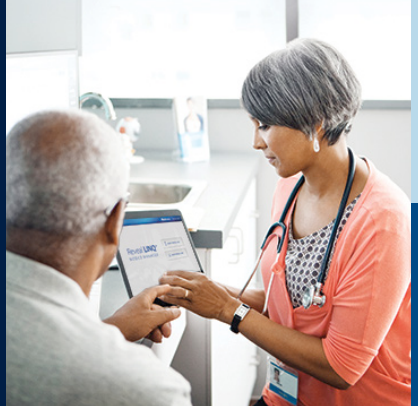
YOUR APP-BASED DEVICE MANAGEMENT SOLUTION

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



Medtronic

Supported Tablets

Supported iPad® Tablets

iPad Pro® 9.7
iPad Pro 12.9 (First Generation)
iPad Pro 10.5
iPad Air® 2
iPad Air

Supported Android™ Devices

Google Pixel C™
Samsung Galaxy® Tab A 10.1
Samsung Galaxy Tab S2 9.7
Samsung Galaxy Tab S 10.5
Samsung Galaxy Note Pro 12.2
Samsung Galaxy Note 10.1 2014

For healthcare professionals only.

Please note that the Reveal LINQ Mobile Manager app, and the use of the Medtronic Patient Connector (Model 24965 or 24967), are *only* supported on tablets that meet both of the following requirements:

- The tablet is listed under "Supported Tablets" above; and
- The tablet meets the "Preferred Configuration" or "Minimum Configuration" specifications on the "Supported Tablet Specifications" chart below.

The app is not supported for download except on the list of Supported Tablets above.

Supported Tablet Specifications

Feature	Preferred Configuration	Minimum Configuration
Device Type	Tablet	Tablet
OS	Any of the following versions (including their respective minor versions) is compatible: ▪ Android Lollipop 5.x ▪ Android Marshmallow 6.x ▪ Android Nougat 7.x ▪ Android Oreo 8.x ▪ iOS 10.x ▪ iOS 11.x	Any of the following versions: ▪ Android Lollipop 5.x ▪ iOS 10.x
Processor	ARM — 2 GHz, if host device is Android	ARM — 1 GHz, if host device is Android
Bus Width	64-bit, if the host device is Apple®	64-bit, if the host device is Apple
Display Resolution[1]	> 1024 × 768	1024 × 768
RAM	2 GB	1 GB
Onboard Memory	≥ 8 GB	8 GB
Weight	< 1.5 lbs	None
Audio	Yes	Yes
Wi-Fi	802.11 b/g/n	802.11 b/g/n
Cellular	Optional	Optional
Bluetooth®	Yes (v4.0 BLE is required, if running on iOS)	Yes (v4.0 BLE is required, if running on iOS)
Density-independent Pixels	960 dp × 720 dp[2]	960 dp × 720 dp[2]

[1] Apple Inc. requires that all applications created for the iPad host device platform satisfies one of the following:
- 2048-by-1536 resolution at 264 pixels per inch (ppi) – For all 9.7" and 7.9" iPad tablets
- 2732-by-2048 resolution at 264 pixels per inch (ppi) – For 12.9" iPad tablets
- 2224-by-1668 resolution at 264 pixels per inch (ppi) – For 10.5" iPad tablets

Any Apple tablet that meets the supported resolutions and specifications above will be able to download the application from the app store.

[2] This density-independent pixel specification corresponds to the "xlargeScreens" attribute in the Android manifest.

For simplicity, the Android platform groups all actual screen sizes into four generalized sizes: small, normal, large, and extra-large. The selection for this is made in the Android Manifest of the application before it is packaged for distribution. Typically extra-large (xlarge) are 8" and above, but for some tablets in the 7-8" range, the category they fall into isn't always clear. This is because the size is not based on physical inches but on density-independent pixels (dp). For this application, the category in the Android Manifest will be xlarge (at least 960 dp x 720 dp). Any tablet that is 8" but not classified as xlarge by the Android Application Store will not be able to download the application from the app store.

Brief Statement
Reveal LINQ™ Insertable Cardiac Monitor and Reveal LINQ™ Mobile Manager System

Indications
Reveal LINQ Insertable Cardiac Monitor
The Reveal LINQ insertable cardiac monitor 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

This device has not been specifically tested 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.

Contraindications
There are no known contraindications for the implant of the Reveal LINQ insertable cardiac monitor 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.

Warnings/Precautions
Reveal LINQ Insertable Cardiac Monitor
Patients with the Reveal LINQ insertable cardiac monitor 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 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.

Potential Complications
Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manuals for detailed information regarding the instructions for use, intended use, 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 this device to sale by or on the order of a physician.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic