

Medtronic

Accuracy matters.

The **AccuRhythm™ AI platform** is an artificial intelligence system that applies deep learning algorithms to LINQ II™ insertable cardiac monitor (ICM) data flowing into the CareLink™ network. The algorithms reduce false alerts from the two most common sources of ICM false alerts – atrial fibrillation (AF) and Pause.¹⁻⁴

The AccuRhythm AI AF algorithm enhancement further reduces AF false alerts, preserves sensitivity, and delivers actionable alerts you can trust.

97.4%
reduction in
Pause false alerts¹

Retained 100% true Pause alerts¹

88.2%
reduction in
AF false alerts⁵

Retained 99% true AF alerts⁵

[†]The validation study performance and time study results were projected onto 16,301 LINQ II patients to calculate false alert reduction per year in 200 LINQ II ICM patients.

[‡]Estimated time savings was calculated based on 11.3 minutes per non-actionable ICM transmission.⁶

91%
reduction in LINQ II
false alerts⁵

401
hours reduction in
clinic review time^{†‡5}



References

- ¹Cheng YJ, Ousdigian 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.
- ²Radtke A, Ousdigian KT, Haddad TD, Koehler JL, Colombowala IK. Artificial Intelligence Enables Dramatic Reduction of False Atrial Fibrillation Alerts from Insertable Cardiac Monitors. *Heart Rhythm*. August 1, 2021;18(8):S47.
- ³AccuRhythm™ AI Clinician Manual Supplements M015316C001 and M048573C001.
- ⁴Ousdigian K, Cheng YJ, Koehler J, et al. Artificial Intelligence Dramatically Reduces Annual False Alerts from Insertable Cardiac Monitors. Presented at AHA Conference 2021.
- ⁵Radtke A, Hall M. AccuRhythm AI AF & Pause Algorithms White Paper. April 2023. Medtronic data on file.
- ⁶Seiler A, Biundo E, Di Bacco M, et al. Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation. *JMIR Cardio*. October 15, 2021;5(2):e27720.

Brief Statement

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 cardiac 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 (800) 328-2518 (Technical Services), (800) 551-5544 (Patient Services), and/or consult Medtronic's website at medtronic.com.

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

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 medtronic.com.

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

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