many different types of reports.

(See Ex. 2007 at 13-18.) A screenshot of the main reports page is shown below:



(Ex. 2007 at 16.) Some of the “most commonly used reports” were the “Quick View Summary Report,” “Sensor Daily Overlay” Report, “Sensor Overlay by Meal” Report, and “Daily Summary” Report. (Ex. 2007 at 13-15.) All of the different types of report were “displayed in PDF format.” (Ex. 2007 at 16.) They could “be viewed online, saved, printed and/or e-mailed.” (*Id.*)

e. Data Gaps

95. In my experience and based on my review of the literature that has been provided in this proceeding, as of 2009, when an issue occurred in a CGM system, the system would display an alarm message, and sometimes it would display a data gap in place of glucose data on the receiver unit. I have not seen evidence in this proceeding of a CGM system that would fill a data gap with missing data on the receiver's display except for the 056 patent.

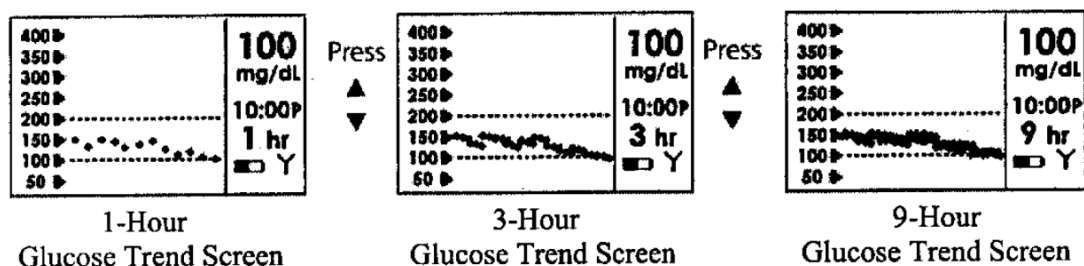
96. This is unsurprising because, as of 2009, one of the primary uses of CGMs was to uncover patterns in a PWD's glucose levels and assess how their lifestyle impacted glucose levels. This information could be gleaned through historical reports. Such patterns were not detectable with only a few hours of glucose data. Therefore, whether the CGM receiver displayed a data gap for a short period of time or filled in the gap with data, it would not have impacted the long-term patterns that were detectable with historical reports. And since all CGMs were adjunctive in 2009, the backfilled data could not have been used for making treatment decisions anyhow. Additionally, displaying the backfilled data might not be desirable in all situations and could potentially confuse patients. (*See infra* ¶¶ 159-162.)

97. One of DexCom's earlier systems, the STS-7 launched in about 2007 (Ex. 2025 at 8), is an example of an early CGM system. The STS-7 displayed glucose

readings numerically and on a trend graph that could be set to 1-hour, 3-hour, or 9-hour time scales.

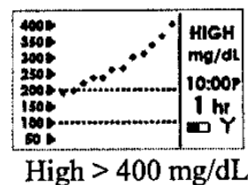
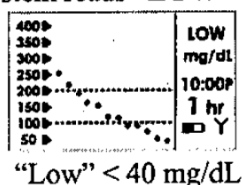
4.1 GLUCOSE TREND SCREENS

You can see trend graphs of your glucose information from the past 1-hour, 3-hour and 9-hour periods by pressing the Up ▲ and Down ▼ Arrows on your STS® Receiver. These Glucose Trend Screens allow you to see where your glucose levels have been and where your glucose levels are headed.



(Ex. 2001 at 34.) If glucose levels dropped below 40 mg/dL or exceeded 400 mg/dL, the system replaced the numerical value with a message of “LOW” or “HIGH,” respectively.

- The STS-7 System reports glucose readings from 40 to 400 mg/dL and updates glucose readings every 5 minutes.
- The STS-7 System reads “LOW” when <40 mg/dL and “HIGH” when >400 mg/dL



(Ex. 2001 at 34.)

98. While the system was being used, certain conditions could interrupt the system’s capability to provide glucose readings. The User’s Guide explains:

4.6 MISSING STS-7 GLUCOSE INFORMATION (GLUCOSE DATA GAPS)

At times your STS-7 System will not display glucose information or provide alerts. These Glucose Data Gaps can happen when:

1. The Transmitter and Receiver are out of range.
2. The STS Receiver does not understand the STS-7 Sensor signal.
3. The STS-7 System needs another BG fingerstick readings for calibration because the STS-7 Sensor readings do not match your blood glucose meter readings.

Reasons for "Glucose Data Gaps" and what to do to receive new STS-7 readings are described in the Sections below.

WARNING:

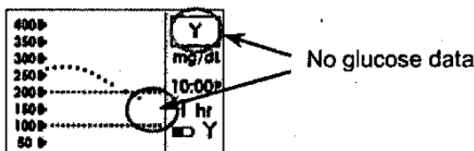
- This device is not designed to replace a blood glucose meter. Especially during Glucose Data Gaps, rely on your blood glucose meter.
- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose confirm them using your blood glucose meter.

(Ex. 2001 at 38.)

99. One reason for glucose data gaps was when the STS-7 Transmitter and Receiver went out of wireless range:

4.6.1 MISSING GLUCOSE READINGS – NO "Y"

- Anytime you see the Antenna Icon "Y" in the Status Box instead of a glucose reading the STS Receiver has "missed" the last glucose reading sent by the Transmitter to the Receiver.



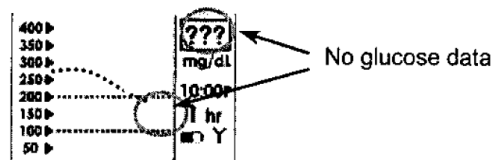
- Make sure your STS Receiver is within 5 feet of the STS Transmitter/STS Sensor Pod. If it is not, move your STS Receiver closer and wait at least 5 minutes. The "Y" icon in the Status Box should go away and you will receive a STS-7 glucose reading in the next 5-10 minutes.
- If you are still having trouble receiving STS-7 readings because of this problem, contact DexCom Technical Support at 1-877-DEXCOM4 (339-2664).

(Ex. 2001 at 38.)

100. Another reason for glucose data gaps was when the STS-7 Sensor generated readings that the system could not understand:

4.6.2 MISSING GLUCOSE READINGS – “???”

During continuous glucose monitoring your STS[®] System may get a reading that it does not understand. When this occurs you will see 3 question marks (???) in the STS Receiver Status Box.



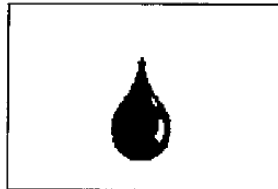
- Check the placement of your STS-7 Sensor to make sure it is still sticking well to your skin and that nothing is rubbing the STS-7 Sensor Pod (i.e. clothing, seat belts, etc.).
- The (???) can also happen because your glucose readings are rapidly rising or rapidly falling.
- The STS Receiver can tell if there are “Major” or “Minor” issues with your Sensor signal where it cannot calculate a STS-7 glucose reading. Minor sensor issues can be resolved (go away) and the STS-7 System will be able to give you more glucose readings.
- A series of “Major” issues with your Sensor can cause the STS Receiver to automatically turn off before the end of a full 7-day session (see Section 4.7). If you see the “Failed Sensor” Screen you will need to replace your STS-7 Sensor and start a new continuous glucose monitoring session.
- Glucose readings will be displayed again once the STS-7 System determines it is okay to do so.

(Ex. 2001 at 39.)

101. A third reason for glucose data gaps was when the STS-7 needed to be re-calibrated:

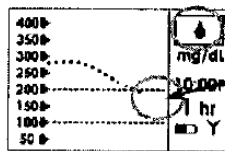
4.6.3 MISSING GLUCOSE READINGS – “” DURING CALIBRATION UPDATE/RECALIBRATION

- When you take and upload a BG fingerstick for calibration (Section 4.5), the STS®-7 System checks how well it is functioning compared to the BG meter. The calibration update process takes about 15 minutes. During your first calibration update attempt, the STS-7 System may determine that another BG reading is needed. The Calibration Update Screen will appear again (shown below) and the STS Receiver will vibrate.



Calibration Update Screen

- Clear this Screen by pressing any button. The display will return to the 1-hour Trend Screen. You will see a blood drop icon in the Status Box instead of a glucose reading.



No glucose data

Awaiting Calibration Fingerstick Icon

- The blood drop icon indicates that the STS-7 System requires at least one more BG fingerstick reading to start displaying glucose readings and providing alerts again.
- Take another BG fingerstick and upload this information to the Receiver. After you do this, your STS-7 System will take about 15 minutes to update calibration. The blood drop symbol will remain in the upper right corner during the 15-minute period.
- After successful re-calibration your STS-7 System will display glucose readings, trends and provide Alerts and ALARMS again.

(Ex. 2001 at 40.)

102. In each instance, the system displayed a data gap and did not backfill it with the missing data.

103. Several of DexCom's products that followed the STS-7, including the SEVEN Plus, G4, and G5, operated in the same way—they displayed data gaps for

different reasons but did not backfill them. (*See, e.g.*, Ex. 2030 (SEVEN Plus Users Guide) at 52, 64, 71, 76-77; Ex. 2002 (G4 Platinum User's Guide) at 93; Ex. 2031 (G5 Mobile User Guide) at 204-205.)

104. In 2016, DexCom received FDA approval to update the "G5 Mobile iOS App Software and G5 Mobile Transmitter Firmware for DexCom's G5 Mobile Continuous Glucose Monitoring System" to "backfill data from the CGM if there are data gaps within the last 3 hours." (Ex. 2003 at 1.)

105. Therefore, from DexCom's first CGM system until the G5 was updated in 2016, all of DexCom's products displayed data gaps for various reasons but did not backfill them.

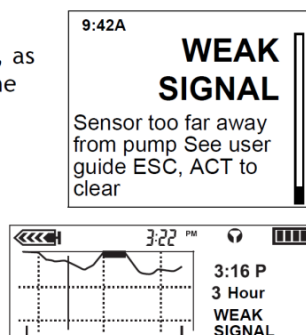
106. The Medtronic Paradigm® REAL-Time documentation also does not disclose backfilling missing data on a CGM display. The insulin pump is described as displaying glucose readings numerically and on a trend graph that could be set to 3-hour and 24-hour time scales. (*See, e.g.*, Ex. 1011 at 64.)

107. The Paradigm® User Guide explains that the user might encounter certain alarms while using their insulin pump, such as a weak signal:

Weak signal

Alerts you when the pump does not receive data for a period of time, as set in Missed Data. Move the pump closer to the transmitter or move the transmitter and the pump to a new location on your body.

NOTE - You may see a Weak Signal recorded on the sensor graphs without receiving an alert. An alert condition will start once the pump has not received sensor data for the length of time set in Missed data (page 13).



(Ex. 1011 at 73.)

108. If the “WEAK SIGNAL” persisted for more than 40 minutes, the pump would display a “LOST SENSOR” alert. (Ex. 1011 at 73.)

109. Other alarm conditions listed in the Paradigm® User Guide include “Low transmr,” “Bad transmr,” “Bad sensor,” “Sensor end,” “Cal error,” “Meter BG now,” “Meter BG by,” “Low glucose,” “High glucose,” and “Sensor error.” (Ex. 1011 at 74-76.) There is no disclosure, however, of displaying a data gap on the pump’s screen when any of these other conditions occurred. Instead, Paradigm® User Guide indicates that one of several alarm messages would be displayed. (Ex. 1011 at 74-76.)

110. There is also no disclosure anywhere in the Paradigm® User Guide that suggests a data gap appearing on the pump’s screen would be backfilled with missing data. Instead, for a troubleshooting technique when the transmitter and receiver stopped communicating wirelessly, the Paradigm® User Guide discloses “[m]ove the pump closer to the transmitter or move the transmitter and the pump to

a new location on [their] body.” (Ex. 1011 at 73.) There’s no explanation for how the missing data could be obtained.

E. Overview of the 056 Patent

111. The 056 patent was filed on August 25, 2021 and issued on April 12, 2022. (Ex. 1001 at 1.) It is a continuation of an application that was filed on April 30, 2021 (Application No. 17/245,719, which is now U.S. Patent No. 11,116,431). That application was a continuation of an application that was filed on December 21, 2018 (Application No. 16/228,910, which is now U.S. Patent No. 11,013,431). That application was a continuation of an application that was filed on March 4, 2016 (Application No. 15/061,774, which is now U.S. Patent No. 10,194,844). That application was a continuation of an application that was filed on June 24, 2013 (Application No. 13/925,694, which is now U.S. Patent No. 9,310,230). That application was a continuation of an application that was filed on April 28, 2010 (Application No. 12/769,635, which is now U.S. Patent No. 8,483,967), which was the first patent application filed in the family. (Ex. 1001 at 1.)

112. Each of the above-mentioned applications also claim priority to provisional application No. 61/173,600, which was filed on April 29, 2009. (Ex. 1001 at 1.)

113. Based on the above, it is my understanding that the claims of the 056 patent are entitled to a priority date of April 28, 2010 based on the filing date for the

first application in the patent family, and are entitled to a priority date of April 29, 2009 based on the filing date of the provisional application. My understanding is that Abbott asserts it is entitled to the priority date of April 29, 2009 based on the provisional application, and that DexCom has not challenged that assertion in this IPR. For purposes of my declarations, I have applied April 29, 2009 as the relevant priority date. However, my opinions would not change even if the claims of the 056 patent were entitled to a priority date of April 28, 2010 based on the filing date for the first application in the patent family.

114. The 056 patent has one independent claim and 29 dependent claims. I understand that DexCom has challenged the patentability of all claims 1-30 except for claims 13 and 29.

115. Independent claim 1 is provided below. For ease of reference, I have adopted the claim element numbering that DexCom and Mr. Gross used.

[1.A] A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:

[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;

[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:

[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

[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

[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,

[1.G] output to the display of the receiver unit, a numerical value representing the processed sensor data,

[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,

[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;

[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;

[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

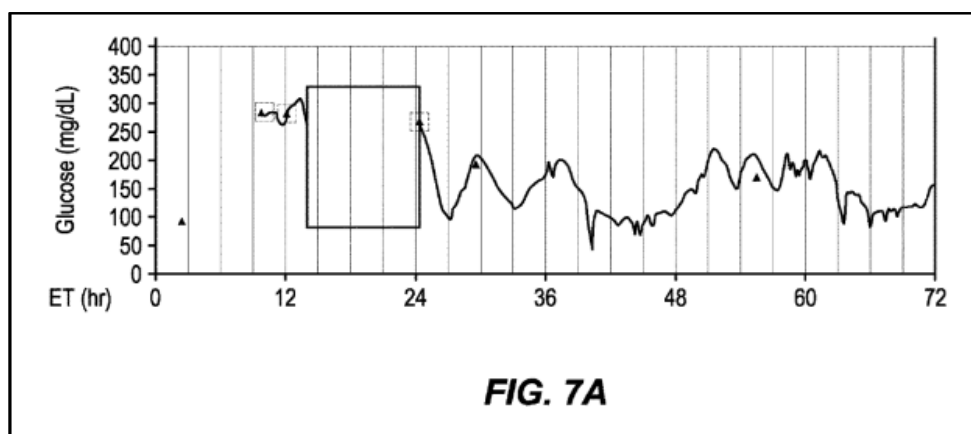
[1.L] wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and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

116. The 056 patent discloses and claims inventions that relate to backfilling data gaps in a CGM system when adverse conditions occur. (Ex. 1001 at 15:24-26.) As shown above in claim 1, the claimed glucose monitoring system comprises “a glucose sensor” and “a data processing and transmitter unit coupled to the glucose sensor.” (*Id.* at 15:27-32.) A portion of the glucose sensor is “configured to be positioned under skin of the user” and “sample a biological fluid of the user to provide sensor data.” (*Id.* at 15:27-30.) The data processing and transmitter unit comprises “a processor,” “memory,” and “a radio frequency transceiver.” (*Id.* at 15:31-36.) The claimed glucose monitoring system further comprises “a receiver unit,” which includes “a processor,” “memory,” “a radio frequency transceiver,” “an antenna,” and “a display.” (*Id.* at 15:52-54.)

117. In operation and as claimed, the data processing and transmitter unit can be configured to “receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit.” (Ex. 1001 at 15:39-41.) It is further configured to “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.” (*Id.* at 15:42-47.) The processed sensor data is transmitted “over a Bluetooth wireless communication link.” (*Id.* at 15:48-51.) The receiver unit, in turn, is configured to receive “the processed sensor data over the Bluetooth wireless communication link,” and to output to the display of the receiver unit “a numerical value representing the processed sensor data” and “a first line graph that is a substantially continuous depiction of the processed sensor data over time.” (*Id.* at 15:56-64.)

