Axilum Robotics

Solutions for Robotic TMS

Discover in this brochure the key advantages of robot-assisted TMS

Axilum Robotics TMS-Robot
Setting a new standard for Transcranial Magnetic Stimulation

Improving TMS implementation

1985
TMS stimulator

2000
Image guided TMS

Today
Robot assisted TMS

Since the development of the first **TMS stimulator** at the University of Sheffield in 1985[1], TMS has known numerous technological improvements.
In 2000, based on anatomical MR images of the subject, **neuro-navigation** allowed to personalize the definition of the targeted cortical area, improving the accuracy of the transcranial magnetic stimulations. However, subject's head movements during a session, loss of contact of the coil with the scalp, variations in the orientation of the coil which is held by a human operator or attached to a rigid stand, and even variability of operator attention and experience, many factors explain why **it remains challenging to obtain an accuracy of a few millimeters in a repeatable manner**. Improving all these practical parameters is crucial to support the increasing use of TMS worldwide in neuroscience research, clinical trials or patient treatment.

Since 2000, development of robotics in the medical and surgical areas (neuro-surgery, mini-invasive surgery, orthopedic surgery, radiotherapy…) encourages technical procedures to become safer, more accurate and more easily repeatable. Axilum Robotics leverages 15 years of advances in neuro-navigation and medical robotics research by introducing the **first and only robot specifically designed to assist Health Care Professionals and researchers in their TMS protocols**.

By automating the positioning of the TMS coil under the supervision of a neuronavigation system, Axilum Robotics **TMS-Robot improves accuracy and repeatability** of TMS protocols while keeping a high level of **safety** for the patients and optimizing medical resources management.

1. Barker AT, Jalinous R & Freeston I. 1985. Non-invasive magnetic stimulation of the human motor cortex. Lancet 1:1106-1107.

Looking for TMS execution excellence

CHALLENGES IN THE EXECUTION OF TMS PROCEDURES

A small rotation in coil position (i.e. 7°) can induce variations of 25% or more in stimulus intensity with a resulting difference in biological outcomes of unpredictable magnitude (MEP drop by 60% after 7° tilt)[2] (FIG. 1). Moreover, using a simple holder to position a coil during TMS can lead to substantial deviations in the induced electric field (electric field reduced by 32% after 30 mn)[3] (FIG. 2).

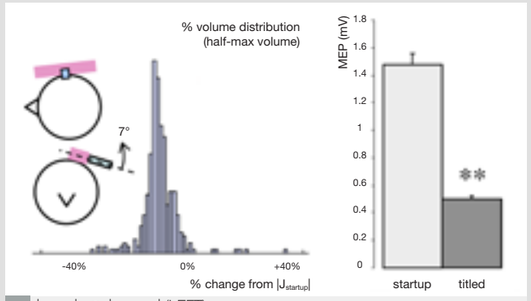
AUTOMATED POSITIONNING OF THE COIL ON TARGET

Once the stimulation targets and coil self-rotation have been defined in the neuronavigation system, Axilum Robotics TMS-Robot positions the coil tangentially at these targets, **ensures contact between coil and head, and compensates for any head movements during the session, keeping the coil position and orientation with respect to the brain**.

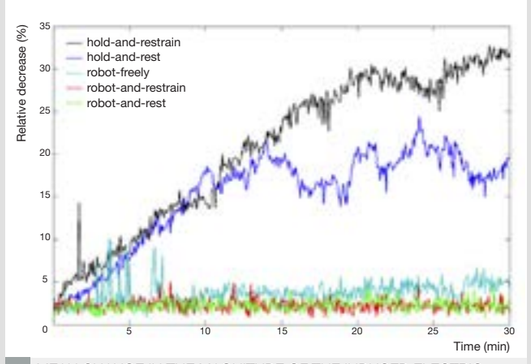
IMPROVED ACCURACY AND REPEATABILITY

TMS-Robot will allow to considerably improve the accuracy and the repeatability of the TMS stimulation.

