

HaGuide

USER'S MANUAL

2.0.0

Revision – 2.0



For additional languages go to

<https://www.alphaomega-eng.com/HG-V2-0>

Defining Neuroscience Technology

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For additional information on the device, including questions on infection control procedures, please contact: info@alphaomega-eng.com

TABLE OF CONTENTS

Proprietary Notice	2
TABLE OF CONTENTS.....	3
WARNINGS.....	4
1. INTRODUCTION.....	6
1.1.1. FDA System Classification	6
1.2. Indications for use.....	6
1.3. conditions of use	7
2. INSTALLATION INSTRUCTION.....	9
2.1. purpose	9
2.2. prerequisites	9
2.2.1. Minimum Hardware Requirements	9
2.2.2. System Requirements	9
2.2.3. Software Requirements	9
2.2.4. Optional Requirements.....	9
2.3. Installation.....	9
2.3.1. Preparation	9
2.3.2. Instructions	10
2.4. Running the software.....	12
2.5. Updating the software	12
2.6. Uninstalling the software	12
2.7. Troubleshooting	12
3. PRODUCT DESCRIPTION AND PERSPECTIVE	13
4. SYSTEM SYMBOLS:	14
5. LOG IN	15
5.1. HaGuide home-page	15
6. HAGUIDE FEATURES.....	19
6.1. HaGuide.....	19
6.2. Lead Electrophysiology.....	20
6.3. Lead Correlation.....	21
6.4. Internet connectivity.....	23
Appendix A- Minimum Required Protection Information.....	23
7. CONTACT US	28



WARNINGS

- Only qualified personnel, who have been trained by Alpha Omega Ltd., should be allowed to operate this equipment.
- Any modifications made to the equipment without explicit approval from Alpha Omega Ltd., voids warranty and service contract obligations, and poses a potential safety threat to both operators and patients.
- Do not install any software packages (Matlab, C++, SDK software or others) on the system unless provided by Alpha Omega Ltd. for the explicit use on the MER system.
- A possible hazard is/can be caused by the summation of leakage currents when several items of the equipment are interconnected.
- A thorough understanding of the technical principles, clinical applications, and risks associated with these treatments is necessary before using this system. Please read this entire manual before attempting to activate the system. Completion of the training program is required before the use of the Neuro Omega system.
- when using bipolar on a patient, make sure Headstage is disconnected from the MER system
- Timely updated the operating system, firewall, and the browser when notified by the service provider and anti-virus license
- Do not click any links, websites, or icons from untrusted sources
- In no case can the Alpha Omega MER systems and/or HaGuide replace the Surgeon's experience or knowledge of anatomical structures. The device is intended to assist the surgeon in the decision-making process during surgery



CAUTIONS

- US federal law restricts the sale of this device to or on the order of a physician.
- Discard according to the local regulations and law.
- Avoid trans-thoracic stimulation.
- Avoid sharing system's logging passwords
- We recommend uploading the data to Alpha Omega secure server
- Check speed test of your device before uploading data to the server
- Pay attention to the progress bar while uploading data to the server
- Avoid accidental contact between connected applied parts which are in use and other conductive parts including those connected to protective earth

NOTES

Before starting MER check the impedance

The minimum bandwidth required for the NeuroSmart system is 4 Megabits per second

The minimum bandwidth required for the Neuro Omega system is 70 Megabits per second

Abbreviations

Term/Abbreviation	Definition
AO	Alpha Omega
DBS	Deep Brain Stimulation
DLOR	Dorsolateral Oscillatory Region
ECOG	ElectroCortiGram or ElectroCorticoGraphy
EEG	Electroencephalography
EMG	Electromyography
FDA	Food and Drug Administration
IPG	Implantable Pulse Generator
ISO	International Organization for Standardization
MER	Microelectrodes electrical recording
NRMS	Normalized Root Mean Square, the RMS represents the mean value of the signal.
PC	Personal Computer
PD	Parkinson's Disease
PSD	Power Spectrum Density
RMS	Root Mean Square
STN	Subthalamic Nucleus
VMNR	Ventromedial Non-Oscillatory Region

1. INTRODUCTION

HaGuide is a software that includes the HaGuide, Lead Electrophysiology and Lead Correlation features. The tool is stand-alone software that can be run with the Neuro Omega system or the NeuroSmart system, and also on an external PC.

The purpose of the HaGuide is to facilitate the user activity during Deep Brain Stimulation (DBS) surgery by presenting a real-time method to accurately divide the Subthalamic Nucleus (STN) region during surgery based on microelectrode recording and to aid in the placement of the Lead.

The Software gives a clear identification of the STN entry and exit as well as introduces a detection of a distinct region's boundaries and gives the user a recommendation for stimulation location in the STN. Furthermore, the tool presents real-time graphs of power spectrum density and RMS of the region.

Alpha Omega LeadConfirm cable and adapter simplify the connectivity of Medtronic, Boston Scientific and Abbott DBS Lead to Alpha Omega physiological navigation systems for recording and stimulation (Alpha Omega MER systems). The Lead Electrophysiology feature of the HaGuide Software collects the Lead recordings and displays the Power Spectrum Density (PSD) of the lead electrophysiological data. The Lead Correlation feature computes and displays the correlation between electrophysiological signals recorded using the MER during navigation, to those recorded from a compatible DBS Lead.

The software also serves the user in documenting information during the DBS surgery.

The HaGuide can be connected to the internet, and the relevant intraoperative data collected during DBS surgery can be uploaded to the selected cloud (Alpha Omega's cloud or the HCP cloud, as selected by the physician - no other uploading is *feasible*) by the physician for Neurologist use.

Regulatory

1.1.1. FDA System Classification

Product Code: GZL

CFR Section: 21 CFR 882.1330

Regulation Name: Depth electrode

Relevant Keywords:

- Electroencephalograph
- Stimulator
- Electrical
- Evoked response
- Electromyography
- Diagnostic

Trade Name: Neuro Omega/NeuroSmart System

Classification: Class II

1.2. INDICATIONS FOR USE

The HaGuide is real-time software installed in Neuro Omega and/or NeuroSmart systems.

For information regarding incorporation of the HaGuide in Neuro Omega and NeuroSmart systems, please refer to the respective system's User Manual.

Neuro Omega Indications for use:

The Neuro Omega system with the incorporated HaGuide (the improved HaGuide), including the Drive Headstage unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes.

The subject device, the Neuro Omega System with the incorporated HaGuide is also intended:

- To monitor, record, and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record, and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG).
- To measure, record, and display the electrical activity of the patient's brain obtained from two or more electrodes on the head (EEG).
- To measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes.
- To provide stimulation via electrode pairs or a hand-held bipolar probe for use in functional brain mapping procedures during treatment of patients with a seizure disorder.

The Neuro Omega with the incorporated installed HaGuide, is intended for intraoperative use by medical personnel. Within hospitals, laboratories, clinics, or nursing home settings or outside of a medical facility under the direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

NeuroSmart Indications for use:

The NeuroSmart System with the incorporated HaGuide, is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes

1.3. CONDITIONS OF USE

The device may be used by medical personnel within a hospital, laboratory, clinic, or nursing home setting, or outside of a medical facility under the direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording. The following are the HaGuide use conditions:

Environment:

- ◆ Conditions of visibility:
 - Ambient luminance range: Normal
 - Viewing distance: N/A
 - Viewing angle: N/A

Frequency of use: As per the specific case

Mobility: Mobile

Quality of Service (QoS) Specification:

Bandwidth	bandwidth between 7-70Mb upload BandWidth depending on #channels and type of MER system (Neuro Omega or NeuroSmart)
Frequency and power	2.4GHzL 36 dBm/4w
Operating distance	5 GHz: 23–30 dBm / 0.2 - 1.0 w ~50m
Security	WPA2/WPA3

Cybersecurity needs and requirements:

- Timely updated the operating system, firewall, and the browser when notified by the service provider and anti-virus license
- Do not click any links, websites, or icons from untrusted sources
- Avoid sharing system's logging passwords
- We recommend uploading the data to Alpha Omega secure server

For Standalone software:

Securing a firewall is the vital first step to ensure only authorized administrators have access to it. Please refer to Appendix A for cybersecurity requirements.

