CHAPTER 16:

CGM COMPONENTS, TYPES AND WEAR

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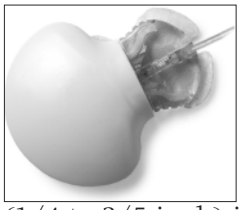
In this chapter, the three components of the second-generation CGM systems will be described. (The MiniMed CGM system and the Cygnus Glucowatch comprised the first-generation systems.) A discussion of life with CGM use will follow. Finally, the features of four commercially available devices will be compared.

THE THREE COMPONENTS OF CURRENT CGMs

There are three basic components of all second-generation CGMs. They are the sensor, the transmitter, and the receiver/monitor.



1. SENSOR. The sensor is a small probe that sits under the skin and measures the glucose levels. Sensors range in size from 6 mm to 15 mm (1/4 to 3/5 inch) in length and are as thin or thinner than a pump infusion set cannula. They insert beneath the skin much like a pump set. Special insertion devices help guide the sensors in and reduce discomfort with insertions. Like pump cannulas, the CGM sensors are flexible and need the help of a needle to insert them under the skin. As soon as the sensor is inserted, the needle is removed and the sensor stays in place.

CGM sensors react to the glucose in the interstitial fluid. They produce a special chemical signal, which is then interpreted as a glucose value. The sensor is removed and replaced after three to seven days of wear.

2. TRANSMITTER. The transmitter is the part of the CGM that contacts the sensor and sends glucose information to the receiver. All CGM systems secure the transmitter to the sensor and to the skin so that it does not move around or fall off. Some transmitters sit on a plastic cradle directly over the inserted sensor, and some click into the side of the sensor piece. Transmitters are usually made of plastic and are waterproof for swimming and showering. Transmitters vary in size and shape, but they are usually 6 mm to 12 mm (1/4 to 1/2 inch) thick and about the size of a thumb or silver dollar.

The transmitter sends the glucose information from the sensor to the receiver by radio frequency. The transmitter can communicate with the receiver over distances of up to 10 feet depending on the system. Sometimes cell phones and other devices may interfere with the transmission distance. Most transmitters are powered by batteries that can be replaced or recharged as needed.

3. RECEIVER or MONITOR. The receiver (sometimes called the monitor) receives the information from the transmitter. This device is usually the size of a pager or insulin pump, and it is worn on a belt, in a pocket, or sometimes in a purse or backpack. Some receivers are actually part of an insulin pump (The MiniMed Paradigm REAL-Time system), so that the user does not have to carry a separate CGM receiver. Others, such as the Freestyle Navigator, have a built-in blood sugar meter so the user does not have to carry an additional meter.

The receiver displays sensor glucose values every one to five minutes. It also displays trend graphs of past glucose values or arrows that show whether glucose levels are rising or falling. All three systems have high and low glucose alarms that may be set by the user. The Paradigm REAL-Time and the Navigator also have important alarms for predicting low glucose levels.

All receivers also give the time of day and the date. Some people who wear a CGM give up wearing a watch. They check the time on their CGM and can also check their glucose level and trend graph.

DAILY CGM WEAR

To understand what it is like to use CGM, it is important to understand the different events that occur during a sensor wear. CGM use starts with the insertion of a sensor and ends when that sensor expires. The process is then repeated.

Sensor insertion: For patients with sensitive skin, numbing cream can be applied prior to sensor insertion. When it is time to insert, a site is selected and cleaned with an alcohol swab. A new sensor is removed from packaging and inserted into the skin. Some inserters are spring loaded to automatically insert and remove the needle, while others are inserted at the control of the user. After insertion, the site is checked for bleeding. Blood is wiped away if necessary. The transmitter is connected to the sensor and sometimes secured with extra tape. The user then programs the monitor to start the warm up period.

Warm up period: The first several hours of sensor wear do not give the user any sensor readings. This is called the calibration period or warm-up period, and it varies in length with each CGM. During this time, the sensor is "getting wet" in the interstitial fluid, adapting to the stress of the insertion, and preparing to read glucose levels.

