

(special REPORT

## CONTINUOUS GLUCOSE MONITORING

# Ready for prime time?

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## terms to know

Should you decide to purchase a continuous glucose monitor, you'll want to know these terms and concepts:

**Get set for what's being hailed as the third generation for monitoring glucose levels in a mere 25 years. Prior to the 1980s, getting a glucose status report meant testing your urine. Since then, increasingly smaller, faster, and simpler meters have made checking glucose quicker, easier, and much more accurate.**

Today, "we're at the cusp of the next monitoring revolution—continuous glucose monitoring," says Gary Scheiner, M.S., CDE, owner of Integrated Diabetes Services near Philadelphia and author of *Think Like a Pancreas* (Marlowe & Co.) who's lived with type 1 diabetes for 20 years.

Continuous glucose monitoring is the wave of the future for keeping track of your body's glucose levels. That's why you should understand the technology, learn about the continuous glucose monitors already on the market, and weigh the benefits and drawbacks of using these systems. Once you've digested the details, you can discuss with your health-care provider whether you should add continuous glucose monitoring to your diabetes care.

### How the Systems Work

Think of the output from a continuous glucose monitor (CGM) as a running video of your glucose levels. Compare that to the output from your regular blood glucose meter. Those meters act more like still cameras, taking readings at incremental times during the day when you choose, which means you may miss some highs and lows. The CGM gives you a glucose number—without a skin prick—every few minutes, adding up to hundreds of readings a day. If the CGM detects a high or low reading, it sends you an action alert predicting impending trouble. These alerts can help you take action to control any highs and lows. Working with your diabetes educator or health-care provider, you'll set up the receiver with your desired

**Calibrate:** CGMs need to be calibrated regularly to help keep glucose readings as accurate as possible. Calibration is done by checking blood glucose with a blood glucose meter. The frequency of calibrations differs for each device.

**Interstitial fluid:** The word "blood" isn't used before the word "glucose" when describing continuous glucose monitoring because the sensors measure interstitial fluid, not blood. Interstitial fluid fills spaces between the tissue cells. Blood glucose and interstitial glucose levels can be different (see "lag time").

**Lag time:** When blood glucose is changing rapidly, the glucose level in interstitial fluid can lag by about 10 minutes and may not be as accurate in real time as the result from a fingertip blood glucose check. For this reason, people using CGMs should calibrate their monitors with a blood glucose result when their glucose levels are fairly stable, such as several hours after a meal or when waking up. Glucose levels are the least stable just after meals, during intense physical activity, or when blood glucose is falling.

**Warm-up time:** Every three to five days, a new sensor needs time to "settle in" and get ready to provide accurate results. Warm-up times vary among CGMs from two to 10 hours. During this warm-up time, the CGM will not provide accurate glucose readings.

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high and low thresholds to detect your personalized glucose boundaries. The receiver also details glucose trends and how quickly—or slowly—glucose levels are changing in your body. Plus the CGM stores all your data for later analysis on your computer or online with company-specific data management software.

John Walsh, P.A., CDE, coauthor of *Pumping Insulin* (Torrey Pines Press), describes this first generation of CGMs as the Model Ts of the continuous-monitoring evolution. Like Henry Ford's first cars, today's CGMs have many similarities and few unique qualities. The systems fall into two groups—*independent* of an insulin pump or integrated with a pump. Each system offers software to analyze readings and track trends, as well as 24/7 phone and Internet support.

Every system approved by the U.S. Food and Drug Administration (FDA) so far consists of a glucose sensor, a transmitter, and a receiver. The glucose sensor, the smallest component, is placed under your skin in the interstitial fluid (see "Terms to Know," page 17), from which it gleans the readings. So it measures the glucose in your interstitial fluid, not in your blood. The sensor contains an electrode that creates a small current to detect changes in glucose levels. The transmitter snaps onto the sensor to send the results to the receiver. The receiver pulls information from the transmitter and shows you the results. It can be a handheld device, an insulin pump, or the shell of a pump. To learn more about specific systems, see "Continuous Glucose Monitors," below.

### Ongoing Research

A number of small studies have proven the accuracy and benefits of continuous glucose monitoring. Most show improved blood glucose control with lower A1Cs and participants spending less time overall living with glucose levels that are either too high or too low for good health.

