

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.	)	
Petitioner,	)	
	)	Case No.:
vs.	)	IPR 2023-01251
	)	
ABBOTT DIABETES CARE INC.,	)	
Patent owner.	)	
_____	)	

DEPOSITION OF ANDREW AHMANN, MD
Portland, Oregon
Friday, October 11, 2024; 7:05 a.m.

TAKEN IN BEHALF OF THE PATENT OWNER

REPORTED BY:

Victoria A. Guerrero, CSR, RDR, RMR, CRR

Job No. 20871

Pages 1 through 139

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4 DEXCOM, INC.)
5 Petitioner,)
6 vs.) Case No.:
7 ABBOTT DIABETES CARE INC.,) IPR 2023-01251
8 Patent owner.)
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16 BE IT REMEMBERED that, pursuant to Rules of the
17 United States Patent and Trademark Office, the
18 deposition of ANDREW AHMANN, MD was taken before
19 Victoria A. Guerrero, Oregon Certified Shorthand
20 Reporter, Registered Diplomate Reporter, Registered
21 Merit Reporter, and Certified Realtime Reporter, on
22 Friday, October 11, 2024, commencing at the hour of
23 7:05 a.m., in the conference room of the law firm of
24 Klarquist Sparkman LLP, in the City of Portland,
25 County of Multnomah, State of Oregon.

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ANDREW AHMANN, MD

DexCom v Abbott

Friday, October 11, 2024

Victoria A. Guerrero, CSR, RPR, RMR, CRR

MARKED	DESCRIPTION	PAGE	LINE
Exhibit 2035	Position Statement, Standards of Medical Care in Diabetes-2007	68	12
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Exhibit 2037	Position Statement, Standards of Medical Care in Diabetes from January 2005	78	9
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1 Friday, October 11, 2024; 7:05 a.m.

2 Portland, Oregon

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4 Whereupon, ANDREW AHMANN, MD, having first
5 been sworn by the Oregon Certified
6 Shorthand Reporter, testified under oath as
7 follows:

8
9 EXAMINATION

10
11 BY MR. HANSEN:

12 Q Good morning, Dr. Ahmann. Have you ever
13 been deposed previously?

14 A Yes.

15 Q About how many times?

16 A I would say maybe five or six times.

17 Q And in what capacity have you been
18 previously deposed?

19 A Always as an expert witness, I guess.

20 Q Have you testified previously as an expert
21 in a patent case?

22 A I testified in a previous case in 2018 that
23 I'm to understand had something to do with a patent,
24 but that's not the part that -- it had to do with
25 sort of a liability so it related to a specific

1 patient and so forth. So I viewed it as a liability
2 case, but I'm not sure how it was defined in other
3 terms.

4 Q So before your involvement in this present
5 matter, from your point of view your prior work as
6 an expert witness involved liability cases, medical
7 malpractice and the like?

8 A Yes, most of them.

9 Q Were there any that did not?

10 A Well, just that case, I suppose, was a
11 matter of whether the problem that occurred in that
12 patient should have related to a patent -- something
13 related to a patent. I, at the time, wasn't even
14 aware of that. It was more related to I think a
15 fracture of a sensor that was actually something
16 that we knew about, but didn't injure patients.

17 Q What did you do to prepare for your
18 deposition today?

19 A Overall, you're saying?

20 Q Yes.

21 A Overall, over the last several months I
22 suppose I reviewed literature, I certainly reviewed
23 the documents that are included in my declaration,
24 had multiple discussions with the Klarquist staff
25 involved to develop the declaration and bring it to

1 its final form, which was over a month ago now.

2 And certainly reviewed the documents, the
3 various declarations multiple times.

4 Q When you say you reviewed various
5 declarations multiple times, what declarations are
6 you referring to?

7 MR. MASON: Objection. Form.

8 THE WITNESS: My declaration, Brian Gross'
9 declaration, and Dr. Wright's declaration, what
10 apparently was his first declaration or his
11 initial.

12 BY MR. HANSEN:

13 Q You mentioned Brian Gross. Have you ever
14 met Brian Gross?

15 A No, not to my knowledge.

16 Q Have you ever had any conversations with
17 him?

18 A No.

19 Q Did you ever discuss with him any of his
20 testimony in his declarations in this matter?

21 A No.

22 Q Now, are you aware that Mr. Gross has two
23 declarations in this matter?

24 A I guess I might not understand all the
25 terminology, but I'm aware of only one declaration.

1 I'm aware that he had -- two times where his
2 testimony was reviewed.

3 Q You said that there were two times when his
4 testimony was reviewed. Can you explain a little
5 more what your understanding is about that?

6 A Maybe I'm wrong. I thought he was deposed
7 twice, but I might be wrong about that.

8 Q Well, he has been deposed twice, but the
9 second time was yesterday. Have you reviewed or
10 discussed his testimony from yesterday?

11 A No.

12 Q But you did review his testimony from his
13 earlier deposition?

14 A Yes.

15 Q You also mentioned Dr. Wright. Have you
16 ever met Dr. Wright?

17 A I don't recall meeting him, but I may have
18 because I -- looking at his CV, he ran in some of
19 the same circles in terms of working with the
20 American Diabetes Association and other activities.
21 But I don't know him personally, no.

22 Q What is the American Diabetes Association?

23 A The American Diabetes Association is a
24 professional -- well, it's a society that's actually
25 quite unique in that it's a combination of

1 professionals and people with diabetes or lay people
2 who are interested and affected by diabetes. And
3 it's been around for 70 years, I believe. But it
4 includes a professional component that he was
5 involved in, as was I.

6 Q And what was the nature of your involvement
7 with the American Diabetes Association?

8 A Going back to the regional involvement, I
9 was president of the regional board for the American
10 Diabetes Association for probably 15 years. I was
11 involved in multiple national committees including
12 the Professional Standards Committee,
13 Professional -- yeah -- Standards Committee. And
14 several other committees.

15 And, of course, presented scientific
16 presentations at the American Diabetes Association
17 scientific sessions which are held each June, a
18 number of activities. I was just a strong supporter
19 of advocacy with the American Diabetes Association.

20 Q Did I understand that at the national level
21 you served on a committee dealing with standards of
22 care?

23 A Uh-huh.

24 Q What is meant by the terminology "standards
25 of care"?

1 A The standards of care for diabetes, various
2 people -- there's various -- several organizations I
3 would say that provide a list of standards of care
4 from their view, though I believe the American
5 Diabetes Association ones are the most respected and
6 most often cited.

7 It's a committee of about, I would say, 12
8 to 15 people. They get together a couple times a
9 year. They are each assigned components of going
10 through the most recent literature and updating --
11 the standards are updated every year in January and
12 supplemented in the Diabetes Care Journal which is
13 the primary care journal. It's based on evidence.

14 So every standard -- every recommendation
15 that comes from a standard is based on a level of
16 scientific evidence. So it can be everything from
17 an A, which means there's absolute proof, no
18 question about it; to E, which is expert opinion.

19 Q And over what period of time did you serve
20 on the committee that was responsible for generating
21 such standards of care?

22 A That's a two-year assignment.

23 Q You did serve on the committee?

24 A Yes.

25 Q And you served on it for two years?

1 A Right.

2 Q And when was that?

3 A Okay. I'll have to refer to my
4 documentation here. It's interesting how difficult
5 it is to find things. Interestingly, I'm having a
6 difficult time finding it. I'm sorry. I can't
7 identify it now, but I suspect it was in about the
8 year 2010 or 2008 to 2010.

9 Q Okay. Now, you said that the standards of
10 care, there was a committee. And how large was the
11 committee --

12 A I think it was about 12 to 15 members.

13 Q And you said that the American Diabetes
14 Association is composed of medical professionals and
15 also people with diabetes.

16 Is that also true of the makeup of this
17 committee for standards of care?

18 A Right. The committee would be made up of
19 sort of a spectrum of people that would include some
20 diabetes educators, so those could be dieticians or
21 nurses, physicians or other -- other advanced
22 practice providers. That would be like PAs or nurse
23 practitioners. But would always have also assigned
24 to it a -- some lay people with diabetes as
25 representatives.

1 Q You said that the standards of care were
2 based on evidence. What do you mean by that?

3 MR. MASON: Objection to form. Scope.

4 THE WITNESS: In the context of medical
5 practice, evidence refers to scientific
6 literature, scientific studies that are done,
7 they're graded on the quality of the study.
8 Some are prospective studies which get the
9 highest rating, some are retrospective studies
10 but still valid. And that's where the quality
11 is, there's sort of a rating system for that
12 that's been in place for quite some time that
13 is adhered to and that's where they get the
14 letters A, B, C, and then E for expert.

15 BY MR. HANSEN:

16 Q And who is it that assigns or grades the
17 different publications that are considered as
18 evidence to support the ADA standards of care?

19 MR. MASON: Objection. Form.

20 THE WITNESS: It's an iterative process
21 over the years. So what happens each year when
22 they get together, and as I mentioned each
23 member of that group will be assigned to a
24 section, that individual will then go back and
25 look at the previous ones and see if anything

1 has changed, but will also do a literature
2 review of all the things that have been
3 published over the last year or two and then
4 define -- bring that to the committee. Though,
5 the evidence part is determined by the whole
6 committee in the end as they review each of the
7 changes they make in the standards of care.

8 BY MR. HANSEN:

9 Q You said that there are other organizations
10 other than the American Diabetes Association who
11 also have developed standards of care?

12 A Yeah. They have -- we'll see slightly
13 different descriptions of them, but the Endocrine
14 Society, the American Association of Clinical
15 Endocrinologists, the American College of
16 Physicians, which is an internal medicine group,
17 those are examples of some -- I think even the
18 American Academy of Family Practice may make some as
19 well.

20 Q I believe you said that in your opinion the
21 most authoritative, the most reliable standards of
22 care are those that are promulgated by the American
23 Diabetes Association?

24 MR. MASON: Objection. Form.

25 THE WITNESS: I would say that statement

1 is opinion, but I would say it's also based on
2 the fact that's the most often cited and most
3 often implemented into institutional practices.

4 BY MR. HANSEN:

5 Q Now, you said that -- from looking at
6 Dr. Wright's CV that you saw that the two of you
7 might have, I think you said, run in the same
8 circles to a certain extent.

9 Can you explain what you meant by that?

10 MR. MASON: Objection. Form.

11 THE WITNESS: I can't recall if I have his
12 CV in here, but I think at some point I saw his
13 CV or maybe looked it up, to be honest with
14 you. But anyway, he was -- there's a -- there
15 are a group of interest groups in the American
16 Diabetes Association. And I believe in 2018 to
17 2020 he was the head of the interest groups for
18 primary care.

19 There's been an effort by the
20 American Diabetes Association which the
21 professional arm has been people, for the most
22 part over history, that were specialists in
23 diabetes care, endocrinologists for the most
24 part.

25 And they're trying to get more

1 primary care engaged in the process. And so
2 they started developing, they have various
3 interest groups, but that one was developed and
4 he was the head of that interest group in, I
5 think, 2018 to 2020.

6 They meet at the scientific sessions.
7 Scientific sessions are held in June. They're
8 the largest diabetes meetings in the world. So
9 I wouldn't run into him necessarily, but I know
10 that he was engaged with the American Diabetes
11 Association.

12 BY MR. HANSEN:

13 Q To your knowledge, was Dr. Wright ever
14 involved on the committee for developing standards
15 of care?

16 MR. MASON: Objection. Form.

17 THE WITNESS: I don't recall that from
18 looking for his CV, so I don't know for sure.

19 BY MR. HANSEN:

20 Q You're familiar with the acronym CGM?

21 A Yes.

22 Q And what is your understanding of what that
23 acronym stands for?

24 A Well, it's continuous glucose monitoring.
25 Or that's the description of the practice, I

1 suppose. Or it could be considered a continuous
2 glucose monitor, which is the device.

3 Q When did you first become aware of CGM
4 devices or CGM practice?

5 A Exact time, obviously I couldn't state, but
6 I think about 2000. That's when the CGMS, the first
7 Medtronic sensor that was not a realtime, but what
8 we call a blinded sensor. And so we started to use
9 it in patients almost immediately.

10 Q And what was the name of that product?

11 A CGMS.

12 Q And you said that was a Medtronic product?

13 A Correct.

14 Q And you said it was blinded. And what do
15 you mean by "blinded"?

16 A If you look to what happened, I think in
17 about 2004 -- I may be wrong about the exact year.
18 It would be 2004, 2005 -- Medtronic developed what
19 they call realtime sensor. The difference being
20 that the product that was the CGMS product was
21 something the patient couldn't see any data from.
22 They'd have to bring it in, download it, review it
23 with their provider to see any information. And so
24 it wasn't a patient-oriented product.

25 Q Just to make sure I understand correctly.

1 With a blinded device like the CGMS, the data was
2 not available directly to the user; is that correct?

3 A Correct.

4 Q The device would store data that could be
5 later downloaded with a medical professional such as
6 a doctor?

7 A Yes.

8 MR. MASON: Objection. Form.

9 BY MR. HANSEN:

10 Q And that data could then be used to
11 generate various types of reports?

12 MR. MASON: Objection. Form.

13 THE WITNESS: Correct. I mean, you could
14 see the data. And I can't recall because of
15 that long ago how long their reports were or
16 what their reports looked like. They didn't
17 really look like the MiniMed -- or the CareLink
18 reports that later came, but there was some
19 sort of a printout.

20 BY MR. HANSEN:

21 Q And the practice was the user would bring
22 the device to an appointment with a doctor and the
23 doctor and the user would review the data together?

24 MR. MASON: Objection. Form. Scope.

25 THE WITNESS: I would suspect that there's

1 two different ways that you do it. For the
2 most part, I think that's correct. You have an
3 appointment and you review it with the patient.
4 On other occasions you write a report about
5 what it said and potentially convey that to the
6 patient.

7 BY MR. HANSEN:

8 Q Convey the report to the patient?

9 A Right.

10 Q So you could communicate with the patient
11 either directly in a person-to-person visit or via
12 written report to the patient?

13 MR. MASON: Objection. Form. Scope.

14 THE WITNESS: Yes, but -- and that might
15 be conveyed -- most often it's going to be
16 conveyed to the patient in a direct manner.
17 But that might be done by a diabetes educator
18 rather than the physician who read it.

19 BY MR. HANSEN:

20 Q And I think you said that Medtronic later
21 introduced a device that had what I think you called
22 a realtime feature?

23 A Right. They changed the name of it, then
24 called it the Guardian realtime? I'm sorry.
25 Guardian RT, but the RT stood for realtime. And

1 then subsequently implemented that or added that to
2 the Paradigm pump system. So that was called the
3 Paradigm REAL-Time system.

4 Q Are you familiar with the Medtronic product
5 called CGM Gold?

6 MR. MASON: Objection. Form. Scope.

7 THE WITNESS: I recall the terminology,
8 but I don't remember the distinctions. I think
9 that was one of the early forms and probably
10 was related to the CGMS, but I can't tell you
11 for sure.

12 BY MR. HANSEN:

13 Q And when do you believe the Medtronic
14 devices with realtime capability were first
15 introduced?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: I believe they were approved
18 by the FDA -- well, trying to think if I have
19 that in my binder here. I probably don't. I
20 do have that date -- the evidence that in 2006
21 is when they had to get the -- that's called
22 the Paradigm REAL-Time -- Paradigm REAL-Time
23 system was in 2006.

24 But that was adding in the Guardian
25 to the pump system. I believe the pump was --

1 the original Guardian RT was approved in 2004,
2 2005, but I don't think I have the
3 documentation exactly here.

4 BY MR. HANSEN:

5 Q And what document were you just referring
6 to, Dr. Ahmann?

7 A This was the document 1040 -- the 1041
8 which was a comment on US Food and Drug
9 Administration drug evaluation research about
10 premarket approval for the PMI -- or PMA.

11 And then subsequently, 1044 just refers to
12 the fact that it was -- Medtronic got FDA approval
13 for the first insulin pump with realtime continuous
14 monitoring on April 13, 2006.

