Medtronic

Accuracy matters.

Experience the difference

AccuRhythm™ AI algorithms for the Reveal LINQ™ insertable cardiac monitor (ICM)

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BEST NEW TECHNOLOGY SOLUTION - MONITORING

What can AccuRhythm AI do for your Reveal LINQ ICM clinic?

Experience the difference of Reveal LINQ ICM now with AccuRhythm AI algorithms for AF and pause.

Reveal LINQ, the most studied insertable cardiac monitor (ICM) in the market – trusted in over one million implants[1] – is now enhanced with proven artificial intelligence (AI), providing data that's more actionable – without compromise.[2] Preserving over 99.9% true pause and 98.2% true AF alerts relative to Reveal LINQ ICM, AccuRhythm AI algorithms significantly improve the clinic experience.[2]

Validation with data from real-world ICM patients demonstrated:

AF algorithm

89.5%
Reduced false alerts[2]

98.2%
Preserved true alerts[2]

Pause algorithm

80.2%
Reduced false alerts[2]

99.9%
Preserved true alerts[2]

To alleviate clinician review burden, these algorithms address the two most common sources of ICM false alerts – atrial fibrillation (AF) and Pause.[2-4]

The AccuRhythm AI platform applies deep learning AI algorithms to Reveal LINQ ICM data flowing into the CareLink™ network.

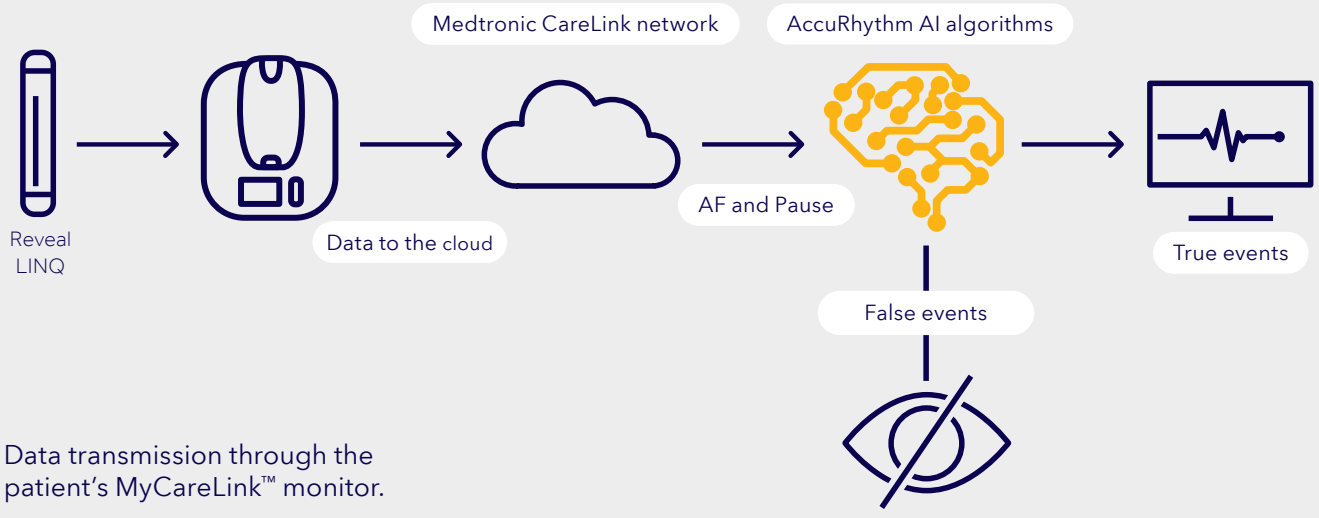
How does AccuRhythm AI work?

AccuRhythm AI algorithms were rigorously trained and developed based on over one million professionally adjudicated ECGs to preserve sensitivity and provide data-driven insights free from bias. Once performance was validated, the AI algorithms were locked to ensure an unbiased lens.[2,4-7]

Bypass logic ensures that clinically relevant events are still sent to you for review.

Greater confidence

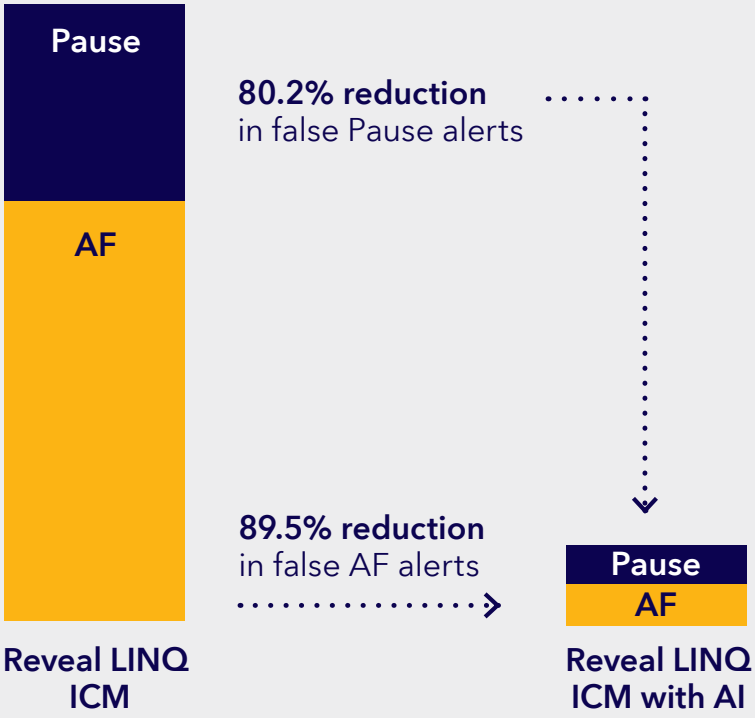
How do AccuRhythm AI algorithms work?



