

TYPE 1

TYPE 2

Generat

The Next ion: Continuous Glucose Monitors

**These “real-time”
monitors promise
to change the
way we chart ups
and downs, by
delivering
readings every
few minutes
around the clock.
But don’t toss
your old monitors
just yet!**

By Amy Tenderich

CONTINUOUS GLUCOSE MONITORS MAY BE THE BIGGEST thing on the horizon when it comes to improving diabetes control. Besides doing away with multiple finger pricks each day, this new generation of blood glucose sensors promises to put tremendous power in patients’ hands.

Rather than providing a one-time “snapshot” of your blood glucose at a single point in time—as today’s meters do—continuous monitors deliver readings every few minutes around the clock, so you can watch the whole “movie.”

This will let you and your doctor chart your ups and downs on a running basis, so you can identify problems and make corrections in your regimen.

These monitors offer the potential to greatly improve the lives of people with diabetes through:

- **Action alerts.** On-screen arrows would let you know if your blood glucose is on the way up or down, so you can take immediate action
- **Safety guards.** An alarm would alert you to hypoglycemia (dangerously low blood glucose levels) or hyperglycemia (dangerously high blood glucose levels) the moment they hit
- **Improved control.** Studies show that using a continuous monitor can make an enormous difference in glucose control for both type 1 and type 2 patients—crucial for avoiding long-term diabetes complications

Yet despite all the promising news, it’s not time to send your regular monitor off to the scrap heap just yet.

First, cost is an issue. Early systems run from \$800 up to \$3,000 for the monitor, plus up to \$5,000 per year for sensor supplies. Health insurance coverage and patient reimbursement rates have not yet been clarified. Second, there's still much we don't know about continuous monitoring products, starting with how accurate they will be compared to current meters.

Measuring Stick Needed

A number of products are gradually being evaluated and approved by the U.S. Food and Drug Administration (FDA), but the process has been something of a struggle: No measure exists yet to rate their accuracy and performance. So how should the FDA assess them?

David C. Klonoff, MD, and his team at the Diabetes Technology Society in Northern California are working to overcome this hurdle. They've established a panel of international experts from diabetes-related industries, government (including the U.S. Army and NASA), academia, and health care organizations (including the American Diabetes Association) to create a set of standards that will serve as a measuring stick for each new continuous glucose monitor (CGM) product.

"Creating standards like this will jumpstart this industry," Klonoff says. "It will help accelerate evaluation of a whole load of new products for immediate glucose monitoring, and will likely encourage lots of new companies

to innovate—so people with diabetes will get their hands on new technology that can help them *now, faster.*"

Accuracy Issues

Evaluating medical devices is a tricky business. It involves a lot of math and review of clinical data. The FDA's core consideration is whether a product is *accurate enough* for its intended use.

Currently, the readings from standard glucose monitors are compared to laboratory results, with an eye to matching data within a 20 percent error margin. Meanwhile, patient studies illustrate the product's ability to detect high and low glucose levels, and its value in improving diabetes control (measured via A1C test results).

New continuous monitors will likely be evaluated in the same way,

through a mix of analytics and clinical results, says Steven Gutman, MD, director of the FDA's Division of Clinical Laboratory Devices. While the new meters may be less accurate initially, "they will generate more quantity and different types of information that might allow them to meet FDA safety and effectiveness requirements."

While Klonoff's panel and the FDA work to cook up an ideal evaluation recipe, two systems from Medtronic and one from DexCom have already been approved. Over the last few months, the FDA deemed these products accurate enough for personal use as long as the patient takes a fingerstick reading before making any therapy decisions.

"It's important to recognize that real-time continuous glucose monitoring adds more clinical value than [conventional] meters can provide.

Real-Time Monitors To Watch



MiniMed Guardian RT

Approved by the FDA in July 2005 for patients 18 years and older. RT stands for "real time." Currently available in select cities across the United States, for "supplementary use" alongside a standard monitor only.

www.minimed.com/products/guardianrt/



DexCom STS

"Short-term sensor" was approved by the FDA in March 2006. A small sensor worn on the body transmits data wirelessly to a handheld receiver, making it "tubeless" and more convenient to wear.

www.dexcom.com/

It allows patients to intervene on a real-time basis to avoid the extremes ... and ultimately this could lead to better A1C results,” says John Mastrototaro, PhD, vice president of Sensors and Implantable Products at Medtronic Diabetes.

Perfecting CGM is also key to eventually developing an “artificial pancreas.” The continuous monitor will be connected to an automatic insulin pump, fit with a special sensor to form a complete system that will allow people with diabetes to live almost as if they didn’t have it, Klonoff says. Developers are experimenting with both internal and external models.

Patient Perspective

One of the first questions patients ask is: “Will I still have a needle stuck in me somewhere?” The answer is yes. Many companies are

working on non-invasive monitoring via a patch or sensor that sits above the skin. But that technology is still being refined. The devices on the fast track to patients now are “subcutaneous,” meaning inserted under the skin via a tiny flexible probe.

CGM devices measure blood glucose levels in the interstitial fluid (the fluid surrounding body cells) every 5 minutes and store the readings. The data can later be downloaded to a computer to produce detailed charts of a person’s glucose levels throughout the day.

While this sounds high-tech, experts insist that patients do not need to be computer-savvy to use the meters. “Real-time CGM is actually very intuitive,” Mastrototaro says. “Patients can look down and see their glucose values every 5 minutes. When they hear a high or low glucose alert, they check their

glucose with a fingerstick measurement and react accordingly. So it’s actually quite basic.”

Is continuous monitoring for everyone? Essentially, yes. Both type 1 and type 2 patients can discover how diet, exercise, medication, and other factors affect their blood glucose and track how fast their glucose levels are moving and in what direction. The real-time high and low glucose alerts are especially valuable for patients suffering from hypoglycemic unawareness (a dangerous inability to sense the normal warning signs of low blood glucose). Since the technology is new, patients are instructed to double-check results with a fingerstick reading before treating a high or low.

To date, the FDA has approved the Guardian RT and Paradigm REAL-Time System from Medtronic Diabetes, and DexCom’s STS (short-term sensor)—for use by adults 18 and over. These products generally are rolled out incrementally, city-by-city across the country, so check with your doctor about availability in your area. Meanwhile, several other products are under consideration, and studies are showing that continuous monitoring can be safe and very effective for children as well.

New technologies can only prove their true value through patient use over time, and real-time monitoring is no exception. ▲

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MiniMed Paradigm REAL-Time System

The world’s first integrated combination of a continuous sensor and an insulin pump, approved by the FDA in April 2006. The closest thing yet to a fully automated “closed-loop” system, aka an artificial pancreas.

www.minimed.com/products/insulinpumps/realtime/index.html



Abbott Navigator

Being evaluated by the FDA now. Company is working on an improved adhesive for a longer, 5-day wear period (instead of just 3 days).

www.abbottdiabetescare.com/freestylenavigator/qa.aspx



Glucoband

Next generation of the troubled GlucoWatch, this will be a wristwatch-like monitor that does not need to penetrate the skin. Introduced internationally, but still being studied in the United States.

www.calistomedical.com/eng/?p=glucoband