15 Q So you're reading from what appears to be a
16 table; is that correct?

17 A This is a description of the exhibit. But
18 I can go into the exhibit which I feel very
19 confident gives the same information.

20 Q Okay. So we just need to make sure that
21 the record is clear for anyone who might review it
22 in the future.

23 What exhibit are you referring to?

24 A Exhibit 1041. And it is the premarket
25 approval, the PMA, from the FDA. Paradigm REAL-Time

1 system; generic name, sensor; glucose invasive;
2 Medtronic MiniMed. And the PMA number is P980022.
3 Was received 10/4/2005. Decision date was actually
4 4/7/2006. But this is on the PMA.

5 And the 1044 is just a news release that
6 sort of was used to indicate this is when Medtronic
7 announced that they have final approval April 13,
8 2006, out of Minneapolis, which is where the
9 Medtronic home office is.

10 FDA approved the MiniMed Paradigm REAL-Time
11 insulin pump and continuous glucose monitoring
12 system, a progressive new therapy available for
13 patients who use insulin to treat diabetes.

14 Q Again, I need to make sure the record is
15 clear. When we started talking about these
16 exhibits, you were looking at a table?

17 MR. MASON: Objection. Form.

18 THE WITNESS: Correct. I was looking at
19 the list of exhibits that I have included in
20 the review over the recent months. And the
21 table has a description of the title of each
22 exhibit. And I was using that because I
23 thought it was reliable data, which does
24 actually correlate with the actual exhibits as
25 I reviewed them after that.

1 BY MR. HANSEN:

2 Q Could I please see that table that you're
3 referring to?

4 A Uh-huh. I think the only documents that
5 aren't in the binder are my CV and my actual
6 declaration.

7 Q Thank you. Do you know if Medtronic's CGM
8 Gold was blinded?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: I don't recall. I'm not
11 sure that I used Gold very much at all.

12 BY MR. HANSEN:

13 Q Did you use the CGMS?

14 A Correct.

15 MR. MASON: Objection. Form. Scope.

16 THE WITNESS: So it may have just been a
17 continuation of that and I didn't pay attention
18 to the terminology.

19 BY MR. HANSEN:

20 Q How did you use the CGMS?

21 A CGMS is something that we would have had
22 our -- one of our diabetes education, make an
23 appointment with our patient to see the diabetes
24 educator. The diabetes educator would apply or
25 insert the catheter for the sensor and the carrier.

1 You carried a device with you at the time, recorder.

2 And then bring that back in after the
3 number of days, which I think at that time was --
4 I'm pretty sure it was three days, but it may have
5 been longer for that particular device because it
6 was different than the eventual realtime devices.
7 But I think it was for three days. And then it
8 would be downloaded and then sent to us to review.

9 Q And when you say it was downloaded, you're
10 referring to the data that had been collected by the
11 device?

12 A Correct.

13 MR. MASON: Objection. Form. Scope.

14 BY MR. HANSEN:

15 Q And who would download the data?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: I'm sure it was different in
18 different practices. For us it was the
19 diabetes educator who had placed it on the
20 patient in the first place.

21 BY MR. HANSEN:

22 Q Were these blinded CGMS devices useful?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: I think they were definitely
25 useful. They didn't give a lot of information

1 because you were limited a number of days and
2 what we probably would have done at that time
3 was give them a diary that they would keep
4 track of what happened during those days in
5 terms of their activities so we could give them
6 some instruction.

7 But because of the short duration and
8 it wasn't repetitive, you didn't do it
9 repetitively, it was limited compared to what
10 was available later.

11 BY MR. HANSEN:

12 Q So it would have been more useful if it had
13 a longer duration?

14 A Longer duration would be more useful. I
15 guess when you talk about useful it's depending
16 also, too, whether you're talking about use to the
17 provider or use to the patient.

18 Because the patient -- the population of
19 patients with Type 1 diabetes which were the ones
20 that were using these products up until they were
21 approved probably for Type 2 in 2015 or so, the
22 population of patients with Type 1 diabetes would
23 get a lot of information on what was happening
24 realtime. So realtime was dramatically better than
25 the original blinded studies.

1 Q Now, I think you said that with the CGM
2 device there were two components that were worn or
3 used by the patient?

4 A Again, that's 25 years ago so I can't
5 recall, but I believe that you had a little device
6 that the patient had to carry on their belt or
7 something with a direct line going under the skin.
8 The other terminology that eventually developed was
9 professional CGM, meaning it was intended only for
10 professional use because the patient couldn't see it
11 at the time of the actual number at the time of the
12 actual recordings.

13 So with the professional model, nowadays
14 you don't have to have that extra component. They
15 can store it in the actual sensor just as you do in
16 the realtime -- for the way that it would be, for
17 instance, in a pump system.

18 Q Have you ever been involved in designing,
19 for example, the electronic components of a CGM
20 device?

21 MR. MASON: Objection. Form.

22 THE WITNESS: Involved in developing? No,
23 I would say not.

24 BY MR. HANSEN:

25 Q Have you ever written software for a CGM

1 device?

2 A No.

3 Q Are you familiar with the concept of
4 computational constraints as it applies to CGM
5 devices?

6 A I don't think to a degree that I feel
7 confident I could render a valid description of
8 that, no. I mean, I've heard the terminology, I
9 know the understanding of what's going on in the
10 background, but I don't actually understand that or
11 would propose to find out typical deviations that
12 would occur related to that.

13 Q Are you familiar with the concept of memory
14 limits as applied to CGM devices and products?

15 MR. MASON: Objection. Form. Scope.

16 THE WITNESS: Yes.

17 BY MR. HANSEN:

18 Q Do you consider yourself an expert in the
19 matter of memory limits as they're applied to CGM
20 devices and products?

21 MR. MASON: Objection. Form.

22 THE WITNESS: No. I don't know that I
23 would even imagine what an expert would be,
24 whether it's a technical aspect of how long you
25 make that limit or something else. But no, I

1 wouldn't say I was an expert in that.

2 BY MR. HANSEN:

3 Q What is your understanding of memory limits
4 as applied to CGM devices?

5 A I think that with any device that is
6 basically a computer, that you have a limit to the
7 memory. And as you get to things like CGM, it's
8 going to be depending on the sides and the memory
9 that you can build into it and the battery, what the
10 battery can support and everything else.

11 So I know that, for instance, in the case
12 of the Guardian RT or the Paradigm REAL-Time system,
13 that the memory limit was 40 minutes. And that's 40
14 minutes for the transmitter because the
15 transmitter's the stuff that can hold information.
16 In modern-day ones, the memory limit is much bigger.

17 I know they have a product, for instance,
18 the Libre product has a memory limit of eight hours.
19 So each device has different memory limits.

20 Q So your understanding of memory limits is
21 that there are limits on the memory of -- on the
22 amount of data that can be stored by the device?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: I guess that would be my
25 general understanding, is that memory limits

1 for that purpose. I'm sure there's other
2 components of memory, but the one that's most
3 relevant to me as a clinician is that one.

4 BY MR. HANSEN:

5 Q You said that there would be other
6 components of memory. What do you mean by that?

7 A Well, I just don't know about what is -- I
8 mean, there's going to be memory in the pump. It
9 might be separate from what's happening in the
10 transmitter, how often you have to download to get
11 all of the information. I don't even recall in that
12 case.

13 Because as time -- I'm more familiar with
14 the modern products and a lot of those are
15 automatically sent up to the cloud or they have
16 memories for at least a month or longer. So that's
17 a separate memory. And I don't know what other
18 memory might be in a pump that you can interrogate.

19 Q Let me see if I understand correctly. So
20 it's your understanding that for the Paradigm
21 products, for example, that the memory for what is
22 displayed as realtime data to the user is 40 minutes
23 worth of data; is that correct?

24 MR. MASON: Objection. Form. Scope.

25 THE WITNESS: For the realtime product as

1 a continuous glucose monitor in the transmitter
2 which seems to be the limiting factor, it was
3 40 minutes.

4 BY MR. HANSEN:

5 Q Now, are you aware that with the Guardian
6 and Paradigm products, that using CareLink or using
7 software in the doctor's office, that you can
8 download up to 90 days' worth of data?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: With all the products you
11 can get 90 days now and that relates to the
12 fact that it all goes into the cloud. And when
13 you go into -- as we go directly into the
14 portals and pull the data, we can set it for 1
15 day, 3 days, 7 days, 14 days, 30 days, 90 days.
16 So that is all stored there nowadays.

17 Back then, I can't recall for certain
18 whether we could go out to 90 days, but I know
19 we could go to at least 30 days.

20 BY MR. HANSEN:

21 Q When you say "back then," what do you mean?

22 A I'm sorry. I was referring to the fact
23 that a lot of my involvement in this case relates to
24 patent issues that were related to prior to 2009 or
25 2010. And so back in that time period the CareLink

1 was a very good product, but was not -- but is not
2 quite the same in terms of that capacity, for
3 instance, that it is now, when everything goes up
4 into the cloud. It didn't do that back then.

5 Q So using CareLink, how much data was
6 available with the Paradigm product in 2009?

7 MR. MASON: Objection. Form. Scope.

8 THE WITNESS: I wouldn't say for
9 certainty. I'm sure it was at least 30 days.
10 It may have been 90 days, but I don't recall.

11 BY MR. HANSEN:

12 Q And was all of that same data available for
13 display to the user --

14 MR. MASON: Objection. Form.

15 BY MR. HANSEN:

16 Q -- in realtime?

17 MR. MASON: Scope.

18 THE WITNESS: In realtime? Well, at least
19 the sensor would show them on their receiver --
20 I'm sorry. What the CGM would show them on
21 their receiver is information for 3 or for 24
22 hours. It could go out to 24 hours. So at
23 least at any given time they could only look at
24 24 hours.

25 Now, they had the option of going in,

1 at least it wasn't very long after CareLink
2 became available that patients were -- had the
3 option to go in and upload their product. They
4 could do that. But that isn't realtime, of
5 course. That realtime, all they could see was
6 3 hours or 24 hours or what's going on right
7 now.

8 BY MR. HANSEN:

9 Q So the amount of data that was available
10 via CareLink was different than the amount of data
11 that was available for display to the user?

12 MR. MASON: Objection. Form. Scope.

13 THE WITNESS: If I were to use amount of
14 data, I would say the number of points or
15 number of days was different than it was on the
16 monitor that they had on the receiver that they
17 had.

18 BY MR. HANSEN:

19 Q For present purposes, let's talk about the
20 amount of data for the number of days or the number
21 of hours. I just want to make sure I understand
22 your testimony correctly.

23 So you're saying that in terms of data that
24 was available to the user on the display, that the
25 maximum was 24 hours --

1 MR. MASON: Objection. Form.

2 BY MR. HANSEN:

3 Q -- is that correct?

4 MR. MASON: Scope.

5 THE WITNESS: As I recall, that's true.

6 BY MR. HANSEN:

7 Q But they could get data for, you said, I
8 think, 30 days and it might have even been 90 days
9 using CareLink?

10 A Yes.

11 MR. MASON: Objection. Form. Scope.

12 BY MR. HANSEN:

13 Q And in terms of the memory on the device,
14 where was the data for CareLink stored?

15 MR. MASON: Objection. Form. Scope.

16 THE WITNESS: Can you repeat the question?

17 BY MR. HANSEN:

18 Q In terms of memory on the device, do you
19 know where the data for CareLink was stored?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: Well, the data would be, my
22 assumption, only way I can imagine or was aware
23 of it at the time, was that the data is stored
24 in the receiver, which in the Paradigm system
25 would be the pump.

1 BY MR. HANSEN:

2 Q And where was the data for user display
3 stored, to your understanding?

4 MR. MASON: Objection. Form. Scope.

5 THE WITNESS: The data that is viewed by
6 the patient you said?

7 BY MR. HANSEN:

8 Q Yes.

9 A Yeah, that would be in the pump as well.

10 Q In your understanding did the Paradigm
11 system have more than one type or location of
12 memory?

13 MR. MASON: Objection. Form. Scope.

14 THE WITNESS: I'm not aware of that. I
15 would -- I wouldn't even want to make an
16 assumption about that.

17 BY MR. HANSEN:

18 Q Do you have a copy of your declaration with
19 you?

20 A Yes, I do.

21 Q And that's Exhibit 1055?

22 A Yes, it is.

23 Q Could you turn please to page 8 of your
24 declaration?

25 A Yes.

1 Q Do you see the table on pages 8, 9, and
2 continuing to page 10?

3 A Yes. The description of material?

4 Q Yes. Is this a complete list of all the
5 materials you considered in connection with the
6 opinions set forth in your declaration?

7 A Yes.

8 Q Is there anything missing?

9 A Not that I'm aware of, no.

10 Q It lists items by exhibit number, do you
11 see that?

12 A Yes.

13 Q One of those exhibit numbers is
14 Exhibit 1053, the deposition transcript of
15 Dr. Wright.

16 A Correct.

17 Q I don't see here the deposition transcript
18 for Mr. Gross. Did you review the deposition
19 transcript of Mr. Gross?

20 A I'm uncertain. I don't know. I thought
21 that I had seen part of that, but I don't remember
22 any details, and I don't know when that was, and I
23 guess it wasn't part of what I used to form my
24 declaration.

25 Q So I guess sitting here today, based on

1 your best present recollection, do you believe that
2 you reviewed the transcript of Mr. Gross or not?

3 A I just can't recall.

4 Q Well, what's your best recollection?

5 MR. MASON: Objection.

6 BY MR. HANSEN:

7 Q I think you said before that you thought
8 you had?

9 MR. MASON: Objection. Form.

10 THE WITNESS: I think that I confused, to
11 some degree, the declarations and the
12 deposition reports. So it's possible I was
13 mistaken that way. And I also know that
14 Dr. Wright comments on different elements of it
15 in his declaration. So it may be that I was
16 just referring to that. So I can't say that I
17 reviewed his declaration -- I mean, his
18 deposition report.

19 BY MR. HANSEN:

20 Q Have you ever had a conversation with
21 Mr. Gross about computational constraints in a CGM
22 device and how that relates to selecting the
23 features to implement in the device?

24 MR. MASON: Objection. Form.

25 THE WITNESS: No. I can expound on that.

1 I would say it was because my role in this
2 process, as I was instructed, was to put a
3 clinical evaluation of the data that was
4 relevant to someone who was skilled -- related
5 to their skill at the time, as a POSITA, or
6 PO-SEE-TA (phonetic). And therefore I didn't
7 focus on any of the detailed technological
8 aspects. So I wouldn't have had -- I certainly
9 didn't have a discussion with him and I didn't
10 review any such data.

11 BY MR. HANSEN:

12 Q Did you have any discussions with Mr. Gross
13 relating to memory constraints in terms of selecting
14 features for a CGM product?

15 MR. MASON: Objection. Form.

16 THE WITNESS: No.

17 BY MR. HANSEN:

18 Q Did you have any discussions with Mr. Gross
19 about battery constraints in terms of selecting
20 features for a CGM product?

21 MR. MASON: Objection. Form.

22 THE WITNESS: No.

23 BY MR. HANSEN:

24 Q Have you had any discussions with anyone
25 else about battery constraints relating to selecting

1 features for a CGM product?

2 MR. MASON: Objection. Form.

3 THE WITNESS: Certainly not related to
4 this -- to these proceedings and the actual --
5 the formation of my declaration. Whether my
6 whole career I had, I can't recall, but it
7 would have been incidental.

8 BY MR. HANSEN:

9 Q So with respect to the opinions in your
10 declaration, have you had any discussions or
11 consideration of memory constraints relative to
12 selecting features for a CGM device?

13 MR. MASON: Objection. Form.

14 THE WITNESS: Is there a particular point
15 in my declaration that you are referring to
16 that I could look at?

17 BY MR. HANSEN:

18 Q No. I'm just asking a question.

19 A I mean, again, as my understanding, and
20 there may be many technical elements beyond that,
21 but my understanding of memory limits and so forth,
22 in my use, what's conveyed to a provider who is
23 using the product or to the patient, for that
24 matter, you know, I'm relying, I guess largely, on
25 some of the data that came from the Medtronic

1 materials that are included here that the most
2 specific one was that 40-minute time period.

