MiniMed™ 770G System

Smartphone Connected Hybrid Closed Loop Technology for Individuals Ages 2+

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Medtronic

The MiniMed™ 770G hybrid closed loop system, our newest insulin pump system, offers the most advanced SmartGuard™ technology also featured in the MiniMed™ 670G system with the additional benefits of smartphone connectivity and an expanded age indication to individuals as young as two years old.

With the MiniMed™ 770G system, individuals can display pump and continuous glucose monitoring (CGM) data through one integrated app and receive notifications on their personal smartphone or their care partner's connected smartphone.

The hybrid closed loop system self-adjusts[1] basal insulin based on the needs of the individual. Basal insulin is 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.

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.[2] 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.

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, and stroke.[3] Lows can be life-threatening, particularly at night when they are most difficult to manage. T1D is associated with an estimated loss of life-expectancy of up to 13 years.[4] **Despite this, less than one third of people with T1D in the U.S. are achieving target blood glucose control levels.[5]**

How Does the MiniMed™ 770G System Work?

The MiniMed™ 770G system is powered by an advanced algorithm – SmartGuard™ technology – and the Guardian™ Sensor 3 and the Guardian™ Link 3 transmitter. Together, these devices help maximize the time people are within a target glucose range by automatically increasing or decreasing the amount of basal insulin delivered based on real-time sensor values and insulin need.

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 need to enter mealtime carbohydrates, accept bolus correction recommendations, and periodically calibrate the sensor.

Medtronic is committed to simplifying and improving diabetes management through the advancement of smart algorithms with reduced patient input.

Key Features & Information

The MiniMed™ 770G system automatically adjusts delivery of basal insulin based on CGM sensor glucose values in people with type 1 diabetes, age 2 and older. The new MiniMed™ 770G system comes with the Guardian™ Sensor 3, the Guardian™ Link 3 transmitter, the MiniMed™ Mobile app, the CareLink™ Connect app and a Bluetooth® compatible Accu-Chek® Guide Link meter from Roche.

The system can enable auto-uploads of data to the CareLink™ platform so that individuals and families can share their pump and glucose data remotely with their clinician and have more productive in-person or telehealth visits and trainings.

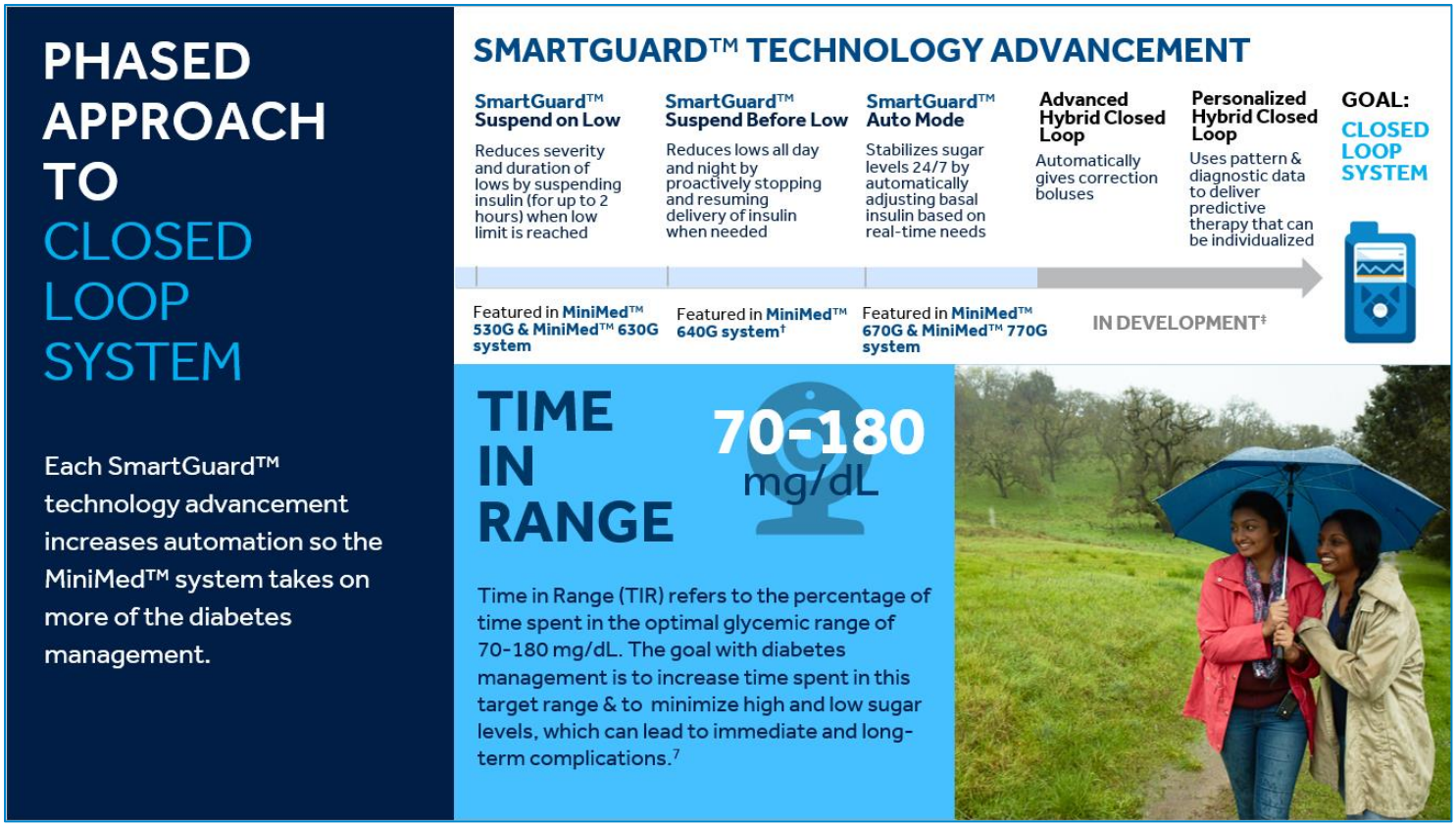
The system's expanded indication to individuals as young as two is the lowest age indication by the FDA for an automated insulin pump system and allows greater technology access to pediatric populations, as well as an elevated level of care for parents and care partners who will now be able to leverage remote monitoring capabilities.[1]