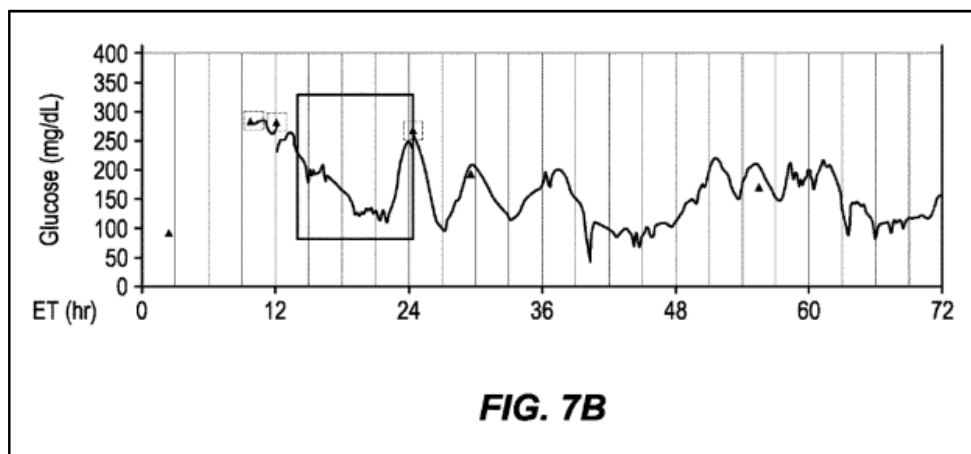
118. As the user monitors their glucose levels, the claimed monitoring system is “configured to detect an adverse condition” that “results in the receiver unit displaying a data gap.” (*Id.* at 15:65 to 16:3.) An example is shown in FIG. 7A below.



119. The specification for the 056 patent explains that adverse conditions can include “for example, [an] inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter

unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level[.]” (Ex. 1001 at 13:19-27.)

120. According to claim 1, “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.” (Ex. 1001 at 16:4-7.) After the adverse condition is corrected, the receiver unit outputs to the display the “processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled.” (*Id.* at 16:8-12.) An example is illustrated in FIG. 7B below.



121. Therefore, the glucose monitoring system that is claimed in the 056 patent is able to recover and display glucose data from a time period associated with an adverse condition.

VII. SOME OF MR. GROSS' OPINIONS ARE NOT BASED ON, AND AT TIMES ARE CONTRADICTED BY, PRIOR ART, AND THEY APPEAR TO USE THE 056 PATENT AS A BLUEPRINT

A. Person of Ordinary Skill in the Art

122. In paragraphs 51 and 52 of his declaration, Mr. Gross opines:

As of April 2009, I believe that persons of ordinary skill in the art (“POSITAs”) would have 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 transmit 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.

(Ex. 1008, ¶ 51.)

POSITAs may be part of an interdisciplinary team with others having relevant experience in the areas set forth above and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals. This definition of a POSITA would not differ materially for a date of April 2010.

(Ex. 1008, ¶ 52.)

123. For purposes of this declaration, I do not necessarily disagree with Mr. Gross that a POSITA could have the educational level that he states in paragraph 51

of his declaration. However, I disagree with his opinion in paragraph 52 that such a person *may be* part of an interdisciplinary team. In my opinion, it would be *imperative* that a POSITA be part of such an interdisciplinary team.

124. First, CGMs involve a wide range of technologies and are developed by teams of engineers and scientists with diverse backgrounds and fields of expertise, including fields such as biology, chemistry, biochemistry, materials science, mechanical engineering, electrical engineering, computer science or computer engineering, and control systems to name a few. CGMs are also regulated by the FDA as Class II medical devices (i.e., moderate to high risk to the patient or user)⁹ and therefore undergo rigorous testing and examination before being approved for use. Thus, by their very nature, CGMs require interdisciplinary teams for research, development, testing, manufacturing, regulatory approval, and so forth.

125. Based on his deposition testimony, Mr. Gross appears to agree with me that a POSITA would need to be part of an interdisciplinary team:

Q. So I want to make sure I understand this. In your opinion, a software engineer with two years of industry experience working with medical devices and systems for measuring EEG signals, that would be a person of ordinary skill in the art in the field of the '056 patent?

[objection omitted]

⁹ 21 C.F.R. § 862.1345.

THE WITNESS: So in order to do product development, you would have to have the right skill set on your team. And when I build teams looking for specific domain expertise, for example someone who understands electrochemical sensors, someone who understands microprocessor control and signal processing, someone who understands RF communication, I would be sure that their knowledge set was competent in the domain I needed to build a team with.

(Ex. 2027 at 147:4-20.)

126. I understand that one of the factors for determining the level of ordinary skill in the art is to evaluate the types of problems encountered in the art. Here, the “art” of the 056 patent relates to continuous glucose monitoring systems used by PWDs and physicians to monitor glucose levels. The types of problems encountered involve adverse conditions that interrupt the operation of CGMs and result in data gaps appearing on the CGM display in place of glucose values.

127. The dependent claims of the 056 patent say that the adverse conditions could include conditions such as a sensor communication error (claim 3), signal error associated with the glucose sensor (claim 4), signal error associated with the data processing and transmitter unit (claim 5), signal error associated with the receiver unit (claim 6), system malfunction associated with the data processing and transmitter unit or system malfunction associated with the receiver unit (claim 7), inability of the receiver unit to display or output at least a portion of the first line graph (claim 8), sensor instability (claim 9), calibration failure (claim 10),

monitoring system failure (claim 11), sensor misposition error (claim 13), temperature measurement outside a predetermined range (claim 14), analyte level exceeding a predetermined threshold (claim 15), rate of change of an analyte level exceeding a predetermined threshold (claim 16), data unavailability (claim 17), or a signal error associated with the blood glucose reference data (claim 25).

128. In my opinion, a POSITA should understand the causes for these types of conditions and the potential impact they could have on a patient's health and safety. For example, CGMs in the 2009 time frame were known not to be very accurate at times, which is why they all required PWDs to perform fingerstick measurements before treatment decisions and insulin dosing. (Ex. 2016 at 3.) Some adverse conditions could exacerbate the system's inaccuracy even further, such as a calibration failure or an analyte level exceeding a predetermined threshold, and therefore pose safety concerns for the patient. Other types of problems encountered could be more technological than clinical, such as adverse conditions affecting the wireless transmission of data to the receiver unit.

129. POSITAs addressing such a broad range of problems would need different backgrounds and expertise. As explained above, some problems encountered are clinical in nature. In my opinion, a POSITA who is a clinician on the interdisciplinary team should have at least an advanced degree in a medical science, such as a doctor of medicine (MD), doctor of osteopathic medicine (DO),

nurse practitioner (NP), or physician assistant (PA), and a few years of supervised training in diabetes management, including interpreting reports and providing clinical decision support.

130. Other problems that are more technical in nature could be handled by an electrical engineer, for example, rather than a clinician. Therefore, in my opinion, Mr. Gross' opinion that a POSITA *may be* part of an interdisciplinary team is not correct. In my opinion, it is mandatory that a POSITA have clinical experience and/or be on an interdisciplinary team with a clinician.

131. Based on my review of Mr. Gross' education, work history, and deposition testimony, in my opinion, he lacks relevant clinical experience and does not meet the minimum qualifications I have set forth above for a clinician on the interdisciplinary team. For example, he does not have an MD, DO, NP, or PA degree, nor does he have experience in diabetes management.

132. During his deposition, Mr. Gross stated that has not prescribed a CGM before (Ex. 2027 at 36:14-17), nor has he helped a diabetic select a CGM that is right for them (*id.* at 36:18-21), instructed a diabetic on how to use a CGM (*id.* at 48:18-20), or helped a diabetic determine target thresholds to manage their glucose levels (*id.* at 48:21-25). He also stated that he has not administered insulin (*id.* at 36:25-37:4), calculated a bolus insulin dose (*id.* at 38:2-4), or calculated a basal insulin dose before (*id.* at 38:5-7). Mr. Gross also has not used a CGM to monitor his own

glucose levels (*id.* at 39:7-12), nor has he torn down or reverse-engineered a CGM (*id.* at 39:17-25), or reviewed source code for software that runs on a CGM (*id.* at 40:1-3). Mr. Gross stated that he has not used an insulin pump before (*id.* at 40:13-15), nor has he torn down or reverse-engineered an insulin pump (*id.* at 41:1-5). Mr. Gross also didn't appear familiar with certain terms of art that would be expected of a POSITA clinician, such as "adjunctive use," "non-adjunctive use," and "MARD" (*id.* at 50:11-20).

133. Therefore, although Mr. Gross has a degree in electrical engineering and a degree in biomedical engineering, he lacks relevant education and experience to qualify as a clinician in my opinion. Additionally, Mr. Gross' opinions are not accompanied by, or based on, another expert in this proceeding, such as a clinician expert. Accordingly, in my opinion, many of Mr. Gross' opinions are not from the perspective of a POSITA at the time of the invention. I address some of his specific opinions below.

B. Mr. Gross' Opinions Are Not Based On Evidence Or Accurate Historical Facts, And Appear To Use The 056 Patent As A Blueprint

134. Although paragraphs 54-61 of Mr. Gross' declaration fall under the heading "Ordinary Level of Skill In The Art," many of the statements in those paragraphs appear to be what Mr. Gross believes a POSITA would know instead of providing support for his opinions about the skill level of a POSITA.

135. At any rate, many of Mr. Gross' statements in paragraphs 54-61 are not supported by any sources. That is particularly troubling because it appears that Mr. Gross simply recites many aspects of the 056 patent in these paragraphs and then concludes that these aspects were all known. My understanding is that an obviousness analysis must be supported by factual underpinnings and have a rational basis. Yet much of what Mr. Gross says in paragraphs 54-61 have no factual basis.

136. For example, in paragraphs 55, 56, and 57 of his declaration, Mr. Gross makes many statements about what a POSITA would have known, what skills they would have had, and what they would have done. (Ex. 1008 at ¶¶ 55-57.) However, Mr. Gross does not support any of those statements with sources, and so it is unclear what his basis is for these statements.

137. Moreover, many of the statements appear to be copied from or based on concepts disclosed in the 056 patent. For example,

Gross Statement (Ex. 1008)	056 Patent (Ex. 1001)
"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." (¶55)	"There are time periods where the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event. For example, the sensor may be configured for periodic calibration, such as, after 2 hours after insertion, 10 hours after insertion, 12 hours after insertion, 24 hours after insertion, 48 hours after insertion, or 72 hours after insertion, or one or more combinations thereof. If a

	predetermined calibration event is triggered but a successful calibration does not result, after a certain time period (for example, a predetermined grace period during which to calibrate), the receiver unit may no longer display the monitored and processed glucose information. Other conditions may also result in rendering the condition unsuitable for sensor calibration including, but not limited to, detection of a failure mode of a sensor, sensor data values being outside a predetermined range, rate of change of sensor data values being above a predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.” (11:6-25)
“POSITAs would have accounted for missing data using technical concepts known at the time, including programing [sic] 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, and regenerating it once the system recovered.” (¶55)	“Other conditions may also result in rendering the condition unsuitable for sensor calibration including, but not limited to, detection of a failure mode of a sensor, sensor data values being outside a predetermined range, rate of change of sensor data values being above a predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.” (11:19-25) “In one embodiment, a method may include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or

	more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during an adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.” (13:43-55)
“POSTIAs [sic] would have been skilled at programming a microprocessor to detect the failed reception of glucose data, sensor instability, rapidly changing glucose values, glucose level excursions, faulty or interrupted glucose readings, and other conditions associated with measuring, transmitting, receiving, and calibrating glucose data.” (¶56)	“In one embodiment, a method may include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during an adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.” (13:43-55) “The one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a

	monitoring system failure condition.” (13:56-59) “The sensor instability condition may include one or more of an early signal attenuation condition of the sensor, sensor misposition error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.” (13:60-67) “The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.” (14:1-5)
“POSITAs would have been skilled a [sic] programming a microprocessor to respond to these conditions by, for example, prompting or delaying calibration, storing glucose data in memory, and displaying a gap in graphed glucose levels when glucose data is not received.” (¶56)	“There are time periods where the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event. For example, the sensor may be configured for periodic calibration, such as, after 2 hours after insertion, 10 hours after insertion, 12 hours after insertion, 24 hours after insertion, 48 hours after insertion, or 72 hours after insertion, or one or more combinations thereof. If a predetermined calibration event is triggered but a successful calibration does not result, after a certain time period (for example, a predetermined grace period during which to calibrate), the receiver unit may no longer display

	the monitored and processed glucose information.” (11:6-18) “[I]f it is determined that the sensor 101 is not calibrated or calibration condition for calibrating the sensor 101 is not met, in one aspect, the primary receiver unit stores the analyte related sensor data in a memory (550) and temporarily disables display of the sensor data (560) to the user (for example, if a calibration event has not occurred and the calibration grace period has expired).” (12:9-15) “In one aspect, the display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period (for example, including a predetermined grace period measured from the scheduled calibration). Thereafter, upon successful calibration, the system resumes display of the processed and calibrated analyte sensor data. However, there may be a time period or a gap in the output display during which the necessary calibration did not occur in a timely manner. For example, as shown in FIG. 7A, if sensor data is displayed as a graphical display, during time periods where the analyte monitoring system 100 was not properly calibrated, analyte related sensor data was not processed and/or displayed, resulting in a gap in the graphical display.” (12:26-39)
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“POSITAs would have known that the failure to convert sensor signals to calculated analyte concentrations could be caused by a variety of conditions, including faulty or interrupted sensor readings and calibration errors based on, for example, sensor instability, extreme temperatures, extreme glucose levels, rapid glucose changes, and issues with blood glucose reference values.” (§59)	“The one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.” (13:56-59) “The sensor instability condition may include one or more of an early signal attenuation condition of the sensor, sensor misposition error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.” (13:60-67) “The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.” (14:1-5)
“POSITAs would understand that failure to calculate analyte concentrations would cause missing analyte data and lead to the inability to display this missing data.” (§59)	“[I]n accordance with the embodiments of the present disclosure, gaps in monitored analyte levels using an analyte monitoring system [can be] due to, for example, inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level.” (13:19-27)

“POSITAs would have found it obvious to display a gap to indicate when analyte data is missing due to failed communication, failed calibration, or another condition.” (¶60)	“In one aspect, the display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period (for example, including a predetermined grace period measured from the scheduled calibration). Thereafter, upon successful calibration, the system resumes display of the processed and calibrated analyte sensor data. However, there may be a time period or a gap in the output display during which the necessary calibration did not occur in a timely manner. For example, as shown in FIG. 7A, if sensor data is displayed as a graphical display, during time periods where the analyte monitoring system 100 was not properly calibrated, analyte related sensor data was not processed and/or displayed, resulting in a gap in the graphical display.” (12:26-39)
“POSITAs would have found it obvious to display previously missing data by filling-in/re-populating this data is analytes graphs.” (¶60)	“In one aspect, once successful calibration of the sensor data occurs, the calibration parameters from this calibration event may be used to process the sensor data during the period of disabled output or display (620). Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630). By way of an example, FIGS. 7A and 7B illustrate the replacement of a period of unprocessed sensor data with corresponding

	backfilled processed sensor data, in one embodiment.” (12:62-13:5) “In one embodiment, a method may include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during an adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.” (13:43-55)
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138. The only apparent source for Mr. Gross’ statements in these paragraphs is the 056 patent. He did not cite to any other sources and the language that he used closely parallels language from the 056 patent as I have shown above.

139. In paragraph 58 of his declaration, Mr. Gross also states that “POSITAs would also have recognized from reviewing any of the *Patel*-2009 (Ex1012), Paradigm REAL-Time (Ex1011), *Patel*-2008 (Ex1015), or *Shahmirian* (Ex1023) references that failed communication would cause missing data that could not be displayed.” (Ex. 1008 ¶58.) I disagree.

140. Regarding Patel-2009, I note that DexCom's Petition actually says the opposite of Mr. Gross: "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." (Petition at 29-30.) As DexCom's petition correctly concludes, Patel-2009 lacks disclosure of whether data is displayed or not. Thus, Mr. Gross' opinion that a POSITA would recognize that missing data would not be displayed based on Patel-2009 is not correct in my opinion.

141. Regarding Shahmirian, I disagree that a POSITA would review that reference and recognize that failed communication would cause missing data that could not be displayed. Shahmirian does not disclose detecting an adverse condition or displaying a data gap, and Mr. Gross does not appear to contend otherwise because he did not identify disclosure from Shahmirian that meets those claim elements. (*See* Ex. 1008 at ¶ 212.) Indeed, I have not seen anywhere in his declaration where Mr. Gross has identified disclosure from Shahmirian in which a data gap is output to a display.

142. Mr. Gross' statements in paragraph 59 are contradicted by his declaration in general. Throughout his declaration, the only condition that Mr. Gross attributes to causing a data gap is an out-of-range condition regarding wireless communications. (*See, e.g., id.* at ¶¶ 108-109, 211.) Although Mr. Gross mentions

other conditions, and although he says that POSITAs would know about them and would know that they cause data gaps, Mr. Gross does not provide any evidence to support those statements. Thus, I cannot assess what his basis is.

