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Neuro Omega™

Physiological Navigation System for Neurosurgery and Neurophysiological Medical Applications

Advanced User Manual
Revision 1.5

CE 0297

2020-06

PROPRIETARY NOTICE

For additional information on the device, including questions on infection control procedures, please contact:

	EC REP
Contact Information:	**Name and Address of the European Authorized Representative:**
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Terms and Conditions

Thank you for your interest in Alpha Omega Engineering Ltd. ("ALPHA OMEGA") products and services. The following provisions set forth the terms and conditions on which ALPHA OMEGA sells Goods and provide Services (the Goods and Services jointly shall be referred to hereunder as the "Products").

Purchase of any Products sold by ALPHA OMEGA shall be subject to the terms and conditions contained herein. Buyer acknowledges and agrees that these terms and conditions supersede the terms and conditions of any purchase order or other documentation used by Buyer and, except for delivery and billing addresses, prices, quantities and items ordered, any conflicting or additional terms are void and have no effect, but that Buyer may place orders by use of purchase orders and other documentation for its convenience purposes only.

1. PRICE AND PAYMENT

1.1. The price of the Products will be ALPHA OMEGA's quoted price, exclusive of value added or other taxes, charges or duties payable as a result of the transaction. All pricing quotes must be documented in writing and signed by ALPHA OMEGA to be valid. All quotations issued by ALPHA OMEGA for the supply of Products shall remain open for acceptance for the period stated in the quotation or, if none is stated, for ninety (90) days. In all other cases, prices payable are those currently in effect in ALPHA OMEGA's then current pricelist. Unless otherwise agreed in writing, extra charges will apply for delivery and packaging.

1.2 Unless otherwise agreed in writing, payment in full shall be made to ALPHA OMEGA in the currency invoiced, no later than thirty (30) days from the date of invoice.

1.3 Until payment in full is received, the property in the Goods remains with ALPHA OMEGA and, if in the Buyer's possession, the Goods will be held by Buyer as bailee and returned immediately to ALPHA OMEGA upon demand in unused and undamaged condition.

1.4 In the event of late payment, ALPHA OMEGA reserves the right: (i) to suspend deliveries and/or cancel any of its outstanding obligations; and (ii) to charge interest at a rate of up to 1½% per month (or the highest rate permitted by applicable laws, if lower) from the due date. Buyer also agrees to pay all collection costs, expenses and reasonable attorneys' fees for collection of any amount due and unpaid.

2. SHIPMENTS, DELIVERY AND ACCEPTANCE

2.1 Freight charges (including shipment insurance) will be prepaid by Buyer. Orders will be shipped via a transportation mode, carrier and shipment insurance selected by ALPHA OMEGA. Unless otherwise stated in an agreement, shipment of Products will be made F.O.B. ALPHA OMEGA Factory in Israel (Incoterms 2000).

2.2 The Buyer shall inspect all Goods immediately upon their arrival and shall, within 7 days from such inspection, give notice in writing to ALPHA OMEGA of any matter or thing by reason whereof it is alleged that the goods are not in accordance with ALPHA OMEGA's specifications. Notwithstanding, a notice with respect to alleged failure to meet the specifications with respect to non-disposable products ("Capital Equipment"), which could not have been detected before the first use of the Capital Equipment may be made in writing within 7 days from the first use of the Capital Equipment, provided that such use will be made within forty five (45) days as of the delivery of the Product. All claims will be subject to the terms of the Warranty set forth in Section 5 hereunder, provided however that claims resulting from shipping damages will be subject to the terms of the applicable shipment insurance. If the Buyer shall fail to give the above notice, the Goods shall be deemed to comply in all respects with their specifications and any applicable contract.

2.3 In the event a package arrives with visible damages, Buyer should not open the package. Buyer shall immediately contact ALPHA OMEGA and shall comply with its instructions.

3. CANCELATION AND RETURNS

3.1 Any order by Buyer may be cancelled or changed only with the consent of ALPHA OMEGA at its discretion. Prior written consent from ALPHA OMEGA is required before a return will be accepted. If a Product is returned with such consent, it shall thereupon become the property of ALPHA OMEGA. Disposable items, sterile items and wearable items, can't be returned. Requests with

respect to return of Goods may be submitted in writing by Buyer within 45 days from the date of the invoice. It is hereby clarified that ALPHA OMEGA's consent may be granted only in the event the Goods do not meet ALPHA OMEGA's specifications in a material way and provided further that ALPHA OMEGA shall have the opportunity to repair any malfunctioning component or item, prior to granting such consent. All Products must be returned in saleable condition. ALPHA OMEGA will accept Products for return only if they are not damaged or used. Returned Product must be sent freight prepaid to the appropriate address indicated by ALPHA OMEGA. No credit will be issued for unauthorized returns.

3.2 When Products are authorized to be returned for any reason other than for breach of warranty, the amount of credit will be subject to a minimum restocking charge of 30%, provided however that in the event that the Goods were customized per Buyer's request, additional charge will be added.

4. BUYER'S RESPONSIBILITY

4.1 Buyer shall ensure that the Products will be operated by trained and competent operators only.

4.2 BUYER shall ensure that Products is operated in a safe and competent manner in strict compliance with established safety operating procedures (including ALPHA OMEGA's User's Manual as revised from time to time) and applicable laws and regulations.

4.3 BUYER shall notify ALPHA OMEGA promptly as soon as any unusual operating peculiarity appears.

4.4 BUYER shall notify ALPHA OMEGA if the Products are moved from its present location. Should the Buyer choose to move Products to a new location, the packing, unpacking, and actual movement of the Products is at the Buyer's sole responsibility, cost and expense.

5. WARRANTY

5.1 ALPHA OMEGA warrants that its Goods substantiality meet ALPHA OMEGA's specifications at the time of delivery and shall be substantially free from defects in material and workmanship for as long as they are used on or before the specified expiry date of the product and used in accordance with the written instructions for use issued by ALPHA OMEGA on the date the Goods were shipped to Buyer. The warranty set forth herein is conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations of ALPHA OMEGA. All warranties for Goods shall expire at the earlier of the product expiration date and one (1) year from the date of shipment from ALPHA OMEGA.

5.2 ALPHA OMEGA's warranty hereunder shall not apply: (i) if a Product is not used in accordance with its instructions or if it is used for a purpose not indicated on the specifications; (ii) if any maintenance, repairs, modifications, alterations or other work has been performed by Buyer or others on such item, other than work performed by ALPHA OMEGA or with ALPHA OMEGA's authorization and according to its approved procedures; (iii) if Products have been subject to abuse, misuse, negligence, accident, improper installation, maintenance or use; (iv) if Products have been combined with or installed on/with products, or equipment of the Buyer or any other third party, not authorized in writing by ALPHA OMEGA; (v) for wear and tear damage, damages due to liquids, moisture, freezing, computer viruses or other damage incurred by the acts or omissions of the Buyer or its employees or agents and/or abnormal working conditions at the Buyer's premises; or (vi) have been damaged by causes beyond the control of ALPHA OMEGA (including without limitation, shipping and conveying damages and damages made as a result of force majeure) (the "Warranty Exclusions"). The warranty furnished hereunder does not extend to damage to items purchased hereunder resulting in whole or in part from the use of components, accessories, part s or supplies not furnished by ALPHA OMEGA.

5.3 ALPHA OMEGA will not be responsible for damage incurred to the P roducts' attachments caused by sterilizing of the attachments using techniques other than those recommended to Buyer by ALPHA OMEGA.

5.4 All warranty claims on Goods must be made in writing within the warranty period set forth above and by not more than seven (7) days after Buyer first learned of the defect, provided however that claims with respect to damages, defects and/or non-compliance with specifications which could have been observed or detected by Buyer within the applicable notice period set forth in Section 2.2 above will be subject to such shorter notice period. Buyer shall provide ALPHA OMEGA a detailed explanation of any warranty claim on goods.

5.5 ALPHA OMEGA's sole obligation and Buyer's exclusive remedy for a breach of this warranty shall be to repair, replace or refund, at ALPHA OMEGA's discretion, any malfunctioning component or item, provided that ALPHA OMEGA is reasonably satisfied that claimed breach of warranty actually exists and was not caused by the Warranty Exclusions. ALPHA OMEGA further reserves the right to substitute and use, at its option, new and/or improved, or remanufactured parts, which are capable of performing a function similar to that of the replaced parts. Buyer shall provide labor for the removal of the defective component or item and installation of its replacement at no charge to ALPHA OMEGA. Buyer shall bear all risk of loss or damage to returned

Goods while in transit. In the event no defect or breach of warranty is discovered by ALPHA OMEGA upon receipt of any returned item, the item will be returned to Buyer at Buyer's expense and Buyer will reimburse ALPHA OMEGA for the transportation charges, labor and associated charges incurred in testing the allegedly defective item.

5.6 ALPHA OMEGA will not be responsible for replenishing BUYER's supply of items consumed or damaged during the use of the Products. This includes but is not limited to: Microelectrodes, Deep Brain Stimulation (DBS) Electrodes, EMG Contact Electrodes, Guiding Cannula, flexible shafts, compact disks, electrode cables, electrode holders and any other item consumed in the course of using the Products.

5.7 ALPHA OMEGA shall not be under any obligation to provide warranty hereunder for Products which were removed from the originally identified location without ALPHA OMEGA's prior written consent.

5.8 With respect to Services - ALPHA OMEGA warrants that all Services to be provided by ALPHA OMEGA under applicable services agreement or its warranty obligation hereunder will be carried out with reasonable care and skill. ALPHA OMEGA's sole liability for breach of this warranty shall be to re perform the Services in question. This warranty shall only extend for a period of thirty (30) days after the completion of the applicable Services and any claim shall be submitted in writing within such period.

5.9 EXCEPT AS EXPRESSLY PROVIDED HEREIN, ALPHA OMEGA PROVIDES THE GOODS "AS IS", WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND, WHETHER STATUTORY EXPRESSED OR IMPLIED, WITH RESPECT TO ANY PRODUCTS, PARTS OR SERVICES PROVIDED BY ALPHA OMEGA, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY AS TO THE GOODS' TITLE, QUALITY, ACCURACY, COMPLETENESS, OPERABILITY, USE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. THE SOLE AND EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY IS LIMITED TO THE REMEDIES PROVIDED HEREIN ABOVE.

5.10 Products provided, but not manufactured, by ALPHA OMEGA are not warranted by ALPHA OMEGA and Buyer must instead rely on the representations and warranties, if any, provided directly to Buyer by the manufacturer of such product.

6. LIMITATION OF LIABILITY

6.1 ALPHA OMEGA shall not be liable for any loss or damage due to inability to use the Products, or due to failure of the Products to perform properly. BUYER agrees to hold ALPHA OMEGA harmless from any loss or damage arising out of the maintenance, operation or use of the Products, or any test Products, other than any loss or damage directly and solely resulting from the negligence of ALPHA OMEGA.

6.2 ALPHA OMEGA SHALL NOT BE SUBJECT TO NOR INCUR, AND THE BUYER HEREBY RELEASES ALPHA OMEGA FROM, ANY CLAIM, ACTION OR LIABILITY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL LOSS OR DAMAGE TO PERSONS OR PROPERTY, OR DAMAGES OTHERWISE ARISING OUT OF OR IN CONNECTION WITH FURNISHING OF PRODUCTS, PARTS OR SERVICE HEREUNDER, OR THE PERFORMANCE, USE OF, OR INABILITY TO USE ANY PRODUCTS, PARTS OR SERVICE, OR OTHERWISE, WHETHER BASED IN CONTRACT, WARRANTY, TORT, INCLUDING WITHOUT LIMITATION, NEGLIGENCE, OR ANY OTHER LEGAL OR EQUITABLE THEORY EVEN IF ALPHA OMEGA HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES IN PARTICULAR ALPHA OMEGA WILL NOT BE LIABLE FOR LOSS OF PROFITS, SAVINGS OR REVENUE; DAMAGE TO REPUTATION; LOSS OF USE OF A PRODUCT OR ANY ASSOCIATED PRODUCTS; COST OF CAPITAL; COST OF ANY SUBSTITUTE GOODS, PRODUCTS, FACILITIES OR SERVICES; DOWNTIME; AND THE CLAIMS OF THIRD PARTIES INCLUDING BUYER'S CUSTOMERS.

6.3 ALPHA OMEGA's total liability for any claim or action shall not exceed the prorated purchase price actually paid by Buyer for the Products out of which such claim or action arose.

7. GENERAL

7.1 These Terms and Conditions and any dispute or claim arising out of or relating to these terms or the sale of Products (" Claim") shall be governed by and construed under laws of the state of Israel, notwithstanding its law of conflicts of law. If any Claim cannot be settled amicably between the parties, the parties hereby submit the Claim to the exclusive jurisdiction of the courts of the State of Israel.

7.2 These Terms and Conditions constitute the entire agreement between ALPHA OMEGA and Buyer with respect to t h e subject matter hereof. Any previous agreements between the parties with respect to the subject matter hereof are superseded. Notwithstanding the foregoing, additional special terms and conditions of ALPHA OMEGA may be applicable with respect to

certain products and to the Services provided by Alpha Omega, such additional terms and conditions shall be provided in a separate agreement.

7.3 Any representation, promise, statement or description by ALPHA OMEGA or by any officer, employee, consultant, agent, or dealer of ALPHA OMEGA or any other person is expressly excluded and the Buyer acknowledges that it has relied solely upon its own inspection, skill and judgment in placing an order for the Goods or Services and not by reason of any such representation, promise, statement or description.

7.4 No changes to, waiver of, or addition to any of these terms and conditions shall be effective unless agreed to in writing and signed by ALPHA OMEGA. ALPHA OMEGA reserves the right at any time to amend these terms and conditions, and Buyer shall be deemed to accept such amended terms and conditions by ordering products herein offered after the date of such amendment. ALPHA OMEGA's failure or delay to exercise or enforce any of its rights hereunder shall not constitute or be deemed to be a waiver of such rights or forfeiture of such rights, and ALPHA OMEGA may, at its option, from time to time, exercise any of its rights or remedies.

7.5 ALPHA OMEGA will use its reasonable efforts to fill orders, but ALPHA OMEGA shall not be liable for nonperformance or delays caused by a shortage of raw materials, manufacturing problems, delivery or labor problems, priorities, acts of regulatory agencies or judicial bodies, discontinuation of a product line, acts of God? or third parties, infringement claims, or other causes beyond its reasonable control. Buyer agrees that in such events ALPHA OMEGA may allocate Products among all Buyers as it deems reasonable, without liability. ALPHA OMEGA reserves the right from time to time to substitute a Product with a product that has the same function as such Product, or to delete a Product.

7.6 Any notices required or permitted under this Agreement shall be in writing and shall be deemed delivered upon personal delivery, overnight delivery or three days following deposit in the mail addressed as follows, in the case of ALPHA OMEGA, to: Nazareth Industrial Park Building Mount Precipice P.O. Box 2268 Nazareth 1612102, Israel, and in the case of Buyer, at the address designated on Buyer's purchase order or to such other address as either party may substitute by written notice.

7.7 Buyer will comply with all federal, state and local laws (including the Uniform Commercial Code), regulations and ordinances applicable to its business and

activities and will indemnify ALPHA OMEGA for any and all claims, damages, penalties, assessments and liabilities imposed on ALPHA OMEGA relating to or resulting from Buyer’s failure to comply with such applicable laws, regulations and ordinances.

7.8 These Terms and Conditions bind Buyer and its successors and permitted assigns.

7.9 Buyer may not change, adulterate, obscure, remove or deface trademarks, tradenames or labels appearing on any Product of ALPHA OMEGA.

7.10 In all cases, all intellectual property rights in and to, and all technology relating to, the Products supplied to Buyer, their design and all improvements thereto or thereof, whether or not such Product, design or improvement is made pursuant to Buyer's specifications or at Buyer's expense, shall be and remain the exclusive property of ALPHA OMEGA.

7.11 If any of the products are medical devices, Buyer acknowledges that it is familiar with the Safe Medical Devices Act of 1990 (the "Devices Act") and the reporting obligations imposed on device users thereunder. In this regard, Buyer agrees to notify ALPHA OMEGA within ten (10) days of the occurrence of any event identified in the Devices Act imposing a reporting obligation on Buyer and/or ALPHA OMEGA (except for events representing an imminent hazard that require notification to the United States Food and Drug Administration (the "FDA") within seventy-two hours, in which case, such notice will be delivered to the other party immediately). Buyer shall maintain adequate tracking for the products to enable ALPHA OMEGA to meet the FDA requirements applicable to the tracking of medical devices.

7.12 Buyer shall purchase the Products for its own use only, and shall not resell the Products to any other party. Buyer represents it has examined the Products and that they are acceptable and clinically suitable for its intended purposes.

7.13 All intellectual property rights in the Products shall at all times remain vested in ALPHA OMEGA and/or its licensors. Any user license as may be granted to the Buyer shall be non-transferable and non-exclusive and shall only be used for the Buyer’s own internal business purposes of operating the Goods. The use of the Products shall be subject to the terms and conditions of such user license. Off the shelf license products embedded in the Product are subject to the EULA governing the license thereof.

Contents

CHAPTER 1. OVERVIEW

The Neuro Omega system is designed for different neurosurgery and neurophysiologic clinical applications including recording from and stimulate brain motor and sensory neurons to accurate navigation of electrodes for neurosurgery target localization in treatment of movement disorders by and to aid in the placement of depth electrodes.
The device is also designed for measuring bioelectric signals produced by muscles and stimulate peripheral nerves to aid in the diagnosis and prognosis of neuromuscular disease (EMG).
The device may also be used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).
The subject device, the Neuro Omega System may also be used to measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes.
The subject device, the Neuro Omega System may also be used to provide stimulation via electrode pairs or a hand held bipolar probe for use in functional brain mapping procedures during treatment of patients with seizure disorder.

1.1. SCOPE

The purpose of the Neuro Omega Medical Manual is to provide information for the use of the Neuro Omega system in medical treatment.

> **Warning:**
> Do not use this manual for conducting research procedures.

1.2. REGULATORY

1.2.1. Adverse Effects

The possible adverse effects relating to Stereotactic Neurosurgery are:

- The possibility of intracranial hemorrhage associated with the introduction of probes into the brain.
- Visual field impairment with optic tract injuries.
- Contra lateral motor deficit with corticospinal injury.

1.2.2. FDA System Classification

- **Product Code**: GZL
- **Subsequent Product Code**: GWF, IKN, GWQ, GYC

- **CFR Section**: 21 CFR 882.1330
- **Regulation Name**: Depth electrode
- **Subsequent Regulation Names**:
  - Electroencephalograph
  - Stimulator
  - Electrical
  - Evoked response
  - Electromyography
  - Diagnostic
- **Trade Name**: Neuro Omega System
- **Common Name**: Intraoperative neurophysiological recording and stimulating device
- **Classification**: Class II

1.3. INTENDED USES

Neuro Omega system 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 Neuro Omega System 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 seizure disorder.

The device is intended for intraoperative use by medical personnel. Within hospitals, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

1.4. 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 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 Neuro Omega system use conditions:

- **Environment**:
  - Conditions of visibility:
    - Ambient luminance range: Normal
    - Viewing distance: N/A
    - Viewing angle: N/A
  - **Physical**:
    - Temperature range: 0°C to +40°C
    - Relative humidity range: 10% - 80%, non-condensing
    - Ambient pressure range: 500 hPa to 1060 hPa
    - Background sound pressure level: Normal
- **Frequency of Use**: As per specific case
- **Mobility**: Mobile

1.5. WARNINGS

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 other) on the system unless provided by Alpha Omega Ltd. for the explicit use on the Neuro Omega.
- Neuro Omega system and Neuro Omega drive Headstage should be connected to Alpha Omega NeuroProbes for recording and stimulation
- External systems connected to the Neuro Omega must be independently isolated, or powered through the trolley, as this has its own isolation transformer.
- Possible hazard caused by the summation of leakage currents when several items of equipment are interconnected.

- The Neuro Omega system should be placed outside of the patient environment or any area that can, intentionally or unintentionally, come in contact with the patient.
- A thorough understanding of the technical principles, clinical applications, and risks associated with this treatment is necessary before using this system. Please read this entire manual before attempting to activate the system. Completion of the training program is required prior to use of the Neuro Omega system.
- The Neuro Omega does not incorporate means to protect the patient against burns when used with high frequency surgical equipment.
- The analog and digital input output panel (ADIO) is not an applied part, and therefore should not be connected to the patient without proper electrical isolation.
- In case of unwarranted SW crash/freeze, disconnect patient Head stage cable from Neuro Omega prior to turn off/on system.
- In case of unwarranted Remote Control crash/freeze, disconnect Remote Control cable from Neuro Omega system and reconnect it.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Neuro Omega, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

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.

Notes:

- Some of the Neuro Omega system components can be provided either non-sterile or sterile. Please refer to *Preparing the Neuro Omega System* for detailed sterilization instructions of system and accessories.
- It is the user's responsibility to qualify any deviations from the recommended method of processing.
- There are no expected hazards resulting from simultaneous use of other patient-connected medical electrical equipment, for example, a cardiac pacemaker or other electrical stimulators.
- Please contact the manufacturer or local distributor to request a copy of the insulation diagram if needed.
- The Neuro Omega can be operated normally after the interruption of supply mains.

- Dispose the equipment at the end of its service life according with local regulations
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

1.6. ELECTROMAGNETIC CONFORMANCE

The following tables contain information on electromagnetic emissions for guidance and manufacturer's declaration:

- ***Guidance and Manufacturer's Declaration – Electromagnetic Emissions***
- ***Guidance and Manufacturer's Declaration – Electromagnetic Immunity***
- ***Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Neuro Omega***

Notes:

- This product has been tested and found to comply with the limits for Class A Medical Device according to IEC 60601-1 and IEC 60601-1-2 Standards. The limits for Class A equipment were derived for medical environments to provide reasonable protection against interference with licensed communication and medical equipment.
- This product must be installed and put into service according to the EMC information provided in the tables below.
- Portable and mobile RF communications equipment can affect this product.

Warnings:

- This is a Class A product. This product is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Neuro Omega or shielding the location.
- The use of accessories, transducers, and cables other than those specified by the manufacturer may result in increased emissions or the decreased immunity of the Neuro Omega.
- The Neuro Omega should not be used adjacent to or stacked with other equipment. If adjacent of stacked use is necessary, the Neuro Omega should be observed to verify normal operation in the configuration in which it will be used.

The Neuro Omega is intended for use in the electromagnetic environment specified in ***Table 1***. The user of the Neuro Omega should assure that it is used in such an environment.

Table 1: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1, Class A	The Neuro Omega uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interferences in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The Neuro Omega is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Warning**: Neuro Omega is intended for use by healthcare professionals only. Neuro Omega may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Neuro Omega or shielding the location.
Voltage fluctuations/flicker emissions IEC 61000-3-3: 2013	Complies	

The Neuro Omega is intended for use in the electromagnetic environment specified in ***Table 2***. The customer or the user of the Neuro Omega should assure that it is used in such an environment.

Table 2: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 test level	Compliance	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be less than 30%.
Electrostatic fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% U_T; 1cycle and 70% U_T; 25/30 cycles Single phase at 0° 0% U_T; 250/300 cycle	0% U_T; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% U_T; 1cycle and 70% U_T; 25/30 cycles Single phase at 0° 0% U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Neuro Omega requires continued operation during power mains interruptions, it is recommended that the Neuro Omega be powered from an uninterruptible power supply (UPS) battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the Neuro Omega, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3V/m	3V/m	

	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	3V/m from 0.15 to 80MHz; 6V/m from 0.15 to 80MHz and 80% AM at 1kHz 10V/m from 80MHz to 2.7GHz	Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Neuro Omega is used exceeds the applicable RF compliance level above, the Neuro Omega should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Neuro Omega.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

The Neuro Omega is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Neuro Omega can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Neuro Omega as recommended in ***Table 3***, according to the maximum output power of the communications equipment.

Table 3: Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Neuro Omega

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHZ to 2.5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

For transmitters rated at maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 - 390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710		LTE Band 13,		0.2	0.3	9	9

745 780	704 - 787	17	Pulse modulation[b]) 217 Hz				
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b]) 18 Hz	2	0.3	28	28
1720 1845 1970	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b]) 217 Hz	2	0.3	28	28
2450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b]) 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation[b]) 217 Hz	0.2	0.3	9	9
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							

There are functions that are essential for safe use of the Neuro Omega:

1. Max stimulation amplitude 7mA
2. Stimulation amplitude accuracy
3. Limitation of Headstage max movement
4. Limitation of max step size

Severe Electromagnetic disturbance beyond specified in following tables can cause degradation of these functions and may lead to hazardous situation:

1. The Stimulation pulses should not exceed the maximum amplitude
2. The stimulation pulses must be within 15% of the required amplitude
3. The drive should not exceed 1mm in each step
4. The Drive should not move down the depth of 40mm

CHAPTER 2. SYSTEM DESCRIPTION

The Neuro Omega system consists of the following units:

- ***Main Unit and Trolley***: The Main Unit contains all interfaces with analog and digital inputs and outputs unit, as well as all connections to the different modules. The Main Unit, the screens and speakers, and the computer are all fitted on the trolley.
- ***Drive Headstage Module***: Includes the Drive Headstage, which contains the mechanism that manipulates the electrode, records from the electrode, and provides stimulation**.**
- ***MER*** Headstage Module***:*** Includes the MER Headstage, which contains the mechanism that records from the electrode and provides stimulation
- ***Headbox Modules***: Of two types. One allows for recording EMG signals, and one allows for recording EEG signals.
- ***Remote*** Control: Allows for easy system operation, including manipulating the electrode and providing stimulation through the Drive Headstage.

2.1. MAIN UNIT AND TROLLEY

The Main Unit is the processing core of the system, and is attached to the trolley. The Main Unit is comprised of the following three panels:

- The front panel (***Figure 1***) houses LEDs to display Neuro Omega's power state. When functioning properly, the green LED on the top is lit and there are at least 3 cyclically flashing lights in the center of the panel.

Figure 1: Front Panel

- On the right side is the Modules panel (***Figure 2***), which houses the following connections:

Connection	Location	Reference
Drive Headstage / MER Headstage	green	See section 2.2 for information about the Drive Headstage and the Drive Headstage module. See section 2.3 for information about the MER Headstage.
Headbox modules according to configuration	cascading up, multicolored	See section 2.4 for information about the Headbox modules.
Remote	Small, yellow	See section *0* for information about the remote.

