OptimDBS

Clinician User Guide for using marked MRI

Revision 4

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1. General Information

This document explains how to retrieve and use during surgery marked MRI with brain targets processed by OptimDBS, a stand-alone software developed by RebrAIn.

It is recommended that you read this user guide carefully before use.

This symbol indicates that the product is a medical device.

Users should pay particular attention to this symbol indicating important warnings and precautions to be taken into account to use the marked MRI in best conditions and in complete safety. This symbol is used to indicate potentially hazardous situation which, if not avoided, may result in negligible, minor or moderate injury.

Indicates the need for the user to consult this instruction for use.
This electronic user guide (in English and other available languages) can be downloaded on RebrAIn website; or via the link included in the notification email sent when the marked MR image is uploaded on transfer.rebrain.eu.
A hard copy of this user guide may be requested at no additional cost and delivered within 5 working days.

OptimDBS is a CE marked medical device qualified as class I.
It complies with the requirements of the European Directive 93/42/EEC on medical devices and requirements of MDR 2017/745 on legacy devices. Marked MRI processed by OptimDBS can therefore be used in accordance with its intended use and its clinical claims, in countries of the European Union where the legislation authorizes it.

This symbol indicates the manufacturer, as defined in European Directive 93/42/EEC.

2. Description of OptimDBS and marked MRI outputted

OptimDBS is a semi-automatic stand-alone software application that helps clinicians with surgery planning. From a cerebral MRI of the patient in 3D DICOM Format, OptimDBS outputs an MRI (3D DICOM) with visual indicators at the predicted target coordinates to offer a solution for functional stereotactic targeting in order to add confidence to the clinician's targeting method.

Deep brain stimulation (DBS) is a type of surgical treatment for neurodegenerative diseases such as Parkinson's disease and essential tremor. A crucial step in this procedure is the identification of the brain targets where current is to be delivered through implanted electrodes to alleviate the patient's symptoms. Gamma-knife therapy (radiosurgery, RS) or thermal lesion (high intensity focused ultrasound, HIFU) are other surgical treatments that use the same type of targeting to locate the positions at which controlled lesions need to be delivered.

OptimDBS can predict specific brain targets to support the clinician in their usual targeting method during surgical procedures. The software application is exclusively used by qualified RebrAIn operators. Once the clinician has provided to RebrAIn with an anonymized MRI image in 3D DICOM format, the operator can process to it with OptimDBS. OptimDBS outputs an MRI image with visible markers (white crosses) where the predicted targets are located, which is then sent back to the clinician to assist them during the surgical procedure.

The output image provided by OptimDBS shall in no circumstance be used as the clinician's targeting method. It shall only be used as an additional source of information for the clinician to either increase their confidence in their usual targeting methods or prompt further verifications at the clinician's own discretion.

3. Intended use of OptimDBS and marked MRI outputted

Intended Use

OptimDBS is a stand-alone software application intended to provide a standardized method of neurosurgery stereotaxic target visualization by using prediction algorithms for the treatment of Parkinson's disease and essential tremor. From a cerebral MRI of the patient (3D DICOM), it outputs an MRI in standard 3D DICOM format with visual indicators at the predicted target coordinates which are meant to be used by the clinician as a cross-comparison tool to increase confidence in their usual targeting methods.

Patient Population

OptimDBS is indicated for patients with Parkinson's disease or essential tremor eligible for surgical indication (DBS, lesions surgery). Patient eligibility is the responsibility of the clinician who is following the patient.

Intended user

The marked MRI images that have been processed by OptimDBS are intended to be used by the clinician who performs the neurosurgical intervention.

Contraindications

There is no contraindications when using marked MRI images processed by OptimDBS.

Undesirable side effects

No adverse effects are expected when using the MRI images marked with predicted brain targets.

Responsibility

The images processed by OptimDBS only provide additional assistance to clinicians. They do not replace or substitute standard targeting methods.

4. Clinical benefits and performance characteristics

4.1. Clinical benefits

With the current intended purpose, clinicians are asked to refer to their own targeting methods in case this method disagree with the marked MRI obtained with OptimDBS. Thus, no patient's benefit is directly expected. If OptimDBS confirms the correct position of the target, OptimDBS increases the clinician's confidence in his gesture, otherwise OptimDBS invites the surgeon to question his targeting and thus could potentially increase the quality of patient care.

4.2. Technical performance

The technical performances of OptimDBS are as follows:

- Implementation of 2 models, both validated, to indicate the position of targets (STN and VIM) for surgical brain procedures;
- Reading of MRI images in 3D DICOM format;
- Semi-automatic processing of MRI images in 3D DICOM format to indicate the targets;
- Output image (marked MRI) remains in DICOM format for compatibility with surgical brain procedures equipment (e.g. planning station)

5. Precautions and safety information

5.1. Disclosure of Residual Risks

Residual risks disclosure is covered with the following warnings, as well as with information indicated in ***§5.2*** and ***§5.3***.

ATTENTION

- The marked MRI image should be used by qualified healthcare professionals with skills in medical imaging and neurosurgery.
- Images processed by OptimDBS only provide additional help to clinicians. They do not replace or substitute the usual targeting methods.
- The marked MRI image should be used by the clinician only as a cross-comparison tool to increase confidence in their usual targeting methods and to secure the surgical procedure.
- The quality and accuracy of the marked MRI images strongly depend on the quality of the provided MRI in 3D DICOM format. Therefore, an MRI with good quality and contrast is needed. Refer to **§6.1** for more information.
- All MRIs sent to RebrAIn for targeting process must be pseudonymized. In case of anonymization issues, the files provided will be erased from our databases and you will be required to upload your files again.
- Patient name and date verification require a special attention from the clinician, especially after the de-anonymization process.
- Patient eligibility and choice of surgical procedure are the responsibility of the patient's clinicians.
- When using the marked MRI image as a cross-comparison tool during surgery, the clinician should verify the sides and quality of the fused images.
- Clinicians should submit a request for MRI processing at least one day before the scheduled surgery date.

