

The FreeStyle Libre 3 + continuous glucose monitor system

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INTRODUCTION

The FreeStyle Libre 3 + continuous glucose monitor system (CGM) measures a diabetes patient's glucose concentration once every minute with a small disposable sensor (about the size and shape of a stack of two pennies) adhesively fastened to the patient's upper arm, with a small flexible probe extending through the skin into the interstitial fluid, in which the glucose concentration is measured.

The glucose level readings are sent by Bluetooth to a small "reader" unit or to a smartphone equipped with the appropriate app. The readings are stored there and can be displayed as a graph and in other ways. They can also be transmitted from that receiving device, over the Internet, to a central database facility, and from there can be accessed by the patient's physician.

A sensor will operate for up to 15 days, and by that time would normally be replaced, usually done by the patient. The process is fairly simple.

This article describes the system and its construction, features, and operation.

1 BACKGROUND

For persons afflicted with the disease *diabetes mellitus* ("diabetes" for short), it is important to remain aware of the concentration of glucose in the blood (the "blood sugar" level). The pattern of this value is important for the patient's physician in assessing the efficacy of the patient's diabetes treatment regimen.

In addition, ideally, the patient will adjust the dose of insulin to be self-administered before each meal based, in part, on the blood glucose concentration existing at that time.

Classically, the determination by the patient of his glucose concentration is done with a "finger stick" instrument. With this, a spring loaded "lancing device" propels a small blade a short distance into the patient's finger, provoking the discharge of a small drop of capillary blood.

This is then picked up, by capillarity(!), with the tip of a disposable "test strip" projecting from the test instrument. Through a very clever

electrochemical process, from this the instrument can ascertain the glucose concentration in this small drop of blood. This is closely related to the actual glucose concentration in arterial blood, which is the metric of actual interest.

The patient can then note this and perhaps record it on a “log sheet” (although typically the instrument will store the readings for quite a period).

There are a number of disadvantages of such a system. Making this test several times a day is an inconvenience, albeit small. But perhaps the most prominent shortcoming is that, for the patient’s physician to have the best understanding of the working of the patient’s diabetes therapy, it is desirable to know how the glucose level varies over the day (including overnight), perhaps as finely as once per hour. But it is not practical for the patient, for example, to make a measurement with a finger-stick instrument every hour of the day (and certainly not overnight).

This problem is overcome by the use of a continuous glucose monitor (CGM) system. In this, a sensor, responsive to the patient’s glucose level, remains in place on the patient. It determines the glucose level at short intervals, and in some way transfers these to a receiving device that will display the most recent reading (and may, for example, provide graphs of the readings over various periods of time, and give various statistical summaries).

The system described in this article is a modern example of a CGM system, the FreeStyle Libre 3+ system (sometimes styled as the “FreeStyle Libre 3 Plus” system), made by Abbott Diabetes Care, Inc., a unit of Abbott Laboratories.

2 DISCLAIMER

Nothing in this article is intended as medical advice. Discussions of the use of the system are based on information in the literature, and are included here only to give context for the technical discussion of the system.

The description here of this CGM system is in no way meant to recommend this product over other comparable products.

3 PERSONAL EXPERIENCE

I have type 2 diabetes, and use insulin as part of my therapy. In April, 2020, at the suggestion of my endocrinologist, I began using an earlier version of this continuous glucose monitor system, the FreeStyle Libre 14-Day CGM system. The system has generally behaved well, and has proven to be very beneficial to the management of my diabetes.

In March, 2026, at the suggestion of the manufacturer of these systems, and with the concurrence of my endocrinologist, I converted to the use of the FreeStyle Libre 3+ system, a newer product from the same manufacturer, the system described in this article.

4 TERMINOLOGY

4.1 About “patient”

In this article I refer to the person using the CGM system as the “patient”, rather than as the “user”, as we might expect.

This is in keeping with the language most often used by the manufacturer of the system. It is consistent with the fact that this system is normally only available on the prescription of a physician¹, presumably in the course of the person’s treatment for diabetes or such, the person thus being a “patient”.

4.2 Names for components

The names I use here for the various components of the system are my own. They often differ, for example, from the terms used in such documents as the patents concerning the system, which in some cases are not as descriptive.

5 THE SENSOR

5.1 Placement

The preferred location of the sensor is on the back of the upper arm.

5.2 Appearance and dimensions

Figure 1 shows the FreeStyle Libre 3+ sensor from the “back” as it would appear when in place on the patient’s skin.



