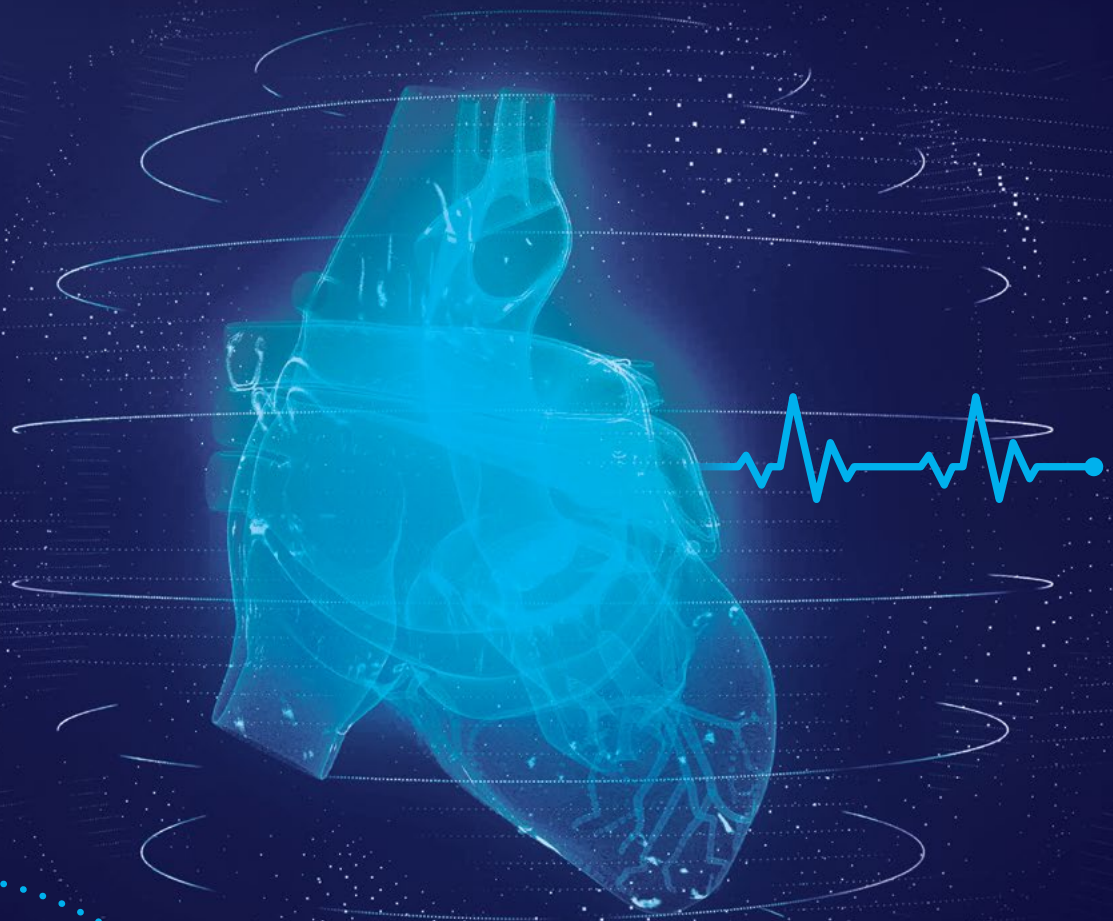
Medtronic

# Accuracy matters.



## See what others miss.

**LINQ II™**
Insertable Cardiac Monitoring (ICM) System.
The world's most accurate ICM.[1-13]

Personalized for the patient's lifestyle.
Customized for the clinician's workflow.

# Greater confidence

- Most accurate algorithms based on published clinical evidence[1-13]
- Advanced AccuRhythm™ AI algorithms enabling optimal outcomes[14-16]
- The lowest published rate of AF false positives[14,15,17]
- Exclusive PVC detector and pause detection algorithm

Medtronic LINQ II™

**LINQ II**
Insertable Cardiac Monitoring System

# Seamless experience

- World's first ICM with remote programming[†18]
- 4.5-year longevity[‡18]
- Two monitoring options, including a Bluetooth®-enabled mobile app, to fit patient lifestyle and increase patient compliance[19,20]
- Smart memory management eliminates the need for manual transmissions[18]

[†]First European (TUV notified body) approved remote programmable device.
[‡]Nominal settings.

