ProMRI® checklist for the cardiology department

This checklist helps to ensure the safe application of an MRI scan on patients with a BIOTRONIK pacing system which has been labeled MR Conditional.*

We recommend to use this checklist by ticking off the boxes in order to ensure a granted MR Conditional scan with BIOTRONIK ProMRI® systems.

Patient

Name: _____

Address: _____

City: _____

Pacemaker system (please insert)

Pacemaker

Leads

- ☐ The implanted pacemaker system consists exclusively of BIOTRONIK MR Conditional labeled components (pacemaker and lead(s)).
- ☐ There are no other implants in the patient's body.
- ☐ The pacing system has been implanted for at least 6 weeks.
- ☐ The implanted pacing system is in the patient's chest area.
- ☐ The measured pacing threshold does not exceed 2.0 V at 0.4 ms pulse width.
- ☐ The ascertained lead impedance is between 200 and 1500 Ohm.
- ☐ Ensure that the pacemaker is programmed to MRI mode immediately before the MRI scan, and reprogrammed to the initial settings after the scan.

Name and signature _____ Date _____

*Details on these conditions and requirements can be found in the BIOTRONIK manual "ProMRI, MR Conditional Pacing Systems". You can download this document as a PDF file from our website: **www.biotronik.com/manuals/home**. Alternatively, contact your local BIOTRONIK representative.

ProMRI®
More access. More options.

ProMRI®
Checklist and quick reference guide

Overview ProMRI® combinations	Safio S 53	Safio S 60	Solia S 45	Solia S & T 53	Solia S & T 60
Evia SR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Evia DR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Entovis SR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Entovis DR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Estella SR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Estella DR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Ecuro SR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®
Ecuro DR(-T)	ProMRI®	ProMRI®	ProMRI®	ProMRI®	ProMRI®

Caution: Limitation due to lead combinations that are not MR Conditional

To constitute an MR Conditional pacing system, connect in each case only Safio or Solia models to one of the listed pacemakers. The combination of Safio and Solia leads in one pacing system is not tested MR Conditional.

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Conditions for the MRI examination with a BIOTRONIK ProMRI®-System

Safe usage of an MRI scan on a patient having an implanted pacemaker is only possible under highly specific prerequisites and conditions. **MRI use is contraindicated in any other cases.**

Restrictions for the patient and the cardiac device system

- The implanted system consists only of a lead and a pacemaker, which are each labeled MR Conditional separately, and in combination make up an MR Conditional system.
- There are no other implants in the patient's body. For example:
  - Other pacemakers or ICDs
  - Leads no longer in use
  - Lead adapters
  - Lead extensions
- The patient does not have fever.
- The patient's height is at least 1.4 meters.
- The system has been implanted for at least 6 weeks.
- The implanted pacing system is in the patient's chest area.
- The calculated pacing threshold does not lie above 2.0 V amplitude at 0.4 ms pulse width.
- The ascertained lead impedance is between 200 and 1500 Ohms.
- The implant is programmed to a special MRI mode immediately before the MRI scan.
- The conditions applicable to specific devices or systems such as specific permissible positioning zones, minimum patient height, etc. are adhered to.

Requirements of the MRI scanner

- Use of a clinical MRI machine with
  - A closed tube
  - Cylindrical magnets
  - A static magnetic field strength of 1.5 Tesla.
- The slew rate of the MRI scanner's gradient fields should not exceed 216 T/m/s.
- No additional local transmitting coils are used.

Restrictions during the MRI scan

- The MRI scan can only be performed with the patient in dorsal position.
- The permissible positioning zone defined below has to be adhered to.
- The overall MRI scanning time accumulated from the imaging times as displayed by the MRI scanner must not exceed 30 minutes.
- The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- Emergency equipment for reanimation must be kept at hand and properly certified staff must be available.
- Monitor the patient's hemodynamics during the entire MRI scan by continuously recording at least one of the following parameters:
  - Blood oxygen saturation
  - Blood pressure
  - ECG

Note: Only use devices for this which are permitted for patient monitoring in an MRI environment.

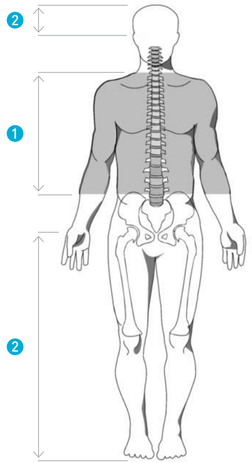
Note:
The ECG function integrated in the MRI scanner is often not permitted for patient monitoring.

Conditions for specific products

In addition to the preconditions and basic conditions for all ProMRI® products, the following special conditions apply to the combination of pacemaker and lead:

- The total duration of examinations with the ProMRI® pacing system must be below 10 hours. Explanation of the term 'total length of examination': When a patient with an implanted pacing system is succumbed to several MRI examinations in a row, the duration of each examination is recorded and these times are accumulated. This sum is almost equal to the total exposition time during which the devices were exposed to the strong magnetic field.

- Adherence to the permissible positioning ranges. The permissible positioning ranges are bodily regions upon which a laser mark may be set in order to position the isocentre of the MRI scanner. These areas absolutely have to be adhered to during the MRI scan. However, receipt only coils can also be positioned outside this area. As a result of this limitation and due to the technical givens of the MRI scanner, no imaging data can be collected for this part of the body (the scan exclusion zone).



Permissible positioning zone and scan exclusion zone

The following applies for the MR Conditional systems:

Legend:
1. Scan exclusion zone
2. Permissible positioning zone

Starting from the foot end, the maximum allowed positioning mark for the isocenter (laser light) is at the hip bone level.

Starting from the top of the skull, the maximum allowed positioning mark for the isocenter is at the level of the eyes.

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ProMRI® checklist for the radiology department

Checklist before MRI scanning

This checklist helps to ensure the safe application of an MRI scan on patients with a BIOTRONIK pacing system which has been labeled MR Conditional.*

We recommend to use this checklist by ticking off the boxes in order to ensure a granted MR Conditional scan with BIOTRONIK ProMRI® systems.

- ☐ The patient does not have fever.
- ☐ The patient's height is at least 1.4 meters or 4.6 feet.
- ☐ The MRI scan will only be performed with the patient in dorsal position.
- ☐ Use of a clinical MRI system with a closed tube, cylindrical magnets and a static magnetic field strength of 1.5 tesla.
- ☐ The slew rate of the MRI scanner's gradient fields should not exceed 216 T/m/s.
- ☐ No additional local transmitting coils are used.
- ☐ The overall MRI scanning time accumulated from the imaging times as displayed by the MRI scanner must not exceed 30 minutes.
- ☐ The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- ☐ The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- ☐ Starting from the top of the skull, the maximum allowed positioning mark for the isocenter (laser light) is at the level of the eyes.
- ☐ Starting from the foot end, the maximum allowed positioning mark for the isocenter is at the hip bone level.
- ☐ Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- ☐ Monitor the patient's hemodynamics during the entire MRI scan by continuously recording at least one of the following parameters: Blood oxygen saturation, Blood pressure, ECG
  Note: The ECG function integrated in the MRI scanner is often not permitted for patient monitoring.
- ☐ Ensure with cardiology department, that the pacemaker is programmed to MRI mode prior to the MRI scan.

Name and signature

Date

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