Medtronic News

Medtronic Announces U.S. Launch of the MiniMed® 630G System with New User-Friendly Insulin Pump Design and SmartGuard(TM) Technology

DUBLIN - August 11, 2016 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the U.S. commercial launch of its MiniMed 630G system with SmartGuard technology FDA approved for the treatment of people with diabetes mellitus sixteen years of age and older. The MiniMed 630G features a new insulin pump hardware platform and new user-friendly design that combines personalized diabetes management with industry-leading clinical performance. The MiniMed 630G system is the newest member of the MiniMed family-the most prescribed integrated insulin delivery system brand in the world.

After interviewing more than 1,000 people with diabetes and testing user-experience, the enhanced features of the MiniMed 630G system were finalized to take into account what matters most to those with diabetes. This collaborative process with the patient community resulted in a new, user-friendly pump design that is waterproof,1 has remote bolus functionality, and features a high-definition, full-color screen that supports easy navigation and enables increased customization with more intuitive menus.

The MiniMed 630G system exclusively uses the CONTOUR®NEXT LINK 2.4 blood glucose meter from Ascensia Diabetes Care to provide blood glucose test results that have been shown to be highly accurate2. The meter automatically transmits blood glucose results to calculate boluses using the Bolus Wizard® calculator and to calibrate the CGM sensor, which helps prevent manual entry errors. It also allows patients to discreetly give themselves a bolus of insulin remotely from the meter, providing added convenience to help patients manage their diabetes effectively.

"This latest innovation demonstrates Medtronic's vision to transform diabetes care to enable greater freedom and better health through a commitment to continually improving both outcomes and user experience," said Alejandro Galindo, president of the Intensive Insulin Management business at Medtronic.

The MiniMed 630G system combines its proprietary SmartGuard technology featured in the MiniMed 530G system with a brand new user-friendly design. The new pump platform fully integrates continuous glucose monitoring (CGM) and SmartGuard technology, which is designed to trigger an alarm when the CGM sensor glucose level reaches a preset low threshold and suspends insulin delivery if the user is unresponsive to the alarm. SmartGuard technology is the only feature available in the U.S. that takes action against lows,3 and is the only system proven to reduce the frequency of nighttime low episodes3 by a third. 4,5

Data from the ASPIRE In-Home Study published in the *New England Journal of Medicine*,4 demonstrated that SmartGuard technology not only reduces the number of low events3 per week by 30 percent but also shortens the length/intensity of those events at night by 37.5 percent without increasing A1C (a measure of average blood sugar levels over three months).5 These results were validated with real-world data from the company's CareLink® Personal software that included an analysis of 3,770,311 days of patient data, which demonstrated SmartGuard technology users experience about half as many nighttime lows3 than those using a pump and sensor alone.6 MiniMed integrated insulin pump therapy with CGM has also been proven to provide better glucose control than multiple daily injections without increasing hypoglycemia (low blood sugar).7

"Low blood sugar at night is of particular concern, when up to 75 percent of severe hypoglycemia occurs and patients are unlikely to be aware of symptoms while they are asleep," said Satish Garg, M.D., Editor-in-Chief of Diabetes Technology and therapeutics and professor of pediatrics and medicine and director of the adult diabetes program at the University of Colorado Denver, Barbara Davis Center for Childhood Diabetes. "The ability to automate the suspension of insulin at night is an important feature as prolonged hypoglycemia could be life-threatening."





MiniMed® 630G System
Click the thumbnail above for a larger image.

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 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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.

1 MiniMed 630G is waterproof in up to 12 feet of water for up to 24 hours at the time of manufacture; Guardian Link Transmitter is waterproof in up to 8 feet of water for up to 30 minutes. See IFU for care instructions to help maintain waterproof.
2 Bailey TJ et al. Accuracy, Precision, and User Performance Evaluation of the CONTOUR®NEXT LINK 2.4 Blood Glucose Monitoring System. Data presented at the 7th International Conference on Advanced Technologies & Treatments for Diabetes 2014
3 < 65 mg/dL, measured in sensor glucose values.
4 Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *N Engl J Med.* 2013;369(3):224-232.
5 Based upon limited sample size and duration of ASPIRE In-Home study.
6 Data from only the voluntary CareLink® Personal uploads from the MiniMed 530G system in the U.S. available from October 15, 2013 to November 29, 2015 evaluated. Based on 3,770,311 days of data with 41,287 users (79.7% with SmartGuard on) reporting 2,239,637 SmartGuard events.
7 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.

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