# Medtronic

CareLink SmartSync™ MRI Access Application SureScan Labeling Supplement

Medtronic and Medtronic logo are trademarks of Medtronic. TM\* Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. The following list includes trademarks or registered trademarks of a Medtronic entity in the United States or in other countries.

Advisa DR MRI™, Advisa SR MRI™, Advisa™, Amplia MRI™, Astra™, Azure™, CareLink Encore™, CareLink SmartSync™, CareLink™, Claria MRI™, Cobalt™, Compia MRI™, Crome™, Ensura DR MRI™, Ensura SR MRI™, Ensura™, Evera MRI™, Evera™, Medtronic CareLink™, Micra™, Mirro MRI™, Percepta™, Primo MRI™, Serena™, Solara™, SureScan™, Visia AF MRI™, Visia AF™, Visia™

## CareLink SmartSync™ MRI Access Application SureScan Labeling Supplement About this guide

This guide is intended to be used only by health care professionals.

The primary source for MRI SureScan labeling for an implanted device is the MRI technical manual for the implanted device.

There may be multiple programmers that you can use to program SureScan mode for a Medtronic implanted device. Refer to the appropriate labeling for the programmer and the implanted device for information about device and lead checks, programming procedures, and algorithms that either you or the programmer must perform when programming SureScan parameters.

This supplemental guide is intended to assist you in locating the instructions for use that are available depending on the implanted device and the programmer that you are using to program SureScan mode to ON or OFF.

CareLink Model 2090 Programmer or a CareLink Encore Model 29901 Programmer – Refer to the MRI technical manual for the implanted device's MRI SureScan labeling and reference information for programming SureScan parameters.

**CareLink SmartSync Device Manager Application** – Refer to the MRI technical manual for the implanted device's MRI SureScan labeling. Refer to the app help for the implanted device's CareLink SmartSync device application for reference information for programming SureScan parameters.

**CareLink SmartSync MRI Access Application** – 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.

**Note:** 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.

Refer to *Table 1* for information about which programmers can be used to program SureScan parameters for an implanted device. Then, refer to the section in this guide that describes the applicable MRI SureScan labeling for the programmer you are using.

Note: Only product models that are compatible with the CareLink SmartSync MRI Access application are listed in Table 1.

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

Table 1. Compatible programmers for programming SureScan parameters

Product name	Product model	Compatible programmer
Advisa DR MRI SureScan	A2DR01	Medtronic CareLink Model 2090 Programmer
	A3DR01	Medtronic CareLink Encore Model 29901 Programmer
Advisa SR MRI SureScan		CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application

**Table 1.** Compatible programmers for programming SureScan parameters (continued)

Product name	Product model	Compatible programmer		
Amplia MRI CRT-D SureScan	DTMB1D1	Medtronic CareLink Model 2090 Programmer		
	DTMB1D4	Medtronic CareLink Encore Model 29901 Programmer		
	DTMB2D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	DTMB2D4			
Amplia MRI Quad CRT-D SureScan	DTMB1Q1			
	DTMB1QQ			
	DTMB2Q1			
	DTMB2QQ			
Astra S DR MRI SureScan	X3DR01	Medtronic CareLink Model 2090 Programmer		
Astra S SR MRI SureScan	X3SR01	Medtronic CareLink Encore Model 29901 Programmer		
Astra XT DR MRI SureScan	X1DR01	CareLink SmartSync Device Manager Application		
	X2DR01	CareLink SmartSync MRI Access Application		
Astra XT SR MRI SureScan	X1SR01			
	X2SR01			
Azure S DR MRI SureScan	W3DR01	Medtronic CareLink Model 2090 Programmer		
Azure S SR MRI SureScan	W3SR01	Medtronic CareLink Encore Model 29901 Programmer		
Azure XT DR MRI SureScan	W1DR01	CareLink SmartSync Device Manager Application		
	W2DR01	CareLink SmartSync MRI Access Application		
Azure XT SR MRI SureScan	W1SR01			
	W2SR01			
Claria MRI CRT-D SureScan	DTMA1D1	Medtronic CareLink Model 2090 Programmer		
	DTMA1D4	Medtronic CareLink Encore Model 29901 Programmer		
	DTMA2D1	CareLink SmartSync Device Manager Application		
	DTMA2D4	CareLink SmartSync MRI Access Application		
Claria MRI Quad CRT-D SureScan	DTMA1Q1			
	DTMA1QQ			
	DTMA2Q1			
	DTMA2QQ			
Cobalt DR MRI SureScan	DDPB3D1	CareLink SmartSync Device Manager Application		
Codan Di i Willi Guicocali	DDPB3D4	CareLink SmartSync MRI Access Application		
Cobalt HF CRT-D MRI SureScan	DTPB2D1			
	DTPB2D4			
Cobalt HF Quad CRT-D MRI SureScan	DTPB2Q1			
	DTPB2QQ			
Cobalt VR MRI SureScan	DVPB3D1			
<del></del>	DVPB3D4			
Cobalt XT DR MRI SureScan	DDPA2D1			
Sobalt At British is Surcosum	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			

