

AccuRhythm™ AI Platform

AccuRhythm™ AI platform applies artificial intelligence (AI) algorithms to LINQ II™ insertable cardiac monitors (ICM).

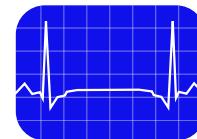
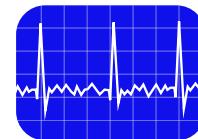


LINQ II™

is a small, wireless ICM for patients with abnormal heart rhythms who experience infrequent symptoms, including dizziness, palpitations, syncope (fainting) and/or chest pain, requiring long-term monitoring or ongoing management.

The algorithms address the two most common sources of ICM false alerts:

Atrial Fibrillation (AF) and Pause,¹⁻⁴

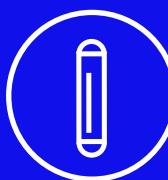


Atrial Fibrillation

Pause

AccuRhythm AI Features

AccuRhythm AI applies AI to heart rhythm event data collected by the LINQ II ICM, improving the accuracy of information physicians receive so they can better diagnose and treat abnormal heart rhythms.



Patient Device



Transmits Data



Received by Physician

By the Numbers

319

Hour Reduction
in Clinical Review Time^{4,*}
(for every 200 LINQ II Patients)

97%

Reduction in Pause
False Alerts¹

84%

Reduction in LINQ II
False Alerts⁴

74%

Reduction in AF
False Alerts²

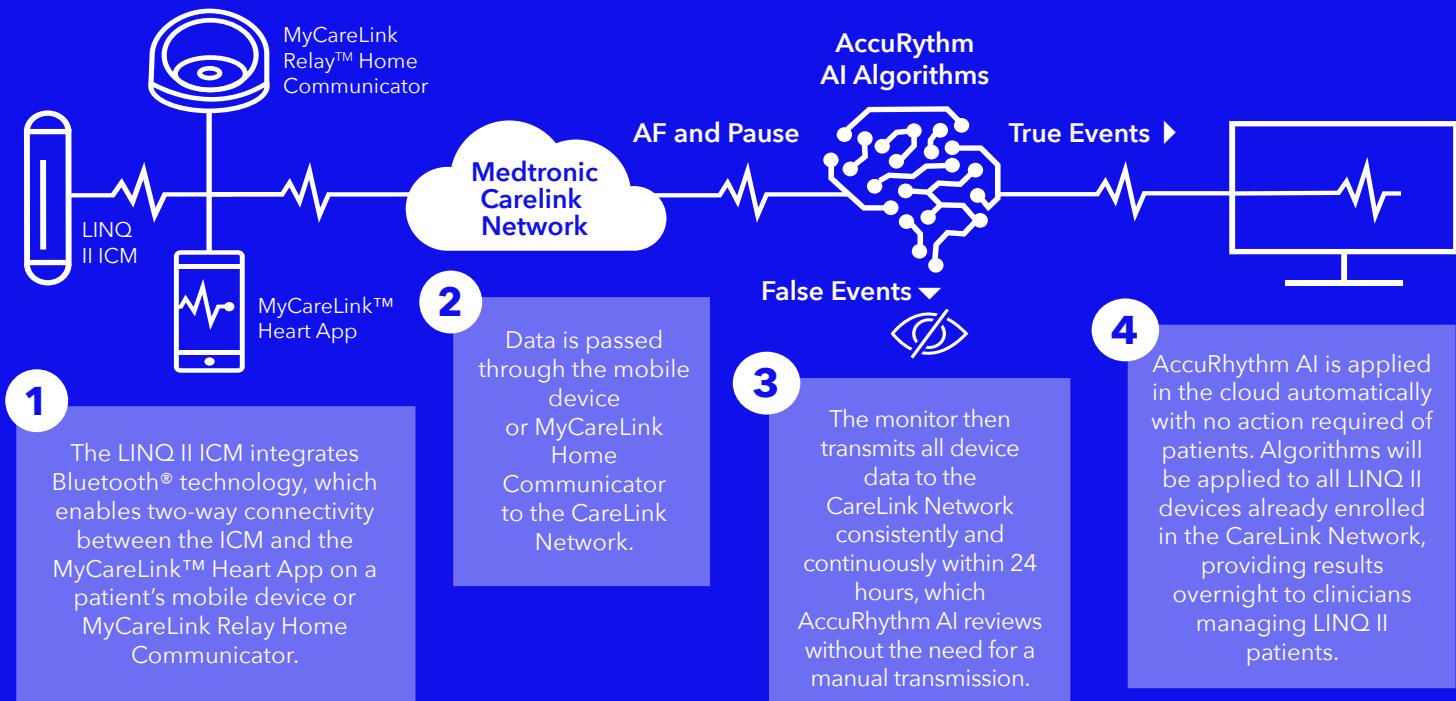
References

- 1 Cheng YJ, Ousdigan KT, Koehler J, et al. Innovative Artificial Intelligence Application Reduces False Pause Alerts while Maintaining Perfect Trye Pause Sensitivity for Insertable Cardiac Monitors. Presented at Heart Rhythm Society Conference July 31, 2021.
- 2 Radtke A, Ousdigan KT, Haddad TD, et al. Artificial Intelligence Enables Dramatic Reduction of False Atrial Fibrillation Alerts from Insertable Cardiac Monitors. Heart Rhythm Journal. Published online August 1, 2021.
- 3 AccuRhythm™ Clinician Manual Supplements M015316C001 and M015314C001.
- 4 Ousdigan K, Cheng YJ, Koehler J, et al. Artificial Intelligence Dramatically Reduces Annual False Alerts from Insertable Cardiac onitors. Presented at AHA Conference 2021.

* 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

How AccuRhythm AI Works

AccuRhythm AI is 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.



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.

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, 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 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 cardiac arrhythmia

The device has not been tested specifically for pediatric use.

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.

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