

Diabetes Bites

September, 2011



Integrated Diabetes Services presents a quick synopsis of the latest diabetes discoveries and happenings. Send your comments or questions to:

info@integrateddiabetes.com*

**this e-mail goes to office administration. To reach Gary Scheiner directly, e-mail gary@integrateddiabetes.com.*

To reach Karen Franey directly, e-mail karenf@integrateddiabetes.com

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333 E. Lancaster Ave., Suite 204

Wynnewood, PA 19096

(610) 642-6055

(877) 735-3648

Fax: (610) 642-8046

www.integrateddiabetes.com

www.type1university.com

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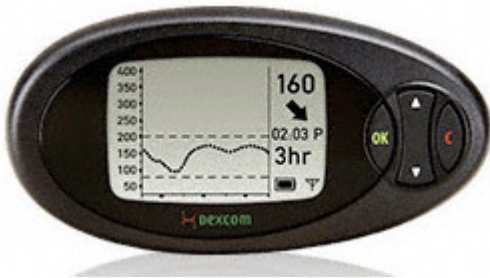
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The Great Sensor Debate: Which System Reigns Supreme?

Last week, Abbott *finally* announced the official withdrawal of the Freestyle Navigator continuous glucose monitoring (CGM) system from the U.S. market. Not that it came as a surprise. Despite receiving rave reviews for its accuracy, Navigator was plagued with manufacturing and cost reimbursement problems and was not being sold or supported for the past year.



Navigator's demise leaves two systems in contention for CGM supremacy: Medtronic and Dexcom. Having worn all of the systems for extended periods of time and trained dozens of patients on each, and having no formal allegiance to any particular company (other than my own), I am in a unique position to evaluate the CGMs and offer an unbiased expert opinion.

A few weeks ago, I was able to get my hands on some of Medtronic's new Enlite sensors and an inserter (don't ask how), which are available only in Europe. Medtronic has claimed that their new sensors are more accurate and comfortable than their traditional Sof-Sensors, so I figured it was time to do some side-by-side, three-at-a-time comparisons. Now keep in mind that I am what they call in scientific circles an "n of 1". That means that this is far from a controlled scientific experiment. It reflects the observations from one person's experience and does not necessarily prove anything... so take this for what it's worth.



So let's get to it. Here's my impression of the Dexcom Seven Plus, Medtronic Real-Time (using Sof-Sensor) and Medtronic Real-Time (using Enlite sensor).

Dexcom Seven Plus has a leg-up in a number of areas. The sensor is very comfortable to insert (I usually feel nothing when inserting and withdrawing the introducer needle), and the sensor itself lasts a long time: usually 12-14 days. The built-in adhesive holds the sensor in place quite well for a week or more. It is flat and tapered. The calibrations can be performed at any time (even when the blood sugar is in a state of flux). The transmitter never requires charging. The display on the receiver is large and bright. And the alerts, both audible and vibratory, are strong enough to be noticed by most people even while they are sleeping. The receiver can be set to vibrate initially, and then only beep if the user fails to confirm the vibratory alert.

Another pleasant aspect of the Dexcom is its simplicity. There are very few steps in the start-up process, and only a handful of menus on the receiver/programmer. It is intuitive enough that most people can self-train using the company's online modules. Error messages are few and far between.

Dexcom's accuracy is generally quite good. I typically find that the sensor matches the fingerstick calibrations fairly well by the end of the first day of sensor usage, and matches most closely from days 3-12, at which point things start to deteriorate. Again, individual use may vary, but my personal experience seems to match that of most of my clients. From initial calibration to sensor failure, I experience an average discrepancy of 10-12% between the Dexcom sensor and simultaneous fingerstick calibrations.

On the downside, Dexcom sensors are more expensive than Medtronic sensors, but the difference isn't much when you consider how long the sensors last. The transmitter range isn't the greatest (roughly six feet, but sometimes less than that), and the transmitter does not store any information the way the Medtronic transmitter does. Having to charge up

the receiver every 3-5 days is a bit of a hassle, especially for people like me who travel a great deal. The charger latches on to sensitive filaments in the transmitter; sometimes the filaments bend out of shape, rendering it unchargeable. In terms of data analysis, the Dexcom receiver does not generate any statistics for the user. The data downloading process is rather slow, and the current software only runs on PCs. In addition (subtraction?), the Dexcom receiver does not let the user know how long their sensor has been in use, how long until a calibration is due, or when their current sensor expires.