**Table 1.** Compatible programmers for programming SureScan parameters (continued)

Product name	Product model	Compatible programmer		
Compia MRI CRT-D SureScan	DTMC1D1	Medtronic CareLink Model 2090 Programmer		
	DTMC1D4	Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	DTMC2D1			
	DTMC2D4			
Compia MRI Quad CRT-D SureScan	DTMC1QQ			
	DTMC2QQ			
Crome DR MRI SureScan	DDPC3D1	CareLink SmartSync Device Manager Application		
	DDPC3D4	CareLink SmartSync MRI Access Application		
Crome HF CRT-D MRI SureScan	DTPC2D1			
	DTPC2D4			
Crome HF Quad CRT-D MRI SureScan	DTPC2Q1			
	DTPC2QQ			
Crome VR MRI SureScan	DVPC3D1			
	DVPC3D4			
Ensura DR MRI SureScan	EN1DR01	Medtronic CareLink Model 2090 Programmer		
Ensura SR MRI SureScan	EN1SR01	Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
Evera MRI S DR SureScan	DDMC3D1	Medtronic CareLink Model 2090 Programmer		
	DDMC3D4	Medtronic CareLink Encore Model 29901 Programmer		
Evera MRI S VR SureScan	DVMC3D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	DVMC3D4	CareLink SmartSync With Access Application		
Evera MRI XT DR SureScan	DDMB1D1			
	DDMB1D4			
	DDMB2D1			
	DDMB2D4			
Evera MRI XT VR SureScan	DVMB1D1			
	DVMB1D4			
	DVMB2D1			
	DVMB2D4			
Micra AV	MC1AVR1	Medtronic CareLink Model 2090 Programmer		
Micra VR	MC1VR01	Medtronic CareLink Encore Model 29901 Programmer		
	MC1VR01US	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
Micra AV2	MC2AVR1	CareLink SmartSync Device Manager Application		
Micra VR2	MC2VR01	CareLink SmartSync MRI Access Application		
Mirro MRI DR SureScan	DDME3D1	Medtronic CareLink Model 2090 Programmer		
	DDME3D4	Medtronic CareLink Encore Model 29901 Programmer		
Mirro MRI VR SureScan	DVME3D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	DVME3D4	Care Entite Office for it Access Application		
Percepta CRT-P MRI SureScan	W1TR01	Medtronic CareLink Model 2090 Programmer		
	W1TR04	Medtronic CareLink Encore Model 29901 Programmer		
Percepta Quad CRT-P MRI SureScan	W4TR01	CareLink SmartSync Device Manager Application		
	W4TR04	CareLink SmartSync MRI Access Application		
Primo MRI DR SureScan	DDMD3D1	Medtronic CareLink Model 2090 Programmer		
	DDMD3D4	Medtronic CareLink Encore Model 29901 Programmer		
Primo MRI VR SureScan	DVMD3D1	CareLink SmartSync Device Manager Application		
	DVMD3D4	CareLink SmartSync MRI Access Application		

**Table 1.** Compatible programmers for programming SureScan parameters (continued)

Product name	Product model	Compatible programmer		
Serena CRT-P MRI SureScan	W1TR02	Medtronic CareLink Model 2090 Programmer		
	W1TR05	Medtronic CareLink Encore Model 29901 Programmer		
Serena Quad CRT-P MRI SureScan	W4TR02	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	W4TR05	CareLink SmartSync Mini Access Application		
Solara CRT-P MRI SureScan	W1TR03	Medtronic CareLink Model 2090 Programmer		
	W1TR06	Medtronic CareLink Encore Model 29901 Programmer		
Solara Quad CRT-P MRI SureScan	W4TR03	CareLink SmartSync Device Manager Application		
	W4TR06	CareLink SmartSync MRI Access Application		
Visia AF MRI VR SureScan	DVFB1D1	Medtronic CareLink Model 2090 Programmer		
	DVFB1D4	Medtronic CareLink Encore Model 29901 Programmer		
Visia AF MRI XT VR SureScan	DVFB2D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application		
	DVFB2D4	CareLink SmartSync with Access Application		
Visia AF MRI S VR SureScan	DVFC3D1			
	DVFC3D4			

### Medtronic



Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA www.medtronic.com +1 763 514 4000

### EC REP

Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands +31 45 566 8000

#### Canada

Medtronic Canada ULC 99 Hereford Street Brampton, Ontario L6Y 0R3 Canada 1 800 268 5346

#### **Technical manuals**

www.medtronic.com/manuals

© 2023 Medtronic M042213C001 A 2023-02-26

