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 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

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

MR CONDITIONAL USE INSTRUCTIONS

MR Conditional System Configuration

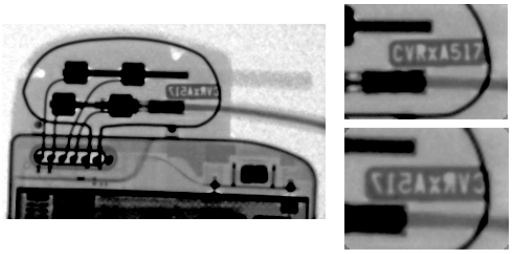
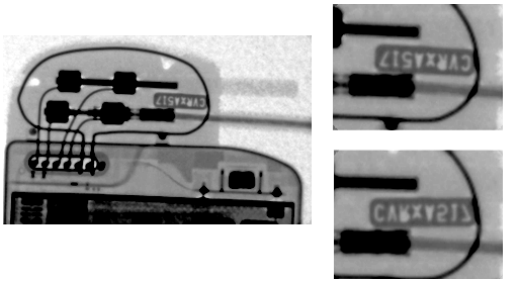
- IPG Model 2102 (Barostim NEO™)
- IPG Model 2104 (Barostim NEO2™)
- Lead Models 1036 – Single lead implant only

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.

Non-clinical testing has demonstrated that the Barostim NEO and NEO2 (IPG and a single lead) are MR Conditional. A patient with this Barostim System implanted can be safely scanned in an MR system with the conditions stated below.

Pre-MRI

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.

	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**
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.

NOTE: Programming sessions must be ended, and the Model 9010 or 9020 Programmer Computer powered off before the patient enters the MR environment. Ensure the programmer remains off until the patient exits the MR environment. Do not bring any component of the Model 9010 or 9020 Programmer System into the MR environment.

Head and Brain Imaging Using a Transmit/Receive Head Coil

- Static magnetic field of 1.5 Tesla (1.5T).
- Maximum spatial gradient field less than or equal to 30 T/m (3000 G/cm).
- Maximum Gradient Slew Rate less than or equal to 200 T/m/s.
- Use only “transmit/receive” head coil (without neck accessory coil).
  Note: see section titled “MR Warnings”
- Imaging of the head with the patient in the head first supine position.
- Maximum head averaged specific absorption rate (SAR) of 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.
- 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.

Lower Extremity Imaging

- Static magnetic field of 1.5 Tesla (1.5T).
- Maximum spatial gradient field less than or equal to 30 T/m (3000 G/cm).
- Maximum Gradient Slew Rate less than or equal to 200 T/m/s.
- Maximum whole-body average specific absorption rate (SAR) of 2.0 W/kg for 60 minutes of continuous scanning in Normal Operating Mode at 1.5T.
- Conventional horizontal cylindrical bore MRI scanner.
- Patient in a feet first (supine, prone or lateral decubitis position).
- Transmission with the body coil or with a transmit/receive coil that does not extend outside of the bore.
- 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.

RF Heating, MRI Artifacts, and Displacement

	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.
MRI Artifacts	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. Under the scan conditions defined above, the 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.	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.
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.	

Post-MRI

	IPG Model 2102 Serial # less than or equal to 2102002999	IPG Model 2102 Serial # greater than or equal to 2102003000 Or Model 2104
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.

MR PRECAUTIONS

- 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.

MR WARNINGS

- Do not subject the system to the MR environment if the lead is suspected to be damaged, cut, or has been repaired. Do not bring any component of the Model 9010 or 9020 Programmer System or the External Inhibit Magnet into the MR environment.

	Head and Brain Imaging using a Transmit/Receive Head Coil	Lower Extremity Imaging
Condition specific MR Warnings	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.	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.

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