But the major drawback to the Dexcom system is that the display is not yet integrated into an insulin pump. With so many CGM users also being pump users, this is a significant shortcoming. Having to wear a pump and carry around a CGM display isn't just inconvenient; it can also be impractical – particularly for young children and anyone who is very active. Since it is not tethered to me the way my pump is, I've misplaced my Dexcom receiver more times than I can count. Sometimes I offer a reward to my kids: "First one to find dad's Dexcom gets five bucks," or something to that effect.

The Medtronic Real-Time CGM (using Sof-Sensors) includes both the Guardian system and sensor-augmented pumps (522, 523, 722 and 723). The major advantage, at least with the sensor-augmented pumps, is the all-in-one concept. No need to carry around a receiver for the CGM since everything displays right on the pump screen. The transmitter stores up to 40 minutes of data, in case the receiver is temporarily out of range. Once back in range, the last 40 minutes of data "dumps" right into the pump or Guardian. The latest Medtronic Real-Time systems allow the user to customize the various alert settings by time of day – a nice feature for those who want to be warned of highs/lows aggressively at some times of day, but less aggressively at others. Like Dexcom, Medtronic offers alerts for high/low glucose levels and rise/fall rate of change. But Medtronic also offers predictive alerts – letting the user know if a high or low threshold is expected to be crossed in a given period of time. Although this feature can generate many "false positive" alarms, it can be helpful to those who must be extremely vigilant about preventing hypoglycemia.

When viewing trend graphs on-screen, the user has the option of scrolling back in time to view specific data points. Advanced statistics, such as average, standard deviation, and "area under the curve" can be generated right on the pump/receiver. Data from Medtronic Real-Time downloads through the internet to a website called "Carelink" which produces some excellent graphs, charts and statistical analyses. When using a sensor-augmented pump, the CGM data is combined with pump data (basal & bolus delivery, carb entries, fingerstick readings) to create more comprehensive reports.

There are several downsides to the Medtronic Real-Time system, starting with complexity. Starting a new sensor is a multi-phase process that requires almost as much luck as it takes technical skill. Error messages often occur during the early stages of sensor usage. Calibrations should only be entered when glucose levels are in a steady state, and must be performed on certain schedule or the system stops generating data.

The alerts/alarms on the Real-Time systems are not strong enough to be noticed by many users. This includes both the vibration and the beeps. The display screen is smaller than Dexcom's, and the contrast is not all that good. And the transmitter requires re-charging at least once every 6-7 days or it stops working.

Medtronic's Sof-Sensors can be uncomfortable to insert, using a long, heavy-gauge introducer needle. Extra tape is needed to hold the sensor and transmitter in place from the get-go. The sensor longevity falls far short of Dexcom, rarely lasting more than a week. Regardless of how long the sensors continue working, they tend to be reasonably accurate only during days 2 to 4 or 2 to 5. Each time I used a sof-sensor beyond 5 days, despite calibrating properly, the system took on the feel of a "random number generator". From my experience, the average difference between Medtronic Sof-Sensors and simultaneous fingerstick calibrations has been approximately 18%.

Medtronic's new (and pending, in the U.S.) **Enlite sensors** have a shorter and much thinner introducer needle, and insert at a 90-degree angle to the skin. There is also extra tape on the sensor to help keep the transmitter (same MiniLink transmitter as is used with the Sof-Sensor) firmly attached. Using the new Enlite insertion device, the new

sensors are considerably more comfortable and easier to insert than the Sof-Sensors. I would rank the Enlite sensors equal to Dexcom in this regard.

However, the accuracy of the Enlite sensors seemed to be no better than that of the Sof-Sensors. Over a three-week period, the Enlite sensors averaged a 19% variance from the fingerstick calibrations. Unlike Sof-Sensors, Enlite tended to err on the *low* side rather than the high side. While this may be beneficial for those trying to prevent hypoglycemia, it can produce enough false low alarms to discourage the average user from fully trusting the device.

