visor2

TMS Neuronavigation



User Guide

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Manufacturer

eemagine Medical Imaging Solutions GmbH

Gubener Str. 47

D-10243 Berlin, Germany

E-Mail: info@eemagine.com

Representation

ANT Neuro B.V.

Colosseum 22

NL-7521 PT Enschede, Netherlands

Phone: +31 (0)53 43 65 175

E-Mail: info@ant-neuro.com

www.ant-neuro.com/products



Important notices:

The visor2 software is a CE class IIa device according to the MDD Annex IX.

In Canada, visor2 is registered as medical device class II according to the MDR, under MDL number 88778.

Outside the EU and Canada, application of the visor2 software is for research only and not for clinical use.

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1 GENERAL INFORMATION

This document serves as the User Guide for the visor2 system. It contains important information about the operation of the system, its specification and limitations. Especially, it contains several safety warnings that are to be obeyed at any time.

visor2 consists of the visor2 software and additional hardware required to operate the system.

1.1 INTENDED USE



visor2 software is used to aid 3D navigation for positioning of Transcranial Magnetic Stimulation (TMS) coils over preselected brain regions in scientific research or clinical procedures. visor2 software is to be used with a compatible TMS stimulator, a compatible optical tracking system and further compatible accessories. Optionally, a compatible amplifier for measuring electrophysiological signals can be connected. The visor2 software allows to record and view electrophysiological signals from the patient. It visualizes the activated motor cortex area over the anatomical images of the patient's brain based on the analysis of the evoked muscle response after the application of a TMS pulse.

The visor2 software must be operated by a trained physician, and must not be used during surgical operations.

1.2 CONTRAINDICATIONS

visor2 is a system aiming at supporting you in positioning a TMS coil over anatomically or functionally interesting areas. The system optionally records and processes electrophysiological signals to guide the user in the coil placement. **vi**sor2 is a 3D navigation system, and, as such, has no contraindications. The TMS stimulator you are using has contraindications.

Warning: Before performing transcranial magnetic stimulation, read carefully the complete list of contraindications in the documentation of your TMS stimulator.

1.3 CLASSIFICATION

visor2 software is classified as a CE class IIa medical device, and is classified under NBOG BPG Guideline 2009-3 as active medical device, code MD 1111 (software).

visor2 software acts as accessory to other medical devices to facilitate their use or to help locating motor controlling areas on the brain's surface. visor2 software is an active device to monitor the position of TMS coils and to help locating motor areas on the brain's surface as assistance in diagnosis. visor2 software is not intended to be used as therapeutic device, nor for controlling/monitoring the performance of such devices, and is intended to be used only with TMS devices in Class IIa and compatible EEG/EMG amplifiers in Class IIa. The visor2 software is not intended for direct diagnosis or monitoring of vital physiological processes/parameters.

1.4 FEATURES

visor2 software allows for

- Import of anatomical and functional 3D image data (MRI, CT, fMRI)
- Semi-automated image segmentation of skin and brain
- Coil calibration for 3D navigation using a specially designed calibration board
- Registering the patient's head to the segmented skin using a combined landmark and surface matching algorithm
- Real-time display of the position of one or two TMS coils relative to the patient's 3D image data and segmentation
- Calculation and display of the induced electric field for TMS stimuli
- Display of stimulation sites, i.e. coil positions at the moment the TMS stimulus was invoked
- Navigated targeting at pre-defined targets or existing stimulation sites
- EMG recording and the display of the EMG stimulation responses

1.5 LIMITATIONS

- The accuracy of the localization of the coil and the other tracked tools is typically within 2mm (RMS), see also Appendix 7: System components Technical Specifications for further accuracy information.
- The accuracy of the localization depends not only on the overall accuracy of the system, but also on your diligence when using it. Be aware of the following:
 - During the whole navigated TMS session, the position of the head tracker must not change. If the
 position of the head tracker changes with respect to the position of the patient's head, the patient
 registration is no more valid.
 - From the accuracy point of view, the patient registration is the most critical step. Be precise when digitizing the positions of the nasion and the left and right preauricular points and perform always the head shape based registration.
 - The segmentation of the scalp in the MRI directly influences the patient registration quality. Check the segmentation result for agreement with the MRI before using it for the neuronavigation session.
 - During coil calibration, be sure that the coil center matches the point of origin on the board. Any displacement will be reflected in the precision of the coil localization.
 - During each TMS session, be sure to validate your coil calibration. This ensures that the coil tracker has not shifted with respect to the coil by more than 2mm. If validation fails or in doubt, recalibrate your coil.
 - o A geometrically distorted MR scan will decrease considerably the overall accuracy.
 - The calculation of the electric field induced by the TMS coil is based on an approximation of the head shape. The calculated values are only indicative.
 - The strength of the electric field is calculated on the vertexes of the curvilinear surface. The map is then
 obtained by interpolation. Be sure to generate a fine curvilinear mesh if you need a precise localization of
 the field maximum.
 - The probability of excitation of the underlying cells depends not only on the direction and the intensity of the applied field but also on the shape and orientation of the neurons.

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 Depending on the user settings, the extent of the area under a non-vanishing electric field may vary. Be aware that cells outside the area indicated by visor2 might be stimulated, and that cells within it might not.

1.6 SAFETY WARNINGS



- visor2 is to be used only by physicians, trained on the use of the system, and aware of the visor2 indications of
 use and limitations.
- Use only tracking tools provided by ANT/eemagine. Use with utmost care; prevent accidental falling tools, as this may result in irreversible damage/breaks! Never use damaged tools!
- Use the pointer tool very carefully when digitizing the positions of the anatomical landmarks, especially preventing the pointed tip to cause harm. When placing the pointer with your hand, use the other to steady the patient's head.
- Handle all tracker tools very carefully. Avoid touching the reflecting sphere markers. Check for the integrity of all tools before each session with **vi**sor2. When replacing the sphere markers, press them completely to the bottom.
- Make sure you always use the correct calibration board for coil calibration. Please refer to your distributor for a full list of compatible hardware.
- Maneuver the visor2 cart carefully. Your full attention is required when moving the system, which may only be
 performed in TRANSPORTATION MODE. In order to prevent tip-over accidents, use your two hands, and make use
 of the handle; never push the cart sideways (SEE ALSO page 17).
- After loading an MRI scan, always check the correct left-right orientation. After loading an fMRI always check that the left-right orientation is correct and that the functional scan is correctly co-registered with the anatomical one.
- The use of Analyze as import data format for MRI scans is discouraged as there is ambiguity about the image orientation. If you need to work with Analyze images, it is most important to check the left-right orientation for every patient and data set.
- After performing the registration, always verify its goodness. Use the pointer tool to indicate the positions of several anatomical landmarks, and verify it they are correctly displayed on the 3D view.
- If high accuracy of the motor mapping results is required, e.g. as input into pre-surgical procedures, verify that the head reference has not shifted during the session. Use the verification step at the end of the Neuronavigation workflow.
- Perform a screen calibration (see section Screen Calibration) if the absolute EMG / EEG amplitude is to be
 determined by the height of the EMG / EEG amplitude displayed on screen. Amplitudes on an uncalibrated screen
 don't match the true amplitudes of the EMG / EEG.

1.7 SAFETY MEASURES

1.7.1 GENERAL

- Do not use the system in an operating room.
- visor2 must not be used as sole basis for the planning of surgical procedures.
- The visor2 software must not be used as a diagnostic tool for inspecting 3D medical images.
- The visor2 software is not certified for the recording of EEG.
- The system is not to be immersed in any liquid. If any liquids or moisture penetrate the system or a part thereof, remove the plug from the wall socket and have the system checked by the manufacturer.

- Do not store any liquids in and/or on the cart. Before starting to use the system, verify that there are no liquids stored in/on the cart.
- Do not plug in equipment or power cord extensions to the medical isolation transformer when provided as part of the visor2 system. Do not change the power connections. Do not block access to its main power switch. Also see Appendix 7: System components Technical Specifications for further regulatory information.
- Setup and switch on the equipment before the patient comes in; do not touch any electrical contact/connector simultaneously with the patient.
- WARNING: do not modify this equipment without authorization of the manufacturer.

1.7.2 AMPLIFIER

- The only external power supply that may be used is the original supply, which came with the amplifier. DO NOT
 replace it with anything else. If any third-party type of supply is used then patient safety is not guaranteed.
- Make sure that the wall socket is well earthed.
- Inspect the power cord often for damage. Do not operate the system with a damaged power cord.
- Take care in arranging patient and sensor cables to avoid patient entanglement or strangulation.
- Do not wind the cables in a loop smaller than 5 cm or bend them sharply, this may damage the cables.
- Do not bend the fiber optic link too sharply, as it may break.
- Do not use the system when any part of it is damaged.
- Do not connect active sensors or electrodes to any of the amplifier inputs.
- Before any optional batteries are replaced disconnect the patient from the amplifier, make sure that the external power supply is disconnected and the device is switched off.
- Reusable electrodes present a potential risk of cross-contamination. Please refer to the documentation that came with your CE certified electrodes for instructions on how to prevent this.
- The system is not defibrillator proof.
- The system is not suitable for use in an inflammable mixture of anesthetics and air, oxygen or nitrous oxide..
- The system is not to be immersed in any liquid.
- If any liquids or moisture penetrate the system or a part thereof, remove the plug from the wall socket and have the system checked by the manufacturer.
- Do not expose the system to direct sunlight, heat from a source of thermal radiation, excessive amount of dust, moisture, vibration, or mechanical shock.
- Do not use sharp objects such as pencil-points or pen-tips to manipulate the buttons on the control panel, as this can cause damage.
- ELECTRICAL SHOCK HAZARD: Do not connect electrode inputs to earth ground. Connecting an earth ground might result in electrocution.
- ELECTRICAL SHOCK HAZARD: Refer servicing to approved technicians only.

1.7.2.1 RECOMMENDATIONS FOR RECORDING

- Before the first use for EMG recording, each amplifier must be calibrated to the visor2 system.
- Check the signal quality of the EMG before the first stimulation in an EMG-TMS-session
- It is recommended to prevent overload on the CPU resources during EMG acquisition, as may be caused by network activity (e.g., internet browser, or e-mail program), or virus scanners.
- If possible, disconnect the PC from a network during EMG acquisition.

- If you must use a virus scanner, please check if you can disable it during recording, and verify its settings for any scheduled periodic activity.
- After installation and verification of the proper recording procedures, it is best to use the same USB port always for the connection of the amplifier/USB interface.
- Disable the Windows selective suspend feature for energy saving for every USB 2.0 port the MobiMini Bluetooth dongle shall be used with: 1. Plug the dongle into the first USB 2.0 slot 2. Go to the Windows device manager and open the overview of connected Bluetooth devices at "Bluetooth Radios" 3. Select the properties of the Bluetooth device "Generic Bluetooth Radio" 4. Select the "Power Management" tab and deactivate the entry "Allow the computer to turn off this device to save power" 5. Repeat steps 2 4 for every USB 2.0 slot available
- The use of many different USB devices on the recording PC may result in an instable system configuration. In that
 case, please disconnect devices, and/or remove the associated driver through the Windows "Device Manager"
 control.
- **vi**sor2 does not support a 'continuous' recording mode, because of a size limit of CNT files of 2GB. The user should be aware of practical restrictions for the duration of one recording file, for example:
 - → record maximally at most 4 hours with 32 channels at 2048Hz, equally so for 64 channels at 1024Hz; After this time, you need to start a new session.

Notes:

- This is considering 'normal' EEG. As the EEProbe *.cnt format compresses the data, these values depend
 on the information content of the EEG and might vary between patients and sessions
- o If you require longer recordings, you can enable the option "Extended mode" in the CNT Export Settings (Tools → Options → CNT Export Settings). This will store the data in the extended EEProbe format, allowing for 17TB (terra bytes, 1TB = 1000GB) of recording data and virtually endless recordings. However, please be aware that this format is not yet supported by most third party software. For more information, please contact support@eemagine.com.

1.7.2.2 PRECAUTIONARY MEASURES

- When the amplifier is not in use for more than a few days, switch off the device, and (if applicable), remove or disconnect batteries to prevent damage in case they start leaking.
- Do not use an operating cellular phone within 30 cm of the amplifier, the cables and the electrodes, to avoid excessive noise on the signals.

1.7.2.3 MAINTENANCE

Maintenance is limited to regular cleaning and, if applicable, changing of batteries. There are no user serviceable parts within the device. Repairs can only be performed by the manufacturer. Due to design no calibrations are needed.

1.7.2.4 **CLEANING**

- Before cleaning, make sure that the amplifier is turned off and not in contact with a patient. Cleaning of the amplifier can be done with a slightly damp soft cloth. Do not use aggressive chemicals for cleaning.
- The amplifier is not suitable for sterilization.
- For information on how to clean an accessory, please refer to its own manual.

1.7.2.5 CHANGING BATTERIES (IF APPLICABLE)

 Before batteries are replaced, disconnect the patient from the amplifier, make sure that the external power supply is disconnected and the device is switched off.

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- Replace batteries simultaneously, and make sure they are all of the same type. Take into account the orientation of the batteries.
- Dispose of batteries according to local regulations.

1.7.3 OPTICAL TRACKING SYSTEM

- Do not look directly into the laser-emitting aperture. The laser module on the position sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.
- Do not use the system in the presence of flammable materials such as anesthetics, cleaning agents, and endogenous gases. Flammable materials may ignite, causing personal injury or death.
- Radio frequency communications equipment, including portable and mobile devices, may adversely affect the performance of the system.
- Do not use the system in an MRI environment without first determining the performance, including the positioning accuracy; please consult with service personnel of ANT/eemagine first.
- Do not transport or store the position sensor outside the recommended storage temperature range, as this may
 cause the system to go out of calibration. Reliance on data provided by an out of calibration position sensor may
 lead to inaccurate conclusions and may cause personal injury. A calibration procedure must be performed before
 using the position sensor after it has been transported or stored outside the recommended storage temperature
 range.
- Do not use cables or accessories other than those listed in this guide.
- All user maintenance must be done by appropriately trained personnel. Maintenance by untrained personnel may
 present an electric shock hazard.
- Do not attempt to bypass the grounding prong on the power cord by using a three-prong to two-prong adapter.
 The system must be properly grounded to ensure safe operation. Failure to do so presents an electric shock hazard.
- Do not immerse any part of the system or allow fluid to enter the equipment. If fluids enter any part of the system they may damage it and present a risk of personal injury.
- Do not sterilize the system as this may cause irreversible damage to its components. Reliance on data provided by a damaged position sensor may lead to inaccurate conclusions.
- Do not use the position sensor without inspecting it for cleanliness and damage both before and during a
 procedure. Reliance on data provided by an unclean or damaged position sensor may lead to inaccurate
 conclusions.
- Do not use markers without inspecting them for cleanliness and damage both before and during a procedure. Reliance on data produced by unclean or damaged markers may lead to inaccurate conclusions.
- Do not obstruct the normal flow of air around the position sensor (for example, draping or bagging the position sensor). Doing so will affect the position sensor's operational environment, possibly beyond its recommended thresholds. Reliance on data provided by a position sensor that is outside of recommended thresholds may lead to inaccurate conclusions.
- Take precautions to ensure that people with restricted movement or reflexes (for example, patients undergoing medical procedures) do not look directly into the laser-emitting aperture. Patients undergoing medical procedures may be restricted in the availability of adverse-effects reflexes (turning away eyes and/or head, closing eyes) due to pharmaceutical influences and/or mechanical restraints. The Class 2 laser module on the

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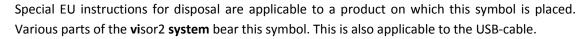
position sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

- Use of laser controls or adjustments or performance of laser-related procedures other than those specified may result in hazardous radiation exposure.
- Before using the system, make sure the power LED on the position sensor has stopped flashing. The power LED will flash while the position sensor warms up.

1.8 OPERATING ENVIRONMENT REQUIREMENTS

- There must be a clear line of sight between the position sensor and the tools to be tracked.
- The tools must be inside the characterized measurement volume.
- Make sure that sources of background IR light in the 800 nm to 1100 nm range (e.g. sunlight, some operating room lights) are minimized. The position sensor is sensitive to IR light. Since the position sensor functions by detecting IR light reflected from, or emitted by, markers, other sources of IR light can interfere with the optical tracking system.
- Make sure that there are no large reflective surfaces within the field of view.
- The environmental conditions must be as follows: the atmospheric pressure must be 70 kPa to 106 kPa, the relative humidity must be 30% to 70%, and the temperature must be 10°C to 40°C.

1.9 DISPOSING OF WASTE EQUIPMENT





The symbol means that the products must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service.

1.10 CONTACT INFORMATION

For more information and for reporting problems with **vi**sor2, please contact your local distributor, or contact the manufacturer directly at support@eemagine.com

1.11 COMPATIBILITY

visor2 supports all types of TMS stimulators, class IIa, according to the Medical Device Directive.

The list of coils compatible with **vi**sor2 is constantly growing. Please contact your distributor or send an email to support@eemagine.com to find out if your coil is supported.

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2 Introduction

The visor2 product is a system made for real-time tracking of objects in space. visor2 has been designed for tracking TMS (transcranial magnetic stimulation) coils relative to the patient's head, real-time forward calculation of the electric field induced in the brain due to the magnetic pulse, definition of target positions, real-time display of MRI, TMS stimulation and related information in various ways and the recording and analysis of electrophysiological signals.

The product is manufactured by eemagine Medical Imaging Solutions GmbH, Berlin, Germany and represented by ANT Neuro BV, Enschede, Netherlands (www.ant-neuro.com).

2.1 How the documentation is organized

Together with the visor2 system, you will be provided with the following documentation:

• This User Guide. This document is intended to introduce you to the basic use of the visor2 system. Example cases will help you to start a TMS neuronavigation session, set markers, targets, create and navigate through the brain. You will also learn how to perform more advanced procedures such as offline motor mapping. About two hours are required to become familiar with the main features of the product, following the steps as described in this document.