Figure 2: Modules Panel

- On the left is the Analog/Digital Input/Output panel (ADIO panel) (***Figure 3***), which houses the external connections, through BNC and D-Type, as follows:
  - ANALOG-IN: Eight analog input ports, sampled in 12-bit ADC, and acquired in continuous mode
  - ANALOG-OUT: Eight analog output ports, sampled in 16-bit DAC, for rerouting any signal to an external device
  - DIG-IN: Four digital input ports, sampled as single bits or 16-bit ports
  - DIG-IN: Two digital input ports, sampled as 16-bit ports
  - DIG-OUT: Eight digital output ports for future use

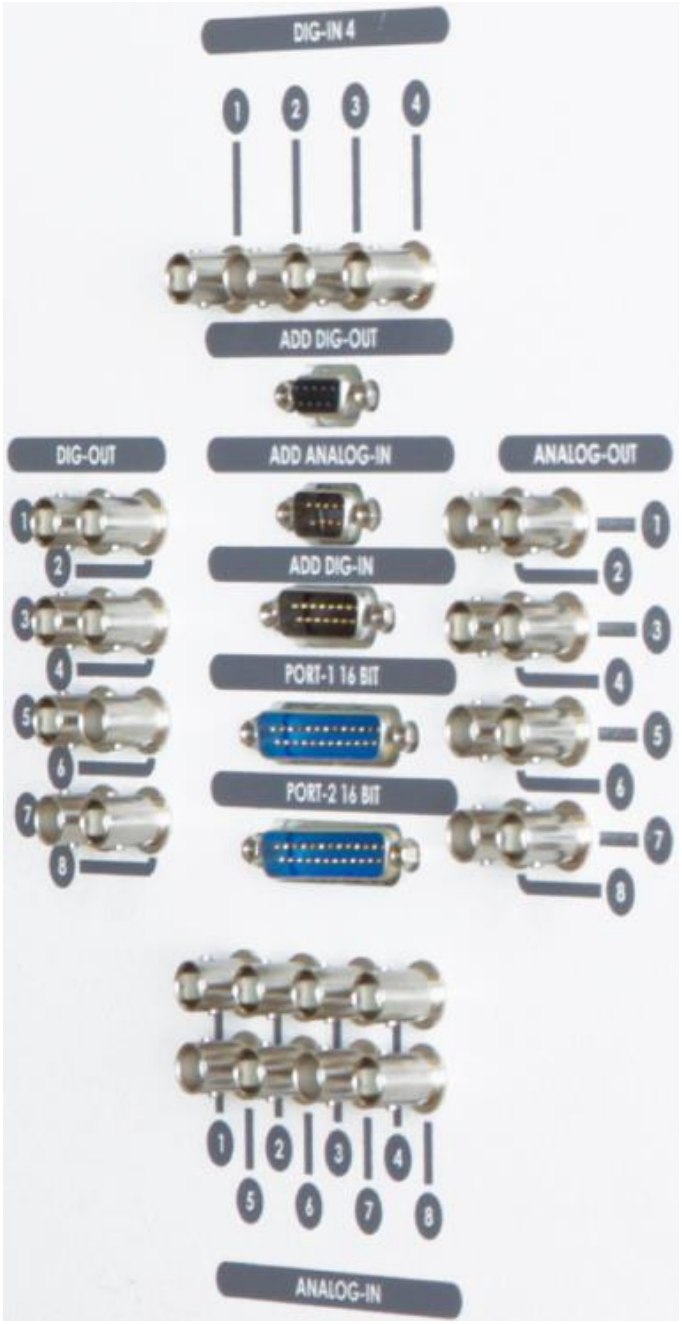


Figure 3: ADIO Panel

The bottom of the Main Unit (***Figure 4***, as seen from under the main unit) houses the following connections:

- Three Ethernet connections for communication between the Main Unit and the computer
- Connection to the computer for the remote control via USB
- Two audio output connections
- Power switch for main unit

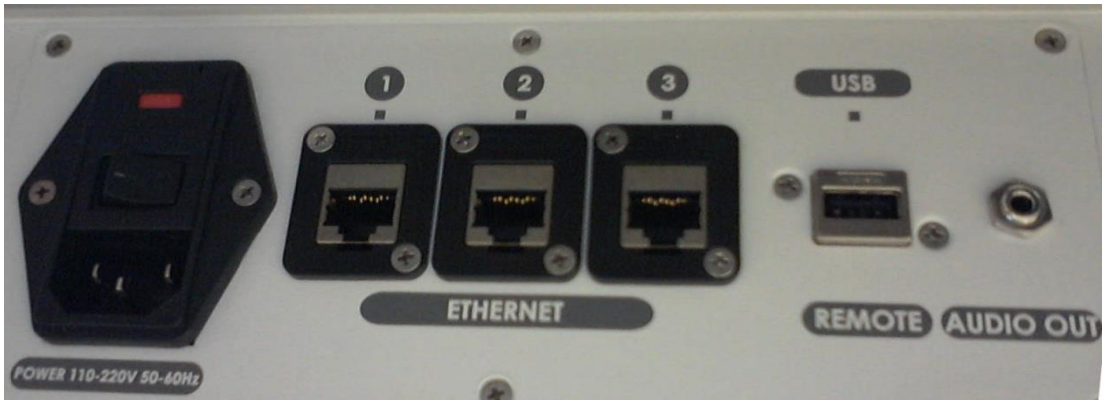


Figure 4: Bottom of Main Unit

The trolley (***Figure 5***, ***Figure 6***, and ***Figure 7***) is utilized as follows:

- On the left, the computer, a panel PC connecting to the Main Unit via Ethernet
- System On/Off switch
- On the right, a second monitor
- Two speakers
- The Main Unit
- Above the Main Unit, resting on the outer surface, the keyboard and mouse
- Below the Main Unit, a standalone storage box
- Storage arms for cable wrapping
- Rear:
  - Handle
  - Holders for Headbox modules
  - Holder for the remote control

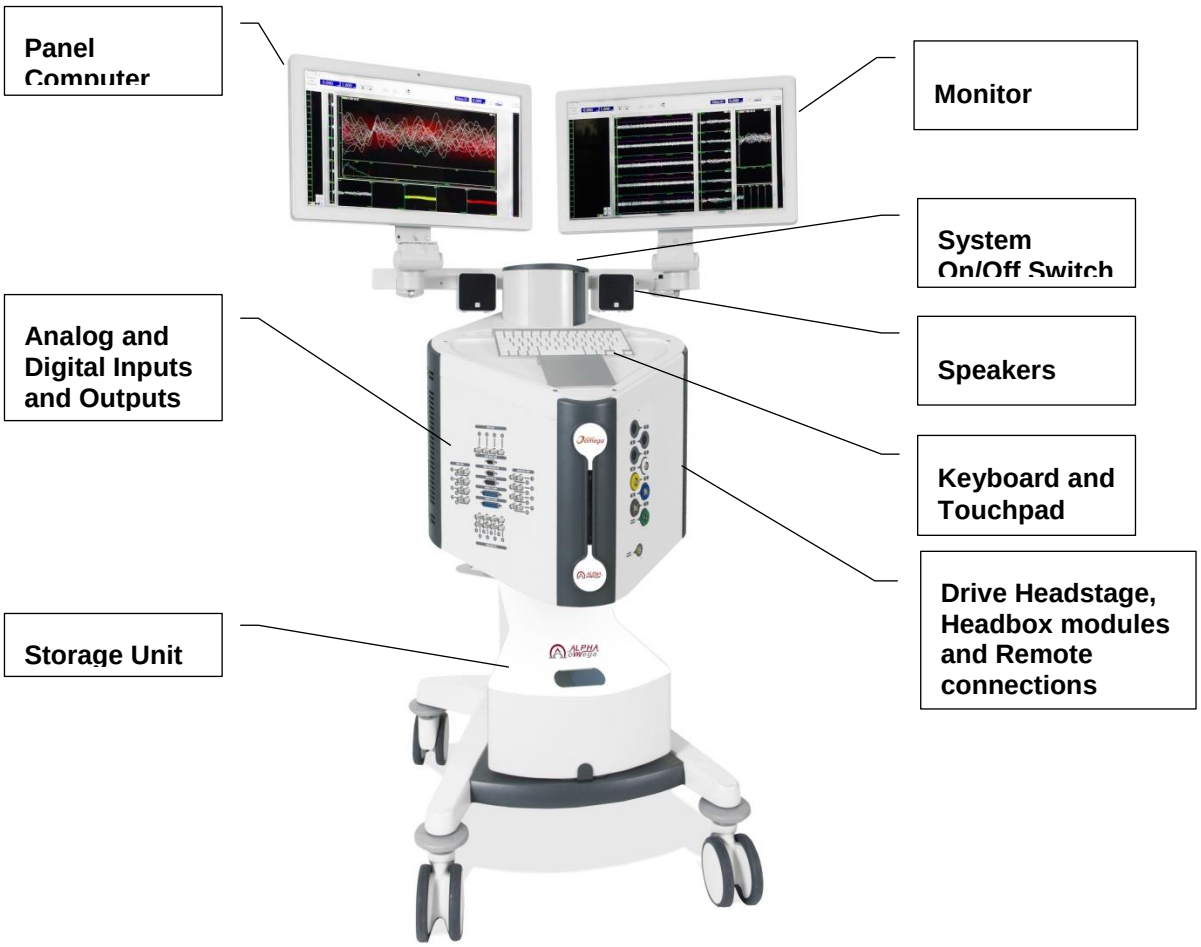


Figure 5: Main Unit and Trolley Front View

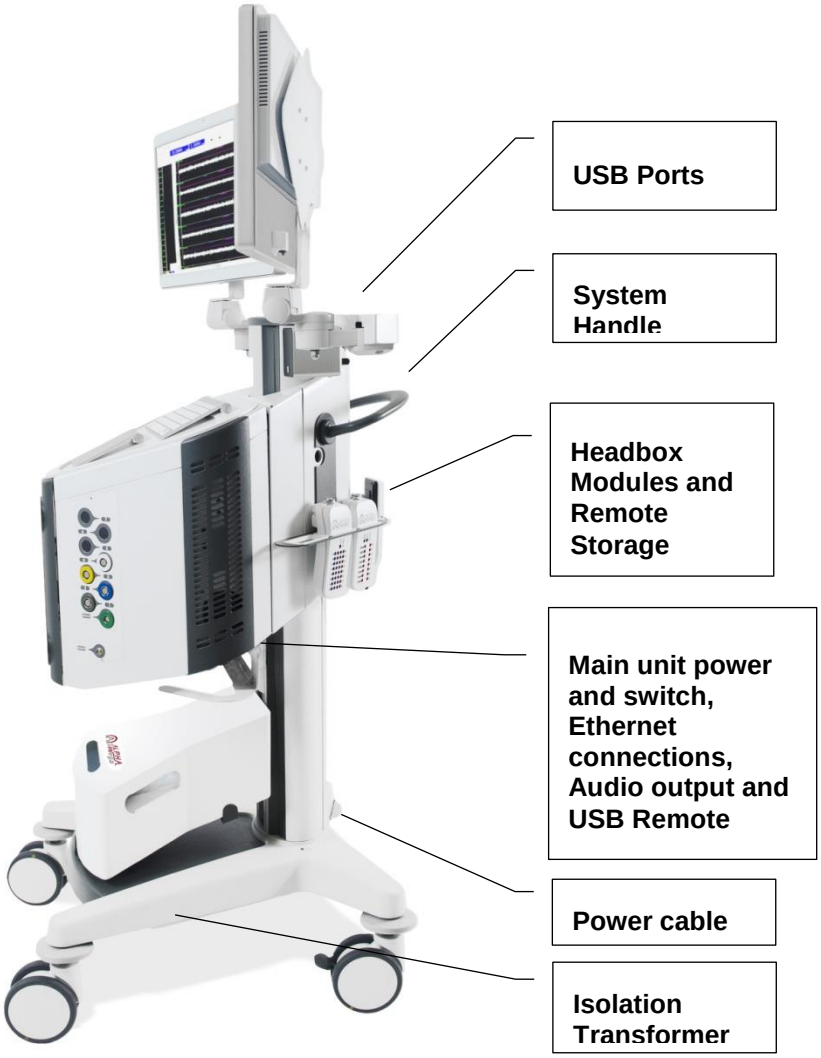


Figure 6: Main Unit and Trolley Side View

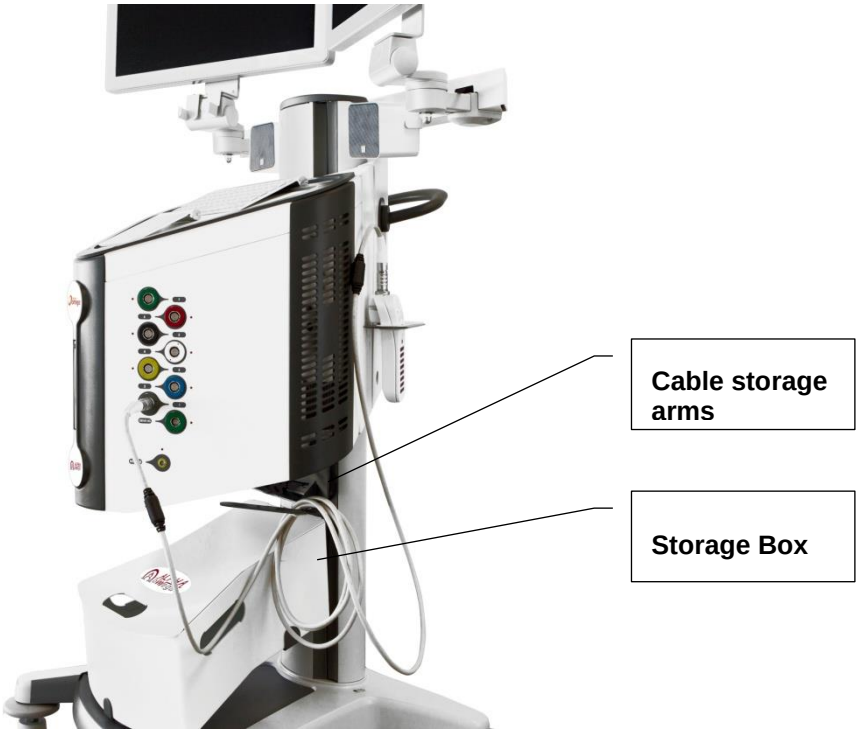


Figure 7: Side View of Cable Storage

2.2. DRIVE HEADSTAGE MODULE

> **Note:** This section does not apply for the Neuro Omega MER Headstage.

The Drive Headstage module is mounted on either a Stereotactic frame or frameless systems, and provides the framework for recording and stimulating from up to five electrodes. The Neuro Omega records the data from each of up to five micro contacts and five macro contacts as separate channels.

The Drive Headstage module is comprised of the following components:

- ***One of the following Drive Headstages:***
  - ***NeuroFortis Neuro Omega Drive Headstage***
  - ***Neuro Omega Drive Headstage***
  - ***Neuro Omega Autoclavable Drive Headstage***
  - ***Autoclavable Drive***

2.2.1. NeuroFortis Neuro Omega Drive Headstage

The Drive Headstage contains the mechanism that manipulates the electrodes, digitizes the acquired signals and provides stimulation.

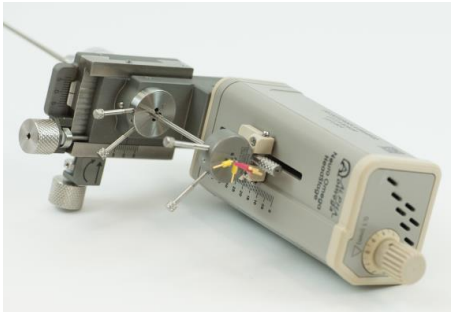


Figure 8: NeuroFortis Neuro Omega Drive Headstage

This mechanism is made up of the following components:

- The drive motor, which uses its own scale to measure depth
- An external scale, calibrated from 0-40 mm with 1 mm resolution, which does the following:
  - Helps you monitor Headstage movement accuracy
  - Enables you to compare the depth data as displayed by the software with the depth from the drive motor scale
- A turn wheel and scale, with 0.1 mm resolution, which is used to advance the Headstage manually.
- A digitizing amplifier, which does the following:
  - Amplifies, filters, and converts the signal collected from the microelectrode from analog to digital
  - Enables the measurement of the electrode's impedance
- Data acquisition and processing boards
- Electrode positioning control board, for up to five electrodes in tandem
- The Drive Headstage and the components comprising the Drive Headstage module appear in Figure 9

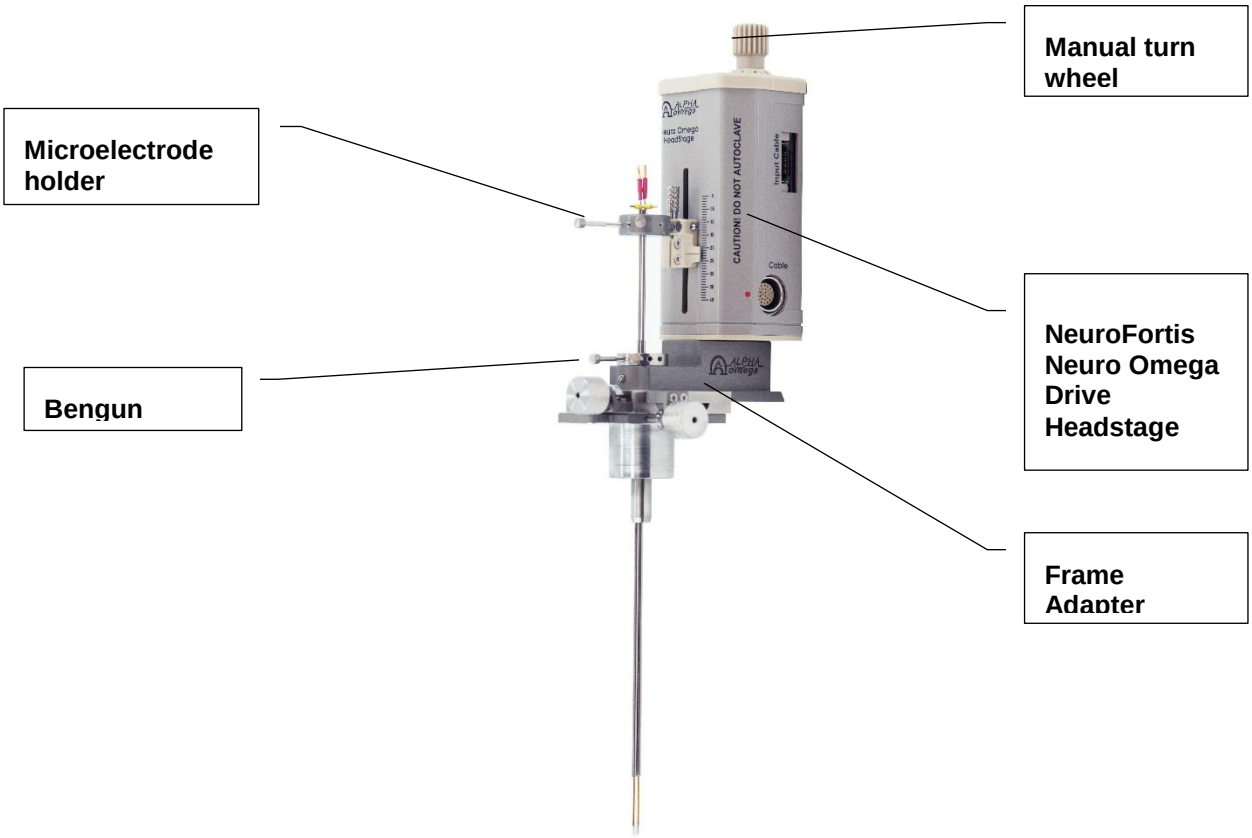


Figure 9: NeuroFortis Neuro Omega Drive Headstage Module

2.2.2. Neuro Omega Drive Headstage

The Drive Headstage (***Figure 10***) contains the mechanism that manipulates the electrodes, digitizes the acquired signals and provides stimulation.

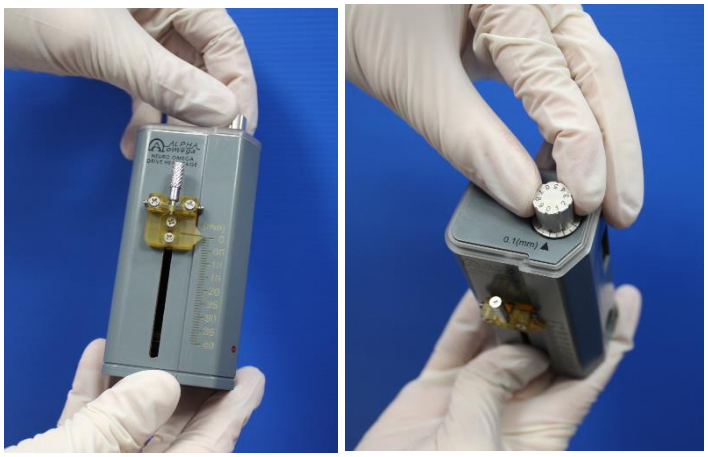


Figure 10: Neuro Omega Drive Headstage

This mechanism is made up of the following components:

- The drive motor, which uses its own scale to measure depth
- An external scale, calibrated from 0-40 mm with 1 mm resolution, which does the following:
  - Helps you monitor Headstage movement accuracy
  - Enables you to compare the depth data as displayed by the software with the depth from the drive motor scale
- A turn wheel and scale, with 0.1 mm resolution, which is used to advance the Headstage manually.
- A digitizing amplifier, which does the following:
  - Amplifies, filters, and converts the signal collected from the microelectrode from analog to digital
  - Enables the measurement of the electrode's impedance
- Data acquisition and processing boards
- Electrode positioning control board, for up to five electrodes in tandem

2.2.3. Neuro Omega Autoclavable Drive Headstage

The Autoclavable Drive Headstage (Figure 11) contains the mechanism that manually manipulates the electrodes, digitizes the acquired signals and provides stimulation.

Figure 11: Neuro Omega Autoclavable Drive Headstage

This mechanism is made up of the following components:

- An external scale, calibrated from 0-40 mm with 1 mm resolution, which does the following:
  - Helps you monitor Headstage movement accurately
- A turn wheel and scale, with 0.05 mm resolution, which is used to advance the Headstage manually.
- A digitizing amplifier, which does the following:
  - Amplifies, filters, and converts the signal collected from the microelectrode from analog to digital
  - Enables the measurement of the electrode's impedance
- Data acquisition and processing boards
- Electrode positioning control board, for up to five electrodes in tandem
- The Neuro Omega Autoclavable Drive and the components comprising the Neuro Omega Autoclavable Drive module appear in Figure 12.

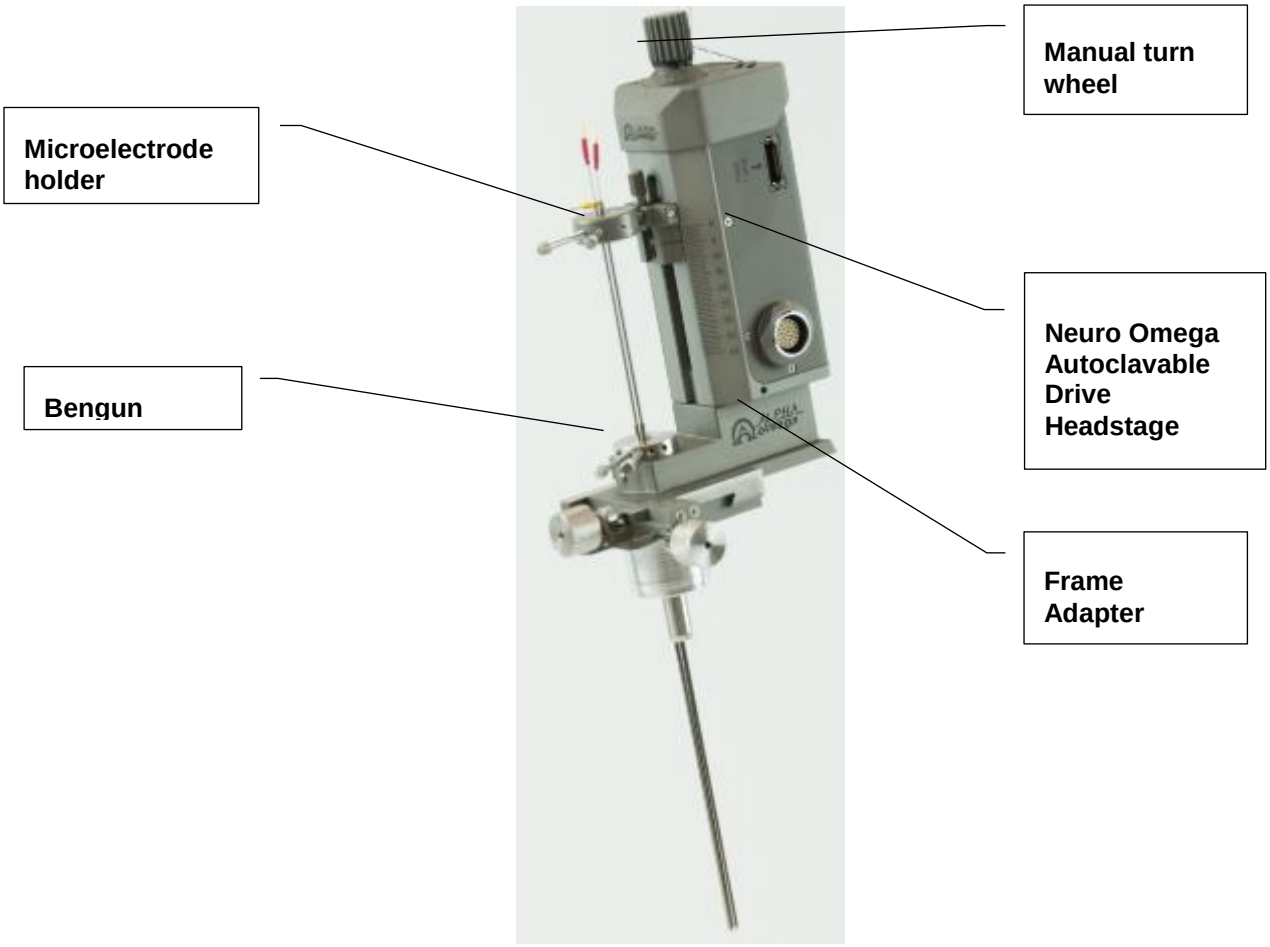


Figure 12: Neuro Omega AutoClavable Drive HeadStage

2.2.4. Autoclavable Drive

The Autoclavable Drive contains the mechanism that manipulates the electrodes.

Figure 13: Autoclavable Drive

This mechanism is made up of the following components:

- An external scale, calibrated from 0-40 mm with 1 mm resolution, which does the following:
  - Helps you monitor Headstage movement accuracy
- A turn wheel and scale, with 0.1 mm resolution, which is used to advance the Headstage manually.
- Electrode positioning control board, for up to five electrodes in tandem
- The Autoclavable Drive and the components comprising the Autoclavable Drive module appear in Figure 14.

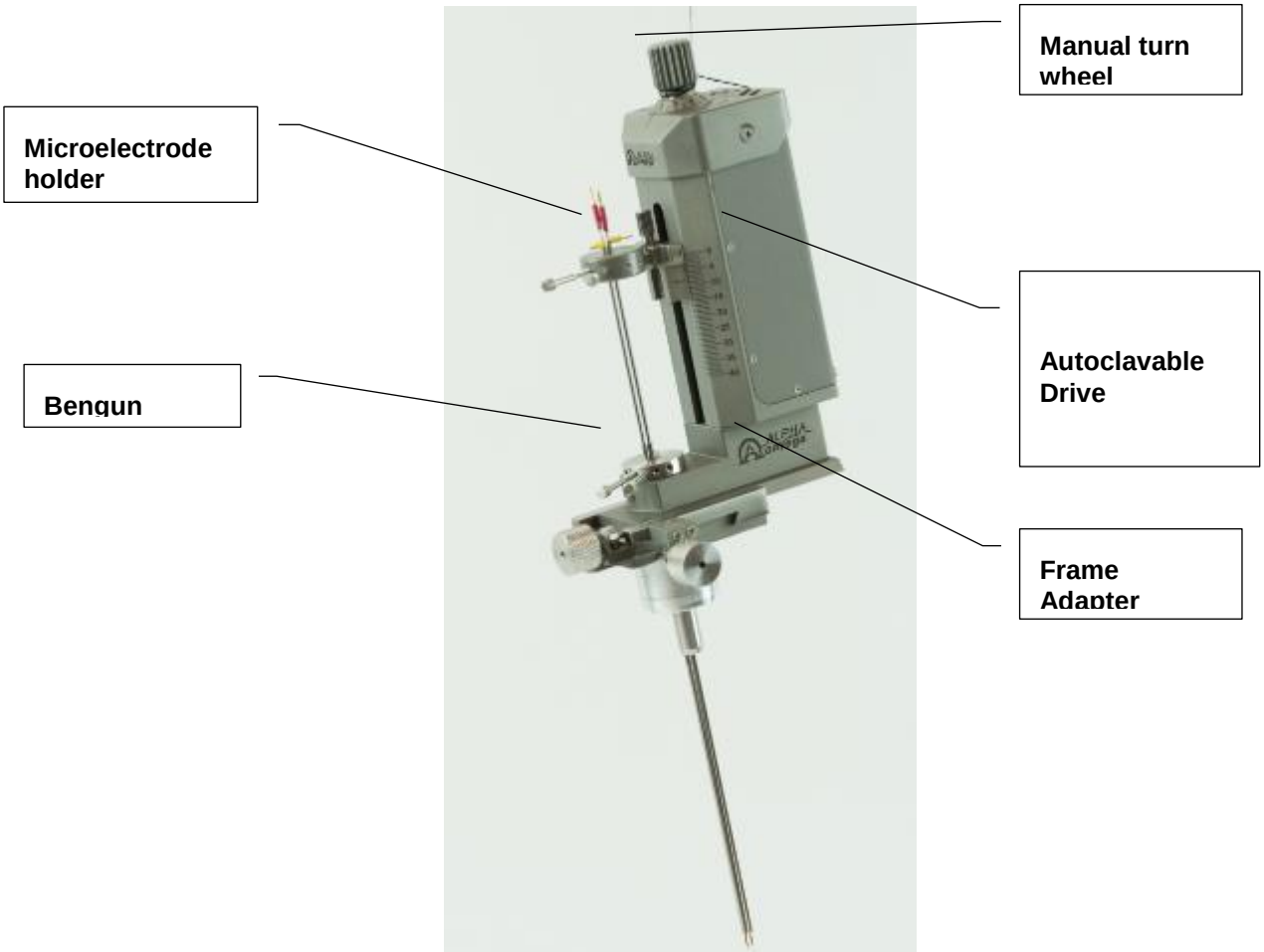


Figure 14: Autoclavable Drive

2.2.5. Electrode Holder and Bengun

The Bengun (***Figure 15***) attaches to the frame adaptor, and holds the cannula stationary so that the electrode can advance up and down. You can place up to five cannulas in the Bengun at a time. Each outside hole is 2 mm away from the center hole.

