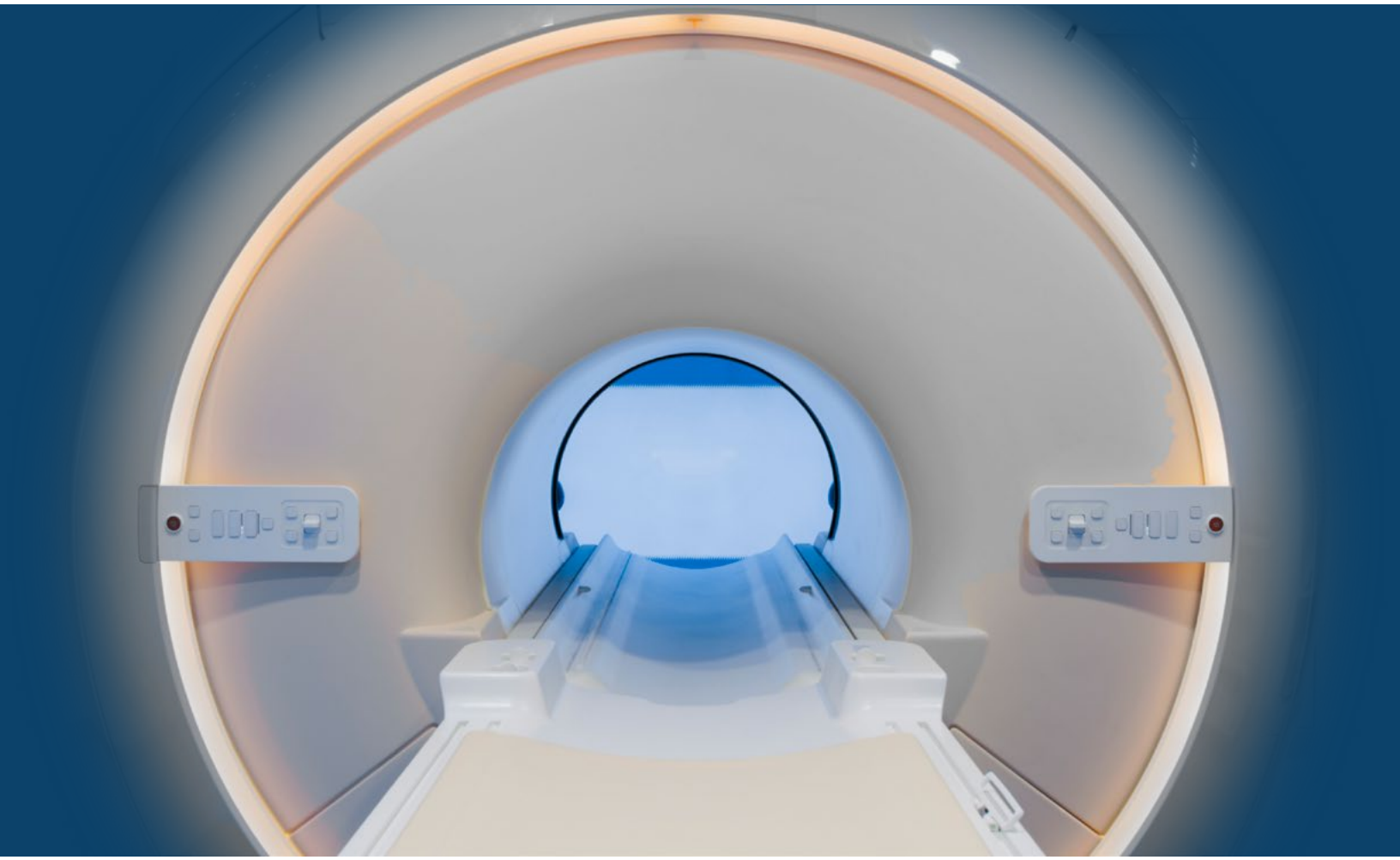
remedē® System



MRI FAQ

ZOLL®

On 03/28/2023, the **rem**edē® System received FDA approval for MR Conditional labeling. This document is a list of frequently asked questions created to help you better educate yourself and your patients.

MRI FAQ

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1. What are the different classifications of MRI Safety labeling?

The MR environment has unique safety hazards for patients with implants, external devices and accessory medical devices. Implants, medical devices and other equipment used in or near the MR environment should be labeled as MR Unsafe, MR Conditional or MR Safe.

MR Unsafe: items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.

MR Conditional: items may safely enter the MRI scanner room only under the specific conditions provided in the labeling. Patients should not be scanner unless the device can be positively identified as MR conditional AND the conditions for safe use are met.

The conditions for safe use will be different based on the intended use of the device

MR Safe: items pose no safety hazard in the MR environment. They may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.

2. Which classification of MRI Safety label did the **rem**edē System receive?

The **rem**edē System received FDA approved with the MR Conditional safety labeling. To proceed with an MRI scan for patients implanted with the **rem**edē System, specific guidelines must be followed including a pre-MRI scan check.

During the MRI, specific procedures must be followed that limit scan time and require rest time between scans, based on the power of the magnetic field created.