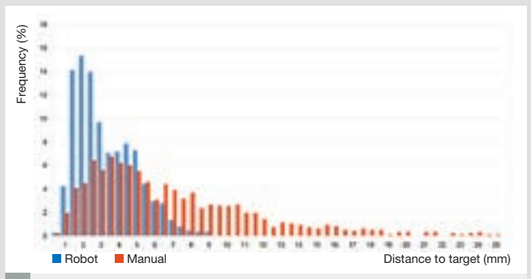
In a study[4] intended to compare navigated, robotic coil positioning with TMS-Robot to manual coil positioning for motor cortex mapping using healthy volunteers, absolute (FIG. 3) and test-retest reliability were significantly improved by robotic assistance ($p < 0.01$ for all tests) by a factor of 2 (~3 mm vs. ~6 mm). Of special interest was the number of stimulations that were below 5 mm from the target. Whereas this rate was as low as 50% under manual conditions, it increased to 90% with the robot-controlled coil placement.



1 $|J_{TILTED}|$ VS. $|J_{STARTUP}|$ (LEFT)
AVERAGE MEP AMPLITUDES IN "STARTUP" AND "TILTED" POSITIONS (RIGHT)



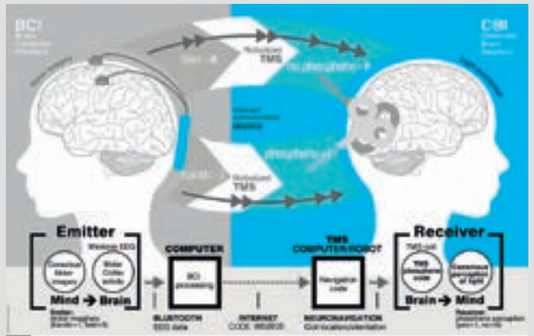
2 MEAN CHANGE IN THE MAGNITUDE OF THE INDUCED ELECTRIC OVER TIME



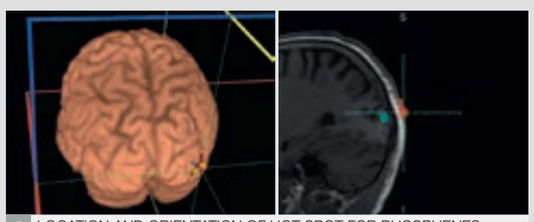
3 ABSOLUTE RELIABILITY

2. Toschi N. et al. Transcranial magnetic stimulation in heterogeneous brain tissue: clinical impact on focality, reproducibility and true sham stimulation. J Psychiatr Res. 2009 Jan;43(3):255-64
3. Richter L. et al. Stimulus Intensity for Hand Held and Robotic Transcranial Magnetic Stimulation. Brain Stimul. 2013 May;6(3):315-21
4. Ginhoux R. et al, A Custom Robot for Transcranial Magnetic Stimulation: First Assessment on Healthy Subjects, Proceedings of the 35th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC'13), Osaka, Japan, July 3-7, 2013.

Access to new and innovative TMS protocols

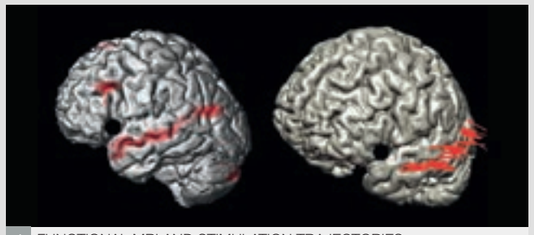


1 BRAIN-TO-BRAIN (B2B) COMMUNICATION SYSTEM OVERVIEW



2 LOCATION AND ORIENTATION OF HOT SPOT FOR PHOSPHENES PRODUCTION OVERLAID ON MRI IMAGE

3 DOUBLE COIL ACTIVE/PLACEBO FIXED TO THE ROBOTIC ARM



4 FUNCTIONAL MRI AND STIMULATION TRAJECTORIES

ACCESS TO COMPLEX TMS PROTOCOLS

Axilum Robotics TMS-Robot is able to perform a wide range of tasks, from the simple holding of the TMS coil at a predefined target, to the controlled movement of the TMS coil along complex trajectories in the brain.

In a successful brain to brain communication experiment[5], using TMS to trigger phosphenes in the receiver's brain, Axilum Robotics TMS-Robot ensured a perfect repeatability during sessions consisting in up to 140 stimulations at the same target (FIG. 1).
Placement of hot spot for phosphene production has been defined on an MRI of the subject as well as two different coil directions to trigger or not phosphenes (FIG. 2).

In an ongoing double blind clinical trial, the robot is able to position easily a heavy double coil Active + Placebo and to stay on target during a rTMS treatment session (FIG. 3).

In other cases, **with a large and complex stimulation area**, the stimulation of a single target may be insufficient. The robot moving the stimulation coil at a constant speed along a specific path may be necessary to cover the whole targeted area (FIG. 4).

