OptimMRI

Clinician's User Guide

for using annotated MR image

This document explains how to retrieve and use an annotated MR image with brain's region(s) of interest processed by OptimMRI, a software developed by RebrAIn.

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

MD This symbol indicates that the product is a medical device.

Rx This symbol indicates that the product is prescription only.

⚠ Users should pay particular attention to this symbol indicating important warnings and precautions to be considered to use the annotated MR images in best conditions and in complete safety.

📖 Indicates the need for the user to consult these instructions for use.
This electronic user guide (in English and other available languages) can be downloaded on RebrAIn website; or on "Help" menu on transfer.rebrain.us once logged in.
A hard copy of this user guide may be requested at no additional cost and delivered within 5 working days.

🏭 This symbol indicates the manufacturer.

2. Description of OptimMRI

OptimMRI is a software application for processing medical images of the brain that enables 3D visualization and analysis of anatomical structures. Specifically, the software can be used to read DICOM compatible pre-operative MR images acquired by commercially available imaging devices. These images can be processed to generate 3D markers in specific regions of the anatomy intended to provide qualified medical professionals with adjunctive tools to aid them in routine clinical practice for processing, visualizing, interpreting and planning neurosurgical functional procedure.

OptimMRI uses machine learning and image processing techniques to facilitate localization of the Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) regions of interest.

The software is exclusively used by qualified and trained RebrAIn operators. Once the medical professional has provided a pre-operative MR image in 3D DICOM format to RebrAIn, the operator can process it with OptimMRI: the operator manually places AC-PC line, and 17 specific landmarks per required hemisphere (left and right) on known, visible brain structures, that are used by the algorithm to indicate the position of the regions of interest (STN or VIM) with visible 3D markers. OptimMRI will output an MR image (3D DICOM) where the identified regions of interest are annotated with white 3D crosses. This annotated MR image is then sent back to qualified medical professionals to provide adjunctive radiological information and facilitate planning in neurosurgical procedures.

3. Indications for Use of OptimMRI

Indications for Use

OptimMRI is a software application intended to aid qualified medical professionals in processing, visualizing, and interpreting anatomical structures from medical images. The software can be used to process pre-operative DICOM compatible MR images to generate 3D annotated models of the brain that aid the user in neurosurgical functional planning. The annotated MR images can further be used in conjunction with other clinical methods as an aid in localization of the Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) regions of interest.

Patient population

OptimMRI is software intended to process MR images of the brain to locate anatomical regions of interest. Qualified medical professionals are responsible for selecting eligible patient population with Parkinson's disease or essential tremor who may benefit from localization of STN and VIM to aid in neurosurgical functional planning.

Intended user

The intended users of OptimMRI are trained RebrAIn Operators who are responsible for processing pre-operative MR images and returning 3D annotated images to medical professionals. The annotated MR images are intended to be used by qualified medical professionals (including but not limited to surgeons, neurologists and radiologists) who plan to localize regions of the brain such as Subthalamic Nuclei (STN) and Ventral Intermediate Nucleus (VIM) during neurosurgical functional planning.

Contraindications

There are no contraindications when using annotated MR images processed by OptimMRI as adjunctive radiological information for localization of the STN and VIM regions of interest.

Undesirable side effects

No adverse effects are expected when using the MR images annotated at the region(s) of interest (STN or VIM).

Responsibility

The images processed by OptimMRI only provide additional assistance to qualified medical professionals. They do not replace or substitute standard planning methods.

4. Clinical benefits and performances characteristics

4.1. Clinical benefits

The STN and VIM regions of interest computed by OptimMRI shall be used as adjunctive radiological information to facilitate localization of regions of the brain during the pre-operative review and aims at helping users in neurosurgical functional planning.

With the current Indications for Use, the output MR image shall be compared with the medical professional's intended planification to either increase confidence in their position, or prompt further verifications at the medical professional's own discretion.

If the annotated MR image is consistent with the medical professional's intended planification, then the neurosurgical functional planning is safe and secure.

4.2. Technical performance

The technical performances of OptimMRI are as follows:

- Implementation of 2 models, both validated, to compute the position of regions of interest (STN and VIM) for neurosurgical functional planning;

- Reading of MR images in 3D DICOM format;

- Semi-automatic processing of MR images in 3D DICOM format to annotate regions of interest;

- The annotated output MR image remains in 3D DICOM format for compatibility with other software used for planification of neurosurgical procedures.