2. INSTALLATION INSTRUCTION

2.1. PURPOSE

The purpose of these installation instructions is to guide the end-user to properly install the HaGuide on an external PC as a standalone software.

2.2. PREREQUISITES

The following requirements and prerequisites must be satisfied to ensure proper installation and software functionality.

2.2.1. Minimum Hardware Requirements

- Processor: Intel® Core™ i5 9500 (6 core @ 3 GHz) or equivalent.
- RAM: 8 GB DDR4 Memory (16 GB is recommended).
- Storage: At least 20 GB of free storage (Solid State Drive is recommended).
- GPU: No specific graphics card/GPU is required.

2.2.2. System Requirements

- Windows 10/11 Pro 64 bit.

2.2.3. Software Requirements

- Microsoft Visual C++ 2010 Redistributable - x64.
- Microsoft Visual C++ 2015-2022 Redistributable - x64.
- WinPcap 4.1.3

All software requirements are provided with the HaGuide installation package and should be installed immediately after installing the software.

2.2.4. Optional Requirements

- Secured internet connection for OR report uploading.

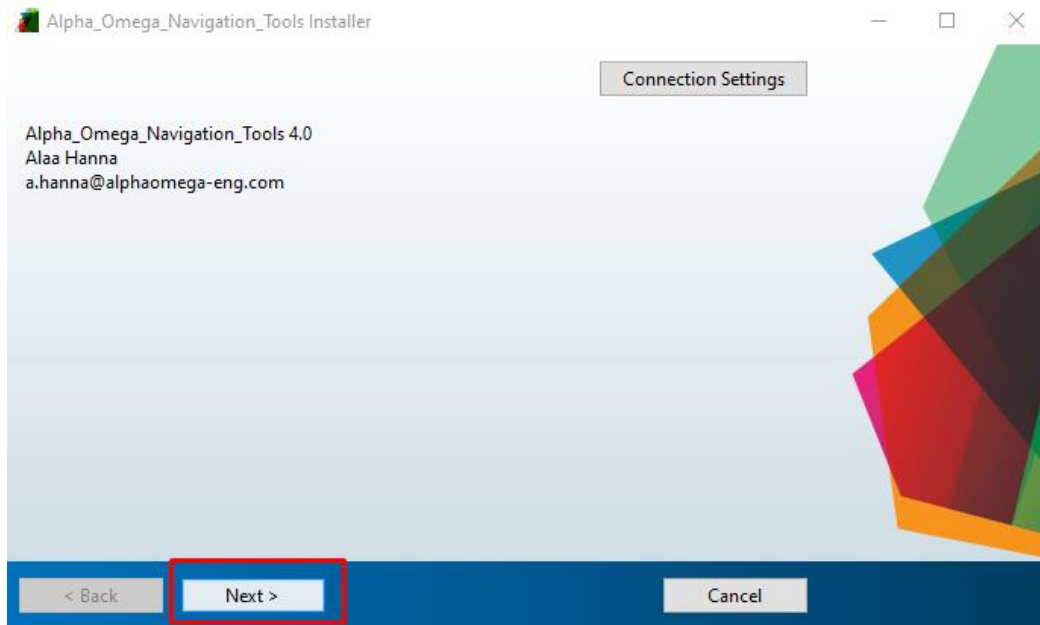
2.3. INSTALLATION

2.3.1. Preparation

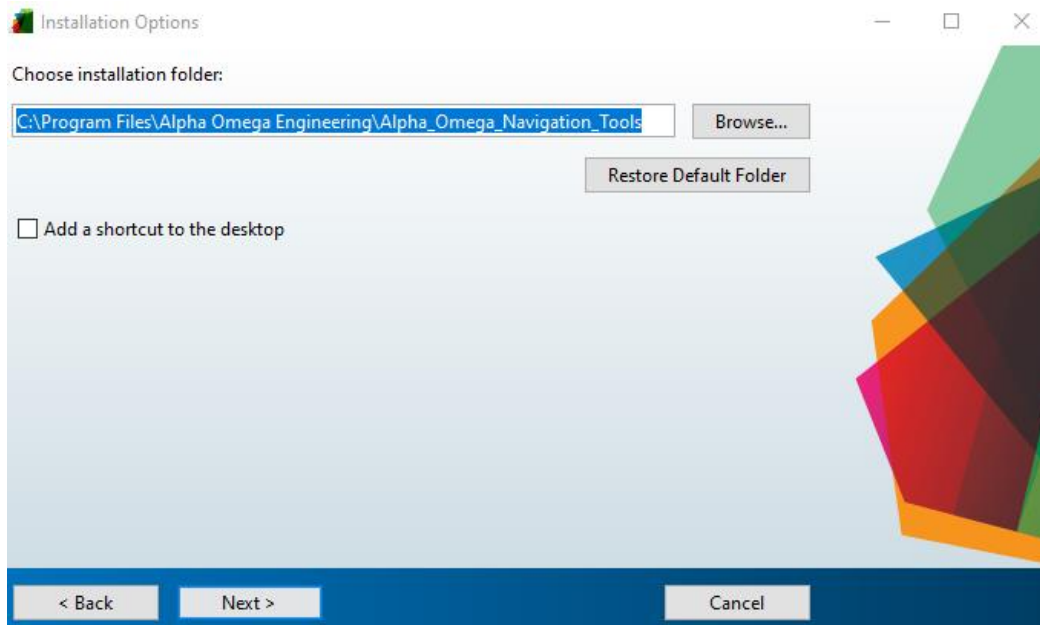
- Make sure that no previous versions of the HaGuide are installed on your system.
- We recommend that you close other applications during the installation procedure.
- Make sure that you have administrator privileges to install the software.
- Make sure that your laptop is sufficiently charged and/or plugged to an AC power source.
- The installation procedure should take between 5-10 minutes, don't turn off your system while the installation is running.

