



MEMORANDUM

Medtronic F2Q15 - Worldwide sales rise 9% on US launch of 530G; Diabetes solutions business; MiniMed 640G launch this quarter - November 20, 2014

Executive Highlights

- Worldwide Medtronic Diabetes revenue totaled \$430 million, growing 9% as reported and 10% operationally year-over-year (YOY). Globally, pumps grew in the mid-single digit range, and CGM grew over 40% ("outstanding"). F2Q15 US sensor sales grew ~59%.
- Medtronic Diabetes now has three distinct units: (i) intensive insulin management in type 1 & 2 diabetes; (ii) non-intensive solutions for type 2 diabetes; (iii) services & solutions.
- Medtronic is planning a "limited launch" of the MiniMed 640G system in international markets this quarter (F3Q15), followed by a broader launch in F4Q15 (Jan-Apr 2015).

Medtronic reported F2Q15 financial results yesterday morning in a call led by CEO Mr. Omar Ishrak. Below, we enclose our top 10 financial and business highlights from the call.

Financial and Business Highlights

- Worldwide Medtronic Diabetes revenue totaled \$430 million, growing 9% as reported and 10% operationally year-over-year (YOY). Globally, pumps grew in the mid-single digit range, and CGM grew over 40% ("outstanding"). In the US, F2Q15 sensor sales grew ~59%.
- US sales of \$257 million grew 12% YOY and 6% sequentially. The YOY comparison was particularly easy in the US, as F2Q14 sales one year ago did not grow at all (just prior to the MiniMed 530G launch). The launch ramp may be tapering at this point.
- Outside the US, growth was 6% as reported and 9% operationally on sales of \$173 million - this was the first quarter in the past nine where reported growth did not exceed 7%.
- Notably, Medtronic has realigned its diabetes group into three distinct units to become a "more holistic diabetes company": (i) intensive insulin management in type 1 and type 2 diabetes; (ii) non-intensive diabetes solutions for type 2 diabetes; (iii) diabetes services and solutions.

R&D Pipeline Highlights

- Medtronic is planning a "limited launch" of the MiniMed 640G system (predictive low glucose management with Enlite 3 sensor) in international markets this quarter (F3Q15), followed by a broader launch in F4Q15 (January-April 2015). The timing was a one-quarter delay from [Medtronic's F1Q15 call](#) in August.
- Management mentioned the [October 14 start](#) of the US pivotal study of the MiniMed 640G system (predictive low glucose management/Enlite 3 sensor). [See the ClinicalTrials.gov posting here](#). The FCC recently posted the user manual (in five parts) and photos of the MiniMed 640G [online here](#).
- The MiniMed 620G, a CGM-integrated pump customized for the Japanese market, has begun a limited launch and will also more broadly launch in F4Q15 (January-April 2015).
- No details were shared on the CGM pipeline. At [DTM 2014](#), Medtronic's Dr. Rebecca Gottlieb shared new data on the company's fourth-generation (Enlite 3) and fifth generation sensors -MARDs of 12% and 8%, respectively.

9. The pivotal trial of Medtronic's [Guardian Mobile](#) system (Bluetooth-enabled standalone CGM/ smartphone app) was not mentioned on the call, but is [now recruiting patients](#).

10. The rest of Medtronic's pipeline was not mentioned, including the MiniMed 670G system (hybrid closed loop) and MiniMed Flex (a "hybrid" durable pump)

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FINANCIAL AND BUSINESS HIGHLIGHTS

1. Worldwide Medtronic Diabetes revenue totaled \$430 million, growing 9% as reported and 10% operationally year-over-year (YOY). Sequentially, worldwide revenue rose 3% from sales of \$416 million in F1Q15. The YOY comparison was fairly easy vs. modest 4% Worldwide growth one year ago. Still, \$430 million represented Medtronic's third-highest quarterly sales ever, all coming in the past four quarters following the MiniMed 530G launch in the US. Globally, pumps grew in the mid-single digit range, and CGM grew over 40% ("outstanding"). In the US, F2Q15 sensor sales grew ~59%, and even more in F1Q15. For the fourth straight quarter, management cited the "strong" ongoing US launch of the MiniMed 530G/Enlite (it started in F3Q14 in October 2013), and specifically warned investors of a challenging YOY comparison in the upcoming quarter (F3Q15) - indeed, that will be the real test of the sustainability of the MiniMed 530G launch, since growth was 16% globally and 21% in the US one year ago. Part of the growth was attributed to \$23 million in deferred revenue recognized upon the device's launch.