# Greater confidence

## Industry-leading accuracy, AI-powered insights

The AccuRhythm AI platform is an artificial intelligence system that applies deep learning algorithms to LINQ II ICM data flowing into the CareLink™ network.

The algorithms address the two most common sources of ICM false alerts – Atrial Fibrillation (AF) and Pause.[14,15,17]

Validation data demonstrated:

### AF algorithm

**74.1%**
Reduced false alerts[15]

**99.3%**
**Preserved true alerts[15]**

### Pause algorithm

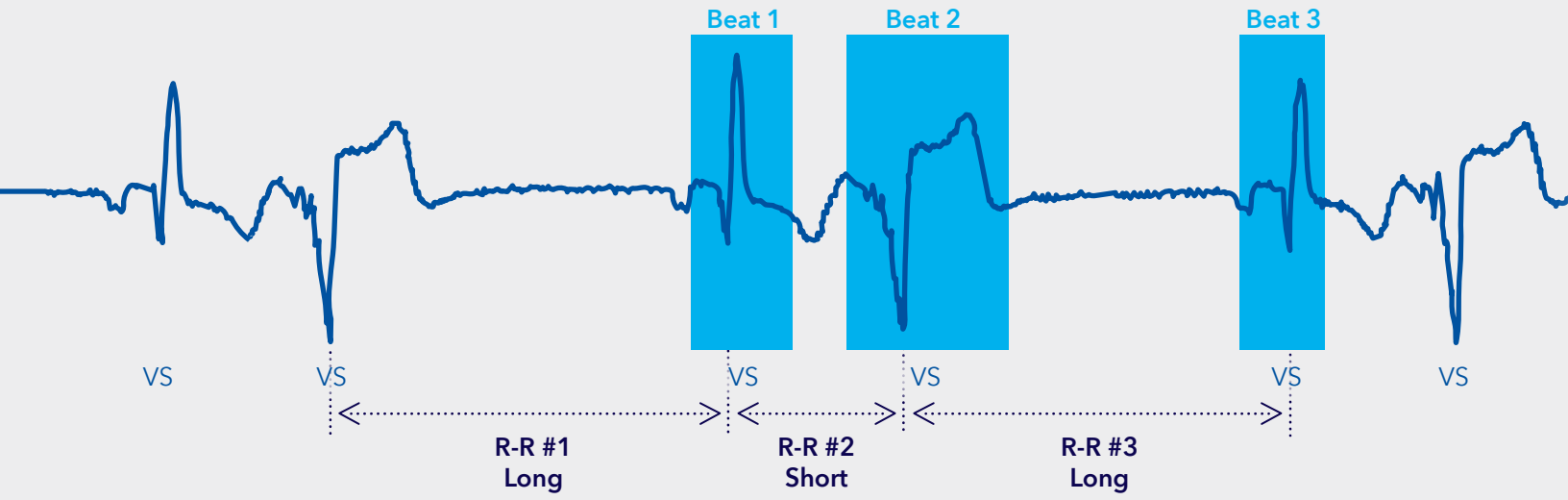
**97.4%**
Reduced false alerts[14]

**100%**
**Preserved true alerts[14]**

Experience the transformational benefits of AccuRhythm AI algorithms, which further enhance the accuracy of LINQ II ICM data.[14-23]

Scan the QR code to watch videos and learn how AccuRhythm AI algorithms work.

## Exclusive PVC detector may help identify high-risk patients.[21,22]



AccuRhythm AI algorithms can save clinicians approximately 319 hours of false alert review yearly for every 200 LINQ II ICM patients.[§16]

84%

reduction in LINQ II false alerts[16]

319

hours reduction in clinic review time[§16]

[§]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.