Calibration points: At the end of the warm-up period, the CGM system will alert the wearer that it needs a calibration blood sugar value to start recording glucose information. This is because the sensor needs a reference value to interpret the chemical signals under the skin. After entering the first calibration blood sugar value into the receiver, the CGM will start reading the real-time glucose numbers.

At different times throughout the sensor life, the CGM will require more calibrations to maintain the readings. These typically occur a few times a day, depending on the system. Calibrations help determine how accurately the device is reporting sensor glucose values. The user can strongly influence how good a calibration blood sugar is going to be. **The best times to calibrate are when blood sugars are very stable (i.e., before a meal or when no rapid-acting insulin has been given in the past two hours).** This is one of the most important factors for accurate CGM readings and cannot be overemphasized. If a person has just eaten or given an insulin dose, the blood sugar will be changing more rapidly and the calibration value may confuse the sensor. Sometimes the CGM will report a calibration error and ask the user to redo it. At other times it will accept the suspect value and become less accurate in its readings as a result.

Additional blood sugar checking: All CGM readings are intended as additional information and not as a replacement for blood sugar checking. This means that the user is still advised to check blood sugars when he/she eats, gives insulin or suspects a low or high blood sugar. This can be done as often as necessary on a blood sugar meter and will not affect the CGM glucose readings.

Alarms and alerts: The user may set the alarms to sound or vibrate when the sensor glucose level is too high or too low. Low glucose alarms may be particularly important in keeping the user safe, especially during sleep or when the person has trouble identifying lows. The person/family must respond to alarms by pushing buttons on the receiver or it will continue alarming.

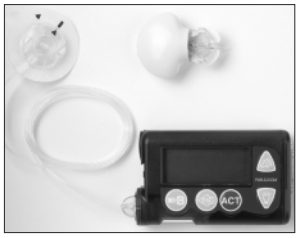
End of sensor life: At the end of the sensor life (three to seven days), the receiver will alert the person/family that the sensor must be replaced. At this point, the transmitter is detached from the sensor mount and all tape is carefully removed. The sensor is lifted out of the skin and discarded in a sharps container. The skin should be evaluated for redness, pain, excessive bleeding or pus that may indicate infection. Most sites heal uneventfully, as with a pump insertion.

New sensor: The cycle is then repeated for the next sensor wear. A new site must be chosen at least two inches from the previous site. In between sensor wears the batteries in the receiver or transmitter may be replaced or recharged. The data may also be downloaded from the device (although this can also be done during a sensor wear).

A COMPARISON OF FOUR CGM SYSTEMS

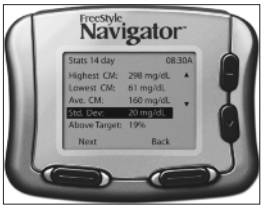
The following paragraphs and Table 1 present details about four CGM systems available today. Note that the specifics are likely to change as the companies upgrade their systems. For additonal comparison of CGM systems, go to www.ChildrenwithDiabetes.com/continuous.htm.

MiniMed REAL-Time Systems
(www.minimed.com)



MiniMed has two similar systems available (both using the same transmitter and sensor): The Guardian REAL-time system has a typical CGM receiver; the Paradigm REAL-time uses the Paradigm 522 or 722 insulin pump as the CGM receiver — although the sensor does not control or affect the insulin pump delivery. Both systems have a three-day sensor life and a two-hour warm up period after sensor insertion. The MiniMed sensors are placed in a special insertion device that is spring loaded. The inserter is placed on the skin and the sensor is inserted at a 45º angle with the push of a button. The needle is manually removed. Both systems have warning alarms for high and low glucose levels. The main screen displays the glucose level and arrows to indicate direction of change. One arrow up or down (↑ or ↓) indicates a moderate change in glucose levels and two arrows up or down (⇈ or ⇊) indicate a rapid change. The Guardian REAL-time also has prediction alarms which alert before the glucose levels go too low or high. The Paradigm REAL-time may be an advantage for those who already have the 522 or 722 model insulin pumps. This prevents having to wear a second device.

