NEUROTHERAPEUTICS
aleva

MRI Guidelines
for the directSTIM DBS System

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℞ ONLY 2019

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Additional Information

Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, warranty information and related information.

Table of Contents

1. Introduction

This manual is intended for physicians and other healthcare professionals (HCPs) responsible for managing patients implanted with the directSTIM DBS System, as well as radiologists and other HCPs involved in performing Magnetic Resonance Imaging (MRI) scans on such patients.

This manual provides guidelines on whether and how to perform a MRI scan on a patient implanted with the directSTIM DBS System.

Caution: *Read this manual before performing a MRI scan on a patient implanted with the directSTIM DBS System.*

Caution: *MR conditional scan may be safely performed when implanted only with the directSTIM DBS System components listed in this manual and only under the specific conditions during a MRI scan defined in this manual. Other configurations have not been evaluated.*

The directSTIM DBS System can be implanted to deliver unilateral or bilateral stimulation, with the most common implantation for bilateral stimulation. For bilateral stimulation, two leads and two extensions are connected to an implantable stimulator. For unilateral stimulation, one lead and one extension are connected to an implantable stimulator.

Indications for Use

The Aleva directSTIM™ Deep Brain Stimulation (DBS) System is indicated for patients with disabling tremor or symptoms of Parkinson's disease. Studies have shown that deep brain stimulation is effective in controlling essential tremor and symptoms of Parkinson's disease that are not adequately controlled with medication. Additionally, deep brain stimulation is effective in controlling dyskinesias and fluctuations associated with medical therapy for Parkinson's disease. The stimulation sites for patients diagnosed with Parkinson's disease are the subthalamic nucleus (STN) and the globus pallidus interna (GPi). The stimulation site for patients diagnosed with essential tremor is the ventral intermediate nucleus (VIM).

2. MR Conditional System Description

The MRI Guidelines apply to a complete directSTIM DBS System that consists of the following components presented in Table 1:

Table 1: directSTIM components eligible for a full body MR conditional scan.

Components
directSTIM 24-Channel Pulse Generator (PN-12000)
directSTIM 12-Electrode Lead 40cm - 12 contacts (PN-11500)
directSTIM 12-Connector Extension 60cm - 12 contacts (PN-12100)

Additional accessories:

- Anchoring sleeve* (opaque: PN-11549 or transparent: PN-11505) is provided and can be used with:
  - » Zimmer Biomet® Refobacin® Plus Bone Cement (not provided)
  - » Zimmer Biomet Model 01-7345 12 mm medium straight plates (not provided)
  - » Zimmer Biomet Model 91-610X 1.65 mm self-drilling HT x-drive titanium screws (not provided)
- Boston Scientific SureTek™ burr hole cover* (Modell DB-4600-C) (not provided)

Zimmer Biomet components MRI safety information: https://www.zimmerbiomet.com/en/support/mri.html

*Materials that do not interact with magnetic fields.

3. Safety Information

Contraindication

Do not perform MRI scans on "lead-only" systems or with broken, intermittent, or fragmented leads.

Warnings

MRI System: Only use 1.5T Full Body transmit/receive, RF quadrature only coils. Use hydrogen/proton imaging only. Do not use other transmit/receive coils (e.g. linear coils). Only 1.5T coils have been evaluated.

Active Scan time: Do not exceed cumulative active scan time (with RF On) of 30 minutes per imaging session. If 30 minutes of active scan time is reached, allow 60 minutes of non-active time before proceeding. Exceeding the active scan time increases the risk of tissue heating.

MRI Scanner Operating Mode: Apply the required B1+rms or SAR limit in the Normal Operating Mode. Do not conduct MRI scans in the First Level or Second Level Controlled Operating Modes as it may increase the risk of potential adverse effects listed below in "*Potential Interactions with MRI environment*".

Stimulator in storage mode: The directSTIM 24-channel Implantable Pulse Generator (stimulator) must be set in storage mode before an MRI session and before entering the MRI scan room. Performing MRI without setting the stimulator in storage mode may lead to unintended stimulation and potential patient harm.