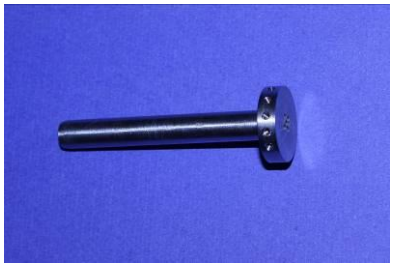


Figure 15: Bengun

The electrode holder (***Figure 16***) attaches to the scale of the Drive Headstage, and holds the electrode in place within the respective cannula. The electrode is manipulated up and down by the drive motor. You can place up to five electrodes in the holder at a time, all moving in tandem by the same motor.

Figure 16: Electrode Holder

The Bengun can be attached according to two layouts, depending on the orientation of the five holes relative to the midline. Layout 1 is referred to as **X**, and layout 2 is referred as **+** (***Figure 17***). The electrode holder comes in both these layouts separately. When you attach the Bengun and the electrode holder, you must verify that both are according to the same layout.

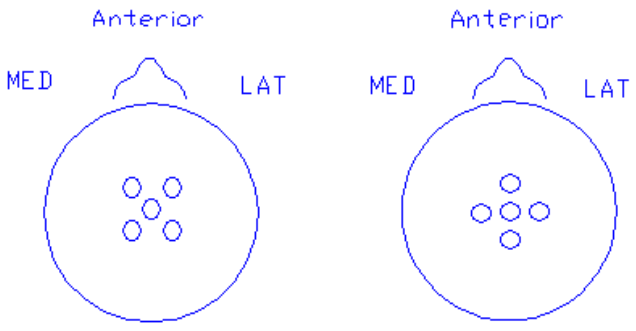


Figure 17: Layout 1 (X) on Left, Layout 2 (+) on Right

2.2.6. Frame Adaptor

The frame adaptor fits onto the Stereotactic frame and serves as the base on which to attach the Drive Headstage.

The Drive Headstage uses various frame adaptors to attach to any of several Stereotactic frames, such as CRW's Radionics and Leksell's Elekta. It can also be mounted on other, frameless systems such as NexFrame by Medtronic and Starfix by FHC, using adaptors provided by Alpha Omega. Other configurations can be easily customized upon request.

2.2.7. Electrodes

Neuro Omega uses electrodes with two possible micro to macro tip distances, as seen in ***Table 4***.

Table 4: Tip Distances

Electrode Model No.	Electrode Type	Micro to Macro Tip Distance (mm)
STR-009080-10	Shielded	3
STR-009079-10	Non-shielded	3
STR-901079-10	Non-shielded	10
STR-009081-10	Shielded	27
STR-090244-10	Shielded	3

> **STR-090244-10 is used with ONLY with NexDrive and NOT AO Drive**

> **STR-090244-10 requires Nexdrive MicroElectrode Holder CAT# 700-000316-00**

Micro to macro tip distance is important for configuring settings, section ***0***.

Electrodes can be either shielded or unshielded, depending on user preference. For more electrode types and preferences, see the Neuroprobe user manual.

2.2.8. Electrode Input Cable

The electrode input cable is the interface between the Drive Headstage and the electrodes. This cable allows for recording and stimulation from five electrodes simultaneously through the five micro tips and five macro tips. This cable is one time use only.

Red color connectors are for the micro contact and yellow color for the macro contact. Both the red and yellow connectors are labeled one through five for identification and connection. In addition, this cable has a ground clip for the recording and stimulation ground.

2.2.9. Cannulas

Neuro Omega uses a number of cannula models of differing lengths. The electrode within the cannula is inserted based on length, thereby affecting its starting depth and distance from target, as seen in ***Table 5***. Measurements are in millimeters.

Table 5: Cannula Models

Frame	Cannula Catalogue No.	NeuroProbe Compatibility	Cannula Length*	Starting Depth on Drive	Distance to Target	Target Depth on Drive
CRW/Leksell	STR-000021-10	Shielded	167±0.5	0	25±0.5	25
CRW/Leksell	STR-007721-10	Shielded	177±0.5	10	15±0.5	25
CRW/Leksell	STR-008221-10	Shielded	182±0.5	15	10±0.5	25
CRW/Leksell	STR-000076-10	Non-shielded	167±0.5	0	25±0.5	25
Nexframe/Starfix	STR-020121-10	Shielded	201.5±0.5	5	15±0.5	20

* Including 5 mm stopper above Bengun

Starting depth is important when setting the starting depth, described in section ***2.8.1***.

For more information, see the Cannula user manual.

Distance to target is important for configuring settings, described in section ***0***. The distance to the target is the distance from the tip of the cannula (where the electrode starts) to the center of the frame (target).

Calculations for determining the distance from the target appear in the following sections:

- ***Using CRW and MicroMar Frames***
- ***Using Leksell Frames***
- ***Using Nexframe Frames***
- ***Using Starfix Frames***
- ***Using Libenger Frame***

2.2.9.1. Using CRW and MicroMar Frames

Figure 18 shows a distance of 25 mm from the tip of the cannula to the target. The arc of the CRW is 160 mm to the target.

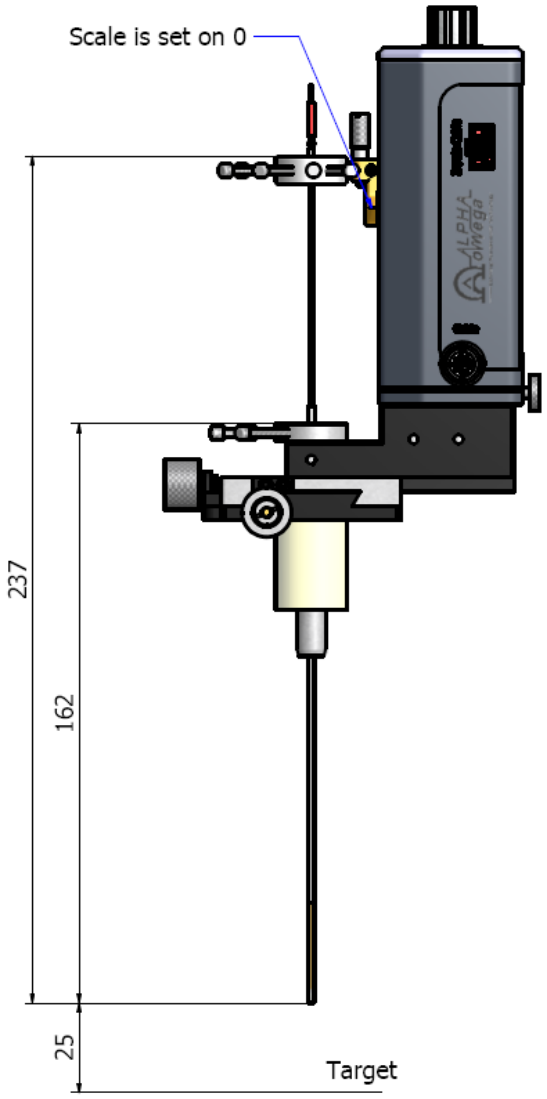


Figure 18: Using CRW and MicroMar Frames

2.2.9.2. Using Leksell Frames

Figure 19 shows a distance of 25 mm from the tip of the cannula to the target. The arc distance to target is 30mm larger than the CRW/MicroMar frames and therefore the instrument stop holder should be used to offset the drive Headstage assembly.

Note: Make sure to set the instrument stop holder (bracket) to +30mm

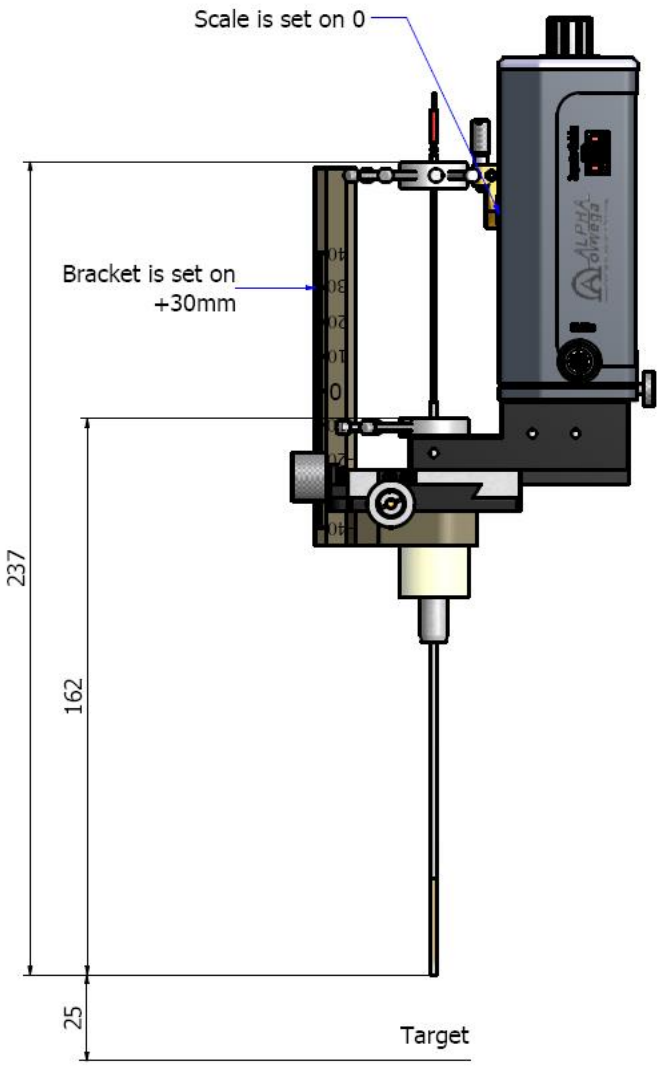


Figure 19: Using Leksell Frames

2.2.9.3. Using Nexframe Frames

When using the Nexframe frame adaptor (***Figure 20***), set the Z-stage (***Figure 21***, Detail A).

> **Note**: When using the Nexprobe Image-guided Probe with Medtronic IGS system, add 75 mm.
>
> **Note**: The target is at 20mm depth on the drive.

Set the drive Headstage to a starting depth of 5mm (***Figure 21***, Detail B), distance to target is 15mm (target at 20mm depth).

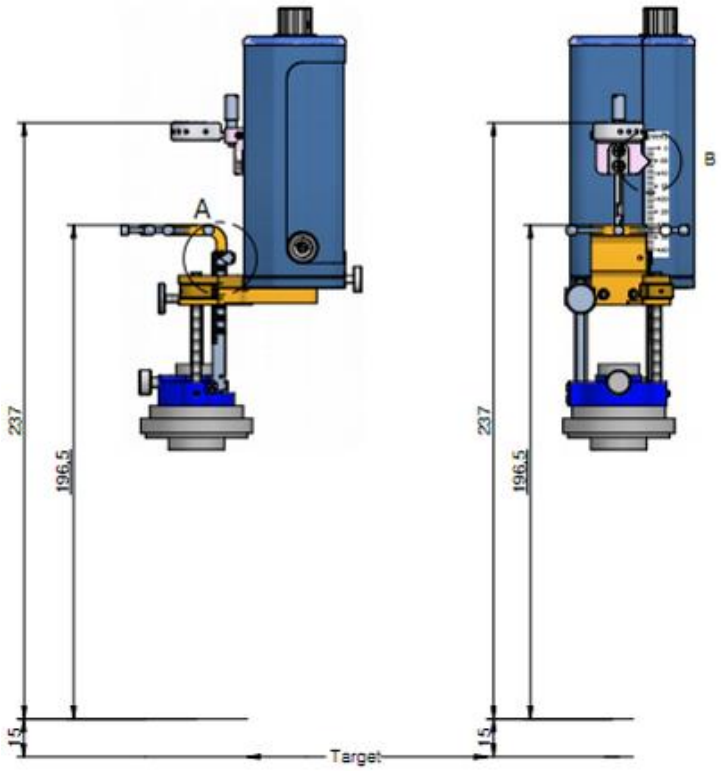


Figure 20: Using Nexframe Frames

Figure 21: Z Stage (Detail A) and Distance to Target (Detail B)

2.2.9.4. Using Starfix Frames

When using the Starfix frame adaptor (***Figure 22)***, set the T-scale (***Figure 23***, Detail A).

> **Note**: Verify the T-scale value on the Starfix frame, and set adapter scale accordingly.
>
> **Note**: The below drawings are for T40 platform.
>
> **Note**: The target is at 20mm depth on the drive.

Set the drive Headstage to a starting depth of 5mm (***Figure 23***, Detail B), distance to target is 15mm (target at 20mm depth).

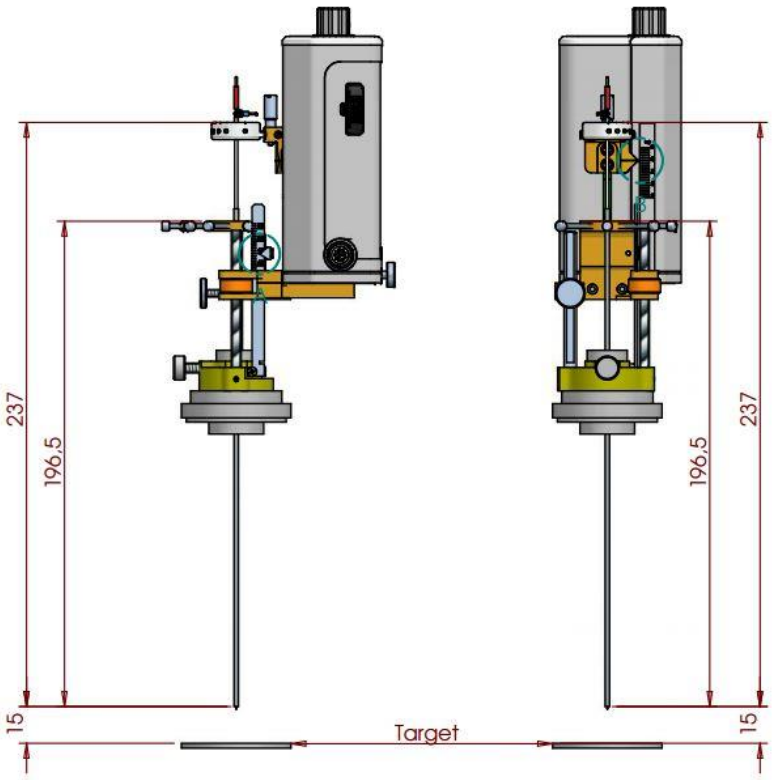


Figure 22: Using Starfix Frames

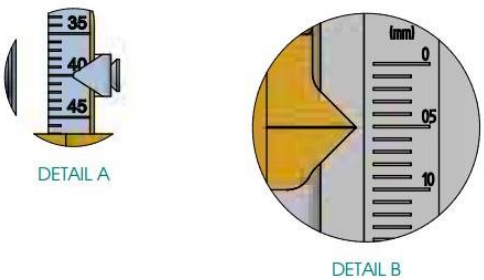


Figure 23: T-Scale (Detail A) and Distance to Target (Detail B)

2.2.9.5. Using Libenger Frames

Figure 19 shows a distance of 25 mm from the tip of the cannula to the target. The arc distance to target is 30mm larger than the CRW/MicroMar frames and therefore the instrument stop holder should be used to offset the drive Headstage assembly. See Figure 24

Note: Make sure to set the instrument stop holder (bracket) to +30mm

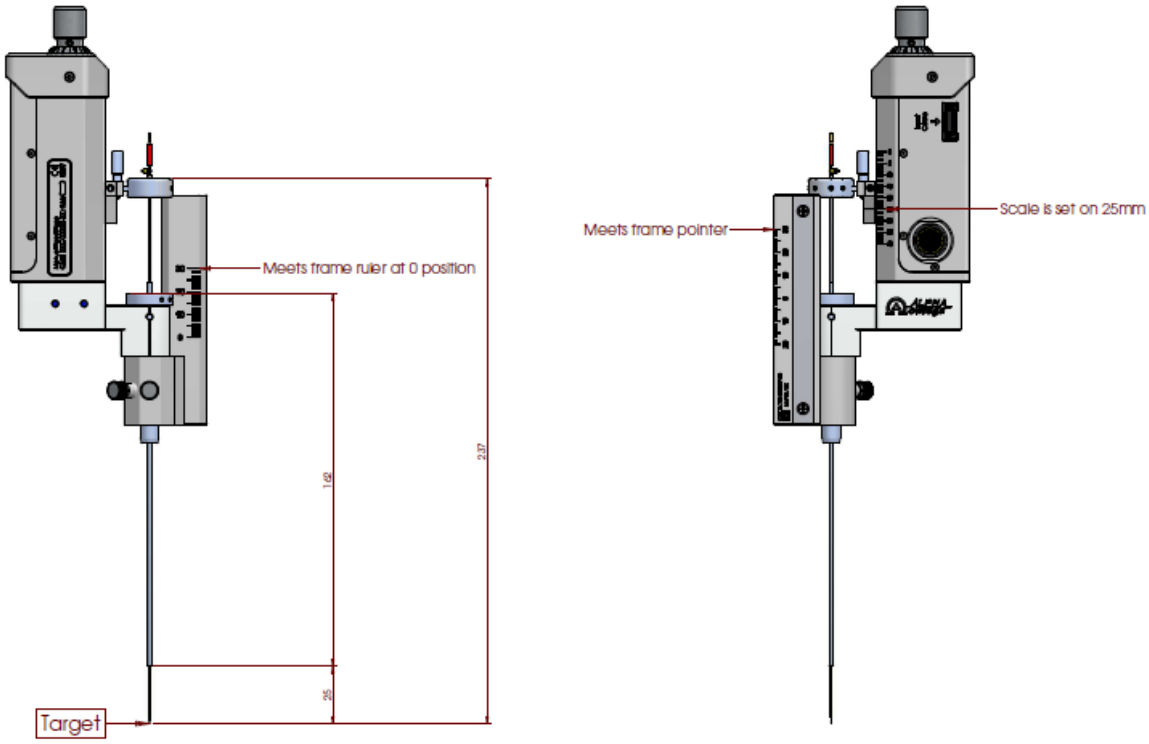


Figure 24: Using Libenger Frames

2.3. MER HEADSTAGE MODULE

The MER Headstage module provides the framework for recording and stimulating from up to five electrodes. The Neuro Omega records the data from each of up to five micro contacts and five macro contacts as separate channels.

The MER Headstage module is comprised of the following components:

- *Neuro Omega MER*

- *Neuro Omega MER Electrode Input Cable*

2.3.1. Neuro Omega MER Headstage

The Neuro Omega MER Headstage (***Figure 25***) contains the mechanism that manipulates the electrodes, digitizes the acquired signals and provides stimulation.

Figure 25: Neuro Omega MER Headstage

This mechanism is made up of the following components:

- A digitizing amplifier, which does the following:
  - Amplifies, filters, and converts the signal collected from the microelectrode from analog to digital
  - Enables the measurement of the electrode's impedance
- Data acquisition and processing boards

2.3.2. Neuro Omega MER Electrode Input Cable

The electrode input cable is the interface between the MER Headstage and the electrodes. This cable allows for recording and stimulation from five electrodes simultaneously through the five micro tips and five macro tips. This cable is one time use only.

Black color connectors are for the micro contact and red color for the macro contact. Both the black and red connectors are labeled one through five for identification and connection. In addition, this cable has a ground clip for the recording and stimulation ground.

2.4. HEADBOX MODULES

Notes:

- The Headbox modules are electrically classified as type Body Floating (BF). The ground of the module must not be connected to any other ground. These modules are labeled with the following sign:

- The Headbox modules can be used with standard touch proof DIN connector patient electrodes.

There are two types of Headbox modules:

- The EMG Headbox module (***Figure 26***), for differential muscle electrophysiological recording, contains the following:
  - 16 channels, with one **+** (plus) input and one **-** (minus) input touch-proof connectors for each channel
  - One ground touch-proof connector (black)
  - One global stimulation return touch-proof connector (white)

Figure 26: EMG Headbox Module

The EEG/ECOG Headbox module (***Figure 27***) is used for referential brain recording, Cortical stimulation and contains the following:

- 16 channels, with one touch-proof connector for each channel
- One **-** (minus) touch-proof connector for global reference
- One ground touch-proof connector (black)

Figure 27: EEG/ECOG Headbox Module

Each Headbox module is supplied with a Velcro strap for easy attachment to the patient. The Headbox module, the cable, and the connection on the Main Unit are all color coded, as follows:

- **Gray**: Module 1
- **Blue**: Module 2
- **Yellow**: Module 3
- **White**: Module 4
- **Black**: Module 5
- **Red**: Module 6
- **Green**: Module 7

2.5. REMOTE CONTROL

The remote control is hand-held and comes with an LCD screen. It is connected to the Main Unit with a flexible cable and allows easy system operation.

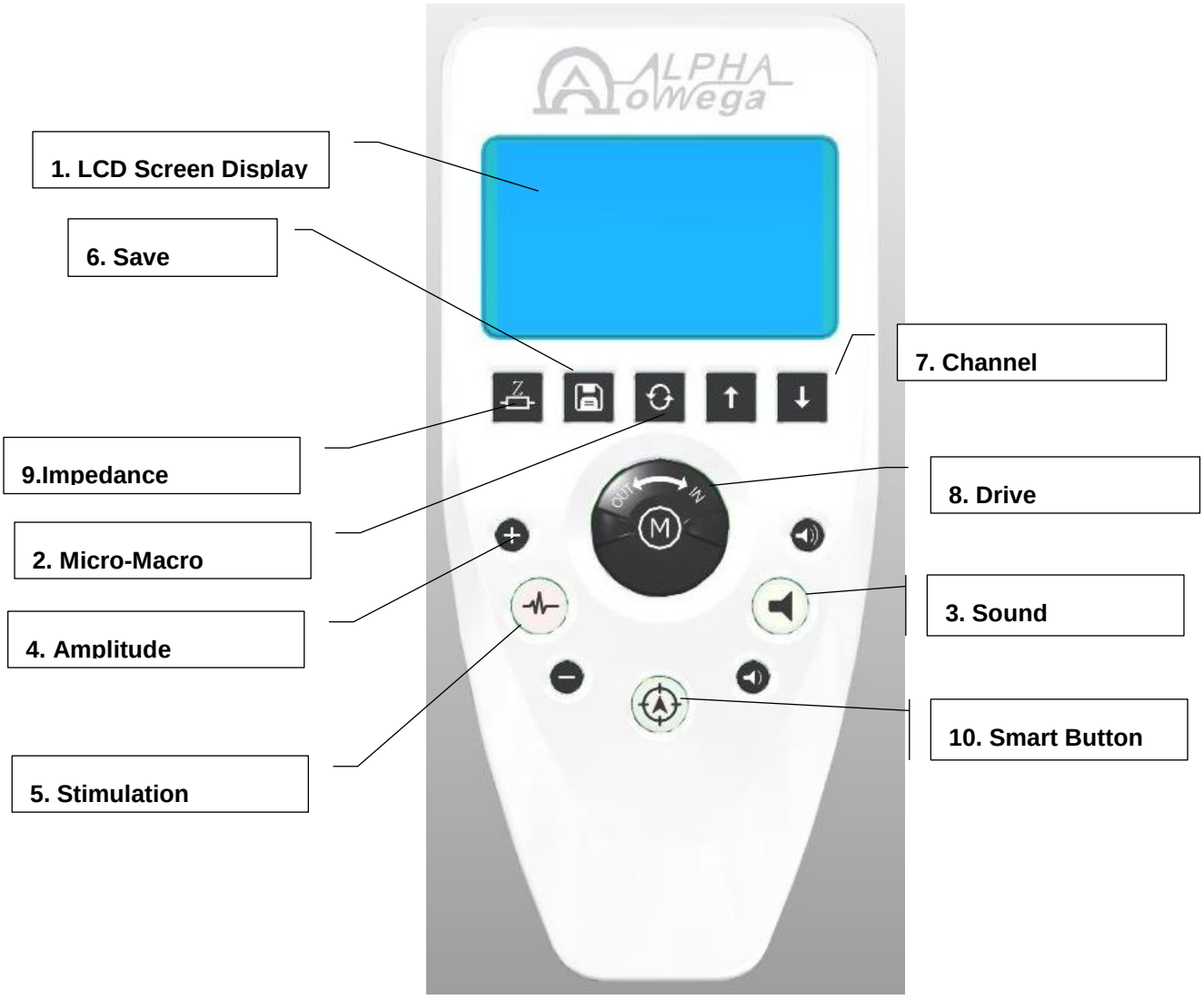


Figure 28: remote Control

1. LCD Screen Display
2. **Micro-Macro**: Switches between the micro and macro tip, for the purposes of stimulation and sound
3. **Sound**: Activates or deactivates the sound of the selected channel
4. **Amplitude** (+/ -): Two buttons to increase or decrease the stimulation current amplitude
5. **Stimulation**: Activates the stimulus current, applying the selected current stimulation to the selected channel
6. **Save**: Starts saving the current data set to the log file
7. **Channel**: Two buttons to toggle between different channels
8. **Drive**: Thumb wheel button to advance the electrode up and down (in/out), with speed control
9. **Impedance Check:** of all applied Micro and Macro Contacts
10. Smart Button: to drive with HaGuide tool

2.6. STIMULATION PEDAL

The stimulation pedal is on-floor device and can be connected to the Neuro Omega by USB, to allow the user to perform stimulation by pressing on the pedal using the feet.

Figure 29: stimulation Pedal

2.7. STERILE ITEMS

In addition to the non-sterile single use items, Alpha Omega offers sterile alternatives. With these accessories, there is no need for additional sterilization. The accessories can be transferred into the sterile field through the sterilization pouch.

> **Warning:** Do not use the contents if there is any evidence of damage to the package or package seal that could compromise sterility

Contents of unopened, undamaged package are sterile and non-pyrogenic.

There are three sterile accessories options:

- Sterile Electrodes

- Sterile Cannulas and Stylets

- Sterile Electrode Cable

2.8. SETTING THE ELECTRODE STARTING POINT

> **Note:** This section does not apply for the MER Headstage

The electrode starting depth is set based on the calculated distance above the target. The electrode tip must be flush with the end of the cannula, placing the electrode tip at the same distance from the target as the cannula tip.

