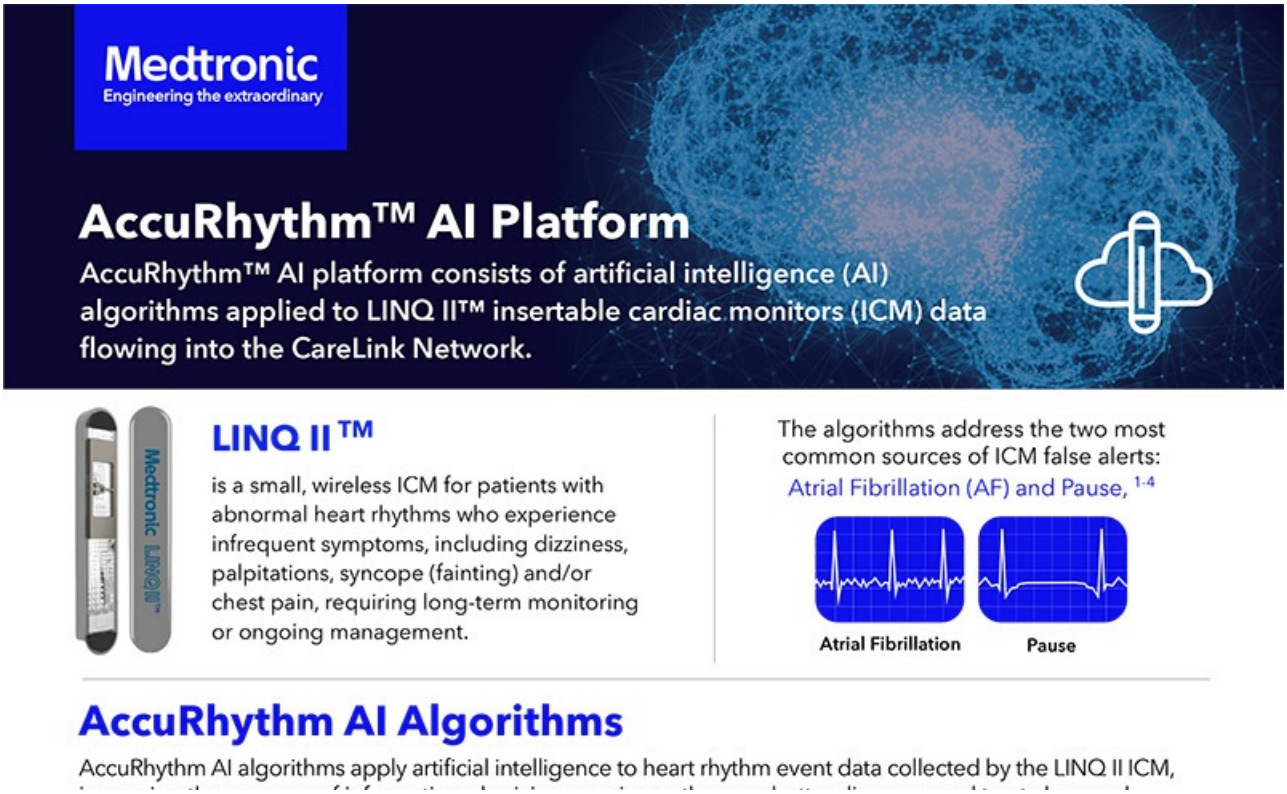
APR 12, 2022

Medtronic announces upcoming market release of AI algorithms for cardiac monitoring in Europe

AccuRhythm AI algorithms shown to reduce false alerts by 84%

Medtronic today announced two AccuRhythm™ AI algorithms will be applied to LINQ II™ insertable cardiac monitors (ICM) through cloud-based updates in Europe later this spring. 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.

The two AI algorithms – specific to the most common ICM false alerts, atrial fibrillation (AF) and pause (asystole) [i], [ii] – have shown to reduce the number of false alerts by as much as 84%, saving clinicians approximately 319 hours of clinic review time (for every 200 LINQ II patients) according to recent data presented at the 2021 American Heart Association Scientific Sessions in November.[iii]



improving the accuracy of information physicians receive so they can better diagnose and treat abnormal heart rhythms.

By the Numbers

401 Hour Reduction in Clinical Review Time [4,*,**] (for every 200 LINQ II Patients)

91% Combined Reduction in LINQ II False Alerts [4]

97% Reduction in Pause False Alerts [1]

88% Reduction in AF False Alerts [2]

References

1 Cheng YJ, Ousdigian KT, Koehler J, et al. Innovative Artificial Intelligence Application Reduces False Pause Alerts while Maintaining Perfect True Pause Sensitivity for Insertable Cardiac Monitors. Presented at Heart Rhythm Society Conference July 31, 2021.

2 Radtke A. et al. Accelerating Improvements to Arrhythmia Classifiers with AI-curated Dataset. Poster presented at: HRS New Orleans May 2023

