UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
WACO DIVISION

DEXCOM, INC., Plaintiff v. ABBOTT DIABETES CARE, INC., ABBOTT DIABETES CARE SALES CORP. Defendant.	Civil Action No.: 6:21-cv-690

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff DexCom, Inc. ("DexCom" or "Plaintiff"), through its undersigned counsel, brings this action against Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp. (collectively, "Abbott" or "Defendants"). In support of this First Amended Complaint ("Complaint"), DexCom alleges as follows:

THE PARTIES

1. Plaintiff DexCom, Inc. is a Delaware corporation having its principal place of business at 6340 Sequence Drive, San Diego, CA 92121.

2. DexCom is the owner by assignment of U.S. Patent No. 11,000,213 ("the '213 Patent") (attached as Exhibit 1), U.S. Patent No. 10,980,452 ("the '452 Patent") (attached as Exhibit 2), U.S. Patent No. 10,702,215 ("the '215 Patent") (attached as Exhibit 3), U.S. Patent No. 10,702,193 ("the '193 Patent") (attached as Exhibit 4), and U.S. Patent No. 10,993,642 ("the '642 Patent") (attached as Exhibit 5) (collectively, the "Patents-in-Suit").

3. Defendant Abbott Diabetes Care, Inc. is a Delaware corporation with its principal place of business at 1360 South Loop Road, Alameda, CA 94502.

4. Defendant Abbott Diabetes Care Sales Corp. is a Delaware corporation with its principal place of business at 1360 South Loop Road, Alameda, CA 94502.

5. Abbott Diabetes Care Sales Corp. is registered to do business in Texas.

6. Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp. have regular and established places of business in this District, including at 8701 Bee Caves Rd., Austin, TX 78746 and 12501B Research Boulevard, Austin, TX 78759. On information and belief, Abbott Diabetes Care, Inc. employs quality managers, program managers, and manufacturing process engineers among others at those locations. Upon information and belief, Abbott Diabetes Care, Inc. uses and manufactures infringing Abbott products in this district, while Abbott Diabetes Care Sales Corp. uses, offers to sell, and sells infringing products in this district.

7. The Diabetes Care division of Abbott Laboratories, which on information and belief includes at least Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp., is or has also solicited employees in this district including posting open positions in Austin, Texas for a Project Manager and a Senior Manufacturing Process Engineer.

8. Adam Heller, a co-founder of TheraSense, which was acquired by Abbott in 2004 and became Abbott Diabetes Care, is a professor emeritus in Chemical Engineering at The University of Texas at Austin. https://che.utexas.edu/faculty-staff/faculty-directory/heller/

9. Abbott employees in this District will likely have information relevant to the accused products, infringement, and damages, including how the components of the infringing products are sourced, what materials are used in the infringing products, how the infringing products are manufactured, how the infringing products are sterilized, how the infringing products are calibrated, and how many products are manufactured, among other relevant issues.

10. Abbott has placed or contributed to placing infringing products like the Abbott Freestyle Libre 2 Flash Glucose Monitoring System ("Abbott Libre 2") and the Abbott Freestyle Libre 14 day ("Abbott Freestyle") into the stream of commerce via an established distribution channel knowing or understanding that such products would be sold and used in the United States, including in the Western District of Texas. On information and belief, Abbott has also derived substantial revenues from infringing acts in the Western District of Texas, including from the sale and use of infringing products like the Abbott Libre 2.

JURISDICTION AND VENUE

11. This is a Complaint including causes of action for patent infringement arising under 35 U.S.C. § 271 et seq. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 1367.

12. This Court has specific personal jurisdiction over Defendants at least because Defendants conduct business in this Judicial District. DexCom's causes of action arise, at least in part, from Defendants' contacts with and activities in the State of Texas and this Judicial District. Upon information and belief, Defendants have committed acts of infringement within the State of Texas and this Judicial District by, *inter alia*, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the '213 Patent, the '452 Patent, the '215 Patent, '193 Patent, and/or the '642 Patent.

13. Abbott has committed acts within this District giving rise to this action and has established sufficient minimum contacts with the State of Texas such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), (c), and 1400(b) because (1) Defendants have a regular and established place of business in this Judicial District, and (2) Defendants have committed and continue to commit acts of patent infringement in this Judicial District by, inter alia, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the '213 Patent, the '452 Patent, the '215 Patent, the '193 Patent, and/or the '642 Patent.

THE PATENTS-IN-SUIT

15. This action involves the following patents: U.S. Patent No. 11,000,213, U.S. Patent No. 10,980,452, U.S. Patent No. 10,702,215, U.S. Patent No. 10,702,193, and U.S. Patent No. 10,993,642.

