UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case IPR2023-01251
Patent 11,298,056 B2

REPLY DECLARATION OF BRIAN D. GROSS

DEXCOM EXHIBIT 1057
Dexcom v. Abbott
IPR2023-01251

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I, Brian D. Gross, do hereby declare as follows:

I. INTRODUCTION

1. My name is Brian D. Gross, and I have been retained as an independent expert on behalf of Petitioner Dexcom, Inc. in connection with the above-captioned Inter Partes Review ("IPR") proceeding to provide my analyses and opinions on certain issues related to U.S. Patent No. 11,298,056 (hereinafter "the '056 Patent").

2. On July 24, 2023, I provided a declaration (EX1008, "Original Declaration") that I understand was filed in the proceeding on August 1, 2023. Among other things, the Original Declaration presents details regarding my introduction and engagement (¶¶1-3), my background and qualifications (¶¶4-8) with further details provided in my CV (EX1009), and my understanding of patent law (EX1008, ¶¶12-24). In addition, my Original Declaration presents an analysis of U.S. Patent No. 11,298,056 (¶25, et seq.), including certain "fundamental concepts of glucose monitoring" that were well-known by April 2009 (¶¶31-49), the ordinary level of skill in the art (¶¶50-61), and an assessment of whether claims 1-12, 14-28 and 30 of the '056 Patent were obvious to persons having this ordinary skill in the art ("POSITAs") as of April 2009 in view of certain prior art references including: publications related to the Medtronic MiniMed Paradigm REAL-Time System that were available on the Medtronic Diabetes website as of October 2007 (EX1011), and prior art patents and patent publications to Himanshu Patel (EX1012,

EX1015), James D. Causey, III (EX1017), John Mastrototaro (EX1019), and Varaz Shahmirian (EX1023). EX1008, ¶¶62-259. In preparing my Original Declaration, I reviewed the materials identified in paragraph 10 of that Original Declaration (spanning pgs. 11-14). EX1008, ¶10.

3. This "Reply Declaration" supplements my Original Declaration by responding to certain aspects of the Declaration of Dr. Eugene E. Wright, Jr. MD (EX2013) and the Declaration of Aaron Striegel, Ph.D. (EX2015) as filed on May 22, 2024. I also considered portions of the July 24, 2024, deposition testimony of Aaron Striegel (EX1054), the July 25, 2024, deposition testimony of Eugene Wright (EX1053), and certain other exhibits (with numbers in the range EX2001-2034) filed by Patent Owner.

4. In addition to the materials identified in paragraph 10 of my Original Declaration (EX1008, ¶10), I have reviewed and considered the materials identified in Section II (paragraph 6) below in preparing my Reply Declaration.

5. It remains my opinion that claims 1-3, 5-8, 11-12, 17-24, 26-28 and 30 of the '056 patent are rendered obvious by the combination of Patel-2009 (EX1012) and Paradigm REAL-Time (EX1011) as discussed in the first ground of my Original Declaration. EX1008, ¶¶62-140. As further discussed, it is also my opinion that claims 4, 9-10, 14-16, and 25 of the '056 patent are rendered obvious by the combination of Patel-2009 (EX1012), Paradigm REAL-Time (EX1011), and

Causey (EX1017) as discussed in the second ground of my Original Declaration. EX1008, ¶¶141-174. Finally, it is my opinion that claims 1-12, 14-18, 20-28, and 30 of the ’056 patent are rendered obvious by the combination of Patel-2008 (EX1015), Mastrototaro (EX1019), Shahmirian (EX1023), and Causey (EX1017) as discussed in the third ground of my Original Declaration. EX1008, ¶¶195-259; *see also id.*, ¶194 (which should be corrected to say “It is my opinion that *Patel*-2008 with incorporated references and the *Patel*-2008/*Mastrototaro*/*Shahmirian*/*Causey* Combination render obvious claims [1-12, 14-18, 20-28, and 30] as set out below.”). None of the arguments or exhibits submitted with Patent Owner’s Response change my conclusions. In fact, as I discuss below (*see infra* Sections III-IV), evidence submitted by Patent Owner, and additional evidence, further support my conclusions in the Original Declaration and further demonstrate that claims 1-12, 14-28, and 30 of the ’056 patent were obvious to a POSITA before April 2009.

II. MATERIALS CONSIDERED AND INFORMATION RELIED UPON REGARDING THE ’056 PATENT

6. In addition to materials considered as part of my Original Declaration (EX1008, ¶10), I reviewed and considered the following materials, and any other materials cited below, in preparing this Reply Declaration:

LIST OF EXHIBITS[1]

Exhibit Nos.	Description
1041	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Paradigm Real Time System, Premarket Approval, dated April 7, 2006. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022S013 on July 21, 2023.
1044	Medtronic Inc., News Release: Medtronic Receives FDA Approval for World's First Insulin Pump with Real-Time Continuous Glucose Monitoring, dated April 13, 2006. Retrieved from https://web.archive.org/web/20060427084431/http://wwwp.medtronic.com:80/Newsroom/NewsReleaseDetails.do?itemId=1144875806140&lang=en_US on July 21, 2023.
1052	Affidavit of Nathaniel E. Frank-White, Exhibit A ("Supplemental Paradigm REAL-Time Archive")
1053	Deposition Transcript of Eugene E. Wright Jr., M.D. (July 25, 2024)
1054	Deposition Transcript of Aaron Striegel, Ph.D. (July 24, 2024)
1055	Declaration of Andrew Ahmann M.D., dated August 30, 2024
1058	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Medtronic MiniMed Guardian RT, Premarket Approval P980022/S011, dated July 18, 2005. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022S011A.pdfon August 26, 2024.
1059	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Medtronic MiniMed Guardian RT, Summary of Safety and Effectiveness Data (SSED). Retrieved from

[1]Note that my Original Declaration misnumbered exhibits authored by Breton (EX1045) and Burge (EX1046).

Exhibit Nos.	Description
	https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022B.pdf on August 26, 2024.
1063	Howard Wolpert, M.D. *Establishing a Continuous Glucose Monitoring Program*, Journal of Diabetes Science and Technology, 2:2 (2008)
1065	LinkedIn Summary of Scott Harper
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
2007	CareLink™ Personal Getting Started Guide
2009	FCC Frequency Table
2010	Bluetooth Basics
2011	LinkedIn Summary of Brian Gross
2012	U.S. Patent No. 9,577,934
2013	Declaration of Eugene E. Wright, Jr. MD
2014	Curriculum Vitae of Eugene E. Wright, Jr. MD
2015	Declaration of Aaron Striegel, Ph.D.
2016	Cappon et al., *Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications*, J. Diab. Metab. 43:383-397 (2019)
2017	American Diabetes Association, Role of Continuous Glucose Monitoring in Diabetes Treatment (2018), available at https://pubmed.ncbi.nlm.nih.gov/30958664/
2018	The MiniMed Paradigm® REAL-Time Insulin Pump User Guide for Pediatric Models MMT-522K/MMT-722K
2019	DexCom STS-7 Continuous Glucose Monitoring System User's Guide Submitted Under FCC ID PH29402

Exhibit Nos.	Description
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
2025	Das et al., *Review—Electrochemistry and Other Emerging Technologies for Continuous Glucose Monitoring Devices*, ECS Sensors Plus (2022)
2026	Almurashi et al., *Emerging Diabetes Technologies: Continuous Glucose Monitors/Artificial Pancreases*, 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., *Flash Glucose Monitoring: The Future Is Here*, Diabetes Tech. & Therapeutics 19.S2 (2017)
2030	DexCom SEVEN Plus Users Guide
2031	DexCom G5 Mobile CGM System User Guide
2033	Atmel Product Guide (Winter 2008), available at https://media.digikey.com/pdf/Data%20Sheets/Atmel%20PDFs/Products%20Select%20Guide.pdf
2034	Atmel - ATmega169P Datasheet, available at https://ww1.microchip.com/downloads/en/DeviceDoc/doc8018.pdf

7. In addition to materials identified in paragraph 6 above and paragraph 10 of my Original Declaration (EX1008, ¶10), I may also consider and rely on additional documents and information not yet available to rebut arguments raised by

Wright and Striegel in response to my Original Declaration. Further, I reserve the right to revise, supplement, and/or amend my opinions based on new information or further development in these or related proceedings.

8. Like my Original Declaration, I have also relied on my professional experience in formulating the opinions expressed in this Reply Declaration. *See* EX1008, ¶11.

III. OPINIONS RESPONSIVE TO THOSE OF DR. STRIEGEL

9. I have considered certain statements made in the Declaration of Aaron Striegel, Ph.D. (EX2015, "the Striegel Declaration"). In this section I provide opinions responsive to Dr. Striegel.

A. A POSITA Would Implement The System Such That It Displayed All Available CGM Data For The User's Selected Time Window

10. In his declaration, Dr. Striegel appears to opine that a POSITA would implement the Paradigm system by storing glucose values that are received from a transmitter in a display buffer (e.g., "store up to 24 hours of real-time glucose values in the display buffer on a FIFO basis as it is received from the transmitter," EX2015, ¶ 47). He then opines that the received glucose values are "duplicated," suggesting that this duplication is from the display buffer to a long-term memory (e.g., "[i]n this system, the data received by the transmitter would also be stored in the long-term memory, i.e., would be duplicated once received," *Id.*, 48).

