

How Can You Benefit from SmartFocus® nTMS Mapping?

Navigated transcranial magnetic stimulation (nTMS) is traditionally for patients undergoing treatment for brain tumor or other lesions in close proximity to areas of the brain essential for movement or language.

A brain scan (MRI) is useful to show the size and location of a tumor but does not provide enough information to determine the function of the brain tissue in close proximity to the tumor.

SmartFocus® nTMS technology provides physicians with unique tools to accurately map essential brain functions, like movement or language, directly onto an MRI-based 3D model of your own brain. This model can help you and your physician to make the best possible treatment decision. The information is also useful later for planning and guiding the treatment.

Studies have shown that nTMS mapping can:

- ✔ Determine if surgery is a safe option¹
- ✔ Help preserve areas of the brain essential for movement or language¹
- ✔ Allow more tumor to be removed²
- ✔ Prolong lives of patients with glioma²

1.) Frey D, Vajkoczy P, Picht T. Navigated transcranial magnetic stimulation improves the treatment outcome in patients with brain tumors in motor eloquent locations. *Neuro-Oncology* 2014; nou110v1-nou110.

2.) Raffa G. et al. The role of navigated transcranial magnetic stimulation for surgery of motor-eloquent brain tumors: a systematic review and meta-analysis. *Clinical Neurology and Neurosurgery* 180 (2019) 7–17.

“ nTMS makes surgery safer, the resection rates are higher and—in the end – the outcomes are better. ”

Bernhard Meyer, MD, Professor & Chair
Department of Neurosurgery, Klinikum Rechts der Isar,
Technical University of Munich, Germany

Indications and Safety

INDICATIONS FOR USE

The Nexstim Navigated Brain Stimulation (NBS®) System 5 is indicated for non-invasive mapping of the primary motor cortex of the brain to its cortical gyrus. The Nexstim NBS® System 5 provides information that may be used in the assessment of the primary motor cortex for pre-procedural planning.

Nexstim NexSpeech®, when used together with the NBS® System 5, is indicated for non-invasive localization of cortical areas that do not contain essential speech function. NexSpeech® provides information that may be used in pre-surgical planning in patients undergoing brain surgery. Intra-operatively, the localization information provided by NexSpeech® is intended to be verified by direct cortical stimulation. FDA-cleared, CE-marked

NBS® SHOULD NOT BE USED FOR

1. Patients with non-removable conductive, ferromagnetic, or other magnetic-sensitive metal anywhere in the head or within 30 cm (12 in) of the stimulation coil. Examples include cochlear implants, implanted electrodes or stimulators, aneurysm clips or coils, stents, bullet fragments, ocular implants, and stents.
2. Patients who have an active or inactive implanted device (including device leads), including deep brain stimulators, cochlear implants, cardiac pacemakers, and vagus nerve stimulators. Contraindicated use could result in serious injury or death.
3. Patients with increased intracranial pressure or patients with intracardiac lines, intravenous pumps, or dose calculators.

Failure to follow these restrictions could result in serious injury or death.

RISKS AND SIDE EFFECTS

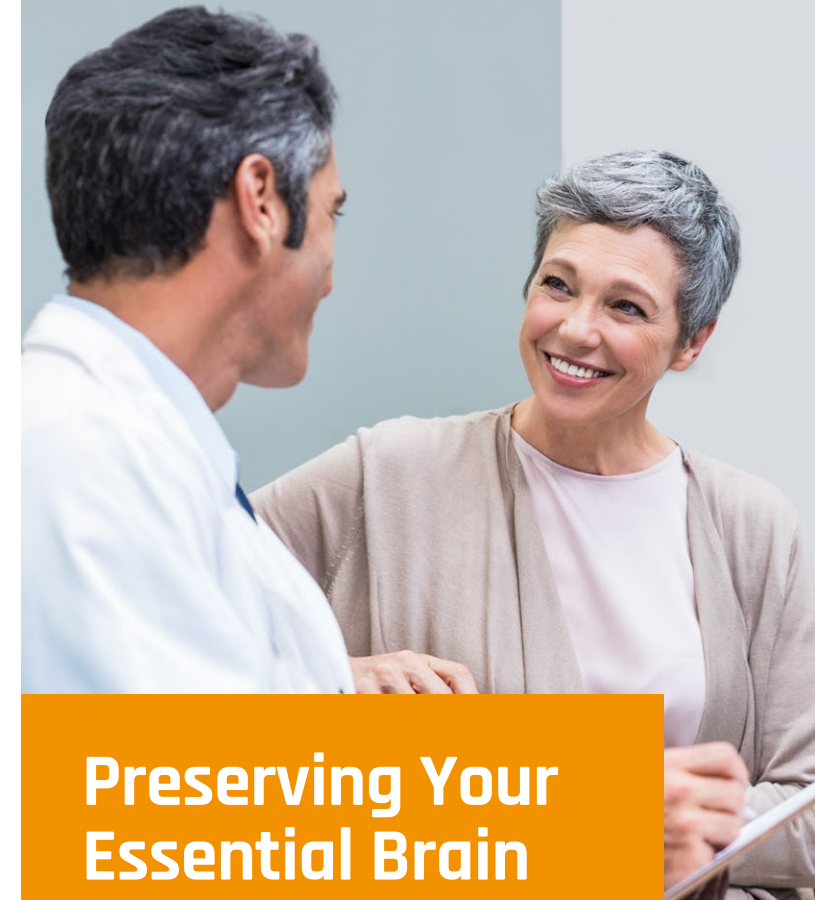
Seizures (convulsions): Cortical magnetic stimulation runs the risk of inducing seizures; although they are rare. In ordinary clinical use, the estimated risk of seizure is approximately 1 in 30,000 treatments (0.003%) or 1 in 1,000 patients (0.1%).

