The FreeStyle Libre 14-Day continuous glucose monitor system

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INTRODUCTION

The FreeStyle Libre 14-Day continuous glucose monitor system (CGM) measures a diabetes patient's glucose concentration every minute with a small. disposable sensor (about the size and shape of a poker chip) adhesively fastened to the patient's upper arm, with a small probe extending through the skin.. A record of the measurements at 15-minute intervals (for up to 8 hours) is retained in the sensor. The readings can then be picked up, via near field communication (NFC), with either a small "reader" or by a smartphone equipped with a special app, and displayed as a graph and in other ways.

The sensor must be replaced every 14 days, normally done by the patient. The process is fairly simple for the patient, but "behind the curtain" it involves a complex process of assembling and preparing the sensor and then emplacing it on the patient's arm.

In this article I describe the system and its features and overall operation, but emphasis is on a detailed discussion (with numerous photos) of the process of assembly, preparation, and emplacement of a sensor.

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 patent's physician in assessing the efficacy of the patient's diabetes treatment regimen.

In addition, typically the patient will typically 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 them 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.

The patient can then note this and perhaps record this 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 closely as once per hour. 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 (and several others) 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

2 THE SYSTEM

The FreeStyle Libre 14-Day continuous glucose monitor system (CGM), developed and distributed by Abbott Diabetes Care, Inc., a unit of Abbott Laboratories, measures a diabetes patient's glucose concentration "continuously" with a small sensor (about the size and shape of a poker chip) fastened with adhesive to the patient's upper arm. A tiny flexible probe with an electrochemical glucose concentration detector at its tip it extends through the skin into the subcutaneous interstitial fluid, where the blood glucose concentration is manifest.

The glucose concentration is actually measured every minute, and the latest reading retained in the sensor. In addition, the readings at 15 minute intervals are stored in the sensor, up to 8 hours of readings being stored. The most recent measurement and the entire body of stored data is read out of the sensor, via NFC (near field communication), by either a small "reader" or by an iOS or Android smartphone equipped with a special app. The last 24 hours of data is displayed as a graph, and graphs for earlier days (up to 90 days in the past) can also be displayed.

The sensor must be replaced every 14 days, normally done by the patient. The process is fairly simple for the patient, but "behind the curtain" it

involves a complex "dance" of assembling and preparing the sensor conducted by two complicated devices, and then emplacing it on the patient's arm.

3 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 and its mechanisms.

The description of this CGM product is in no way meant to suggest it over other comparable and competitive products.

4 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 the FreeStyle Libre 14-Day continuous glucose monitor system. The system has (except for one minor glitch) behaved well, and has proven to be beneficial to the management of my insulin regimen.

5 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 physician[1], presumably in the course of the person's treatment for diabetes or such, the person thus being a "patient".

6 THE SENSOR—A FIRST LOOK

Figure 1 shows the sensor from the "back" as it would appear when in place on the skin.

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[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").

Figure 1. Sensor as installed, from the back

It is approximately 1.18″ (30 mm) in diameter and 0.20″ 5 mm) thick. It weighs approximately 0.18 oz) (5 g).

Figure 2 shows the completed sensor as it would be when installed, seen from the front (which would actually be up against the skin of the patient's arm, held in place with a circular disk of double sided tape, with a very tenacious adhesive, which is not present in this photo).

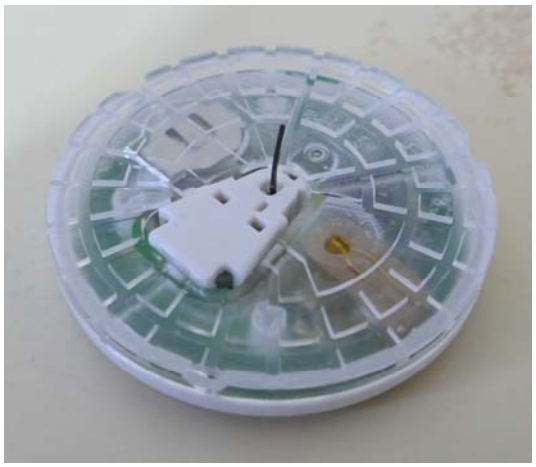

Figure 2. Sensor as installed, from the front

The small black "tail" is the probe that enters the patient's flesh. It carries at its end the actual glucose concentration detector.

We will learn much more about the sensor in later sections.

7 EMPLACEMENT OF A SENSOR—OVERVIEW

7.1 Introduction

In this section, for context, I will concisely describe the overall process of preparing and emplacing a sensor, from the viewpoint of the patient, with no

discussion of ribs and latches and detents and such. We will learn of all those in a later, more detailed description of the process.

7.2 What the patient gets

Figure 3. Sensor pack

7.2.1 *The sensor pack*

The "sensor pack" is a molded plastic cup with a foil seal over its top. We see it in figure 3.

Contrary to its name, it does not contain the "sensor" as that term is used in connection with this system as described for the patient. Rather, as received, it contains what I will call the "probe module", a small unit that carries the *probe*.

7.2.2 *The sensor applicator*

Figure 4 shows the "sensor applicator" (hereinafter generally just "applicator"). As received, it contains what I will call the "body" of the sensor.

Figure 4. Sensor applicator (as received)

7.3 The procedure

The patient removes the foil seal from the sensor pack and unscrews the cap from the applicator (the latter involving the breaking of a "tamper-evident seal"). Underneath is a blue cylinder that is the business end of the applicator. (We will see it in detail in a later section.) The sensor body is down inside this cylinder.

The patient aligns a black line on the applicator with one on the sensor pack, inserts the blue cylinder into the innards of the sensor pack, and presses the applicator all the way into the sensor pack. This installs the probe module into the sensor body, completing the sensor,.