There are two methods for setting the electrode depth:

- Method 1, described in section ***2.8.1***, is simpler and does not factor tolerances.
- Method 2, described in section ***0***, is more precise, but endangers the electrode tip.

2.8.1. Setting Electrode Starting Depth Method 1

This procedure describes method 1 for setting the starting depth of the electrodes, which is simpler.

To set the starting depth of the electrodes:

- Refer to ***Table 5: Cannula Models***, and based on the cannula you are using, adjust the turn wheel to the correct starting depth.

2.8.2. Setting Electrode Starting Depth Method 2

This procedure describes method 2 for setting the starting depth of the electrodes, which is more precise, but endangers the electrode tip. The procedure should be performed entirely in the sterile field prior to beginning the assembly.

Warning: When handling the electrode, be very careful not to damage the tip. At all times during the handling of the electrode, make sure that the micro tip is retracted into the macro sheath.

Notes:

- The following figures are shown on the Neuro Omega Drive Headstage. **Please note**, the same mechanical steps are applied on NeuroForits Neuro Omega Drive Headstage and Autoclavalbe Drive setting.

1. Insert the cannula without stylet in the center hole of the Bengun.

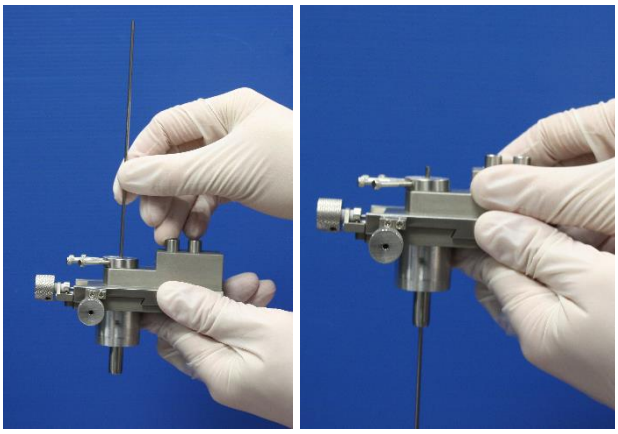


Figure 30: Cannula Inserted into Bengun Center Hole

2. Tighten the Bengun screw.

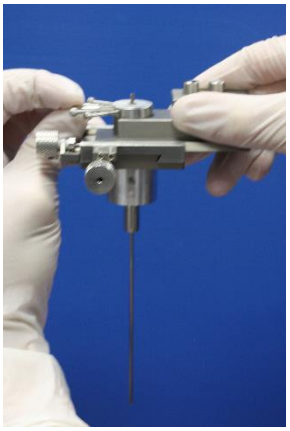


Figure 31: Holding Screw

3. Attach desired electrode holder (x or +) to the Drive Headstage, and secure screw

Figure 32: Attaching Electrode Holder

Attach the Drive Headstage to the frame base adaptor and tighten the screw on the back side of the Drive Headstage.

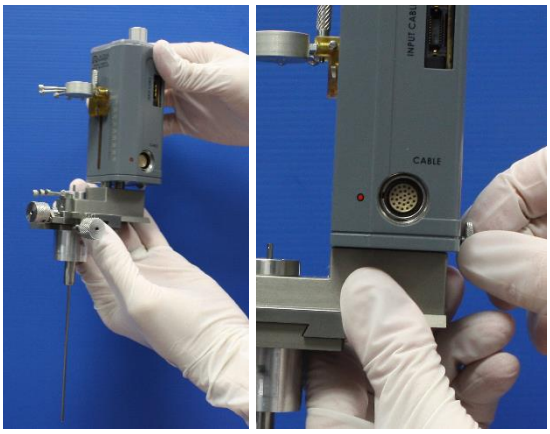


Figure 33: Attaching Driving Unit

4. Remove an electrode from the sterilization tray or sterile packet. Pull the electrode tip back into its protective sheath (***Figure 34***).

> **Warning:** Be careful not to damage the fragile tip.

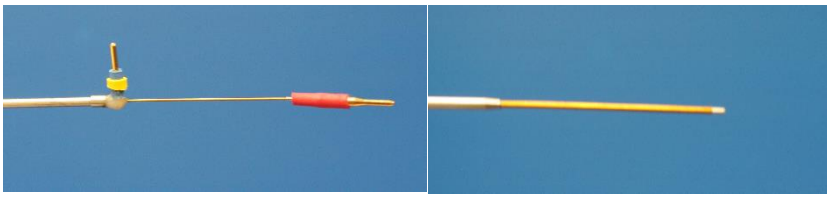


Figure 34: Retracted Electrode Tip

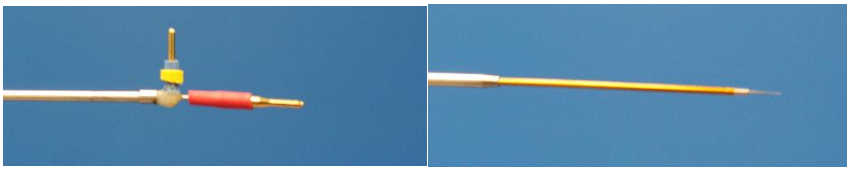


Figure 35: Exposed Electrode Tip

5. Once the electrode is in the cannula, push the electrode into the electrode holder all the way until it reaches the metal collar, and tighten the microelectrode holder screw.

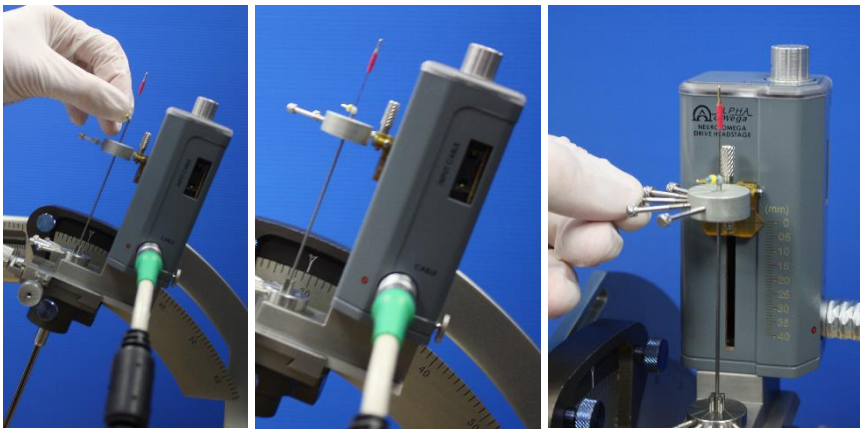


Figure 36: Electrode in Place

6. Push the electrode micro tip to expose it, and then turn the manual wheel until the electrode and its tip are extended outside the cannula.

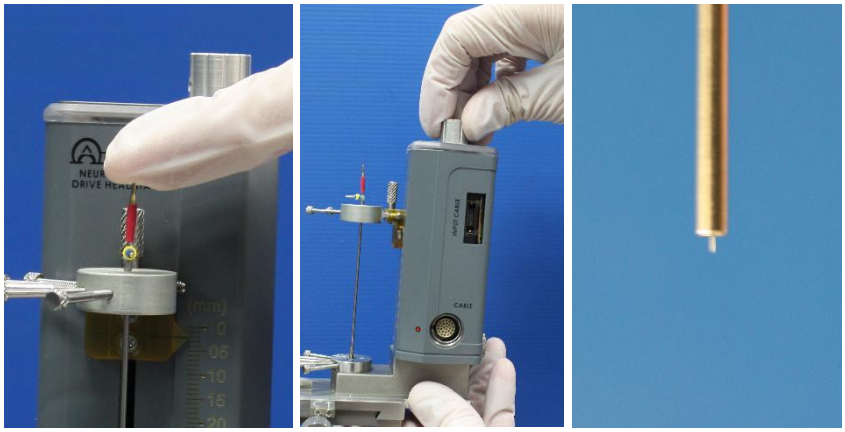


Figure 37: Electrode and Tip outside Cannula

7. Slowly turn the thumb wheel in the opposite direction to retract the electrode into the cannula, until the tip of the electrode is flush with the tip of the cannula. Doing this

against a white background will help to make the tip stand out.

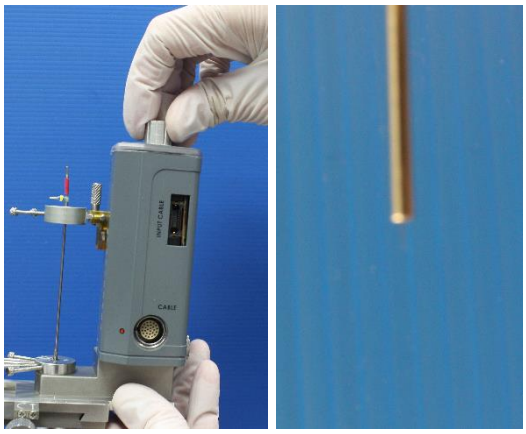


Figure 38: Electrode Tip Flush with Cannula Tip

8. Read and record the depth from the scale on the Drive Headstage. This is the Starting Depth Value.

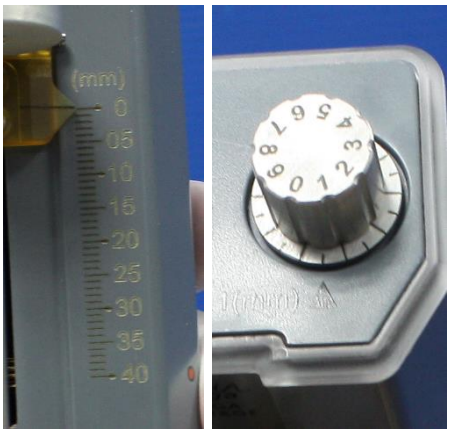


Figure 39: Reading Drive Scale

9. Disassemble Drive Headstage as follows:

- ❖ Retract the electrode tip by pulling pin connector up.
- ❖ Loosen the electrode screw.
- ❖ Remove the electrode.

Figure 40: Removing electrode

10. Unscrew the Drive Headstage back screw and remove Drive Headstage from frame adapter.

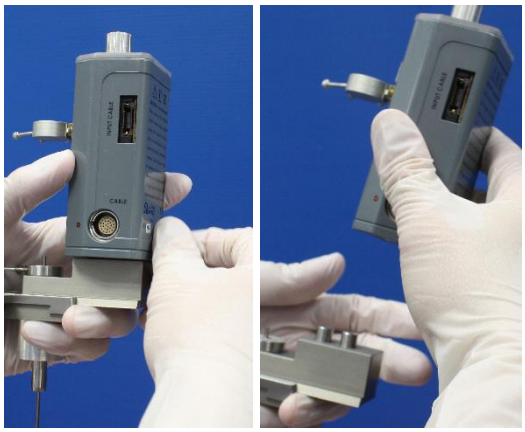


Figure 41: Removing Drive Headstage

2.9. ASSEMBLING THE HEADSTAGE

> **Note:** This section does not apply for the MER Headstage

This procedure describes how to assemble the Neuro Omega Drive Headstage on the frame.

Prerequisites:

- Set the electrode starting point, as described in section *2.8*

- Frame attached to the skull of the patient, and the area of entry prepared

To assemble the Headstage:

11. Attach the Bengun to the frame adaptor (***Figure 42***), in the configuration matching that of the electrode holder, either **X** or **+**.

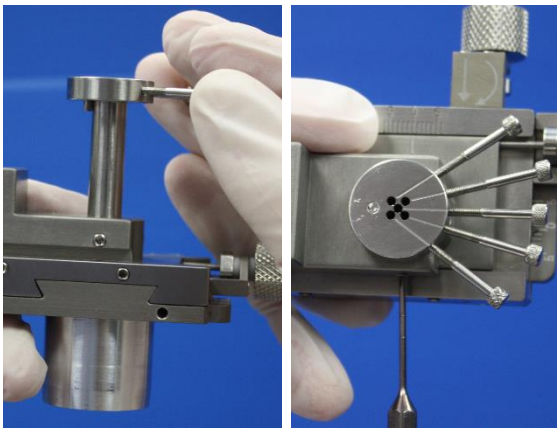


Figure 42: Attaching the Bengun to the Frame Adaptor (X position)

12. Attach and secure the frame adaptor to the frame (***Figure 43***).

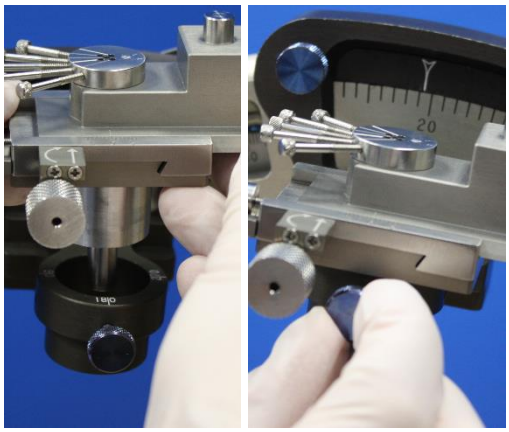


Figure 43: Attaching Frame Adaptor to the Frame

13. Holding the cannula from the stylet collar, insert the cannula through the Bengun hole (***Figure 44***) and into patient's tissue.

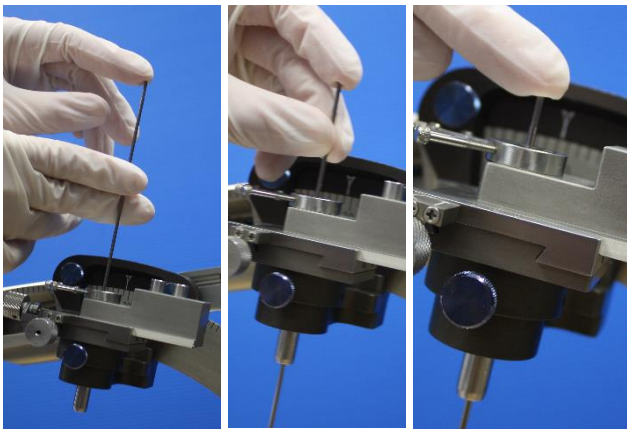


Figure 44: Inserting the Cannula through the Bengun Hole

14. Tighten the Bengun screw (***Figure 45***), and then remove the stylet from the cannula.

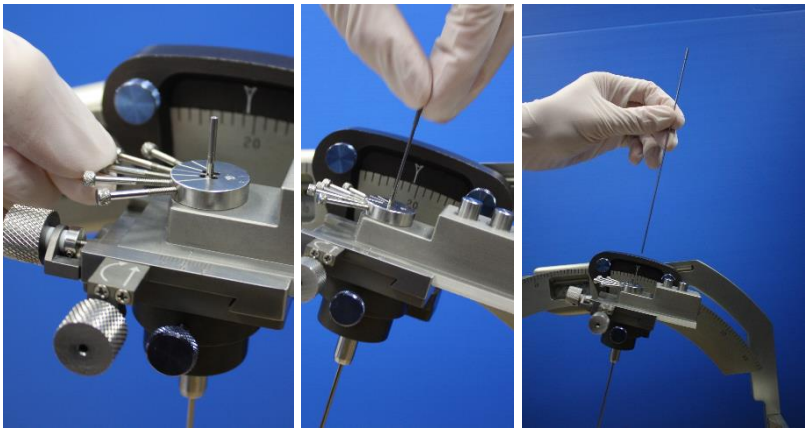


Figure 45: Tightening the Holding Screw and removing stylet

Repeat steps 12 and ***13*** for each electrode you are using.

15. Loosen the screw on the Headstage scale pointer, attach the electrode holder to the drive, and then tighten the screw.

Figure 46: Attaching the Electrode Holder to the Drive

16. Connect the Drive Headstage green cable to the Drive Headstage.

Note: When inserting the cable:

- Verify that the red dots on the drive and on the Main Unit are aligned with those on the cable (*Figure 47*).
- Do not twist the cable when inserting.
- Hold from the metal connector, not the cable.
- Soft click will be felt when the cable is connected (the red dot on the cable disappears).

Figure 47: Aligning the Red Dots on the Drive and the Cable

17. Attach the Drive Headstage to the frame adaptor and secure screw.

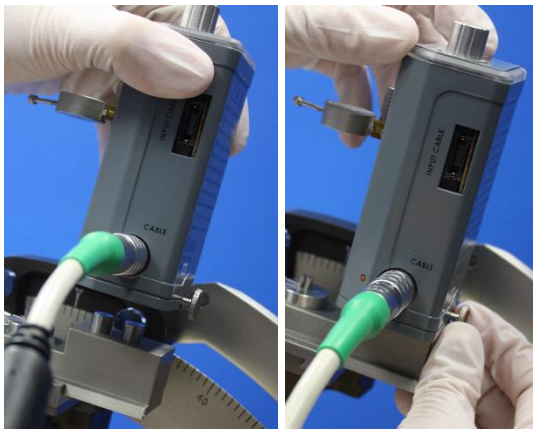


Figure 48: Inserting Electrode into Electrode Holder

18. Verify that the tip of the electrode is retracted, and then insert the electrode through the hole of the electrode holder and then into the cannula, until the collar where it catches on the drive.

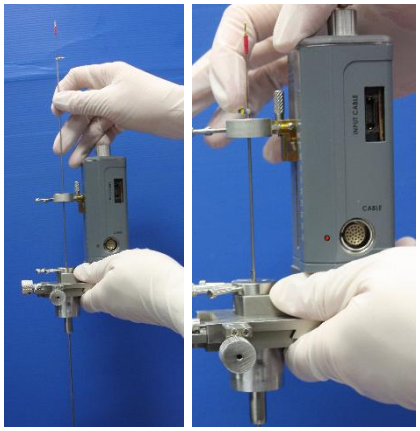


Figure 49: Inserting Electrode into Electrode Holder

19. Tighten the electrode holding screw

Figure 50: Tightening the Electrode Holding Screw

20. Repeat steps 19 and ***20*** for each electrode you are using.

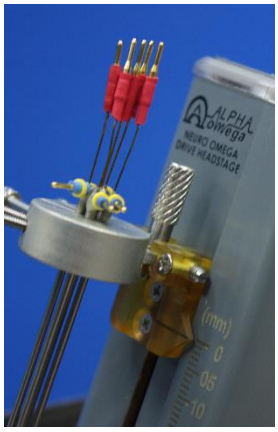


Figure 51: All used electrodes inside

21. To connect the input cable, do the following:

a. Connect the input cable to the Drive Headstage.

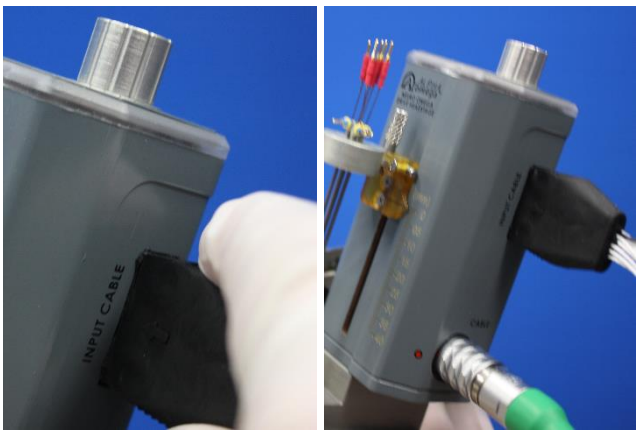


Figure 52: Connect Electrode Input Cable

22. Connect ground black wire alligator to any bengun screw

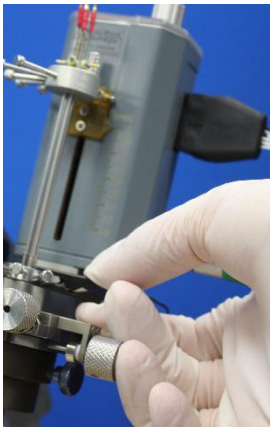


Figure 53: Connect Electrode Input Cable

23. Connect the red wires to the red micro tip connectors.

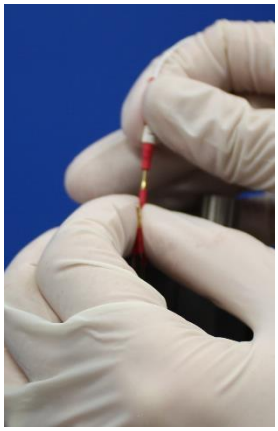


Figure 54: Connect Electrode Input Cable

24. Expose electrode tip.

Figure 55: Connect Electrode Input Cable

25. Connect the yellow wire to the yellow macro tip connector.

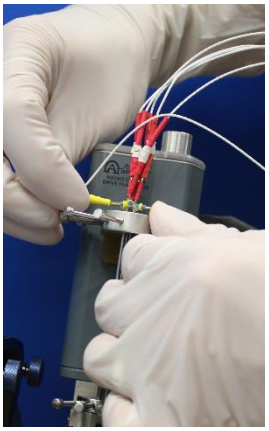


Figure 56: Connect Electrode Input Cable

26. Repeat steps c, 24 and 26 for each electrode you are using.

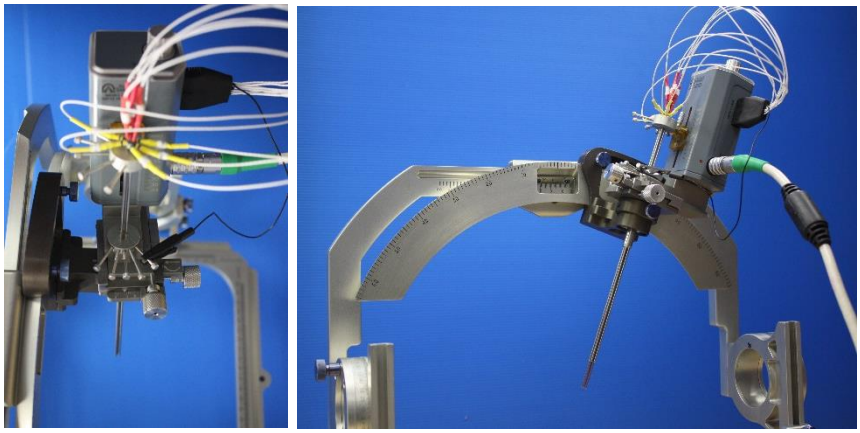


Figure 57: Final Assembly

27. Start the microelectrode recording session.

2.10. MICROELECTRODE INSERTION USING THE QUICK SWITCH

1. Insert the first central cannula
2. Install the electrode holder
3. Insert the first electrode
4. Open the additional track slot
5. Slide the new cannula through the slot until it meet the Bengun
6. Lock the new cannula
7. Remove the stylet
8. Close the slot by the screw
9. Inset the additional NeuroProbe and Lock it
10. Do the steps 4-9 for all cannulas wanted to add

2.11. HEADBOX MODULES ASSEMBLY

There are two types of Headbox modules:

- The EMG module comprised of 16 pairs of touch-proof connectors. See section ***2.11.1*** for assembling the EMG module.
- EEG/ECOG module comprises 16 touch-proof connectors. See section ***2.11.2*** for assembling the EEG/ECOG module.

2.11.1. Assembling the EMG Module

Warnings:

- Information on the output waveforms, pulse durations, pulse repetition frequencies, maximum amplitude of output current is shown under section ***4.19*** of this manual.
- Avoid trans-thoracic stimulation.
- In order to use a video monitor as a part of the visual stimulator, it should be connected to the Neuro Omega trolley isolated power source.
- Operation in close proximity (for example 1 m) to a shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.
- Avoid intentional or unintentional contact between connected but unapplied parts and other conductive parts including those connected to protective earth.

This procedure describes how to assemble the EMG module, for use in implanting the DBS or advanced research.

To assemble the EMG module:

- Connect the EMG module to the like-colored port on the Main Unit, using the like-colored cable.

> **Note:** When inserting the cable, verify that the red dots on the Headbox and on the Main Unit are aligned with those on the cable (*Figure 58*).

Figure 58: Red Dot on the Headbox

- Connect the electrode pairs to the EMG module, for each electrode both the + (plus) input and - (minus) input connectors.
- Connect the ground connector.
- Connect the stimulation global return connector, if in use.

2.11.2. Assembling the EEG/ECOG Module

> **Warnings:**
>
> - The conductive parts of electrodes and their connectors including the neutral electrode, should **not** contact other conductive parts and earth.

This procedure describes how to assemble the EEG/ECOG module, for use in implanting the DBS or advanced research.

To assemble the EEG/ECOG module:

- Connect the EEG/ECOG module to the like-colored port on the Main Unit, using the like-colored cable.

> **Note:** When inserting the cable, verify that the red dots on the Headbox and on the Main Unit are aligned with those on the cable (see *Figure 58*).

- Connect the electrodes to the EEG/ECOG Headbox module.
- Connect the ground connector.

2.12. CONNECTING EXTERNAL SYSTEMS

This procedure describes how to connect any external systems to the Alpha Omega, such as:

- Matlab or C++ system
- External analog or digital input or output systems

You can power the systems through the trolley's isolation transformer, or through an independent isolation transformer.

> **Warning:**
>
> - External systems connected to the Neuro Omega must be independently isolated, or powered through the trolley, as this has its own isolation transformer.
> - External systems connected to the Neuro Omega by Ethernet port must include Ethernet Isolator in line.

To connect a Matlab or C++ system do the following:

- Power the system through the trolley's isolation transformer (see ***Figure 6***) as follows:
  - On the base of the Main Unit, remove the cover to the isolation transformer.
  - Plug the external computer in to the transformer.
  - Return the cover, threading the power cord parallel to the Alpha Omega system's power cord.
- Connect the Ethernet, through an Ethernet Isolator, at the bottom of the main unit (see ***Figure 4***).

To connect an external system, perform one of the following:

- Power the system through the trolley's isolation transformer (see ***Figure 6***) as follows:
  - On the base of the Main Unit, remove the cover to the isolation transformer.
  - Plug the external computer in to the transformer.
  - Return the cover, threading the power cord parallel to the Alpha Omega system's power cord.
  - Power the system through an independent isolation transformer.

On the Input/Output panel, connect the system to the required connection.

Repeat the above steps for each system you want to connect.

CHAPTER 3. PREPARING THE NEURO OMEGA SYSTEM

Note: *Sterilization must be performed before assembling the system for operation.*

Note: *See "Neuro Omega Accessories Detailed Reprocessing Instructions" for detailed sterilization notes and instructions.*

This chapter covers the following types of sterilization procedures:

1. STERRAD 100NX and STERRAD NX
2. Vpro-Lumen
3. Autoclave (Note: The Autoclave sterilization procedure does not apply for the NeuroForits Neuro Omega Drive Headstage, Neuro Omega Drive Headstage)
4. Washing Machine (Note: The washing machine cleaning procedure does not apply for the NeuroForits Neuro Omega Drive Headstage, Neuro Omega Dirive Headstage)

W A R N I N G
Only qualified personnel, who have been trained by Alpha Omega Ltd., are allowed to conduct the sterilization.

This workflow describes how to prepare the Neuro Omega system for surgery, and is the prerequisite for microelectrode recording, for identifying the target

To prepare the Neuro Omega system:

Clean and sterilize the Neuro Omega system, as described in following section.

System Setup including the following.

a) Prepare the cannula entrance area.

b) Set the electrode starting depth.

c) Assemble the Neuro Omega system.

d) Assemble the Drive Headstage Module

e) Connect all required external systems to the Main Unit.

3.1. CLEANING AND STERILIZING THE NEURO OMEGA COMPONENTS

Notes:

- All screws must be removed before sterilization for noted components. All removed screws must be sterilized by placing them inside the tray's small compartment.

