ProMRI

MR conditional device systems

Technical Manual

371712

Rev. CJ (2020-02-27)

BIOTRONIK

excellence for life

CE 0123 2010

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin / Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

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1 Changes in this Technical Manual

The changes relate to the following technical manual:

Technical manual	Order number	Old revision	New revision
MR conditional device systems	371712	CF	CJ

There are the following changes in this technical manual:

#	Change	In section
Graphical highlighting	Introductory sentence	Effects [Page 7]
Classification changed	Introductory sentence	Combinations of MR Conditional ICDs [Page 9] Combinations of MR Conditional Pacemakers [Page 27]
Tables adjusted	Plexa (ProMRI) DF-1 S Plexa (ProMRI) DF-1 SD Plexa (ProMRI) S Plexa (ProMRI) SD	Single-Chamber ICDs with DF-1 Connection [Page 9] Single-Chamber ICDs with DF4 Connection [Page 12] Dual-Chamber ICDs with DF-1 Connection [Page 14] Dual-Chamber ICDs with DF4 Connection [Page 16] Triple-Chamber ICDs with DF-1 Connection [Page 18] Triple-Chamber ICDs with DF4 Connection [Page 21] Triple-Chamber ICDs - QP Model with DF-1 Connection [Page 23] Triple-Chamber ICDs - QP Model with DF4 Connection [Page 25]
Graphical highlighting	Introductory sentence	Conditions for device systems without scan exclusion zone [Page 33] Conditions during the MR scan [Page 33] MRI Scanner Conditions [Page 34]

#	Change	In section
Graphical highlighting	Introductory sentence	Conditions for device systems with scan exclusion zone [Page 35] Conditions during the MR scan [Page 36] MRI Scanner Conditions [Page 36] Permissible Positioning Zone [Page 37]
Classification changed	Cardiological follow-up [Page 44]	MR Scan Procedure with Pacemakers and ICDs [Page 39]
Table adjusted	BIOMONITOR IIIm	Cardiac Monitors [Page 45]
Graphical highlighting	Introductory sentence	Conditions for cardiac monitors [Page 45] Conditions during the MR scan [Page 46] MRI Scanner Conditions [Page 46]
Cardiac monitor added	BIOMONITOR IIIm	Conditions during the MR scan [Page 46] Cardiac Monitors [Page 58]
Leads added	Plexa (ProMRI) DF-1 S Plexa (ProMRI) DF-1 SD Plexa (ProMRI) S Plexa (ProMRI) SD	ICD Leads [Page 59]
Spelling changed	Corox leads	Left Ventricular Leads [Page 63]
Classification changed	Blind Plugs [Page 67]	Overview of MR Conditional Products [Page 48]

2 Basic Information

About this Technical Manual

Subject matter of this technical manual

This technical manual provides information on safely conducting an MR scan on patients with an implanted MR conditional device system from BIOTRONIK.

In particular, it describes the restrictions and general conditions and safety measures to follow before and during an MR scan of a patient with a BIOTRONIK device system.

Keep this technical manual for later use.

What this technical manual does not cover

Correct and safe use of the ICD, pacemaker, cardiac monitor, the leads and blind plugs is described in the technical manuals provided with the products and is not a subject of this technical manual.

Likewise, correct and safe use of an MRI scanner is not described in this technical manual.

MR conditional

Patients with an MR conditional device system can undergo an MR scan under certain conditions.

A primary factor for an MR scan is whether a scan exclusion zone must be maintained.

The device system can consist of a pacemaker or an ICD with associated leads and blind plugs or a cardiac monitor. Each device is not only identified separately as MR conditional but also approved as MR conditional as a device system.

ProMRI

BIOTRONIK devices, leads, and blind plugs that are labeled with the brand name ProMRI also have the following symbol on their package:

MR conditional:

Patients with a device system having implanted devices labeled with this symbol on the packaging can be examined using an MR scan under precisely defined conditions.

ProMRI is the BIOTRONIK name and trademark for these products.

MRI approval in the country

If you are planning to perform an MR scan with an MR conditional device system from BIOTRONIK, please contact the responsible authorities or BIOTRONIK beforehand to determine whether these products are actually approved as MR conditional in your country.

Target Group

This technical manual is directed at physicians and medical personnel who perform an MR scan on patients having an ICD, pacemaker or cardiac monitor.

Preparation and performance of an MR scan on patients having an ICD, pacemaker or cardiac monitor require close cooperation between specialists from two areas of expertise: cardiology and radiology.

Cardiologist

A cardiologist must be consulted in advance for the selection of a patient for the MR scan.

The cardiologist must also be familiar with the BIOTRONIK programmer and especially with testing the implanted device for functional safety before and after the MR scan.

Radiologist

The radiologist is required for successful and safe performance of the MR scan.

In particular, he or she must be familiar with MRI scanners and the preparation and performance of MR scans.

Intended Medical Use

Device system

The intended medical use of the pacemaker, ICD, cardiac monitor, lead(s) and blind plug(s) applies to the use of the device system.

Please observe the technical manuals for the device, the lead(s), and the blind plug(s).

MRI indication

A patient with an MR conditional device system can be selected for an MR scan under the following conditions:

- There is a clear indication.
- There is no doubt as to the predictable diagnostic benefit based on a risk/benefit analysis.

Intended use

An MR scan can be performed on a patient having an MR conditional device system from BIOTRONIK if the requirements and conditions for an MR scan are strictly observed.

3 Safety Warnings

Interactions between Implanted Device and MRI Scanner

MR conditional BIOTRONIK devices

BIOTRONIK has developed device systems that are approved MR conditional applying constructive measures in relation to material selection and design.

Problematic interactions

Significant mechanisms which can lead to problematic interactions with device systems are described here.

Restrictions and special conditions for an MR scan reduce the probability of side effects.

The effects on the device and patient explained below are therefore minimized and limited to a tolerable level, though a residual risk cannot be excluded.

Fields in the MRI scanner

3 types of fields are generated in an MR scan:

Static magnetic field

- A consistently strong, uniform magnetic field which is constantly present in the MRI scanner and its immediate surroundings, even if no scan is being performed.

Gradient magnetic fields

- A low-frequency pulsed magnetic field with a relatively low amplitude. During the MR scan, the patient is exposed to 3 gradient magnetic fields that are perpendicular to each other.

HF field (high-frequency field)

- This is a high-frequency electromagnetic field which activates the protons at their resonant frequency. It is switched on several times for short periods during the MR scan. The HF field is created by so-called emitting coils, which also serve as receiver coils. A differentiation is made between the coil integrated in the MRI scanner and local coils (e.g., head coil with transmitting function).

Effects

⚠ **WARNING**

The following affect the MR scan and imaging:

Force of the static magnetic field and the gradient magnetic fields

- Implanted ferromagnetic materials are subject to the force of static magnetic fields and of gradient magnetic fields. Implanted devices can transmit pressures, tensile force or vibrations to the surrounding tissue. During the MR scan, patients may feel a slight pulling sensation or vibration at the implantation site.

Interactions resulting from induced voltages

- Gradient magnetic fields and electromagnetic high frequency fields can induce electrical AC voltages in metallic devices that can in some cases result in undesirable cardiac pacing and negatively affect the implanted device.

Thermal interactions

- Gradient magnetic fields and electromagnetic high frequency fields can cause warming of the device housing and the contact surfaces of the leads to the body, which can lead to thermal exposure and damage to the surrounding tissue. This thermal tissue damage can be temporary or lasting and can cause deterioration of the lead's pacing and sensing functions.

Image interference and artifacts

- The device system may have undesirable effects on MR imaging. Artifacts and distortion are possible if a device system is within the field of view of an MRI scanner. Image interference is less likely if a device system is outside the field of view.

Contraindications

An MR scan on patients with a device system is always contraindicated for device systems which have not been identified as MR conditional by BIOTRONIK and have not been approved for MRI applications by a responsible authority.

An MR scan on patients with an MR conditional device system is also contraindicated when any of the listed conditions is not adhered to.

This technical manual does not deal with the contraindications of MR scans which do not result from interactions with a device system.

4 Combinations of MR Conditional ICDs

General considerations

Devices and leads are sold independently of each other. You should therefore consult the following tables to determine which combinations of device and lead(s) are considered MR conditional device systems.

The conditions and requirements that must be observed for the respective combination are also indicated.

The abbreviations FBS and EXZ

The abbreviation **FBS** stands for **F**ull-**B**ody **S**can and means that no scan exclusion zone applies for such products.

The abbreviation **EXZ** stands for **Ex**clusion **Z**one and means that a scan exclusion zone must be observed for such products.

⚠ WARNING

Limitation due to lead combinations that are not MR conditional

ICD-lead combinations that are not listed should be treated as non MR conditional.

