MRI Programming Checklist

remedē® System | Model 1100/1600

Set Up for Visit

- ☐ Connect the programming wand to the USB port
- ☐ Connect the power supply to the tablet and connect to power source
- ☐ Press Power button
- ☐ Double click on **rem**edē 5.x icon on the tablet to start session
- ☐ Place programming wand over the device
- ☐ Look for a blinking green light on programming wand to signal a good telemetry connection
- ☐ Ensure programmer time matches local time. If time does not match, go to Tools pull down, Set PC time.

PRE-MRI Initial Interrogation

1. Select the Interrogate button Interrogate

- ☐ Review any messages and select OK

2. Verify lead information

- ☐ Go to Tools, Patient Info
- ☐ Confirm whether patient has a right or left stimulation lead and whether there are any abandoned leads [non-viable]
  - **If the patient has a non-viable lead entered, do not proceed with the MRI**

3. Confirm battery Status [Summary Tab]

- ☐ If Battery Status is "EOL" and voltage ≤ 2.50V, **do not proceed as device is at end of life (EOL) and impedances cannot be measured**

4. Evaluate all unipolar impedances

- ☐ Select Impedance icon Ω
- ☐ Test each UNIPOLAR electrode [see table below]
  - Select a test configuration (Cathode – Electrode 1, Anode - Can)
  - Select Read Impedance
  - Report any impedance above the max threshold or below the min threshold (any reading with a "<" or ">" value)
- ☐ **Do not proceed with MRI if out of range** and call Respicardia for further guidance
- ☐ Note for testing: for a left lead you will test cathodes 1...4; for a right lead you will test cathodes 1...6

Cathode 1 – Anode Can = _____
Cathode 2 – Anode Can = _____
Cathode 3 – Anode Can = _____
Cathode 4 – Anode Can = _____
Cathode 5 – Anode Can = _____ **Only test for a right lead; >2,500 is expected for left lead**
Cathode 6 – Anode Can = _____ **Only test for a right lead; >2,500 is expected for left lead**

5. End Session: Follow P-Tire Steps

- ☐ Confirm patient settings and press program [Program]
- ☐ Click **Set Time** or Set with PC Time: Tools, Time
- ☐ Click Interrogation to confirm device is in desired mode
- ☐ Remove Wand from patient
- ☐ Click End Session [End Session]

Patient is ready for MRI

Important Safety Information
The **rem**edē® System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the **rem**edē System is appropriate. The **rem**edē® System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the **rem**edē System MRI guidelines manual. The **rem**edē System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The **rem**edē System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all the risks and benefits associated with the implantation of the **rem**edē System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events. **Rx Only.** The **rem**edē® System, **rem**edē® EL System, and **rem**edē® EL-X System have received FDA approval. The **rem**edē® System model 1001 has received CE Mark approval.

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