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 1-877-691-7483.

MR UNSAFE DEVICES

The following IPGs and leads are contra-indicated for MR exposure:

- IPG Models 2000 (Rheos™), 2100 (Barostim™ LEGACY), 2101 (XR-1)
- Lead Models 1010, 1014
- Leads repaired (even with Lead Repair Kit Model 5010)
- Known damaged leads

MR CONDITIONAL USE INSTRUCTIONS

MR Conditional System Configuration

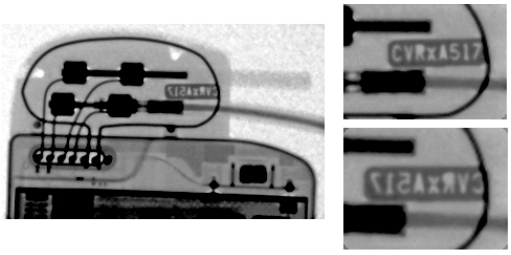
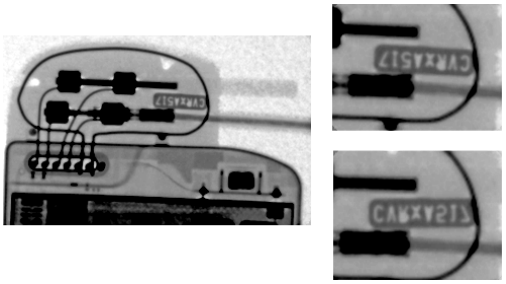
- IPG Model 2102 (Barostim NEO™)
- IPG Model 2104 (Barostim NEO2™)
- Lead Models 103X

The Barostim NEO and Barostim NEO2 IPGs are manufactured with a titanium case and contains 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 System is MR Conditional. A patient with this device 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 Barostim NEO2™ IPG device is different based on model and serial number. The model and serial number are indicated by the X-Ray ID tag.

	Model 2102 Serial # less than or equal to 2102002999	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 programmer and in such a state will function as an effectively passive device.	NO Upon entering the magnetic field, the Barostim NEO and Barostim 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 Programmer Computer powered off before the patient enters the MR environment. Ensure the programmer remains off until the patient exits 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 21 T/m (2100 G/cm).
- 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 15 minutes of scanning in Normal Operating Mode at 1.5T.
  Note: The head coil must be the controlling condition.
- Implanted systems with a single lead or with dual lead (unilateral or bilateral) configuration with or without the Barostim NEO and Barostim NEO2 IPG (stimulator) may be scanned.
- 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 21 T/m (2100 G/cm).
- Maximum MR system reported Average Specific Absorption Rate (SAR) of 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode
- 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
- Implanted systems with a single lead or with dual lead (unilateral or bilateral) configuration with or without the Barostim NEO or Barostim NEO2 IPG (stimulator) may be scanned.
- Location of the entirety of the implanted Barostim System is outside of the MR scanner cylindrical bore.

  Additionally, if using an MRI scanner with bore length less than 48":

  - And the patient has an implanted barostimulator device with attached leads, maintain at least a 24" separation between the center of the bore and any part of the Barostim System.
  - And the patient has the lead(s) alone, maintain at least a 25.5" separation between the center of the bore and any part of the Barostim lead(

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 expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.	Under the scan conditions defined above, the Barostim System is expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.
MRI Artifacts	In non-clinical testing, under the scan conditions defined above, the image artifact caused by the device extends approximately 65mm from the Barostim NEO or Barostim NEO2 IPG (stimulator) 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- 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 CVRx IPG device was approximately 0.8 N when scaled to 21T/m incorporating a 1.5-fold safety factor. 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 5.1 N·mm incorporating a 10-fold safety factor. The magnetically induced torque was found to be 6 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

	Model 2102 Serial # less than or equal to 2102003999	Model 2102 Serial # greater than or equal to 2102004000 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 programmer and functionality of the device confirmed.	NO Upon exiting the magnetic field, the Barostim NEO or Barostim 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 MR if the lead is suspected to be damaged, cut, or has been repaired.
- Do not bring any component of the Model 9010 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 contraindicated, 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.

The Barostim™ System is CE Marked and approved for sale for heart failure patients in the European Union (EU). It is also CE Marked and approved for sale for hypertension patients in the EU.

For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk/

⚠ CANADA ONLY: EXCLUSIVELY FOR CLINICAL INVESTIGATIONS.

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