11. However, when asked at deposition, Dr. Striegel clarified his opinion of what would happen with incoming glucose data received from the transmitter, ultimately explaining that data would be stored in long-term memory but would not necessarily be stored in the display buffer at the time of arrival. For example, he explained why that storage of incoming data to long-term memory was critical:

> [A]s the data would come in; and we want to make sure, no matter what, it's saved somewhere so it will be around for later. … I would say, hey, this is important data. I need to make sure it's never lost, so I want to stick that in the long-term storage.

EX1054, 112:7-18. He then further explained how this incoming data might not pass through the display buffer:

> [T]here's no guarantee that it would have traversed the display buffer because it -- depending upon when it would arrive, the user could have been doing other things. Depending upon what the display is showing, it may have -- it may never make its way into the display buffer itself.

Id., 112:20-113:1.

12. This is consistent with his explanation of "display buffer" as something that would hold information associated with what should appear on the display at a given moment, i.e., "the display buffer is what I want to show." *Id*., 113:2-3. And that might be a menu or a trend graph. For example he testified that the contents of the display buffer depend on the content being shown (which could include information other than trend graph data): "I think I would characterize it as saying

these are the -- the display buffer contains the pixels that I want to light up based on the decisions that I made on how I might want to manifest whatever I might want to display." *Id*., 81:15-20, *see also Id.*, 66:14-18, 67:4-6, 79:14-80:6. He further acknowledges that the display buffer could be updated with pixel information associated with a different image if a user switches from a trend graph to another display view (e.g., a menu display). *Id.*, 81:22-82:3.

13. I agree with Dr. Striegel that a display buffer (sometimes called a frame buffer), as a general concept in system design, would typically store pixel information relating to an image to be displayed, which would be updated each time the display is updated and/or a user selects a new view to be displayed. *Id.* 71:25-72:11, 81:15-20. For example, the Paradigm Real-Time Insulin Pump user documentation stipulates that if no buttons are pressed on the pump in 30 seconds, the screen returns to HOME screen. EX2018, 30. From there, a user can interact with the pump to access other views, such as a 3 hour graph or 24 hour graph of glucose (e.g., by pressing "ESC" once or twice, respectively). EX1011, 64. Based on the Paradigm Real-Time Insulin Pump user documentation, different data views may need to include various different data types, such as information relating to the last 3 or 24 hours of discrete CGM data, insulin bolus data information, error text, glucose level rate of change, alert information, local time, etc. EX1011, 64. Further, a POSITA would understand that other views of data available to the user, including

the set up and status screens (*see* e.g., *id.*, 44, 63), all include different data represented on the display. Thus, in alignment with Dr. Striegel's testimony at deposition, a POSITA would understand that the display of the Paradigm system is updated often, which would, in turn, cause the above-described display buffer to be updated to reflect pixel values for the screen that is to be presented at a given time.

14. As further acknowledged by Dr. Striegel, incoming glucose data would always be stored in a long-term memory, but may not immediately be stored in the display buffer (e.g., "depending on what the display is showing…it may never make its way into the display buffer itself," EX1054, 112:20-113:1). Accordingly, as explained by Dr. Striegel at deposition, incoming glucose data would be stored in long-term storage but not necessarily the display buffer. *Id.* In such instances, when a user then selects to view a trend graph (e.g., a 3-hour or 24-hour trend graph), the system would need to retrieve the glucose data for generating the image of the trend graph from the long-term storage in order to refresh the display. *See, e.g.*, EX2015, ¶ 42 (describing how historical data in non-volatile memory could be "accessed for retrieving discrete data values"). This need to retrieve the CGM data from long-term storage would exist any time the screen was required to display information that included CGM data, whether that be trend graphs or alarms or the longer 31-day personal history.

15. Thus, under Dr. Striegel's description of the Paradigm system, the display would display information (e.g., 3-hour and 24-hour trend graphs) reflecting the data that was stored in long-term (e.g., non-volatile) storage. This is consistent with how a POSITA would implement such a system: as the user switches among different types of display, access any needed data from long-term memory and load the corresponding display information into the display buffer. *See also* EX1054, 71:25-72:11, 79:14-80:6, 81:15-20, 81:22-82:3. Since missing data that is later received would be stored in this long-term storage according to Dr. Striegel (*see* EX2015, ¶ 50), any data gaps previously shown in the trend graphs would be backfilled once the previously missing (and now re-populated) data was loaded from long-term memory into the display buffer. In short, when a user chooses to view trend graphs after the glucose data has already come in, the display buffer is filled with information from long-term memory and thus includes any data that has been re-populated.

16. To the extent that Dr. Striegel opines that the Paradigm system would continue to display data gaps even though re-populated data is "stored in the pump's long-term memory," (*see Id.*) a POSITA would not understand the Paradigm documentation to teach or suggest this hypothetical approach, and would instead find such an approach to be unnecessarily complex and disadvantageous to a user for at least the reasons described below.

17. For example, with the system configured to retrieve the glucose data from long-term storage to refresh the display (*see* above at ¶ 14), display of re-populated data would require no extra software to fetch, parse, and render that data. In an event that causes data to be missed for a period of time, upon resuming communications, the pump would receive the next CGM data point as well as the prior up-to-40-minutes of missing CGM data. *Id.*; EX1011, 8. Fetching the recently received data and handing that data to a data parser/renderer would consume the same amount of resources (power, CPU cycles, memory) as if there was no re-populated data in the first place. There is a fixed amount of data that would be returned for a full 3-hour (about 36 data points) or 24 hour (about 288 data points) request. EX1011, 83. Indeed, implementing the system to display only non-repopulated data would create a more complicated (and thus harder-to-manage) system and actually consume more resources because it would require separate storage of repopulated and non-repopulated data, and then selective retrieval of particular data types depending on where and what was being displayed. For example, under such an over-complicated approach, display of Personal History information or downloading to CareLink would require accessing both repopulated and non-repopulated data, whereas trend graphs would require accessing only non-repopulated data. This illustrates why, from a technical perspective, withholding this

helpful CGM data from the pump's display would actually require more work and complexity.

18. Thus, I disagree with Dr. Striegel that concerns over "processing costs and power" would dissuade a POSITA from displaying available backfilled (re-populated) data in a graph on the user's screen. EX2015, 56. For example, because the display is still being fed by data in a display buffer even when re-populated data is presented, there would be no latency issues involved in displaying the re-populated data in graphs. And as explained above, any processing costs and power associated with updating the display upon arrival of backfilled data would be the same with and without backfilled gap data. For at least these reasons, a POSITA would understand that Paradigm teaches displaying re-populated data on the infusion pump display of the Paradigm System, once received.

19. Given the above standard approach towards using a display buffer, a POSITA would have to go out of their way and add software routines if they wanted to implement the display buffer to *not* display re-populated data. Put differently, the most simple, elegant, straightforward, and natural implementation based on the Paradigm documentation (e.g., including EX1011) would be to store the re-populated data in persisted (e.g., long-term) memory and then update the display buffer as needed to reflect the requested view on the user's display. In the event the

requested view is for a trend graph (e.g., the 3-hour or 24-hour graph), this would result in the graph being updated to fill in any prior gaps with the re-populated data.

20. The background and experience outlined in my Original Declaration (EX1008, ¶¶4-8), my CV (EX1009), and in paragraph 30 below has provided me with insights into the process of medical product development and resulting aims of designers of medical device systems. A POSITA would be motivated to provide the simple, elegant, straight-forward and natural implementation described above because it would align with a designer's goals including reducing system complexity and increasing compatibility of the system. For example, in the process of product development, one aim of a designer is sustainability – e.g., the ability to apply a given process to multiple aspects of the product or across operating hardware. Designing different processing routines to handle the 3-hour and 24-hour trend graphs as suggested by the approach outlined in the Striegel Declaration would work against this aim. Using the simpler display routine described herein for all of the different kinds of data views (e.g., trends, graphs, history, menu screens, etc.) is less prone to errors, easier to design, model, simulate, implement, test, and document, and more sustainable over time. Furthermore, accessing any needed data from long-term memory and loading the corresponding display information into the display buffer to render a view such as a trend graph has the additional advantage of providing the most up-to-date and complete CGM readings (e.g., readings that

include any re-populated data that is stored in long-term memory of the pump) to a user responsive to the user's request—another important aim of designers of medical devices.

21. For at least these additional reasons, a POSITA would have understood from EX1011 that the Paradigm System would be 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," as required by claim 1 of the '056 Patent.

