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## Why Can't a Diabetes Device Be as Cool as an iPod?

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### Introduction

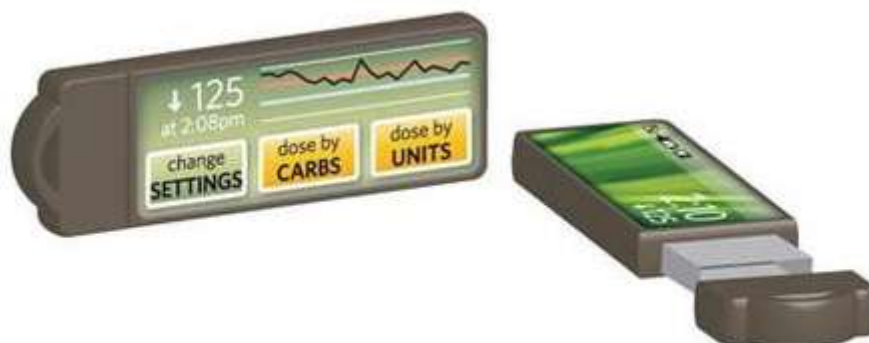
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For many people with diabetes, bulky blood glucose meters and insulin pumps have become distant memories. It was barely 3 years ago, however, that the paucity of user-friendly technology for people with diabetes drove Amy Tenderich to launch a design contest on DiabetesMine, an informational and community Website.<sup>[1]</sup> There, she posted what turned out to be a landmark open letter to Steve Jobs, Apple Chief Executive Officer, calling on him (and other consumer designer experts) to revolutionize the design of diabetes devices.<sup>[2]</sup>

Tenderich, who was diagnosed with type 1 diabetes mellitus as an adult, was inspired by the Apple® iPod® and wondered why people like her, whose lives depend on medical devices, couldn't get something with a similar design aesthetic to manage diabetes. Medical device manufacturers, she says, were stuck in a bygone era.

"The whole mind-set of the industry in the past was hospital driven," Tenderich told Medscape. "The old idea was that diabetic patients were very sick and laid up in a hospital bed, so it wasn't very important for them to have lifestyle devices. We needed a paradigm shift in mind-set. These are devices that we carry around with us day in and day out. They go to bed with us; they go to the bathroom with us; they go to the shower with us; and they have sex with us. It couldn't be more important for these devices to be appealing from a form-factor standpoint."

In her open letter, Tenderich called on Jobs to help bring about "a sweeping change in industry-wide mentality." Although he failed to respond to her challenge at that time, other people did, and in the following months, many individuals and organizations came forward with prototypes, designs, and ideas for glucose monitoring and insulin delivery. Inspired by Tenderich's online plea, a San Francisco-based design company, Adaptive Path, produced the Charmr, a concept glucose meter combined with an insulin pump, universally controlled by a device the size of a universal serial bus (USB) stick (Figure 1).<sup>[3]</sup>



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**Figure 1.** Charmr design concept for diabetes management. Image courtesy of Adaptive Path, San Francisco, California. Used with permission.

The Charmr's technology was not new; both the OmniPod<sup>®</sup> (Insulet Corporation; Bedford, Massachusetts) and the MiniMed Paradigm<sup>®</sup> REAL-Time (Medtronic, Inc.; Northridge, California) were already available in the United States, but Adaptive Path's approach aimed to "humanize" this type of device. The designers of the Charmr spent time with people who had diabetes, following their routines and learning what motivated them to stay healthy. The final prototype featured innovations, such as a touchscreen interface on the controller that was designed to be plugged into a flash drive so that data could be quickly uploaded, patterns monitored, and information transmitted to physicians. The originality of the design was recognized by design professionals worldwide when the Charmr was selected as a finalist in the 2008 International Design Excellence Awards (IDEA), an annual program cosponsored by *BusinessWeek* magazine and the Industrial Designers Society of America.

Although public response to the Charmr was enthusiastic, the device did not advance beyond the concept phase. Adaptive Path, which still receives inquiries about the potential availability of the Charmr, said that they are working with several (unnamed) medical device companies to adapt some of the Charmr's design aspects for inclusion in other devices.

