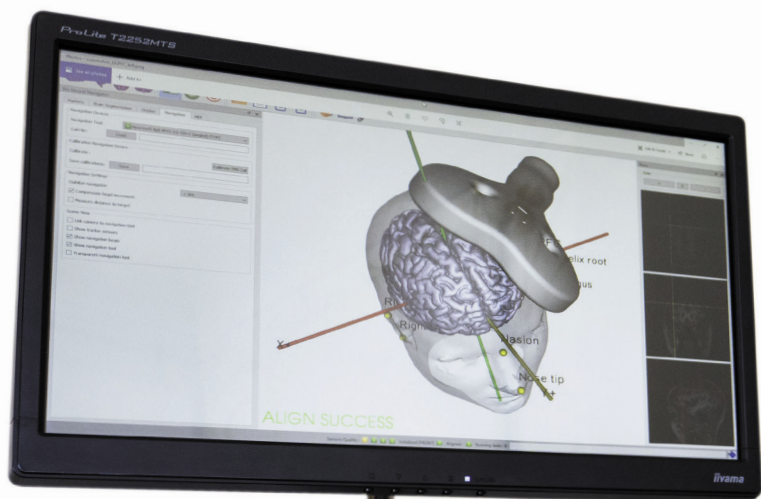


NEURAL NAVIGATOR



Precision makes Perfection



Neuronavigation for TMS treatment

- Compatible with multiple TMS brands
- MRI-guided navigation with PACS import
- Automatic brain segmentation and target placement
- Certified for medical use in USA, EU, Australia & more

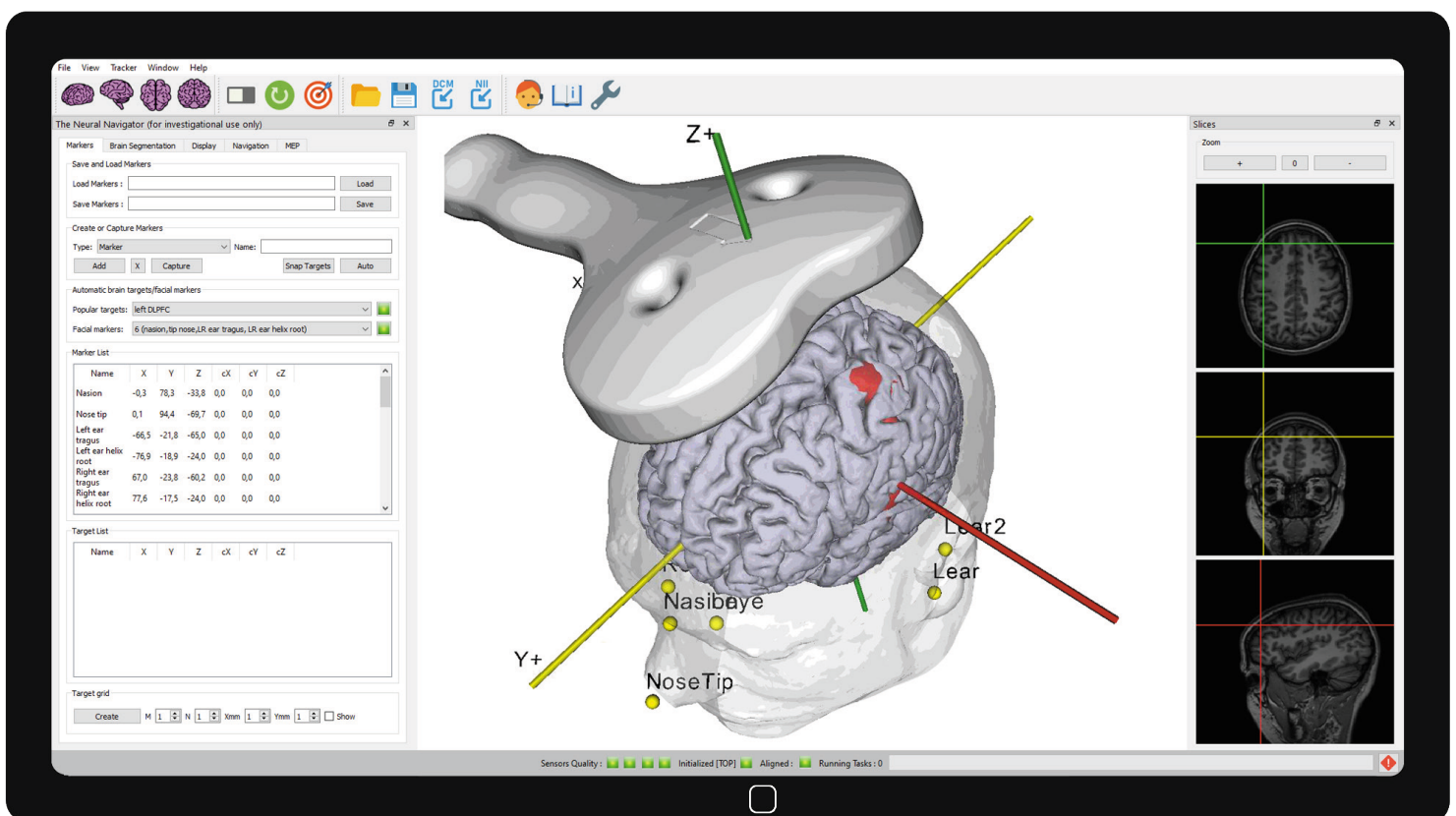


THE NEURAL NAVIGATOR

The Neural Navigator is designed to navigate Transcranial Magnetic Stimulation (TMS) to the target brain region with millimeter accuracy to ensure precise stimulation. Neuronavigation has been shown to improve the accuracy of 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 full-automatic brain segmentation and automated identification of facial markers and popular treatment targets. Its efficient registration technology accurately guides the placement of the TMS coil over a functional or structural target, or over a previous stimulation target.

