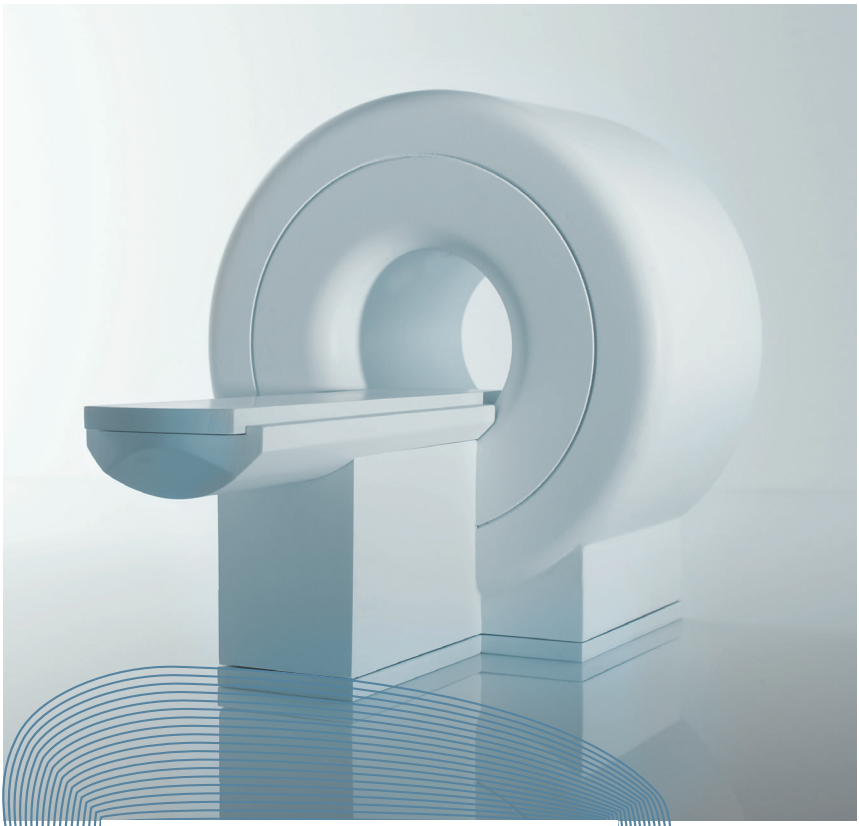

ProMRI®

Checklist and Quick Reference Guide

BIOTRONIK
excellence for life

Conditions for MR scans with a BIOTRONIK **Pro**MRI® system[1]

Usage of an MR scan on a patient having an implanted pacemaker, CRT-P, ICD, or CRT-D is only possible under highly specific prerequisites and conditions. BIOTRONIK offers a comprehensive, breakthrough portfolio of device systems approved for MR scans. These products are marked as "ProMRI®."

Please use the matrices starting on page 10 of this brochure or the BIOTRONIK ProMRI® System Technical Manual to check whether the patient's ProMRI® device-lead combination is approved for full body MR scans. The requirements listed in this guide apply to all ProMRI® systems.

1 For MRI information for BIOTRONIK's insertable cardiac monitor, consult the device technical manual.

Conditions for MR scans with a BIOTRONIK **Pro**MRI® system (continued)

Restrictions for the patient and the cardiac device system

- The device system consists of a pacemaker, CRT-P, ICD, or CRT-D with the respective leads that are separately labeled MR conditional and, when combined, constitutes an MR conditional device system (See charts on p. 10).
- There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

  Note: An MRI scan is permitted only if the product-specific conditions are met for all implants and if no metal implantable device longer than 5 cm is in the vicinity of a BIOTRONIK lead within a distance of less than 4 cm.
- The leads have been implanted for at least 6 weeks.
- The device system is implanted pectorally.
- The measured pacing threshold is not above 2.0 V at 0.4 ms pulse width.
- The device system should be functioning normally prior to an MRI.
- The battery status is neither ERI nor EOS.
- The device is programmed to an MRI mode (ON or AUTO) before the MR scan.

Requirements of the MRI scanner

- Use of a clinical MRI scanner with a closed bore, cylindrical magnets and a static magnetic field strength of 1.5 Tesla.
- The slew rate of the MRI scanner's gradient fields should not exceed 200 T/m/s per axis.

Restrictions during the MRI scan

- The mean specific absorption rate (SAR) for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- The patient's condition must be continuously monitored during the entire MR scan using at least one of the following parameters: blood oxygen saturation, blood pressure or ECG.

