

Study Analyzes Real-World Use of Medtronic's MiniMed 530G System

February 12, 2015 8:00 AM CT



Diabetes Technology & Therapeutics Publishes Retrospective Analysis Detailing Impact of Threshold Suspend in Addressing Hypoglycemia

DUBLIN - February 12, 2015 - Medtronic plc (NYSE:MDT) today announced results of a retrospective analysis based on real-world data from over 20,000 MiniMed® 530G users, which found that the pump's Threshold Suspend feature reduced hypoglycemia, especially at night, without significantly increasing hyperglycemia. The results, titled "[Retrospective Analysis of the Real-World Use of the Threshold Suspend Feature of Sensor-Augmented Insulin Pumps](#)," were published online, ahead of print, in *Diabetes Technology & Therapeutics*.

"Hypoglycemia is a serious concern for people with diabetes, especially when it occurs at night because sleep blunts awareness of hypoglycemia's symptoms," said Francine R. Kaufman, M.D., chief medical officer and vice president of global, clinical and medical affairs for Medtronic Diabetes. "The present analysis showed that when people with diabetes use the Threshold Suspend feature on the MiniMed 530G system in the real world, they experience the same reduction in hypoglycemia that was observed in research trials."

The MiniMed 530G system is the first and only system to offer Threshold Suspend, which suspends insulin delivery for up to two hours when the sensor glucose value reaches a pre-set low level and if the user is unable to respond to the Threshold Suspend alarm. Results of the analysis include:

- **Overall hypoglycemia was reduced by 69 percent:** Patient-days where the Threshold Suspend feature was enabled showed 69 percent less time in hypoglycemia (sensor glucose values ≤ 50 mg/dL) compared to patient-days when the feature was not enabled (0.64% vs. 2.09%, respectively, $p < 0.001$).
- **Night-time hypoglycemia was reduced by 73 percent:** The reduction in hypoglycemia seen on Threshold Suspend-enabled days was more pronounced during nighttime than during daytime hours. A 73 percent reduction in time in hypoglycemia occurring at night was seen on patient-days when the Threshold Suspend feature was on (percent of sensor glucose values ≤ 50 mg/dL, sensor glucose percentages equivalent to 17 minutes/night when Threshold Suspend was off vs. 5 min/night for when Threshold Suspend was on, $p < 0.001$).

"The Threshold Suspend feature on the MiniMed 530G system has been a critical milestone toward Medtronic's goal to develop a fully automated artificial pancreas," said Alejandro Galindo, vice president and general manager of the Intensive Insulin Management business at Medtronic. "Our integrated insulin delivery systems are the only ones that can take action, mimicking the functioning of a healthy pancreas, to help people with diabetes enjoy greater freedom and better health."

These results are similar to outcomes observed in the ASPIRE In-Home study, which was published in *The New England Journal of Medicine* in July of 2013. In both datasets, there were significantly fewer sensor glucose values in the hypoglycemic range in subjects using the Threshold Suspend feature compared to those in the control group using sensor-augmented pump therapy.

About the Retrospective Study

The effectiveness of the Threshold Suspend feature in the real-world setting was conducted by retrospectively analyzing anonymized, aggregated data from more than 20,000 users of the MiniMed 530G system who uploaded to the CareLink® Personal Therapy Management Software for Diabetes. MiniMed 530G users have discretion to turn Threshold Suspend on and off. The study design calculated the amount of time that users spent with Threshold Suspend turned on (82%) and compared performance data from that segment against user time spent with the feature turned off. Study endpoints were

to evaluate Threshold Suspend impact on overall hypoglycemia and impact on night-time hypoglycemia.

CareLink allows both patients and their healthcare providers to view critical information from the patient's insulin pump, CGM and blood glucose meter in order to optimize their diabetes management. The online software displays the information in charts, graphs and tables, making it easy to discover glucose patterns and trends and make therapy adjustments, as needed.

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 the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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