143. In the last sentence of paragraph 59 of his declaration, Mr. Gross states that “POSITAs would also have recognized from reviewing either of the Paradigm REAL-Time (Ex1011) or *Causey* (Ex1017) references that each of these conditions would cause missing data that could not be displayed.” (Ex. 1008 at ¶ 59.) I disagree.

144. The Paradigm® REAL-Time documentation discloses only one figure that Mr. Gross says shows a data gap. (Ex. 1008 at ¶ 109.) The figure that Mr. Gross identifies corresponds to a “Weak Signal” alert, which is “when the pump does not receive data for a period of time” due to a wireless connection failure. (Ex. 1011 at 73.) For every other condition, the Paradigm® REAL-Time documentation discloses displaying an alarm message. (*See id.* at 73-76.) Therefore, in my opinion, a POSITA would not understand the Paradigm® REAL-Time documentation to disclose displaying a data gap for any reason other than failed wireless communications. Any other condition would result in displaying an alarm message.

145. In my opinion, *Causey* does not disclose displaying a data gap for any condition. For example, in paragraph 144 of his declaration, Mr. Gross relies on *Causey* at 15:48-65. But in that portion of *Causey*, it is disclosed that data that is already being displayed to the user may be replaced with newly calibrated data, not

that data is withheld from being displayed. (*See* Ex. 1017 at 15:48-65.) As another example, Mr. Gross assesses claim element [1.I], which recites “displaying a data gap,” but he does not contend that Causey teaches that claim element. (*See* Ex. 1008 at ¶ 212.) Therefore, in my opinion, Mr. Gross’ opinions in paragraph 59 of his declaration are not supported by evidence, and are, in fact, contradicted by the evidence that he cites.

146. In paragraph 60 of his declaration, Mr. Gross states that “[i]n order to apprise users that analyte data is missing without presenting inaccurate data, POSITAs would have found it obvious to display a gap to indicate when analyte data is missing due to failed communication, failed calibration, or another condition.” (Ex. 1008 at ¶ 60.) I disagree for the reasons I explained in the preceding paragraphs. In particular, the Paradigm® REAL-Time documentation discloses displaying alarm messages when a variety of conditions occur, but not data gaps. (Ex. 1011 at 73-76.) Causey discloses that newly-calibrated data can be displayed in place of previously-calibrated data. (Ex. 1017 at 15:48-65.) Therefore, instead of displaying a data gap, Causey discloses the opposite and always displays data, even if it will be updated. (*Id.*)

147. In paragraph 60 of his declaration, Mr. Gross also states that “POSITAs would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin

dosing decisions, and prevention or treatment of hyper and hypo-glycemia. (Ex. 1008 at ¶ 60.) However, Mr. Gross does not cite any prior art that discloses displaying “previously missing data.” And the only prior art that he contends does so, the Paradigm® REAL-Time documentation, is in relation to a failed wireless communication. Therefore, Mr. Gross’ opinions are not based on evidence that I have seen.

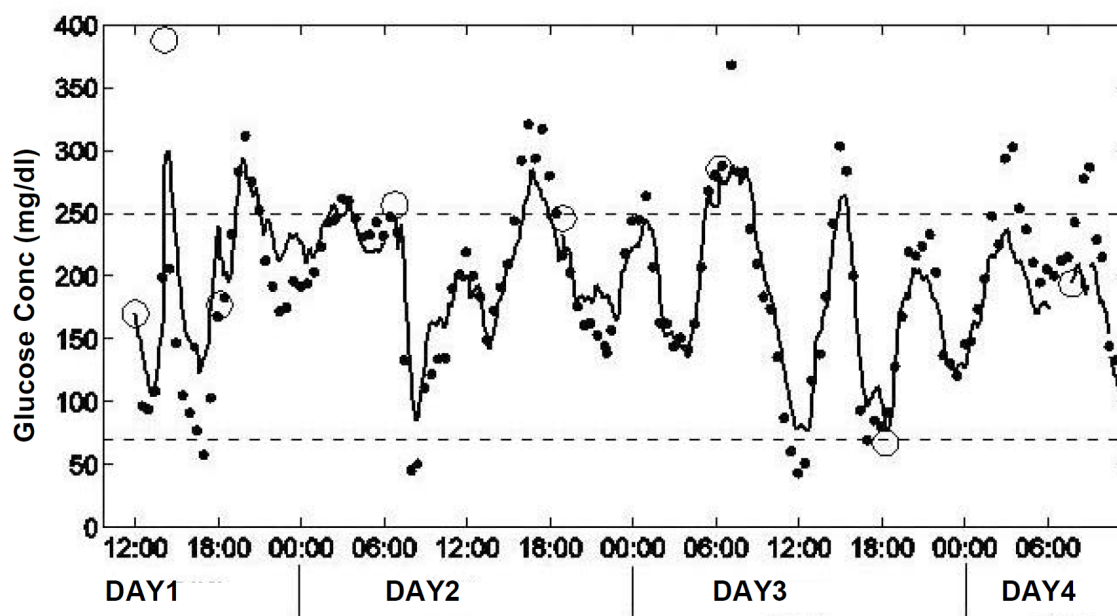
148. Additionally, Mr. Gross incorrectly states that POSITAs would have wanted to present as much data as possible for insulin dosing decisions. Mr. Gross is mistaken because, as of 2009, all CGMs were approved for adjunctive use only. (*See supra* ¶¶ 80-83.) None could be used to calculate insulin doses, which required fingerstick measurements; therefore, providing missing data for “insulin dosing decisions” is not valid. (*Id.*)

149. Moreover, the thrust of Mr. Gross’ opinions in paragraph 60 are based on providing the user with “accurate” data. As I previously explained, however, CGMs generally, and the Paradigm® REAL-Time system especially, were known to be inaccurate at times. (*See supra* ¶¶ 75-79.) Therefore, in my opinion, it would not have been critical to provide all missing data in the 2009 time frame, as CGMs were still fairly new and not being used as life-saving tools as they are now.

150. For example, the typical overall MARD for a CGM in 2009 was about 15% to 25%, which means that a PWD’s CGM readings differed from their actual

glucose levels by that percentage. (*See supra* ¶¶ 75-79.) The Paradigm® REAL-Time System is a good example of how poorly some systems performed in the 2009 timeframe.

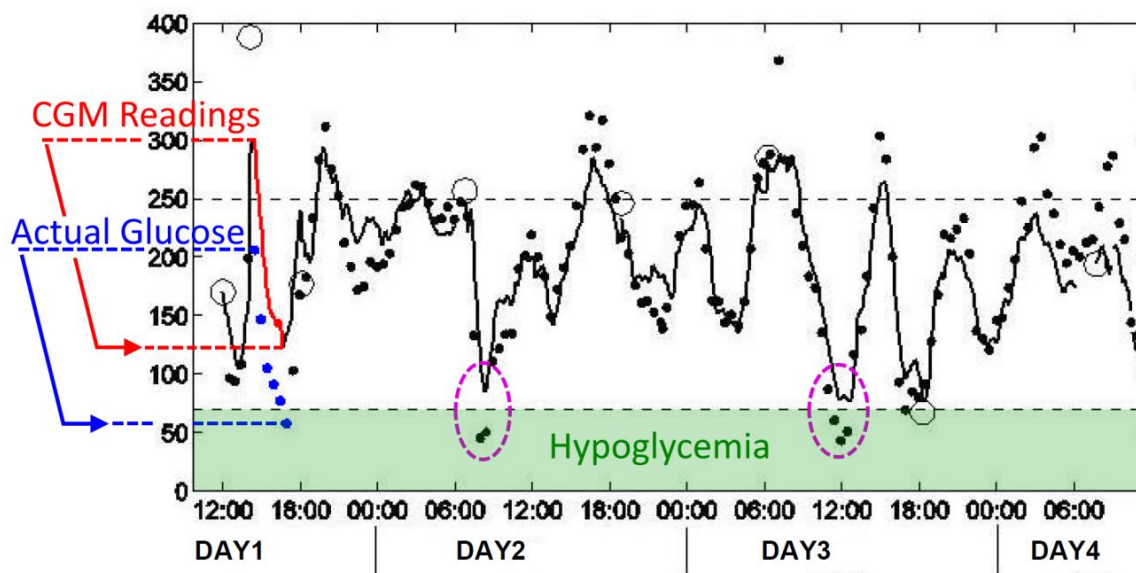
151. In the Paradigm® User Guide, Chapter 7 provides details on “sensor accuracy.” The graph below is from Chapter 7 and “is a representative example of continuous sensor tracing vs. reference blood glucose reading, where [the] sensor showed average (typical) performance.” (Ex. 1011 at 96.)



“The closed circles (•) represent the reference blood glucose readings, and the solid line (—) represents the sensor glucose value.” (*Id.*)

152. There are several aspects about this graph that concern me regarding the accuracy of the Paradigm® REAL-Time system. The first aspect is that, in several instances, the CGM readings were significantly different from the actual

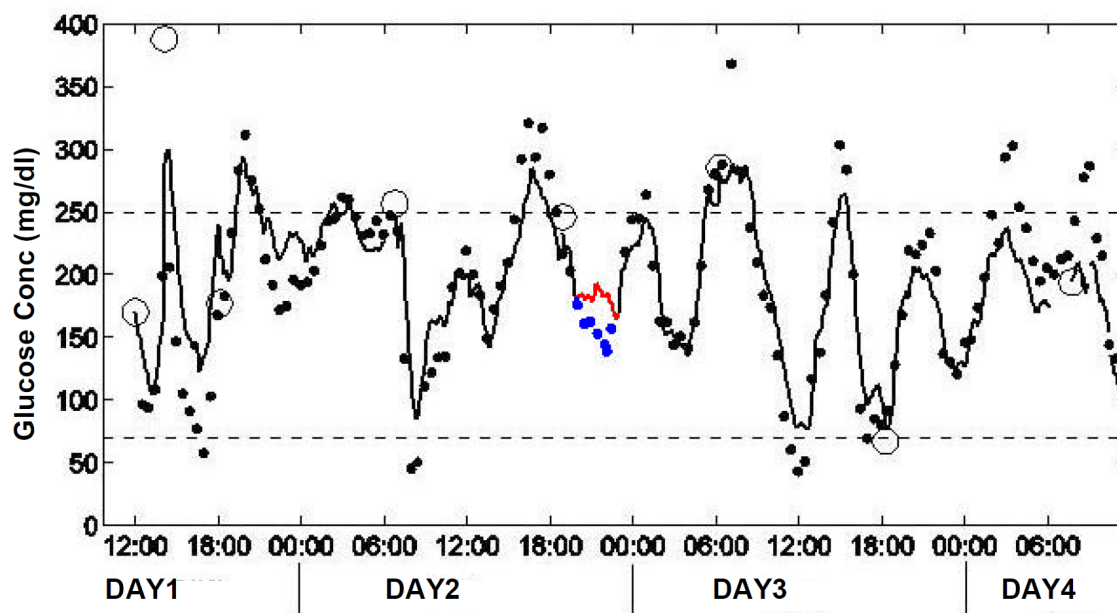
glucose levels. For example, right before 18:00 on DAY 1, the CGM readings (in red below) indicated that the subject's glucose levels had dropped from about 300 to 125 mg/dL, but their actual glucose levels (in blue below) dropped from about 210 to 60 mg/dL. Importantly, 60 mg/dL is in the hypoglycemic range.



(Ex. 1011 at 96 (annotations added).) Based on the CGM data, the subject would not have known that they were hypoglycemic and would have thought they were in their target range.

153. Other inaccuracies like this, in which hypoglycemic episodes were masked due to the CGM readings being significantly off from actual glucose readings, occurred again on DAY 2 around 8:00 and DAY 3 around 12:00 (purple annotations). Indeed, in these instances, the subject's glucose levels dropped to about 50 mg/dL or even lower, which is very dangerous.

154. Another aspect that concerns me about the graph and the accuracy of the Paradigm® REAL-Time system is that, sometimes, the subject's glucose levels were trending in the direction opposite of what the CGM data indicated they were trending. This occurred, for example, on DAY 2 around 20:00 as shown below.



(Ex. 1011 at 96 (red indicates upward trend of CGM data while blue indicates downward trend of actual glucose levels). This happened again to some degree on DAY 3 around 18:00.

155. A third aspect that concerns me about the graph and the accuracy of the Paradigm® REAL-Time system is that CGM readings were sometimes above actual glucose levels and sometimes they were below actual glucose levels. For example, on DAY 1 around 19:00, DAY 2 around 16:00, DAY 3 around 6:00, 14:00, and 20:00, and DAY 3 from about 2:00 until 8:00, the CGM readings were all below the

subject's actual glucose levels. Yet, on DAY 1 around 16:00 and 21:00, DAY 2 around 8:00, and DAY 3 around 12:00, the CGM readings were above the subject's actual glucose levels. Thus, a PWD using this system would not know whether their CGM readings were accurate, whether the direction of trend was accurate, and whether their actual glucose levels were above or below the CGM readings.

C. Other Evidence Calls Into Question Mr. Gross' Opinions

156. Mr. Gross' opinions in paragraph 60 of his declaration about how POSITAs would be motivated to provide PWDs with as much data as possible are also contradicted by the state of the art at the time of the invention. For example, DexCom's CGM products displayed data gaps when certain conditions occurred, but they did not backfill the data gaps. (*See supra* ¶¶ 95-105.) This is an important factor because, if backfilling data gaps were as important and critical in 2009 as Mr. Gross suggests, and as obvious to implement as Mr. Gross opines, then one would think that a company like DexCom would have implemented a backfilling solution into its products far sooner than 2016. The fact that DexCom did not is strong evidence, in my opinion, that the invention of the 056 patent was not so obvious in 2009.

157. Another bit of evidence that I find contradicts Mr. Gross' opinions in paragraph 60 of his declaration is his opinion regarding claim 19 of the 056 patent. That claim states: "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.” (Ex. 1001 at 17:8-11.) The “second line graph” refers to the backfilled data that is output to the display to fill in the data gap according to claim 1.

158. In Mr. Gross’ analysis of claim 19, he states that “POSITAs would have found it obvious to wait a predetermined time (*e.g.*, one, two, three update cycles) before displaying re-populated glucose data.” (Ex. 1008 at ¶ 129.) Since most update cycles in 2009, including for the Medtronic Paradigm® REAL-Time System, was 5 minutes, Mr. Gross’ opinions mean that POSITAs would have found it acceptable to withhold up to 15 minutes of CGM data before displaying it on the screen. Therefore, in Mr. Gross’ opinion, the CGM data is not so critical after all since POSITAs would be inclined to hold it from the PWD for a period of time.

159. Some of DexCom’s own patents also seem to contradict Mr. Gross’ opinions. For example, U.S. Patent No. 10,085,640, which is owned by DexCom, was filed in 2016. (Ex. 2023 at 1.) In that patent, DexCom noted that it might not be wise to backfill missing data “because after a certain amount of time, some of the data may become stale to certain components of the system, backfilling may consume too much battery power of one or more components of the system (*e.g.*, transmitter 102), and/or a component of the system (*e.g.*, display 104) requesting the backfilled data may only be configured to display a certain range of data.” (Ex. 2023 at 30:25-32.)

160. That patent also explains that PWDs can become confused by backfilling data gaps on a CGM display:

Another challenge arises with distinguishing between data that was received as scheduled upon transmission or through a backfill process. When a user misses an alarm because a device was out of range, but looks at their smartphone and sees that glucose data is available in the time range of when an alarm should have issued, the user can become confused or assume there was an error with the alarm. However, the smartphone did not have the data at the time of the alarm but instead backfilled the data subsequently.

(Ex. 2023 at 36:37-46.) I agree that these would be reasons why backfilling data gaps might not always be the best idea. Notably, this patent is from 2016, and so these concerns were equally valid, if not more, in 2009.

161. DexCom has another patent, also filed in 2016, that raises other valid concerns for why backfilling a data gap on a CGM display might not be the best idea. That patent is U.S. Patent No. 9,996,668. (Ex. 2024.) It explains that PWDs who use a CGM might miss some of the data during the nighttime while they're asleep, and therefore "may not want backfill data to be automatically displayed because the automatic insertion of backfill data may mask the nighttime gap(s) in data and mask that the receiver was not receiving data." (Ex. 2024 at 5:32-40.)

162. Another reason not to display backfilled data according to this patent is because it "may be stale in the sense that it might not capture the current glucose

state of the host wearing the sensor.” (*Id.* at 7:21-23.) “With stale data, a user may not want to take action based on the sensor data, while with more current non-backfill data, a user may take action based on the sensor data.” (*Id.* at 7:23-26.) Yet another reason to not send backfilled data to the receiver is because “[d]ata backfilling may consume power at the transmitter and/or receiver (which can reduce available battery resources).” (*Id.* at 18:59-61.) I also agree with each of these reasons, which support my opinion that the inventions of the 056 patent were not obvious in 2009.