2.3.2. Instructions

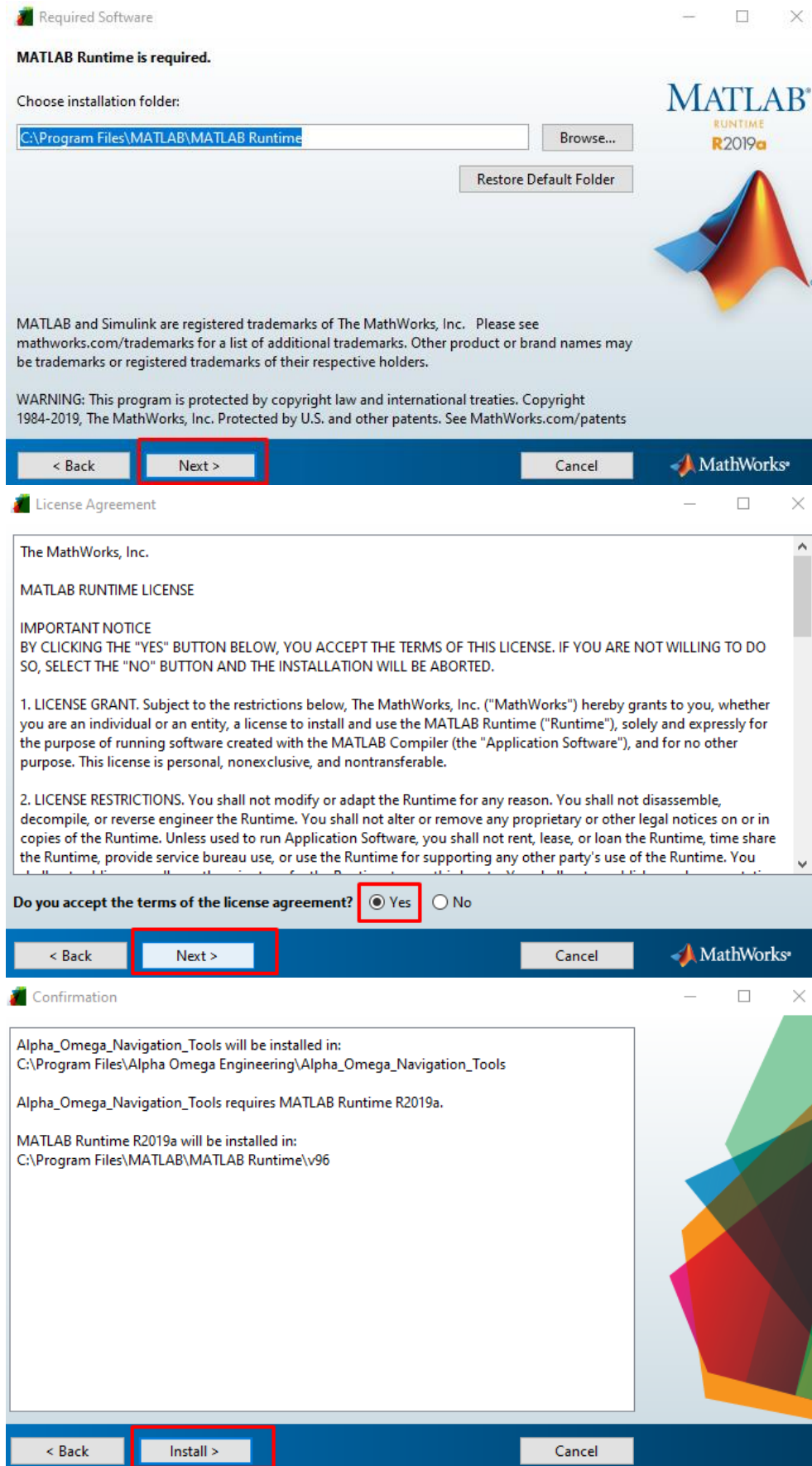
1. Locate the installation file “Alpha_Omega_Navigation_Tool” that was provided by an Alpha Omega Representative. Right click on the file, select “Run as administrator” and approve if prompted.
2. Follow the instructions in the software installer:



3. Choose the installation folder, it's recommended to keep the default path. Also, you can create a desktop shortcut if needed:



4. The installer will also install MATLAB Runtime:



5. Wait for the installation to complete.

6. Install the prerequisite software:

- a. Go to the installation folder (default location is C:\Program Files\Alpha Omega Engineering\Alpha_Omega_Navigation_Tools\application).
- b. Locate the installation files for the required software in section 1.2.3 above and install them:

 vc_redist.x64

 vcredist_x64-2010

 WinPcap_4_1_3

7. Restart the PC.

2.4. RUNNING THE SOFTWARE

- A license text file is needed to run the software. This license is unique for each PC and will be provided by an Alpha Omega representative. The license text file should be included in the same folder that you will run the application from.
- In order to run the software, go to the installation folder (default: C:\Program Files\Alpha Omega Engineering\Alpha_Omega_Navigation_Tools\application) and run the software file “Alpha_Omega_Navigation_Tools” with administrator privileges.
- You can choose to create a desktop shortcut for the software in the installation process or by right clicking the application file -> “Send to” -> “Desktop (create shortcut)”. It is recommended to move the shortcut to a separate folder in the desktop.
- Don’t delete any of the files in the installation folder or any files created by the software in shortcut folder.

2.5. UPDATING THE SOFTWARE

If required, a software update and relevant instructions will be provided by an Alpha Omega representative.

2.6. UNINSTALLING THE SOFTWARE

- To uninstall the software, open Windows Settings (can be found in the start menu), go to “Apps”, click on the software “Alpha_Omega_Navigation_Tools”, press “Uninstall” and follow the instructions.
- Alternatively, the software can be uninstalled in the Control Panel.
- After uninstalling the software, you delete the installation folder and restart the system.
- You can also uninstall the MATLAB Runtime software (if not used by other programs) using the same instructions.

2.7. TROUBLESHOOTING

If the software cannot be installed, make sure that you have the necessary prerequisites and followed all steps.

For further help, please contact Alpha Omega.

3. PRODUCT DESCRIPTION AND PERSPECTIVE

The HaGuide is a real-time software incorporated in electrophysiological recording and stimulating systems (like Neuro Omega and NeuroSmart systems). It includes two features:

1. **HaGuide:** accurately detect the STN region and robustly detects Intra STN detection of Dorso-lateral Oscillatory Region (DLOR) and Ventro Medial Non-Oscillatory Region (VMNR) boundary.
The tool presents real-time graphs of power spectrum density and RMS of each region.
2. **Lead Electrophysiology:** The software collects and display electrophysiological recordings from the DBS lead, using the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739)
3. **Lead Correlation:** The HaGuide Software can aid in the placement of a compatible DBS Lead, when the lead is connected to the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739) and to the Neuro Omega System or NeuroSmart System.

HaGuide can be connected to the Internet through Internet Wi-Fi or internet cable. The relevant intraoperative data collected during DBS surgery can be uploaded to the selected cloud (Alpha Omega's cloud or the HCP cloud, as selected by the physician and no other uploading is feasible) by the physician for Neurologist use.

Alpha Omega Server:

The HaGuide provides an option to upload raw data and OR reports to the Alpha Omega server.

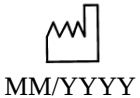
- The raw data include the MER .mpx files and the workspace files that were saved during the surgery by the Neuro Omega or NeuroSmart system (if enabled by the user).
- The OR report includes all the HaGuide parameters, OR notes, stimulation assessments, and lead recording.

The Alpha Omega server adheres to industry cybersecurity standards.

The HaGuide Software in both its modes, a standalone software and a software installed on Neuro Omega/NeuroSmart systems, can upload data for storage via secured protocols (FTPS, HTTPS) to Alpha Omega server using the internet connectivity.

Neuro Omega/NeuroSmart software does not upload data to any web server. They are able to connect locally to the HaGuide I, which is the only channel through which data can be uploaded to Alpha Omega server. The HaGuide cannot download or retrieve any data from Alpha Omega server

4. SYSTEM SYMBOLS:

No.	Symbol	Description
1		Type BF applied part
2		Type b applied part
3		Attention, consult accompanying documents
4		Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
5		Non-sterile
6		MANUFACTURER
7		DATE OF MANUFACTURE (Month / Year)
8		CONSULT INSTRUCTIONS FOR USE
9		CONSULT INSTRUCTIONS FOR USE FOR ADDITIONAL LANGUAGES – URL link
10		Catalog Number
11		Unique Device Identification

5. LOG IN

5.1. HAGUIDE HOME-PAGE

At a successful login, you will get to the HaGuide home page, where you can see the MER system, and the tool is connected with the Neuro Omega system or Neuro Smart system.