Table 1: Medtronic Diabetes Worldwide Sales

	F2Q14	F3Q14	F4Q14	F1Q15	F2Q15
Worldwide Sales (millions)	\$393	\$436	\$460	\$416	\$430
Year-on-Year (YOY) Growth:					
<i>Reported</i>	4%	16%	13%	13%	9%
<i>Operational</i>	3%	16%	13%	12%	10%
Sequential Growth	7%	11%	6%	-10%	3%

- Management again said the growth translated into "global share gains in insulin pumps" and "US share gains in CGM." No further details were provided.** We assume this is share growth vs. one year ago but not necessarily vs. the second calendar quarter of 2014. This was more vague than in financial updates following the MiniMed 530G launch ([F4Q14](#) and [F3Q14](#)), where management shared numerical estimates of the company's US pump and CGM market share gains (ranging from four to six percentage-point gains). In these past calls, management did not provide more detail as to how the estimates were obtained/sourced and from what base; as we understood it, they reflected "internal estimates," as we had of course suspected, since Dexcom doesn't publish units so the calculation is actually not technically possible to make using public numbers.
 - The "US share gains in CGM" were hard to interpret, given Dexcom's string of six consecutive quarters with 60%+ growth.** Our financial model estimates that Medtronic's US CGM market share (by sales) declined from ~42% in F1Q15 to ~40% in F2Q15 (based on ~15% of Medtronic sales from CGM [per the [2014 Analyst Day](#)] and

Dexcom's [2Q14](#) and [3Q14](#) calls). Meanwhile, of the 803 CGM users in the dQ&A patient panel, 29% were using Medtronic devices as of 3Q14, a number that has held fairly steady over the past seven quarters. (For more information, please contact Richard.wood@d-qa.com.) When pressed in Q&A, management said that US sensor sales grew ~59% in F2Q15, and even more than that in F1Q15. That would put Medtronic's CGM growth on a similar footing to Dexcom's US sales growth, which we estimated at 48% in 3Q14 and 55% in 2Q14 (Dexcom's international business is growing significantly, which boosts the consolidated growth over 60%).

- **Overall, we are not sure how Medtronic is internally calculating the share gains and would appreciate granularity on the calculations that go into them.** One possibility is that Medtronic is viewing every new MiniMed 530G system sold as a new CGM user, and quoting share gains among "new-to-CGM users." Hard to know without more information...

2. US sales of \$257 million grew 12% YOY and 6% sequentially. The YOY comparison was particularly easy in the US, as F2Q14 sales one year ago did not grow at all (just prior to the MiniMed 530G launch). We estimate the US provided 76% of F2Q15 growth, up from 72% in F1Q15 and 57% in F4Q14 - this speaks to just how much the US business is driving growth right now on the launch of the MiniMed 530G. (For context, prior to the system's US launch last year, the international business provided the majority of business growth going back to early 2011. However, the launch ramp may be tapering: 12% is the lowest Medtronic Diabetes US growth rate in the past year, and it has trended down following a peak in F3Q14 after launch (21%, 15%, 16%, and 12%). With that in mind, we expect US sales growth will be on the weaker side in the upcoming quarter (F3Q15), particularly with a very tough YOY Comparison.

