Solutions for Robotic TMS

Discover in this brochure the key advantages of robot-assisted TMS
Since the development of the first TMS stimulator at the University of Sheffield in 1985, 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.

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 mm)³ (Fig.2).

AUTOMATED POSITIONING 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 study² 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.

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 experiment⁵, 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 phosphenes 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).

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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.
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.

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.

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: 1955 mm Base dimensions: 1530 x 770 mm Weight: 374 kg
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 Mag & More, Magstim and MagVenture 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.
Axilum Robotics has been certified to match the requirements of UKAS and SCC ISO 13485 standard by the Notified Body SGS 0120. This certification confirms that the company fulfills the requirements applicable in Europe and Canada to organizations manufacturing and commercializing medical devices.

**REGULATIONS IN THE EUROPEAN UNION**

Axilum Robotics TMS-Robot is a Class IIa medical device. It holds the CE mark whose conformity has been assessed by Notified Body SGS 0120.

**REGULATIONS IN CANADA**

Axilum Robotics TMS-Robot is a Class II medical device. It holds Medical Device Licence number 92610 issued by Health Canada according to the Canadian Medical Device Regulations, Section 36.

**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, Canada or the USA, please contact Axilum 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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This brochure provides non contractual information. All terms and specifications are subject to change without prior notice. Available functionalities depend on compatible neuronavigation systems and their software version.