For the software there are three states (see figure 1):

- 1- **Connected**: when it connects to the MER system
- 2- **Disconnected**: when it is not connected to the MER system
- 3- **Working offline**: This state is available when the MER system is not connected, it allows the user to view existing patient information

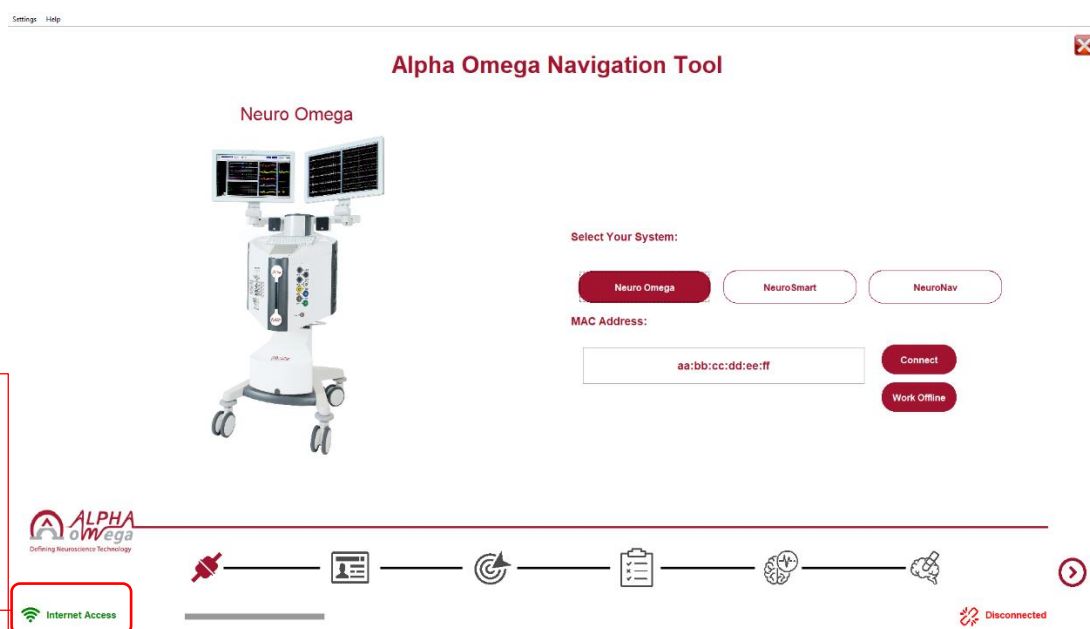


Figure 1 Home-page

In case of unsuccessful connection due to wrong selection of the system or wrong MAC address, the System will prompt the user to enter appropriate MAC address, select another system or continue working offline. See Figure 2.

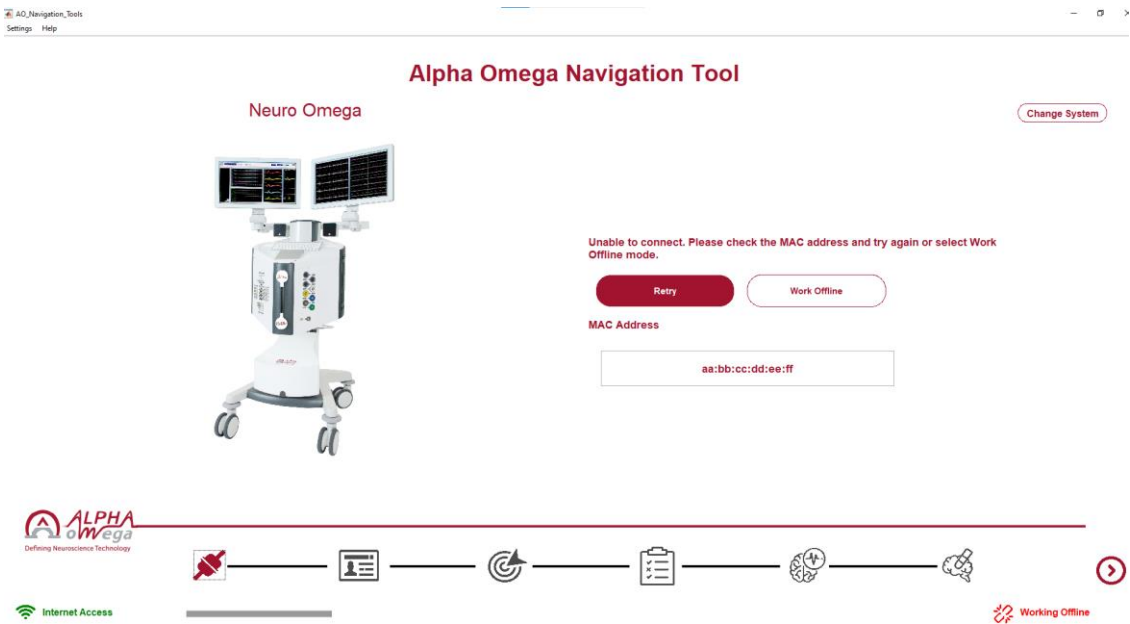


Figure 2 Reconnection

On the Settings bar, the user can enter the Navigation settings (General, MER, Stimulation, Lead Electrophysiology, HaGuide Settings). See Figure 3:

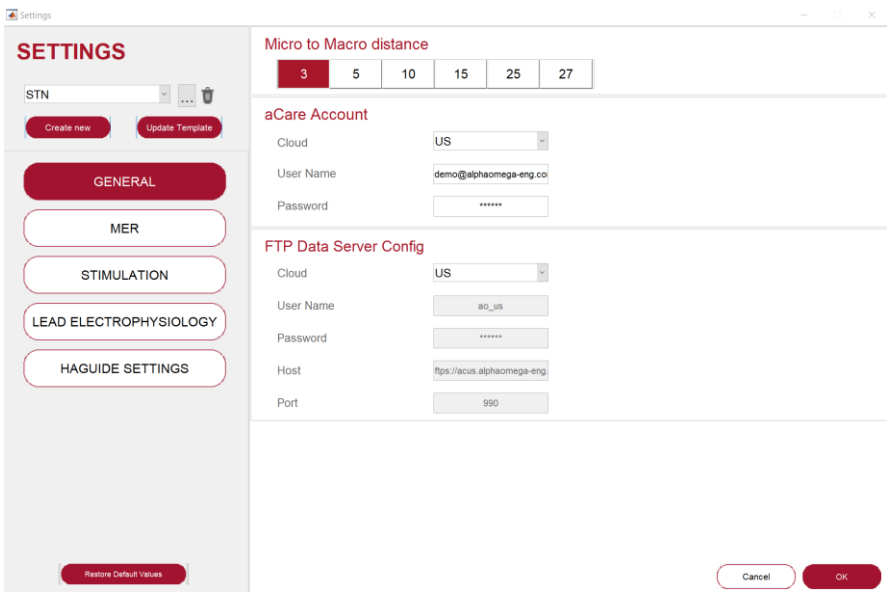


Figure 3 Settings

On the next page, Hospital information (Hospital name, Neurosurgeon, Neurologist, and Electrophysiologist) and Patient information (Patient reference, Gender, Years of Birth, Disorder, Patient state, Medication Used for Anesthesia, Monitoring Method) are requested to be filled (the fields with * are required to be filled). See figure 4.

When the system is connected, the SW can autofill the fields from the NO/NS SW

Alpha Omega Navigation Tool

Hospital Information

Hospital Name

Neurosurgeon

Neurologist

Electrophysiologist

Patient

*Patient Reference

*Gender ☐ Male ☐ Female

*Year of Birth

*Disorder

Patient State

Medication Used for Anesthesia

☒ Propofol ☐ Remifentanyl ☐ Ketamine

☐ Other...

Monitoring Method

☒ BIS ☐ MAC

Internet Access

Connected

Figure 4 Patient and Hospital information

On the planning page, we choose the surgery condition for the specific case (Target Type, Target Plan, Settings (Target Region), Frame Type, Planning Coordinates, IPG Model, Lead Type). See figure 5.

Alpha Omega Navigation Tool

Planning Information

*Target Type

STN

VIM

Other

Target Plan

☐ Top

☐ Middle

☒ Bottom

Settings

STN

Frame Type

Leksell

Planning Coordinates

Frame AC - PC

	Left	Right
X		89
Y		95.5
Z		110.5
Arc		75.6
Ring		62.5

IPG Model

Medtronic Percept PC

*Lead Type

Select Lead

Medtronic SenSight 33005

Internet Access

Working Offline

Figure 5 Planning

On the same page, pressing “IPG Model” brings you a list of IPG Models.

By pressing “Lead Type” will present to you all the supported Lead Types. See figure 6.