Single-Chamber ICDs with DF-1 Connection

<table>
<tr><th></th><th colspan="4">VR-T</th></tr>
<tr><th></th><th>Idova 7
Iforia 5/7
Ilesto 5/7</th><th>Inventra 7
Iperia 5/7
Itrevia 5/7</th><th>Ilivia 7
Intica 5/7</th><th>Ilivia Neo 7
Intica Neo 5/7</th></tr>
<tr><td>Linox^{smart} (ProMRI) S
65; 75</td><td colspan="4" rowspan="6">1.5 T FBS
3.0 T EXZ</td></tr>
<tr><td>Linox^{smart} (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego DF-1 (ProMRI) S
65; 75</td></tr>
<tr><td>Protego DF-1 (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
65; 75</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
60</td><td rowspan="2">---</td><td colspan="3" rowspan="2">1.5 T FBS
3.0 T EXZ</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
60/16</td></tr>
</table>

	VR-T	
	Iforia 3	**Inlexa 3**
Linox^{smart} (ProMRI) S 65; 75	1.5 T FBS	
Linox^{smart} (ProMRI) SD 65/16; 65/18; 75/18		
Protego DF-1 (ProMRI) S 65; 75		
Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18		
Plexa (ProMRI) DF-1 S 65; 75		
Plexa (ProMRI) DF-1 SD 65/16; 65/18; 75/18		
Plexa (ProMRI) DF-1 S 60	---	1.5 T FBS
Plexa (ProMRI) DF-1 SD 60/16		

	VR-T
	Lumax 740 Lumax 640
Linox^{smart} (ProMRI) S 65; 75	1.5 T EXZ
Linox^{smart} (ProMRI) SD 65/16; 65/18; 75/18	
Protego DF-1 (ProMRI) S 65; 75	
Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18	

Single-Chamber ICDs - DX Model with DF-1 Connection

	VR-T DX			
	Idova 7 Iforia 5/7 Ilesto 5/7	**Inventra 7 Iperia 5/7 Itrevia 5/7**	**Ilivia 7 Intica 5/7**	**Ilivia Neo 7 Intica Neo 5/7**
Linox^{smart} (ProMRI) S DX 65/15; 65/17	1.5 T FBS 3.0 T EXZ			
Protego DF-1 (ProMRI) S DX 65/15; 65/17				
Plexa (ProMRI) DF-1 S DX 65/15; 65/17				

	VR-T DX
	Lumax 740 Lumax 640
Linox^{smart} (ProMRI) S DX 65/15; 65/17	1.5 T EXZ
Protego DF-1 (ProMRI) S DX 65/15; 65/17	

Single-Chamber ICDs with DF4 Connection

	VR-T			
	Idova 7 Iforia 5/7 Ilesto 5/7	**Inventra 7 Iperia 5/7 Itrevia 5/7**	**Ilivia 7 Intica 5/7**	**Acticor 7 Rivacor 3/5/7**
Linox^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18	1.5 T FBS 3.0 T EXZ			1.5 T FBS 3.0 T FBS
Protego (ProMRI) S 65; 75				
Protego (ProMRI) SD 65/16; 65/18; 75/18				
Plexa (ProMRI) S 65; 75				
Plexa (ProMRI) SD 65/16; 65/18; 75/18				
Plexa (ProMRI) S 60	---	1.5 T FBS 3.0 T EXZ		
Plexa (ProMRI) SD 60/16				

	VR-T	
	Iforia 3	**Inlexa 3**
Linox^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18	1.5 T FBS	
Protego (ProMRI) S 65; 75		
Protego (ProMRI) SD 65/16; 65/18; 75/18		
Plexa (ProMRI) S 65; 75		
Plexa (ProMRI) SD 65/16; 65/18; 75/18		
Plexa (ProMRI) S 60	---	1.5 T FBS
Plexa (ProMRI) SD 60/16		

Single-Chamber ICDs - DX Model with DF4 Connection

	VR-T DX
	Acticor 7 Rivacor 5/7
Plexa ProMRI S DX 65/15; 65/17	1.5 T FBS 3.0 T FBS

Dual-Chamber ICDs with DF-1 Connection

<table>
<tr><th></th><th colspan="4">DR-T</th></tr>
<tr><th></th><th>Idova 7
Iforia 5/7
Ilesto 5/7</th><th>Inventra 7
Iperia 5/7
Itrevia 5/7</th><th>Ilivia 7
Intica 5/7</th><th>Ilivia Neo 7
Intica Neo 5/7</th></tr>
<tr><td>Safio S / Setrox S
53</td><td colspan="4" rowspan="10">1.5 T FBS
3.0 T EXZ</td></tr>
<tr><td>Solia JT / Siello JT
45; 53</td></tr>
<tr><td>Solia S / Siello S
45; 53; 60</td></tr>
<tr><td>Linox^{smart} (ProMRI) S
65; 75</td></tr>
<tr><td>Linox^{smart} (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego DF-1 (ProMRI) S
65; 75</td></tr>
<tr><td>Protego DF-1 (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
65; 75</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
60</td><td rowspan="2">---</td><td colspan="3" rowspan="2">1.5 T FBS
3.0 T EXZ</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
60/16</td></tr>
</table>

<table>
<tr><th></th><th colspan="2">DR-T</th></tr>
<tr><th></th><th>Iforia 3</th><th>Inlexa 3</th></tr>
<tr><td>Safio S / Setrox S
53</td><td colspan="2" rowspan="9">1.5 T FBS</td></tr>
<tr><td>Solia JT / Siello JT
45; 53</td></tr>
<tr><td>Solia S / Siello S
45; 53; 60</td></tr>
<tr><td>Linox^{smart} (ProMRI) S
65; 75</td></tr>
<tr><td>Linox^{smart} (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego DF-1 (ProMRI) S
65; 75</td></tr>
<tr><td>Protego DF-1 (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
65; 75</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) DF-1 S
60</td><td rowspan="2">---</td><td rowspan="2">1.5 T FBS</td></tr>
<tr><td>Plexa (ProMRI) DF-1 SD
60/16</td></tr>
</table>

<table>
<tr><th></th><th>DR-T</th></tr>
<tr><th></th><th>Lumax 740
Lumax 640</th></tr>
<tr><td>Solia S / Siello S
45; 53; 60</td><td rowspan="5">1.5 T EXZ</td></tr>
<tr><td>Linox^{smart} (ProMRI) S
65; 75</td></tr>
<tr><td>Linox^{smart} (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego DF-1 (ProMRI) S
65; 75</td></tr>
<tr><td>Protego DF-1 (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
</table>

Dual-Chamber ICDs with DF4 Connection

<table>
<tr><th></th><th colspan="4">DR-T</th></tr>
<tr><th></th><th>Idova 7
Iforia 5/7
Ilesto 5/7</th><th>Inventra 7
Iperia 5/7
Itrevia 5/7</th><th>Ilivia 7
Intica 5/7</th><th>Acticor 7
Rivacor 3/5/7</th></tr>
<tr><td>Safio S / Setrox S
53</td><td colspan="3" rowspan="8">1.5 T FBS
3.0 T EXZ</td><td rowspan="10">1.5 T FBS
3.0 T FBS</td></tr>
<tr><td>Solia JT / Siello JT
45; 53</td></tr>
<tr><td>Solia S / Siello S
45; 53; 60</td></tr>
<tr><td>Linox^{smart} (ProMRI) DF4 SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego (ProMRI) S
65; 75</td></tr>
<tr><td>Protego (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) S
65; 75</td></tr>
<tr><td>Plexa (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) S
60</td><td rowspan="2">---</td><td colspan="2" rowspan="2">1.5 T FBS
3.0 T EXZ</td></tr>
<tr><td>Plexa (ProMRI) SD
60/16</td></tr>
</table>

	DR-T	
	Iforia 3	**Inlexa 3**
Safio S / Setrox S 53	1.5 T FBS	1.5 T FBS
Solia JT / Siello JT 45; 53		
Solia S / Siello S 45; 53; 60		
Linox^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18		
Protego (ProMRI) S 65; 75		
Protego (ProMRI) SD 65/16; 65/18; 75/18		
Plexa (ProMRI) S 65; 75		
Plexa (ProMRI) SD 65/16; 65/18; 75/18		
Plexa (ProMRI) S 60	---	1.5 T FBS
Plexa (ProMRI) SD 60/16		

Triple-Chamber ICDs with DF-1 Connection

	HF-T			
	Idova 7 Iforia 3 Iforia 5/7 Ilesto 5/7	**Inventra 7 Iperia 5/7 Itrevia 5/7**	**Ilivia 7 Intica 5/7 Inlexa 3**	**Ilivia Neo 7 Intica Neo 5/7**
Safio S / Setrox S 53	1.5 T FBS	1.5 T FBS	1.5 T FBS	1.5 T FBS
Solia JT / Siello JT 45; 53				
Solia S / Siello S 45; 53; 60				
Linox^{smart} (ProMRI) S 65; 75				
Linox^{smart} (ProMRI) SD 65/16; 65/18; 75/18				
Protego DF-1 (ProMRI) S 65; 75				
Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18				
Plexa (ProMRI) DF-1 S 65; 75				
Plexa (ProMRI) DF-1 SD 65/16; 65/18; 75/18				
Plexa (ProMRI) DF-1 S 60	---			
Plexa (ProMRI) DF-1 SD 60/16				
Corox (ProMRI) OTW BP 75; 85	1.5 T FBS			
Corox (ProMRI) OTW-S BP 75; 85				
Corox (ProMRI) OTW-L BP 75; 85				
Sentus (ProMRI) OTW BP L 75; 85; 95				
Sentus (ProMRI) OTW BP S 75; 85; 95				