  Note: The ECG function integrated in the MRI scanner is often not permitted for patient monitoring. Therefore, only use devices which are permitted for patient monitoring in an MRI environment.

ProMRI® checklist for the radiology department

Checklist before MRI scanning

This checklist will help to ensure the safe application of an MR scan on patients with a BIOTRONIK device system that has been labeled MR Conditional.*

We recommend checking the boxes off while using this checklist to ensure that an MR Conditional scan with BIOTRONIK ProMRI® systems is permissible. Please check to see whether the patient's ProMRI® device-lead combination is approved for a full body MR scan.
(See charts on p. 10.)

General requirements for patients with ProMRI® systems

- ☐ Use of a clinical MRI scanner with a closed bore, cylindrical magnets and a static magnetic field strength of 1.5 Tesla.
- ☐ The slew rate of the MRI scanner's gradient fields should not exceed 200 T/m/s per axis.
- ☐ The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- ☐ The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- ☐ Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.

☐ The patient should be continuously monitored in an appropriate manner during the entire MR scan. The following parameters can be observed: blood oxygen saturation, blood pressure, ECG.

Note: The ECG function integrated in the MRI scanner is often not permitted for patient monitoring. Therefore, only use devices which are permitted for patient monitoring in an MRI environment.

☐ Ensure with the cardiology department that the device is programmed to MRI mode (ON or AUTO) prior to the MR scan.

Name and signature

Date

* Details on these conditions and requirements can be found in the BIOTRONIK ProMRI® System Technical Manual (www.manuals.biotronik.com). Alternatively, contact your local BIOTRONIK representative or visit www.manuals.biotronik.com.

ProMRI® checklist for the cardiology department

Use the following checklist to ensure that patients implanted with a BIOTRONIK device system labeled "MR Conditional" can receive an MR scan safely.*

We recommend that you check off the boxes in order to be certain that a full body MR Conditional scan with BIOTRONIK ProMRI® systems is permissible.

Patient

Name _____

Address _____

City _____

Cardiac device system (please complete)

Device _____

Leads _____

_____

ProMRI® checklist for the cardiology department (continued)

- ☐ The device system consists of a pacemaker, CRT-P, ICD, or CRT-D with the respective leads that are separately labeled MR conditional and, when combined, constitutes an MR conditional device system (See charts on p. 10).
- ☐ There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- ☐ Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

  Note: An MRI scan is permitted only if the product-specific conditions are met for all implants and if no metal implantable device longer than 5 cm is in the vicinity of a BIOTRONIK lead within a distance of less than 4 cm.
- ☐ The leads have been implanted for at least 6 weeks.
- ☐ The device system is implanted pectorally.
- ☐ The measured pacing threshold is not above 2.0 V at 0.4 ms pulse width.
- ☐ The device system should be functioning normally prior to an MRI.
- ☐ The battery status is neither ERI nor EOS.
- ☐ Ensure that the device is programmed to an MRI mode (ON or AUTO) before the MR scan and reprogrammed to the initial settings after the scan.
- ☐ Post MR scan requirements met (See p. 10).

Name and signature

Date

* Details on these conditions and requirements can be found in the BIOTRONIK ProMRI® System Technical Manual (www.biotronikusa.com/manuals). Alternatively, contact your local BIOTRONIK representative or visit www.manuals.biotronik.com.

Post MR scan requirements

General Considerations

After the MR scan, the patient must undergo follow-up device interrogation. This is necessary for the patient's safety for two reasons:

- To reprogram the device to original pacing parameters.
- To assess the device system for any adverse effects caused by the MR scan.

MRI AutoDetect

Using Home Monitoring is recommended when the MRI Program is set to AUTO. For devices with Home Monitoring functionality, a Home Monitoring-supported follow-up is performed and transmitted to the Home Monitoring Service Center during the night after the MR scan.

For patients with the MRI Program set to AUTO, the device automatically switches back to the permanent program after the patient exits the MRI scanner.

