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NALU NEUROMODULATION SYSTEM

PATIENT ELIGIBILITY FORM AND PRE-MRI CHECKLIST

Important Note: The anatomical position of the Nalu Neuromodulation System implanted in the patient must be known prior to performing the MRI examination. The supervising physician (e.g., the radiologist) must review the information provided by the implanting physician, the patient's Medical Device Identification Card, and/or obtain an x-ray to determine the anatomic location of the implanted Nalu Neuromodulation System in the patient's body.

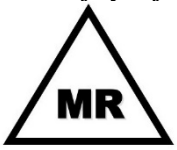
Additionally, the patient must undergo a proper MRI screening procedure according to the MRI facility's policies and procedures.

NEUROLOGY/REFERRING PHYSICIAN: Please complete the PATIENT ELIGIBILITY FORM and include information pertaining to the location of the implanted Nalu Neuromodulation System. Provide the PATIENT ELIGIBILITY FORM to your patient to take to the MRI Center and make a copy to include in the patient's medical file.

MRI/RADIOLOGY: Patient safety will be ensured by using the information on this form and filling out the PRE-MRI CHECKLIST to verify the use of the acceptable conditions, with special attention to the location of the Nalu Neuromodulation System and in consideration of the anatomic area of interest for the MRI examination. Additionally, specific conditions must be followed to ensure patient safety relative to the prevention of excessive heating of the Nalu Neuromodulation System.

Important Note: In addition to utilizing the PATIENT ELIGIBILITY FORM AND PRE-MRI CHECKLIST and PRE-MRI CHECKLIST, carefully review the latest Nalu Neuromodulation System Instructions for Use (IFU) available online at nalumed.com and follow all relevant information before proceeding with the MRI examination.

MRI Safety Information



MR Conditional

WARNING: A MRI examination performed outside the guidelines may result in the MRI-related, electromagnetic fields adversely interacting with this implanted device, potentially injuring the patient and damaging the device.

NALU MEDICAL TECHNICAL AND CLINICAL SUPPORT IS AVAILABLE MONDAY THROUGH FRIDAY, 8 AM – 5 PM PACIFIC STANDARD TIME PLEASE CALL US AT 760.448.2360or visit www.nalumed.com

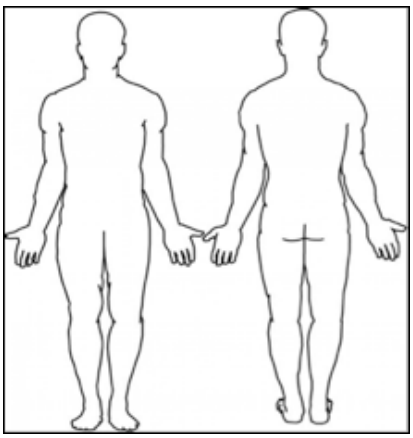
Date: ___/___/____

CONTACT INFORMATION

Patient Name (last name/first name): _____
Referring Physician (last name/first name): _____
Physician's Phone #: _____

NALU NEUROMODULATION SYSTEM

Model Number: _____
Nalu Neuromodulation System Position: _____



Circle the position of the Nalu Neuromodulation System

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PRE-MRI CHECKLIST

CHECKLIST: To be filled out by MRI/Radiology personnel prior to MRI.

The MRI examination will be performed on the patient with the implanted Nalu Neuromodulation System because there is a valid indication as determined by the supervising physician and all guidelines must be carefully followed to ensure patient safety.

All external components of the Nalu Neuromodulation System are MR Unsafe and are contraindicated for the MR system room. Therefore, the Therapy Disc, Wearable Garment and Adhesive Clip must be removed before the patient is allowed into the MR system room.

Therapy Disc:	☐ Removed	☐ N/A Note:_____
Adhesive Clip:	☐ Removed	☐ N/A Note:_____
Wearable Garment:	☐ Removed	☐ N/A Note:_____

Spinal Cord Stimulation (SCS) or Peripheral Nerve Stimulation (PNS)

Head and Extremities

Each condition indicated below must be carefully followed and verified to ensure patient safety:

- ☐ Static magnetic field of 1.5 Tesla (T)/64 MHz or 3.0 T/128 MHz, only.
- ☐ Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- ☐ Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.
- ☐ No external components of the Nalu Neurostimulation system are permitted the MRI system room.
- ☐ For head/brain MRI examinations, only the transmit/receive RF head coil is permitted for use. **No parts of the implanted Nalu Neurostimulation System may be within the transmit/receive RF head coil.**
- ☐ For extremity MRI examinations, only use a transmit/receive RF coil that includes a knee, foot/ankle, or wrist transmit/receive RF coil. **No part of the implanted Nalu Neurostimulation System is allowed within the transmit/receive RF coil used.**
- ☐ The conscious patient must be instructed to notify the MR system operator of any pain, discomfort, or unusual sensation that may occur during the MRI examination.
- ☐ The MR system operator must maintain verbal and visual communication with the patient so that the MRI examination can be terminated in the event of painful nerve stimulation or other adverse or unusual event.

Under the scan conditions defined above, the Nalu Neurostimulation System is expected to produce a maximum temperature rise of 2.5ºC after 15 minutes of continuous scanning (i.e., per pulse sequence) when using one of the above types of transmit/receive RF coils at a maximum, whole body averaged SAR of 2 W/kg. In non-clinical testing, the image artifact caused by the Nalu Neurostimulation System extends approximately 10 mm from this implant when imaged using a gradient echo pulse sequence and a 3 T MRI system.