2.2 System components

The following components are part of the visor2 system:

- The visor2 software running on the PC.
- The optical tracking system (*Polaris Spectra or Polaris Vicra* from Northern Digital Inc.) for measuring distances
 and orientations of tracking tools. The position sensor comes with an arm and is mounted on a tripod, wallmounted or attached to the visor2 cart. A single cable leads to the supply unit, which is connected with the power
 supply and via a USB cable with the PC.
- First coil tracking tool **NT-112**. This tool is attached at the coil handle to allow tracking the coil's position and orientation.
- Second coil tracking tool NT-143. This tool is only needed in case you would like to navigate two TMS coils at a
 time (visor2 XT license required). This tool is attached at the coil handle of the second coil to allow tracking the
 coil's position and orientation.
- Calibration board. The board is used for determining the position and orientation of the coil tracking tool relative
 to the coil itself. This needs to be done after fixation of the tracking tool. Note that for some coils, special
 calibration boards are provided.

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- Reference tracking tool at patient's head NT-103. The reference tool allows tracking head movements and makes sure that measured positions remain relative to the patient's head during sessions of electrode digitization or TMS stimulation.
- Pointer tracking tool NT-115 to mark nasion-ear-positions and collect head shape points.
- TriggerBox NH-134 with Remote 2-button control NH-135. The remote control is connected to TriggerBox and from there via USB to the PC. It allows the user to operate visor2 without the PC's keyboard. The remote control has two buttons: left in blue color, and right in green color. Dialog buttons in the visor2 workflows make reference to these button colors. In addition, the TriggerBox allows input of TTL pulses from the TMS stimulators via BNC cables and transmits them to the PC.
- Amplifier and its components, which may vary depending on the type of your amplifier.

The following image shows how to connect the hardware devices:

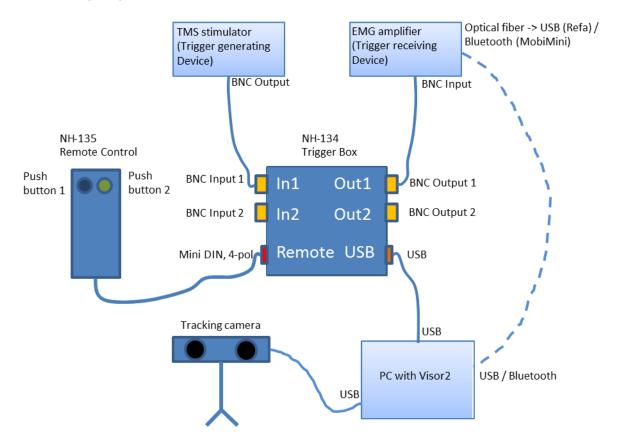


FIGURE 1 HARDWARE SET-UP OF THE VISOR2 SYSTEM



Make sure that your TMS Stimulator is always connected to BNC Input 1 (In1)! In case you would like to navigate two TMS coils simultaneously, connect the TMS Stimulator for the first coil to BNC Input 1 and the Stimulator for the second coil to BNC Input 2.

If you run an EMG / EEG session with two coils, connect the amplifier to BNC port OUT1. The trigger box will automatically merge the stimuli from both input ports IN1 and IN2 and feed them to the OUT1 port.

2.3 THE TRACKING TOOLS

With the term tracking tool we mean any object than can be tracked by the infrared tracking camera. Tracking tools are provided with sphere markers, which reflect infrared light emitted by IR-LEDs, attached to the position sensor. The geometrical configuration of a tracking tool is described in .rom configuration files. The tracking tools provided with **vi**sor2 are illustrated in Figure 2.

The **pointer tool** is used during the patient registration. You will be asked to digitize with the pointer the positions of different anatomical landmarks on the patient's head. The **coil tracker** has to be rigidly attached to the coil, and allows tracking the position and orientation of the coil during a navigated TMS session. The **reference tool** has to be fixed to the patient's head. In order to allow the patient to move during the TMS session, all positions are expressed relative to the position of the reference tool. The **calibration board** is used when calibrating a coil. After having calibrated a coil, the calibration board will not be necessary anymore during the TMS session.

- It is very important that the reference tool does not move with respect to the patient's head!
- Please make sure that you always use a calibration board compatible with your coil! The program will present you
 with a list of boards that can be used with your coil. Never use a different one!







Coil tracker. The lower part is specific to your coil model.

The wing part with the reflective spheres is universal:

NT-112 for the first coil and NT-143 for the second coil.





Reference tool NT-103. Note that it comes together with a clip for fixating it with a headband or on an EEG cap.

Alternatively, you can use it with disposable snap stickers to affix it directly on the skin.

Calibration board NT-104 (standard). For a wide range of coils, we also offer tight fit calibration boards that allow an even easier calibration. For details ask your local distributor!

FIGURE 2: THE VISOR2 TRACKING TOOLS

2.4 THE VISOR 2 CART

The system can optionally be provided with a cart, which facilitates the transport. The cart has two possible configurations:

- Operation mode. During operation, the wheels of the cart should be <u>locked</u> and the position sensor <u>rigidly</u> <u>fixated</u>. The position sensor should be positioned in such a way that the patient's head is always in the field of view and that there are no obstacles which might obstruct the line of sight.
- **Transportation mode.** Before moving the cart, please <u>remove</u> the position sensor, <u>fold down</u> the sensor mount arm and unlock the wheels. The cart should be maneuvered by holding the provided pull handle.

2.5 PATIENT DATA MANAGEMENT

The first time the *Visor 2 software* is run, it is important to select the root directory where all patient-related data will be stored. The root directory can be selected by changing the Default MRI File Folder under Tools Options MRI Import Menu. It is extremely important to set the root directory only once. If this directory is changed, access to existing patient data will be lost (these may be retrieved by copying all patient directories into the new root directory).

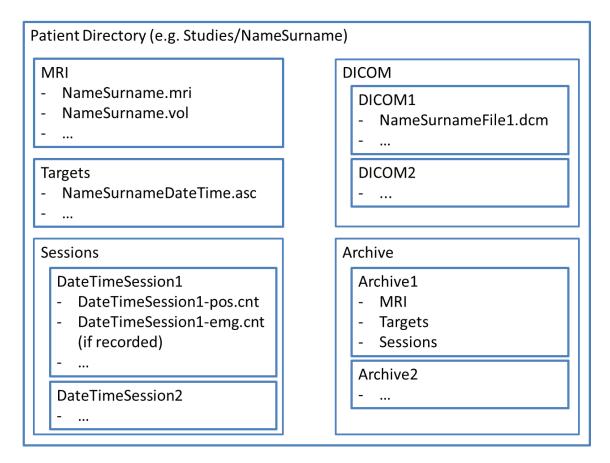


FIGURE 3: PATIENT DATA STRUCTURE

For each patient, a new patient directory will be created in the root directory, according to the structure shown in Figure 3.



It is important to understand that all navigation data refer to the underlying MRI that was used during data acquisition. That is, Session and Target data are only valid when analyzed using the current MRI. Therefore, if new MRI data is used for a later session, the current Target and Session data is archived together with their respective old MRI in a separate directory called "Archive", see section Load MRI.

2.6 APPLICATION WORKFLOWS

The **vi**sor2 is structured in five main workflows, which are accessible through the corresponding toolbar, as displayed in Figure 4.

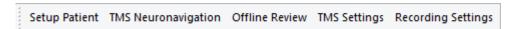


FIGURE 4: THE WORKFLOWS TOOLBAR

When **vi**sor2 is used for the first time, the TMS Settings workflow needs to be run first. It allows the selection of the coil type to be used in the stimulation session and its calibration. The workflow allows calibrating all coils which might be used for stimulation. It is necessary to run this workflow only if a new coil needs to be calibrated: the selection of the active coil is done within the main TMS Neuronavigaton workflow.

The Recording Settings workflow needs to be run only if the **vi**sor2 **system** is provided with an amplifier (XT License). It allows defining the amplifier type, the number and the labels of the recording channels and the sampling rate. It is necessary to run this workflow the first time **vi**sor2 is used and each time the configuration of the recording channels needs to be changed.

Online Neuronavigation can only be started if all necessary patient data have been prepared. This is achieved within the Setup Patient workflow which allows to user to prepare all necessary 3D patient data for the navigation, starting from a patient's MR scan or using standard data. This workflow also allows defining stimulation targets for a subsequent Neuronavigation session.

The main application workflow, the TMS Neuronavigation can be started either through the corresponding button in the *Workflows* toolbar, or directly from the Setup Patient workflow, after it has been successfully completed. The TMS Neuronavigation workflow will guide the user to perform all steps which are necessary to start the navigation and signal recording and processing.

The Offline Review workflow can be started either through the corresponding button in the *Workflows* toolbar, or from the TMS Neuronavigation workflow, after this has been finished. Through optimized views this workflows allows the user to easily review and analyze all data that have been generated during a navigated TMS session.

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3 SETUP PATIENT

Before starting a TMS session with **vi**sor2, an MR scan of the patient needs to be imported and segmented, in order to obtain a realistic head model of the scalp and of the brain. The brain surface will be then used to create the curvilinear surface, a mapping surface on which the 3D image texture is projected, which shows the cortical structures at different depths. In order to be able to co-register the MR scan with the head models, and later to register the patient with the corresponding MR scan, it is necessary to define the coordinate markers. All data will be copied to a patient-specific folder for later use in the Neuronavigation session.

Alternatively, if no patient MRI is available, standard data can be used. In this case, an MRI of a healthy adult together with a pre-calculated segmentation is copied to the patient data folder. *Note:* The QT version of **vi**sor2 supports only standard MRIs.





In any case, the final step of the Setup Patient workflow allows you to pre-define targets you want to stimulate in a later Neuronavigation session. Targets can be chosen directly on the MRI or curvilinear surface or by referring to atlas coordinates.

3.1 Creating a new patient entry

To prepare data of a new patient for **vi**sor2, select the option *Create New Patient*. Enter the patient's name in the text field provided. All patient related data including MRI, 3D models, TMS sessions, EMG recordings will be saved in a directory named according to what you type in here. If a patient with the same name already

exists, a warning will be issued and you will be asked to enter a different name. In such a case, please add a unique identifier to the name of the patient, e.g. the middle initial or append the date of birth.

Next, you need to select if you want to work with patient specific MRI data or use standard MRI data, see section Load MRI. When all entries have been provided, press the [Specify MRI Fiducials] button to proceed in the workflow.

3.2 EDIT EXISTING PATIENT DATA

If you want to use another MRI for an existing patient or if you want to define new targets, choose the *Modify Existing Patient* option. Use the drop-down box to select the patient.

3.2.1 Defining New Targets

New targets can be defined based on the existing MRI by selecting the *Do not change MRI* option. Press the [Define Targets] button to arrive directly on the *Define Targets* page.

3.2.2 Provide a New MRI

Select the *Import patient MRI* option to associate a new MRI data set with the patient. This allows you to import MRI data from file, see section *Load MRI* and to create a new head model, see section Create Model.



Please be reminded that targets and session data relate to the MRI that has been loaded when performing target definition and running a Neuronavigation session. Therefore, importing a new MRI renders these data invalid. Every time you import a new MRI, visor2 copies the old MRI together with the sessions performed using this MRI and the corresponding targets to a separate Archive folder, see the chapter on patient data management.

3.3 LOAD MRI

You can choose whether to associate patient-specific MRI data or standard MRI data with the patient. The third option *Do not change MRI* is only available for existing patients and allows you to define a new set of targets on previously imported MRI data.

3.3.1 STANDARD MRI

If you choose this option, an MRI of a healthy adult together with a pre-calculated segmentation is copied to the patient data folder. There is no need to define MRI Fiducials or run a custom segmentation; it has all been done for you already. When pressing the [Define Targets] button, the workflow proceeds directly to the *Define Targets* page.

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We recommend using patient-specific MRI data whenever available. If you choose to work with standard data, please be reminded that

- Navigation accuracy might suffer from imperfect matching of the patient's head shape with the provided standard head
- Neuronal structures differ widely between patients; any anatomical data shown on the standard MRI will not match the true anatomy of the patient
- Mappings performed with the standard data will show the correct hot-spot relative to the registered scalp, but not relative to the standard brain's anatomical structure.

3.3.2 PATIENT-SPECIFIC MRI

To import a new MRI data-set for the patient, you need to follow these steps:

- Select the type of your MR scan. You can chose between DICOM, Analyze, Nifti or the ASA format, if you already saved your original MR as ASA MRI file type.
- Click the *Browse* () button. Indicate the MR scan you want to import. In case you selected DICOM as the image type, a special DICOM import dialog will appear. For details see section Review Exported DICOM.
- Click the [Specify MRI Fiducials] button to proceed.

3.3.3 MRI REQUIREMENTS

The following restrictions apply to the MRI import:

Supported formats	DICOM; Nifti; Analyze; ASA		
Field of View	 The entire head must be included: the nose (the tip should not be cropped), the ears, the forehead and the chin; The headrest or the scanning table must not be included in the scan. 		
Image Properties	 T1 weighted scans; Maximally 512³ voxel. If your MR scan contains more than 256 slices in any direction, this direction be automatically down-sampled to 256 slices. Uniform spacing in each direction is recommended; Uncompressed format. 		



The use of Analyze as import data format for MRI scans is discouraged as there is ambiguity about the image orientation. Please ask your radiology department to provide you with Nifti or DICOM images instead. If you need to work with Analyze images, it is most important to check the left-right orientation for every patient and data set.

3.4 Specify MRI Fiducials

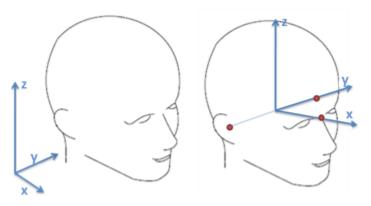


FIGURE 5: THE MRI- BASED (LEFT) AND THE NASION-EAR BASED (RIGHT) COORDINATE SYSTEMS

Before setting the coordinate markers, all positions are expressed in the MRI-based coordinate system. The coordinates of the crosshair are visible either on the *Status Bar*, or on a tooltip, which becomes visible when dragging the crosshair in the *MRI View*.

The three coordinate markers for nasion and the left and right preauricular points are required to define a head-based coordinate frame for the MRI. Based on this coordinate frame, the MRI can be overlaid with the head model and other 3D boundary objects. When the nasion-ear coordinate markers are set, all positions are expressed in the Nasion-ear coordinate system.

Place the crosshair to the position where you want your nasion marker to be placed. This can be done by either dragging the crosshair directly in the *MRI View* or through the slice slider in the *MRI* Toolbar.

- Press the Nasion Marker button (Nasion marker).
 A green border indicates that the point has been defined.
- Repeat the procedure for the left and right preauricular points.
- Click the [Create Head Model] button to proceed.

The MRI with the nasion-ear markers will be copied from its original location and stored in ASA file format in the patient directory (please see the "Patient Data Management" section).

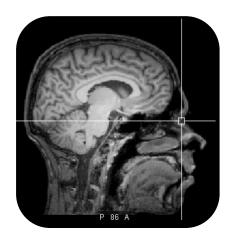


FIGURE 6: CROSSHAIR INDICATING THE NASION





- Only trained medical personnel are allowed to identify the positions of the coordinate markers.
- Please set the position of the coordinate markers very carefully. Remind that, during neuronavigation, the same points need to be identified on the patient, through the pointer tool.
- If different persons are responsible for the preparation of the 3D data and for the registration of the patient, the positions of the preauricular points need to be unambiguously defined

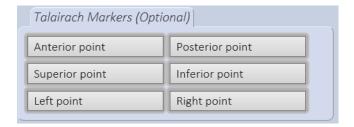
3.4.1 TALAIRACH MARKERS

The "Specify MRI Fiducials" page also allows you to set Talairach markers if you need to convert positions from and into this standardized head coordinate system during a later TMS session. For more information about the Talairach system and how to set the accompanying image markers, see Appendix 2: MRI coordinate systems.

1. Set the Nasion-Ear-markers as described above. A section which allows you to set the ACPC markers becomes visible.



Use the buttons to set the anterior commissure, posterior commissure and inter-hemispheric point
markers: Place the crosshair in the 3d MRI view on the correct location and mark the spot by
pressing the corresponding button. After all three points have been defined, the MRI view switches
to the ACPC view automatically.



3. Use the Talerach Markers buttons to set the boundary points of the brain, defining the limits of the Talairach coordinate space. AP: anterior point, PP: posterior point, SP: superior point, IP: inferior point, LP: left point, RP: right point. To set the two points for each direction, switch ACPC view orientation according to this direction by clicking on the orientation icons of the MRI slice toolbar.



Make sure you set the

boundary points according to the ACPC view in the lower right of the 3D image view.

After having defined all markers, press the [Create Head Model] button. The Talairach markers are automatically saved with the MRI and are loaded when using the MRI for a TMS session.

3.5 CREATE MODEL

Segmentation is used to divide the MRI into the scalp and brain compartments. The segmented regions will serve as basis for generating the realistic head models of the different head compartments. During a TMS session with visor2, you will need a head model of the scalp and of the brain. The scalp head model is necessary to improve the registration accuracy by performing a so called shape-based registration, where points digitized on the patient's head by means of a pointer are matched to the patient scalp. The head model of the brain serves as basis for extracting the curvilinear surfaces. These are concentric surfaces, the most outer one lying on the brain head model, which reflect the morphological structure of the brain. The estimated electric field produced by the coil is projected onto the curvilinear surfaces, allowing therefore viewing the distribution of the field at different cortical depths.

In the Segmentation workflow, you have the possibility to choose between manual brain segmentation and automatic segmentation of the brain based on the straight forward scalp segmentation. If you need an accurately segmented brain, we encourage you to perform manual brain segmentation. If the quality of the segmented brain is not crucial, the complete segmentation procedure can be completed very quickly by performing only the scalp segmentation and automatically creating the brain segmentation based on the segmented scalp. Figure 7 shows the result of a manual and automatic segmentation of the brain on the same MR scan.