163. Based on the above, it is my opinion that Mr. Gross’ opinions about what a POSITA would know and do in 2009, as stated in paragraphs 54-61 of his declaration, are not supported by evidence, are contradicted by the state of the art and evidence from that timeframe, and in some cases, appear to simply repeat much of what is disclosed in the 056 patent. For these reasons, and because he lacks the necessary qualifications, in my opinion, Mr. Gross does not approach the claims of the 056 patent from the perspective of a POSITA.

VIII. OPINIONS ON CLAIM 1 UNDER GROUNDS 1 AND 2

164. In my opinion, at least claim elements [1.K] and [1.L] of independent claim 1 are not disclosed in the prior art. Therefore, in my opinion, neither Ground 1 nor Ground 2 renders the claims of the 056 unpatentable. I provide my reasons below.

A. Claim Element [1.K]

165. Claim element [1.K] recites: “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 that data gap is backfilled.” (Ex. 1001 at 16:8-12.)

166. Mr. Gross opines that claim element [1.K] is met by the Paradigm® REAL-Time documentation for the following reasons:

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 remaining. (Ex1011, 8.) Thus, when the transmitter and insulin pump are out-of-range for less than 40 minutes (e.g., a 30-minute swim), data gaps do not persist because they are entirely re-populated once transmission is re-established after being lost. (Ex1011, 8; see also paragraph 60 above (POSITAs would find it obvious to re-populate missing analyte data when it becomes available after failed communication is resolved).)

(Ex. 1008 at ¶ 112.)

167. I disagree with Mr. Gross that the Paradigm® REAL-Time documentation is referring to “output[ting] to the display, after the adverse condition

is corrected, processed sensor data for the time period corresponding to the adverse condition such that that data gap is backfilled.” Rather, in my opinion, the Paradigm® REAL-Time documentation is referring to storing data in the memory of the insulin pump so that it can be retrieved for historical reports. My opinion is based on many considerations.

168. First, in paragraph 112 of his declaration, Mr. Gross identifies only page 8 from the Paradigm® REAL-Time documentation. That page contains a number of frequently asked questions (FAQs) from what appears to be Medtronic’s website in the 2007 time frame. (Ex. 1011 at 8.) The Paradigm® REAL-Time documentation, however, also includes a user guide for the Paradigm® Insulin Pump, but it does not mention anything about filling in missing data on the insulin pump’s screen. (*See* Ex. 1011 at 30-105.)

169. This is the first clue that makes me doubt that the statement on Medtronic’s website discloses claim element [1.K]. If the Paradigm® REAL-Time System retrieved missing data when the transmitter and receiver reconnected after a period of time and then displayed that missing data on the pump’s screen, I would expect the user guide for the Paradigm® REAL-Time System to explain that. I reviewed the Paradigm® user guide, however, and I did not find any such statement. Mr. Gross also did not identify any such statement in the user guide. Therefore, I

would find it somewhat odd that important functionality like that would be explained only through an FAQ on a website and not in the user guide for the system.

170. The FAQ that Mr. Gross bases his opinion on is on page 8 of the Paradigm® REAL-Time documentation and states:

How much data does the MiniLink REAL-Time Transmitter store? If I move outside of the six foot (two meters) transmission range – will I lose my data?

When the MiniLink REAL-Time Transmitter is separated from the insulin pump for more than six feet (approximately 2 meters), the transmission is considered "out of range." The transmitter holds 40 minutes worth of memory, so even though your system is "out of range," continuous glucose monitoring (CGM) data can be re-populated in the insulin pump.

If your system is out-of-range for longer than 40 minutes, when reviewing historical reports you would notice "data gap" where information is missing during this period of time.

(Ex. 1011 at 8.)

171. The response to this FAQ states that “[t]he transmitter holds 40 minutes worth of memory” when the system is “out of range” as Mr. Gross says it does. However, whether or not this response discloses claim element [1.K] really amounts to whether the phrase, “data can be re-populated in the insulin pump,” means that the 40 minutes of data is then displayed on the insulin pump screen. In my opinion, it does not.

172. The very next sentence in the response to this FAQ tells us that the data will be shown on “historical reports”:

If your system is out-of-range for longer than 40 minutes, when reviewing historical reports you would notice “data gap” where information is missing during this period of time.

(Ex. 1011 at 8.) This statement says that the re-populated data is stored in memory of the insulin pump and that, when reviewing “historical reports,” up to 40 minutes of the missing data will be shown. Anything outside of the 40 minutes will appear as a “data gap” on the historical report. There is no mention of the insulin pump’s screen in this response to the FAQ.

173. The term “historical report” refers to reports that the CareLink Personal software generated. For example, another FAQ and response states:

**Can I use the MiniMed Paradigm REAL-Time System on an airplane?
Must I turn off the radio frequency during flight?**

International standards and U.S. Federal Communications Commission (FCC) regulations require that devices using radio frequency capabilities should not be used on an aircraft. As a result, you must disconnect the transmitter from the glucose sensor while traveling on an airplane; however, you can continue using the insulin pump. It is not sufficient to simply turn the continuous glucose monitoring (CGM) feature off on the insulin pump, the transmitter will continue to transmit on the RF frequency and must be disconnected from the glucose sensor to stop.

While in flight, you need to manually test your glucose levels using a standard meter (i.e. the Paradigm Link monitor). When downloading data and reviewing historical reports, you will notice "data gap" where information is missing during this period of time.

(Ex. 1011 at 12-13.) In the last sentence, this FAQ refers to “downloading data and reviewing historical reports.”¹⁰ Data stored in the insulin pump’s memory was “download[ed]” to the CareLink software. For example, the CareLink User Guide identifies the Paradigm® Insulin Pump as one of the devices from which data could be downloaded to CareLink. (See Ex. 2007 at 3.)

174. Likewise, the term “historical report” refers to one of several different types of reports that the CareLink software could generate. I provided details about such reports earlier and I refer back to that discussion. (See ¶ 94.) As I mentioned, the reports generated by CareLink were “displayed in PDF format.” (Ex. 2007 at 16.) These reports were not displayed on the insulin pump, which Mr. Gross says is the “receiver” in claim 1. (See Ex. 1008 at ¶ 102.)

175. Therefore, in my opinion, the only reference to where missing data could potentially be viewed is in “historical reports,” and there is no doubt that “historical reports” refers to reports generated by CareLink. I do not see anything in the FAQs that Mr. Gross relies on that refers to viewing missing data on the insulin pump’s screen.

¹⁰ This FAQ is also similar to the one that Mr. Gross relies on because it then says that the user would “notice ‘data gap’ where information is missing during this period of time.” (Ex. 1011 at 13.) Like the FAQ that Mr. Gross relies on, this FAQ is referring to what the user would notice on “historical reports,” as there is no mention about what the user would or would not notice on the insulin pump screen.

176. I understand that Abbott made similar arguments in a preliminary response to DexCom's petition and that the PTAB preliminarily disagreed with Abbott. The PTAB stated:

As such, we presently do not agree with Patent Owner's arguments seeking to limit Paradigm REAL-Time's mention of viewing backfilled data in "historical reports" to viewing backfilled data only on a PC using CareLink software, as opposed to viewing the backfilled data on line graphs that are displayed on the insulin pump. *See, e.g.*, Ex. 1011 (Paradigm REAL-Time), 8. Stated differently, on this record we do not agree with Patent Owner's argument that "historical reports" are viewable only on a PC. This is because even if historical data is viewable in CareLink, it is also clear that the insulin pump itself displays historical data.

(PTAB's Institution Decision at 30.)

177. I agree that historical "data" is viewable on the insulin pump. But all of the FAQs in Exhibit 1011, including the FAQ that Mr. Gross relies on, use the phrase "historical reports," not "historical data." I see no evidence in Exhibit 1011 in which "historical report" is used to refer to data that is viewable on the insulin pump's screen.

178. I understand that part of the reason the PTAB reached its conclusion is because the FAQ Mr. Gross relies on "appears in a section of Paradigm REAL-Time relating to the MiniLink REAL-Time Transmitter," and that there was no "mention

of the separate CareLink product.” (PTAB’s Institution Decision at 31.) The PTAB, however, repeated only a portion of an FAQ to make this point. (PTAB’s Institution Decision at 31.) The complete FAQ is:

Can I swim, shower, or bathe with the MiniLink Transmitter?

Yes, the transmitter is waterproof, so you can swim, shower, or bathe with the transmitter and glucose sensor connected. The transmitter with the glucose sensor connected can be worn for a depth of eight feet (2.4 meters) for 30 minutes. However we do not recommend immersing them in very hot water (like a jacuzzi).

There should be no problems due to rain, splashing, or the accidental submersion in water. To participate in water activities, you can easily disconnect from your insulin pump.

As long as the transmitter is within 6 feet (approximately 2 meters) of the insulin pump, continuous glucose monitoring (CGM) data will be displayed on the insulin pump's screen. If the MiniLink REAL-Time Transmitter and insulin pump are out-of-range for longer than 40 minutes, only the last 40 minutes will be re-populated. When reviewing historical reports, you would notice a "data gap" where information is missing during this period of time.

(Ex. 1011 at 8.)

179. While it is correct that this FAQ is in a section relating to the transmitter, it is not correct in my opinion that this FAQ does not mention CareLink because it explicitly refers to “historical reports,” which are generated by CareLink. Additionally, the transmitter transmitted data to the insulin pump for all reasons, including so that data could be displayed on the pump’s screen or re-populated in memory for historical reports. Therefore, it is of no consequence that this FAQ is in a section relating to the transmitter.

180. In addition to the FAQs referring to “historical reports” generated by CareLink for where some missing data could potentially be viewed, my opinion that the FAQ is not referring to displaying missing data on the insulin pump’s screen is informed by several other considerations.

181. The first consideration is the language Medtronic chose to use in the FAQ that Mr. Gross relies on. It says that “data can be re-populated *in the insulin pump*.” (Ex. 1011 at 8.) It would be grammatically incorrect, and very strange to say the least, if Medtronic used the word “in” to describe something that was going to be displayed “on” a screen. For example, it is a common expression in computer terminology to say that something is “stored in memory.” It would be incorrect to assume that because something is stored in memory, it is automatically displayed *on* a screen. For example, I can store gigabytes worth of data “in memory” on a USB drive, but that says nothing about whether that data can be displayed on a screen.

182. Another part of the Paradigm® REAL-Time documentation supports this point. With respect to reference measurements taken by a BGM, the Paradigm® REAL-Time documentation explains:

Meter: You can program your pump to automatically receive your blood glucose (BG) readings from your meter. When a BG reading is taken, the value is automatically transferred to the pump and *stored in its memory* as a calibration point. The calibration point is used to calculate the real-time sensor glucose values that are displayed. *The*

meter can also be used to download data stored in the pump to a computer.

(Ex. 1011 at 37.) This passage uses the word “in” twice to refer to storing data in memory, which is further evidence that “data re-populated in the insulin pump” also refers to storing data in memory.

183. Another consideration is that the prior art references Mr. Gross relies on for Grounds 1, 2, and 3 in his declaration each include discussions about retrospectively analyzing data by downloading it from the CGM system and/or by reviewing it in historical reports, including reports generated by CareLink, but none include discussions about displaying missing data in place of a data gap on a CGM display.¹¹ Considering that each reference is from Medtronic, one would presume that at least some of the Medtronic patents and applications that Mr. Gross relies on would also contain a description of backfilling missing data, but they do not.

184. For example, there is a section in the FAQs in the Paradigm® REAL-Time documentation that relates to “CareLink Therapy Management Software.” (Ex. 1011 at 11-12.) This section addresses what CareLink is, what CareLink costs, how to access CareLink, how to use CareLink, whether the information CareLink stores

¹¹ I understand that Mr. Gross opines that the phrase, “re-populated in the insulin pump,” does refer to displaying missing data in place of a data gap on the Paradigm’s screen, but that is only his interpretation, which I disagree with. Mr. Gross does not refer to any other statements or figures in any other prior art reference that disclose this feature of the 056 patent claims.

is secure, how long it takes to upload data to CareLink, how to generate reports with CareLink, and what systems CareLink can receive data from. (Ex. 1011 at 11-12.)

185. Similarly, Patel-2009 (Ex. 1012) explains:

Logged data can be downloaded from the characteristic monitor 200 to a PC, PDA, or the like, for detailed data analysis. Alternatively, in accordance with the present invention, glucose values may be calculated and logged by the transceiver 100. Accordingly, the logged data may be downloaded directly from the transceiver 100 by the PC, PDA, insulin pump or the like.

(Ex. 1012 at [0047]; *see also* [0081].)

186. Patel-2008 (Ex. 1015) also explains:

Additionally, the data received from the glucose sensor/transmitter may be communicated to other locations using the BlackBerry's cellular capabilities. Data can be sent to other phones, central servers, and the like using "Short Message Service" (commonly known as "SMS" or "text messaging"). Data may also be sent to email addresses, other computers, and/or central servers using the BlackBerry's internet capabilities (GPRS, EDGE, EV-DO, 1xRTT, UMTS/HSDPA, Wi-Fi, WiMax, ZigBee, Wi-bro, and the like). ... This data can then be uploaded to a web based diabetes management server like Carelink® (managed by Medronic MiniMed, Inc.). The data may also be sent to other servers, doctor's offices, parents, caregivers, or the like and insulin dosage recommendations may be made.

(Ex. 1015 at [0032]; *see also* [0048].)

187. Causey (Ex. 1017) explains:

Several programming options will be available in the infusion device 1010, and will include up to three customized basal profiles, a carbohydrate (or bolus) calculator and an alarm clock, as well as remote and on-device programming. Additionally, a physician/educator will be able to configure the infusion device 1010 through a Communications Station 1008 to provide or restrict access to certain programming options. ... This information can be used alone or combined with information from a Glucose Meter and/or a Glucose Sensor to assist the user and/or the health care professional in making intelligent therapy decisions. Moreover, the information, programs and data may be downloaded to a remote or local PC, laptop, station, or the like, for analysis and review by a MiniMed or a trained health care professional through the transmitter/receiver 1026. The data may also be downloaded through a Communication-Station 1008 to a remotely located computer 1006 such as a PC, lap top, or the like, over communication lines, by modem or wireless connection, as shown in FIG. 25.

(Ex. 1017 at 9:34-59.)

188. Mastrototaro (Ex. 1019) explains:

The telemetered characteristic monitor transmitter 100 takes characteristic information, such as glucose data or the like, from the percutaneous sensor set 10 and transmits it via wireless telemetry to the characteristic monitor 200, which displays and logs the received glucose readings. Logged data can be downloaded from the

characteristic monitor 200 to a personal computer, laptop, or the like, for detailed data analysis.

(Ex. 1019 at [0041]; *see also* [0037], [0071].)

189. Shahmirian (Ex. 1023) explains:

In preferred embodiments, information is transmitted from the BG monitoring system 20 to the infusion pump 30 via the relay device 10, and then downloaded to a storage media from the infusion pump 30. The storage media may include one or more of a personal computer (PC), a central server, an electronic memory, a personal digital assistant (PDA), a cell phone, a laptop computer, magnetic memory, silicon memory, a data storage device, and the like.

(Ex. 1023 at [0063]; *see also* [0074], [0082].)

190. Therefore, I find it quite compelling that the prior art in this proceeding discloses and provides details about preserving data in memory so that it can be retrospectively analyzed and/or imported into historical reports, but does not disclose or provide any details about displaying missing data on a CGM display to backfill a displayed data gap.