The applicator is pulled out of the sensor pack. At this point the complete sensor is down inside the blue cylinder, ready to be emplaced on the patient's arm.

The patient places the nose of the blue cylinder against the skin, surrounding the intended site. The applicator is pressed down. The blue cylinder retreats into the applicator body.

When the blue cylinder is entirely pressed into the applicator body, the sensor has been pressed onto the patient's skin, to be held there by a tenacious adhesive. There is a smart "snap" as another operation happens. The applicator is pulled away, leaving the sensor in place.

The sensor pack and its foil seal, and the applicator and its cap, are discarded.

8 PRINCIPLE OF MEASUREMENT

8.1 Measurement technique

On the sensor (on the probe module) is a small flexible probe that extends through the patient's skin and the flesh, there to contact the subcutaneous interstitial fluid (in which the blood glucose concentration is 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 (the interstitial fluid), allowing determination of the potential of the working electrode with respect to the electrolyte.

The generated current and the working electrode potential are measured by factory-calibrated circuitry in the sensor body proper, leading to a determination of the glucose concentration.

8.2 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.
- mmol/L (millimoles[2] of glucose per liter of blood), the customary unit in the UK and Canada.

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

8.3 Relationship to other glucose concentration measurements

It has been widely demonstrated that 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. This 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.

An interesting distinction that has been widely reported has to do with the fact that "finger stick" measurements of glucose concentration can be artificially high if the patient is taking acetaminophen (a very common pain and fever reliever), while measurement of glucose concentration in the subcutaneous interstitial fluid (as done with the system being discussed here) is much less affected by this phenomenon.

9 EMPLACEMENT OF A SENSOR IN DETAIL—THE PLAYERS

9.1 Introduction

Before I describe the details of the "dance" at the emplacement of a sensor, I will introduce the players we have not already met.

9.2 The sensor probe

Figure 5 shows a sketch of the sensor probe element. It is made on a "flex circuit" substrate.

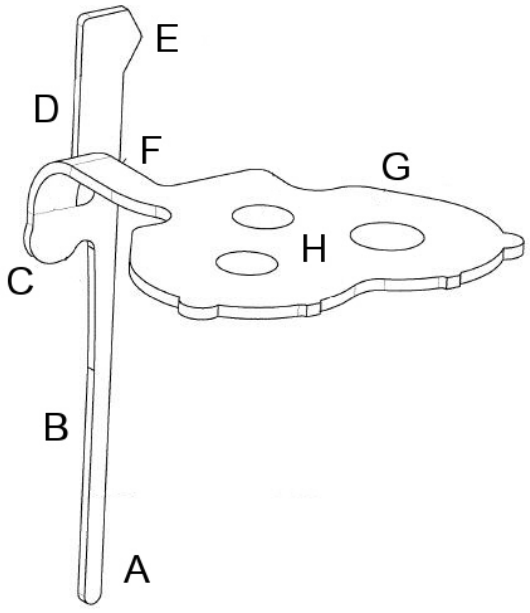

Figure 5. Probe

The vertical section B is the probe proper. In region A are the actual three electrodes of the glucose detection system. The probe proper is

approximately 0.009" (about 0.23 mm) thick and about 0.014" (about 0.36 mm) in width).

Tab "D" will be used to locate the probe in the probe module.

Portion F carries the leads coming from the three detector electrodes. Portion G carries three contact pads, H, which are at the ends of the those three leads.

Figure 6 is an actual photo of the probe element. (The probe proper is a bit ragged, and tghe whole thing a bit bent, as a result of considerable handling of the probe element in the course of this study.)

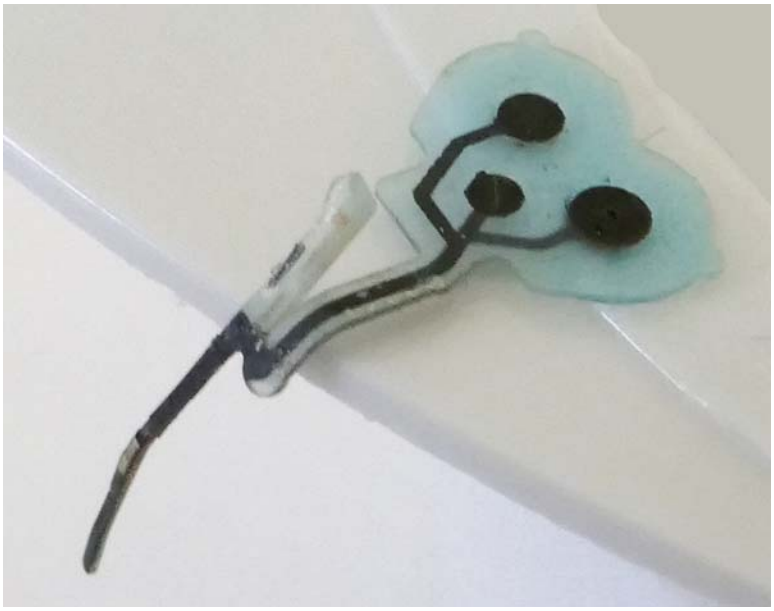

Figure 6. Probe element

Figure 7 shows what is likely the cross-sectional structure of the probe proper near its tip.