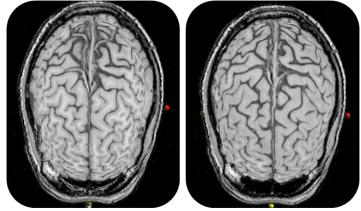
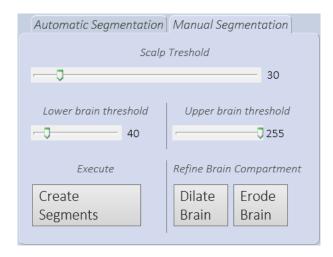


FIGURE 7: LEFT - AUTOMATIC SEGMENTATION OF THE BRAIN FROM THE SCALP, RIGHT - MANUAL SEGMENTATION OF THE BRAIN

The scalp can be found relatively easy based on the contrast in grey value and so-called 3D region growing algorithms. For volumetric T1-weighted scans, the range of grey values for the scalp is between about 25 and 255 (although very much depending on the scan parameters. The threshold values used for the brain are usually in the range of 30 to 80, depending on the MRI. If the threshold values are inappropriate, the boundary may also contain other parts of the head, such as the scalp. This can in most cases be overcome by adjusting the threshold values. The segmentation of the brain is based on the morphological operation called opening, which breaks up thin connections between regions selected by the threshold criterion. In this way the brain is separated from the rest of the head. Since regions not belonging to the brain will be removed, it is very important to properly define the "seed point" within the brain, before starting the segmentation.

3.5.1 Manual Brain Segmentation



- Select the lower intensity threshold for the scalp segmentation. The voxels which will be classified as belonging to the scalp, according to the selected threshold values, are rendered in yellow. If the lower voxel intensity threshold is too low, small artifacts connected to the head and in the proximity of the head will appear (Figure 8).
- Try to increase the value of the lower threshold until the artifacts connected to the head disappear. Remind that the artifacts not connected to the head will be removed by performing the segmentation feature.
- Select the lower and the higher intensity thresholds for the brain segmentation. The voxels which will be classified as belonging to the brain, according to the selected threshold values, are rendered in red. The red-rendered brain structure should be disconnected from the rest of the head. Increase the value of the lower threshold until a sufficient degree of separation between the brain and the remaining head structures is reached (Figure 9).

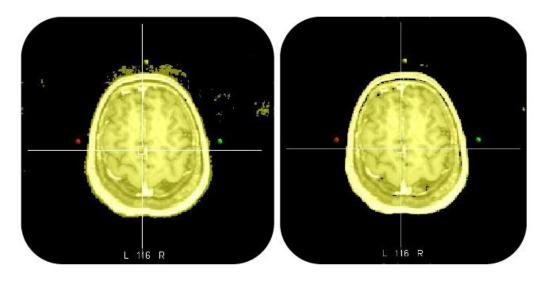


FIGURE 8: SEGMENTATION OF THE SCALP. LEFT: THE THRESHOLD VALUES ARE NOT CORRECT, AND SMALL ARTIFACTS ARE VISIBLE IN THE PROXIMITY OF THE HEAD. RIGHT: CORRECTLY DETERMINED THRESHOLD VALUES.

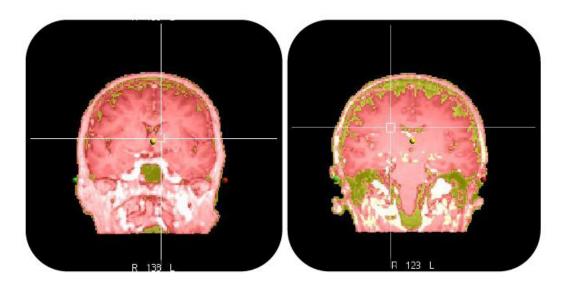


FIGURE 9: SEGMENTATION OF THE BRAIN. LEFT: THE LOWER THRESHOLD IS TOO LOW AND THE BRAIN STRUCTURE IS CONNECTED TO THE SCALP. RIGHT: CORRECTLY DETERMINED THRESHOLD VALUES, THE BRAIN IS SUFFICIENTLY SEPARATED FROM THE SCALP

- Select the number of curvilinear surfaces to be generated. The curvilinear surfaces are closed concentric surfaces generated from the brain head model by moving inwards by a 1mm step.
- Place the crosshair within the brain.
- Start the segmentation by clicking the [Create Segments] button. The segmented scalp and brain compartments will be displayed in the *MRI View*, the scalp on the left side, the brain on the right as indicated in Figure 10 .



FIGURE 10: MRI VIEW AFTER SUCCESSFULL SCALP AND BRAIN SEGMENTATION

- If the result of the segmentation is not satisfactory, readjust the thresholds, position the crosshair within the brain and perform the segmentation again.
- If necessary, the segmentation of the brain can be readjust by performing a "dilation operation" or an "erosion operation" of the segmented compartment.
- Create and export the head models of the brain and the scalp by clicking the [Create Model] button. The head models will be displayed in the *MRI View*, as indicated in Figure 11.

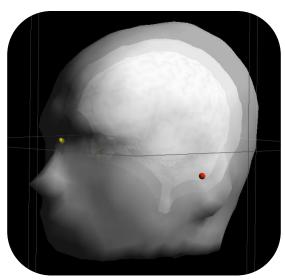
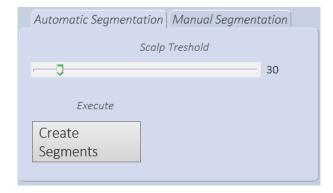
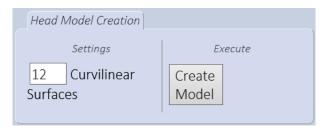


FIGURE 11: SCALP AND BRAIN HEAD MODELS, AFTER MANUAL SEGMENTATION

3.5.2 AUTOMATIC BRAIN SEGMENTATION



- Select the lower intensity threshold for the scalp segmentation. The voxels which will be classified as belonging to the scalp, according to the selected threshold values, are rendered in yellow. If the lower voxel intensity threshold is too low, small artifacts connected to the head and in the proximity of the head will appear. Try to increase the value of the lower threshold until the artifacts connected to the head disappear. Remind that the artifacts not connected to the head will be removed by performing the segmentation feature.
- Select the number of curvilinear surfaces to be generated. The curvilinear surfaces are closed concentric surfaces generated from the brain head model by moving inwards by a 1mm step.
- Start the segmentation by clicking the [Create Segments] button. The segmented scalp and brain compartments will be displayed in the *MRI View*, the scalp on the left side, the brain on the right as indicated in Figure 10. Please remind that the rendered brain is only the starting scalp surface from which the brain will be automatically generated.



Create and export the head models of the brain and the scalp by clicking the [Create Model] button. The
head models will be displayed in the MRI View, as indicated in Figure 12.

After completing the segmentation, the MR image of type ASA (.mri), which includes the positions of the coordinate markers and the head models of the scalp and the brain will be exported in the patient directory.

Click the [Define Targets] button to proceed.



FIGURE 12: SCALP AND BRAIN HEAD MODELS, AFTER AUTOMATIC SEGMENTATION



- Only trained medical personnel is allowed perform the segmentation.
- The quality of the scalp segmentation directly influences the accuracy of the TMS navigation.
- Always check if the segmented scalp surface agrees with the scalp- air-boundary visible in the MRI.

3.6 Define Targets

The Setup Patient workflow gives you the possibility to define targets on the brain anatomy. The defined targets will be saved and exported in the patient directory, and can be loaded within the TMS Neuronavigation workflow. During navigation, the **vi**sor2 **software** will help you targeting the identified markers, as explained in *Stimulate at Targets* section.



Place the crosshair at the desired target position. This can be done in several ways:

 Directly drag the crosshair in the MRI View to the desired position.

- Use the slice sliders in the MRI Toolbar.
- Directly enter the coordinates through the Go to MRI Coordinate dialog under Edit / Goto MRI Coordinates....Depending on the coordinate markers that have been set, you will be able to specify the coordinates in different coordinate systems.

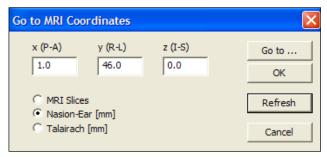


FIGURE 13: THE GO TO MRI COORDINATES DIALOG. NOTE THAT THE TALAIRACH SYSTEM IS ONLY AVAILABLE IF TALAIRACH MARKERS HAVE BEEN SET.

Once you are sure the crosshair is at the right position, press the [Add marker] button. A dialog will appear prompting you to enter the marker label. Enter the target name and Click OK. Repeat to add more targets, if necessary.

If you wish to start a neuronavigation session with the data you just generated, you should directly proceed to the Neuronavigation workflow, by clicking the [Proceed to Neuronavigation] button. Otherwise, terminate the workflow by pressing the [End Workflow] button.

3.7 FILE STRUCTURE

The Setup Patient workflow allows you to easily load your MR scan and generate and export the brain and scalp head models. If all the steps are performed correctly, after completing the workflow, the following files will be generated:

- ASA MRI. Your original MR scan will be exported into the ASA .mri type. The ASA MRI file defines also the positions of the coordinate markers.
- The scalp and brain head models and the curvilinear surfaces, organized as follows:
 - A boundary definition file of the scalp and the brain (meg-x.bnd)
 - A boundary definition file, for each of the curvilinear surfaces (clrf-x.bnd).
 - A curvilinear surface definition file, pointing to curvilinear boundaries files (clrf.vol).
 - A head model definition file, pointing to the scalp and brain boundaries files (meg.vol).

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- Target markers. A file containing the target coordinates in nasion-ear-coordinates and the corresponding target labels (.asc). The file name is concatenated of the patient name and the date and time the targets were defined.

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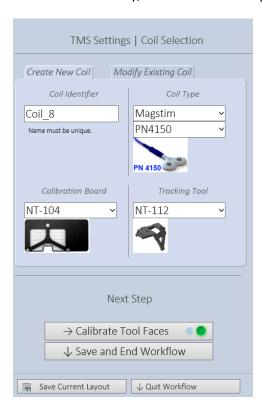
4 TMS SETTINGS

The TMS Settings workflow needs to be executed each time you need to calibrate a new coil or you connect the position sensor to a different USB port. It should also be the first step when starting **vi**sor2 for the first time. The TMS Settings workflow can be started by clicking the corresponding button in the workflows toolbar.

4.1 COIL SELECTION

The page allows you to define the coil you need to calibrate or recalibrate:

- If you have already defined this coil for use with **vi**sor2, select the entry "Modify Existing Coil" and choose your coil from the drop-down box.
- If you want to define a new coil for the use with visor2, select "Create New coil" and choose:
 - The manufacturer
 - The coil model
 - The calibration board that will be used later for calibrating the coil
 - An identifier for the coil. It is not allowed to use the same identifier for two different coils, even if their manufacturer or model differs.
 - The tracking tool. Choose NT-112 for the first coil in a TMS session and NT-143 if you want to use the
 coil as second coil during the simultaneous navigation of two TMS coils. If you operate visor2 with
 one coil only, choose NT-112 always.





Press the [Calibrate Tool Faces] button to proceed. You will now be prompted to calibrate the coil. Once you have successfully calibrated the coil, you can either terminate this workflow or you can go back to calibrate another coil.

4.2 Before the first calibration of a new coil

Each coil that is used with the Visor system for the first time has to be provided with a permanent marker on its upper face. Place one of the stickers that came with your Visor system on the upper right part of the coil's upper face. The sticker serves as a control point to validate the accuracy of a calibration, see *Calibration procedure*. Don't worry about the exact location of the sticker; it is only important that it is easily accessible during the calibration procedure, see Figure 17.

4.3 CALIBRATION PROCEDURE

In order to be able to precisely track the position of your coil, visor2 needs to find out how the tracking tool is attached to the coil. During the calibration procedure, visor2 will calculate the position of the origin of the coordinate system attached to the coil with respect to the coil tracker. Moreover, visor2 will calculate the distance between the control point on the coil and the coil tracker. This distance will be used by visor2 as a discriminator of the validity of the coil calibration. During time in fact, although rigidly attached, it might happen that the coil tracker slides along the coil handle. The performed calibration is then no longer valid and the coil needs to be recalibrated. Summarizing, the calibration procedure is necessary:

- Each time a coil tracker is attached to the coil.
- Each time the coil validation procedure fails. During a TMS session with visor2, after having selected the stimulating coil, you will be asked to validate the calibration. Even though this step is not mandatory, we strongly encourage you doing so.

4.4 STEP 1: CALIBRATE TOOL FACES

Before the actual calibration of the coil, **vi**sor2 checks and refines the geometry of the wing tool. This ensures that the tracking camera can always determine the position of the coil with maximum precision, independently of which wing tool face is presented to the camera.

Please attach the wing tool to your coil now, make sure it cannot slip on the coil handle and present the wing tool frontally to the camera. The indicator lights on the right show the visibility status of the left and right face of the wing tool, respectively. A green light indicates that the tool face is visible to the camera. A red light indicates that the camera cannot determine the position of the face: Either the face is not visible to the camera or the camera's operation is impaired, e.g. by to much infrared ambient light. In this case, the source of the problem is indicated next to the tool's visibility indicator.

When both faces are visible to the camera, press [Calibrate] or operate the green button on your remote control. If the calibration succeeds, you will be informed by a green text box and the workflow will automatically proceed to the second step. If the calibration fails, a red error text box will inform you about the source of the problem. Correct the problem and re-try the calibration.

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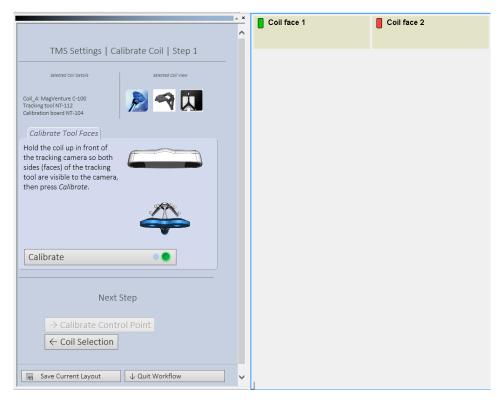


FIGURE 14: CALIBRATION DIALOG, STEP 1 "CALIBRATE TOOL FACES"

4.5 STEP 2: CALIBRATE CONTROL POINT

In the second step, a reference point is defined which allows to check if the wing tool changed its position relative to the coil. Make sure that the control point sticker with the black cross on yellow ground is affixed to the coil. Hold the coil such that the camera can see the wing tool (it does not matter which face of the tool you use – after step 1 both tool faces are calibrated to each other). Hold the pointer such that the tip is on the center of the sticker's black cross and the reflective spheres are visible to the camera.

When ready, press [Calibrate] or operate the green button of the remote control. If the calibration succeeds, you will be informed by a green text box and the workflow will automatically proceed to the third step. If the calibration fails, a red error text box will inform you about the source of the problem. Correct the problem and re-try the calibration.

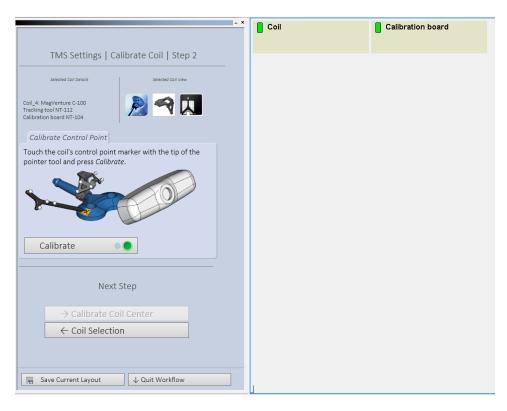


FIGURE 15 CALIBRATION DIALOG, STEP 2 "CALIBRATE CONTROL POINT"

4.6 STEP 3: CALIBRATE COIL CENTER

In this last step, the position of the coil's center point ("hot-spot") relative to the coil's wing tool is calibrated. Keep in mind that the tracking camera can only measure the position of the wing tool; the position of the coil's hot-spot needs to be calculated from there using the coil center calibration.

To calibrate you will need the calibration board selected for this coil on the Coil Selection page. The calibration board's identifier and image are also presented on the Calibrate Coil Center page again. Please make sure that you use the correct calibration board; otherwise the calibration results will be inaccurate.

Attach the coil on your calibration board. Place the coil in such a way that the center of the coil matches the point of origin on the board. The coil tracker attached to the coil might prevent from seeing whether the coil is properly centered. It is advisable to control the correct coil placement on the board by viewing it from the back side of the calibration board, as shown in Figure 16. Once you have placed the coil correctly, fix its position through the provided screws. *Note:* If your coil supports a tight fit special calibration board, you only need to place the coil in it and make sure it is properly fitted.

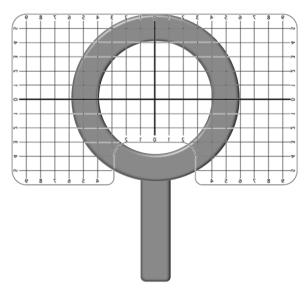


FIGURE 16: BACK VIEW OF THE CALIBRATION BOARD WINDOW WHEN CALIBRATING A COIL

Place the coil and the calibration board such that the camera can see the coil's wing tool and the calibration board, as showed in Figure 17. When ready, press [Calibrate] or operate the green button of the remote control. If the calibration succeeds, you will be informed by a green text box. If the calibration fails, a red error text box will inform you about the source of the problem. Correct the problem and re-try the calibration.

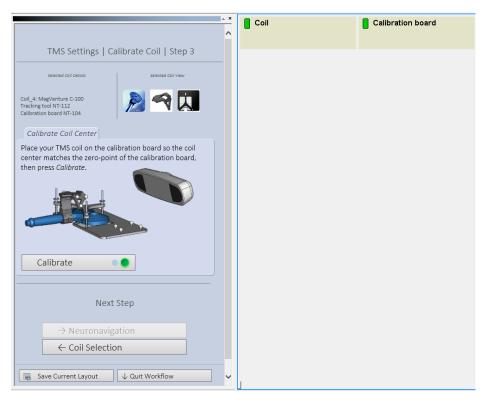


FIGURE 17: INDICATE THE COIL CONTROL POINT WITH THE POINTER

After successful calibration you can either return to the Coil Selection page to define and calibrate another coil – e.g. a coil with wing tool NT-143 for a neuronavigation session with two coils – or directly proceed to the Neuronavigation workflow.

5 EMG / EEG RECORDING

Note: This chapter applies to visor2 XT only.

5.1 RECORDING SETTINGS

Before you start a Neuronavigation workflow with EMG / EEG recording, you need to select the default montage folder for your amplifier. This needs to be done only once at the first start of the system and whenever you choose to use a different amplifier type. Select Tools → Options ... and then Montages → User Montages File Name. Browse for the montage file of your amplifier. All montages are stored in subfolders of C:\Program Files\Visor2\Data\Montages\visor\. The respective montages reside in:

Refa 64 eeg + 4 bipolar + 4 aux channels	Refa64\ Refa_64.mtg
Refa 32 eeg + 4 bipolar + 4 aux channels	Refa32\Refa_32.mtg
Mobi6 (6 channels)	MobiMini6\ Mobi_6.mtg
MobiMini (2 channels)	MobiMini2\ Mobi_2.mtg

The Recording Settings workflow is dedicated to all amplifier related settings. The recording settings need to be configured before starting the first recording with the amplifier provided within the **vi**sor2 **system** and each time you wish to change the recording configuration i.e. the number and labels of the recording channels, the sampling rate and the mapping channels. The Recording Settings workflow can be started by clicking the corresponding button in the workflows toolbar.