"Further research is under way," says Claudia Graham, Ph.D., vice president of global therapy access with Medtronic, Inc. Graham also has type 1 diabetes. "Medtronic has invested in longer and larger clinical trials. Within several years, we hope to demonstrate that people can practice better glucose management with a continuous glucose monitor at their side," she says. "However, showing an impact on diabetes complications will take longer research trials."

## continuous glucose monitors

Below are the continuous glucose monitors now available.

### NAME:

### Abbott FreeStyle Navigator

### MANUFACTURER:

Abbott Laboratories

### APPROVAL YEAR:

Under review by FDA. Approval is pending

### WHO CAN USE IT:

People age 18 and older

### COMPONENTS:

Sensor (replace every five days), transmitter, handheld receiver

### DESCRIPTION:

The sensor attaches to a plastic mount on your skin with a disposable self-insertion device. The transmitter snaps into the sensor mount on your skin's surface and transmits glucose data wirelessly to the handheld receiver. A 10-foot range allows the sensor to be worn on areas of the body other than the abdomen. You can wear the receiver or carry it in a pocket or purse.

Readings every one to two minutes. Has a 10-hour warm-up time. Has a FreeStyle blood glucose meter built into the receiver. The sensor and transmitter are waterproof.

FreeStyle CoPilot

### FEATURES & FACTORS:

www.abottdiabetescare.com

### DATA MANAGEMENT SOFTWARE:



### WEB SITE:

### DexCom STS (Short Term Sensor)

### MANUFACTURER:

DexCom

### APPROVAL YEAR:

People age 18 and older

Sensor (replace every three days),\* transmitter (replace every six months), handheld receiver

The sensor is inserted with a disposable self-insertion device. The transmitter snaps to the sensor. Both are held in place with adhesive on your abdomen (only approved site).

The transmitter sends glucose data wirelessly to the receiver. Wear the receiver or carry it in a pocket or purse.

Readings every five minutes. Has a two-hour warm-up time. The sensors aren't waterproof, so you'll need to buy a shower patch.



### DexCom DM Consumer Data Manager

www.dexcom.com

\*Note: A seven-day sensor is awaiting FDA approval.

## FDA Approval with Caveats

The FDA has approved several continuous glucose monitors. Considered by the FDA to be medical devices, each system has passed a rigorous approval process. The FDA's biggest concern has been accuracy and safety. The agency hasn't approved use of CGM results in lieu of a traditional blood glucose meter check prior to a treatment action, such as taking insulin to cover food, driving, or exercising. On these occasions, you should still check your blood glucose with your meter. You'll also need to use your blood glucose meter to calibrate the CGM's accuracy at regular intervals. Keep in mind the acceptable accuracy for blood glucose meters is to stay within 20 percent of the actual number. The same expectation is being applied to CGMs.

An accurate reading is just as critical for you and your health-care providers as it is for the FDA. Experts around the globe have been fine-tuning several sophisticated error grids and other analyses to assess CGM accuracy. However, users play a big role. "To maximize accuracy, people must properly and continuously calibrate these devices," says Alison Evert, M.S., R.D., CDE, of the University of Washington in Seattle.

## Covering the Costs

Both the initial and ongoing costs for continuous glucose monitoring supplies are high. The initial cost for the receiver, the first transmitter, and a few months of sensors ranges from \$4,000 to \$5,000. After the first year, annual costs are about \$4,000 for sensors and replacement transmitters.

"We're hopeful that costs will come down when the volume of sales goes up," Graham says.

Who pays for these systems?

At this point, you do. "Health plans are reimbursing CGMs on a case-by-case basis," Graham says. Reimbursement is now the exception rather than the rule. Most people are paying for CGMs out of pocket, once they have a prescription from their health-care provider. "To get health plans to cover CGMs, insurance providers need to see that these devices make a difference in care and outcomes," Graham says.

"Medtronic has a reimbursement strategy that, over the next few years, will ensure CGM coverage for people who need it most." Then insurers will require health-care providers to complete a certificate of necessity, as they do now for insulin pumps.

