MyCareLink Heart™ App
For Heart Devices with BlueSync™ Technology

LINQ II™
Insertable Cardiac Monitoring System (ICM)
Patients can now use their smartphone to automatically transfer device data via the MyCareLink Heart mobile app. Visit MCLHeart.com for a list of compatible smartphones and tablets.

**How It Works**

1. LINQ II with BlueSync™ technology
2. Data is sent to the CareLink™ network
3. Patient’s mobile device
4. Cellular or Wi-Fi
5. Your clinic

**Select Features**

- **Connectivity Status**
  - Green check mark confirms connectivity

- **Automatic Notifications**
  - Patient notified if not connected for 4 days
  - Guides patients to reconnect
  - Reduces clinic time spent on disconnected monitor follow-up

- **Symptom Marking**
  - Rhythm symptom correlation
  - Enables patient to specify:
    - Symptom(s)
    - Level of activity
  - Clinic flexibility to turn symptom marking on/off per patient

**End-to-end encryption**
This guide describes how to use the MyCareLink Heart mobile app (called “app” from now on) for patients with LINQ II insertable cardiac monitors (ICMs).

**LINQ II ICM Home Screen on App**

- **Record New Symptoms**
  Allows the patient to record symptoms. Recorded symptoms correlate with heart rhythm at time of episode.*

- **My Heart Device**
  Displays implant date, ICM device name, model number, and serial number.

- **Education**
  Provides educational information for LINQ II patients on their LINQ II system and remote monitoring.

- **My Clinic**
  Displays patient’s clinic information such as address and phone number.

- **Symptom History**
  A log of patient-recorded symptoms that were sent to their clinic.

- **Connectivity Status**
  This section displays device connectivity status to the app.

*For LINQ II devices with symptom marking enabled. For patients without symptom marking enabled, this feature is not enabled or visible.

Available on:

- [App Store](https://apps.apple.com)
- [Google Play](https://play.google.com)
Set the Foundation for the Future of Connected Health

MyCareLink Heart for the BlueSync-enabled LINQ II ICM has been designed to provide the following benefits to both patients and the clinic:

**Patient Engagement Promotes Patient Satisfaction**

- Integrate remote monitoring into your patient’s daily life using a patient-owned smartphone and eliminate the need for a bedside monitor.
- Provides patients peace of mind with access to select heart device data.
- Activated patients are significantly more likely to engage in healthy behaviors.

**Patient Compliance Results in Increased Clinic Efficiencies**

- Patient monitoring — even outside the home — helps deliver quality of care in line with HRS guidelines.
- Reduce clinic time spent on follow-up activities.
- Automatic notifications help patients stay connected.

**Upgradeability Sets the Foundation for Future Technologies**

Similar to consumer apps, as technology advances, so will MyCareLink Heart — throughout the life of the cardiac device.

Patients need to keep their mobile technology up-to-date to use the app for monitoring.

**BlueSync Security**

Security for the new Bluetooth® connectivity and features was designed to protect the device, patient data, and connectivity. In addition to extensive internal product security testing, Medtronic has also engaged outside specialized security testing firms.

Visit www.medtronic.com/security for up-to-date security information.

**Restricted Device Access**

- The LINQ II ICM does not accept programming from unauthorized sources.
- MyCareLink Heart cannot be used to program the LINQ II ICM. The app acts as a pass-through only.

**End-to-end Encryption**

Data are encrypted in the ICM using NIST* government standards for security (used in critical applications like banking) before being transmitted to the CareLink network via the app.

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*NIST: National Institute of Standards and Technology.
Automatic Notifications

- Designed to reduce clinic time spent on follow-up activities.
- Can also be delivered via text message and email.