3.1.1. Electronic Accessories

Components			Cleaning And Disinfection			Sterilization		
Name	Catalogue Number	Picture	Manual Cleaning	Automated washing	STERRAD 100NX	STERRAD NX	V-PRO Lumen	Autoclave
Neuro Omega Drive Headstage	750-000020-00		YES		YES	YES	YES	
NeuroFortis V.5 Neuro Omega Drive Headstage	750-000070-00	 *recognition throught the holes on the front scale side	YES		YES	YES	YES	
NeuroFortis V.6 Neuro Omega Drive Headstage	750-000070-00	 *recognition throught the SN 06-### And no holes from the front scale side	YES	YES	YES	YES	YES	
Neuro Omega Autoclavable Drive Headstage	750-000025-00			YES				YES

Components			Cleaning And Disinfection		Sterilization			
Name	Catalogue Number	Picture	Manual Cleaning	Automated washing	STERRAD 100NX	STERRAD NX	V-PRO Lumen	Autoclave
Autoclavable Drive	750-000027-00			YES				YES
Neuro Omega MER Headstage	750-000023-00			YES	YES	YES	YES	YES
Neuro Omega Headstage Cable	190-700026-00		YES	YES	YES	YES	YES	YES
Ground Wires	700-000426-00		YES	YES	YES	YES	YES	YES
Sterilization Tray for Headstage and cable	366-000122-22	 *Cleaning and Sterilization instructions should follow the Drive Headstage type	YES	YES	YES	YES	YES	YES

Components			Cleaning And Disinfection			Sterilization		
Name	Catalogue Number	Picture	Manual Cleaning	Automated washing	STERRAD 100NX	STERRAD NX	V-PRO Lumen	Autoclave
Net Sterilization Tray for Headstage and Cable	366-000422-22	 *Cleaning and Sterilization instructions should follow the Drive Headstage type	YES	YES	YES	YES	YES	YES

3.1.2. Warnings

Warnings:

- Do not immerse
- Don't clean with ultrasonic
- Agents with an active ingredient of chlorine or chloride should not be used because this may lead to corrosion of stainless steel parts
- Don't use Autoclave for sterilization for Neuro Omega Drive Headstage and NeuroFortis Drive Headstage

3.1.3. Limitations on reprocessing

Cautions:

- Do not reprocess accessories in case of visual damage.

Notes:

- Some items may require special attention; refer to the compatibility matrix special notes

3.1.4. Point of Use

Remove excess soil with a clean disposable cloth.

3.1.5. Containment and Transportation

Always use sterilization trays for containment and transportation. Do not flip or rotate trays during transportation.

Always reprocess accessories as soon as possible after use.

3.1.6. Cleaning and Disinfection Protocol

Notes:

Automated machinery cleaning (does not apply for Neuro Omega Drive Headstage - 750-000020-00, NeuroFortis Neuro Omega dive Headstage 750-000070-00)

Place all accessories in a clean sterilization tray.

3.1.6.1. NeuroFortis Neuro Omega Drive Headstage V.5 Cleaning and Disinfection Protocol

Cautions:

- Accessories should be handled with care. Avoid any mechanical stress to components

Notes:

- Cleaning and disinfection must be performed prior to sterilization

NeuroFortis Neuro Omega Drive Headstage Manual cleaning:

Remove the accessories from the sterilization trays. Using a clean soft cloth that has been soaked in a detergent solution wipe the trays and its inserts to remove any visible soil. Use soft bristle brushes to reach hard-to-clean areas.

Notes:

- Some items may require special attention; refer to the compatibility matrix special notes

Remove NeuroFortis Neuro Omega Drive Headstage (**750-000070-00**) from the sterilization trays. Make sure to disassemble by unscrewing holding knob on back and on the scale.

Cautions:

- Neuro Omega accessories should be handled with care. Avoid any mechanical stress to components
- Agents with an active ingredient of chlorine or chloride should not be used because this may lead to corrosion of stainless steel parts
- Pay special attention to lumens, crevices and hard to reach places.

Notes: Cleaning and must be performed prior to sterilization

Equipment: PH Neutral Detergent Cleaning Wipes, Lint-Free Wipes (see notes below).

Alpha Omega cleaning protocol:

1. Wipe with PH neutral detergent cleaning wipes until both the cleaning wipes and the device are visually free of soil. Pay special attention to lumens, crevices and hard reach places.
2. Wipe with lint-free wipes saturated with cold tap water and clean until both the lint-free wipes and the device are visually free residual detergent.
3. Dry the device with dry lint-free wipes until the device was visually free of any moisture.

3.1.6.2. Neuro Omega Drive Headstage Cleaning and Disinfection Protocol

Neuro Omega Drive Headstage Manual cleaning:

Remove the accessories from the sterilization trays. Using a clean soft cloth that has been soaked in a detergent solution wipe the trays and its inserts to remove any visible soil. Use soft bristle brushes to reach hard-to-clean areas.

Notes:

- Some items may require special attention; refer to the compatibility matrix special notes

Remove Neuro Omega Drive Headstage (750-000020-00) from the sterilization trays. Make sure to disassemble by unscrewing holding knob on back and on the scale. See figure below.

Figure 59: Remove screws on Drive Headstage

Cautions:

- Neuro Omega accessories should be handled with care. Avoid any mechanical stress to components
- Agents with an active ingredient of chlorine or chloride should not be used because this may lead to corrosion of stainless steel parts
- Pay special attention to lumens, crevices and hard to reach places.

Notes: Cleaning and must be performed prior to sterilization

Equipment: PH Neutral Detergent Cleaning Wipes, Lint-Free Wipes (see notes below).

Alpha Omega cleaning protocol:

4. Wipe with PH neutral detergent cleaning wipes until both the cleaning wipes and the device are visually free of soil. Pay special attention to lumens, crevices and hard reach places.
5. Wipe with lint-free wipes saturated with cold tap water and clean until both the lint-free wipes and the device are visually free residual detergent.
6. Dry the device with dry lint-free wipes until the device was visually free of any moisture.

3.1.6.3. Neuro Omega AutoClavable Drive Headstage Cleaning and Disinfection Protocol

Treatment	Time (mm:ss)	Temperature	Clean Solution
Pre-wash	Minimum 02:00	Cold Tap Water	N/A
Wash	Minimum 5:00	Hot Tap Water (Heated to 55°C)	**Alkaline 10.6 PH Detergent** (2-6ml/Liter) Or **Neutral pH Detergent**: Steris Prolystica 2X Concentrate Enzymatic Cleaner (1/8 - 3/8) oz. per gallon
Rinse	Minimum 02:00	Hot Tap Water (Heated to 55°C)	N/A
Thermal Disinfection	Minimum 03:00	Extra hot Tap Water (Heated to 90°C)	N/A
Drying	Minimum 35:00	99°C	N/A

3.1.6.4. Neuro Omega NeuroFortis Drive Headstage V.6 Cleaning and Disinfection Protocol

- For the Quick Switch please make sure to conduct the following steps befor the Automated machine washing cycle.
- Adjust all screws so that lumens are open prior to cleaning.
- Rinse the article under running utility (tap) water to remove gross soil.
- While rinsing brush the article with a soft bristled brush to aid in soil removal.

3.1.6.5. Machinery washer parameters

Treatment	Time (mm:ss)	Temperature	Clean Solution
Pre-wash	Minimum 02:00	Cold Tap Water	N/A
Wash	Minimum 5:00	Hot Tap Water (Heated to 55°C)	Alkaline 10.6 PH Detergent (2-6ml/Liter) Or Neutral pH Detergent: Steris Prolystica 2X Concentrate Enzymatic Cleaner (1/8 - 3/8) oz. per gallon
Rinse	Minimum 02:00	Hot Tap Water (Heated to 55°C)	N/A
Thermal Disinfection	Minimum 03:00	Extra hot Tap Water (Heated to 90°C)	N/A
Drying	Minimum 12:00 – 20:00 Maximum	110°C	N/A
	Minimum 20:00 – 35:00 Maximum	99 °C	N/A
Extra Drying Time	Refere to section below		

3.1.6.6. Extra Drying time

Alpha Omega recommend one of the following extra drying methods to avoid Sterrad process failure.

3.1.6.6.1. Compartment dryer

For minimum 40:00 Minutes heated up to 55°C

3.1.6.6.2. Manual drying using medical compressed air

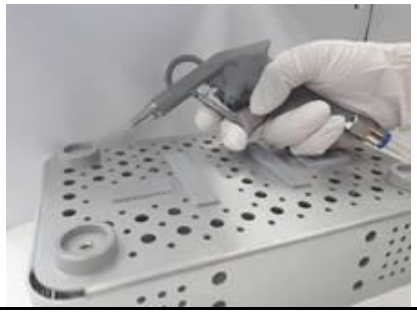
Following the recommended time, pressure and instruction details:

Drying time	Minimum 5:00 Minutes
Air pressure	Minimum 4 bar – Maximum 8 bar

Before starting the drying process, please make sure the air pistole is disinfected to avoid bacterial transmission to Alpha Omega's part.

The following table displays critical wet regions that should be blown out during drying with medical compressed air to avoid Sterilization process faliure:

Make sure the air pistole is close as possible to Alpha Omega part's openings and hollows

Position #	Description	Picture
1	Sterilization Tray Base Fetters on the Bottom	
2	Sterilization Tray Cover fixtures	
3	Sterilization Tray Silicon rubber	

4	Sterilization Tray Screws net	
5	HS Cable ODU Connectors	
6	HS Cable ODU Green Silicon rubber	
7	HS Cable Cable Jacket	
8	NeuroFortis drive Headstage Scale pointer	

9	NeuroFortis drive Headstage Scale pointer slot	
10	NeuroFortis drive Headstage Base	
11	NeuroFortis drive Headstage Knob and top cover holes	
12	NeuroFortis drive Headstage ODU Connector	
13	NeuroFortis drive Headstage Input cable connector	

- Note: Repeat position 8-13 several times until the item is dry

3.1.7. Maintenance, Inspection and Testing

Visually inspect all items for damage and wear. In the event of any visual damage, remove item from use and contact Alpha Omega.

All sterilizable accessories must undergo a preventive maintenance procedure that will be carried out by Alpha Omega every 6 months. Please refer to chapter 6.

3.1.8. Packaging

Notes:

- Refer to the compatibility matrix special notes for special packaging instructions

See the figure below (Figure 59) for proper item placement in the tray. Insert the components into the Tray as shown in the figure below.

Figure 60: NeuroFortis Neuro Omega Drive Headstage inside Sterilization Tray

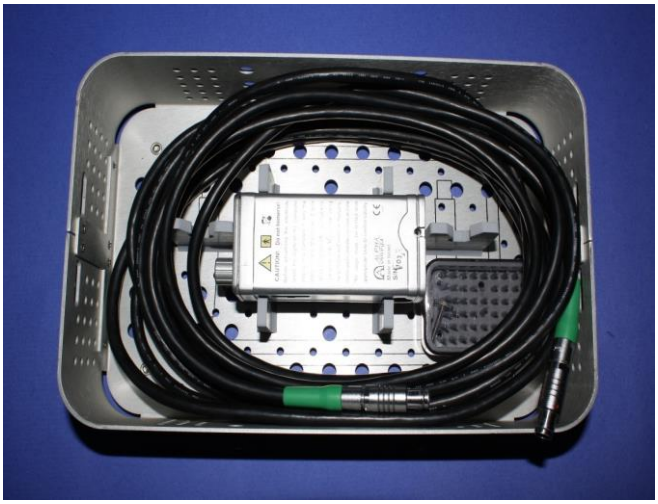


Figure 61:Neuro Omeg Drive Headstage

3.1.9. Sterilization

Sterilize using one of the following methods:

- Full Standard STERRAD NX cycle.
- Full Standard STERRAD 100NX cycle.
- V-PRO Lumen
- AutoClave (refer to section 3.1.1 for Autoclavable items)

3.1.9.1. Sterilization Using Autoclave

Sterilizer Type	Prevacuum
Preconditioning Pulses	3
Minimum Temperature	132°C
Minimum Full Cycle Time	4 minutes
Minimum Dry Time	60 minutes

3.1.10. Storage

Follow standard hospital operating procedure for storing of accessories. No particular requirements.

3.2. MECHANICAL ACCESSORIES CLEANING, DISINFECTION AND STERILIZATION

3.2.1. Mechanical Accessories

Notes:

- Not all of the components will be available with all systems

Component Name	Catalog Number	Compatibility	Picture	Cleaning And Disinfection	Sterilization
Microelectrode Holder	+: 341-000312-00 x: 341-000311-00	Leksell, CRW, Rosa and Compass		Automated washing Machine	Autoclave
Frameless Microelectrode Holder	+: 700-000313-00	Starfix, NexFrame		Automated washing Machine	Autoclave
Leibinger Electrode Holder	x: 341-000144-00	Leibinger		Automated washing Machine	Autoclave
NexDrive Microelectrode Holder	700-000316-00	NexFrame		Automated washing Machine	Autoclave
Quick Switch	+: 700-000898-00 x: 700-000897-00	Leksell, CRW, Rosa and Compass		Automated washing Machine	Autoclave

Note: NexDrive microelectrode holder 700-000316-00 compatible only to NexDrive

Component Name	Catalog Number	Compatibility	Picture	Cleaning And Disinfection	Sterilization
Frameless Quick Switch	+: 700-000899-00	StarFix, NexFrame		Automated washing Machine	Autoclave
BenGun	700-000307-01	Leksell, CRW, Leibinger ZD/RM, Rosa and Compass		Automated washing Machine	Autoclave
BenGun and Microelectrode Screws	341-000056-05	Leksell, CRW, Rosa, Compass, Starfix and NexFrame		Automated washing Machine	Autoclave
Leibinger Microelectrode Holder and BenGun screws	341-001728-00	Leibinger RM/ZD		Automated washing Machine	Autoclave
Screwdriver	365-000015-00	Leksell, CRW, Rosa, Compass, Starfix, NexFrame, Leibinger RM/ZD		Automated washing Machine	Autoclave
X/Y Frame Adapter	Leksell: 341-309001-00 CRW: 341-309002-00 Compass: 341-3090003-00	Leksell, CRW, Rosa and Compass		Automated washing Machine	Autoclave
X/Y Frame Adapter Thumb Screw	700-001330-03	All X/Y Frame adapters		Automated washing Machine	Autoclave

Component Name	Catalog Number	Compatibility	Picture	Cleaning And Disinfection	Sterilization
Non-X/Y Frame Adapter	Leksell: 341-309011-00 CRW: 341-309010-00 Compass: 341-3090003-00	Leksell, CRW, Rosa and Compass		Automated washing Machine	Autoclave
Leibinger Frame Adapter RM/ZD	341-309018-00	Leibinger RM/ZD		Automated washing Machine	Autoclave
Leibinger RM Bracket	700-000032-00	Leibinger RM		Automated washing Machine	Autoclave
Bracket ZD Leibinger	700-000847-00	Leibinger ZD		Automated washing Machine	Autoclave
NexFrame Adapter	Nexframe: 700-000320-00	NexFrame		Automated washing Machine	Autoclave
Starfix Frame Adjustable Adapter	Starfix: 700-001320-00	Starfix		Automated washing Machine	Autoclave

Component Name	Catalog Number	Compatibility	Picture	Cleaning And Disinfection	Sterilization
Starfix Frame Fixed Adapter	T30: 700-001995-00 T35: 700-001996-00 T40: 700-001998-00 T45: 700-001999-00 T50: 700-001997-00			Automated washing Machine	Autoclave
DBS Holder	700-000420-00	Leksell, CRW, Rosa, Compass and Leibinger ZD/RM		Automated washing Machine	Autoclave
Short DBS Holder	700-000422-00	Leksell, CRW, Rosa, Compass and Leibinger ZD/RM		Automated washing Machine	Autoclave
Frameless DBS Holder	700-000428-00	Nexframe, Starfix		Automated washing Machine	Autoclave
DBS Ruler	215-001111-00	Leksell, CRW, Rosa, Compass, Leibinger ZD/RM, Nexframe and Starfix		Automated washing Machine	Autoclave
Autoclave Sterilization Tray	366-000022-22	Leksell, CRW, Rosa, Compass, Leibinger ZD/RM, Nexframe and Starfix		Automated washing Machine	Autoclave

Component Name	Catalog Number	Compatibility	Picture	Cleaning And Disinfection	Sterilization
Net Sterilization Tray for Mechanical accessories	366-000322-22	Leksell, CRW, Rosa, Compass, Leibinger ZD/RM, Nexframe and Starfix		Automated washing Machine	Autoclave

3.2.2. Warnings

Warnings:

- Agents with an active ingredient of chlorine or chloride should not be used because this may lead to corrosion of stainless steel parts

3.2.3. Limitations on reprocessing

Cautions:

- Do not reprocess Neuro Omega accessories in case of visual damage.

Notes:

Some items may require special attention; refer to the compatibility matrix special notes

3.2.4. Point of Use

Remove excess soil with a clean disposable cloth.

3.2.5. Containment and Transportation

Always use sterilization trays for containment and transportation. Do not flip or rotate trays during transportation.

Always reprocess accessories as soon as possible after use.

3.2.6. Preparation for Cleaning

3.2.6.1. Sterilization Tray

Remove the accessories from the sterilization trays. Using a clean soft cloth that has been soaked in a detergent solution wipe the trays and its inserts to remove any visible soil. Use soft bristle brushes to reach hard-to-clean areas.

3.2.6.2. Mechanical Accessories

Notes:

- Some items may require special attention; refer to the compatibility matrix special notes

For the DBS Holder (700-000420-00 or 700-000428-00), make sure to remove the holder from the rod.

For the microelectrode holder (341-000312-00 or 341-000311-00) and Bengun (700-000307-00), make sure to remove all screws (341-000056-00).

3.2.6.3. Cleaning and Disinfection Instructions

Warnings:

- Agents with an active ingredient of chlorine or chloride should not be used because this may lead to corrosion of stainless steel parts

Cautions:

- Neuro Omega accessories should be handled with care. Avoid any mechanical stress to components
- Pay special attention to lumens, crevices and hard to reach places.

Notes:

- Cleaning and disinfection must be performed prior to sterilization

3.2.6.4. Cleaning and Disinfection Protocol

Alpha Omega cleaning protocol:

Machine washing using a detergent with pH 10-11 (Alkaline):

Machine wash cycle including:

1. Pre-washing with cold water (temperature less than 30 °C (86 °F)), for minimum 2 minutes.
2. Cleaning with detergent at a temperature of 55 °C (131 °F) for 5 minimum minutes.
3. Thermal disinfection - without detergent at 90 °C (194 °F) for minimum 3 minutes for thermal
4. Rinse with hot water at 55 °C (131 °F) for minimum 2 minutes.
5. Dry the equipment in the washer-disinfector at minimum 99 °C (210 °F) for minimum 35 minutes.

Machinery washer parameters

Treatment	Time (mm:ss)	Temperature	Clean Solution
Pre-wash	Minimum 02:00	Cold Tap Water	N/A
Wash	Minimum 5:00	Hot Tap Water (Heated to 55°C)	Alkaline 10.6 PH Detergent (2-6ml/Liter) Or Neutral pH Detergent: Steris Prolystica 2X Concentrate Enzymatic Cleaner (1/8 - 3/8) oz. per gallon
Rinse	Minimum 02:00	Hot Tap Water (Heated to 55°C)	N/A
Thermal Disinfection	Minimum 03:00	Extra hot Tap Water (Heated to 90°C)	N/A
Drying	Minimum 12:00 – 20:00 Maximum	110°C	N/A
	Minimum 20:00 – 35:00 Maximum	99 °C	N/A

3.2.7. Maintenance, Inspection and Testing

Visually inspect all items for damage and wear. In the event of any visual damage, remove item from use and contact Alpha Omega.

All sterilizable accessories must undergo a preventive maintenance procedure that will be carried out by Alpha Omega every 6 months. Please refer to chapter 6. X/Y frame adapters must undergo inspection and testing every 20 cases.

3.2.8. Packaging of Mechanical Accessories

The following items can be placed in the Alpha Omega autoclave sterilization tray,

1. X/Y Frame Adapter or Nexframe/Starfix Frame Adapter
2. Electrodes (single use – do not reuse)
3. Cannulas (single use – do not reuse)
4. Stylets (single use – do not reuse)
5. Non-X/Y Frame Adapter
6. DBS Ruler
7. DBS Holder

8. BenGun
9. Microelectrode Holder
10. BenGun and Mircroelectrode Holder Screws
11. Screwdriver

See the figure below (Figure 60) for proper item placement in the tray. After packing the accessories in the tray, individually wrap the tray in two layers of 1 ply polypropylene wrap.

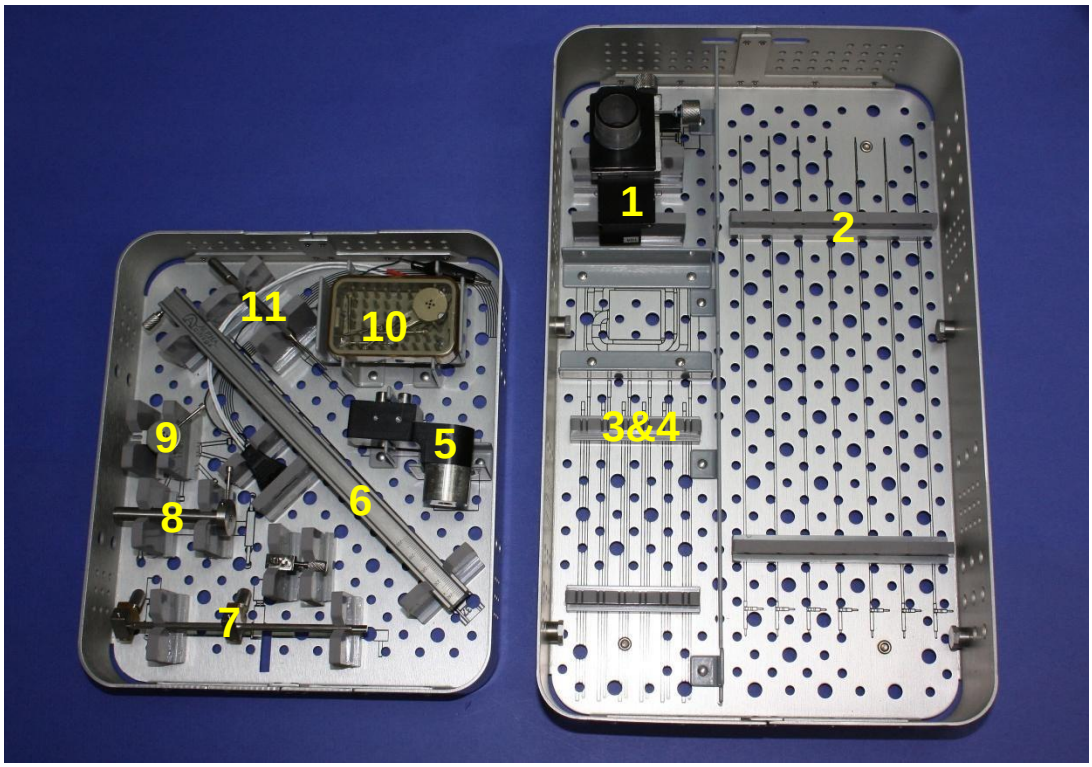


Figure 62:Mechanical Accessories Sterilization Tray

3.2.9. Sterilization Using Autoclave

Sterilizer Type	Prevacuum
Preconditioning Pulses	3
Minimum Temperature	132°C
Minimum Full Cycle Time	4 minutes
Minimum Dry Time	60 minutes

Notes:

- If a dry time amount less than 60 minutes is used, the accessories would be considered an immediate use steam sterilization (IUSS). All IUSS cycles should be used immediately and cannot be stored.

3.2.10. Storage

Follow standard hospital operating procedure for storing of accessories. No particular requirements

CHAPTER 4. OPERATION OF THE NEURO OMEGA SYSTEM

4.1. USING THE NEURO OMEGA SYSTEM FOR MICROELECTRODE RECORDING AND STIMULATION

Prepare the Neuro Omega system for use, as described in section *CHAPTER 3*.

Power on the Neuro Omega, as described in section ***4.2***.

Do one of the following:

- If the patient's info has not yet been supplied, then supply the patient's info, as described in section ***4.4***.
- If the patient's info was supplied on an earlier occasion, then select the patient, as described in section ***4.5***.

Define events, as described in section ***4.7***.

Verify diagnostic indicators, as described in section ***4.8***.

Do one of the following:

- For first time use, configure drive and save settings, as described in section ***0.***
- After first time use, verify the starting depth of the electrode, as described in section ***4.10***.

Create a new trajectory, as described in section ***4.11***.

Check impedance, as described in section ***4.13***.

Determine placement by manipulating the Drive Headstage, as described in section ***4.14***, and at each recording site, doing the following:

- Monitor neural activity, as described in section ***4.15***.
- Assess OPRA, as described in section ***4.16***
- Mark significant events, as described in section ***4.17***.
- Print the trajectory as needed, as described in section ***4.17.34.18***.
- Save data manually to the log file as needed, as described in section ***4.19***.

Stimulate motor and sensory neurons, as described in section ***4.20***.

Define, and then during stimulation monitor, the potential evoked by stimulation, as described in section ***4.21***.

Defining and Monitoring the Peristimulus Histogram (PSTH), described in section ***4.21***

Starting the Neuro Omega Player, as described in section **4.23**.

4.2. POWERING ON THE NEURO OMEGA

This procedure describes how to power on the Neuro Omega.

To power on the Neuro Omega:

Turn on the unit from the trolley (Figure 5).

If the **Patient Info** window (Figure 63) does not appear automatically, double-click the Neuro Omega shortcut.

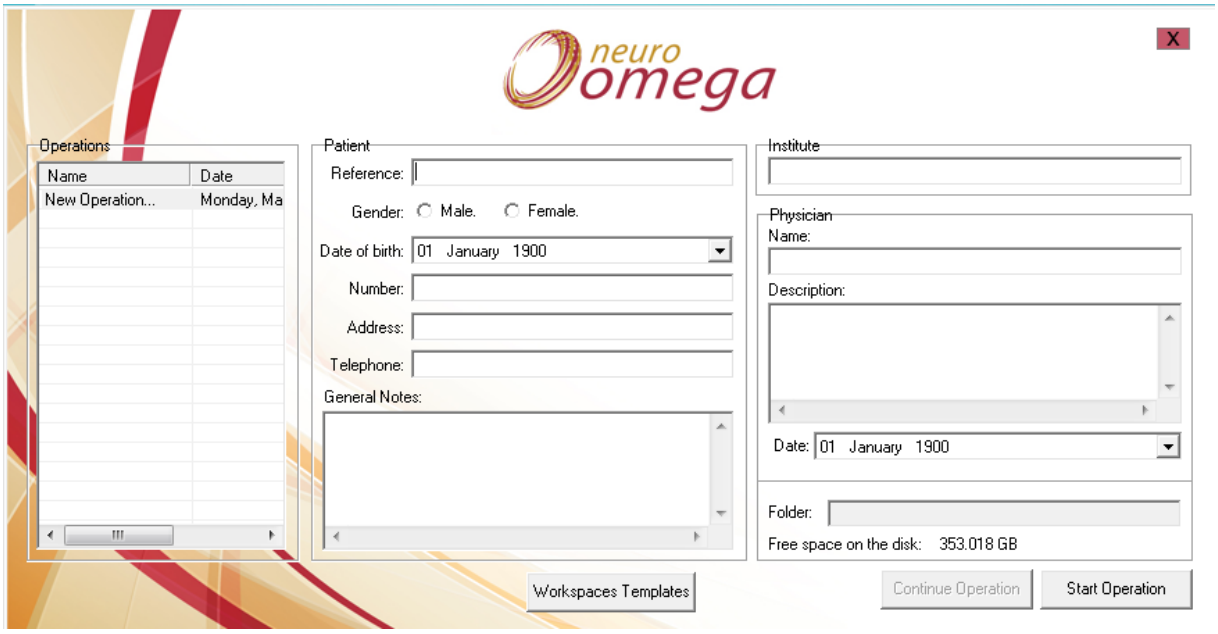


Figure 63: Patient Info Window

4.3. WORKSPACE MAKER

This procedure describes how to use the Workspace maker depending on the surgery and the functions in use.

To choose Workspace:

Press on **Workspaces Templates** button in the Patient Info Window.

The Choose Workspace Template Window is displayed (see Figure 64).