5. Grau C et al., Conscious Brain-to-Brain Communication in Humans Using Non-Invasive Technologies, 2014, PLOS ONE.
Images 1 and 2 courtesy of study authors. Image 4 courtesy of Dr. Foucher, ICube Lab, Strasbourg.

TMS-Robot Key Features

LARGE WORKSPACE

The original, patented, **hemispherical architecture** of the robotic arm allows the positioning of the coil's stimulation hot spot around a hemisphere. This architecture enables access to all stimulation areas while the head is located inside the work hemisphere. The computer-controlled patient seat facilitates the adjustment of the patient head inside the workspace.

ACCURACY AND REPEATABILITY: REDUCING THE "HUMAN FACTOR"

The robotic arm and the patient seat include 9 high-precision position sensors.

Accuracy is below 1 mm and repeatability is below 0.1 mm in the measurement space of the neuronavigation system.

When the navigation system allows the control of the stimulator, the pulse can be sent automatically when the the coil is precisely above the target.

The device keeps its accuracy and repeatability for any duration of the procedure and for any number and positions of the targets: Complex stimulation procedures which are difficult, or even impossible to implement manually, are made easier with Axilum Robotics TMS-Robot.

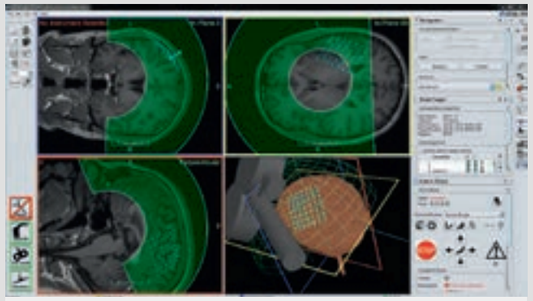
EXAMPLE OF COIL EQUIPPED WITH ITS FORCE SENSOR

COIL ORIENTATION CONTROL

The hemispherical architecture of the robotic arm allows to:

– Orientate the coil when applied on the head surface to reach the desired internal structures.
– Control the self-rotation of the coil to define the direction of the induced electric field.

This provides a way to control precisely the stimulation entry point and the stimulated internal structures.



EXAMPLE OF LOCALITE TMS NAVIGATION WITH AXILUM ROBOTICS MODULE

HEAD MOTION COMPENSATION

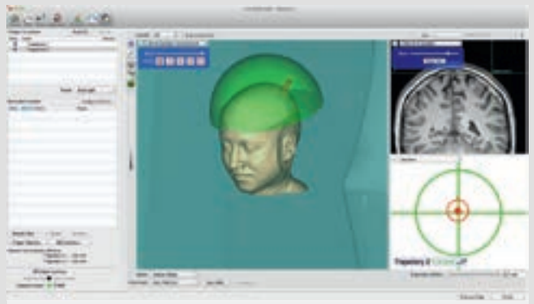
The neuronavigation system monitors the coil position and orientation in real time to compensate for any movement of the head measured by its 3D optical tracking system during the stimulation.

CONTACT DETECTION AND CONTROL

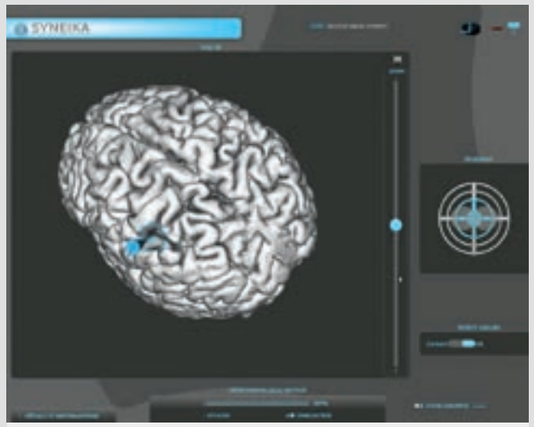
A flat **force sensor** that is non-sensitive to the magnetic field is affixed on the inferior surface of the TMS coil to measure the contact between the coil and the head. The robot's embedded firmware controls the applied force in real time so that it does not exceed the coil's own weight. **Therefore, stimulations can be delivered only when the coil is in contact with the head**.

ERGONOMY

Axilum Robotics TMS-Robot does not add a separate user interface. **The operator can control the robot and define the desired movements and positions of the coil from the graphical user interface of a compatible neuronavigation system**. The computer-controlled patient seat is reclinable and its height and depth can be set by a compatible neuronavigation system to adapt to the patient's morphology.