<table>
<thead>
<tr>
<th>Text</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>“You are now enrolled and connected to your clinic.”</td>
<td>Enrolled in the CareLink network</td>
</tr>
<tr>
<td>“Open MyCareLink Heart so the app can reconnect your heart device and clinic.”</td>
<td>No recent connection</td>
</tr>
</tbody>
</table>

Connectivity Status Notifications

<table>
<thead>
<tr>
<th>Text</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Bluetooth is off.”</td>
<td>Bluetooth is turned off on mobile device</td>
</tr>
<tr>
<td>“Check Wi-Fi/Cellular Connections.”</td>
<td>Mobile device is not connected to the internet</td>
</tr>
<tr>
<td>“Please keep your app open and within 3 feet (1 meter) of your heart device.”</td>
<td>App is out of range of heart device</td>
</tr>
</tbody>
</table>

**Note:** Because the app is shared across device types, the notification will display 3 feet versus the required 5 feet.
DOWNLOAD AND SETUP OVERVIEW

For detailed, step-by-step instructions on download and setup, refer to MyCareLink Heart Download and Setup Guide for Apple® or Android™, or visit MCLHeart.com.

Before starting, check the following items:

- Does the patient have an active App Store® ID and password? This is required in order to download the app.
- Verify your patient has a valid email address.

STEP 1: Download App

Download via MCLHeart.com or directly from the App Store. This is also a way to screen patients* for phone compatibility.

*The start of remote monitoring is NOT dependent on email verification.
STEP 2: Pair App with ICM and CareLink network

- Enter the patient’s name and email address. Create a password and input the device’s serial number. Click submit and wait a few minutes for pairing to complete.

STEP 3: Verify Email*

Navigate to email and select "Verify Email."

STEP 4: Enroll in CareLink network

In addition to pairing their ICM to the app, the patient needs to be enrolled in the CareLink network to be remotely monitored and to see app content. Select smartphone or tablet as the patient’s monitoring choice when associating a monitor to the LINQ II ICM at device insertion.

For more information on download and setup, visit MCLHeart.com

For best practice, download the app as early as possible. However, app setup should not occur until device insertion.

Scan this QR code to download the app from your smartphone or tablet via your compatible app store.
CONDITIONS FOR USE

To ensure the patient is being consistently monitored, the following must be done:

FOR APPLE DEVICES

1. Bluetooth ON
2. Internet connectivity: cellular or Wi-Fi ON

FOR ANDROID DEVICES

1. Bluetooth ON
2. Internet connectivity: cellular or Wi-Fi ON
**KEEP CONNECTED FEATURE**

For Apple iOS devices

The "Keep Connected" on MyCareLink Heart app recognizes when users* swipe up and force the app to close. This feature provides timely and actionable patient education.

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3. **Phone/tablet within 5 feet (1.5 meters) of device**

4. **App open in background or foreground**

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3. **Phone/tablet within 5 feet (1.5 meters) of device**

4. **App running in background or foreground**

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*Apple iOS users only.
Symptom Marking

- Record New Symptoms is optional and is enabled in the Medtronic CareLink network.
- Patients can manually record any symptoms they experience between in-office visits.
- A log of symptoms recorded is visible on the patient’s smartphone.
- Corresponding heart rhythm at the time of symptom is stored in ICM and sent to the CareLink network.

Setting: Symptom Recording — Updating a Secondary Device to a Primary Device

Symptom recording is allowed on the patient’s device that is identified as the primary device. Patients with multiple paired phones may need to update a secondary phone to a primary if they wish to mark symptoms with that device.
Explore the MyCareLink Heart™ Mobile App Tutorial

- Visit [www.medtronic.com/MCLHeartDemo](http://www.medtronic.com/MCLHeartDemo) from your smartphone or tablet.
- Select the tutorial for the LINQ II ICM.
- Explore the app setup, demo, features, and FAQ options.
What phones and tablets will be compatible?
See MCLHeart.com for an up-to-date list of compatible devices. The app has minimum system requirements for the mobile device and operating system version. The patient will need to update or replace their mobile device to continue to use the app to transfer data.

Can multiple heart devices be supported on the same phone/tablet/app?
No. Only one heart device can be connected to the MyCareLink Heart app at a time. MyCareLink Heart does not look for and cannot simultaneously connect to multiple heart devices from multiple patients.

Can a LINQ II patient log in to the app on multiple phones/tablets?
Yes. However, it is recommended only 1–2 mobile devices be used at a time. Before using their second phone/tablet, the patient needs to have paired their first phone/tablet. Then they can use their username and password to log in with their second phone/tablet.