Table 2: Medtronic Diabetes Sales - US

	F2Q14	F3Q14	F4Q14	F1Q15	F2Q15
US Sales (millions)	\$229	\$270	\$270	\$242	\$257
US Sales Growth (YOY)	0%	21%	15%	16%	12%
US Sequential Sales Growth	10%	18%	0%	-10%	6%
US Contribution to Overall Medtronic Diabetes Growth	0%	80%	57%	72%	76%

3. Outside the US, growth was 6% as reported and 9% operationally on sales of \$173 million - this was the first quarter in the past nine where reported growth did not exceed 7%. However, the comparison was fairly challenging to growth of 10% in F2Q14. Notably, management cited 27% emerging market growth for Medtronic Diabetes - this is presumably from a pretty low base, as only ~8% of the Diabetes business came from emerging markets as of the [June 2014 Analyst Day](#) (~\$14 million in sales in F2Q15). Still, it is an encouraging metric and perhaps a sign of expansion to come. The launch of the MiniMed 640G in the upcoming quarters does bode well for the international business, particularly as the US business faces some pretty tough YOY comparisons. International sales declined 1% sequentially from F1Q15 sales of \$174 million.

Table 3: Medtronic Diabetes Sales - International

	F2Q14	F3Q14	F4Q14	F1Q15	F2Q15
International Sales (millions)	\$164	\$166	\$190	\$174	\$173
International Sales Growth (YOY, Reported)	10%	8%	10%	8%	6%

International Sequential Sales Growth	2%	1%	15%	-8%	-0.6%
International Contribution to Overall Growth	100%	20%	43%	28%	24%

4. Notably, Medtronic has realigned its diabetes group into three distinct units to become a "more holistic diabetes company, not just a type 1 pump and sensor company," said Medtronic Diabetes President Mr. Hooman Hakami in Q&A. Medtronic will build the second and third businesses through both organic and inorganic means.

- **Intensive insulin management in type 1 and type 2 diabetes.** This is Medtronic's core pump and CGM business. At its [June 2014 Analyst Day](#), Medtronic reported its global market share as ~70% in durable pumps and ~60% in CGM, or ~\$1.33 billion in annual pump sales and ~\$240 million in CGM sales in FY14 (an 85% pump/15% CGM split).
- **Non-intensive diabetes solutions for type 2 diabetes.** Management called this vertical its "step into type 2 in a broad way," and it will begin with the [Sanofi partnership first announced at ADA](#) (building off an [Analyst Day](#) focused on type 2 and the [Opt2mise trial results published in the Lancet](#) this past summer). Management is "excited" about "innovative things on the horizon with Sanofi," though no further details were provided. We imagine pre-filled simple patch devices or basic pumps are being considered.
- **Diabetes services and solutions,** will focus on improving the customer experience by bringing together data management and customer support solutions, including consumable supplies and financial services. This new foray will leverage the existing CareLink data management platform and the [recently-acquired Cardiocom business](#). The latter provides integrated telehealth and patient services for the management of chronic diseases - the initial focus in ~80,000 patients has been on heart failure, but we had always suspected a foray into diabetes was possible. In addition, a move into services was first highlighted at the company's [2014 Analyst Day](#), where management cited three areas of opportunity for Medtronic Diabetes: (i) global penetration; (ii) type 2 focus; and (iii) new business-to-consumer business models. The mention of "consumable supplies" made us think that a business like Neighborhood Diabetes (purchased by Insulet in 2011) is in the realm of possibility, where Medtronic could play more of a one-stop-shop role. Other possibilities could include teams nurses/educators to help patients manage their diabetes. We think there is a lot of potential in this business vertical, particular as healthcare becomes more value based and payment becomes increasingly capitated. Dexcom CEO Mr. Terry Gregg has warned of a day when medical device manufacturers will be paid for outcomes, and Medtronic seems to be setting itself up for this day.

R&D PIPELINE

5. Medtronic is planning a "limited launch" of the MiniMed 640G system (predictive low glucose management with Enlite 3 sensor) in international markets this quarter (F3Q15), followed by a broader launch in F4Q15 (January-April 2015). The timing was a one-quarter delay from [Medtronic's F1Q15 call](#) in August, which expected the launch to happen in F2Q15; however, it is consistent with the prior timing that called for a launch by the end of FY 15 (April 2015). Management said that user evaluations have been successfully completed and the company is now ramping manufacturing. This is the most granularity we've ever heard on the pump's launch and it sounds like it will indeed happen soon. The product already has a CE Mark.