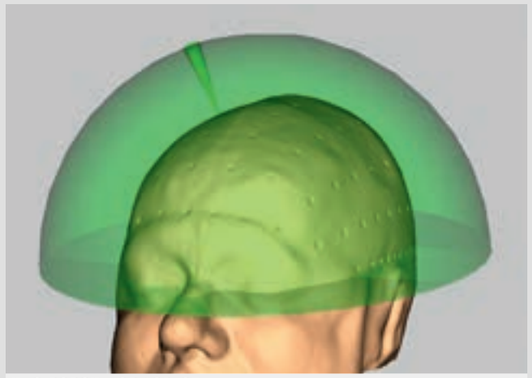
EXAMPLE OF BRAINSIGHT TMS NAVIGATION WITH AXILUM ROBOTICS MODULE



EXAMPLE OF SYNEIKA TMS NAVIGATION WITH AXILUM ROBOTICS MODULE

SAFETY

The patient head is located in the center of the work hemisphere by means of the computer-controlled seat. Each joint of the robot arm is equipped with mechanical hard stops to limit their movement amplitude. **Thanks to the hemispherical architecture of the arm, the coil cannot draw a straight line when moving from one side of the head to another, but only move around that hemisphere**. This prevents the coil or the robotic arm to hit the patient's head during coil positioning. Moreover, the robot's embedded firmware limits the force applied by the coil on the head in real time for a safe and comfortable session.



TMS-ROBOT WORK SPACE

ACCESSORIES

A seat booster is available as an option when the size of the patient is below 147 cm.

DIMENSIONS AND WEIGHT

Axilum Robotics TMS-Robot fits to any space and enters into most elevators thanks to its practical dimensions and reasonable weight. It can be moved easily on its integrated wheels.

Minimum height: 1 955 mm
Base dimensions: 1 530 x 770 mm
Weight: 374 kg

Setting your robotized TMS system

Axilum Robotics TMS-Robot, in combination with a compatible neuronavigation system and a compatible coil connected to its stimulator, offers a full robot assisted TMS system allowing the automatic execution of an image guided TMS session planned in advance.

Whether you need a complete TMS system or a robotic assistance to an existing TMS system, Axilum Robotics can provide you with the best solution for your needs.