Abbott Freestyle Navigator
(www.abbottdiabetescare.com)



The Navigator sensor is worn for five days before replacement and has an automatic inserter included with each sensor. It inserts at a 90º angle. The needle is concealed during entry and removal so the user/family never has to see it. A Freestyle meter is built into the Navigator so a second blood sugar meter does not have to be carried. The Navigator has high and low glucose level alarms as well as alarms for predicted high and low glucose levels. On the main screen, a 45º arrow (↘ or ↗) indicates a moderate rate of change in the glucose level. A straight up or down arrow (↑ or ↓) indicates a rapid rate of change. Because multiple readings are used in the rise and fall prediction, this is often the most accurate of the warning alarms. Some people feel that the shorter warm-up period (two hours) for the Guardian, Paradigm REAL-Time and DexCom STS is an advantage over the Navigator's 10 hour warm up. It is our belief, however, that all the sensors are more accurate after the first 12 hours. Anyone using a CGM should be cautious with sensor readings during the first day of wear. Accuracy usually improves over the life of any sensor. The Freestyle Navigator is not FDA approved at the time of this writing.

DexCom STS (www.dexcom.com)

The DexCom system is the simplest of the three devices with a few key features. The sensors are worn for either three or seven days, and have a built-in inserter that conceals the needle, similar to the Navigator. It inserts manually, however, and the user controls the speed of insertion. The sensors are at a 45º angle. The DexCom has a fixed alarm at 50 mg/dl (2.8 mmol/L) that cannot be turned off, as well as programmable low and high alarms. One note on the DexCom is that the accuracy is affected by acetaminophen products like Tylenol. If these products are taken while wearing the sensor, the CGM readings will be inaccurate for a few hours, and should not be used. The DexCom STS has the smallest transmitter, which is an advantage in very small children. At the time of this writing, the DexCom is not approved by the FDA for use in children.

ADHESIVE ISSUES AND SUGGESTIONS

(Appreciation is expressed to Kimberley Krapek, RN, MS, CDE of Abbott Diabetes Care for help with this section.)

When discussing insulin pump therapy or continuous glucose sensor wear, it is imperative that a thorough discussion of adhesive issues be completed during the training of each device. Adhesion of insulin infusion sets or continuous glucose sensors can be problematic in certain regions of the country where heat and humidity are high during summer months and in patients whose body encourages poor adhesion of sets due to hairiness, excessive sweating, oiliness or weight. Adhesion problems are one of the most frequent complaints that we receive.

The following tips can be helpful in the discussion of adhesion issues patients may face. It is important to remember every patient is different. What works for one patient may not work for others, what works one time may not work another. Some patients may need all the help they can get to keep the sets in place, while others may only need reinforcements during particular activities or at specific times of the year. All patients need to know the problem is not unique to one product and there are ways that can help improve the adhesion properties of each set. Some suggestions are:

First start with a clean dry skin base (clean skin with alcohol swab)

- Ensure that the skin is absolutely dry before applying the tape.
- Avoid putting sets on in a bathroom that is steamy or humid. If you must use an area where humidity is high, use a hair dryer on a low warm setting for a moment before applying the tape to improve the skin's dryness.
- If using a barrier such as IV Prep, Mastisol or others, make sure to use the product according to the manufacturer's directions. Many of these substances enhance adhesive properties of the tape only when the skin is completely dry. Applying adhesive tape to a site that is wet will lead to poor adhesion.
- Use alcohol to clean the area. This removes oils that may interfere with proper adhesion.
- Avoid use of lotions and perfumes on skin that will be under the tape.
- Avoid using moisturizing bath soaps that contain lotion or oil on the site for insertion.
- Use a moistened loofa sponge over the site where the insertion is to occur to help exfoliate the skin and rid it of unnecessary dead skin cells that will impede proper and lasting adhesion.
- If perspiration interferes with a set staying adhered, try using a solid form of antiperspirant. This can be difficult to find without a deodorant attached to it. Health food stores often carry solid antiperspirants in the form of a rock crystal.

Reinforce sites properly

There are many products on the market to help with adhesive issues: IV Prep, Mastisol, Hypafix™, Skin Prep and Skin Tac™ are products that can be used to help sites stick better.