Impedances out of range: Impedances out of range (high, indicated with red colour in the Clinician Programmer impedance settings screen, or low with yellow colour) may be a result of a compromised lead-stimulator connection. Scanning under these conditions may increase the risk of potential adverse effects listed below in "*Potential Interactions with MRI environment*".

Potential Interactions with MRI environment: During an MRI scan, there are potential interactions with the implanted DBS System. Following the safety instructions in the next chapters of this manual will minimize the potential interactions which are:

- **Heating:** the MRI RF field interacts with the implanted DBS System and can produce significant heating effects at the lead electrode/tissue and/or stimulator/tissue interface. The heating can cause tissue damage, edema, burns, discomfort, pain, injury, device damage and/or the need for additional intervention.
- **Main Magnetic Field Interactions:** The MRI magnetic field may exert force and torque on the implanted lead and/or stimulator. Patients may have a tugging sensation, discomfort or pain at the sight of the lead or stimulator implant. Patients with recent implant incisions may feel surgical wound discomfort.
- **Induced Stimulation:** During an MRI scan, energy may be induced into the DBS System potentially causing unintended stimulation or unusual sensations.

If interactions occur and cause the patient discomfort, stop the MRI scan.

If an MRI scan is performed outside of the conditions advised in this manual, the risks of interactions described above may be increased or result in more serious harms. These may include unintended stimulation, pain, tissue damage, burns, nerve injury, cerebrovascular accidents, coma, paralysis, or death.

Gradient Systems: Do not use gradient systems producing gradient slew rates more than 200 T/m/s because they have not been evaluated and may cause increased risk of untintended stimulation.

Body Temperature: The MRI conditional evaluation has been performed for patients with a typical body temperature of 37°C. Elevetated body temperature in conjuction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.

No Blankets: Do not cover the patient with blankets or heated blankets. Blankets raise the body temperature and increase the risk of tissue heating, which would cause tissue damage.

Patient Position: Patient must be positioned in supine or prone position during the scan.

Patient Psychological and Mental condition: Patient should be in a psychological condition and mental state to be able to provide immediate feedback in case of discomfort during the scan.

Supervision: A person with expert knowledge about MRI must ensure that all procedures of this manual are followed and than the MRI scan parameters during both the prescan and the actual MRI examination are within the recommended settings listed in this manual.

External components: The following external components of the directSTIM DBS System are not evaluated for MRI safety and therefore must not be brought in the MRI environement:

- directSTIM External Pulse Generator Model 12400 (trial stimulator)
- directSTIM Clinician Programmer Model 12200
- directSTIM Patient Programmer Charger Model 12300
- directSTIM Magnet 12700

Precautions

Return of Symptoms: Patients may become anxious or their symptoms may return once stimulation is turned OFF. Ensure that the patient has been given the appropriate medical care to manage the return of the syptoms before performing an MRI scan.

Image Artifact: The directSTIM DBS System has minimal image distrotion when the stimulator and leads are out of the field of view. Significant image distrotion can occur when the stimulator and/or leads are within the field of view. The image distortion must also be considered when interpreting the MRI images.

4. Instructions when performing MRI scan with a full System implanted

A patient implanted with a full directSTIM DBS System can safely undergo an MRI scan when the implant and MRI system conditions described in this section are met.

Check for the most recent MRI Guidelines

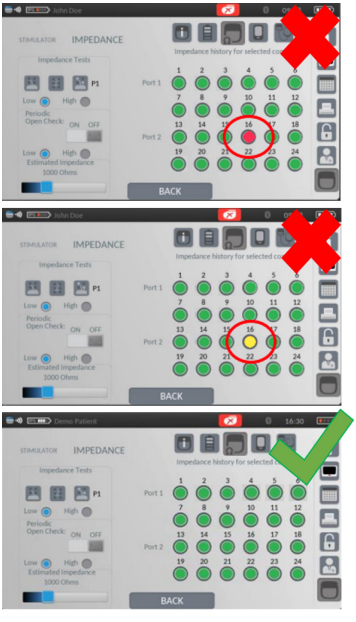
The most recent MRI Guidelines for the directSTIM DBS System are on the Aleva Neurotherapeutics SA website: https://www.aleva-neuro.com/ ,or they can also be obtained by calling +41 21 353 87 64.