ProMRI® system check

Pacemakers

Leads	Bradycardia Devices		
	Eluna DR-T Entovis DR-T Eluna SR-T Entovis SR-T	Edora 8 DR-T Edora 8 DR Evity 8 DR-T Enitra 8 DR-T Evity 6 DR-T Enitra 6 DR-T Enitra 6 DR	Edora 8 SR-T Edora 8 SR Evity 8 SR-T Enitra 8 SR-T Evity 6 SR-T Enitra 6 SR-T Enitra 6 SR
Setrox S 53	ProMRI®	ProMRI®	ProMRI®
Setrox S 60			
Siello S 45			
Siello S 53			
Siello S 60			
Solia S 45			
Solia S 53			
Solia S 60			

* Detailed information about ProMRI® can be found in the BIOTRONIK ProMRI® System Technical Manual. You can download this document as a PDF file from the website: www.biotronikusa.com/manuals. Alternatively, contact your local BIOTRONIK representative or visit the website www.manuals.biotronik.com.

CRT-Ps

Leads	Bradycardia Devices	
	Edora 8 HF-T Evity 8 HF-T Enitra 8 HF-T	Edora 8 HF-T QP Evity 8 HF-T QP Enitra 8 HF-T QP
Setrox S 53	ProMRI®	ProMRI®
Setrox S 60		
Safio S 53		
Safio S 60		
Siello S 45		
Siello S 53		
Siello S 60		
Solia S 45		
Solia S 53		
Solia S 60		
Corox (ProMRI) OTW 85 BP		N/A
Corox (ProMRI) OTW-S 85 BP		
Corox (ProMRI) OTW-L 85 BP		
Sentus (ProMRI) OTW QP S-75	N/A	ProMRI®
Sentus (ProMRI) OTW QP S-85		
Sentus (ProMRI) OTW QP S-95		
Sentus (ProMRI) OTW QP L-75		
Sentus (ProMRI) OTW QP L-85		
Sentus (ProMRI) OTW QP L-95		
Sentus (ProMRI) OTW QP S-75/49		
Sentus (ProMRI) OTW QP S-85/49		
Sentus (ProMRI) OTW QP S-95/49		
Sentus (ProMRI) OTW QP L-75/49		
Sentus (ProMRI) OTW QP L-85/49		
Sentus (ProMRI) OTW QP L-95/49		

DX DF-1 ICDs

Leads	Tachycardia Devices	
	Iperia VR-T DX Inventra VR-T DX Iforia VR-T DX	Ilivia 7 VR-T DX Intica 7 VR-T DX Intica 5 VR-T DX
Linox^{smart} S DX 65/15	ProMRI®	ProMRI®
Linox^{smart} S DX 65/17		
Plexa ProMRI DF-1 S DX 65/15		
Plexa ProMRI DF-1 S DX 65/17		

DF-1 ICDs

Leads		Tachycardia Devices		
		Iperia DR-T (DF-1) Iforia DR-T (DF-1)	Ilivia 7 DR-T (DF-1) Intica 7 DR-T (DF-1) Intica 5 DR-T (DF-1)	Iperia 7 VR-T (DF-1) Inventra 7 VR-T (DF-1) Ilivia 7 VR-T (DF-1) Intica 7 VR-T (DF-1) Intica 5 VR-T (DF-1)
Atrial	Setrox S 53	ProMRI®		N/A
	Siello S 45			
	Siello S 53			
	Siello S 60			
	Solia S 45			
	Solia S 53			
	Solia S 60			
RV	Plexa ProMRI DF-1 S 65	ProMRI®		ProMRI®
	Plexa ProMRI DF-1 S 75			
	Plexa ProMRI DF-1 SD 65/16			
	Plexa ProMRI DF-1 SD 65/18			
	Plexa ProMRI DF-1 SD 75/18			
	Linox^{smart} S 65			
	Linox^{smart} S 75			
	Linox^{smart} SD 65/16			
	Linox^{smart} SD 65/18			
	Linox^{smart} SD 75/18			

DF-4 ICDs

Leads		Tachycardia Devices		
		Iperia DR-T (DF4) Iforia DR-T (DF4)	Ilivia 7 DR-T (DF4) Intica 7 DR-T (DF4) Intica 5 DR-T (DF4)	Iperia 7 VR-T (DF4) Inventra 7 VR-T (DF4) Ilivia 7 VR-T (DF4) Intica 7 VR-T (DF4) Intica 5 VR-T (DF4)
Atrial	Setrox S 53	**ProMRI®**	**ProMRI®**	**N/A**
	Siello S 45			
	Siello S 53			
	Siello S 60			
	Solia S 45			
	Solia S 53			
	Solia S 60			
RV	Protego S 65	**ProMRI®**	**ProMRI®**	**ProMRI®**
	Protego S 75			
	Protego SD 65/16			
	Protego SD 65/18			
	Protego SD 75/18			
	Plexa ProMRI S 65			
	Plexa ProMRI S 75			
	Plexa ProMRI SD 65/16			
	Plexa ProMRI SD 65/18			
	Plexa ProMRI SD 75/18			

