



CareLink SmartSync™ MRI Access Application Help

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1 Introduction

1.1 Description

The CareLink SmartSync MRI Access application (called the “MRI app” or “the app” from now on) is used by a healthcare professional to prepare a compatible Medtronic implanted device for an MRI scan by turning SureScan mode to ON before the patient receives an MRI scan. After the MRI scan is complete, the MRI app is used to turn SureScan mode to OFF and return the implanted device to pre-scan settings.

Before the MRI app is used to turn SureScan mode to ON, the patient must be screened to confirm that the patient has a single compatible MR-conditional Medtronic implanted device that is part of a complete MRI SureScan system. For devices that use leads, the leads are also considered part of the MRI SureScan system.

1.2 About the MRI Access application

The CareLink SmartSync MRI Access application is part of a system that includes the following components:

- Model 24967 patient connector (referred to as the patient connector)
- A compatible tablet
- CareLink SmartSync MRI Access application (referred to as “MRI app” or “the app”)

The MRI app includes the following features:

- Bluetooth® connectivity to communicate with the patient connector¹
- Tablet connectivity tools for sharing and printing reports
- Ability to export data
- Ability to update the MRI app software using an Internet connection
- Ability to communicate with implanted devices

Table 1. MRI app software component model numbers

Software model number	Software component name
M01A01	CareLink SmartSync Platform Application
M01A02	CareLink SmartSync Common Application
D02U001	CareLink SmartSync MRI Access Host Application
D00U003	CareLink SmartSync Azure™ Astra™ Application
D00U004	CareLink SmartSync Percepta™ Serena™ Solara™ Application
D00U005	CareLink SmartSync Cobalt™ Crome™ Application
D00U006	CareLink SmartSync Micra™ VR Application
D00U007	CareLink SmartSync Micra™ AV Application
D00U008	CareLink SmartSync Viva™ Consulta™ Syncra™ Advisa™ Ensura™ Application
D00U009	CareLink SmartSync Claria™ Amplia™ Compia™ Application
D00U010	CareLink SmartSync Evera MRI™ Application
D00U011	CareLink SmartSync Visia AF™ Application
D00U022	CareLink SmartSync Micra™ AV2 Application CareLink SmartSync Micra™ VR2 Application

1.3 Patient session workflow steps

The MRI Access app guides a clinician through the steps to turn SureScan mode to ON in a patient’s device in preparation for an MRI scan, and to turn SureScan mode to OFF after the MRI scan. The following list is an overview of the patient session workflow.

1. The clinician confirms the patient’s system is MR conditional.
2. The clinician initiates interrogation of the implanted device.
3. The MRI app interrogates the implanted device and performs device and lead checks.
4. The clinician ensures that the patient is continuously monitored.
5. The clinician requests that SureScan mode be turned to ON.
6. The MRI app turns SureScan mode to ON and applies the pre-scan algorithm to program appropriate pacing parameters.
7. The clinician confirms that the patient is comfortable and can continue with the scan.
8. The clinician removes the patient connector.

¹ The Bluetooth® word mark is a registered trademark of Bluetooth SIG, Inc. and any use of this mark by Medtronic is under license.

9. The clinician conducts the MRI scan.
10. The clinician re-establishes the connection between the implanted device and the app.
11. The clinician requests SureScan mode be turned to OFF.
12. The MRI app turns SureScan mode to OFF and applies the post-scan algorithm to program appropriate pacing parameters.

1.4 MRI SureScan labeling for implanted devices

Before you scan a patient, you must ensure full compliance with labeling in the MRI technical manual for the implanted device.

The MRI app help supplements the MRI technical manual by providing information that pertains to workflow steps, device and lead checks that are performed, and algorithms that are applied when using the MRI app to program SureScan parameters. The MRI app help should be used along with the MRI technical manual.

Refer to the MRI technical manual for the implanted device's MRI SureScan labeling for the following topics:

- MRI conditions for use.
- MRI warnings, precautions, and potential adverse events.
- Radiology requirements and considerations.
- Cardiology requirements, and in particular screening to ensure the implanted system meets the following requirements:
 - The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
 - The device is implanted in the left or the right pectoral region for devices other than Micra.
 - The device is implanted in the right ventricle for Micra devices.
- Pre-MRI scan operations, and in particular, screening the patient to ensure that the patient does not have additional implanted cardiac devices, or if other devices are present, that the other devices are MR conditional and that scanning occurs in compliance with the device labeling.

The MRI app help provides information about device and lead checks and algorithms that are performed by the app to automate the programming of SureScan parameters. Refer to the MRI app help for labeling related to the following topics:

- Warnings and precautions related to the use of the app and its components.
- Intended users and workflow for use of the MRI app.
- Instructions for turning SureScan mode to ON and OFF using the app.
- Additional device and lead checks that are performed by the app.
- Descriptions of algorithms the app uses to program device parameters when turning SureScan mode to ON and OFF.
- Patient monitoring requirements when using the app to turn SureScan mode to ON.

1.5 Device and lead checks performed by the MRI app

The MRI technical manual for the implanted device outlines a number of required device and lead checks when using the CareLink 2090 programmer or the CareLink SmartSync Device Manager for enabling SureScan mode in an MR Conditional cardiac device. The CareLink SmartSync MRI Access app will automatically perform the necessary device and lead integrity checks when the device is being programmed using the app. These may include verifying the device status, the electrical integrity of implanted lead wires connected to the device, as well as relevant implanted device settings. Pre-scan and post-scan tests of the right ventricular (RV) lead pacing capture threshold (PCT) are not required when using the MRI app to program an implanted device into and out of MRI SureScan mode.

The MRI app also performs the following additional device checks before MRI SureScan is turned to ON.

Active VT/VF event – The app checks whether the implanted device detects an active ventricular tachycardia or ventricular fibrillation event. If an active VT/VF event is detected then the app does not allow SureScan mode to be turned ON.

Device reset – The app checks whether the implanted device has undergone a full device reset. If the implanted device has undergone full reset, then the app does not allow SureScan mode to be turned ON. For more information, see *Section 3.11, Device reset detected*, page 18.

1.6 MRI app algorithms

1.6.1 About MRI app algorithms

The MRI app algorithms are automatic and no interaction from the clinician is necessary.

1.6.2 Pre-scan algorithm

The pre-scan algorithm automatically determines and programs the appropriate device parameters required to turn SureScan mode to ON. The pacing mode and rate will automatically be determined to provide the necessary pacing support for the patient. The pacing mode and rate that the app programs is included in the device report in the app.

1.6.3 Post-scan algorithm

The post-scan algorithm automatically evaluates and programs the appropriate implanted device parameters to return the implanted device to the pre-scan settings. In some cases, if it is determined appropriate for the implanted device, the pacing output of the implanted device may be increased to ensure proper pacing support is maintained after the MRI scan is complete and MRI SureScan mode is disabled. Any changes to the patient's pacing output are captured in the final device report. The pacing output adjustment is automatic and will continue to be monitored and adjusted by the patient's implanted device as needed to ensure pacing support is maintained.

1.7 Intended use of the app

1.7.1 Intended use

The intended purpose is to interrogate, program, or execute tests on a Medtronic cardiac device.

1.7.2 Intended users

The CareLink SmartSync MRI Access app is intended for use by healthcare professionals or Medtronic representatives in a clinical or hospital environment. Healthcare professionals include clinicians or MR technologists within a radiology staff who are not trained on cardiac implantable electronic devices (CIEDs).

Note: The presence of someone trained on CIEDs or other cardiology personnel is not required for use of the MRI app.

1.7.3 Intended patient population

The CareLink SmartSync MRI Access app is intended for use with patients that have a Medtronic implanted cardiac device that is compatible with the app.

1.7.4 Expected clinical benefits

The clinical benefit of the CareLink SmartSync MRI Access app is to prepare a Medtronic implanted device to safely undergo an MRI scan.

1.7.5 Indications for use

For information about the indications for the implanted device, refer to the manual for the implanted device.

1.7.6 Contraindications

There are no known contraindications for the use of the MRI app.

1.8 Warnings and precautions

These warnings and precautions apply when using the app in combination with the other system components.

Equipment compatibility – The app must be used only with compatible Medtronic implantable devices. If the app is used with other implantable devices, direct stimulation through energy coupling may occur. The app is not compatible with programmable devices of other manufacturers.