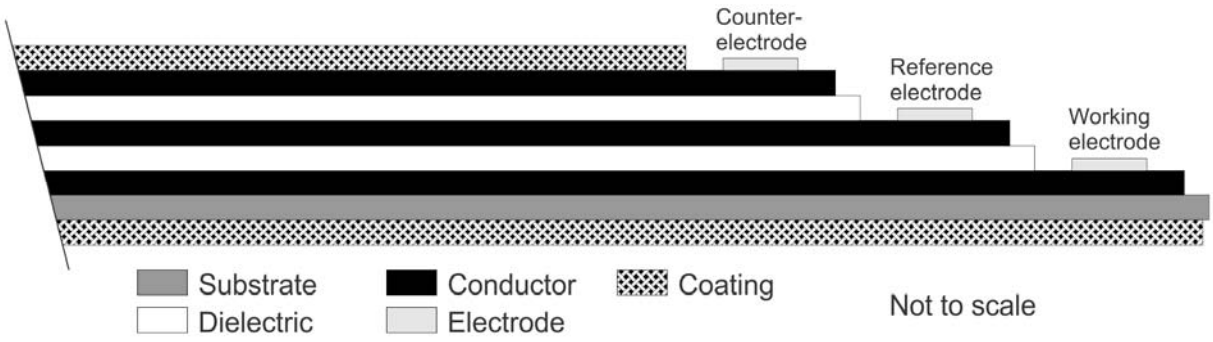

Figure 7. Possible cross-sectional structure of probe

It should be fairly self-explanatory. Seemingly all of portion "B" is covered by a protective coating, except over the electrodes themselves (in region A).

9.3 The probe module

Figure 8 shows what I call the *probe module*, with the probe element in place.

Figure 8. Probe module

The black object extending downward on the left is the probe itself, (portion B in figure 5). With the sensor in place, most of the extending length of the probe (about 0.225", about 5.7 mm) will be in the patient's flesh, in contact with the subcutaneous interstitial fluid. How it gets there is part of the story of the "dance".

Portion C (figure 5) of the probe element extends up into a thin slot in the "tower" at the left to locate the probe element in the module. For portion F, extending to our right, the edge furthest from us lies in a horizontal slot under the rightmost portion of the tower on the left. This holds portions A-E in place vertically.

Portion F is at the far right, inside the contact cluster, which closes, clamshell-like, around portion G. On the cluster we see a set of three resilient electrical contacts (black), the lower ends of which touch contact pads H on the probe.

When the probe module is in place in the sensor body, the top ends of these contacts touch the three contact pads on the sensor body (see figure 11), connecting the probe to the circuitry in the sensor body.

The contacts are surrounded by a wall of flexible translucent plastic which will protect the contact region from any ingress of water when the sensor is in place (see section 10.12).

About centered on the near side we see a latch tab. This (with its mate on the opposite side and another on our right) will engage notches in the recess in the sensor body to retain the probe module in the sensor body.

9.4 The introducer needle

The probe proper is very flexible, in part so it will not aggravate the flesh through which it will extend when the sensor is in place. But thus it is way too limp to, of itself, pierce the skin and underlying flesh when the sensor is emplaced.

Accordingly, when the sensor is emplaced, the probe is surrounded by the *introducer needle*, a very small stainless steel channel, cut off diagonally at the far end to provide a very sharp point. We see the introducer needle in figure 9.

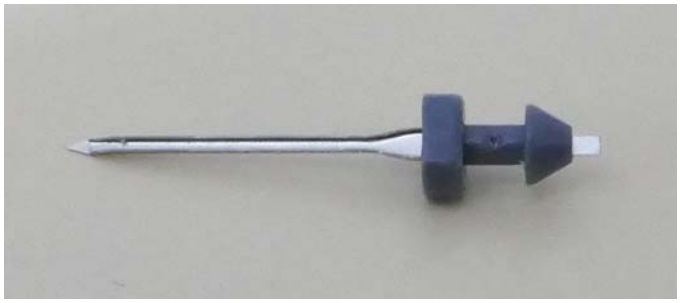

Figure 9. Introducer needle

Its cross section is approximately 0.020″ wide and 0.020″ deep.

This part will surround the probe when it is to enter the patient's skin and into his flesh.

Figure 10. Introducer needle in place

In figure 10, we see the introducer needle in place in the probe module, surrounding the probe proper. The probe sits edgewise in the channel in the needle. The placement of the needle is done in the factory, so, as received, the probe module already is fitted with the introducer needle, as seen. The flange on the plastic "tail" of the needle has a flat on it. This serves to properly establish the proper orientation of the introducer needle when it is put in place.

Feature C of the probe element (see figure 5), lies against one side of the thin slot in the module through which section D of the probe passes. When the needle is inserted, Feature E lies in the bottom of its channel, and is pressed to what is our left in figure 5.

This causes the entire vertical portion of the probe to rotate slightly about feature C, causing section A-B of the probe to reliably lie against the bottom of the needle's channel. Thus the probe is entirely embraced by the needle, prepared to be driven through the patient's skin.

The barb on the far right will be gripped by part of the applicator mechanism when the sensor is assembled. This is used to extract the introducer needle after the completed sensor is in place on the patient's arm (leaving the probe itself in place).

9.5 The sensor body

Figure 11 shows the sensor body proper, as it would be at the beginning of the assembly "dance" (except that it would have the adhesive disk in place, which is not in place in this photo).

Figure 11. Sensor body proper, from the front

It is seen from the front (the face that will be against the patient's arm when installed).

Note the sort-of trapezoidal recess. This will receive the *probe module* (see figure 8) when the sensor is assembled during the emplacement process. Note the three circular contact pads (two of them surrounded by "shield rings"). The resilient electrical contacts on the probe module will contact these when the sensor is assembled, connecting the probe to the circuitry in the sensor body.

Near us we see the small battery that powers the sensor. I have not yet dissected a sensor body to ascertain the nature of this battery.

10 EMPLACEMENT OF A SENSOR—THE PROCESS IN DETAIL

10.1 Introduction

In this section we will follow the procedure used by the patient in emplacing a new sensor, describing in details the "dance" of the various components.

10.2 Identification

Both the sensor pack and the sensor applicator labels contain a code (*e.g.*, "G19") and a serial number. Both these identifiers should match between the two items.

10.3 Recommended site

The site recommended for application of the sensor is on the back of the upper arm. The patient should, from sensor to sensor, slightly vary the location, or perhaps even alternate between the two arms.