Figure 1. FreeStyle Libre 3+ sensor as installed, from the back

Photo by Douglas A. Kerr

¹ In this article I will refer to the medical “provider” involved as a “physician”, recognizing that in many cases this might actually be a medical paraprofessional, such as a “physician’s assistant” or “certified nurse practitioner” (which in some states, or in some written contexts, may also be identified as “physicians”).

The 3+ sensor is approximately 0.83" (21 mm) in diameter and is approximately 0.12 (3 mm) thick. It weighs approximately 0.04 oz (1 g).

Figure 2 shows the sensor as it would be when emplaced (but here not emplaced), seen from the front, the side that would actually be against the skin of the patient's arm, then held in place with a circular disk of double sided tape with a very tenacious adhesive (not present in this photo).



Figure 2. Sensor as installed, from the front

Photo by Douglas A. Kerr

5.3 The probe and introducer needle

The small black "tail" arising from the sensor (seen in Figure 2) is the flexible probe that will be in the patient's flesh. It carries at its tip the actual glucose concentration detector.

It is initially surrounded by a small "U" cross-section metal channel with a sharp pointed end, the "introducer needle" (not present in Figure 2). This will enable the probe to be pushed into the patient's flesh, which we could not do with the probe itself (it being "limp as a noodle"). We see it (not in place) on the left in Figure 3.

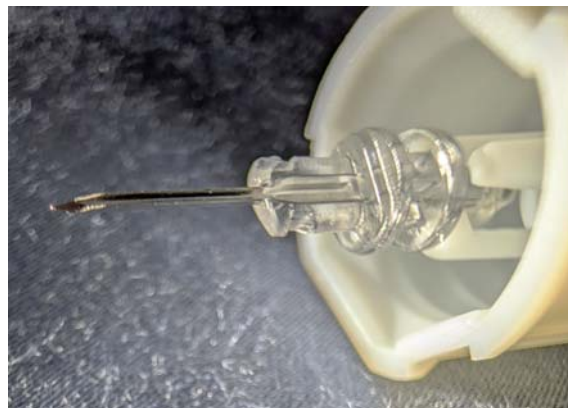


Figure 3. Introducer needle, hub, and extraction cup

To the right we see the introducer needle hub (clear plastic), which holds the needle in place. Further to the right we see the hub's tail gripped by latches in the needle extraction cup (white), which will eventually pull the needle clear.

The needle is approximately 0.4 mm in width and a little greater than that in depth, its diagonal dimension roughly corresponding to the diameter of a 23 gauge hypodermic needle. Approximately 5 mm of its length will enter the patient's flesh.

Before the applicator is opened, the probe (with the surrounding introducer needle) is protected and kept sterile by a hermetically-sealed tubular needle cap.

5.4 The sensor applicator

The sensor applicator (hereinafter generally just "applicator") contains the complete sensor, ready to be emplaced, but so far inactive. We see it, as received by the patient, in Figure 4.



Figure 4. Sensor applicator as received

Photo by Douglas A. Kerr

6 EMPLACEMENT OF THE SENSOR

6.1 The procedure

The patient unscrews the knurled cap (seen at the bottom in Figure 4) from the applicator proper (which breaks a "tamper-evident seal"). The thread is coarse and multi-start so the cap comes free quickly.

We see, in Figure 5, after this has been done, the applicator proper (bottom) and the removed applicator cap (top).



Figure 5. Applicator proper (bottom) and applicator cap (top)

Underneath the cap, now projecting from the applicator proper, is an orange cylinder, which is the business end of the applicator. It will later be driven back into the applicator, but there is a detent arrangement that initially resists such movement, mainly to prevent the cylinder to be driven back into the application by shock forces encountered during shipment.

The sensor is down inside this cylinder, cradled in a plastic support platform, held in place by plastic spring fingers (more about that shortly). On the side toward us is a disk of double-sided adhesive tape, which will later adhere the sensor to the patient's skin.

The needle cap was engaged by latches in the applicator cap when the cap was put on during assembly at the factory. Thus the removal of the applicator cap pulls the needle cap away from the sensor, the needle cap remaining in the applicator cap. We see the tip of the needle cap near the center of the applicator cap in the upper part of Figure 5.

The probe (surrounded by the introducer needle) is then exposed, protruding from the sensor (as we see in the lower part of Figure 5).

