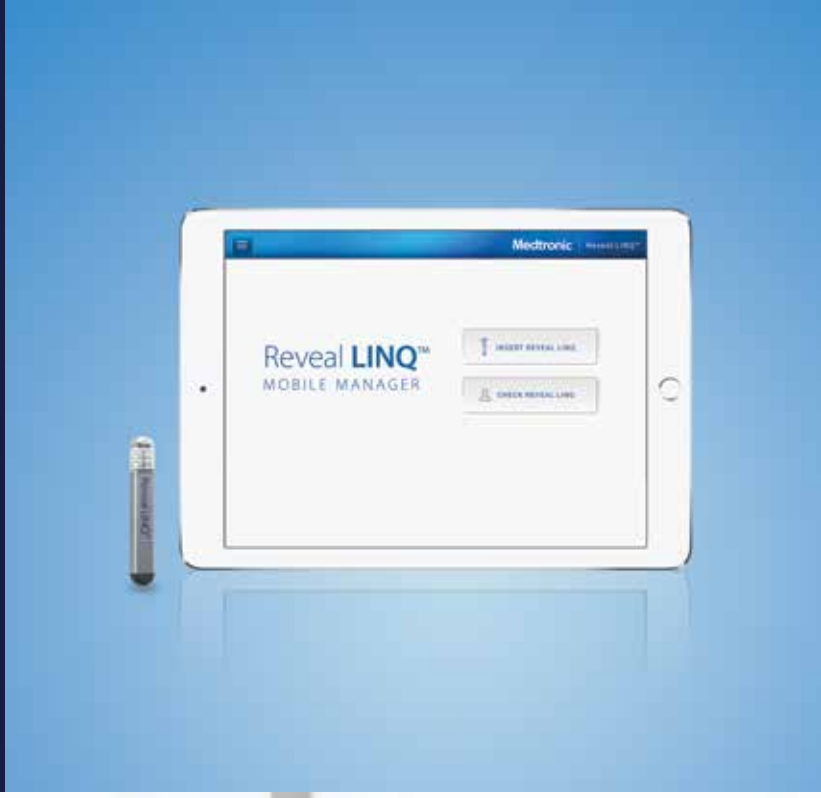
YOUR APP-BASED DEVICE MANAGEMENT SOLUTION

Reveal LINQ™ Mobile Manager
For the Reveal LINQ™
Insertable Cardiac Monitor



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Medtronic

A STREAMLINED SOLUTION TO SIMPLIFY MONITORING

The Reveal LINQ Mobile Manager is an innovative, app-based device management system that makes it possible to manage all of your Reveal LINQ work flow needs — right from your tablet.

Medtronic is dedicated to ongoing enhancements that keep you connected to your patients with simple, secure, and integrated solutions.

THE REVEAL LINQ MOBILE MANAGEMENT SYSTEM

Reveal LINQ ICM

Patient Connector

Mobile Manager Application

CareLink™ Network

App available for download on supported tablets

LINQ Medtronic

Download on the App Store

GET IT ON Google Play

Available on the Apple® App Store and the Google™ Play Store

SIMPLE

An easy-to-use device management system with intuitive functionality, guided animations, and the convenience of mobile, app-based technology.

SECURE

Dedicated protection of patient health data with added user authentication, ability to view pending uploads, and ability to remotely disable data flow if the tablet is lost or stolen.

INTEGRATED

A single work flow solution for managing device activation, registration, CareLink™ pre-enrollment patient education, and follow-up device checks.

The Reveal LINQ Mobile Manager can only be used with the Reveal LINQ ICM and the Medtronic Patient Connector, available from Medtronic. To verify supported tablets, visit LINQMobileManager.com.

Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement 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 763-514-4000 and/or consult the Medtronic website at medtronic.com.

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 **medtronic.com.**

www.medtronic.com/manuals

Consult instructions for use at this website. 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.

The Medtronic MyCareLink patient monitor and the Medtronic CareLink network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink patient monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Reveal LINQ™ Insertable Cardiac Monitor, Reveal LINQ™ Mobile Manager System and Patient Assistant
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.
Reveal LINQ Mobile Manager System: The Reveal LINQ Mobile Manager app is intended for programming and interrogating the Reveal LINQ ICM LNQ11. The Medtronic patient connector is a portable electronic device using low frequency inductive telemetry to communicate with the Reveal LINQ ICM. The patient connector uses Bluetooth® technology to transmit implantable heart device data to the Reveal LINQ Mobile Manager app for further processing. The patient connector is intended to be used by healthcare personnel only in a clinical or hospital environment. **Patient Assistant:** The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ insertable cardiac monitor to initiate recording of cardiac event data in the implanted device memory.
Contraindications: There are no known contraindications for the implant of the Reveal LINQ ICM or for the Reveal LINQ Mobile Manager system. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.
Reveal LINQ Insertable Cardiac Monitor
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.
Reveal LINQ Mobile Manager System: Before inserting the Reveal LINQ ICM, verify that the patient connector and mobile device are fully charged. The patient connector and mobile device may run out of power during the insertion procedure if they are not fully charged. You will not be able to program or interrogate the patient's Reveal LINQ ICM until the patient connector and the mobile device have power.

Only use the patient connector to communicate with the intended implanted device. Do not use the patient connector to communicate with other implanted devices. Using the patient connector to communicate with other implanted devices can interfere with those devices, potentially affecting the other implanted device's functionality or therapy delivery.

Use of wireless devices — The patient connector incorporates radiofrequency (RF) communications components which may affect other devices and equipment in the medical environment. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. RF interference may affect device performance. Electromagnetic Compliance (EMC) testing shows that the patient connector provides reasonable protection against harmful interference and provides EMC immunity in a typical medical installation. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. However, there is no guarantee that interference will not occur in a particular installation. If the patient connector does cause harmful interference to other devices or is negatively impacted by other devices, correct the interference by one or more of the following measures: reorient or relocate the patient connector and other devices; increase the separation between the patient connector and other devices by at least two meters (approximately 6 feet); and/or turn off any interfering equipment.

Radiofrequency (RF) interference — Portable and mobile RF communications equipment can interfere with the operation of the patient connector. There is no guarantee that it will not receive interference or that any particular transmission from this system will be free from interference. To avoid interference, do not use the patient connector and mobile device within 2 m (6 feet) of other wireless communications equipment. Using the patient connector near these devices could interfere with communication between the Reveal LINQ ICM and the patient connector.
Security — Maintain adequate physical security of the patient connector to prevent unauthorized use that could lead to harm to patients. Bluetooth communication in the patient connector is encrypted for security. Medtronic inductive telemetry uses short-range communication to protect patient information. If the patient connector should fail, there is no risk of patient harm.

Environmental precautions — To ensure safe and effective operation, use the device with care to avoid damage to the patient connector from environmental factors that may impair its function. Care is exercised in design and manufacturing to minimize damage to devices under normal use. However, electronic devices are susceptible to many environmental stresses. Specifically, the patient connector may be affected by electrostatic discharge (ESD). In an environment likely to cause ESD, such as a carpeted floor, discharge any charge collected on your body before touching the device.

Patient Assistant
Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

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.

Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network and CareLink™ Mobile Application
Intended Use: The Medtronic MyCareLink patient monitor and CareLink network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. 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. 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. CareLink network availability and mobile device accessibility 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 and subject to coverage availability. Standard text message rates apply.

Contraindications: There are no known contraindications.

Warnings and Precautions: The MyCareLink patient monitor must only be used for interrogating compatible Medtronic implantable devices.

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 1-800-328-2518 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.

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