Importance of instructions for use – Before using the MRI app, take the following actions:

- Read the instructions for use for the MRI app.
- Read the instructions for use for the patient connector.
- Read the MRI technical manual for the patient's implanted device. The MRI app turns on or turns off MRI SureScan mode. When MRI SureScan mode is turned on or turned off, the patient's implanted device must meet all of the labeling conditions defined in the MRI technical manual.
- To ensure that the implanted device is MR Conditional when part of a complete SureScan system, refer to <http://www.mrisurescan.com>.

Magnetic interference – Some tablets may be sensitive to magnetic interference. Keep strong magnetic sources (such as magnetic programming heads, patient magnets like the Model 9466 Tachy Patient Magnet, or other strong magnetic field generators) away from direct contact with the tablet when working with the app.

Note that the Model 24967 patient connector does not include a magnet and is not a source of magnetic interference.

Note: MRI magnetic fields that are present in Zone 3, as defined by the American College of Radiology, are not expected to interfere with the operation of the tablet.

Magnetic resonance (MR) unsafe – The tablet used with the MRI app and the patient connector are MR Unsafe. Do not bring any components of the MRI app system into Zone 4 (magnet room), as defined by the American College of Radiology.

Patient screening – Before using the app with a patient, follow your patient screening process to determine the MR-conditionality of the patient's implanted devices and whether the patient has a complete SureScan system. A complete SureScan system is required for use in the MR environment.

The MRI app does not support cases where the patient has multiple implanted devices that are detected by the app. Follow your patient screening process to determine if the patient has multiple implanted devices. When the app detects multiple implanted cardiac devices, it displays the Unsupported Case message and prevents use of the app.

For more information, see *Section 3.12*.

Preparation for patient rescue – In case you need to quickly reconnect to the implanted device to turn SureScan mode to OFF, the MRI app and patient connector should be available nearby whenever the MRI app has been used to turn SureScan mode to ON.

In the event that patient rescue is required, an external defibrillator must be immediately available.

MRI SureScan mode – Do not scan a patient without first turning MRI SureScan mode to ON. Scanning the patient without turning the MRI SureScan mode to ON may result in patient harm or damage to the SureScan system.

- Do not turn MRI SureScan mode to ON until the patient is ready to receive the MRI scan. While MRI SureScan mode is turned to ON, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia.
- If the implanted device is turned to an asynchronous pacing mode, arrhythmia risk may be increased.
- For CRT (Cardiac Resynchronization Therapy) implanted devices, CRT support may be suspended while MRI SureScan mode is turned to ON. Patients may experience dizziness or shortness of breath without CRT support.

Turn MRI SureScan mode to OFF as soon as the scan is complete. Do not leave the device in MRI SureScan mode after the scan is complete.

Tablet and app interaction – Due to the dynamic nature of the tablet environment, operating system events such as notifications, alarms, and messaging can take priority and therefore move the app to the background. Tapping, pressing buttons, and using gestures on the tablet can also result in moving the app to the background or closing the app. For example, the app moves to the background if you lock the tablet.

When the app moves to the background or closes, the app pauses communication or loses communication with the implanted device.

When you restore the app from the background, the app attempts to re-establish communication with the implanted device and displays the system status. If the app was closed, you must restart the app and ensure the patient connector is connected to the tablet.

Tablet language settings – Tablets allow you to change the language used to display information. If you change the language used on your tablet, the tablet automatically closes any apps that are currently running (including the MRI app). You may need to reopen the MRI app after changing the tablet language setting.

Pairing the patient connector – Verify that the app is paired to the correct patient connector. Pairing to a different patient connector can result in confusion during a patient session or the delay of a procedure.

Modification of equipment – Do not modify any hardware or software component of the MRI app system. Modifications may reduce system effectiveness and impact user or patient safety. Modifying any component without the approval of Medtronic could void the user's authority to operate the equipment.

Radiofrequency (RF) interference – Portable and mobile RF communications equipment can interfere with the operation of components of the MRI app system. There is no guarantee that the MRI app system will not receive interference or that any particular transmission from this system will be free from interference.

Use of wireless devices – The MRI app system incorporates radiofrequency (RF) communications components that 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 compatibility (EMC) compliance testing shows that the components of the MRI app system provide reasonable protection against harmful interference and provide EMC immunity in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

If any component does cause harmful interference to other devices or is negatively impacted by other devices or by the environment, correct the interference by taking one or more of the following measures:

- Reorient or relocate the component and other devices.
- Increase the separation between the component and other devices by at least 2 m (approximately 6 feet).
- Turn off any interfering equipment.

1.9 Download or order the instructions for use

To view, download, or print a PDF version of this app help, go to www.medtronic.com/manuals or contact a Medtronic representative.

The PDF version of this app help can be viewed using a current version of any major internet browser. For best results, use Adobe™* Acrobat™* Reader software with the browser.

Paper copies of this app help are available to customers free of charge. They should arrive in 3 to 7 days. To order, go to www.medtronic.com/manuals or contact a Medtronic representative.

1.10 Notice of Privacy Practices

To read the Medtronic Notice of Privacy Practices, go to www.medtronic.com/smartsync/us-privacy.

1.11 Reporting errors and serious incidents

If a serious incident related to the app occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

If you find information in this app help that is incorrect, contact Medtronic.

2 Important information before using the MRI app

2.1 Screening patients

The MRI app does not screen patients or replace your patient screening process. A complete SureScan system is required for use in the MR environment. To verify that components are part of a SureScan system, visit <http://www.mrisurescan.com>. Any other combination may result in a hazard to the patient during an MRI scan. Verify that requirements in the **MRI Conditions for Use** and **MRI Warnings and Precautions** in the MRI technical manual for the implanted device are followed.

Notes:

- Restrictions may exist for implant position, other nearby implants, accessory components of the system such as lead adaptors or extenders, and abandoned implanted leads. The restrictions should be verified as part of the patient screening process.
- Some electrical device and lead checks indicated in the MRI technical manual are handled automatically when using the MRI app.

Warning: Do not scan a patient without first turning MRI SureScan mode to ON. Scanning the patient without turning MRI SureScan mode to ON may result in patient harm or damage to the SureScan system.

Cautions:

- A complete SureScan system is required for use in the MR environment. Before using this app with a patient, follow your patient screening process to determine the MR-conditionality of the patient's implanted devices and whether the patient has a complete SureScan system.
- The MRI app does not support cases where the patient has multiple implanted devices that are detected by the app. Follow your patient screening process to determine if the patient has multiple implanted devices. When the app detects multiple implanted cardiac devices, it displays the Unsupported Case message and prevents use of the app.

Note: MRI SureScan mode cannot be turned to ON if the device is recommended for replacement.

For more information, see *Section 3.12*.

2.2 Patient monitoring requirements

Proper patient monitoring is required while MRI SureScan mode is ON.

- Maintain continuous visual and verbal contact with the patient
- Continuously monitor the patient's heart rate, using instrumentation such as pulse oximetry (plethysmography) or electrocardiography

Note: If the patient's hemodynamic function is compromised or experiences a cardiac arrhythmia during the MRI scan, discontinue the scan, remove the patient from the magnet room, turn MRI SureScan mode to OFF, and take the proper measures to restore the patient's hemodynamic function.

All devices – The following warnings and cautions are applicable to all implanted devices.

Warning: Arrhythmia risk may be increased for a patient who is programmed to an asynchronous pacing mode while the MRI SureScan mode is ON. Therefore, proper patient monitoring is required during the entire time when the MRI SureScan mode is ON.

Cautions:

- In case you need to quickly reconnect to the implanted device to turn SureScan mode to OFF, the MRI app and patient connector must be available nearby whenever the MRI app has been used to turn SureScan mode to ON.
- **Preparation for patient rescue** — In the event that patient rescue is required, an external defibrillator must be immediately available.

Implantable cardioverter defibrillator (ICD) devices – The following warning is applicable to all ICDs.

Warning: While the MRI SureScan mode is ON, tachyarrhythmia detection and therapy are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia

Transcatheter pacing devices – The following note is applicable to all Micra devices.

Note: Monitoring is required whether the device is active or whether the device is programmed to Device Off.

Cardiac resynchronization therapy defibrillator (CRT-D), and cardiac resynchronization therapy pacemaker (CRT-P) devices – The following warning is applicable to all CRT-D and CRT-P devices.

Warning: While the MRI SureScan mode is ON, many CRT patients will not receive CRT support. This lack of CRT support might cause dizziness or shortness of breath. Refer to the MRI technical manual for the implanted device for additional information.