So there you have it: My “n of 1” experience with the currently available CGM systems. As you can see, there are pros and cons to everything. That’s where your personal preferences come into play. What’s really important to you? Accuracy? Convenience? Cost? Comfort? Loudness? Whether you’re looking to use a CGM for the first time or are ready to upgrade from your current system, there are many options to consider. As for me? I’ll just stick with my

Editor’s note: The author’s printer ran out of ink just before the article was completed. He apologizes for any grief this may cause. Questions (or complaints) may be sent to gary@integrateddiabetes.com. Gary’s practice, Integrated Diabetes Services, offers a CGM trial service for those looking to sample a CGM and receive expert analysis of the data. This service, along with all of the practice’s diabetes management consulting services, are available in-person or remotely via phone and the internet. Call (877) 735-3648 or visit www.integrateddiabetes.com for details. To learn more about using CGM to improve your control, visit www.type1university.com.

Type-1 University:

Advanced Education. Anytime, Anywhere

Many people have participated in Type-1 University “live” webinars. But did you know that recordings of the live classes are available for viewing anytime, anywhere on just about any computer or smartphone? T1U “podcasts” feature the full class presentations and synchronized audio. Each pre-recorded class purchase allows you up to 70 minutes of viewing time. The classes last anywhere from 40-60 minutes, so there is plenty of time to pause, rewind, or stop and go back at a later time. You can also peruse multiple classes using your 70 minutes of viewing time.

Pre-recorded classes cost just \$19.95 each. The username and passcode are transferrable, so get one (or two or ten) for yourself or someone you know. The full catalog of pre-recorded classes includes:

- Blood Glucose Control During Sports & Exercise**
- Mastering Pump Therapy**
- Advanced Carb Counting**
- Sports/Exercise and Blood Sugar Control**
- Strike the Spike: After-Meal Glucose Control**
- Getting the Most from Your Continuous Glucose Monitor**
- Weight Loss for Insulin Users**
- Fine-Tuning Basal Insulin**
- Managing Pregnancy and Type-1 Diabetes**
- Using Symlin to Improve Diabetes Control**

For any additional information about Type-1 University, please contact the “registrar” (OK, she’s also our receptionist) at 877-735-3648. You can also check out Type-1 University and “Friend” us on Facebook: <http://www.facebook.com/pages/Type-1-University/191612930853897>

News Youz* Can Use

(*Philly for “you all”)

BCG Revives “Almost Dead” Pancreases

Described in the New York Times as a “cheap generic drug used as as a vaccine against tuberculosis,” bacillus-Calmette-Guerin (BCG for short) has shown promise as a treatment for type-1 diabetes. BCG appears to halt the autoimmune process that causes beta cell destruction. Four out of six patients with long-standing type-1 diabetes who received BCG in two injections spaced four weeks apart started producing insulin again. Dr. Denise Faustman and her team at Massachusetts General Hospital hope to begin enrolling patients in a larger-scale study within the next year. These findings come on the heels of several other studies in which various medications failed to overcome the immune system’s destruction of the beta cells of the pancreas. Working around the body’s own immune system continues to be one of the primary challenges in finding a cure for type-1 diabetes.

Pee Your Way to Better Control

Several presentations at this year’s ADA Scientific Sessions focused on a new class of oral medications. SGLT-2 inhibitors lower glucose by reducing the kidneys’ ability to keep sugar in the bloodstream. Instead of “spilling” sugar into the urine when BG levels are above 160-180mg/dl, spilling would occur much earlier. Both lower glucose with modest weight loss and low risk of hypoglycemia were observed with these therapies. Because they do not rely on insulin secretion for activity, SGLT-2 inhibitors have been shown to improve glucose control in patients with type 1 diabetes as well. Since the ADA Sessions took place, the U.S. Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee recommended against approval of dapagliflozin, the first SGLT-2 inhibitor, due to safety concerns of bladder and breast cancers. The FDA’s ruling on whether to approve the therapy is anticipated later this year.

Insulininnovations

Also at the ADA Sessions, a new basal insulin, degludec, was reported. Compared to insulin glargine (Lantus), insulin degludec had similar effect on A1C, but was associated with a lower rate of nocturnal and severe hypoglycemia. The improvement is linked to less variability in the degludec’s action from day to day. There were also several reports of novel approaches to provide faster mealtime insulin. A new formulation of human insulin (Linjeta) was shown to have a more rapid onset of action than insulin lispro (Humalog). Other methods to accelerate absorption of rapid-acting analogs include using a warming patch at the pump infusion site and use of micro-needle infusion sets. The need for faster insulin action is particularly important if we are to develop a truly safe and effective closed loop system.