The following conditions must be met before and during an MRI scan:

Table 2: directSTIM DBS System Implant conditions and recommended methods to determine eligibility.

Condition	Recommended method to determine eligibility
1. The patient is implanted only with the components listed in Table 1.	• Check patient ID card or patient records and ensure that the model numbers mentionned in Table 1 match the model numbers implanted. • Confirm with the physician responsible for implanting the patient's DBS System that the model numbers of the implanted components are the same with the model numbers mentioned in Table 1.

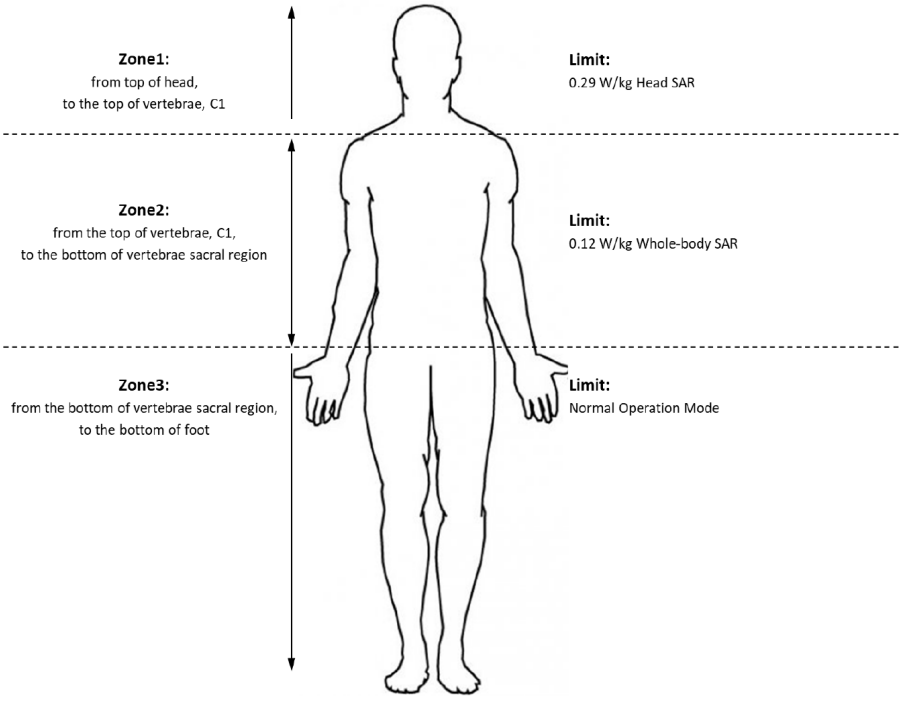
2. The directSTIM 24-channel Implantable Pulse Generator is implanted close to the clavicle (pectoral region). The directSTIM DBS 12-electrode lead(s) is inserted with an angle of 0 to 30° between the distal end of the lead and the sagital plane and 50 to 80° angle between the distal end of the lead and the transverse/axial plane. Both extensions must be routed on the same side of the IPG.	• Check patient records. • Examine the patient by palpation to determine where the stimulator is located. • Verify by X-ray.
3. The complete system is implanted: no "lead-only" systems have been evaluated for MR safety.	• Check patient records. • Confirm with the physician responsible for implanting the patient's DBS System, that the implantable components indicated in Table 1 of this manual are implanted as per the implantation manuals of the directSTIM DBS System.
4. The stimulator is charged before the MRI scan. *Note: the patient should bring the Patient Programmer Charger (PPC) to the MRI center.* **Warning:** *As the PPC is MR unsafe, it must be left outside the MR scanner room.*	• Ensure there are at least three (3) bars in the stimulator battery icon on the Patient Programmer Charger screen: 

5. No evidence can be found of fractured leads or compromised stimulator-extension-lead connection. An impedance measurement must be performed by the physician that manages the DBS treatment of the patient and who has access to the Clinician Programmer. **Warning:** *The Clinician Programmer is MR unsafe and must be left out of the MR scanner room.*	• Verify that all the electrode contacts on the Clinician Programmer impedance settings screen  If needed, repeat impedance measurement with "High" setting.