10.4 Preparation of the site

The patient should first thoroughly remove any residue of adhesive from the prior sensor. Then the site should be thoroughly washed, rinsed, and dried, and the preparation completed with a fresh alcohol swab.

10.5 The sensor pack

In figure 4 we saw the sensor pack as received.

Notwithstanding its name, It does not actually contain the entire sensor but rather only what I call the *probe module* (with the *introducer needle* already in place).

The sensor pack, until the seal is removed, is sterile (sterilized by radiation). This recognizes that the probe (and, briefly, the introducer needle) will pierce the patient's skin.

Figure 12 shows the sensor pack with the foil seal removed.

Figure 12. Sensor pack

The black object I call the *sensor pack piston*. It can be pressed down into the sensor pack case.

We can see the owl-face-like group of the three electrical contacts on the probe module. The probe module sits on a pedestal that is part of the sensor pack case, held in place by a plastic clip that is part of the piston. The module itself is hard to see, in part as it is partially obscured by the clip.

The introducer needle is in place in the probe module, and its tail extends towards us in the photo.

The tips of three flexible arms, part of the piston, ride on ribs in the sensor pack case to maintain the orientation of the piston as it shortly will move into the case. With the piston in its initial position (as seen), these arm tips sit in notches in the ribs, providing a detent function that keeps the piston from too easily starting to descend into the case.

10.6 The sensor applicator

10.6.1 *Introduction*

In figure 4 we saw the sensor applicator, as received.

The translucent cap is removed by unscrewing it on a coarse multi-start thread to prepare to use the applicator. When the cap is removed, a thin tamper ring is disrupted, showing that the cap has been removed.

In figure 13 we see what is under that cap.

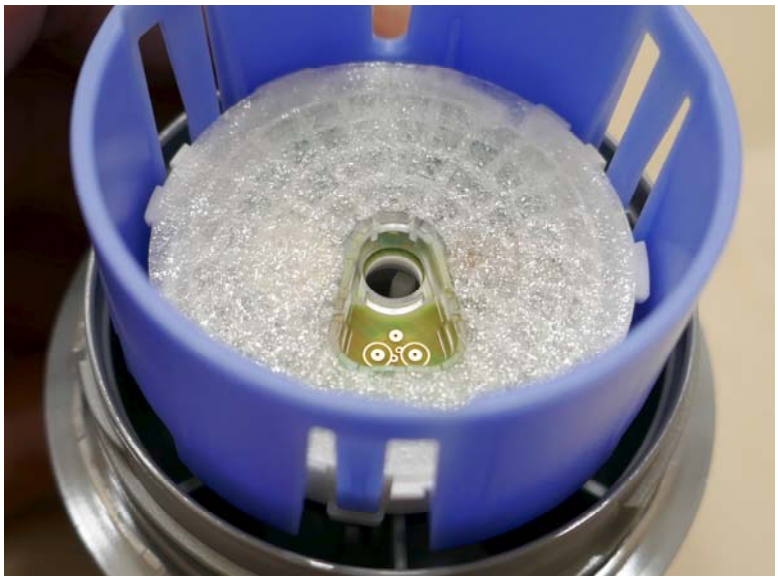

Figure 13. Sensor applicator opened

Prominent is the *blue cylinder* (and I will continue to call it just that), which will play several roles in mechanism operation.

We see the sensor body, with the adhesive disk in place, seated in the *sensor carrier* (not much of which is visible here). The sensor carrier is welded to three fins on the applicator body. so it is actually part of the body.

We see the three contact pads on the body that will be used to make the electrical connections to the probe module.

10.6.2 *Securing the sensor body*

Before the translucent cap was removed, a tubular post in the center of the cap had been holding the sensor body very securely on its platform by pressing on the body's center (through a cutout in the adhesive disk).

Figure 14. Hold-down tube

Figure 14 shows this (using a post that had been surgically removed from the applicator cap) The adhesive disk which would normally be in place on the sensor body is gone in this photo.

With the cap removed, the sensor body continues to be held in place by three radially flexible fingers on the edge of the sensor carrier (not easily seen in figure 13, but see figure 19 in Appendix A) whose tips go into small notches on the sensor body periphery (thus holding the body in place in the carrier and with the proper orientation). These fingers are spring loaded inward, but, in addition, with the blue cylinder extended (as it is initially), three ribs on the inside of the cylinder forcibly press the fingers into the sensor body, so the body is securely held in place.

10.6.3 *Keeping the blue cylinder extended*

The blue cylinder is at this point fully extended. The tips of three thin fingers on the blue cylinder (we see one in figure 13 at about 2 o'clock) touch tabs on the sensor carrier and completely prevent the blue cylinder from being pressed into the applicator at this stage of the operation.

The tips of three flexible detent arms, part of the cylinder, at its rear (we can see them in figure 22 in Appendix A.), ride on ribs in the applicator housing.

With the cylinder in its initial position, fully extended (as seen above), those tips are in small notches in the ribs, providing a detent function ("position 1") that would prevent the cylinder from too easily beginning to move into the applicator.

10.7 Completing the sensor

10.7.1 *Pressing the applicator into the sensor pack*

With the sensor pack foil seal removed, and the cap removed from the applicator, the applicator is aligned with the sensor pack (there being black lines on both for this purpose) and pressed firmly into the sensor pack.

An annular well in the sensor pack piston (see figure 12) accommodates the blue cylinder as the applicator is pressed into the sensor pack. There is a "fin" intruding into the annulus (it is at 6 o'clock in figure 12), but the blue cylinder has a slot in it to clear that fin if the applicator is being inserted into the sensor pack with the proper orientation. (We see that slot clearly in figure 15, near us.)

