1.5 AND 3T MRI CHECKLIST

SureScan™ Pacing, Defibrillation, CRT-D and CRT-P Systems

CARDIOLOGIST CHECKLIST

☐ **Full Medtronic MRI SureScan System implanted**

☐ **SureScan Systems Verification**

Consult patient records to verify only Medtronic MR-Conditional Systems constructed from the following components are implanted:

Medtronic SureScan MRI pacemakers

Advisa MRI™ A3DR01 and A3SR01, Ensura MRI™ EN1DR01 and EN1SR01, *EnRhythm MRI™ EMDR01, Azure™ XT MRI W2DR01 and W2SR01, Azure™ S MRI W3DR01 and W3SR01, Astra™ XT MRI X2DR01 and X2SR01, Attesta MRI ATDR01, ATDRL1, ATDRS1 and ATSR01, Sphera MRI SPDR01, SPDRL1 and SPSR01, Q series MRI Q80A2, Q70A2, Q50A2 and Q20A2, G series MRI G70A2 and G20A2

*EnRhythm MRI is not labelled for 3T, 1.5T conditions apply!

Medtronic SureScan MRI ICDs

Evera MRI™ DDMB2D4, DDMC3D4, DVMB2D4, DVMC3D4, DDMB2D1, DDMC3D1, DVMB2D1, DVMC3D1
Visia AF MRI™ DVFB2D4, DVFC3D4, DVFB2D1, DVFC3D1
Primo MRI™ DDMD3D1, DDMD3D4, DVMD3D1, DVMD3D4
Mirro MRI™ DDME3D1, DDME3D4, DVME3D1, DVME3D4
Cobalt XT MRI™ DDPA2D1, DDPA2D4, DVPA2D1, DVPA2D4
Cobalt MRI™ DDPB3D1, DDPB3D4, DVPB3D1, DVPB3D4
Crome MRI™ DDPC3D1, DDPC3D4, DVPC3D1, DVPC3D4

Medronic SureScan MRI CRT-Ds & CRT-Ps

Claria MRI™ DTMA2D4, DTMA2D1, Claria MRI Quad DTMA2QQ, DTMA2Q1
Amplia MRI™ DTMB2D4, DTMB2D1, Amplia MRI Quad DTMB2QQ, DTMB2Q1
Compia MRI™ DTMC2D4, DTMC2D1, Compia MRI Quad DTMC2QQ
Percepta™ Quad W4TR04, Percepta™ W1TR04, Serena™ Quad W4TR05, Serena™ W1TR05, Solara™ Quad W4TR06, Solara™ W1TR06
Cobalt XT HF MRI™ DTPA2D1, DTPA2D4, Cobalt XT HF MRI™ Quad DTPA2Q1, DTPA2QQ
Cobalt HF MRI™ DTPB2D1, DTPB2D4, Cobalt HF MRI™ Quad DTPB2Q1, DTPB2QQ
Crome HF MRI™ DTPC2D1, DTPC2D4, Crome HF MRI™ Quad DTPC2Q1, DTPC2QQ

Note: For Medtronic SureScan MRI CRT-Ds and CRT-Ps without an atrial lead, a model 6725 pin plug can be used to plug the right atrial port. For Medtronic SureScan MRI DF1 devices with a single coil lead, a model 6719 pin plug can be used to plug the SVC Port.

Medtronic SureScan MRI leads

Sprint Quattro MRI™
(Models: 6947M-55, 6947M-62, 6935M-55, 6935M-62, 6935-58, 6935-65, 6947-58, 6947-65, 6946M-55, 6946M-62)
CapSure Sense MRI™
(Models: 4574-45, 4574-53, 4074-52, 4074-58)
CapSureFix MRI™
(Models: 5086MRI-45, 5086MRI-52, 5086MRI-58)
CapSureFix Novus MRI™
(Models: 4076-35, 4076-45, 4076-52, 4076-58, 4076-65, 4076-85, 5076-35, 5076-45, 5076-52, 5076-58, 5076-65, 5076-85)
CapSure Z Novus MRI
(Models: 5054-52, 5054-58, 5554-45, 5554-53)
SelectSecure™ MRI
(Models : 3830-59,3830-69, 3830-74)
Attain Ability™ MRI
(Models: 4196-78, 4196-88, 4296-78, 4296-88, 4396-78, 4396-88)
Attain Performa™ MRI
(Models: 4298-78, 4298-88, 4398-78, 4398-88, 4598-78, 4598-88)
Attain Stability™ MRI
(Models: 20066 or 4796-88)
Attain Stability Quad™ MRI
(Models: 4798-78, 4798-88)
Crystalline Actfix MRI™
(Models: ICQ09B-35, ICQ09B-45, ICQ09B-52, ICQ09B-58, ICQ09B-65, ICQ09B-85)