## Designs for the Future

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One of Amy Tenderich's suggestions to Steve Jobs was that Apple might sponsor a contest for the best independently designed medical device for use in diabetes. Although Apple did not take this on, the surge of interest in new designs led to the launch in 2008 of the annual DiabetesMine<sup>™</sup> Design Challenge, which invites individuals and organizations to submit design concepts (either devices or Web applications known as "apps") for consumer-friendly tools aimed at improving daily life for people with diabetes. The first winner was [Log for Life](#), an online diabetes logbook for glucose, carbohydrate intake, medication, exercise, and other data, designed to interface with smartphones.

Since 2009, the Challenge has been financially supported by the California HealthCare Foundation, an independent philanthropic organization that "aspires to improve the way healthcare is delivered and financed in California and beyond by promoting innovations in care and broader access to information." The Challenge is also endorsed by [medGadget](#) (the *Internet Journal of Emerging Medical Technologies*) and the global design and innovation firm IDEO, which is based in Palo Alto, California.

The 2009 Challenge attracted over 150 entries from entrepreneurs, developers, students, patients, and caregivers who submitted concepts for new, noninvasive glucose monitoring technologies; gaming and toys for diabetes education; and programs for patient motivation and support. The panel of judges (experts in healthcare and diabetes treatment) awarded the grand prize to 2 graduate students from Northwestern University, Chicago, Illinois, who submitted the LifeCase/LifeApp System, which converted the Apple iPhone<sup>™</sup> into a controller for a combined glucose monitor and insulin pump (Figure 2).<sup>[4]</sup>



**Figure 2.** LifeCase/LifeApp System. Image courtesy of Amy Tenderich. Used with permission.

The LifeCase, which attached to a standard iPhone, included a glucose meter, lancing device (clipped to the side), and strip storage. The software interface, LifeApp, combined diabetes management software, insulin pump management software, and logs of meals and glucose readings. Data would be displayed on the phone screen. Because the LifeApp would connect wirelessly with a user's insulin pump, the pump could be made smaller and less obtrusive because it would no longer require its own interface.

Tenderich acknowledges that a lot of improvements have taken place in diabetes devices since she posted her open letter. "I have at least had a part in stirring up conversation about this," she said modestly. Although none of the DiabetesMine Challenge winning designs have been produced commercially, other devices with similar features have become available. The OneTouch® UltraMini® blood glucose meter by LifeScan, Inc. (Johnson & Johnson Pharmaceutical Research & Development, L.L.C.; New Brunswick, New Jersey), which comes in a range of colors (similar to Apple's iPod nano®), "definitely has much more of the cool consumer look that people were hoping for," Tenderich said (Figure 3). The Contour® USB meter (Bayer Diabetes Care; Tarrytown, New York) is a blood glucose meter with plug-and-play diabetes management software that is similar in some respects to the Charmr concept (Figure 4).



**Figure 3.** OneTouch® UltraMini® blood glucose meter by LifeScan, Inc. Image courtesy of Johnson & Johnson. Used with permission.



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**Figure 4.** The Contour® USB meter Image courtesy of Bayer Diabetes Care; Tarrytown, New York. Used with permission.

The 2010 DiabetesMine Design Challenge<sup>[5]</sup> is now open and accepting entries until April 30, 2010. This year, for the first time, open community voting on the DiabetesMine Website will determine the top 10 finalists. The winners, to be announced in June 2010, will be selected by a judging team made up of experts in diabetes care, medical technologies, design, and venture capital funding. The judging team includes Samantha Katz, codesigner of the 2009 prize-winning LifeCase/LifeApp system, who is now Global Product Manager at Medtronic Diabetes and is working on the company's next-generation pump. She and her fellow judges will name 3 grand-prize winners, who will each receive \$7000 cash, plus a complimentary consulting session with experts at IDEO, and other prizes. The winners of 2 separate categories, the "Most Creative Idea" and the "Best Kids' concept" (for children under age 17) will each receive \$1000 cash.

## Barriers to New Technology

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Although using the iPhone as the interface for controlling a complete diabetes management system is an attractive idea, several big stumbling blocks must be overcome, cautions Tenderich. First, Apple has given no indication to date on whether it would agree to development of the iPhone hardware as a medical device, which would require regulatory approval by the US Food and Drug Administration (FDA).