3 And I don't -- and so that's the only piece
4 of memory constraints that I would be most
5 knowledgeable about.

6 Q Do you have any opinions on how memory
7 constraints relate to the features that were or were
8 not available in the Paradigm products?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: Could you please repeat the
11 first part of that?

12 BY MR. HANSEN:

13 Q Do you have any opinions about how memory
14 constraints relate to the features that were or were
15 not available in the Paradigm products?

16 MR. MASON: Objection. Form.

17 THE WITNESS: Only my impressions or my
18 experience in my review of the materials that I
19 would imagine that any kind of memory
20 constraints would relate to, you know, to
21 things such as how much was reserved in the
22 transmitter and potentially how much was
23 related to the receiver. But I don't think
24 that that was very relevant to this case.

25 ///

1 BY MR. HANSEN:

2 Q In forming your opinions in your
3 declaration, did you have any discussion or
4 consideration of computational constraints as it
5 relates to selecting features for a product such as
6 the Paradigm?

7 MR. MASON: Objection. Form. Caution the
8 witness not to reveal substance of any
9 communications with attorneys to the extent
10 that's being asked for.

11 THE WITNESS: All I can say is I can't
12 remember discussions about computational
13 requirements or whatever in terms of memory
14 discussions. I think that the terminology I
15 would have seen within the declaration, for
16 instance, of Brian Gross, to some degree, and
17 then Dr. Wright in his review of some of that.
18 It wasn't my focus, so I didn't really expect
19 to be able to render any professional opinion
20 on that.

21 BY MR. HANSEN:

22 Q Referring back to your declaration that's
23 Exhibit 1055 and the list of materials considered,
24 did you consider a declaration or deposition
25 testimony by Dr. Striegel?

1 A No.

2 Q Now, in your list of materials considered,
3 the first item listed is Exhibit 1008, the
4 declaration of Brian Gross dated July 24, 2023.

5 A Yes.

6 Q Are you aware that Mr. Gross has a second
7 declaration in this matter?

8 A I think that question was asked earlier and
9 I don't recall the distinctions necessarily between
10 declarations. I know that he had a second
11 deposition. I guess I'm not aware of a second
12 declaration.

13 Q If you had reviewed a second declaration,
14 would you have listed it here in the table of
15 materials considered?

16 A Yes. And I know I didn't review a second
17 declaration.

18 Q All right. I think we've been going for
19 about an hour. We try to take a break about every
20 hour so that we don't exhaust you too much. So why
21 don't we go off the record now so we can take a
22 short break.

23 MR. MASON: Okay.

24 (Off record from 8:02 a.m. to 8:20 a.m.)

25 ///

1 BY MR. HANSEN:

2 Q Dr. Ahmann, over the break did you discuss
3 your testimony today with counsel?

4 A No. No.

5 Q Did you discuss this deposition with
6 counsel over the break?

7 A No.

8 Q Did you discuss the subject matter of your
9 opinions in your declaration with counsel over the
10 break?

11 A No.

12 Q Let's refer back to your declaration that's
13 Exhibit 1055. And there is a table that begins on
14 page 18 of your declaration. Can you find that?

15 A Okay.

16 Q What is this table in your declaration?

17 MR. MASON: Objection. Form.

18 THE WITNESS: It's basically statements
19 from Brian Gross' report or declaration with
20 the supporting exhibit numbers that he was
21 using to determine, as I understand it at
22 least. And these were things that I brought up
23 because they were relevant to where I was
24 aiming my evaluations.

25 ///

1 BY MR. HANSEN:

2 Q So in your declaration -- this is
3 Exhibit 1055, I'm looking at paragraph 25, it begins
4 on page 15; do you see that?

5 A Okay.

6 Q And in that at the start of paragraph 25
7 you state that you reviewed paragraphs 51 through 61
8 and 80 from Mr. Gross' declaration signed and dated
9 on July 24, 2024; is that correct?

10 MR. MASON: Objection. Form.

11 THE WITNESS: Yes. But I should point out
12 that that was a typographical error. That --
13 because the date of -- the actual date I think
14 is -- it might be July 24, but of 2023.

15 BY MR. HANSEN:

16 Q Okay. But in any event, regardless of the
17 date, those are the paragraphs that you reviewed?

18 MR. MASON: Objection. Form.

19 THE WITNESS: I reviewed more than that,
20 but this portion -- I described the things that
21 I thought were relevant to my declaration at
22 different times through my declaration. In
23 this particular case it was referenced to those
24 paragraphs.

25 ///

1 BY MR. HANSEN:

2 Q And then there's some bullet points in
3 paragraph 25 and each of those bullet points relates
4 to either paragraph 60 or paragraph 80 in Mr. Gross'
5 July 24 declaration?

6 MR. MASON: Objection. Form.

7 THE WITNESS: That's 60 and 80, those
8 particular ones. Let me see. I could take
9 time and go back through his declaration, make
10 sure I had this all referenced properly, but
11 yes, that's my interpretation, my recall.

12 BY MR. HANSEN:

13 Q Well, in each of those bullet points
14 there's a citation at the end, correct?

15 A Yes.

16 Q There's four bullet points, at the end of
17 each bullet point there's a citation. The first
18 citation is to paragraph 60 of Mr. Gross' July 24
19 declaration, correct?

20 MR. MASON: Objection. Form.

21 THE WITNESS: Yes.

22 BY MR. HANSEN:

23 Q And for the other three bullet points, the
24 citation is to paragraph 80 of Mr. Gross' July 24
25 declaration, correct?

1 MR. MASON: Objection. Form.

2 THE WITNESS: Again, I'd have to go back
3 to be sure, but that's what we have here and I
4 assume I referenced that properly.

5 BY MR. HANSEN:

6 Q And then in paragraph 26 you identify
7 certain exhibits and state that, It is my opinion
8 that these references support the opinions in
9 paragraphs 60 and 80 of Mr. Gross' report; is that
10 correct?

11 A That's what's stated. I'd have to go back
12 again and make sure that these are all referenced
13 properly. Anyway, I think if you look at the ones
14 you're referring to in 26, I believe that's all
15 true.

16 Q And you have a copy of Mr. Gross' July 24
17 declaration before you; is that correct?

18 A Yes.

19 Q I'm going to be asking you to look at
20 paragraphs 60 and 80 in Mr. Gross' declaration. And
21 then looking at your own declaration in the table
22 that begins on page 18 of your own declaration.

23 A Page 18, you said?

24 Q Yeah. So let's look first -- I'm sorry. I
25 don't mean to make you jump around. Let's look

1 first at Mr. Gross' declaration. So let's look at
2 paragraph 60.

3 Do you see in paragraph 60 that one of the
4 exhibits cited by Mr. Gross is Exhibit 1012?

5 A Yes.

6 Q And what paragraphs of Exhibit 1012 are
7 cited by Mr. Gross in his declaration?

8 MR. MASON: Objection. Form.

9 THE WITNESS: I'd assume that means
10 paragraphs 4 and 6.

11 BY MR. HANSEN:

12 Q Yes. Did I say something different?

13 A No, you didn't say. You asked what
14 paragraphs. I assume that means paragraphs 4 and 6
15 after it says Exhibit 12 [sic].

16 Q I believe that's the convention, yes.

17 I mean, you can look at Exhibit 12 [sic] if
18 you want, but I'm simply asking you to confirm which
19 paragraphs Mr. Gross cited to in his declaration
20 from Exhibit 1012.

21 MR. MASON: Objection. Form.

22 BY MR. HANSEN:

23 Q Looking at Mr. Gross' declaration, can you
24 confirm that he cited paragraphs 4 and 6 from
25 Exhibit 1012?

1 A I would say paragraphs 4 and 6 have some
2 elements that relate to the discussion but are not
3 very specific to some of the points of failed
4 communication or failed delay calibration.

5 Q Okay. But if you look at Mr. Gross'
6 declaration, in paragraph 60 on page 36, with
7 respect to Exhibit 1012, the paragraphs that he
8 cites are 4 and 6, correct?

9 MR. MASON: Objection. Form.

10 THE WITNESS: That would be my assumption,
11 though I'm not familiar -- completely familiar
12 with the way that it's represented in terms of
13 brackets.

14 BY MR. HANSEN:

15 Q Okay. Now let's look at your declaration
16 in the table on page 18. Well, before we do that,
17 in Mr. Gross' declaration let's look at
18 paragraph 80. That's the other paragraph that you
19 addressed. So we've looked at paragraph 60, now
20 let's look at paragraph 80.

21 And do you see in paragraph 80 with respect
22 to Exhibit 1012 that Mr. Gross again cites
23 paragraph 4 and 6?

24 A Yes.

25 Q And do you see at the end of

1 paragraph 80 he also cites paragraph 86 from
2 Exhibit 1012?

3 A I'm sorry. Would you repeat that last
4 part?

5 Q If you look at the end of paragraph 80, do
6 you see that Mr. Gross also cites paragraph 86 from
7 Exhibit 1012?

8 A Yes.

9 Q Now, if you now turn to page 18 of your
10 declaration, do you see that the first two entries
11 are for Exhibit 1012 in your table?

12 MR. MASON: Objection. Form.

13 THE WITNESS: Yes.

14 BY MR. HANSEN:

15 Q And you have identified paragraphs 5 and 40
16 in your table on page 18, correct?

17 MR. MASON: Objection. Form.

18 BY MR. HANSEN:

19 Q Referring to Exhibit 1012. So in your
20 declaration, which is Exhibit 1055, in your
21 declaration, in the table that begins on page 18,
22 the first two rows relate to Exhibit 1012, correct?

23 MR. MASON: Objection. Form.

24 THE WITNESS: At least are referenced as
25 Exhibit 1012.

1 BY MR. HANSEN:

2 Q And the content there is the content that
3 you've identified in Exhibit 1012 as supporting
4 Mr. Gross' opinions; is that correct?

5 MR. MASON: Objection. Form.

6 BY MR. HANSEN:

7 Q And specifically Mr. Gross' opinions in
8 paragraphs 60 and 80 of his declaration.

9 MR. MASON: Objection. Form.

10 THE WITNESS: Yes. At least quoting, I --
11 guess I'm repeating the references that he
12 gave, but really quoting from what his
13 declaration stated.

14 BY MR. HANSEN:

15 Q So in the first row in your table on
16 page 18 of your declaration you quote paragraph 5
17 from Exhibit 1012, correct?

18 A Well, he quoted that. I guess I repeated
19 that, yes.

20 Q Okay. I'm going to ask you to rethink what
21 you just said because I think what you just said was
22 not accurate. Let's start with answering my
23 question, first of all.

24 My question is, in your table on
25 paragraph 18 of your declaration, the first row

1 quotes paragraph 5 from Exhibit 1012, correct?

2 MR. MASON: Objection. Form.

3 THE WITNESS: I don't know for sure how it
4 relates to form, but I guess you can interpret
5 that since I placed down what Mr. Gross put for
6 his references was my reference as well.

7 BY MR. HANSEN:

8 Q Okay. Again, I'm going to ask you to
9 answer my question. You seem to be answering a
10 different question. And I think you're going to
11 realize in a few minutes that the answer you just
12 gave is not correct. So I don't want you to be
13 giving inaccurate testimony. So if you would just
14 answer my question.

15 What paragraph of Exhibit 1012 are you
16 referencing and quoting in the first row of the
17 table in your declaration?

18 MR. MASON: Objection. Form.

19 THE WITNESS: I assume it's paragraph 5.

20 BY MR. HANSEN:

21 Q And what paragraph are you referencing and
22 quoting in the second row of the table on page 18 in
23 your declaration?

24 A Paragraph 40.

25 Q So with respect to Exhibit 1012, you

1 identified paragraph 4 and -- I'm sorry --
2 paragraph 5 and paragraph 40 as the paragraphs that
3 you believe support Mr. Gross' opinions in
4 paragraphs 60 and 80 of his declaration; is that
5 correct?

6 MR. MASON: Objection. Form.

7 THE WITNESS: Yes.

8 BY MR. HANSEN:

9 Q But in Mr. Gross' declaration, when he
10 identified the paragraphs from Exhibit 1012 that
11 allegedly support his opinions, he did not identify
12 paragraph 5 and he did not identify paragraph 40,
13 correct?

14 MR. MASON: Objection. Form.

15 THE WITNESS: Can you lead me to where
16 that was stated in his --

17 BY MR. HANSEN:

18 Q Yeah. We looked at it just a minute ago.
19 So paragraph 60 in his report where he cited
20 paragraphs 4 and 6, not paragraphs 5 and 40.

21 Are you looking at Gross' declaration?

22 A Yes.

23 Q Paragraph 60. And we looked at this just a
24 few minutes ago. And in paragraph 60 of Mr. Gross'
25 declaration he cites with respect to Exhibit 1012

1 paragraphs 4 and 6, not paragraphs 5 and 40,
2 correct?

3 MR. MASON: Objection. Form.

4 THE WITNESS: I can see that in
5 paragraph 60, he did cite 4 and 6. And in this
6 it's number 5. But I can't tell whether I'm
7 specifically referencing, again, 60 or whether
8 I just made sort of an error in terms of
9 organization. But yes, as is stated here, the
10 reference cited I have is paragraph 5.

11 BY MR. HANSEN:

12 Q So in your declaration with respect to
13 Exhibit 1012 -- so let's step back. Let's again --
14 again, we did it a few minutes ago, but I want you
15 to be sure that you understand what you're dealing
16 with here. Why don't you also look again -- we
17 looked at it a few minutes ago, look at
18 paragraph 80 in Mr. Gross' declaration.

19 And we previously confirmed that with
20 respect to Exhibit 1012 Mr. Gross cites paragraphs
21 4, 6, and 86.

22 MR. MASON: Objection. Form.

23 THE WITNESS: The reference that's stated
24 here is correct in being paragraph 5 as it
25 relates to the statements that are to the

1 right. The organizational structure may be off
2 in terms of making it assume that it's the same
3 statement as number -- as paragraph 60. But
4 the statement to the right in that table does
5 correlate to paragraph 5 in Exhibit 1012.

6 BY MR. HANSEN:

7 Q Okay. So with respect to Exhibit 1012,
8 Mr. Gross in his paragraphs 60 and 80 cited
9 paragraphs 4, 6, and 86, correct?

10 MR. MASON: Objection. Form.

11 THE WITNESS: In paragraph 60, correct.

12 BY MR. HANSEN:

13 Q And 80. In paragraphs 60 and 80 Mr. Gross
14 cited three paragraphs from Exhibit 1012.
15 Specifically he cited paragraphs 4, 6, and 86,
16 correct?

17 MR. MASON: Objection. Form.

18 THE WITNESS: Can you identify where we
19 saw paragraph 86?

20 BY MR. HANSEN:

21 Q It's towards the end of paragraph 80.

22 A Yes.

23 Q And in your declaration, when you
24 identified support from Exhibit 1012 for Mr. Gross'
25 opinions in paragraph 60 and 80 of his declaration,

1 you did not identify paragraphs 4, 6, and 86, you
2 instead identified paragraphs 5 and 40, correct?

3 MR. MASON: Objection. Form.

4 THE WITNESS: For purposes of my
5 declaration, it does include paragraph 5 which
6 correlates to the statements that -- that he
7 made that are to the right of that reference
8 number.

9 BY MR. HANSEN:

10 Q Well, the statements to the right of that
11 reference number, that's a quotation of paragraph 5
12 and paragraph 40 from Exhibit 1012, correct?

13 A Yes.

14 Q So again, when Mr. Gross cited Exhibit 1012
15 in his paragraphs 60 and 80, he specifically cited
16 to paragraphs 4, 6, and 86 from 1012, correct?