191. Another consideration is the state of the art in 2009 with regard to display units. I can personally attest to the importance of reviewing historical reports with PWDs, as I have done so many times in my practice. Having electronic or hard copies of reports makes it easy to discuss the PWD's glucose levels with them. We typically sit in my office and go through the reports together. This is one of the most

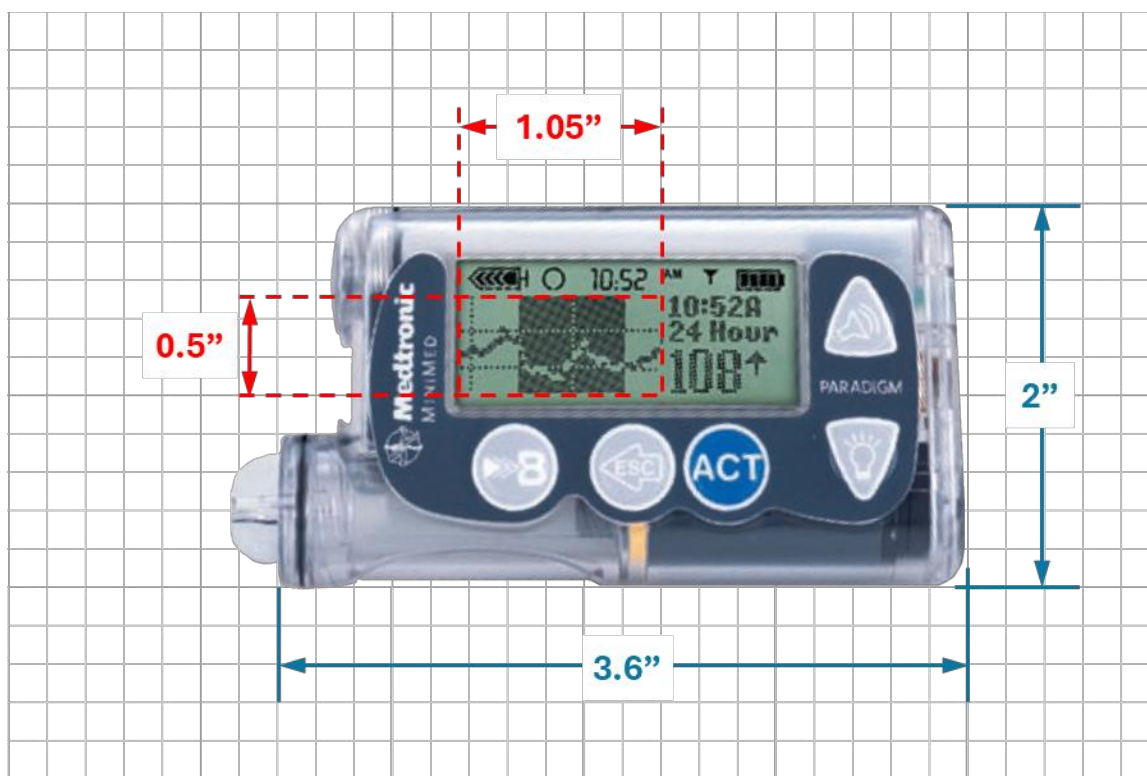
useful features of CGMs—that they provide an in-depth recorded history of glucose levels and other information that can be analyzed for patterns and insights. While the information displayed on CGMs in real-time is useful, the primary use of CGMs in 2009 in my experience was to analyze historical data.

192. From what I recall in the 2009 timeframe, there was not a huge emphasis on making sure the PWD had a continuous graph with no gaps partly because the screens at that time were small (especially compared to today's standards). For example, Patel-2008 uses Blackberries and iPods as example receiver units, which were both popular devices at the time. (*See* Ex. 1015 at [0036], [0040].) But those device had very small screens. It would have been difficult to even notice a data gap for a short duration, such as 5-10 minutes, especially if the time scale was set to something large, such as 24 hours. I would not have expected there to be much emphasis on making sure each pixel had data, especially knowing that the information was being stored for historical analysis on a PC.

193. The size of the Paradigm® Insulin Pump's display is another good example. I reviewed Dr. Striegel's report where he provided a scaled illustration of the size of the trend graph on the Paradigm® Insulin Pump using a picture from the Paradigm® User Guide and its stated dimensions. (*See* Ex. 2015 at ¶¶ 51-55.)

194. Dr. Striegel notes that the Paradigm® REAL-Time documentation says the 722 Insulin Pump was 2" x 3.6" x 0.8". (Ex. 2015 at ¶ 51 (citing Ex. 1011 at 6).)

Using that information, Dr. Striegel estimated that the trend graph on the Paradigm® Insulin Pump was about 1.05” x 0.5”:



(Ex. 2015 at ¶ 52.) Dr. Striegel’s methodology is sound and I have no reason to doubt the accuracy of these estimates.

195. The small size of the Paradigm® Insulin Pump’s trend graph supports my opinion that, in 2009, the emphasis was on preserving data for historical reports, not necessarily ensuring that all missing data was displayed. For example, insulin pumps are primarily used by Type 1 diabetics, and Type 1 diabetics are more likely to suffer from diabetic retinopathy. This is a point Patel-2009 makes.

196. In paragraph [0066], Patel-2009 explains:

It is noted that the typical user can be expected to have somewhat diminished visual and tactile abilities due to complications from diabetes or other conditions. Thus, the display 214 and buttons should be configured and adapted to the needs of a user with diminished visual and tactile abilities. In alternative embodiments, the value can be conveyed to the user by audio signals, such as beeps, speech or the like.

(Ex. 1012 at [0066].) Thus, the tiny display on the Paradigm® Insulin Pump would not have made it easy for someone to see a tiny data gap and whether or not that gap was subsequently backfilled, especially if the time scale were set to something large, like 24 hours, and especially if the user's vision is impaired.

197. Yet another consideration for why the Paradigm® REAL-Time documentation does not disclose filling in a data gap with missing data is because, like every other system at the time, the Paradigm® REAL-Time system could not be used for making treatment decisions or for calculating insulin doses. All CGMs at that time, including the Paradigm® REAL-Time system, was approved for adjunctive use only. (*See supra* ¶¶80-83.) Thus, the missing data was not as critical as it might be considered today, where some CGMs are used non-adjunctively. (*See supra* ¶¶80-83.)

198. Another consideration is Mr. Gross' opinions for claim 19. In paragraph 112 of his declaration for element [1.K], Mr. Gross refers back to his paragraph 60 and comments "POSITAs would find it obvious to re-populate missing analyte data

when it becomes available after failed communication is resolved.” (Ex. 1008 at ¶ 112.) But this statement is contradicted by his statement in paragraph 129 for claim 19, which states “POSITAs would have found it obvious to wait a predetermined time (e.g., one, two, three update cycles) before displaying re-populated glucose data.” (Ex. 1008 at ¶ 129.) Thus, Mr. Gross contradicts himself about the importance of providing missing data to the display. (*See also* ¶¶ 157-158.)

199. In his declaration, Dr. Striegel provides a technical explanation for how a system like the Paradigm® Insulin Pump could operate based on the disclosure in Ex. 1011. For example, in Dr. Striegel’s opinion, an embedded system that has a display could include two memories—one memory to store data for display purposes and one memory to store data for long-term purposes. (Ex. 2015 at ¶ 42.)

200. As Dr. Striegel explains, the memory for display purposes would likely be a type of RAM, whereas the memory for long term storage would likely be a flash memory. (Ex. 2015 at ¶ 42.) Dr. Striegel explains how and why some data would be stored in each, and why that would lead to displaying a data gap but not filling it, while still preserving data for downloading and retrospective analysis. (Ex. 2015 at ¶¶ 42-50.) I agree with Dr. Striegel’s opinion and find that it further supports my opinion that the Paradigm® REAL-Time documentation does not disclose claim element [1.K].

201. In paragraph 114 of his declaration, Mr. Gross also references Patel-2009 for element [1.K], but he does not say that Patel-2009 meets this claim element.

Rather, he states:

Patel-2009 supplements Paradigm® REAL-Time by disclosing 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].)

(Ex. 1008 at 113.)

202. In my opinion, Patel-2009 does not disclose element [1.K] at least because it lacks disclosure about what data is displayed on glucose graphs, including whether any missing data is ever displayed. This is a point that DexCom made in the Petition and that I agree with. (*See* Pet. at 28-29 (“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.”).)

203. Additionally, the portion of Patel-2009 that Mr. Gross relies on is consistent with the disclosure of the Paradigm® REAL-Time documentation. For example, Patel-2009 refers to “synchronizing” data between the transmitter and receiver, but does not say that the data is displayed. (Ex. 1012 at [0086].) That is equivalent, in my opinion, to the disclosure in the Paradigm® REAL-Time

documentation about re-populating data in the memory of the insulin pump. That data is also not displayed.

204. Finally, the PTAB partly relied on Mr. Gross' opinions in paragraph 60 of his declaration in finding that the Paradigm® REAL-Time documentation could be interpreted to mean that the system displayed missing data on the pump's screen. (*See* PTAB's Institution Decision at 33.) I have already explained why, in my opinion, Mr. Gross' opinions in paragraphs 54-61 of his declaration, including paragraph 60, should be given little consideration. I refer back to that explanation for why the PTAB should not rely on paragraph 60 of Mr. Gross' declaration for element [1.K]. (*See supra* ¶¶ 122-163.)

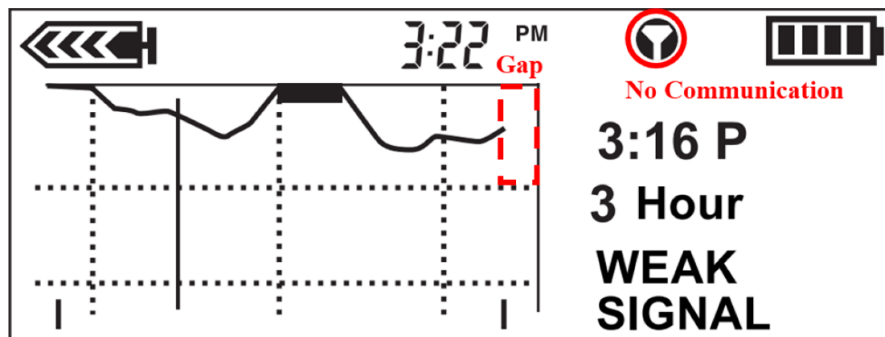
205. Based on the above, it is my opinion that the prior art used in Ground 1 does not disclose claim element [1.K].

B. Claim Element [1.L]

206. Claim element [1.L] recites: "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." (Ex. 1001 at 16:13-20.)

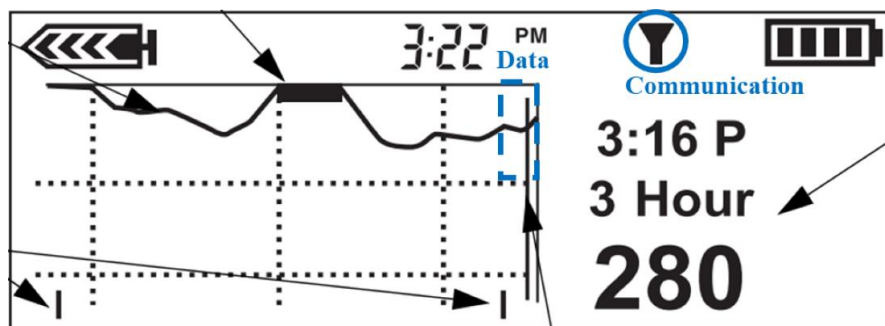
207. For claim element [1.L], Mr. Gross relies on the Paradigm® REAL-Time documentation. (See Ex. 1008 at ¶¶ 114-115.)

208. First, Mr. Gross relies on a graph from Chapter 6 of the Paradigm® REAL-Time documentation, which relates to “Troubleshooting and alarms,” and opines that the graph shows “a data gap during ‘failed reception of sensor data from the transmitter to the pump’ while ‘communication is lost.’” (Ex. 1008 at ¶ 114.) He annotated that graph in red, which I have reproduced below.



(Ex. 1008 at ¶ 114.)

209. Next, Mr. Gross relies on a graph from Chapter 5 of the Paradigm® REAL-Time documentation, which relates to “Using your sensor,” and opines that the graph shows “re-populating data gaps with glucose data stored in the transmitter’s memory.” (Ex. 1008 at ¶ 114.) He annotated that graph in blue, which I have reproduced below.



(Ex. 1008 at ¶ 115.)

210. Mr. Gross then created a composite figure using his two annotated graphs and concluded that “POSITAs would recognize that a data gap existing during reception failure is re-populated once communication is re-established.” (Ex. 1008 at ¶ 115.) I disagree with these opinions.

211. First, the two graphs are from different chapters of the Paradigm® User Guide and appear to have no relation to one another. For example, Chapter 5 relates to “Using your sensor,” while Chapter 6 relates to “Troubleshooting and alarms.” (Ex. 1011 at 63, 71.) The topics covered in these chapters are different, and there is no indication that the graph in these chapters are intended to convey a relationship with one another, especially a temporal relationship.

212. Second, the graphs cannot be related because they display inconsistent information. Both graphs display a current time of 3:22 PM. However, the graph from Chapter 6 shows “WEAK SIGNAL,” and as Mr. Gross annotated, the transmitter was not in communication with the pump at that time. The graph from Chapter 5, on the other hand, shows the transmitter and pump in communication,

which Mr. Gross also annotated. Thus, comparing the two graphs, the transmitter and pump were both in communication and not in communication at the same time, which is naturally impossible.

213. Third, I understand that Abbott made a similar argument in a preliminary response and that the PTAB agreed with Abbott. Specifically, the PTAB said: “We presently agree with Patent Owner that ‘[t]here is no express or implicit disclosure in Ex. 1011 that the Chapter 5 rendering is showing a backfilled data gap from the Chapter 6 rendering.’” (PTAB’s Institution Decision at 33.) This further supports my opinions.

214. Finally, in paragraph 115 of his declaration, Mr. Gross again relies on his opinions in paragraph 60 of his declaration. (*See* Ex. 1008 at ¶ 115 (citing ¶ 50).) As I explained above, in my opinion, Mr. Gross’ opinions in paragraph 60 (and others) should be given little consideration. (*See supra* ¶¶ 122-163.) Therefore, Mr. Gross’ opinions in paragraph 60 do not change my opinion that the Paradigm® REAL-Time documentation does not disclose claim element [1.L].

IX. OPINIONS ON CLAIM 1 UNDER GROUND 3

215. In my opinion, at least claim elements [1.I], [1.K], and [1.L] of independent claim 1 are not disclosed in the prior art. Additionally, in my opinion, a POSITA would not combine or modify the prior art references used in Ground 3.

Therefore, in my opinion, Ground 3 does not render the claims of the 056 unpatentable. I provide my reasons below.

A. A POSITA Would Not Have Been Motivated To Combine Or Modify The Prior Art References Used In Ground 3

216. In paragraphs 26-32 above, I provide my understanding on the law of obviousness as it has been explained to me by Abbott's counsel. This includes my understanding of what it means for there to be a motivation to combine or modify prior art references. Based on that understanding, it is my opinion that a POSITA would not have been motivated to combine or modify the references used in Ground 3.

217. First and foremost, it is my understanding that DexCom, and by extension Mr. Gross, contends that Patel-2008 (Ex. 1015) incorporates by reference each of Causey (Ex. 1017), Mastrototaro (Ex. 1019), and Shahmirian (Ex. 1023) such that "these patents and patent applications are effectively part of *Patel*-2008 as if their disclosures were explicitly contained therein." (*See* Ex. 1008 at ¶¶ 178, 189.)

218. I do not have an opinion on the legal significance of this statement because I am not a lawyer, but Abbott's counsel informs me that the statement is incorrect. According to Abbott's counsel, Patel-2008 incorporates only certain features from Causey, Mastrototaro, and Shahmirian, and not their entire disclosures.

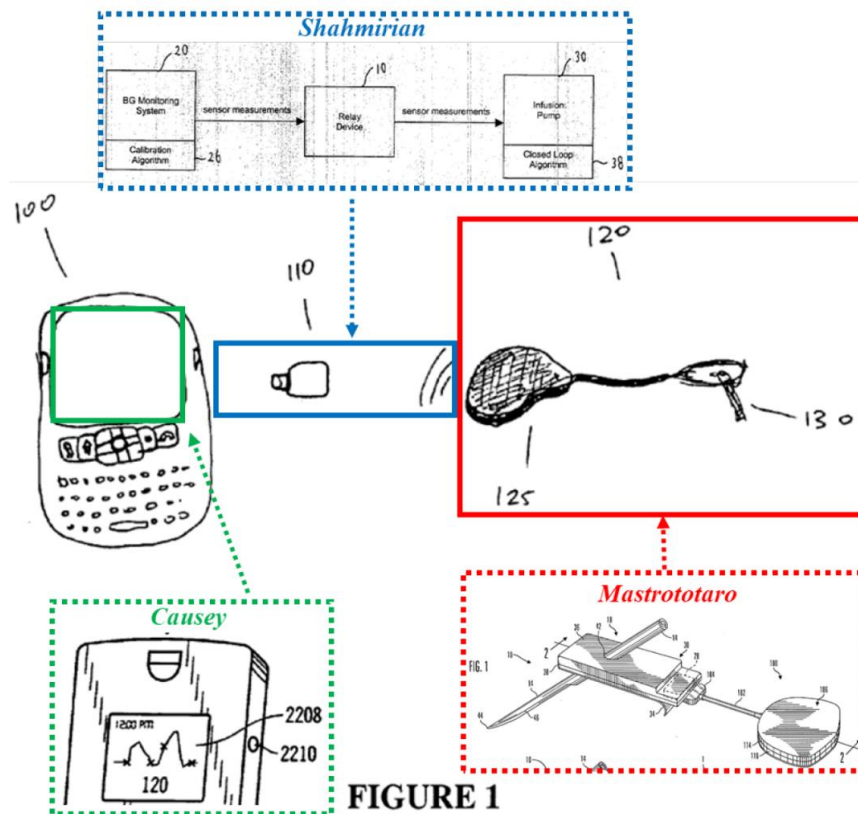
219. Nevertheless, Abbott's counsel asked me to respond to Mr. Gross' opinions regarding whether a POSITA would have been motivated to combine Patel-

2008, Causey, Mastrototaro, and Shahmirian, and the portions of those references that Mr. Gross relies on.

220. In paragraph 190 of his declaration, Mr. Gross states:

In addition, POSITAs would have been motivated to integrate the glucose sensor and transmitter in Mastrototaro, bi-directional communications of Shahmirian, and monitor control programs of Causey into the diabetes management system of Patel-2008.