New Pump Resources from Medtronic

Medtronic, maker of Paradigm insulin pumps and Real-Time CGM, has announced the opening of its new and improved consumer website. The new site, located at www.medtronicdiabetes.com, features an assortment of educational resources, training support and customer service options, including:

- Explanations of various alarms & alerts
- Demonstration on how to change reservoir & various infusion sets
- Infusion and CGM site management
- Strategies for using your pump’s sensor features
- Use of carelink personal online software
- Supply ordering services

Strong Parenting Yields Better Control

A study conducted at Schneider Children's Medical Center of Israel found an association between more authoritative parenting by fathers (but not mothers) and better glycemic control in children with type-1 diabetes ages 11-18. A sense of hopelessness in fathers and permissiveness among mothers was associated with worse glycemic control and adherence. The findings highlight the importance of fathers' involvement in children's diabetes management. The research was published in the August, 2011 edition of Diabetes Care.

Air Travel May Affect Insulin Pumps

Researchers at John Hunter Children's Hospital in Australia have discovered that changes in cabin pressure during flights may cause insulin pumps to deliver too much or too little insulin. After learning of a 10-year-old girl with type 1 diabetes whose blood sugar got too low an hour after take-off, they placed ten insulin pumps (Animas and Medtronic) on a commercial flight. During takeoff (when air pressure was decreasing), the pumps delivered about a unit of insulin, on average. During descent, when pressure was increasing, some insulin was sucked back into the pumps -- causing them to give out less than a unit too little insulin.

The researchers recommend disconnecting the pump before take-off and after landing and making sure there are no air bubbles in the insulin before reconnecting it. They further suggest priming the tubing (while disconnected) after landing. However, because of the small amounts of insulin involved, these concern might only apply to those who are sensitive to small doses of insulin – including young children and adults using less than 30 units daily.

Report Available from diaTribe Regarding Potential Cures for Type 1 Diabetes

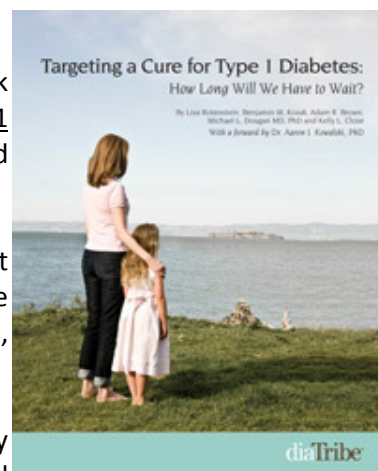
How Long Will We Have to Wait?

Every person touched by diabetes wants to know when there will be a cure. A lot of work is going on, but what are the chances of a breakthrough? [Targeting a Cure for Type 1 Diabetes](#) is diaTribe's comprehensive overview of where we are and where we're headed in that search.

Rich in detail and written for patients and their families, the report features the latest information on the most promising approaches for curing diabetes. These include immune therapeutics, islet and pancreas transplantation, beta cell regeneration agents, and the artificial pancreas.

With an introduction by Dr. Aaron Kowalski of the JDRF, and with concluding remarks by diaTribe Editor-in-Chief, Kelly Close, [Targeting a Cure for Type 1 Diabetes](#) is essential reading for anyone who wants to know more about what a cure might look like or when it will be available. Although a cure may not be right around the corner, this report lays bare the possibilities of all the exciting research now underway.

The report is available as a free electronic download by signing up for the diaTribe® mailing list: <http://www.diatribes.com/subscribe.php>



App Focus: “Daily Coach”

Last month, QuantiaCare released its fourth application, DailyCoach with (yours truly) Gary Scheiner, MS, CDE. Daily Coach provides interactive tools and insights that will help people incorporate physical activity into the daily routines at work, at home and everywhere in between.

After only a few days in the Apple App Store, DailyCoach was featured as a top-10 New and Noteworthy health and fitness application. Please help us keep the momentum strong by downloading (see links below), rating the app, and referring it to a friend... or two.