- **[At DTM 2014](#), Dr. Pratik Choudhary (King's College London, London, UK) enthusiastically shared preliminary data (unpublished) from a 60-person user evaluation of the Medtronic MiniMed 640G system.** Data had only been collected from a small subset of patients (n=10), but showed, as expected, that predictive low glucose suspend

reduced the prevalence of hypoglycemia. Over a two-week span, patients experienced an average of 11.9 predictive suspends/week (~203 predictive suspends in total), and on only four of those occasions (2%) did blood glucose values reach the low threshold of ~54 mg/dl. Data on time in range was not shared, though our brief glance at representative traces suggested encouraging glycemic control.

6. Management mentioned the [October 14 start](#) of the US pivotal study of the MiniMed 640G system (predictive low glucose management/Enlite 3 sensor). [See the ClinicalTrials.gov posting here](#). The trial will enroll up to 84 patients at up to eight centers in the US (the seven listed are Stanford, AMCR Institute, Barbara Davis Center, Yale, Atlanta Diabetes Associates, University of Virginia, Rainier Clinical Research). It will test the next-gen MiniMed 640G predictive low glucose management pump with the Enlite 3 sensor (80% smaller than the original Enlite; intelligent diagnostics that are expected to result in enhanced accuracy). The study's expected completion date is December 2014. It's a single-arm study (a big improvement from the onerous ASPIRE in-clinic study, which was a challenging crossover design) that will increase patients' basal rate to induce hypoglycemia (another improvement over ASPIRE, which used exercise to induce hypoglycemia). The MiniMed 640G's low limit will be set at 65 mg/dl, and a subsequent observation period will evaluate its performance. The primary outcomes are serious adverse events, unanticipated device effect, severe hypoglycemia, DKA, and rescue events during in-clinic procedures. The study took some time to get rolling - it first appeared on ClinicalTrials.gov around the time of Medtronic's F4Q14 call in May, meaning the start was delayed by about five months.

- **The FCC recently posted the user manual (in five parts) and photos of the MiniMed 640G [online here](#).** At the link titled, "[User Manual 4](#)," there are details on the predictive low glucose management feature, called "SmartGuard." There is an overwhelming amount of information on the icons, settings, and criteria by which a "Suspend before low" event occurs. However, it does seem very customizable, and Medtronic has done a good job on pages 164-167 to provide more patient friendly examples and diagrams to illustrate some of the scenarios that could arise:
 - Suspend before low, non-responsive, auto resume basal (trending upwards)
 - Suspend before low, responsive, manually resume basal
 - Suspend before low, responsive, stays suspended
 - Suspend on low, response after basal delivery resumes
- **For a "suspend before low" event to occur, both of these must happen:**
 - The sensor glucose value is at or within 70 mg/dl above the low limit.
 - The sensor glucose value is predicted to reach or fall below a level that is 20 mg/dl above the low limit within approximately 30 minutes.
- **Following a mandatory 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:**
 - The sensor glucose is at least 20 mg/dl above the low limit.
 - The sensor glucose is estimated to be more than 40 mg/dl above the low limit in 30 minutes
 - [Note: the pump will resume basal insulin delivery after a maximum two-hour suspension]

7. As expected, the MiniMed 620G, a CGM-integrated pump customized for the Japanese market, has begun a limited launch and will also more broadly launch in F4Q15 (January-April 2015). Medtronic has completed successful user evaluations and is now ramping manufacturing. The MiniMed 620G will use the new next-gen pump platform, but it will not have threshold or predictive suspend. Management has called the MiniMed 620G the "first integrated system in Japan," implying Medtronic currently does not sell a CGM sensor-integrated pump in the country.