The Neural Navigator is certified as a medical device in the United States of America, the European Union, Brazil, Canada and Australia.



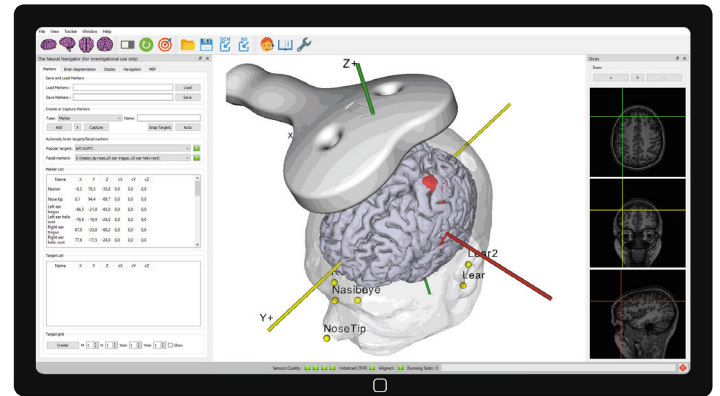
MAIN COMPONENTS

Magnetic position tracking

The Neural Navigator uses simultaneous real-time magnetic position tracking of the TMS coil and the patient's head in order to ensure accurate TMS coil placement, even in case of head movement. Magnetic position tracking allows continuous TMS coil tracking without disruptions due to line-of-sight obstructions. Our magnetic tracking algorithm has been rigorously tested and is robust to electromagnetic distortions during stimulation.

Compatibility

The Neural Navigator supports several TMS brands including Neurosoft, MagStim and MagVenture and allows import of a wide range of MRI formats from PACS or an external drive.



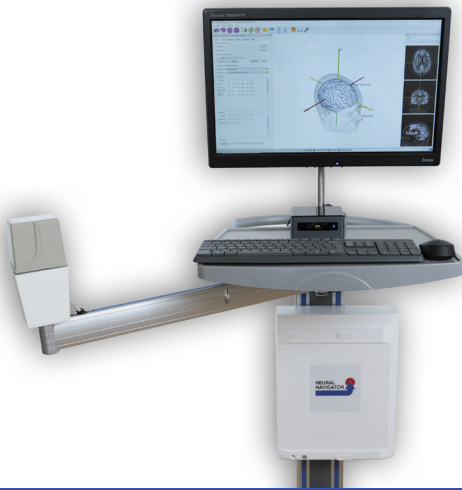
The software suite

This comprehensive software suite offers 3D and 2D visualization of MRI data, automatic brain segmentation and automated placement of markers and targets. It can guide TMS coil placement over a functional or structural target or over a previous stimulation target.

SOLUTIONS

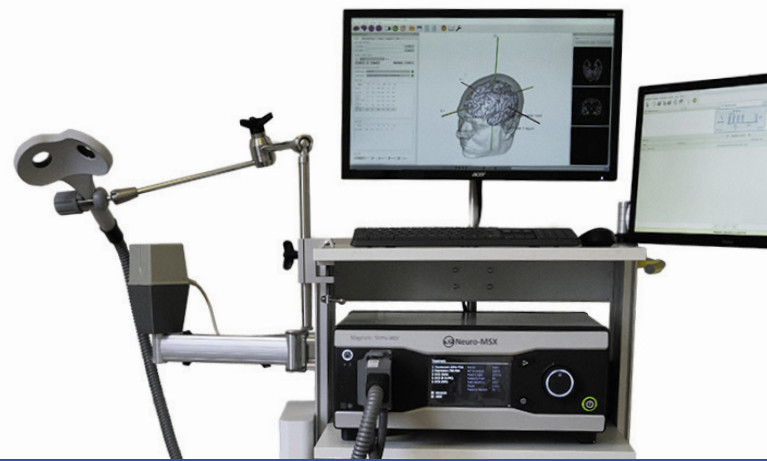
Standalone

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 is mounted to the back of the chair and the materials in the chair are chosen such that magnetic tracking is undisturbed. 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 allows 2D and 3D visualization of structural and functional MRI data. It supports automated identification of facial markers and popular treatment targets and allows full-automatic brain segmentation.

The Neural Navigator employs an easy-to-use registration algorithm, which allows real-time navigation of the TMS coil with a precision of 4 mm or better. The TMS coil can be guided to a functional or structural target or to a previous stimulation target. It contains tools to monitor and optimize navigation accuracy, including head movement compensation and distance-to-target measurements.

The Neural Navigator allows reproduction of previously used TMS coil placement on the patient's individual MRI and on a generic head model. It provides several tools to guide and optimize the reproduction of previous TMS coil locations.

Supported MRI data types

The Neural Navigator is fully compatible with the most commonly used MRI formats, including DICOM and Nifti data formats. It allows import of MRI data through PACS integration or from an external data source.

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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