## Guardian REAL-Time System

Medtronic MiniMed

2006

People age 7 and older

Sensor (replace about every three days), transmitter, waterproof rechargeable portable charger, receiver

The sensor is inserted with a disposable self-insertion device. The transmitter snaps to the sensor. The transmitter, which must be worn on your abdomen, sends glucose data wirelessly to the receiver, which must be worn on your body. The receiver is the shell of the Medtronic Paradigm insulin pump.



Readings every five minutes.

Two models, one for ages 7 to 17 and another for ages 18 and older.

Predictive and rate-of-change alarms are integrated.

CareLink Personal Therapy Management Software

[www.minimed.com](http://www.minimed.com)

## Paradigm REAL-Time Insulin Pump and CGM System

Medtronic MiniMed

2006 (for age 18 and older) and 2007 (for ages 7 to 17)

People age 7 and older

Sensor (replace about every three days), transmitter, waterproof rechargeable portable charger, receiver

The sensor is inserted with a disposable self-insertion device. The transmitter snaps to the sensor. The transmitter sends glucose data wirelessly to the pump, which must be worn on your body because it's delivering insulin continuously through the infusion-set tubing. The receiver is integrated into the shell of the Paradigm insulin pump.

Readings every five minutes. Integrates CGM with insulin pump (user controls insulin delivery). Can only be used with the Paradigm pump.

CareLink Personal Therapy Management Software  
[www.minimed.com](http://www.minimed.com)



### Weighing the Benefits

Among diabetes experts, consensus is building on the benefits and drawbacks of continuous glucose monitoring. "People must tiptoe into this technology and be very aware of its pluses and minuses," Scheiner says. "Too often, people want to believe a new device is a panacea—one step away from a new pancreas."

For some, the benefits are worth the costs. The frequent stream of glucose readings gives you more knowledge and insight to manage your diabetes. It can help you avoid serious highs and lows. You can use the numbers to verify correct insulin dosing and timing. The constant monitoring also means you can cut back on

the number of daily blood glucose checks and finger sticks if you are now performing more than four checks a day.

The potential drawbacks are significant. The high costs of the current systems and lack of health-care coverage are big hurdles for many. Plus you still need to use your blood glucose meter to check the CGM's accuracy. (You may experience false alarms and alerts due to inaccuracies.) You'll also need to realize that when your blood glucose is changing rapidly, readings from your CGM will lag behind your meter readings from your fingertips. This is called lag time (see "Terms to Know," page 17). When you receive high and low readings, you may be tempted to

overcorrect, causing even more swings in glucose levels. Plus having more readings means spending more time interpreting results and managing your diabetes, as long as you can find someone who's qualified and willing to help you. Add all this to the simple but important fact that some of the devices can be a little cumbersome to wear.

### It's Up to You

Should you rush to your health-care provider to get a prescription for a continuous glucose monitor? "Everyone can learn a lot and improve their control with a CGM," Scheiner says. "But is it worth the cost and inconvenience?" Answers from current users vary.

## should you try continuous glucose monitoring?

Answer the following questions regarding your diabetes management and knowledge to see if you're a good candidate for continuous glucose monitoring.

- |   |           |   |           |
|---|-----------|---|-----------|
| <b>1. You take insulin several times a day</b> (both long- and rapid-acting) or use an insulin pump, or you have type 2 diabetes and are thinking about starting insulin. | (Y)   (N) | <b>8. You check your blood glucose levels</b> at least four times a day.  | (Y)   (N) |
| <b>2. You understand and use these concepts:</b> duration of insulin action, carbohydrate counting, adjustment of insulin or food intake for physical activity.           | (Y)   (N) | <b>9. You're willing and able to change</b> the sensor and calibrate it with blood glucose checks.  | (Y)   (N) |
| <b>3. You have the knowledge and ability</b> to make safe and effective short-term diabetes treatment decisions.  | (Y)   (N) | <b>10. You're willing and able to cover</b> the costs of a CGM system.  | (Y)   (N) |
| <b>4. You don't feel symptoms</b> when your blood glucose is dropping (hypoglycemia unawareness).   | (Y)   (N) | <b>11. You're ready to master a new technology.</b>   | (Y)   (N) |
| <b>5. Your blood glucose can drop dramatically</b> during the night or at other times.  | (Y)   (N) | <b>12. You're comfortable wearing devices</b> on your skin and carrying the necessary equipment.  | (Y)   (N) |
| <b>6. You want to make a big change in your lifestyle</b> and/or accomplish a physical goal.  | (Y)   (N) | <b>13. You're willing to undergo training</b> and climb the learning curve.   | (Y)   (N) |
| <b>7. You're actively involved in your own diabetes care.</b>   | (Y)   (N) | <b>14. Your health-care provider</b> knows how to start you on a CGM or can refer you to a health-care provider or diabetes educator who does.        | (Y)   (N) |
|   |           | <b>15. Your health-care provider will download</b> your CGM data and help you analyze it or can refer you a diabetes educator who can.                | (Y)   (N) |
|   |           | <b>If you answered "yes" to all or most</b> of these questions, you should discuss using a continuous glucose monitor with your health-care provider. |           |