2.3 Patient comfort

The MRI app will adjust the patient's device pacing settings when appropriate to ensure pacing support is maintained during the MRI scan. Some patients may perceive the change to their device settings when the MRI SureScan mode is turned to ON. Ensure the patient is comfortable after the MRI SureScan mode has been turned to ON. If the patient experiences any prolonged discomfort from the change of device settings, the MRI SureScan mode should be turned to OFF, which resets all settings to the pre-SureScan mode states. Refer the patient to his or her cardiologist in the event of prolonged patient discomfort. The MRI SureScan parameters that were enabled on the implanted device are available for review in the MRI SureScan Parameters report and can be provided to cardiology.

Patient discomfort may be related to the following conditions:

Accelerated heart rate – When appropriate, the MRI app will program a faster pacing rate when turning the MRI SureScan mode to ON in order to provide the necessary pacing support in a safe manner. This can result in a faster heart rate that may be perceptible by the patient.

Pacing sensation – Some patients may rarely experience pacing during normal waking hours. If determined to be appropriate, the MRI app may enable cardiac pacing to ensure proper pacing support is maintained during the MRI scan. In rare cases, patients may feel their cardiac pacing. If any prolonged patient discomfort occurs, turning the MRI SureScan mode to OFF will restore the original device settings.

Dizziness or shortness of breath – For patients with Cardiac Resynchronization Therapy (CRT) devices, while the MRI SureScan mode is programmed to ON, many will not receive CRT support. This lack of CRT support might cause dizziness or shortness of breath. This form of patient discomfort may not occur immediately. Therefore, proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to ON. Turning the MRI SureScan mode to OFF will restore CRT Therapy.

Diaphragmatic stimulation – Diaphragmatic stimulation is the stimulation of the patient's diaphragm, which can result in a hiccup like sensation. In rare circumstances, this could occur due to elevated pacing output settings meant to ensure proper pacing support is maintained during the MRI scan. If this occurs, turning the MRI SureScan mode to OFF will revert the device back to its normal settings and diaphragmatic stimulation should terminate.

Caution: Do not scan patients who are experiencing diaphragmatic stimulation. If the patient is experiencing diaphragmatic stimulation, it may be difficult for the patient to remain still in order to obtain a quality MRI scan.

2.4 Radiology requirements for transvenous cardiac devices

See the **Radiology requirements for transvenous cardiac devices** table for the radiology requirements for the implantable devices that are listed in the **Applicable transvenous cardiac device models** table.

If the patient's product model is not listed in the **Applicable transvenous cardiac device models** table, then consult the MRI technical manual for the implanted device for the appropriate radiology requirements.

Transvenous pacemaker, ICD, and CRT – A pacemaker, ICD, or CRT device with one or more leads connected to the heart through the venous system.

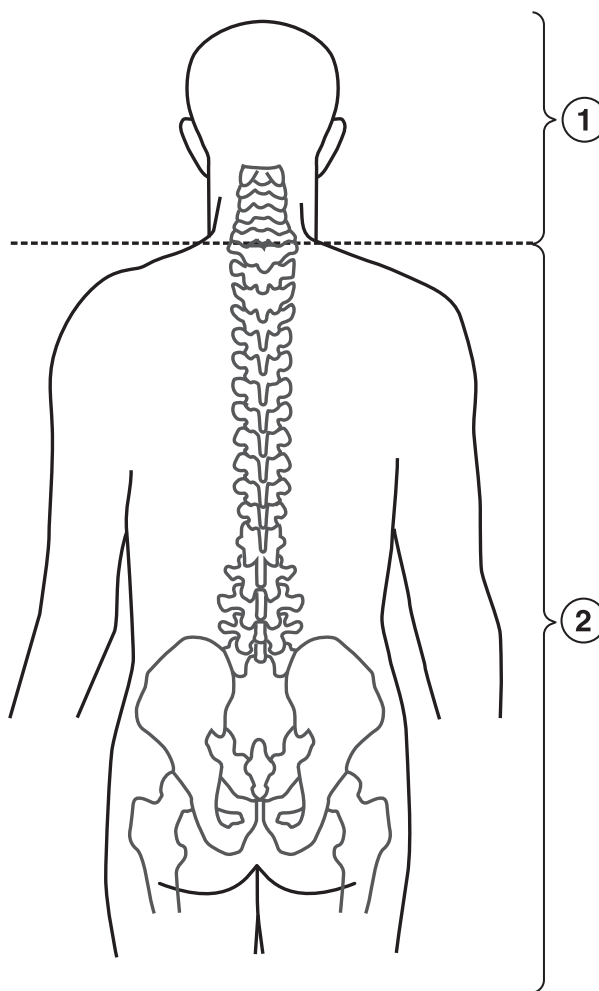
The safety and reliability of the SureScan system have been evaluated and approved for scanning patients using MRI equipment that has the following operating characteristics:

Table 2. Radiology requirements for transvenous cardiac devices

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	<ul style="list-style-type: none">• Static magnetic field of one of the following strengths:<ul style="list-style-type: none">– 1.5 T– 3 T• Maximum spatial gradient of ≤ 20 T/m (2000 gauss/cm)• Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s

Table 2. Radiology requirements for transvenous cardiac devices (continued)

Scanner operation	1.5T – MRI radio frequency (RF) power – Normal Operating Mode <ul style="list-style-type: none"> The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg. The head SAR must be ≤ 3.2 W/kg.
	3T – MRI radio frequency (RF) power – First Level Controlled Operating Mode or Normal Operating Mode: <ul style="list-style-type: none"> B_{1+RMS} must be ≤ 2.8 μT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra.

Figure 1. 3T scan location requirements

1 No B_{1+RMS} restrictions

2 B_{1+RMS} not to exceed 2.8 μ T

Note: Specific models may not be available in your geography.

Table 3. Applicable transvenous cardiac device models

Product name	Product model
Advisa DR MRI SureScan	A2DR01
	A3DR01
Advisa SR MRI SureScan	A3SR01

Table 3. Applicable transvenous cardiac device models (continued)

Amplia MRI CRT-D SureScan	DTMB1D1
	DTMB1D4
	DTMB2D1
	DTMB2D4
Amplia MRI Quad CRT-D SureScan	DTMB1Q1
	DTMB1QQ
	DTMB2Q1
	DTMB2QQ
Astra S DR MRI SureScan	X3DR01
Astra S SR MRI SureScan	X3SR01
Astra XT DR MRI SureScan	X1DR01
	X2DR01
Astra XT SR MRI SureScan	X1SR01
	X2SR01
Azure S DR MRI SureScan	W3DR01
Azure S SR MRI SureScan	W3SR01
Azure XT DR MRI SureScan	W1DR01
	W2DR01
Azure XT SR MRI SureScan	W1SR01
	W2SR01
Claria MRI CRT-D SureScan	DTMA1D1
	DTMA1D4
	DTMA2D1
	DTMA2D4
Claria MRI Quad CRT-D SureScan	DTMA1Q1
	DTMA1QQ
	DTMA2Q1
	DTMA2QQ
Cobalt DR MRI SureScan	DDPB3D1
	DDPB3D4
Cobalt HF CRT-D MRI SureScan	DTPB2D1
	DTPB2D4
Cobalt HF Quad CRT-D MRI SureScan	DTPB2Q1
	DTPB2QQ
Cobalt VR MRI SureScan	DVPB3D1
	DVPB3D4
Cobalt XT DR MRI SureScan	DDPA2D1
	DDPA2D4
Cobalt XT HF CRT-D MRI SureScan	DTPA2D1
	DTPA2D4
Cobalt XT HF Quad CRT-D MRI SureScan	DTPA2Q1
	DTPA2QQ
Cobalt XT VR MRI SureScan	DVPA2D1
	DVPA2D4
Compia MRI CRT-D SureScan	DTMC1D1
	DTMC1D4
	DTMC2D1
	DTMC2D4
Compia MRI Quad CRT-D SureScan	DTMC1QQ
	DTMC2QQ

Table 3. Applicable transvenous cardiac device models (continued)

