Nyxoah MRI Scanning Guidelines Europe

Nyxoah®

The path to restful nights

MRI Safety Information

The Genio® Implantable Stimulator (IS) is a Magnetic Resonance (MR) Conditional device which means that under MR environment the implant is safe within certain conditions.

This section contains important information regarding the Genio® IS and the conditions in which a patient implanted with the Genio® IS can safely undergo an MRI scan. MRI scans must be performed only as described in this section.

MRI Technician warnings and precautions

- Genio® system external devices (such as the Genio® DP or AC) shall not be brought by the patient to the MRI scan room and used during the MRI scan. The use of the Genio® DP and AC during an MRI scan is prohibited.
- Do not scan patients with fever.
- During the MRI scan, continuously monitor the patient, notice any signs of anxiety and/or discomfort.
- In case the patient feels uncomfortable pain or heating during the MRI scan, consider stopping the scan. Consider administration of anaesthetics to reduce patient's pain or discomfort.
- The MRI scan should be conducted at least 6 weeks after patient implantation or revision surgery.

Potential risks associated with MRI scans

The Genio® IS device has been designed to minimize the potential adverse events that could result in patient harm. The potential MRI-related adverse events are listed below:

- Implant heating causing damage to tissue in contact with the implant
- Implant migration causing damage to tissue in contact with the implant
- Implant migration causing the implant to be surgically removed (and replaced)
- Unintended over stimulation causing damage to tissue in contact with the implant
- Unintended stimulation causing discomfort due to electrical stimulation
- Device malfunction causing the implant to be surgically removed (and replaced)
- Diagnostic problems due to artifacts — shadowing on the MRI image in the vicinity of the implant causing loss or disturbance of diagnostic information

MRI Scan Conditions

Non-clinical testing has demonstrated the Genio® IS is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 1.5 Tesla and 3 Tesla, with:

- Maximum spatial field gradient of 1000 G/cm (10 T/m)
- Maximum force product of 18,000,000 G2/cm (18 T2/m)
- Maximum switched gradient slew rate per axis of 200 mT/m/ms
- Maximum switched gradient amplitude per axis of 45 mT/m
- Full body MRI scan in Normal Operation Mode for 15 minutes duration

Scan Condition 1 (1.5T)

For the torso (excluding thorax) and lower regions landmark position a maximum Whole Body Averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, for a continuous scanning of 30 minutes, the Genio® Implantable Stimulator is expected to produce a maximum temperature rise of less than:

- 1.05°C (2 W/kg, 1.5 Tesla) RF-related temperature increase.
- 0.5°C (42 T/SRMS) gradient magnetic field induced temperature increase.

Scan Condition 2 (1.5T)

For the head/neck/thorax landmark position a Head Averaged (HA) specific absorption rate of 3.2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, for a continuous scanning of 15 minutes, the Genio® Implantable Stimulator is expected to produce a maximum temperature rise of less than:

- 5.14°C (2 W/kg WBA and 3.2 W/kg HA, 1.5 Tesla) RF-related temperature increase.
- 0.5°C (42 T/SRMS) gradient magnetic field induced temperature increase.

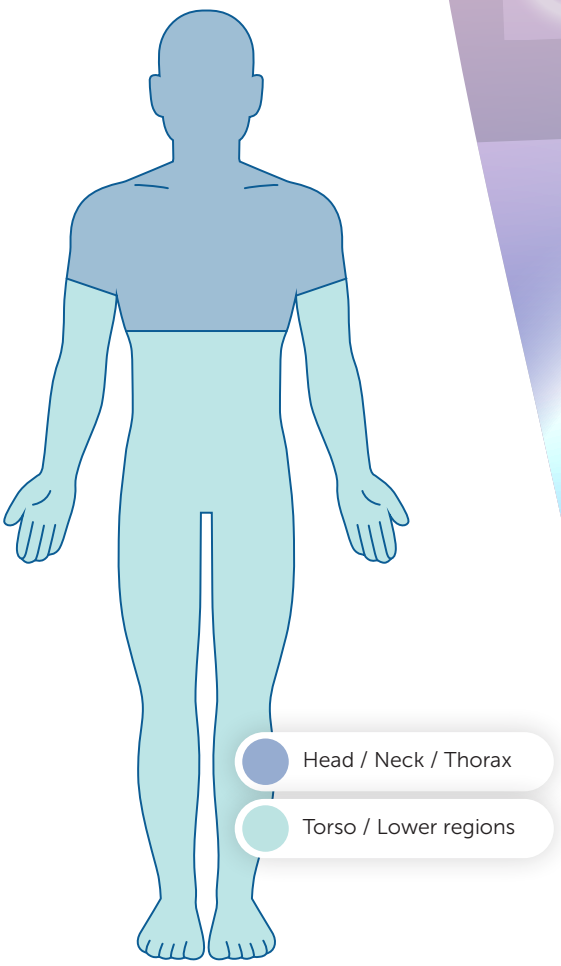

Figure 1: Scan Condition (1.5T and 3T)

Scan Condition 3 (3T)

For the torso and lower regions (excluding thorax) landmark position a maximum Whole Body Averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, for a continuous scanning of 30 minutes, the Genio® Implantable Stimulator is expected to produce a maximum temperature rise of less than:

- 1.2°C (2 W/kg, 3 Tesla) RF-related temperature increase.
- 0.5°C (42 T/SRMS) gradient magnetic field induced temperature increase.

Scan Condition 4 (3T)

For the head/neck/thorax landmark position a Head Averaged (HA) specific absorption rate (SAR) of 3.2 W/kg (Normal Operating Mode) and a Whole Body Averaged (WBA) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, for a continuous scanning of 15 minutes, the Genio® Implantable Stimulator is expected to produce a maximum temperature rise of less than:

- 5.5°C (2 W/kg WBA and 3.2 W/kg HA, 3 Tesla) RF-related temperature increase.
- 0.5°C (42 T/SRMS) gradient magnetic field induced temperature increase.

MR-induced malfunction testing with device exposure to the static field B0, the switched gradient field (dB/dt), the RF field (B1, E) and combined fields in 1.5 Tesla and 3 Tesla MR systems passed all tests in compliance with relevant standards.

In non-clinical testing, the image artifact caused by the device extends approximately 49.4 mm from the Genio® Implantable Stimulator when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Patented and design protected technology.

CE marked since 2019.

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