	HF-T
	Lumax 740 **Lumax 640**
Solia S / Siello S 45; 53; 60	1.5 T EXZ
Linox^{smart} (ProMRI) S 65; 75	
Linox^{smart} (ProMRI) SD 65/16; 65/18; 75/18	
Protego DF-1 (ProMRI) 65; 75	
Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18	
Corox (ProMRI) OTW BP 75; 85	
Corox (ProMRI) OTW-S BP 75; 85	
Corox (ProMRI) OTW-L BP 75; 85	
Sentus (ProMRI) OTW BP L 75; 85; 95	
Sentus (ProMRI) OTW BP S 75; 85; 95	

Triple-Chamber ICDs with DF-1 Connection – DX Leads

	HF-T	
	Ilivia 7 Intica 5/7 Inlexa 3	**Ilivia Neo 7 Intica Neo 5/7**
Linox^{smart} (ProMRI) S DX 65/15; 65/17	1.5 T FBS	
Protego DF-1 (ProMRI) S DX 65/15; 65/17		
Plexa (ProMRI) DF-1 S DX 65/15; 65/17		
Corox (ProMRI) OTW BP 75; 85		
Corox (ProMRI) OTW-S BP 75; 85		
Corox (ProMRI) OTW-L BP 75; 85		
Sentus (ProMRI) OTW BP L 75; 85; 95		
Sentus (ProMRI) OTW BP S 75; 85; 95		

Triple-Chamber ICDs with DF4 Connection

<table>
<tr><th></th><th colspan="4">HF-T</th></tr>
<tr><th></th><th>Idova 7
Iforia 3
Iforia 5/7
Ilesto 5/7</th><th>Inventra 7
Iperia 5/7
Itrevia 5/7</th><th>Ilivia 7
Intica 5/7
Inlexa 3</th><th>Acticor 7
Rivacor 3/5/7</th></tr>
<tr><td>Safio S / Setrox S
53</td><td colspan="3" rowspan="8">1.5 T FBS</td><td rowspan="15">1.5 T FBS
3.0 T FBS</td></tr>
<tr><td>Solia JT / Siello JT
45; 53</td></tr>
<tr><td>Solia S / Siello S
45; 53; 60</td></tr>
<tr><td>Linox^{smart} (ProMRI) DF4 SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Protego (ProMRI) S
65; 75</td></tr>
<tr><td>Protego (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) S
65; 75</td></tr>
<tr><td>Plexa (ProMRI) SD
65/16; 65/18; 75/18</td></tr>
<tr><td>Plexa (ProMRI) S
60</td><td rowspan="2">---</td><td colspan="2" rowspan="2">1.5 T FBS</td></tr>
<tr><td>Plexa (ProMRI) SD
60/16</td></tr>
<tr><td>Corox (ProMRI) OTW BP
75; 85</td><td colspan="3" rowspan="5">1.5 T FBS</td></tr>
<tr><td>Corox (ProMRI) OTW-S BP
75; 85</td></tr>
<tr><td>Corox (ProMRI) OTW-L BP
75; 85</td></tr>
<tr><td>Sentus (ProMRI) OTW BP L
75; 85; 95</td></tr>
<tr><td>Sentus (ProMRI) OTW BP S
75; 85; 95</td></tr>
</table>

Triple-Chamber ICDs with DF4 Connection – DX Leads

	HF-T
	Acticor 7 Rivacor 5/7
Plexa ProMRI S DX 65/15; 65/17	1.5 T FBS 3.0 T FBS
Corox (ProMRI) OTW BP 75; 85	
Corox (ProMRI) OTW-S BP 75; 85	
Corox (ProMRI) OTW-L BP 75; 85	
Sentus (ProMRI) OTW BP L 75; 85; 95	
Sentus (ProMRI) OTW BP S 75; 85; 95	

Triple-Chamber ICDs - QP Model with DF-1 Connection

	HF-T QP		
	Ilivia 7 Intica 5/7	**Ilivia Neo 7 Intica Neo 5/7**	**Inlexa 3**
Safio S / Setrox S 53	1.5 T FBS 3.0 T EXZ		1.5 T FBS
Solia JT / Siello JT 45; 53	1.5 T FBS		
Solia S / Siello S 45; 53; 60	1.5 T FBS 3.0 T EXZ		
Linox^{smart} (ProMRI) S 65; 75	1.5 T FBS		
Linox^{smart} (ProMRI) SD 65/16; 65/18; 75/18			
Protego DF-1 (ProMRI) S 65; 75			
Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18			
Plexa (ProMRI) DF-1 S 60; 65; 75	1.5 T FBS 3.0 T EXZ		
Plexa (ProMRI) DF-1 SD 60/16; 65/16; 65/18; 75/18			
Sentus (ProMRI) OTW QP L 75; 85; 95			
Sentus (ProMRI) OTW QP S 75; 85; 95			
Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95			
Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95			

Triple-Chamber ICDs - QP Model with DF-1 Connection – DX Leads

	HF-T QP	
	Ilivia 7 Intica 5/7	**Ilivia Neo 7 Intica Neo 5/7**
Linox^{smart} (ProMRI) S DX 65/15; 65/17	1.5 T FBS	
Protego DF-1 (ProMRI) S DX 65/15; 65/17		
Plexa (ProMRI) DF-1 S DX 65/15; 65/17	1.5 T FBS 3.0 T EXZ	
Sentus (ProMRI) OTW QP L 75; 85; 95		
Sentus (ProMRI) OTW QP S 75; 85; 95		
Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95		
Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95		

Triple-Chamber ICDs - QP Model with DF4 Connection

	HF-T QP			
	Inventra 7 Iperia 5/7 Itrevia 5/7	Ilivia 7 Intica 5/7	Acticor 7 Rivacor 3/5/7	Inlexa 3
Safio S / Setrox S 53	1.5 T FBS 3.0 T EXZ		1.5 T FBS 3.0 T FBS	1.5 T FBS
Solia JT / Siello JT 45; 53	1.5 T FBS			
Solia S / Siello S 45; 53; 60	1.5 T FBS 3.0 T EXZ			
Linox^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18	1.5 T FBS			
Protego (ProMRI) S 65; 75				
Protego (ProMRI) SD 65/16; 65/18; 75/18				
Plexa (ProMRI) S 60; 65; 75	1.5 T FBS 3.0 T EXZ			
Plexa (ProMRI) SD 60/16; 65/16; 65/18; 75/18				
Sentus (ProMRI) OTW QP L 75; 85; 95				
Sentus (ProMRI) OTW QP S 75; 85; 95				
Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95				
Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95				

Triple-Chamber ICDs - QP Model with DF4 Connection – DX Leads

	HF-T QP
	Acticor 7 Rivacor 5/7
Plexa ProMRI S DX 65/15; 65/17	1.5 T FBS 3.0 T FBS
Sentus (ProMRI) OTW QP L 75; 85; 95	
Sentus (ProMRI) OTW QP S 75; 85; 95	
Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95	
Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95	

5 Combinations of MR Conditional Pacemakers

General considerations

Devices and leads are sold independently of each other. You should therefore consult the following tables to determine which combinations of device and lead(s) are considered MR conditional device systems.

The conditions and requirements that must be observed for the respective combination are also indicated.

Note

For Evia, Entovis, Estella, and Ecuro models up to and including serial number 66237094, the following applies:

- A maximum slew rate of 125 T/m/s per axis
- A scan exclusion zone (see Conditions for device systems with scan exclusion zone [Page 35])
- A static magnetic field strength of 1.5 T

The abbreviations FBS and EXZ

The abbreviation **FBS** stands for **F**ull-**B**ody **S**can and means that no scan exclusion zone applies for such products.

The abbreviation **EXZ** stands for **Ex**clusion **Z**one and means that a scan exclusion zone must be observed for such products.

⚠ **WARNING**

Limitation due to lead combinations that are not MR conditional

Pacemaker-lead combinations that are not listed should be treated as non MR conditional.

Note

If a lead with scan exclusion zone is used in a device system, the conditions for the scan exclusion zone apply to the entire device system.