6. The stimulator is set in storage mode before entering the MR scanner room by holding the magnet (PN-12700) at least 5 seconds over the stimulator. **Warning**: *The magnet is MR unsafe (refer to "MR Unsafe Components", chapter 3) and must be left out of the MR scanner room.*	• Ensure that the stimulator is in storage mode: connection between the stimulator and the PPC should not be possible.  • If the physician managing the patient's DBS is present, he/she can set the stimulator in storage mode using the "storage mode" button on the Clinician Programmer. Refer to Appendix A of this manual for instructions. • If no Clinician Programmer is available, confirm that after holding the magnet over the stimulator, that the PPC is not able to connect to the stimulator.

Table 3: MRI environment conditions for scanning and recommended actions.

Condition	Recommended actions
1. MRI environement must meet the following criteria: • MRI magnet strength of 1.5 Tesla (T) only, in a horizontal closed bore system (no open-sided, vertical-field, standing or extremity systems). • Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s. • Maximum spatial field less than or equal to 40 T/m (40 gauss/cm).	Check the technical specifications of the MRI Scanner.
2. MRI coil setup: • Transmit coil: 1.5T Full Body volume transmit, RF quadrature only. • Receive-only coil: any type. • Hydrogen/proton imaging only.	Check the technical specifications of the MRI Full Body Coil.


Zone1:
from top of head,
to the top of vertebrae, C1
Limit:
0.29 W/kg Head SAR
Zone2:
from the top of vertebrae, C1,
to the bottom of vertebrae sacral region
Limit:
0.12 W/kg Whole-body SAR
Zone3:
from the bottom of vertebrae sacral region,
to the bottom of foot
Limit:
Normal Operation Mode

3. For a Full Body Coil, scan sequences must have Standard Absorbtion Rate (SAR) values as follows: • **Zone 1**: isocenter is above vertebra C1 » **Head SAR must be less or equal to (≤) 0.29 W/kg** • **Zone 2**: isocenter is between vertebra C1 and vertebra S5 (sacral region) • **Full-body SAR must be less or equal to (≤) 0.12 W/kg** • **Zone 3**: isocenter is below vertebra S5 » **Default full-body SAR (2 W/kg) at Normal Operation Mode is allowed**	• Check if Full Body Transmit/Receive Coil is being used. • Check patient ID card and confirm that the patient is fully implanted (leads + extensions + stimulator) with a directSTIM DBS System. • Confirm anatomical location of the isocenter or where the landmark is placed on the body of the patient during setup. • If the landmark or isocenter is above C1, check that the head SAR is set below or equal to 0.29 W/kg or B1+rms is set below or equal to 1.30 μT. This parameter should be applied for the whole duration of the scan. • If the landmark or isocenter is between C1 and S5, check that the whole (full)-body SAR is set below or equal to 0.12 W/kg or B1+rms is set below or equal to 0.74 μT. This parameter hould be applied for the whole duration of the scan. • If the landmark or isocenter is below S5, the MR scanner can be set in the default Normal Operation Mode (whole-body SAR of 2 W/kg). This parameter hould be applied for the whole duration of the scan.