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The [Edit Montages] button allows to edit the existing montages or to add new ones. The montage defines the configuration of the recording channels i.e. their number and labels. The **vi**sor2 **software** already comes with a predefined set of montages which fit to your amplifier type. If you wish to edit them or add new ones, please see Appendix 1: Montages.

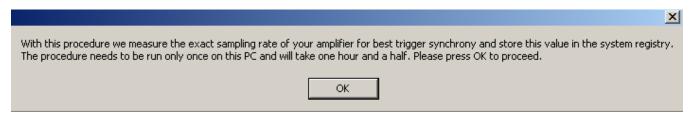
- 1. Select the amplifier type. The amplifier type determines the range of available sampling rates.
- 2. Select the sampling rate, depending on your application.
- 3. Select the recording montage. The recording montage indicates the configuration of the recording channels.
- 4. Select the mapping montage. The mapping montage indicates those channels that will be used to retrieve the mapping values: only these channels will be processed online, the peak-to-peak values of the corresponding responses will be calculated and projected onto the brain anatomy, as explained in *Finding* the hot spot of more muscles. Please remind that the mapping montage must be either equal to the recording montage or its subset.
- 5. Select whether to run the Impedance Check or not. This is only relevant in the case EEG is being recorded as well. If this option is checked you will have the possibility to run the Impedance Check within the main TMS Neuronavigation workflow.

5.2 AMPLIFIER CALIBRATION

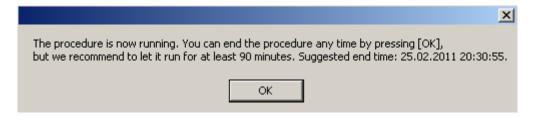
This step needs to be performed whenever a new amplifier should be used for working with **vi**sor2. It synchronizes the clocks of the PC and the amplifier and allows thus to correlate precisely the recorded EMG signal with the recorded TMS coil position. Perform the following steps:

- Start the visor2 application
- Select Tools → Macro → Run Macro... from the Menu bar

- Locate the file C:\Program Files\Visor2\Data\Scripts\Amplifier Calibration\Visor Calibrate Clock.vbs
 and open it
- You will now be informed that the amplifier calibration is about to start. Press the *OK* button to proceed.



- Let the calibration run for at least your intended TMS session length. For example, if you plan one hour rTMS sessions, let the calibration run for one hour, too.
- You can end the calibration any time by pressing the OK button again



- Close the current workflow by selecting File → Close Study. You can now start working with visor2.

If you have already performed a calibration, but you would like to repeat it, e.g. because you plan longer sessions now, just re-run the **vi**sor2 Calibrate Clock.vbs macro as described above:

- You will be asked if you want to delete the existing calibration. Press the *Yes* button to proceed, press *No* to cancel.



- After deleting the old calibration you need to close the current workflow. Choose File → Close Study.
- You can now re-calibrate your amplifier as described above.

6 NEURONAVIGATION

This section describes how to perform navigated TMS with **vi**sor2. It assumes that a valid head model of your patient/patient is already generated (chapter 3 "Setup Patient") and coils for tracking are calibrated (chapter 4 "TMS Settings"). If you want to run a session with EMG recording, you also need correct recording settings (chapter 5 "EMG / EEG Recording").

The following description depicts the features available with a **vi**sor2 XT license. Users with a **vi**sor2 LT or QT license will not be able to use any EMG / EEG features or work with two coils simultaneously.

6.1 Choose coil and stimulator

In this first step, you need to select the coil(s) that you would like to use for the neuronavigation session. Please select first the stimulator type from the drop down box on the left. Afterwards, select the calibrated coil that is connected to this stimulator and which you would like to use for the session. Please note that only calibrated coils will be available in the dialog.



FIGURE 18. SELECT STIMULATOR TYPE AND COIL FOR THE SESSION



FIGURE 19. OPTIONAL: ADD A SECOND COIL FOR THE NEURONAVIGATION SESSION (XT LICENSE ONLY)

If you want to run a session with only one TMS coil, press the button [Validate Single Coil] to proceed. If you want to navigate two coils simultaneously, press the [Add Second Coil] button. In the latter case, the page refreshes and a dialog allows you to select the coil that will be used as a second coil in the session.

Please note that only coils calibrated with the NT-112 or NT-123 coil tracker can be used as first coil. Coils calibrated with the NT-143 coil tracker can only be used as second coil in a session with two simultaneous coils.

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6.2 VALIDATE COIL

You are now prompted to validate your coil calibration. During the calibration procedure, **vi**sor2 calculates the distance between the control point indicated on the coil and the centre of tracking tool attached to the coil. To ensure that the position of the coil tracker did not shift with respect to the coil, during the validation procedure **vi**sor2 measures the distance between the tracker and the control point. If this distance differs from the distance value saved during the calibration by more than 2mm, the validation will fail.

The validation of the coil calibration can be skipped. However, the accuracy of the position of the coil as displayed by **vi**sor2, and therefore the estimated position of the induced electric field maximum, depends entirely on the accuracy of the registration and the validity of the coil calibration. We therefore recommend you to validate the calibration of your coil in each TMS session.

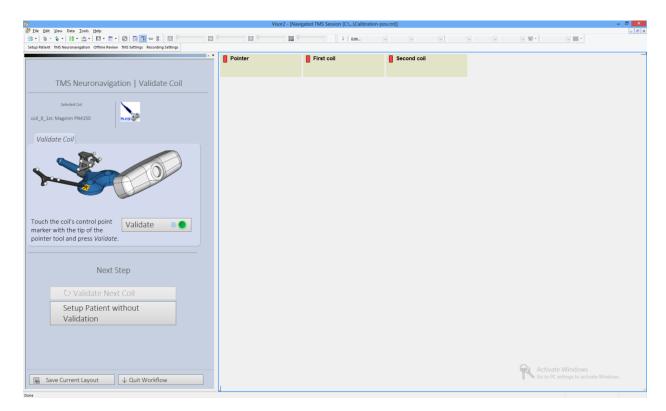
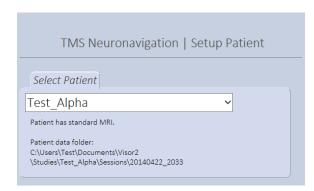


FIGURE 20. COIL VALIDATION DIALOG. PLACE THE POINTER ON THE CONTROL POINT AND PRESS [VALIDATE]

- Place the pointer's tip in the center of the control point on the coil.
- While indicating the coil's control point, press the *Validate* button. Remind that the during the validation procedure, the coil tracker and the pointer need to be seen by the position sensor. If any of these tools is not visible to the position sensor while pressing the *Validate* button, you will need to repeat this step.
- If the validation succeeds, the workflow automatically proceeds to the next step. Otherwise, you will see an error message. In this case, you can repeat the validation and try to place the pointer more precisely on the control point.
- If the validation fails again, the relative position of the coil tracker with respect to the coil changed and you need to calibrate your coil again. Quit the workflow and re-calibrate the coil as described in chapter 4 "TMS Settings".
- If you run a session with two coils (XT license only), you will first be prompted to calibrate the first coil. After a successful validation, you will be prompted to validate the second coil.

6.3 SELECT PATIENT

After you have ensured that the coil calibration is still valid, you are now ready to prepare the patient for the session. In this step, you should load the patient data you have previously prepared in the Setup Patient workflow.



- Select the patient. The drop down box offers you all patients from the patient root directory as explained in the section on Patient Data Management. If you run the Neuronavigation workflow right after the Setup Patient workflow, this field will already refer to the patient who's MRI has been processed.
- If patient setup was run with standard data, a reminder will be presented that standard MRI data is used for the Neuronavigation.

After you have selected the patient, choose the options to read stimuli from a previous session, to read target markers or to run a session with EMG / EEG recording (see below). Finally, press the [Define Coord. System] button to proceed to the next workflow step.

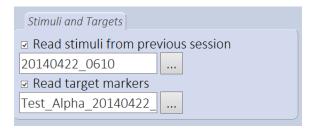
6.3.1 READ STIMULI FROM PREVIOUS SESSION

The dialog allows you to optionally read data from a previous session for comparison and use as target information. The stimulus information can be used to exactly reproduce a previous stimulation, see section *Reproduce Stimuli*.

- Select the checkbox *Read stimuli from* previous session.
- Click the *Browse* button (). A file browser opens.
- Browse for the session you would like to import and select the session's .pos.cnt file in the session's folder.

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 The text displayed in the *read stimuli* text field refers to the date and time of the selected study. In the example, 20140422_0610 refers to a study started on April 22nd, 2014 at 06:10 o'clock.



Hint: By default, the file browser opens in the base directory of the selected user. To import a session associated with the current MRI, go to the respective Sessions\SessionDateTime folder. To import an archived session, please go to the Archive\ArchiveX\Sessions\SessionDateTime folder. Please be reminded that when importing a study associated with an archived MRI, the spatial agreement between old data and current MRI depends on the accuracy with which the nasion-ear-markers were set in both MRI.

6.3.2 READ TARGET MARKERS

This option allows you to read previously defined targets markers. These markers can be used during the Neuronavigation to exactly stimulate a pre-selected point, see section *Stimulate at Targets*.

- Select the checkbox *Read target markers.*
- Click the *Browse* button (...). A file browser opens.
- Browse for the target file you would like to import.
- The text displayed in the read target markers field refers to the patient name and the target definition time. In the example,

 20140422_0610 refers to targets defined on April 22^{nd} , 2014 at 06:10 o'clock.

Stimuli and Targets
☑ Read stimuli from previous session
20140422_0610
☑ Read target markers
Test_Alpha_20140422

Hint: By default, the file browser opens in the base directory of the selected user. To import targets associated with the current MRI, go to the respective Targets folder. To import archived targets, please go to the Archive\ArchiveX\Targets folder. Please be reminded that when importing targets associated with an archived MRI, the spatial agreement between old data and current MRI depends on the accuracy with which the nasion-ear-markers were set in both MRI.

6.3.3 Session with EMG



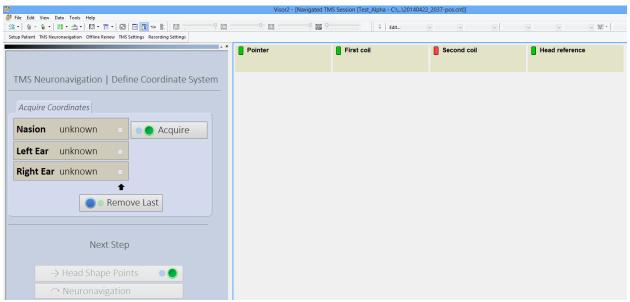
If you want to run a session with EMG / EEG recording, tick the box "Start EMG". Depending on the amplifier type and your recording settings (see chapter 5.1 "Recording Settings"), your next step with either be Impedance Check or Define Coordinate System.

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6.4 Define Coordinate System

The patient and his 3D representation need now to be registered. This means that the geometrical transformation mapping the physical space to the image space needs to be estimated. This can be done if the coordinates of three points, in this case the nasion and the left and right preauricular points, can be identified both on the MR scan and on the real patient.

In the Setup Patient Workflow, you have already set the nasion-ear coordinate markers on the MRI. The positions of these anatomical landmarks have to be determined now on the real patient, with the pointer tool.



- Identify the position of the nasion on the patient and place the pointer tip on it. Press the Acquire button or the green button of the response device. If you accidentally digitize the wrong point, you can always remove the acquired position by pressing the Remove last button or pressing the blue button of the response device.
- Repeat the procedure with both left and right preauricular points.
- If the pointer or the head reference tool could not be seen by the camera, an error message

- is shown. Make sure, both are visible and repeat the sampling.
- After having measured successfully the three positions of the nasion-ear-system, click the [Head Shape Points] button to proceed with refining the registration using sampled scalp points or press [Neuronavigation] to skip this step and work with the registration defined by the three landmarks.

During the digitization of the points both the pointer and the head reference tool have to be seen by the tracking camera. During this step, the *Measurement View*, indicating the visibility status of all tracking tools, is displayed next to the Specify Head Coordinate System dialog. If a tracking tool is seen and recognized by the position sensor, it will be indicated in green color, otherwise, in red.



FIGURE 21: TOOL VISIBILITY STATUS IN THE MEASUREMENT VIEW

6.5 HEAD SHAPE POINTS GENERATION

When using only the three nasion-ear-markers, performing the transformation between the physical coordinate system to the MRI coordinate system can lack necessary accuracy. If the shape of the patients head is known both in the physical and the image space, more sophisticated and accurate shape-based algorithms can be used to estimate the mapping transformation.

If MRI data for the patient was available, you have generated an exact head model of the patient in the Setup Patient workflow. The shape of the patient's scalp in the image space is therefore known. During this step, you should generate an approximation of the patient's head shape by digitizing as many points on the patient's head as possible. It is important not only to acquire a sufficient number of head shape points (a minimum of 20 points is required) but the area covered by the acquired points should be sufficiently wide. It is therefore important to acquire points not only over the top of the head, but also from the face, in the proximity of the eyes and the nose.

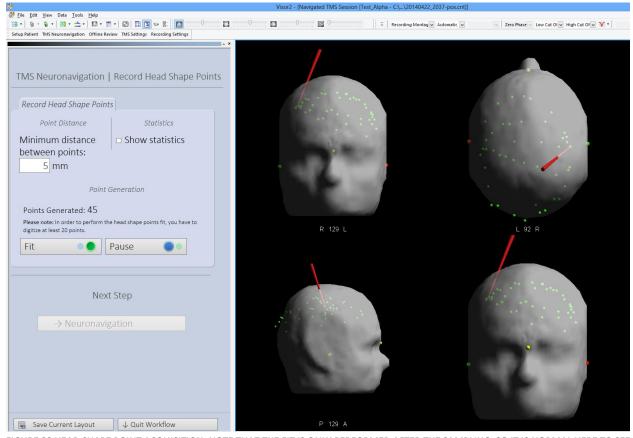


FIGURE 22 HEAD SHAPE POINT ACQUISITION. NOTE THAT THE FIT IS ONLY PERFORMED AFTER THE SAMPLING, SO IT IS NORMAL HERE TO SEE A DISCREPANCY BETWEEN SAMPLED POINTS AND DISPLAYED SCALP.

Adjust the minimum distance between the points to be acquired (optional).

- If you check the checkbox "Show statistics", the shape-based estimate of the transformation will be displayed when proceeding to the next step.
- Take the pointer tool in the hand and place the tip on the patient's head.
- Press the [Start] button for recording head shape points while moving continuously with the tip of
 the pointer over the patient's head. The digitized head shape points are visualized online in the HSP
 Acquisition View, as shown in Figure 22.
- Note that no sampling will be performed if the pointer or the head reference are not visible to the camera.
- If you want to make a break in order to move the pointer away from the head's surface and resume the digitization in a different region of the head, you can press the [Pause] and resume the digitization by pressing the [Start] button again, once you have placed the pointer correctly.

When you have completed the digitization, press the [Fit] button. The alignment between head model and recorded head shape points will be calculated and applied to all navigation data and you will be forwarded to the next step.



Please note that while moving the pointer, its tip needs always to be in contact with the patient/patient's head

Hint: To check the outcome of the registration, enable the view of the pointer ("show") in the 3D view properties and align the pointer with a number of feature points on the patient's face such as the nasion. The display should show the pointer at exactly the corresponding position on the head model.

6.6 NEURONAVIGATION

After performing the coil validation, you have completed all necessary steps to start the neuronavigation session. Depending whether or not you are recording the EMG signal, you will be displayed different views and options.

On the top left, you can choose the "active coil". The tasks you select in the central panel are performed for the active coil:

- Stimulate: The electric field is displayed only for the active coil. Note that stimuli are *recorded* for both coils all the time; independent of the active coil and the currently selected task.
- Reproduce stimuli: Navigates the active coil to the position where a previous stimulus was given.
- Stimulate at targets: Navigates the active coil to a position to best stimulate a predefined target.
- Replace coil: Allows you to "hot-swap" the active coil for another previously calibrated coil with the same coil tracking tool type.
- Validate: Check if the coil calibration for the active coil is still valid.

The other tasks in the central panel are independent of the active coil:

- Markers: Allows you to define additional targets.
- rTMS filter: activates grouping of incoming rTMS stimuli into one rTMS stimulus entity.
- EMG settings: Control the time window for the peak-to-peak extraction in the EMG recording after a stimulus.

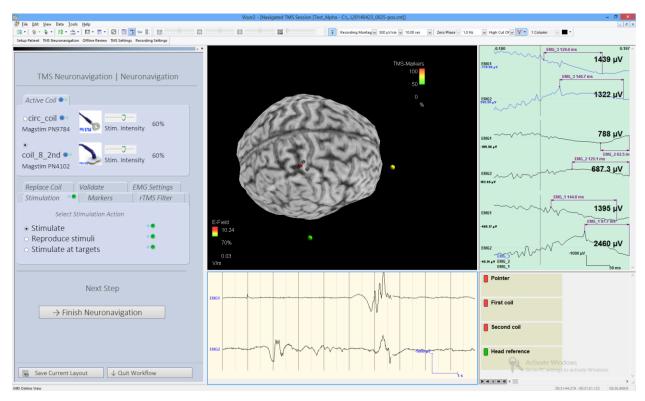


FIGURE 23. NEURONAVIGATION STEP. VIEW FOR A SESSION WITH TWO TMS COILS AND EMG RECORDING.

6.6.1 Neuronavigation with EMG Recording

The main view consists of the following subviews:

- The MRI Online View, displaying the real time position of the coil respect to the patient/patient's brain.
- The Average View, displaying the last evoked muscle responses.
- The Online Data View, displaying the free running EMG signal.
- The *Tool Status View*, indicating the visibility status of the tracking tools.

