Medtronic News

Medtronic Announces FDA Clearance and Results of Artificial Intelligence Algorithms for Cardiac Monitoring

AI Algorithms Enhance LINQ II™ Insertable Cardiac Monitor Diagnostic Accuracy for Improved Management of Patients

DUBLIN, July 28, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced U.S. Food and Drug Administration (FDA) clearance for two AccuRhythm™ AI algorithms for use with the LINQ II™ insertable cardiac monitor (ICM). AccuRhythm AI applies artificial intelligence (AI) to heart rhythm event data collected by LINQ II, improving the accuracy of information physicians receive so they can better diagnose and treat abnormal heart rhythms. AccuRhythm AI validation data will be presented this week at Heart Rhythm 2021, the Heart Rhythm Society's annual Heart Rhythm meeting.

The small, wireless LINQ II ICM is the world's most accurate ICM,[1-4] and the new cloud-based AccuRhythm AI algorithms further enhance LINQ II ICM's delivery of accurate heart rhythm alerts. The algorithms address the two most common ICM false alerts – atrial fibrillation (AF), an irregular or rapid rhythm in the upper chambers of the heart; and asystole, a long pause between heartbeats.[5-6] Medtronic developed the AccuRhythm AI platform and initial algorithms using its proprietary, diverse and debiased database of more than 1 million electrocardiogram heart rhythm episodes.

AccuRhythm AI validation results to be presented at Heart Rhythm 2021 include:

- The AF algorithm reduced LINQ II ICM false AF alerts by 74.1% and preserved 99.3% of true AF alerts.
- The Pause algorithm reduced LINQ II false pause alerts by 97.4% and preserved 100% of true pause alerts.

"Applying AccuRhythm AI to LINQ II data is a significant ICM innovation, enabling us to reduce clinical inefficiencies resulting from false alerts, and help physicians better identify and focus on the actionable data they need to treat their patients," said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiovascular Diagnostics and Services business, which is part of the Cardiovascular Portfolio at Medtronic.

The AccuRhythm AI algorithms will be released on the CareLink™ Network later this year for use by all implanted LINQ II devices in the United States.

"We are excited to integrate AI capabilities to further elevate the accuracy of LINQ II ICM – and provide clinicians with greater confidence in patient care decisions," said Julie Brewer, president of the Cardiovascular Diagnostics and Services business at Medtronic. "We look forward to introducing additional diagnostic innovations to advance patient management in the future."

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

[1]BiotronikBioMonitor™ 2 Technical Manual. 2017.

[2]NölkerG, et al. J Cardiovasc Electrophysiol. 2016;27:1403-1410.

[3]Confirm Rx™ ICM DM3500 FDA Clearance Letter. 2017.

[4]PürerfellnerH, et al. Europace. 2018;20:f321-f328.

[5]Catherine O`Shea, Melissa E. Middeldorp, Anthony G. Brooks, Jeroen M. Hendriks, Celine Gallagher, Niraj Varma, Rakesh Gopinathannair, Suzanne A. Feigofsky, Dennis H. Lau, Kevin R. Campbell, Prashanthan Sanders. Remote Monitoring Of Implantable Loop Recorders: False-positive Alert Episodes. Poster presented at: HRS 2020 Science Online. May 2020. https://cslide-us.ctimeetingtech.com/hrs20/attendee/eposter/poster/71.

[6]AccuRhythm Clinician Manual Supplements M015316C001 and M015314C001.

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