The white labyrinth-like structure in the applicator cap is not a mechanical part, but rather is made of a desiccant material to absorb (perhaps technically *adsorb*) any water vapor trapped under the cap, keeping all the working parts dry. Its complicated shape is to give it a large surface area through which it takes in the water vapor.

We cannot see the spring fingers that hold the sensor in place in Figure 5. They are hidden behind the edges of the adhesive disk, whose diameter is a bit greater than that of the sensor. But we can see the spring finger

arrangement in the left hand image of Figure 6. which shows the sensor supporting platform, on a “spent” applicator, with the orange cylinder fully pressed back into the applicator, as it would be after the sensor is emplaced.

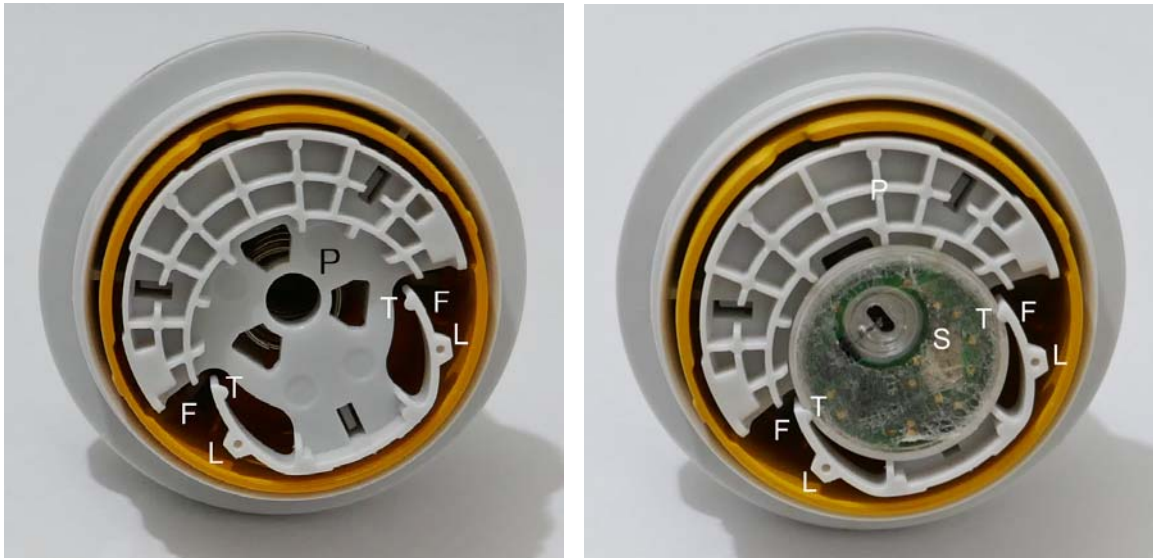


Figure 6. Spring fingers

Photo by Douglas A. Kerr

The right hand image is a photo “staged” for the purpose of further showing the operation of the spring fingers. The applicator here is again actually a “spent” one,. It shows, for the present purpose, a used sensor (S), without the adhesive disk.

The sensor is nestled in a “nest” in the sensor supporting platform (P), held in place radially by the two spring fingers (F), which are part of the same molded plastic part as the platform. At their tips there are small projections that overlap the edge of the sensor to keep it in place axially.

On each finger there is a lug (L). With the orange cylinder in its actual initial position (not as seen here), cam surfaces on the inside of the cylinder press on the lugs, applying extra force on the spring fingers toward the sensor. This reduces the chance that shocks encountered in shipping could dislodge the sensor from its nest.

When the orange cylinder is pressed back into the applicator (as will happen shortly), those cams move out of play, removing this extra force from the spring fingers. Then (as we will see shortly) the sensor can easily be pulled clear of its nest.

Again. as best seen in Figure 5, the detector probe (surrounded by the introducer needle) projects from the underside of the sensor through a hole in the tape disk.

The patient now places the nose of the orange cylinder against the skin, surrounding the intended site of application. The applicator is pressed toward the patient, forcing the orange cylinder back into the applicator (after

overcoming the initial resistance to movement from the detent arrangement). We see this operation in Figure 7.



Figure 7. Applying the sensor

This presses the detector probe (surrounded by the sharp-ended introducer needle) into the patient's flesh. The underside of the detector is ultimately pressed against the patient's skin, to be held there by a very tenacious layer of adhesive on the disk of double-sided tape.