COMPATIBLE TMS EQUIPMENTS

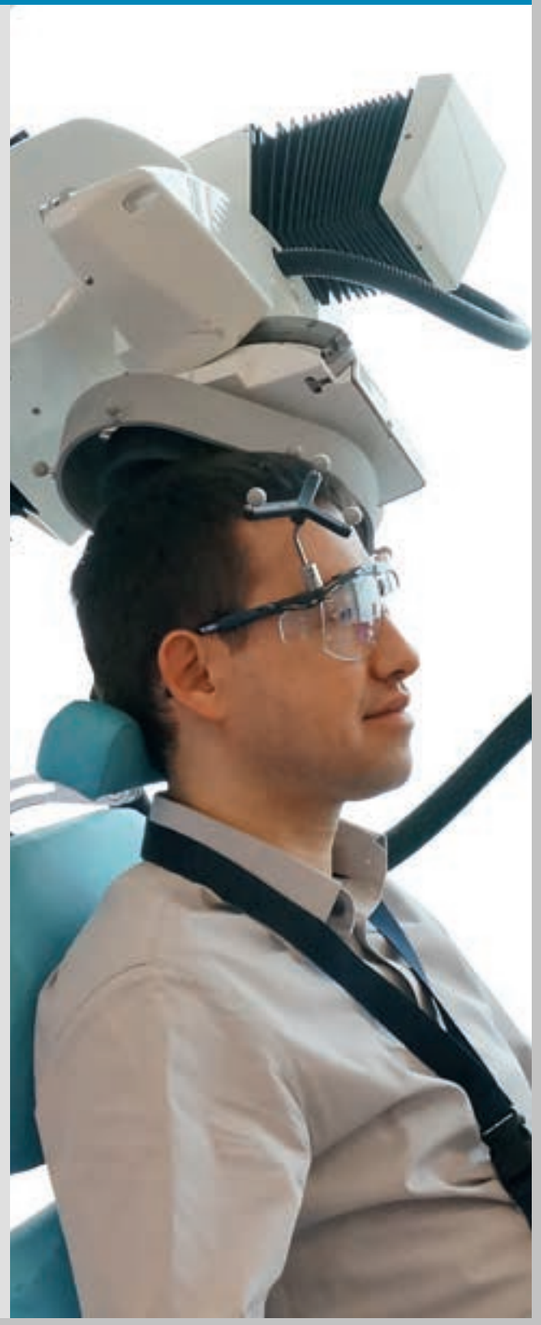
Neuronavigation Systems

Axilum Robotics has established partnerships with leading manufacturers **Localite**, **Rogue Research** and **Syneika** to ensure a seamless integration of TMS-Robot with their products equipped with an optional robot supervision module. The fully integrated TMS system takes advantage of the 3D optical tracking system provided by the neuronavigation system. TMS-Robot connects to a compatible neuronavigation system using a simple Ethernet cable.

TMS Coils and Stimulators

Axilum Robotics has established partnerships with leading manufacturers **Deymed, Mag & More, Magstim, MagVenture and Neurosoft** to ensure a seamless integration of TMS-Robot with their cooled TMS coils*. Mechanical adaptors ensure stable, safe and calibrated mounting of TMS and rTMS coils onto the robotic arm. Flat force sensors, designed by Axilum Robotics are fixed to the inferior surface of the compatible coils.

* Updated list of compatible coils on request.



Training, Support and Servicing

INSTALLATION AND TRAINING

The delivery and installation of your TMS-Robot will be organized by Axilum Robotics Support Team. Installation includes one day of training and hands-on with your staff and is organized by our highly qualified Support Team.

ASSISTANCE

Need help? Axilum Robotics Support Team assists you in getting the best of your equipment and running optimized TMS protocols. Whether you bought or rented the device, you are entitled to 1 year of remote assistance with unlimited phone, email and web support. Do you prefer a physical assistance? We can also participate to your preliminary experimental sessions or first patients.

MAINTENANCE

Axilum Robotics Support Team organizes servicing during the initial year of warranty. Wants to extend the warranty? Sign up for our maintenance contract. This includes at least 1 visit per year for hardware inspection and calibration check by our technical staff.

Resources

DEMONSTRATIONS/ HANDS ON OPPORTUNITIES

Axilum Robotics TMS-Robot is available for demonstrations and trial at leading worldwide TMS centers in France, Europe, and USA. Our Sales Team would be pleased to organize a meeting at any of these sites.

DEMONSTRATION VIDEOS

Check out our demo videos on youtube.com/axilumrobotics to watch different robotic TMS systems implementing several procedures, such as rTMS on the DLPFC or brain mapping.

SELECTED PUBLICATIONS

Selected publications about Axilum Robotics TMS-Robot available on www.axilumrobotics.com

Financing your equipment

Whether you're looking for a complete robot assisted TMS system or a robotic assistant, support and servicing plans, several options are possible: purchase, rental or leasing, helping you optimize your budget according to your requirements.

Regulatory information

QUALITY

Axilum Robotics has been certified ISO 13485. This certification confirms that the company fulfills the requirements applicable in Europe to organizations manufacturing and commercializing medical devices.

REGULATORY INFORMATIONS

TMS-Robot is manufactured by Axilum Robotics Before use, please read user instructions carefully. Axilum Robotics TMS-Robot is not covered by health insurances.

REGULATIONS IN THE EUROPEAN UNION

Axilum Robotics TMS-Robot is a Class IIa medical device.

REGULATIONS IN THE USA

Axilum Robotics TMS-Robot is not FDA cleared. Please note that the use of Axilum Robotics TMS-Robot for the positioning of Transcranial Magnetic Stimulation (TMS, rTMS) coil is considered investigational in the USA.

REGULATIONS IN OTHER COUNTRIES

For regulations of **Axilum Robotics TMS-Robot** outside the European Union or the USA, please contact Axilum Robotics.

Axilum Robotics
TMS-Robot

Accuracy and repeatability

Safety

CE marked Class IIa medical device

Axilum Robotics
Medical procedures performance through robotics

Axilum Robotics was founded in 2011 in Strasbourg, France, by a team of leading experts in medical robotics. TMS-Robot is the first CE marked medical robot specifically designed for Transcranial Magnetic Stimulation (TMS).
The objective of the company is to provide researchers and health care professionals with robotic solutions to improve both technical medical procedures and medical resources management.
Axilum Robotics is ISO 13485 certified for its Quality Management System since 2013.

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