As the "mound" in the center of the piston enters the blue cylinder, three tabs on the mound press outward the three latch strips on the blue cylinder, freeing the cylinder to move back into the applicator when required (although the detent function previously described will prevent that from happening "easily").

10.7.2 *The stroke of the applicator*

Further movement of the applicator makes the blue cylinder bottom on the bottom of the annular well in the piston. Thus, even further movement of the applicator will cause the blue cylinder to depress the piston, overcoming the detent that holds the piston in its initial position.[3]

This forces the clip (part of the piston) that holds the probe module in place on its "pedestal" to slip down over the probe module, freeing it to depart. This also clears the area so that the sensor body, in its place on the applicator, can approach the probe module and eventually "swallow" it.

When the piston bottoms, a small further movement of the applicator occurs. This last movement makes the sensor body "swallow" the probe module. Any further movement of the applicator is prevented by the mouth of the applicator body striking the flange of the piston.

This last movement forces the blue cylinder into the applicator by about 0.125" (3.2 mm) (the cylinder is free to move since the three latch strips have earlier been pushed out of the way).

10.7.3 *The second detent position*

Now the detent arms on the rear of the blue cylinder drop into a second set of notches on the fins on which the arms ride, providing a new detent action ("position 2") holding the blue cylinder in that slightly pushed-in position.

The point of moving the blue cylinder to this second location is to render impotent the flat latches that initially prevented the blue cylinder from moving, making it possible, during a later stage, for the blue cylinder to be pushed further in (but not too easily, because of the position 2 detent).

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[3] The detent that now holds the blue cylinder from moving into the applicator is more potent than the detent that holds the sensor pack piston in its initial position, and thus the blue cylinder is able to break the piston free and depress it.

This final movement of the applicator body (which carries the sensor body nestled in its platform) completes the seating of the probe module into the sensor body. The probe module is held in place in the recess in the body by the latches on the module mentioned earlier.

At this point the contacts have been made that establish the electrical connections between the probe module and the sensor body. And this starts the electronics in the body.

The patient, probably unaware of all he has just caused, removes the applicator from the sensor pack.

10.8 The applicator with the completed sensor

Figure 15 shows the business and of the applicator at this point.

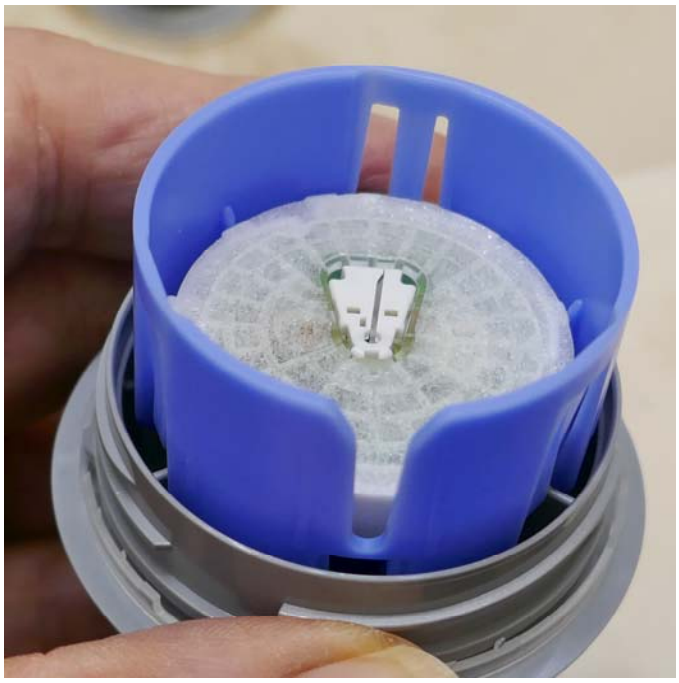

Figure 15. Applicator with completed sensor

We see the probe module now in place in the sensor body, with the sharp-ended introducer needle still surrounding the probe. The blue cylinder is still protruding, but not quite as far as originally. It is now free to be pushed further into the applicator, but not from a small, perhaps accidental force, since it is held in its current position by the “position 2” detent I mentioned earlier.

Figure 16. Sensor complete showing tail of introducer needle.

Although we can't see it with the sensor still in place in the applicator, the tail of the introducer needle now protrudes from the back of the sensor [4]. We see that in figure 16 (a "staged" shot).

At this point, that tail is actually gripped by three catches in the extraction plunger, not seen above. But figure 17 shows that engagement with a "loose" introducer needle and extraction plunger (another "staged" shot).

Figure 17. Introducer needle gripped by extraction plunger

10.9 Emplacing the sensor

The patient then presses the applicator against the skin at the intended site. The mouth of the blue cylinder touches the site first, making certain that the axis of the applicator is perpendicular to the skin. As the applicator is

[4] See section 10.12 for a more precise description of the construction there.

pressed onward, the blue cylinder will retreat into the applicator (at first overcoming the effect of the position 2 detent).

The friction of the cylinder detent arms sliding on their fins in the applicator housing assures that there continues to be a significant force between the blue cylinder and the skin, holding the blue cylinder in place. This helps to assure that the approach of the sensor to the site is "straight on" (else the penetration of the probe, in the sharp-ended introducer needle, might be bungled, resulting in injury to the patient and likely leading to the malfunction of the sensor).

Eventually, the adhesive face of the sensor contacts the skin, and the pressure applied by the patient on the applicator presses it into good contact with the skin.

As the blue cylinder was driven into the applicator body, the three ribs on the cylinder that had been forcibly holding inward the sensor body retaining fingers on the sensor carrier come clear of those fingers. It would now be possible for the sensor to come clear of the sensor carrier, only needing to overcome the spring force of the fingers.

10.10 Extracting the introducer needle

At just this point in the applicator travel, when the blue cylinder has essentially gone fully back into the applicator body, the blue cylinder releases three latches that have been holding the extraction plunger in place[5], releasing the plunger, and a spring drives the plunger back.

