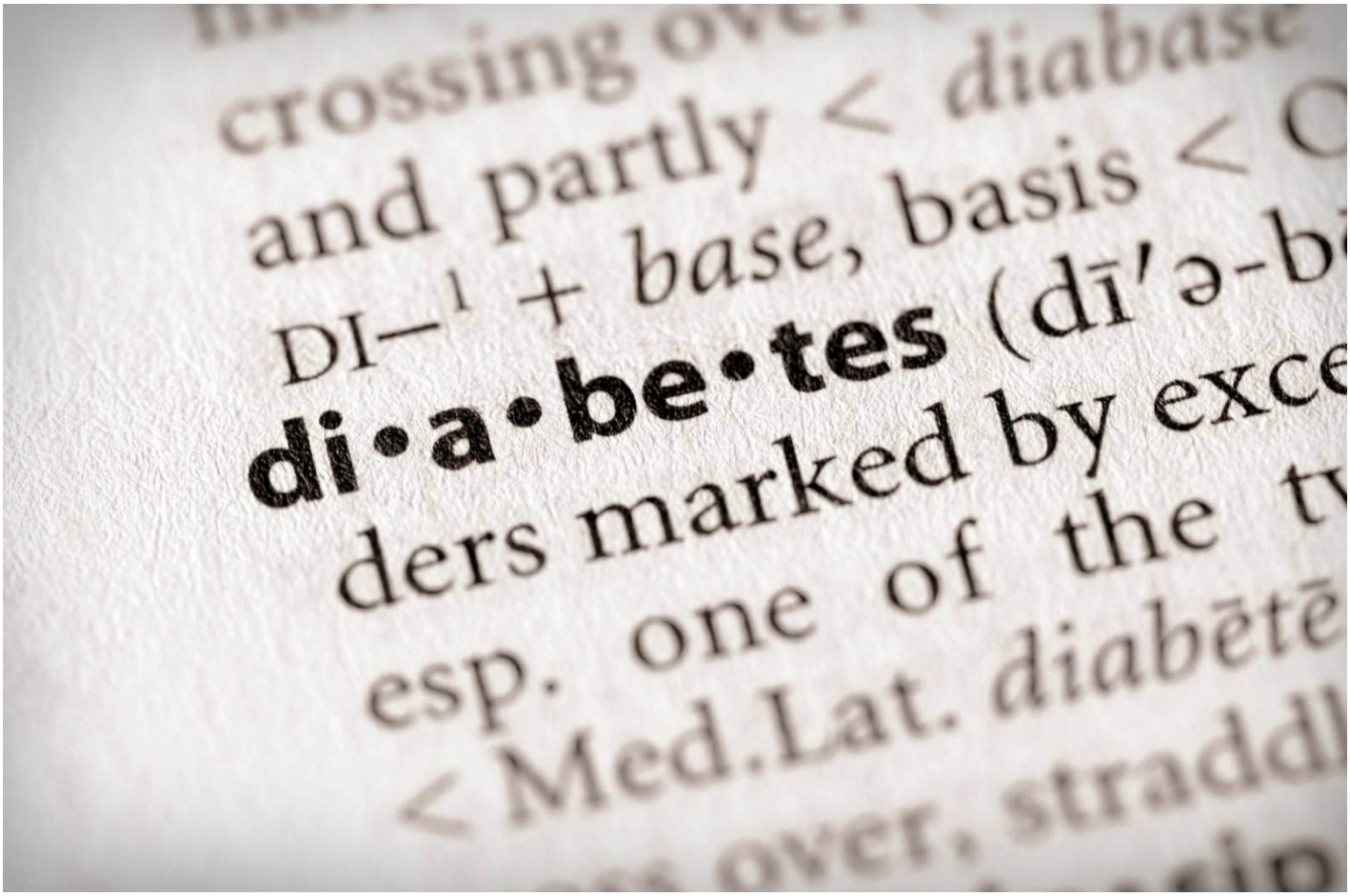
Tiny Monitor Gives Diabetics Frequent, Automatic Readings

University of California, San Francisco (UCSF)



The first non-invasive continuous monitoring device, pioneered at the University of California, San Francisco, helps patients better manage diabetes.

In 2002, many people with type 1 diabetes rejoiced when they learned that a new technology offered relief from being a human pincushion. Diabetics who were tired of pricking their fingers to check their blood sugar levels, or ignored or avoided the process altogether — and, by doing so, increased their chances for hypoglycemia — had a new, portable, convenient option.

That non-invasive score-keeper was the GlucoWatch® Biographer™, the world's first wristwatch monitoring device, which incorporates technology invented at the University of California, San Francisco. As a supplement to finger-prick devices, the easy-to-use GlucoWatch® has helped diabetics and their doctors become better informed about the patient's disease.

