

## Latest MiniMed 670G real-world data in ~120,000 users: 71% time-in-range in Auto Mode across all ages - May 28, 2019

*Data from n=119,274 users over 3 years; Reduced episodes of hypo- and hyperglycemia when in hybrid closed loop; Aligns with previous real-world and pivotal trial data*

This morning, Medtronic [shared](#) the largest batch of real-world data gathered from 119,274 MiniMed 670G users from March 2017 to May 2019 - at 7.9 million patient days, this is easily the largest automated insulin delivery data set ever shared. 670G users with Auto Mode turned on spend a mean 71% time-in-range (70-180 mg/dl), while those with the feature turned off spend ~61% time in 70-180 mg/dl. That's a difference of 2.3 hours per day in-range, which adds up to 35 extra days per year. Nice!

Those with Auto Mode turned on experienced 28% fewer episodes of hypoglycemia (<70 mg/dL for >20 minutes) and 55% fewer episodes of hyperglycemia (>250 mg/dL for >3 hours). The more conventional time <70 (rather than < 70 for 20 minutes or more) and >180 mg/dl were not reported - likely because comparisons to "less than 70 for 20 minutes" and "time >250" looked better.

Medtronic now reports 180,000+ users on 670G, meaning these data come from nearly two-thirds of the global user base.

The figures are in close agreement with those presented at [ATTD 2019](#), in which real-world 670G Auto Mode time-in-range was 69% for type 1s (n=~60,000) and 75% for type 2s (n=~2,000). Further, 71% in-range is essentially identical to the time-in-range observed in the [adult pivotal study](#) (72%), and ~1.5 hours greater than that seen in the [2-6 year-old](#) (64%; not yet approved by FDA) and [7-13 year-old](#) (65%) pivotals. It's excellent to see this first-generation hybrid closed loop system continue to deliver real-world outcomes for larger populations on par with those seen in a more controlled trial setting.

- **The press release is mostly worded for marketing, leaving a number of unanswered questions:** How many of the 119,274 users mentioned in the press release fall in each group - Auto Mode turned on vs. off? Are those users *different* - i.e., is usage of Auto Mode a marker of a more engaged/attentive/educated/connected user? What percent of the day are Auto Mode users actually spending in Auto Mode? How many fingerstick calibrations per day is the average Auto Mode user doing? What do results look like when broken down by age group or by type 1 vs. type 2 diabetes? Will we hear more at ADA?
- **This real-world data compares the outcomes of Auto Mode turned on vs. off; it is *not* comparing Manual vs. Auto Mode use in the same person** (i.e., the comparison used in the pivotal study). This leaves open the (high) possibility that these two groups are composed of different populations. That is, an individual who successfully stays in Auto Mode - and is willing to perform additional calibrations, reliably bolus for meals, has access to CGM, etc. - may have different levels of baseline engagement or access vs. an individual in manual mode. It would be interesting to see how the analysis would look different comparing manual vs. Auto Mode in the same user. Even still, showing >70% time-in-range at this scale is an excellent sign for this product and future products to come.

**71%** Average Time in Range for MiniMed™ 670G system\*  
[ 2.3 additional hours per day or 35 days per year ]

**Hypoglycemia**  
SG < 70 mg/dL

**28%** Reduced episodes  
lasting > 20 minutes

**Hyperglycemia**  
SG > 250 mg/dL

**55%** Reduced episodes  
lasting > 3 hours

\*with SmartGuard™ Auto Mode turned on  
Aggregated Data on File. US MiniMed™ 670G system users from CareLink™ Personal data is from  
March 17 2017 to May 9, 2019 and CareLink™ System data is from March 17 2017 to March 1, 2019.  
Users= 119,274; Patient days: 7,984,915.

**Medtronic**

--by Albert Cai, Brian Levine, Adam Brown, and Kelly Close