# Seamless monitoring experience

BlueSync™ technology within LINQ II ICM enables secure, wireless communication via Bluetooth Low Energy without compromising longevity.[18]

## MyCareLink Heart™ Mobile App

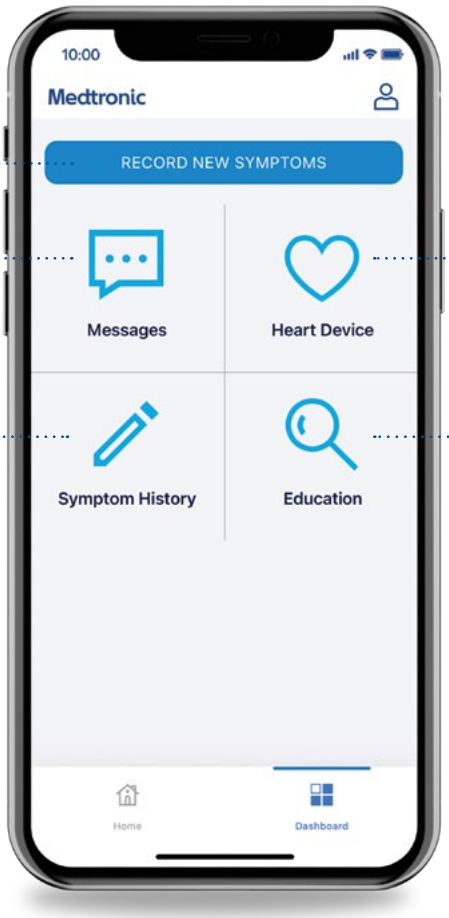
Patients can use their smartphone to automatically transfer device data via the MyCareLink Heart mobile app, even outside the home.[Ω††‡‡18]

Now, you have the choice to provide the MyCareLink Heart mobile app to your patients on a Medtronic-provided smartphone, if the patient doesn't have their own compatible device.

**Symptom marker**
Recorded symptoms correlate with heart rhythm at the time of episode

**Messages**
Important messages about transmission status and using the app

**Symptom history**
A log of symptoms to share with a doctor at an office visit




**My heart device**
Displays implant date, ICM device name, model number, and serial number

**Education**
Provides information about living with the LINQ II device

MyCareLink Heart mobile app also delivers:

**Patient compliance**
Provides information that results in increased clinic efficiencies[19,20,23]

**Patient engagement**
Promotes patient satisfaction[19]

**Upgradability**
Sets the foundation for future technologies

## MyCareLink Relay™ Home Communicator

(alternative monitoring option)

- Bluetooth home communicator offers your patients an easy, reliable monitoring alternative.‡‡
  - Requires little to no user interaction
  - Requires no manual pairing
- For patients who are unable to or prefer not to use a smartphone.
- Physician may choose to include an optional Patient Assistant for patients to mark symptoms as they happen.


ΩPlease visit MCLHeart.com for a list of compatible smartphones and tablets.
††Patients must keep their smartphone or tablet up to date to use the app.
‡‡Where cellular or Wi-Fi connectivity is available.

# Seamless programming experience

First ICM with remote programming[§§18]

- Reduces patient office visits and scheduling hassles
- Enables remote programming capability for all device parameters post-insertion from the clinic

Remote access to full ECGs eliminates the need for manual transmissions[18]

Patient data transmitted to CareLink network via MyCareLink Relay home communicator or MyCareLink Heart mobile app

Clinician initiates reprogramming via CareLink network

Secure connection

Cellular connection

Bluetooth connection

Wi-Fi connection

[§§]First European (TUV notified body) approved remote programmable device.


Monitors act as
a pass-through

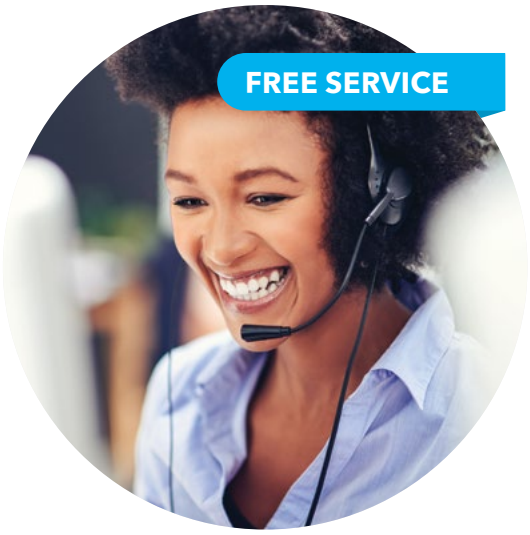
Device settings are
automatically updated without
the need for an office visit

# Exclusive service offerings


### Get Connected Service[ΩΩ]

The Get Connected service guides patients through the process of:

- Monitor screening and ordering
- Setup
- First transmission




### Stay Connected Service[ΩΩ]

Provides expert troubleshooting and support for patients experiencing issues with connectivity or monitor equipment.

