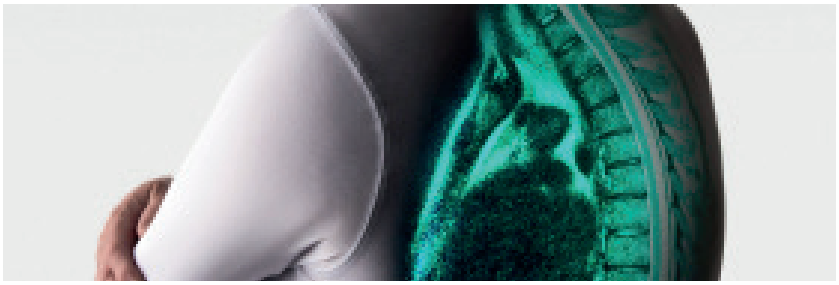
Conditions Overview



MRI Scanning Conditions for BIOTRONIK Systems Approved for Full-Body Scanning*

ProMRI®

Before You Start Using This Checklist

Check if the implanted BIOTRONIK system is MR conditional using the ProMRI® SystemCheck at www.promricheck.com.

This checklist can be used if the implanted system is MR conditional and approved for full-body MRI scanning. If the system is MR conditional and approved for MRI scanning observing an exclusion zone, please refer to the appropriate checklist.

General Considerations

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.

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.

Checklist for Cardiologists

The Following Conditions Are Required for an MRI Scan

- ☐ The device system consists of an implated device with the respective leads and blind plugs that are separately labeled MR conditional and, when combined, can constitute an MR conditional device system.
- ☐ There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- ☐ Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

Note: An MRI scan is permitted only if the product-specific conditions are met for all implants and if no metal implantable device longer than 5 cm is in the vicinity of a BIOTRONIK lead within a distance of less than 4 cm.

- ☐ The lead(s) has/have been implanted for at least six weeks.
- ☐ The device system was implanted pectorally.
- ☐ The determined pacing threshold does not lie 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 MRI mode immediately before the MRI scan.

Note: Read the ProMRI manual for instructions if the device includes the MRI AutoDetect function. This function enables automatic programming of the MRI mode after detection of the fields of the MRI scanner

* Conditions applicable in CE region

This checklist has been created with great care but does not substitute the manual "ProMRI MR conditional device systems" which contains all comprehensive information regarding ProMRI. This manual is available in 24 languages at www.manuals.biotronik.com.

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MRI Scanning Conditions for BIOTRONIK Systems Approved for Full-Body Scanning

Checklist for Radiologists

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 dorsal position.
- ☐ The mean specific absorption rate (SAR) for the whole body as displayed by the MRI scanner must not exceed 2.0 W/kg.

Note: The combination of Solia S or Siello S and pacemakers enables a mean specific absorption rate (SAR) for the whole body up to 4.0 W/kg as displayed by the MRI scanner.

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

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

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 3.0T.
- ☐ 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.

Note: Read the ProMRI manual for instructions if the device includes the MRI AutoDetect function. This function enables automatic programming of the MRI mode after detection of the fields of the MRI scanner

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Conditions Overview

MRI Scanning Conditions for BIOTRONIK Systems with an Exclusion Zone*

ProMRI®

Before You Start Using This Checklist

Check if the implanted BIOTRONIK system is MR conditional using the ProMRI® SystemCheck at www.promricheck.com.

This checklist can be used if the implanted system is MR conditional and approved for MRI scanning observing an exclusion zone. If the system is MR conditional and approved for full-body scanning, please refer to the appropriate checklist.

General Considerations

An MRI scan can be performed safely on patients with a 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.

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.

Checklist for Cardiologists

The Following Conditions Are Required for an MRI Scan

- ☐ The device system consists of an implanted device with the respective leads and blind plugs that are separately labeled MR conditional and, when combined, can constitute an MR conditional device system.
- ☐ There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- ☐ Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

Note: An MRI scan is permitted only if the product-specific conditions are met for all implants and if no metal implantable device longer than 5 cm is in the vicinity of a BIOTRONIK lead within a distance of less than 4 cm.