Patients with symptom marking enabled will only be able to mark symptoms from one mobile device at a time. To make a mobile device the primary device for symptom marking, go to Menu > Settings > Symptom Recording. A non-primary mobile device can be set to primary at any time if there is a Wi-Fi or cellular data connection.

What languages does the MyCareLink Heart app display?
The language can be changed within the user’s phone/tablet settings. If the user’s phone/tablet is not set to one of the available languages, the MyCareLink Heart app will display in English.

Visit MCLHeart.com for a list of available languages for the app.

What happens if the app requirements for use are not met (e.g., app closed, Bluetooth OFF, or smartphone/tablet not within range of ICM)?
After 4 days without communication between the app and the ICM or the app and the CareLink network, the patient will receive a notification (or text or email if enabled in app settings) with instructions on how to reconnect.

Will Bluetooth telemetry drain the ICM’s battery?
Yes, but the ICM is designed to work with the app. Like any telemetry, Bluetooth Low Energy telemetry uses the battery of the heart device. However, LINQ II has the same or better longevity than previous Medtronic ICM devices. Longevity gains come from a combination of:
- Redesigned hardware architecture that optimizes current drain
- Bluetooth Low Energy designed for implanted device use

What is MyCareLink Heart mobile app optimization?
This feature determines frequency of communication between the patient’s monitoring option and their LINQ II ICM. This feature is OFF by default for all indications. When enabled, this setting will affect the device’s battery longevity.*

When do I enable this feature?
Consider enabling this feature for MyCareLink Heart mobile app patients only when increased connectivity between the patient app and the device is clinically preferred.*

Will the ICM device interact with a car’s Bluetooth functionality?
Automobiles typically use Bluetooth Classic to communicate with a mobile device to stream audio due to the high bandwidth needs for streaming audio. The BlueSync devices use Bluetooth Low
Energy and are not compatible with Bluetooth Classic. The car will not attempt to establish a connection with the ICM, and the device won’t be able to detect Bluetooth Classic transmissions.

What happens when there is a mobile operating system update?
When smartphone/tablet manufacturers issue OS updates, Medtronic will work diligently to evaluate whether the MyCareLink Heart application (app) has to be updated to remain compatible with the new OS version. However, if the app needs to be updated, there may be a delay between a new OS release and an app update. The patient will receive a notification on their phone/tablet if the app is NOT compatible with a new OS version. In addition, if the patient updates their phone/tablet to an incompatible OS version, an in-app message will be displayed.

What happens if the pairing gets interrupted (e.g., patient steps away from phone/tablet, loss of connectivity, phone/tablet out of battery)?
The patient may receive a message that their app setup was not complete if there is an interruption during the app and ICM pairing process. If that occurs, the patient will need to open the app to restart the process.

How much cellular data does the MyCareLink Heart app use each month?
When used with the LINQ II ICM system, the app consumes 15 MB/month. This is equivalent to about 2 min/day of web surfing.

The app consumes data for three reasons: Remote monitoring, patient viewing data on the app, and diagnostic logging (to ensure app performance).

Cellular data is only used in the absence of a Wi-Fi connection.

What if a patient has a bedside monitor and wants to switch to the MyCareLink Heart app?
If a patient with a BlueSync-enabled device is using a MyCareLink Relay™ Home Communicator and wishes to change to the MyCareLink Heart mobile app: From the Patient Details > Equipment tab, select the Provide New Equipment button and select smartphone/tablet as the new monitor.

If the phone/tablet is stolen, what will someone see in the app?
Just like other apps, if the phone/tablet has Wi-Fi or cellular connection, the data on the app will be available on the phone/tablet for a viewer to see. We recommend protecting the phone/tablet with a PIN code, swipe gesture, or fingerprint. Also, like other apps, the “remote wipe” feature will delete the app.

Will others be able to use the LINQ II device’s Bluetooth signal?
The ICM protects itself from unauthorized access. Communication to devices enabled with BlueSync technology is only accepted from Medtronic apps and monitors. Connection attempts by non-Medtronic devices or apps are rejected by the ICM.