In order to create new Workspace see section 4.3.1

In order to edit existing Workspace see section 4.3.2

In order to delete existing Workspace see section 4.3.3

For windows default see section 4.3.4

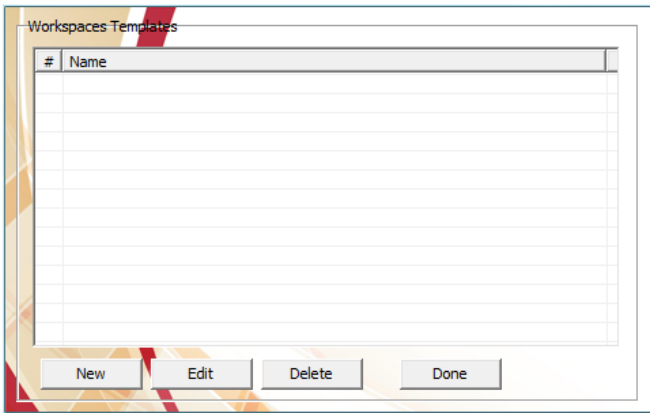


Figure 64 : Choose Workspace Templates Window

4.3.1. Create New Workspace

This procedure describes how to create new Workspace according to the used functions in the surgery.

- Press on New button in the Choose Workspace Templates Window (Figure 64). System Modules Window (Figure 65) will appear.

  This window contains all the system modules ports according to the system configuration. Only available modules will appear.

- Choose in each port the module you want to connect. If the port won't be used in this workspace, you can choose the option "Not used".

- Check the Analog/Digital Input/Output box if you intend to use the ADIO panel.

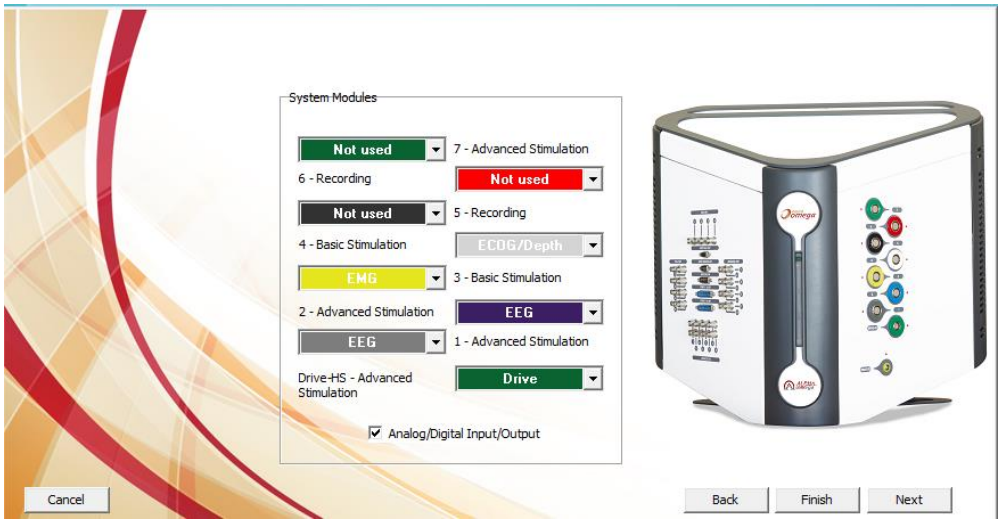


Figure 65: System Modules Window

- The first module is the Drive. Select the type of drive you are using. Neuro Omega System can support the following drives:
  - Neuro Omega Drive Headstage
  - Neuro Omega NeuroFortis Drive Headstage
  - Neuro Omega MER Headstage
  - Neuro Omega Autoclavable Drive Headstage

FHC Drive

- NEX Drive

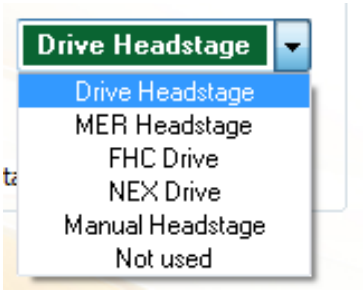


Figure 66: Drive Modules

- Press **Next** in order to continue setting the channels.

4.3.1.1. EEG Module:

This procedure describes how to map EEG contacts according to the map type (Figure 67).

You can choose to use one of two map types:

- EEG map 10-20.
- EEG map extended 10-20.

Note: it is possible to select\unselect contacts you need to use

Map the electrode contacts as required.

Each module contains 16 EEG contacts, you can map each available EEG contact as following:

- According to EEG location on the map. By pressing **Map Channels** the contacts will be named after the contact location on the map.
- Default mapping. By pressing Default, the contacts will be named according to the contact type and Headbox number.
- User defined map, using free text. Click the channel name, and then change it as required.
- Contacts that are not mapped will be marked as "Not used". Click the contact name and choose "Not used".

Note: If you used all the map locations, the other contacts will be marked as "Not used".

Press **Next** to continue with the workspace settings.

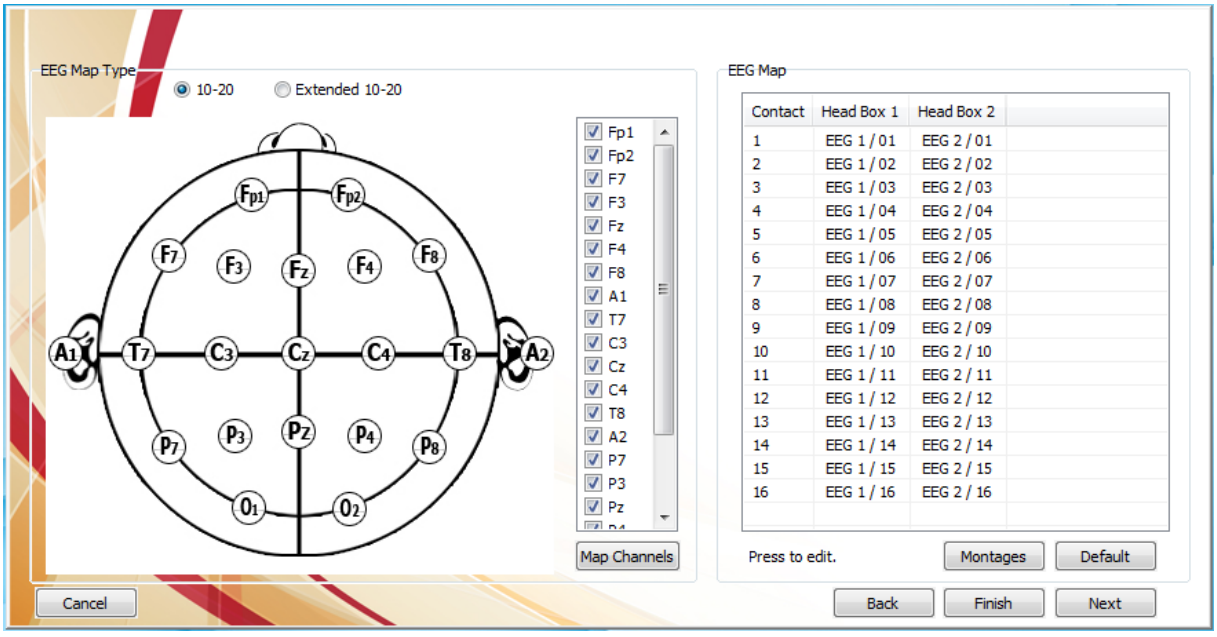


Figure 67: 10-20 EEG map

4.3.1.2. EEG Montage

This procedure describes how to map EEG contacts according to the predefined Montage.

1. Press map channels (figure 107).

2. Press Montages. Choose to use one of the following predefined montages:

- Longitudinal Map
- Transverse Map
- Referential Map

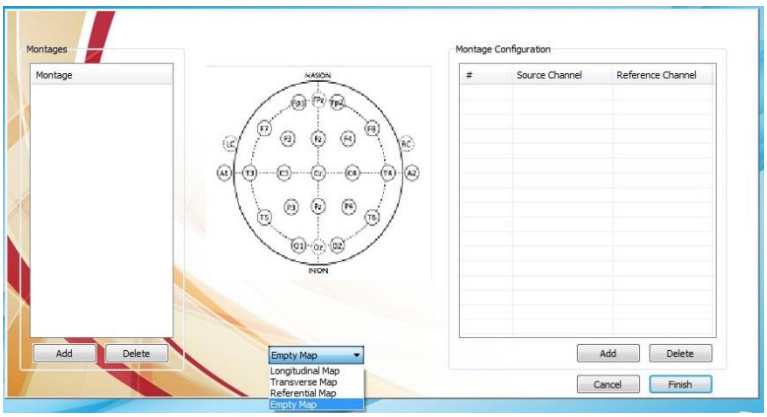


Figure 68: Montages

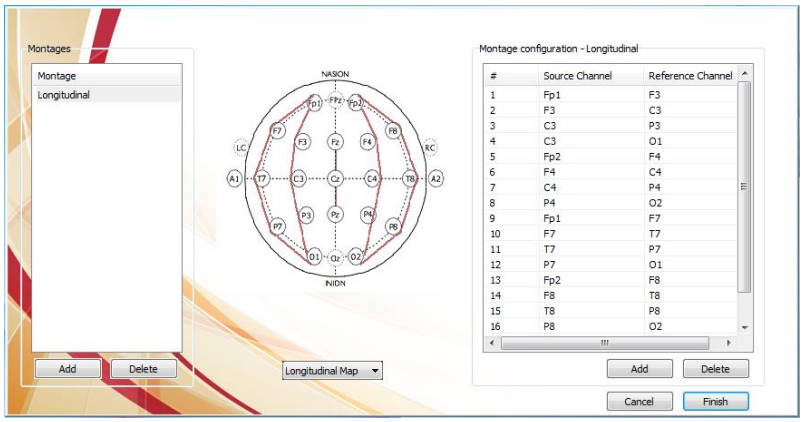


Figure 69: Longitudinal

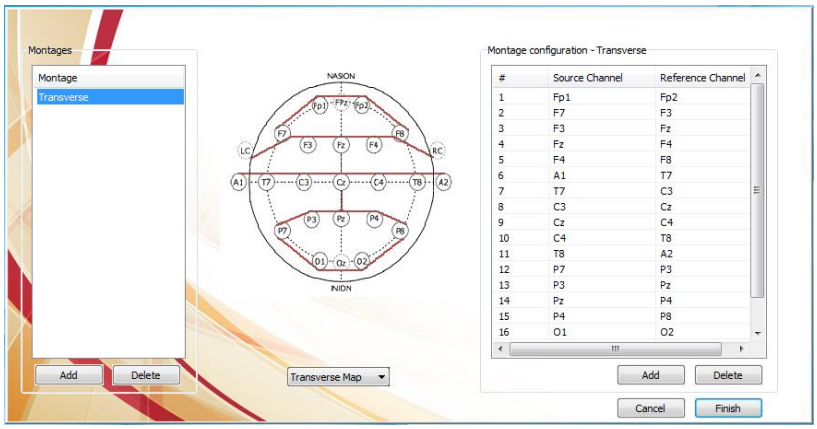


Figure 70:Transverse

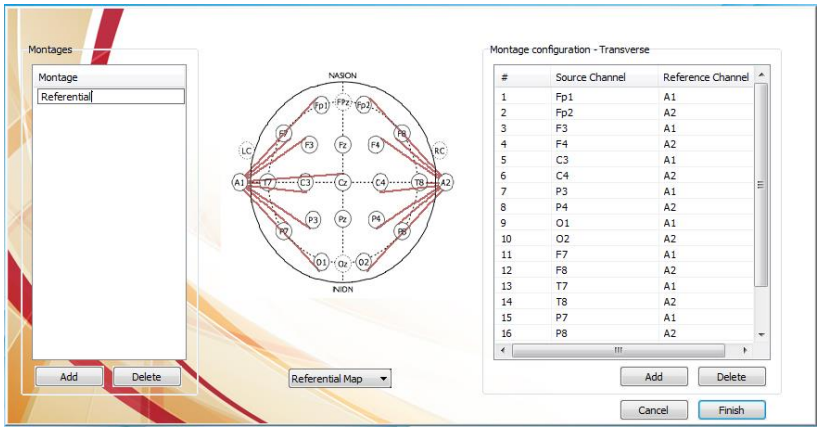


Figure 71:Referential

- Choosing empty map configuration enable the user to add desired amount of channels, and define the source and reference contacts.

When opening the software, the Montage Map channels will appear as in the following figure, each channel named with its' source and reference EEG contacts.

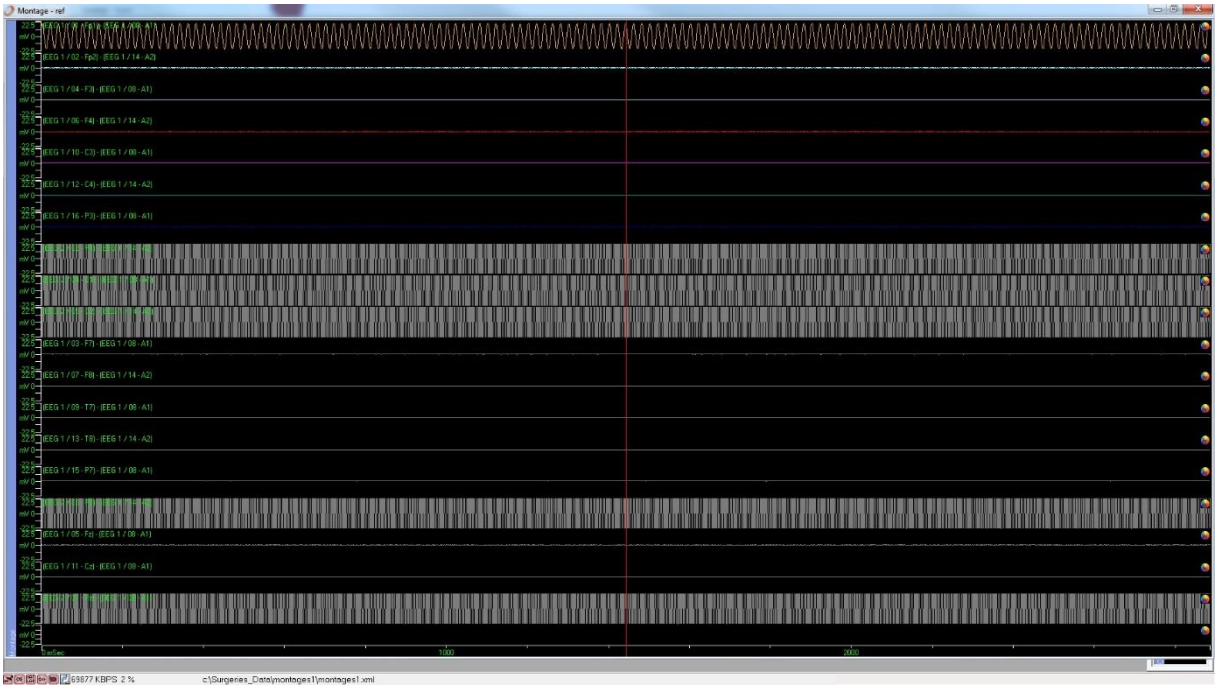


Figure 72:Montage channels display

To change signal display color press the icon on the let in the display channel window:

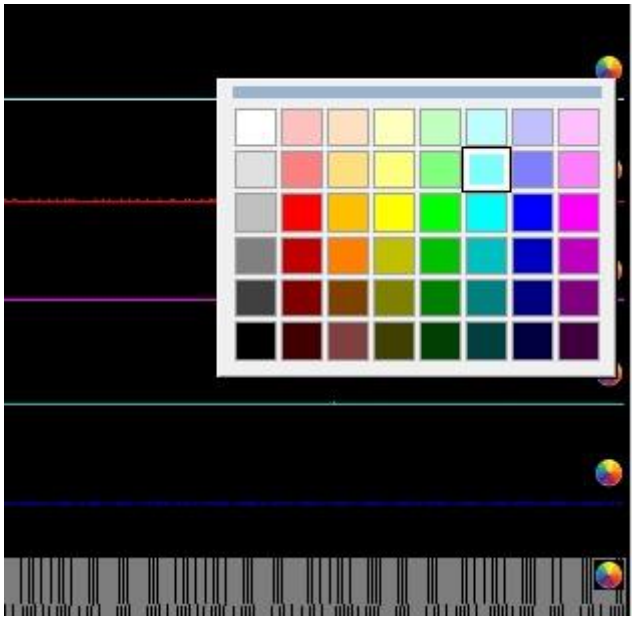


Figure 73: Change signal display color

In the option menu, user can apply digital input trigger to display within the EEG signal channel display:

- Right click on the desired channel and chose options
- Options popup window will appear (figure 68)
- User can switch to other montage setup by pressing montages and select the new desired montage.
- Show info line, can be V-checked to be displayed

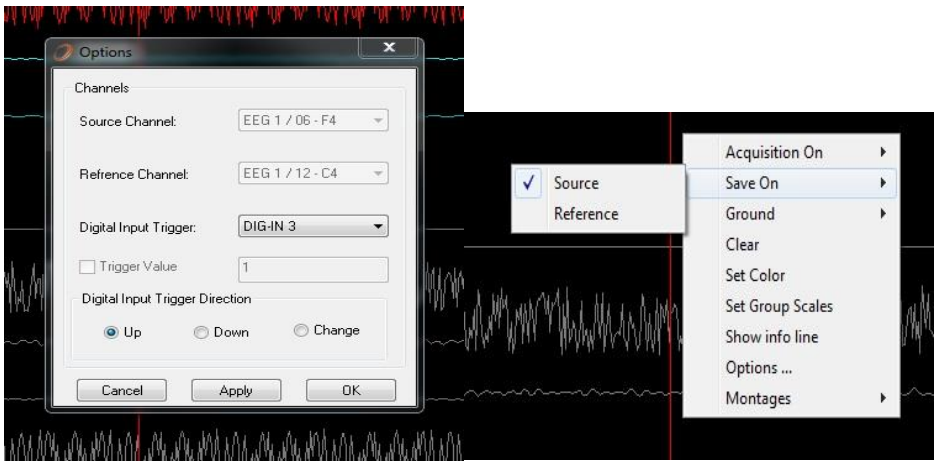


Figure 74: option to add digital inut trigger

4.3.1.3. EMG Module

This procedure describes how to map EMG contacts. **(**Figure 75**)**

Map the electrode contacts as required.

Each module contains 16 EMG contacts, you can map each available EMG contact as following:

- Default mapping. By pressing Default, the contacts will be named according to the contact type and Headbox number.
- User defined map, using free text. Click the channel name, and then change it as required.
- Contacts that are not mapped will be marked as "Not used".

Note: If you used all the map locations, the other contacts will be marked as "Not used".

Press **Next** to continue with the workspace settings.

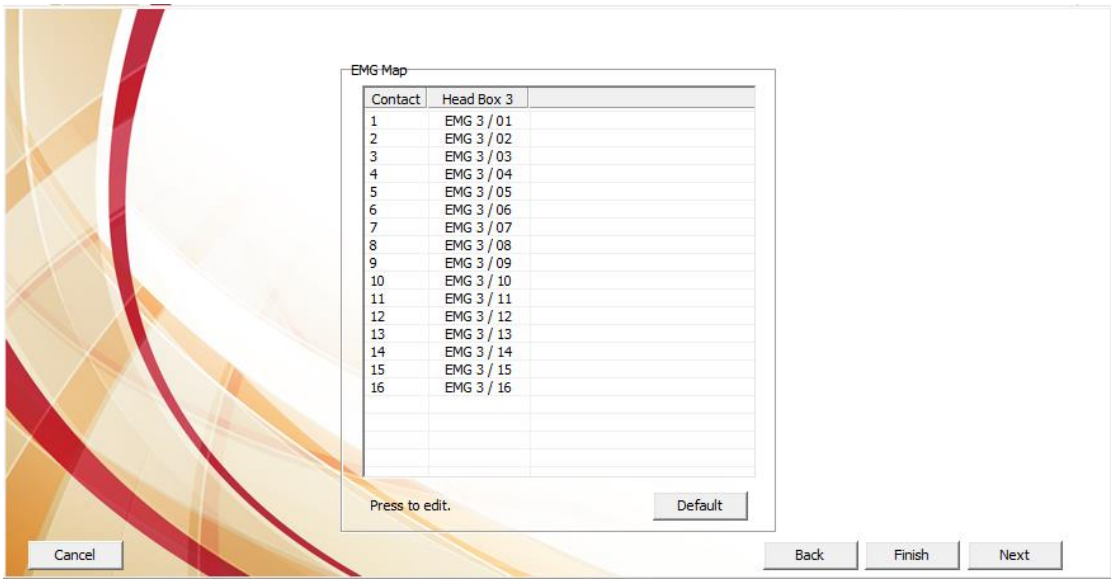


Figure 75: EMG contact mapping

4.3.1.4. ECOG Module

This procedure describes how to map ECOG contacts. **(**Figure 76**).**

1. Add, delete or edit the electrode contacts as required.

Each module contains 16 ECOG/Depth contacts; you can add/delete or edit Arrays as follows:

- Press the **Add** button in order to add an Array.
- The array can be named via the defined map, using free text. Click on the array name and change it.
- The array type can be changed, by clicking the type and choosing Micro or Macro.

- For each array type, choose the filters limits – HF or LF. See spec.
- The array size can be changed by clicking the size value and typing a new one.
- The array starting index can be changed by clicking on the starting index value and typing new one.
- Choose an array and press on **Delete** button in order to delete the array.

2. Map the electrode contacts as required.
   - Default mapping. By pressing Default, the contacts will be named according to the contact type and Headbox number.
   - Press on **Map Channels** button and all the channels will be mapped according to the arrays entries.
   - User defined map, using free text. Click the channel name, and then change it as required.
   - Contacts that are not mapped will be marked as "Not used".

> **Note:** If you used all the map locations, the other contacts will be marked as "Not used".

3. Press Next to continue with the workspace settings.

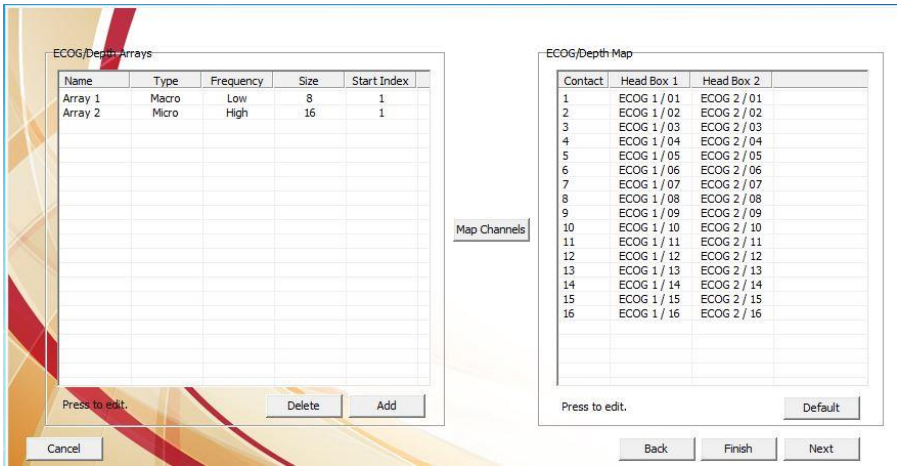


Figure 76: ECOG/Depth Contact Mapping

4.3.1.5. ADIO Panel

This procedure describes how to select Analog/Digital ports according to the surgery.

Select Analog/Digital ports according to the use. (Figure 77)

- Digital Input 1-4
- Digital Output 1-8
- Additional Digital Input
- Additional Digital Output
- Analog Input 1-8
- Analog Output 1-8
- Port 1 - 16 bit
- Port 2 -16 bit

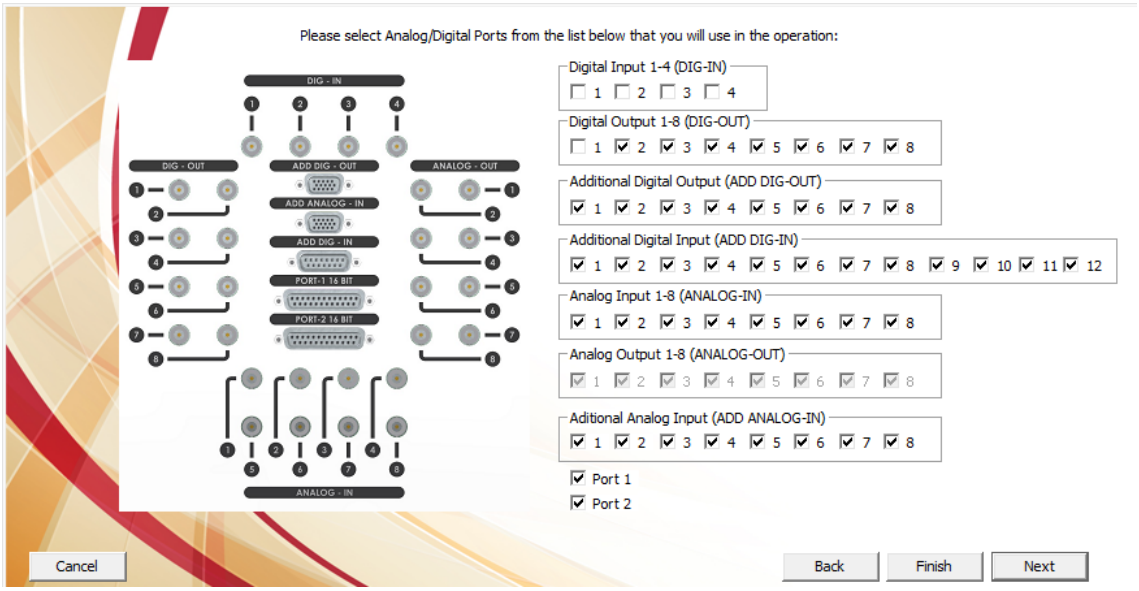
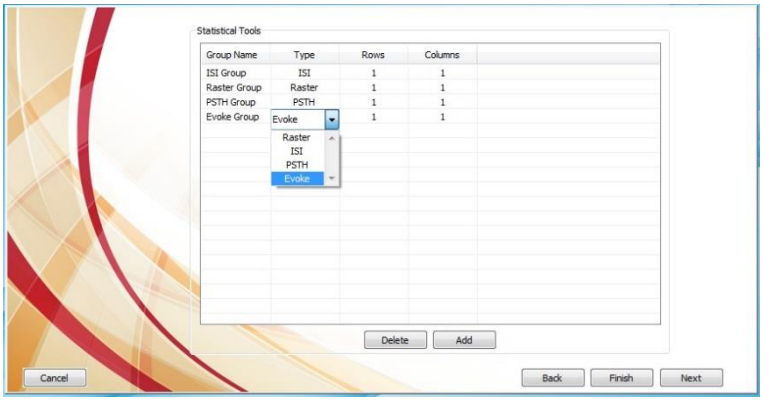


Figure 77: Analog/Digital Ports

4.3.1.6. Statistical Tool

This procedure describes how to create statistical tools groups to display on the software.



Add desired amount of statistical groups.

Click on the cell in the type column to select of the following statistical tools:

- ISI
- Raster
- PSTH
- Evoke

Select number of rows and columns for group, maximum 8 rows/columns.

Press Next to continue. A Save Workspace Window (Figure 78) will appear.

Write the workspace name in the New Workspace Template File Name.

Press Save.

Choose Workspace Window will appear with all the current workspaces.

Choose the Workspace you created and press Done.