Headache: The most common side effects reported during clinical trials are mild headache and scalp pain or discomfort.

Muscle Twitching: You may feel twitches in the muscles of your arm, leg or face during the magnetic stimulation

Skin Irritation: There is a small risk of mild skin irritation at the location where the muscle electrode sensors have been placed.

Changes in hearing: The loud “click” produced by the TMS stimulator can cause temporary hearing changes following treatment. This is prevented by wearing soft foam ear plugs during treatment.



Preserving Your Essential Brain Functions

nTMS mapping: When you need to consider brain surgery.

How Does nTMS Work?

Mapping sessions are done while you are awake and reclined in a comfortable chair. A clinician rests a handheld „coil“ gently against your head and delivers a series of pulses to map your brain. The technique is non-invasive and not painful. A typical motor mapping session takes approximately 20-45 minutes.

With navigated transcranial magnetic stimulation (nTMS), a magnetic field, briefly generated in the hand-held coil, passes harmlessly and non-invasively down into your brain. This magnetic field generates a small electric field in the outer layer (cortex) of your brain. The strength of the field is adjusted to gently nudge your muscles into action, when neurons carrying motor function are detected. The response can then be measured by electrodes placed on your hand, face or leg, for example.

By combining your MRI brain scan to the data of these muscle responses generated by nTMS, the locations of the brain's essential functional areas can be shown as a “map” on your own MRI.



Mapping Speech and Language Function

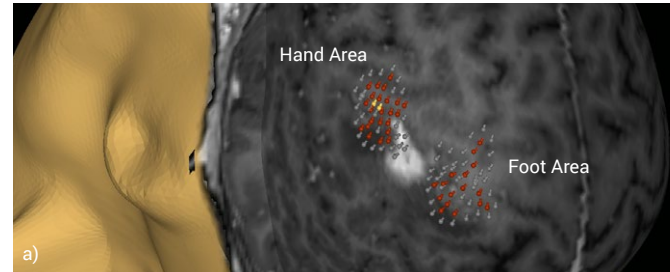
By turning the coil on and off rapidly, nTMS can disrupt normal brain activity—although only in a small, targeted part of the cortex. This feature is the basis of nTMS language mapping. By asking you to perform tasks like naming objects on a screen in front of you, nTMS can reliably determine which areas of the cortex are not essential for language. This information allows your treatment team to better plan a safe operation when it cannot be ruled out that the tumor involves language areas.

How Does nTMS Help Plan Neurosurgery?

A 62-year-old female patient came to her physician after experiencing weakness on her right side, especially the right hand and facial muscles. She was diagnosed with a glioblastoma. The MRI brain scan showed a tumor very close to areas of the brain important for movement. The MRI alone could not allow for a treatment decision because liquid (edema) surrounding the tumor blurred the MR-image. Her treatment decision was difficult.

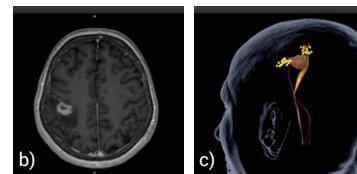
nTMS mapping clearly showed that the essentially important motor areas needed for movement were clear of the tumor area.

Using the nTMS “hot spots”, the MR-data could be analyzed to visualize the nerve fibers connecting the motor cortex to the muscles. Now, her neurosurgeon was sure that the tumor could be removed safely, without risking damage to vital motor function.



The patient agreed to surgical resection—improving her quality of life and hopefully prolonging her life expectation.

After her surgery, the patient regained use of her right side with only slight paresis which continued to improve over time. Without nTMS mapping, surgical resection would have been considered to be too risky.



- a) nTMS map showing important areas for motor function
 - b) MRI brain scan with tumor close to motor area
 - c) Fiber tracts connecting the motor cortex to the muscles
- © Case and Images courtesy of PD Dr. Thomas Picht / Charité Berlin

nTMS at [Clinic Name]

We offer nTMS mapping as part of our professional services. Please contact us if you require more information on brain imaging, brain mapping or our approach to diagnostics and decision making in neurosurgery.

For an appointment, please contact:

[Clinic Name]
[Clinic Contact Person]
[Clinic Email/Phone]
[Clinic Website]



[Clinic Name] is using **Nexstim NBS System with SmartFocus® nTMS technology.**

More information about Nexstim: www.nexstim.com

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