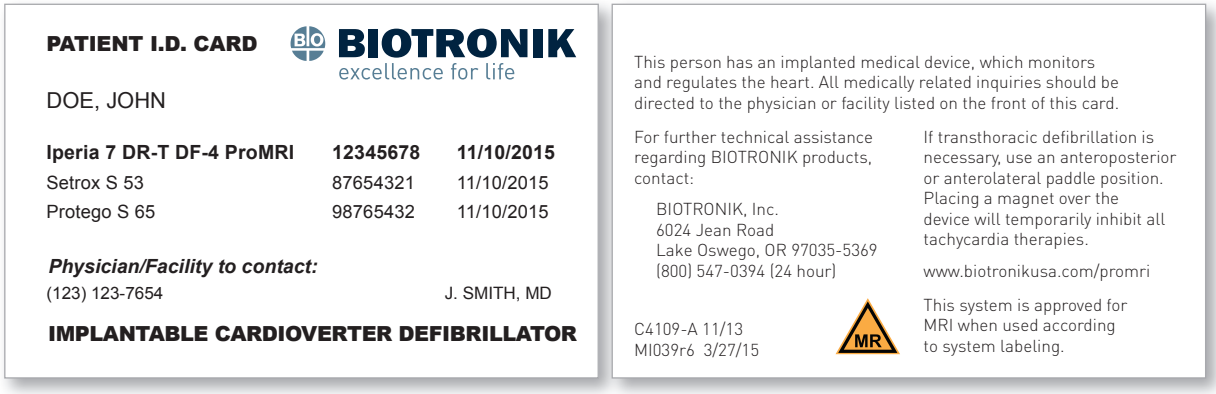
Radiology Checklist

MRI Procedure Requirements

Step 1: Screen Patient

❒ Verify that patient has a complete MRI compatible pacemaker or ICD system using one or more of the following methods:

1. Use the patient ID card to identify the device and leads implanted.



PATIENT I.D. CARD BIOTRONIK excellence for life

DOE, JOHN

Iperia 7 DR-T DF-4 ProMRI	**12345678**	**11/10/2015**
Setrox S 53	87654321	11/10/2015
Protego S 65	98765432	11/10/2015

Physician/Facility to contact:
(123) 123-7654 J. SMITH, MD

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

This person has an implanted medical device, which monitors and regulates the heart. All medically related inquiries should be directed to the physician or facility listed on the front of this card.

For further technical assistance regarding BIOTRONIK products, contact:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394 (24 hour)

If transthoracic defibrillation is necessary, use an anteroposterior or anterolateral paddle position. Placing a magnet over the device will temporarily inhibit all tachycardia therapies.

www.biotronikusa.com/promri

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MI039r6 3/27/15

MR

This system is approved for MRI when used according to system labeling.

2. Call BIOTRONIK 24-hours a day at 1 (800) 547-0394 to verify the patient's pacing system.
3. Use the patient's records to verify that a complete ProMRI® system has been implanted.
4. Confirm that the patient does not have any other previously implanted (active or abandoned) cardiac implants such as leads, lead extenders, or lead adaptors

   Other implanted active or passive MR conditional medical devices are permitted if metal implantable devices larger than 5 cm are located 4 cm or greater distance from the ProMRI® lead

Step 2: Schedule

❒ Contact cardiology to obtain clearance documents, for example:

- BIOTRONIK Cardiology Order document

❒ Schedule a health professional to monitor the patient during MRI exam.

❒ Schedule a trained professional to program the patient's pacemaker or ICD into and out of ProMRI mode.

Continued >

Details on these conditions and requirements can be found in the BIOTRONIK ProMRI® System Technical Manual or by visiting www.biotronikusa.com/promri.

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Radiology Checklist MRI Procedure Requirements

Step 3: Conduct MRI Scan Using the Following Guidelines

- ❒ Confirm with the cardiology department that the pacemaker or ICD is programmed to MRI mode prior to the MRI scan.
- ❒ Use 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 200 T/m/s per axis.
- ❒ The MR scan should be performed with the patient in supine position.
- ❒ The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- ❒ The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- ❒ Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- ❒ Continuously monitor the patient's condition during the entire MR scan using at least one of the following parameters: blood oxygen saturation, blood pressure or ECG.

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.

Step 4: Manage Patient Post-Scan

- ❒ Ensure a trained professional re-programs patient's device to previous settings.
- ❒ Check the pacing thresholds to ensure a proper safety margin.

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