The plunger extracts the introducer needle from the patient and pulls it out through the back of the sensor (see section 10.12). It is carried into the depths of the applicator, where it will be safe from any inadvertent contact by the patient (it is **very** sharp) as the applicator is later being set aside and disposed of.

This extraction of the introducer needle makes a smart "snap", and it is a common misconception that this if from the sensor being "slapped" onto the skin by a spring loaded plunger. But, as described above, the sensor is just pressed against the skin by pressure put on the applicator by the patient. The snap is the retraction of the introducer needle.

At the end of its travel back into the applicator, the three detent arms on the blue cylinder drop over latch steps on the ribs, holding the cylinder so it cannot slip back out of the applicator while the now-spent applicator is being handled (perhaps for disposal) by the patient.

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[5] Further details of this are given in Appendix A.

10.11 Pulling the applicator clear

The patient removes the applicator. The sensor, at this point being held only lightly in the sensor carrier by the three retaining fingers under only their own spring force, is easily pulled free and remains on the patient's skin. The patient may wish to give the sensor an extra push against the arm to be certain that the adhesive pad has been fully put into place.[6]

10.12 A construction detail

If we look at figure 1, we note an interesting construction at the center of the back of the sensor. This is actually the tip of a "tower" that is part of the probe module (see figure 8, on the left).

The cruciform hole through this tower is what guides the introducer needle. And it is through this hole that the tail end of the introducer needle actually emerges from the back of the complete sensor when it is ready to be emplaced.

This is clearly not a waterproof configuration. If the patient showers, bathes, or otherwise or washes his arm, water can go through the hole and around the tower.

But this water cannot enter the sensor body proper, which is sealed. And the points of electrical contact on the probe module are surrounded by a flexible plastic boot on the probe module to prevent water from reaching them.

11 ENHANCING THE ADHESION OF THE SENSOR

Although the adhesive on the adhesive disk is very effective, and usually will easily achieve a tenacious bond, for a few patents the adhesion is not as effective as is needed.

For such situations, there are available small wipes that apply to the skin a tacky "adhesive primer". This is applied to the skin, after it has been thoroughly cleaned, just before the sensor is applied.

I have not used these.

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[6] This is how an old Scottish telephone engineer (hint: not Alexander Graham Bell) does it. But that is how telephone engineers are.

Figure 18. Reader

12 STARTING THE NEW SENSOR

12.1 Using the reader

If the patient intends to at all use the "reader' (perhaps to use only the reader), it must next "start" the new sensor. This step is not applicable if the reader intends to only use a smartphone to take the data from the sensor, in which case the sensor is started with the smartphone. But if he intends to use both the reader and the smartphone, the sensor must be started with the reader first.

We see the reader in figure 18.

The reader is started and its back held within about half an inch of the sensor. The reader interrogates the sensor over an NFC[7] link. The sensor responds with its serial number and an indication that it is now "started". But the reader advises the patient that no data from the sensor will be available for an hour.

This period is 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 glucose concentration at the probe site and the general glucose concentration in the subcutaneous interstitial fluid) and stabilization of the detection process.

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[7] 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.

12.2 Using the smartphone

If a smartphone equipped with the appropriate app is to be used, it must now make peace with the sensor. With the phone unlocked, the patient holds the NFC hot spot of the phone about a half inch from the sensor. The sensor responds with its serial number and an indication that it is now "started".

But, if the sensor has not already run for an hour after being started by the reader (or perhaps that was not even done), the phone reports that no data can be gotten from the sensor until the completion of that period.

13 SYSTEM OPERATION

13.1 Introduction

Now that we have heard about the "dance of the components" that accompanies the emplacement of a sensor, we can learn a bit about the features and operation of the overall system.

The discussion will almost entirely be predicated on the use of an Android smartphone, with the special app, as the data acquisition and reading device. Many of the basic functions can also be done with the reader, but it is limited in its capability.

13.2 Data storage in the sensor

The sensor determines the glucose level in the subcutaneous interstitial fluid once a minute. The latest measurement is stored in the sensor, but not all of the measurements are stored on a longer term basis, Only measurements at intervals of 15 minutes are stored on a longer term basis.

The "longer term" memory in the sensor will only store 8 hours worth of data (32 readings). The implications of that will be discussed shortly.

13.3 "Scanning" the sensor

Periodically the patient will pick up the data from the sensor with the smartphone. The smartphone (with the FreeStyle Libre app, "LibreLink"), unlocked, is held with the NFC hot spot about an inch from the sensor. The phone will beep twice (or shake twice, depending on the configuration settings for the app) when the data had been acquired.

This is commonly described as "scanning" the sensor. I don't find the tem apt, but I will use it here for conciseness and consistency.

Almost certainly, all 32 readings in the sensor memory are transmitted. Each reading is time-tagged, and the app in the phone probably only adds to its accumulation of data readings those that are not already on hand.

In addition, the latest reading (fresh within no more than a minute) is sent, and is displayed prominently on the phone screen. Also indicated by a symbol on the screen is whether the glucose concentration is rising, falling, or steady.

The screen also shows a graph of the last 24 hours of data—if possible..

Note that because the sensor only stores 8 hours worth of data (hard to believe, isn't it), unless the sensor is scanned at least every 8 hours, there will be gaps in the data stored in the phone (or the reader).

Up to 90 days of data (on a "rolling" basis) is retained in the phone (or the reader).

13.4 Qualified readings

During the 11 hour period after the readings of a new sensor become available (during which the healing and stabilization process may not have fully played out), each time the sensor is scanned, the screen display of the current glucose concentration includes an icon that, in effect, means:

> 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.

In addition, later on, if the recent measurements are extreme in value or are varying more rapidly than usual, that same warning icon is displayed if the sensor is scanned.

