MRI Guidelines for the RNS® System

℞ Only

DN 1017451 Rev 6
Rev Date: 2020-02

TABLE OF CONTENTS

INTRODUCTION

This manual is a supplement to RNS® System product manuals and focuses specifically on the use of 1.5 Tesla (T) horizontal, closed-bore MRI systems for MRI scans on patients with the RNS® System.

ABOUT THIS MANUAL

Caution: Read these guidelines in their entirety before performing an MRI scan on patients who are implanted with any component of the RNS® System.

Caution: MR imaging may be performed safely on patients implanted with the RNS® System only under the specific conditions defined in this manual. The instructions do not apply to other products or other configurations that have not been evaluated.

RNS® Neurostimulator model RNS-320 of the RNS® System is MR Conditional.

RNS® Neurostimulator model RNS-300M of the RNS® System is MR Unsafe. Having an MRI scan with a model RNS-300M neurostimulator implanted may result in serious injury or possible death.

RNS® System External Components: All external components and accessories such as the Magnet, RNS® Tablet, NeuroPace® Programmer, NeuroPace® Remote Monitor, and Wand are MR Unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the MRI scanner room.

These guidelines are intended for use by physicians managing the treatment of patients with the RNS® System and by radiologists and other health care professionals performing MRI scans on patients implanted with the RNS® Neurostimulator and/or NeuroPace Leads. Healthcare professionals or patients with questions about the RNS® System in the MR environment should contact NeuroPace or the physician managing the RNS® System.

This document details the conditions under which a patient with the RNS® System can safely obtain an MRI scan. All conditions described herein must be met to ensure the safety of the patient exposed to the MR environment. This manual provides safety information and instructions for MRI scan of patients with the RNS® System, including how to identify eligible RNS® System patients, how to check and set the RNS® System before and after MRI, and what type of MRI machine and parameters to use.

The instructions in this manual apply only to an RNS® System comprising the RNS® Neurostimulator model RNS-320 or to an incomplete RNS® System (no RNS® Neurostimulator implanted).

The risk of explant of RNS® System components to create an MR conditional configuration outlined in this manual should be evaluated by a health care professional.

MR LABELING FOR NEUROPACE PRODUCTS

Implantable Components of the RNS® System

MR Unsafe

Table 1: MR Unsafe Implantable RNS® System Components

Component	Model Number(s)
Neurostimulator	RNS-300M
Cranial Prosthesis[1]	P-01

[1] No longer distributed commercially and has not been evaluated for MRI safety.

MR Conditional

Table 2: MR Conditional Implantable RNS® System Components

Component	Model Number(s)
Neurostimulator	RNS-320
Depth Lead	DL-330-3.5 DL-330-10 DL-344-3.5 DL-344-10
Cortical Strip Lead	CL-315-10 CL-325-10 CL-335-10
Connector Cover, Connector Plug	CC-01, CP-01
Ferrule, Ferrule Clamp	F-01, FC-01

MR Safe

Table 3: MR Safe Implantable RNS® System Components and NeuroPace Products

Component	Model Number(s)
Lead Strain Relief, Lead Cap, Suture Sleeve	LSR-01, LC-01, SS-01

External Components of the RNS® System

All external components and accessories of the RNS® System are MR Unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the MRI scanner room.

Table 4: External Components of the RNS® System

Component	Model Number(s)
Magnet	M-01
RNS® Tablet	5000
Wand	W-02
NeuroPace® Programmer	PGM-300
NeuroPace® Remote Monitor	All models (DTR-300, DTR-300-E, 5100)

OBTAIN CURRENT LABELING

The current version of these instructions can be found on the NeuroPace website at ***www.NeuroPace.com/resources***. If you have any questions, please contact NeuroPace.

CONTACT NEUROPACE

NeuroPace, Inc.
455 N. Bernardo Ave.
Mountain View, CA 94043

Customer Service: 866-726-3876 (Toll Free in the United States), ***customerservice@neuropace.com***

Website: ***www.NeuroPace.com***

Refer to the applicable NeuroPace® product manuals for additional device descriptions, device specifications, instructions for use, indications for use, contraindications, warnings and cautions. Refer to the clinical summary booklet for information on the clinical study results of the RNS® System and adverse event data.

