

## Medtronic Insulin Pump with Threshold Suspend Reported to Safely Reduce Nocturnal Hypoglycemia Without Increasing A1C

(Thomson Reuters ONE via COMTEX) --ASPIRE In-Home Study Published in New England Journal of Medicine and Presented at American Diabetes Association Annual Scientific Sessions

CHICAGO - June 22, 2013 - Study results published today in the New England Journal of Medicine and to be presented at the American Diabetes Association (ADA) 73rd Scientific Sessions report that the Threshold Suspend feature of a sensor-augmented insulin pump from Medtronic, Inc. (NYSE: MDT) safely reduces nocturnal hypoglycemia without affecting glycated hemoglobin level (HbA1C). Threshold Suspend - a first-of-its-kind automated insulin pump feature unique to an investigational MiniMed® integrated system - automatically suspends insulin delivery temporarily when sensor glucose values reach a pre-set low level. It is also an important step toward Medtronic's ultimate goal to develop a fully automated artificial pancreas for people with diabetes.

"Hypoglycemia can be catastrophic for people with diabetes, especially at night when patients are likely to be unaware of symptoms because they are asleep," said Richard M. Bergenstal, M.D., executive director of the International Diabetes Center at Park Nicollet Health Services in Minneapolis and past president of medicine and science, American Diabetes Association. "These data are very important because they provide strong evidence that sensor-augmented insulin pump therapy with a Threshold Suspend feature can reduce hypoglycemia at home - and it can do it safely, without increasing the patients' risk for long-term complications by raising their A1C."

Under an investigational device exemption (IDE) granted by the FDA, the ASPIRE[1] In-Home study compared two MiniMed sensor-augmented insulin pumps (integrated insulin pump with continuous glucose monitoring): one with the Threshold Suspend feature and one without. While a MiniMed integrated insulin pump with continuous glucose monitoring has been proven to provide better glucose control than multiple daily injections without increasing hypoglycemia[2], this is the first, large in-home study to show the results of the integrated system when Threshold Suspend is incorporated.

"ASPIRE In-Home met both its safety and efficacy endpoints and it provides additional clinical validation for Threshold Suspend, the first diabetes technology to automatically take action based on sensor glucose values," said Francine Kaufman, M.D., vice president of global medical affairs of the Diabetes business at Medtronic. "The study results are important as we continue to move toward our goal of developing a fully automated system, or artificial pancreas, that will one day require very minimal interaction from the patient."

### Summary of New England Journal of Medicine Publication

Two hundred and forty-seven patients with type 1 diabetes and documented nocturnal hypoglycemia were randomly assigned to receive a sensor-augmented insulin-pump therapy with (121) or without (126) the Threshold Suspend feature for three months. The primary safety outcome was change in HbA1C, a measurement that shows an individual's average blood glucose control over a three month period. The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemic events. AUC is a standard way to summarize two key parameters of hypoglycemic events - the magnitude and the duration. Reported results:

- The mean AUC for nocturnal hypoglycemic events was 37.5 percent lower in the Threshold Suspend group[3].
- Nocturnal hypoglycemic events occurred 31.8% less frequently in the Threshold Suspend group than in the control group.[4]
- The mean AUC for combined daytime and nighttime hypoglycemic events was 31.4% lower in the threshold-suspend group

than in the control group[5].

- There was no change in HbA1C in either group.
- No serious adverse events occurred in the Threshold Suspend group.[6]

In addition, the ASPIRE In-Home: Rationale, Design, and Methods of a Study to Evaluate the Safety and Efficacy of Automatic Insulin Suspension for Nocturnal Hypoglycemia will be online on June 23, 2013 by Journal of Diabetes Science and Technology.

#### About Threshold Suspend

The first-of-its-kind Threshold Suspend feature, exclusive to MiniMed insulin pumps, works by suspending insulin delivery for up to two hours when an individual's sensor glucose value reaches a preset low sensor level. Once the threshold is met, the insulin pump will alarm and suspend all insulin delivery for two hours. Insulin delivery can be resumed by the patient at any time. The feature is commercially available internationally in the MiniMed Veo System (where the feature is called Low Glucose Suspend). Threshold Suspend is also a part of the MiniMed 530G, which is not commercially available in the U.S. at this time, and is currently under review at the FDA. The MiniMed 530G system is the first system submitted for approval under the new product classification, "OZO: Artificial Pancreas Device System, Threshold Suspend," created by the U.S. Food and Drug Administration.

To view a larger image of the MiniMed integrated system, [click here](#).

#### About the Diabetes Business at Medtronic

The Diabetes business at Medtronic ([www.medtronicdiabetes.com](http://www.medtronicdiabetes.com)) is the world leader in advanced diabetes management solutions, including integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, as well as world-class, 24/7 expert consumer and professional service and support.

#### About Medtronic

Medtronic, Inc. ([www.medtronic.com](http://www.medtronic.com)), headquartered in Minneapolis, 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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[1]Automation to Simulate Pancreatic Insulin REsponse

[2] 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.

[3] The mean AUC of nocturnal hypoglycemia was 37.5% lower in the Threshold Suspend Group than the Control Group (980±1200 vs. 1568±1995 mg/dL x min, respectively, p<.001)

[4] Nocturnal hypoglycemic events occurred 31.8% less frequently in the threshold-suspend group than in the control group (1.5±1.0 vs 2.2±1.3 per patient-week, P<0.001)

[5] The mean AUC of day and night hypoglycemia events was 31.4% lower in the Threshold Suspend Group than the Control

Group (798±965 vs. 1164±1590, p<.001

[6] Four patients in the Control Group had a severe hypoglycemia event.

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Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1710360

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