Crome DR MRI SureScan	DDPC3D1
	DDPC3D4
Crome HF CRT-D MRI SureScan	DTPC2D1
	DTPC2D4
Crome HF Quad CRT-D MRI SureScan	DTPC2Q1
	DTPC2QQ
Crome VR MRI SureScan	DVPC3D1
	DVPC3D4
Ensura MRI SureScan	EN1DR01
Ensura SR MRI SureScan	EN1SR01
Evera MRI S DR SureScan	DDMC3D1
	DDMC3D4
Evera MRI S VR SureScan	DVMC3D1
	DVMC3D4
Evera MRI XT DR SureScan	DDMB1D1
	DDMB1D4
	DDMB2D1
	DDMB2D4
Evera MRI XT VR SureScan	DVMB1D1
	DVMB1D4
	DVMB2D1
	DVMB2D4
Mirro MRI DR SureScan	DDME3D1
	DDME3D4
Mirro VR MRI SureScan	DVME3D1
	DVME3D4
Percepta CRT-P MRI SureScan	W1TR01
	W1TR04
Percepta Quad CRT-P MRI SureScan	W4TR01
	W4TR04
Primo MRI DR SureScan	DDMD3D1
	DDMD3D4
Primo MRI VR SureScan	DVMD3D1
	DVMD3D4
Serena CRT-P MRI SureScan	W1TR02
	W1TR05
Serena Quad CRT-P MRI SureScan	W4TR02
	W4TR05
Solara CRT-P MRI SureScan	W1TR03
	W1TR06
Solara Quad CRT-P MRI SureScan	W4TR03
	W4TR06
Visia AF MRI VR SureScan	DVFB1D1
	DVFB1D4
Visia AF MRI XT VR SureScan	DVFB2D1
	DVFB2D4
Visia AF MRI S VR SureScan	DVFC3D1
	DVFC3D4

2.5 Radiology requirements for Micra AV and VR cardiac devices

See the **Radiology requirements for Micra AV and VR cardiac devices** table for the radiology requirements for the implantable devices that are listed in the **Applicable models** table.

If the patient's product model is not listed in the **Applicable models** table, then consult the MRI labeling for the patient's product model for the appropriate radiology requirements.

Transcatheter pacemaker – A pacemaker with no leads that is implanted into the right ventricle of the heart with a delivery catheter that accesses the chamber through the femoral vein.

The safety and reliability of the device have been evaluated for scanning patients, using MRI equipment that has the following operating characteristics:

Table 4. Radiology requirements for Micra AV and VR cardiac devices

Scanner type	Horizontal field, cylindrical bore, clinical system
Scanner characteristics	<ul style="list-style-type: none">Hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5 T or 3.0 T and a maximum spatial gradient of ≤ 25 T/m (2500 gauss/cm)Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s)
Scanner operation	MRI radio frequency (RF) power. The whole body averaged specific absorption rate (SAR) must be ≤ 4.0 W per kilogram (W/kg). The head SAR must be ≤ 3.2 W/kg.

Table 5. Applicable models

Product name	Product model
Micra AV	MC1AVR1
Micra VR	MC1VR01
	MC1VR01US

2.6 Radiology requirements for Micra AV2 and VR2 cardiac devices (MC2AVR1 and MC2VR01)

See **Radiology requirements for Micra AV2 and VR2 cardiac devices** for the radiology requirements for the implantable devices that are listed in **Applicable models**.

If the patient's product model is not listed in **Applicable models**, then consult the MRI labeling for the patient's product model for the appropriate radiology requirements.

Transcatheter pacemaker – A pacemaker with no leads that is implanted into the right ventricle of the heart with a delivery catheter that accesses the chamber through the femoral vein.

The safety and reliability of the device have been evaluated for scanning patients, using MRI equipment that has the following operating characteristics:

Table 6. Radiology requirements for Micra AV2 and VR2 cardiac devices

Scanner type	Either: <ul style="list-style-type: none">Horizontal field, cylindrical boreTransverse field – Perpendicular to Patient (AP or LR)
Scanner characteristics	<ul style="list-style-type: none">Hydrogen proton magnetic resonance imaging equipment with a static magnetic field of ≤ 3.0 T and a maximum spatial gradient of ≤ 25 T/m (2500 gauss/cm)Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s)
Scanner operation	MRI radio frequency (RF) power. The whole body averaged specific absorption rate (SAR) must be ≤ 4.0 W per kilogram (W/kg). The head SAR must be ≤ 3.2 W/kg.

Table 7. Applicable models

Product name	Product model
Micra AV2	MC2AVR1
Micra VR2	MC2VR01

3 Using the MRI app

3.1 Start a patient session

Before you start a patient session, the app must be connected to a paired patient connector.

For information on pairing a patient connector, see *Section 4.2*.

Caution: Before beginning a patient session, ensure the batteries in the patient connector and the tablet are charged or that they are connected to the power mains.

When the app is connected to a patient connector, the first page you will see when you open the app is the **Welcome! Before you begin:** screen.

To begin a patient session, select the check box after confirming that the patient has been screened properly and will be monitored, then tap **CONTINUE**.

3.2 Turn SureScan mode to ON

To turn SureScan mode to ON, begin a new patient session and follow the steps presented in the app.

When you initiate a new patient session, the app interrogates and performs checks on the implanted device and lead or leads. If the implanted device and lead or leads checks pass, the app directs you to a page that identifies the model of the implanted device. Tap **TURN SureScan ON**.

On the **SureScan is ON** screen, ensure that the patient is comfortable. If the patient is experiencing prolonged discomfort, tap **TURN SureScan OFF**. For more information about patient comfort requirements, see *Section 2.3, Patient comfort, page 10*.

If the patient is comfortable, tap **CONTINUE** and remove the patient connector from the patient.

3.3 Conduct the MRI scan

When SureScan mode is ON, the patient is ready to receive an MRI scan. The patient can be moved to Zone 4 (magnet room), as defined by the American College of Radiology, and receive an MRI scan.

Once the MRI scan is complete, remove the patient from Zone 4 (magnet room), where you may proceed to reconnect to the patient's implanted device to turn MRI SureScan mode to OFF.

3.4 Reconnect to continue

After the patient's MRI scan is complete, you must reestablish a connection with the implanted device to turn SureScan mode to OFF. To reconnect to the implanted device, use the following steps.

1. Remove the patient from Zone 4 (magnet room), as defined by the American College of Radiology.
2. Place the patient connector over the implanted device.
3. Press the button on the patient connector.

The patient connector will reconnect with the implanted device and the app workflow will proceed to the next step.

If you are having difficulty reconnecting to the implanted device, try the following troubleshooting steps.

- Make sure the patient connector battery is fully charged.
- Reposition the patient connector over the device.
- Confirm the patient and implanted device information for the current session match the patient you are working with.

The MRI app supports one patient session at a time. If there is an active session, the app will only connect to the device that was interrogated at the beginning of the session. The patient name and implanted device from the current session are displayed on the upper left of the app workflow.

If the patient connector is placed over an implanted device that was not interrogated in the open session, the app will remain on the **Reconnect to Continue** screen. To resume the current patient session, place the patient connector over the implanted device listed in the app session.

3.5 Turn SureScan mode to OFF

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to ON, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased. Also, if the device is intended to deliver CRT support, while MRI SureScan mode is programmed to ON the patient receives no CRT support. This lack of CRT support might cause dizziness or shortness of breath. Be sure to program MRI SureScan mode to OFF as soon as the scan is complete.

If SureScan mode is not programmed to OFF, the implanted device will remain in SureScan mode until the device's SureScan mode timeout period automatically expires. The timeout period for SureScan mode is dependent on the device type, and not all devices have a timeout period. It is important to turn SureScan mode to OFF and return the implanted device to the patient's prescribed settings as soon as possible so that the device's therapies are available to the patient. Refer to the MRI technical manual for the implanted device for more information about the timeout period.

To turn SureScan mode to OFF, use the following steps.

1. Remove the patient from Zone 4 (magnet room), as defined by the American College of Radiology.
2. Place the patient connector over the patient's implanted device.
3. Perform one of the following steps.
 - If the patient session is still active in the app, on the **Patient Ready for MRI** screen, tap **MRI IS COMPLETE**. After the app establishes a connection to the implanted device, tap **TURN SureScan OFF**.
 - If the patient session has been closed, begin a new patient session. When the app interrogates the implanted device and detects that SureScan mode is programmed to ON, the app will redirect you to a page stating that SureScan is ON and ask you if the MRI exam is complete.
4. On the **SureScan is OFF** screen, tap **COMPLETE** to end the patient session.

3.6 Additional workflows to turn SureScan mode to OFF

After SureScan mode is turned to ON, if the patient experiences continued discomfort or an adverse event occurs, be sure to understand how to turn off SureScan mode based on your location in the app workflow.

Caution: In case you need to quickly reconnect to the implanted device to turn SureScan mode to OFF, the MRI app and patient connector should be available nearby whenever the MRI app has been used to turn SureScan mode to ON.

Table 8. Possible app workflow conditions and the method for turning SureScan mode to OFF if an adverse event occurs.

App workflow condition	Actions to turn SureScan mode to OFF
App on SureScan is ON screen	Tap TURN SureScan OFF .
App on Remove Patient Connector screen	<ol style="list-style-type: none"> 1. Tap BACK. 2. Tap TURN SureScan OFF. <p>Note: If the patient connector was removed, replace it over the implanted device area.</p>
App on Patient Ready for MRI screen	<ol style="list-style-type: none"> 1. Tap MRI IS COMPLETE. 2. Place the patient connector over the implanted device area and press the button on the patient connector. 3. After the app establishes a connection with the implanted device, tap TURN SureScan OFF.
The app patient session is closed	<ol style="list-style-type: none"> 1. On the Welcome! Before you begin: screen, start a new session by selecting the check box and tap CONTINUE. 2. Place the patient connector over the implanted device area and press the button on the patient connector. 3. The app detects that SureScan mode is turned to ON. From the on-screen options, select YES, TURN SureScan OFF.

3.7 App messages on the Do Not Scan page

If the app determines that SureScan mode cannot be turned on, then it will list the reason on the **Do Not Scan** screen.

The following table lists the possible **Do Not Scan** messages that can appear in the app. Not all messages apply to all devices.

Table 9. Do Not Scan screen messages


App message	Action to be taken
The device settings at implant have not been marked as complete.	Notify the radiologist or other physician supervising the MRI exam.
Lead impedance exceeds limits or cannot be verified.	
Bipolar pacing is required for MRI SureScan. One or more leads is currently configured for unipolar pacing.	
The implanted device has unexpectedly reset since the patient's last device check.	
The device is near its replacement date.	
The implanted device has invalid or incomplete information stored on it.	
The patient's average heart rate exceeds 95 bpm and the implanted device has invalid information stored on it.	
Pacing threshold exceeds limits or cannot be verified.	
The device must be implanted for more than 6 weeks before the MRI exam.	
Data entered in the implanted device indicates there is another device present. The MRI Access app does not support multiple pacing devices.	
The patient's average heart rate exceeds 120 bpm.	<p>If the patient is experiencing anxiety about the scan, try interrogating the device again at a later time after the patient has calmed.</p> <p>If the patient continues to have an elevated heart rate and cannot undergo an MRI exam, then notify the radiologist or other physician supervising the MRI exam.</p>
The patient is experiencing an arrhythmia that the device is currently treating or monitoring.	<p>The device is currently treating or monitoring the patient. Closely monitor the patient.</p> <p>Notify the radiologist or other physician supervising the MRI exam.</p>

3.8 End a patient session

Ending a patient session will close the connection between the app, patient connector, and the patient's implanted device.

Note: Ending the session does not change the status of MRI SureScan mode in the implanted device. If you end the patient session while SureScan mode is programmed to ON, you must start a new app workflow to re-interrogate the implanted device in order to turn SureScan mode to OFF.

Use the following steps to end a patient session.

1. Tap  > **End Session**.
2. On the confirmation message, tap **YES, END SESSION**.

3.9 Managing sessions with multiple patients

After you have prepared a patient for an MRI scan and placed the implanted device into SureScan mode, you can use the MRI app to prepare another patient for an MRI scan.


The MRI app can only have one patient session active. You must end the first patient session before you can start a new session with the second patient.


Note: Ending the patient session does not change the SureScan mode in the implanted device.


Caution: The MRI app and patient connector should be available nearby whenever it has been used to turn SureScan mode to ON in case you need to quickly reconnect to the implanted device to turn SureScan mode to OFF.


To work with multiple patients, use the following steps.

1. With the first patient, follow the MRI app workflow steps to turn SureScan mode to ON and prepare the patient for an MRI scan.

Note: Ensure the patient is continuously monitored while SureScan mode is programmed to ON.
2. From the **Patient Ready for MRI** screen, complete the following steps.
 - a. Tap  > **End Session**.
 - b. Tap **YES, END SESSION**.

3. Place the patient connector over the second patient's implanted device.
4. Using the MRI app, start a new patient session and prepare the second patient for an MRI.
5. After SureScan mode has been programmed to ON for the second patient's implanted device, from the **Patient Ready for MRI** screen, complete the following steps.
 - a. Tap  > **End Session**.
 - b. Tap **YES, END SESSION**.
6. After the first patient's MRI scan is complete, place the patient connector over the first patient's implanted device and restart the MRI app workflow.

Note: Confirm the patient's name and device serial number in the MRI app banner.
7. The MRI app will interrogate the patient's device and detect that SureScan mode is programmed to ON and will ask you if the patient's MRI exam is complete. If the patient's MRI exam is complete, tap **YES, TURN SureScan OFF**.
8. Use the following steps to complete the MRI app workflow:
 - a. Tap  > **End Session**.
 - b. Tap **YES, END SESSION**.
 - c. Remove the patient connector from the first patient.
9. After the second patient's MRI scan is complete, place the patient connector over the second patient's implanted device and restart the MRI app workflow.

Note: Confirm the patient's name and device serial number in the MRI app banner.
10. The MRI app will interrogate the second patient's device and detect that SureScan mode is programmed to ON and will ask if the patient's MRI exam is complete. If the patient's MRI exam is complete, tap **YES, TURN SureScan OFF**.
11. Use the following steps to complete the MRI app workflow: and remove the patient connector from the second patient.
 - a. Tap  > **End Session**.
 - b. Tap **YES, END SESSION**.
 - c. Remove the patient connector from the second patient.

3.10 SureScan mode already turned on

If the patient's implanted device is in SureScan mode and you begin a new patient session, the MRI app will display the **SureScan is ON. Is the patient MRI exam complete?** page with the following options.

- **NO, PREPARE FOR MRI EXAM**
- **YES, TURN SureScan OFF**
- **VIEW DEVICE REPORT**

SureScan mode may have been enabled by the patient's cardiologist or a Medtronic representative before he or she arrived for an MRI scan. The device report in the app includes information about the current parameter settings.

If you select **NO, PREPARE FOR MRI EXAM**, the MRI app will guide you through the steps to prepare the patient to receive an MRI exam.

If the MRI exam is complete, select **YES, TURN SureScan OFF** to continue with the MRI app workflow to turn SureScan mode to OFF.

The MRI app also displays the remaining time that the implanted device will remain in SureScan mode. The implanted device will automatically turn SureScan mode to OFF after a certain period of time. If the MRI scan has not yet been completed and additional time is necessary, determine if the MRI scan will take longer than the remaining time that the implanted device will have SureScan mode ON. If the MRI scan will take longer than the remaining time and if the MRI app was originally used to turn SureScan mode ON, use the MRI app to turn SureScan mode to OFF and then turn SureScan mode back ON to reset the timeout. If SureScan was originally enabled by cardiology, refer the patient to cardiology for programming SureScan mode to ON.

3.11 Device reset detected

The app will notify you if it detects that the implanted device has reset.

The app can detect a device reset any time it communicates with the implanted device. If a full device reset is detected during the pre-scan device checks, the app will not allow SureScan mode to be programmed to ON.

When a full reset occurs, the implanted device defaults to parameters that are appropriate for the device model. For more information about the default reset values for a device model, refer to the parameter tables in the device manual for that model. For more information about device resets, refer to the implanted device's manual.

If a full or partial device reset is detected after SureScan mode is programmed to ON, then the app will program SureScan mode to OFF and the app will not apply the post-scan pace output algorithm. Notify the radiologist or other physician supervising the MRI exam. The device report contains information that can be reviewed by the patient's cardiologist or a Medtronic representative. The device report will be temporarily available in **Saved Reports**.

3.12 Multiple implanted devices detected

The MRI app does not support cases where a patient has multiple implanted cardiac devices that are detected by the app. When the app detects multiple implanted cardiac devices, it displays the **Unsupported Case** message and prevents use of the app.

Caution: The patient connector may not detect another implanted device if its implant location is outside of the patient connector's telemetry range when interrogating the first detected device. Follow your clinic's patient screening protocols to determine if the patient has multiple implanted cardiac devices. The MRI app is not intended to replace your patient screening protocols for determining if the patient has multiple implanted cardiac devices.

If the patient has multiple implanted devices, consult the patient's cardiologist or a Medtronic representative to arrange programming SureScan mode to ON using a supported Medtronic programmer.

Both implanted devices may be MR-conditional and compatible with the MRI app. However, the app only supports cases where the patient has only one implanted cardiac device that is part of a complete SureScan system.

