MiniMed® 670G System

The World's First Hybrid Closed Loop System

MEDIA CONTACT: Janet Kim | +1-818-576-5014
janet.kim@medtronic.com | www.medtronicdiabetes.com

Medtronic

The MiniMed® 670G system is the first and only hybrid closed loop system commercially approved to **personalize** and **automate** the delivery of **basal insulin**, the background insulin present in your body 24 hours a day that's needed to maintain stable blood sugar levels in between meals and overnight. The system is approved for people with type 1 diabetes ages 14 years and older.

Type 1 Diabetes (T1D)
An estimated 1.25 million Americans are living with T1D including about 200,000 people under the age of 20. This number is expected to increase to 5 million by 2050. T1D is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that converts sugar into usable energy. It can impact both children and adults at any age and has a significant negative impact on quality of life. Its onset is sudden and causes dependence on multiple daily injections of insulin or an insulin pump.

The complications stemming from high and low blood sugar levels can lead to serious short and long term complications including kidney failure, blindness, nerve damage, heart attack, stroke, and pregnancy complications. Lows can be life-threatening, particularly at night when they are most difficult to manage. Indeed, T1D is associated with an estimated loss of life-expectancy of up to 13 years.[1] **Despite this, less than one third of people with T1D in the U.S. are achieving target blood glucose control levels.**

How Does the MiniMed 670G System Work?
Powered by the system's advanced algorithm – SmartGuard® HCL technology – and the company's new Guardian Sensor 3, it constantly adjusts the amount of insulin delivered to patients every 5 minutes based on their unique needs. This automation works to maximize Time in Range (TIR), or the time blood sugar levels stay within a predefined target range. 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.

This latest advancement demonstrates Medtronic's commitment to simplifying and improving diabetes management through the advancement of smart algorithms that achieve greater glucose control with reduced patient input. This represents an important advancement in the management of type 1 diabetes and improving quality of life for those living with this chronic and burdensome disease.

Key Features & Information

Through SmartGuard HCL technology, the system builds on industry leading algorithms developed by Medtronic to offer therapy customization. This enables patients and providers to choose from three increasing levels of automation that best fit their diabetes management needs:

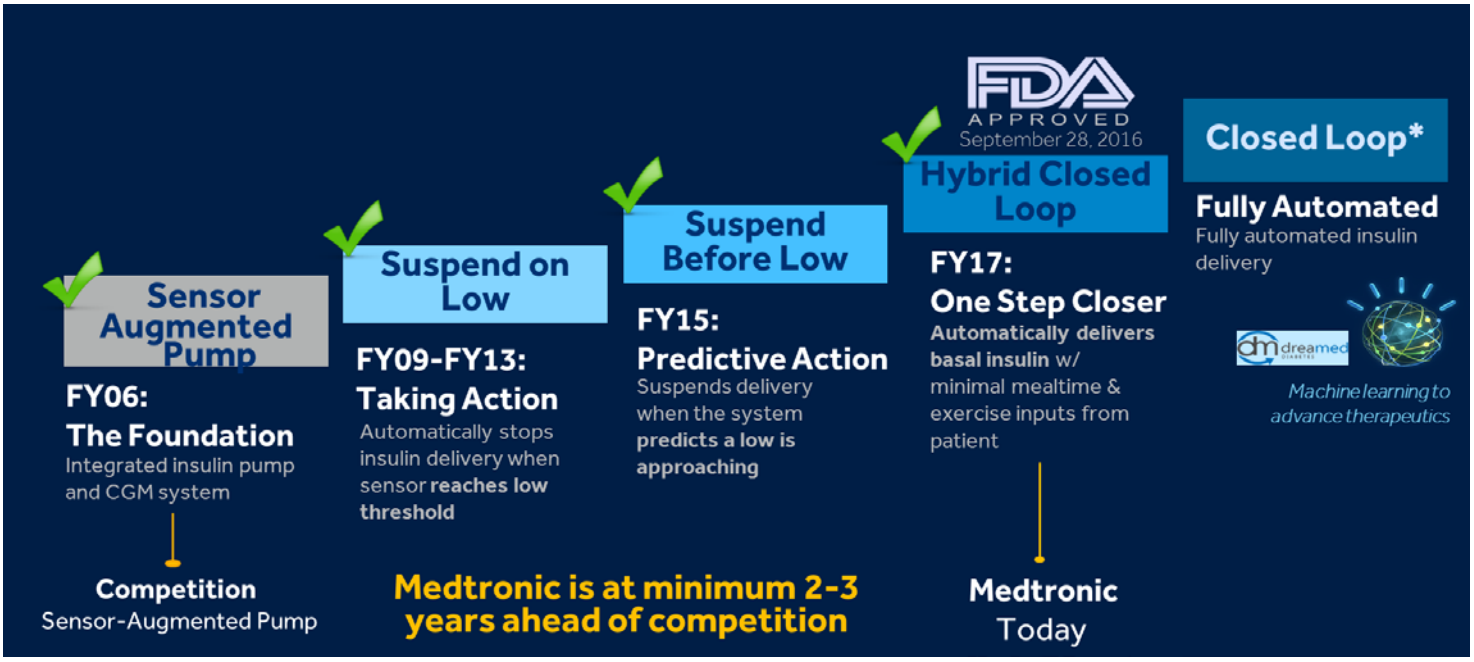
- **Suspend on Low:** Suspends insulin delivery for up to two hours when sensor glucose levels reach a pre-set low limit.
- **Suspend before Low:** Suspends insulin delivery before sensor glucose levels reach a pre-set low limit and automatically resumes delivery when levels recover. This feature was previously only available to patients outside of the U.S. in the company's MiniMed 640G system approved for sale in Europe.
- **Auto Mode:** Stabilizes blood sugar levels 24 hours a day by automatically adjusting basal insulin delivery based on real-time insulin needs.

Clinical Evidence

Medtronic is the first company to initiate and complete a U.S. pivotal trial of hybrid closed loop technology. The data from this study was included in its PMA submission to the FDA in June 2016 – the first and only company to file for commercial approval. The data, which was published in the Journal of the American Medical Association, did not identify any safety issues and showed patients with type I diabetes experienced less glycemic variability, more time in the target range, less exposure to hypoglycemia and hyperglycemia, and reduced A1C compared to baseline data using sensor-augmented pumps. [i] The trial is the largest and longest at-home hybrid closed loop study with 124 patients and over 12,000 study days included in the evaluation. Medtronic is also running a post-approval study of the MiniMed 670G system to collect safety data in a real-world setting.

A Phased Approach to a Fully Automated, Closed Loop System

Developing and commercializing a fully automated, closed loop system will be achieved through a phased approach. After decades of research, Medtronic took the first commercial step in 2006 by introducing the world's first integrated insulin pump and CGM. With each advancement, Medtronic introduces increased automation in its algorithm to address key clinical challenges and reduce time and effort, so people with diabetes can spend less time managing their diabetes and more time living full lives.



*Future concept only; not investigational nor commercially available.

The MiniMed 670G system requires a prescription and is approved for people with type 1 diabetes, ages 14 and older. **WARNING: May not be safe for children under 7 or those using less than 8 units of insulin per day.** Please visit www.medtronicdiabetes.com for detailed product and important safety information.

WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. Always confirm your sensor glucose reading using your BG meter, and follow the instructions of your healthcare professional to treat low glucose. Using Suspend on low alone to prevent or treat low glucose may result in prolonged hypoglycemia.

WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

[1] Jama 2015; 313(1):1-9)
[2] Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. *JAMA*. [In press]
[3] Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. *N Engl J Med* 2010;363:311–320