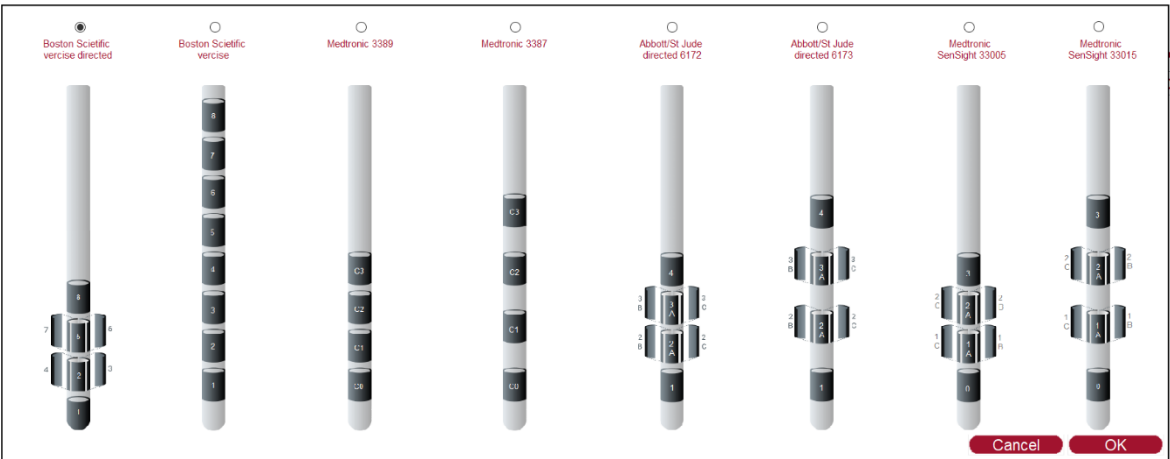


Figure 6 Lead selection

After filling in the previous information, trajectory information will be requested.

On this page, the user should select the surgery brain side (left or right), the BenGun* type (cross or plus), target depth in mm, to select in case if using the AlphaProbe electrode (cleared under K120098), and the placement of the selected electrode/s according to BenGun type. See figure 7.

*DBS surgery accessory components. For further information please refer to the Mechanical Accessories user manual.

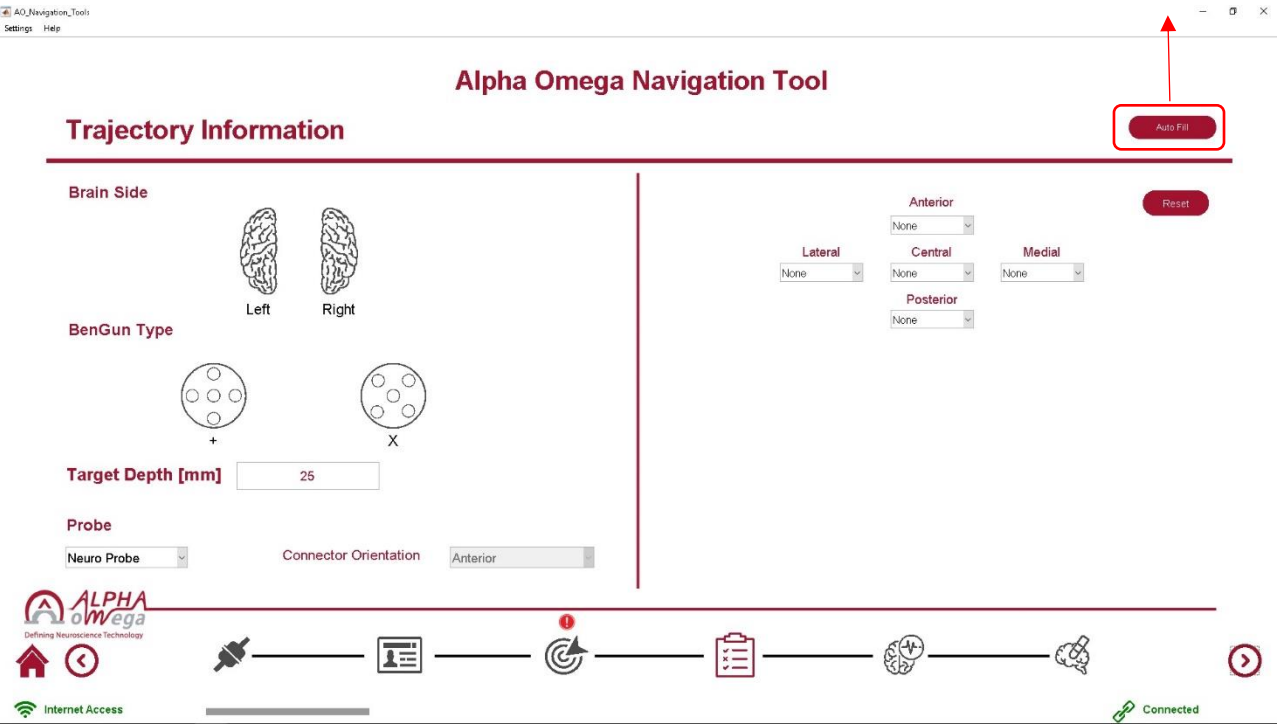


Figure 7 Trajectory Information

6. HAGUIDE FEATURES

6.1. HAGUIDE

On HaGuide as presented in figure 8 below:

RMS and PSD charts will be displayed after pressing “start”:

- Single view: show only the selected track
- Multiple view: show all available tracks

HaGuide chart:

- HaGuide results
- User results

STN results:

- Out of STN
- Dorsolateral Oscillatory Region (DLOR)
- Ventromedial Non-oscillatory (VMNR)