[ΩΩ] Talk to your Medtronic representative to learn how to sign up for these free services.

**References**

[1] Pürerfellner H, Sanders P, Sarkar S, et al. Adapting detection sensitivity based on evidence of irregular sinus arrhythmia to improve atrial fibrillation detection in insertable cardiac monitors. *Europace*. November 2018;20(FI_3):f321-f328.
[2] Nölker G, Mayer J, Boldt L, et al. Performance of an Implantable Cardiac Monitor to Detect Atrial Fibrillation: Results of the DETECT AF Study. *J Cardiovasc Electrophysiol*. December 2016;27(12):1403-1410.
[3] Confirm Rx™* ICM K163407 FDA clearance letter. 2017.
[4] Confirm Rx ICM K182981 FDA clearance letter. 2019.
[5] Jot Dx™* ICM K212206 FDA clearance letter. 2021.
[6] Monitoring Devices Merlin™* PCS help manual for SJM Confirm™*, Confirm Rx ICM, Jot Dx manual. 2021.
[7] BIOTRONIK BioMonitor™* 2 technical manual. 2017.
[8] BIOTRONIK BIOMONITOR III technical manual. 2020.
[9] BIOTRONIK BIOMONITOR IIIm technical manual. 2020.
[10] BIOTRONIK BIOMONITOR III. K190548 FDA clearance letter. 2019.
[11] BIOTRONIK BIOMONITOR IIIm. K201865 FDA clearance letter. 2020.
[12] Lux-Dx™* ICM K212206 FDA clearance letter. 2020.
[13] Lux-Dx ICM user manual. 2020.
[14] Cheng YJ, Ousdigian KT, Koehler J, Cho YK, Kloosterman M. Innovative Artificial Intelligence Application Reduces False Pause Alerts while Maintaining Perfect True Pause Sensitivity for Insertable Cardiac Monitors. Presented at HRS 2021.
[15] Radtke A, Ousdigian KT, Haddad TD, Koehler JL, Colombowala IK. Artificial Intelligence Enables Dramatic Reduction of False Atrial Fibrillation Alerts from Insertable Cardiac Monitors. Presented at HRS 2021.
[16] Ousdigian K, Cheng YJ, Koehler J, et al. Artificial Intelligence Dramatically Reduces Annual False Alerts from Insertable Cardiac Monitors. Presented at AHA Conference 2021.
[17] AccuRhythm clinician manual supplements M015316C001 and M015314C001.
[18] LINQ II LNQ22 ICM clinician manual. M974764A001D.
[19] Cronin EM, Ching EA, Varma N, Martin DO, Wilkoff BL, Lindsay BD. Remote monitoring of cardiovascular devices: a time and activity analysis. *Heart Rhythm*. December 2012;9(12):1947-1951.
[20] Varma N. Remote monitoring of patients with CIEDs following the updated recommendations — Easing or adding to postimplant responsibilities? *Cont Cardiol Educ*. December 2016;2(4):198-204.
[21] Penela D, Fernández-Armenta J, Aguinaga L, et al. Clinical recognition of pure premature ventricular complex-induced cardiomyopathy at presentation. *Heart Rhythm*. December 2017;14(12):1864-1870.
[22] Penela D, Van Huls Van Taxis C, Aguinaga L, et al. Neurohormonal, structural, and functional recovery pattern after premature ventricular complex ablation is independent of structural heart disease status in patients with depressed left ventricular ejection fraction: a prospective multicenter study. *J Am Coll Cardiol*. September 24, 2013;62(13):1195-1202.
[23] Fowles JB, Terry P, Xi M, Hibbard J, Bloom CT, Harvey L. Measuring self-management of patients' and employees' health: further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. *Patient Educ Couns*. October 2009;77(1):116-122.

**Brief statements**

**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 (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 prescription 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 the Medtronic website at medtronic.com.

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