5. Warning

	ATTENTION
⚠	▪ The annotated MR image should be used by qualified medical professionals with skills in neurology and medical imaging. ▪ The images processed by OptimMRI only provide additional information to qualified medical professionals. They do not replace or substitute standard neurosurgical functional planning methods. ▪ The annotated MR image should be used by the qualified medical professionals only as a cross-comparison tool to increase confidence in their usual planification methods and to secure the neurosurgical functional planning. ▪ The quality and accuracy of the annotated MR images strongly depend on the quality of the MR image provided in 3D DICOM format. Therefore, an MR image with good quality and contrast is needed. ▪ All MR images sent to RebrAIn for processing 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 qualified medical professional, especially after the de-anonymization process. ▪ Patients' eligibility and choice of surgical procedures are the responsibility of the qualified medical professionals. ▪ When using the annotated MR image as a cross-comparison tool during neurosurgical functional planning, the qualified medical professional should verify the sides and quality of the fused images. ▪ OptimMRI is not intended for processing intra-operative MR images

6. Precautions

6.1. Compliant use

The use of these annotated pre-operative MR images (3D DICOM) is reserved for qualified medical professionals who plan to localize STN or VIM region(s) of interest during neurosurgical functional planning. The annotated MR images can be used in conjunction with other clinical methods for further processing and visualization as an aid in localization of the STN and VIM regions of interest.
Any inappropriate use is prohibited.

6.2. Malfunction and incident reporting

For any problems related to the uploading/downloading of MR images or if the annotated MR image:
- is incompatible with surgical planning or stereotactic image guided surgery software used;
- is unavailable or;
- shows a discrepancy between the STN and VIM regions of interest localized by the qualified medical professional and the ones annotated by OptimMRI;

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

In case a problem arises with the annotated image processed by OptimMRI (see above), qualified medical professionals must operate the patient according to their own planning methods.

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

6.3. 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 "Portable Document Format" (PDF). A suitable PDF reader application, 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.us/, from the "help" menu once logged in

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.

7. Instructions for use

7.1. Imaging requirements

The models used by RebrAIn for processing MR images with OptimMRI to localize STN and VIM regions of interest 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 OptimMRI 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

7.2. Pseudonymization of MR images

It is required to pseudonymize a patient's MR image. This can be done by using your own anonymization process or by using software tools dedicated to MR image anonymization. The de-anonymization process and the cross-referencing of patient data are the responsibility of the qualified medical professional and/or the hospital.

7.3. Application for MR image annotation

Uploading MR images (3D DICOM) of a patient and downloading MR images annotated at the requested region(s) of interest can be done using an appropriate MR images exchange application (https://transfer.rebrain.us/).

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

A manual concerning the use of the MR images exchange application is sent to each qualified medical professional when they log in for the first time, and is available for download on the website once logged in.

The following information must be provided during the request:
- The requested region of interest: STN or VIM;
- The hemisphere to be processed in case of a unilateral annotation (left or right).

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

7.4. Use of the annotated image during a neurosurgical procedure planning

The STN and VIM regions of interest provided by OptimMRI correspond to the following:

- **STN region of interest**: STN itself;
- **VIM region of interest**: VIM itself and the Zona Incerta (ZI).

The image processed by OptimMRI is provided in 3D DICOM format, a standard and internationally accepted format. Once downloaded, the annotated MR image may be used on any device, used for neurosurgical functional planning, compatible with this format.

The brain regions of interest annotated by OptimMRI are indicated by white crosses, as shown below:
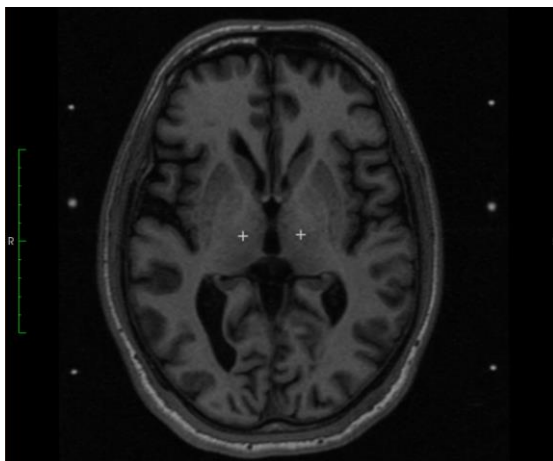
It is possible that the regions of interest annotated are not on the same slice of the MR image. In this case, it is necessary to navigate between the different slices of the image to find the annotated regions of interest.

8. LEGAL CONDITIONS - EXCLUSION OF WARRANTY / LIMITATION OF LIABILITY

By using this product, you agree to these terms and conditions of use. If you do not agree with the provisions set out, you are not allowed to use this product.
This clinician's user guide (CUG) is a non-binding document and may be changed by RebrAIn if necessary. The product shall only be used in compliance with CUG.
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9. Copyrights or trademarks

OptimMRI is the property of RebrAIn.

10.   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 license, see https://med.inria.fr/about/license.

11. Contact

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