To help deal with this situation, or in case for some reason the patient just wants to take a reading on a finger-stick (capillary blood) basis, the FreeStyle Libre reader itself also includes a finger-stick glucose meter function.

If a finger-stick glucose measurement is taken with the reader, the result is automatically added to the data log being accumulated in the reader. That result (or one taken with a different finger-stick glucose meter) can also be manually entered into the smartphone app to be included into the data log there.

13.5 Sensor life

A sensor will operate for up to exactly 14 days, after which it stops operating and must be replaced. This seems to be based on a safe consideration of progressive decline in the operation of the probe with time. If we ask the smartphone app for a 24 hour graph of readings, the display includes an indication of how many days are left in the scheduled life of the sensor. A similar indication is given on the reader after a scan with it.

In addition, the phone gives an alert (typically with a sound, depending on the phone settings) when there are three days left, when there is one day left, when there is only one hour left, and when the time has expired and operation of the sensor has ceased.

It is important to note that when the sensor's exactly 14-day life cycle has expired, we cannot retrieve any data from the sensor. Thus, depending on when we have "scanned" the sensor, we might lose as much as 8 hours worth of accumulated measurements. If the sensor life is about to expire, it is probably a good practice to scan it to avoid this loss of data.

When replacing the sensor, once the new sensor has been "initialized", we cannot read any data from the former sensor. Accordingly, it is probably a good practice, when about to replace the sensor, to scan the "current" one. (This may turn out to be the same practice suggested just above.)

13.6 Notations

We can manually enter into the phone such things as the dosage of rapid-acting or long-acting insulin taken, meals eaten (perhaps including an estimate of the carbohydrate load), or exercise done (with a coarse scale of intensity). A free-form text note can also be entered. These entries are time tagged. They can either be entered to be time tagged "as of now" or as of an earlier time.

13.7 Other forms of report

We can set a minimum and maximum glucose concentration level. The smartphone will then report the fraction of the time (over some selected past period) that the patient's glucose concentration is within that range (an important metric for diabetes management).

We can call up a graph of glucose concentration for any 24 hour period within the range of stored data. We can get a distribution of glucose concentration by time of day for various periods. We can get a report of occurrences of extremely low glucose concentration (hypoglycemic episodes). There are a number of other reports available.

13.8 Upload and download of data

A patient using the system may be entitled to a database account maintained by an Abbott "partner". Assuming that the smartphone has access to the Internet, the phone will periodically upload all the new data readings to that account. The patient can then, either from an app on the smartphone or from an application on a desktop or laptop computer, download that data and have it presented in a wide range of formats.

As near as I know, this service will retain the data for an indefinite period. Thus reports done by download of the data in that account can include the data from as far back as the patient has had this service.

13.9 Access by the patient's physician

Arrangements can be made so that the patient's physician (or such) can download the patient's data from the central data base for review.

14 NEWER VERSIONS

As of this writing, Abbott has subsequently introduced two new generations of their CGM system, each with two successive versions. The latest version of the latest generation is called the FreeStyle Libre 3+ CGM system. It is considerably different in the design of the sensor, the manner in which it is applied, and the features provided. It is discussed in some detail in the companion article, "The FreeStyle Libre 3+continuous glucose monitor system". by this same author presumably available where you got this.

15 ACKNOWLEDGEMENT

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Appendix A
Sensor carrier, extraction plunger, and blue cylinder details

A.1 INTRODUCTION

In this appendix we will see some of the internal details of the sensor carrier and extraction plunger, and blue cylinder of the applicator.

A.2 THE SENSOR CARRIER

The sensor carrier supports the sensor body before insertion of the probe module and after. We see it in figure 19.

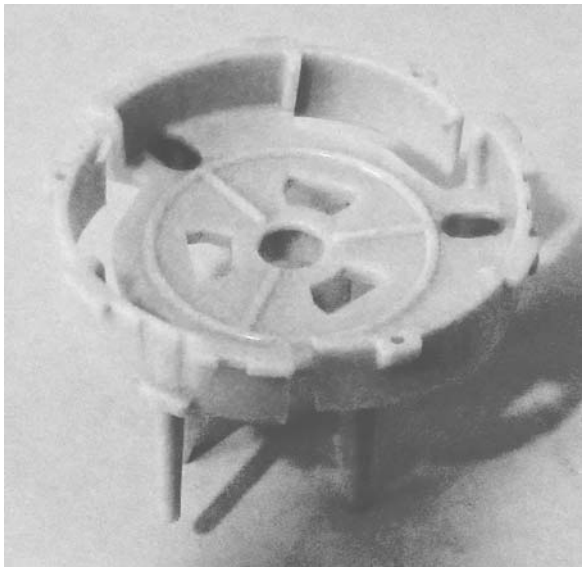

Figure 19. Sensor carrier

The sensor carrier is welded onto the tips of three fins that are integral with the applicator housing (it has been surgically removed for its photos here). Thus it is in effect a part of the applicator body.

We can see the three integral spring fingers whose pointed tips (at about our 2 o'clock, 6 o'clock, and 10 o'clock), pressing into notches on the periphery of the sensor body, will hold the sensor body or completed sensor in place and properly oriented.

On each finger we see a little rectangular boss (with a small hole). It is against these bosses that the ribs in the blue cylinder press to hold the fingers securely against the sensor body (and later the completed sensor) until almost the very end of the emplacement operation. Then, only the spring force presses the fingers in, still holding the assembled sensor in place but allowing it easily come free when the applicator is polled away.

A.3 THE EXTRACTION PLUNGER

In figure 20 we see the sensor carrier in a different view, along with the extraction plunger and extraction plunger spring.