All NeuroPace® manuals are available at ***www.NeuroPace.com*** or by contacting NeuroPace, Inc.

MRI SAFETY INFORMATION

An MRI scan may be safely performed on patients with the RNS® System only under the specific conditions of safe use detailed in this manual. These guidelines detail the steps necessary for a patient with an RNS® System to obtain an MRI scan safely. The structure of this manual is based on the chronological order in which the conditions of use must be satisfied before, during, and after the MRI scan. This manual also provides checklists in the appendices to guide compliance with the MR conditions.

The conditions specified in these guidelines address: (1) the implantable components of the RNS® System (the "device system"), (2) the patient, and (3) the MRI system. Each of these must conform to the MR conditions of use specified in this manual.

NEUROLOGY Health care professional(s) must ensure that the conditions specified in the **Before Scan (Neurology)** and **After Scan (Neurology)** sections are met, and should use **Appendix A: Pre-Scan Checklist (Neurology)** and **Appendix C: Post-Scan Checklist (Neurology)**.

RADIOLOGY Health care professional(s) must ensure that the conditions specified in the **During Scan (Radiology)** section are met, and should use **Appendix B: Scan Checklist (Radiology)**.

WARNINGS

WARNING: FOLLOW REQUIRED MR CONDITIONS OF USE

Only use conditions described in these guidelines, including putting the neurostimulator into MRI Mode. Using different conditions may result in device damage or malfunction and serious patient risks including permanent brain damage which may cause severe injury, coma, or death.

WARNING: PATIENT SUPERVISION REQUIRED

As with any MRI scan, carefully monitor the patient throughout the MRI examination both visually and audibly. Discontinue the MRI examination immediately if the patient becomes unresponsive or reports any problems.

WARNING: EXTERNAL DEVICES

Observe normal precautions that prohibit taking unnecessary external devices into the MRI scanner room. External devices subject to magnetic effects can pose serious hazards by becoming projectiles. All external components and accessories of the RNS® System such as the Magnet, RNS® Tablet, NeuroPace® Programmer, NeuroPace® Remote Monitor, and Wand are MR Unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the MRI scanner room.

POTENTIAL EFFECTS OF MR EXPOSURE

Exposure of the RNS System to the MR Environment may impact the patient, the device system or the MR image.

Patient

Following the conditions of safe use in this manual will minimize the potential interactions described below. If the following effects cause any patient discomfort, stop the MRI scan.

- **Heating:** The MRI RF (radio frequency) fields induce currents and voltages on the lead system that can produce significant heating effects at the lead-electrode-tissue interface. Failure to follow these guidelines can cause serious injury.
- **Vibration or movement:** The MRI magnetic field may exert translation, torque or vibration effects on the implanted neurostimulator, potentially causing a slight tugging or vibration sensation at the site of the neurostimulator. Failure to follow these guidelines could cause injury or impairment requiring medical intervention.
- **Gradient induced current:** An MRI may induce low levels of current through implanted leads, potentially causing a tingling sensation.

Device System

- **Device Reset:** In the unlikely event of a device reset during MR scanning, the RNS Tablet used post-scan to restore the neurostimulator to normal operation will display one or more alerts that describe the cause of the reset. When the type of reset is recoverable, the tablet displays instructions to guide recovery of the neurostimulator, typically by reprogramming the neurostimulator. If the reset is not recoverable, or if recovery is unsuccessful, note the cause of the reset and contact NeuroPace.

MR Image

- **Image Artifacts:** Implantable RNS® System components may produce artifacts and distortions in the MR image near the implanted components. Radiologists and clinicians must be aware of this when selecting imaging parameters and interpreting MR images.

OTHER POTENTIAL LIMITATIONS

NeuroPace has not evaluated the safety or effect of other implanted devices or implanted device components from other manufacturers used in combination with or in proximity to the implanted RNS® System components described in this manual. Contact the appropriate device manufacturer with questions regarding other devices or device components.

MR CONDITIONS OF USE

BEFORE SCAN (NEUROLOGY)

Prior to exposing the RNS® System to the MR environment, eligibility and preparation requirements must be met. ***Appendix A: Pre-Scan Checklist (Neurology)*** provides a checklist to ensure compliance with these requirements. The checklist is also available on the NeuroPace website.