16. DexCom is the owner, by assignment, of U.S. Patent No. 11,000,213, titled "System and methods for processing analyte sensor data for sensor calibration." A true and correct copy of

U.S. Patent No. 11,000,213 granted by the U.S. Patent & Trademark Office is attached as Exhibit 1.

17. DexCom is the owner, by assignment, of U.S. Patent No. 10,980,452, titled "Analyte sensor." A true and correct copy of U.S. Patent No. 10,980,452 granted by the U.S. Patent & Trademark Office is attached as Exhibit 2.

18. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,215, titled "Systems and methods for dynamically and intelligently monitoring a host's glycemic condition after an alert is triggered." A true and correct copy of U.S. Patent No. 10,702,215 granted by the U.S. Patent & Trademark Office is attached as Exhibit 3.

19. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,193, titled "Analyte sensing biointerface." A true and correct copy of U.S. Patent No. 10,702,193 granted by the U.S. Patent & Trademark Office is attached as Exhibit 4.

20. DexCom is the owner, by assignment, of U.S. Patent No. 10,993,642, titled "Analyte sensor." A true and correct copy of U.S. Patent No. 10,993,642 granted by the U.S. Patent & Trademark Office is attached as Exhibit 5. A true and correct copy of the certificate of correction for US 10,993,642 is attached as Exhibit 6.

BACKGROUND

21. The human pancreas plays an essential role in converting the food we eat into fuel for the body's cells. The pancreas has two main functions: an exocrine function that helps in digestion and an endocrine function that regulates blood sugar. Two of the main pancreatic hormones are insulin, which acts to lower blood sugar, and glucagon, which acts to raise blood sugar. Maintaining proper blood sugar levels is crucial to the functioning of key, life-sustaining organs including the brain, liver, and kidneys.

22. Diabetes mellitus is a disorder in which the pancreas either cannot create sufficient insulin, or in which insulin is not effective. *See, e.g.,* '213 Patent at 1:40-43. Diabetes comes in two types. A person whose pancreas cannot create sufficient insulin has Type 1 or insulin

dependent diabetes. *Id*. A person whose body does not use insulin effectively has Type 2 or non-insulin dependent diabetes. *Id.*

23. More than 34 million Americans suffer from diabetes. https://www.diabetes.org/resources/statistics/statistics-about-diabetes. It is the seventh leading cause of death in the United States. *Id.*

24. In the diabetic state, the victim suffers from high blood sugar. *See, e.g.*, '213 Patent at 1:43-47. Left untreated, long-term high blood sugar, or hyperglycemia, can lead to kidney failure, nerve damage, and blindness, among other health related issues. https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631. Treating persistent hyperglycemia often requires insulin. https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-treatment/art-20044084. The use of insulin, however, can also be dangerous if not properly monitored. It can lead to the opposite problem, low blood sugar.

25. The condition of having low blood sugar, known as hypoglycemia, in people with diabetes is generally the result of either an inadvertent overdose of insulin, or after a normal dose of insulin, an extraordinary amount of exercise or insufficient food intake. '213 Patent at 1:47-51. Hypoglycemia can be dangerous and if left untreated, it can result in muscle weakness, confusion, unconsciousness, or even death. https://www.mayoclinic.org/diseases-conditions/diabetic-hypoglycemia/symptoms-causes/syc-20371525.

26. Historically, people with diabetes often had to carry around and frequently use a self-monitoring blood glucose (SMBG) monitor. SMBGs typically required the patient to prick their finger to collect a small amount of blood that would be used to measure blood glucose levels at that moment in time. '213 Patent at 1:52-54. Because the time intervals between these measurements could be spread far apart, people with diabetes often did not find out they were experiencing hyper- or hypo-glycaemia until it was too late. *Id*. at 1:54-60.