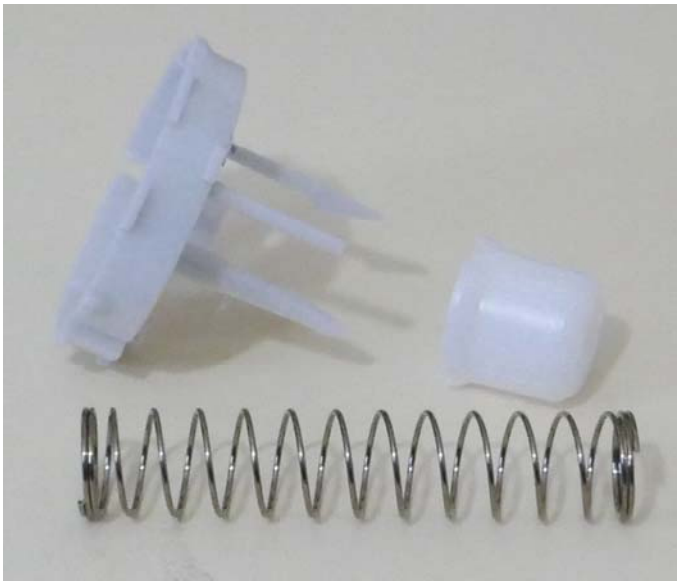

Figure 20. Sensor carrier, extraction plunger, and extraction plunger spring

In figure 21 we see the sensor carrier with the extraction plunger in place as it would be with the applicator as received. In reality, the extraction plunger spring would be inside the extraction plunger, but it was not feasible to have it there for this photo.

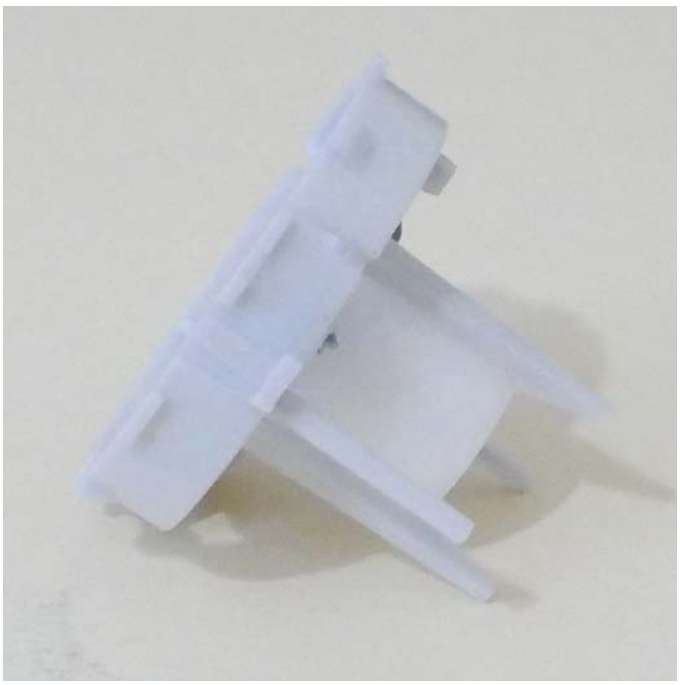

Figure 21. Sensor carrier with extraction plunger in place

Note that, after transfer of the probe module into the sensor body, the probe module, with the introducer needle in place, has been forced into the sensor body. The tail barb of the needle extended through the back of the sensor body, and had been caught by three catches on the extraction plunger (as we saw in figure 17), which is in the position we see just above.

The extraction plunger is nestled between three prongs on the back of the sensor carrier. Each has at its end a latch-like feature which holds the cylinder in place against the force of its spring. These latch-like features have inclined flanks such that, if the prongs were free as we see them in the photo, the force of the spring on the plunger would cam the prongs apart, allowing the plunger to escape their grip and move.

But in reality, with the applicator in its state prior to application of the sensor onto the patent's arm, with the blue cylinder still extended, a sleeve on the blue cylinder (see section A.4 and figure 22) closely surrounds the three prongs, confining them so they cannot be cammed out by the force of the plunger spring.

But, during the application operation, as the applicator comes fully into contact with the patient's arm (as the competed sensor is pressed onto the skin), the blue cylinder is sufficiently driven back into the applicator that this sleeve on it comes clear of the tips of the three prongs. Then the extraction plunger, under the force of its spring, cams the prongs apart and escapes their grip, traveling to the far back end of the applicator housing, taking the introducer needle with it.

Figure 22. Blue cylinder

A.4 THE BLUE CYLINDER

In figure 22 we see the blue cylinder, emphasizing its back part (of which we get no view with the cylinder in place in an intact applicator). I delayed showing it until now so that the context of some of its features would be in hand.

At about our 7 o'clock, rising from near the bottom of the cylinder as we see it here, we see one of the three thin, flat latches that, touching tabs on the sensor carrier, will initially prevent the blue cylinder from being pressed back into the applicator body.

We see at the center a cylindrical sleeve. As discussed above, its interior will, in the starting position of the blue cylinder, hold together the three latch prongs that hold the extraction plunger in place, preventing the plunger from moving into rear of the applicator under the force of its spring.

We also see two of three loop-shaped detent levers. These travel along ribs in the applicator body. With the blue cylinder fully extended (as it will be when the applicator is first opened), these sit in detent notches in those ribs, holding the blue cylinder against inadvertent movement into the applicator body, which could prematurely cause the release of the extraction plunger. Later, when the cylinder has been moved slightly into the applicator body, they will sit in a second set of detent notches in the ribs, to a similar end.

Then, as described earlier, when the blue cylinder is pressed smartly against the patient's arm (to emplace the sensor), these levers come out of that second set of detent notches so the blue cylinder can move into the applicator and, when it is essentially entirely into the applicator housing, release the prongs holding the extraction plunger. Then those levers drop over steps in the ribs, locking the blue cylinder against slipping back out of the now-spent applicator.

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