To provide confirmation that all pre-scan conditions have been satisfied, the physician managing the RNS® System should provide the completed checklist to the MRI radiology professional. The managing physician should also advise the patient to bring the most up-to-date patient ID card to all MRI appointments.

Before Scan – Eligibility

The conditions specified in this section must be met prior to MR exposure. A patient with the RNS® System is eligible for an MRI scan if all the eligibility requirements detailed below are met. The device system, the patient, and the MRI system must each be evaluated for MRI eligibility.

Device System Eligibility

Only specific implantable components of the RNS® System, identified by model number, are eligible for MRI. ***Table 5*** below lists all implantable components of the RNS® System that are MR safe or MR conditional, and are therefore eligible for MRI.

Table 5: MRI Scan-Eligible RNS® System Components

Component	Model Number(s)
Neurostimulator[1]	RNS-320
Depth Lead	DL-330-3.5, DL-330-10, DL-344-3.5, DL-344-10
Cortical Strip Lead	CL-315-10, CL-325-10, CL-335-10
Connector Cover, Connector Plug	CC-01, CP-01
Ferrule, Ferrule Clamp	F-01, FC-01
Lead Strain Relief, Lead Cap, Suture Sleeve	LSR-01, LC-01, SS-01

[1] **The model RNS-300M neurostimulator is MR Unsafe.**

Note: All NeuroPace lead models are eligible for MRI. The leads can be attached or unattached to the neurostimulator. Unattached leads can be capped or uncapped. Leads that are cut or broken (at any point along the length of the lead) are eligible for MRI.

Note: An incomplete RNS® System (no neurostimulator implanted) remains eligible for MRI as long as all the implanted components are listed in the table.

Patient Eligibility

Only patients who meet the conditions below are eligible for MRI.

- **Eligible Device System:** Patient must have an eligible device system. All components of the RNS® System implanted in the patient must be listed in ***Table 5: MRI Scan-Eligible RNS® System Components***.

  To determine patient eligibility, the physician managing the RNS® System should complete ***Appendix A: Pre-Scan Checklist (Neurology)*** by using the Patient Data Management System (PDMS) to obtain a record of the RNS® System components implanted in the patient.
- **Neurostimulator Battery Status**: Must not be at EOS (end of service).
- **Patient Recovery**: In the clinician's judgment, the patient should have adequate time to recover from any invasive procedure related to the implantable components of the RNS® System before exposure to the MR environment. Wait at least 10 days after any lead implant or repositioning before having an MRI scan.
- **Patient Body Temperature**: Patient must not have a fever.

WARNING: ELEVATED BODY TEMPERATURE

Elevated body temperature (>37 degree C, 98.6 degree F) increases the risk of tissue heating, which could cause tissue damage and severe patient injury.

MRI System Eligibility

Only MRI systems which meet the conditions below are eligible for use with patients implanted with the RNS® System. Before taking steps to prepare a patient for MR exposure, the physician managing the RNS® System should verify that the MRI facility performing the scan has an MRI scanner that meets the following specifications:

- Horizontal field, closed-bore (cylindrical) system
- Static magnetic field strength of **1.5 T**
- Spatial field gradient ≤ **30 T/m** (3,000 gauss/cm)
- Gradient slew rate ≤ **200 T/m/s** per axis

Before Scan – Preparation

The condition specified in this section must be met after confirming eligibility and prior to MR exposure. This condition applies to the device system.[1]

- **Turn On MRI Mode:** Before the scan, a physician managing the RNS® System must turn on MRI Mode with the RNS® Tablet. MRI Mode is necessary to protect the patient and the neurostimulator. Follow the instructions below to turn MRI Mode on.