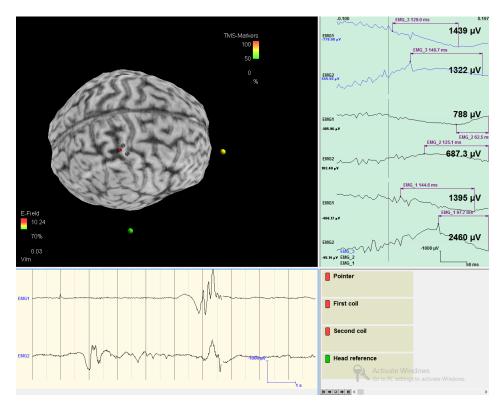


FIGURE 24: NEURONAVIGATION WITH EMG RECORDING

The properties of each subview can be changed trough the View Properties dialog, accessible by double clicking the subview or through the subview context menu option "View Properties".

In the MRI Online View, a TMS coil is represented with a simplified sketch of its shape, as indicated in Figure 25, and with the projection along the coil axis of its center on the brain, more precisely, on the current curvilinear slice, called Coil target. The loops of the TMS coil are hereby visualized at the downside of the coil casing. The Coil target reflects the orientation of the coil, and it allows therefore to determine whether the coil is held tangentially to the brain at the stimulation point.

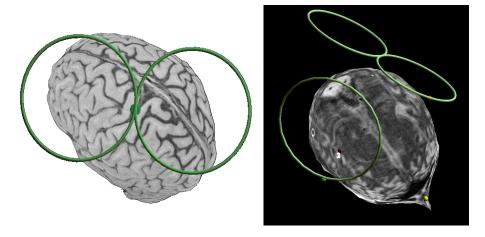


FIGURE 25: 3D COIL REPRESENTATION. LEFT: SINGLE COIL SESSION. RIGHT: NAVIGATING TWO COILS SIMULTANEOUSLY.

When performing a TMS stimulus with your stimulator (usually via the foot switch or push button at the coil, or through a programmed interface) the **vi**sor2 **system** receives a trigger via the TTL connection cable and trigger unit and sets a stimulus marker at the coil position at this time point. The TMS Markers are shown as 3D lenses, as displayed in Figure 26. Their position corresponds to the projection of the coil's normal line to the curvilinear. Please note that if you select a different curvilinear slice, also the position of the TMS Markers change as they are only projections of the stimulus position.

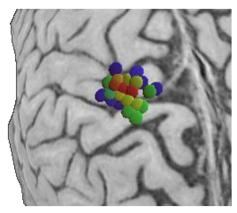


FIGURE 26: TMS MARKERS



- Always check EMG signal quality before starting to stimulate in an EMG-TMS-session using the EMG online view.
- In case of bad signal quality, check proper electrode placement and the connection of the reference electrode.

6.6.2 THE INDUCED ELECTRIC FIELD

During neuronavigation, while moving the coil over the patient's head, you will see the estimated electric field projected onto the cortical structures. The electric field induced by a TMS coil depends on:

- The coil position and orientation
- The coil geometrical structure and its physical properties
- The spatial distribution and electromagnetic properties of the head's tissue.

In **vi**sor2 a simplified model of the true physics of electric field generation is used. To allow for real-time display, the head is modeled as a spherical conductor with the center being at the origin of the nasion-ear-system. The coil is approximated by a superposition of magnetic dipoles, located inside the loops representing the coil.

The electric field is displayed on the currently activated curvilinear surface. The field intensity is color-coded by the field strength relative to the field maximum on the current curvilinear slice.

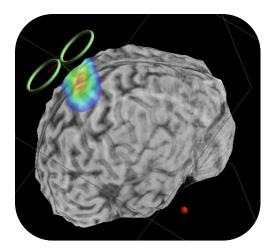


FIGURE 27: THE ELECTRIC FIELD INDUCED BY THE TMS COIL

Through the View Properties, as explained in detail in *Adjusting view properties* you can adjust different properties of the electric field visualization, such as the threshold value, the color palette etc. You can also select to display always the position of the maximum estimated electric field and the corresponding field strength or to always snap the current slice position to the field maximum.

6.6.3 Reproduce stimuli and Stimulate at Targets

visor2 assists you when you want to stimulate at predefined target positions or if you want to reproduce a previous stimulus. In the *Stimulation* panel, select "Reproduce stimuli" for navigating the coil to the exact position where a previous stimulus was given or "Stimulate at targets" to guide the coil to an optimal place to stimulate the marked spot, respectively.

After the selection of the task, the view layout will change. For "Reproduce stimuli" select the previous stimulus that you would like to reproduce in the TMS Stimulus List at the bottom right of the screen. For "Stimulate at targets" select the respective target marker in the Image marker list at the bottom right screen.

Stimulate at Targets

- 1. In the "Stimulation" group box, select Stimulate at targets. The view layout will be automatically adjusted. A list view, displaying all available target markers, will be shown.
- 2. Adjust the intensity slider to the stimulation intensity of your stimulator.
- 3. In the target list, select the target you want to stimulate at. Markers that can be targeted are labeled with the type **Sensor**. The targeting helper will be displayed.
- 4. When the coil rings match the targeting crosshair, stimulate.

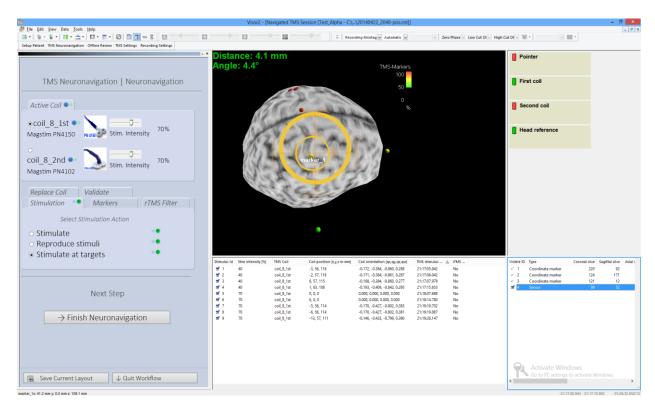


FIGURE 28. STIMULATE AT TARGETS. SELECT THE TARGET IN THE IMAGE MARKER LIST AT THE BOTTOM RIGHT.

Reproduce Stimuli

- 1. In the "Stimulation" group box, select Reproduce stimuli. The view layout will be automatically adjusted. A list view, displaying all loaded and previously applied stimuli, will be shown.
- 2. Adjust the intensity slider to the stimulation intensity of your stimulator.
- 3. In the stimuli list, select the stimulus you want to reproduce. The targeting helper will be displayed.
- 4. When the coil rings match the targeting crosshair, stimulate.

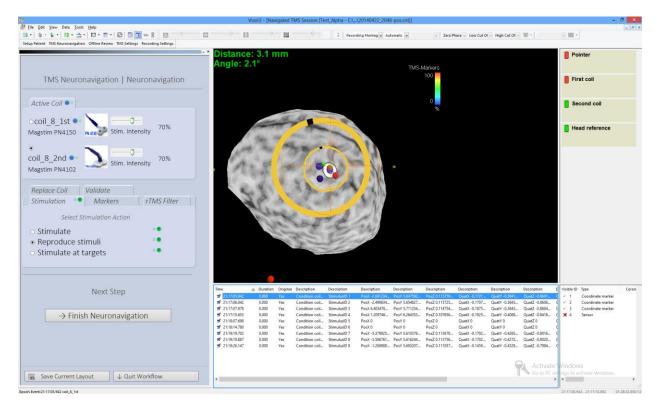


FIGURE 29. REPRODUCE STIMULI. SELECT THE STIMULUS IN THE TMS STILULUS LIST AT THE BOTTOM.

For both tasks, target helper rings will guide you to position the coil accurately. As illustrated in Figure 30, the targeting rings indicate the position and the orientation of the target, whereas the crosshair of the targeting helper indicates the position and orientation of the coil, as displayed in Figure 31. When targeting, you should try to position the coil in such a way that the targeting helper and the rings match.

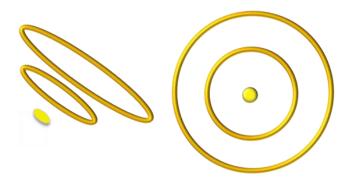


FIGURE 30: THE TARGETING RINGS

Your point of view is attached to the coil: while you move the coil, you will see the brain surface moving with respect to the coil, see Figure 32. As opposed to the *MRI Online View*, you cannot rotate the view, since the viewing perspective is fixed. For zooming in the view, you can still use the mouse wheel.

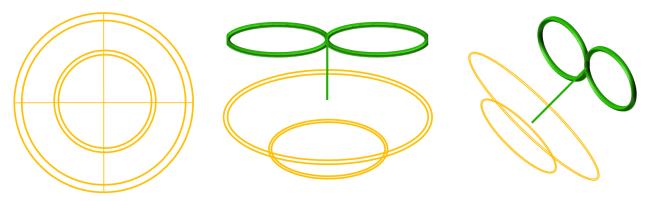


FIGURE 31: THE COIL RINGS INDICATE THE COIL POSITION AND ORIENTATION

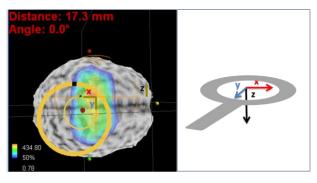


FIGURE 32: DISPLACEMENT TARGET-COIL

The targeting bars help you understand in which direction you need to move the coil to reach the target. While the displayed distance refers to the absolute value, the length of each of three targeting bars represents the displacement target-coil in each of the three directions, as illustrated in Figure 32. The navigation helper rings and bars react immediately to your position changes and guide you to the right spot.

Visor2 displays two figures of merit for the targeting: a distance and an angle value. If you are *reproducing previous stimuli* **vi**sor2 will calculate

- the distance as the difference in position
- the angle as the difference in orientation

of the coil between the previous stimulus orientation and the current one.

If you selected Stimulate at targets, visor2 will calculate

- the distance as the distance of the target marker to the normal line of the coil
- the angle as the angle between a line from the center of the head through the target marker and the normal line of the coil

In the View Properties, as illustrated in detail in *Adjusting view properties*, you can set the threshold values for the distance and the angle. Once the distance and the angle between the coil and the target fall below the defined thresholds, the values will be rendered in green, indicating you that the desired targeting precision is achieved, as displayed in Figure 29. This needs some exercise as the coil has to have the right position *and* orientation and both change while moving it, so don't be frustrated if the results are not perfect in the first session.

6.6.4 RTMS

If you are performing rTMS, you should apply the online rTMS filter and set the Inter-train interval according to the settings of your TMS Stimulator. Through this value, **vi**sor2 distinguishes between a train of stimuli in rTMS and single pulses applied one after the other. Every train of TMS pulses will be marked as an rTMS event, characterized by its duration, frequency and number of pulses. Use "Pause between pulse trains > 3.0s" if your Inter-train Interval is longer than 3 seconds or if you apply only 1 train. Use "Pause between pulse trains > 0.3s" otherwise. Note that Inter-train Intervals of less than 0.3 seconds are not supported. To switch the rTMS filter off, i.e. to treat every pulse as separate stimulus, select "No rTMS Filter".



FIGURE 33 RTMS FILTER SETTINGS

visor2 automatically displays a statistic about the rTMS pulses received. The TMS Stimulus list below the 3D render view displays the number of stimuli received in the rTMS train and calculates the rTMS frequency out of it.

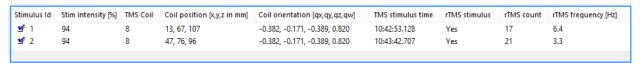


FIGURE 34 RTMS STATISTICS IN THE TMS STILULUS LIST. THE TWO COLUMNS AT THE RIGHT GIVE THE NUMBER OF STIMULI IN A TRAIN AND THE PULSE FREQUENCY, RESPECTIVELY.

Further, the 3D render view can be adjusted to show how the coil moved during the rTMS train. In the 3D image view properties, go to the TMS Marker tab and activate the TMS coil positions -> Shading checkbox. The 3D visualization will now show small, connected dots that indicate the trace of the coil during the rTMS train. Note that this visualization is available during the session as well as in the offline review.

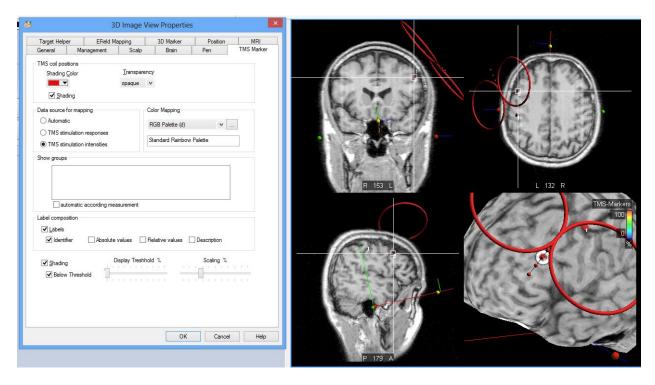


FIGURE 35 THE TMS COIL POSITION -> SHADING OPTION ALLOWS TO DISPLAY THE POSITIONS OF THE TMS COIL DURING A SINGLE RTMS TRAIN. THE POSITIONS ARE INDICATED AS RED DOTS CONNECTED WITH A BLACK LINE.

6.6.5 ONLINE EMG SETTINGS

visor2 allows you to control the visualization of the evoked motor responses and the settings for the extraction of the response peak.

- The number of events is the number of evoked motor responses which will be displayed in the Average View in a waterfall plot. If you select "1", only the last evoked response will be displayed. If you select more, the single sweeps will be displayed in a waterfall plot, the most recent one being on the top.
- The display window is the width of the motor response that will be displayed in the Average View, relative to the time of the incoming TMS pulse.
- The peak search is the time interval where the peak-to-peak of the evoked motor response is searched for, relative to the time of the incoming TMS pulse.

Please remind to click the [Apply Settings] button after changing the online EMG settings.

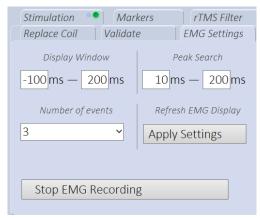


FIGURE 36: THE ONLINE EMG SETTINGS

To stop the EMG recording, e.g. because you are going to stimulate away from the EMG hotspot, press the [Stop EMG Recording] button. This will close the EMG recording file and disable the amplifier. Please note that for technical reasons it is not possible to restart the recording afterwards!

6.6.6 REPLACE COIL

If you have calibrated several coils, you can switch them during the TMS session. This can be useful if e.g. one of the coils overheats and you want to replace it with a fresh coil. Select the option "Replace Coil". In the drop-down box below, you can now select a coil from the list of all calibrated coils.



FIGURE 37 SWITCH COIL DURING A TMS SESSION

The coil you select in the drop-down box immediately becomes active. Make sure to validate your new coil to ensure correct calibration, see chapter Validate coil.

6.6.7 VALIDATE

This method allows you to validate whether the displayed 3D information is still correct. This method helps you check whether:

- The head reference tool that the patient is wearing has shifted during the session and therefore decreased the accuracy of the displayed information.
- The coil tracker has shifted respect to the initial position on the coil and therefore decreased the accuracy of the displayed information.

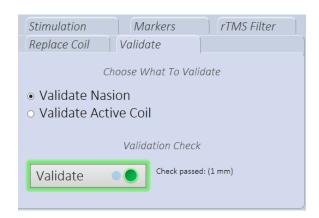
If possible, validate the accuracy of the session multiple times during the session and every time there is a suspect that the patient moved the head reference tool or that the coil tracker shifted.

6.6.7.1 VALIDATE NASION

- Go to the "Validate" tab, select "Validate Nasion".
- Hold the pointer tool on the nasion of the patient.
- Press the green button on the remote control or the Validate button on the GUI.
- If the distance between the nasion position at the beginning of the session and the current nasion position is smaller than 5 millimeters, you will see the message "Check passed".
 Otherwise you will get the message "Check failed".

6.6.7.2 VALIDATE COIL

- Go to the "Validate" tab, select "Validate Active Coil".
- Hold the pointer tool on the coil's control point, as explained in *Validate coil*.
- Press the green button on the remote control or the *Validate* button on the GUI.
- If the coil tracker has not shifted (threshold distance 5mm), you will see the message "Check passed". Otherwise you will get the message "Check failed".







In case of a failing accuracy check we strongly recommend to stop and restart the session. All results obtained so far should be treated with utmost care!

6.6.8 FINDING THE MOTOR HOT SPOT



FIGURE 38: TMS MARKERS COLOR CODED WITH A BLUE-WHITE-RED PALETTE

- Select the task "Stimulate".
- Adjust the Online EMG settings according to your preferences.
- When you stimulate, the TMS Marker will be color coded according to the peak-to-peak value of the evoked motor response. Every time you stimulate, the relative value of each TMS Marker will be recalculated, and the new color applied.
- If you want to change any of the properties of the TMS Markers like the mapping color palette, the display threshold or the size, you can do that through the TMS Marker Tab in the MRI Online View Properties dialog, as explained in Adjusting view properties.



 Please remind that the TMS Markers indicate only the projections of the coil center on the brain, color coded according to the intensity of the evoked response. Please be aware that the real cortical representation of the muscle being mapped might deviate from the location of the TMS Markers associated with the highest response amplitude.

6.6.9 FINDING THE HOT SPOT OF MORE MUSCLES

visor2 gives you the possibility to map more muscles at the same time, without having to run several neuronavigation sessions. If you are recording the EMG at several muscles, a TMS marker will be placed for each recording channel, and color coded relatively to the maximum response of that muscle.

TMS Markers associated to different muscles are visually easily distinguishable, having a different pattern printed on the top face of the marker, as shown in Figure 39. **vi**sor2 can map simultaneously up to eight muscles at the same time.

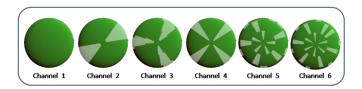


FIGURE 39: TMS MARKERS FOR THE FIRST SIX EMG CHANNELS

When mapping several muscles, you can record continuously the EMG at all channels, or you can switch EMG channels ON and OFF during a session. A TMS Marker will be placed only for enabled channels.

If you record the EMG for all channels continuously, a TMS marker will be placed for each TMS pulse and for each EMG channel, as shown in Figure 40. Through the TMS Marker Tab in the MRI Online View Properties

dialog, you can select the channels to be displayed and the channel specific display threshold (as explained in *Adjusting view properties*).