8. Management said it is "making good progress" on its sensor pipeline as it advances towards a closed loop system. No further details were shared. At [DTM 2014](#), Medtronic's Dr. Rebecca Gottlieb shared new data on the company's fourth-generation (Enlite 3) and fifth generation sensors:

- **The fourth-generation sensor (Enlite 3) has demonstrated an MARD of 12% vs. fingersticks (n=112 sensors; 5,043 paired points).** The max daily MARD was 13%. The sensor required an average of 2.3 calibrations per day, and 92% of data was displayed. As a reminder, this sensor adds intelligent diagnostics to measure sensor health. This data was consistent with that shown by Dr. Bruce Buckingham [at EASD 2014](#). Overall, it does mark an improvement over the original Enlite, though it is not as accurate as [Dexcom's new G4AP algorithm](#) (MARD: 9.0%).
- **The fifth generation sensor demonstrated an MARD of 8% vs. YSI in a small 29-sensor study (n=933 paired points).** The maximum daily MARD was 11%, with a higher data display rate (97%) and fewer calibration per day (2.0) than Enlite 3. The fifth generation technology adds a redundant sensor to create the most reliable fused sensor signal. The algorithm weights the output of the more reliable sensor more heavily. Dr. Gottlieb did not specify if this was the orthogonal glucose oxidase/optical sensor - we assume it was not.

9. The pivotal trial of Medtronic's [Guardian Mobile](#) system (Bluetooth-enabled standalone CGM/smartphone app) was not mentioned on the call, but is [now recruiting patients](#). The 100-patient study will evaluate the performance of the Enlite 3 Sensor over seven days (three in-clinic vs. YSI) when used with the Guardian Mobile App and MiniMed 640G Pump - this implies that like Dexcom's Gen 5, Enlite 3 CGM data may be viewable both on a pump screen and on a smartphone app. The study is taking place at six centers and has an estimated primary completion date of November 2014 (January 2015 for full completion). This has been a very rapid turnaround from when the product was [first announced in September](#) - major kudos to Medtronic for moving this ahead so quickly, so it stands to really improve the CGM experience.

- **As of [Dexcom's 3Q14 call](#), an FDA submission of the Gen 5 mobile platform was expected in 1Q15.** Like Guardian Mobile, the primary focus of Gen 5 is the Bluetooth transmitter, which will be able to speak to two separate devices via Bluetooth. Data will be shared through apps on the phone and to the cloud. Dexcom also has integrations with Asante and Insulet, which will bring pump data into Dexcom's app and Dexcom CGM data onto the Insulet handheld. Users of Gen 5 will have access to the already-launched Share remote monitoring system. Otherwise, Gen 5 will use the G4 Platinum sensor and the just-launched G4AP algorithm. Management is "hopeful for a quick approval," and indeed, given that the Share backend architecture laid the groundwork for Gen 5, we believe this is a reasonable expectation.

10. The rest of Medtronic's pipeline was not mentioned, including the MiniMed 670G system (hybrid closed loop) and MiniMed Flex (a "hybrid" durable pump) - these devices were first introduced at [2014 Analyst Day](#).

PIPELINE SUMMARY

Pipeline Product	Latest Timeline
MiniMed 620G (sensor-augmented, Japanese language)	Limited launch in Japan underway, with broader launch in F4Q15 (Jan-Apr 2015).
MiniMed 640G (predictive low glucose management)	Obtained CE Mark; Limited international launch in upcoming quarter (F3Q15), with broader launch in F4Q15. In-clinic study in US underway.
Enlite 3 CGM sensor (fourth generation)	Will launch with MiniMed 640G (see above).

