

ProMRI

MR conditional device systems

Technical Manual

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1 Basic Information

About this Technical Manual

Subject matter of this technical manual

This technical manual provides information on safely conducting an MRI 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 MRI 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 MRI scan under certain conditions.

A primary factor for an MRI 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 package can be examined using an MRI 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 MRI 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.

Intended Medical Purpose

Target group

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

Preparation and performance of an MRI 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 MRI 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 MRI scan.

Radiologist

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

In particular, they must be familiar with MRI scanners and the preparation and performance of MRI scans.

Intended Medical Purpose

Device system

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

Safety Messages 2

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

Restrictions and special conditions for an MRI 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 MRI 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 MRI 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 MRI 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 MRI scan and imaging:

Force of the Static Magnetic Fields 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 MRI 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 MRI 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 MRI 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 MRI scans which do not result from interactions with a device system.

3 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

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 Full-Body Scan and means that no scan exclusion zone applies for such products.

The abbreviation EXZ stands for Exclusion Zone and means that a scan exclusion zone must be observed for such products.

MARNING

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

| | VR-T | | | |
|--------------------------------------------------------|-------------------------------------|-----------------------------------------|------------------------|--------------------------------|
| | 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 65; 75 | 1.5 T FBS 3.0 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 | | | | |
| 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 | | 3.0 T EXZ | | |

| | VR-T | | | |
|--------------------------------------------------------|-----------|-----------|--|--|
| | Iforia 3 | Inlexa 3 | | |
| Linox ^{smart} (ProMRI) S 65; 75 | | | | |
| Linox ^{smart} (ProMRI) SD 65/16; 65/18; 75/18 | 4.5.7 | | | |
| Protego DF-1 (ProMRI) S 65; 75 | | EDC | | |
| Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18 | 1.5 T FBS | | | |
| 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 | | 1.51 FD3 | | |

| | VR-T |
|--------------------------------------------------------|------------------------|
| | Lumax 740 Lumax 640 |
| Linox ^{smart} (ProMRI) S 65; 75 | |
| Linox ^{smart} (ProMRI) SD 65/16; 65/18; 75/18 | 1.5 T EXZ |
| Protego DF-1 (ProMRI) S 65; 75 | 1.0 I LAZ |
| 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 | | | | |
| | | | | |
| | | V | R-T DX | |

| | 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 | I.J I LAZ | |

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 | | | | |
| Protego (ProMRI) S 65; 75 | | | | |
| Protego (ProMRI) SD 65/16; 65/18; 75/18 | | | 1.5 T FBS 3.0 T FBS | |
| Plexa (ProMRI) S 65; 75 | | | | |
| Plexa (ProMRI) SD 65/16; 65/18; 75/18 | | | | |
| Plexa (ProMRI) S 60 | 1.5 T FBS | 1.5 T FBS 3.0 T EXZ | | |
| Plexa (ProMRI) SD 60/16 | | | | |
| Pamira S 60; 65; 75 | | | 1.5 T FBS | |
| Pamira SD 60/16; 65/16; 65/18; 75/18 | | | 3.0 T EXZ | |

| | VR-T | | |
|---------------------------------------------------------------|-----------|-----------|--|
| | Iforia 3 | Inlexa 3 | |
| 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 | 1.5 T FBS | | |
| 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 | | 1.3 1 FD3 | |

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 |
| Pamira S DX 65/15; 65/17 | 3.0 T FBS |

Dual-Chamber ICDs with DF-1 Connection

| | DR-T | | | |
|-----------------------------------------------------------|-------------------------------------|-----------------------------------------|------------------------|--------------------------------|
| | 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 |
| Safio S / Setrox S 53 | | | | |
| 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 | 1.5 T FBS 3.0 T EXZ | | | |
| 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 | | 3.0 T EXZ | | |

| | DR-T | | |
|--------------------------------------------------------|----------|------------|--|
| | Iforia 3 | Inlexa 3 | |
| Safio S / Setrox S 53 | | | |
| 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 | 1.5 T | FBS | |
| 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 | | נסח ו נו.ו | |
| | | | |

| | DR-T | | | |
|-----------------------------------------------------------|------------------------|--|--|--|
| | Lumax 740 Lumax 640 | | | |
| Solia S / Siello S 45; 53; 60 | | | | |
| Linox ^{smart} (ProMRI) S 65; 75 | | | | |
| Linox ^{smart} (ProMRI) SD 65/16; 65/18; 75/18 | 1.5 T EXZ | | | |
| Protego DF-1 (ProMRI) S 65; 75 | | | | |
| Protego DF-1 (ProMRI) SD 65/16; 65/18; 75/18 | | | | |

Dual-Chamber ICDs with DF4 Connection

| | | | DR-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 |
| Safio S / Setrox S 53 | | | | |
| Solia JT / Siello JT 45; 53 | | | | |
| Solia S / Siello S 45; 53; 60 | | | | |
| Linox ^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18 | | 1.5 T FBS | | 1.5 T FBS |
| Protego (ProMRI) S 65; 75 | 3.0 T EXZ | | | |
| Protego (ProMRI) SD 65/16; 65/18; 75/18 | | | 1.5 T FBS | 1.5 T FBS |
| Plexa (ProMRI) S 65; 75 | | | 3.0 T FE | 3.0 T FBS |
| Plexa (ProMRI) SD 65/16; 65/18; 75/18 | | | | |
| Plexa (ProMRI) S 60 | | 1.5 T FBS | | |
| Plexa (ProMRI) SD 60/16 | | 3.0 T I | EXZ | |
| Pamira S 60; 65; 75 | | | 1.5 T FBS | |
| Pamira SD 60/16; 65/16; 65/18; 75/18 | | | 3.0 T EXZ | |

| | DR | ?- T | | |
|---------------------------------------------------------------|-----------|-------------|--|--|
| | Iforia 3 | Inlexa 3 | | |
| Safio S / Setrox S 53 | | | | |
| Solia JT / Siello JT 45; 53 | | | | |
| Solia S / Siello S 45; 53; 60 | 1.5 T FBS | | | |
| 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 | | 1.31703 | | |

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 | | | | | |
| 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 | 1.5 T FBS | | | | |
| 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 | | | | 1.5 T FBS | |
| Plexa (ProMRI) DF-1 SD 65/16; 65/18; 75/18 | | | 1.3 1 FD3 | | |
| Plexa (ProMRI) DF-1 S 60 | | | | | |
| Plexa (ProMRI) DF-1 SD 60/16 | | | | | |
| Corox (ProMRI) OTW BP 75; 85 | | | | | |
| Corox (ProMRI) OTW-S BP 75; 85 | | | | | |
| Corox (ProMRI) OTW-L BP 75; 85 | 1.5 T FBS | | | | |
| 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 | |
| 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 | 4 F T EV7 |
| Corox (ProMRI) OTW BP 75; 85 | 1.5 T EXZ |
| 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 | | |
| 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 | 15.7 | FBS |
| Corox (ProMRI) OTW-S BP 75; 85 | 1.0 1 | 1 00 |
| 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

| | | | 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 | Acticor 7 Rivacor 3/5/7 |
| Safio S / Setrox S 53 | | | | |
| Solia JT / Siello JT 45; 53 | | | | |
| Solia S / Siello S 45; 53; 60 | | | | |
| Linox ^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18 | 4.5.7.500 | | | |
| Protego (ProMRI) S 65; 75 | | 1.5 T FBS | | |
| Protego (ProMRI) SD 65/16; 65/18; 75/18 | | | | |
| Plexa (ProMRI) S 65; 75 | | | | |
| Plexa (ProMRI) SD 65/16; 65/18; 75/18 | | | | |
| Pamira S 60; 65; 75 | | | 1.5 T FBS | 1.5 T FBS 3.0 T FBS |
| Pamira SD 60/16; 65/16; 65/18; 75/18 | | | 1.5 1 FDS | |
| Plexa (ProMRI) S 60 | | 1.5 T F | -DC | |
| Plexa (ProMRI) SD 60/16 | | 1.5.11 | -03 | |
| Corox (ProMRI) OTW BP 75; 85 | | | | |
| Corox (ProMRI) OTW-S BP 75; 85 | 1.5 T FBS | | | |
| 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 – DX Leads