Cardiology Requirements for Medtronic SureScan MRI pacemakers	Cardiology Requirements for Medtronic SureScan MRI defibrillators (ICDs) and Medtronic SureScan MRI Cardiac Resynchronization defibrillators (CRT-Ds) and Cardiac Resynchronization pacemakers (CRT-Ps)
Post-lead maturation period (approximately 6 weeks) * EnRhythm MRI > 6 weeks	
RV Pacing Threshold ≤ 2.0 V at 0.4 ms for pacemaker dependent patients * EnRhythm MRI Pacing Threshold ≤ 2.0 V at 0.4 ms	
The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history. (Pacing lead impedance 200-1,500 Ω)	The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history. (Pacing lead impedance 200 -3,000 Ω, Defibrillation lead impedance 20-200 Ω)
The patient has no implanted lead-extenders, lead adaptors or abandoned leads.	
Multiple MR-Conditional devices acceptable if MR labeling conditions for all implants can be satisfied. * EnRhythm MRI patients with previously implanted (active or abandoned) medical devices, leads, lead extenders or lead adaptors are contraindicated for an MRI scan.	
The SureScan system is implanted in the left or right pectoral region and operating within the projected service life.	
Do not scan patients who exhibit diaphragmatic stimulation when the device is pacing asynchronously during the MRI SureScan mode. It may be difficult for the patient to remain still in order to obtain a quality MRI scan.	

☐ **Program MRI SureScan Mode ON before the scan (OFF after the scan)**

☐ **Patient Monitoring**

Proper patient monitoring must be provided during the MRI scan and includes both of the following actions: ▪ maintaining continuous visual and verbal contact with the patient ▪ continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography	Proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On and includes both of the following actions: ▪ maintaining continuous visual and verbal contact with the patient ▪ continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography

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

☐ **Patient ready to get an MRI Scan**

For a complete set of operating and programming guidelines and restrictions, refer to the respective MRI Technical Manual for any SureScan device.

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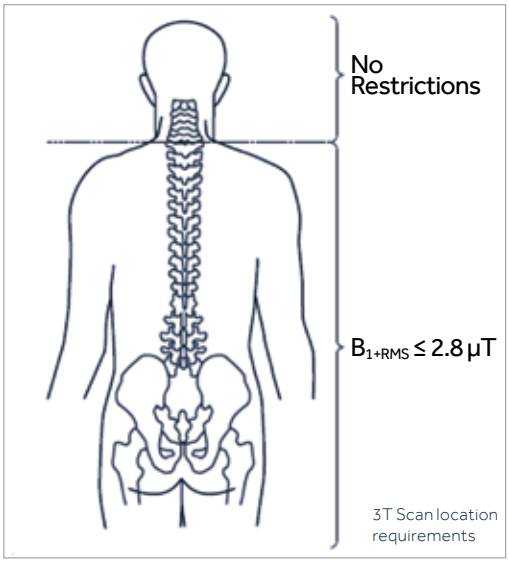
RADIOLOGIST CHECKLIST

☐ A Full Medtronic MR-Conditional System Confirmed by Cardiologist or Patient Records

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	▪ Static magnetic field of one of the following strengths: – 1.5T (EnRhythm MRI is 1.5T only) – 3T ▪ Maximum spatial gradient of ≤ 20 T/m (2,000 gauss/cm) ▪ Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s



3T Scan location requirements

☐ MRI Scanner Operation

1.5T—MRI radiofrequency (RF) power—Normal Operating Mode
- The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg
- Head SAR must be ≤ 3.2 W/kg

3T—MRI radiofrequency (RF) power - First Level Controlled Operating Mode or Normal Operating Mode
- B_{1+RMS} must be ≤ 2.8 µT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra (see figure above)
- Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra

For Pacemaker Patients:
- Continuous patient monitoring is required during the MRI scan
- In the event that patient rescue is required, an external defibrillator must be immediately available
- EnRhythm MRI patient may not be positioned on his or her side within the MRI bore (lateral decubitus position). The use of local transmit-only coils or local transmit-receive coils placed directly over the pacing system is contraindicated

For Defibrillator, CRT-D (Cardiac Resynchronisation Defibrillator) and CRT-P (Cardiac Resynchronisation Pacemaker) Patients:
- Continuous patient monitoring is required while the MRI SureScan mode is programmed to On
- In the event that patient rescue is required, an external defibrillator must be immediately available

☐ Perform the Indicated Scan

☐ Cardiology to Program the MRI SureScan Mode OFF

Brief Statement
See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

Updated: January 2020

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