4. Cumulative active scan time (with RF ON) should be limited to maximum 30 minutes per imaging session. If 30 minutes of active scan time is reached, allow 60 minutes of non-active time before proceeding.	Check the active scan time of the MR scanner.
5. Patient must be in supine or prone position during the scan.	Continuously monitor the patient to ensure correct position during the MR scan.
6. Patient should be in a psychological condition and mental state to be able to provide immediate feedback of any discomfort during the scan.	Maintain visual and audio monitoring of the patient throughout the MR scan. Verify that the patient is feeling normal and is responsive during and between MR scans. Stop the MRI immediately, if the patient becomes unresponsive to questions or experiences any adverse effects (refer to “Potential Interactions with MRI environment”, chapter 3).

5. Post-MRI Procedures

- Verify that the patient has not experienced any adverse effects as a results of the MRI. Potential adverse effects are listed in "*Potential Interactions with MRI environment*", in chapter 3 *"Safety Information"*. Contact the patient's physician and Aleva Neurotherapeutics if the patient has experienced any adverse effects.
- After the MR scan has been completed and the patient has exited the MR scanner room, the stimulator must be brought out of storage mode. In order to bring the stimulator out of storage mode, remind the patient to briefly charge the stimulator with the Patient Programmer Charger (PPC) to bring it out of storage mode. Instructions are included in Appendix A of this manual and in the Patient's manual.
- Verify that the stimulator is operational; i.e. it can be connected with the PPC and the stimulation can be turned ON. Contact Aleva's customer service at +41 21 353 87 64, if error messages are displayed or the stimulator is not operational.

Note: When the stimulator is out of storage mode the stimulation does not automatically turn ON. Patient or physician must turn ON the stimulation.

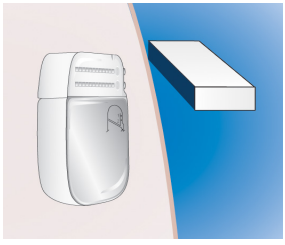
6. Appendix A - Setting the stimulator in and out of storage mode

Before the scheduled MRI scan, the stimulator must be set in storage mode. To do that, the magnet (PN-12700) can be used by the patient or the stimulator can be set in storage mode by the physician responsible for the patient's DBS treatment by using the Clinician Programmer.

Note: Before setting the stimulator in storage mode, confirm that an impedance measurement has been performed by the patient's physician before the MR scan. Verify that there are no impedances out of the acceptable range (indicated with red or yellow colour on the impedance settings screen). Refer to the directSTIM DBS System CP Manual for instructions on how to perform an impedance measurement.

1. If the magnet is used to set the stimulator in storage mode, follow these steps (instructions for patient and physician):

- Hold the magnet for at least during5 seconds over the stimulator.



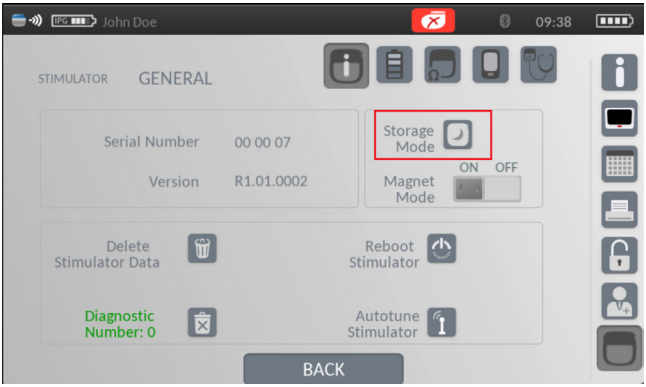
- When the stimulator is set in storage mode, the PPC - stimulaor communication is lost:

- Check if you can connect the PPC to the stimulator.

Warning: The magnet and Patient Programmer Charger must be left out of the MR scan room as they are not evaluated for MRI safety (they are labelled as “MR unsafe”).

2. If the Clinician Programmer is used to set the stimulator in storage mode, follow these steps (instructions for physician):

- On the Clinician Programmer (CP) screen (any screen), tap on the  button to access the general settings screen. Make sure that the CP is connected to the patient's stimulator. Tap on the "storage mode" button to set the stimulator in storage mode:



- When the stimulator is set in storage mode, the CP - stimulator communication is lost:

- Check if you can connect the CP to the stimulator.