- Use of an under-bandage for insulin infusion sets can help retain sets only when the under-bandage is placed on clean, dry skin.
- Sandwiching the infusion set between two pieces of IV3000, Tegaderm or Polyskin® is a common practice. Under-bandage use is discouraged with CGM sensors due to potential damage to the sensor. Some people cut a hole in the IV3000 where the sensor is inserted.
- Use a sturdy tape to secure safety loops with infusion sets. Micropore™, Durapore™ and Transpore™ are examples of tape that will help secure a safety loop. Use of a safety loop will save an insulin infusion site should the pump become dislodged from its carrier or pocket or get caught on/in something. Develop a habit of a safety loop and you will save many sites from premature dislodging.
- Kendall Kerlix FlexWrap™ is a colorful woven bandage that can assist in securing sites worn on the arm or leg.
- When using an over-bandage minimize the possibility of moisture collection under the over-bandage. This can be accomplished by using a tight-fitting over-bandage that conforms to the contour of the site. Any open area that allows for moisture to collect will diminish the adhesive success of a set or site.

Place sites properly

- Avoid placing sites with adhesive tape over skin that is creased or wrinkled; or in areas prone to bending, rubbing etc.
- Stand upright and avoid hunching over when placing a set or site.
- ROTATE sites, give skin time to breathe and repair itself. Using the same site repeatedly not only can lead to scarring and potential interruption of consistent insulin delivery, it can also lead to skin irritation and adhesion issues.
- If the site you choose is hairy, either use scissors to trim the hair as close to the skin surface as possible or gently shave the area. If using a razor, be sure the blade is sharp to avoid ingrown hairs.

SUMMARY

CGMs are comprised of a sensor, transmitter and receiver. Each system requires calibration blood sugar values to continually read sensor glucose values. Wearing a CGM is similar to wearing an insulin pump. It takes time to become comfortable with wearing the CGM and understanding how to operate it. CGM systems can provide extra safety features like alarms and trend arrows to help with diabetes management.

DEFINITIONS

Calibrations: Blood sugar values that must be entered into a CGM receiver in order to keep the sensor reading accurately. These are usually entered one to two times per day.

Receiver (or monitor): The part of the CGM that displays glucose information every one to five minutes. It also displays trend information, alarms and time and date.

Sensor: The small probe that sits under the skin and measures the glucose levels in the interstitial fluid. It is usually comparable in size to a pump infusion cannula.

Transmitter: The part of the CGM that collects information from the sensor and transmits it to the receiver. The transmitter remains on the body attached to the sensor.

TABLE 1:

FEATURES OF FOUR SECOND-GENERATION CGM SYSTEMS

	MiniMed Guardian REAL-Time	**MiniMed Paradigm REAL-Time**	**Freestyle Navigator**	**DexCom STS**
Parts of system	Sensor, transmitter, receiver	Sensor, transmitter, insulin pump	Sensor, transmitter, receiver	Sensor transmitter, receiver
Communication between transmitter and monitor	6 feet	6 feet	10 feet	5 feet
Sensor life	3 days	3 days	5 days	3 or 7 days
How it obtains BG data	Manual entry	BD Link meter or manual entry	Freestyle meter built into receiver	Manual entry
Initial warm-up calibration period	2 hours	2 hours	10 hours	2 hours
Number of calibrations/day	2 per day	2 per day	4 in 5 days	2 per day
Frequency of real time readings	5 minutes	5 minutes	1 minute	5 minutes
Trend arrows	Yes	Yes	Yes	No
Hypo and hyper alarms	Yes	Yes	Yes	Yes
Predictive hypo/hyper alarms	Yes	No	Yes	No
Trend graphs	Yes	Yes	Yes	Yes
Downloading software	Yes	Yes	Yes	Yes
Waterproof transmitter	Yes	Yes	Yes	Yes
Cost of system	$1,339 starter kit with monitor, transmitter and and 4 sensors	Cost of Paradigm pump plus start up kit: $999 transmitter and 10 sensors	To be determined	$800 (transmitter is replaced every 6 months: $250)
Cost of sensors	$35 each	$35 each	To be determined	$35 each
FDA approved: adults/children	Yes/Yes (peds version)	Yes/Yes (peds version)	Not yet/Not yet	Yes/Not yet