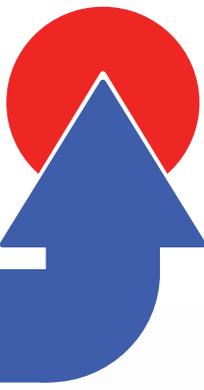


NEURAL NAVIGATOR



Precision makes Perfection



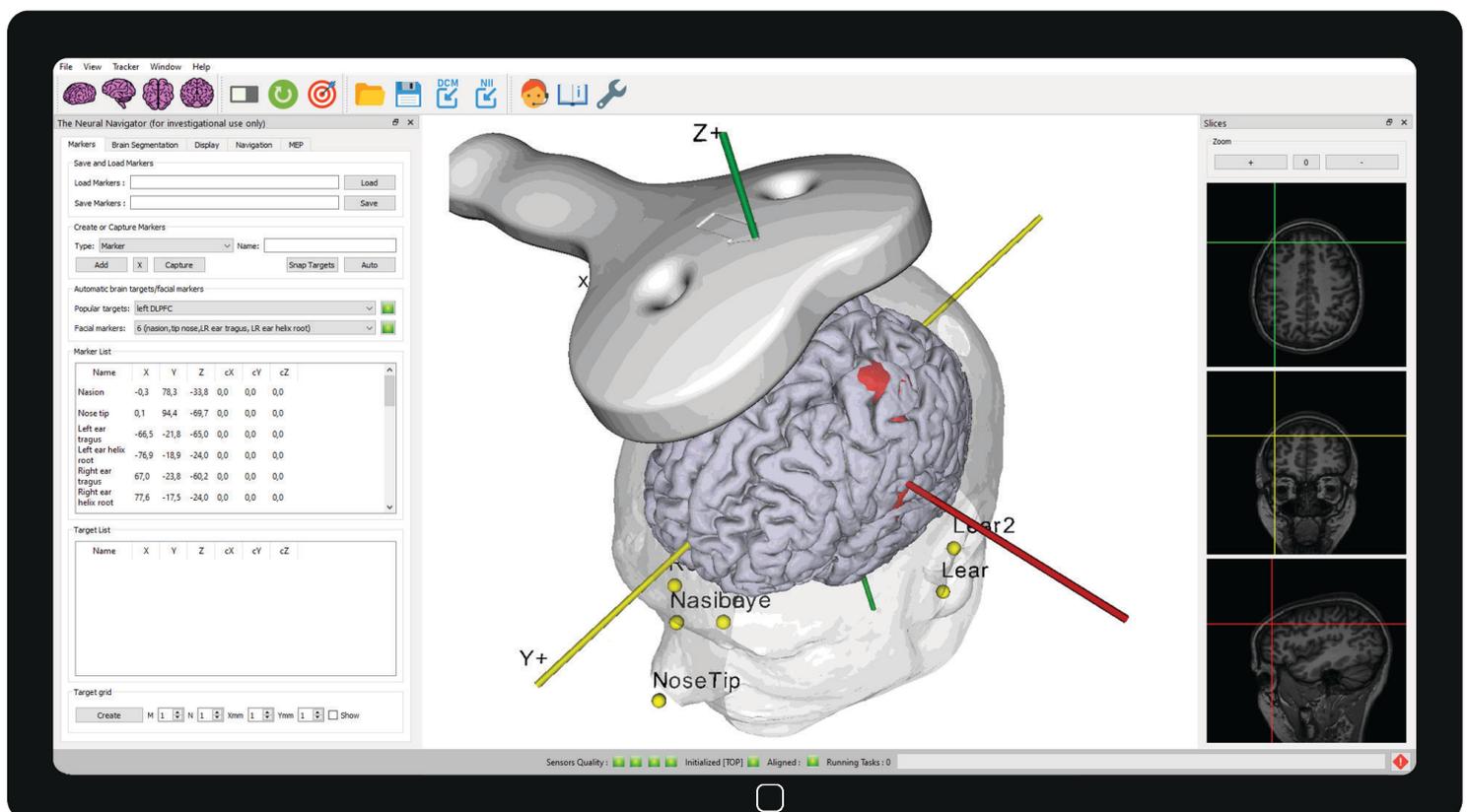
Neuronavigation for TMS treatment

- MRI-guided neuronavigation
- Automatic identification of popular treatment targets
- Certified for medical use in Canada, EU & more

THE NEURAL NAVIGATOR

The Neural Navigator is designed to guide Transcranial Magnetic Stimulation (TMS) in order to precisely stimulate a brain region. Using the patient's own MRI scan, the TMS coil can be navigated toward the target brain region with millimeter precision. Neuronavigation has been shown to improve TMS treatment of major depressive disorder, resulting in better treatment outcomes.

The Neural Navigator is easy to use because of its clear and efficient workflow. It offers automatic identification of facial markers and popular treatment targets and semi-automatic brain segmentation. It is certified as a medical device in the European Union, Brazil, Canada and Australia. It adopts a well validated registration technology and has been rigorously tested. The Neural Navigator has been actively used since 2004 in many labs around the world.