Single-Chamber Pacemakers

	SR and SR-T	
	Ecuro Entovis Estella Evia	**Eluna 8 Epyra 6/8 Etrinsa 6/8**
Safio S / Setrox S 45	1.5 T EXZ 3.0 T EXZ	
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T EXZ	
Solia S / Siello S 45; 53; 60		
Solia JT / Siello JT 45	1.5 T FBS	
Solia JT / Siello JT 53	1.5 T FBS 3.0 T EXZ	
Solia T / Siello T 53; 60		

	SR and SR-T	S and SR
	Edora 8 Evity 6/8 Enitra 6/8	**Enticos 4**
Safio S / Setrox S 45	1.5 T EXZ 3.0 T EXZ	1.5 T EXZ
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T FBS	1.5 T FBS
Solia S / Siello S 45	1.5 T FBS 3.0 T EXZ	
Solia S / Siello S 53; 60	1.5 T FBS 3.0 T FBS	
Solia JT / Siello JT 45	1.5 T FBS	
Solia JT / Siello JT 53	1.5 T FBS 3.0 T FBS	
Solia T / Siello T 53; 60		

Dual-Chamber Pacemakers

	DR and DR-T	
	Ecuro Entovis Estella Evia	**Eluna 8 Epyra 6/8 Etrinsa 6/8**
Safio S / Setrox S 45	1.5 T EXZ 3.0 T EXZ	
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T EXZ	
Solia S / Siello S 45; 53; 60		
Solia JT / Siello JT 45; 53		
Solia T / Siello T 53; 60		

	DR and DR-T	D and DR
	Edora 8 Evity 6/8 Enitra 6/8	**Enticos 4**
Safio S / Setrox S 45	1.5 T EXZ 3.0 T EXZ	1.5 T EXZ
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T FBS	1.5 T FBS
Solia S / Siello S 45	1.5 T FBS 3.0 T EXZ	
Solia S / Siello S 53; 60	1.5 T FBS 3.0 T FBS	
Solia JT / Siello JT 45	1.5 T FBS 3.0 T EXZ	
Solia JT / Siello JT 53	1.5 T FBS 3.0 T FBS	
Solia T / Siello T 53; 60		

Triple-Chamber Pacemakers

	HF and HF-T	
	Entovis Evia	**Eluna 8 Epyra 8 Etrinsa 8**
Safio S / Setrox S 45; 53; 60	1.5 T EXZ	
Solia S / Siello S 45; 53; 60		
Solia JT / Siello JT 45; 53		
Solia T / Siello T 53; 60		
Corox (ProMRI) OTW BP 75; 85		
Corox (ProMRI) OTW-S BP 75; 85		
Corox (ProMRI) OTW-L BP 75; 85		
Sentus (ProMRI) OTW BP L 75; 85; 95		
Sentus (ProMRI) OTW BP S 75; 85; 95		

⚠ **WARNING**

Limitation due to lead combinations that are not MR conditional

Any combination of Safio/Setrox and Solia/Siello leads with the above triple-chamber pacemakers is not an MR conditional device system.

	HF-T
	Edora 8 Evity 8 Enitra 8
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T FBS
Solia S / Siello S 45	1.5 T FBS
Solia S / Siello S 53; 60	1.5 T FBS 3.0 T FBS
Solia JT / Siello JT 45	1.5 T FBS

	HF-T
	Edora 8 Evity 8 Enitra 8
Solia JT / Siello JT 53	1.5 T FBS 3.0 T FBS
Solia T / Siello T 53; 60	
Corox (ProMRI) OTW BP 75	3.0 T FBS
Corox (ProMRI) OTW BP 85	1.5 T FBS 3.0 T FBS
Corox (ProMRI) OTW-S BP 75	3.0 T FBS
Corox (ProMRI) OTW-S BP 85	1.5 T FBS 3.0 T FBS
Corox (ProMRI) OTW-L BP 75	3.0 T FBS
Corox (ProMRI) OTW-L BP 85	1.5 T FBS 3.0 T FBS
Sentus (ProMRI) OTW BP L 75	3.0 T FBS
Sentus (ProMRI) OTW BP L 85; 95	1.5 T FBS 3.0 T FBS
Sentus (ProMRI) OTW BP S 75	3.0 T FBS
Sentus (ProMRI) OTW BP S 85; 95	1.5 T FBS 3.0 T FBS

Triple-Chamber Pacemakers - QP Model

	HF-T QP
	Edora 8 Evity 8 Enitra 8
Safio S / Setrox S 53; 60	1.5 T FBS 3.0 T FBS
Solia S / Siello S 45	1.5 T FBS
Solia S / Siello S 53; 60	1.5 T FBS 3.0 T FBS
Solia JT / Siello JT 45	1.5 T FBS
Solia JT / Siello JT 53	1.5 T FBS 3.0 T FBS
Solia T / Siello T 53; 60	
Sentus (ProMRI) OTW QP L 75; 85; 95	
Sentus (ProMRI) OTW QP S 75; 85; 95	
Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95	
Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95	

6 Full-Body Scan

Requirements for an MR Scan

An MR scan can be performed safely on patients with an MR conditional device system from BIOTRONIK only if very specific requirements and basic conditions are met.

In any other case, an MR scan is contraindicated.

Conditions for device systems without scan exclusion zone

⚠ WARNING

The following conditions are required for an MR scan:

- The device system consists of a pacemaker or an ICD with the respective leads and possibly one or more blind plug(s) that are separately labeled MR conditional and, when combined, constitute an MR conditional device system.

See Combinations of MR Conditional ICDs [Page 9]

and Combinations of MR Conditional Pacemakers [Page 27].

- Other active or passive devices are permitted if they are identified as MR conditional by the manufacturer.

Note

An MR scan is permitted only if the product-specific conditions are met for all devices and if no metal implantable device longer than 5 cm is within 4 cm of a BIOTRONIK lead.

- There are no other active or abandoned cardiac devices (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- The lead(s) has/have been implanted for at least six weeks.
- The device system was implanted pectorally.
- The measured pacing threshold is not above 2.0 V at 0.4 ms pulse width.

Note

If the pacing threshold on the LV lead exceeds 2.0 V, you can use a mode that does not cause any BiV pacing (OFF, D00, A00 or V00). Activate this MRI mode only if it is acceptable to the patient for the duration of activation.

- The determined lead impedance is between 200 and 1500 Ω.
- The battery status is neither ERI nor EOS.
- The device is programmed to an MRI mode before the MR scan.

See: MR Scan Procedure with Pacemakers and ICDs [Page 39]

Conditions during the MR scan

⚠ WARNING

The following conditions must be maintained during the MR scan:

- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- The mean specific absorption rate (SAR) for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.

Only the combination of Solia S or Siello S and pacemakers enables a mean SAR for the whole body up to 4.0 W/kg as displayed by the MRI scanner.

When used in combination with additional leads, the displayed mean SAR for the whole body must still not exceed 2.0 W/kg.

- The SAR for the head displayed by the MRI scanner must not exceed 3.2 W/kg.
- Continuously monitor the patient's condition during the entire MR scan using at least one of the following parameters: blood oxygen saturation, blood pressure or ECG.
- 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.

MRI Scanner Conditions

⚠ **WARNING**

The MRI scanner must meet the following conditions:

- Use of a clinical MRI scanner with a closed bore, cylindrical magnets, and a static magnetic field strength of 1.5 T or 3.0 T.

See: Combinations of MR Conditional ICDs [Page 9]

and Combinations of MR Conditional Pacemakers [Page 27].

- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.
- For the head and the extremities, local transmitter and receiver coils are approved for use in addition to the local receiver coils.
- Only local receiver coils may be used for the thorax.

7 Scan Exclusion Zone

Requirements for an MR Scan

An MR scan can be performed safely on patients with an MR conditional device system from BIOTRONIK only if very specific requirements and basic conditions are met.

In any other case, an MR scan is contraindicated.

Conditions for device systems with scan exclusion zone

⚠ WARNING

The following conditions are required for an MR scan:

- The device system consists of a pacemaker or an ICD with the respective leads and possibly one or more blind plug(s) that are separately labeled MR conditional and, when combined, constitute an MR conditional device system.

See Combinations of MR Conditional ICDs [Page 9]

and Combinations of MR Conditional Pacemakers [Page 27].

- Other active or passive devices are permitted if they are identified as MR conditional by the manufacturer.

Note

An MR scan is permitted only if the product-specific conditions are met for all devices and if no metal implantable device longer than 5 cm is within 4 cm of a BIOTRONIK lead.

- There are no other active or abandoned cardiac devices (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- The patient does not have a fever.
- The patient is at least 1.40 m tall.
- The lead(s) has/have been implanted for at least six weeks.
- The device system was implanted pectorally.
- The measured pacing threshold is not above 2.0 V at 0.4 ms pulse width.

Note

If the pacing threshold on the LV lead exceeds 2.0 V, you can use a mode that does not cause any BiV pacing (OFF, D00, A00 or V00). Activate this MRI mode only if it is acceptable to the patient for the duration of activation.

- The determined lead impedance is between 200 and 1500 Ω.
- The battery status is neither ERI nor EOS.
- The device is programmed to an MRI mode before the MR scan.

See: MR Scan Procedure with Pacemakers and ICDs [Page 39]

Conditions during the MR scan

⚠ WARNING

The following conditions must be maintained during the MR scan:

- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- The MR scan must only be performed with the patient in supine position.
- The permissible positioning zone and scan exclusion zone must be observed.
- The overall duration of the examination, i.e. of the imaging sequences displayed by the MRI scanner, must not exceed 30 minutes. However, an MR scan lasting longer than 30 minutes can be performed if the HF field is switched off for at least 4 minutes after 30 minutes.
- The mean specific absorption rate (SAR) for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- The SAR for the head displayed by the MRI scanner must not exceed 3.2 W/kg.
- Continuously monitor the patient's condition during the entire MR scan using at least one of the following parameters: blood oxygen saturation, blood pressure or ECG.
- 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.

MRI Scanner Conditions

⚠ WARNING

The MRI scanner must meet the following conditions:

- Use of a clinical MRI scanner with a closed bore, cylindrical magnets, and a static magnetic field strength of 1.5 T or 3.0 T.

See: Combinations of MR Conditional ICDs [Page 9]

and Combinations of MR Conditional Pacemakers [Page 27].

- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.

Note

For Evia, Entovis, Estella, and Ecuro models up to and including serial number 66237094, a maximum slew rate of 125 T/m/s per axis is valid.

- For the head and the extremities, local transmitter and receiver coils are approved for use in addition to the local receiver coils.
- Only local receiver coils may be used for the thorax.

Permissible Positioning Zone

⚠ WARNING

The permissible positioning zone explained below must always be maintained during MR scans of patients with restricted device systems.

Isocenter

Starting from the feet, the permissible positioning zone for the isocenter of the high-frequency coil is at the greater trochanter level.

Starting from the top of the skull, the permissible positioning zone for the isocenter is at the level of the eyes or the lower edge of the orbital margin.

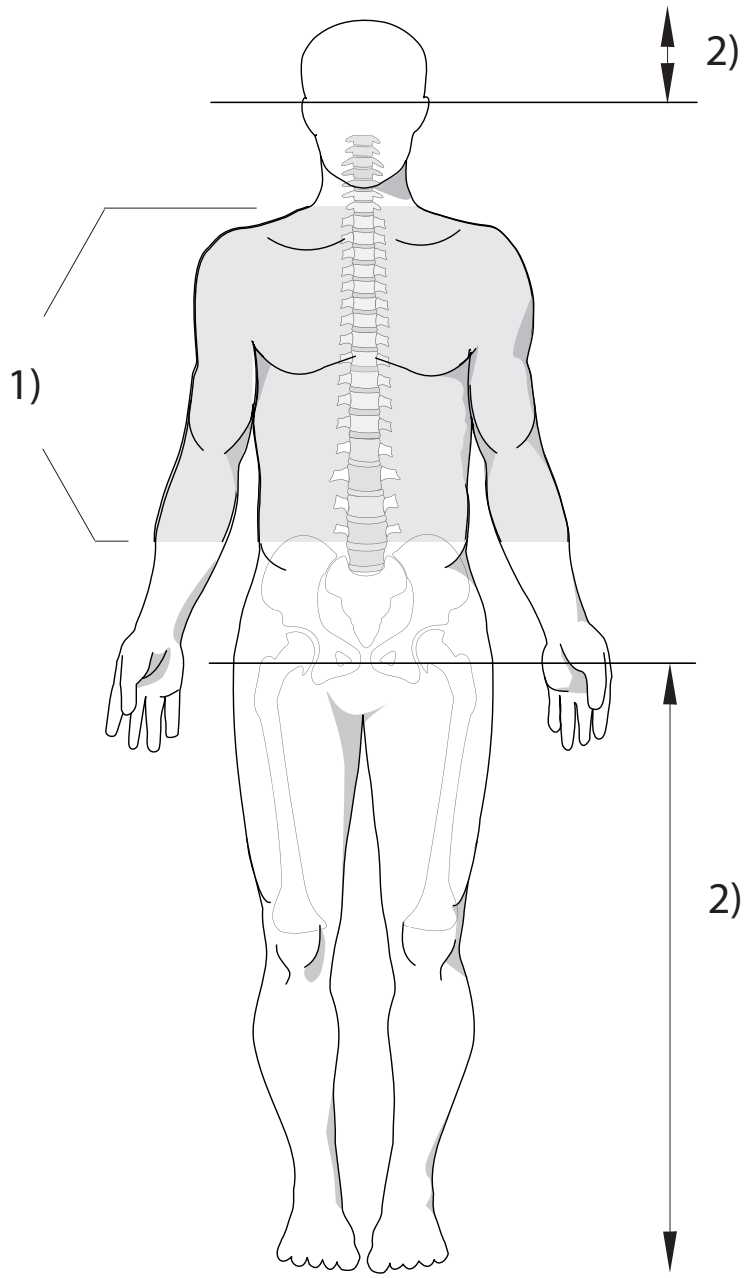
In practice, this means that the line of the MRI scanner's laser positioning marks must be within this zone.

Field of view

An MRI scanner's field of view is the area within which imaging data can be obtained.

The scan exclusion zone is determined by the MRI scanner's field of view and the size of the patient.

For device systems with scan exclusion zone, the following applies:



1	Scan exclusion zone	2	Permissible positioning zone

8 MR Scan Procedure with Pacemakers and ICDs

Preparation and performance of an MR scan on patients with a pacemaker or an ICD require close cooperation between a specialist for the device system and a specialist for the MR scan.

MRI AutoDetect Function

The MRI AutoDetect function means that the device has a sensor that recognizes the fields of an MRI scanner and automatically switches into the predefined MRI mode. The device automatically switches back into the permanent program one minute after leaving the MRI scanner.

In device systems with the MRI AutoDetect function, you can set the patient's device to the MRI program AUTO up to 2 weeks prior to the MR scan at the preliminary examination.

The device does not need to be reprogrammed after the MRI scan.

The MRI AutoDetect function is active for a maximum of 14 days from the day it is programmed and allows for an indefinite number of MRI scans during this period. The programming expires at 23:59 h of the selected day.

The following ICDs have the MRI AutoDetect function:

- Ilivia models
- Intica models
- Ilivia Neo models
- Intica Neo models
- Acticor models
- Rivacor models

The following pacemakers have the MRI AutoDetect function:

- Edora models
- Evity models
- Enitra models

Devices that have the MRI AutoDetect function can also be programmed manually as usual to the MRI mode prior to an MR scan.

The function permitting the device to be programmed to automatic MRI mode increases patient safety and simplifies the process for an MR scan.

Preparation

Patient selection

Make sure that your patient, the MRI scanner, as well as the implanted device meet the conditions for an MR scan by reading the corresponding chapter.

Check whether your patient's device system has a scan exclusion zone.

Preliminary cardiological examination

The preliminary cardiological examination is a preparatory measure for the MR scan.

1. Interrogate the device.
2. Perform full follow-up.

Check the following prerequisites for an MR scan:

- Threshold: 2.0 V / 0.4 ms max.
- Lead impedance: 200 ... 1500 Ω
- Battery status: neither ERI nor EOS

Note

If the pacing threshold on the LV lead exceeds 2.0 V, you can use a mode that does not cause any BiV pacing (OFF, D00, A00 or V00). Activate this MRI mode only if it is acceptable to the patient for the duration of activation.

⚠ WARNING

Risk of death due to deactivated ICD functions

The MRI mode causes an ICD to be unable to detect dangerous heart rhythms and deliver any therapy shocks.

An ICD patient must be continuously observed between activation of the MRI program and reactivation of the therapy program, and an external defibrillator must be kept constantly ready.

Health risk to patients due to limited pacemaker or ICD function

Continuous cardiological monitoring of the patient must be ensured until the device system's full functionality is restored in the follow-up examination.

Switching on the MRI program

1. Open the MRI program. There are 4 options:

   Select **[Follow-up]** → **[MRI]**.

   Select **[Parameters]** → **[Program sets]** → **[Show MRI program]**.

   Select **[Parameters]** → **[Bradycardia]** → **[MRI program]**.

   Select **[Parameters]** → **[Bradycardia/CRT]** → **[MRI program]**.
2. Carefully read the prerequisites and basic conditions in the **[MRI checklist]** window.
3. Switch on the MRI program.
4. Select an MRI mode.
5. Select the check box **[I accept the conditions for MRI examinations]**.
6. Select **[OK]**.
7. Select **[Program]**.

MRI AutoDetect function

1. Open the MRI program. There are 2 options:

   Select **[Follow-up]** → **[MRI]**.

   Select **[Parameters]** → **[MRI]**.
2. Make sure that the patient is approved for an MR scan by reading the information in the field **[MRI checklist]** in the left part of the window.
3. Tick the **[Patient is approved for MRI scan]** check box.
4. Select the **[AUTO]** entry from the **[MRI program]** field in the right part of the window.
5. Select **[Expiration date]** and enter a date that is not more than two weeks in the future.
6. Select an MRI mode.
7. Select **[Program]**.

With the **[Test MRI]** button, you can check the suitability of the settings for the patient before transmitting the MRI program.

If the sensor in the device detects an MRI scanner, it automatically switches to the preprogrammed MRI mode.

Note

Patient should be informed to avoid close proximity of the device to significantly larger than commonly observed magnetic fields (greater than 1 mT) while MRI AutoDetect is enabled and the "Expiration date" has not expired.

Non-compliance might result in an unintended activation of the MRI mode.

Typically, the magnetic sensor activates the MRI mode when the magnetic flux density exceeds 10 mT.

Note

If the device has the activated Home Monitoring function, a Home Monitoring-supported follow-up is performed and transmitted during the night after the MR scan.

Capture control should also be set for pacemaker-dependent patients when using the MRI AutoDetect function.

Switching on the MRI program manually

For devices with the MRI AutoDetect function, you can also switch on the MRI programming manually.

1. Open the MRI program. There are 2 options:

   Select **[Follow-up]** → **[MRI]**.

   Select **[Parameters]** → **[MRI]**.
2. Make sure that the patient is approved for an MR scan by reading the information in the field **[MRI checklist]** in the left part of the window.
3. Tick the **[Patient is approved for MRI scan]** check box.
4. Select the **[ON]** entry from the **[MRI program]** field in the right part of the window.
5. Select an MRI mode.
6. Select **[Program]**.

With the **[Test MRI]** button, you can check the suitability of the settings for the patient before transmitting the MRI program.

Radiological information

On the **[MRI]** tab you can select the parameters for the MRI program and see information about the MR scan (**[MRI checklist]**).

Using the **[Radiological information]** button, you open another window that provides important information about the MRI program and the device, including the serial number.

Print out this information and provide it to the radiologist, because without the printout, it is not possible to perform an MR scan.

Change parameters

You will leave the MRI program if you change any parameters after programming. The pacing rate can be changed without leaving the MRI program (except for: Evia, Entovis, Estella, Ecuro).

When programming the MRI mode, the original settings are saved in the device. With Evia, Entovis, Estella, and Ecuro, however, they are saved in the programmer.

After completion of the MR scan, these settings can be accessed again during the cardiological follow-up examination by repeating interrogation. This simplifies restoration of the status from before the MR scan. Please note that Evia, Entovis, Estella, Ecuro require using the same programmer as for the preliminary examination.

MRI mode pacemaker

Different MRI modes are available depending on the device and can all be selected in the **[MRI checklist]** window.

Activate one of the possible MRI modes:

- OFF – recommended for patients not dependent on their pacemaker.
- D00, A00, V00 – recommended for pacemaker-dependent patients depending on the particular indication.
- D00-BiV or V00-BiV – recommended for pacemaker-dependent patients with a triple-chamber pacemaker for biventricular pacing.

The following parameters are set on the pacemaker by the programmer:

- Pulse amplitude (A/RV): 4.8 V
- Pulse width (A/RV): 1.0 ms
- Pacing rate: adjustable from 70 to 160 bpm (preset to: 90 bpm)
- Pacing rate for Evia, Entovis, Estella, Ecuro: 80 bpm (not adjustable)
- All automatic functions are deactivated
- Home Monitoring remains active (except for: the single- and dual-chamber devices Evia, Entovis, Estella, Ecuro)
- Magnet response is set to SYNC (synchronous)
- The programmed settings for the LV lead are applied for the biventricular MRI mode (except for: Evia and Entovis)

MRI mode ICD

Different MRI modes are available depending on the device and can all be selected in the **[MRI checklist]** window.

Activate one of the possible MRI modes:

- OFF – recommended for patients not dependent on their pacemaker.
- D00, V00 – recommended for pacemaker-dependent patients depending on the particular indication.
- D00-BiV or V00-BiV – recommended for pacemaker-dependent patients with a triple-chamber ICD for biventricular pacing (except for: Lumax 640 HF-T and Lumax 740 HF-T).

The following parameters are set on the ICD by the programmer:

- Pulse amplitude (A/RV): 5.0 V
- Pulse width (A/RV): 1.0 ms
- Pacing rate: adjustable from 70 to 160 bpm (preset to: 90 bpm)
- All automatic functions are deactivated.
- ICD therapy is inactive.
- Magnet response is set to SYNC (synchronous).
- The magnet response corresponds to MRI programming V00, D00, OFF (only with the MRI AutoDetect function).
- Home Monitoring remains active.
- The programmed settings for the LV lead are applied for the biventricular MRI mode.

Performance

The MR scan can be conducted as usual if the following requirements are met:

- The contraindications listed in the respective sections as well as the necessary conditions for an MR scan have been taken into consideration.
- The patient has been previously examined by a cardiologist and the implanted device is switched to a mode especially suitable for an MR scan.
- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- For the MRI AutoDetect function, the value **[Expiration date]** was checked before the examination by the radiologist.

Follow-Up

Subsequent to the MR scan, the patient must immediately undergo cardiological follow-up.

This is necessary for the patient's safety for 2 reasons:

- The device is switched back into a mode which provides the patient with adequate therapy.
- It checks whether the device system or the heart muscle have incurred damage during the MR scan.

MRI AutoDetect function

In patients that have a device with activated Home Monitoring function, a Home Monitoring-supported follow-up is performed and transmitted to the Home Monitoring Service Center during the night after the MR scan.

The device automatically switches back into the permanent program one minute after leaving the MRI scanner.

Cardiological follow-up

The cardiological examination following an MR scan is to be performed as follows:

1. Interrogate the device.
2. Reactivate the program which was effective prior to programming the MRI mode.
3. Reactivate the ICD therapy if necessary.
4. Transmit the reactivated program to the device.
5. Perform full follow-up.
6. Conduct any further examinations.

⚠ WARNING

Risk of death for ICD patients without the MRI AutoDetect function

Reactivation of the ICD therapies may be life-saving for an ICD patient.

The patient can stop being continuously monitored and an external defibrillator no longer needs to be kept ready after the reactivation of ICD therapies has been reliably reactivated.

9 Cardiac Monitors

General considerations

In the following table you can find the conditions to be met and the requirements for the respective product.

The abbreviations FBS and EXZ

The abbreviation **FBS** stands for **F**ull-**B**ody **S**can and means that no scan exclusion zone applies for such products.

The abbreviation **EXZ** stands for **Ex**clusion **Z**one and means that a scan exclusion zone must be observed for such products.

BioMonitor	1.5 T FBS
BioMonitor 2-AF	1.5 T FBS 3.0 T FBS
BioMonitor 2-S	
BIOMONITOR III	
BIOMONITOR IIIm	

Requirements for an MR Scan

An MR scan can be performed safely on patients with an MR conditional device system from BIOTRONIK only if very specific requirements and basic conditions are met.

In any other case, an MR scan is contraindicated.

Conditions for cardiac monitors

⚠ WARNING

The following conditions are required for an MR scan:

- The cardiac monitor is labeled and certified MR conditional.
- Other active or passive devices are permitted if they are identified as MR conditional by the manufacturer.

Note

An MR scan is permitted only if the product-specific conditions are met for all devices and if no metal implantable device longer than 5 cm is within 4 cm of the cardiac monitor.

- There are no other active or abandoned cardiac devices (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- The device system was implanted pectorally.

Conditions during the MR scan

⚠ WARNING

The following conditions must be maintained during the MR scan:

- The MR scan must only be performed with the patient in supine position (not applicable to the BIOMONITOR III and BIOMONITOR IIIm).
- The mean specific absorption rate (SAR) for the whole body as displayed by the MRI scanner must not exceed 2.0 W/kg with BioMonitor.
  BioMonitor 2, BIOMONITOR III, and BIOMONITOR IIIm, however, allow for an SAR up to 4.0 W/kg.
- The SAR for the head displayed by the MRI scanner must not exceed 3.2 W/kg.

MRI Scanner Conditions

⚠ WARNING

The MRI scanner must meet the following conditions:

- Use of a clinical MRI scanner with a closed bore, cylindrical magnets, and a static magnetic field strength of 1.5 T or 3.0 T.

See table in the Cardiac Monitors chapter.

- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.
- For the head and the extremities, local transmitter and receiver coils are approved for use in addition to the local receiver coils.
- Only local receiver coils may be used for the thorax.

10 MR Scan Procedure with Cardiac Monitors

Preparation and Performance

Preparation and performance of an MR scan on patients with a cardiac monitor require close cooperation between a specialist for the device and a specialist for the MR scan.

Patient selection

Make sure that your patient, the MRI scanner, as well as the implanted device meet the conditions for an MR scan by reading the corresponding chapter.

Requirements for an MR Scan [Page 45]

Preparation

Note

Prior to the MR scan, save the device data using the programmer; the data saved in the device may be overwritten during the MR scan.

Performance

The MR scan can be conducted as usual if the following requirements are met:

- The contraindications listed in the respective sections as well as the necessary conditions for an MR scan have been taken into consideration.
- The patient has been previously examined by a physician.

⚠ Caution

Invalid recordings

After the MR scan, the cardiac monitor's memory may contain invalid data due to possible interactions between the MRI scanner and the implanted device.

Recordings stored during an MR scan should be discarded.

11 Overview of MR Conditional Products

In the following you will find an overview of those BIOTRONIK products that have been tested under the conditions of an MR scan and have been approved as MR conditional.

However, only very specific combinations of devices and leads are approved as MR conditional device systems.

You can find more detailed information on this topic in the relevant chapters:

- Combinations of MR Conditional ICDs [Page 9]
- Combinations of MR Conditional Pacemakers [Page 27]
- Cardiac Monitors [Page 45]

ICDs

The following **ICDs** are MR conditional:

Ilivia Neo models

Model	Order number
Ilivia Neo 7 VR-T	429531
Ilivia Neo 7 VR-T DX	429530
Ilivia Neo 7 DR-T	429529
Ilivia Neo 7 HF-T	429528
Ilivia Neo 7 HF-T QP	429527

Intica Neo models

Model	Order number
Intica Neo 7 VR-T	429560
Intica Neo 7 VR-T DX	429559
Intica Neo 7 DR-T	429558
Intica Neo 7 HF-T	429553
Intica Neo 7 HF-T QP	429552
Intica Neo 5 VR-T	429570
Intica Neo 5 VR-T DX	429569
Intica Neo 5 DR-T	429568
Intica Neo 5 HF-T	429567
Intica Neo 5 HF-T QP	429566

Acticor models

Model	Order number
Acticor 7 VR-T	429526
Acticor 7 VR-T DX	429525
Acticor 7 DR-T	429524
Acticor 7 HF-T	429523
Acticor 7 HF-T QP	429522

Rivacor models

Model	Order number
Rivacor 3 VR-T	429574
Rivacor 3 DR-T	429573
Rivacor 3 HF-T	429572
Rivacor 3 HF-T QP	429571
Rivacor 5 VR-T	429565
Rivacor 5 VR-T DX	429564
Rivacor 5 DR-T	429563
Rivacor 5 HF-T	429562
Rivacor 5 HF-T QP	429561
Rivacor 7 VR-T	429536
Rivacor 7 VR-T DX	429535
Rivacor 7 DR-T	429534
Rivacor 7 HF-T	429533
Rivacor 7 HF-T QP	429532

Ilivia models

Model	Order number: DF-1 connection	Order number: DF4 connection
Ilivia 7 VR-T	404625	404626
Ilivia 7 VR-T DX	404624	------
Ilivia 7 DR-T	404622	404623
Ilivia 7 HF-T	404601	404602
Ilivia 7 HF-T QP	404620	404621

Intica models

Model	Order number: DF-1 connection	Order number: DF4 connection
Intica 7 VR-T	404634	404635
Intica 7 VR-T DX	404633	------
Intica 7 DR-T	404631	404632
Intica 7 HF-T	404627	404628
Intica 7 HF-T QP	404629	404630
Intica 5 VR-T	404689	404690
Intica 5 VR-T DX	404688	------
Intica 5 DR-T	404686	404687
Intica 5 HF-T	404683	404684
Intica 5 HF-T QP	406932	404685

Inlexa models

Model	Order number: DF-1 connection	Order number: DF4 connection
Inlexa 3 VR-T	404703	404704
Inlexa 3 DR-T	404701	404702
Inlexa 3 HF-T	404699	404700
Inlexa 3 HF-T QP	416037	416038

Inventra models

Model	Order number: DF-1 connection	Order number: DF4 connection
Inventra 7 VR-T	399442	399440
Inventra 7 VR-T DX	399436	------
Inventra 7 DR-T	399430	399428
Inventra 7 HF-T	393019	393020
Inventra 7 HF-T QP	------	393011

Iperia models

Model	Order number: DF-1 connection	Order number: DF4 connection
Iperia 7 VR-T	393034	393030
Iperia 7 VR-T DX	393032	------
Iperia 7 DR-T	392409	392423
Iperia 7 HF-T	393007	393009
Iperia 7 HF-T QP	------	401657
Iperia 5 VR-T	393050	393051
Iperia 5 VR-T DX	393048	------
Iperia 5 DR-T	392418	392419
Iperia 5 HF-T	393027	393025
Iperia 5 HF-T QP	------	402656

Itrevia models

Model	Order number: DF-1 connection	Order number: DF4 connection
Itrevia 7 VR-T	393038	393039
Itrevia 7 VR-T DX	393036	------
Itrevia 7 DR-T	392411	392425
Itrevia 7 HF-T	393013	393015
Itrevia 7 HF-T QP	------	401661
Itrevia 5 VR-T	393056	393057
Itrevia 5 VR-T DX	393054	------
Itrevia 5 DR-T	392416	392421
Itrevia 5 HF-T	393065	393063
Itrevia 5 HF-T QP	------	402657

Idova models

Model	Order number: DF-1 connection	Order number: DF4 connection
Idova 7 VR-T	383592	383593
Idova 7 VR-T DX	383601	------
Idova 7 DR-T	383576	383577
Idova 7 HF-T	383560	383561

Iforia models

Model	Order number: DF-1 connection	Order number: DF4 connection
Iforia 7 VR-T	390083	390089
Iforia 7 VR-T DX	390095	------
Iforia 7 DR-T	390069	390075
Iforia 7 HF-T	390056	390062
Iforia 5 VR-T	390119	390121
Iforia 5 VR-T DX	390123	------
Iforia 5 DR-T	390115	390117
Iforia 5 HF-T	390111	390113
Iforia 3 VR-T	391919	391920
Iforia 3 DR-T	391917	391918
Iforia 3 HF-T	391915	391916

Ilesto models

Model	Order number: DF-1 connection	Order number: DF4 connection
Ilesto 7 VR-T	390082	390088
Ilesto 7 VR-T DX	390094	------
Ilesto 7 DR-T	390068	390074
Ilesto 7 HF-T	390055	390061
Ilesto 5 VR-T	390118	390120
Ilesto 5 VR-T DX	390122	------
Ilesto 5 DR-T	390114	390116
Ilesto 5 HF-T	390110	390112

Lumax models

Model	Order number
Lumax 740 VR-T	381459
Lumax 740 VR-T DX	381463
Lumax 740 DR-T	381461
Lumax 740 HF-T	381462
Lumax 640 VR-T	381468
Lumax 640 VR-T DX	381472
Lumax 640 DR-T	381470
Lumax 640 HF-T	381471

Pacemakers

The following **pacemakers** are MR conditional:

Edora models

Model	Order number
Edora 8 SR-T	407157
Edora 8 SR	407164
Edora 8 DR-T	407145
Edora 8 DR	407152
Edora 8 HF-T	407138
Edora 8 HF-T QP	407137

Evity models

Model	Order number
Evity 8 SR-T	407158
Evity 8 DR-T	407146
Evity 8 HF-T	407140
Evity 8 HF-T QP	407139
Evity 6 SR-T	407161
Evity 6 DR-T	407149

Enitra models

Model	Order number
Enitra 8 SR-T	407159
Enitra 8 DR-T	407147
Enitra 8 HF-T	407142
Enitra 8 HF-T QP	407141
Enitra 6 SR-T	407162
Enitra 6 SR	407165
Enitra 6 DR-T	407150
Enitra 6 DR	407153

Enticos models

Model	Order number
Enticos 4 S	407168
Enticos 4 SR	407167
Enticos 4 D	407156
Enticos 4 DR	407155

Eluna models

Model	Order number
Eluna 8 SR-T	394971
Eluna 8 SR	394972
Eluna 8 DR-T	394969
Eluna 8 DR	394970
Eluna 8 HF-T	394968

Epyra models

Model	Order number
Epyra 8 SR-T	394975
Epyra 8 DR-T	394974
Epyra 8 HF-T	394973
Epyra 6 SR-T	394980
Epyra 6 DR-T	394979

Etrinsa models

Model	Order number
Etrinsa 8 SR-T	394978
Etrinsa 8 DR-T	394977
Etrinsa 8 HF-T	394976
Etrinsa 6 SR-T	394983
Etrinsa 6 SR	394984
Etrinsa 6 DR-T	394981
Etrinsa 6 DR	394982

Note

For Evia, Entovis, Estella, and Ecuro models up to and including serial number 66237094, the following applies:

- A maximum slew rate of 125 T/m/s per axis
- A scan exclusion zone (see Conditions for device systems with scan exclusion zone [Page 35])
- A static magnetic field strength of 1.5 T

Evia models

Model	Order number: uncoated	Order number: coated
Evia SR-T	371998	372034
Evia SR	371997	372033
Evia DR-T	371996	372032
Evia DR	371995	372031
Evia HF-T	381534	381535
Evia HF	381532	381533

Entovis models

Model	Order number: uncoated	Order number: coated
Entovis SR-T	371994	372030
Entovis SR	371993	372029
Entovis DR-T	371992	372028
Entovis DR	371991	372027
Entovis HF-T	381530	381531
Entovis HF	381528	381529

Estella models

Model	Order number: uncoated	Order number: coated
Estella SR-T	377387	377386
Estella SR	377385	377384
Estella DR-T	377383	377382
Estella DR	377381	377380

Ecuro models

Model	Order number: uncoated	Order number: coated
Ecuro SR-T	377371	377370
Ecuro SR	377369	377368
Ecuro DR-T	377367	377366
Ecuro DR	377365	377364

Cardiac Monitors

The following **cardiac monitors** are MR conditional:

BioMonitor

Model	Order number
BioMonitor	394119

BioMonitor 2

Model	Order number
BioMonitor 2-AF	398493
BioMonitor 2-S	398494

BIOMONITOR III

Model	Order number
BIOMONITOR III	436066

BIOMONITOR IIIm

Model	Order number
BIOMONITOR IIIm	450218

Please also refer to the respective chapters: Requirements for an MR Scan [Page 45] and MRI Scanner Conditions [Page 46].

ICD Leads

The following **leads** are MR conditional:

ICD lead Plexa (ProMRI) DF-1 S

Model	Order number
Plexa ProMRI DF-1 S 60	413996
Plexa ProMRI DF-1 S 65	413997
Plexa ProMRI DF-1 S 75	413998
Plexa DF-1 S 60	395707
Plexa DF-1 S 65	395708
Plexa DF-1 S 75	395709

ICD lead Plexa (ProMRI) DF-1 SD

Model	Order number
Plexa ProMRI DF-1 SD 60/16	413999
Plexa ProMRI DF-1 SD 65/16	414000
Plexa ProMRI DF-1 SD 65/18	414001
Plexa ProMRI DF-1 SD 75/18	414002
Plexa DF-1 SD 60/16	395703
Plexa DF-1 SD 65/16	395704
Plexa DF-1 SD 65/18	395705
Plexa DF-1 SD 75/18	395706

ICD lead Plexa (ProMRI) DF-1 S DX

Model	Order number
Plexa ProMRI DF-1 S DX 65/15	414005
Plexa ProMRI DF-1 S DX 65/17	414006
Plexa DF-1 S DX 65/15	395710
Plexa DF-1 S DX 65/17	395711

ICD lead Plexa (ProMRI) S

Model	Order number
Plexa ProMRI S 60	402265
Plexa ProMRI S 65	402266
Plexa ProMRI S 75	402267
Plexa S 60	395722
Plexa S 65	395723
Plexa S 75	395724

ICD lead Plexa ProMRI S DX

Model	Order number
Plexa ProMRI S DX 65/15	436909
Plexa ProMRI S DX 65/17	436910

ICD lead Plexa (ProMRI) SD

Model	Order number
Plexa ProMRI SD 60/16	402261
Plexa ProMRI SD 65/16	402262
Plexa ProMRI SD 65/18	402263
Plexa ProMRI SD 75/18	402264
Plexa SD 60/16	395718
Plexa SD 65/16	395719
Plexa SD 65/18	395720
Plexa SD 75/18	395721

ICD lead Linox^{smart} (ProMRI) S

Model	Order number
Linox^{smart} ProMRI S 65	377166
Linox^{smart} ProMRI S 75	377167
Linox^{smart} S 65	369818
Linox^{smart} S 75	369819

ICD lead Linox^{smart} (ProMRI) SD

Model	Order number
Linox^{smart} ProMRI SD 65/16	377169
Linox^{smart} ProMRI SD 65/18	377170
Linox^{smart} ProMRI SD 75/18	377171
Linox^{smart} SD 65/16	359066
Linox^{smart} SD 65/18	359067
Linox^{smart} SD 75/18	359068

ICD lead Linox^{smart} (ProMRI) S DX

Model	Order number
Linox^{smart} ProMRI S DX 65/15	377211
Linox^{smart} ProMRI S DX 65/17	377212
Linox^{smart} S DX 65/15	365500
Linox^{smart} S DX 65/17	365501

ICD lead Linox^{smart} (ProMRI) DF4 SD

Model	Order number
Linox^{smart} ProMRI DF4 SD 65/16	394102
Linox^{smart} ProMRI DF4 SD 65/18	394103
Linox^{smart} ProMRI DF4 SD 75/18	394104
Linox^{smart} DF4 SD 65/16	359070
Linox^{smart} DF4 SD 65/18	359071
Linox^{smart} DF4 SD 75/18	359072

ICD lead Protego DF-1 (ProMRI) S

Model	Order number
Protego DF-1 ProMRI S 65	414062
Protego DF-1 ProMRI S 75	414063
Protego DF-1 S 65	414028
Protego DF-1 S 75	414030

ICD lead Protego DF-1 (ProMRI) SD

Model	Order number
Protego DF-1 ProMRI SD 65/16	414058
Protego DF-1 ProMRI SD 65/18	414059
Protego DF-1 ProMRI SD 75/18	414060
Protego DF-1 SD 65/16	414015
Protego DF-1 SD 65/18	414016
Protego DF-1 SD 75/18	414017

ICD lead Protego DF-1 (ProMRI) S DX

Model	Order number
Protego DF-1 ProMRI S DX 65/15	414064
Protego DF-1 ProMRI S DX 65/17	414065
Protego DF-1 S DX 65/15	414031
Protego DF-1 S DX 65/17	414032

ICD lead Protego (ProMRI) S

Model	Order number
Protego ProMRI S 65	394099
Protego ProMRI S 75	394100
Protego S 65	379969
Protego S 75	379968

ICD lead Protego (ProMRI) SD

Model	Order number
Protego ProMRI SD 65/16	399414
Protego ProMRI SD 65/18	399415
Protego ProMRI SD 75/18	399416
Protego SD 65/16	399409
Protego SD 65/18	399410
Protego SD 75/18	399411

Left Ventricular Leads

The following **leads** are MR conditional:

Left ventricular lead Corox (ProMRI) OTW

Model	Order number
Corox ProMRI OTW 75-BP	381487
Corox ProMRI OTW 85-BP	381488
Corox OTW 75-BP	354805
Corox OTW 85-BP	354807
Corox ProMRI OTW-L 75-BP	381492
Corox ProMRI OTW-L 85-BP	381491
Corox OTW-L 75-BP	368345
Corox OTW-L 85-BP	368346
Corox ProMRI OTW-S 75-BP	381489
Corox ProMRI OTW-S 85-BP	381490
Corox OTW-S 75-BP	355148
Corox OTW-S 85-BP	355149

Left ventricular lead Sentus (ProMRI) OTW

Model	Order number
Sentus ProMRI OTW BP L-75	398676
Sentus ProMRI OTW BP L-85	398677
Sentus ProMRI OTW BP L-95	398678
Sentus OTW BP L-75	372330
Sentus OTW BP L-85	372331
Sentus OTW BP L-95	372332
Sentus ProMRI OTW BP S-75	401176
Sentus ProMRI OTW BP S-85	401177
Sentus ProMRI OTW BP S-95	401178
Sentus OTW BP S-75	400722
Sentus OTW BP S-85	400723
Sentus OTW BP S-95	400724

Model	Order number
Sentus ProMRI OTW QP L-75	401182
Sentus ProMRI OTW QP L-85	401183
Sentus ProMRI OTW QP L-95	401184
Sentus OTW QP L-75	386835
Sentus OTW QP L-85	386836
Sentus OTW QP L-95	386837
Sentus ProMRI OTW QP S-75	401179
Sentus ProMRI OTW QP S-85	401180
Sentus ProMRI OTW QP S-95	401181
Sentus OTW QP S-75	400719
Sentus OTW QP S-85	400720
Sentus OTW QP S-95	400721
Sentus ProMRI OTW QP L-75/49	408718
Sentus ProMRI OTW QP L-85/49	408719
Sentus ProMRI OTW QP L-95/49	408720
Sentus OTW QP L-75/49	408715
Sentus OTW QP L-85/49	408716
Sentus OTW QP L-95/49	408717
Sentus ProMRI OTW QP S-75/49	406081
Sentus ProMRI OTW QP S-85/49	406082
Sentus ProMRI OTW QP S-95/49	406083
Sentus OTW QP S-75/49	406078
Sentus OTW QP S-85/49	406079
Sentus OTW QP S-95/49	406080

Pacemaker Leads

The following **leads** are MR conditional:

Pacemaker lead Safio S

Model	Order number
Safio S 45	370944
Safio S 53	370945
Safio S 60	370946

Pacemaker lead Setrox S

Model	Order number
Setrox S 45	350973
Setrox S 53	350974
Setrox S 60	350975

Pacemaker lead Siello S

Model	Order number
Siello S 45	362700
Siello S 53	362701
Siello S 60	362702

Pacemaker lead Siello T

Model	Order number
Siello T 53	362705
Siello T 60	362706

Pacemaker lead Siello JT

Model	Order number
Siello JT 45	362703
Siello JT 53	362704

Pacemaker lead Solia S

Model	Order number
Solia S 45	377176
Solia S 53	377177
Solia S 60	377179

Pacemaker lead Solia T

Model	Order number
Solia T 53	377180
Solia T 60	377181

Pacemaker lead Solia JT

Model	Order number
Solia JT 45	399626
Solia JT 53	395134

Blind Plugs

The following **blind plugs** are MR conditional:

⚠ WARNING

Included BIOTRONIK blind plugs are approved as MR conditional. BIOTRONIK BS IS-1 and BS IS4 blind plugs are certified as MR conditional when used in the LV connector port of the respective device.
BIOTRONIK BS IS-1 blind plugs are certified as MR conditional when used in the atrial connection of the respective triple-chamber device (exception: Lumax 640 HF-T and Lumax 740 HF-T).

Model	Order number
Blind plug BS IS4 (single pack)	403725
Blind plug BS IS4 (pack of 5)	403724
Blind plug BS IS-1 (single pack)	395081
Blind plug BS IS-1 (pack of 10)	330834
Blind plug BS DF-1 (single pack)	395082
Blind plug BS DF-1 (pack of 10)	119602