  Note: It is strongly recommended that the neurostimulator remain in MRI Mode only for as long as necessary. ***While in MRI Mode, the neurostimulator is not detecting or delivering therapy to the patient.*** *Additionally, the neurostimulator uses more battery power in MRI Mode than in normal operating mode. Note that the neurostimulator can be in MRI Mode for up to approximately two days per year without affecting battery longevity. Battery longevity estimates are specified in the RNS® System Physician Manual.*

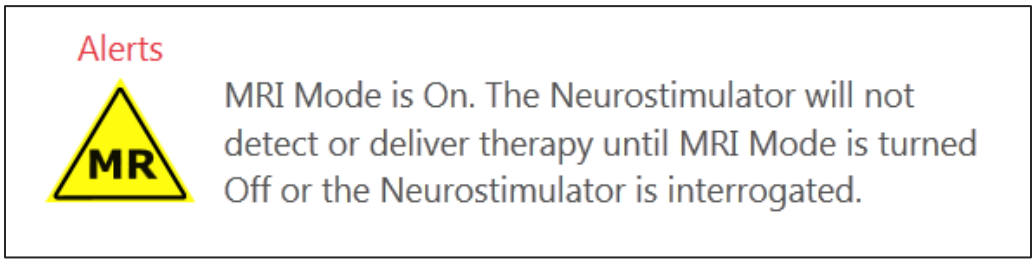
  Note: Device status, including MRI Mode status, will propagate to the Patient Data Management System (PDMS) whenever the RNS® Tablet is connected to the internet, and therefore be available to all authorized users.

  Instructions to Turn MRI Mode ON

  Using an RNS® Tablet, **MRI MODE** must be turned **ON** prior to a patient implanted with an RNS® Neurostimulator model RNS-320 receiving an MR scan. This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe. Log in to the RNS® Tablet and interrogate the RNS® Neurostimulator. Select **NEUROSTIM INFO** from the **HOME** screen to open the **NEUROSTIM INFO** screen. At bottom right, the **NEUROSTIM INFO** screen reports **MRI MODE IS: OFF** and provides the corresponding button to **TURN MRI MODE ON**.

[1] The condition in this section—MRI Mode—applies specifically to the neurostimulator itself. The condition does not apply if no neurostimulator is implanted.

To turn MRI Mode on, place the wand within approximately 1 inch of the neurostimulator, concave side of wand facing the neurostimulator, and select **TURN MRI MODE ON**. The tablet immediately sends the programming signal to turn MRI Mode on. A telemetry dialog indicates progress. Upon completion, the **NEUROSTIM INFO** screen displays an alert at upper left indicating that MRI Mode is on.



At bottom right, the screen reports **MRI MODE IS: ON**, and the button toggles to **TURN MRI MODE OFF**.

DURING SCAN (RADIOLOGY)

Before conducting an MR scan, either a review of the completed Pre-Scan Checklist provided by the physician managing the patient's RNS System or a consultation with the managing physician should confirm that all pre-scan conditions have been met.

The conditions specified in this section must be met during MR exposure. These conditions apply to the MRI system and to the patient.

Appendix B: Scan Checklist (Radiology) provides a checklist to ensure compliance with these requirements. The checklist is also available on the NeuroPace website.

MRI System Eligibility

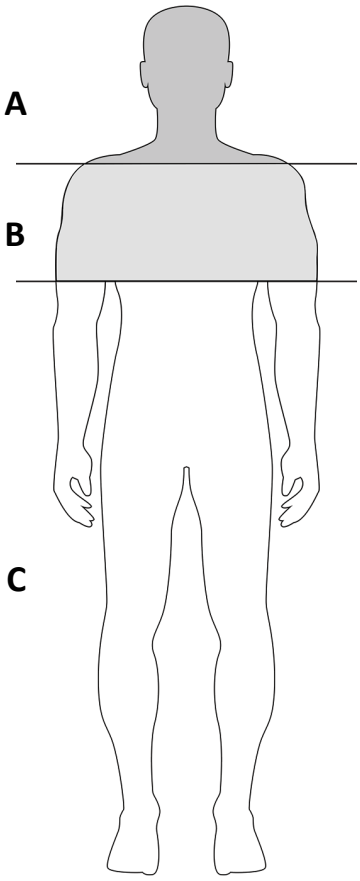
The MRI scanner must meet the following specifications:

- Horizontal field, closed-bore (cylindrical) system
- Static magnetic field strength of **1.5 T**
- Spatial field gradient ≤ **30 T/m** (3,000 gauss/cm)
- Gradient slew rate ≤ **200 T/m/s** per axis

MRI Scan Conditions

The MRI scan must meet the conditions according to the scan region encompassing the landmark position as illustrated below.