| | HF-T |
|----------------------------------------|--------------------------|
| | Acticor 7 Rivacor 5/7 |
| Plexa ProMRI S DX 65/15; 65/17 | |
| Pamira S DX 65/15; 65/17 | |
| Corox (ProMRI) OTW BP 75; 85 | |
| Corox (ProMRI) OTW-S BP 75; 85 | 1.5 T FBS 3.0 T FBS |
| 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 | | FBS | |
| Solia JT / Siello JT 45; 53 | 1.5 T | FBS | |
| Solia S / Siello S 45; 53; 60 | | FBS | |
| 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 | | | 1.5 T FBS |
| Plexa (ProMRI) DF-1 S 60; 65; 75 | | | |
| Plexa (ProMRI) DF-1 SD 60/16; 65/16; 65/18; 75/18 | 1.5 T FBS | | |
| Sentus (ProMRI) OTW QP L 75; 85; 95 | | | |
| Sentus (ProMRI) OTW QP S 75; 85; 95 | 3.0 T EXZ | | |
| 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 | ERS | |
| Protego DF-1 (ProMRI) S DX 65/15; 65/17 | 1.5 T FBS | | |
| Plexa (ProMRI) DF-1 S DX 65/15; 65/17 | | | |
| Sentus (ProMRI) OTW QP L 75; 85; 95 | | | |
| Sentus (ProMRI) OTW QP S 75; 85; 95 | 1.5 T FBS 3.0 T EXZ | | |
| 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 | | T FBS T EXZ | | |
| Solia JT / Siello JT 45; 53 | 1.5 | T FBS | | |
| Solia S / Siello S 45; 53; 60 | | T FBS I T EXZ | | |
| Linox ^{smart} (ProMRI) DF4 SD 65/16; 65/18; 75/18 | | | | |
| Protego (ProMRI) S 65; 75 | 1.5 T FBS | | 1.5 T FBS 1.5 T FBS 3.0 T EXZ 3.0 T FBS | |
| Protego (ProMRI) SD 65/16; 65/18; 75/18 | | | | |
| Plexa (ProMRI) S 60; 65; 75 | | | | 1 5 T FDC |
| Plexa (ProMRI) SD 60/16; 65/16; 65/18; 75/18 | | | | 1.5 T FBS |
| Pamira S 60; 65; 75 | 1.5 T FBS | | | |
| Pamira SD 60/16; 65/16; 65/18; 75/18 | | 3.0 T EXZ | | |
| Sentus (ProMRI) OTW QP L 75; 85; 95 | 1.5 T FBS 3.0 T EXZ | | | |
| Sentus (ProMRI) OTW QP S 75; 85; 95 | | | 1.5 T FBS | |
| 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 | |
| Pamira S DX 65/15; 65/17 | |
| Sentus (ProMRI) OTW QP L 75; 85; 95 | 1.5 T FBS |
| Sentus (ProMRI) OTW QP S 75; 85; 95 | 3.0 T FBS |
| Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95 | |
| Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95 | |

Combinations of MR Conditional Pacemakers 4

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

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 33]]
- A static magnetic field strength of 1.5 T

The abbreviations FBS and EXZ

The abbreviation FBS stands for Full-Body Scan and means that no scan exclusion zone applies for such products.