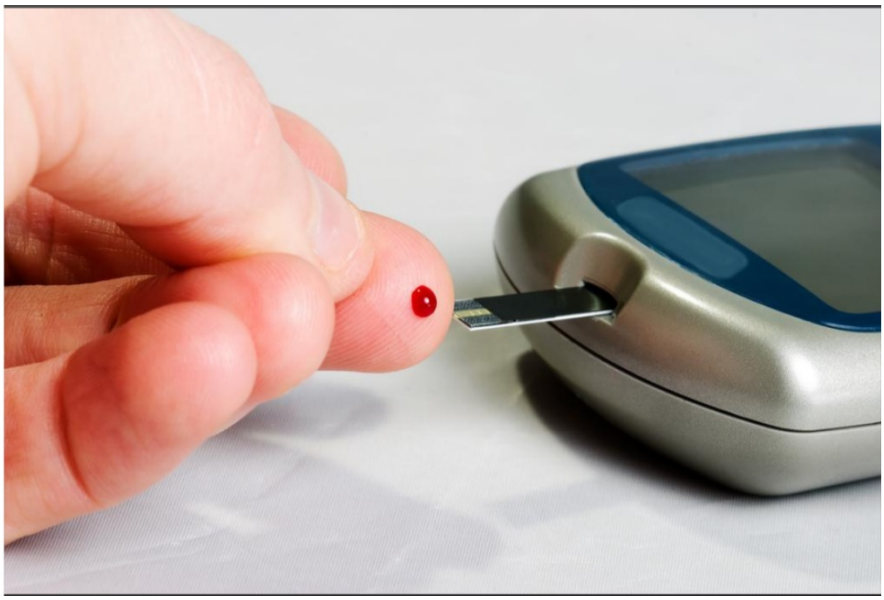


Figure 1

27. DexCom's continuous glucose monitoring systems ("CGMs") offer a more convenient method for tracking glucose levels which can provide more robust data regarding glucose trends as compared to point-in-time SMBG measurements. DexCom's CGMs measure glucose levels in the interstitial fluid. Generally, the monitor itself consists of a sensor that is worn on the body and automatically obtains glucose readings. The data is transmitted to a nearby receiver to display the readings. DexCom's CGMs allow users to see almost immediately when their blood glucose departs from an ideal range, and also allow users (and potentially their care givers and health care providers) to see the trend of their blood glucose. DexCom's CGMs also help people make informed decisions about nutrition, physical activity, and medication.

28. DexCom is a pioneer in the field of CGMs. In 2006, DexCom introduced its first generation CGM to help people more conveniently and effectively manage their blood sugar levels. The Dexcom G5 Mobile was the world's first real time CGM approved for adults and children two years and older. The G5 was also the world's first CGM that could interoperate with an app on a user's smartphone rather than requiring the user to carry around a separate receiver.

29. Today, DexCom sells the Dexcom G6 integrated continuous glucose monitoring ("iCGM") system for determining glucose levels in children two years and older and adults with

diabetes. The Dexcom G6 is indicated by the FDA for use as both a standalone CGM and for integration with third party devices, *i.e.*, iCGM. It is the first FDA-approved iCGM system, designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems.

Figure 2

INVENTIVE CONCEPTS OF THE PATENTS-IN-SUIT

30. The claims of the Patents-in-Suit disclose a number of innovations DexCom has introduced for monitoring glucose. For example, the ’213 and ’642 Patents disclose novel innovations that allows DexCom to perform factory calibration on its sensors, which obviates the need for the user to perform manual calibration, which require at least one finger-stick, on its sensors.

31. As another example, the ability of certain glucose monitors to be worn for long periods of time raises other types of problems. In order to effectively function for the life of the sensor, the sensor has to be protected from water that would otherwise damage the sensor electronics. The ’452 Patent discloses an innovative sealing design that enables the sensor to resist water such as in a shower or a pool and operate continuously over its lifetime.

32. The ’215 Patent discloses another innovation DexCom made to improve the usability and benefits provided by the use of glucose monitors. Whereas, prior art glucose monitors required users to check their blood glucose levels to determine whether they were too low or too high, the ’215 Patent discloses a system that provides automatic notifications when detected blood glucose levels are at potentially dangerous levels. The two-indicator system disclosed by the ’215 Patent further allows the user to be notified before the onset of a hypo-glycemic state so that corrective action can be taken.

33. The ’193 Patent discloses a novel arrangement of layers for the transcutaneous sensor that, among other benefits, improves the accuracy of the sensor after insertion as well as the spacing of the electrodes to reduce a user’s pain during and after sensor insertion.

34. Each of these patent-protected innovations is used by Abbott without DexCom’s permission in its infringing FreeStyle Libre devices, including but not limited to the FreeStyle Libre 14 day, the FreeStyle Libre 2, and the FreeStyle Libre 3 (collectively, the “FreeStyle Libre Products”).

COUNT I

Abbott’s Infringement of U.S. Patent No. 11,000,213

35. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

36. DexCom is the owner, by assignment, of U.S. Patent No. 11,000,213, titled “System and methods for processing analyte sensor data for sensor calibration.” A true and correct copy of the ’213 Patent is attached as Exhibit 5.

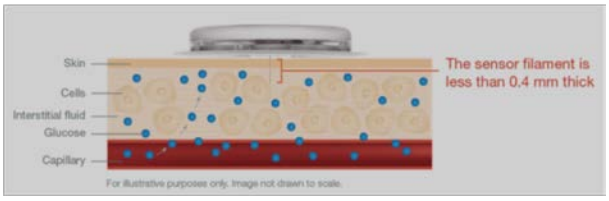
37. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the ’213 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products with factory calibration in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.*, https://abbott.mediaroom.com/2017-09-27-No-More-Routine-Finger-Sticks-1-for-Americans-with-Diabetes-Abbott-s-FreeStyle-R-Libre-Approved-in-the-U-S.