Clinical Evidence[6]*

In June 2019, Medtronic announced completion of its pivotal trial evaluating the MiniMed™ 670G system in pediatric patients two to six years of age, which supported the submission of this latest system. Data demonstrated glycemic outcomes in children as young as two that were comparable to those observed in older adolescents and adults with hybrid closed loop (SmartGuard™ Auto Mode) enabled. In the study, A1C and Time in Range from 151 children were assessed alongside outcomes from 124 adolescents and adults over two weeks in Manual Mode and three months in Auto Mode. There were no episodes of severe hypoglycemia or diabetic ketoacidosis, and no serious device-related adverse events while in Auto Mode.

A Phased Approach to a Fully Automated, Closed Loop System

Medtronic is working toward a phased approach to developing a fully automated, closed loop system. With each advancement made to its SmartGuard™ algorithm, Medtronic's insulin pump systems enable increased automation requiring decreased patient interaction with the system. Medtronic is committed to simplifying and improving diabetes management through the advancement of smart algorithms that achieve greater glucose control with reduced patient input.



IMPORTANT SAFETY INFORMATION: MINIMED™ 770G SYSTEM

The MiniMed™ 770G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 770G system includes SmartGuard™ technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose (SG) values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values. The Medtronic MiniMed™ 770G system consists of the following devices: MiniMed™ 770G insulin pump, the Guardian™ Link (3) transmitter, the Guardian™ Sensor (3), one-press serter, the Accu-Chek® Guide Link blood glucose meter, and the Accu-Chek® Guide test strips. The system requires a prescription. The Guardian™ Sensor (3) has not been evaluated and is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian™ Sensor (3). All therapy adjustments should be based on measurements obtained using the Accu-Chek® Guide Link blood glucose meter and not on values provided by the Guardian™ Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the Accu-Chek® Guide Link blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an alternative site. It is not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise.

WARNING: Do not use the SmartGuard™ Auto Mode for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in SmartGuard™ Auto Mode.

WARNING: Do not use the MiniMed™ 770G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 770G system.

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms. Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional. The safety of the MiniMed™ 770G system has not been studied in pregnant women. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult http://www.medtronicdiabetes.com/important-safety-information#minimed-770g and the appropriate user guide at http://www.medtronicdiabetes.com/download-library

*The study does support that the system is relatively safe. However, the study had limitations, including a relatively small number of patients, no comparative control group, and a study period that lasted only three months. In addition, the amount of time the system was used in the Manual Mode was shorter than the time in Auto Mode. Due to these study limitations, caution is advised when attempting to extrapolate these results to individual patient results. There could be significant differences.
† Not available in U.S.
‡ In development. Safety and effectiveness have not been established. Not for sale in the U.S.

References:

[1] Refers to SmartGuard™ Auto Mode. Some user interaction required. Individual results may vary.
[2] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, Ga: Centers for Disease Control And Prevention, U.S. Dept of Health and Human Services; 2017.
[3] Brownlee M, Aiello LP, Cooper ME, Vinik AI, Plutzky J, Boulton AJM. Complications of diabetes mellitus. In: Melmed S, Polonsky KS, Larsen PR, Kronenberg HM, eds. *Williams Textbook of Endocrinology*. 13th ed. Philadelphia, PA: Elsevier; 2016:chap 33.
[4] Jama 2015; 313(1):1-9).
[5] T1D exchange data.
[6] Salehi P, Roberts AJ, Kim GJ. Efficacy and Safety of Real-Life Usage of MiniMed 670G Automode in Children with Type 1 Diabetes Less than 7 Years Old. Diabetes Technol Ther. 2019;21(8):448-451. doi:10.1089/dia.2019.0123.
[7] Runge AS, Kennedy L, Brown AS, et al. Does time-in-range matter? Perspectives from people with diabetes on the success of current therapies and the drivers of improved outcomes. Clin Diabetes. 2018;36(2):112-119.