The abbreviation EXZ stands for Exclusion Zone 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 3.0 T | |
| Safio S / Setrox S 53; 60 | 1.5 T | FBS |
| Solia S / Siello S 45; 53; 60 | 3.0 T EXZ | EXZ |
| Solia JT / Siello JT 45 | 1.5 T | FBS |
| Solia JT / Siello JT 53 | 1.5 T FBS 3.0 T EXZ | FBS |
| Solia T / Siello T 53; 60 | | EXZ |

| | 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 | |
| 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 | 1.5 T FBS |
| Solia JT / Siello JT 45 | 1.5 T FBS | 1.3 1 FB3 |
| Solia JT / Siello JT 53 | 1.5 T FBS | |
| Solia T / Siello T 53; 60 | 3.0 T FBS | |

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 3.0 T | |
| Safio S / Setrox S 53; 60 | 1.5 T FBS 3.0 T EXZ | |
| Solia S / Siello S 45; 53; 60 | | FBS |
| Solia JT / Siello JT 45; 53 | | EXZ |
| 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 | |
| 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 | 1.5 T FBS |
| Solia JT / Siello JT 45 | 1.5 T FBS 3.0 T EXZ | 1.3 1 1 03 |
| 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 | | |
| 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 | 1.5 T | EXZ |
| 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 Pacemakers

⚠ 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.

| 13 Hot all Mix conditional device system. | WF 7 |
|-------------------------------------------|--------------------------------|
| | 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 |
| Solia JT / Siello JT 53 | 1.5 T FBS |
| Solia T / Siello T 53; 60 | 3.0 T FBS |
| 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 | 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 | |
| Solia T / Siello T 53; 60 | |
| Sentus (ProMRI) OTW QP L 75; 85; 95 | 1.5 T FBS |
| Sentus (ProMRI) OTW QP S 75; 85; 95 | 3.0 T FBS |
| Sentus (ProMRI) OTW QP L-XX/49 75; 85; 95 | |
| Sentus (ProMRI) OTW QP S-XX/49 75; 85; 95 | |

Full-Body Scan 5

Requirements for an MRI Scan

An MRI 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 MRI scan is contraindicated.

Conditions for device systems without scan exclusion zone



MARNING

The following conditions are required for an MRI 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 7]

and Combinations of MR Conditional Pacemakers [Page 25].

Other active or passive devices 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 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 MRI scan.

See MRI Scan Procedure with Pacemakers and ICDs [Page 37].

Conditions during the MRI scan

↑ WARNING

The following conditions must be maintained during the MRI 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 MRI 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

MARNING

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 7]

and Combinations of MR Conditional Pacemakers [Page 25].

- 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.

Scan Exclusion Zone 6

Requirements for an MRI Scan

An MRI 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 MRI scan is contraindicated.

Conditions for device systems with scan exclusion zone



MARNING

The following conditions are required for an MRI 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 7]

and Combinations of MR Conditional Pacemakers [Page 25].

Other active or passive devices 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 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 MRI scan.

See MRI Scan Procedure with Pacemakers and ICDs [Page 37].

MRI Scanner Conditions

Conditions during the MRI scan

MARNING

The following conditions must be maintained during the MRI scan:

- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- The MRI 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 MRI 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 MRI 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 7]

and Combinations of MR Conditional Pacemakers [Page 25].

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

M WARNING

The permissible positioning zone explained below must always be maintained during MRI 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.

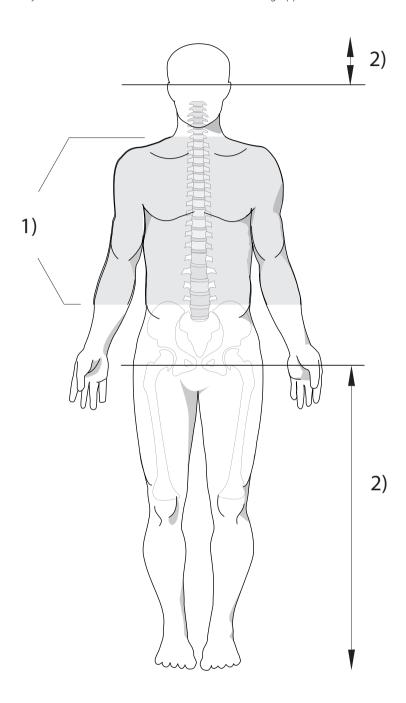
In practice, this means that the line of the MRI scanner's laser positioning marks must be within this zone.