Data transmission through the patient's MyCareLink™ monitor.

Reduce false alerts

AF and Pause generate **~90% of false alerts** in the ICM space[3]



The AccuRhythm AI algorithms can save clinicians approximately

186 hours

of false alert review yearly for every 200 Reveal LINQ ICM patients.[†‡2]

85% cumulative reduction in Reveal LINQ ICM false alerts[2]

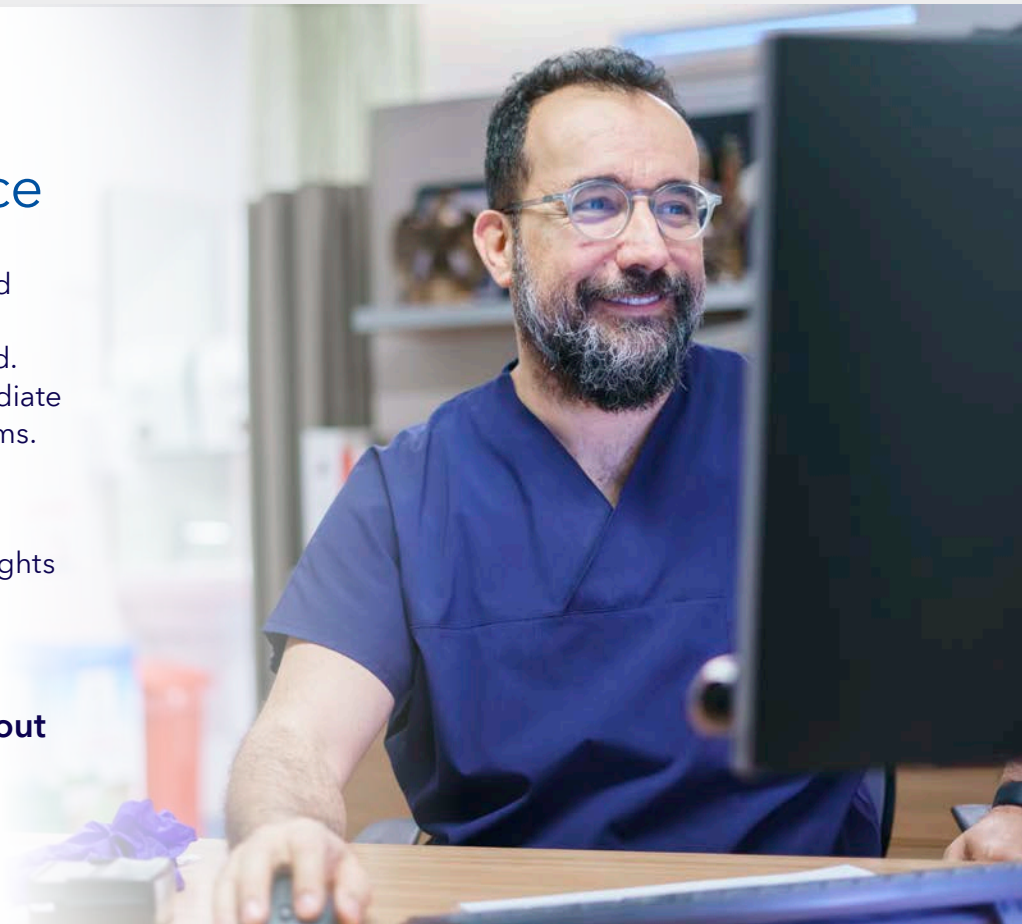
[†]The validation study performance and time study results were projected onto 104,315 Reveal LINQ patients to calculate false alert reduction per year in 200 Reveal LINQ ICM patients.
[‡]Estimated time savings was calculated based on 11.3 minutes per non-actionable ICM transmission.[8]

Seamless experience

Moving product updates into the cloud enables application of algorithms to Reveal LINQ devices already implanted. This allows clinics to experience immediate benefits from AccuRhythm AI algorithms.

Allow us to seamlessly transform your experience by leveraging Medtronic history, expertise, and data-driven insights in the cardiac monitoring space.

Talk to your Medtronic sales representative to learn more about AccuRhythm AI algorithms.



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Brief Statement

Reveal LINQ™ Insertable Cardiac Monitor (ICM) System and Accessories

Indications
The Reveal LINQ Insertable Cardiac Monitor (ICM) is an implantable patient-activated and automatically-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 implant of the Reveal LINQ ICM or its accessories. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions
Patients with the Reveal LINQ 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 precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

Accessories available for use with Reveal LINQ ICM may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events or Potential Complications
Potential complications of the Reveal LINQ device 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 Reveal LINQ ICM accessory.

See the device manuals for detailed information regarding the implant procedure, indications, 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 www.medtronic.com.

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

AccuRhythm AI ECG Classification System

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.

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