38. At least as of the filing of the complaint on June 30, 2021, Abbott has knowledge of the ’213 Patent.

39. As a non-limiting example, the Abbott Libre 2 is a glucose monitoring system that infringes claim 1 of the ’213 Patent.

See, e.g., Abbott Libre 2 User’s Manual at 18.

40. The Abbott Libre 2 includes a transcutaneous electrochemical glucose sensor having an in vivo portion configured to be inserted into a body of a host; and an ex vivo portion configured to remain outside of the body of the host.



See, e.g., https://www.freestyle.abbott/za/en/benefits-of-cgm.html.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor

Measures your glucose while on your body (only visible after applied).

Libre 2 User Manual at 18.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

41. The Abbott Libre 2 includes a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous electrochemical glucose sensor in the host, wherein the sensor data is associated with a glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor, and wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the in vivo portion of the transcutaneous electrochemical glucose sensor.

Images of the Freestyle Libre 2 processor(s) in the sensor and handheld receiver.

What is Factory Calibration?

Factory calibration of sensors removes the need for determining the sensor sensitivity from the user's responsibility and instead places it in the hands of the sensor manufacturer. The sensor sensitivity is determined during the sensor manufacturing process, and that information is included with every sensor in the form of a sensor code. That code can be preprogrammed into the sensor electronics such that no user interaction is required to enter the code, eliminating the risk of transcription error.

The factory calibration process includes the following steps:

- Manufacture sensor lots with low sensor to sensor variability.
- Sample a number of sensors from each sensor lot and test them in the laboratory (in vitro) for their response to glucose and determine their glucose sensitivity.
- Convert the lot glucose sensitivity into a sensor code.
- Program the sensor code into the sensor electronics memory.
- Demonstrate that the initially determined sensor sensitivity does not change over the sensor shelf life.

Since the variation between the sensors in one sensor lot is small, the laboratory tested sensors are representative of the remaining sensors in the sensor lot, which will be used by patients. The code information provides the necessary sensor sensitivity or calibration factor for every sensor in the sensor lot to convert the electrical sensor current into a glucose value. The determination of the code may include corrections for the difference between in vitro and in vivo sensor testing, which can be determined analytically or empirically through clinical trials, and which can be applied universally to all sensor lots.

This process determines how the sensor responds to glucose and will provide glucose data after sensor insertion without the necessity of a BG test by the user. It does, how-

See, e.g., Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, Udo Hoss at S-45 (annotated); *see also* FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary.

42. On information and belief, Abbott, with knowledge of the ’213 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the ’213 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the ’213 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users’ direct infringement and that Abbott’s acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of the June 30, 2021, complaint.

43. Abbott’s infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT II

Abbott’s Infringement of U.S. Patent No. 10,980,452

44. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

45. DexCom is the owner, by assignment, of U.S. Patent No. 10,980,452, titled “Analyte sensor.” A true and correct copy of the ’452 Patent is attached as Exhibit 2.

46. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the ’452 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.*, https://www.diabetescare.abbott/products.html.

47. At least as of the filing of the complaint on June 30, 2021, Abbott has knowledge of the ’452 Patent.

48. As a non-limiting example, the Abbott Libre 2 comprises a system for measuring an analyte concentration in a host.

See, e.g., Abbott Libre 2 User's Manual at 18.

49. The Abbott Libre 2 comprises a transcutaneous analyte sensor.

> The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

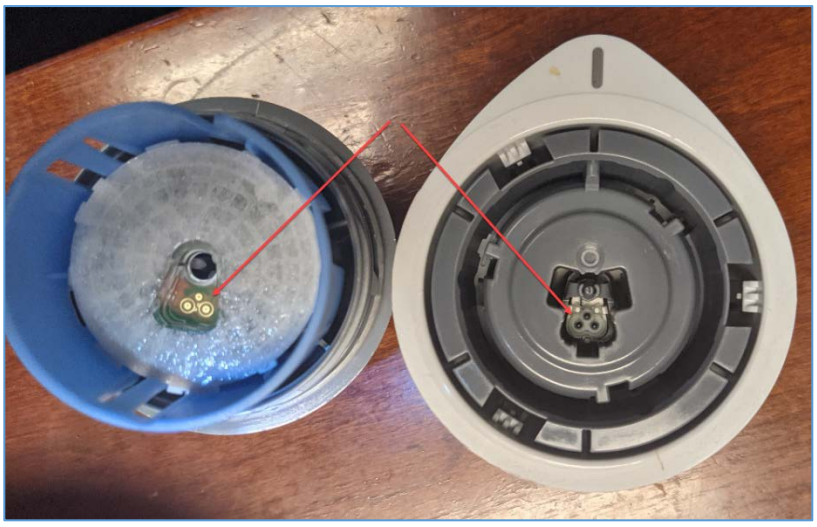
See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