B. The Size Of The Display Screen Does Not Suggest That Re-populated Data Would Be Withheld From A User

22. In addition to the arguments above, Dr. Striegel attempts to support his opinion that re-populated data would not be displayed by referencing the size of the insulin pump's display screen (and corresponding size of a displayed trend graph) for the MiniMed Paradigm 522 and 722 models. EX2015, ¶¶51-52. For example, Dr. Striegel concludes that "[t]he small size of the graph suggests a limited benefit for backfilling a data gap on the pump's screen." EX2015, ¶54. I disagree with Dr. Striegel's conclusion, not only because a POSITA would understand Paradigm as teaching backfilling a data gap on the pump's screen (e.g., *see* EX1011, 8), but also because the above conclusion from Dr. Striegel is rooted in assumptions that are not

supported by the teachings of Paradigm, and it does not reflect the considerations of a POSITA when reading the teachings of Paradigm.

23. For example, as detailed above, a POSITA would have found it obvious to display re-populated data on the infusion pump display in Paradigm based on the teachings of the Patel-2009/Paradigm combination (EX1011, 8), since an aim of designers of medical devices is to provide the most up-to-date and complete sensor data to a user to help the user make medical decisions, determine when to perform a calibration operation (*see id.*, 37-38), and/or understand a medical status of the user. A POSITA would further understand that several graphical data points (e.g., representing 40 minutes of glucose measurements) would provide a user with an even greater extent of historical information regarding the trends or outliers. For example, the Paradigm system uses 20 minutes of glucose data to determine trend arrow representations, so a POSITA would at least understand that 20 minutes of re-populated data would be useful in showing the user's glucose trends for that period of time. *Id.*, 65. For at least these reasons, a POSITA would have been motivated to include re-populated data in the displayed 3-hour or 24-hour trend graphs, regardless of the size of the graph.

24. Further, Dr. Striegel contends that 40 minutes of re-populated data represents 8 glucose readings, which "would have been represented in a single pixel given the size of the display" on a 24-hour graph or "occupy 8 pixels" on a 3-hour

graph. EX2015, ¶55. Nowhere does Dr. Striegel explain how he reached those pixel representation designations, as he only discussed the size of the infusion pump's screen and not its pixel resolution (e.g., the number of pixels that are able to be displayed in the screen). A more accurate evaluation of the visibility of data, given the information provided about the display in Paradigm, would reference a percentage of the graph that the re-populated data would represent. For a 3-hour trend graph, 40 minutes of re-populated data would represent over 22% of the graph, or nearly a quarter of the length of the graph. In the event there were multiple weak signal events in a 3-hour period, then the re-populated data could occupy an even higher percentage of the graph.

25. Given that re-populated data could represent such a large portion of a trend graph in Paradigm, I do not agree with the assertion by Dr. Striegel that there would be a limited benefit of updating the display of the infusion pump to show the re-populated data. EX2015, ¶56. Moreover, even if the re-populated data constituted a smaller percentage of the displayed trend graph or provided such a "limited benefit," for the reasons described above regarding the storage and retrieval of re-populated data, any attempt to intentionally withhold the re-populated data from the display in such instances would actually consume additional computing resources and add unnecessary complexity, and further would detract from a designer's aim to provide the most up-to-date and complete glucose data to the user. For at least these

additional reasons, a POSITA would have been motivated to include any re-populated glucose data in the trend graphs displayed on the infusion pump.

IV. OPINIONS RESPONSIVE TO THOSE OF DR. WRIGHT

26. I have considered certain opinions expressed in the Declaration of Eugene E. Wright, Jr., MD (EX2013, "the Wright Declaration"). In this section, I provide opinions responsive to Dr. Wright.

A. My Opinions Are Supported By Experience And The References Cited In My Original Declaration, And Further Confirmed By Dr. Ahmann

27. Based on review of Dr. Wright's declaration and deposition transcript, I note that he does not disagree with the experience level of a POSITA provided in my Original Declaration. EX2013, ¶123. This experience level is:

> 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.

EX1008, ¶51; EX2013, ¶122. In addition, I noted that:

> 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.

EX1008, ¶52. On the other hand, Dr. Wright opines that "it would be ***imperative*** that [this] POSITA be part of such an interdisciplinary team." EX2013, ¶123.

28. Even if, for argument's sake, my own personal lack of clinical experience made me unqualified to opine on the perspective of a POSITA, as Dr. Wright suggests, Dr. Andrew Ahmann has confirmed my opinions that were critiqued by Dr. Wright. *See* EX1055, ¶¶24-25. I have reviewed Dr. Ahmann's testimony, and his clinical insight only reinforces the opinions in my Original Declaration. Moreover, given Dr. Ahmann's significant clinical experience working with patients to treat diabetes, his declaration provides me with the clinical insight and background that would have been imparted as part of an interdisciplinary team such that I satisfy Dr. Wright's definition of a POSITA. Dr. Wright acknowledged that if I were "provided with clinical background in rendering [my] opinions," then I "would certainly then have the clinical input that would be necessary to be a POSITA and opine on clinical consequences." EX1053, 33:17-25; *see also id.*, 31:20-25 & 32:20-33:3 (Dr. Wright acknowledging that if I worked on a team with a clinician, I "would then fulfill what [he] would consider to be a POSITA").

Accordingly, informed by Dr. Ahmann's clinical perspective, I am now more than qualified to opine on the perspective of a POSITA.

29. Moreover, even without Dr. Ahmann's insight, I am qualified to opine on the perspective of a POSITA as defined by Dr. Wright, given *inter alia* my decades of experience designing and developing physiological monitoring systems and associated medical devices; my experience consulting with clinicians as part of system/device design and development; and my knowledge and experience with treatment of diabetes, as informed and corroborated by the publications cited in my original declaration. As explained in the following paragraphs, I have decades of experience directing and working on interdisciplinary teams of engineers and designers, working with clinicians on physiological monitoring systems (including CGM systems), and treating diabetes as a paramedic. In addition, as discussed in my Original Declaration, my opinions are informed by publications written by clinicians like Bruce Buckingham, who were engaged in the treatment of type-1 diabetes and the clinical study of CGM systems before 2009.

30. As discussed in my Original Declaration, my resume, and during my deposition, I have decades of experience directing and working on interdisciplinary teams to develop medical devices from design to clinical testing and FDA approval, and through commercialization, including:

- From roughly 1991 until 1993, as a product scientist in product development engineering at VivaScan to research, design, develop, and build a microprocessor-controlled physiological monitoring device to determine glucose and other analytes in the blood (EX1008, ¶5; EX1009);
    - specifically, at VivaScan, I was part of the science team which was a three-member technical team, where my role ranged from designing and building discrete component electrical instrumentation to managing animal and human subject studies for a near infrared glucose analyzer (EX2027, 18:12-20:3);
    - preceding my experience at VivaScan, my master's thesis in biomedical engineering involved calibrating gas and temperature sensor arrays for *in vitro* and *in vivo* studies of an intraluminal membrane oxygenator;
- From roughly 1993 to 2001 as a field trial and clinical validation manager at Hewlett Packard Medical Systems and Agilent Technologies where I served multiple cross-functional teams spanning the patient monitoring and home care monitoring portfolio to help manage some design challenges by implementing quality process improvements (EX2027, 20:4-21:12; EX1009);
- From roughly 2001 to 2006 as a senior manager of clinical research at Philips, I both performed and oversaw clinical research in that I was responsible for the design and execution of clinical studies as well as overseeing the teams

that were doing clinical validations for products under the quality management system, including preclearance studies necessary to seek FDA premarket approval (EX2027, 21:18-22:19; EX1009);

- From roughly 2006 to 2014 as principal scientist and clinical system architect at Philips, I was focused on risk management, usability strategy and design goals, and including physiological monitoring systems that cached missed data and transmitted this data when sufficient bandwidth became available (EX1008, ¶7; EX1009);
    - specifically, as a principal scientist at Philips, I helped direct interdisciplinary product implementation teams on their trade-off decisions and as a clinical systems architect I was also responsible for managing key opinion leaders (many of whom were clinicians) to ensure that their feedback and insights were incorporated into product, and business roadmaps (EX2027, 22:20-23:17);
    - this work led to my being the listed inventor of U.S. Patent No. 9,577,934, which was filed in February 2009, originating from a February 2008 provisional, and relates to caching and later restoring patient data, including heart rate data. EX2012; EX2027, 155:9-156:13. Dr. Striegel's testimony that experience with heart rate sensing would translate to glucose monitoring (EX1054, 101:11-104:1), emphasizes

that my expertise with monitoring, caching, and gap-filling cardiac data supports my qualification as a POSITA and further informs the opinions presented in my Original Declaration and in this Reply Declaration.