Important Note: An MRI examination performed outside these guidelines may result in the electromagnetic fields used with MRI technology to interact adversely with an implanted Nalu Neurostimulation System potentially injuring the patient and/or damaging the device. Due to the risks of using MRI in a patient with an active implanted device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Spinal Cord Stimulation (SCS) ONLY

Full Body

Each condition indicated below must be carefully followed and verified to ensure patient safety:

- ☐ 40cm Nalu leads are implanted epidurally with stimulating contacts in the vicinity of T8-T10 and the IPG pocketed laterally (left or right) from the vicinity of L2
- ☐ Static magnetic field of 1.5 Tesla (T)/64 MHz only.
- ☐ Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- ☐ Up to 15-minute exposure to whole-body continuous scanning with a SAR value of 1.0 W/kg so that the temperature rise would be less than 6 degrees Celsius.
- ☐ No external components of the Nalu Neurostimulation system are permitted in the MRI system room.

- ☐ The conscious patient must be instructed to notify the MR system operator of any pain, discomfort, or unusual sensation that may occur during the MRI examination.
- ☐ The MR system operator must maintain verbal and visual communication with the patient so that the MRI examination can be terminated in the event of painful nerve stimulation or other adverse or unusual event.

Under the scan conditions defined above, the Nalu Neurostimulation System is expected to produce a maximum temperature rise of 6°C after 15 minutes of continuous scanning (i.e., per pulse sequence) when using one of the above types of transmit/receive RF coils at a maximum, whole body averaged SAR of 2 W/kg.
In non-clinical testing, the image artifact caused by the Nalu Neurostimulation System extends approximately 10 mm from the implant when imaged using a gradient echo pulse sequence and a 3 T MRI system.
Important Note: An MRI examination performed outside these guidelines may result in the electromagnetic fields used with MRI technology to interact adversely with an implanted Nalu Neurostimulation System potentially injuring the patient and/or damaging the device. Due to the risks of using MRI in a patient with an active implanted device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Additional conditions for all MRI Examinations

- Do not perform an MRI if the patient has a device or device component lead(s), extension, etc. attached to the Nalu Implantable Pulse Generator or leads from a different manufacturer attached to the Nalu Implantable Pulse Generator. The risk of performing an MRI examination under those circumstances has not been evaluated and, thus, may cause harm to the patient and/or the components.
- A patient implanted with a Model 12001-040 40 cm lead(s) connected to a Model 11003-002 or Model 11004-002 Ported IPG; or a Model 12005-025 25 cm tined lead or Model 12005-040 40 cm tined lead connected to a Model 11006-002 4-Contact Ported IPG can undergo an MRI examination under the specified conditions. Do not perform an MRI if the leads have been disconnected from the IPG.
- A patient implanted with a Model 11001-040, Model 11002-040 IPG with integrated lead(s) can undergo an MRI examination under the specified conditions.
- Nalu Neurostimulation System external components are not allowed in MRI system room. These components include Therapy Discs (Model 34001 or Model 34002), the iOS or Android device with the Nalu Remote Control application, Charger, Clinician Programmer, Belts, Limb Cuffs, surgical instruments or accessories. All such parts are **MR Unsafe** and are not be permitted in the MRI system room.
- Do not perform MRI on a patient undergoing the trial phase of the Nalu Implantable Pulse Generator (i.e. the patient has a percutaneously implanted lead and an external Trial Therapy Disc (Model 34002).
- Do not perform MRI on a patient that has any other active medical implants.

Preparation of the Patient Prior to the MRI Examination

- Inform the patient of the risks associated with undergoing an MRI examination: an MRI exam performed outside recommended guidelines may result in the electromagnetic fields used with MRI technology interacting adversely with an implanted Nalu Neurostimulation System, potentially injuring the patient and/or damaging the device.
- A trained healthcare professional with the proper knowledge of MRI technology such as an MRI safety-trained radiologist, MRI technologist, MRI nurse, or MRI physicist must ensure that the MRI examination will be conducted according to the information presented in this document.
- Document the patient's programming parameters.
- Perform an impedance check. Do not perform an MRI if the impedance is greater than 10 kΩ.
- Remove the Therapy Disc from the patient before entering the MRI system room.
- Do not sedate or anesthetize the patient so that the patient can inform the MRI system operator of any unusual sensations or problems associated with the MRI examination.
- Instruct the patient to immediately inform the MRI system operator if any discomfort, stimulation, shocking, or heating is experienced during MRI.

Considerations during the MRI Examination

- Similar to other MRI examinations, carefully monitor the patient throughout the MRI procedure both visually and audibly. Immediately discontinue the MRI examination if the patient reports any problems or unusual sensations.

Considerations after the MRI Examination

- After the patient leaves the MRI system room, turn the Therapy Disc on and verify connection to the Implantable Pulse Generator.
- Perform an impedance check.

All of the components of the Nalu Neurostimulation System are MR Unsafe except for the following:

- *Nalu Implantable Pulse Generators (Dual Integrated Model 11002-040, Single Integrated Model 11001-040)*
- *Nalu Implantable Pulse Generators (Single Integrated 25 cm Tined Model 11005-025, Single Integrated 40 cm Tined Model 11005-040)*
- *Nalu Implantable Pulse Generators (Dual Ported Model 11004-002 connected to two 40 cm Nalu Lead Model 12001-040, Single Ported Model 11003-002 connected to a 40 cm Nalu Lead Model 12001-040)*
- *Nalu Implantable Pulse Generator (Single 4-Contact Ported Model 11006-002 connected to a 25 cm Nalu Tined Lead Model 12005-025 or a 40 cm Nalu Tined Lead Model 12005-040)*
- *Nalu Anchor (Model 13001).*

WARNING

Do not bring MR Unsafe components of the Nalu Neurostimulation System into the MRI system room.

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