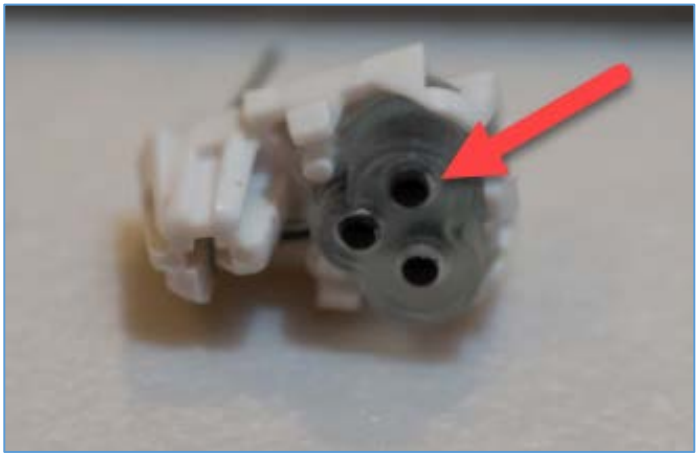
50. The Abbott Libre 2 comprises sensor electronics configured to operatively connect to the transcutaneous analyte sensor.

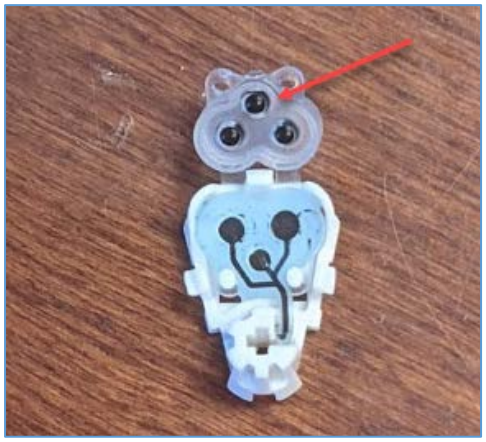
> The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

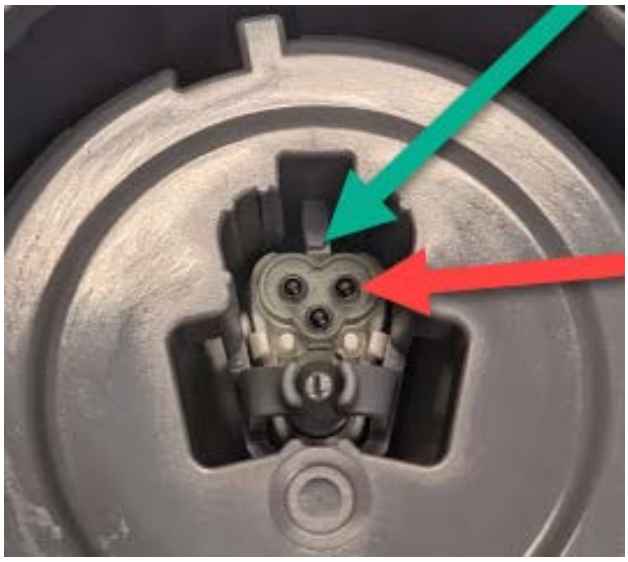
51. The Abbott Libre 2 comprises an electrical contact configured to operably connect the transcutaneous glucose sensor to the sensor electronics.

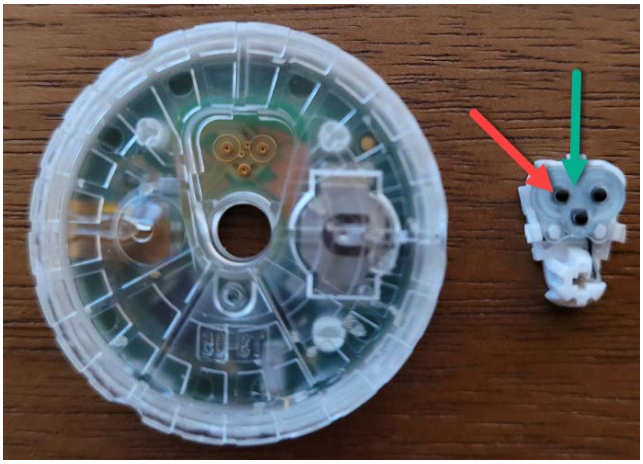






52. The Abbott Libre 2 comprises a sealing member comprising a sealing member upper portion and a sealing member lower portion, wherein the sealing member at least partially surrounds the electrical contact and at least a portion of the transcutaneous glucose sensor when the transcutaneous glucose sensor is operably connected to the sensor electronics, wherein the sealing member substantially seals at least a portion of the electrical contact from moisture, and wherein an ex vivo portion of the transcutaneous glucose sensor is sandwiched between the sealing member upper portion and the sealing member lower portion.