17 MR. MASON: Objection. Form.

18 THE WITNESS: It appears that you're
19 correct. In 60 and 80 he quoted paragraphs
20 4 and 6, and in 80 he referenced paragraphs
21 4 and 6 and 86. And in my declaration where
22 I'm referring to a specific statement it
23 referred to paragraph 5.

24 But I don't know if -- I mean,
25 paragraph 5 seems to be consistent with what I

1 intended to convey and consistent with the
2 documents. But you're right, it doesn't
3 correlate with what's in 60 and 80.

4 Although it doesn't -- it may be that
5 it's incorrect to say my opinion -- in my
6 opinion these reference support the opinions of
7 paragraphs 60 and 80 of Mr. Gross' report,
8 because it potentially includes other
9 paragraphs as well.

10 BY MR. HANSEN:

11 Q Now, we previously talked about a second
12 declaration for Mr. Gross and you said you had never
13 seen a second declaration for Mr. Gross; is that
14 correct?

15 A Yes.

16 Q So since you've never seen Mr. Gross'
17 second declaration, I will share with you that in
18 his second declaration with respect to Exhibit 1012
19 he cites paragraphs 5 and 40, the ones that you
20 cited.

21 Can you explain how it is that you just
22 happened to cite the same paragraphs in your
23 declaration that he cited in his second declaration
24 that you never saw?

25 MR. MASON: Objection. Form. Scope.

1 THE WITNESS: I would assume that it means
2 working with the group that somehow some of the
3 excerpts were pulled in without my having that
4 documentation and I didn't go back and look at
5 each individual paragraph that he quoted to
6 make sure it conveyed what I wanted to convey.

7 BY MR. HANSEN:

8 Q And so when you say working with a group,
9 you mean that you were working with a group of
10 attorneys and Mr. Gross was working with the same
11 group of attorneys?

12 MR. MASON: Objection. Form. Scope.

13 THE WITNESS: That's the only possibility.
14 That's the possibility I would consider, yes.

15 BY MR. HANSEN:

16 Q And would you be surprised to learn that
17 there are many other striking similarities between
18 Mr. Gross' second declaration which you never saw
19 and your declaration?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: I think I would be
22 surprised, but I can see where it would happen
23 if I didn't go back and confirm each of the
24 individual references. And presumably that's
25 what happened.

1 BY MR. HANSEN:

2 Q I'm going to ask you with regard to your
3 declaration that's Exhibit 1055 to refer to the
4 table again, and specifically to the third row of
5 the table that begins on page 18 and continues over
6 to page 19.

7 A Yes.

8 Q Is that a quote from Exhibit 1029, an
9 article by Mastrototaro?

10 A I'm quite sure it is. I think I can
11 specifically recall that from the exhibit. To pick
12 out that exact quote, I would have to go through
13 this whole article. Looks like it begins at the
14 beginning of page S13, MiniMed --

15 (Reporter requests clarification.)

16 THE WITNESS: On S13, bottom paragraph of
17 the first column it says there is -- well, the
18 part that specifically relates to here starts
19 at the bottom of that paragraph or that column,
20 MiniMed has taken a first step in advancing the
21 practice of glucose self-monitoring by
22 developing a short-term continuous glucose
23 sensor. The sensor is inserted subcutaneously
24 and capable of reliable operation for up to
25 three days.

1 So I think, it looks to me like this
2 is a direct quote from Mastrototaro's article
3 that's cited.

4 BY MR. HANSEN:

5 Q Do you know Dr. Mastrototaro?

6 A I met him.

7 Q Have you ever worked with him?

8 A As an advis- -- in planning for what was
9 called Star 3 study, certainly he -- among a group
10 of a large group he was there to answer questions we
11 had. And I may have been in an advisory capacity to
12 work with him as well.

13 Q Now, in this paragraph from the
14 Mastrototaro article it has an acronym SMBG. Are
15 you familiar with that acronym?

16 A Could you repeat that, SMGB?

17 Q Yes.

18 A Yes. SMBG I'm familiar.

19 Q What does it stand for?

20 A Self-monitored blood glucose. And it
21 relates to finger stick blood glucose, essentially.

22 Q So by finger stick glucose, you refer to a
23 process where a patient, in order to measure their
24 blood glucose, would prick their finger with a
25 lancet, get a drop of blood on a test strip, place

1 the test strip in a blood glucose meter, and the
2 blood glucose meter would then provide an estimated
3 blood glucose value; is that correct?

4 MR. MASON: Objection. Form.

5 THE WITNESS: It's interesting
6 terminology, because we never would refer to it
7 as estimated. But, in fact, it's a measured
8 glucose value. The accuracy is a question of
9 any given single point.

10 BY MR. HANSEN:

11 Q Okay. So I'll state the question again and
12 I won't say "estimated."

13 So by SMBG, you're referring to a process
14 where in order to measure blood glucose value at any
15 particular point in time, the patient would prick a
16 finger with a lancet, place a drop of blood on a
17 test strip, place the test strip in a blood glucose
18 meter, and then the blood glucose value would be
19 displayed on the blood glucose meter for the
20 patient; is that correct?

21 A Yes.

22 MR. MASON: Objection. Form.

23 BY MR. HANSEN:

24 Q And that's the process that's commonly
25 referred to as SMBG or a finger stick measurement in

1 the field, correct?

2 MR. MASON: Objection. Form.

3 THE WITNESS: Or meter glucose.

4 BY MR. HANSEN:

5 Q Meter glucose. So SMBG, you could also
6 call it meter glucose or you could refer to it as a
7 finger stick measurement?

8 MR. MASON: Objection. Form.

9 BY MR. HANSEN:

10 Q Is that correct?

11 A Yes.

12 Q Now, turning back to your declaration,
13 Exhibit 1055, and specifically this entry in your
14 table relating to the Mastrototaro article, do you
15 have that in front of you?

16 A Yes.

17 Q Do you see at the end of the excerpt that
18 you quoted, it says, quote, Data are collected once
19 every five minutes by a pager-sized monitor device
20 and can be periodically downloaded into a computer
21 for analysis and interpretation?

22 A Yes.

23 Q Is that statement what you were describing
24 earlier with respect to the operation of what you
25 refer to as Medtronic CGMS?

1 MR. MASON: Objection. Form.

2 THE WITNESS: Yes. As a description of
3 the early continuous glucose monitors. This
4 article was written, I think, in 2000.

5 BY MR. HANSEN:

6 Q Let's now turn to page 22 in your expert
7 declaration, Exhibit 1055. Do you have that in
8 front of you now?

9 A Yes.

10 Q And do you see that you have quoted an
11 excerpt from Exhibit 1040?

12 A Yes.

13 Q And that Exhibit 1040 you describe is a
14 Buckingham article published in 2008?

15 A Yes.

16 Q And the excerpt is taken from pages 300 and
17 301 of Exhibit 1040?

18 A Okay. Yes. Yes. Did you have a question
19 on it?

20 Q So with reference to the excerpt that you
21 quoted, the first -- or I'm sorry, the last sentence
22 of the first paragraph states, A second way to look
23 at CGM data is in the retrospective analysis of CGM
24 reports. This information is beneficial to the
25 patient, but also has great potential benefit to the

1 healthcare provider when making treatment
2 recommendations.

3 Do you see that?

4 A Yes, sir.

5 Q And is this referring to the situation
6 where data is downloaded from a CGM device either to
7 the cloud or in the doctor's office so that the
8 doctor and the patient can review historical
9 reports?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: I don't know if
12 Dr. Buckingham uses the words "historical
13 reports." I don't recall that we ever referred
14 to them as historical reports, but we refer to
15 them as CareLink reports. And yes, that does
16 relate to downloading of material and
17 retrospective evaluation.

18 BY MR. HANSEN:

19 Q And do you agree that these reports, these
20 retrospective reports were beneficial to the
21 patient?

22 A In their discussions with the physician,
23 yes.

24 Q And do you agree that these retrospective
25 reports had great potential benefit to the

1 healthcare provider when making treatment
2 recommendations?

3 MR. MASON: Objection. Form. Scope.

4 THE WITNESS: This is Dr. Buckingham
5 speaking using the term "great." But remember,
6 this was a developing technology. And I think
7 he was referring to the fact that yes -- and
8 remember, the word is "potential," not proven
9 how much any particular element of the overall
10 process of the continuous glucose monitor did.

11 BY MR. HANSEN:

12 Q So this article was published in 2008. So
13 as of 2008, are you saying that with respect to the
14 various features and functionalities of a CGM device
15 that the relative value or importance of any
16 particular feature had not yet been proven out?

17 MR. MASON: Objection. Form. Scope.

18 THE WITNESS: I think there's two
19 different angles. Depends on what you refer to
20 as proven. So I think Dr. Buckingham was
21 speaking sort of as a POSITA, as somebody who
22 was experienced in that time and day and at the
23 time of the technology development. And he was
24 speaking to his experience and his hope for
25 what this was.

1 In terms of -- if you're looking at
2 evidence base, you're right. Evidence base had
3 to be -- in fact, I don't believe that there's
4 ever been anything that has specifically shown
5 that CareLink has -- accounts for what percent
6 of success of continuous glucose monitoring.

7 BY MR. HANSEN:

8 Q Now, in this same excerpt from the
9 Buckingham article from Exhibit 1040, in the second
10 paragraph it says, One of the main contributions of
11 CGM is to reveal glucose excursions, including lows
12 during sleep and numerous post-prandial, that would
13 be missed by finger stick blood glucose monitoring;
14 do you see that?

15 A Yes.

16 Q What is meant by lows during sleep?

17 MR. MASON: Objection. Form. Scope.

18 THE WITNESS: That may come up in other
19 questions, but one of the concerns, of
20 course -- maybe I should restate that.

21 One of the potential benefits, and
22 again we're saying potential, though at this
23 point it's certainly been proven, potential
24 benefits at that time was reduction in
25 hypoglycemia overall. And in particular,

1 hypoglycemia, some of the early CGM data would
2 suggest nocturnal hypoglycemia, nighttime,
3 sleep time hypoglycemia, was unrecognized by
4 many patients.

5 So I think he's referring to the fact
6 that because you have a continuous glucose
7 monitor and you can see patterns over time, you
8 could identify more evidence of low blood
9 sugars.

10 BY MR. HANSEN:

11 Q So if you continue in that same paragraph
12 at the top of page 23 in your expert declaration it
13 says, 75 percent of hypoglycemic seizures occur at
14 night which is of great concern to many patients and
15 parents of children with diabetes. By measuring
16 interstitial glucose levels overnight, CGM is able
17 to provide an alarm system to alert the patient of
18 pending or actual hypoglycemia.

19 Is that consistent with what you were just
20 explaining in your answer to my previous question?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: I'm not sure the question
23 was the same. In fact, yes, they do have
24 alarms, patients can turn off the alarms,
25 patients don't recognize the alarms, but that's

1 one of the potential benefits for continuous
2 glucose monitoring is to identify,
3 retrospectively see that, or when you wake up
4 in the morning, look at your monitor and you
5 can see that that occurred, but you may or may
6 not wake up from the alarms.

7 BY MR. HANSEN:

8 Q But one feature of CGM devices in 2008 was
9 alarms to warn users of pending hypoglycemia?

10 A Yes.

11 MR. MASON: Objection. Form. Scope.

12 BY MR. HANSEN:

13 Q And the alarms could, at least in theory,
14 wake a patient up during the middle of the night in
15 the event that hypoglycemia was imminent while they
16 were sleeping?

17 MR. MASON: Objection. Form. Scope.

18 THE WITNESS: Yes.

19 BY MR. HANSEN:

20 Q Now, if you turn to page 17 of your
21 declaration, do you see that you have some excerpts
22 from Exhibit 1011?

23 A Yes.

24 Q And on page 17 there's an excerpt from
25 page 24 of Exhibit 1011.

1 A Yes.

2 Q And do you see in that excerpt there is a
3 row dealing with realtime alarms?

4 A Yes.

5 Q And according to this, the Paradigm had
6 both audible and vibrating alarms?

7 A Yes.

8 Q Now, I'm going to ask you to refer to
9 paragraphs 26 and 27 in your declaration. So that
10 spans page 16 to page 24.

11 MR. MASON: Leland, I'll let you know
12 we've been going about an hour.

13 MR. HANSEN: All right. We can take a
14 break after this question.

15 BY MR. HANSEN:

16 Q Could you please confirm that in these
17 paragraphs, paragraphs 26 and 27, and all of the
18 quotes that you include in paragraphs 26 and 27,
19 that there's no specific discussion of backfilling
20 data in a CGM device?

21 MR. MASON: Objection. Form.

22 THE WITNESS: Could you repeat for me
23 which particular pages of my declaration you
24 were extending it to?

25 ///

1 BY MR. HANSEN:

2 Q So I'm asking you specifically about
3 paragraphs 26 and 27. And that paragraph 26 begins
4 on page 16 and paragraph 27 ends on page 24.

5 A Right. I could be wrong, but I don't
6 believe any of these -- this particular component
7 does refer to backfilling.

8 MR. HANSEN: Okay. Your counsel had asked
9 for a break. We can go ahead and take a short
10 break.

11 (Off record from 9:22 a.m. to 9:40 a.m.)
12 (Exhibit 2035, Position Statement,
13 Standards of Medical Care in Diabetes-2007,
14 was marked.)

15 BY MR. HANSEN:

16 Q Dr. Ahmann, I'm handing you a document
17 marked as Exhibit 2035. You previously testified
18 about the Standards of Medical Care in Diabetes that
19 were promulgated by the American Diabetes
20 Association; is that correct?

21 A Yes.

22 Q And as you look at Exhibit 2035, do you
23 recognize this as the Standards of Medical Care in
24 Diabetes for the year 2007 from the American
25 Diabetes Association?

1 MR. MASON: Objection. Form.

2 THE WITNESS: Technically, this particular
3 article is a position statement as opposed to
4 the usual standards. But it would be
5 incorporated into the standards, yes.

6 BY MR. HANSEN:

7 Q So this would be incorporated into the
8 standards?

9 MR. MASON: Objection. Form.

10 THE WITNESS: Most likely.

11 BY MR. HANSEN:

12 Q What was the purpose of this document, this
13 position statement?

14 MR. MASON: Objection. Form. Scope.

15 THE WITNESS: They don't call it -- it
16 looks to -- this is going back to 2007, it's
17 dated. They don't really -- in modern day they
18 still do this, but they don't call it a
19 position statement. I believe they just refer
20 to it as modification or something to that
21 effect. Because this particular one seems to
22 be -- I have to take that back. This was the
23 rudimentary -- this was -- it was either 2006
24 or so that the standards of care were
25 initiated.

1 And, of course, they started out with
2 just a few pages. Now there are hundreds of
3 pages. But this was an example of what has now
4 become a more extended, refined document, I
5 guess I'd say.

6 BY MR. HANSEN:

7 Q But this was the Standards of Medical Care
8 in Diabetes for 2007?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: As promoted by the American
11 Diabetes Association, yes.

12 BY MR. HANSEN:

13 Q And if you look at the table of contents on
14 the first page, do you see that there's a Section V,
15 Diabetes Care?

16 A Yes.

17 Q And it says that that section begins on
18 page S8.

19 A Yes.

20 Q And within the section on diabetes care
21 there's a Section V(C) for glycemic control?

22 A Yes.

23 Q And within Section V(C) there's a
24 Section V(C)(1)(a) for self-monitoring of blood
25 glucose?

1 MR. MASON: Objection. Form.

2 THE WITNESS: Yes, there is.

3 BY MR. HANSEN:

4 Q And if you refer to that section, do you
5 see that it begins on page S9?

6 A Yes.

7 Q And there are the recommended standards of
8 medical care as it applies to self-monitoring of
9 blood glucose?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: Yes.

