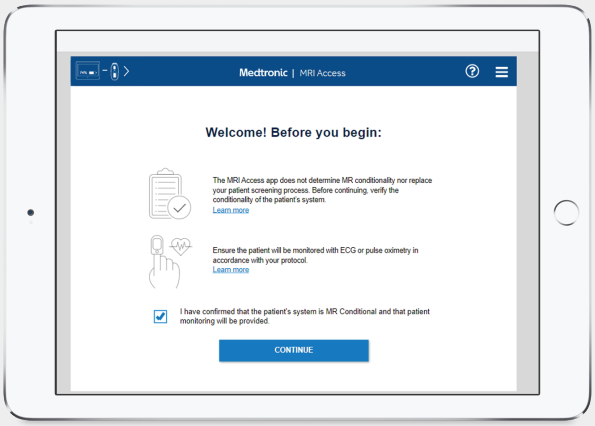
Medtronic

CareLink SmartSync™
MRI Access app

Compatibility guide



The CareLink SmartSync MRI Access app ("MRI Access app") can be used to enable SureScan™ MRI mode. The app can only be used with certain Medtronic cardiac devices. This compatibility guide shows which devices are compatible with the app.

MRI Access app compatible devices

IPG	Astra™ MRI (X1DR01, X1SR01, X3DR01, X3SR01)	Azure™ MRI (W3DR01, W3SR01, W1DR01, W1SR01)	
ICD	Cobalt™ XT (DDPA2D4, DDPA2D1, DVPA2D4, DVPA2D1)	Cobalt™ (DDPB3D4, DDPB3D1, DVPB3D4, DVPB3D1)	Crome™ (DDPC3D4, DDPC3D1, DVPC3D4, DVPC3D1)
CRT-P	Percepta™ MRI (W4TR01, W1TR01)	Serena™ MRI (W4TR02, W1TR02)	Solara™ MRI (W4TR03, W1TR03)
CRT-D	Cobalt™ XT (DTPA2QQ, DTPA2Q1, DTPA2D4, DTPA2D1)	Cobalt™ (DTPB2QQ, DTPB2Q1, DTPB2D4, DTPB2D1)	Crome™ (DTPC2QQ, DTPC2Q1, DTPC2D4, DTPC2D1)

Cardiology department

Brief Statement
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 SureScanTM 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 4 (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.

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