(Ex. 1008 at ¶ 190.) Mr. Gross then provides the following figure:



(Ex. 1008 at page 113.)

221. In paragraph 191, Mr. Gross states:

POSITAs would have been motivated to combine the sensor and transmitter of *Mastrototaro*, the communications of *Shahmirian*, and the monitor control programs of *Causey* to effectuate a diabetes management system with the monitoring, communication, and display functionalities disclosed in *Patel-2008*. (Ex1015, [0038], [0045], [0052], [0056-57]; *see* paragraphs 176-177 above.)

(Ex. 1008 at ¶ 191.)

222. I disagree with Mr. Gross' opinions in paragraph 191 of his declaration because he has not explained why a POSITA would have chosen the specific references of *Mastrototaro*, *Shahmirian*, and *Causey* or why a POSITA would have combined them to "effectuate a diabetes management system."

223. For example, in paragraph 176 of his declaration, Mr. Gross states that *Patel-2008* discloses "a system 'for managing diabetes using a consumer electronic device [(“CED”)], including a medical device for taking a physiological reading of a user.'" (Ex. 1008 at ¶ 176.) He further states that "[t]he 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)." (Ex. 1008 at ¶ 176.)

224. However, in his combination of references, Mr. Gross replaces *Patel-2008*'s sensor 130 and transmitter 125 with a sensor and transmitter from *Mastrototaro*, but he does not explain why. For example, he does not explain what is different between *Mastrototaro*'s and *Patel-2008*'s sensors and transmitters, why

one is better than the other, why one provides certain benefits, etc. Instead, Mr. Gross says it is to “effectuate a diabetes management system.” (Ex. 1008 at ¶ 191.) But Patel-2008 already discloses a “diabetes management system,” and Mr. Gross does not explain why a POSITA would want to modify it.

225. The same is true for Causey and Shahmirian. Mr. Gross does not provide any particular benefit that either of these references offer over Patel-2008, or why a POSITA would want to modify Patel-2008 to incorporate these references.

226. Another reason I disagree with Mr. Gross is because he does not provide a reason for why these specific references were chosen over others mentioned in Patel-2008. For example, Patel-2008 states:

The glucose monitoring device 120 includes a glucose transmitter 125 and a subcutaneous glucose sensor 130 of the type described [in] U.S. Pat. No. 5,391,250 entitled ‘Method of Fabricating Thin Film Sensors’, U.S. Pat. No. 6,484,046 entitled ‘Electrochemical Analyte Sensor,’ U.S. Pat. Nos. 5,390,671, 5,568,806 and 5,586,553, entitled ‘Transcutaneous Sensor Insertion Set,’ U.S. Pat. No. 6,809,653 entitled ‘Telemetered Characteristic Monitor System And Method of using The Same,’ and U.S. patent application Ser. Nos. 09/377,472, 11/225,790, 11/225,296, **11/322,568 [Mastrototaro]** and entitled ‘Telemetered Characteristic Monitor System And Method Of Using The Same,’ all of which are specifically incorporated by reference herein.

(Ex. 1015 at [0033].) Mastrototaro is therefore one of ten patent documents that Patel-2008 references in connection with “a glucose transmitter 125 and a

subcutaneous glucose sensor 130,” but Mr. Gross does not explain why he chose Mastrototaro over these other patent documents. Therefore, I cannot assess whether his reasons were valid because he did not provide any reasons.

227. The same is true of Causey. Patel-2008 states:

The PDA/Smartphone 100 may be selected from any number of devices including the very popular BlackBerry® line of devices manufactured by Research in Motion. Other devices include the popular Treo devices produced Palm, Inc (Treo 600, 650, 680, 700w, 700p, 700wx, 750w), the HTC line of devices (AT&T 8525, AT&T Tilt, T-Mobile Dash, T-Mobile Wing, and the like), the Apple iPhone, and the like. Other devices and connectors are of the type described in U.S. Pat. Nos. 6,558,320 and 6,641,533 [Causey] entitled “Handheld Personal Data Assistant (PDA) with a Medical Device and Method of Using the Same,” and U.S. patent application Ser. No. 10/429,385 entitled “Handheld Personal Data Assistant (PDA) with a Medical Device and Method of Using the Same, all of which are specifically incorporated by reference herein.

(Ex. 1015 at [0034].) As with Mastrototaro, Mr. Gross does not explain why he selected Causey’s CED over the numerous devices specifically identified in paragraph [0034] of Patel-2008 or over the other two patent documents referenced in that paragraph. Each of those would “effectuate a diabetes management system,” which Mr. Gross provides as the only motivation for combining the references. Thus, each would be equally valid, yet for an unknown reason, Mr. Gross selected Causey.

228. Mr. Gross also does not explain why he selected specific disclosures or embodiments from the references that he chose to combine with Patel-2008. For example, Mastrototaro explains that sensor data could be calibrated in the transmitter unit or in the receiver unit. (*See* Ex. 1019 at [0035]). Mr. Gross selected the former, but he does not explain why. In my opinion, it is likely because claim element [1.D] requires “process[ing] the sensor data using calibration data” in the transmitter (Ex. 1001 at claim 1), and so Mr. Gross used claim 1 of the 056 patent to determine which portion of Mastrototaro’s disclosure to combine with other prior art. Based on my understanding of the law as it has been explained to me, that sounds like hindsight bias.

229. In paragraph 192 of his declaration, Mr. Gross states:

POSITAs would have also been motivated to incorporate the monitoring, communication, and display functionalities features of *Mastrototaro*, *Shahmirian*, and *Causey* to convey as much accurate glucose information to a user as possible without providing inaccurate information. (*See* paragraphs 60, 80 above.)

(Ex. 1008 at ¶ 192.)

230. As I explained above, in my opinion, Mr. Gross’ opinions in paragraph 60 (and others) should be given little consideration. (*See supra* ¶¶ 122-163.) Therefore, Mr. Gross’ opinions in paragraph 60 do not change my opinion that he does not provide a valid motivation to combine the references in Ground 3.

231. Additionally, Mr. Gross does not explain his statement in paragraph 192, such as why Causey, Mastrototaro, and Shahmirian would enable “convey[ing] as much accurate glucose information to a user as possible without providing inaccurate information,” or why the other documents that Patel-2008 would not enable that. Instead, it appears again that Mr. Gross has selected these specific references to try and match the claims of the 056 patent.

232. For all of these reasons, in my opinion, Mr. Gross has not provided a satisfactory explanation for why a POSITA would (i) combine Causey, Mastrototaro, and Shahmirian with Patel-2008 over other references mentioned in Patel-2008, or (ii) select the specific teachings within these references over other teachings that relate to other embodiments.

B. Claim Element [1.I]

233. Claim element [1.I] recites “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.” (Ex. 1001 at 15:65-16:3.)

234. In paragraph 211 of his declaration, Mr. Gross states that “*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.’” (Ex. 1008 at ¶ 211.) I

disagree at least because, in my opinion, there is no disclosure in Patel-2008 of “detec[ing] an adverse condition.”

235. For this claim element, Mr. Gross first relies on Figure 7(b) of Patel-2008 and annotates it to show a “Missing Data Gap.” (Ex. 1008 at ¶ 211.) This figure, however, does not indicate whether or how Patel-2008 “detect[s] an adverse condition,” and so Figure 7(b) does not disclose claim element [1.I], nor does it appear that Mr. Gross contends otherwise.

236. Mr. Gross then relies on paragraph 57 of Patel-2008, but he does not identify any particular statement in that paragraph. Nevertheless, there is nothing in paragraph 57 that indicates whether or how Patel-2008 “detect[s] an adverse condition.”

237. Presumably, in paragraph 57 of Patel-2008, Mr. Gross is relying on the sentence that mentions “missing data 728.” That sentence states:

Also, FIG. 7(b) shows an example of missing data 728 and how the data bar 718 shows a blank white space during the time no data was received.

(Ex. 1015 at [0057].) Again, there is nothing in this sentence that indicates whether or how Patel-2008 “detect[s] an adverse condition.” Therefore, in my opinion, paragraph 57 of Patel-2008 also does not disclose claim element [1.I].

238. With regard to Patel-2008, Mr. Gross also states:

Conditions associated with out-of-range (*i.e.*, extreme) glucose readings and sensor calibration are also detected. (Ex1015, [0044].)

(Ex. 1008 at 211.) I disagree with this statement, and also disagree that this discloses claim element [1.I].

239. First, Patel-2008's reference to "out-of-range" in no way implies "extreme" glucose readings as Mr. Gross suggests. PWDs will typically consult their physician to help determine what an appropriate range is for their glucose levels. For example, the range might be between 80 mg/dL and 180 mg/dL. The PWD will then target this range and try to spend as much time within the range as possible. This is a metric known as "time in range" or TIR.

240. If the PWD's glucose levels go outside of their target range, they will be "out-of-range" as Patel-2008 mentions. However, their glucose levels might be only 1 mg/dL above or below their thresholds. For example, if a PWD and their physician determine that the target range should be 75 mg/dL to 180 mg/dL, the PWD's glucose levels would be out of range at 74 mg/dL or 181 mg/dL. While both readings would be "out-of-range," neither would be "extreme" as Mr. Gross suggests.

241. Second, even if Patel-2008's system were able to detect "out-of-range" and "sensor calibration" as Mr. Gross suggests, neither is described in Patel-2008 as causing a data gap, including one that is backfilled upon correction of the condition.

Instead of causing a data gap, Patel-2008 says that “[s]oftware can provoke the CED to place a telephone call to selected phone numbers based on” events such as “out-of-range BG readings, imminent or current hypo- or hyper glycemc events, sensor calibration requirements, and the like.” (Ex. 1015 at [0044].) Therefore, Patel-2008 discloses that certain events like “out-of-range BG readings” result in Patel-2008’s CED making calls—not in the CED displaying a data gap. Therefore, in my opinion, paragraph 44 of Patel-2008 does not disclose claim element [1.I], and accordingly, Patel-2008 does not disclose this claim element.

242. In paragraph 212 of his declaration, Mr. Gross states:

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.)

(Ex. 1008 at ¶ 212.) I disagree that either *Shahmirian* or *Causey* disclose claim element [1.I].

243. As an initial matter, claim element [1.I] states that “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.” However, nowhere in paragraph 212 of his declaration does Mr. Gross explain how either Shahmirian or Causey meet this claim element. Instead, Mr. Gross simply identifies disclosure in Shahmirian and Causey without explaining what their significance is, how the disclosures relate to claim element [1.I], or how their combination meets claim element [1.I].

244. In any event, regarding Shahmirian, Mr. Gross relies on paragraphs 102 and 111. Paragraph 102 states:

In yet other alternative embodiments, the infusion pump 30 communicates with the BG monitoring system 20 to indicate that the sensor data has been received and/or to echo the sensor data so that the data can be retransmitted if it was received inaccurately.

(Ex. 1023 at [0102].)

245. Paragraph 102 of Shahmirian does disclose claim element [1.I]. This paragraph merely says that data is retransmitted if it was received inaccurately—it does not say that the inaccurate data could or would cause a data gap on the display. In fact, a POSITA would understand this paragraph to mean that if inaccurate data is received, it would not cause a data gap because Shahmirian tells us that the data will be retransmitted.

246. Paragraph 111 of Shahmirian states:

The signals from the infusion pump 30 may include signals to request information from the BG monitoring system 20, verify receipt of

information, echo information received, transmit information to be downloaded to the BG monitoring system 20, and the like. In additional alternative embodiments, signals may be initiated at the relay device 10 and sent to the BG monitoring system 20 and/or the infusion pump 30.

(Ex. 1023 at [0111].)

247. Paragraph 111 of Shahmirian also does not disclose claim element [1.I] and Mr. Gross does not explain how it does. While that paragraph notes that the “infusion pump 30” may “verify receipt of information” and “echo information received,” there’s no explanation for what happens if the “receipt of information” is not verified, or if “information received” is not echoed back, including whether such a situation could or would cause a data gap. Therefore, Shahmirian does not disclose claim element [1.I] in my opinion.

248. Mr. Gross also relies on the disclosure in Causey at column 22, lines 28-45. That states:

In further embodiments, the microprocessor 216 monitors the sensor signals from the sensor monitor 212 to determine when the characteristic meter 300 should be used to perform tests to be used for calibration of the sensor data signals. For instance, the microprocessor 216 could indicate that the calibration test should be delayed if the sensor data signals from the sensor monitor 212 are changing too rapidly and suggest a calibration reading when the sensor data readings are relatively stable. Also, the characteristic monitor 200’ of the medical device module 200 may prompt the user to perform calibration

at periodic preset intervals. Alternatively, the characteristic monitor 200' of the medical device module 200 may prompt the user to perform the calibration based upon event-triggered intervals, that are either user input, such as meals, exercise, or the like, or that are trend input, such as large excursions in glucose levels, faulty or interrupted data readings, or the like.

(Ex. 1017 at 22:28-45.)

249. This portion of Causey does not disclose claim element [1.I], and Mr. Gross does not explain how it does. Rather, the cited portion of Causey explains the unremarkable process of periodically re-calibrating a CGM.

250. In the 2009 timeframe, all CGMs required an initial calibration and periodic re-calibrations throughout the duration of the sensor session. For example, the User's Guide for DexCom's STS-7 explains:

The STS-7 System requires 2 BG fingerstick readings at the first calibration prompt. The STS Receiver will prompt you for these readings about 2 hours after you insert a new STS-7 Sensor (See Section 3.1).

After initial calibration, if you have not uploaded another BG reading in 12 hours the STS Receiver will request a new BG reading for calibration update.

(Ex. 2001 at 25.)

251. When the PWD's glucose levels were changing rapidly, however, it was not advisable to perform a blood glucose measurement for calibration. (*See, e.g.*, Ex. 2002 (G4 User's Guide) at 78 ("Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute.").)

252. The cited portion of Causey is merely explaining that calibration should be delayed when glucose levels are changing too rapidly. That does not mean, however, that it will cause a data gap. Rather, as was typical, calibration parameters would continue to be used to calibrate sensor data while a request for an updated calibration was pending. That is what Causey discloses in the portion that Mr. Gross cites. It does not disclose "detect[ing] an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap" as required by claim element [1.I].

253. Finally, the reference to "large excursions in glucose levels" and "faulty or interrupted data readings" in Causey is referring to when the system could prompt for an updated calibration reading (i.e., "event-triggered"). That is unrelated to whether or not information is displayed on a CGM display, such as a data gap.

254. Therefore, in my opinion, Mr. Gross has not shown how Shahmirian or Causey, in addition to Patel-2008, discloses claim element [1.I]. Furthermore, in my opinion, none of these references do disclose claim element [1.I] for the reasons I provided above.

C. Claim Element [1.K]

255. Claim element [1.K] recites “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 that data gap is backfilled.” (Ex. 1001 at 16:8-12.)

256. For this claim element, Mr. Gross relies on Shahmirian and Causey. (See Ex. 1008 at ¶¶ 214-216.) In my opinion, however, neither reference discloses claim element [1.K], whether alone or combined together.

257. In paragraph 214 of his declaration, Mr. Gross says the following regarding Shahmirian:

“[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.” (Ex1023, [0103].) “Once the sensor data is received, ... the most recent sensor measurement” is displayed. (Ex1023, [0103].)

(Ex. 1008 at ¶ 214.) These two sentences, however, refer to two different embodiments and are reversed from the order in which they appear in Shahmirian. Mr. Gross did this presumably to make them sound closer to claim element [1.K]. Regardless, these sentences do not disclose claim element [1.K] despite the order in which they are considered.

258. For example, with respect to its first embodiment, Shahmirian explains:

Once the sensor data is received, the infusion pump 30 shows the most recent sensor measurement on the display 100.

(Ex. 1023 at [0103].)

259. That passage says that the most recent sensor measurement is displayed.

It does not disclose outputting processed sensor data for a time period corresponding to an adverse condition such that a data gap is backfilled. In fact, the passage does not reference any adverse conditions at all, data gaps, or backfilling data gaps. It simply says that data is displayed. To be clear, it says that only the “most recent sensor measurement is displayed.” That indicates that, even if there was a data gap, and even if missing data was transmitted to the infusion pump 30, only the most recent sensor measurement would be displayed. This passage does not disclose displaying anything beyond the “most recent sensor measurement,” such as missing data to fill in the gap, which is required by claim element [1.K].

260. With respect to its second embodiment, Shahmirian explains:

In particular alternative embodiments, 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.

(Ex. 1023 at [0103].)

261. As an initial matter, Shahmirian does not explain what the infusion pump 30 does with the “additional sensor data” when it receives it from the BG monitoring system 20. This is an important omission because the data may not be displayed. For example, the “additional sensor data” might be stored in the infusion pump 30 so that it can be preserved for historical reports as the Paradigm® REAL-Time System does. (*See supra* ¶¶ 165-205.) Indeed, this is supported elsewhere in Shahmirian. (*See* Ex. 1023 at [0063] (“In preferred embodiments, the BG monitoring system 20 stores information in a memory (not shown) of the BG monitoring system 20 for subsequent review and/or downloading to a storage media.”).)

