Medtronic

CareLink SmartSync™ MRI Access Application SureScan Labeling Supplement

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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	A3SR01	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 Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	DTMB1D4	
	DTMB2D1	
	DTMB2D4	
Amplia MRI Quad CRT-D SureScan	DTMB1Q1	
	DTMB1QQ	
	DTMB2Q1	
	DTMB2QQ	
Astra S DR MRI SureScan	X3DR01	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
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	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
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	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	DTMA1D4	
	DTMA2D1	
	DTMA2D4	
Claria MRI Quad CRT-D SureScan	DTMA1Q1	
	DTMA1QQ	
	DTMA2Q1	
	DTMA2QQ	
Cobalt DR MRI SureScan	DDPB3D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	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	

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 Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	DTMC1D4	
	DTMC2D1	
	DTMC2D4	
Compia MRI Quad CRT-D SureScan	DTMC1QQ	
	DTMC2QQ	
Crome DR MRI SureScan	DDPC3D1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	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 DR MRI SureScan	EN1DR01	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
Ensura SR MRI SureScan	EN1SR01	
Evera MRI S DR SureScan	DDMC3D1	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	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	
Micra AV	MC1AVR1	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
Micra VR	MC1VR01	
	MC1VR01US	
Micra AV2	MC2AVR1	CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
Micra VR2	MC2VR01	
Mirro MRI DR SureScan	DDME3D1	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	DDME3D4	
Mirro MRI VR SureScan	DVME3D1	
	DVME3D4	
Percepta CRT-P MRI SureScan	W1TR01	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	W1TR04	
Percepta Quad CRT-P MRI SureScan	W4TR01	
	W4TR04	
Primo MRI DR SureScan	DDMD3D1	Medtronic CareLink Model 2090 Programmer Medtronic CareLink Encore Model 29901 Programmer CareLink SmartSync Device Manager Application CareLink SmartSync MRI Access Application
	DDMD3D4	
Primo MRI VR SureScan	DVMD3D1	
	DVMD3D4	

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

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