After the scheduled MRI scan, the stimulator must be set out of storage mode. To do that, the Patient Programmer Charger (PPC) has to be used to charge briefly the stimulator:

- Turn ON the PPC. Tap "Cancel" on the notification that will appear since the stimulator is in storage mode and cannot communicate with the PPC.

- Connect the charging paddle to the PPC an tap on  . Position the charging paddle over the stimulator and start charging. After 5-10 seconds, the stimulator is out of storage mode and the PPC can connect to the stimulator. Confirm by checking that the connection is established:

A press on  can reinitate a connection if the PPC does not reconnect automatically.

- Turn on the stimulation and confirm by checking the icon on the PPC screen:

7. Appendix B - MRI Eligibility Form

directSTIM DBS System Full Body MRI Patient Eligibility Form

This form provides information about the patient's implanted DBS System MRI scan eligibility. It may be provided to the radiologist to support the confirmation of the patient MRI scan eligibility.

Patient and Physician Information

Patient Name:	
Date:	
Physician Name:	
Office Address:	
Phone:	

Implant conditions (check applicable boxes)

MRI Eligible		Not MRI Eligible	
	Full System implanted only consisting of the following components:		Lead-only system
☐	directSTIM DBS System full implanted with the following components: » directSTIM 24-Channel Implantable Pulse Generator (PN-12000) » directSTIM 12-Electrode Lead 40cm - 12 contacts (PN-11500) » directSTIM 12-Connector Extension 60cm - 12 contacts (PN-12100) » Accessories: Anchoring sleeve (opaque: PN-11549 or transparent: PN-11505) is provided and can be used with: » Zimmer Biomet® Refobacin® Plus Bone Cement (not provided) » Zimmer Biomet Model 01-7345 12 mm medium straight plates » Zimmer Biomet Model 91-610X 1.65 mm self-drilling HT x-drive titanium screws (not provided) Boston Scientific SureTek™ burr hole cover* (Modell DB-4600-C) (not provided)	☐	

☐	The directSTIM 24-channel Implantable Pulse Generator is implanted close to the clavicle (pectoral region). The directSTIM DBS 12-electrode lead(s) is inserted with an angle of 0 to 30° between the distal end of the lead and the sagital plane and 50 to 80° angle between the distal end of the lead and the transverse/axial plane. Both extensions must be routed on the same side of the IPG.	☐	The directSTIM 24-channel Implantable Pulse Generator is implanted in other locations than indicated. The directSTIM DBS 12-electrode lead(s) is inserted with an angle out of the ranges indicated. Extensions are not routed on the same side of the IPG.
☐	NO evidence of fractured leads or compromised stimulator - extension - lead connection.	☐	Evidence of fractured leads or compromised stimulator - extension - lead connection.

Impedance Check results

Impedance Check performed by:	
Date of impedance measurement:	
Date of scheduled MRI scan:	
Results / Indicate how many contacts (Port 1 and Port 2) are green/ red/yellow:	Green : Red: Yellow:

Instructions for the Patient or MRI center prior to the MRI scan

Inform the patient of the potential risks of undergoing an MRI scan with the MR conditional directSTIM DBS System.

Ask the patient to:

- Fully charge (at least 3 bars must be visible in the stimulator battery level) their stimulator before the scheduled MRI scan.
- Bring with them the Patient Programmer Charger (with the paddle) also charged.
- Bring the magnet.

If the patient does not bring the Patient Programmer Charger, the physician responsible for the patient's DBS must be present with the Clinician Programmer to set the stimulator in storage mode. However, the stimulator cannot be set out of storage mode without the Patient Programmer Charger. The patient will be off stimulation until the stimulator is set out of storage mode.

Warning: Patient Programmer Charger and magnet are "MR unsafe" and must be left out of the MR scanner room.

Aleva Customer Service

If you have any questions about the directSTIM DBS System, call your product distributor for assistance. If additional assistance is needed, contact Aleva Customer Service at +41 21 353 87 64

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