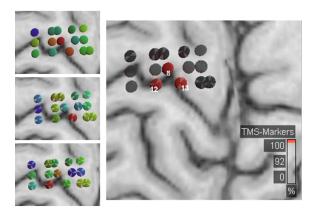


FIGURE 40: MAPPING OF THREE MUSCLES. LEFT: SINGLE CHANNEL VIEW, FOR EACH CHANNEL. RIGHT: ALL CHANNELS, WITH A DISPLAY
THRESHOLD SET TO ALLOW THE VISUALIZATION ONLY OF THE TMS MARKERS ASSOCIATED WITH THE LARGEST RESPONSE

To be able to switch the channels ON and OFF, please select the "Neuronavigation MRI Online Multichannel" view layout, through the *MRI View* context menu. The Channel List view will be displayed in the right bottom corner, as displayed in Figure 41.

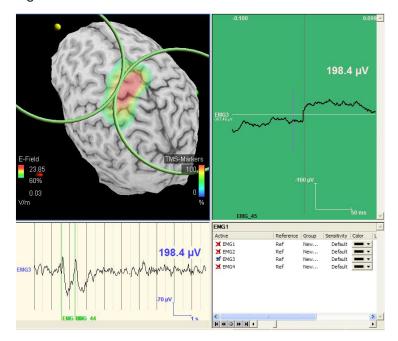


FIGURE 41: MULTICHANNEL MAPPING VIEW LAYOUT

If you change the enabled EMG channels during a neuronavigation session, in the *MRI View*, per default, only the channel/s enabled during the last TMS pulse will be displayed. This can be easily changed through the *TMS Marker* Tab in the *MRI Online View Properties* dialog, as explained in *Adjusting view properties*.

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6.6.10 STIMULATING AT THE FOUND HOT SPOT

- Select the task "Reproduce stimuli". The "NeuroNavigation Targeting Stimulus" view will be displayed, as in Figure 42. Per default, you will see only those TMS Markers with a response exceeding the 75% of the maximal evoked response. The TMS Markers will be displayed together with a label, indicating their identification number.
- Select the TMS Marker you want to reproduce from the TMS Marker list, displayed in the bottom, as shown in Figure 42. The identification numbers of the TMS Markers are also displayed in the TMS Marker list. The selected TMS Marker will be highlighted, as shown in the enlargement of Figure 42. The targeting helper will assist you in reproducing the selected stimulus, as explained in Reproduce stimuli section.
- Stimulate. The previously selected TMS Marker will remain the active target until you don't select a new one

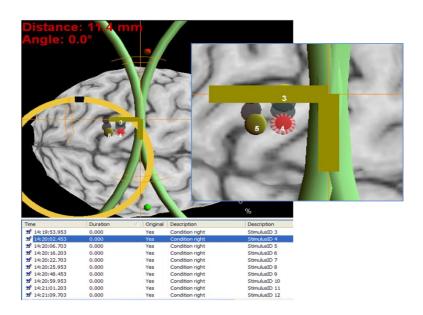


FIGURE 42: THE VIEW WHEN TARGETING AT THE HOT SPOT

Please remind that, if you want to apply rTMS at the found hot spot, you need to stop the EMG recording, by clicking the *Stop EMG Recording* button.

6.7 TERMINATING THE SESSION

To terminate the session, click the *Finalize* button. You are now invited once again to check if the head reference of the patient has moved during the session. Therefore, hold the pointing device at the nasion of the patient and press the Validate Nasion button. If the distance between the nasion position at the beginning of the session and the current nasion position is smaller than 5 millimeters, you will see the message "Check passed". Otherwise you will get the message "Check failed" together with an estimate of the shift of the head reference tool, informing you that since all positions are measured relative to the head reference tool, the estimated positions of the stimulated sites might not be accurate. Please take this into account when reviewing this session. Please remind that while on this step, position information (and EMG if applicable) are still being recorded.

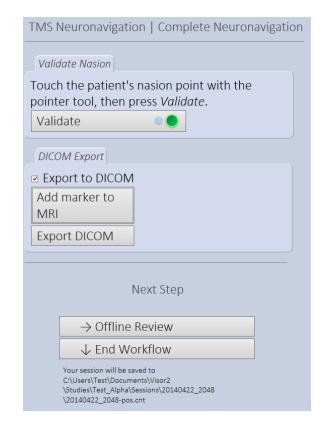


FIGURE 43. FINALIZING THE NEURONAVIGATION SESSION.



In case of a failing accuracy check we strongly recommend to treat all results obtained with utmost care. If in doubt, repeat the session or discard the results!

6.7.1 EXPORTING TO DICOM

visor2 allows you to define image markers that can be exported to MR images of type DICOM. The image markers can be set after having analyzed the positions of the TMS Markers and the corresponding motor response peak values. visor2 allows you to define and export multiple image markers, which will look like white squares (side length 4mm) in the exported DICOM MR image, as shown in Figure 44. Check the "Export to DICOM" checkbox. The "NeuroNavigation DICOM Export" view will be displayed, as in Figure 43. Per default, you will see only those TMS Markers with a response exceeding the 75% of the maximal evoked response. The TMS Markers will be displayed together with a label, indicating their identification number.

- Position the crosshair at the location where you wish your image marker to be placed. If you want to place the image marker over a TMS Marker, select the TMS Marker in the list. The position of the crosshair will be adjusted according to your selection, as displayed in Figure 45.
- Click the Add Marker button. A dialog will appear. Enter the label for the marker and click OK.

- The defined image marker should be visible in the MRI View.
- If you want to define and export more image markers before exporting to DICOM, repeat from step 2.
- Export to DICOM by clicking the *Export DICOM* button. The DICOM will be exported in the patient directory, as explained in the "Patient Data Management" section.



FIGURE 44: MARKERS EXPORTED IN DICOM

Depending on your requirements, you can define several image markers and export them all at once into one DICOM image, or you can export several DICOM images, each having a unique image marker.

You may now either proceed to the Offline Review by pressing the *Proceed to Review* button or you can terminate the session by pressing the *Complete Session* button.

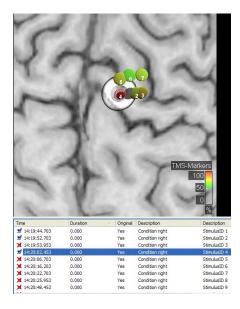


FIGURE 45: POSITIONING THE CROSSHAIR OVER A TMS MARKER

7 OFFLINE REVIEW

When performing a navigated TMS session, visor2 records the positions and orientations of all tracking tools. Each time a magnetic pulse is applied, visor2 records the position and the orientation of the coil in the moment of stimulation, the time, the duration and the set stimulation intensity. If the EMG has also been recorded during the Neuronavigation session, visor2 records also the latencies and the amplitudes of the evoked motor responses.

You can choose between reviewing the recorded sessions or the exported DICOM images. When reviewing the sessions, you can explore the 3D spatial distribution of the stimuli, the induced electric fields and the evoked responses, if the EMG has been recorded. When reviewing the exported DICOM images, you can explore the sites on the patient's original MRI that have been identified and marked.

7.1 REVIEW SESSION

7.1.1 LOAD SESSION DATA

- Select the patient, as explained in section Select Patient.
- Select "Review TMS session" button.



- Choose the session to review

- The entry in the text box refers to the session's date and start time. In the figure above, "20141407_2023" refers to a session from the 7th of April 2014 that was started at 08:23pm.
- o If you have started the Offline Review workflow directly from a Neuronavigation session, the session field will already refer to the last session and you don't need to browse for it.
- Otherwise, click the *Browse* button (). Sessions performed with the current MRI of the patient are stored in the folder called "Sessions" under their start date and time.

- Sessions performed with an earlier MRI are stored under the folder "Archive/ArchiveX/Sessions" in the directory of the selected patient. For more information on data storage please refer to the section on Patient Data Management.
- Click the [Review and Export] button to proceed.

The program will automatically load the MRI and head model associated with this session and present it together with the session data.

7.1.2 REVIEW SESSION

7.1.2.1 NEURONAVIGATION SESSION WITH EMG

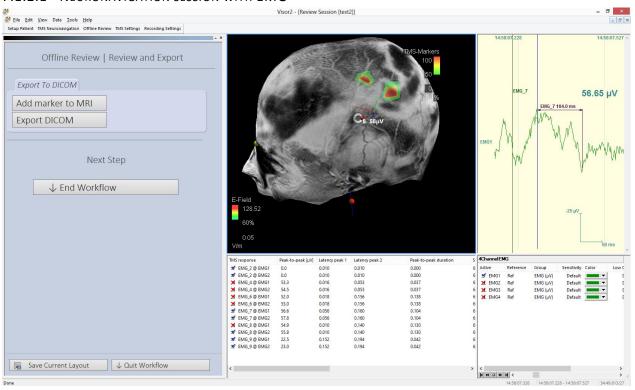


FIGURE 46 OFFLINE REVIEW FOR NEURONAVIGATION SESSION WITH EMG

Per default, you will see only those TMS Markers with a response exceeding the 75% of the maximal evoked response. The TMS Markers will be displayed together with a label, indicating their identification number. Centrally at the bottom, the list of all events will be displayed, as shown in Figure 46. TMS Responses are labeled EMG_X@channel where X is the stimulus number and channel is the label of the EMG channel. So EMG_7@EMG1 refers to the 7th stimulus on channel EMG1.

The TMS Response view gives you detailed information about the stimulus response:

- Stimulus ID
- Channel label
- Peak to peak response (voltage difference between the global maximum and global minimum) in the search window defined during the Neuronavigation session

- Latency of first peak (can be maximum or minimum, depending on the montage applied), measured from the trigger recorded in the amplifier
- Latency of the second peak
- Time difference between the two latencies
- Stimulation intensities, i.e. the percentage of maximum stimulator output selected for the stimulus
- Label of the coil with which the stimulus was given
- Coil position and orientation in nasion-ear-coordinates
- Time of the stimulus

When a TMS Marker is selected in the list:

- The TMS Marker will be highlighted in the MRI View
- The crosshair will jump to the position of the selected TMS Marker;
- The electric field induced in the moment the TMS pulse was applied will be calculated and displayed;
- The coil, as positioned and oriented in the moment the pulse was applied, will be displayed;
- The free running EMG will jump to the time the pulse was applied.

7.1.2.2 NEURONAVIGATION SESSION WITHOUT EMG

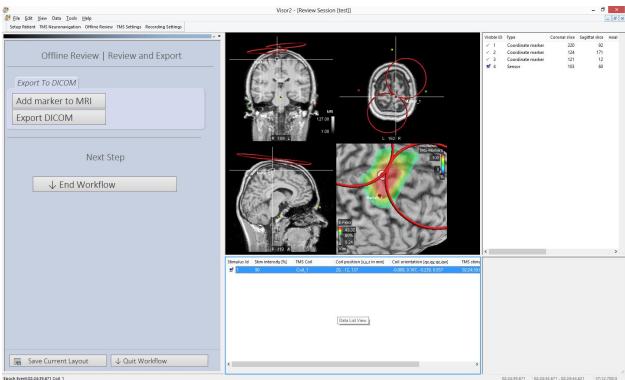


FIGURE 47: OFFLINE REVIEW FOR NEURONAVIGATION SESSION WITHOUT EMG

If a TMS session without EMG is reviewed, the view simplifies to display the stimuli with the stimulator output intensities, see Figure 47. The TMS Stimulus list presents:

- Stimulus ID
- Stimulation intensities, i.e. the percentage of maximum stimulator output selected for the stimulus

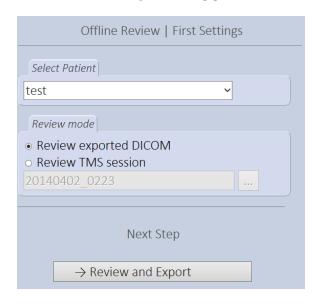
- Label of the coil with which the stimulus was given
- Coil position and orientation in nasion-ear-coordinates
- Time of the stimulus

7.1.3 EXPORT TO DICOM

To export a marker to DICOM, the following steps need to be performed:

- Position the crosshair at the location where you wish your image marker to be placed. If you want to
 place the image marker over a TMS Marker, select the TMS Marker in the list. The position of the
 crosshair will be adjusted according to your selection, as displayed in Figure 47.
- 2. Click the Add Marker button. A dialog will appear. Enter the label for the marker and click OK.
- 3. The defined image marker should be visible in the *MRI View*. If you want to define and export more image markers before exporting to DICOM, repeat from step 1.
- 4. Enable the image markers that you would like to export, disable the ones that you did not want to export to the DICOM file.
- 5. Export to DICOM by clicking the *Export DICOM* button. The DICOM will be exported in the patient directory, as explained in the "Patient Data Management" section. The markers appear as a bright white cube of voxel size 2 in the exported MRI.

7.2 REVIEW EXPORTED DICOM



- Select the Patient for whom you want to review the exported DICOM data.
- Select the "Review exported DICOM" option.
- Click the [Review and Export] button to proceed. The "Open DICOM Images" dialog will be presented, and all available DICOM images of the selected patient will be shown, as displayed in Figure 48.
- Select the DICOM you want to review and click the [OK] button.
- The DICOM data will be displayed.

Remark: The "Open DICOM Images" dialog allows you also to browse for DICOM data anywhere on your PC:

- If you want to change patient, press the Browse button and select the proper patient directory. Make sure that the Include Subdirectories In Search checkbox is checked.
- Press the Refresh button (). All available DICOM images of the selected patient will be displayed.
- Select the DICOM you want to review and click the OK button.

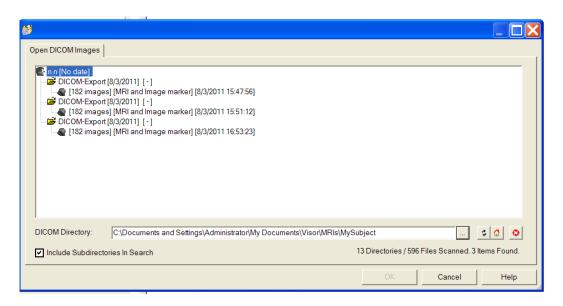


FIGURE 48: OPEN DICOM IMAGES DIALOG



FIGURE 49 THE EXPORTED IMAGE MARKER IS DISPLAYED AS WHITE SQURE IN THE DICOM

8 ADVANCED PROCEDURES

8.1 LOADING FUNCTIONAL MRI DATA

Before defining target markers, you can load 3D functional data, such as fMRI or EMG/ERP data. Markers can be then directly placed on 3D co-registered and superimposed anatomical and functional data.

- Start a new study under File/ New.
- Load your MR scan under Data/ Read/ 3D Image.
- Load your head model under Data/ Read/ Head Model.
- Load your fMRI scan under **Data/ Read/ 3D Image**. Be sure to select the right file type in the *Open 3D Image dialog*.
- Right click the 3D View and under View layout select the Set Target Marker layout.
- The MRI and the fMRI will be co-registered and superimposed. The fMRI will be projected onto the curvilinear surfaces, as shown in Figure 50. You can set target markers both on the 2D slices as well as on the 3D display by clicking at the desired location.
- Set and export the markers as explained in the *Define Targets* section.

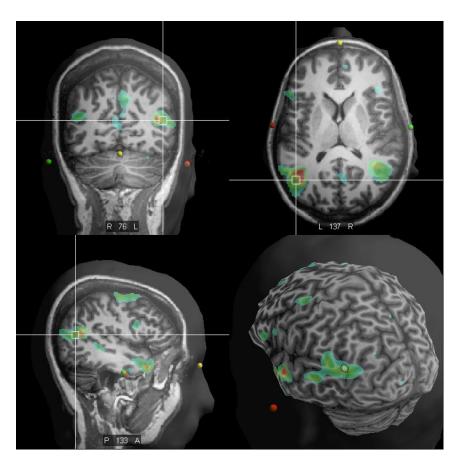


FIGURE 50: 3D VISUALIZATION OF SUPERIMPOSED MRI AND FMRI

8.2 ADJUSTING VIEW PROPERTIES

In this section the view properties specific for **vi**sor2 are described. For description of all view properties in all views, please refer to the *User Manual*.

The kind of **vi**sor2 specific view properties that can be changed depends on the step within the **vi**sor2 workflow and the view layout shown in the view panel. For example, in the Head **Shape Points Generation** step the *Neuro Navigation HSP Acquistion View* is shown. The 3D image view properties dialog provides some additional tabs:

- Pen
- TMS Coil
- Target Helper
- Efield Mapping
- TMS Marker

In order to change view properties, double-click a view or right-click and select view properties from the context menu. Then, the properties dialog with the context depending tabs opens.

The **Pen** tab allows you, as in other views and for other objects, to change color and transparency of the pen tool.



FIGURE 51: THE PEN TAB OF THE 3D IMAGE VIEW PROPERTIES DIALOG

In the **Neuro Navigation** step when *Neuro Navigation MRI Online View* is shown, the **Efield Mapping** tab is needed if you want to change the display of the induced electric field by TMS stimulations.

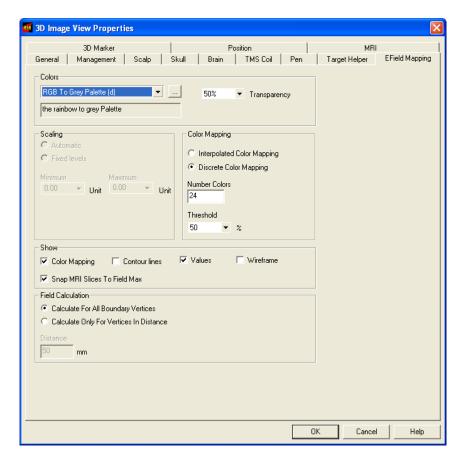


FIGURE 52: EFIELD MAPPING TAB OF THE 3D IMAGE VIEW PROPERTIES DIALOG. IN THE SHOW CONTROL GROUP, CONTROLS VALUES

AND SNAP MRI SLICES TO FIELD MAX HAVE BEEN CHECKED

After checking the "Values" checkbox, the location of the maximum of the electric field on the current curvilinear slice is highlighted, and the corresponding field strength is displayed. After checking the "Snap MRI Slices To Field Max" checkbox, the MRI slices change their position and snap to the position of the current maximum of the e-field (see Figure 53 below).



