REMOTE PROGRAMMING OPTIONS

We understand many healthcare systems are looking for options to limit vendor interactions and patient exposure. Medtronic is committed to meeting our service excellence standards while protecting the health and welfare of our customers, our employees, and the patients who rely on our products.

1 CareLink™ 2090 with RemoteControl

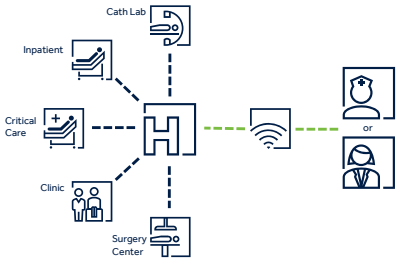
Remote Programmer Control

CareLink 2090 RemoteControl can provide remote testing and programming support of the device in the hospital, MRI center, and clinic.

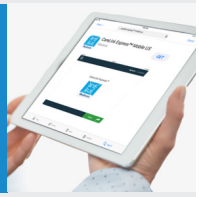
A local Medtronic device specialist supports a real-time, full programming session from remote location, reducing personal interactions and the need for personal protective equipment.

Remote device management from any patient care setting within the hospital:

- Critical care
- Inpatient
- Cath lab
- Surgery center
- Patient clinic



2 CareLink Express™ Mobile



Remote Interrogation and View

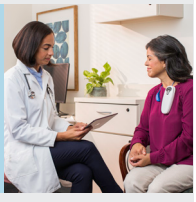
The CareLink Express Mobile system can remotely provide vital Medtronic cardiac device interrogation data quickly, while reducing the risk of exposure for both patients and your staff.

Utilizing CareLink Express Mobile as the first-line solution when a device interrogation is necessary can better determine the care pathway for cardiac device patients and minimize the time a patient and staff must wait.

Medtronic remote support tools allow you to quickly reach a Medtronic device specialist to program remotely, review a device interrogation, or program from an extended distance.

Innovation doesn't end at implant.

3 CareLink SmartSync™ Device Manager and Reveal LINQ™ Mobile Manager



Distance Programming and Testing

Distance Use: CareLink SmartSync Device Manager and Reveal LINQ Mobile Manager can be used to program and test from a distance[1]:

- iPad to Patient Connector: 32 feet
- Patient Connector to Bluetooth®-enabled cardiac device: 6.5 feet

iPad WebEx Screen Share: Troubleshoot in real time with a Medtronic representative from a remote location. WebEx screen sharing is available via your tablet to troubleshoot on the CareLink SmartSync Device Manager and Reveal LINQ Mobile Manager apps.

Medtronic

Reference

[1] CareLink SmartSync™ technical manual.

Brief Statements

CareLink Express™ Mobile System, including the CareLink Express Apps (Model 31301 and 31302) and Patient Connector

Indications (or intended use): The CareLink Express app is intended for interrogating Medtronic cardiac devices and uploading the data to the CareLink™ network. The CareLink Express app is installed on a compatible mobile device with internet access. The CareLink Express app communicates with the Medtronic Patient Connector and sends implanted cardiac device data to the Medtronic propriety CareLink network for clinical review. The CareLink Express app should be used by healthcare personnel only in a clinical or hospital environment.

Contraindications: There are no known contraindications for the CareLink Express app or the Patient Connector.

Warnings and precautions: Only use the Patient Connector to communicate with the intended implanted device.

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 2 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. **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: *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 system to sale by or on the order of a physician.

CareLink™ 2090 Programmer

The Medtronic CareLink programmer system is comprised of prescription devices indicated for use in the interrogation and programming of implantable medical devices. Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient's condition and pacing system used. The Medtronic CareLink programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron.

Using RemoteView™ for remote control: This section provides general information for using RemoteView for remote control of the programmer.

Remote control safety: The remote viewer cannot respond to emergency medical conditions that require use of equipment outside of the programmer; neither can the remote viewer provide physical assistance with the programmer. The programmer user must be qualified to respond to emergency medical conditions that may occur during routine use of the programmer. The programmer user also must have the training and ability to perceive patient conditions and react accordingly. The patient care facility has the responsibility to provide appropriate personnel with the patient.

The remote control functionality should not be used with patients for the following situations:

▪ Underlying rhythm test with pacer-dependent patients ▪ Arrhythmia inductions and EP studies
▪ Cardioversion

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential 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 Model 24970A CareLink SmartSync™ Device Manager Base and Associated Apps

Indications: The base is intended to be used as part of the CareLink SmartSync Device Manager system. Clinicians use the base to analyze the electrical performance of cardiac leads during device implant or invasive troubleshooting. Clinicians use the base's ECG connections along with the app display to view, measure, and record live cardiac waveforms. The base is intended to be used by healthcare professionals only in operating environments under direct medical supervision.

Contraindications: The base is not intended for use as an external pulse generator (EPG) outside of the implant procedure. In addition, the patient's age and medical condition may dictate the lead analyses appropriate for the patient.

See the CareLink SmartSync 24970A and Technical Manual and 24967 Patient Connector Technical Manual before using the CareLink SmartSync Device Manager for detailed information regarding the procedure, indications or intended uses, 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.

Medtronic Model 24967 Patient Connector and Associated Apps

Indications: The patient connector is intended to be used with Medtronic apps to interrogate, analyze, and/or program implantable Medtronic devices. The patient connector uses Bluetooth® technology to transmit that data to a Medtronic app for further processing. The patient connector is intended to be used by healthcare personnel only in a clinical or hospital environment.

Precautions: 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.

See the 24967 Patient Connector Technical Manual before using the CareLink SmartSync Device Manager for detailed information regarding the procedure, indications or intended uses, 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.

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

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.

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.

Warnings/Precautions

Reveal LINQ Insertable Cardiac Monitor: 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. 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 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.

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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic