Medtronic

Compatibility guide

Options for enabling MRI SureScan™ mode

IPG	Model	CareLink SmartSync™ MRI Access app	CareLink™ 2090 programmer	CareLink Encore™ 29901 programmer	CareLink SmartSync™ device manager
Azure™ MRI	W3DR01, W3SR01, W1DR01, W1SR01	✓	✓	✓	✓
Advisa™ MRI	A2DR01, A3SR01	✓	✓	✓	✓
Astra	X3DR01, X3SR01, X1DR01, X1SR01	✓	✓	✓	✓
Attesta™	ATSR01, ATDR01, ATDRL1, ATDRS1		✓	✓	
Revo MRI™	RVDR01		✓	✓	
Sphera	SPSR01, SPDR01, SPDRL1		✓	✓	

TPS	Model	CareLink SmartSync™ MRI Access app	CareLink™ 2090 programmer	CareLink Encore™ 29901 programmer	CareLink SmartSync™ device manager
Micra™ AV	MC1AVR1	✓	✓	✓	✓
Micra™ VR	MC1VR01, MC1VR01US	✓	✓	✓	✓

CRT-P	Model	CareLink SmartSync™ MRI Access app	CareLink™ 2090 programmer	CareLink Encore™ 29901 programmer	CareLink SmartSync™ device manager
Percepta™ MRI	W1TR01, W4TR01	✓	✓	✓	✓
Serena™ MRI	W1TR02, W4TR02	✓	✓	✓	✓
Solara™ MRI	W1TR03, W4TR03	✓	✓	✓	✓

ICD	Model	CareLink SmartSync™ MRI Access app	CareLink™ 2090 programmer	CareLink Encore™ 29901 programmer	CareLink SmartSync™ device manager
Cobalt™	DDPB3D1, DDPB3D4, DVPB3D1, DVPB3D4, DDPA2D1, DDPA2D4, DVPA2D1, DVPA2D4	✓			✓
Crome™	DDPC3D1, DDPC3D4, DVPC3D1, DVPC3D4	✓			✓
Evera™ MRI	DDMC3D1, DDMC3D4, DVMC3D1, DVMC3D4, DDMB1D1, DDMB1D4, DVMB1D1, DVMB1D4	✓	✓	✓	✓
Mirro	DDME3D1, DDME3D4, DVME3D1, DVME3D4	✓	✓	✓	✓
Primo MRI™	DDMD3D1,DDMD3D4, DVMD3D1, DVMD3D4	✓	✓	✓	✓
Visia AF MRI™	DVFB1D1, DVFB1D4, DVFC3D1, DVFC3D4	✓	✓	✓	✓

CRT-D	Model	CareLink SmartSync™ MRI Access app	CareLink™ 2090 programmer	CareLink Encore™ 29901 programmer	CareLink SmartSync™ device manager
Cobalt™	DTPB2D1, DTPB2D4, DTPB2Q1, DTPB2QQ, DTPA2D1, DTPA2D4, DTPA2Q1, DTPA2QQ	✓			✓
Crome™	DTPC2D1, DTPC2D4, DTPC2Q1, DTPC2QQ	✓			✓
Amplia MRI™	DTMB1D1, DTMB1D4, DTMB1Q1, DTMB1QQ	✓	✓	✓	✓
Claria MRI™	DTMA1D1, DTMA1D4, DTMA1Q1, DTMA1QQ	✓	✓	✓	✓
Compia MRI™	DTMC1D1, DTMC1D4, DTMC1QQ	✓	✓	✓	✓

Brief Statements
CareLink SmartSync™ MRI Access Application
Indications (or Intended Use)
The CareLink SmartSync™ MRI Access Application (MRI app) is intended for use by a trained healthcare professional or Medtronic representative in a clinical or hospital environment to prepare a compatible Medtronic MR conditional implanted cardiac device for an MRI scan and to return the device to pre-scan settings after the MRI scan is complete. The MRI app is installed on a compatible tablet and communicates with the Medtronic Model 24967 Patient Connector to interrogate the implanted device, perform device checks, and engage the automatic algorithms that program the appropriate device parameters prior to and after the MRI scan.
Contraindications
There are no known contraindications for the use of the MRI app.
Warnings and Precautions
The MRI app does not screen patients or replace the patient screening process. A complete SureScan™ system is required for use in the MR environment. The tablet used with the MRI app and the Model 24967 Patient Connector are MR Unsafe and cannot be used in Zone (magnet room), as defined by the American College of Radiology.
See the CareLink SmartSync™ MRI Access Application Help, CareLink SmartSync™ MRI Access Application SureScan Labeling Supplement, and 24967 Patient Connector Technical Manual for detailed information regarding the procedure, indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events.
Refer to the MRI Technical Manual for the implanted device for information on MRI warnings and precautions and potential adverse events. The MRI app turns on and turns off MRI SureScan mode. When MRI SureScan mode is turned on or turned off, the patient's implanted device must meet all the labeling conditions defined in the MRI Technical Manual. See the Device Manual for the implanted device for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events.
For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic Model 24967 Patient Connector
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 trained healthcare professionals or Medtronic representatives in a clinical or hospital environment.
Contraindications
There are no known contraindications for the use of the Patient Connector.
Warnings and Precautions
The Patient Connector may experience connectivity or performance issues. See the 24967
Patient Connector Technical Manual for details and troubleshooting instructions.
See the 24967 Patient Connector Technical Manual before using the MRI app for detailed information regarding the indications or intended uses, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

CareLink™ 2090 Programmer and 2290 Analyzer
The Medtronic CareLink 2090 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 2090 programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron. The Medtronic 2290 Analyzer is an accessory that installs into the Medtronic CareLink 2090 programmer. The Analyzer is intended for use by a clinician to analyze the pacing and sensing performance of the cardiac lead system during the implant of a cardiac arrhythmia management device, or during invasive troubleshooting of a cardiac lead system. There are no known contraindications to the use of a lead analysis device. The patient's age and medical condition, however, may dictate the pacing modes and lead analyses appropriate for the patient.Using RemoteView™ for RemoteControl™: This section provides general information for using RemoteView for remote control of the programmer. RemoteControl 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 RemoteControl functionality should not be used with patients in the following situations: ▫ Underlying rhythm test with pacer-dependent patients ▫ Arrhythmia inductions and EP studies ▫ Cardioversion ▫ 2290 Pacing System Analyzer.
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 these devices to sale by or on the order of a physician.

CareLink Encore™ 29901 Programmer
The Medtronic CareLink Encore™ 29901 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 Encore 29901 programmer must be used only for programming implantable devices manufactured by Medtronic or Vitatron. *See the device manuals for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-929-4043 and/or consult the Medtronic website at medtronic.com.*

Medtronic Model 24970A CareLink SmartSync™ Device Manager Base
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 CareLink SmartSync Device Manager Patient Connector
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.
Precaution
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 CareLink SmartSync 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
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic