CVRx™
Medicine *Re*Envisioned™

MRI USE INSTRUCTIONS

1. SCOPE

This document is a supplement. For full system description and instructions for use, please refer to the System Reference Guide. If you have any questions or require any clarifications please contact your CVRx representative or call CVRx at 1-877-691-7483.

2. MR UNSAFE DEVICES

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

- IPG Models 2000 (Rheos), 2100 (Neo Legacy), 2101 (XR-1)
- Lead Models 1010, 1014
- Leads repaired with Lead Repair Kit Model 5010

3. MR CONDITIONAL USE INSTRUCTIONS

MR Conditional System Configuration

- IPG Model 2102 (Neo)
- Lead Models 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037

The Neo device is 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 CVRx Neo system is MR Conditional.

Patients implanted with this system can be subject to an MR scan under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T).
- Maximum spatial gradient field less than or equal to 21 T/m.
- Use only transmit/receive head coil (without neck accessory coil).
- 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 should be the controlling condition – See Specific Test Condition Results*
- Implanted systems with a single lead or with dual lead (unilateral or bilateral) configuration with or without the Neo IPG (stimulator) may be scanned.
- The Neo IPG must be programmed OFF (non-therapeutic mode) prior to scanning and in such a state will function as an effectively passive device.
- Following MR exposure, when the device is turned on, proper functionality of the device must be confirmed.

MR Warnings

- Scanning may not be performed with the body coil in transmit mode. Use of body coil transmission can result in unsafe heating with this device. 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.
- Do not subject the system to MR if the lead is suspected to be damaged, cut, or has been repaired using a Model 5010 Lead Repair Kit. If there is uncertainty as to whether the lead has been repaired it is suggested that an X-ray be performed to verify. Acceptable lead condition should be verified using lead impedance measurement using the CVRx programmer. If an implanted lead impedance measurement indicates “Low” or “High”, MR is contraindicated.
- Do not bring any component of the Model 9010 Programmer System or the External Inhibit Magnet into the MR environment.

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.
- Monitor the patient status while therapy is turned off.

Specific Test Condition Results

RF Heating

1.5 Tesla MR

In non-clinical testing with head coil excitation, the CVRx barostimulator system produced a total temperature rise of less than 2ºC when exposed to a maximum specific absorption rate (SAR) of 1.26 W/kg for 16.2 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B19 software, Erlangen, Germany). Scaling to head SAR at 3.2 W/kg (scale factor of 1.0) yields a maximum expected temperature total rise of less than 2°C during Normal Operating Mode. When scanning using the transmit/receive head coil the head SAR limitation is expected to be controlling, and thus the averaged whole-body SAR limitation should not be approached. Considering the unlikely scenario of the whole-body average SAR limitation being controlling, scaling of the observed heating to the whole-body SAR limitation indicates that whole body averaged SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than or equal to 3.5 ºC in Normal Operating Mode.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

3.0 Tesla MR

Testing at 3.0 T yielded a maximum expected total temperature rise of 5.0°C under hypothetical conditions of limiting whole-body averaged SAR during head scanning. This scenario is assessed as unlikely based upon the observation that during head scanning, the head SAR limit is typically controlling. Reporting in this way has been chosen in light of the limitation on available post-scan head SAR data from some 3.0T scanners.

MRI Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact followed the approximate contour of the device and extended radially up to 4.8cm from the implant on gradient echo imaging at 1.5T in tests performed in accordance with ASTM F2119. For the lead portion of the system only, the artifact extent was approximately 0.6cm on spin-echo and gradient-echo imaging.

Other

Magnetically induced displacement force and torque testing indicated that the implants posed no known elevated risks with regard to displacement force and torque in the MR environment.

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