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## Medtronic begins MiniMed 670G US launch to 20,000+ Priority Access participants; shipments begin next week and last into fall - June 7, 2017

### Executive Highlights

- Today, Medtronic [initiated](#) the MiniMed 670G US launch, starting with over 20,000 Priority Access Program participants (current 630G users). Orders will start shipping next week and continue to ship "over the next few months" into fall 2017. Medtronic is also now taking new orders from other customers (e.g., 530G users) that want to get on the MiniMed 670G. We assume this broader group will start getting the system in the fall.
- Today's [announcement](#) shared data from the ~750-person MiniMed 670G Customer Training Phase: participants spent 74% time-in-range (in line with 72% in the pivotal trial); a median 92% of the time in Auto Mode (up nicely from 87% in the pivotal trial); and had a "94% overall satisfaction rate" with the 670G training and onboarding process.
- The Guardian Sensor 3's improved accuracy is a big focus of marketing - "the only continuous glucose monitor trusted and approved by the FDA to power a hybrid closed loop system." In the Customer Training Phase, the new sensor reported an MARD of 10.6% vs. fingersticks. The sensor will be a major focus of Medtronic's exhibit hall booth, including a virtual reality demonstration.
- We'll see a lot more on the MiniMed 670G this week at ADA, including in a webcast [Diabetes Investor Day update](#) on Saturday (2-4 pm PT), a Product Theater led by Drs. Rich Bergenstal and Jennifer Sherr (Monday, 10:15 am PT), plenty in the exhibit hall, and several abstracts ([126-LB](#), [1049-P](#), [1053-P](#)).

*As expected following its [1Q17 \(F4Q17\) update](#) two weeks ago, Medtronic [initiated](#) the MiniMed 670G US launch today, starting with over 20,000 Priority Access Program participants (current 630G users). Orders to these customers will start shipping next week and continue to be fulfilled "over the next few months" into fall 2017. In parallel, Medtronic will now take new orders from other customers (e.g., 530G users, other pump companies' customers) that want to get on the MiniMed 670G. It's not clear when these systems will ship, though we might guess sometime in the fall.*

*This long-awaited launch comes ~8 months following the earlier-than-expected [September FDA approval](#) of the world's first hybrid closed loop. Medtronic has been very careful to proceed cautiously with this launch, given the need for careful hands-on training and expectations management.*

*Today's [press release](#) also provided a few new updates on the ~750-person MiniMed 670G Customer Training Phase that started [in March](#). Participants:*

- Spent 74% time-in-range (70-180 mg/dl) during the Customer Training Phase, in line with 72% in the three-month pivotal trial;
- Spent a median 92% of the time in Auto Mode, up nicely from 87% in the pivotal;
- Had a "94% overall satisfaction rate" with the 670G training and onboarding process.

*The Guardian Sensor 3 reported an MARD of 10.6% vs. fingersticks in the Customer Training Phase, right in line with the labeled MARD of 10.6% vs. YSI (two calibrations per day at minimum, though 3-4 are recommended). The [press release](#) repeatedly emphasizes that the new Guardian Sensor 3 is more accurate and "the only continuous glucose monitor trusted and approved by the FDA to power a hybrid closed loop system." This is a clear note to: (i) potential users worried about Medtronic's CGM accuracy; and (ii) a competitive nod to Dexcom's G5 marketing as the only CGM FDA approved for non-adjunctive use. As a*

reminder, Guardian Sensor 3 is approved for adjunctive use (e.g., a confirmatory fingerstick is needed for a bolus), even though the pump can modulate basal insulin delivery automatically (within bounds) based on CGM values. The sensor will be a major focus of Medtronic's exhibit hall booth, including a virtual reality demonstration.

As noted [two weeks ago](#), the MiniMed 670G marketing places a big focus on less diabetes burden and spending more time-in-range. Medtronic is still using similar language as we heard after the [September FDA approval](#) - "hybrid closed loop" and "automated delivery of basal insulin" - though the tone is noticeably more excited and emphatic about less diabetes burden. As the launch expands beyond early adopters jumping to get on the system, we wonder if this broader group will have similar experiences as customer training phase users.

Perhaps the biggest question of all is whether the 670G - and upcoming products like it - will expand the pump and CGM markets. How many patients in each of these groups will make the leap to get on hybrid closed loop devices:

- MDI+fingersticks - the majority of type 1s, but the most distanced from wearing two devices on the body.
- MDI+CGM - a fast-growing market, fueled by Dexcom and Abbott's efforts to expand CGM adoption (Medtronic is coming soon here too).
- Pump+fingersticks or pump+CGM - the most obvious candidates to go on to hybrid closed loop, though still not a given.

We can't wait to see how this plays out and how different competitive closed-loop products stack up ([see our landscape here](#)). MDI dosing decision support is also fast coming market via connected pens combined with CGM and titration software ([see our landscape here](#)). How will the market segment and what products will provide the best outcomes: cost ratio for payers and the best benefit:hassle ratio for patients and HCPs?