- From roughly 2014 to 2022 as a fellow scientist and clinical system architect at Philips where I taught, trained, mentored, and supervised members of the organization with less experience, as well as drove risk management and design tradeoff decisions for the businesses and research groups including the creation and direction of integrated global teams (EX1008, ¶7; EX1009);
    - specifically, as a fellow scientist at Philips, I was responsible for driving innovation across the cluster, doing a lot of alignment in architecture, ensuring that quality management systems and safe agile practices are being followed appropriately as well as tutoring and mentoring less experienced engineers and developers (EX2027, 23:23-24:11);
- further, while at Philips, I was part of cross-functional evaluation and due diligence teams looking into technologies related to continuous glucose monitoring and insulin pumps to evaluate these products' quality, manufacturability, design, sustainability (EX2027, 29:22-30:21);
- finally, I worked with CGM technology and reviewed CGM data as part of a Philips contract to deliver CGM technologies to the Department of Defense

in which I was involved in the study design, clinical deployment, and the instrumentation instructions to support a clinical team in their clinical practice and research (EX2027, 38:10-39:4, 40:4-12, 48:8-17; 80:22-81:9).[2]

Through these decades of experience, I have gained an appreciation for the knowledge, skills, and motivations of biomedical engineers working with clinicians and others on interdisciplinary medical product development teams. My opinions draw on this experience. *E.g.*, EX1008, ¶11.

31. Further, as discussed in my resume and during my deposition, I have experience as a paramedic providing care (including administration of medications), to stabilize patients who were experiencing complications from diabetes, including diabetic coma and insulin shock. EX2027, 35:20-36:1; EX1009. This experience with diabetes appears to meet or exceed the experience of the sole inventor of the ’056 patent, Wesley Scott Harper, who only has a bachelor’s degree in bioengineering. EX1065.

32. Third, to the extent they are clinical in nature, my opinions in paragraphs 60 and 80 of my Original Declaration are based on references cited in

[2] The CGM happened to be made by Dexcom, as a subcontractor to Philips. But I did not work or consult for Dexcom as part of this project, have not ever worked for Dexcom, and did not consult for Dexcom prior to this IPR. EX2027, 81:19-82:1.

those paragraphs of my Original Declaration, with specific passages as reproduced in the below table:

References Cited in EX1008, ¶¶60, 80.	**Support for the Clinical Utility Of Providing CGM Data to Patients**
Exhibit 1011, 15	**Exclusive capability of integrating with continuous glucose monitoring technology** When used with the available glucose sensor and MiniLink™ Transmitter components, the MiniMed Paradigm 522 or 722 Insulin Pump displays on-screen REAL-Time data to help you understand more about your glucose control • Displays updated glucose values every five minutes. • Displays 3-hour and 24-hour glucose trend graphs, as well as arrows that indicate how fast, and in what direction, glucose is moving.
Exhibit 1011, 23	**REAL-Time Continuous Glucose Monitoring System** **REAL insights help you take action sooner to improve your glucose control[1-3]** Feature / Specification / Benefit Glucose Sensor: The glucose sensor is inserted, virtually painlessly, through the skin, usually in the stomach area. The glucose sensor sends an electronic signal measuring the amount of glucose in your interstitial fluid. Replace the glucose sensor every three days. — Measures your glucose levels continuously, as an addition to fingerstick measurements. Displays a five-minute average, 24 hours a day. Numerous studies have proven the accuracy of the sensor.[4-6] Calibration: Calibrate your MiniMed Paradigm REAL-Time System at least once every 12 hours. In addition, make sure you always confirm with a fingerstick before making any adjustments in your therapy. — Simple and easy.
Exhibit 1011, 24	**MiniMed Paradigm® 522/722 Insulin Pump** **REAL-Time features give you insights you need to take action** Feature / Specification / Benefit REAL-Time Trend Graphs: Your insulin pump displays glucose trend graphs for 3-hour and 24-hour periods. — Shows you the effects of meals, exercise, insulin, and medication on your glucose control. REAL-Time Readings: Monitors your glucose every minute and displays a five-minute average, 24 hours a day. — Continuous glucose monitoring is proven to improve glycemic control,[1-3] which reduces your risk of long-term complications including eye, nerve, kidney, and heart disease.[7,8] REAL-Time Alarms: Audible or vibrating alarms occur when glucose levels go out of your preset target range. Personalize alarms to meet your specific needs and preferences. You also can turn off your alarms, if you prefer. — Warns you of high or low glucose levels. Use of continuous glucose monitoring is proven to detect highs and lows that fingersticks and A1C testing alone may miss.[1-3,9] REAL-Time Trend Arrows: Single and double arrows point up and down to show the degree and direction of glucose trends. One arrow indicates that glucose has risen or fallen 20-40 mg/dL during the last 20 minutes. Two arrows indicate that glucose has risen or fallen >40 mg/dL during the last 20 minutes. — Up arrows reveal increases in glucose levels. Down arrows reveal decreases in glucose levels. Double arrows suggest a more rapid increase or decrease. Use of continuous glucose monitoring helps reduce the duration of high and low blood glucose and A1C.[1-3,9]

References Cited in EX1008, ¶¶60, 80.	**Support for the Clinical Utility Of Providing CGM Data to Patients**
Exhibit 1012, [0005]	Recently, a variety of implantable electrochemical sensors have been developed for detecting and/or quantifying specific agents … These glucose sensors connected (wired or wirelessly) to a blood glucose monitor can provide continuous glucose readings over a period of time, such as 3 to 5 days. Such readings are useful in monitoring and/or adjusting a treatment regimen which typically includes the regular administration of insulin to the patient.
Exhibit 1012, [0040]	Preferably, the telemetered characteristic sensor system provides for better treatment and glycemic control in an outpatient or home-use environment. For example, the sensor system can provide indications of glucose levels, hypoglycemia/hyperglycemia alerts and outpatient diagnostics. It is also useful as an evaluation tool under a physician's supervision or use in a hospital environment to monitor a patient's health status.
Exhibit 1029, pg. S-13	There is a tremendous need to develop and commercialize a truly simple, accurate method of measuring glucose that can provide a basis for more accurate and directed disease self-management. Generally, it is not practical to perform SMBG frequently enough throughout the day to accurately identify every blood glucose excursion. MiniMed® has taken a first step in advancing the practice of glucose self-monitoring by developing a short-term, continuous glucose sensor. In future product iterations, the sensor will function as a hypoglycemia and hyperglycemia alarm, by notifying the user when blood glucose levels reach preselected thresholds (such as 60 mg/ dL and 200 mg/ dL), and will provide real-time glucose readouts.
Exhibit 1039, pg. 288	**Recent findings** Real-time continuous glucose sensors are new tools to assist in diabetes management. Several devices are currently being sold and additional monitors are expected to be available shortly. These sensors measure interstitial glucose – a distinct physiologic space when compared with the blood glucose. The

References Cited in EX1008, ¶¶60, 80.	**Support for the Clinical Utility Of Providing CGM Data to Patients**
	ability to recognize trends in blood glucose levels provides a new paradigm for making insulin dose decisions and treating hypo- and hyperglycemia.
Exhibit 1039, pg. 292	**Sensor function during hypoglycemia** From a patient perspective, one of the critical functions of a real-time continuous glucose sensor is the ability to detect clinically significant events, both hyper- and hypo-glycemic. Avoidance of nocturnal hypoglycemic seizures is particularly important. Individuals vary in how long they can tolerate hypoglycemia before having a seizure.
Exhibit 1039, pg. 293	They were not overwhelmed by the amount of information provided by real-time monitoring, and 70% thought the use of the Navigator made adjusting insulin doses easier, gave them more confidence in making diabetes decisions and showed them patterns in their blood glucose levels they had not previously been aware of. This study demonstrates that incorporating real-time continuous glucose monitoring into the daily management of type 1 diabetes in children is feasible, and the sensor was perceived as providing valuable information regarding glycemic control by parents and patients.
Exhibit 1039, pg. 293-294	**Clinical experiences with real-time continuous glucose monitoring** Real-time continuous glucose monitoring allows for insulin doses to be based not only on a single glucose value, but with knowledge of which direction the blood glucose is trending. Thus, the premeal dose of short-action insulin can be increased or decreased depending on the direction and speed of glucose changes at the time of the meal. Currently available insulin pumps utilize algorithms to incorporate current glucose levels and the expected carbohydrate intake into suggestions for bolus doses (the 'bolus calculator' or 'bolus wizard' features). With the availability of glucose trend information and rate of change arrows, more sophisticated algorithms can be developed. As an example, a patient might increase a premeal bolus by 20% if the glucose were rising faster than 2 mg/dl-min (this rate of change can be easily determined using trend arrows).