"Intelligent diagnostics" and "improved accuracy & comfort"; 80% smaller than original Enlite	
Guardian Mobile Bluetooth-enabled, transmitter, standalone Enlite 3 CGM	Pivotal US study ongoing (n=100)
MiniMed 670G (hybrid closed-loop)	No official timeline.
Fifth-generation CGM sensor	DTM 2014 presentation showed a MARD of 8% vs. YSI in a small 29-sensor study (n=933 paired points).
MiniMed Flex "Hybrid pump" with a smaller footprint, ability to wear on or off the body	No official timeline.
MiniMed Duo Integrated sensor and infusion set	Launched in Europe. Data presented at AACE 2014 Day #3 .
Orthogonally redundant CGM Glucose oxidase and optical sensing	First-in human data shared at ATTD 2014 ; study ongoing.
Medtronic Sentrino Critical Care CGM	CE Marked in December 2012; controlled EU launch started in Germany and UK

QUESTIONS AND ANSWERS

Q: Could you talk a little bit more about the diabetes space? That's exceptional growth. I was hoping you could talk about what you think the market is doing, and what the persistency is of patients on CGM as you start them up on the products here in the US?

A: The overall market for pumps is growing in the mid-to-high single-digit range. Our performance there in the US and internationally continues to be very, very good, so we're encouraged by what we saw in Q2. In the U.S, we grew 12% overall vs. the prior year and from an emerging market standpoint we're growing exceptionally fast as well - 27% growth. So we feel good about what we see. And it's really driven by the strength of our 530G system in the US, and that obviously drives the pump revenue but also the sensor sales as well, because this is a system. And I think we can continue to see that kind of strength as we think about the second half of the year.

Q: What about the continued usage on CGM as patients go out over time? Do you see a high persistence and consistent use of the sensors once patients start on it?

A: We do actually, yeah. The fact that it's a system helps. It's not a standalone sensor, but the fact that it's a system and the system is regulating based on the sensor values helps with that. So we really have here what is a therapy versus just a standalone component. And I think that helps drive the adoption of the CGM sensor.

Q: And last question, you keep talking about share gains in the US but your competitor is growing over 60%. Is that consistent with the sensor growth you're seeing? Or how do you calculate that?

A: If you take a look at our overall sensor performance just in the US, our sensors grew about 59% in Q2 and higher than that actually in Q1. So for the second consecutive quarter, we've been calculating share gain in the US for sensors.

Q: On the quality spend that's hitting the gross margin line, that just seems like it's dragging out a little bit farther than you had anticipated. Can you talk about a resolution timeline there and how we should think about that going forward.

A: Obviously the biggest impact on the quality is diverting resources into the quality area to focus on both neuro and diabetes. We continue to make sure that we're making all the investment necessary to get that accomplished. It's a high-priority across the organization and so it's top of mind. Diabetes I think is probably getting closer to having it kind of resolved and completed, and so I think that will probably start to lesson as we get here probably into Q3 and Q4...But they're making progress. I think the teams feel good about where they are at, but it has been costly and it is something we give a high priority to as we move ahead. So I think you'll see some improvements as you go in the back half of the year, but I think that headwind will still be there for part of this year and then probably see improvement as you get into FY 2015.

Q: I thought the structural comments on the diabetes franchise were interesting. And I'm wondering how much of this is reorganization, how much of this might you need to build or acquire? And then specifically on the service and solutions, data management is interesting - is that Cardiocom? How deep might you get into supplies and some of the other tertiary products that especially type 2 diabetics might use?

A: Yeah, the genesis of the structure is really for us to become a much more holistic diabetes company not just a type 1 pump and sensor company, but a true global diabetes care organization. That is the emphasis behind the organizational changes that Omar talked about in the text. If you take a look at the three business units that we created, the first one intensive insulin management - this is really our core business where we are going after the type 1 patient and the intensive type 2 with products and solutions. The second one, the non-intensive diabetes therapy business, is really our step into type 2 in a broad way, and this starts with the Sanofi partnership, but I think you'll see from us that it's going to extend. And with Sanofi, I think we've got some really innovative things on the horizon that we are both excited about.

And then service and solutions, this I think absolutely can leverage Cardiocom. There are assets both within diabetes with CareLink and across Medtronic with Cardiocom that can be leveraged as we think about patient management and data management. You will see some additional activity from us along these lines later this year. But I think you can even extend beyond those types of things. I think it will be a mixture of both organic and inorganic activity as we look to build out particularly non-intensive and also service and solutions.

-- by Adam Brown and Kelly Close