At the end of this operation, the final bit of travel of the orange cylinder into the applicator releases the spring-loaded extraction cup that, with a smart "snap", withdraws the introducer needle, pulling it by its hub through a hole in the sensor body (visible in Figure 1), leaving the detector probe naked in the patient's flesh. This action also "turns on" the sensor circuitry, which is powered by a small battery in the sensor.

The orange cylinder is held in this final position (essentially as seen in Figure 6) by a latch arrangement, preventing it from subsequently being pulled or shaken out of the applicator, perhaps as the spent applicator is being handled.

The introducer needle has now retreated deep into the applicator, where its sharp end cannot be inadvertently contacted by the patient as he handles the spent applicator.

The applicator is pulled away from the patient. The sensor remains in place on the patient's skin, and is pulled free from the applicator (out of the spring fingers, which no longer have extra force on them). The spent applicator and its cap are discarded.

6.2 A common but incorrect assumption

It is commonly (but incorrectly) believed that the smart snap heard at the end of this process is the sensor being propelled suddenly against the patient's skin. In fact, the sensor is pressed relatively gently against the patient's skin by the depression of the applicator, with the "snap" being the sound of the withdrawal of the introducer needle from the sensor and into the depths of the applicator.

7 MORE VIEWS OF THE APPLICATOR COMPONENTS

Figure 10 in Appendix B shows an applicator that has been surgically disassembled. It gives more insight into the construction of its components.

8 RECEIVING THE MEASUREMENT DATA

8.1 Receiving devices

In this system, the measurement results can be transmitted to the small companion "reader" or to a smartphone equipped with the appropriate app. Any given sensor can be linked to one or the other, but only one, when the sensor is "started", and the choice of receiving device cannot be changed during the operating life of that sensor.

We see the reader in Figure 8.



Figure 8. Reader

Photo by Douglas A. Kerr

The manufacturer's literature seems to emphasize the use of a smartphone as the receiving device rather than the reader.

8.2 Starting the sensor

After a new sensor has been emplaced, it must be “started”, which involves introducing it to one or the other of the two receiving devices mentioned just above.

To do so, the chosen receiving device is held near the sensor, and it will automatically establish communication with the sensor via the NFC² system.

When introduction pleasantries have been conducted between the sensor and the receiving device, the receiving device vibrates to advise the patient that the sensor has been started. The receiving device then displays a message that a new sensor has been started and will be “ready for use” (will begin reporting data) in 60 minutes.

This delay is in part to allow “healing” of the subcutaneous tissue around the probe (which was of course insulted by the insertion of even this tiny probe, which disturbed the equilibrium between the blood glucose concentration at the probe site and the glucose concentration in the subcutaneous interstitial fluid). It also allows for stabilization of the detection process.

After the conclusion of that period, the receiving device will receive and can display the most recent glucose level measurement. It can display the reported values (from that point on) on a graph and analyze the reported readings on various bases. The life of the sensor from then on will be discussed in Section 10.

9 UNITS OF DISPLAY

At the choice of the patient, set in the receiving device, the glucose concentration readings may be displayed in either of two units:

- mg/dL (milligrams of glucose per deciliter of blood), the customary unit in the US, among other places.
- mmol/L (millimoles³ of glucose per liter of blood), the customary unit in the UK and Canada, among other places.

² Near Field Communication, a system of radio-frequency communication between (for example) a smartphone and another very nearby device (in some cases another smartphone). It operates on a frequency slightly above 13 MHz.

³ A *mole* is the amount of a substance whose weight in grams is numerically the same as the atomic or molecular weight of the substance.

10 THE LIFE SPAN OF THE SENSOR

10.1 Introduction

In this system, the maximum operating life of a sensor is 15 days (360 hours). I do not know exactly what happens if it is in place when that period expires. Likely it stops taking readings and sending the readings to the receiving device.

In any case, this 15-day lifespan fits well with a plan of use in which the patient regularly changes sensors nominally every 14 days (say, every other Friday). No matter at what time on such a Friday the patient would get around to doing this, the sensor will still be almost 24 hours from "expiry".

10.2 The one-hour "hiatus"

Because of the one-hour "hiatus" when a new sensor is emplaced and started, there will be a lapse of one hour in the readings that are captured. There is no way to overcome that.

10.3 Qualified readings

After the completion of the one hour "hiatus" after a new sensor has been started, for the next 11 hours, the screen display of the current glucose concentration on the receiving device includes an icon that means, in effect:

If you had planned to use this reading to make a critical decision as to diabetes treatment (including management of insulin dosage), it would be advisable to instead take a measurement with a "finger-stick" glucose meter.