Table 6: MRI Scan Conditions



SCAN REGION	LANDMARK POSITION	Operating Modes [1]	
		$B_{1+\ RMS}$	SAR
A	Superior to the T2 vertebra	**$B_{1+\ RMS}$ Limit** $B_{1+\ RMS} \leq 2.95\ \mu T$	**Restricted Mode** Head Average SAR ≤ 0.6 W/kg
B	From the T2 to T8 vertebrae	**$B_{1+\ RMS}$ Limit** $B_{1+\ RMS} \leq 4.67\ \mu T$	**Restricted Mode** Whole Body Average SAR ≤ 1.0 W/kg
C	Inferior to the T8 vertebra	**$B_{1+\ RMS}$ Limit** $B_{1+\ RMS} \leq 4.67\ \mu T$	**Normal Operating Mode** Whole Body Average SAR ≤ 2.0 W/kg

[1] *Control for RF Power: SAR is the Specific Absorption Rate. $B_{1+\ RMS}$ is the root-mean-square of the MRI effective component of the RF magnetic field. Not all MRI scanners display the value of $B_{1+\ RMS}$ in which case the maximum SAR value must be used instead. Using the SAR value may result in a more restrictive MRI scan.*

For all scan regions, the MRI scan must meet the following conditions:

- **RF Coils:** Full body RF transmit receive coil (quadrature only), or full body RF transmit coil (quadrature only) with any receive only coil. Do not use a head or extremity transmit coil.
- **RF Exposure Time:** Active scan ≤ 30 minutes per session. Wait 30 minutes between sessions.

Patient: Temperature, Positioning and Monitoring

- **Patient Body Temperature**: Patient must not have a fever.

WARNING: ELEVATED BODY TEMPERATURE

Elevated body temperature (>37 degree C, 98.6 degree F) increases the risk of tissue heating, which could cause tissue damage and severe patient injury. Do not cover the patient with blankets or heated blankets as these can raise the patient's body temperature and increase the risk of tissue heating.

- **Supine Position:** Patient must be placed in the supine position.
- **Continuous Monitoring:** As with any MRI scan, carefully monitor the patient throughout the MRI examination both visually and audibly. Discontinue the MRI examination immediately if the patient becomes unresponsive or reports any problems.

AFTER SCAN (NEUROLOGY)

The conditions specified in this section must be met as soon as possible after MR exposure. These conditions apply to the device system.[2]

Appendix C: Post-Scan Checklist (Neurology) provides a checklist to ensure compliance with these requirements. The checklist is also available on the NeuroPace website.

Device System Status

- **Turn Off MRI Mode:** After the scan, a physician managing the RNS® System (or qualified personnel) must turn off MRI Mode with the RNS® Tablet. Follow the instructions below.

  Note: Please verify that the MRI scan was performed or cancelled prior to turning off MRI Mode.

  Note: It is strongly recommended that the neurostimulator remain in MRI Mode only for as long as necessary. ***While in MRI Mode, the neurostimulator is not detecting or delivering therapy to the patient.*** *Additionally, the neurostimulator uses more battery power in MRI Mode than in normal operating mode. Note that the neurostimulator can be in MRI Mode for up to approximately two days per year without affecting battery longevity. Battery longevity estimates are specified in the RNS® System Physician Manual.*

  Note: Device status, including MRI Mode status, will propagate to the Patient Data Management System (PDMS) whenever the RNS® Tablet is connected to the internet, and therefore be available to all authorized users.

[2] The conditions in this section—MRI Mode and status checks—apply specifically to the neurostimulator itself. These conditions do not apply if no neurostimulator is implanted.

Instructions to Turn MRI Mode OFF

Using an RNS® Tablet, **MRI MODE** must be turned **OFF** after a patient implanted with an RNS® Neurostimulator model RNS-320 receives an MR scan. This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe.

Method 1: If the **NEUROSTIM INFO** screen remains open on the RNS® Tablet that was used to turn MRI Mode on, the button at bottom right of the **NEUROSTIM INFO** screen can be used to turn MRI Mode off. Select **TURN MRI MODE OFF** (while holding the concave side of the wand within approximately 1 inch of the neurostimulator) to turn MRI Mode off. This scenario may occur, for example, if a clinician with an RNS® Tablet is present immediately before the MR scan to turn MRI Mode on, and afterward to turn MRI Mode off.