3 AccuRhythm™ Clinician Manual Supplements M015316C001 and M048573C001.

4 Radtke A, Hall M. AccuRhythm AI AF & Pause Algorithms White Paper. April 2023. Medtronic data on file.

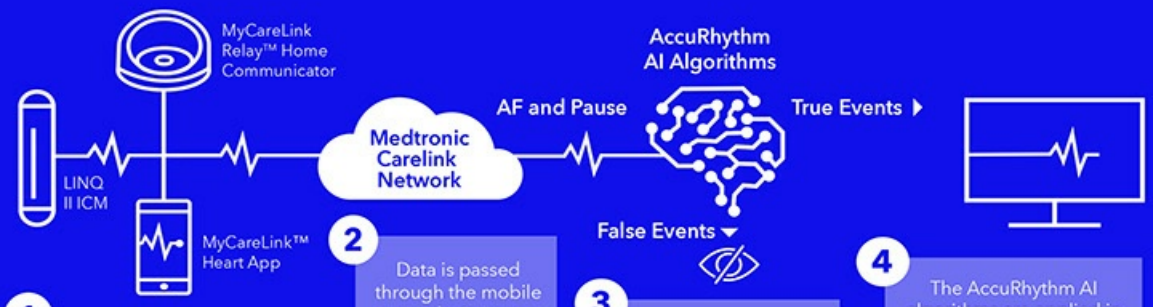
* The validation study performance and time study results were projected onto 16,301 LINQ II patients to calculate the time saved per year in 200 LINQ II ICM patients

** Estimated time savings was calculated based on 11.3 minutes per non-actionable ICM transmission (Seiler et al. JMIR Cardio 2021;5:e27720).

Medtronic.com

How AccuRhythm AI Algorithms Work

The AccuRhythm AI algorithms are applied in the cloud automatically with no action required of LINQ II patients. Algorithms will be applied to all LINQ II devices already enrolled in the CareLink Network™, providing results overnight to clinicians managing LINQ II patients.



1 The LINQ II ICM integrates Bluetooth® technology, which enables two-way connectivity between the ICM and the MyCareLink™ Heart App on a patient's mobile device or MyCareLink Relay Home Communicator.

2 Data is passed through the mobile device or MyCareLink Relay Home Communicator to the CareLink Network.

3 The monitor then transmits all device data to the CareLink Network, which AccuRhythm AI reviews without the need for a manual transmission.

4 The AccuRhythm AI algorithms are applied in the cloud automatically with no action required of patients. Algorithms will be applied to all LINQ II devices already enrolled in the CareLink Network, providing results overnight to clinicians managing LINQ II patients.

About AI

AI is an overarching term for technologies that work to emulate capabilities of the human brain. AI learns to perform a task without human intervention through analysis of a bolus of labeled training data. The AI analyzes features, patterns, and trends within the labeled ECGs to learn correlations to true cardiac events and false cardiac events.

The AccuRhythm AI algorithms are trained on data from more than

1 MILLION

professionally adjudicated electrocardiogram heart rhythm episodes

Brief Statement

If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety, and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1.763.514.4000 and/or consult the Medtronic website at medtronic.com.

For residents of the United States, please reference the relevant safety information (i.e. indications, contraindications, warnings/precautions, and potential complications) associated with the devices covered in this course by clicking here.

If you are located outside the United States, see the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use at manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Medtronic LINQ II™ Insertable Cardiac Monitor System (ICM) and Remote Monitoring

Indications: The LINQ II ICM is an insertable automatically activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardia arrhythmia

Contraindications: There are no known contraindications for the insertion of the LINQ II ICM or its accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Warnings and Precautions: Patients with the LINQ II ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the LINQ II MRI Technical Manual.

Wireless accessories available for use with LINQ II may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events: Potential adverse events from the LINQ II ICM include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin. There are no known adverse events associated with the use of any LINQ II ICM wireless accessory.

See the device manuals for detailed information regarding the implant procedure, indications/intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 (Technical Services), 1-800-551-5544 (Patient Services), and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts prescription devices to sale by or on the order of a physician.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

AccuRhythm AI ECG Classification System Brief Statement

Intended Use: The intended use of the system is to reduce false positive cardiac arrhythmia episodes.

Contraindications: There are no known contraindications for AccuRhythm AI Models ZA400, ZA410, or ZA420.

Precaution: The AccuRhythm AI ECG classification system may incorrectly adjudicate a true positive episode as an AI false episode, causing that episode to be suppressed in the remote monitoring system.

See the device manual for detailed information regarding the intended use, contraindications, warnings, precautions, and potential complications / adverse events. For further information, call Medtronic Technical Services at (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic

710 Medtronic Parkway
Minneapolis, MN
55432-5604 USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000
Medtronic.com

US202214728a EN ©2023
Medtronic. Minneapolis, MN.
All Rights Reserved.
Printed in USA. 9/2023

"As staffing and resource shortages brought on by the pandemic continue to put a strain on clinics and hospitals around the world, reducing clinician burden has never been more important," 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 technology is able to identify and suppress false positives while preserving true positives to ensure clinicians are spending their time reviewing only the episodes that are clinically relevant."

Data presented at Heart Rhythm 2021, the Heart Rhythm Society's annual Heart Rhythm meeting, showed:

- 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.

The small, wireless LINQ II ICM is the world's most accurate ICM,[iv], [v], [vi], [vii] and the cloud-based AccuRhythm AI architecture provides the foundation for additional AI-based algorithm deployment in the future. 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 is applied in the cloud automatically with no action required of patients.

AccuRhythm AI received FDA market clearance in June 2021. Learn more about AccuRhythm AI.

For more information, please contact:
Joey Lomicky, 612-239-1823, joey.lomicky@medtronic.com.

---

[i] 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.

[ii] AccuRhythm Clinician Manual Supplements M015316C001 and M015314C001.

[iii] Ousdigian K, Cheng YJ, Koehler J, et al. Artificial Intelligence Dramatically Reduces Annual False Alerts from Insertable Cardiac Monitors. Presented at AHA Conference 2021.

[iv] BiotronikBioMonitor™ 2 Technical Manual. 2017.

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

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

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

https://news.medtronic.com/Medtronic-announces-upcoming-market-release-of-AI-algorithms-for-cardiac-monitoring-in-Europe