- ☐ The 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 determined pacing threshold does not lie 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 MRI mode immediately before the MRI scan.

Note: Read the ProMRI manual for instructions if the device includes the MRI AutoDetect function. This function enables automatic programming of the MRI mode after detection of the fields of the MRI scanner.

* Conditions applicable in CE region

This checklist has been created with great care but does not substitute the manual "ProMRI MR conditional device systems" which contains all comprehensive information regarding ProMRI. This manual is available in 24 languages at www.manuals.biotronik.com.

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MRI Scanning Conditions for BIOTRONIK Systems with an Exclusion Zone

Checklist for Radiologists

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 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 four minutes after 30 minutes.
- ☐ The mean specific absorption rate (SAR) for the whole body as 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.
- ☐ 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.

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

Note: Read the ProMRI manual for instructions if the device includes the MRI AutoDetect function. This function enables automatic programming of the MRI mode after detection of the fields of the MRI scanner

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

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

- ☐ 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.

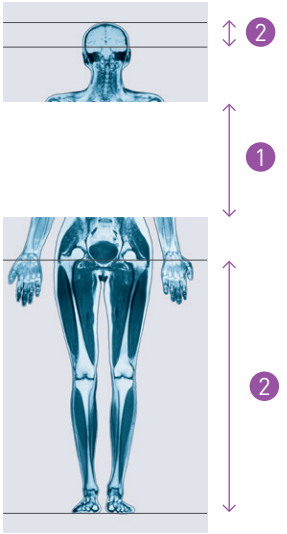
Isocenter

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

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 the orbital margin.

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



1 Scan exclusion zone
2 Permissible positioning zone

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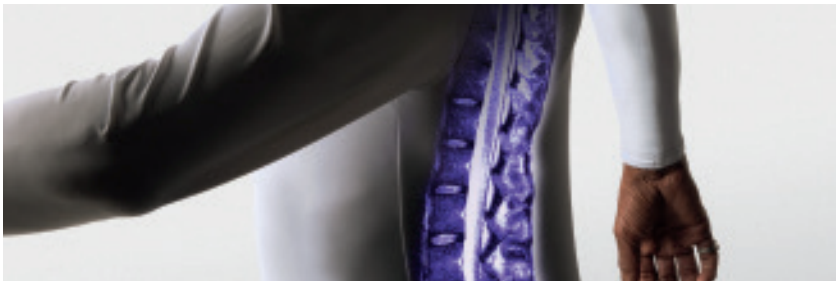
Conditions Overview



MRI Scanning Conditions for BIOTRONIK Cardiac Monitors*

ProMRI®

Before You Start Using This Checklist

This checklist can be used if the implanted system is a BIOTRONIK cardiac monitor. For all other MR conditional BIOTRONIK systems, please refer to the appropriate checklist.

General Considerations

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.

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.

Checklist for Cardiologists

The Following Conditions Are Required for an MRI Scan

- ☐ The cardiac monitor is labeled and certified MR conditional.
- ☐ There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- ☐ Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

Note: An MRI scan is permitted only if the product-specific conditions are met for all implants and if no metal implantable device longer than 5 cm is in the vicinity of a BIOTRONIK lead within a distance of less than 4 cm.

- ☐ The device system was implanted pectorally.

* Conditions applicable in CE region

This checklist has been created with great care but does not substitute the manual "ProMRI MR conditional device systems" which contains all comprehensive information regarding ProMRI. This manual is available in 24 languages at www.manuals.biotronik.com.

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MRI Scanning Conditions for BIOTRONIK Cardiac Monitors

Checklist for Radiologists

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 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 head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.

The MRI Scanner Must Meet the Following Conditions

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

BioMonitor is approved for 1.5 T full body scanning

BioMonitor 2-AF, BioMonitor 2-S, BIOMONITOR III, BIOMONITOR IIIm are approved for 1.5 T and 3.0 T. full body scanning.

- ☐ 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.
- ☐ Use only local receiver coils for the thorax.

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