12 BY MR. HANSEN:

13 Q And in that section, the recommendations as
14 of the year 2007, there's discussion of SMBG?

15 A Right.

16 MR. MASON: Objection. Form.

17 BY MR. HANSEN:

18 Q And SMBG, again, as we discussed earlier,
19 is self-monitoring of blood glucose?

20 A Yes.

21 MR. MASON: Objection. Form.

22 BY MR. HANSEN:

23 Q And do you see in this section on
24 self-monitoring of blood glucose there is no
25 discussion of CGM?

1 MR. MASON: Objection. Form.

2 THE WITNESS: I believe that's true.

3 BY MR. HANSEN:

4 Q Now, in the Standards for Medical Care in
5 2007 there's also a Section VIII, Diabetes Care in
6 Specific Settings; is that correct?

7 A Yes.

8 Q And within Section VIII there's a
9 Section VIII(A) --

10 A Okay. I'm sorry. Go ahead. I was looking
11 at the one where it says specific population, but
12 you're right, VIII is Diabetes Care in Specific
13 Settings.

14 Q And within Section VIII there's a
15 Section VIII(A), Diabetes Care in the Hospital; is
16 that correct?

17 A Yes.

18 Q And can you turn, please, to page S27? And
19 is that where Section VIII(A) begins?

20 A Yes.

21 Q And within Section VIII(A) there's a
22 Section 1, Blood glucose targets; and then a
23 Section 2 on the next page, S29, Treatment options;
24 and then there's a Section 3, Self-management in the
25 hospital; do you see that?

1 A Okay. Let's step back. So the first one
2 you referred to as blood glucose targets where the
3 first element is 1(A) under general medicine
4 surgery, but you're just referring to the category
5 of blood glucose targets overall.

6 And then the second one you said was what?

7 Q Well, let me withdraw the question. Let's
8 skip to self-management in the hospital.

9 A Okay.

10 Q You see the heading "Self-management in the
11 hospital" on page S30?

12 A Yes.

13 Q And you understand that this is part
14 of Section VIII(A) Diabetes Care in the Hospital?

15 A Yes.

16 Q And do you see that under "Self-management
17 in the hospital" there's a discussion of SMBG?

18 A Yes.

19 Q And do you see that there's no discussion
20 of CGM?

21 A Yes.

22 MR. MASON: Objection. Form.

23 BY MR. HANSEN:

24 Q Now, if you turn to the next page, do you
25 see the heading, 9, Continuous blood glucose

1 monitoring?

2 A Yes.

3 Q And do you recognize that that is part of
4 Section VIII(A) about diabetes care in the hospital?

5 MR. MASON: Objection. Form.

6 THE WITNESS: Yes.

7 BY MR. HANSEN:

8 Q So on page S31 under the heading
9 "Continuous blood glucose monitoring," it concludes
10 in the last sentence, Until more studies are
11 published, it is premature to use continuous glucose
12 monitoring except in a research setting; did I read
13 that last sentence correctly?

14 A Yes, as specifically pertains to use in the
15 hospital.

16 Q And that was the Standards of Medical Care
17 according to the American Diabetes Association for
18 the year 2007, correct?

19 MR. MASON: Objection. Form. Scope.

20 THE WITNESS: Yes, but these are printed
21 in January of 2007. So these were formulated
22 prior, probably before July of 2006.

23 BY MR. HANSEN:

24 Q Okay. But it is the Standards of Medical
25 Care published by the American Diabetes Association

1 for the year 2007, correct?

2 MR. MASON: Objection. Form. Scope.

3 THE WITNESS: Published in 2007, yes.

4 BY MR. HANSEN:

5 Q And with respect to continuous blood
6 glucose monitoring in the hospital, it says, "Until
7 more studies are published, it is premature to use
8 continuous blood glucose monitoring except in a
9 research setting." Correct?

10 MR. MASON: Objection. Form.

11 THE WITNESS: In the hospital, yes.

12 BY MR. HANSEN:

13 Q And that was the accepted standard of care
14 for the year 2007?

15 MR. MASON: Objection. Form. Scope.

16 THE WITNESS: Yes.

17 BY MR. HANSEN:

18 Q And with respect to the section we looked
19 at previously which dealt with the standard of care
20 for self-monitoring of blood glucose, there's no
21 mention of CGM at all, correct?

22 MR. MASON: Objection. Form. Scope.

23 THE WITNESS: I would have to read through
24 the whole document to make sure that there's no
25 statement in there. But I think that that is

1 correct. In the earliest iterations of the
2 standards of care they did not include CGM.
3 (Exhibit 2036, Position Statement,
4 Standards of Medical Care in Diabetes-2006,
5 was marked.)

6 BY MR. HANSEN:

7 Q Okay. I'm handing you Exhibit 2036. Do
8 you recognize this as the Standards of Medical Care
9 in Diabetes for the year 2006 as published by the
10 American Diabetes Association?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: Yes.

13 BY MR. HANSEN:

14 Q And let's look again at Section V(C)(1)(a),
15 Self-monitoring of blood glucose. Can you turn to
16 that section? It begins on page S10.

17 A Yes.

18 Q Can you confirm that in that section
19 there's discussion of SMBG, but no discussion of
20 CGM?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: Under this section, no,
23 there's no discussion of CGM.

24 BY MR. HANSEN:

25 Q And can you turn to Section VIII(A),

1 Diabetes Care in the Hospital?

2 A Yes.

3 Q And specifically, if you turn to Section
4 VIII(A)(3), Self-management in the hospital. That
5 should be on page S31.

6 A Yes, I see that.

7 Q And can you confirm that in that section
8 there's a discussion of SMBG, but no discussion of
9 CGM?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: Yes.

12 BY MR. HANSEN:

13 Q And if you turn to Section VIII(A)(8), it's
14 on page S32.

15 A Yes.

16 Q Can you confirm that section is Bedside
17 blood glucose monitoring, correct?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: That's the section, yes.

20 BY MR. HANSEN:

21 Q And there's no discussion of CGM in that
22 section either, correct?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: Yes.

25 ///

1 BY MR. HANSEN:

2 Q In fact, in this entire document, Standards
3 of Medical Care in Diabetes for the year 2006,
4 there's no discussion of CGM at all, correct?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: I haven't read through the
7 whole document, but I'm quite sure there wasn't
8 at that time.

9 (Exhibit 2037, Position Statement,
10 Standards of Medical Care in Diabetes from
11 January 2005, was marked.)

12 BY MR. HANSEN:

13 Q I'm now handing you Exhibit 2037. Do you
14 recognize this as the Standards of Medical Care in
15 Diabetes for the year 2005 as published by the
16 American Diabetes Association?

17 MR. MASON: Objection. Form. Scope.

18 BY MR. HANSEN:

19 Q And could you turn in this document to
20 Section V(C)(1)(a), Self-monitoring of blood
21 glucose?

22 A Yes.

23 Q And that begins on page S10?

24 A Correct.

25 Q And can you confirm that in that section

1 there's discussion of SMBG, but no discussion of
2 CGM?

3 MR. MASON: Objection. Form. Scope.

4 THE WITNESS: Yes.

5 BY MR. HANSEN:

6 Q And could you turn, please, to Section
7 VIII(A), Diabetes care in the hospital? And
8 specifically within Section VIII(A), let's look at
9 subsection 3, Self-management in the hospital. That
10 begins on page S26, do you see that?

11 A Yes.

12 Q And do you see that there's discussion in
13 that section of SMBG, but no discussion of CGM?

14 MR. MASON: Objection. Form. Scope.

15 THE WITNESS: I agree.

16 BY MR. HANSEN:

17 Q And in Section VIII(A)(8), Bedside blood
18 glucose monitoring on page S27, do you agree that
19 there's no discussion of CGM?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: Yes. One point of
22 clarification, by the way, is that SMBG is --
23 interesting, as we've sort of previously
24 confirmed the terminology, but in fact in the
25 hospital it isn't self-monitored. Even though

1 in the self-care thing, in the one component it
2 suggests that they can -- that there is such a
3 thing as self-management, I'd say less than
4 1/10th of a percent of patients actually
5 self-monitor. So self-monitoring here refers
6 to a nurse using a point-of-care device.

7 BY MR. HANSEN:

8 Q And if you look at Section VIII it says
9 that that point-of-care device would be identical or
10 similar to devices for home SMBG?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: I'm sorry. Where is that?

13 BY MR. HANSEN:

14 Q The last sentence in Section VIII, Bedside
15 blood glucose monitoring.

16 A Correct. I can't say in most institutions
17 it was identical, but they're similar.

18 Q And there's no mention of CGM, correct?

19 A Correct.

20 MR. MASON: Objection. Form. Scope.

21 BY MR. HANSEN:

22 Q And in fact, in the entire document,
23 Standards of Medical Care in Diabetes for the year
24 2005, there's no mention of CGM, correct?

25 MR. MASON: Objection to form. Scope.

1 THE WITNESS: Without reading it, I can't
2 say absolutely. But in the parts that we
3 reviewed here, I see no evidence of that.

4 MR. MASON: Since we're on a break from
5 the questioning, I'm going to object to the
6 introduction of these exhibits to the extent
7 patent owners intend to rely on them in any
8 certain reply.

9 BY MR. HANSEN:

10 Q I'm now handing you Exhibit 2038. Do you
11 see that the title of this document is Defendant and
12 Counterclaim Plaintiff's DexCom Inc.'s Objections
13 and Responses to Plaintiff's Third Set of
14 Interrogatories, 26 through 43?

15 A I see that, correct.

16 MR. MASON: Counsel, I just want to note,
17 this has been marked Highly Confidential,
18 Outside Attorneys' Eyes Only. And I just want
19 to note that on the record.

20 In allowing the witness to see this,
21 I assume patent owners have either gotten
22 permission or are waiving any confidentiality
23 with respect to this document. Since we don't
24 have a protective order, I don't want to look
25 at this if it has AEO information that I've not

1 been authorized to see.

2 And I don't want the witness to look
3 at it if he has not been authorized to see it.

4 MR. HANSEN: So what I've given you -- I
5 was just about to explain this -- it's not the
6 complete document. I've given you the part
7 that relates to Interrogatory No. 28. And that
8 portion of the document I've confirmed does not
9 contain any confidential information. So this
10 is something that you, Dr. Ahmann, and you,
11 Andy, can see.

12 BY MR. HANSEN:

13 Q I've specifically given you pages 1 through
14 2, 11 through 22 from the document. Are you
15 familiar with the concept of an interrogatory?

16 A No. Don't understand the terminology.

17 Q Okay. So in a patent infringement lawsuit
18 in Federal Court the parties are allowed to ask
19 questions in writing of the other party. The
20 question is called an interrogatory. It's just the
21 term the courts use.

22 But there's a written question and then the
23 other party provides a written answer. They can
24 also object. So in this instance, in this document,
25 Abbott had served interrogatories on DexCom,

1 specifically interrogatories 26 through 43. And
2 this is an excerpt from the document where DexCom is
3 responding, is answering Abbott's interrogatory.
4 And the pages I've given you relate specifically to
5 Interrogatory No. 28.

6 So you will see on page 12 --

7 A May I ask counsel, am I able to read this?

8 MR. MASON: So, I mean, again, I'm
9 assuming there's no -- just to preserve our
10 objections. What I'm objecting to is this
11 document is an incomplete document. I don't
12 know when it's dated.

13 And I will take counsel at their word
14 that they have permission to share this with
15 individuals who have not signed the protective
16 order in the District Court action. I see that
17 there's identification of individuals at
18 DexCom, I see that there is information related
19 to non-infringing alternatives. And so, again,
20 I will take counsel at their word.

21 But this is marked as Highly
22 Confidential, Outside Attorneys' Eyes Only. So
23 I want your assurance, Leland, that you have
24 full permission from whoever has provided these
25 confidentiality designations, that you have

1 permission to share those with people who have
2 not signed the protective order in the District
3 Court.

4 MR. HANSEN: Well, what I will tell you is
5 that we have confirmed in the materials that
6 I've given you that there is no information
7 that would be governed by the protective order,
8 in this case in the materials I've given you.

9 MR. MASON: And I want to make sure,
10 Mr. Hansen, you've confirmed with counsel for
11 DexCom in the District Court litigation that
12 none of the information here is designated or
13 deemed confidential.

14 MR. HANSEN: So we sent them, some time
15 ago, a letter indicating that that was our
16 understanding and asking them to indicate if
17 they disagreed and they have not disagreed.

18 MR. MASON: But they have not removed the
19 confidentiality designation, correct? My
20 understanding is they have not removed the
21 confidentiality designation.

22 I can't prevent from you introducing
23 this to the witness, but it sounds like
24 confidentiality has not been waived and
25 permission has not been granted by DexCom and I

1 want to note that on the record.

2 MR. HANSEN: All right. Well, as I said,
3 I'm confident that there is no confidential
4 information in what we've provided to
5 Dr. Ahmann and to yourself, Andy.

6 MR. MASON: I maintain the objections as
7 to the incomplete document and untimely
8 submission of document.

9 BY MR. HANSEN:

10 Q If you turn 12, Dr. Ahmann, do you see the
11 heading Interrogatory No. 28?

12 A Yes, I do.

13 Q And as you review the interrogatory, do you
14 see that the interrogatory asks DexCom to -- and
15 it's got a romanette i, Describe each alleged
16 non-infringing alternative; do you see that?

17 A I'll have to read through this. I'm sorry.

18 MR. HANSEN: While you're reviewing that,
19 just so that we have a date associated with the
20 document, we'll amend the exhibit --

21 MR. MASON: I mean, I think the exhibit's
22 been marked already. I don't know that we can
23 amend exhibits. Are you introducing another
24 exhibit?

25 MR. HANSEN: Well, it's part of the same

1 document.

2 MR. MASON: As noted on the record, it's
3 an incomplete document. You don't have a
4 question pending. Maybe it's best that we
5 break, Leland, and just resolve this.

6 I mean, this is my client's Highly
7 Confidential, Outside Attorneys' Eyes Only
8 information, it's been marked as such. I don't
9 have any evidence that they've waived that
10 designation or removed that designation.

11 These are presumptively public
12 proceedings. So anything that's discussed here
13 or filed from this deposition is going to be
14 publicly available. So I need assurances as
15 counsel for DexCom that their confidential AEO
16 information is not being revealed to the
17 public.

18 So I think it's just best that we
19 break now and resolve this quickly.

20 MR. HANSEN: All right. We can take a
21 break.

22 MR. MASON: Thank you.

23 (Off record from 10:15 a.m. to 10:59 a.m.)

24 BY MR. HANSEN:

25 Q Dr. Ahmann, while we were on the break did

1 you have any conversations with anyone about your
2 testimony today?

3 A No.

4 Q Did you have any conversations with anyone
5 about your opinions in this case today?

6 A No.

7 Q Did you have any conversations with anyone
8 about the interrogatory response that we were
9 discussing before the break?

10 A No.

11 Q Okay. We're going to temporarily withdraw
12 that interrogatory response as an exhibit. So we're
13 withdrawing Exhibit 2038. And we'll come back to
14 that later.

15 So I'm now handing you Exhibit 2024. Do
16 you see --

17 A Can I just ask a question? So it's not a
18 new exhibit, but just a new exhibit to me, right?

19 Q That's what I was going to ask you about
20 here in just a minute. Do you see that Exhibit 2024
21 is a copy of US Patent 9,996,668?

22 A Yes.

23 Q And do you see that the applicant is
24 identified as DexCom Inc.?

25 A Yes.

1 Q And do you see that the assignee is
2 identified as DexCom Inc.?

3 A That was referring to what?

4 Q The assignee.

5 A Oh, correct.

6 Q And you're familiar with DexCom?

7 A As a company, yes.

8 Q And what has your relationship with DexCom
9 been over the years?

10 MR. MASON: Objection. Form.

11 THE WITNESS: I would say that we have
12 been frequent users of their CGM clinically for
13 a long time. They've been one of the leaders
14 in the field. That we've done a number of
15 clinical research studies for them and I don't
16 think I've ever actually been on any advisory
17 board for them and helped in development of
18 several research protocols.