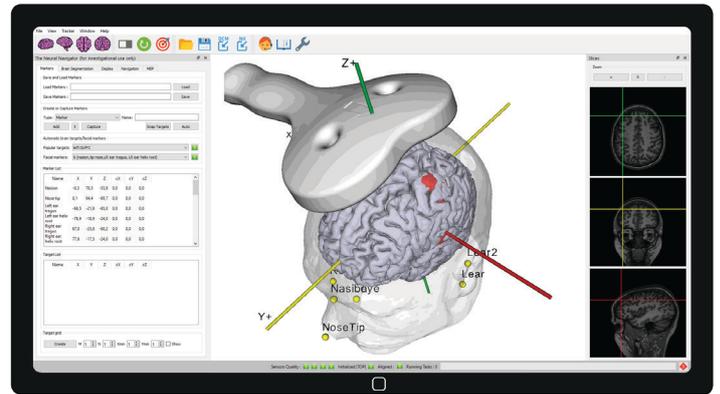
MAIN COMPONENTS

Magnetic position tracking

The position of the TMS coil and the patient's head is tracked using a magnetic position tracking device built into the Neural Navigator. It is smaller than a laptop, unlike large optical tracking systems. It uses magnetic induction tracking with a weak pulsed DC magnetic field. This technique is hardly sensitive to electromagnetic distortions, the presence of a normal TMS coil does not distort the measurements.

Compatibility

The Neural Navigator supports several TMS brands including Neurosoft, MagStim and MagVenture.



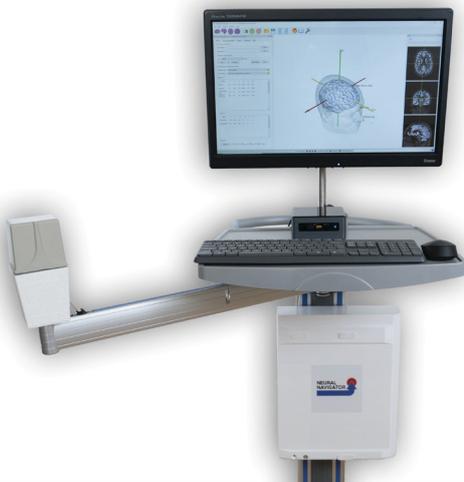
The Neural Navigator software

The Neural Navigator software is a comprehensive software suite with several workflows for image processing, visualization and real time navigation.

SOLUTIONS

Standalone

We offer a standalone solution, which can be used with an existing TMS setup.



Full solution

We also offer a full neuronavigated TMS setup, including neuronavigation and a TMS setup from one of our partners.



ACCESSORIES (optional)

TMS Treatment Chair

This reclining chair is especially designed for use during navigated rTMS treatment. The magnetic field transmitter of the BrainTRAK™ unit is mounted to the back of the chair on a special pad. The materials in the chair are chosen such that magnetic tracking is undisturbed, which was rigorously tested. A special head support that can be mounted on the top surface of the chair lifts the head up allowing easy navigation. This product is CE certified (class I) for clinical use.



SPECIFICATIONS

The Neural Navigator can target brain areas indicated on an MRI scan with a precision of 4 mm or better. It can load and visualize individual MRI scans and fMRI activation maps. The Neural Navigator supports automatic identification of facial markers and popular treatment targets and allows semi-automatic brain segmentation. One can navigate the TMS coil to the target in the brain in real time while looking at the screen. On the screen a 3D rendering of the TMS coil and brain are shown exactly at the position and orientation where they currently are.

A yellow beam is shown at the center of the TMS pulse, extending into the brain. This allows one to see exactly which area is targeted. Pre-set neuroanatomical target markers can be pinpointed accurately. The virtual camera can also be linked to the TMS coil center to obtain a birds-eye view of the brain as if you are looking down along the TMS pulse, with a crosshair to aid targeting of the brain region of interest. Furthermore, The Neural Navigator contains tools to judge navigation accuracy, make suggestions how to improve it based on real-time simulations, test the 3D digitizing hardware, and many more.

Supported MRI data types

The Neural Navigator is fully compatible with the most commonly used DICOM and Nifti data formats. Nifti files, appearing with .nii and .img/.hdr extensions, are the standard data format used in SPM8 and SPM12. The software can also read the older Analyze format used in SPM9 and SPM2. The software also reads Nifti data from more recent AFNI, FSL and Brainvoyager versions.

Position tracking hardware

The BrainTRAK™ position tracking device digitizes 3D position and orientation of the hand held pointer and the TMS coil at a rate of 100Hz. It adopts a weak pulsed DC magnetic field generated by a small emitter, and measures magnetic induction in the sensors located inside the pointer and TMS coil socket to determine location and orientation. The spatial accuracy is better than 1 mm within a range of ~70cm from the transmitter. The tracking hardware operates in a stand-alone case, with its own power supply, and connects to the PC or laptop through a USB port. The system can be used in combination with a laptop, greatly increasing mobility. The complete navigation setup fits in a regular sized suitcase, which makes it ideal for bed-side investigations.

Technical

Electrical: Power line 100 - 240V ~ 50/60 Hz; input power 50 VA. Type: Class I Device with Type B Applied Part (probes). Installation class 2, Safety class 1. Operation environment: temperature 5°C to 40°C; between 10% and 90% non-condensing humidity; Maximum allowed height 2000m, maximum air pressure 79.4 kPa. Storage/transportation conditions: ambient air temperature between -40 °C and 70 °C in environments with a relative humidity between 5% and 95%. IP class: IP20. MDD Device class: IIa

Regulatory

The Neural Navigator is CE certified as a class IIa medical device in the European Union, FDA-approved in the USA, InMetro and ANVISA certified in Brazil, Health Canada certified for medical use in Canada and TGA certified for medical use in Australia. In these regions the Neural Navigator can be used for clinical purposes. The Neural Navigator as an electrical medical device is IEC606011 3rd edition (Electrical Safety) and IEC60601-1-2 3rd edition (electromagnetic compatibility) compliant. RoHS and WEEE compliant



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