262. Shahmirian provides another potential use for the additional sensor data. In the paragraph following the one Mr. Gross cites, Shahmirian explains:

A calibration algorithm is used to convert sensor data into sensor measurements, and then the sensor measurements are used in a closed loop algorithm to generate fluid delivery commands to operate the infusion pump 30.

(Ex. 1023 at [0104].) Thus, the “additional sensor data” could also be used in a closed loop system to automatically adjust fluid delivery rather than being displayed to the user.

263. Moreover, if any of the “additional sensor data” were to be displayed at all, for example, based on combining Shahmirian’s two embodiments as Mr. Gross suggests, only “the recent sensor measurement” would be displayed according to the

first embodiment. (*See* Ex. 1023 at [0103].) Accordingly, Shahmirian does not teach displaying all missing data, which is required by claim element [1.K].

264. Therefore, in my opinion, Shahmirian does not disclose claim element [1.K] in either of its two embodiments. Nor does the combination of the embodiments disclose claim element [1.K], and Mr. Gross does not explain how they do. For example, even if the embodiments were reversed and combined in the manner Mr. Gross suggests, they would teach (i) the BG monitoring system 20 sending the infusion pump 30 additional sensor data that the BG monitoring system 20 is missing, and then (ii) displaying the most recent sensor measurement. The combination of these two embodiments, even arranged in the manner in which Mr. Gross suggests, still would not disclose backfilling a data gap as required by claim element [1.K] at least because only the most recent sensor measurement is displayed.

265. In paragraph 215 of his declaration, Mr. Gross says the following about Causey:

Causey also discloses updating display of glucose data to show newly calibrated glucose values and differences with previously displayed data. (Ex1017, 15:59-65.)

(Ex. 1008 at ¶ 215.)

266. At column 15, lines 59-65 that Mr. Gross cites, Causey explains:

In addition, the calibrated data using results from the characteristic meter 2300 can be displayed to provide a user with updated trend and

glucose level data. This may also be used to update and show differences between the newly calibrated (or additional calibration) data and the data as it was prior to the new calibration (or additional calibration).

(Ex. 1017 at 15:59-65.)

267. Mr. Gross does not explain how this disclosure in Causey meets claim element [1.K], which requires “output[ting] 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.” (Ex. 1001 at 16:8-12.)

268. In any event, in my opinion, Causey teaches the opposite of claim element [1.K]. For example, Causey tells us that calibrated data may be used “to update and show differences between the newly calibrated ... data and the data as it was prior to the new calibration.” In other words, instead of withholding data such that a data gap might form, Causey teaches the opposite and always displays the data, even if the data might later be replaced with newly calibrated data.

269. Mr. Gross makes two additional arguments for why, in his opinion, claim element [1.K] is met. However, in my opinion, neither is convincing.

270. First, in paragraph 216 of his declaration, Mr. Gross states:

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. (*See* paragraph 60 above.)

(Ex. 1008 at ¶ 216.)

271. Mr. Gross again refers back to his paragraph 60, but as I explained above, in my opinion, Mr. Gross' opinions in that paragraph (and others) should be given little consideration. (*See supra* ¶¶ 122-163.) At any rate, neither Shahmirian nor Causey, nor the combination of those two references, teaches backfilling a data gap on the display. Nothing in Mr. Gross' paragraph 60 (that should be accepted as credible) changes that fact. Mr. Gross also does not provide an explanation for his opinions, but instead expresses them as a fact. In my opinion, a POSITA would not recognize filling in a data gap based on Shahmirian's and Causey's disclosures for the reasons I provided above; namely, because (i) neither reference discloses a data gap or backfilling a data gap, (ii) Shahmirian teaches displaying only the most recent sensor measurement, and (iii) Causey teaches always displaying data rather than a data gap.

272. Second, in paragraph 216 of his declaration, Mr. Gross states:

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 (*See* paragraph 58-60 above.)

(Ex. 1008 at ¶ 216.)

273. Mr. Gross again refers back to his paragraphs 58-60, but as I explained above, in my opinion, Mr. Gross' opinions in these paragraphs (and others) should

be given little consideration. (*See supra* ¶¶ 122-163.) Besides, this reference is circular. In paragraphs 58 and 59, Mr. Gross purports to rely on Shahmirian and Causey, respectively, to develop his opinions in those paragraphs. (*See* Ex. 1008 at ¶¶ 58, 59.) But here, Mr. Gross is relying on those paragraphs purporting to support his opinions about Shahmirian and Causey.

274. In any event, a POSITA reviewing Shahmirian and Causey would not recognize filling in a data gap for the reasons I provided above; namely, because (i) neither reference discloses a data gap or backfilling a data gap, (ii) Shahmirian teaches displaying only the most recent sensor measurement, and (iii) Causey teaches always displaying data rather than a data gap.

275. Therefore, in my opinion, Mr. Gross has not shown that claim element [1.K] is disclosed in the prior art. Indeed, in my opinion, it is not disclosed in the prior art for the reasons I provided above.

D. Claim Element [1.L]

276. Claim element [1.L] recites: “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.” (Ex. 1001 at 16:13-20.)

277. Mr. Gross' analysis of claim element [1.L] is very brief. In paragraph 217 of his declaration, he observes that "*Patel-2008* discloses a glucose line graph with a missing data gap." (Ex. 1008 at ¶ 217.) Mr. Gross does not assert that *Patel-2008* discloses claim element [1.L]. Indeed, *Patel-2008* does not disclose this claim element since "missing data 728" (shown in Figure 7(b)) is never filled.

278. That is the end of Mr. Gross' prior art analysis. He does not identify any other prior art that he asserts discloses claim element [1.L].

279. Mr. Gross does include an additional statement in paragraph 218 of his declaration:

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

(Ex. 1008 at ¶ 218.)

280. However, Mr. Gross does not explain *why* or provide evidence for *why* a POSITA would have found it obvious to modify *Patel-2008* that way, especially given that *Patel-2008* does not teach filling in "missing data 728." Although he refers back to his paragraph 60, as I explained above, in my opinion, Mr. Gross' opinions in that paragraph (and others) should be given little consideration. (*See supra* ¶¶ 122-163.)

281. Furthermore, Mr. Gross' opinions in paragraph 60 are not specific to Ground 3. For example, nowhere in paragraph 60 does Mr. Gross address claim

element [1.L], which recites that “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.” (See Ex. 1008 at ¶ 60.)

282. Therefore, in my opinion, Mr. Gross has not identified any prior art that teaches claim element [1.L], nor has he provided an explanation for why claim element [1.L] would have been obvious to a POSITA at the time of the invention.

X. OPINIONS ON CERTAIN DEPENDENT CLAIMS

283. As explained above, in my opinion, claim 1 is not obvious under Grounds 1, 2, or 3. Because claim 1 is the only independent claim, none of the dependent claims are obvious for the same reasons. In my opinion, the dependent claims below are not obvious for additional, independent reasons.

A. Claim 4

284. Claim 4 recites that “the adverse condition comprises a signal error associated with the glucose sensor.” (Ex. 1001 at 16:28-30.)

1. Grounds 1&2

285. In paragraph 157 of his declaration, Mr. Gross relies on Causey for claim 4 and states:

Causey discloses monitoring sensor signals to detect faulty or interrupted glucose readings, prompting or delaying calibration based on those faulty or interrupted readings, and updating glucose graphs to display glucose data once calibrated. (Ex1017, 15:43-65, 22:28-45.) Therefore, glucose data would fill in glucose graphs once calibrated following faulty or interrupted glucose readings (*i.e.*, sensor signal error). (Ex1017, 15:59-65.)

(Ex. 1008 at ¶ 157.) I disagree with these opinions.

286. There is no disclosure in *Causey* about data gaps, and therefore no disclosure about filling in data gaps, much less data gaps caused by “a signal error associated with the glucose sensor” as required in claim 4. In my opinion, Mr. Gross is piecing together different parts of *Causey* to try and create the impression that *Causey* discloses data gaps and backfilling them, when it does not.

287. For example, at column 15, lines 43-65, *Causey* explains that “the calibrated data using results from the characteristic meter 2300 can be displayed to provide a user with updated trend and glucose level data,” which “may also be used to update and show differences between the newly calibrated (or additional calibration) data and the data as it was prior to the new calibration (or additional calibration).” (Ex. 1017 at 15:59-65.)

288. As I explained above in relation to claim element [1.K], this disclosure in *Causey* is the opposite of the claimed invention of the 056 patent. (*See supra* ¶¶ 265-268.) Here, *Causey* says that calibrated data may be used “to update and show

differences between the newly calibrated ... data and the data as it was prior to the new calibration.” In other words, instead of withholding data such that a data gap might form, Causey teaches the opposite and always displays the data, even if the data might later be replaced with newly calibrated data.

289. Regarding the other portion of Causey that Mr. Gross relies on, column 22, lines 28-45, as I explained above in relation to claim element [1.I], this portion of Causey merely explains the unremarkable process of periodically re-calibrating a CGM. (*See supra* ¶¶ 248-253.)

290. Causey’s disclosure of “prompting or delaying calibration” does not necessarily mean that a data gap would occur. (*See supra* ¶¶ 248-253.) Rather, as was typical, calibration parameters could continue to be used to calibrate sensor data while the need for an updated calibration was pending. (*See supra* ¶¶ 248-253.) That is what Causey describes in the portion that Mr. Gross cites. There is no disclosure in Causey about ceasing to display glucose readings for *any reason*, including when calibration is delayed.

291. Indeed, that is what Causey discloses in the other portion that Mr. Gross relies on: “[T]he calibrated data using results from the characteristic meter 2300 can be displayed to provide a user *with updated trend and glucose level data*. This may also be used to *update* and *show differences* between the newly calibrated (or

additional calibration) data and the data *as it was prior to the new calibration* (or additional calibration).” (Ex. 1017 at 15: 59-65.)

292. Thus, instead of displaying a data gap as Mr. Gross appears to assume would happen from “prompting or delaying calibration,” Causey teaches the opposite: its system continues displaying glucose data until a new calibration measurement is entered, and then the system replaces the displayed data with updated values. Therefore, in my opinion, Causey does not disclose claim 4.

293. In paragraph 158 of his declaration, Mr. Gross states:

Alternatively, POSITAs would have found it obvious to update glucose graphs to display glucose data calibrated following faulty or interrupted glucose readings and other sensor signal errors. (See paragraphs 59-60 above.)

(Ex. 1008 at ¶ 158.)

294. Mr. Gross does not support this statement with any evidence or explain *why* a POSITA would have found it obvious to update glucose graphs in the manner that Mr. Gross states.

295. Moreover, Mr. Gross again refers back to his own opinions in paragraphs 59-60. As I explained above, in my opinion, Mr. Gross’ opinions in those paragraphs (and others) do not have a good foundation. (See *supra* ¶¶ 122-163.) Further, Mr. Gross’ opinions in paragraphs 59-60 of his declaration are based partly on Causey’s disclosure and are therefore incorrect for the same reasons I explained

above about Causey. That also makes Mr. Gross' opinions circular (e.g., he relies on Causey to develop opinions about what a POSITA would allegedly know, and then uses those opinions to interpret how a POSITA would understand Causey). (*See supra* ¶ 273.)

296. Therefore, in my opinion, Mr. Gross has not shown that claim 4 is unpatentable under Ground 2.

2. Ground 3

297. Mr. Gross' opinions in paragraphs 222-223 for claim 4 under Ground 3 are identical to his opinions in paragraphs 157-158 for claim 4 under Ground 2. (*See* Ex. 1008 at ¶¶ 157-158, 222-223.) Therefore, for the same reasons explained above for Ground 2, in my opinion, Mr. Gross has not shown that claim 4 is obvious under Ground 3 as well.

B. Claim 21

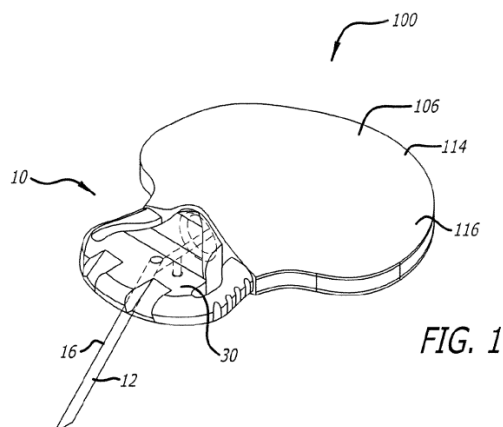
298. Claim 21 recites that "the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within a single integrated housing." (Ex. 1001 at 17:15-19.)

1. Grounds 1&2

299. For Ground 1, in paragraph 132 of his declaration, Mr. Gross states:

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

(Ex. 1008 at ¶ 132.) Mr. Gross then reproduces Figure 1 of Patel-2009 (shown below) and cites to paragraphs 56 and 59 of Patel-2009.



(See Ex. 1008 at ¶ 132.)

300. I disagree with Mr. Gross that Patel-2009 discloses claim 21. As a matter of fundamental importance, Patel-2009 clearly discloses a traditional two-piece architecture for CGMs in which a reusable transmitter is connected to a sensor after the sensor has been inserted beneath the skin rather than a transmitter and “at least a portion of the glucose sensor [that] are disposed within a single integrated housing.” (See *supra* ¶¶ 62-74.)

301. Indeed, the portion of Patel-2009 that Mr. Gross relies on says that the “transceiver 100 *fits directly onto* ... the sensor set 10.” (Ex. 1008 at ¶ 132.) This shows that the transceiver and sensor are separate, and that they are connected to one another by the user, instead of both being “disposed within a single integrated housing.” This is supported in several other places in Patel-2009.

302. For example, Patel-2009 explains that “the sensor interface 122 [of transceiver 100] will include circuitry and/or a mechanism for ***detecting connection to the sensor set 10.***” (Ex. 1012 at [0061].) It further explains that this “would provide the capability to save power and to more quickly and efficiently start initialization of the sensor set 10.” (*Id.*) Thus, the transceiver 100 separately connects to sensor set 10.

303. Indeed, Patel-2009 explains that the transceiver 100’s “batteries have a life in the range of 3 months to 2 years” (Ex. 1012 at [0061]), indicating that the transceiver 100 is reusable. (*See supra* ¶¶ 62-74.)

304. Patel-2009 also explains that the “transceiver 100 is directly ***coupled to*** a sensor set 10.” (Ex. 1012 at [0056].) It further explains that “the transceiver 100 is ***detachably coupled*** to the mounting base 30 housing the sensor set 10,” and that the “transceiver 100 is coupled to the sensor set ***after the sensor set has been placed into body 100 of the user.***” (*Id.*) Patel-2009 also says that the transceiver 100 and sensor set 10 are coupled “using a male/female connection.” (*Id.*)

305. Patel-2009 also provides advantages of having a separate transceiver 100 and sensor set 10. For example, it says that “the transceiver 100 may be detached from the sensor set 10 while the sensor set 10 is implanted in the body 1000 of the user, ***thus allowing the transceiver 100 to independently attach to other complementary devices if desired.***” (*Id.*) Therefore, rather than being “disposed

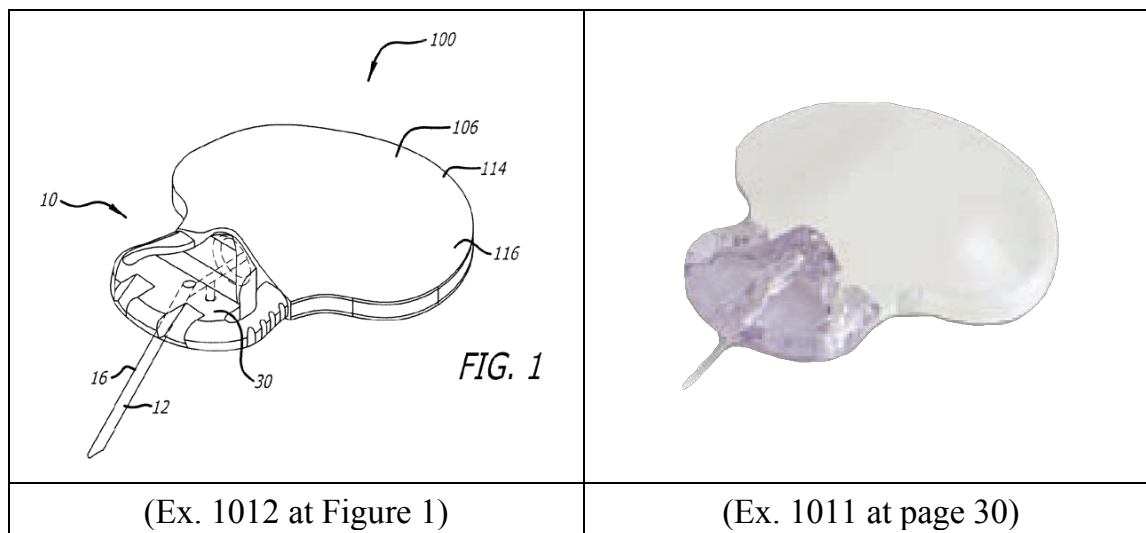
within a single integrated housing,” Patel-2009 teaches that the transceiver 100 and sensor set 10 are detachably coupled to one another after the sensor set 10 has been inserted.