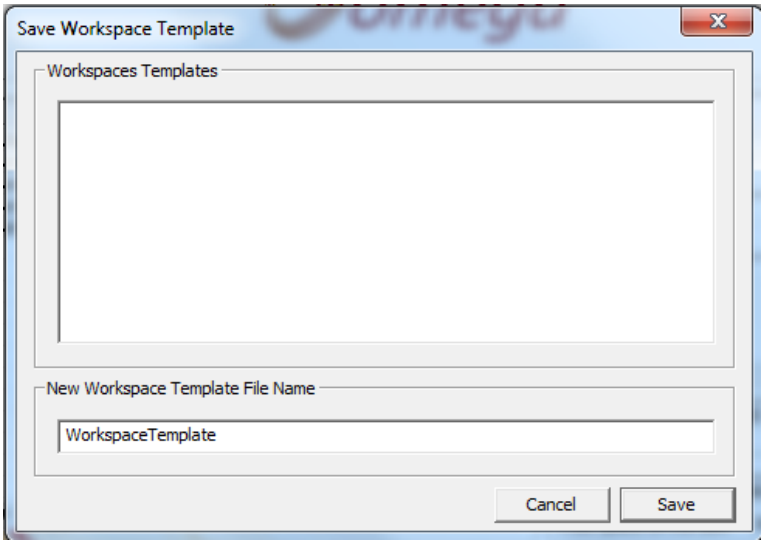


Figure 78: Save Workspace Template

4.3.2. Edit Workspace

This procedure describes how to edit existent Workspace according to the used functions in the surgery.

Choose the Workspace you want to edit from Choose Workspace Template (see Figure 64).

Press on **Edit** button.

System Modules Window (Figure 65**)** will appear with all the current Workspace settings.

Edit the workspace settings according to section ***(4.3.1).***

For EEG Module Editing see section (4.3.1.1).

For EMG Module Editing see section (4.3.1.3).

For ECoG Module Editing see section (4.3.1.4)

For ADIO Editing see section (4.3.1.4).

Press the **Finish** button in case the editing is done.

Save Workspace Window (Figure 78**)** will appear. You can change the workspace name or write over the current one.

Press **Save** button**.**

4.3.3. Delete Workspace.

This procedure describes how to delete existent Workspace.

Choose the Workspace you want to delete from Choose Workspace Template (Figure 64)

Press the **Delete** button.

The chosen workspace will be deleted.

4.3.4. Windows Default

This section describes which windows will appear according to the Workspace configuration.

Module	Windows
Drive	- Continuous group per all the drive SPK channels. - Continuous group per all the drive Macro LFP channels. - Segmented group per all the drive segmented channels.

Module	Windows
	- Evoked Potential - Inter Spike Interval Selected - Peristimulus time Histogram Selected - Raster Selected
EEG	- Continuous group per all used EEG contacts.
EMG	- Continuous group per all used EMG contacts.
ECOG/Depth	- Continuous group per each Micro/Macro ECOG/Depth array that have ECOG/Depth contact mapped to one of it entries. - Segmented group per each Micro ECOG/Depth contact mapped to one of it entries. - Continuous group per all ECOG/Depth contacts that are mapped not to an array entry.
ADIO	- Digital adapter group per all Digital Input channels. - Digital adapter group per all the Digital Output channels bits. - Digital adapter group per all Additional Digital Input channels. - Digital adapter group per all Additional Digital Output channel bits. - Continuous adapter group per all Analog Input channels. - Continuous adapter group per all Additional Analog Input channels. - Digital adapter group per Port 1. - Digital adapter group per Port 2.

4.4. SUPPLYING PATIENT INFO

This procedure describes how to supply patient info for the patient on whom the operation is to be performed. It is a prerequisite for recording neural activity for a new patient.

To supply patient info for a new patient:

In the **Patient Info** window (see Figure 63), in the **Operations** list, select **New Operation**.

In the Patient area, in the **Reference** field, enter the patient's reference. This reference will create a new folder under this name/number for data logging.

> **Note:** For purposes of privacy, the patient's name should not be used.

In the **Patient**, **Institute**, and **Physician** areas, enter information as required.

Click **Start Operation**. The Choose Workspace Template window (Figure 79) will appear.

Choose workspace and press **Start**.

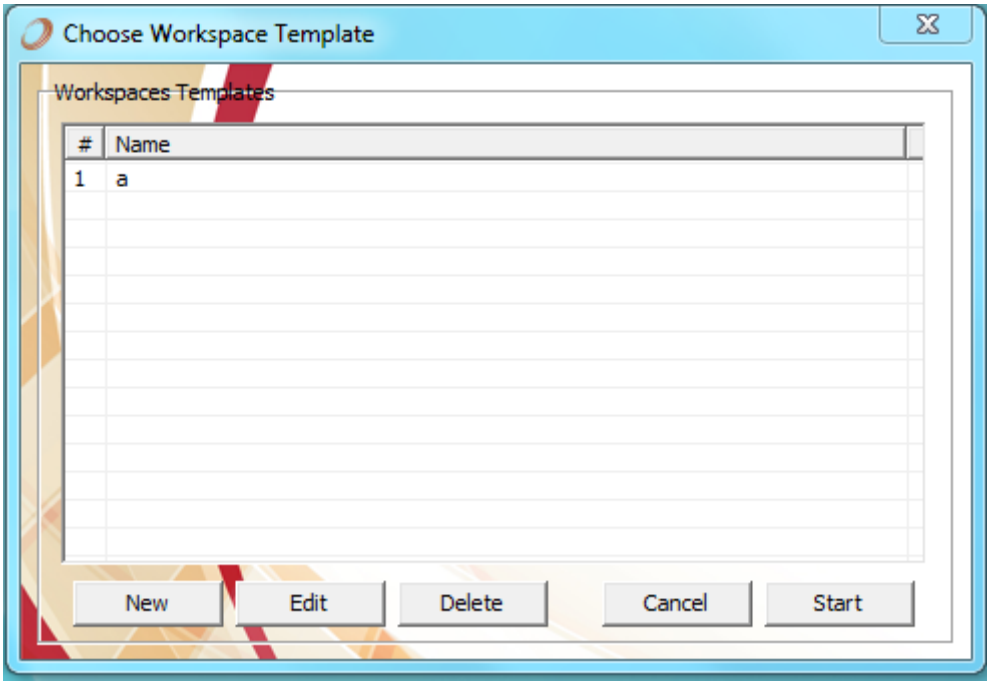


Figure 79: Choose Workspace Template Window

The main window appears.

4.5. SELECTING AN EXISTING PATIENT

This procedure describes how to select a patient on whom the operation is to be performed, whose info was supplied on an earlier occasion. This is a prerequisite for recording neural activity for an existing patient.

To select an existing patient:

In the **Patient Info** window (see Figure 63), in the **Operations** list, select the patient's reference on whom the operation is to be performed.

Click **Continue Operation**.

The main window appears.

4.6. NEURO OMEGA INTERFACE NAVIGATION

The Neuro Omega interface is made up of the following components:

- **Toolbar**: See section ***4.6.1*** for more information.
- **Workspace**: See section ***4.6.2*** for more information.
- **Trajectory Graph**: See section ***4.6.2.1*** for more information.
- **System Diagnostics**: See section ***4.6.4*** for opening system diagnostics.

4.6.1. Toolbar

The toolbar is comprised of two rows of buttons and controls.

The top row contains the following buttons:

- **Clear All** : Restarts all readings in the open Workspace windows
- **Pause** : Pauses all readings in the open Workspace windows
- **Restore Layout** : Returns all windows to their default positions – closing windows not opened by default, and opening windows open by default
- **Window List** : Opens the Windows dialog box for activating and closing Workspace windows (see section ***4.6.2.1***)
- **Events Properties** : Opens the Events Control Panel for defining events (see section ***4.7***), marking events (see section ***4.17.1***), and adding remarks (see section ***4.17.2***)
- **Analog Output** : Opens the Analog Output dialog box for routing a channel to an external device (see section ***5.4***)
- **Sound Level Bar** **:** Controls the computer main volume level

- **Sound Suppression Bar** 

: Controls the level of sound suppression of the channel that is heard by filtering out any signal below the bar threshold

The left side of the bottom row of the toolbar (***Figure 80***) contains buttons and controls for driving the electrode.

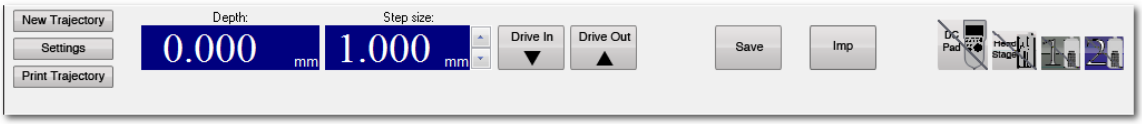


Figure 80: Toolbar, Bottom Row, Left Side

The buttons and controls on the left side of the bottom row of the toolbar (*Figure 80*) are as follows:

- **New Trajectory**: Opens the **Set Position** dialog box for creating a new trajectory (see section ***4.10***)
- **Settings**: Opens the Settings dialog box (see section ***0***)
- **Print Trajectory**: Opens the Print Trajectory dialog box (see section ***4.17.3***)
- **Depth**: Displays the current depth of the trajectory (see section ***4.14***)
- **Step Size**: Allows you to change the step size when driving the electrode in and out (see section ***4.14***)
- **Drive In/Out**: Allows you to drive the electrode in and out according to the step size (see section ***4.14***)
- **Save**: Allows you to manually start saving the current data set at the site to the log file (see section ***4.19***)
- **Imp**: Checks the impedance and opens the **Impedance** dialog box (see section ***4.13***)
- **Diagnostic Indicators**: Displays the diagnostic indicators for the remote control, the Headstage, and each of the Headboxes (see section ***4.7***)

The right side of the bottom row of the toolbar (***Figure 81***) contains buttons and controls for stimulation.

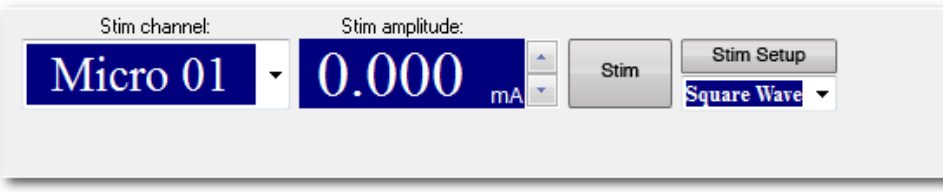


Figure 81: Toolbar, Bottom Row, Right Side

The buttons and controls on the right side of the bottom row of the toolbar (*Figure 81*) are as follows:

- **Stim Channel**: Allows you to change the channel receiving stimulation (see section ***4.20.2***)
- **Stim Amplitude**: Allows you to change the amplitude of the stimulation (see section ***4.20.2)***
- **Stim**: Applies stimulation (see section ***4.20.2***)
- **Stim Setup**: Opens the Stimulation Setup dialog box for applying stimulation (see section ***4.20.1***)

4.6.2. Workspace

The Workspace (***Figure 82***), which is to the right of the Trajectory graph (see section ***4.6.2.1***), contains all of the Workspace windows involved in monitoring and stimulating brain activity. A graph displays activity from one channel, and each Workspace window contains one or more graphs.

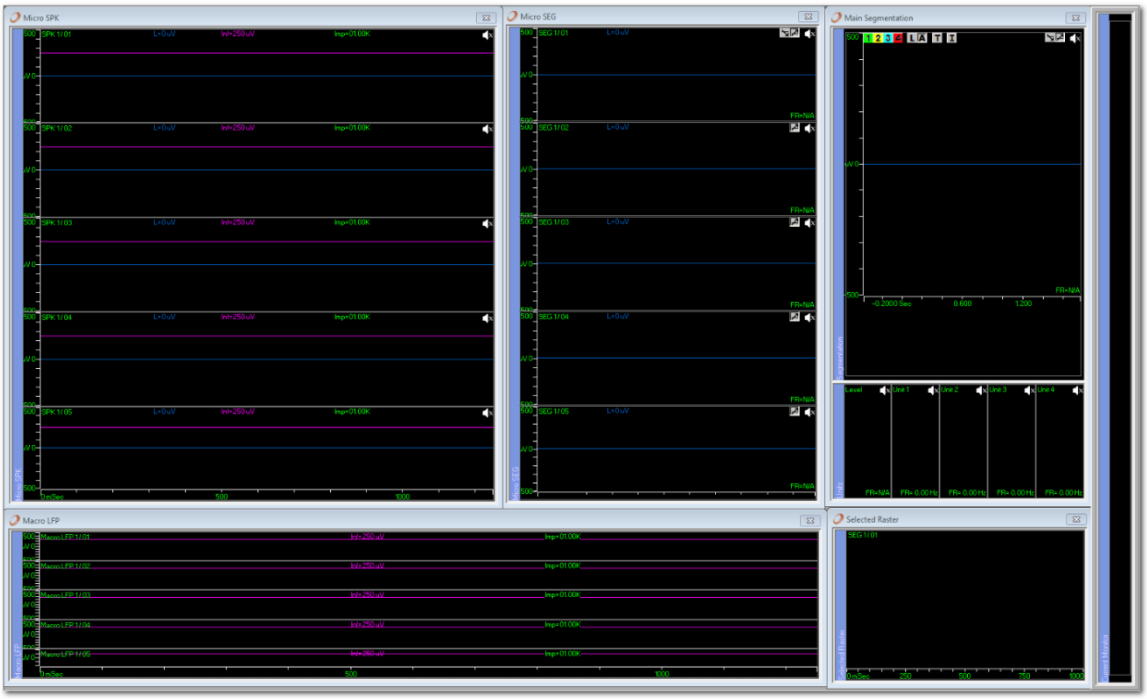


Figure 82: Workspace

The following procedures describe actions you can perform on Workspace windows in the course of using the Alpha Omega system for implanting the DBS electrode and advanced research:

- To close and open a Workspace window, see section ***4.6.2.1.***
- To pop a Workspace window out of the Workspace and onto the computer's desktop, or back into the Workspace, see section ***4.6.2.2***.

- To restore the Workspace layout to the default, see section ***4.6.2.3***.
- To clear all of the open Workspace windows from displaying their channels and have them restart, see section ***4.6.2.4***.
- To pause all open Workspace windows from displaying their channels, see section ***4.6.2.5***.

4.6.2.1. Closing and Opening a Workspace Window

This procedure describes how to close a Workspace window open in the Workspace, and open a Workspace window that you closed or that closed by default.

To open and close a Workspace window:

Close a Workspace window in any of the following ways:

a. Click the  at the top right corner of the window.

Click the  at the top left corner of the window, and then select **Close**.

Close more than one Workspace window at a time as follows:

a. From the toolbar, click  **Window List**.

The **Window** dialog box opens (***Figure 83***).

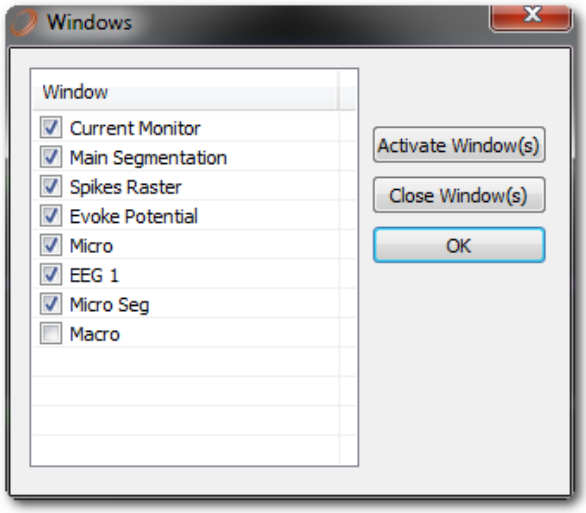


Figure 83: Window Dialog Box

Clear the checkbox of the window you want to close.

The window closes.

Open Workspace windows as follows:

a. From the toolbar, click  **Window List**.

The **Window** dialog box opens (see ***Figure 83***).

Select the checkboxes of the windows you want to open.

The windows appear in the Workspace.

4.6.2.2. Popping a Workspace Window In and Out

This procedure describes how to pop a Workspace window in and out of the main Alpha Omega window, which is helpful when dealing with a large number of Workspace windows.

To pop a Workspace window in and out of the main Alpha Omega window:

In the Workspace, in the upper-left hand corner of the Workspace window, click  , and then click **Pop Out**.

The Workspace window appears outside of the main Alpha Omega window.

Outside the main Alpha Omega window, in the upper-left hand corner of the Workspace window, click  , and then click **Pop In**.

The Workspace window returns to the Workspace.

4.6.2.3. Restoring the Workspace Layout

This procedure describes how to restore the layout of the all windows in the Workspace to their default positions, closing windows not open by default and opening windows open by default.

To restore the Workspace layout:

On the toolbar, click  .

The Workspace layout returns to the default.

4.6.2.4. Clearing All Workspace Windows

This procedure describes how to clear all of the open Workspace windows from displaying their channels and have them redrawn from the current moment.

To clear all open Workspace windows and have them restart:

On the toolbar, click  .

The open Workspace windows clear and are redrawn from the current moment.

4.6.2.5. Pausing Workspace Windows

This procedure describes how to pause all open Workspace windows from displaying their channels.

To pause all open Workspace windows:

On the toolbar, click  .

The open Workspace windows pause. While paused, the pause button changes to  .

To resume the Workspace window operation, click  .

The Workspace windows return to their activity, and the pause button returns to  .

4.6.3. Trajectory Graph

The **Trajectory** graph, which is to the left of the Workspace (see section ***4.6.2***), primarily describes the distance of the micro tip to the target. See ***Figure 84*** for a description of the Trajectory graph.

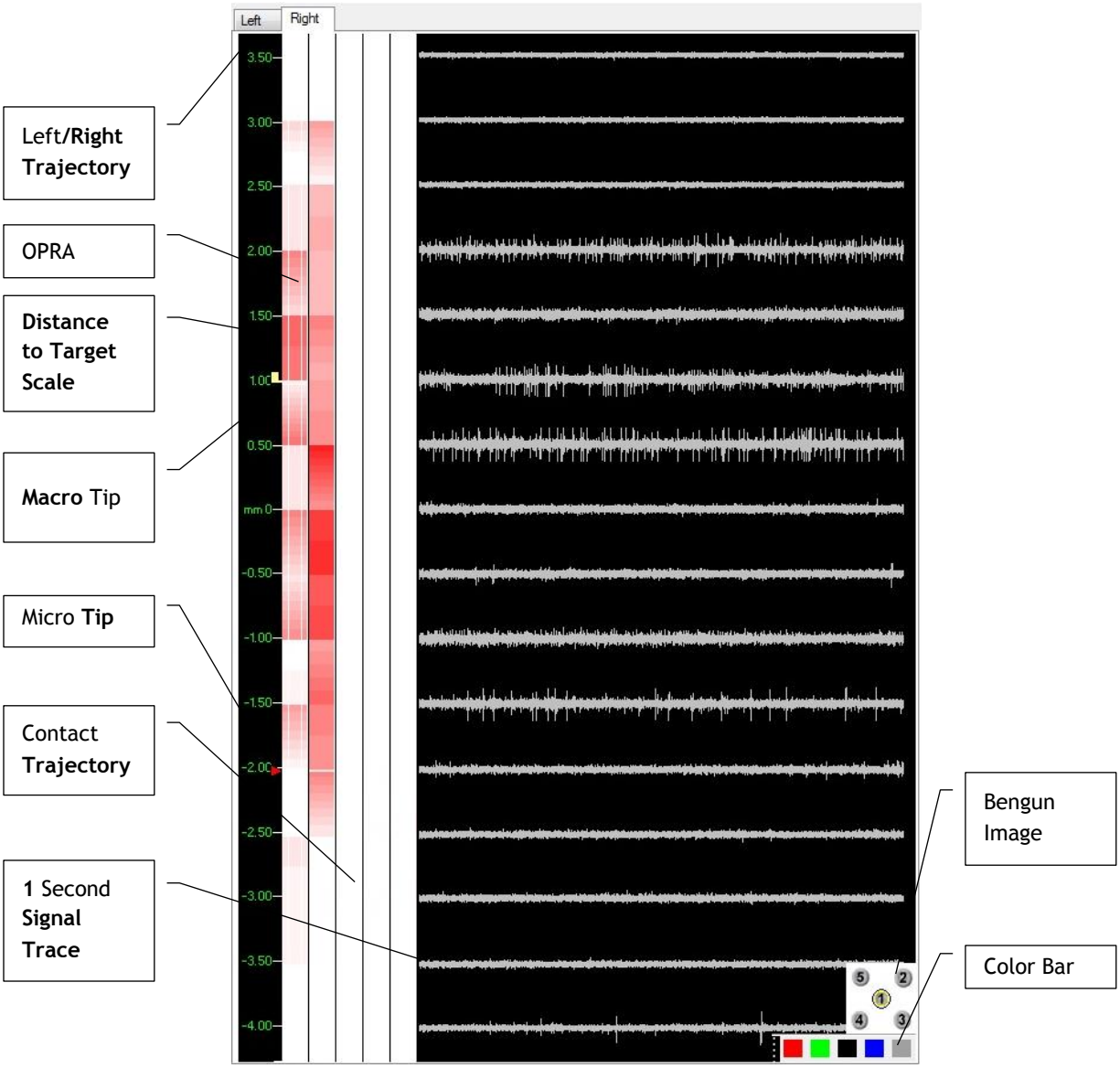


Figure 84: Trajectory Graph

The markers to the left of the graph, on the right side of the scale, are as follows:

- The white marker 

precisely indicates the current location of the electrode's macro tip.
- The red carrat 

precisely indicates the current location of the electrode's micro tip.

4.6.4. Viewing System Diagnostics

This procedure describes how to view system diagnostics, in the **System State** dialog box.

> **Note:** Viewing system diagnostics should be done in conjunction with an Alpha Omega trained user. This should be used as a troubleshooting step.

To view System Diagnostic:

Press **CTRL+SHIFT+A**.

The **System State** dialog box appears (***Figure 85***).

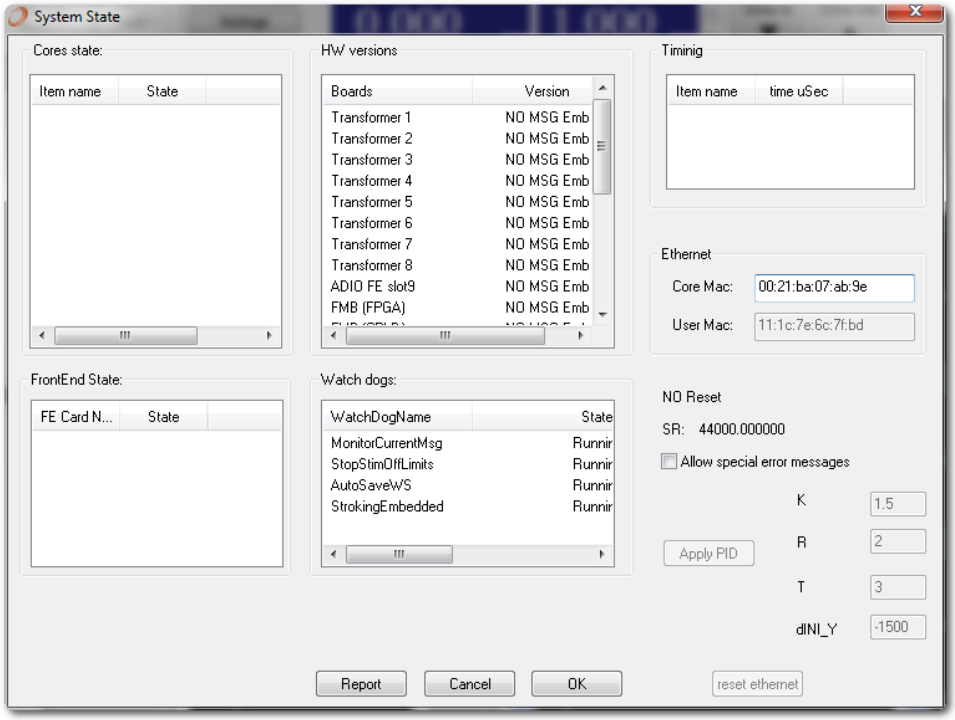


Figure 85: System State Dialog Box

To exit, click one of the following:

- **X** at the top right corner of the window.
- **Cancel**
- **OK**

4.7. EVENT DEFINITION

You can define events prior to the operation that you expect to occur during the operation, so they can be marked during the operation. These events are logged with the data acquired from the electrodes and general-purpose analog and digital inputs.

The following procedures are involved:

- *Defining Events*
- *Editing Events*
- *Deleting an Event*
- *Events Definition Table*

4.7.1. Defining Events

This procedure describes how to define new events that you expect to occur during the operation.

To define events:

From the toolbar, click **Events Properties**.

The **Events Control Panel** appears (*Figure 86*), which contains a number of predefined events for convenience.

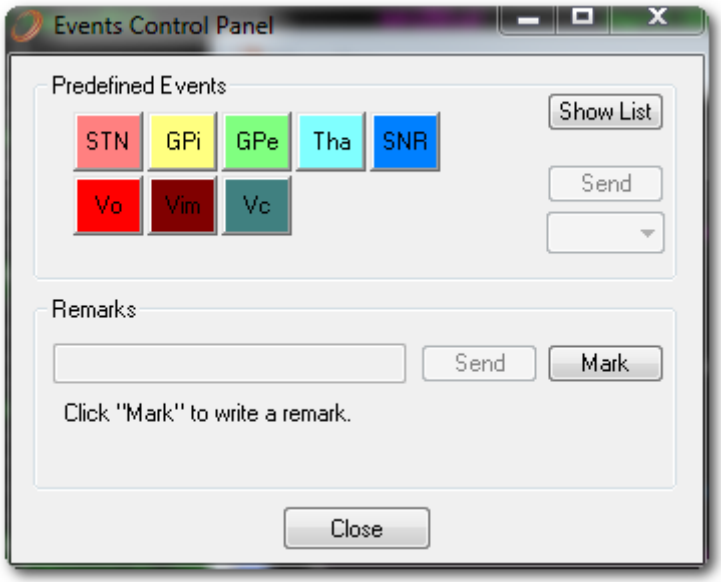


Figure 86: Events Control Panel

Click Show List.

The **Events Definition** dialog box appears (*Figure 87*), with a table containing one defined event per row. See for a description of the Events Definition table.

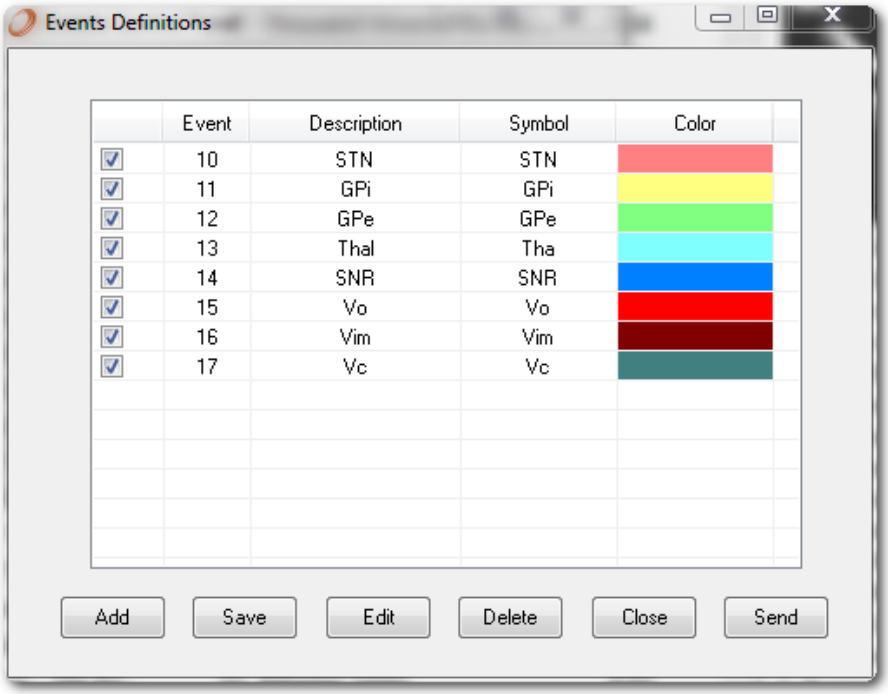


Figure 87: Events Definition Dialog

Click **Add**.

The **Create Event** dialog box opens to allow you to add an event (***Figure 88***).