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:



7 MRI Scan Procedure with Pacemakers and ICDs

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

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

Preparation

Patient selection

Make sure that your patient, the MRI scanner, as well as the implanted device system meet the conditions for an MRI 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 MRI scan.

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

Check the following prerequisites for an MRI scan:

- Threshold: max. 2.0 V / 0.4 ms
 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.

↑ WARNING

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] \rightarrow [MRI].

Select [Parameters] \rightarrow [Program sets] \rightarrow [Show MRI program].

Select [Parameters] \rightarrow [Bradycardia] \rightarrow [MRI program].

Select [Parameters] \rightarrow [Bradycardia/CRT] \rightarrow [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] \rightarrow [MRI].

Select [Parameters] \rightarrow [MRI].

- 2. Make sure that the patient is approved for an MRI scan by reading the information in the [MRI checklist] field 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 MRI 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] \rightarrow [MRI].

Select [Parameters] \rightarrow [MRI].

- 2. Make sure that the patient is approved for an MRI scan by reading the information in the **[MRI checklist]** field 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 MRI 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 MRI 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 MRI 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 MRI 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 **IMRI 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): 1.0ms
- 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): 1.0ms
- 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 MRI 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 MRI 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 MRI 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 MRI 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 MRI 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 MRI 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 MRI 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 a full follow-up.
- 6. Conduct any further examinations.

↑ WARNING

VARNING

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

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.

Cardiac Monitors 8

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 Full-Body Scan and means that no scan exclusion zone applies for such products.

The abbreviation EXZ stands for Exclusion Zone and means that a scan exclusion zone must be observed for such products.

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

Requirements for an MRI Scan

An MRI 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 MRI scan is contraindicated.

Conditions for cardiac monitors



↑ WARNING

The following conditions are required for an MRI 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 MRI 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 MRI scan

MARNING

The following conditions must be maintained during the MRI scan:

- The MRI 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.

MRI Scan Procedure with Cardiac Monitors 9

Preparation and Performance

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

Patient selection

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

Requirements for an MRI Scan [Page 43]

Preparation

Note

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

Performance

The MRI 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 MRI scan have been taken into consideration.
- The patient has been previously examined by a physician.

Invalid recordings

After the MRI 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 MRI scan should be discarded.

Overview of MR Conditional Products 10

MARNING

In the following you will find an overview of those BIOTRONIK products that have been tested under the conditions of an MRI 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 7]
- Combinations of MR Conditional Pacemakers [Page 25]
- Cardiac Monitors [Page 43]

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 |

ICDs

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 |

Pacemakers

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 33])
- 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

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 MRI Scan [Page 43] and MRI Scanner Conditions [Page 44].

ICD Leads

ICD Leads

The following **leads** are MR conditional:

ICD lead Pamira S

| Model | Order number |
|-------------|--------------|
| Pamira S 60 | 428768 |
| Pamira S 65 | 428769 |
| Pamira S 75 | 428770 |

ICD lead Pamira SD

| Model | Order number |
|-----------------|--------------|
| Pamira SD 60/16 | 428771 |
| Pamira SD 65/16 | 428772 |
| Pamira SD 65/18 | 428773 |
| Pamira SD 75/18 | 428774 |

ICD lead Pamira S DX

| Model | Order number |
|-------------------|--------------|
| Pamira S DX 65/15 | 428775 |
| Pamira S DX 65/17 | 428776 |

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 ProMRIS 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 Leads

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 Leads

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 Leads

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:



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 |