References Cited in EX1008, ¶¶60, 80.	**Support for the Clinical Utility Of Providing CGM Data to Patients**
Exhibit 1039, pg. 294	One of the keys to achieving a significant benefit in glycemic control when using a real-time sensor is to look at sensor glucose levels and glucose trends frequently throughout the day. Patients who were most successful in using a real-time sensor were looking at the sensor 10–20 times a day and greatly missed the comfort of knowing their glucose levels when they were not wearing the sensor.
Exhibit 1039, pg. 295	**Conclusion** Real-time continuous glucose monitoring offers a great benefit to patients who want to actively manage their diabetes; however, widespread adoption of this technology will be delayed until insurance plans authorize this treatment. Continuous monitoring may be of particular benefit to patients with hypoglycemia unawareness, inpatients, athletes and pregnant women. Both patients and physicians need to learn how to best utilize the real-time data and pending hypo- and hyperglycemic alarms to make treatment decisions.
Exhibit 1040, pg. 300-301	**Introduction** This article contains an overview of continuous glucose monitoring (CGM) in general and covers basic concepts focusing on how to use this technology in everyday clinical practice. There are two major ways people use these devices. Patients use real-time CGM (RT-CGM) throughout the day, looking at their glucose trends and making adjustments in real time to their diabetes management, and they use the alarms to alert them during the day and night of possible hypoglycemic and hyperglycemic events. A second way to look at CGM data is in the retrospective analysis of CGM reports; this information is beneficial to the patient but also has great potential benefit to the health care provider when making treatment recommendations. One of the main contributions of CGM is to reveal glucose excursions, including lows during sleep and numerous postprandial highs that would be missed by finger stick blood glucose monitoring. In a Diabetes Research in Children Network

References Cited in EX1008, ¶¶60, 80.	**Support for the Clinical Utility Of Providing CGM Data to Patients**
	(DirecNet) study comparing CGM with eight-point testing, the postprandial glucose peaks were two to three times higher using CGM data compared to eight-point glucose testing using a glucose meter.[1] A second important reason for using CGM is for the detection and possible prevention of hypoglycemia.
Exhibit 1040, pg. 304	When subjects were able to see and react to their RT-CGM glucose values, they spent 26% more time in the target glucose range (80–140 mg/dl) compared with blinded wear ($P < 0.0001$), and they also spent 21% less time in the hypoglycemic range (240 mg/dl).

Dr. Ahmann agrees that my opinions are supported by these originally cited references. *See* EX1055, ¶26. He found these and other opinions from my original declaration "sound and consistent with his clinical experience, as well as the supporting literature." EX1055, ¶¶24-25.

33. In addition to the references cited in my Original Declaration, my opinions in paragraphs 60 and 80 of my Original Declaration are supported by a 2008 article authored by Dr. Howard Wolpert as outlined below:

Original Declaration (EX1008)	Wolpert (EX1063)
¶59: 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,	(At 308) One of the important issues that needs to be strongly emphasized in patient education is the fact that the sensor should only be calibrated when the glucose level is relatively stable and there is steady-state equilibration between glucose concentrations in the blood and interstitial fluid

Original Declaration (EX1008)	Wolpert (EX1063)
rapid glucose changes, and issues with blood glucose reference values.	compartment… If the CGM is calibrated with a blood glucose measurement postprandially, this will result in an upward bias of the sensor readings and compromise the accuracy of the device in detecting hypoglycemia.
¶60: When failed communication or failed/delayed calibration is resolved and previously missing data becomes available, 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. ¶80: One purpose of continuous glucose monitoring is to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia by providing accurate glucose concentrations and trend information in real-time.	(At 307) Real-time continuous glucose monitoring (RT-CGM) devices provide detailed information on glucose patterns and trends, and on alarms that alert the patient to both hyper- and hypoglycemia. This technology can dramatically improve the day-to-day management of patients with diabetes and promises to be a major advance in diabetes care. To derive the full potential benefit from RT-CGM the patient needs to have good diabetes self-management skills.

In addition, Dr. Ahmann agrees that Dr. Wolpert's 2008 article (EX1063) supports my conclusions. EX1055, ¶27. Dr. Wolper's opinions are especially relevant because Dr. Wright acknowledged that Dr. Wolpert is "knowledgeable about the use of CGM data for diabetes management." EX1053, 55:14-56:3.

34. Even if Dr. Wright disagrees with my qualifications, he agrees with my originally-articulated conclusion that a POSITA knew "that it was important to

provide as much accurate glucose data as possible to PWDs" from a CGM in 2009. EX1053, 41:3-10.

B. The Prior Art And My Experience Both Support My Opinions On The Knowledge And Skills That A POSITA Would Have Possessed

35. I have reviewed paragraphs 134-138 of Dr. Wright's declaration. Broadly, these paragraphs discuss my opinions on the knowledge and skills of a POSITA as articulated in paragraphs 54-61 of my Original Declaration. EX1008, ¶¶54-61. Notably, Dr. Wright does not disagree that a POSITA would have had the articulated skills and knowledge in 2009. EX2013, ¶¶134-138. Rather, he suggests that my statements have "no factual basis" or "appear to be copied from or based on concepts disclosed in the 056 patent." EX2013, ¶¶135, 137. The skills and knowledge articulated in my Original Declaration are informed by my years of device design experience as discussed above and in my original declaration (paragraph 30 above; EX1008, ¶¶4-8), and also confirmed by the prior art documents, as discussed in the next paragraph.

36. As demonstrated by the following chart, support for my opinions can be readily found in prior art references. To the extent that such knowledge and skills are also discussed in the '056 patent, that patent does not suggest these were unknown or unconventional.

POSITA Knowledge & Skills	Support in Prior Art
¶55: 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.	**EX1029 at S13** ("There is a tremendous need to develop and commercialize a truly simple, accurate method of measuring glucose that can provide a basis for more accurate and directed disease self-management. Generally, it is not practical to perform SMBG frequently enough throughout the day to accurately identify every blood glucose excursion.") **EX1011 at 86-88** (applying Clark Error Grid to compare clinically acceptable CGM results in zones A & B against clinically significant errors in zones C, D, & E); **EX1046 at 112** (under heading "CGM: A Significant Advance in Diabetes Care," including "Accurate determination of blood glucose concentrations is a prerequisite for the application of state-of-the-art intensified diabetes management…" then discussing the deficiencies of SMBG fingerstick measurements and the potential for CGM.)
¶55: 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**.	**EX1012 at [0086]** ("Another advantage is that glucose history information is stored on the transceiver 100. Thus, because the transceiver 100 can be networked to a plurality of devices, the information is available to any receiver or network node on demand. Furthermore, the transceiver 100 can continuously calculate glucose values even when a remote device is not in proximity to the user. Thus, when communication between the transceiver 100 and the remote device fails, the calibration algorithm can continue to calculate glucose data points. Preferably, when communication is re-established, the remote device can synchronize data with the transceiver 100 and receive glucose values calculated while the remote device was not communicating with the transceiver 100." **EX1011 at 75** ("Cal error If Cal error occurs after entering a meter BG, wait until your BG is stable to enter a new meter BG for calibration.

POSITA Knowledge & Skills	Support in Prior Art
	If error repeats, you will get a Bad Sensor alarm and you will need to replace the sensor. Some possible causes for the error are: ➠ An incorrect blood glucose value was entered from the meter into the pump. ➠ You entered your blood glucose value too late after selecting the Meter BG option. ➠ The blood glucose values are rising or falling very quickly. ➠ The sensor needs additional time to stabilize after being inserted. ➠ The sensor is ready to be replaced and is no longer reading glucose values correctly.”) **EX1011 at 8** (three FAQs and corresponding responses, including (1) “What happens when the Minilink REAL-Time Transmitter and insulin pump move out of range?,” (2) “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?,” and (2) “Can I swim, shower, or bathe with the Minilink Transmitter?”); **10** (FAQ and corresponding response to “I wear a MiniMed Paradigm REAL-Time System and sometimes I get a WEAK SIGNAL or a LOST SENSOR message. What does this mean?”; “two FAQs and corresponding responses to (1) “Why do I have to calibrate?” and (2) “Sometimes when I enter a meter reading, the system displays a CAL ERROR. What is a CAL ERROR and what should I do when I get one?”); **12** (FAQ and corresponding response to “Is the MiniMed Paradigm REAL-Time System affected by computers, cell phones or airport detectors?”); **41** (interruption of wireless transmission due to “transmitter orientation and the pump position on the body” and interference from other devices,

POSITA Knowledge & Skills	Support in Prior Art
	including "cell phones, cordless phones and wireless networks"); **73** ("Weak Signal" alarm "when the pump does not receive data for a period of time, as set in Missed Data"); **EX1015 at [0057], Fig. 7(b)** ("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."). **EX1030 at 10:56-11:21** (a variety of "calibration cancelation event" (*e.g.*, unstable sensor, sensor disconnect, out-of-range, or calibration error) in which glucose values are no longer considered valid); **10:39-49** (discussing unstable signal); **14:2-14** (discussing calibration error where the modified sensitivity ratio (MSPSR) is not within a valid range); **17:30-56** (discussing out-of-range limit for glucose concentration during calibration (*e.g.*, 200 mg/dl)). **EX1017 at 22:15-45** (delaying calibration "if the sensor data signals from the sensor monitor 212 are changing too rapidly"). **EX1011 at 10** (two FAQs and corresponding responses to (1) "Why do I have to calibrate?" and (2) "Sometimes when I enter a meter reading, the system displays a CAL ERROR. What is a CAL ERROR and what should I do when I get one?").
¶55: POSITAs would have accounted for missing data using technical concepts known at the time, including **programming glucose monitoring**	**EX1017 at 21:51-22:45** ("The programs for controlling the Sensor monitor 212 of the characteristic monitor 200' are also stored in the ROM 204… 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