Method 2: Interrogation of the RNS® Neurostimulator with any RNS® Tablet turns off MRI Mode. During interrogation of a neurostimulator with MRI Mode on, a notification on the RNS® Tablet says that continuing the interrogation will turn MRI Mode off. Select **CONTINUE** to proceed with interrogation and turn MRI Mode off.

- **Check Status:** Interrogation of the neurostimulator with any RNS® Tablet serves as a status check. The physician managing the RNS® System (or qualified personnel) should perform an interrogation, review its results (including the lead impedance measurements and battery status), and view real-time ECoGs. If the RNS® Tablet indicates that the neurostimulator has not resumed its pre-scan function and programmed settings, reprogramming the device may be required. If reprogramming does not resolve an issue, refer to ***Troubleshooting*** in the RNS® System Programming Manual for help, or contact NeuroPace.

NEUROLOGY

NEUROPACE

Appendix A in MRI Guidelines for the RNS® System

RNS® System MRI Pre-Scan Checklist

A physician managing the treatment of a patient with the RNS® System should use this checklist to ensure compliance with the conditions of safe use before an MRI scan. Refer to the entire MRI Guidelines for the RNS® System for complete safety information and guidelines for conducting an MRI scan.

Complete each section below to determine a patient's eligibility for an MRI scan and to prepare an eligible patient for an MRI scan. In order to facilitate communication with MR technicians who will perform the MR conditional scan, the physician should provide the completed form to the MRI radiology professional.

PATIENT INFORMATION

Patient Name	
Physician Name	
Physician Office Address	
Physician Phone	

MRI CENTER INFORMATION

MRI Center Name	
Checklist Delivered Via (select then enter below):	☐ MAIL ☐ EMAIL ☐ PHONE/FAX ☐ OTHER (specify)
Address/Number	

RNS® NEUROSTIMULATOR IMPLANTED IN THE PATIENT

Determine device system eligibility:

- *Use the Patient Data Management System (PDMS) to obtain a record of the RNS® System components implanted in this patient and to confirm the implanted RNS® Neurostimulator model number.*
- *Check the box corresponding to the implanted RNS® Neurostimulator model number.*

RNS® System Component*	Implanted Product (Model #)	MR Elibility
Neurostimulator	☐ RNS-300M	**MR Unsafe**
Neurostimulator	☐ RNS-320	MR Conditional
Neurostimulator	☐ No RNS Neurostimulator implanted (leads only)	MR Conditional

**All NeuroPace lead models are MR Conditional and can be attached or unattached to the neurostimulator. Unattached leads can be capped or uncapped. Leads that are cut or broken (at any point along the length of the lead) are eligible for MRI.*

The following implantable RNS System components are MR Conditional: Connector Cover (CC-01), Connector Plug (CP-01), Ferrule (F-01), Ferrule Clamp (FC-01).The following implantable RNS System components are MR Safe: Lead Strain Relief (LSR-01), Lead Cap (LC-01), Suture Sleeve (SS-01). The following NeuroPace product is no longer distributed commercially and has not been evaluated for MRI safety: Cranial Prosthesis (P-01).

PATIENT ELIGIBILITY

Is the RNS® Neurostimulator implanted in the patient MR Conditional? **If NO, this patient is not eligible for MRI. Do not perform an MRI scan. If YES, the device system is eligible for MRI. Continue with the check-list.**	☐ Yes ☐ No

NEUROLOGY

NEUROPACE

PATIENT PREPARATION

Check each box as the item is addressed. (All boxes should be checked.)

☐ Confirm that the patient has adequate time to recover from any invasive procedure related to the implantable components of the RNS® System prior to the MRI scan. Confirm that at least 10 days will have passed since any lead implant or repositioning before the MRI scan will occur.
☐ Confirm that the battery status is not at EOS (end of service).
☐ Identify if the patient has any non-NeuroPace implants. NeuroPace has not evaluated the safety or effect of implanted devices or implanted device components from other manufacturers in combination with or in proximity to the implanted RNS® System. Contact the appropriate device manufacturer with questions regarding other devices or device components.
☐ Confirm that the MRI facility performing the scan has an eligible MRI System. ***See Appendix B: Scan Checklist (Radiology).***
☐ Warn patient about the potential effects of MR exposure. Refer to ***Potential Effects of MR Exposure*** in the MRI Guidelines for the RNS® System for more information.
☐ Advise patient to take the NeuroPace Patient ID card to MRI appointment.
☐ Arrange to turn on MRI Mode as close to the date of the MRI scan as possible.
☐ Schedule follow-up appointment to satisfy post-scan requirements as soon after the date of the MRI scan as possible. **It is important to turn off MRI Mode soon after the scan to restore therapy and preserve battery longevity.** See ***Appendix C: Post-Scan Checklist (Neurology).***

DEVICE PREPARATION

☐ **Turn on MRI Mode.** This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe.