> *Staying in tight control of glucose levels is key in managing diabetes. Physicians usually advise*

> *doing blood checks by finger prick four to seven times a day; but because of the inconvenience, some patients draw blood only once a day, if at all.*

The trade-off for this relaxed attitude can be deadly. Patients who do not actively manage their diabetes could suffer long-term diabetes-associated complications including blindness, hypertension, stroke, heart disease, kidney disease and amputation.

In 2005 the World Health Organization estimated about 500 million people worldwide suffer from diabetes and only about 40 percent have been diagnosed. More than 20 million people, or about 7 percent of the U.S. population, have the disease and about a third of those are undiagnosed and untreated.

In 2002 — the year that GlucoWatch® Biographer™ was introduced — 224,092 deaths were attributed to diabetes complications, and these numbers are considered low because many older people have multiple chronic conditions. In the same year, the annual economic cost of diabetes was estimated at $132 billion.

Easy-to-Use Tool Changes the Landscape of Glucose Monitoring

Scientists at the UCSF spent eight years developing and patenting the technology behind the GlucoWatch® Biographer™, a first-of-its-kind glucose monitoring device. Blood glucose monitors can offer substantial benefits that other traditional sampling methods don't provide.

For diabetics who want to better manage the disease by tracking glucose levels in a noninvasive, easy-to-read way, the small, portable technology invented at the UCSF has changed the landscape of diabetic monitoring.

In addition to the convenience of being able to wear the monitor, the GlucoWatch® Biographer™ also warns patients before their glucose levels become too low or if there is a sudden, rapid drop in glucose levels. The technology has been an important step toward improving diabetes management.

The U.S. Food and Drug Administration approved the GlucoWatch® Biographer™ in 2001 as a supplement to — not a replacement for — blood testing through finger pricks. It has helped patients make better decisions about diet, medication and physical activities. The frequent readings show how various activities such as exercises, stress, sleep, taking medications and eating meals affect glucose levels. Most important, it can warn patients of low blood glucose levels, which can be fatal.

"The pain-free, wrist-watch device automatically checks sugar levels by transmitting tiny imperceptible electric currents through the skin," explains Yashwant Vaishnav, Ph.D., business development and intellectual property manager with the systemwide Office of Technology Transfer at the University of California. "The concept for the first-of-its-kind technology was developed in 1987, and in 1995 the university licensed the technology to Cygnus Inc. of Redwood City, California."

In 2001, Cygnus began marketing the device in Europe, and in 2002 the second-generation model, the GlucoWatch® G2TM Biographer™, became available in the U.S. for adults and pediatric patients.

The forerunner of recently released selfmonitoring devices, the GlucoWatch® G2 Biographer™ provides noninvasive readings by measuring glucose collected through the skin as opposed to the traditional finger-prick method of collecting readings from whole blood. The Biographer™ provides frequent automatic glucose readings — as often as every 10 minutes for up to 13 hours.

Noninvasive diabetes management begins when the patient places an adhesive AutoSensor, a thin disposable pad, to the back of the watch and straps the GlucoWatch® Biographer™ on the forearm. The sensor adheres to the skin, collects glucose in tiny gel discs in the sensor, then displays the readings on the watch's face.

"Readings are taken noninvasively through the sensor by extracting glucose from interstitial fluids between the skin cells," Vaishnav says.

Though automatic glucose monitoring devices are not for everyone, they can make it easier for diabetics to gather and review information. In addition to convenience, Vaishnav points out, there is another significant benefit for users of the GlucoWatch® Biographer™. "The technology gives the user an archival record. Worn like a watch, it calculates, displays and stores frequently recorded glucose readings," he says.

And a patient doesn't have to be a computer programmer to use the data management system. Before purchasing a glucose monitoring device, patients' physicians or diabetes educators can help discern what information they want patients to record. The technology lets patients scroll back to see glucose readings over a few hours and download the information to a personal computer to save, print out and interface with physicians' computer systems. The GlucoWatch® G2 Biographer™ can store up to 8,500 readings, and the information, once transferred to a computer and plotted as a graph, can offer a good visual picture of patients' histories.

Spawning the Next Generation of Self-Monitoring Devices

Since 2001, the University of California has consented to the transfer of the GlucoWatch® license agreement from Cygnus to Animas Corp, which is dedicated to making insulin pump therapy easier for diabetes patients and healthcare professionals. The company is now selling GlucoWatch® products.

The interest that ensued when the GlucoWatch® Biographer™ was first introduced is still evident today. The University of California's pioneering technology opened the door to other continuous monitoring products that have been and are expected to be introduced to the marketplace as a direct result of the GlucoWatch® Biographer™.

Some new products include the DexCom® Inc. Short-Term Sensor Continuous Glucose Monitoring System, the Medtronic Inc. MiniMed Long-Term Sensor System™ and Guardian® RT Continuous Glucose Monitoring System, and the Abbott Laboratories Freestyle Navigator™.

"The Regents of the University of California maintains ownership of the technology," Vaishnav says. "While there are other newer products on the market, GlucoWatch® was the first commercially available product of its kind."

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