POSITA Knowledge & Skills	Support in Prior Art
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.	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.") **EX1030 at 6:42-52** ("The glucose monitor might contain the necessary Software to calibrate glucose Sensor Signals, display a real-time blood glucose value, Show blood glucose trends, activate alarms and the like"); **10:56-11:21** (a variety of "calibration cancelation event" (*e.g.*, unstable sensor, sensor disconnect, out-of-range, or calibration error) in which glucose values are no longer considered valid); **10:39-49** (discussing unstable signal); **14:2-14** (discussing calibration error where the modified sensitivity ratio (MSPSR) is not within a valid range); **17:30-56** (discussing out-of-range limit for glucose concentration during calibration (*e.g.*, 200 mg/dl)); **EX1011 at 8** ("weak signal" and "lost sensor" discussed in FAQ and corresponding response to "What happens when the Minilink REAL-Time Transmitter and insulin pump move out of range?"); **10** ("weak signal" and "lost sensor" discussed in FAQ and corresponding response to "I wear a MiniMed Paradigm REAL-Time System and sometimes I get a WEAK SIGNAL or a LOST SENSOR message. What does this mean?"); **10** ("Cal error" discussed in FAQ and corresponding response to "Sometimes when I enter a meter reading, the system displays a CAL ERROR. What is a CAL ERROR and what should I do when I get one?"); **43** ("When your sensor and transmitter are connected, and

POSITA Knowledge & Skills	Support in Prior Art
	communication is lost this icon will re-appear."); **73** (discussion of "weak signal"); **75** (discussing of "cal error"); **EX1026 at [0268]** (discussing a disconnect threshold under which values may be ignored), **Fig. 32** ("a block diagram using the derivative of sensor resistance to determine when to recalibrate or replace the sensor in accordance with an embodiment of the present invention").
¶55: POSITAs would have accounted for missing data using technical concepts known at the time, including programming glucose monitoring systems to detect failures that result in data being unavailable for display (e.g., due to a calibration error or loss of communication), **preserving this data in memory, and regenerating it once the system recovered**.	**EX1012 at [0086]**("Another advantage is that glucose history information is stored on the transceiver 100. Thus, because the transceiver 100 can be networked to a plurality of devices, the information is available to any receiver or network node on demand. Furthermore, the transceiver 100 can continuously calculate glucose values even when a remote device is not in proximity to the user. Thus, when communication between the transceiver 100 and the remote device fails, the calibration algorithm can continue to calculate glucose data points. Preferably, when communication is re-established, the remote device can synchronize data with the transceiver 100 and receive glucose values calculated while the remote device was not communicating with the transceiver 100.") **EX1012 at [0013]** ("the processor stores the calculated sensor glucose values in the memory or transmits the calculated sensor glucose values to the at least one remote device through the transmitter"). **EX1011 at 8** (discussing storing 40 minutes of data in transmitter memory). **EX1017 at 22:15-45** ("In preferred embodiments, the sensor monitor 212 is used in conjunction with the micro-processor 216 to store, smooth the data and determine a corresponding analyte level from the signals received from the sensor interface 214."), **22:46-63** ("In addition, the

POSITA Knowledge & Skills	Support in Prior Art
	calibrated data using results from the characteristic meter 300 can be displayed to provide a user with updated trend and glucose level data.”). **EX1030 at 8:56-9:6** (“At a glucose monitor memory storage rate of once every 5 minutes… the memory storage rate may be varied as necessary to capture data with sufficient resolution to observe transients or other changes in the data...”), **11:1-9** (“If the glucose monitor 100 is turned off for a short enough period of time, generally up to 30 minutes, the memory storage values are considered Valid ISIG values as soon as the power is turned back on... Alternatively, the power may be off 30 minutes up to indefinitely and once the power is restored, the memory storage values are Valid ISIG values.”).
¶56: POSITAs 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	**EX1017 at 21:51-22:45** (“The programs for controlling the sensor monitor 212 of the characteristic monitor 200' are also stored in the ROM 204… 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

POSITA Knowledge & Skills	Support in Prior Art
calibrating glucose data.	excursions in glucose levels, faulty or interrupted data readings, or the like.") **EX1030 at 6:42-52** ("The glucose monitor might contain the necessary Software to calibrate glucose Sensor Signals, display a real-time blood glucose value, Show blood glucose trends, activate alarms and the like"); **10:56-11:21** (a variety of "calibration cancelation event" (*e.g.*, unstable sensor, sensor disconnect, out-of-range, or calibration error) in which glucose values are no longer considered valid); **10:39-49** (discussing unstable signal); **14:2-14** (discussing calibration error where the modified sensitivity ratio (MSPSR) is not within a valid range); **17:30-56** (discussing out-of-range limit for glucose concentration during calibration (*e.g.*, 200 mg/dl)). **Ex1026 at [0262]** (discussing filters that are "used to detect and minimize the effects of anomalous digital sensor values"); **[0268]**, (discussing a disconnect threshold under which values may be ignored), **[0321]** (discussing resistance threshold and the rate of change of sensor resistance as mechanism to determine if sensor needs to be recalibrated or replaced); **Fig. 32** ("a block diagram using the derivative of sensor resistance to determine when to recalibrate or replace the sensor in accordance with an embodiment of the present invention"). **EX1042 at 522** (discussing that when using a compile, "the programmer does not need to understand the architecture of the microprocessor being used" because "this task has been delegated to the software engineer who wrote the compiler").
¶56: POSITAs would have been skilled a programming a microprocessor to	**EX1017 at 21:51-22:45** ("The programs for controlling the sensor monitor 212 of the characteristic monitor 200' are also stored in the ROM 204… In further embodiments, the microprocessor 216 monitors the sensor signals from the sensor monitor 212 to determine when the

POSITA Knowledge & Skills	Support in Prior Art
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.	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.") **EX1030 at 8:56-9:6** ("At a glucose monitor memory storage rate of once every 5 minutes… the memory storage rate may be varied as necessary to capture data with sufficient resolution to observe transients or other changes in the data..."), **11:1-9** ("If the glucose monitor 100 is turned off for a short enough period of time, generally up to 30 minutes, the memory storage values are considered Valid ISIG values as soon as the power is turned back on... Alternatively, the power may be off 30 minutes up to indefinitely and once the power is restored, the memory storage values are Valid ISIG values.") **EX1015 at [0057], Fig. 7(b)** ("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.") **EX1042 at 522** (discussing that when using a compile, "the programmer does not need to understand the architecture of the microprocessor being used" because

POSITA Knowledge & Skills	Support in Prior Art
	"this task has been delegated to the software engineer who wrote the compiler").
¶59: 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.	**EX1017 at 22:15-45** ("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.") **EX1011 at 10** ("Cal error" discussed in FAQ and corresponding response to "Sometimes when I enter a meter reading, the system displays a CAL ERROR. What is a CAL ERROR and what should I do when I get one?"); **75** (discussing of "cal error"). **EX1030 at 10:56-11:21** (a variety of "calibration cancelation event" (*e.g.*, unstable sensor, sensor disconnect, out-of-range, or calibration error) in which glucose values are no longer considered valid); **10:39-49** (discussing unstable signal); **14:2-14** (discussing calibration error where the modified sensitivity ratio (MSPSR) is not within a valid range); **17:30-56**

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	(discussing out-of-range limit for glucose concentration during calibration (*e.g.*, 200 mg/dl)).
¶59: POSITAs would understand that failure to calculate analyte concentrations would cause missing analyte data and lead to the inability to display this missing data.	**EX1012 at [0042]** ("The telemetered characteristic sensor transceiver 100 generally includes the capability to transmit and receive data. For example, in a preferred embodiment, the sensor transmitter 100 will receive a calibration value (e.g. from a blood glucose meter, etc.), convert raw sensor signals into calibrated processed glucose values using algorithms stored in the sensor transceiver 100 and then transmit the calibrated glucose values to a third device which has a display to show the calibrated glucose values (e.g. a characteristic monitor 200)." **EX1011 at 37** ("The calibration point is used to calculate the real-time sensor glucose values that are displayed.") **EX1030 at 6:53-7:4** ("As shown in FIG. 2, the data processor 200, may include a display 214 that is used to display the calculated results of the raw glucose sensor data received via a download from the glucose monitor 100."), **11:28-33** ("To calibrate the glucose monitor 100, the calibration factor called a sensitivity ratio (SR) (blood glucose level/Valid ISIG value) is calculated for a particular glucose sensor 12. The SR is a calibration factor used to convert the Valid ISIG value (Nano-Amps) into a blood glucose level (mg/dl or mmol/l)."); **13:35-49** ("And given a glucose sensor reading of 15.0 Nano-Amps after calibration the calculated blood glucose level is: Blood Glucose Level = (15.0-3)*5.96 = 71.5 mg/dl... n alternative embodiments, the offset value is eliminated from the equation for calculating the blood glucose value as follows: Blood Glucose Level = Valid *ISIG*MSPSR*.") **EX1019 at [0071]** ("The raw current signal values generally range from 0 to 999, which represents sensor electrode current in the range between 0.0 to 99.9