19 BY MR. HANSEN:

20 Q Are you familiar with Abbott Diabetes Care?

21 A Yes.

22 Q What has your relationship with Abbott
23 Diabetes Care been over the years?

24 A Again, we use their products, we discuss
25 things with their scientific liaisons and their

1 salespeople, we have a lot of patients on Abbott
2 products. There was a period of time I was on an
3 advisory board very briefly with Abbott quite a long
4 time ago. And I guess that's the extent of it. I
5 don't think I've done any research with their
6 products.

7 Q Referring back now to Exhibit 2024, did you
8 consider this patent, this DexCom patent in forming
9 your opinions set forth in your declaration?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: I would say no. I was
12 informed that my position was not to interpret
13 patent technicality. So I did not really look
14 at specifics of the patent other than those
15 that were presented in some of the other
16 materials such as the declarations.

17 BY MR. HANSEN:

18 Q Let me direct your attention to page 22 of
19 Exhibit 2024. And I'm referring to the pagination
20 that's been added at the bottom right-hand corner of
21 each page.

22 A Okay.

23 Q And do you see column 5 and 6 on that page?

24 A Yes.

25 Q And do you see the paragraph that begins at

1 line 32 in column 5?

2 MR. MASON: Objection. Form. Scope.

3 THE WITNESS: The one in column 5, so the
4 one that begins with, To illustrate further?

5 BY MR. HANSEN:

6 Q Yes. And that paragraph states, quote, To
7 illustrate further, Jane may be asleep and while
8 sleeping she may miss data capture for a given
9 period of time during the night due to, for example,
10 Jane covering the sensor transmitter with her body,
11 for example, rolling over on top of the transmitter.

12 In this example Jane may not want backfill
13 data to be automatically displayed because the
14 automatic insertion of backfilled data may mask the
15 nighttime gaps in data and mask that the receiver
16 was not receiving data.

17 That is, because the system presented a
18 complete set of data, Jane could have an incorrect
19 belief that the system is improperly monitoring her
20 through the night and would alarm should a risky
21 situation be presented.

22 To alleviate this potential problem, Jane
23 may want to see the gaps or a highlight or other
24 graphic indication that graphically indicates that
25 the data is clearly backfill data associated with at

1 least one gap in the transmission of the sensor
2 data. And this way Jane can readily determine that
3 a problem occurred with the sensor transmitter or
4 receiver during the night, unquote.

5 Do you agree with this statement in the
6 DexCom patent that that describes one circumstance
7 when a user may not want data to be automatically
8 backfilled?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: It doesn't seem like it's
11 actually a statement that is of certainty.
12 It's discussing a possibility. I would
13 actually disagree with the concept that you
14 wouldn't want nighttime data of that sort and
15 that -- partly because you can't really do
16 anything if the problem is that you're getting
17 gaps because of the way you're sleeping. You
18 don't change the way you're sleeping. So I've
19 never once, in all the cases that I've seen,
20 ever had this come up.

21 BY MR. HANSEN:

22 Q So have you ever had patients who slept on
23 their transmitter and therefore didn't receive data
24 for a period of time?

25 MR. MASON: Objection. Form. Scope.

1 THE WITNESS: I suspect so, although I
2 think the more common one that I would see
3 would be where they put their transmitter on
4 the bedside -- I mean, they put their receiver
5 on the bedside stand, for instance, and then
6 end up too far away from it is a problem.
7 Because what usually happens when people put
8 pressure on their sensor is it can give you an
9 artificial low, but still continues to read.

10 So I really suspect there must have
11 been some time, but I can recall no specific
12 times, and it's certainly not what we see
13 routinely, nor was it back then, I don't
14 believe.

15 BY MR. HANSEN:

16 Q So it's your understanding of this
17 statement that they were describing -- that DexCom
18 in its patent was describing a possible scenario?

19 MR. MASON: Objection. Form. Scope.

20 THE WITNESS: Possible or potential,
21 right. I don't know that they're saying that
22 they've seen this or how often you see this,
23 but it seems logical it could happen, at least
24 at that time.

25 ///

1 BY MR. HANSEN:

2 Q And you understand that DexCom in this
3 patent is describing a potential situation where the
4 user may not want to have data backfilled?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: I think they're saying a
7 potential one, but I don't see any evidence,
8 nor would I anticipate that the patient's
9 actually ever stated that.

10 BY MR. HANSEN:

11 Q So why do you think DexCom would make this
12 statement in its patent application?

13 MR. MASON: Objection. Form. Scope.

14 THE WITNESS: I can't speak for DexCom. I
15 have no idea.

16 BY MR. HANSEN:

17 Q So when DexCom presented this situation to
18 the United States Patent Office in its patent
19 application, do you believe that DexCom was
20 misleading the patent office about a potential
21 situation where the user would not want to have
22 missing data backfilled?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: Well, I certainly don't
25 think they intended to mislead them, but I

1 don't understand exactly how this developed.

2 BY MR. HANSEN:

3 Q Do you agree with DexCom that they've
4 described a situation here where the user may not
5 want to have missing data backfilled?

6 MR. MASON: Objection. Form. Scope.

7 THE WITNESS: The term "may," I guess,
8 comes into play. Because, you know, I suppose
9 if one out of a hundred felt that way, it's
10 possible. It's nothing that I've ever exposed
11 to ever remember, that I've ever had patients
12 would say anything like that. But it's --
13 again, it's theoretically possible.

14 BY MR. HANSEN:

15 Q Do you see as part of DexCom's statement
16 that we just read that they discussed that
17 backfilled data could be displayed differently than
18 non-backfilled data?

19 MR. MASON: Objection. Form. Scope.

20 THE WITNESS: Can you repeat your
21 question? Just want to make sure I'm
22 interpreting that right.

23 BY MR. HANSEN:

24 Q With reference to this paragraph in
25 Exhibit 2024 that we just read, do you see that

1 DexCom is stating that backfilled data could be
2 displayed differently than non-backfilled data?

3 MR. MASON: Objection. Form. Scope.

4 THE WITNESS: I guess these particular --
5 these particular references, when you get down
6 to the part that says that you could
7 potentially have -- highlight that graph,
8 again, I don't know that it says that's being
9 done at all, but I suspect that it says that's
10 something the patient may request or prefer.

11 BY MR. HANSEN:

12 Q And the reason for displaying backfilled
13 data differently would be so that the user would
14 know and be able to distinguish between backfilled
15 data on the one hand and non-backfilled data on the
16 other hand?

17 MR. MASON: Objection. Form. Scope.

18 THE WITNESS: Again, it would be my
19 conjecture, but I wouldn't -- that presumably
20 what they're saying is a possibility. Though,
21 I don't know that it's ever been done.

22 BY MR. HANSEN:

23 Q Do you understand that in this statement
24 DexCom is explaining that it would be advantageous
25 to display backfilled data differently so that, for

1 example, the user would not wonder about a missed
2 alarm?

3 MR. MASON: Objection. Form. Scope.

4 THE WITNESS: I'm not sure if that's their
5 exact point. But I think that it's inherent in
6 the concept that the patient might want to know
7 that. I mean, I think it's conjecture, but
8 it's reasonable.

9 BY MR. HANSEN:

10 Q So if, for example, the transmitter or the
11 receiver is out of range so that there's a data gap,
12 and during that period of time when there's no data,
13 would the user receive an alarm in an event that
14 their blood glucose was trending hypoglycemic?

15 MR. MASON: Objection to form. Scope.

16 THE WITNESS: They should receive an
17 alarm. If it was actually receiving,
18 obviously. I never thought about whether they
19 receive an alarm if it actually interrupts, if
20 you don't get data at that time. But the -- so
21 potential -- the problem with alarms are that a
22 lot of the patients turn off the alarms because
23 they don't want to be awakened at night or -- I
24 don't remember if it's in these materials or
25 not, but the fact is even from the beginning

1 many patients don't recognize the alarms and
2 then later it's actually worsened that they
3 ignore them even more so.

4 So the alarm part, I suppose people
5 would -- some people appreciate alarms. Some
6 people don't like them. They turn them off.

7 BY MR. HANSEN:

8 Q Do you understand that when a CGM provides
9 an alarm it's based on data from the sensor?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: Yes.

12 BY MR. HANSEN:

13 Q And if there's no data there would be no
14 alarm, correct? There'd be no basis for an alarm if
15 there's no data?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: No alarm for hypoglycemia,
18 right.

19 BY MR. HANSEN:

20 Q No alarms at all if there's no data,
21 correct? Hypoglycemia or hyperglycemia, you can't
22 --

23 MR. MASON: Objection. Form.

24 THE WITNESS: You would see no -- you
25 would not have alarms for deviations of

1 glucose, high or low.

2 BY MR. HANSEN:

3 Q And if the user later looked at the data
4 and saw that they went hypoglycemic but didn't get
5 an alarm, would it be helpful for them to understand
6 that they didn't get an alarm because there was a
7 data gap?

8 MR. MASON: Objection. Form. Scope.

9 THE WITNESS: Could it be helpful? It
10 could. I don't know on average how patients
11 would do that.

12 BY MR. HANSEN:

13 Q And in order for the patient to understand
14 that, one way to inform the patient that there was
15 no alarm because of a data gap would be to display
16 backfilled data differently, correct?

17 MR. MASON: Objection. Form. Scope.

18 THE WITNESS: I don't know if that's
19 within my scope of expertise, actually. But
20 the -- I mean, theoretically, that would be a
21 benefit. I've never seen it, so I don't know
22 why it's not -- technically why it's never been
23 done, to my knowledge.

24 BY MR. HANSEN:

25 Q Would you turn, please, to page 28 of

1 Exhibit 2024?

2 A Okay.

3 Q Do you see the paragraph in column 18 that
4 begins at line 59?

5 A Data backfilling in.

6 Q Yeah. And it says, Data backfilling may
7 consume power to transmitter and/or receiver which
8 can reduce available battery resources.

9 Do you agree with that statement in this
10 DexCom patent?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: I actually don't know --
13 again, I don't know -- I'm not familiar with
14 the power limitations, so I'm not sure I could
15 comment on that. I have no reason to dispute
16 that, but no reason to confirm it either.

17 BY MR. HANSEN:

18 Q Let me direct your attention. Do you have
19 a copy of Exhibit 1011?

20 A Yes.

21 Q Could you turn, please, to page 12 of
22 Exhibit 1011?

23 A Page 12 out of 105?

24 Q Yes.

25 A Okay.

1 Q And do you see there the heading, How do I
2 create reports?

3 A Yes.

4 Q And under that heading it describes how to
5 create historical reports or retrospective reports
6 using the CareLink software?

7 MR. MASON: Objection. Form.

8 THE WITNESS: I'm sorry. Where is that
9 terminology shown?

10 BY MR. HANSEN:

11 Q I wasn't reading it, I was just asking you,
12 under that heading, How do I create reports, does
13 this explain how to create a retrospective
14 historical report using CareLink software?

15 A Yes.

16 MR. MASON: Objection. Form.

17 THE WITNESS: I don't know that it fully
18 explains it, but it describes that it's
19 possible, yeah.

20 BY MR. HANSEN:

21 Q With respect to this exhibit in its
22 entirety, did you consider how the word "report" is
23 used in this document?

24 MR. MASON: Objection. Form.

25 THE WITNESS: I guess as I reflect on my

1 thoughts, it was somewhat confusing -- some
2 pieces of it were confusing and inconsistent.
3 I guess it depends on how a report was
4 described or what circumstances they were
5 referring to when they talk about the report.

6 BY MR. HANSEN:

7 Q So you said in terms of the work of that
8 report, you said that in your opinion you found
9 these terms and the usage of the word "report" to be
10 somewhat inconsistent and confusing?

11 MR. MASON: Objection. Form.

12 THE WITNESS: I would say inconsistent and
13 maybe subject to variable interpretation.

14 BY MR. HANSEN:

15 Q What do you mean by that? In what way is
16 the usage of the term "report" inconsistent in
17 Exhibit 1011?

18 MR. MASON: Objection. Form.

19 THE WITNESS: It's a question of -- it is
20 true that most of the time that they are
21 referring to, they're referring to downloaded
22 reports. But a report -- and maybe that's the
23 distinction, is maybe if you download it you
24 call it a report. But the historical
25 information has two components. That's

1 whatever you download and whatever you see at
2 the time. Which is what -- is also something
3 that we evaluate with the patient in special
4 circumstances or when they're in a clinic visit
5 and have a question.

6 BY MR. HANSEN:

7 Q So I appreciate your answer to the
8 question. I'm specifically asking about the term
9 "report," that term, that word "report."

10 In what way do you think that the word
11 "report" is used inconsistently in Exhibit 1011?

12 MR. MASON: Objection. Form.

13 THE WITNESS: I think somewhere within
14 here they refer to historical reports and other
15 places they talk to history. And so in common
16 parlance, maybe a report is something that
17 always comes after the fact. Therefore, most
18 often they're referring to the downloaded
19 documents.

20 BY MR. HANSEN:

21 Q Okay. Do I understand correctly with
22 respect to the word "history" or "historical," that
23 that's where you think the usage is inconsistent and
24 sometimes confusing?

25 MR. MASON: Objection. Form.

1 THE WITNESS: Only again as I mentioned, I
2 think there's two pieces of historical
3 information. The one is short-term historical
4 information over the last 24 hours that the
5 patient will see, the other one is what happens
6 when you download or you get your choice of
7 what period of time you want to review the
8 data.

9 BY MR. HANSEN:

10 Q And so the term "history" could refer to
11 both, but the word "historical report," that would
12 refer to the latter. That would refer to the data
13 that's downloaded and a report is created; is that
14 correct?

15 MR. MASON: Objection. Form.

16 THE WITNESS: I think people could
17 interpret it that way. I don't know whether it
18 was the best choice of terminology.

19 BY MR. HANSEN:

20 Q Is that how the terms were used in
21 Exhibit 1011?

22 MR. MASON: Objection. Form.

23 THE WITNESS: Can you point to me where it
24 said -- you're referring to report as a word or
25 historical report; can you show me where it

1 says "historical report"?

2 BY MR. HANSEN:

3 Q Let's just step through your testimony. So
4 if I understand correctly, it's your understanding
5 that the word "report," just the word "report," as
6 that word is used in Exhibit 1011, that it's
7 referring to a report generated by CareLink, for
8 example, of retrospective data?

9 MR. MASON: Objection. Form.

10 THE WITNESS: I think that's the most
11 common use of the term.

12 BY MR. HANSEN:

13 Q The term "history" or "historical," you're
14 saying that has two different usages. One referring
15 to short-term history and the other one referring to
16 longer-term history; do I understand your testimony
17 correctly?

18 A Yes.

19 MR. MASON: Objection. Form.

20 MR. HANSEN: Okay. Let's take a short
21 break.

22 (Off record from 11:31 a.m. to 12:14 p.m.)

23 BY MR. HANSEN:

24 Q Dr. Ahmann, I hope you enjoyed some lunch.

25 A Yes.

1 Q Let me direct your attention again to
2 Exhibit 1011. And specifically to the page that's
3 numbered page 59 of 105.

4 A Okay.

5 Q Do you see the heading at the top of that
6 page that says connecting the header to the sensor?

7 A Yes.

8 Q And then point one is, quote, After the
9 sensor is inserted, wait five minutes before
10 connecting the transmitter; did I read that
11 correctly?

12 A Okay.

13 Q And what is shown in the drawing there,
14 kind of in the middle of the page to the right, do
15 you know what I'm referring to?

16 MR. MASON: Objection. Form.

17 THE WITNESS: Yes. The figure?

18 BY MR. HANSEN:

19 Q Yes. What's depicted there?

20 A I assume that's them connecting the
21 transmitter to the sensor.

22 Q The sensor and the transmitter are separate
23 components?

24 MR. MASON: Objection. Form.

25 THE WITNESS: They're separate components

1 at this point. Once the shell gets placed on
2 it, it's the -- acts as one component. Yes,
3 there are two different elements.

