remedē® System

The Latest Advancement in remedē® System Technology

is now MRI compatible

The remedē System is now approved for Magnetic Resonance Imaging (MRI) compatibility under specific conditions.

This new indication makes it available to patients who have a regular need for MRI imaging or may be concerned about requiring an MRI in the future.

Compatibility chart

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

For a complete list of MR compatible accessories, please access our online MRI manual.

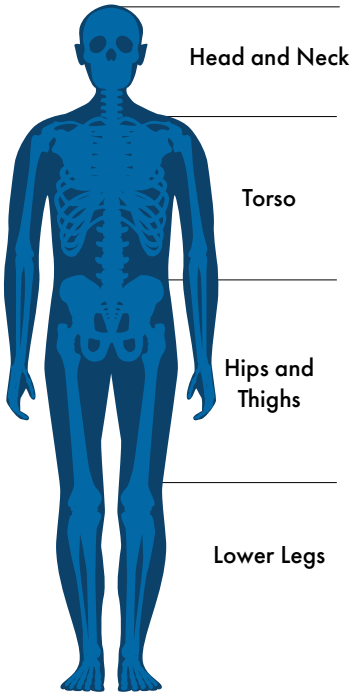
ZOLL®

MRI scanning conditions

Static Magnetic Field Strength (B_0)	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
RF Receive Coil Type	Any
Operating Mode	*See tables below*
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

Scan the QR code
to read all our instructions and recommendations for MRI use

Recommendations for scan durations, zones, and coil positioning restrictions



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						
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

Important Note
Prior to the MRI scan, the **rem**edē® System needs to be checked. Please refer to the MRI manual for detailed information.

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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