HF-T DF-1 CRT-Ds

Leads		Tachycardia Devices	
		Iperia 7 HF-T (DF-1) Inventra 7 HF-T (DF-1)	Ilivia 7 HF-T (DF-1) Intica 7 HF-T (DF-1) Intica 5 HF-T (DF-1)
Atrial	Setrox S 53	**ProMRI®**	**ProMRI®**
	Siello S 45		
	Siello S 53		
	Siello S 60		
	Solia S 45		
	Solia S 53		
	Solia S 60		
RV	Linox^{smart} S 65	**ProMRI®**	**ProMRI®**
	Linox^{smart} S 75		
	Linox^{smart} SD 65/16		
	Linox^{smart} SD 65/18		
	Linox^{smart} SD 75/18		
	Plexa ProMRI DF-1 S 65		
	Plexa ProMRI DF-1 S 75		
	Plexa ProMRI DF-1 SD 65/16		
	Plexa ProMRI DF-1 SD 65/18		
	Plexa ProMRI DF-1 SD 75/18		
LV	Corox (ProMRI) OTW 75 BP	**ProMRI®**	**ProMRI®**
	Corox (ProMRI) OTW 85 BP		
	Corox (ProMRI) OTW-L 75 BP		
	Corox (ProMRI) OTW-L 85 BP		
	Corox (ProMRI) OTW-S 75 BP		
	Corox (ProMRI) OTW-S 85 BP		

HF-T DX (DF-1) CRT-Ds

Leads		Tachycardia Devices
		Ilivia 7 HF-T (DF 1) Intica 7 HF-T (DF-1)
RV	Linox^{smart} S DX 65/15	ProMRI®
	Linox^{smart} S DX 65/17	
	Plexa ProMRI DF-1 S DX 65/15	
	Plexa ProMRI DF-1 S DX 65/17	
LV	Corox (ProMRI) OTW 75 BP	ProMRI®
	Corox (ProMRI) OTW 85 BP	
	Corox (ProMRI) OTW-L 75 BP	
	Corox (ProMRI) OTW-L 85 BP	
	Corox (ProMRI) OTW-S 75 BP	
	Corox (ProMRI) OTW-S 85 BP	

HF-T DF4 CRT-Ds

Leads		Tachycardia Devices	
		Iperia 7 HF-T (DF4) Inventra 7 HF-T (DF4)	Ilivia 7 HF-T (DF4) Intica 7 HF-T (DF4) Intica 5 HF-T (DF4)
Atrial	Setrox S 53	ProMRI®	ProMRI®
	Siello S 45		
	Siello S 53		
	Siello S 60		
	Solia S 45		
	Solia S 53		
	Solia S 60		
RV	Protego S 65	ProMRI®	ProMRI®
	Protego S 75		
	Protego SD 65/16		
	Protego SD 65/18		
	Protego SD 75/18		
	Plexa ProMRI S 65		
	Plexa ProMRI S 75		
	Plexa ProMRI SD 65/16		
	Plexa ProMRI SD 65/18		
	Plexa ProMRI SD 75/18		

HF-T DF4 CRT-Ds (continued)

Leads		Tachycardia Devices	
		Iperia 7 HF-T (DF4) Inventra 7 HF-T (DF4)	Ilivia 7 HF-T (DF4) Intica 7 HF-T (DF4) Intica 5 HF-T (DF4)
LV	Corox (ProMRI) OTW 75 BP	ProMRI®	ProMRI®
	Corox (ProMRI) OTW 85 BP		
	Corox (ProMRI) OTW-L 75 BP		
	Corox (ProMRI) OTW-L 85 BP		
	Corox (ProMRI) OTW-S 75 BP		
	Corox (ProMRI) OTW-S 85 BP		