The FDA defines a medical device as:

...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or any function of the body.<sup>[6]</sup>

Diabetes-related apps written for the iPhone, such as Diabetes Log, Diamedic©, and Glucose-Charter™ -- all of which require manual data entry -- do not come under this definition, nor, probably, would the prototype system for diabetes management with the iPhone that was demonstrated by LifeScan, Inc. in 2009. This prototype, which was designed with the cooperation of Apple, connected a glucose meter with the iPhone via a wireless Bluetooth or cable interface; thus, in this instance the iPhone was just being used as a means of information exchange. However, if a blood glucose meter were to be integrated into the iPhone's hardware, this would come under the medical device definition. The chairman of the Electromagnetic Compatibility and Wireless group of the FDA's Center

for Devices and Radiological Health, Don Witters, said in 2009 that the FDA was starting to look at the regulatory implications of using the iPhone as a wireless medical device.<sup>[7]</sup>

Some devices that have been widely adopted for the management of diabetes have been criticized for lacking randomized trial evidence of clinical accuracy or cost-effectiveness. Richard A. Kahn, PhD, formerly Chief Scientific and Medical Officer of the American Diabetes Association, wrote in *The Lancet*,<sup>[8]</sup> "[T]he technology industry associated with diabetes might lead one to believe that everyone with the disease would benefit enormously from everything available," but the evidence for what is available is "not robust." Even where the outcomes achieved in a well-controlled trial indicate benefit, he wrote, "this might not translate to standard practice in which patients' motivation and the skills of the provider on use of the device will probably be much less than in a trial." Without specifically naming any device, he called for "more and better evidence of medical benefit for what we have now, and solid evidence that what is coming will provide greater benefit at lower cost." He added, "Such imperatives do not disparage technology nor slight its contribution; they simply hold it to a standard it should achieve."

Cost -- or more specifically, reimbursement -- could be another hurdle for new devices for diabetes management. Although most US government and private health insurance providers allow reimbursement for diabetes care devices, reimbursement for device innovations has not been universal. Tenderich said that many patients complain that some of the best innovation ideas were "killed off" because the companies that developed them did not find it profitable enough to move ahead with them commercially or even continue to market them.

An example of this, Tenderich recalled, was the *Pelikan Sun* (Pelikan Technologies, Inc.; Palo Alto, California), an electronic lancet launched in the United States in 2007. Compared with traditional mechanical lancing devices, the Pelikan Sun was associated with a significant reduction in pain and quicker healing of the lanced site. However, it was expensive to purchase (\$200 up front, plus the costs of supplies), and health insurance companies would not cover it. The device was withdrawn from the market earlier this year, although the company emphasized that "this discontinuation is not the result of any product defect."<sup>[9]</sup>

## Keeping Up With Developments

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Many patients with diabetes are frustrated that their endocrinologists are not aware of the latest technologies, and therefore do not know what choices are available, Tenderich said. As a result, they are unable to give their patients appropriate advice, she said.

Endocrinologist Steven Edelman, MD, who has type 1 diabetes mellitus himself, agrees. He told Medscape that although he is a diabetes specialist, he has a difficult time keeping up with the latest technologic developments. Dr. Edelman, Professor of Medicine at the University of California, San Diego School of Medicine, San Diego, California, created the national nonprofit organization Taking Control of Your Diabetes (TCOYD),<sup>[10]</sup> and he believes that the answer lies in educating patients through organizations, such as TCOYD.

"I think we have to rely on people living with diabetes to take the most active role, and help guide their doctors into the best care," he said. "My big model and the whole purpose behind [TCOYD] is patient education, motivation, and self-advocacy."

Tenderich agrees, saying that patients should get involved in health social media. "This can have a huge impact on patients' lives," she said. "I would like to see doctors refer their patients to get involved in some of these patient communities, because they can learn so much about the practical aspects of taking care of their illness, including getting tips and advice about technology."

Tenderich recalled that when the OmniPod first became available, many people were unsure whether it would be comfortable. "Your doctor said that it delivered insulin very well and that you could use it for your diabetes, but patients want to know things like whether it will cause a skin irritation and whether it is really necessary to change it every 3 days," she said. "People used to traditional pumps wanted reassurance that the controller wouldn't become separated or lost."

Ideally, all healthcare providers need to learn about new advances in diabetes management, Dr. Edelman said, in order to provide optimal patient care. "You cannot do it with patients or with doctors alone," he said. "You have to educate them both in parallel and promote communication."

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## Authors and Disclosures

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