# "People must tiptoe into this technology and be very aware of its pluses and minuses."

— Gary Scheiner, M.S., CDE

Lisa, a 64-year-old from the Seattle area, is contemplating a continuous glucose monitor in addition to her pump. The value would be "seeing all the ups and downs of my glucose levels to help me adjust my treatment more smartly," she says. "However, since I don't like things attached to my body, I'm not willing to have more than one item attached."

"It won't give you perfect control," says Katie, a thirty-something attorney who purchased a CGM when she was training to run a marathon. "But I'm getting addicted to it."

Jane, who's had type 1 diabetes for nearly 40 years and is on an insulin pump, is less than satisfied with her continuous glucose monitor. "It doesn't tell me much more information than my blood monitoring results," she says. "Plus it's expensive and time-consuming."

At first, Katie found the information and expense of the CGM to be overwhelming. "You can reduce the costs by not wearing the CGM constantly. I had to hold myself back from micromanaging my glucose levels. Over time, I've learned to use my CGM to track trends and revise my diabetes management," she says. "For example, now I administer my bolus insulin a few more minutes before I start to eat because I've verified that the insulin takes longer to work. And I discovered I had lows during the night, so I've made some basal insulin dose changes."

Evert says it's clear that the current CGMs "are for a rarified breed of people who have diabetes." To help you decide if you're one of them, take our quiz, "Should You Try Continuous Glucose Monitoring?," opposite.

## The Path to Success

To truly benefit from continuous glucose monitoring, you must be willing to take a very active role in managing your diabetes. Before you decide to try it, you need to make sure your knowledge in successfully managing diabetes is up-to-date and advanced. You'll need detailed information on each system so you can choose the one that will work best for you. As you choose a system, verify that you'll receive adequate training and support. Several monitor manufacturers provide a few hours of training, which is generally taught by diabetes educators, while others don't. Ask about the type and amount of training available before you buy.

"We've found if people don't invest time in training, they get frustrated and may discontinue using their CGMs," Evert says. "Follow-up visits with a diabetes educator are key to getting the most from your device."

At Evert's worksite, people are encouraged to download the results of their CGMs at home and bring the printed reports to their clinic visits. These software printouts provide a wealth of information for fine-tuning all aspects of diabetes management.

When you start using your CGM, take it slow and be patient. Use the numbers as a way to keep track of trends rather than as a signal to enact an immediate response. Focus on fixing one problem at a time and don't let yourself get overwhelmed. Be realistic in your expectations. Continuous glucose monitoring won't produce perfect glucose control, and it doesn't remove the daily challenges you face in managing your diabetes.

## Closing the Loop

Continuous glucose monitoring may be just one stop along the path to closing the loop between glucose results and insulin delivery without relying on the human brain to intercede. But most experts, including Scheiner and Evert, believe an FDA-approved closed-loop system remains in the distant future.

"However, we're planning for the next generation of CGMs to be more user-friendly," Graham says. New innovations may appear very soon, because every large blood glucose monitoring and insulin pump company has joined the continuous monitoring race to market. As Tama Donaldson, a spokesperson for Abbott Laboratories, says, "Our interest in insulin pump technology is related to the future development of a reliable, easy-to-use, open-loop diabetes management system." We'll keep you abreast of this revolutionary technology as the story unfolds. ■

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