HF-T QP (DF-1) CRT-Ds

Leads		Tachycardia Devices
		Ilivia 7 HF-T QP (DF-1) Intica 7 HF-T QP (DF-1)
Atrial	Setrox S 53	ProMRI®
	Siello S 45	
	Siello S 53	
	Siello S 60	
	Solia S 45	
	Solia S 53	
	Solia S 60	
RV	Linox^{smart} S 65	ProMRI®
	Linox^{smart} S 75	
	Linox^{smart} SD 65/16	
	Linox^{smart} SD 65/18	
	Linox^{smart} SD 75/18	
	Plexa ProMRI DF-1 S 65	
	Plexa ProMRI DF-1 S 75	
	Plexa ProMRI DF-1 SD 65/16	
	Plexa ProMRI DF-1 SD 65/18	
	Plexa ProMRI DF-1 SD 75/18	

HF-T QP (DF-1) CRT-Ds (continued)

Leads		Tachycardia Devices
		Ilivia 7 HF-T QP (DF-1) Intica 7 HF-T QP (DF-1)
LV	Sentus (ProMRI) OTW QP S-75	ProMRI®
	Sentus (ProMRI) OTW QP S-85	
	Sentus (ProMRI) OTW QP S-95	
	Sentus (ProMRI) OTW QP L-75	
	Sentus (ProMRI) OTW QP L-85	
	Sentus (ProMRI) OTW QP L-95	
	Sentus (ProMRI) OTW QP S-75/49	
	Sentus (ProMRI) OTW QP S-85/49	
	Sentus (ProMRI) OTW QP S-95/49	
	Sentus (ProMRI) OTW QP L-75/49	
	Sentus (ProMRI) OTW QP L-85/49	
	Sentus (ProMRI) OTW QP L-95/49	

HF-T DX QP (DF-1) CRT-Ds

Leads		Tachycardia Devices
		Ilivia 7 HF-T QP (DF-1) Intica 7 HF-T QP (DF-1)
RV	Linox^{smart} S DX 65/15	ProMRI®
	Linox^{smart} S DX 65/17	
	Plexa ProMRI DF-1 S DX 65/15	
	Plexa ProMRI DF-1 S DX 65/17	
LV	Sentus (ProMRI) OTW QP S-75	ProMRI®
	Sentus (ProMRI) OTW QP S-85	
	Sentus (ProMRI) OTW QP S-95	
	Sentus (ProMRI) OTW QP L-75	
	Sentus (ProMRI) OTW QP L-85	
	Sentus (ProMRI) OTW QP L-95	
	Sentus (ProMRI) OTW QP S-75/49	
	Sentus (ProMRI) OTW QP S-85/49	
	Sentus (ProMRI) OTW QP S-95/49	
	Sentus (ProMRI) OTW QP L-75/49	
	Sentus (ProMRI) OTW QP L-85/49	
	Sentus (ProMRI) OTW QP L-95/49	

HF-T QP (DF4) CRT-Ds

Leads		Tachycardia Devices	
		Iperia 7 HF-T QP (DF4) Inventra 7 HF-T QP (DF4)	Ilivia 7 HF-T QP (DF4) Intica 7 HF-T QP (DF4)
Atrial	Setrox S 53	**ProMRI®**	**ProMRI®**
	Siello S 45		
	Siello S 53		
	Siello S 60		
	Solia S 45		
	Solia S 53		
	Solia S 60		
RV	Protego S 65	**ProMRI®**	**ProMRI®**
	Protego S 75		
	Protego SD 65/16		
	Protego SD 65/18		
	Protego SD 75/18		
	Plexa ProMRI S 65		
	Plexa ProMRI S 75		
	Plexa ProMRI SD 65/16		
	Plexa ProMRI SD 65/18		
	Plexa ProMRI SD 75/18		
LV	Sentus (ProMRI) OTW QP S-75	**ProMRI®**	**ProMRI®**
	Sentus (ProMRI) OTW QP S-85		
	Sentus (ProMRI) OTW QP S-95		
	Sentus (ProMRI) OTW QP L-75		
	Sentus (ProMRI) OTW QP L-85		
	Sentus (ProMRI) OTW QP L-95		
	Sentus (ProMRI) OTW QP S-75/49		
	Sentus (ProMRI) OTW QP S-85/49		
	Sentus (ProMRI) OTW QP S-95/49		
	Sentus (ProMRI) OTW QP L-75/49		
	Sentus (ProMRI) OTW QP L-85/49		
	Sentus (ProMRI) OTW QP L-95/49		

The following BIOTRONIK blind plugs are approved as MR conditional.
* BS DF-1
* BS IS-1 (in LV port of respective device)
* BS IS-1 (in RA port of CRT-P and CRT-D devices)
* BS IS4 (in LV port of respective device)

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