For more information on the guidelines and recommendations, please read our MRI Guidelines manual

3. Does this approval extend to patients implanted with the **rem**edē System prior to the MR Conditional labeling?

Yes. With the newly indicated MR Conditional labeling, the condition applies to all **rem**edē IPG and respistim leads implanted before this labeling change. Certain conditions apply to implanted leads; please refer to the **rem**edē System MRI guidelines (section 1.3) for more information. All existing versions of the **rem**edē System are now approved for MR conditional use as shown below:

Compatibility chart

remedē IPG	Model 1001	Model 1100	Model 1600
Conditional MRI compatibility	YES	YES	YES

4. Were any changes made to the device that led to it receiving MR Conditional labeling?

No changes were made to the **rem**edē System in order to obtain MR Conditional labeling. The approval was granted based on additional testing only. This is the reason why we can ensure retro compatibility to all existing **rem**edē System devices already implanted on patients.

5. Can all accessories available for the **rem**edē System enter into an MRI scan?

This is addressed in the **rem**edē System MRI guidelines with the following statement:

Warning: Do not conduct an MRI scan if there are abandoned respistim leads present in the patient.

The following tables provide the model number of components and their status related to MR compatibility. Table 1 and Table 2 show all components listed as MR Conditional. Table 3 shows the list of components that are MR Unsafe. These should not be brought into the MR scanner room.

Table 1 – **rem**edē **System components that are eligible for Whole-body MRI scans and Head Scan (1.5T and 3T) under specified conditions.**

COMPONENT	MODEL NUMBER(S)
remedē IPG	1001, 1100, 1600
respi**stim** Left Stimulation Lead	L Lead Models – 2002, 2003, 2004 LQ Lead Models – 50XX, 51XX, 56XX LQS Lead Models – 40XX, 41XX, 46XX Where "XX" denotes Lead Length in cm (45, 55, 65 or 85 cm)
respi**stim** Right Stimulation Lead	R Lead Models - 3101–3106, 3201–3206, 3601–3606, 3611–3616, 3651-3656

Table 2 – **Off-the-shelf components that are eligible for Whole-body and Head MRI scans (1.5T and 3T) when used with the rem**edē **System under specified conditions.**

COMPONENT DESCRIPTION	USE CONSIDERATIONS
Bipolar Sensing Lead with IS-1 terminal and co-radial coil	The **rem**edē Model 1001/1100 IPGs were evaluated to be MR Conditionally safe using an off-the-shelf, IS-1 bipolar lead with co-radial coil connected to the IPG sensing port. However, prior to an MRI examination, determine whether the patient has a sensing lead inserted into the **rem**edē Model 1001/1100 IPG sensing port. If so, the MR labeling of the sensing lead must be determined and the most restrictive MRI exposure requirements must be used of the medical device implants. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI examination if any conditions or implants that would prohibit or contraindicate an MRI are present.
IS-1 Port Plug (3.5cm) with metallic contacts	The **rem**edē Model 1001 / 1100 IPGs were evaluated to be MR Conditionally safe using an off-the-shelf, IS-1 port plug (3.5 cm in length) with metallic contacts inserted into the IPG sensing port. However, prior to an MRI examination, determine whether the patient has an IS-1 port plug inserted into the **rem**edē Model 1001 / 1100 IPG sensing port. If so, ensure the IS-1 port plug is no greater than 3.5cm in length or has MR conditional approval. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI examination if any conditions or implants that would prohibit or contraindicate an MRI are present.

Table 3 – **Components of the rem**edē **System that are MR Unsafe**

COMPONENT	MODEL NUMBER(S)
Physician Programmer	1002A
Programming Wand	1004A, 1004A-F
EIPG	1006, 1006A
Lead Adapter	1007

6. What about other implants? Can they undergo an MRI scan along with the **rem**edē System?

This is addressed in the **rem**edē System MRI guidelines with the following statement:

Prior to an MRI examination, determine whether the patient has multiple medical device implants, either active medical device implants (such as deep-brain stimulation systems, implantable cardiac defibrillators, etc.) or passive medical device implants (such as spinal hardware, stents, etc.). The most restrictive MRI exposure requirements must be used of the medical device implants. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI examination if any conditions or implants that would prohibit or contraindicate an MRI are present.

7. Why do patients need pre and post MRI scan checks for their **rem**edē device? What do they consist of?

This is addressed in the **rem**edē System MRI guidelines with the following statement:

To minimize the risks of interaction between the MRI field and the **rem**edē System implanted in patients, thus minimizing the risk of injury to the patient and damage to the **rem**edē System, the pre- and post-MRI checks need to be conducted.

Pre-MRI check: the device is interrogated to ensure the lead impedance is within range to ensure the system integrity. A broken wire may enhance RF energy coupling on the lead and increase the possibility of heating damage. If the lead impedance check returns with values out of range, the MRI scan cannot be conducted. If the lead impedance check comes back within range, the **rem**edē System is turned OFF and the patient can proceed with the MRI scan.