FIGURE 53: ACCORDING TO THE SETTINGS IN THE VIEW PROPERTIES, THE MAXIMUM VALUE OF THE E-FIELD IS SHOWN AS WHITE STRING IN THE MRI ONLINE VIEW AND MRI SLICES SNAP AUTOMATICALLY TO THE POSITION TO THIS MAXIMUM VALUE.

The **Target Helper** tab is of great importance if you want to reproduce stimuli. In the Neuro Navigation step, select the task **Reproduce stimuli**. Then, select a stimulus in the list view. The Target Helper will become visible in the *MRI Online View*. To change the properties of this helper, open the *MRI Online View* properties dialog and select the **Target Helper** tab (see Figure 54). This tab allows you to set the distance and angle targeting thresholds. If the current distance coil-target as well as the current angle is smaller than the specified threshold, the targeting values displayed top left in the *MRI Online View* will have a green color. If one of the current values is greater than the threshold, the targeting values are shown in a red color.

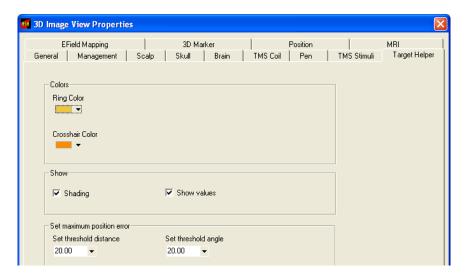


FIGURE 54: THE TARGET HELPER TAB IN THE VIEW PROPERTIES DIALOG

In Figure 55, a situation of the task **Reproduce stimuli** in the **Neuro Navigation** step is shown. You can see the coil (green), not selected stimuli (yellow), the selected stimulus (red) and the target helper (yellow).

At the top left corner, the current distance and angle values of the target helper are shown. Both values are lower than the thresholds defined in the "Set maximum position error" control group. Therefore, these values are shown in green color.

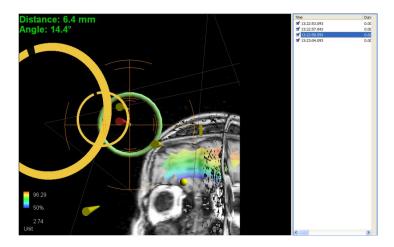


FIGURE 55: NEURO NAVIGATION STEP DURING TASK REPRODUCE STIMULI

After the TMS pulses have been applied, the TMS Marker tab will be available on the properties dialog, as shown in Figure 56.

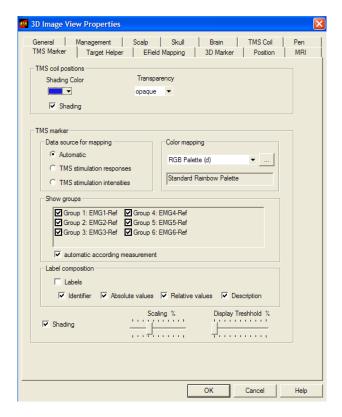


FIGURE 56: THE TMS MARKER TAB

The TMS Marker consists of the two 3D objects:

- The TMS Marker (3D lens) rendered on the current curvilinear slice.
- The corresponding coil position, which is per default turned off during online navigation.

The visibility, color and transparency of these two objects can be controlled independently.

The TMS Markers are always color coded. The following are the options available:

- TMS stimulation responses. The TMS Markers are color coded based on the peak-to-peak value of the extracted motor responses. This option is available only when the EMG is being recorded.
- The stimulation intensities. The TMS Markers are color coded based on the output intensity of the TMS stimulator, which should be set through the corresponding slider prior to stimulation.
- Automatic. Automatic color coding based on data availability (TMS stimulation responses per default, when available).

The color coding palette can also be chosen through the corresponding combobox control. You can choose among predefined standard color palettes, or define your own.



 Please remind that the TMS Markers indicate only the projections of the coil center on the brain, color coded according to the intensity of the evoked response. Please be aware that the real cortical representation of the muscle being mapped might deviate from the location of the TMS Markers associated with the highest response amplitude.

The "Show groups" option is available only when the EMG is being recorded. This control allows you to select the EMG channel being currently mapped. As explained in the section Finding the hot spot of more muscles, a TMS Marker is created for each enabled EMG channel in the moment a TMS pulse is applied. This control allows you to select the mapping channel.

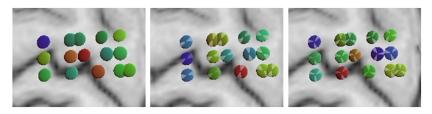


FIGURE 57: SELECTING THE CHANNEL TO MAP

In the example of Figure 57, different channels have been alternatively enabled and disabled. In the case when all channels are turned on, the channel number for which the largest peak-to-peak value has been found will be rendered on the top.

The option "Automatic according measurement" allows to automatically enable the channel/s being active when the last TMS pulse has been applied. For example, if during the mapping procedure, you changed the active channels and you decide to activate only the first and the second channel, from the moment you apply the next TMS pulse, only the TMS Markers associated with the first two channels will be visible.

The label of a TMS Marker, which can optionally be turned on, consists of the following:

- The identifier, being the identification number of the TMS Marker (successive numbering within the session)
- The absolute value, being the extracted peak-to-peak value of the EMG responses, in μV.
- The relative value of the extracted peak-to-peak amplitude compared to the maximal peak-to-peak value found so far for that channel.
- The description, being the channel name, as specified in the Montage.

The size of the TMS Markers can be controlled through the Scaling slider. This changes the size of all TMS Markers.

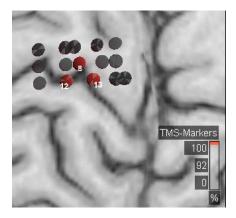


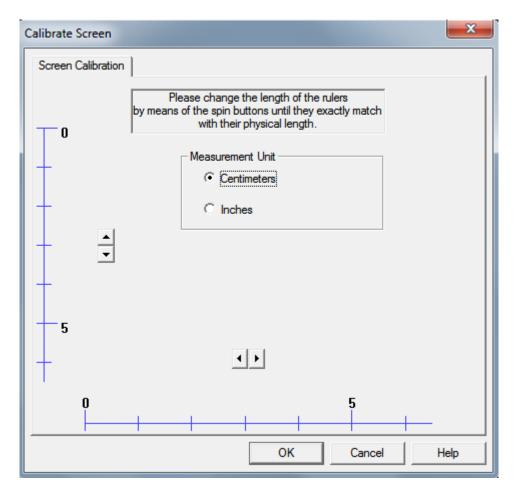
FIGURE 58: DISPLAY THRESHOLD SET TO 100%

The Display Threshold slider allows to gray out those TMS Markers whose peak-to-peak response values lie below the defined threshold. The threshold is expressed in percentage, relative to the maximal peak-to-peak response value found so far for that channel. In the example of Figure 58, the Display Threshold has been set to 100%, meaning that only the TMS Marker with the maximal peak-to-peak response value will be shown for each recording EMG channel.

8.3 SCREEN CALIBRATION

The computer screen and the printer are the central output devices to display the EMG / EEG signals for review. A printer has a physically fixed calibration (given dots per inch, or DPI), whereas a screen is an adjustable device and needs calibration to be used for the measurement and quantification of signals. Therefore, visor2 software provides the screen calibration dialog. In this dialog, the user compares the horizontal and vertical lengths shown on the screen against a ruler that defines these lengths and to serve as a reference.

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visor2 software provides a menu option for the so-called screen calibration. By means of the screen calibration, it can be ensured that a centimeter or inch of EMG / EEG traces on the screen representing a certain time interval has exactly this length.

The dialog for screen calibration can be activated through the menu Tools / Calibrate Screen....

In the upper part of the dialog, you find a text field for a short explanation. Below, the length unit can be chosen as being either cm or inch. To the left, there is a vertical scaling unit. At the bottom, there is a horizontal unit for scaling. For screen calibration, use a ruler and hold it against the scaling unit. Change the length of the scaling unit with the up/down arrow or left/right arrow buttons until your ruler exactly matches the length shown in the scaling unit. The ruler should be at least three inches or six centimeters long to overlay the marker with the scaling unit on the screen. You need to calibrate both, horizontal and vertical directions. Once the dialog has been closed by pressing OK, the setting is saved to the registry of the windows operation system and will be used in all subsequent times of running of visor2 software. The error due to the physical limitation (pixel width) of the screen is one cause of inaccuracies in the screen calibration and is estimated in the following table for a representative set of screen resolutions.

Resolution	Tolerance in mm	Tolerance in %
640 * 480	0.25	0.5
800 * 600	0.5	1
1024 * 768	0.25	0.5
1152 * 864	0.25	0.5
1280 * 960	0.5	1
1280 * 1024	0.5	1
1600 * 1200	0.25	0.5

For optimal results, we recommend a screen size of 21 inches and a resolution of 1600*1200 pixels or more if high accuracy is required. This is especially true with a great number of channels, i.e., when the size per channel is relatively small.

Additional error causes must be taken into account:

- Limited accuracy when comparing the ruler visually against the screen display.
- Limited accuracy of the input EMG / EEG data (wrong calibration of the biosignal amplifiers). The fault tolerance of the incoming EMG / EEG data (tolerance of voltage and time accuracy) depends on the EMG / EEG hardware and should be referenced in the respective documentation.

The visor2 software is for objective reasons unable neither to detect nor to correct such errors.

It is hereby stated that eemagine Medical Imaging Solution GmbH does not warrant in any way that the appearance of the EMG / EEG in the display equals the physical units displayed.

Example for an error estimation of voltage displays:

- Signal size 20 mm (peak-to-peak amplitude) at 100 μV/cm
- Fault tolerance 0.5% = 0.1 mm
- EEG input data tolerance 5% on Voltages (as an example)
- Measurement tolerance (when measuring traces based on a ruler) >= 1 mm.

With the given values, we obtain 200 * 0.005 + 200 * 0.05 + 100 * 0.1 = 1 + 10 + 10 = 21 μ Volt tolerance. A signal with the physical size of 20 mm, which corresponds with 200 μ Volts, would be measurable with a tolerance of 21 μ Volts, whereof 1 μ Volt is due to screen calibration.

8.4 Navigating two coils

Visor2 allows you to navigate two TMS coils simultaneously (XT license required). To perform a session with two coils, you need to prepare a special set-up:

- Connect the BNC trigger cable from the first TMS stimulator with the In1 connector of the trigger box NH-134. Connect the BNC trigger cable from the second TMS stimulator with the In2 connector of the trigger box NH-134.
- In case you would like to record EMG responses for stimuli from both stimulators with one amplifier, connect the Out1 BNC port with the BNC input of the amplifier. The trigger box will automatically merge the input signal from ports IN1 and IN2 and send the combined signal through OUT1.
- 3. In the TMS settings workflow, calibrate your first coil with the tracking tool NT-112 and your second coil with the tracking tool NT-143.
- 4. In the Neuronavigation workflow, select your first coil and stimulator in the first stimulation set. Press [Add Second Coil]. Select your second coil and stimulator in the second stimulation set.
- 5. Proceed and verify the coil calibration first for your first coil and second for your second coil.
- 6. In the neuronavigation step, select the active coil for which you would like to see the electric field or perform targeting operations, see 6.6.

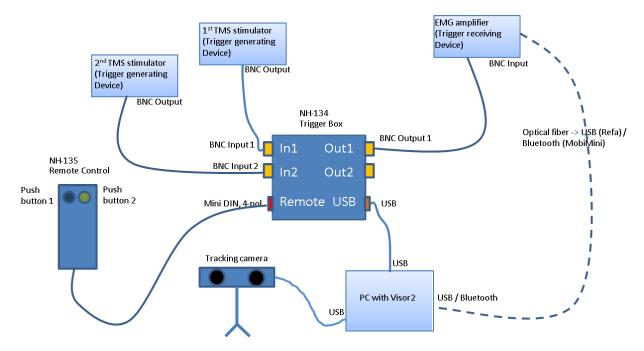


FIGURE 59. SYSTEM SET-UP FOR A NAVIGATION SESSION WITH TWO COILS

APPENDICES

APPENDIX 1: MONTAGES

THE MONTAGE EDITOR

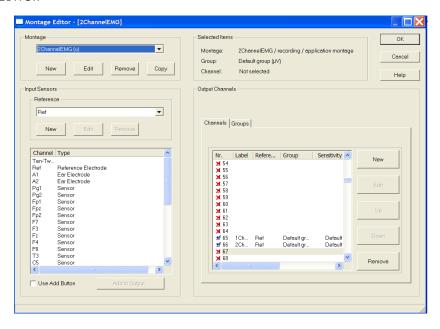


FIGURE 60: MONTAGE EDITOR

A montage is an arrangement of EEG or EMG channels, together with their properties. The montage defines channel configuration, their labels and properties like sensitivity, trace color, and filter parameters. The Montage Editor (Figure 60) allows you to edit the already existing montages, to define new montage from scratch or by copying and editing an existing one. The Montage Editor can be accessed through the Recording Settings workflow, by clicking the corresponding button.

The Montage Editor presents four groups of controls, as shown in Figure 61.

To create a new montage, go to the upper left part of the Montage Editor dialog and click *New*. The *New Montage Dialog* appears. In this dialog the new montage can be labeled, e.g. "EMG 3 Channels" and its storage location defined. If you want to create a montage for data recording you should check the "*Recording Montage*" option.

Click OK. The montage information is now displayed in the upper right part of the Montage Editor.

Go to the lower left corner and unfold the *Reference Menu* to select the reference electrode. The average reference is chosen with the option "AVG".

Select the channel or channels of interest in the *Input Sensors* list and then click *Add to output*. In the lower right part of the *Montage Editor*, the selected channels and their reference will be listed. We suggest you select all the channels.

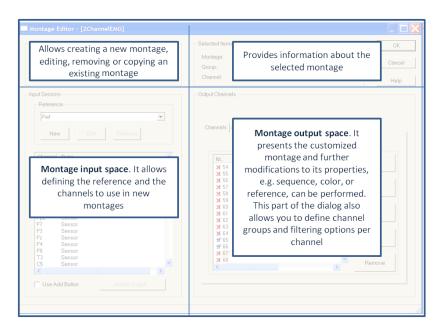


FIGURE 61: MONTAGE EDITOR GROUPS

Click OK to close the dialog and apply the new montage. Once the Montage Editor has been closed, the defined montage will appear in the Recording and Mapping montages list.

If you wish to create a montage similar to an existing one, it is more convenient to create a copy of the existing montage end edit it, rather than defining a new one. This can be done selecting the montage to be copied, clicking the *Copy* button and giving a proper name to the new montage. The newly defined montage will have the same properties and channels as the original one.

The montage allows you to define directly filtering parameters, which will be applied online, once the recording is starting, without need to set them manually. Please remind that these are only display filters, meaning that the data will be recorded raw, without any filters apply. Filtering parameters can be set at different levels:

- Montage level: applies to all channels and all channel groups. The montage filtering parameters can be set by clicking the *Edit* button in the left upper part of the Montage Editor after having selected the proper montage.
- Channel level: applies only to the channel. The channel filter parameters overwrite the montage filtering parameters, if any are present. The channel filtering parameters are set in the Montage output space, by selecting the desired channel and unfolding the desired filtering parameter, as shown in Figure 62.
- You have to keep in mind that all the options specified in a montage, including filtering options, will be applied automatically every time the montage is selected overriding any specification done through the toolbars and menus. In other words, there is a hierarchy of view properties:
 - Channel properties
 - Settings in the EEG toolbar.

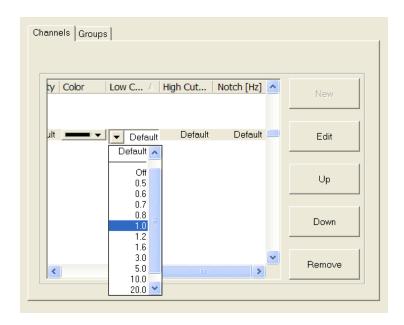


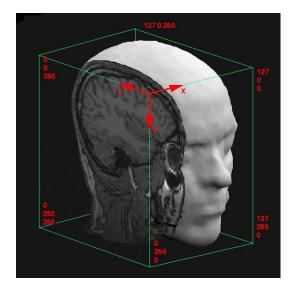
FIGURE 62: CHANNEL FILTERING PROPERTIES

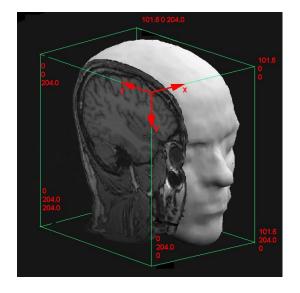
If a property has been defined in the EEG toolbar (lowest level) and then you apply a montage which specifies this property as well you will override the specifications made through the toolbar. Due to this property of montages you can review recorded data with different view properties, e.g. filter settings, or you can review a data file with two different montages synchronously.

APPENDIX 2: MRI COORDINATE SYSTEMS

1. Original MRI system

This system reflects the way the MRI data are stored. There are two variants: voxel based and distance based, which distinguish according to the unit used (voxels or millimeters). The origin is always at the corner of the MRI block that represents the first voxel of the first slice. The x axis is defined by the direction the slices are stacked, the y axis corresponds to the slowest changing index within a slice. The visor2 slice coordinates relate to the voxel based coordinate system.





voxel based original MRI system

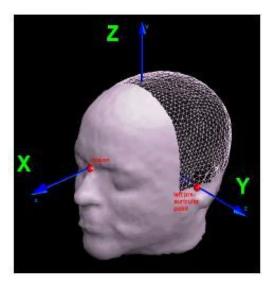
distance based original MRI system (unit millimeters)

2. Fiducial system (Nasion-Ear-System)

This system is defined by so-called fiducial points on the surface of the head. The fiducials used are the nasion and left and right pre-auricular points. The y direction is determined by the connecting line between the two pre-auricular points (pointing left). The origin is then found by projecting the nasion orthogonal onto this line. The x axis is pointing from the origin to the nasion and the z axis is standing perpendicular on the plane spanned by x and y axis.

Note: The orientation of the coordinate axes can be changed in the application options. Select the menu option Tools / Options... and choose the tab 3D Coordinates.