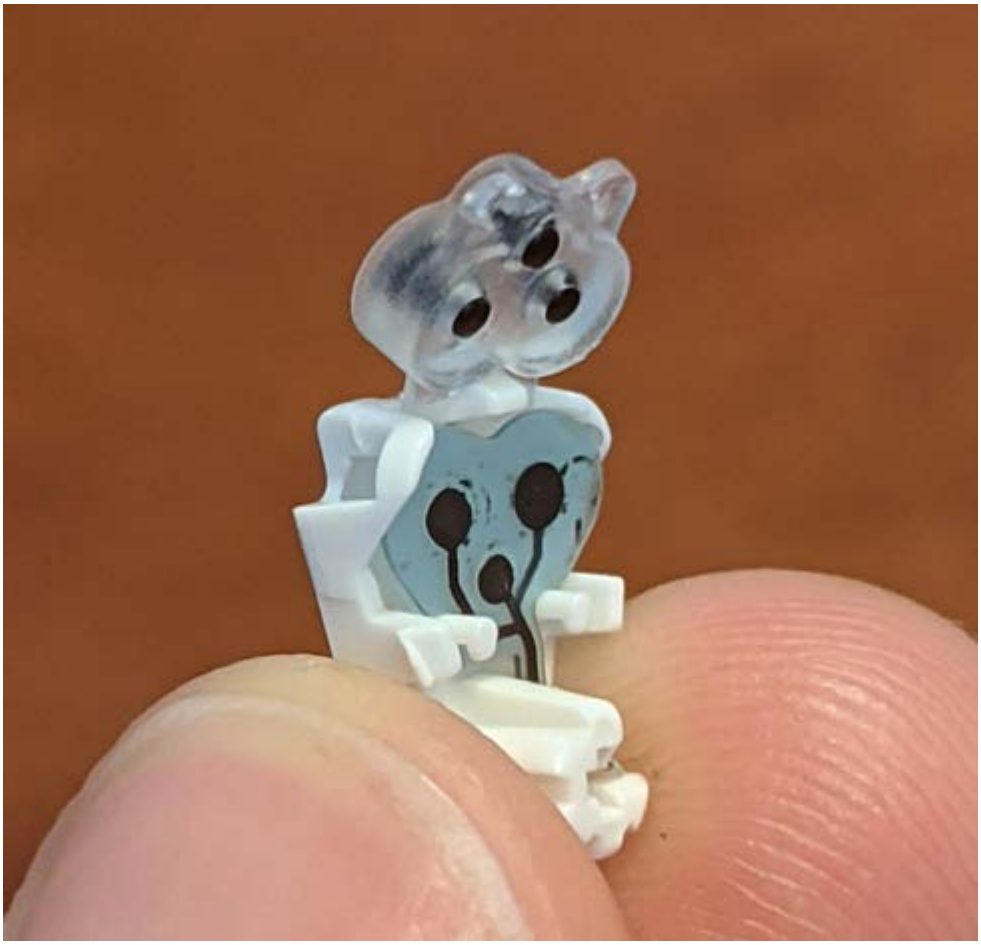


Living With Your System

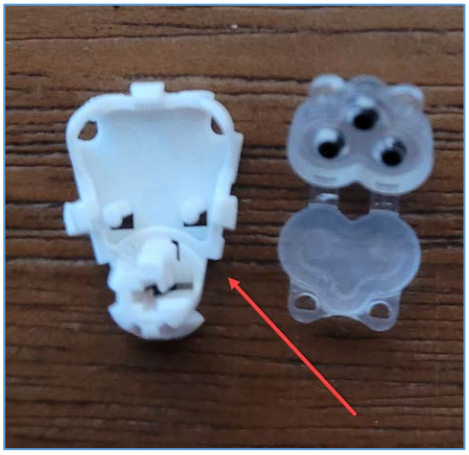
Your System can be used during a wide variety of activities.

Activity	What You Need To Know
Bathing, Showering, and Swimming	The Reader is not water-resistant and should NEVER be submerged in water or other liquid. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your Sensor deeper than 3 feet (1 meter) or immerse it longer than 30 minutes in water.

See, e.g., User Manual at 99.



53. The Abbott Libre 2 comprises a contact holder over which the sealing member and the transcutaneous glucose sensor are at least partially located.



54. On information and belief, Abbott, with knowledge of the '452 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '452 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '452 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of the June 30, 2021, complaint.

55. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT III

Abbott's Infringement of U.S. Patent No. 10,702,215

56. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

57. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,215, titled "Systems and methods for dynamically and intelligently monitoring a host's glycemic condition after an alert is triggered." A true and correct copy of the '215 Patent is attached as Exhibit 3.

58. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 19 of the '215 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the FreeStyle Libre 2 with glucose alarms in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.*, https://www.freestyle.abbott/us-en/products/freestyle-libre-2.html.

59. At least as of the filing of the complaint on June 30, 2021, Abbott has knowledge of the '215 Patent.

60. As a non-limiting example, the Abbott Libre 2 meets the elements of at least claim 19 of the '215 Patent. It is a system for processing data.

> The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

61. The Abbott Libre 2 comprises a continuous analyte sensor configured to be implanted within the body.

> The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., Id.

62. The Abbott Libre 2 comprises sensor electronics configured to receive and process sensor data output by the sensor.

> The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., Id.

63. The Abbott Libre 2 comprises a processor configured to evaluate sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria.

> The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.
>
> The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

> System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.

See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

64. The Abbott Libre 2 comprises a processor configured to evaluate sensor data using a second function to determine whether a parameter indicative of a glucose value meets one or more non-user settable second criteria.

> The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.
>
> The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

> System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.

See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

65. The Abbott Libre 2 comprises a processor configured to activate a first hypoglycemic indicator if the one or more user settable first criteria is met and activate a second hypoglycemic indicator if the one or more non user settable second criteria are met.

> The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.
>
> The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

> System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.

See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

66. The Abbott Libre 2 comprises a processor configured to provide an output based on the activated hypoglycemic indicator.

> The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.
>
> The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

> System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.

See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

67. On information and belief, Abbott, with knowledge of the '215 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '215 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '215 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing glucose monitoring systems, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition,

Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of the complaint on June 30, 2021.

68. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT IV

Abbott's Infringement of U.S. Patent No. 10,702,193

69. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

70. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,193, titled "Analyte sensing biointerface." A true and correct copy of the '193 Patent is attached as Exhibit 4.

71. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '193 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the Libre 2 devices, in the United States in violation of 35 U.S.C. § 271(a). *See, e.g.*, https://www.diabetescare.abbott/products.html.

72. At least as of the filing of the complaint on June 30, 2021, Abbott has knowledge of the '193 Patent.

73. As a non-limiting example, the Abbott Libre 2 is a transcutaneous continuous glucose sensor system.

See, e.g., Abbott Libre 2 User's Manual at 18.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor

Measures your glucose while on your body (only visible after applied).

See, e.g., Libre 2 User Manual at 18.

74. The Abbott Libre 2 comprises a substantially planar sensor.

75. The Abbott Libre 2 comprises a first conductive layer associated with a first electrode.

76. The Abbott Libre 2 comprises a first non-conductive layer located at least in part over the first conductive layer.

78. The Abbott Libre 2 comprises a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer.

79. The Abbott Libre 2 comprises a second non-conductive layer located at least in part over the second conductive layer.

80. The Abbott Libre 2 comprises a third conductive layer associated with a third electrode, wherein the third conductive layer is located at least in part over the second non-conductive layer.

81. The Abbott Libre 2 comprises a membrane located over at least a portion of a working electrode.

82. The Abbott Libre 2 includes at least one of the first electrode, the second electrode, or the third electrode is the working electrode, and wherein the working electrode is configured to measure a signal indicative of a glucose concentration.

83. On information and belief, Abbott, with knowledge of the '193 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '193 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '193 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of the complaint on June 30, 2021.

84. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT V

Abbott's Infringement of U.S. Patent No. 10,993,642

85. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

86. DexCom is the owner, by assignment, of U.S. Patent No. 10,993,642, titled "Analyte Sensor." A true and correct copy of the '642 Patent is attached as Exhibit 5.

87. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '642 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the Libre 2 devices with factory

calibration, in the United States in violation of 35 U.S.C. § 271(a). *See, e.g.*, https://abbott.mediaroom.com/2017-09-27-No-More-Routine-Finger-Sticks-1-for-Americans-with-Diabetes-Abbott-s-FreeStyle-R-Libre-Approved-in-the-U-S.

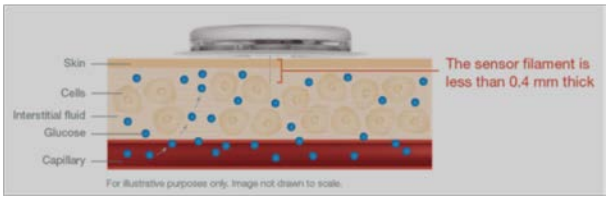
88. At least as of the filing of the complaint on June 30, 2021, Abbott has knowledge of the '642 Patent.