Post-MRI check: after the MRI scan has been conducted, the device is turned back ON, interrogated, and if applicable, restored to pre-MRI setting.

8. What parts of the body can be scanned and what are the coil positioning restrictions?

This is addressed in the **rem**edē System MRI guidelines with the following statement:

MRI scans can be safely conducted in the four zones indicated in Figure 1 below in patients implanted with the **rem**edē System using 1.5T and 3T MR scanners if the scan time conditions in either Table 4 (1.5T Scans) or Table 5 (3T Scans) are met.

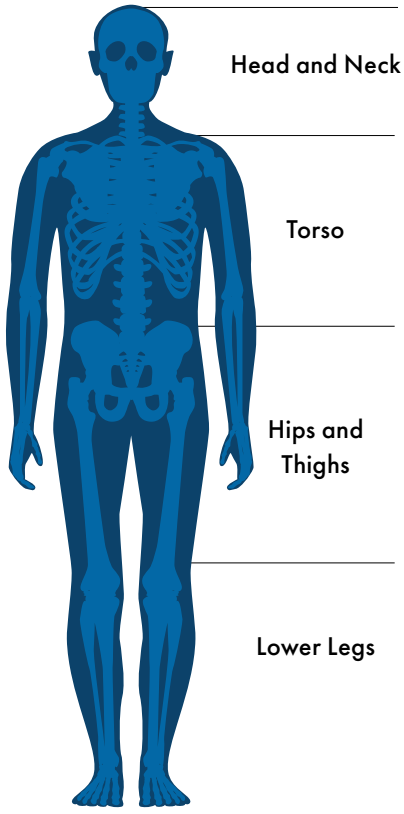

Figure 1. Coil Position Restriction Zones

Table 4 – **1.5T Operating Mode Scan Time Restrictions per Zone**

Field Strength	Zone	Normal Operating Mode*		Whole Body SAR Level: 1 W/kg		Whole Body SAR Level: 0.5 W/kg	
		Active Scan Time (minutes)	Wait Time (minutes)	Active Scan Time (minutes)	Wait Time (minutes)	Active Scan Time (minutes)	Wait Time (minutes)
1.5 T	Head & Neck	4	12	8.5	12	17	12
	Torso	4	12	8.5	12	17	12
	Hips & Thighs	Active RF Scan Time is 60 minutes in a 75-minute time period.					
	Lower Legs						

*SAR limits of Normal Operating Mode as defined in IEC 60601-2-33:2022 (Ed 4.0) (Table 201.104): Whole Body SAR: 2 W/kg, Head SAR: 3.2 W/kg, Partial Body SAR: 2-10 W/kg.

Table 5 – **3T Operating Mode Scan Time Restrictions per Zone**

Field Strength	Zone	Normal Operating Mode*		Whole Body SAR Level: 1 W/kg		Whole Body SAR Level: 0.5 W/kg	
		Active Scan Time (minutes)	Wait Time (minutes)	Active Scan Time (minutes)	Wait Time (minutes)	Active Scan Time (minutes)	Wait Time (minutes)
3 T	Head & Neck	2	12	4.5	12	9.5	12
	Torso	2	12	6	12	12	12
	Hips & Thighs	15	N/A**				
	Lower Legs	Active RF Scan Time is 60 minutes in a 75-minute time period.					

*SAR limits of Normal Operating Mode as defined in IEC 60601-2-33:2022 (Ed 4.0) (Table 201.104): Whole Body SAR: 2 W/kg, Head SAR: 3.2 W/kg, Partial Body SAR: 2-10 W/kg.
** The wait time is not applicable since consecutive 3T scans are not permitted in the Hips & Thighs zone.

9. What are the recommended parameters for the MRI scanner with the **rem**edē System?

This is addressed in the **rem**edē System MRI guidelines with the following statement:
MRI scans can be safely conducted in patients implanted with the remedē System using 1.5T and 3T MR scanners if the following conditions in Table 6 below are met:

Table 6 – **remedē System MRI Scanning Conditions**

A person implanted with the **rem**edē Implant System may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

PARAMETER	CONDITION
Device Name	**rem**edē IPG* respi**stim** Lead* Sensing Lead** IS-1 Port Plug with metallic contacts** *see Table 1 for component description **see Table 2 for component description
Device Configuration	Mode: OFF
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19.1 T/m (1910 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil, Head Coil
Operating Mode	See diagrams and Table 4 & 5 above
RF Conditions	
Scan Duration & Zones	
Image Artifact	The presence of the **rem**edē Implant System may produce an image artifact of 7.8 cm at the IPG and 1.4 cm at the distal end of the lead. Some manipulation of scan parameters may be needed to compensate for the artifact.

10. Which MRI subcategory number is your device listed under?

The **rem**edē System is listed under subcategory 5: The object is acceptable for a patient undergoing an MR procedure or an individual in the MR environment only if specific guidelines or recommendations are followed.

11. Where can I find more information on the MRI conditions and precautions for the **rem**edē System?

All information related to the MRI labeling of the **rem**edē System can be found in the remedē System MRI guidelines available on our website.

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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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