Medtronic News

FDA Approves Medtronic-Proprietary Software for Use with Non-Medtronic Leads to Detect Defibrillator Lead Issues

Thomson Reuters ONE via COMTEX) --LIA Software Proven to Detect Lead Failures More Frequently Than Impedance Alone on Riata, Durata and Endotak Leads

MINNEAPOLIS - Nov. 7, 2013 - Medtronic, Inc. (NYSE:MDT) today announced FDA approval of its Lead Integrity Alert (LIA) software for use with non-Medtronic leads. Proprietary and exclusive software that resides in Medtronic defibrillators, LIA is now approved to report performance issues on Durata® and Riata® defibrillator leads (St. Jude Medical) and Endotak® (Boston Scientific) defibrillator leads when connected to a Medtronic device.

Originally approved by the FDA in 2008 for use with Medtronic defibrillators and leads, LIA has shown the ability to detect pace/sense lead issues in non-Medtronic leads at a greater rate than standard impedance monitoring alone (impedance monitoring measures the electrical continuity of a lead four times per day), according to an analysis recently published in Circulation: Arrhythmia and Electrophysiology. For Durata® and Riata® leads (St. Jude Medical), pace/sense circuit issues were detected by the LIA software approximately six times more frequently than with impedance monitoring. Likewise, for Endotak® (Boston Scientific) leads, pace/sense circuit issues were detected four times more frequently with LIA software.

"This approval affirms the applicability of Medtronic's LIA-enabled defibrillators in detecting lead issues in those leads developed by other manufacturers," said Kenneth A. Ellenbogen, M.D., Kontos Professor of Cardiology at the VCU School of Medicine and Medical College of Virginia Hospital.

In the U.S., approximately 12,000 Medtronic LIA-enabled defibrillators (ICDs and CRT-Ds) are connected to non-Medtronic leads, as identified and monitored remotely via the Medtronic CareLink® Network. This includes approximately 5,100 Endotak leads; 6,100 Riata/Durata® leads from St. Jude Medical; and nearly 500 leads from other manufacturers, including Biotronik and others. Non-Medtronic lead issues identified by LIA were adjudicated by an external panel of physicians who had access to device-stored electrograms and the clinical interpretation of the treating physician.

"We've seen the effectiveness of the LIA software with Medtronic devices and leads these past four years, and we know it can have an impact beyond our leads," said Marshall Stanton, M.D., vice president and general manager of the tachycardia business at Medtronic. "LIA detects lead failures better than impedance alone and this approval provides implanting physicians with performance information on this advanced decision-making tool to benefit the health and well-being of their patients."

LIA is included in the SmartShock(TM) suite of algorithms that yields the lowest occurrence rate of inappropriate shocks for any defibrillator in the industry. [i], [ii]

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

About Medtronic

Medtronic, Inc. (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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[i] Schloss EJ, et al. PainFree SST Trial Primary Results: Low Shock Rates in Patients with Dual and Triple Chamber ICDs Using Novel Detection Algorithms. Heart Rhythm. 2013;10(50):S64.

[ii] Schloss E, et al. PainFree SmartShock technology: trial primary results: inappropriate shock rates in patients with single chamber ICD's using a novel suite of detection algorithms. EHRA Europace 2013 Late Breaking Trial session 1.

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