This reflects the fact that the full "self-calibration" of a new sensor can take up to 12 hours and that earlier reports may not be "fully reliable".

The same icon is shown for later readings that reflect a rapid rate of change. That is because, as discussed in section 13, the glucose level measured by this CGM system (based on the glucose content of the interstitial fluid in the arm) lags behind changes in the arterial glucose level, the property that is actually of importance.

Thus during a period of rapid change of the glucose level. the CGM system may report a glucose level that is substantially different than the current arterial glucose level. Thus the "warning" icon at such times.

11 THE MEASUREMENT ITSELF

11.1 Basis of the description

I have not as of yet learned of the exact measurement technique used in the FreeStyle Libre 3+ CGM system. Its is suspected that it is much the same principle used by the earlier FreeStyle Libre 14-Day CGM system. The

description that follows is that known with fair certainty to be followed in that earlier system.

11.2 Measurement technique

On the sensor is a small flexible probe that extends through the patient's skin and into the flesh, there to contact the subcutaneous interstitial fluid (in which the blood glucose concentration is indirectly manifest).

The probe uses the so-called "wired enzyme" system, which refers to a way in which a layer of enzymes (used as an electrode) is electrically connected to a metallic conductor through various chemical compounds.

A "pad" of such an enzyme is located at the tip of the probe, covered by a membrane-like layer (this constituting the *working electrode*). The interstitial fluid passes through the membrane, and the enzyme causes oxidation of the glucose in the fluid.

This results in the production of several chemical products, including hydrogen peroxide, and the generation of a tiny electric current in the electrode, with the return being through a *counter electrode* located nearby. A *reference electrode* is between the other two electrodes, and is used to acquire the potential of the electrolyte itself (the interstitial fluid), allowing determination of the potential of the working electrode with respect to the electrolyte.

These potentials are measured by factory-calibrated circuitry in the sensor, leading to a determination of the glucose concentration.

12 RELATIONSHIP TO OTHER GLUCOSE CONCENTRATION MEASUREMENTS

It has been widely demonstrated that, in steady state, the glucose concentration in the subcutaneous interstitial fluid, measured in this way, tracks very closely with the glucose concentration in capillary blood (as is commonly measured with "finger stick" glucose meters), which is widely relied on in diabetes management. That in turn has been demonstrated to have a good correlation with the glucose concentration in arterial blood, the metric that is actually of interest with respect to diabetes management.

13 QUALIFIED READINGS IN THE CASE OF RAPID CHANGE

Changes in the arterial glucose concentration are only slowly reflected in the interstitial fluid. Accordingly, if the arterial glucose concentration is changing rapidly, this delay may lead to a significant discrepancy between the glucose level currently reported by this CGM system and the actual current arterial glucose concentration. Thus the icon warning discussed in Section 10.3.

14 LAPSE OF THE BLUETOOTH LINK

In this system, so long as a Bluetooth link can be established between the sensor and the receiving device (which, for any given sensor, can be either the associated “reader” or a smartphone equipped with the appropriate app), glucose readings are transmitted frequently (I think every minute) to that receiving device.

In any case, the sensor stores all glucose readings taken since it was started, up to its 15-day life limit.

So, if there is an extended lapse of that Bluetooth link (perhaps the patient has gone for a walk and left the smartphone in the house), the transfer process will “catch up” when the Bluetooth link can again be established.

15 ALARMS

In this system, the receiving device (either type) can be set to give an alarm (including an audible alert) whenever a glucose reading is received that is outside an “alarm” range set by the patient. This could warn the patient of a possible “dangerous” situation.

The operation of this is of course dependent on there being a continuous Bluetooth connection between the sensor and the receiving device, which essentially means that the patient should continuously have the receiving device on his person or nearby.

16 REPORTING TO A REMOTE DATA BASE

Patients using this CGM system are typically entitled⁴ to the utilization of a central data base facility operated on behalf of Abbott, the manufacturer of the system.

We assume that the patient is using a smartphone as the receiving device, and that the smartphone has access to the Internet.

Once the patient has established an “account” with that facility (done via the smartphone app), the smartphone periodically (the exact time interval is not known to me) sends, via the Internet, all glucose readings since the last successful such report.

The patient can then, for example, log into that facility with a desktop computer and have the glucose readings displayed in various forms and analyzed in various ways.