Apple iOS Users:

<http://itunes.apple.com/us/app/dailycoach-gary-scheiner-powered/id450301954?mt=8>

Android Users:

<https://market.android.com/details?id=com.quantia.co.dailycoach>

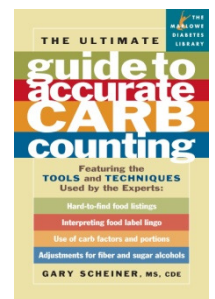
How to Get Into a Sticky Situation

If you have trouble getting your pump infusion sets or continuous glucose sensors to stick to your skin, here's a possible solution: Hypercare Solution. Hypercare is a prescription-only antiperspirant containing a high concentration of aluminum chloride (20%). It comes in a “dabbing bottle” with a sponge-like attachment on top. Applying the solution the night before you plan to insert a sensor or infusion set the following morning seems to work well for most people. Built-in adhesives and over-bandages tend to hold in place much better, and many people also report significantly less itching and, redness and irritation when the skin does not perspire. Hypercare is produced by Stratus Pharmaceuticals: www.stratuspharmaceuticals.com.



The Diabetes Store Is Open!

The Integrated Diabetes Services store features a variety of useful and hard-to-find over-the-counter products for making living with diabetes just a little bit easier. For example, the NutriWeigh computerized nutrition scale and The Ultimate Guide to Accurate Carb Counting, both of which can improve your carbohydrate counting skills tremendously.

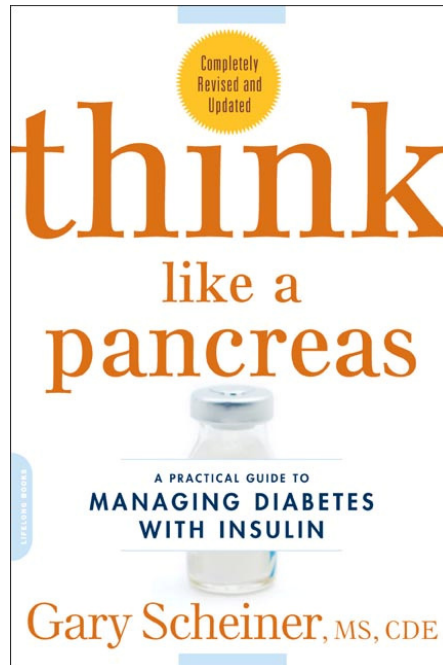


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- Hypoglycemia Treatments
- Sharps Containers
- Skin Wipes
- Lancing Supplies
- Food Scales
- Exercise Videos
- Supply/Travel Cases
- Cooling Pouches
- Ketostix
- Injection Aids

For a complete catalog and to place orders, please visit <http://www.integrateddiabetes.com/webstore/>

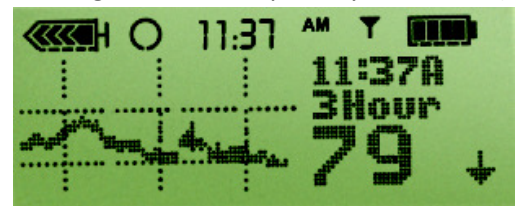
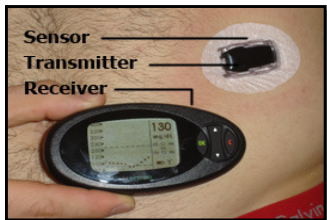
Coming Soon... Think Like A Pancreas, 2nd Edition!



Watch for it later this year.

Sample a CGM

Use of Continuous Glucose Monitors is growing steadily as the systems become more accurate & user-friendly, and insurance coverage expands. Still, many people are hesitant to purchase a system outright without knowing if it's really worth all the effort. If you're interested in trying a CGM (and learning some things that can improve your control), Integrated Diabetes Services offers a CGM Trial Service. This service is available just about anywhere since we can ship the necessary equipment to you and talk you through the sensor attachment process via phone or video chat (skype). Select either a two-week Dexcom Seven-Plus trial, or a one-week Medtronic sensor-augmented pump trial (you must have a Medtronic 522, 722 or Revel pump). The trial service includes a detailed analysis of your sensor data as well as specific recommendations for fine-tuning your glucose control. The cost for the service is \$249, including all necessary equipment, initial training and data analysis. Details can be found at



http://www.integrateddiabetes.com/cg_trialserv.shtml. Call 1-877-735-3648 to schedule.

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