3.13 Working with Micra devices in Device Off state

Caution: Before scanning a patient with a Micra device in the Device Off state, confirm that the patient does not have any other implanted cardiac devices, including a Micra device in the Device Off state. The MRI app does not support scenarios with multiple implanted cardiac devices that are detected by the app. A patient with a Micra device in the Device Off state will likely receive continued therapy from another implanted cardiac device.

Medtronic Micra devices can be safely scanned without additional programming if the device is programmed to Device Off state, or if the device has reached End of Service (EOS) and automatically entered Device Off state. For more information about Device Off state or EOS, refer to the device manual.

Following an MRI scan, Micra devices in the Device Off state do not require additional post-scan programming.

Refer to the appropriate MRI Technical Manual for the implanted device for specified MRI conditions for use.

Note: If a Micra device is not in the Device Off state, the implanted device still requires programming into SureScan mode. Refer to the Micra MRI technical manuals for cardiology requirements for MRI scans.

3.14 Working with insertable cardiac monitors

The following Medtronic insertable cardiac monitors (ICMs) can be scanned safely without additional programming. However, their detectability and compatibility with the MRI app differ.

- Reveal LINQ™ Model LNQ11
- LINQ II™ Model LNQ22
- Reveal® DX Model 9528
- Reveal® XT Model 9529

The Reveal LINQ, Reveal DX, and Reveal XT ICMs can be detected by the MRI app. If both a cardiac device (such as a pacemaker, ICD, or CRT) and one of those Reveal ICMs are detected, the app displays a message that indicates detection of multiple implanted cardiac devices and states that you must use a different Medtronic programmer to turn SureScan to ON for the cardiac device. Consult the patient's cardiologist or a Medtronic representative to arrange programming SureScan mode to ON using a supported Medtronic programmer (such as the CareLink 2090 programmer or the CareLink SmartSync Device Manager).

The LINQ II ICM cannot be detected by the MRI app. If a cardiac device (such as a pacemaker, ICD, or CRT) and a LINQ II ICM are present, you can use the app to turn SureScan to ON for the cardiac device.

For all ICM devices, refer to the appropriate MRI Technical Manual for the implanted device for specified MRI conditions for use.

3.15 View or export saved reports and implanted device data

When you generate a report or save implanted device data during a session, the report or data is saved to the **SAVED REPORTS** window.

Depending on your tablet setup, you can export reports and device data using the following methods:

- Export the reports and device data to various destinations, such as email, network file directories, or cloud storage locations.
- Export the reports to connected printers for printing.

The export options depend on the email, network, and printing apps or connections set up on your tablet.

1. Prepare your tablet.
 - a. Install and configure specific apps, Wi-Fi™* settings, or networking.
 - b. Verify that the tablet shows sufficient signal strength to connect to the network.

For assistance, contact your clinic IT administrator.

2. Tap  > **SAVED REPORTS / DATA**.

3. On the **SAVED REPORTS** window, tap a session to expand the list, then view reports or export reports and device data:

- To view a report, tap **VIEW** next to the report.
- To export reports, select the reports, tap **SEND TO...**, then select the export option or location.

Note: When you select multiple reports to export, the reports export as a single PDF file.

- To export device data and the reports associated with the device data, select the PKG file, tap **SEND TO...**, then select the export option or location.

Note: You are responsible for the management of patient and device data that you export from the app. Examples of patient and device data include printed paper reports, data transferred to a hospital network, and emailed attachments.

3.16 Close the app

If there is an active patient session, refer to the instructions for ending a patient session in this app help.

To close the app, swipe away the app using the tablet operating system.

4 Connecting the patient connector

4.1 About the app and component connections

During the app registration process, the app sends your clinic information and account credentials to Medtronic via the Internet for authentication. In response, Medtronic returns configuration files via the Internet. These files complete the installation of the app and update the patient connector software as needed.

The patient connector uses Bluetooth wireless technology to pair with and connect to the tablet. The tablet must also have an Internet connection for security key authentication. Once the patient connector is paired with the tablet, you can quickly reconnect the patient connector to the app without an Internet connection. To reconnect without an Internet connection, the patient connector must be one of the last 30 patient connectors paired with the tablet. The patient connector must remain within range of the tablet to pair and maintain a connection with the tablet.

When you turn on the patient connector, the patient connector automatically reconnects to the last used tablet.

Note: The patient connector does not automatically reconnect to the app in the following situations:

- The patient connector was connected to a different app more recently than the tablet you are using.
- The app was connected to a different patient connector more recently than the patient connector you are using.

You can also manually connect any patient connector to the tablet. If the patient connector has not previously been paired with the tablet, an Internet connection on the tablet is required for security key authentication. If the patient connector has been previously paired with the tablet but is not the last used patient connector, manually reconnect to the patient connector.

Note: You can connect only 1 patient connector to the app at a time. You are unable to connect the app to a different patient connector during a patient session.

If the connection between the patient connector and the tablet is lost, the patient connector and tablet automatically attempt to re-establish communication. In certain situations after the connection is restored, the app prompts you to press the grey button on the patient connector to identify the patient connector.

4.2 Connect to the patient connector

4.2.1 Pair and connect to a patient connector

You must pair and connect to a patient connector if it has not previously been paired with the tablet, or if the number of paired patient connectors has exceeded 30. Complete the following actions to pair and connect to a patient connector:

1. Ensure that the patient connector is charged or charging.
2. On the tablet, verify that Bluetooth communication is enabled and that there is an Internet connection.
3. If the app is connected to a different patient connector, tap **DISCONNECT**.
4. Tap **CONNECT** or **Select a different patient connector**.
5. Press and hold the patient connector button for 2 s to put the patient connector into pairing mode. The blue light on the patient connector flashes rapidly.

Note: You cannot put the patient connector into pairing mode when it is in use.

6. On the **Select An Accessory** window, tap the serial number of the patient connector.

Note: The patient connector serial number is printed on the bottom of the patient connector.

7. Enter the security key.

Entering the security key ensures that communications are transmitted securely. To enter the security key, complete one of the following actions:

- Tap **SCAN QR** and position the tablet camera over the QR code that is on the bottom of the patient connector. The app scans the QR code and automatically enters the security key.
- Enter the security key in the text field.

Note: The security key is printed on the bottom of the patient connector near the QR code.

4.2.2 Automatically reconnect to the last used patient connector

The patient connector automatically attempts to reconnect to the last used tablet.

An Internet connection is not required to reconnect to a paired patient connector. To reconnect to the last used patient connector, complete the following actions:

1. Open the app.
The app displays the serial number of the last used patient connector below the patient connector status indicator.
2. Turn on the last used patient connector.
The Bluetooth light flashes slowly, and the patient connector automatically initiates a connection to the tablet.
3. If prompted to confirm the connection between the app and the patient connector, press the grey button on the patient connector.
The status area in the app indicates that the patient connector is connected.

Caution: Verify that the app is connected to the correct patient connector. Connecting to an unintended patient connector can result in confusion during a patient session or the delay of a procedure.

- a. Tap **FLASH** in the patient connector connection area.
The lights on the connected patient connector flash for several seconds.
- b. To see the lights on the connected patient connector flash again for several seconds, tap **FLASH AGAIN**.
- c. To stop the flashing lights, press the button on the patient connector.
- d. To return to the previous screen, tap <<.

4.2.3 Manually reconnect to a paired patient connector

The app saves the connection information for up to 30 of the most recently connected patient connectors. By saving the connection information, you can quickly reconnect to a previously paired patient connector without reentering the security key and without needing an Internet connection.

1. Ensure that the patient connector is charged or charging.
2. On the tablet, verify that Bluetooth communication is enabled and that there is an Internet connection.
3. If the app is connected to a patient connector, tap **DISCONNECT** in the patient connector area.
4. Tap **CONNECT** or **Select a different patient connector**.
5. Press and hold the patient connector button for 2 s to put the patient connector into pairing mode. The blue light on the patient connector flashes rapidly.

Note: You cannot put the patient connector into pairing mode when it is in use.

6. On the **Select An Accessory** window, tap the serial number of the patient connector.

Note: The patient connector serial number is printed on the bottom of the patient connector.

7. If prompted to confirm the connection between the app and the patient connector, press the grey button on the patient connector.
The status area in the app indicates that the patient connector is connected.

Caution: Verify that the app is connected to the correct patient connector. Connecting to an unintended patient connector can result in confusion during a patient session or the delay of a procedure.

