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My Initial Impressions of Medtronic's New Pump





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With a great deal of hype, and a few delays from the US Food and Drug Administration (FDA), Medtronic in September 2013 released its newest combined pump and continuous glucose monitor (CGM), the Minimed 530G with Enlite. Medtronic is marketing this device in this country as the "world's first breakthrough in artificial pancreas technology," while putting in tiny print that the product is the first "approved by the FDA. Medtronic has a similar product already approved in Europe."1

After living for 30 years as a multiple daily injector (MDI), I finally considered making the change to pump/CGM use because of the major selling point the Minimed 530G offered: "Threshold Suspend" technology. With this, the pump, when measuring sensor sugar values below a certain predetermined level, will suspend delivery of insulin for up to 2 hours.

I anticipated a smooth transition, and even better glucose control. (Disclosure: My most recent A1C prior to starting on my pump was a 6.7. Prior to that I had 6.6, 6.4 and 6.5. Additional disclosure: CGM measures sensor glucose readings, which are taken from interstitial fluid. These readings are not as accurate as blood glucose readings, and can be up to 20%—or maybe more—off from blood glucose readings.) With 3 months in on my pump usage, here are some of my impressions about the Minimed 530G with Enlite.

Along with the pump and CGM transmitter, I was also sent a supply of CGM sensors, infusion sets, insuling reservoirs, inserters, and a new glucose meter whose readings can be read, via Bluetooth, by the pump. Purchase of the pump/CGM system comes with a subscription to Medtronic's CareLink diabetes management software.

The pump (530G) works exactly as expected, with an accuracy of basal and bolus doses up to 0.025 units. It provides a constant delivery of insulin, along with relative ease in programming, and a quick "Bolus Wizard" function that allows easy bolus programming with a few simple clicks.

CGM Is Great (Unless It's Lying)

The Enlite sensor is sometimes very inaccurate. It can also be very, very noisy.

I've been awakened several times by alarms alerting me that my sensor glucose readings have dipped below preset limits. Occasionally, I have been awakened by the alarm to find the sensor glucose reading at 59. Even after eating numerous glucose tablets and scaling basal rate back to 50%—or even suspending basal delivery altogether—alarms were still going off, with the readings stuck at 59. After testing my blood sugar and receiving readings over 120 (and even 180 on occasion), the CGM would continue to register readings at 59, triggering the alarms.

On contacting support, they informed me that the sensor should only be worn on the midsection (which it was), only works for 6 days before it needs to be changed (my incorrect readings usually came on the third or fourth day of usage), and the transmitter should be charged (which it was). Only once, while talking to a support team member, did I receive confirmation that the readings might just be wrong. (Or that I wasn't the only customer who's brought inaccurate readings to their attention.) I was recently told that, although the current sensors are a drastic improvement on the prior models in terms of comfort and accuracy, they do sometimes offer incorrect readings.

There are also issues with the pump and CGM communication, as "Lost Signal" errors occur when the pump is just a short distance away from the CGM transmitter. (Medtronic's official documentation says the devices should be within 3 feet of each other; I've experienced errors when the devices were almost directly next to each other.)







Alarms

Immediately upon starting CGM usage, I turned my alarms settings to "vibrate," to avoid interruptions during work or sleep. This seems only a polite suggestion, rather than a rule. If the vibrating alarm isn't acknowledged or turned off within a set amount of time, a persistent alarm sounds. Even after an exhaustive scrutiny of the settings, I could not disable this feature.

CareLink Software

Medtronic's CareLink software package is a key tool in keeping ahead of glucose trends. Working in conjunction with the pump/CGM, as well as the Bayer Contour NextLink blood glucose meter, I have been able to view statistical tables, overlays, and summaries over a period of time to be vigilant of any trends and to make adjustments to basal rates and carb ratios for tighter glucose control. The user interface could use an update, but the software itself is a pretty valuable resource.

Customer Support

In a word: poor. I had my devices for 2 weeks when I realized no one had attempted to schedule device training. Several phone calls later, I received assurances that I would receive calls from my personal "Start Right" representative, only to have days and weeks go by without a word. In fact, during the first month as a customer, every conversation relating to my pump/CGM usage was initiated by me. A manager on the Start Right team, after pointing out again that I've received very little client support from my assigned representative, informed me recently that Medtronic has had considerable success selling their 530G with Enlite. They have actually been understaffed to handle the influx of new customers and manage all of the clients.

Summary

Despite this first step in artificial pancreas technology, there's still a long way to go until a true "closed loop" artificial pancreas system is developed. Like an "artificial pancreas," this device can control insulin production when the Enlite sensor detects that sensor glucose readings are too low.

Even with my complaints about the sometimes-inaccurate CGM readings, the customer service and support problems, and the issues with the device's alarms and errors, I feel my control has improved greatly, and I've been able to limit post-meal spikes and dips in blood sugar, while being aware of changes in my insulin consumption due to metabolic changes and other occurrences, such as the "dawn phenomenon."

My frustrations with my pump/CGM are far outweighed by the additional control I feel I have, and the freedom I've experienced from being able to live a life tethered to a small pump, instead of all the additional equipment being an MDI entailed. **EBDM**

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