4 BY MR. HANSEN:

5 Q And is the sensor inserted before the
6 transmitter is connected?

7 MR. MASON: Objection. Form. Scope.

8 THE WITNESS: Yes.

9 BY MR. HANSEN:

10 Q And after the transmitter has been
11 connected to the sensor set, the transmitter can
12 then later be removed from the sensor set, correct?

13 MR. MASON: Objection. Form. Scope.

14 THE WITNESS: It's reusable. So at the
15 completion of the sensor use they would be
16 separated, correct.

17 BY MR. HANSEN:

18 Q And with the Paradigm system, how would the
19 sensor and the transmitter be connected to the pump?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: Let me see. I don't discuss
22 that directly. It's from a radiofrequency
23 communication with a pump, but I don't know for
24 certain back in the time of the Paradigm
25 whether that -- I don't think it was Bluetooth,

1 I think it was just radiofrequency, like you
2 would have with -- kind of like with a cell
3 phone.

4 BY MR. HANSEN:

5 Q Now, when was the Paradigm introduced?

6 MR. MASON: Objection. Form. Scope.

7 THE WITNESS: Again, I think we confirmed
8 earlier from our documents that the Paradigm
9 was approved by the FDA -- well, first of all,
10 remember, there was a Paradigm pump. Paradigm
11 pump preceded the Paradigm REAL-Time. Paradigm
12 REAL-Time referred to the sensor augmented
13 where the CGM was connected to the pump. That
14 FDA approval, as you can see, was in 2006.

15 BY MR. HANSEN:

16 Q The FDA approval for which of those
17 products was in 2006?

18 MR. MASON: Objection. Form.

19 THE WITNESS: That was for the Paradigm
20 REAL-Time.

21 BY MR. HANSEN:

22 Q And so at the time Paradigm REAL-Time was
23 introduced, the standards of care then in place
24 would have been the standards of care for 2006?

25 MR. MASON: Objection to form. Scope.

1 THE WITNESS: I guess I don't understand
2 your question. They're totally different
3 things, when a product is approved and the
4 standards of care. But there are standards of
5 care for 2006 and the Paradigm was -- Paradigm
6 REAL-Time was approved by the FDA in 2006.

7 BY MR. HANSEN:

8 Q Is the Paradigm REAL-Time that was approved
9 in 2006 the same Paradigm REAL-Time that's described
10 in Exhibit 1011?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: Yes, I believe so.

13 BY MR. HANSEN:

14 Q Was the Paradigm REAL-Time approved for use
15 by Type 2 diabetics?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: That's a little bit more
18 complicated question than I originally thought
19 it would be. In that I think the assumption
20 was that it was for Type 2, it was used for
21 people with multiple injections -- I mean,
22 sorry, used only for Type 1. It was for people
23 with multiple injections. And it wasn't until
24 2015 that such things became approved for -- by
25 the FDA for Type 2 diabetes.

1 BY MR. HANSEN:

2 Q So at the time the Paradigm was introduced
3 in 2006, it only had FDA approval for use with Type
4 1 diabetics?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: Let's go back to that
7 document. Because I don't know how detailed it
8 is, but it's 1041. My memory is that it was
9 only approved -- I mean, I know it was only
10 used for Type 1 diabetes. I think it was only
11 approved for Type 1 diabetes. But I can't
12 identify that specifically in any of the
13 documents I have in front of me.

14 BY MR. HANSEN:

15 Q For Type 1 diabetics -- let me ask you to
16 refer to Exhibit 1044. Do you have 1044?

17 A Yes.

18 Q And this is a Medtronic press release?

19 A Correct.

20 Q Do you see that the end of the first
21 paragraph talks about diabetes-related
22 complications?

23 A Yes.

24 Q And it says, Diabetes-related complications
25 including coma, blindness, kidney failure,

1 amputation, impotence, and heart disease?

2 A Yes.

3 Q Are those all diabetes-related
4 complications associated with Type 1 diabetes?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: Well, this is a press
7 release. It's coming from Medtronic. So
8 they're only trying to say the theory about it
9 because this isn't absolutely evidence-based,
10 that they'll help you to control glucose and
11 glucose causes all those. And that yes,
12 whether you have that particular part, is that
13 anybody with diabetes who doesn't control
14 glucose would have those complications. But I
15 don't think they're trying to convey that this
16 is for everybody with diabetes.

17 BY MR. HANSEN:

18 Q Is Type 1 diabetes known to cause
19 blindness?

20 A Yes.

21 Q Is Type 1 diabetes known to impair vision
22 short of blindness?

23 A Yes.

24 Q How common are vision problems with Type 1
25 diabetics?

1 MR. MASON: Objection. Form. Scope.

2 THE WITNESS: I don't think I can give
3 specific numbers. I could tell you they're
4 much lower than they once were. We see very
5 few people who are blind from Type 1 now
6 because with appropriate care you prevent that.

7 BY MR. HANSEN:

8 Q So in 2006, how common were vision
9 problems? Not necessarily blindness, but vision
10 problems associated with Type 1 diabetes?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: A minority of people, but
13 still a specific number. I can't give you an
14 exact percentage at that time.

15 BY MR. HANSEN:

16 Q In 2006, 2007, what were the leading
17 complications related to Type 1 diabetes?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: Within the list that you
20 were referring to --

21 BY MR. HANSEN:

22 Q I don't mind if you refer to the list, but
23 I'm just asking based on your experience.

24 MR. MASON: Same objection.

25 ///

1 BY MR. HANSEN:

2 Q As of 2006, 2009, what complications were
3 commonly associated with Type 1 diabetes?

4 MR. MASON: Objection. Form. Scope.

5 THE WITNESS: That's the kind of
6 information that you would have to have
7 specifics that would be reported by the CDC,
8 for instance, in their data that they publish
9 on a regular basis because it involves so much.
10 So back then I can't say.

11 The most common ones would be the
12 microvascular complications, which are the
13 kidney disease, the eye disease, and the nerve
14 disease. I don't think those are appreciably
15 much different from each other.

16 Blindness would be unusual. And
17 maybe diabetic retinopathy or eye damage would
18 be common, but that doesn't relate to a loss of
19 vision. That would mean an ophthalmologist
20 looking back there could see evidence of
21 diabetes, but it hasn't impacted the patient
22 physically at that point.

23 BY MR. HANSEN:

24 Q Okay. We're still waiting for an answer.
25 You recall that we were previously talking about one

1 of DexCom's interrogatory responses; do you recall
2 that?

3 A I recall it was introduced. I don't know
4 that we talked about it.

5 Q Yeah. We withdrew the exhibit and I'm not
6 going to reintroduce the exhibit, but I want to ask
7 you some questions nonetheless.

8 Do any of your patients use DexCom's G7
9 product?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: I certainly don't think that
12 relates at all to my declaration, but sure.

13 BY MR. HANSEN:

14 Q Does the DexCom G7 have a feature to
15 backfill data gaps?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: I'm embarrassed to say that
18 I have not seen that discussion and I don't
19 know if it does or not.

20 BY MR. HANSEN:

21 Q Can you identify any commercial CGM
22 products that backfill data gaps?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: Again, I don't think I could
25 say with certainty. I would assume the

1 Medtronic, which has been doing it for such a
2 long period of time, has done it. I believe
3 other ones are likely to do it, but I don't
4 know the exact status at this point.

5 BY MR. HANSEN:

6 Q Do any of your patients use Abbott
7 Freestyle Libre products?

8 MR. MASON: Objection. Form. Scope.

9 THE WITNESS: Yes.

10 BY MR. HANSEN:

11 Q Do those products backfill data gaps?

12 MR. MASON: Objection. Form. Scope.

13 THE WITNESS: I don't know. I know they
14 have a memory. I mean, in a sense you would
15 say that they -- it's a little different
16 system. It certainly depends on which of the
17 Libres you're talking about.

18 But Libre 2 is a frequently scanned
19 CGM device. It has an eight-hour memory and
20 you'll always have a gap if you end up going
21 past eight hours. And no, it doesn't make up
22 for that at all. I don't know if the other
23 products have a different system as they've
24 gotten into the realtime.

25 ///

1 BY MR. HANSEN:

2 Q So for your patients that use DexCom and
3 Abbott products, have you ever discussed backfilling
4 data gaps with any of your patients?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: "Ever" is a difficult word,
7 but certainly I don't commonly. I can't recall
8 when I last talked about that.

9 I assume that the state-of-the-art
10 ones have what would be available and they
11 probably have backfill to some degree. But I
12 don't know how that operates or how that
13 affects them. So I don't talk to patients
14 about backfill, no.

15 BY MR. HANSEN:

16 Q So do I understand correctly that you don't
17 recall ever discussing backfilling data gaps with a
18 patient because that's not something that in your
19 opinion really affects the patients?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: I think it's likely that I
22 discussed it partly with them back at the time
23 of the products that I reviewed here for
24 Medtronic because those are the elements that
25 we looked at and would employ with the patient.

1 Nowadays I don't talk to them about it because
2 I don't see gaps that are very significant at
3 all. Almost all gaps we see are related to the
4 loss of signal and presumably it would be for a
5 long time, but gap, you would repopulate part
6 of that.

7 BY MR. HANSEN:

8 Q Do you have a specific recollection of
9 discussing data gaps with a patient relative to a
10 Medtronic product?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: Specific, no.

13 BY MR. HANSEN:

14 Q So assuming that DexCom's G7 backfills data
15 gaps, and assuming that you remove that
16 functionality from G7, do you agree with DexCom that
17 the version without backfilling would be an
18 acceptable alternative to the version with
19 backfilling?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: Well, I mean, I think I have
22 plenty of mentions within my declaration that I
23 believe there's an advantage to backfilling for
24 what the patient sees that particular day.
25 Therefore, I presume that backfilling has some

1 advantage.

2 BY MR. HANSEN:

3 Q So if you were comparing a DexCom G7
4 without backfilling and a DexCom G7 with
5 backfilling, would you agree with DexCom that the
6 one without backfilling would be an acceptable
7 alternative to the version with backfilling?

8 MR. MASON: Objection. Form. Objection.
9 Scope.

10 THE WITNESS: I think in my declaration I
11 would state that the more information, the
12 better. So I would have to say that one with
13 backfilling has some advantages.

14 BY MR. HANSEN:

15 Q So my question is, would the one without
16 backfilling be acceptable?

17 MR. MASON: Objection. Same objections.

18 BY MR. HANSEN:

19 Q An acceptable alternative to the one with
20 backfilling?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: My impression of the word
23 "acceptable" would be are we better with it or
24 without it? Or better with it? Even if it
25 didn't have backfilling, but backfilling is a

1 significant -- there is an advantage in terms
2 of if you had a preference.

3 So if one company were selling it and
4 emphasizing that versus their competitor, you'd
5 choose the one with backfilling.

6 BY MR. HANSEN:

7 Q So let me ask you about another related
8 feature. So I want to ask you about, again, two
9 versions of G7. In the first version it backfills
10 data. And when it backfills data, it fills in the
11 data gap with a line that begins at the beginning of
12 the data gap and ends at the end of the data gap.
13 So that's version one.

14 Version 2 doesn't have that feature. It
15 backfills data, but it doesn't do it in that way.
16 It doesn't do it by having a line that starts at one
17 end of the data gap and extends to the other end of
18 the data gap.

19 Would the second version that displays the
20 data, the backfill data in some other way, would
21 that other version be an acceptable alternative to
22 the first version?

23 MR. MASON: Objection. Form. Scope.

24 And Leland, I've allowed some leeway
25 here, but you're asking about 2020 products

1 that were not discussed at all in Dr. Ahmann's
2 declaration.

3 So at a certain point if you can't
4 tie this to what's actually at issue in this
5 case, we may have to call the Board.

6 BY MR. HANSEN:

7 Q You can answer the question.

8 A I can? My emphasis in the declaration was
9 to focus on that time period that was related to the
10 patent which was before 2010 and preferably even
11 before 2009. And you said is one acceptable?
12 Either one is acceptable. It's a matter of which
13 one has an advantage. And I think it's another case
14 where you could have arguments.

15 Q So let's talk about a hypothetical CGM
16 device in 2009. And the device backfills data gaps.
17 And in the first device the backfilled data is
18 representative of the line that begins at the start
19 of the data gap and ends at the end of the data gap.

20 And in the second device the backfilled
21 data is represented in some other way. In your mind
22 is there any particular advantage associated with
23 displaying the way the data is displayed with device
24 no. 1 as opposed to an alternative way of displaying
25 the same data?

1 MR. MASON: Objection. Form. Scope.

2 THE WITNESS: Number one, I don't think
3 any such thing existed back before 2009, to
4 express it differently. And I think some
5 situations, it would be better -- it would be
6 preferred, but I think that's the issue, is
7 what's preferred? Because I think that for
8 some patients having that extra line, for
9 instance, would be confusing to them rather
10 than beneficial.

11 BY MR. HANSEN:

12 Q So when you said -- I just described two
13 products to you, two hypothetical products. The
14 first one backfilled using a line. The second
15 product backfilled representing the data in some
16 other way. And you said that you didn't think there
17 was a product like that before 2009.

18 Were you referring to both of the products
19 or to only one of the products?

20 MR. MASON: Objection. Form. Scope.

21 THE WITNESS: I'm sorry. I'm referring to
22 specifically one that would in some way have
23 two separate lines.

24 BY MR. HANSEN:

25 Q Meaning a product that would have a line --

1 where the backfill data would be represented by a
2 line?

3 MR. MASON: Objection. Form. Scope.

4 THE WITNESS: No. I think the backfill
5 data would be represented by your line, by your
6 trend value. But it wouldn't -- but I thought
7 you were talking about two separate lines in
8 the second case, hypothetical case.

9 MR. HANSEN: All right. Let's take one
10 last break.

11 (Off record from 12:41 p.m. to 12:48 p.m.)

12 MR. HANSEN: Okay. Dr. Ahmann, I have no
13 further questions at this time.

14 MR. MASON: Maybe just give us five, ten
15 minutes? We're off the record.

16 (Off record from 12:49 p.m. to 1:26 p.m.)
17

18 EXAMINATION
19

20 BY MR. MASON:

21 Q Are you ready to resume your deposition,
22 Dr. Ahmann?

23 A Yes, I am.

24 Q Do you recall earlier today Mr. Hansen
25 asking you questions about reports?

1 A Yes.

2 Q In 2009 did the term "reports" have a well
3 understood meaning in the field?

4 MR. HANSEN: Objection as to form.

5 THE WITNESS: I don't believe it has a
6 specific definition at all or a term that we
7 used in that way.

8 BY MR. MASON:

9 Q And do you recall Mr. Hansen asking you
10 questions about the term "historical reports" in
11 Exhibit 1011?

12 A Yes.

13 Q Do you recall questions from Mr. Hansen
14 about CareLink reports being a type of historical
15 report?

16 A Yes.

17 MR. HANSEN: Objection as to form.

18 Characterization.

19 BY MR. MASON:

20 Q Can you think of any other examples of
21 historical reports?

22 A My definition -- I think anybody's
23 definition would be anything -- I think I mentioned
24 this earlier, anything that would be prior to the
25 time, to the immediate present time. So yes, I

1 think an example -- I should be able to -- yes.

2 So here would be an example in my mind of
3 two different historical reports. One is described
4 as the 3-hour report and the other one's the
5 24-hour, I should say graph, versus the 24-hour
6 graph. But that's historical information that's a
7 report to the patient or the physician is looking at
8 it at that point, it's for the physician as well.
9 So it's an example of a historical report as well.

10 Q And are you referencing a specific
11 document?

12 A I'm sorry. This is in the Medtronic -- and
13 I guess it's Exhibit 1011. And this is on page 64
14 of 105 in that exhibit.

15 Q Thank you. And do you recall Mr. Hansen
16 asking you questions about the standard of care
17 promulgated by the American Diabetes Association
18 earlier today?

19 A Yes.

20 Q And do you recall he asked you about
21 standards of care for 2005, 2006 and 2007?

22 A Yes, exactly.

23 Q And do you know if continuous glucose
24 monitoring ever became part of the standards of care
25 issued by the American Diabetes Association?