- a. Tap **FLASH** in the patient connector connection area.
The lights on the connected patient connector flash for several seconds.
- b. To see the lights on the connected patient connector flash again for several seconds, tap **FLASH AGAIN**.
- c. To stop the flashing lights, press the button on the patient connector.
- d. To return to the previous screen, tap <<.

4.3 Troubleshoot connections

4.3.1 Blue light flashes slowly but does not reconnect

When the blue indicator light on the patient connector is flashing slowly, the patient connector is attempting to automatically reconnect to the last used tablet. To connect to a different tablet, you must make the patient connector available for a different connection.

1. Press and hold the button on the patient connector for 2 s, until the blue light flashes rapidly.
2. Use the app to connect to the patient connector.

See the sections on manually reconnecting the patient connector in this app help.

4.3.2 Blue light is on but is not connected

When the blue indicator light on the patient connector is on, the patient connector is connected to a tablet but is not the last used patient connector. To connect to the patient connector, complete the following actions:

1. To put the patient connector into pairing mode, press and hold the grey button on the patient connector for 2 s, until the blue light flashes rapidly.

Note: You cannot put the patient connector into pairing mode when it is in use.

2. Use the app to connect to the patient connector.

See the sections on manually reconnecting the patient connector in this app help.

4.3.3 Component missing from the Select An Accessory window

The connection information stored in the tablet can get out of sync with the patient connector. If this occurs, the blue light on the patient connector shows a connection to the tablet, but the patient connector does not show up in the **Select An Accessory** window. To re-establish the connection between the patient connector and the app, you must unpair the tablet and the patient connector, then restart the connection.

1. On the tablet, open the settings, then open the Bluetooth connection settings.
2. Verify the serial number on the patient connector.
3. Select the patient connector, then use the Bluetooth settings to unpair or forget the connection.
4. Return to the app, then restart the connection to the patient connector.

4.4 Troubleshooting patient connector position

When you position the patient connector incorrectly over the implantable device, the telemetry status light changes.

For issues between the patient connector and implanted device, take one of the following actions:

- Confirm that the implanted device is a Medtronic device.
- Confirm that the telemetry light on the patient connector is solid green.
- Reposition or rotate the patient connector.
- Move the patient connector closer to the implanted device.
- Remove any sources of electromagnetic interference (EMI) that can affect the telemetry signal.

Interference between the patient connector and other electronic equipment can result in reduced quality of service. Reduced quality of service can result in slow data transmission speeds or poor communication strength.

To address possible interference between the patient connector and other electronic equipment, take one or more of the following actions:

- Reorient or relocate the electronic equipment.
- Increase the separation between the patient connector and the electronic equipment.
- Connect the electronic equipment to an outlet on a different circuit, if the patient connector is plugged into the outlet for charging.
- Move the patient connector and tablet closer together.
- For assistance, contact a Medtronic representative.

5 Managing the MRI app settings

5.1 Manage patient data privacy

5.1.1 About patient data privacy management

Manually or automatically remove all protected health information (PHI) from the app.

When you remove PHI, the app deletes the following files:



- Contents of the **SAVED REPORTS**, unless the files are currently being exported or copied
- Temporary files stored on the app

When a session is in progress or while files are being exported, you are unable to delete PHI. If deletion is interrupted manually, some PHI remains on the app.

Note: You are responsible for the use of this tool, as well as for the management of patient and device data that has already been exported from the app. Examples of patient and device data that can be exported from the app include printed paper reports, reports transferred to a hospital network, or emailed attachments.

5.1.2 Delete protected health information



To manually delete all saved reports, implanted device data (PDD files), and other PHI stored on the app, complete the following actions:

1. Tap  > **SETTINGS > PATIENT DATA PRIVACY**.
2. Tap **DELETE ALL PROTECTED HEALTH INFORMATION**.
3. To close the patient data privacy screen, tap  > **SYSTEM CONNECTION**.

5.1.3 Configure the interval to delete protected health information

For added security and convenience, the app can automatically delete saved reports and implanted device data (PDD files). The reports and implanted device data are deleted based on age of the information. You can configure how long reports and implanted device data are retained before they are automatically deleted.


The date and time that a report or implanted device data is created determines its age. When you open the app or restore it from the background, reports or implanted device data that meet the deletion criteria are permanently deleted.

1. Tap  > **SETTINGS > PATIENT DATA PRIVACY**.
2. In the **SCHEDULED DELETE** configuration area, select one of these options:
 - **Reports older than 1 day**
 - **Reports older than 2 days**
 - **Reports older than 7 days**
 - **Reports older than 14 days**
3. To close the patient data privacy screen, tap  > **SYSTEM CONNECTION**.

5.2 Manage the profile settings

Use the profile tabs to view the following information:

- Location information
- Hardware information
- Software information

1. Tap  > **SETTINGS > PROFILE**.
2. To view and manage your location information, tap **LOCATION INFO** and use the following options.

Option	Description
Clinic	Name of your clinic.
Location Description	Description of the clinic location.
Country	Country where your clinic is located. Not editable.
Application ID	Unique identifier of the MRI app. Not editable.
Account #	Medtronic account number. Required field.
Last Name	Last name or surname of your Medtronic representative.
First Name	First name or given name of your Medtronic representative.
Phone #	Phone number for your Medtronic representative.
Fax #	Fax number for your Medtronic representative.
Email	Email address for your Medtronic representative.

3. To view the hardware information, tap **HARDWARE INFO**.

Note: You are unable to change the **HARDWARE INFO** fields.

Option	Description
Tablet Model	Model of the tablet on which the MRI app is installed.
Tablet OS	Tablet operating system and version number.
Patient Connector Model	Model of the patient connector that is currently connected to the MRI app.
Version	Firmware version installed on the patient connector that is currently connected to the MRI app.
Patient Connector Serial Number	Serial number of the patient connector that is currently connected to the MRI app.

4. To view the software information, tap **SOFTWARE INFO**.


Note: You are unable to change the **SOFTWARE INFO** fields.

Option	Description
SOFTWARE COMPONENT	Name of each software component installed on the MRI app.
VERSION	Version of each software component installed on the tablet.
SOFTWARE MODEL	Software model number.
UDI	Unique device identifier (UDI) of the component.
CHECK FOR UPDATES	Tap to check for updates to the MRI app and to the software on the MRI components.

5. To close the profile settings screen, tap  > **SYSTEM CONNECTION**.


5.3 Configure rate unit labels

The app can display rate values with either the bpm or min⁻¹ unit label.

1. Tap  > **SETTINGS > PREFERENCES > UNITS**.
2. Select the desired unit:
 - To show all rate unit labels in bpm, tap **bpm**.
 - To show all rate unit labels in min⁻¹, tap **min⁻¹**.


5.4 Configure filename preferences

To help you manage reports and implanted device data, configure the app to include patient information in the filenames of reports and implanted device data. The app includes the patient information in the beginning of the filename when you export the file using one of the tablet operating system export options. The patient information (for example, the patient name and the implanted device serial number) is from the implanted device.

1. Tap  > **SETTINGS > PREFERENCES > FILENAMES**.
2. Select the checkboxes associated with the patient information that you want to include in the filenames.

5.5 Export user preferences

You can export the user preferences from one app installation and import the user preferences to one or more other app installations. The tablet must be connected to the Internet when you export the user preferences. To export the user preferences, complete the following actions:

1. Tap  > **SETTINGS > PREFERENCES > USER PREFERENCES**.
2. Tap **CREATE USER PREFERENCES QR CODE**.
3. On the **SET NAME OF USER PREFERENCES** window, enter a name to describe the user preferences that you are exporting.
4. Tap **CREATE QR CODE**.
5. On the **USER PREFERENCES QR CODE CREATED** message, complete one of the following actions:
 - To export the QR code, tap **SEND TO...**, then select the export option or location.
 - To view the QR code, tap **VIEW QR CODE**.

Note: You are responsible for the security and use of all information exported from the app.

5.6 Import user preferences

5.6.1 Import user preferences during installation

If you exported a User Preferences QR Code from an existing app installation, you can import those user preferences to another app installation. To import user preferences when you are installing the app, complete the following actions:

1. On the **SETUP COMPLETE** screen during system configuration, tap **IMPORT USER PREFERENCES**.
2. To allow the CareLink SmartSync app to access the tablet camera, tap **OK**.
3. Scan the User Preferences QR Code.
4. On the **USER PREFERENCES IMPORTED** message, tap **CLOSE**.
5. On the **SETUP COMPLETE** screen, tap **START USING THE SYSTEM**.