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	nanoAmperes, and is converted to characteristic values, such as glucose values in the range of 40 to 400 mg/dl.”) **EX1023 at [0104]** (“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.”) **EX1026 at [0284]** (“The calibrator applies a calibration algorithm to convert the digital sensor values Dsig, which are typically in counts into blood glucose values.”), **[0285]** (“Then a digital sensor value Dsig is compared to the blood glucose measurement from the meter and a mathematical correction is applied to convert the digital sensor values Dsig to blood glucose values.”) **EX1027 at 648** (“Whatever the method used for monitoring glucose concentration in diabetic patients, the calibration of the system represents a crucial step. It consists first in the determination of the parameters describing the relationship between the sensor output and the concomitant blood glucose concentration, and secondly in the subsequent use of these parameters to transform in real time the sensor output into an estimation of blood glucose concentration… These parameters S and I_0 are subsequently used to transform at any time the sensor output $I(t)$ into an estimation of glucose concentration $G(t)$, as $G(t) = (I(t)-I_0)/S$.”) **EX1028 at 228** (“The *in vivo* sensitivity coefficient, determined in each individual experiment was used to calculate the apparent subcutaneous glucose level.”); **231** (“This issue is critical since this calibration will allow us to calculate, from the sensor output, an estimation of the prevailing subcutaneous glucose concentration.”) **EX1033 at 1208** (“Medtronic MiniMed’s Guardian RT was the first real-time commercially available CGM

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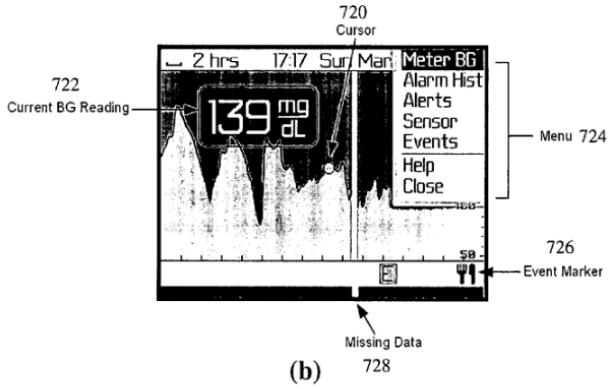
	device. The monitor calculates and displays glucose values every 5 minutes.”) **EX1046 at 113** (“Review of CGM Technology[:] CGM systems operate by measuring the glucose levels in interstitial fluid... The information stored in the receiver is then converted into estimated mean values of glucose standardized to capillary blood glucose levels measured during calibration.”)
¶60: 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.	**EX1015 at [0057], Fig. 7(b)** (“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.”)  **FIGURE 7** **EX1011 at 8** (discussing a “data gap” where missed data exceeded 40 minutes of transmitter memory); **73** (discussing a “weak signal” alarm next to an image displaying a data gap).
¶60: POSITAs would have found it obvious to display previously missing data by filling-in/re-	**EX1011 at 8** (“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

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populating this data is analytes graphs.	‘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. ... 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.”) **EX1012 at [0047]** (noting that the characteristic monitor displays received glucose readings); **[0079]** (discussing the periodic exchange of data between the glucose sensor transceiver and other receivers (i.e., a pump, monitor, computer, cellular phone, etc.) at synchronization); **[0086]** (discussing synchronizing data when communication is re-established). **EX1023 at [0102]** (“In additional alternative embodiments, the infusion pump 30 periodically sends a command signal to the BG monitoring system 20 via the relay device 10, commanding the BG monitoring system 20 to send sensor data to the infusion pump 30, so that the most recent sensor data is available to be shown on the display 100 of the infusion pump 30… In yet other alternative embodiments, the infusion pump 30 communicates with the BG monitoring

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	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.”)

37. Many of Dr. Wright’s critiques relating to the basic “skills and knowledge” of a POSITA address concepts that to me relate more to system design and are not clinical in nature, for example:

- “technical concepts known at the time, including programming glucose monitoring systems” (EX2013, ¶137);
- a POSITAs skill at “programming a microprocessor” (*id.*, ¶137);
- a POSITAs understanding “that failure to calculate analyte concentrations would cause missing analyte data and lead to the inability to display this missing data” (*id.*, ¶137);
- a POSITAs recognition that “failed communication would cause missing data” (*id.*, ¶¶139-142);
- and whether “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” (*id.*, ¶146).

C. A POSITA Would Know That Missing Data Cannot Be Displayed

38. Paragraphs 139-141 of Dr. Wright's report disagree with the statement in paragraph 58 of my Original Declaration 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." EX2013, ¶139 (citing EX1008, ¶58). If a system involves a transmitting device sending data to a receiving device, which then displays the data (as these and many other prior art systems do), then a failed communication of data would result in data not being available at the receiving device, which itself would result in the data not being available for display on the receiving device. Further, each of Patel-2009, Paradigm, and Shahmirian expressly discuss missed data, missed data gaps, synchronizing data after failed communication, and retransmitting additional sensor data that has not been received. *E.g.*, EX1011, 49; EX1012, [0086]; EX1015, [0057], Fig. 7(b); EX1023, [0103]. Paragraph 140 of Dr. Wright's declaration quotes a portion of the Petition, suggesting it is contrary to my opinion. However, that "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" (quoting Petition at 29-30), is not diametrically opposed; it is simply a recognition that Patel-2009 does not expressly disclose "graphs" that

convey missing data and then display that data when received. However, any POSITA would recognize that if a device does not have the data, it cannot display the data. The same is true of Shahmirian.

39. Paragraphs 142-145 of Dr. Wright's report appear to take issue with the statement in paragraph 59 of my Original Declaration that POSITAs would recognize that if the receiving device does not have data due to certain other conditions (*e.g.*, "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"), this missing analyte data could not be displayed. It appears that Dr. Wright's issue with my statements is that the documents do not expressly disclose displaying a data gap in these other situations. EX2013, ¶144. The point of my paragraph 59 is not that any reference expressly discloses displaying a gap for these other conditions. Rather, it is again that POSITAs would recognize that the receiving device would have no data to display and thus that "missing data could not be displayed." EX1008, ¶59. In fact, as noted in my Original Declaration, Causey discussed these specific conditions or analogous conditions as prompting or delaying calibration. EX1017, 22:15-45. Again, a device cannot display data it doesn't have.

D. Based On The Normal, Default Operation Of Paradigm REAL-Time, POSITAs Would Expect Re-Populated CGM Data To Be Displayed On The Insulin Pump's Screen

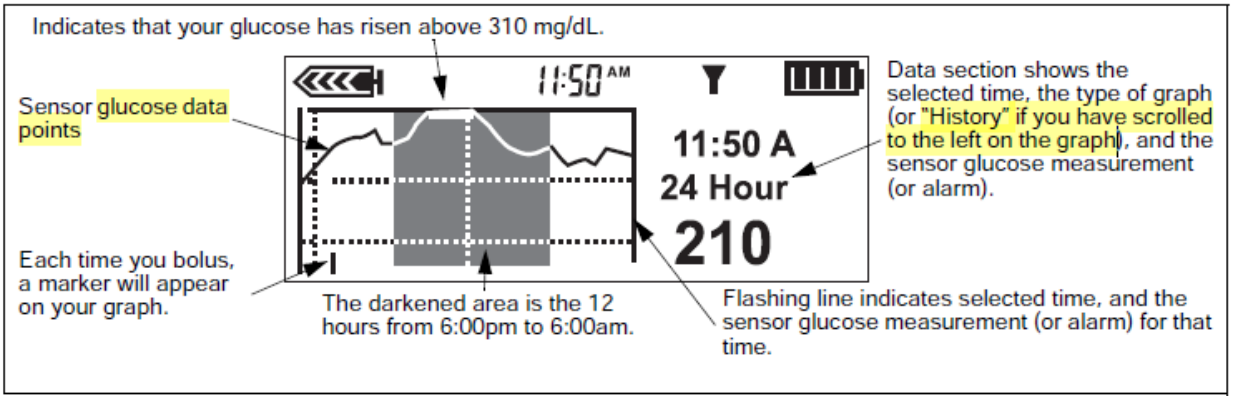
40. I have reviewed paragraphs 165-184 of Dr. Wright's declaration. As explained in the following paragraphs, nothing presented in Dr. Wright's declaration changes my opinions as presented in my Original Declaration. Specifically, I believe that Dr. Wright is reading Paradigm's instructions and FAQs incorrectly by omitting context, including ignoring the normal, default operation that a user would expect from Paradigm REAL-Time.

41. As noted in my Original Declaration, a purpose of incorporating real-time CGM into the Paradigm insulin pump is to display CGM data on the insulin pump's screen. EX1008, ¶¶80-81. As such, it is my opinion that POSITAs would interpret the Paradigm FAQs in light of the normal, default operation that the insulin pump would display *all* CGM data received from the MiniLink Transmitter that fell within the 24 hour window.