5.2. Compliant use

The use of these marked MRI images (3D DICOM) processed by OptimDBS is reserved for clinician planning to perform a neurosurgical intervention for the treatment of patients with Parkinson's disease or Essential Tremor by targeting the subthalamic nucleus, STN, or the ventral intermediate nucleus, VIM.

Any inappropriate use is prohibited.

5.3. Malfunction

For any problems related to loading/downloading MRI images or if the marked MRI image:

- is incompatible with the planning station used during neurosurgery;
- is non available; or
- includes improper STN and VIM regions of interest (e.g., difficulties to identify regions of interest or aberrant localization);

please send an e-mail to: support@rebrain.eu.

If the marked MR image shows a discrepancy between the STN and VIM targets localized by the clinicians and the ones annotated by OptimDBS, RebrAIn recommends performing additional verifications and/or using complementary methods (e.g., indirect, direct or functional brain structures localization), before the surgical intervention, which will contribute to make the procedure safer.

In case of a problem with the marked MRI image processed by OptimDBS (see above), or if a significant mismatch persists after additional verification, clinicians must operate the patient according to their own clinical protocol.

5.4. Incident reporting

Any incident or serious incident that has occurred in relation to the use of marked MRI images should be reported to RebrAIn (support@rebrain.eu) and/or to the competent authority of the Member State in which the event occurs.

6. Instructions for use

6.1. Imaging requirements

The models used by RebrAIn for processing MR images with OptimDBS to localize STN and VIM targets have been tested to perform accurately when using the following requirements:

Slices
- Use a constant slice thickness - Use a slice thickness of 1.5 mm or less are preferred, which usually produces the highest quality data set for image segmentation with OptimDBS Software - Scan contiguous slices and make sure that there is no gap or overlap between slices

Size and pixels
- Use a square image matrix of more than 256 x 256 pixels - Use square pixels

MR Images
- Use preoperative images, axial or coronal slices are preferred - Use MPRAGE or BRAVO - Use of 3D T1 is preferred, but in all cases MR images must allow us to correctly visualize the central grey nuclei - Use of MR image with or without injection - MR images must be free from pathological findings and radiologically visible brain structure distortions

6.2. Pseudonymization of MRIs

It is required to pseudonymize a patient's MRI. This can be done by using your own anonymization process or by using open-source tools or software dedicated to MRI anonymization.

The de-anonymization process and the cross-referencing of patient data are the responsibility of the clinician and/or the hospital.

6.3. Application for MRI marking

Uploading MRI images (3D DICOM) of a patient and downloading MRI images marked with predicted targets can be done using an appropriate web interface:
https://transfer.rebrain.eu/login or https://cloud.acronis.com/login.

The credentials sent by RebrAIn must be used to log in.

A manual concerning the use of those web interfaces is available directly once connected.

However, the following information must be provided during the request:

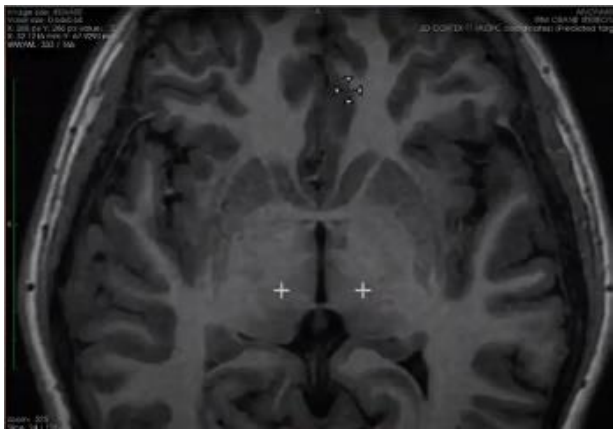
- The brain target: STN or VIM;
- The hemisphere to be targeted in case of unilateral marking.

⚠ **Warning: If the hemisphere is not indicated, bilateral marking will be performed by the RebrAIn operators**

6.4. Use of the marked image during a neurosurgical procedure

The image processed by OptimDBS is provided in 3D DICOM format, a standard and internationally accepted format. Once downloaded, the marked MRI image may be used on any device, used for functional stereotactic targeting, compatible with this format.

The brain targets predicted by OptimDBS are indicated by white crosses, as below:



It is possible that the targets are not on the same slice in the MRI. In this case, it is necessary to navigate between the different slices of the image to find the predicted targets.

7. Legal implications

This Clinician User Guide is a "Material" as described in the Terms and Conditions and/or Term Sheet that you have signed to take advantage of the Rebrain Service.

8. Integrated third-party software:

This software is partly based on medInria, a multi-platform medical image processing and visualization software developed by Inria. For a full description of the copyright, disclaimer and licence, see https://med.inria.fr/about/license.

9. Electronic version of instruction for use

Please note that this service is supplied with electronic instructions for use. Please note that the electronic instructions for use are provided in "PDF" format. A suitable software, such as Adobe Acrobat Reader, is required to read them.

Adobe Reader may be obtained from: https://get.adobe.com/reader/

These instructions (available in different languages) may be accessed at the following address:

- Directly on https://rebrain.eu/en/ifu/
- On https://transfer.rebrain.eu/login, on "help" menu once connected

A hard-copy of the instructions for use may be obtained within 5 working days at no additional charge by contacting RebrAIn at this email address: support@rebrain.eu

10. Contact

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