5.6.2 Import user preferences after installation

If you exported a User Preferences QR Code from an existing app installation, you can import those user preferences after the app has been installed. The tablet must be connected to the Internet when you import user preferences. To import user preferences after the app is installed, complete the following actions:

1. Tap  > **SETTINGS > PREFERENCES > USER PREFERENCES**.
2. Tap **IMPORT USER PREFERENCES**.

3. To allow the CareLink SmartSync app to access the tablet camera, tap **OK**.
4. Scan the User Preferences QR code.
5. On the **USER PREFERENCES IMPORTED** message, tap **CLOSE**.

6 Updating the MRI app

6.1 IT network, tablet, and data information

6.1.1 Required IT network characteristics and configuration

The tablet on which the app is installed must have both Bluetooth wireless technology and access to the Internet.

Bluetooth wireless technology

You must enable Bluetooth wireless technology on the tablet. The Bluetooth connection allows the patient connector to communicate with the app that is installed on the tablet.

Failure to provide Bluetooth communication access prevents the app components from communicating with each other and with implanted devices. If Bluetooth communication is turned off, the app is unable to communicate with the patient connector. The patient connector is used to interrogate and program the implanted device.

Internet

To configure your network, follow the processes and policies of your organization.

Your network must have Internet access, which allows you to complete the following actions:

- Download and install the app.
- Register the app.
- Download and install software or updates necessary for the app to function.
- Authenticate the first connection when pairing the tablet with the patient connector.

Failure to provide information technology (IT) network access prevents the tablet from accessing the Internet, which results in the following limitations:

- Inability to install or update the app and software components
- Inability to download firmware updates for the patient connector
- Inability to receive periodic updates and security enhancements that maintain the security of the app
- Inability to process app component system logs
- Inability to authenticate the first connection between the tablet and the patient connector

Note: Internet access is not required during a patient session or to export and print reports. However, failure to provide access to an information technology (IT) network (for example, a Wi-Fi™* or cellular network) results in the inability to export and print reports using a wireless connection.

6.1.2 Supported tablets and technical specifications

The tablet on which the app is installed must meet the requirements in the CareLink SmartSync Tablet Compatibility Technical Manual.

To download or order the CareLink SmartSync Tablet Compatibility Technical Manual, go to medtronic.com/manuals or contact Medtronic.

Note: The app may not always be compatible with the most current version of the tablet operating system.

6.1.3 Intended information flow

System logs are processed through the app components in the following order:

- Patient connector
- MRI app
- Internet

During installation and updates, the app sends your clinic registration and account credentials to Medtronic via the Internet for authentication. In response, Medtronic returns configuration files to the app via the Internet to install or update the app and component software as needed. The configuration files allow the app to connect to and communicate with the implanted device.

When you are exporting patient data from the app, data flows to the IT network.

Note: You are responsible for the management of patient and device data that you export from the app. Examples of patient and device data include printed paper reports, data transferred to a hospital network, and emailed attachments.

6.1.4 Precautions when connecting to your IT network

Connecting the app to an IT network that includes other equipment could result in unforeseen risks to patients, operators, or third parties. Changes to your IT network, such as adding, disconnecting, updating or upgrading equipment, or changing network configurations, could introduce additional risks. Analyze, evaluate, report, and control any risks identified.

6.1.5 Security

Data in the app is protected by encryption. The app is unable to provide data protection for data exported to another destination. Handle and store the data that you export from the app in accordance with the security policy of your clinic.

To protect patient health information, the tablet must be secured with a passcode. The app is unable to function if a passcode is not defined. For more information on securing the tablet with a passcode, refer to the user instructions for your tablet.


To protect the app, Medtronic recommends that you implement the following security measures:

- Use the app and components only on a managed, trusted network. Verify that your Wi-Fi™* networks comply, at minimum, with wireless standard 802.11b, 802.11g, or 802.11n, and use WPA2 or stronger encryption.
- Secure your network with industry best practices, which can include antivirus software, firewalls, and wireless security policies, according to the policies of your IT department.
- When installing or updating the app, if your tablet displays a message indicating that a security certificate is invalid, the installation or update process is unable to continue. For assistance, contact your local Medtronic representative.

The app closes automatically when the app detects a failure to maintain security.

If you suspect that a cybersecurity event has occurred, stop using the app (if possible). Contact your IT security or biomedical department for information on how to confirm and respond to the suspected incident.

6.2 MRI app updates

When updates are available for app components, the app displays an update message. Additionally, the  (Menu) button appears with a blue dot, and **UPDATES AVAILABLE** appears on the menu, until all available updates are installed.

Medtronic recommends that you install all app updates when they are available.


If you defer an update, the app prompts you to install the available update each time you start the app or end a patient session, until you install the update.

The installation method varies by the type of update:

- When the app displays a message that a newer version of the app must be installed, go to your tablet's app store to install the newer version.
- When the app displays a message that new content is available, tap **UPDATE** to download the content update.

Note: Disable automatic updates from the app store application on the tablet. Automatic app store updates only provide the data for a partial installation of the app.

6.3 Install a new version of the app


When a new version of the app is available, the app displays an update message. Additionally, the  (Menu) button appears with a blue dot, and **UPDATES AVAILABLE** appears on the menu, until all available updates are installed.

Note: If you defer an update, the app prompts you to install the available update each time you start the app or end a patient session, until you install the update.

Install the new version of the CareLink SmartSync app from your tablet app store:

1. Verify that your tablet is connected to the Internet.
2. Go to the app store for your tablet.
3. Install the new version of the CareLink SmartSync app.
4. Restart the app.

6.4 Install a content update

When a content update is available, the app displays an update message. Additionally, the  (Menu) button appears with a blue dot, and **UPDATES AVAILABLE** appears on the menu, until all available updates are installed. The tablet must be connected to the Internet to detect and install the available content update.

Note: If you defer an update, the app prompts you to install the available update each time you start the app or end a patient session, until you install the available update.

To install the new content, tap **UPDATE** in the update message.

Note: If it has been more than 24 hours since you connected the app to the patient connector, you must connect to the patient connector before you can install the update.

6.5 Install required software updates

If it has been more than a year since you updated the app or connected your tablet to the Internet, the app requires you to update the software. The required update ensures that you have the latest and most secure software.

Note: You are unable to use the app until the update installation is complete.

If it has been more than 6 months since you updated the app or connected your tablet to the Internet, data export functions in the app are disabled until a check for software updates is complete.

6.6 Install deferred updates

To install deferred updates, complete the following actions:

1. Tap  > **UPDATES AVAILABLE**.
2. Tap **SOFTWARE INFO > CHECK FOR UPDATES**.


The installation method varies by the type of update:

- If the app displays a message that a newer version of the app is available, go to the app store for your tablet to install the newer version of the app.
- If the app displays a message that new content is available, tap **UPDATE** to download the content update.

After you install the update, you may be prompted to read and accept the license agreement.

6.7 Manually check for and install updates

In addition to automatically checking for updates, the app allows you to manually check for updates.

1. Verify that your tablet is connected to the Internet.
If necessary, enable the Wi-Fi™* setting on your tablet and connect to your network, or verify that the cellular data service for the tablet is connected to the Internet.
2. Verify that the app is connected to a patient connector.
3. Tap  > **SETTINGS > PROFILE**.
4. Tap **SOFTWARE INFO**.
5. Tap **CHECK FOR UPDATES**.

The installation method varies by the type of update:

- If the app displays a message that a newer version of the app is available, go to the app store for your tablet to install the newer version of the app.
- If the app displays a message that new content is available, tap **UPDATE** to download the content update.

After the update installs, you may be prompted to read and accept the license agreement.

6.8 Uninstall the app

The app data is lost when you uninstall the app. If you want to uninstall the app, contact a Medtronic representative for assistance.

7 Troubleshooting

7.1 Messages

To provide you with important information, the app displays various messages. Pay careful attention to all messages and instructions. If you require further assistance, contact a Medtronic representative.

7.2 Service logs

The app automatically saves information about errors or failures to the service log. When you connect the tablet to the Internet, the app sends the service log to Medtronic.

Medtronic uses the information for the following purposes:

- Diagnose and resolve errors and failures
- Improve the app components

Note: The service log saves information about performance, errors, and failures of the app components. The service log does not contain any user, device, patient, or protected health information.

When possible, the service log records information about recoverable and nonrecoverable errors and failures.

All service logs are encrypted for security.

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