42. A POSITA looking at the Paradigm documentation would expect repopulated CGM data to be displayed. For example, Paradigm describes displaying graphs of "the most recent 24 hours of data" and "the most recent three hours of data" on the pump receiver unit. These list no exclusions of repopulated data. EX1011, 64.

24 hour graph

To view the current glucose and a graph of the most recent 24 hours of data, press **ESC** twice from the HOME screen:



EX1011, 64 (excerpted, highlighting added). A 24-hour trend graph can also be seen in this photo from the Paradigm User Guide:

EX1011, 30.

43. Given that the trend graphs display "the most recent 24 hours of data" and "most recent three hours of data" (EX1011, 64), in context, the FAQs teach that up to the last 40 minutes of data is repopulated in the trend graphs once the devices are back in range. EX1011, 8. The user guide simply explains that the most recent 3 or 24 hours "of data" is displayed. EX1011, 64. Thus, a POSITA (or any reader)

would expect that all available data—including repopulated data—would be displayed in the trend graphs.

44. This aligns with Paradigm's repeated emphasis—including in the FAQs—on providing continuous real-time data to users. For example, page 9 of the Paradigm FAQs provides:

> An important benefit of using a CGM system is REAL-Time readings and trend graphs. They allow you to be proactive in your diabetes treatment so you can avoid severe highs and lows. You can see if your glucose is trending up or trending down and take action much earlier. With this information, you will be able to confidently make changes to your daily glucose management to improve your heath.

EX1011, 9 (excerpt). Similarly, Medtronic promotes Paradigm REAL-Time to users to "free [themselves] from multiple daily injections and: Know [their] glucose levels around the clock[;] Discover the effects of [their] diet, exercise, and medication on [their] glucose levels[; and] Help prevent lows and highs." Ex1011, 18. For example, Medtronic provides that the "Mini Med Paradigm 522 or 722 Insulin Pump displays on-screen REAL-Time data to help you understand more about your glucose control," e.g., it "displays 3-hour and 24-hour glucose trend graphs," as a promoted feature of the Paradigm REAL-Time System. EX1011, 15. Further, I understand that Medtronic marketed Paradigm REAL-Time to users as allowing them to see the big picture of their glucose levels "*Right Now* – anytime, anywhere." EX1052, 27. Additionally, as confirmed by Dr. Ahmann, displaying as much CGM data as possible to users is associated with clinical benefits. *E.g.*, EX1055, ¶¶47-61.

45. Dr. Wright appears to read the Paradigm documentation out of context with this default behavior and directs his criticism at the absence of an express description of "filling in missing data on the insulin pump's screen" with the repopulated data. EX2013, ¶168. In my opinion, responding to the frequently asked user question of "If I move outside of the six foot (two meters) transmission range - will I lose my data?" by telling users that "[t]he transmitter holds 40 minutes worth of memory, so … continuous glucose monitoring (CGM) data can be re-populated in the insulin pump" would cause users to expect that re-populated data would be displayed on the insulin pump's screen. EX1011, 8. Similarly, responding to the frequently asked user question "Can I swim, shower, or bathe with the MiniLink Transmitter?" by telling users that "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," and immediately thereafter, "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" would lead readers to expect that the 40 minutes of re-populated CGM data would be displayed on the insulin pump's screen. EX1011, 8. The FAQs do describe when data will be missing (*e.g.*, EX1011, 8 (out of range for 40 minutes); 12-13 (while disconnected on airplane)). So, if there were another instance in which a gap would

persist (e.g., that the pump does not display repopulated data), one would expect the FAQ to also explain that anomaly; but no such FAQ exists.

46. Paragraph 169 of Dr. Wright's declaration makes a similar argument to paragraph 168, but with respect to the Paradigm Sensor Features User Guide. I disagree with both paragraphs because the instructions tell users 1) that CGM data is displayed by the insulin pump and 2) that CGM data will be re-populated in the insulin pump; as such, users will expect that the re-populated CGM data will be displayed by the insulin pump. The lack of an express statement that re-populated data will "fill[] in missing data on the insulin pump's screen" (EX2013, ¶168) in either the Paradigm FAQs or user guide does not prove the negative inference that the insulin pump stops displaying data because it is re-populated data. Rather, because display of CGM data received from the MiniLink transmitter is a normal, default behavior expected by users, I interpret the Paradigm FAQs and Sensor Features User Guide as providing for this expected behavior.

47. Additionally, for the reasons discussed below, I also disagree with Dr. Wright's conclusions that a POSITA would understand that Paradigm REAL-Time only describes displaying re-populated data in reports generated by CareLink. Rather, the FAQs suggest that "historical reports" encompass the glucose "History" reported to users via trend graphs and a POSITA would read "historical reports" as including the "History" of glucose data points displayed in these real-time trend

graphs. Nothing in the FAQs uniquely associates "historical reports" with CareLink. In particular, the second FAQ explicitly teaches repopulating "(CGM) data … displayed on the insulin pump's screen." EX1011, 8.

48. Dr. Wright points to a third FAQ that also refers to "historical reports" and appears under a section entitled "Travel and Environmental Exposure." EX2013, ¶173 (citing EX1011, 12-13). As distinct from the first two FAQs, this FAQ does not relate to repopulated CGM data, but instead relates to situations where the transmitter is disconnected from the sensor and thus has no data to later repopulate. This third FAQ responds to "Can I use the MiniMed Paradigm REAL-Time System on an airplane?" It warns users that the transmitter must be disconnected from the sensor during an airplane flight (pursuant to FCC requirements) and also notes that "[w]hen downloading data and reviewing historical reports, you will notice 'data gap' where information is missing during this period of time." EX1011, 12-13. Nothing in this FAQ restricts "historical reports" to only data downloaded and displayed using CareLink. In fact, it does not even mention CareLink or fall under a section for CareLink.

49. Dr. Wright appears to suggest that this "review" of "historical reports" must be done on later-accessed, downloaded data through the CareLink software (*e.g.*, EX2013, ¶¶172-175), but nothing in the FAQs suggests that all data stored by the pump (original and repopulated) is not *also* displayed on the trend graphs. None

of these FAQs mention CareLink. Nor do any of these three FAQs relate to CareLink. Rather, the two on page 8 appear under an FAQ section related to the "MiniLink REAL-Time Transmitter," and the third FAQ spanning pages 12-13 appears in an FAQ section related to "travel and environmental exposure." Finally, the FAQ section that does relate to CareLink never mentions "historical reports." EX1011, 11-12.

50. Finally, another Paradigm document discusses trend graphs and CareLink in a way that suggests the trend graphs display the same data as the CareLink software, as any reasonable reader would expect. EX1052, 17. As shown in the following screen shot excerpt, a section titled "REAL-Time Trend Graphs" includes bullet points explaining what data the trend graphs show on the display of the pump, and a final bullet point explaining how CareLink helps "easily manage *this data* online" (emphasis added).

REAL-Time Trend Graphs

- Viewable on-screen
- 3-hour and 24-hour glucose trending
- Show patients the effect of meals, exercise, insulin and medication on their glycemic control
- CareLink Personal software helps you and your patients to easily manage this data online so that together you can better manage their diabetes

EX1052, 17. This suggests that the data shown in the trend graphs over time is the same data managed using the CareLink software.

E. Paradigm REAL-Time's FDA Approval Included Management And Adjunctive Treatment Of Type 1 Diabetes

51. Paragraphs 80-83 and 148 of Dr. Wright's declaration relate to FDA approval of CGM systems for adjunctive and non-adjunctive use. Ex2013, ¶¶80-83, 148. However, Dr. Wright admitted that he did not "know when the Paradigm REAL-Time system was originally approved by the FDA," or whether the FDA issued any supplemental approvals. EX1053, 85:14-24. Nor does it appear that Dr. Wright considered the FDA's approved indications for Paradigm REAL-Time and other continuous glucose monitors as discussed in paragraph 52 below.

52. I have reviewed the FDA's original approval of Paradigm REAL-Time as a modification to the Medtronic Guardian RT Continuous Glucose Monitoring System ("Guardian RT") on April 7, 2006, by supplemental pre-market approval ("PMA") number S013 to the original Medtronic CGMS PMA number P980022 (*i.e.*, supplemental approval no. P980022/S013). EX1041. Based on this supplemental PMA, I referred to the FDA's corresponding Guardian RT approval (P980022/S011) for Paradigm REAL-Time's originally approved indications. EX1041; EX1058; EX1059. The FDA-approved indications include:

- "continuous or periodic monitoring of glucose levels in the fluid under the skin in adults (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management;"
- "provid[ing] an indication of when a finger stick may be required;" including

- "real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose episodes."

EX1058, 1; EX1059, 1; EX1041. I note that these indications are consistent with Paradigm REAL-Time's discussion of the "Differences Between Blood Glucose Meter and Continuous Glucose Monitoring Readings," including that "[t]he System helps you discover when is the best time to take a fingerstick" and that "REAL-Time readings and trend graphs … allow [patients] to be proactive in [their] diabetes treatment so [they] can avoid severe highs and lows." EX1011, 9.

I, Brian D. Gross, do hereby declare and state, 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: September 6, 2024

Signature