⁴ This may depend on the details of the arrangement with the entity providing the system to the patient, typically a medical equipment supply firm or pharmacy.

With the consent of the patient, it is then possible to set up the account so that the patient's physician can download the patient's glucose reading history for review.

17 COMPARISON WITH THE FREESTYLE LIBRE 14-DAY SYSTEM

Appendix A summarizes the differences between the FreeStyle Libre 3+ system (discussed in the body of this article) and the earlier FreeStyle Libre 14-day system.

Readers who are especially interested in the details of that earlier system may wish to read the companion article, "The FreeStyle Libre 14-day continuous glucose monitor system", by this same author, presumably available where you got this.

18 PHOTO CREDITS

Except where noted otherwise, the photos in this article were all adapted from ones found on the Internet, with their copyright status unclear. I consider them used here under the doctrine of fair use. Thanks to the various photographers and others for making these photos available.

19 ACKNOWLEDGEMENT

Much thanks to my precious wife, Carla, who, despite being in the throes of recuperation from a series of serious medical adventures, took up her mantle as the fabled "Cherokee red pencil" to copy edit an earlier draft of this tedious manuscript. But errors occurring after that are solely my responsibility.

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Appendix A

Comparison of the FreeStyle Libre 3+ CGM system with the earlier FreeStyle Libre 14-Day CGM system

A.1 INTRODUCTION

The FreeStyle Libre 3+ CGM system differs in a number of ways from the earlier FreeStyle Libre 14-day CGM system. I will discuss several of those in this Appendix.

A.2 INTERVENING SYSTEMS

For continuity, I note that Abbot Diabetes Care, the maker of the two CGM system discussed here, offered three other FreeStyle Libre CGM systems between the eras of the “14-day” and the “3+” systems. They were:

- FreeStyle Libre 2 Flash CGM system
- FreeStyle Libre 2+ Flash CGM system
- FreeStyle Libre 3 CGM system

I will not discuss those systems here.

A.3 RELIABILITY OF READINGS

It has been at least intimated by the manufacturer that the FreeStyle Libre 3+ CGM system gives more reliably accurate readings than the earlier FreeStyle Libre 14-day CGM system. I have no data as to this.

A.4 REPORTING CONCEPT

A.4.1 The FreeStyle Libre 14-day CGM system

In this system, the sensor itself stores the most recent 8 hours (only) of glucose readings. Communication between the sensor and receiving device is established over an NFC (near field communication) wireless link, and the stored data from the sensor is transferred to the receiving device. The data is time tagged, and the receiving device only stores those readings not previously received.

Note that if this process (called “scanning the sensor”) is not done at least every 8 hours, some of the measurement data will be lost.

A sensor can be scanned either by the associated “reader” or a smartphone, if the initial “starting” of the sensor is by the reader. If the initial “starting” of the sensor is by the smartphone, it cannot then be scanned by the reader.

Of course either receiving device will only store (and be able to display) the data reported to it when it is used to scan the sensor. Thus typically the patient will use only one or the other receiving device so long as it is working properly.

A.4.2 The FreeStyle Libre 3+ CGM system

In this system, the reading data is stored in the sensor for up to its “lifetime” (which is 15 days).

As long as a Bluetooth link can be established between the sensor and the receiving device (which, for any given sensor, can be either the associated “reader” or a smartphone equipped with the appropriate app, but not both), glucose readings are transmitted frequently (I think every minute) to that receiving device. There is no concept of explicitly “scanning” the sensor.

If there is an extended lapse of that Bluetooth link (perhaps the patient has gone for a walk and left the smartphone in the house), the transfer process will “catch up” when the Bluetooth link can again be established.

A.5 SENSOR SIZE

The 3+ sensor (to use a short name for the newer system) is much smaller and lighter than the 14-day system sensor. We see the two sensors compared in Figure 9.



Figure 9. FreeStyle Libre 14-day GM system sensor (left), FreeStyle Libre 3+ CGM system sensor (right)

Photo by Douglas A. Kerr

The 14-day system sensor is approximately 1.18” (30 mm) in diameter and approximately 0.20” (5 mm) thick. (not including the detector probe). It weighs approximately 0.18 oz) (5 g).

The 3+ system sensor is approximately 0.83” (21 mm) in diameter and is approximately 0.12 (3 mm) thick (not including the detector probe). It weighs approximately 0.04 oz) (1 g).