89. As a non-limiting example, the Abbott Libre 2 is a glucose monitoring system that infringes claim 1 of the '642 Patent.

See, e.g., Abbott Libre 2 User's Manual at 18.

90. The Abbott Libre 2 includes a transcutaneous glucose sensor having an in vivo

portion configured to be inserted into a body of a host; and an ex vivo portion configured to remain outside of the body of the host.



See, e.g., https://www.freestyle.abbott/za/en/benefits-of-cgm.html.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor

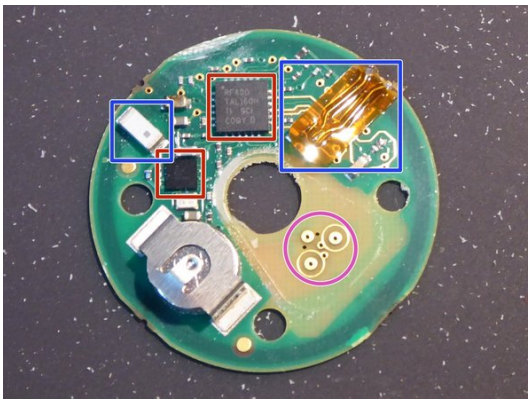
Measures your glucose while on your body (only visible after applied).

Libre 2 User Manual at 18.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

91. The Abbott Libre 2 includes a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous glucose sensor in the host, wherein the sensor data is associated with a glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous glucose sensor, wherein the prior calibration information is associated with a sensor code, wherein the sensor code is located in or on a packaging holding the transcutaneous glucose sensor, wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the in vivo portion of the transcutaneous glucose sensor.



Images of the Freestyle Libre 2 processors in the sensor and handheld receiver.

What is Factory Calibration?

Factory calibration of sensors removes the need for determining the sensor sensitivity from the user's responsibility and instead places it in the hands of the sensor manufacturer. The sensor sensitivity is determined during the sensor manufacturing process, and that information is included with every sensor in the form of a sensor code. That code can be preprogrammed into the sensor electronics such that no user interaction is required to enter the code, eliminating the risk of transcription error.

The factory calibration process includes the following steps:

- Manufacture sensor lots with low sensor to sensor variability.
- Sample a number of sensors from each sensor lot and test them in the laboratory (in vitro) for their response to glucose and determine their glucose sensitivity.
- Convert the lot glucose sensitivity into a sensor code.
- Program the sensor code into the sensor electronics memory.
- Demonstrate that the initially determined sensor sensitivity does not change over the sensor shelf life.

Since the variation between the sensors in one sensor lot is small, the laboratory tested sensors are representative of the remaining sensors in the sensor lot, which will be used by patients. The code information provides the necessary sensor sensitivity or calibration factor for every sensor in the sensor lot to convert the electrical sensor current into a glucose value. The determination of the code may include corrections for the difference between in vitro and in vivo sensor testing, which can be determined analytically or empirically through clinical trials, and which can be applied universally to all sensor lots.

This process determines how the sensor responds to glucose and will provide glucose data after sensor insertion without the necessity of a BG test by the user. It does, how-

See, e.g., Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, Udo Hoss at S-45 (annotated); *see also* FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary.

92. On information and belief, Abbott, with knowledge of the ’642 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the ’642 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the ’642 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users’ direct infringement and that Abbott’s acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of the complaint on June 30, 2021.

93. Abbott’s infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all issues deemed to be triable by a jury.

PRAYER FOR RELIEF

WHEREFORE, DexCom requests the Court grant the relief set forth below:

A. Enter judgment that Defendants have infringed, and continue to infringe, one or more claims of the ’213 Patent, the ’452 Patent, the ’215 Patent, ’193 Patent, and/or the ’642 Patent;

B. Temporarily, preliminarily, or permanently enjoin Defendants, their parents, subsidiaries, affiliates, divisions, officers, agents, servants, employees, directors, partners, representatives, all individuals and entities in active concert and/or participation with them, and

all individuals and/or entities within their control from engaging in the aforesaid unlawful acts of patent infringement;

C. Order Defendants to account for and pay damages caused to DexCom by Defendants' unlawful acts of patent infringement in an amount to be proven at trial, together with pre-judgment and post-judgment interest at the maximum rate permitted by law;

D. Award DexCom the interest and costs incurred in this action; and

E. Award DexCom such other and further relief, including equitable relief, as the Court deems just and proper.

DATED: July 12, 2021

Respectfully submitted,

By */s/ Charles Ainsworth*

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served this 12th day of July, 2021, with a copy of this document via the Court's CM/ECF system.

/s/ *Charles Ainsworth*
CHARLES AINSWORTH