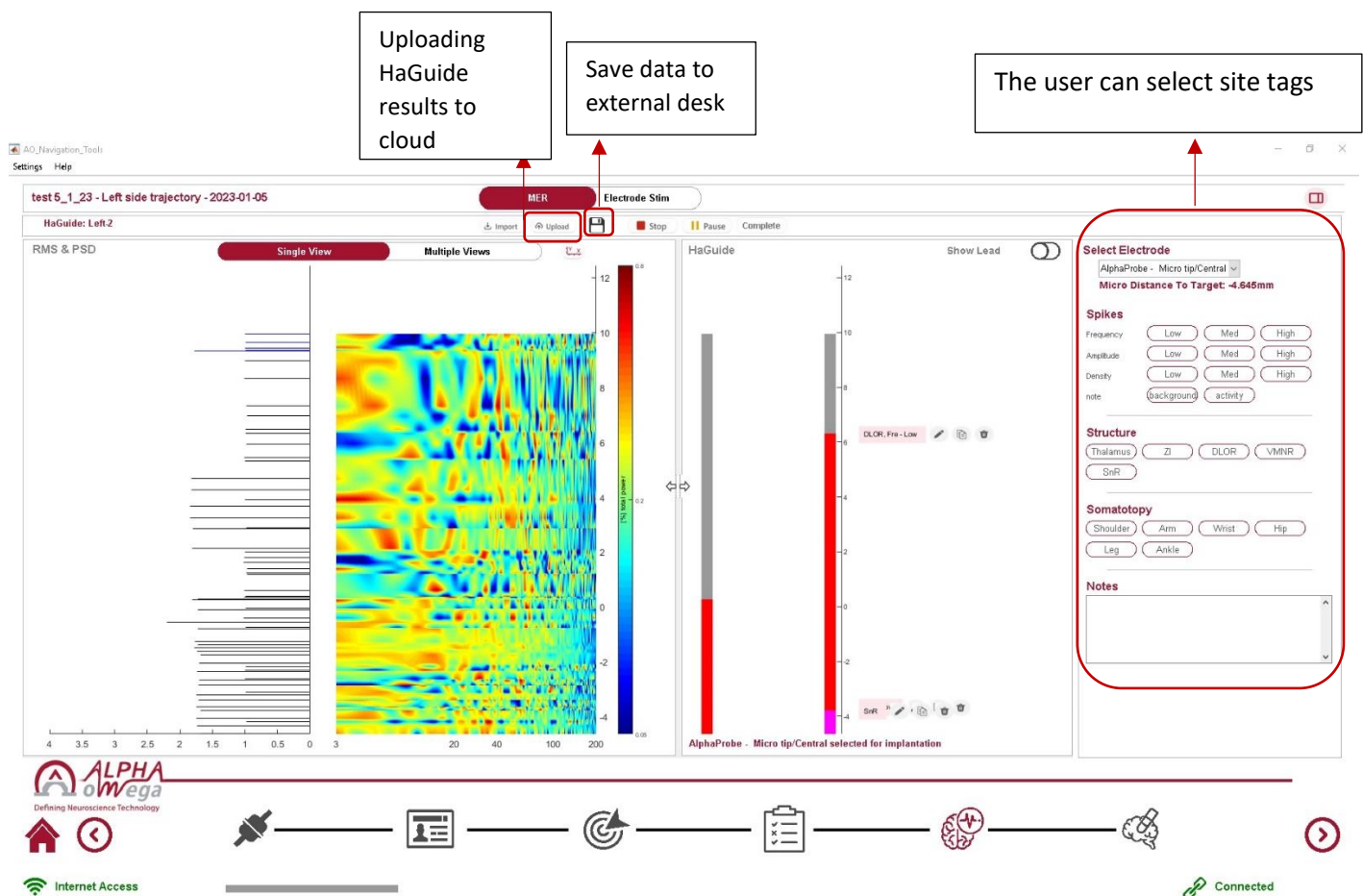


Figure 8 HaGuide

Electrode stim:

The user can select track/electrode and report the symptoms and side effects for the last electrode depth.



Figure 8 Electrode Stim

6.2. LEAD ELECTROPHYSIOLOGY

Following the implantation of the lead to the target region, the HaGuide can collect the recording electrophysiological DBS lead signals using the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739), process these data to PSD signals and display them on the software, see figure 9. This feature is only for displaying and documentation purposes of the electrophysiological DBS lead recording.

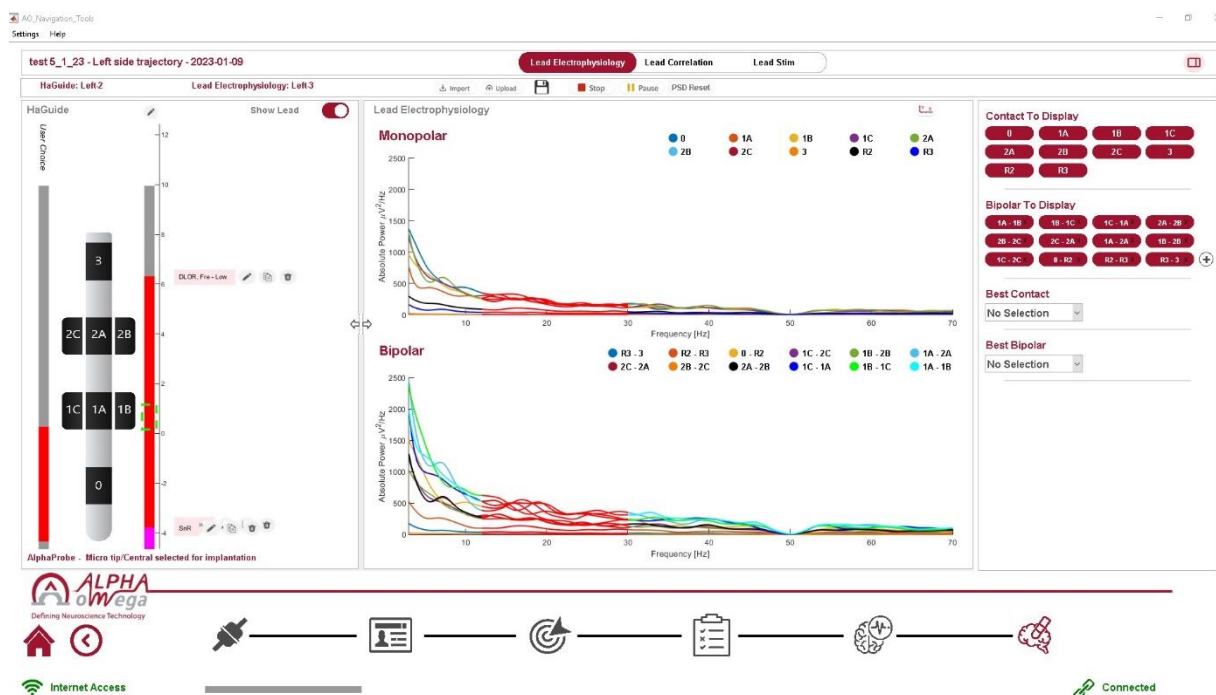


Figure 9 Lead Electrophysiology

6.3. LEAD CORRELATION

Following the lead recording, the HaGuide can analyze the correlation between electrophysiological signals recorded on Alpha Omega MER and those recorded on a compatible DBS Lead that was implanted in the STN by connecting the Neuro Omega or Neuro Smart system to the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739).

The algorithm extracts different Power Spectrum Density parameters of the MER and lead signals: β range (13-35 Hz) peak power, θ range (4-8 Hz) power and γ range (35-60 Hz) power. The correlation is done between the MER power spectra and the Lead power spectra. The results of the correlation are plotted on the Lead Correlation Plot.

The correlation calculation is performed from 2mm above the implanted lead depth to 2mm below the implanted lead depth, in intervals of 0.05 mm.

The algorithm then finds the depth which corresponds to the maximum correlation value computed.

The Lead Correlation plot shows location-based correlation value between peak values of recorded β waves (blue line); correlation between the power values of recorded θ waves (green line); and correlation between the power values of recorded γ waves (red line). Based on a weighed combination of these values, the black dot marks the location where correlation between the MER recording and the lead recording at these frequencies is highest.

Compare the MER with the lead recording and give correlation value

Red: γ

Green: θ

Blue: β

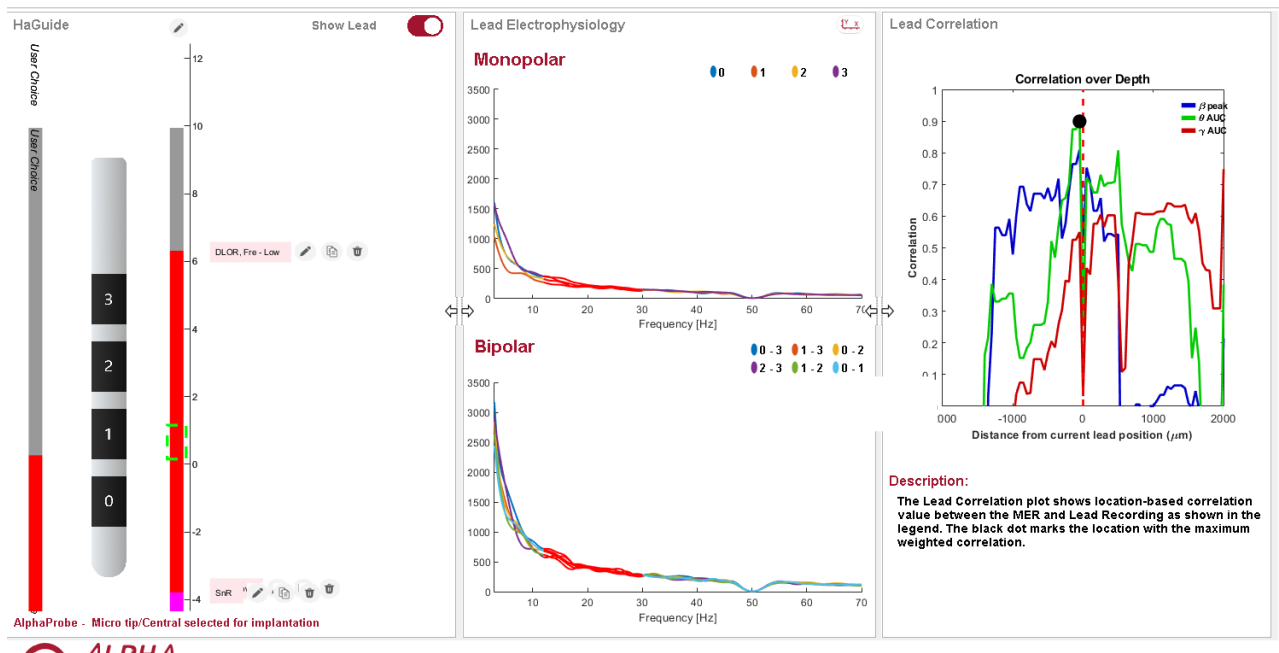


Figure 10 Lead Correlation

Lead Stim:

The user can select lead contact and report the symptoms and side effects for the lead contacts for documentation purposes only.