A.6 SENSOR PREPARATION

A.6.1 The FreeStyle Libre 14-Day CGM system

In this system, the sensor as provided in the sensor applicator does not include what I call the “probe module”. This small plastic module includes the flexible “probe” (as I call it). This module is in a separate container, a

molded plastic cup with a foil seal. The probe module is surrounded here by the introducer needle, and is carefully protected by the internal structure of that container (which is itself quite complex).

In the applicator, the introducer needle (not yet surrounding a probe) projects from the “sensor body” (as I call what is initially in the applicator).

When the patient is about to emplace a new sensor, after taking the cap off the applicator, and removing the foil seal from the cup containing the detector unit, the protruding cylinder of the applicator is pressed into an annular recess in the cup. This presses the detector module into place on the sensor body. The sensor is now complete and ready to be emplaced.

The rest of the emplacement operation proceeds essentially as described in the body of this article for the 3+ system.

A.6.2 The FreeStyle Libre 3+ CGM system

Here, there is only one container provided, the sensor applicator. The sensor in it has its detector probe in place, already surrounded for the moment by the introducer needle. The sensor is ready to be emplaced.

Accordingly, the patient does not need to perform the “assembly” stage of the process as used with the 14-day system.

A.7 ALARMS

A.7.1 The FreeStyle Libre 14-Day CGM system

There are no provision in this system for alarms when the glucose level falls outside of some set limits. Doing so would probably be the province of the receiving device, and in this system that does not continuously receive ongoing reports of the glucose readings from the sensor.

A.7.2 The FreeStyle Libre 3+ CGM system

In this system, the receiving device can be set to give an alarm (including an audible alert) whenever a glucose reading is received that is outside an “alarm” range set by the patient on the receiving device. This is made practical by the fact that ordinarily the receiving device continuously receives (ideally, at one-minute intervals) current glucose reading data from the sensor.

A.8 DATA STORAGE IN THE SENSOR

A.8.1 The FreeStyle Libre 14-Day CGM system

In this system, the sensor itself stores, on a “rolling” basis, only the last 8 hours of glucose readings. Thus, if for some reason, the user fails to scan the sensor for, say, 10 hours, two hours of data is completely lost.

A.8.2 The FreeStyle Libre 3+ CGM system

In this system, the sensor stores all glucose readings over its entire 15 day life span (or until it is removed before that time).

Ordinarily, the receiving device is automatically updated once a minute as to any new data, assuming that the Bluetooth link between the sensor and the receiving device is workable.

However, suppose now that the Bluetooth link between the sensor and the receiving device is disrupted for 12 hours (perhaps the patient goes on a day trip but inadvertently leaves his smartphone at home).

All glucose reading data over that period is still stored in the sensor. When the Bluetooth link is re-established, the smartphone is brought fully up-to-date.

A.9 SENSOR LIFESPAN

A.9.1 The FreeStyle Libre 14-Day CGM system

The limit of the operating life of the sensor in this system is, as the system name would suggest, 14 days.⁵ Exactly 336 hours after it is started, it goes dead, then not even willing to report the stored data, if scanned.

This design property can lead to an operational difficulty.

Suppose a certain patient has adopted the practice of changing the sensor on every other Friday at about 4:00 pm. Suppose that on one Friday he changes the sensor at exactly 4:00 pm.

Now suppose that on the second following Friday, he has, as is his habit, scanned his sensor at around 8:45 am, in preparation for breakfast and at 11:45 am, in preparation for lunch,. He would normally next scan his sensor at about 5:45 pm, in preparation for supper.

But this Friday, at about 4:00 pm., he goes to change his sensor. At 4:01 he tries to scan it to get the data updated in his receiving device before removing the old sensor, but it has (just a minute ago) gone completely dead. All glucose reading data after 11:45 am that day is lost.

There are various ways around this, none of them attractive for the patient.

⁵ This particular product seemingly got that name because its 14-day lifetime was significantly greater than that of the earlier CGM products by this manufacturer (and others), an important marketing advantage, worthy of being made part of the product name.

A.9.2 The FreeStyle Libre 3+ CGM system

The limit of the operating life of the sensor in this system is 15 days (360 hours). I do not yet know exactly what happens when that expires. Likely the sensor will cease making glucose measurements and cease transmitting data to the receiving device.

In any case, if the patient, for example, decides to change the sensor every other Friday at about 4:00 pm, even a few hours after the planned time on such a Friday the old sensor will still be well within its life limit.