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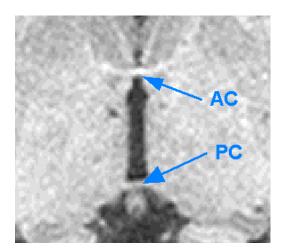


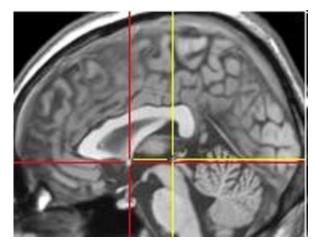
Nasion-Ear-system

3. AC-PC system

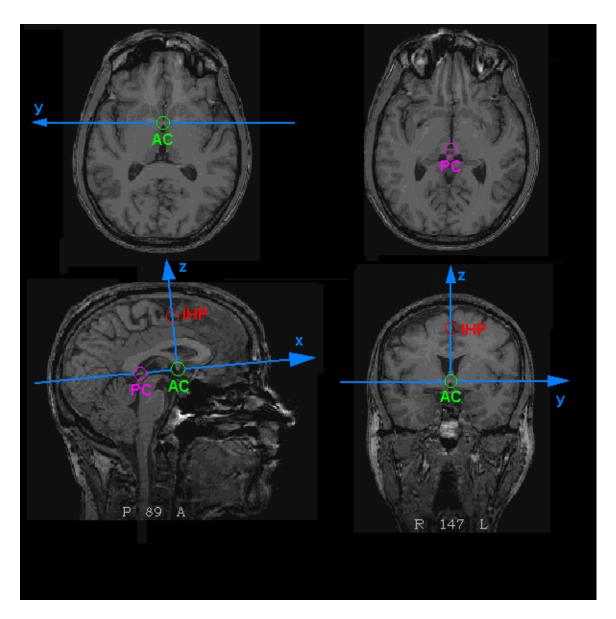
The AC-PC system is an intermediate step towards the Talairach system.

The origin is determined by the anterior commissure (AC), a small fiber bundle connecting the two hemispheres of the brain. A similar fiber bundle, the posterior commissure (PC) determines the orientation of the x axis, which points into anterior direction. The z axis is oriented upwards and perpendicular to the AC-PC line between the two hemispheres. It lies in a plane defined by the AC-PC line and the interhemispherical point (IHP), which can be chosen at an arbitrary spot in the interhemispherical fissure, provided it does not lie on the AC-PC line itself. The y axis points to the left side, orthogonal to the other two axes.





The AC and PC points are shown in an axial plane (left) and in a sagittal plane (right). The AC is the anterior, more frontal, the PC, the posterior point, more to the back of the head.



Definition of the AC-PC coordinate system.

5. Talairach system

The Talairach system is created by a piecewise linear transformation of the AC-PC system. It transforms the brain to a standardized size. As reference points one uses the maximum extension of the cortex along the directions defined by the AC-PC system. The following points are used¹:

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¹ Definitions according to the coordinate axis definition, where x points to the front and y to the left.

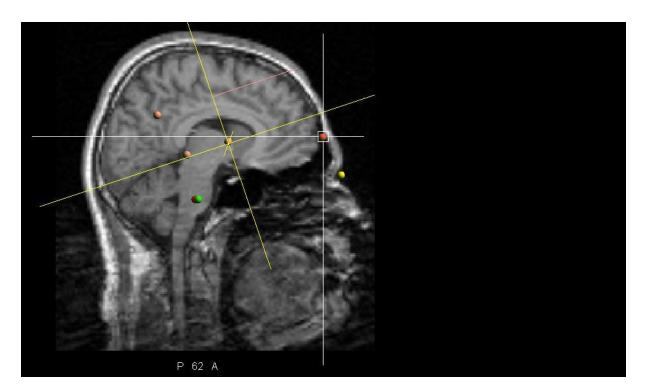
visor2 User Guide

Name of point	Abbreviation	Description
Anterior point	AP	point of the cortex with maximum x coordinate
Posterior point	PP	point of the cortex with maximum negative x coordinate
Superior point	SP	point of the cortex with maximum z coordinate
Inferior point	IP	point of the cortex with maximum negative z coordinate
Right point	RP	point of the cortex with maximum negative y coordinate
Left point	LP	point of the cortex with maximum y coordinate

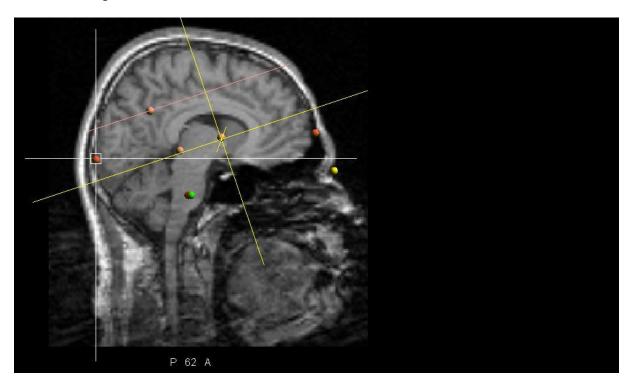
These points, as well as the posterior commissure (PC) get new coordinates assigned, according to which the brain is shrunk or stretched. These are:

	x / mm	y / mm	z /mm
PC	-23	0	0
AP	70	-	-
PP	-102	-	-
IP	-	-	-42
SP	-	-	74
RP	-	-68	-

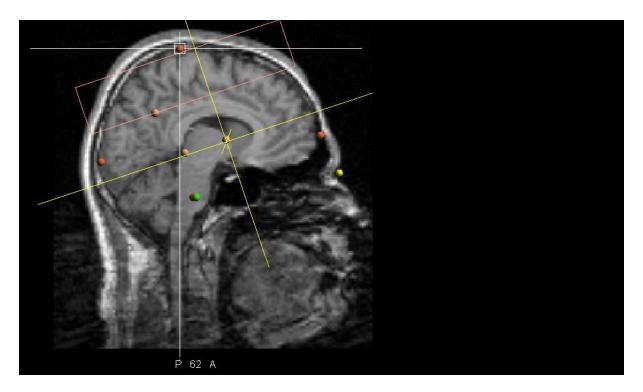
In the following figures it is shown how the MRI looks like in **vi**sor2 after setting each of the Talairach markers (note that the AP marker has been shifted to make the difference to the Nasion-Ear-system more obvious):



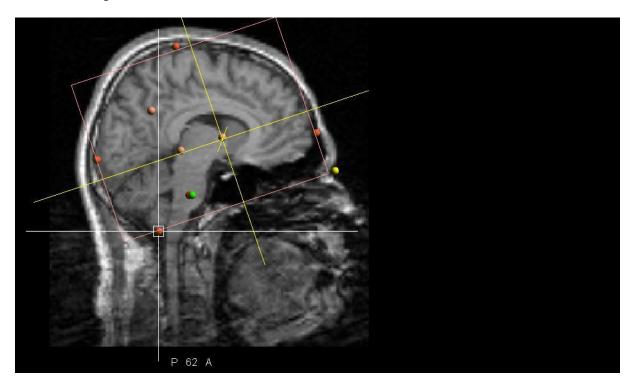
MRI after having set the AP Talairach marker



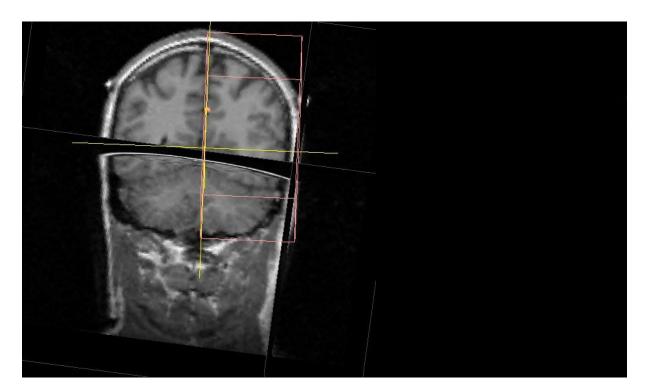
MRI after having set the **PP Talairach marker**



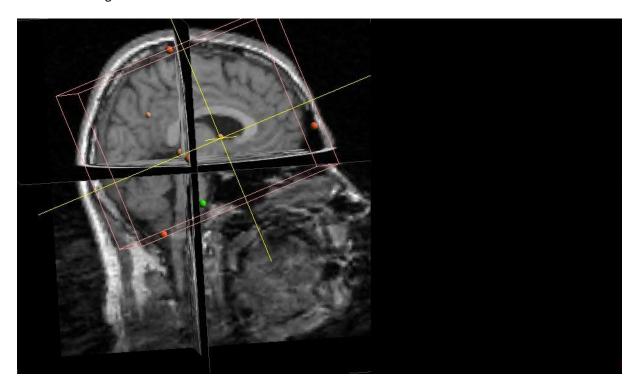
MRI after having set the SP Talairach marker



MRI after having set the **IP Talairach marker**



MRI after having set the RP Talairach marker



MRI after having set the **LP Talairach marker**

Now, all Talairach have been set. The MRI coordinates are now given also in Talairach coordinates. To verify, whether you have set the Talairach markers correctly, scroll through the slices in all three directions. The brain should lie within the red box.

APPENDIX 3: LICENSING

visor2 **software** is protected from unauthorised use by the implementation of a software licensing technology. A valid license is required to run the software. A license may consist of several options, which are enabled based on the license products that were purchased. The options control access to specific features of the software.

LICENSE TYPES

The following license types are available

The **single license** unlocks the software on a single computer. The license is provided as a USB dongle (USB key-lock, see Figure 63).

The **single software license** unlocks the software on a single computer. The license is provided as a registration key

The **trial license** provides 30 days of access to all functionality of the software, and is intended for evaluation and demonstration purposes. The trial license is included with each copy of the software.



FIGURE 63: USB DONGLE

INSTALLATION OF A SINGLE LICENSE

The single license is provided as a USB dongle. The dongle requires a hardware driver for the Windows operating system. The driver is provided by the CodeMeter software, which is installed automatically during the installation.

Installation steps:

- 1. Keep the USB dongle ready, but do not plug it into the computer yet.
- 2. Install **vi**sor2 **software** on the target computer, this will install the CodeMeter driver automatically. Do <u>not</u> run the **vi**sor2 **software** after the installation.
- 3. The CodeMeter icon on wappears in gray colour in the Windows System Tray (bottom-right of the monitor screen, embedded in the Windows Taskbar). The gray colour indicates that no dongle has been connected to the computer.
- 4. Plug the USB dongle into the computer. Windows recognizes the dongle as new hardware. The CodeMeter icon on wappears in green colour. The green colour indicates that one dongle has been connected to the computer.
- 5. The license is now correctly installed.

TRIAL LICENSE

A trial license is included on every new installation of the **vi**sor2 **software**. The trial license grants access to all license options for an evaluation period of 30 days.

Installation steps

- 1. Run the software.
- 2. The trial license window appears. Press the OK button to start the trial license.
- 3. After 30 days, the license will expire. Contact your local distributor, or the manufacturer for purchasing an official license.

LICENSING SUPPORT

Contact your local distributor, or the manufacturer for further support regarding the software licensing.

For specific questions about a dongle, please remember to communicate the serial number, which is located on the side of the dongle.

APPENDIX 4: SUPPORTED DATA FORMATS

New data formats and features are constantly being added. If you don't find your data format mentioned here, please contact us.

The following table presents supported data formats for EEG/EMG, EEG/EMG data export (no additional manipulations are needed to work with these formats).

The following abbreviations will be used:

- PAT --- Patient information
- EVT --- Events
- MNT --- Montages

Formats for EEG/EMG data exporting

Data format	EEG/EMG	PAT	EVT	MNT
ASA (.msr)	Х			Χ
European Data Format (.edf, .rec)	Χ	Χ		Χ
ASCII	Χ		Χ	
EEProbe (.cnt)	Χ		Χ	

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APPENDIX 5: WARRANTY AND SUPPORT

WARRANTY

The warranty period varies by the purchasing condition. Please refer to your purchase agreement for specific information.

Repairs can only be performed by the manufacturer. The warranty is voided by removal or alteration of identification labels on the device or its parts. Warranty is also voided in case screw seals on the enclosure are broken. ANT/eemagine does not warrant uninterrupted or error-free operation of the device.

The warranty does not cover the following:

- Failure resulting from misuse, accident, modification, unsuitable physical or operating environment, or improper maintenance;
- Failure caused by a product for which ANT/eemagine is not responsible;
- Any third party products, including those that ANT/eemagine may procure and provide with or integrate into the system at your request.

SUPPORT

For support, please contact your local dealer. Should it become necessary to return goods for repair, you must contact your local dealer first and fill out and return a **Return Material Authorization** (RMA) form, as will be supplied to you together with the **Shipment instructions**. You may return the goods only after you have received your RMA number. Please include that form in the shipment.

APPENDIX 6: SHORTCUTS AND MOUSE WHEEL FUNCTIONS

Shortcut	Meaning	
Right	Go to the next page (segment, event, selected object)	
Left	Go to the previous page (segment, event, selected object)	
Up	Increase sensitivity	
Down	Decrease sensitivity	
End	Go to the end of the EEG/EMG	
ENTER	Start / Stop automatic scrolling	
+ / -	Increase / Decrease automatic scrolling velocity	
Control + Right	Go to next second (next sample if page width is too small)	
Control + Left	Go to previous second (previous sample if page width is too small)	
Control + Up	Increase page width (less mm / sec)	
Control + Down	Decrease page width (more mm / sec)	
Control + C	Copy the view as bitmap to clipboard	
Control + A	Select all channels and events	
Control + P	Print the view	
Mouse wheel	Zoom in 3d view	

APPENDIX 7: SYSTEM COMPONENTS - TECHNICAL SPECIFICATIONS

visor2 software			
Compliance	Class IIa, MDD 93/42/EEC		
Mode of operation	Continuous		
Supported rTMS frequencies	Up to 20Hz		
Maximum rTMS stimulus count	4000 at 1Hz or 3000 at 5Hz or 2000 at 20Hz		
Maximum motor mapping stimulus count	1000 stimuli		
Tracking System			
Compliance	IEC 60601-1		
Tracking system	NDI Polaris Spectra/Vicra		
Position accuracy, Update rate	0.25 mm (rms), Up to 20 Hz		
Installation	vi sor2 cart; wall mount		
Storage temperature range	-10ºC to 50ºC		
For more details, see accompanying documentation for	or your tracking system.		
Tracking tools			
Compliance	Non-medical, conforms to Essential Requirements of Annex		
	of the Medical Device Directive 93/42/EEC		
Pointer	Four markers, passive		
Coil tracker	Two faces, each face three markers, passive		
Head reference	Four markers, passive		
Calibration board	Four markers, passive		
Amplifiers			
Compliance	Class IIa, MDD 93/42/EEC		
Storage temperature range	-10ºC to 70ºC		
Amplifier	TMS International Mobi series		
Sampling rates available in vi sor2	1024Hz, 512Hz, 256Hz		
Input range, noise, resolution, accuracy	-100mV / +100mV, < 1.5μV rms (@1024 Hz), 12.2 nV per bit,		
	±2%		
Amplifier	TMS International Refa8		
Sampling rates available in vi sor2	2048Hz, 1024Hz, 512Hz, 256Hz or		
	10000Hz, 5000Hz, 2500Hz, 1250Hz, 625Hz		
Input range, noise, resolution, accuracy	-150mV / +150mV, < 1.0μV rms (@128Hz), 18.39 nV per bit,		
	±2%		
For more details, see accompanying documentation for	or your amplifier.		
TriggerBox: input from TMS stimulator			
Compliance	IEC 60601-1-2 (EMC)		
For more details, see accompanying documentation for	or the TriggerBox.		
PC (minimum requirements)			
Compliance	EN 60950, EN 62311		
CPU	Intel Core Duo 3 GHz or better		
RAM	2GB RAM working memory		
Graphics	Video card: DirectX 9.0 Pixel/Vertex shader 2.0 or bette		
	(Nvidia or ATI recommended)		
	Monitor screen resolution: recommended min. 1280x1024		
USB	4 USB 2.0 ports or higher for amplifier, tracking system		
	trigger box, and license dongle		
Software	MS Windows 7 or MS Windows 8.1 in 32 bit or 64 variant		
	MS Internet Explorer 11.0. or higher		
Overall allowed environmental conditions			
Operating temperature	10ºC to 40ºC		
Humidity (relative)	30% to 70%		

APPENDIX 8: MEASURED AND DISPLAYED PARAMETERS

Parameter	Туре	Unit	Range	Accuracy
EMG / EEG potential (Mobi)	measured	Volt [V]	-100mV / +100mV	±2%
EMG / EEG potential (Refa8)	measured	Volt [V]	-150mV / +150mV	±2%
Position accuracy (Tracking	measured	Meter [m]	See datasheet of camera	0.25mm (rms)
camera)			for measurement volume	
EMG / EEG signal on screen ²	displayed	[V/cm]	User defined	±1%
EMG Peak-to-Peak value	displayed	[V]	0mV - 200mV / 300mV	±3%
			(Mobi / Refa8)	
Coil validation error	displayed	[m]	n/a	1mm
Nasion validation error	displayed	[m]	n/a	1mm
Coil distance to target /	displayed	[m,°]	n/a	0.25mm, 0.6°
Reproduce stimuli				

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² Requires calibrated screen, see section Screen Calibration.

APPENDIX 9: EXPLANATION OF SYMBOLS AS USED IN THIS MANUAL AND/OR ON SYSTEM PARTS

Symbol	Meaning	System Components
\triangle	Manual contains important safety information	Position sensor, Host USB converter, tracking tools, amplifier, amplifier power supply, DVD
	Class II device	Amplifier, amplifier power supply
	Type CF	Amplifier, amplifier power supply
	Consult instructions for use	Tracking tools, amplifier, remote control, trigger box, DVD
	Manufacturer	Amplifier, DVD
$\qquad \qquad \square$	Manufactured date	DVD
CE	CE marking	Amplifier, DVD
	Recycle where possible or return to ANT	Position sensor, amplifier, tracking tools, amplifier power supply, amplifier USB unit, remote control, trigger box
	Do not sit	visor2 cart
	Do not push	visor2 cart
*	Laser warning. Consult accompanying documents	Position sensor
I	On (power: connection to mains supply)	Position sensor, host USB converter
U	Status	Position sensor
ነ	Error	Position sensor, host USB converter
*	Laser activation	Position sensor
\odot	Connection port	Position sensor
	Direct current	Host USB converter
•	USB port	Host USB converter
★	Bluetooth	Mobi amplifier