Figure 11 Lead Stim

6.4. INTERNET CONNECTIVITY

When the Neuro Omega incorporated the installed HaGuide is connected to the internet, all the intraoperative data collected during DBS surgery can be uploaded to the cloud for Neurologist use.

The cloud uploaded data (for example region and Coordination of the implantation, HaGuide results, lead correlation and placement, medication/ Anesthetizing) is saved for Neurologist to make an informative use of this data for future Neurology consideration, it helps in documenting the data from the OR.

APPENDIX A- Minimum Required Protection Information

Local user changes

It is necessary to create a local user without administrator privileges with a password.

Then open the manager's account (if it is cancelled) and create a password for it

1. Enter the control panel
2. Select Management Tools
3. computer management
4. Select the Users and Groups menu
 - Create a user with a password
 - Log into an administrator account and cancel the block
 - Right mouse clicks on the admin user and in the password field and creates a "complex" password for the admin

Updates and security

- 1) Go to settings
- 2) Go to Windows update and install all available updates
- 3) Check in advanced settings that update components for other Microsoft product
- 4) Go to Windows Security and check that everything is enabled and marked in green



Virus & threat protection
No actions needed.



Account protection
No actions needed.



Firewall & network protection
No actions needed.

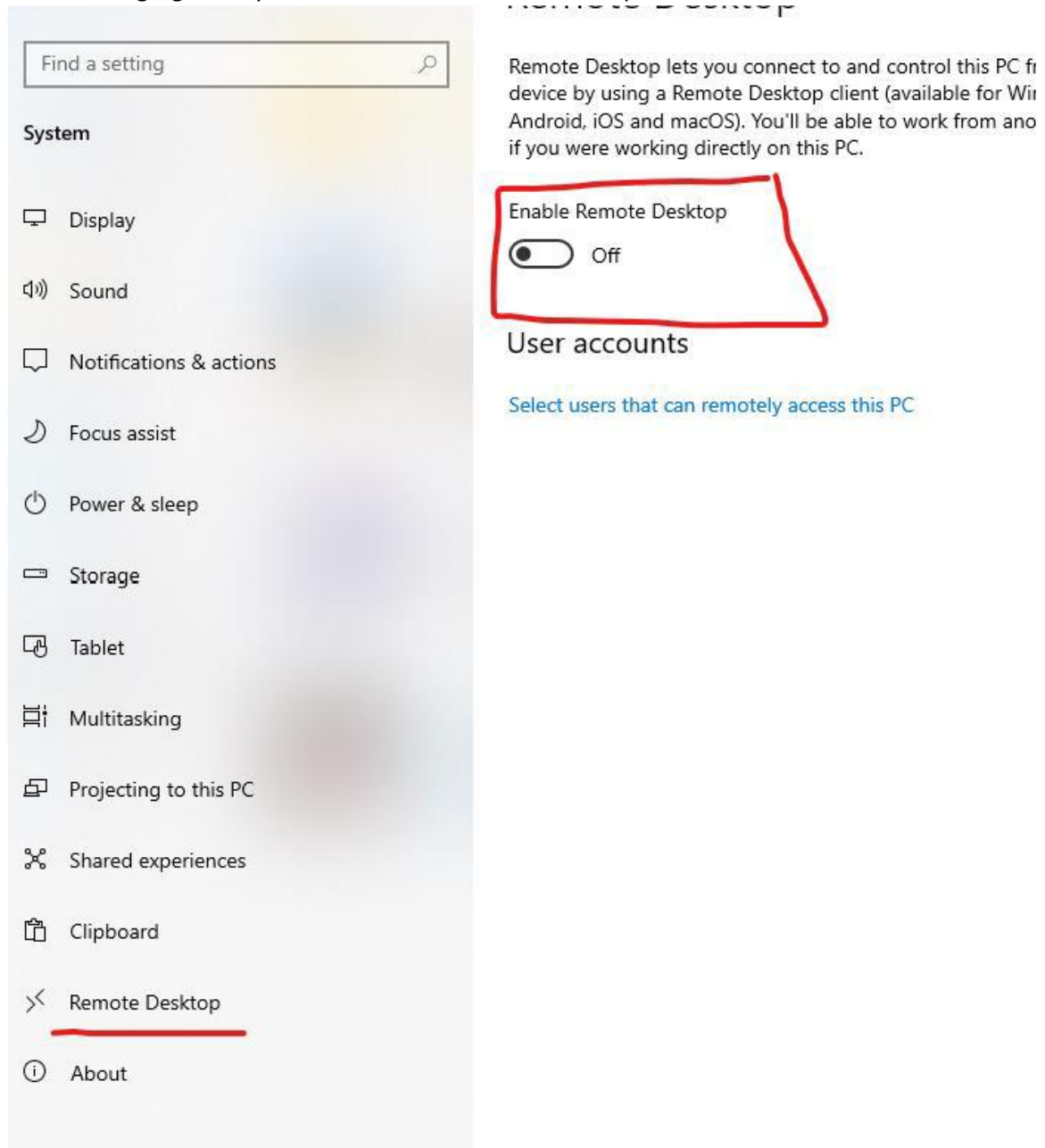


App & browser control
No actions needed.