1 MR. HANSEN: Objection as to form.

2 THE WITNESS: Yes, it definitely became
3 integrated into the standards of care.

4 BY MR. MASON:

5 Q Do you recall when CGM became integrated
6 into the standards of care for the American Diabetes
7 Association?

8 MR. HANSEN: Objection as to form.

9 THE WITNESS: I can't give you a specific
10 year, but I would suspect -- remember when we
11 had the discussion on standards of care,
12 they're based on evidence. And so the only
13 reason that they weren't available in 2007, for
14 instance, was that they felt there was
15 inadequate evidence at that point.

16 A lot of the evidence was coming out
17 around that time. I think DirecNet had several
18 different publications. Dr. Buckingham was
19 very involved in those. And then probably the
20 most profound and most highly rated evidence
21 base around that time was the JDRF study, which
22 I believe was published in 2008.

23 And that would be the kind of
24 evidence that would lead the committee to put
25 that into the standards of care, put something

1 about CGM into the standards of care. So I
2 would think 2008, 2009 would be a good
3 potential time period.

4 MR. MASON: I have nothing further at this
5 time.

6

7

FURTHER EXAMINATION

8

9 BY MR. HANSEN:

10 Q So I have a few follow-up questions.

11 Dr. Ahmann, let's refer back to page 64 of
12 Exhibit 1011.

13 A Uh-huh.

14 Q Do you have that in front of you?

15 A Yes.

16 Q And your counsel just asked you some
17 questions and that's the page that you pointed us
18 to, page 64?

19 A Well, I think I could have -- that's the
20 page I pointed to. I think I could have found that
21 very similar thing in several other places, but yes,
22 that's the one I used.

23 Q Okay. When you first started to describe
24 this you said that it used the word "report" on this
25 page and then you corrected yourself. Because it

1 doesn't use the word "report" on this page, does it?
2 It uses the word "graph," but it doesn't use the
3 word "report," does it?

4 MR. MASON: Objection. Form.

5 THE WITNESS: I did correct to say that
6 the graph was titled as 3-hour and 24-hour.
7 And I didn't expound on the fact it said
8 "history" in the right-hand component of that
9 same graph. But I was trying to indicate that
10 from my mind, this would be a historical
11 report.

12 BY MR. HANSEN:

13 Q Okay. But the word "report" nowhere
14 appears on this page 64 of Exhibit 1011, correct?

15 MR. MASON: Objection. Form.

16 THE WITNESS: The word "report" is not
17 here. To me, the concept of report is here.

18 (Exhibit 2039, Article in Diabetes
19 Technology & Therapeutics: Recommendations
20 for Standardizing glucose Reporting and
21 Analysis to Optimize Clinical Decision
22 Making in Diabetes: The Ambulatory Glucose
23 Profile (AGP), was marked.)

24 BY MR. HANSEN:

25 Q I'm now going to hand you an exhibit marked

1 as Exhibit 2039.

2 MR. MASON: I'm going to object. It is
3 beyond the scope and belated introduction.

4 BY MR. HANSEN:

5 Q Do you recognize, Dr. Ahmann, this
6 document?

7 Well, first of all, do you see that you're
8 listed as one of the authors?

9 A Yes.

10 Q And it's a publication in the Journal of
11 Diabetes Technology & Therapeutics?

12 A Yes.

13 Q Do you recall this article?

14 A Yes, I recall the article in general. I
15 haven't reviewed it for a long time.

16 Q Could you refer to page 200 of your
17 article?

18 A Okay.

19 Q Do you see in the second column the
20 heading, Lack of standardization of glucose
21 reporting?

22 MR. MASON: Objection. Form. Scope.

23 THE WITNESS: It's in column 2 -- oh, you
24 mean the header. Okay. Lack of
25 Standardization, yes.

1 BY MR. HANSEN:

2 Q And do you see that under that header it
3 begins, Currently there are three commercial CGM
4 device manufacturers, DexCom in San Diego,
5 California, Medtronic in Northridge, California, and
6 Abbott Diabetes Care in Alameda, California?

7 A Yes.

8 Q And the next sentence says, Each of these
9 manufacturers provides software to download and
10 analyze the CGM data and generate a report or series
11 of reports?

12 A Yes.

13 Q So the reports that you're discussing here
14 in your article are reports that are downloaded, for
15 example, with CareLink?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: Yes, they are. But that
18 doesn't exclude the potential for other forms
19 of reports.

20 BY MR. HANSEN:

21 Q And there's no discussion here where you
22 describe the display on a user screen as a report,
23 correct?

24 MR. MASON: Objection. Form. Scope.

25 THE WITNESS: No. And I wouldn't have

1 expected us to because I would have been
2 getting into details of multiple different ones
3 and what the differences were. It wasn't the
4 purpose of this article.

5 BY MR. HANSEN:

6 Q A purpose of this article was to discuss
7 the lack of standardization of glucose reporting,
8 correct?

9 MR. MASON: Objection. Form. Scope.

10 THE WITNESS: I wouldn't say that's the
11 purpose of why we did this, the whole meeting.
12 As you can see, this was a consensus report
13 that came from a meeting of a large number of
14 people in the field.

15 BY MR. HANSEN:

16 Q You're not the only author, right?

17 A Right.

18 Q And each of the many authors would have
19 reviewed and contributed to the content of this?

20 A Right.

21 Q And each of the many authors would have
22 approved the content?

23 MR. MASON: Objection. Form. Scope.

24 THE WITNESS: In consensus. Each one
25 didn't have to approve the content, but as a

1 consensus we had to agree.

2 BY MR. HANSEN:

3 Q So as a consensus of the group of authors,
4 when discussing glucose reporting, you discussed the
5 reports that would be generated, for example, by
6 CareLink software?

7 MR. MASON: Objection. Form. Scope.

8 BY MR. HANSEN:

9 Q Not graphs on a user display, correct?

10 MR. MASON: Objection. Form. Scope.

11 THE WITNESS: Correct. Yes. But that
12 doesn't eliminate other possibilities for how
13 you would interpret or use reports. And I
14 think that's part of it when you say --

15 BY MR. HANSEN:

16 Q You spent a lot of time working on your
17 declaration, didn't you?

18 MR. MASON: Objection.

19 THE WITNESS: Yes.

20 BY MR. HANSEN:

21 Q Okay. You reviewed a lot of publications?

22 MR. MASON: Objection. Form.

23 THE WITNESS: Quite a few over time.

24 BY MR. HANSEN:

25 Q And a lot of those publications were

1 identified for you by DexCom's counsel, correct?

2 MR. MASON: Objection. Form.

3 THE WITNESS: The ones that came from --
4 the ones that came from Brian Gross'
5 declaration were ones that were, you know,
6 brought to my attention. Though, at the time I
7 was aware of all those articles, I know those
8 authors, I know them well.

9 But in addition, I added a couple
10 more in addition, yes.

11 BY MR. HANSEN:

12 Q And all the articles and other publications
13 and other sources that you cite in your declaration,
14 not a one uses the word "report" to describe the
15 graph on a user display of a CGM device, correct?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: I would have to go back
18 and -- I mean, I don't have time to review
19 those right now, but I can't say for sure or
20 not.

21 BY MR. HANSEN:

22 Q Well, let me ask the question this way:
23 Can you point me to any evidence in your declaration
24 where the document or authors use the word "report"
25 to refer to a graphical display on the user display?

1 MR. MASON: Objection. Form.

2 THE WITNESS: No, I can't. But I can't
3 tell you that anybody has excluded that either.

4 BY MR. HANSEN:

5 Q Let's go back to Exhibit 1011. I believe
6 you've testified that Exhibit 1011 are documents
7 created by Medtronic that related to its Paradigm
8 REAL-Time product; is that correct?

9 MR. MASON: Objection. Form.

10 THE WITNESS: Yes.

11 BY MR. HANSEN:

12 Q And I believe you've testified that the
13 Paradigm REAL-Time product received FDA approval in
14 2006, correct?

15 MR. MASON: Objection. Form.

16 THE WITNESS: Yes.

17 BY MR. HANSEN:

18 Q So the standards of care that were in place
19 when the Paradigm REAL-Time product was introduced
20 and received FDA approval were the standards of care
21 from 2006, correct?

22 MR. MASON: Objection. Form. Scope.

23 THE WITNESS: I think, as I mentioned
24 before, yes, they both occurred in 2006, but
25 that's not the way standards of care work.

1 BY MR. HANSEN:

2 Q And so you're saying that that's not the
3 way they work because they reflect evidence from
4 before 2006?

5 MR. MASON: Objection. Form.

6 THE WITNESS: There would have had to be
7 substantial evidence prior to, let's say, July
8 and certainly October of 2005.

9 BY MR. HANSEN:

10 Q And the documents that you're looking at in
11 Exhibit 1011, those documents were dated in the
12 latter part of 2007, correct?

13 MR. MASON: Objection. Form.

14 THE WITNESS: I believe these were taken
15 out of 2007, right.

16 BY MR. HANSEN:

17 Q And the standards of care in place in 2007
18 were the standards of care dated from the 2007
19 statement from the American Diabetes Association,
20 correct?

21 MR. MASON: Objection. Form.

22 THE WITNESS: 2007 standards were the
23 2000 standards that were produced in 2007,
24 yeah.

25 ///

1 BY MR. HANSEN:

2 Q When Medtronic published the content of
3 Exhibit 1011, the 2008 standards of care had not
4 been published, correct?

5 MR. MASON: Objection to form.

6 THE WITNESS: Correct.

7 BY MR. HANSEN:

8 Q And when Medtronic published the content of
9 Exhibit 1011, the 2009 standards of care did not
10 exist and had not been published, correct?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: Right.

13 BY MR. HANSEN:

14 Q And when Medtronic first introduced the
15 Paradigm REAL-Time system in 2006, the 2008 and 2009
16 and 2007 standards of care had not been published
17 and did not exist yet, correct?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: Correct.

20 BY MR. HANSEN:

21 Q And are you familiar with the FDA approval
22 process?

23 A In general.

24 Q So if the Paradigm REAL-Time received FDA
25 approval in 2006, when would you expect that the

1 design was finalized?

2 MR. MASON: Objection. Form. Scope.

3 BY MR. HANSEN:

4 Q Sometime prior to that?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: The Guardian RT was
7 obviously available even before that. The
8 Paradigm REAL-Time was a combination of the
9 Guardian RT with the pumps.

10 And so yes, I suspect that the
11 Guardian RT was a number of years before that
12 in terms of design. The Paradigm was probably
13 something they were working on for a couple
14 years before it was published or approved.

15 BY MR. HANSEN:

16 Q Would you expect the design of the Paradigm
17 REAL-Time was final sometime in -- by at least 2005?

18 MR. MASON: Objection. Form. Scope.

19 THE WITNESS: That would be conjecture. I
20 can't conjecture how long they would have had
21 it in front of the FDA, for instance.

22 BY MR. HANSEN:

23 Q Did Medtronic submit clinical data to
24 support FDA approval for Paradigm REAL-Time?

25 MR. MASON: Objection. Form. Scope.

1 THE WITNESS: Yes, they did.

2 BY MR. HANSEN:

3 Q Were you involved in those clinical
4 studies?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: I don't believe so, but you
7 have to -- I hope we're on the same page as to
8 what the FDA is looking for in devices. The
9 FDA looks for safety, they don't look for
10 efficacy. So the efficacy is what would get
11 them into the American Diabetes Association
12 standards of care. Safety is what would get
13 the product approved by the FDA. And I was on
14 panels for the FDA in the past that did look at
15 devices.

16 BY MR. HANSEN:

17 Q So my question is, I'm trying to get at
18 your understanding. Is this generally how it works,
19 that in order to get FDA approval for a device, the
20 manufacturer finalizes a design and then conducts
21 clinical studies using that design and then uses the
22 data from those clinical studies to submit their FDA
23 application?

24 MR. MASON: Objection. Form. Scope.

25 THE WITNESS: Yes.

1 BY MR. HANSEN:

2 Q So if the FDA gave approval in 2006 for the
3 Paradigm REAL-Time, the design would have been final
4 sometime before receiving FDA approval, correct?

5 MR. MASON: Objection. Form. Scope.

6 THE WITNESS: Yes.

7 BY MR. HANSEN:

8 Q And, in fact, the design would have been
9 final followed by clinical studies and then there
10 would have been a submission to the FDA, correct?

11 MR. MASON: Objection. Form. Scope.

12 THE WITNESS: Right. But again, the
13 clinical studies would be primarily safety
14 oriented and not efficacy oriented.

15 BY MR. HANSEN:

16 Q So the standards of care that were in place
17 published when the Paradigm REAL-Time design was
18 finalized, likely would have been from 2005 or
19 possibly at the latest 2006, but likely 2005,
20 correct?

21 MR. MASON: Objection. Form. Scope.

22 THE WITNESS: Could you repeat that? What
23 the first part of your question?

24 BY MR. HANSEN:

25 Q So you've said that the Paradigm REAL-Time

1 received FDA approval in 2006.

2 A I believe that's true.

3 Q Based on your experience with the FDA
4 approval process, how far in advance of FDA approval
5 was the Paradigm REAL-Time design final so that they
6 could begin clinical trials?

7 MR. MASON: Objection. Form. Scope.

8 THE WITNESS: I have no experience on that
9 side of the equation. Even when on the panel,
10 none of that would have been exposed to me as
11 to how long they had been in design.

12 BY MR. HANSEN:

13 Q So you can't say whether the 2006 or 2005
14 standards of care were in place when the Paradigm
15 REAL-Time design was final?

16 MR. MASON: Objection. Form. Scope.

17 THE WITNESS: I think you asked only 2005,
18 2006, I'm not certain. It would be conjecture
19 on my part.

20 MR. HANSEN: Okay. I have nothing
21 further.

22 MR. MASON: And I have nothing further.

23 The witness will read and sign.

24 (Proceedings ended at 1:48 p.m.)

25 (Signature reserved.)

1 REPORTER'S CERTIFICATE

2 I, VICTORIA A. GUERRERO, Certified Shorthand Reporter,
3 Registered Merit Reporter, Registered Professional Reporter,
4 Certified Realtime Reporter, in and for the State of Oregon
5 do hereby certify that, Rules of the United States Patent
6 and Trademark Office, ANDREW AHMANN, MD personally appeared
7 before me at the time and place mentioned in the caption
8 herein; that the witness was by me first duly sworn/affirmed
9 under oath and examined upon oral interrogatories propounded
10 by counsel; that said examination, together with the
11 testimony of said witness, was taken down by me in stenotype
12 and transcribed through computer-aided transcription; and
13 that the foregoing transcript, pages 1 through 138, review
14 requested by the witness or a party, constitutes a true
15 record of said examination of and testimony given by said
16 witness, and of all other oral proceedings had during the
17 taking of said deposition, and of the whole thereof.

18 IN WITNESS WHEREOF, I have hereunto set my hand
19 at Portland, Oregon, this Monday, October 14, 2024.

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21 
22

23 Victoria A. Guerrero, CSR, RDR, RMR, CRR
Thompson Court Reporters
24 Oregon CSR No. 14-0428 (exp. 9-30-2027)
Washington CCR No. 3293 (exp. 3-15-2025)
25 California CSR No. 8370 (exp. 3-15-2025)
Hawaii CSR No. 490 (exp. 12-31-2024)

1 CASE NAME : DEXCOM vs ABBOTT

2 DEPOSITION OF: ANDREW AHMANN

3 DATE TAKEN: OCTOBER 11, 2024

4

5 This is to certify that I have read the
6 transcript of my Deposition taken in the above-entitled
7 cause and that the foregoing transcript accurately
8 states the questions asked and the answers given by me
9 as they now appear.

10 Please check one:
11 _____ I made no corrections

12 _____ Number of corrections made

13 _____
ANDREW AHMANN

14 SUBSCRIBED AND SWORN TO

15 Before me this _____ day

16 of _____ A.D., 2023.

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Notary Public

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CORRECTION PAGE

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PAGE

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