Medtronic News

Medtronic Announces FDA Approval for Minimed™ 770G Insulin Pump System with Smartphone Connectivity for People with Type 1 Diabetes

New Smartphone Connected Hybrid Closed Loop System Will Be Available to Individuals as Young as 2

DUBLIN – September 1, 2020 – Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) approval of its MiniMed™ 770G hybrid closed loop system. This newest insulin pump system offers the company's most advanced SmartGuard™ technology, as featured in the MiniMed™ 670G system, with the added benefits of smartphone connectivity and an expanded age indication down to the age of 2 years old.

This latest system by Medtronic expands the benefits of hybrid closed loop therapy to younger children living with type 1 diabetes and makes it easier to access and share real-time CGM and pump data. The system will enable caregivers and care partners to see user data remotely on their smartphones, with proactive in-app notices sent when sugar levels are out of range. The data can also be shared automatically with clinicians and educators to help facilitate more effective telehealth visits and product trainings. This connectivity also gives Medtronic the ability to provide upgrades to future technology via software updates which can further enhance security and device features.

"We're thrilled to be launching this new system as we understand how important these data sharing features are, particularly right now — with many individuals and families opting to see their doctors virtually via telehealth visits," said Sean Salmon, executive vice president and president of the Diabetes Group at Medtronic. "As a parent, I understand very personally why connectivity is so important and I'm pleased we'll be able to broaden access to hybrid closed loop therapy with the additional peace of mind caregivers need to ensure the well-being of their loved ones. This latest launch underscores my personal commitment to making life easier for people living with diabetes through the technologies we deliver."

The growing body of clinical evidence on hybrid closed loop therapy demonstrates both the safety of the technology and improved clinical outcomes across adults, adolescents and younger children. A clinical study of the MiniMed 670G system conducted in children two to six years of age showed an improvement in outcomes comparable to those observed in older adolescents and adults, and supported the submission of the MiniMed 770G system. 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 SmartGuard Auto Mode (hybrid closed loop algorithm)[1]. There were no episodes of severe hypoglycemia or diabetic ketoacidosis, and no serious device-related adverse events while in SmartGuard Auto Mode.

"When young children are diagnosed with diabetes it is a family disease with parents and caregivers playing a substantial role in diabetes management," said Jennifer McVean, M.D., pediatric endocrinologist with University of Minnesota Health[2]. "Being able to offer my patients an insulin pump system that provides safe, automated insulin delivery[3] and smartphone connectivity is incredibly beneficial. I have seen favorable results with the MiniMed 670G system in my practice, and the younger age indication that the MiniMed 770G system offers can change the lives of even more people living with type 1 diabetes."

The algorithm that powers the insulin pump, known as SmartGuard Auto Mode, refers to the system's ability to continually adjust the amount of insulin delivered every five minutes, 24 hours a day, based on the needs of the individual. The goal of this automated delivery of background insulin is to maximize the time glucose levels are within the optimal target range and to minimize both high and low glucose levels. The new MiniMed 770G system comes with the Guardian™ Sensor 3[4], the MiniMed™ Mobile app (compatible with both iPhone and Android), and Roche Accu-Chek® Guide Link meter, which is Bluetooth® compatible for improved usability.

Medtronic will begin taking orders for the new MiniMed 770G system in the United States this week.

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)
Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] 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

[2] Dr. McVean is a Medtronic patient and paid consultant

[3] Refers to SmartGuard Auto Mode. Some user interaction required. Individual results may vary.

[4] The Guardian Sensor (3) is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3).

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