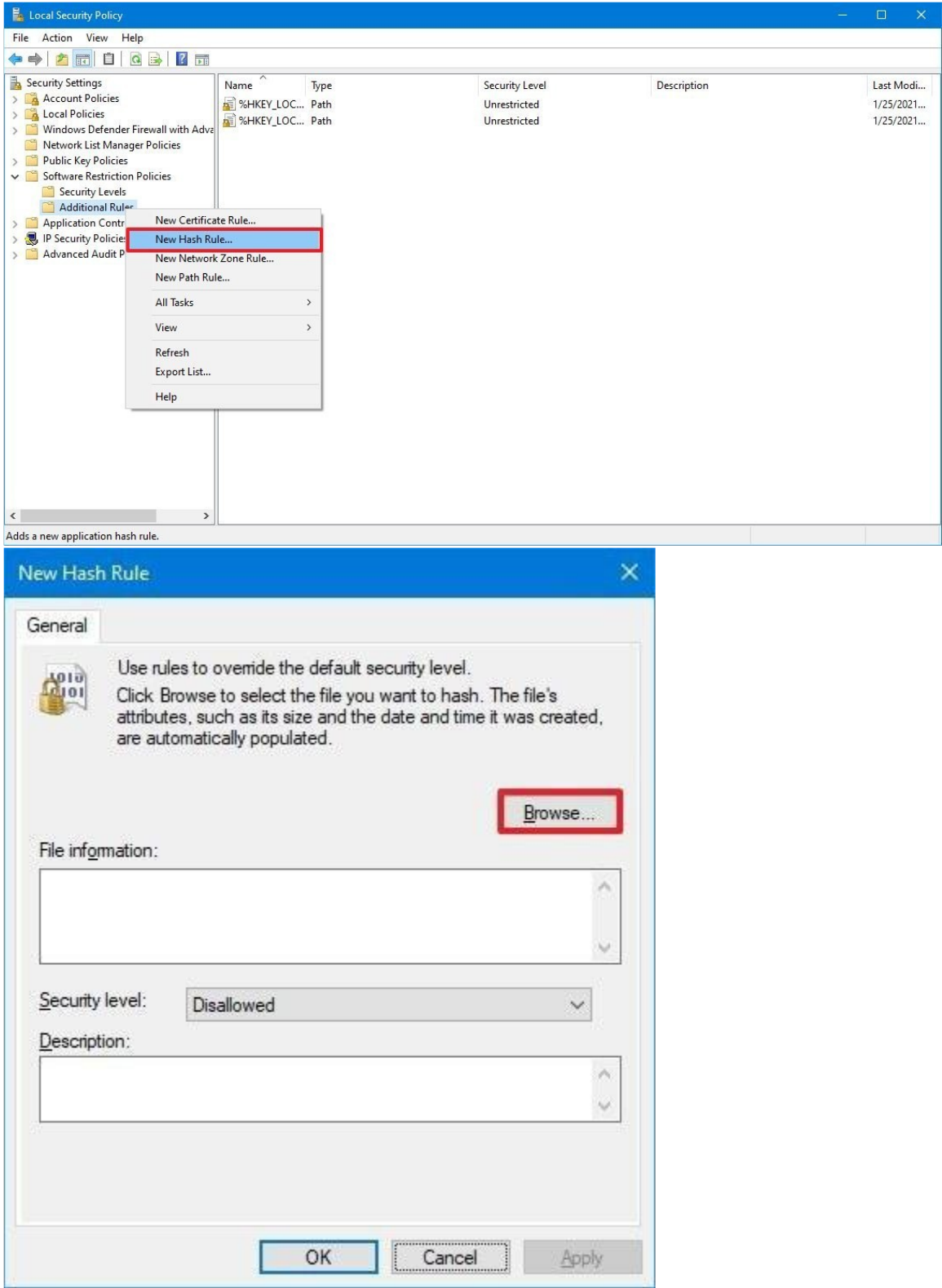
Device security
No actions needed.

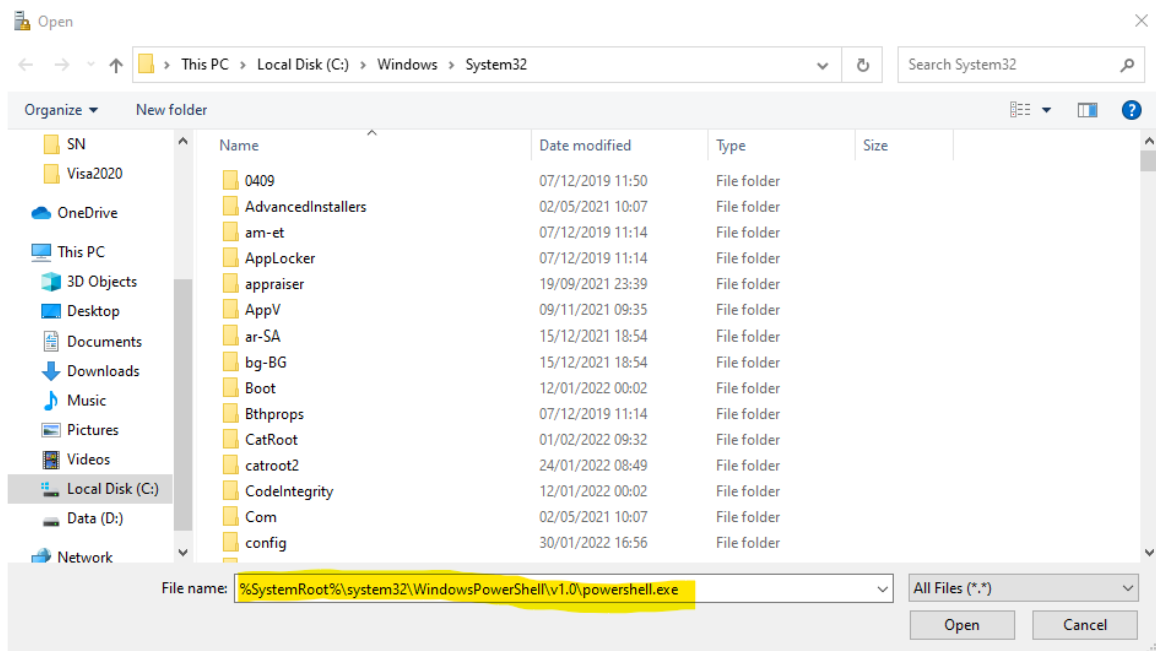
- 5) In the settings, go to "System" and select "Remote Desktop" and make sure that he cancels.



PowerShell blocking

- 1) run the command "Regedit"
- 2) reach the field:
HKEY_LOCAL_MACHINE\SOFTWARE\Microsoft\PowerShell\1\ShellIds\Microsoft.PowerShell
- 3) by right-clicking and selecting "new" and "string value"
- 4) Give the name "Restricted" to the new property and "ExecutionPolicy" to the value,
- 5) Run the command secpol.msc and act according to the following images.

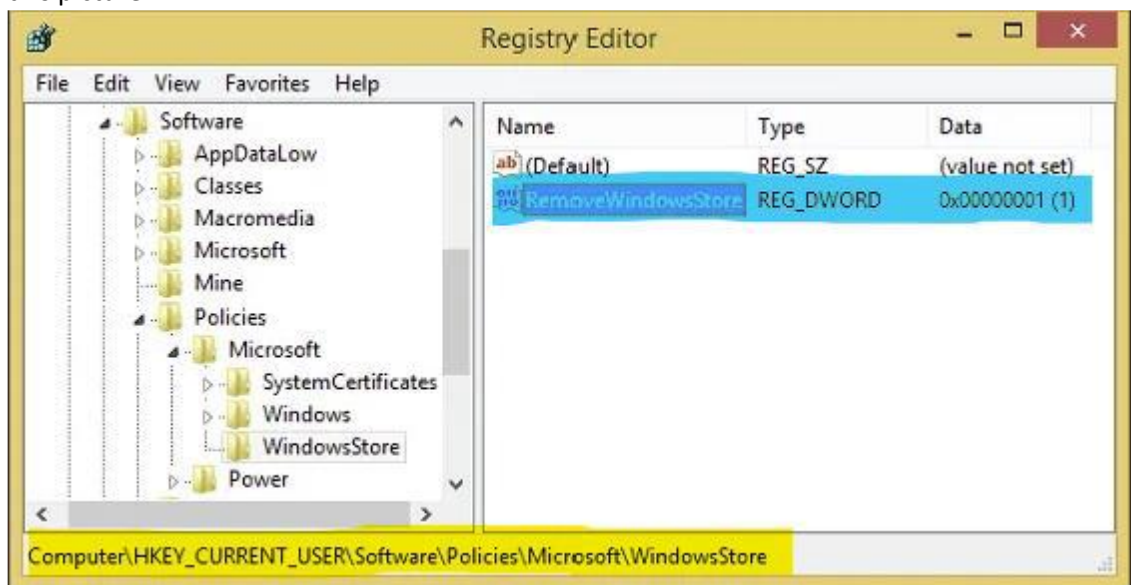




6) The same process again and now for Powershell_ise.exe file

7) Regedit:

Go to Regedit and reach the field marked in yellow and create the line marked in blue According to this picture:



Installation of protection software included EDR

Download from the following link and install, to place a license for the station after installation

<https://dzt-api-amzn-eu-west-1-9af7.apiupe>.

p.hmr.sophos.com/api/download/5585493eb1f1f9de867f8041056f7ebf/SophosSetup.exe

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