CVRx
Outsmart the heart

Magnetic Resonance Imaging (MRI) Instructions for Use

SCOPE

This document is a portion of the Instructions for Use (IFU) for the Barostim™ System. The full instructions for use are available at www.cvrx.com/ifu. If you have any questions or require any clarifications, please contact your CVRx representative or call CVRx at 1-763-416-2343.

MR UNSAFE DEVICES 

The following Barostim IPGs and leads are MR Unsafe:

- IPG Model 2100 (Barostim™ Legacy)
- Lead Models 1010, 1014, 1037
- Leads repaired (even with Lead Repair Kit Model 5010)
- Known damaged leads
- Patients with more than one implanted lead
- Patients with a lead implanted without an IPG

NOTE: The Programmer System (Model 9010 or Model 9020) is also MR Unsafe.

Table 1 – Barostim System MR Conditional Use Safety Information

MRI Safety Information  MR Conditional	
Non-clinical testing has demonstrated that the Barostim NEO and NEO2 (IPG and a single lead) are MR Conditional. A patient implanted with the Barostim system may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient or item malfunction.	
Item Name/Identification	Barostim MR Conditional System consisting of: • IPG Model 2102 (Barostim NEO™) • IPG Model 2104 (Barostim NEO2™) • Lead Model 1036 – Single lead implant only
Additional Resources for MRI Safety Information	This document is a portion of the Instructions for Use (IFU) for the Barostim™ System. The full instructions for use are available at www.cvrx.com/ifu. Call CVRx technical support at: 1-763-416-2343.
Parameter	**Condition of Use/Information**
Static Magnetic Field Strength (B_0)	1.5T only
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew rate per axis	200 T/m/s

RF Transmit Coil Type	**For Head and Brain Imaging:** • Transmit/receive head coil only (without neck accessory coil) **NOTE:** RF Head coil scanning may not be performed with the body coil in transmit mode. Use of body coil transmission can result in unsafe heating. It is noted that some head coils compatible with 1.5T scanning are receive-only and rely on the body coil to transmit RF. Receive-only head coils may not be used. Use of the body coil transmission is warned against, other than specified for lower body extremities. **For Lower Extremity Imaging:** • Transmission with the Body coil • Transmit/receive coil that does not extend over any part of the Barostim System **NOTE:** When lower extremity scanning with a body coil transmission, all parts of the Barostim System must be out of the cylindrical bore of the MR scanner or unsafe heating may result.
RF Receive Coil	**For Head and Brain Imaging:** • Transmit/receive head coil only (without neck accessory coil) **NOTE:** A receive-only head coil is warned against. **For Lower Extremity Imaging:** • Transmit/receive coil that does not extend over any part of the Barostim System
MR System (RF) Operation Mode or Constraints	**1.5T:** Normal Operating Mode
Whole Body Averaged SAR	**For Lower Extremity Imaging:** • 2.0 W/kg for 60 minutes of continuous scanning in Normal Operating Mode at 1.5T
Maximum Head SAR	**For Head and Brain Imaging:** • 3.2 W/kg for 60 minutes of continuous scanning in Normal Operating Mode at 1.5T **Note:** The head coil must be the controlling condition.

Scan Duration and Wait Time	60 minutes of scanning is authorized
Anatomy at Isocenter	**For Head and Brain Imaging:** • No part of the Barostim System may be within the transmit/receive head coil. No part of the Barostim System may be within the imaging field of view. **For Lower Extremity Imaging:** • Location of the entirety of the implanted Barostim System is outside of the MR scanner cylindrical bore. No part of the Barostim System may be within the transmit/receive body coil. No part of the Barostim System may be within the imaging field of view. • Additionally, if using an MRI scanner with bore length less than 48” maintain at least a 24” separation between the center of the bore and any part of the Barostim System.
Patient Characteristics	• Do not subject the system to the MR environment if the lead is suspected to be damaged, cut, or has been repaired.
Patient Position in Scanner	**For Head and Brain Imaging:** • Imaging of the head with the patient in the head-first supine position. **For Lower Extremity Imaging:** • Patient in a feet-first (supine, prone or lateral decubitis position).
Item Configuration	One of the following IPGs connected to a single lead implant only: • IPG Model 2102 (Barostim NEO™) connected to one lead model 1036 • IPG Model 2104 (Barostim NEO2™) connected to one lead model 1036 The Barostim NEO and NEO2 IPGs are manufactured with a titanium case and contain various other metals within the case. The leads are manufactured of stainless steel and various other metals.

MR Image Artifact	**For Head and Brain Imaging:** • No image artifact is associated with scanning under these conditions as the device will be outside of the field of view associated with the scan. However, in non-clinical testing, image artifacts were observed. Image artifact caused by the device extends approximately 67mm from the Barostim NEO or NEO2 IPG (generator) when imaged with a gradient echo pulse sequence and a 1.5T MRI system. The artifact extends approximately 6mm from an individual lead when imaged with a gradient-echo or spin-echo pulse sequence and a 1.5T MRI system. **For Lower Extremity Imaging:** • No image artifact is associated with scanning under these conditions, as the device will be outside of the field of view associated with the scan.
Required Programming Settings	The proper MRI scanning configuration of the Barostim NEO and NEO2 IPG devices are different based on model and serial number. The model and serial number are indicated by the X-Ray ID tag. See Table 2 below for details.

Instructions to be followed before, during and/or after the MRI exam	**Before the MRI Exam:** • Programming sessions must be ended, and the Model 9010 or 9020 Programmer Computer powered off before the patient enters the MR environment. • Do not bring any component of the Model 9010 or 9020 Programmer System into the MR environment. • Prior to scanning, the patient should be instructed to notify the MR system operator of pain, discomfort, heating or other unusual sensations in the area of the device or leads which may require termination of the MR procedure. • The patient should also be instructed to notify the clinician of changes in the patient's condition that may result from the therapy being disabled. **During the MRI Exam:** • Ensure the programmer remains off until the patient exits the MR environment. **After the MRI Exam:** • The proper re-programming of the Barostim NEO and NEO2 IPG devices after an MRI exam are different based on model and serial number. The model and serial number are indicated by the X-Ray ID tag. See Table 3 below for details.

Table 2 – Barostim IPG Required Programming Settings

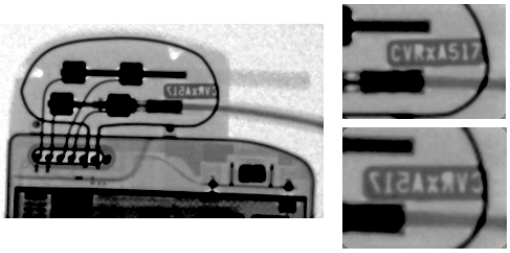
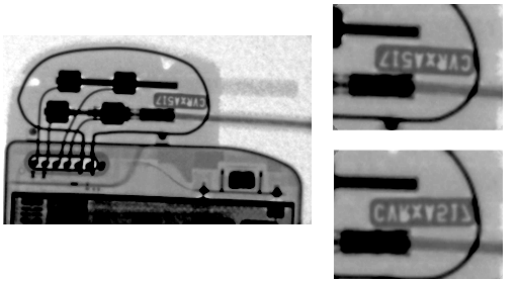
	IPG Model 2102 Serial # less than or equal to 2102002999	**IPG Model 2102 Serial # greater than or equal to 2102003000 or Model 2104**
X-Ray ID Identification	ID tag starts with CVRxA5 and "CVRx" **right-side up** 	ID tag starts with CVRxA5 and "CVRx" **upside down** (Model 2102)  **ID tag starts with CVRxA6 indicates Model 2104**
Is Programmer Required to program IPG OFF prior to scanning?	**YES** The Barostim NEO IPG must be programmed to Therapy OFF with a CVRx 9010 or 9020 programmer and in such a state will function as an effectively passive device.	**NO** Upon entering the magnetic field, the Barostim NEO or NEO2 IPG will automatically suspend therapy output; in such a state will function as an effectively passive device.

Table 3 – Barostim IPG Re-programming After an MRI Exam

	IPG Model 2102 Serial # less than or equal to 2102002999	**IPG Model 2102 Serial # greater than or equal to 2102003000 Or Model 2104**
Is Programmer Required to program IPG ON following scanning?	**YES** Upon exiting the magnetic field, the Barostim NEO IPG must be programmed to Therapy ON with a CVRx 9010 or 9020 programmer and functionality of the device confirmed.	**NO** Upon exiting the magnetic field, the Barostim NEO or NEO2 IPG will automatically be programmed to Therapy ON. The functionality of the device should be confirmed at the next scheduled follow-up or sooner if desired.

Table 4 – RF Heating, Displacement, and Torque Information

	Head and Brain Imaging using a Transmit/Receive Head Coil	Lower Extremity Imaging
RF Heating	Under the scan conditions defined above, the Barostim System is safe for up to 60 minutes of continuous scanning.	Under the scan conditions defined above, the Barostim System is safe for up to 60 minutes of continuous scanning.
Displacement	Magnetically induced displacement force of the Barostim NEO or NEO2 IPG device was approximately 0.3 N when scaled to 30 T/m. The constraining forces on properly implanted devices are sufficient to stabilize the device under the scan conditions defined above.	
Torque	Magnetically induced torque of the IPG component was measured to be less than 71 N·mm. The magnetically induced torque was found to be at least 3 times less than the worst-case gravity torque as defined in the ASTM standard, indicating the risk from magnetically induced torque is no greater than normal daily activity.	

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