306. This understanding comports with Mr. Gross’ opinions in other parts of his declaration. For example, on pages 37-44 of his declaration, Mr. Gross endeavors to show that Patel-2009 is supported by Provisional Application No. 60/976,886. (*See* Ex. 1008 at ¶¶ 62-65.) One of the elements in claim 1 of Patel-2009 is “a housing detachably coupled to a sensor located on a body of a user.” (*See* Ex. 1008 at page 40, last row.) In Mr. Gross’ opinion, paragraphs [0050], [0051], [0054], and Figures 1, 2, 8A, 13, and 18 of Patel-2009’s provisional application supports that claim element. (*See* Ex. 1008 at pages 40-43, lefthand column.)

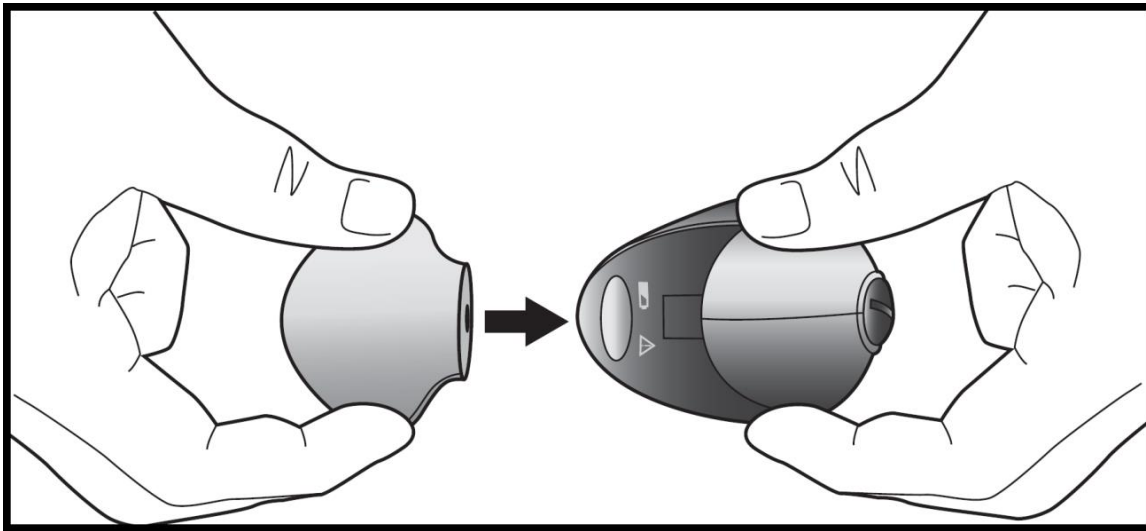
307. Importantly, the disclosure in paragraph [0050] of Patel-2009’s provisional application, which Mr. Gross says discloses “a housing detachably coupled to a sensor located on a body of a user,” is the same disclosure in paragraph [0056] of Patel-2009, which Mr. Gross relies on for claim 21. Similarly, Figure 18 of Patel-2009’s provisional application is the same as Figure 1 of Patel-2009, which Mr. Gross relies on for claim 21. Therefore, Mr. Gross’ opinion that paragraph [0050] and Figure 1 of Patel-2009’s provisional application provides support for the claim element, “a housing detachably coupled to a sensor located on a body of a user,” demonstrates that Patel-2009’s provisional application teaches a traditional

two-piece architecture for a CGM. Thus, Mr. Gross' reliance on that same disclosure for claim 21 is misplaced.

308. Lastly, Figure 1 from Patel-2009 that Mr. Gross relies on for claim 21 is the MiniLink transmitter that the Paradigm® REAL-Time System used.



309. This leaves no doubt that the transceiver 100 and sensor set 10 were separate, detachably connectable units rather than being “disposed within a single integrated housing.” For example, the MiniLink transmitter was rechargeable. (Ex. 1011 at 51-52). The user connected the MiniLink transmitter to a separate charger to recharge the battery.

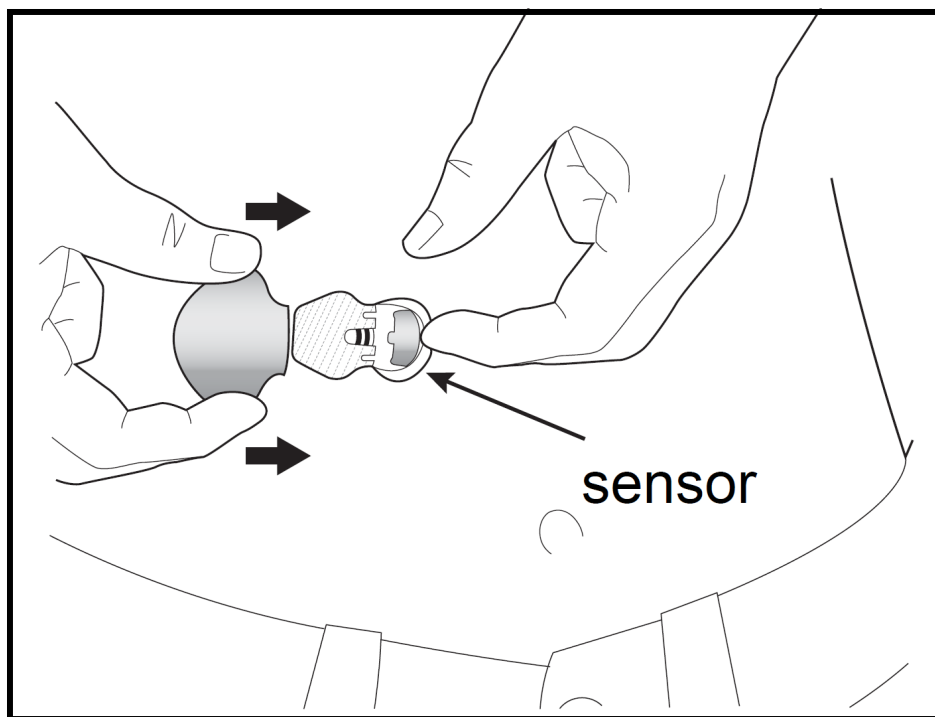


(Ex. 1011 at 52.) The female connector on the MiniLink transmitter shown above, which connected to the battery charger, is also how the MiniLink transmitter connected to the sensor.

310. For example, as I previously explained, the Medtronic Sen-serter® was used with the Paradigm® REAL-Time System to insert the sensor beneath the PWD’s skin. (*See supra* ¶¶ 63-66.) The PWD waited “5 minutes after insertion before connecting the transmitter to the sensor.” (Ex. 1011 at 58.) This was to “[m]ake sure that the site is not bleeding before connection.” (*Id.*)

311. Once five minutes passed and/or the site was no longer bleeding, the PWD connected the transmitter to the sensor. To do so, the Paradigm® User Guide instructed the PWD to “[h]old the transmitter ... to line up the two notches on both sides with the flexible side arms of the sensor.” (Ex. 1011 at 59.) “The transmitter’s flat side with the label should face the skin.” (*Id.*) Then, “[s]lide the transmitter onto

the sensor and push in firmly until the flexible side arms of the sensor ‘click’ into the notches on both sides of the transmitter.” (*Id.*) This is shown below.



(Ex. 1011 at 59.)

312. As Mr. Gross points out from Patel-2009, the transmitter “fits directly onto” the sensor base, which is shown above in the Paradigm® User Guide. However, it is plainly evident from this figure as well that “the data processing and transmitter unit and at least a portion of the glucose sensor” are ***not*** “disposed within a single integrated housing” as required by claim 21.

313. Therefore, in my opinion, Patel-2009 does not disclose claim 21.

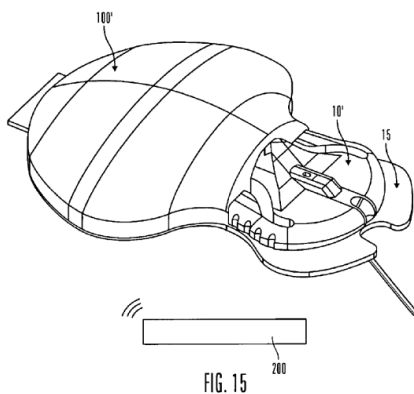
2. Ground 3

314. My opinions for claim 21 under Ground 3 are essentially the same as my opinions for claim 21 under Ground 1. That is because Mr. Gross relies on the same disclosure in Mastrototaro that he relies on from Patel-2009 for Ground 1.

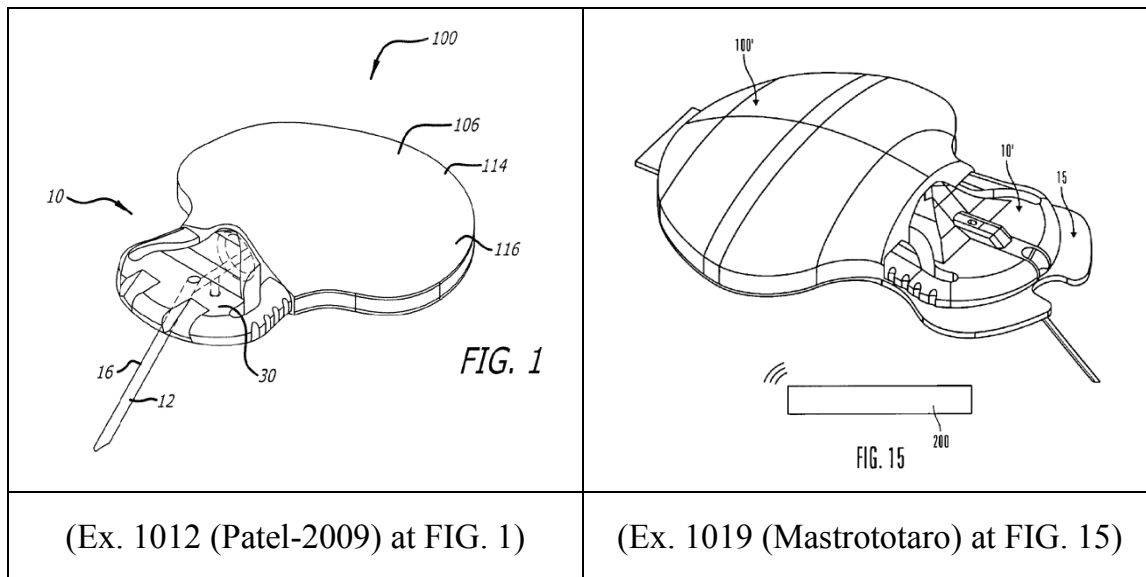
315. Specifically, for Ground 3, in paragraph 250 of his declaration, Mr. Gross states:

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

(Ex. 1008 ¶ 250.) This is the identical wording that he used for claim 21 under Ground 1. (See Ex. 1008 at ¶ 132.) Mr. Gross then reproduces Figure 15 of Mastrototaro (shown below) and cites to paragraph 50 of Mastrototaro.



(See Ex. 1008 at ¶ 250.) Figure 15 of Mastrototaro is almost the same as Figure 1 of Patel-2009, but shown from a different perspective.



316. Indeed, much of the disclosure in Mastrototaro’s paragraph [0050] is the same as the disclosure in Patel-2009’s paragraph [0056].

317. Like Patel-2009, Mastrototaro also explains that “the sensor interface 122 [of transceiver 100] will include circuitry and/or a mechanism for **detecting connection to the sensor set 10.**” (Ex. 1019 at [0055].) It further explains that this “would provide the capability to save power and to more quickly and efficiently start initialization of the sensor set 10.” (*Id.*) Thus, the transceiver 100 separately connects to sensor set 10.

318. Like Patel-2009, Mastrototaro also explains that the transceiver 100’s “batteries have a life in the range of 3 months to 2 years” (Ex. 1019 at [0055]), indicating that the transceiver 100 is reusable. (*See supra* ¶¶ 62-74, 303.)

319. Mastrototaro further explains that in preferred embodiments, “the characteristic monitor transmitter 100’ is **coupled to** a sensor set 10’ using a

male/female connection scheme.” (Ex. 1019 at [0050].) It further explains that “the characteristic monitor transmitter 100’ shall have a female connector interface 400 *built into the housing 1100 of the characteristic monitor transmitter 100’*,” and that “[d]etents at the female connector interface 400 are used to *mate and lock with locking prongs located on the male sensor connector 600 of the sensor set 10’*.” (*Id.*)

320. Therefore, instead of the “data processing and transmitter unit and at least a portion of the glucose sensor [being] disposed within a single integrated housing,” Mastrototaro’s transmitter housing has a female connector that receives a male connector from the sensor set to form the traditional two-piece architecture, just as Patel-2009 teaches. (*See supra* ¶ 304.)

321. Mastrototaro explains that the two-piece architecture is preferred. For example, there are “several advantages” to having “multiple components in the monitor system 1’ (e.g., sensor set 10’, transmitter 100’ and characteristic monitor 20),” such as “facilitat[ing] upgrades or replacements, since one module or the other can be modified or replaced without requiring complete replacement of the monitor system 1’.” (*Id.*) This is in contrast to “other embodiments” in which “the transmitter 100 was discarded along with the sensor set 10 after the 3 to 5 day use.” (*Id.*)

322. Lastly, because Patel-2009 and Mastrototaro disclose the same transmitter and sensor configuration, my opinions above about the Paradigm®

REAL-Time System providing further support for my opinions under Ground 1 apply here to Mastrototaro and Ground 3 as well.

323. Therefore, like Patel-2009 in Ground 1, Mastrototaro does not disclose claim 21 in Ground 3.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: May, 22,
2020

Eugene E. Whynall, Jr. MD

APPENDIX

Materials Considered

DexCom's Petition for *Inter Partes* Review of U.S. Patent No. 11,298,056 (Paper 3)

Abbott's Patent Owner's Preliminary Response (Paper 7)

DexCom's Petitioner's Reply to Patent Owner's Preliminary Response (Paper 9)

Abbott's Patent Owner's Sur-Reply in Support of the Patent Owner Preliminary Response (Paper 10)

PTAB's Decision Granting Institution of *Inter Partes* Review (Paper 11)

Exhibit No.	Description
1001	U.S. Patent No. 11,298,056 ("the '056 Patent")
1008	Declaration of Brian Gross, dated July 24, 2023 ("Gross Decl.")
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-2009</i> ")
1015	U.S. Patent Application Publication No. 2008/0119705 to Patel et al. (" <i>Patel-2008</i> ")
1017	U.S. Patent No. 6,641,533 to Causey et al. (" <i>Causey</i> ")
1019	U.S. Patent Application Publication No. 2006/0202859 to Mastrototaro et al. (" <i>Mastrototaro</i> ")
1023	U.S. Patent Application Publication No. 2004/0122353 to Shahmirian et al. (" <i>Shahmirian</i> ")
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)
2001	STS-7 User's Guide
2002	DexCom G4 Platinum Continuous Glucose Monitoring System User's Guide
2003	FDA Premarket Approval (PMA) for DexCom G5 Mobile Continuous Glucose Monitoring System

Exhibit No.	Description
2007	CareLink™ Personal Getting Started Guide
2015	Declaration of Aaron Striegel, Ph.D.
2016	Cappon et al., <i>Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications</i> , J. Diab. Metab. 43:383-397 (2019)
2017	American Diabetes Association, <i>Role of Continuous Glucose Monitoring in Diabetes Treatment</i> (2018), available at https://pubmed.ncbi.nlm.nih.gov/30958664/
2019	DexCom STS-7 Continuous Glucose Monitoring System User's Guide Submitted Under FCC ID PH29402
2020	DexCom G6 Continuous Glucose Monitoring System User Guide
2021	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User's Guide
2022	Abbott FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual
2023	U.S. Patent No. 10,085,640
2024	U.S. Patent No. 9,996,668
2025	Das et al., <i>Review—Electrochemistry and Other Emerging Technologies for Continuous Glucose Monitoring Devices</i> , ECS Sensors Plus (2022)
2026	Almurashi et al., <i>Emerging Diabetes Technologies: Continuous Glucose Monitors/Artificial Pancreases</i> , J. Indian Inst. Sci. (2023)
2027	Deposition Transcript of Brian Gross (May 2, 2024)
2028	Centers for Disease Control and Prevention—National Diabetes Statistics Report, available at https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed-diabetes.html .
2029	Garg et al., <i>Flash Glucose Monitoring: The Future Is Here</i> , Diabetes Tech. & Therapeutics 19.S2 (2017)
2030	DexCom SEVEN Plus Users Guide
2031	DexCom G5 Mobile CGM System User Guide