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- **Medtronic's [upgrade page](#) does not have any pricing details for in-warranty Medtronic users, but we assume the [previously shared Pathway Program](#) is still in effect:** \$599 or \$3,100 out of pocket to get on the 670G, depending on whether the older Medtronic pump was purchased after or before May 1, 2016 (including a \$400 trade in credit). We'll be interested to see how quickly revenue ramps as the 670G launches to this broader group. Management said the impact of this launch won't be seen until later in FY18 (May 2017-April 2018), though 10%-12% YOY Diabetes growth is expected for the full FY18 - a significant acceleration from 4% growth in [FY17](#).
  - **Presumably the [Switch2System details](#) are still in effect too, meaning in-warranty Animas, Insulet, Roche, and Tandem pumpers can get on the 670G** for a cash price between roughly \$1,060-\$1,760 (notably cheaper than for a current Medtronic customer to upgrade).
- **As noted [two weeks ago](#), Medtronic has confirmed MiniMed 670G coverage with a majority of large commercial payers, including Aetna, Cigna, and Humana. Anthem has notably issued [a truly baffling non-coverage decision for the MiniMed 670G](#), citing that data is "too limited." A number of other plans are still deciding.** The Anthem document is worth a read, as it covers the MiniMed 530G, 630G, and 670G in one piece. It notes right at the top that hybrid closed loop is "considered investigational and not medically necessary under all circumstances." The Anthem decision is truly absurd, as it *will* cover the 530G/630G under certain circumstances, and the 670G pivotal data is miles better on hypoglycemia alone. Further, Anthem *also* cites ~20 other hybrid closed loop studies from academic groups (i.e., not specific to the 670G) in its decision, ultimately concluding: "While these studies demonstrate improved control of glucose concentrations with fewer hypoglycemic events, the data at this time is

limited to studies with small populations, short follow-up times, and other methodological issues, which limit the generalizability of their findings. At this time, the incremental benefit of automated closed-loop control of insulin administration is unclear. There is currently no data available demonstrating health outcome benefits of such technology compared to other treatment methods, including multiple daily injection therapy and continuous insulin infusion therapy with or without a threshold suspend device." WHAT?!

- **Notable language used to describe the MiniMed 670Gs from the [press release](#) and [MiniMed 670G fact sheet](#):**
  - **"The data demonstrating the benefits of this system are compelling** and I'm confident it will simplify diabetes care for both patients and clinicians alike." - Dr. Fran Kaufman
  - **"We've essentially designed a smarter insulin pump that alleviates some of the burden** associated with diabetes management, which can be unrelenting and exhausting." - Alejandro Gallindo, VP of Intensive Insulin Management, Medtronic Diabetes
  - **"Automated basal insulin delivery decreases the level of patient interaction needed**, which can enhance quality of life and alleviate the mental burden associated with the constant management of blood sugar levels throughout the day and night. Patients will only need to enter mealtime carbohydrates, accept bolus correction recommendations and periodically calibrate the sensor."
  - **"...enables personalized and automated delivery of basal insulin**, the background insulin needed to maintain stable blood sugar levels throughout the day and night."
  - **"Through this personalized design, the system is able to maximize Time in Range** - the amount of time sugar levels stay within a range considered healthy by clinical standards."
- **Medtronic's LOOP blog has shared a couple recent posts on the 670G**, including two users' experiences and Dr. Kaufman on the 120 mg/dl glucose target:
  - [Nikhita Answers Your MiniMed 670G System Questions](#)
  - [On Targets and Staying in Range with the MiniMed 670G System](#) (Dr. Fran Kaufman on the 120 mg/dl target and why it cannot be changed)
  - [Nicky Answers Your Questions About the MiniMed 670G system](#)
- **Medtronic also has some [persuasive Facebook marketing for the MiniMed 670G](#), including [a Facebook live with a 670G user \(Nicky\)](#) that has a remarkable 119,000 views.** The focus of the marketing, overwhelmingly, is on reduced diabetes burden.



## Medtronic Diabetes

May 15 at 12:30pm · 🌐

"This thing is no joke! I've been on 6 of Medtronic insulin pumps over the past 18 years. In those years, I can say there have been two specific times when I felt like my life was changed by pump therapy. The first time was when I started on the pump for the first time with the MiniMed 507C and the second was when I went into Auto Mode on the MiniMed 670G system. I have to admit, while I've been very excited about this pump, but I was a bit skeptical about how accurate it would be and how well it would truly work. I can now say with 100% confidence that this thing is truly amazing! Until you have a chance to put it on and watch it work its magic you have no idea how amazing this system truly is. I literally got chills when I first turned on Auto Mode, and I continue to be amazed at how well this keeps me in range. Sure, I still have to be good at counting carbs, but the way this system has learned me and what my needs are is nothing short of amazing." - Joe, Medtronic employee

- Medtronic issued an [urgent field safety notification about a month ago](#) for 6-series pumps (630G, 640G, 670G). It concerns a "rare and temporary condition" in which the keypad buttons on the pump may become temporarily stuck and the keypad becomes unresponsive. This is most likely happen from pressure differences, typically when traveling in an airplane during takeoff or landing. In most cases, Medtronic says the pump will resolve this issue on its own within 30 minutes. Otherwise, users should pull out the battery to clear the issue. Medtronic is very clear that 6-series pumps do not need to be returned or replaced. Ultimately, this seems like a minor hiccup, and we only stumbled on this on [Medtronic's Facebook page](#). Still, this is a whole new pump platform, so we'll be washing closely for other hardware issues going forward.

### Close Concerns Questions

**Q: When will the 670G ship to non-priority access program participants?**

**Q: To what extent is the MiniMed 670G/Guardian Sensor 3 a threat to other pump players (Animas, Tandem, Roche, Insulet), Dexcom, and Abbott?**

**Q: Who will be second-to-market in the US with a hybrid closed loop? ([See our competitive landscape here.](#))**

**Q: Will the MiniMed 670G and other closed-loop devices expand the pump and CGM markets? Where will penetration be in five years?**

*-- by Adam Brown and Kelly Close*