CLINICIAN CONFIRMATION

☐ Check this Box to confirm that the information has been reviewed, is accurate as entered, and will be communicated to the MRI Center indicated above.

PERSON COMPLETING FORM (PRINT NAME) _____ **DATE COMPLETED** _____

RNS® System MRI Post-Scan Checklist

Appendix C in MRI Guidelines for the RNS® System

A physician managing the treatment of a patient with the RNS® System should use this checklist to ensure compliance with conditions of safe use after an MRI scan. Refer to the entire MRI Guidelines for the RNS® System for complete safety information and guidelines for conducting an MRI scan.

POST-SCAN CONDITIONS

☐ Confirm that MRI scan was performed or cancelled.
☐ **Turn off MRI Mode.** This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe.
☐ Perform post-scan RNS® System checks. Confirm that the neurostimulator has been restored to its pre-MRI settings. If necessary, reprogram the neurostimulator. Immediately contact NeuroPace to report any suspected device anomalies after MR exposure.

RADIOLOGY

NEUROPACE

RNS® System MRI Scan Checklist

Appendix B in MRI Guidelines for the RNS® System

MRI personnel should use this checklist to ensure compliance with conditions of safe use during an MRI scan. Refer to the entire MRI Guidelines for the RNS® System for complete safety information and guidelines for conducting an MRI scan.

ELIGIBLE MRI SYSTEM CONDITIONS

☐ MRI scanner is a horizontal field, closed-bore (cylindrical) system.
☐ MRI scanner has static magnetic field strength of 1.5 T.
☐ Spatial field gradient does not exceed 30 T/m (3,000 gauss/cm).
☐ Gradient slew rate does not exceed 200 T/m/s per axis.

MRI SYSTEM CONDITIONS

☐ RF Coils: Full body RF transmit receive coil (quadrature only), or full body RF transmit coil (quadrature only) with any receive only coil. Do not use a head or extremity transmit coil.
☐ RF Exposure Time: Active scan time ≤ 30 minutes per imaging session. Wait 30 minutes between sessions.
☐ For landmark positions superior to the T2 vertebra, maximum B_{1+rms} is 2.95 µT.
☐ For landmark positions from the T2 to T8 vertebrae, maximum B_{1+rms} is 4.67 µT. If B_{1+rms} is not available, then the scan sequence has a maximum Whole Body average SAR of 1.0 W/kg.
☐ For landmark positions inferior to the T8 vertebra, maximum B_{1+rms} is 4.67 µT. If B_{1+rms} is not available, then Normal Operating Mode may be used (with maximum Whole Body average SAR of 2.0 W/kg).

PATIENT CONDITIONS

☐ Confirm that the patient has no MR Unsafe items such as the Magnet.
☐ Confirm that **MRI Mode is on** and that all other pre-scan conditions have been met by consulting the physician managing the RNS® System or the Pre-Scan Checklist provided.
☐ Place patient in the supine position.
☐ Confirm that patient does not have a fever.
☐ As with any MRI scan, continually monitor patient throughout the scan. Verify that the patient has not experienced any adverse effects as a result of the MRI.
☐ Remind patient of the importance of returning to the physician managing their RNS® System in order **to turn MRI Mode off, restore therapy, and end extra battery consumption.**

NeuroPace, Inc. 455 N. Bernardo Ave.,
Mountain View, CA 94043 1-866-726-3876

DN 1017451 Rev 6 Rev Date: 2020-02

NeuroPace, Inc.
455 N. Bernardo Ave.
Mountain View, CA 94043

Customer Service: 1-866-726-3876
(Toll Free in the US)
Fax: 650-237-2855
Website: www.NeuroPace.com