And in any case, if there is no further complication, the smartphone will be fully up to date whenever the old sensor is removed (whereupon it indeed goes "dead").

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Appendix B

Applicator disassembled

Figure 10 shows an applicator surgically disassembled. It can help understand the overall construction of the applicator.

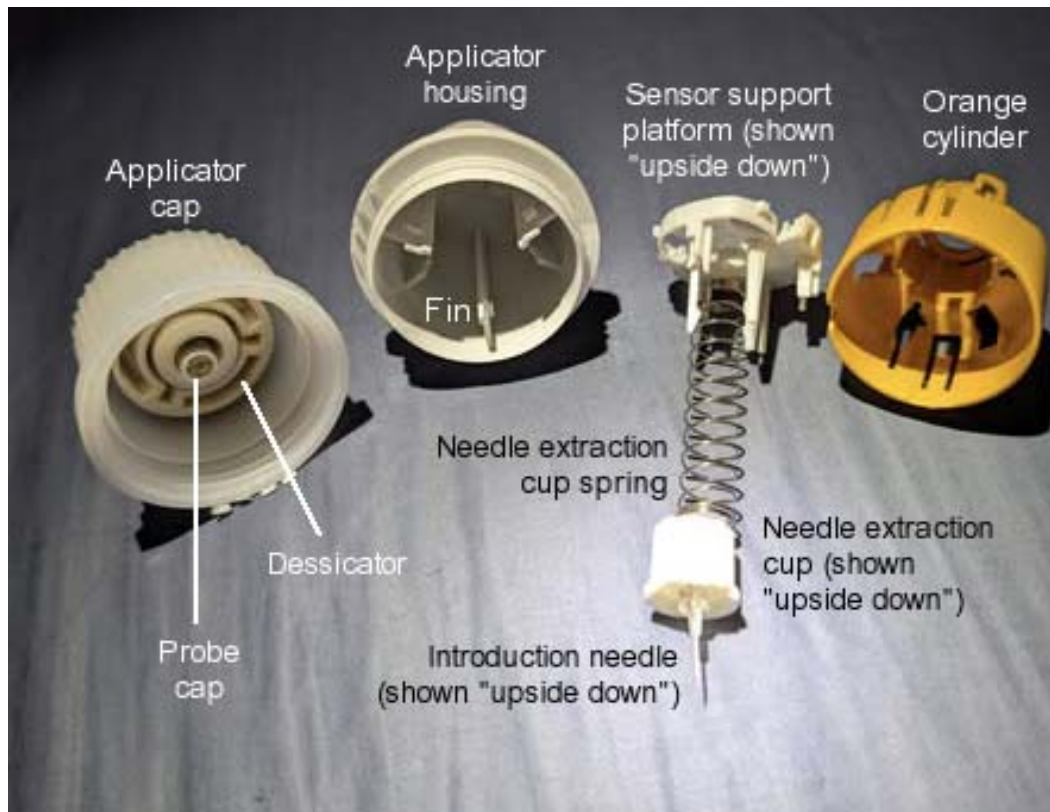


Figure 10. FreeStyle Libre 3+ applicator disassembled

In the *applicator cap* we see (at its center) the *probe cap*, which had protected the probe and introduction needle before the patient begins the emplacement process. We also see the labyrinth-like *desiccator*, which takes up any water vapor applicator in the applicator while in transit or storage.

Inside the applicator housing we see three *fins* (one labeled). The sensor support platform is welded to the top of these during factory assembly.

Next we see the *sensor support platform*, here turned around so that various features on its top can be seen. Prominent among these are three long latches, which hold the needle extraction cup in its initial position until the orange cylinder is fully pushed in during emplacement.

On the far right we see the *orange cylinder*. It is much more complicated than we might at first suspect, with many features involved in such tasks as guiding the motion of the cylinder, providing for a detent to help the cylinder retain its initial position during shipping and initial handling by the patient, and so forth.

In the interior of its smaller-diameter portion (away from us in this photo) are cam surfaces that, until the orange cylinder is fully pushed into the applicator, hold the extraction cup latches engaged.

There are slits in the cylinder that allow it to travel past the three fins in the applicator housing.

Below we see the *needle extraction cup*, again “turned around” so that we can see it gripping the tail of the *introduction needle hub*. We also see the *introduction needle* itself.

With the applicator assembled, as delivered, the *needle extraction cup spring*, compressed, is mostly in the interior of the needle extraction cup.

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