RebrAIn

OptimDBS

Clinician User Guide

Review 2

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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.

The instructions for use (in French and English) can be downloaded on the RebrAIn website: https://rebrain.eu/ or on a specific web interface made available to clinicians.

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.

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2. Description of OptimDBS

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

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. Warning

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.
- 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. Precautions

5.1. 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.

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

A manual concerning the use of the web interfaces is sent to each clinician when they log in for the first time.

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**

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;
- show a discrepancy between the targets obtained during the clinician's usual targeting and the targets obtained on the MRI image processed by OptimDBS,

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

In case of a problem with the marked image processed by OptimDBS (see above), clinicians must operate the patient according to their own clinical protocol.

6. Instructions for use

6.1. Pseudonymization of MRIs

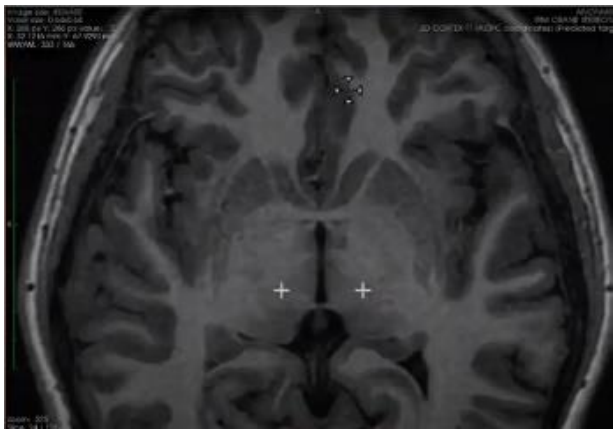
It is required to pseudonymize a patient’s MRI. This can be done by using your own anonymization process or by using open-source tools or software dedicated to MRI anonymization.

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

6.2. Use of the marked image during a neurosurgical procedure

The image processed by OptimDBS is provided in 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 CONDITIONS - EXCLUSION OF WARRANTY / LIMITATION OF LIABILITY

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8. Copyrights or trademarks

OptimDBS is the property of RebrAIn.

9. 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

10. Contact

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