What does “Active” mean?
“Active” means the app is able to communicate with your patient’s heart device and clinic. Your patient’s heart device communicates with the app throughout the day. If your patient’s LINQ II device has data to share, the app will notify your clinic that there is information to view.
This MyCareLink Heart™ Clinician Guide for LINQ II™ insertable cardiac monitoring system is provided for general educational purposes only and should not be considered the exclusive source for this type of information. This training does not replace or supersede approved labeling. The content will be shared with physicians and allied health professionals who seek a deeper understanding of the operation and use of Medtronic products and therapies with the intent of enhancing their knowledge of features and operations described in the clinician manuals. At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation. Changes in a patient's disease and/or medications may alter the efficacy of a device's programmed parameters or related features and results may vary. The device functionality and programming described in this MyCareLink Heart™ Clinician Guide for LINQ II™ insertable cardiac monitoring system are based on Medtronic products and can be referenced in the published device manuals.

If you are located outside the United States, see the device manual for detailed information regarding 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 www.medtronic.eu.

Consult instructions for use at www.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.

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.

Indications, Safety, and Warnings
If you are located in the United States, please refer to the brief statement(s) at right 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 www.medtronic.com.

References
Brief Statement
LINQ II™ Insertable Cardiac Monitor System (ICM) and Remote Monitoring

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.

Possible risks associated with the implant of the LINQ II insertable cardiac monitor include, but are not limited to, infection at the surgical site, device migration, erosion of the device through the skin, and/or sensitivity to the device material. Accessories available for use with LINQ II may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

The LINQ II insertable cardiac monitor is prescribed by your physician and is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this product, results may vary. For further information, please call the Medtronic toll-free number at 1-800-551-5544 (7:00 a.m. to 6:00 p.m., Monday-Friday, Central Time) or see the Medtronic website at www.medtronic.com.

Medtronic CareLink™, MyCareLink™, MyCareLink Smart™ Patient Monitors, MyCareLink Smart™ Application, Medtronic CareLink™ Network, CareLink™ Mobile Application, and Medtronic MyCareLink Connect™ Patient Website

Intended Use

The Medtronic CareLink, MyCareLink, MyCareLink Smart patient monitors, MyCareLink Smart application, CareLink network, and the CareLink mobile application are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices to the Medtronic CareLink network based on physician instructions and as described in the product manual. Medtronic CareAlert™ notifications are not intended to be used as the sole basis for making decisions about patient medical care. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation.

The CareLink mobile application and the MyCareLink Smart mobile application have minimum requirements for the mobile device and operating system. The minimum requirements for the mobile device and operating system are expected to change over time. Periodically, the patient may need to update their mobile device’s operating system, or replace their mobile device to continue to use the app to transfer data to the CareLink network.

The MyCareLink Connect patient site is intended to provide patients, their friends/family, and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink network. The MyCareLink Connect patient website is dependent on certain browser software, and that software is expected to change over time. Patients that are experiencing technical issues with the MyCareLink Connect patient website should contact Medtronic patient services at the number below.

Data availability, alert notifications and patient messages are subject to internet connectivity, access, and service availability. The CareLink and MyCareLink patient monitors and the MyCareLink Smart reader must be on and in range of the device. The MyCareLink Smart reader must also be within range of the patient's mobile device. The CareLink network and mobile device accessibility to the CareLink network may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the internet is required for the CareLink mobile app and the MyCareLink Smart monitoring system and subject to coverage availability. Standard data and text message rates apply. Message frequency depends on account settings and clinic scheduling.

Contraindications

There are no known contraindications.

Warnings and Precautions

The CareLink, MyCareLink, and MyCareLink Smart patient monitors must only be used for interrogating compatible Medtronic implantable devices. While using the CareLink or MyCareLink patient monitor, do not use a cellular phone while the antenna is positioned over the implanted device.

The CareLink and MyCareLink monitors are intended for use within the prescribing country. The MyCareLink Smart patient monitors may be used internationally. Standard mobile device availability and rates apply.

See the device manuals for detailed information regarding the instructions for use, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-929-4043 and/or consult the Medtronic website at medtronic.com.

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