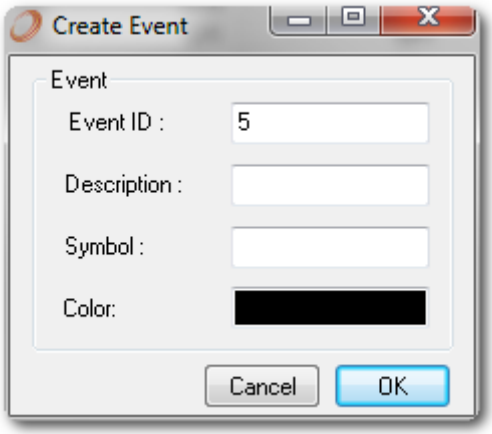


Figure 88: Create Event Dialog Box

Do the following:

a. In the **Event ID** field, enter the event ID. By default, the first available event ID appears, though this can be replaced.

Note: The event ID is what is saved to the log file.

In the **Description** field, enter a short description of the event.

In the **Symbol** field, enter the symbol as it should appear in the **Events Control Panel**.

In the color field, click on the color to open the color palette, and then select the color as it should appear in the **Events Control Panel**.

Click **OK**.

The **Create Event** dialog box closes.

Repeat steps ***0-0*** for each new event you want to define.

In the **Events Definition** dialog box, do the following:

a. Select the checkboxes of events that you want to appear as individual buttons in the **Events Control Panel**.

Clear the checkboxes of events that you want to appear as options in the drop-down menu of the **Events Control Panel**.

Click **Save** to save your changes and close the **Events Definition** dialog box.

4.7.2. Editing Events

This procedure describes how to edit events that you expect to occur during the operation.

To edit events:

From the toolbar, click **Events Properties**.

The **Events Control Panel** appears (see ***Figure 86***), which contains a number of predefined events for convenience.

Click Show List.

The **Events Definition** dialog box appears (see ***Figure 87***), with a table containing one defined event per row. See for a description of the Events Definition table.

Select the event you want to edit, and then click **Edit**.

The **Create Event** dialog box opens to allow you to edit the event (see ***Figure 88***).

Do the following:

a. In the **Event ID** field, edit the event number.

In the **Description** field, edit the event description.

In the **Symbol** field, edit the symbol as it should appear in the **Events Control Panel**.

In the color field, click on the color to open the color palette, and then edit the color as it should appear in the **Events Control Panel**.

Click **OK**.

The **Create Event** dialog box closes.

Repeat steps ***0-0*** for each event you want to edit.

In the Events **Definition** dialog box, do the following:

a. Select the checkboxes of events that you want to appear as individual buttons in the **Events Control Panel**.

Clear the checkboxes of events that you want to appear as options in the drop-down menu in the **Events Control Panel**.

Click **Save** to save your changes and close the **Events Definition** dialog box.

4.7.2.1. Deleting an Event

This procedure describes how to delete an event from the **Events Control Panel**.

To delete an event:

From the toolbar, click **Events Properties**.

The **Events Control Panel** appears (see ***Figure 86***), which contains a number of predefined events for convenience.

Click Show List.

The **Events Definition** dialog box appears (see ***Figure 87***), with a table containing one defined event per row. See 4.7.3 for a description of the Events Definition table.

Select the event you want to delete, and then click **Delete**.

The event is deleted.

4.7.3. Events Definition Table

A description of each column is detailed below:

- **First column (no title)**: A checkbox appears here after an event is defined. When this box is checked, the event on that line appears in the Events Control Panel dialog as a button; otherwise, it will appear in the drop down list.

- **Event**: The event code is shown in this column. Event codes are automatically assigned but can be changed by the user; valid values are any number from 5 to 65536; values 0 through 4 are reserved for system use.
- **Description**: Description of the event.
- **Symbol**: A 3-digit alpha-numeric symbol to identify the event. This will appear on the event's button, or represent the event in the drop-down list of the Events Control Panel.
- **Color**: This color will be saved in the data file, and can be used later in offline review. If a button is created representing the event in the Events Control Panel dialog, its background will be of that color.

4.8. VERIFYING DIAGNOSTIC INDICATORS

This procedure describes how to verify that all Neuro Omega system components are connected, and that the Main Unit is reading them correctly.

To verify diagnostic indicators:

On the toolbar, check if any diagnostic indicators appear, as follows:

- 

: Indicating that the Remote Control is not functioning or not connected
- 

: Indicating that the Drive Headstage or MER Headstage module is not functioning or not connected.
-  –  : Indicating that the Headbox modules are not functioning or not connected.

Fix the connections of any component as required.

Verify that no diagnostic indicators appear for the modules in use.

Verify that pedal is connected  , as no red X banning the icon on the down left corner of the screen.

4.9. CONFIGURING DRIVE AND SAVE SETTINGS

4.9.1. Neuro Omega Drive Headstage/ NeuroFortis Drive Headstage

This procedure describes how to configure Neuro Omega drive Headstage/ NeuroFortis Drivw Headstage and save settings, which is required for first time use, and may be returned to subsequently as needed.

When building the workspace template the first module is the Drive. Select Drive Headstage.

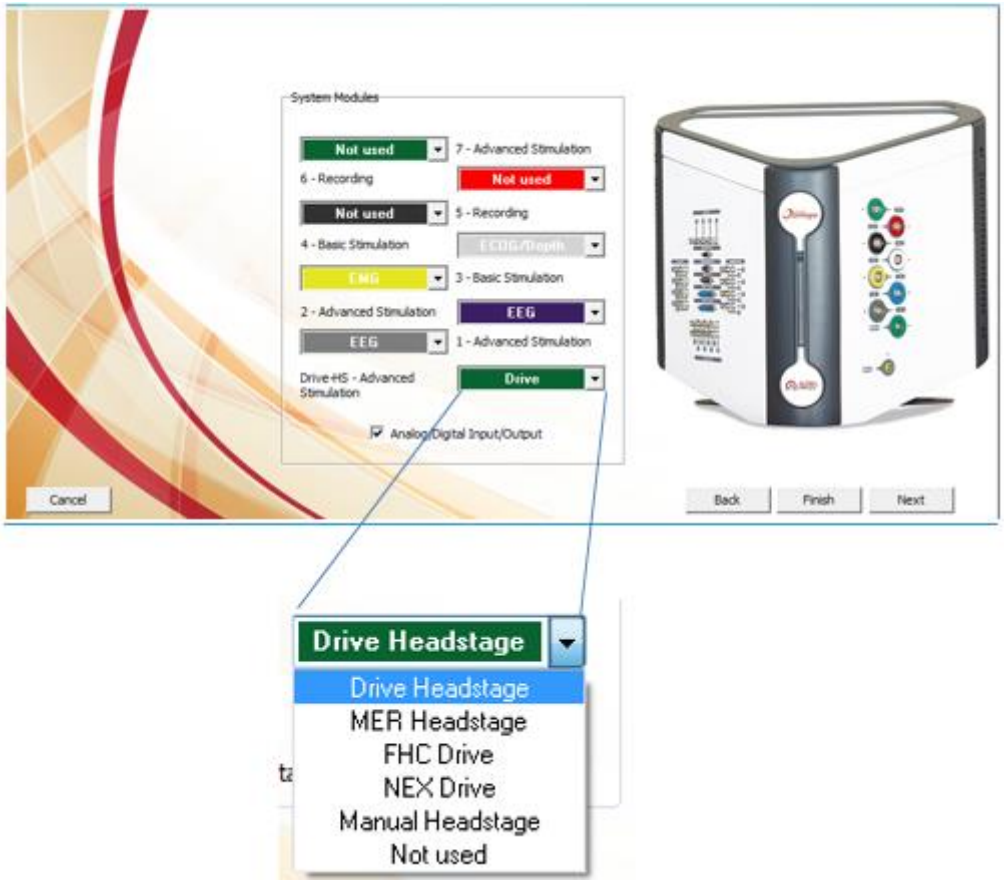


Figure 89: select Drive Module

To configure drive and save settings:

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears (***Figure 90***).

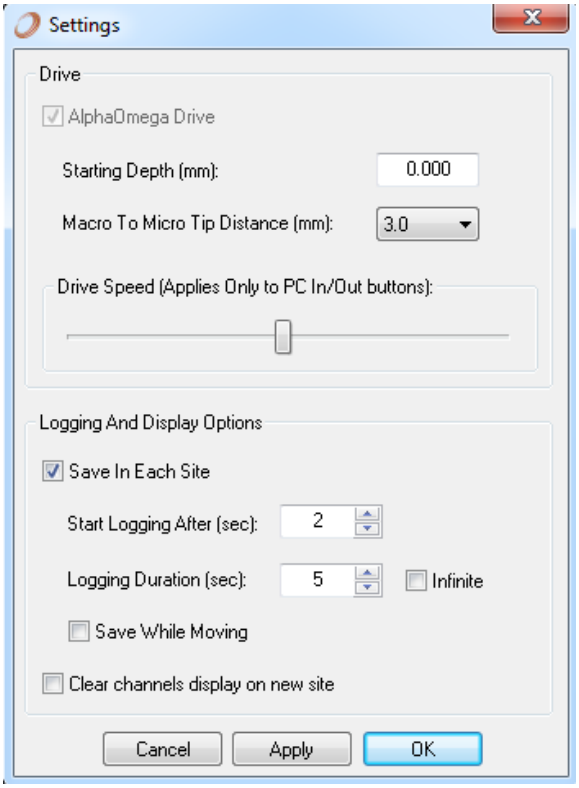


Figure 90: Settings Dialog Box

In the **Starting Depth** field, refer to Table 5, ***page 40***, and based on the cannula you are using, enter the correct starting depth.

In the **Macro to Micro Tip Distance** dropdown list, refer to Table 4, ***page 39***, and based on the electrode you are using, select the correct distance.

In the **Drive Speed** area, move the slider to the right to increase the drive speed, or to the left to decrease the drive speed.

In the Logging And Display Options, do one of the following:

a. Select **Save in Each Site** if you want Headstage and Headbox data saved to the log file each time the electrode stops advancing, and then proceed to step ***0***.

Clear **Save in Each Site** if you want to manually click **Save** to start saving Headstage and Headbox data manually, and then proceed to step 0.

> **Note**: For more information about saving, see **section 4.19**.

If you selected **Save in Each Site**, do the following:

a. From the **Start Logging After** dropdown list, select the length of time (in seconds) for Neuro Omega to wait after electrode stops advancing, to start saving data to the log file.

From the **Logging Duration** dropdown list, select the length of time for Neuro Omega to save data to the log file. The Infinite checkbox can be selected if nonstop saving is required.

Select the **Save while Moving** checkbox if you want Neuro Omega to continue saving data to the log file after it has started, or after you have clicked **Save** – even if you have since advanced the electrode.

Select the **Clear channels display on new site** checkbox if you want all the windows to be cleared from data at every new site.

> **Notes:**
>
> - The drive moves until a step is reached, regardless of drive speed.
> - The thumb wheel on the remote control (see section ***4.14***) overrides the drive speed defined in the **Settings** dialog box.
> - When using the MER Headstage the thumbwheel cannot be used.
> - Note: When using Manual Headstage, Drive speed is not applicable.

Click **OK**.

The **Settings** dialog box closes, and the settings are saved.

4.9.2. Neuro Omega Autoclavable Drive Headstage and MER Headstage

This procedure describes how to configure Autoclavable drive Headstage and save settings, which is required for first time use, and may be returned to subsequently as needed.

When building the workspace template the first module is the Drive module. Select **MER Headstage.**

Figure 91: select MER Headstage Module

To configure Autoclavable drive Headstage/MER Headstage and save settings:

On the main screen, on the toolbar, click **Settings**.

To verify starting depth:

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears. In the **Starting Depth** field, enter the drive starting depth value.

- To use a distance to target calculation, enter the value as a negative number (for example, starting 20mm above target should enter -20 into the starting depth).
- To use the values on the drive, enter the actual depth, as it appears on the drive.

- In the Macro to Micro Tip Distance dropdown list, refer toTable 4, page 39, and based on the electrode you are using, select the correct distance.
- In the Logging And Display Options, do one of the following:
  - Select **Save in Each Site** if you want Headstage and Headbox data saved to the log file each time the electrode stops advancing.

Clear **Save in Each Site** if you want to manually click **Save** to start saving Headstage and Headbox data manually.

> **Note**: For more information about saving, see **section 4.19**.

If you selected **Save in Each Site**, do the following:

- From the **Start Logging After** dropdown list, select the length of time (in seconds) for Neuro Omega to wait after electrode stops advancing, to start saving data to the log file.

From the **Logging Duration** dropdown list, select the length of time for Neuro Omega to save data to the log file. The Infinite checkbox can be selected if nonstop saving is required.

Select the **Save while Moving** checkbox if you want Neuro Omega to continue saving data to the log file after it has started, or after you have clicked **Save** – even if you have since advanced the electrode.

Select the **Clear channels display on new site** checkbox if you want all the windows to be cleared from data at every new site.

> When using the MER Headstage or the Autoclavable drive Headstage the thumbwheel on the remote control cannot be used.
>
> - Note: When using Autoclavable drive Headstage, Drive speed is not applicable.

Click **OK**.

The **Settings** dialog box closes, and the settings are saved.

4.9.3. FHC/NEXDRIVE Display Unit Controller

This section describes how to connect the FHC/NexDrive display unit controller to the Neuro Omega system in order to synchronize the Microelectrode depth.

For Neuro Omega Synchronization with FHC/NexDrive display unit controller the following components will be needed:

- RS-232 adapter
- VGA to USB

FHC/NexDrive display unit controller connections:

1. Connect the RS-232 adapter to FHC/NexDrive display unit controller.
2. Connect the RS-232 cable to the USB input in the back of Neuro Omega PC.

SOFTWARE SELF-TEST INDICATIONS

Indicating that the FHC/NexDrive display unit controller not functioning or not connected

Indicating that the FHC/NexDrive display unit controller is connected.

4.9.3.1. FHC Drive settings

This procedure describes how to configure FHC drive and save settings, which is required for first time use, and may be returned to subsequently as needed.

To configure FHC **drive and save settings:**

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears (***Figure 90***).

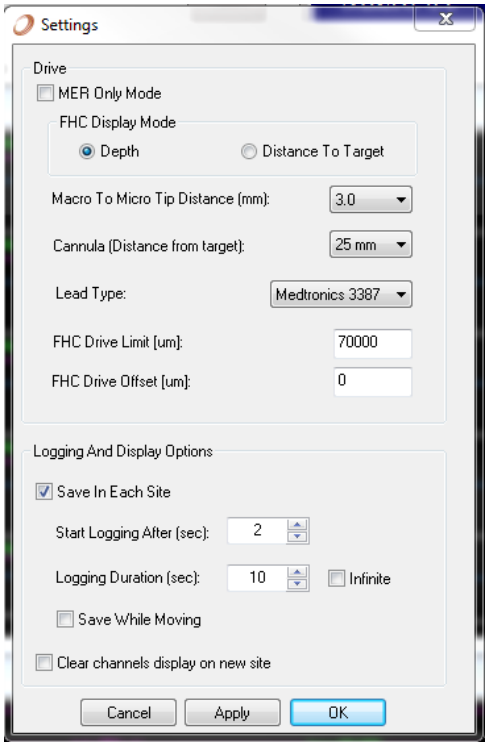


Figure 92: Settings Dialog Box

In the **FHC Display Mode**, you can chose wither to display on the DDU (Digital Display Unit) the **depth** of the drive or the **distance to target** .

In the **Macro to Micro Tip Distance** dropdown list, refer to Table 4, ***page 39,*** and based on the electrode you are using, select the correct distance.

In the **Cannula** dropdown list, refer to Table 4, ***page 32,*** and based on the electrode you are using, select the correct distance.

In the **Lead Type** dropdown list, select the lead type.

In the **FHC Drive limit**, insert the drive limit in um.

In the **FHC Drive Offset**, insert the drive offset, this will change the offset depth display on the DDU and on the UI accordingly.

In the Logging And Display Options, do one of the following:

a. Select **Save in Each Site** if you want Headstage and Headbox data saved to the log file each time the electrode stops advancing, and then proceed to step ***0***.

Clear **Save in Each Site** if you want to manually click **Save** to start saving Headstage and Headbox data manually.

Note: For more information about saving, see **section 4.19.**

If you selected **Save in Each Site**, do the following:

a. From the **Start Logging After** dropdown list, select the length of time (in seconds) for Neuro Omega to wait after electrode stops advancing, to start saving data to the log file.

From the **Logging Duration** dropdown list, select the length of time for Neuro Omega to save data to the log file. The Infinite checkbox can be selected if nonstop saving is required.

Select the **Save while Moving** checkbox if you want Neuro Omega to continue saving data to the log file after it has started, or after you have clicked **Save** – even if you have since advanced the electrode.

Select the **Clear channels display on new site** checkbox if you want all the windows to be cleared from data at every new site.

Click **OK**.

The **Settings** dialog box closes, and the settings are saved.

4.9.3.2. NEX Drive settings

This procedure describes how to configure Nexdrive and save settings, which is required for first time use, and may be returned to subsequently as needed.

To configure Nexdrive and save settings:

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears (***Figure 90***).

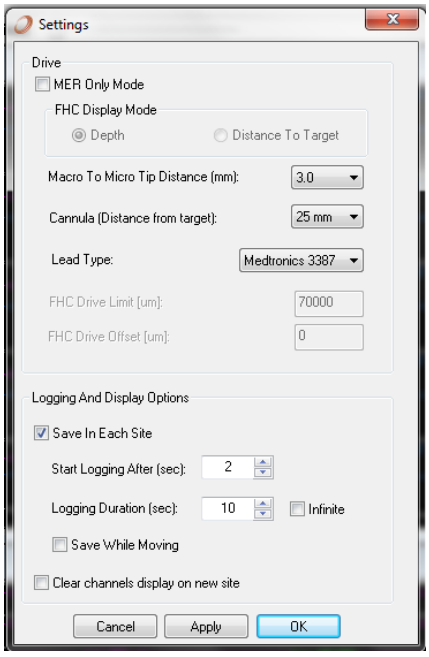


Figure 93: NexDrive Dialog setting

In the **FHC Display Mode**, you can chose is grayed out.

In the **Macro to Micro Tip Distance** dropdown list, refer to Table 4, ***page 39,*** and based on the electrode you are using, select the correct distance.

In the **Cannula** dropdown list, refer to Table 4, ***page 32,*** and based on the electrode you are using, select the correct distance.

In the **Lead Type** dropdown list, select the lead type.

In the Logging And Display Options, do one of the following:

a. Select **Save in Each Site** if you want Headstage and Headbox data saved to the log file each time the electrode stops advancing.

a. Clear **Save in Each Site** if you want to manually click **Save** to start saving Headstage and Headbox data manually.

Note: For more information about saving, see **section 4.19**.

If you selected **Save in Each Site**, do the following:

a. From the **Start Logging After** dropdown list, select the length of time (in seconds) for Neuro Omega to wait after electrode stops advancing, to start saving data to the log file.

From the **Logging Duration** dropdown list, select the length of time for Neuro Omega to save data to the log file. The Infinite checkbox can be selected if nonstop saving is required.

Select the **Save while Moving** checkbox if you want Neuro Omega to continue saving data to the log file after it has started, or after you have clicked **Save** – even if you have since advanced the electrode.

Select the **Clear channels display on new site** checkbox if you want all the windows to be cleared from data at every new site.

Click **OK**.

The **Settings** dialog box closes, and the settings are saved.

4.10. VERIFYING STARTING DEPTH

This procedure describes how to verify the starting depth. This is a prerequisite for creating a new trajectory.

4.10.1. Drive Headstage Module

To verify starting depth:

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears (see ***Figure 90***).

In the **Starting Depth** field, refer to Table 5, ***page 40***, and based on the cannula you are using, verify the correct starting depth.

4.10.2. MER Headstage Module

To verify starting depth:

On the main screen, on the toolbar, click **Settings**.

The **Settings** dialog box appears (see ***Figure 90, page 123***).

In the **Starting Depth** field, enter the drive starting depth value.

- To use a distance to target calculation, enter the value as a negative number (for example, starting 20mm above target should enter -20 into the starting depth).
- To use the values on the drive, enter the actual depth, as it appears on the drive.

4.11. CREATING A NEW TRAJECTORY

This procedure describes how to create a new trajectory with up to five electrodes, each electrode as its own track.

> **Note:** When continuing an operation, all existing trajectories are resumed.

To create a new trajectory:

Verify the following:

a. The electrode tip is advanced in the cannula to the starting position, as described in section ***2.9***.

The Headbox modules are assembled, as described in section ***2.11***.

On the main screen, on the toolbar, click **New Trajectory**, and then, in the confirmation box, click **Yes**.

Do one of the following:

a. If the **Set Position** dialog box appears (***Figure 94***), do the following:

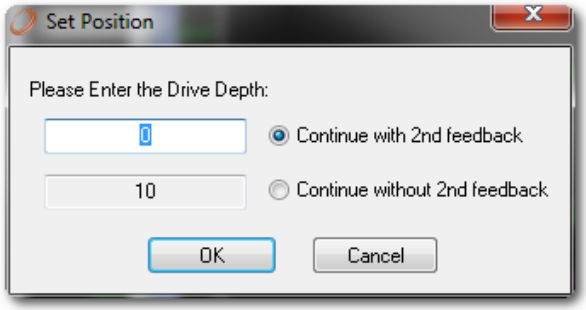


Figure 94: Set Position Dialog Box

i. Manually set the drive position, as described in section ***4.12***.

A popup appears asking if you want to move the drive to the starting depth.

Continue with step ***4***.

If the **Set Position** dialog box does not appear, proceed to step ***0***.

In the popup, click **Yes**.

> **Note:** For safety reasons, when moving to the starting depth, the drive can only move forward towards the target manually. Therefore, if the drive must advance to reach the starting position, and in step ***0*** you clicked **Yes**, the drive stays in place. A popup appears, notifying you that you cannot reset forward.

If the drive must advance to reach the starting position, then you must advance it manually.

The **New Trajectory** dialog box appears (***Figure 95***).

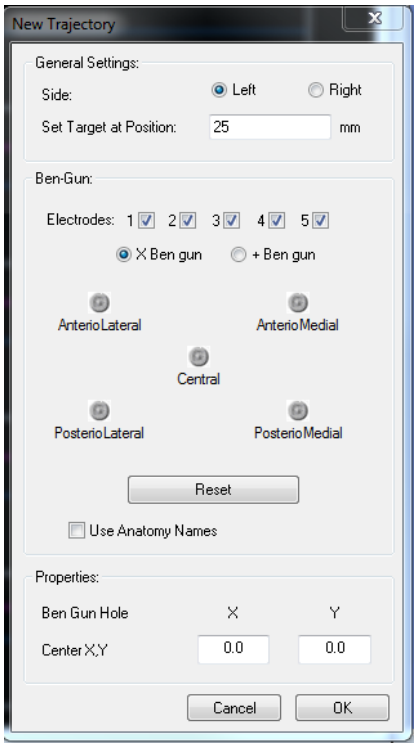


Figure 95: New Trajectory Dialog Box

In the **General Settings** area, select the operation side.

In the **Set Target at Position** field:

a. For the Drive Headstage – type the distance, in millimeters, from the electrode tip to the target, as shown in Table 5, ***page 40***.

For the MER Headstage – this value cannot be set, see Section ***4.10.2*** on how to set the starting depth and trajectory.

When using the Nexframe or Starfix frames – the target position is at 20mm. See Sections ***2.2.9.3*** and ***2.2.9.4***.

Select the checkboxes for the electrodes you want to use, and then select the Bengun configuration. Select the electrode tracks in the order that you want them to appear in the Workspace.

Select the Use Anatomy Names checkbox to display the Anatomy names in the Workspace.

The trajectories are numbered in the order that you click them.

If you have manually moved the XY frame adapter, then in the **Properties** area, in the **X** and **Y** fields, type the offset values accordingly.

Click **OK**.

The following happens:

- The trajectory configuration is finalized.
- The program creates the trajectory and activates OPRA.
- The Workspace displays the trajectory in the **Trajectory** graph, which primarily describes the distance of the micro tip to the target. See section 4.6.3 for a description of the **Trajectory** graph.

4.12. SETTING DRIVE POSITION

This procedure describes how to manually set the drive position. This is important if the value on the Drive Headstage does not match the position according to the software, or if there is a problem with the Drive Headstage. This could happen if the drive was attached at a position other than that from which it was previously detached.

To manually set the drive position:

In the **Set Position** dialog box (see ***Figure 94***), select **Continue with 2nd Feedback**.

In the upper field, enter the value you read on the drive.

Click **OK**.

Neuro Omega compares the value you entered with the 2nd feedback, which is the value from the motor. One of the following happens:

- If the value you entered agrees with the value from the motor, the **Set Position** dialog box closes.
- If the value from the motor disagrees with the value from the drive, the **Set Position** dialog box closes but then reopens. Proceed to step ***0***.

Select **Continue without 2nd Feedback** (Figure 96), and then, in the upper field, enter the value you read on the drive.

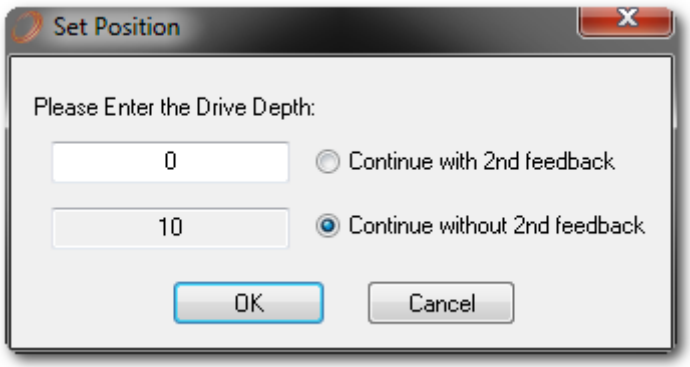


Figure 96: Set Position – Continuing without 2nd Feedback

Click **OK**.

The **Set Position** dialog box closes, and Neuro Omega continues with the value from the drive; not the value from the motor or from the software.

Note: If, as in step *0*, you must continue without the feedback from the motor, contact Alpha Omega support.

4.13. CHECKING IMPEDANCE

This procedure describes how to check the impedance of the electrodes and the modules. This is important to verify their accuracy and integrity.

Notes:

- It is recommended to check impedance immediately after the micro tip has exited the cannula, 3 mm below the starting depth.
- The impedance measurment frequency must be aligend with the recording bandwidth range, if the impedance frequency is outside the bandwidth range of any channel the impedance signal will be filtered out (get wrong measurment) and an error meassage (Figure 75) will appear.

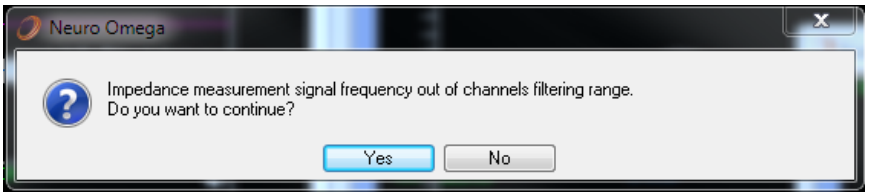


Figure 97

To check impedance:

In the main window, in the toolbar, click **Imp**.

The following happens:

- The **Impedance** dialog box appears.
- Impedance is recalculated.
- The **Imp** button is deactivated.

Impedance measurement for the different contact types is as follows:

- Impedance for the micro tips is calculated with a 1000 Hz sine wave.
- Impedance for the macro tips is calculated with a 1000 Hz sine wave.
- Impedance for the Headbox modules is calculated with a 30 Hz sine wave.

To recalculate while the window is open, click **Recalculate**.

4.14. MANIPULATING THE DRIVE HEADSTAGE

> **Note:** This section does not apply for the MER Headstage

This procedure describes how to lower the electrode towards the target, using the drive. This procedure is performed in conjunction with section ***4.15***.

To lower the electrode toward the target:

In the **Trajectory** area, do the following:

❖ Verify you are viewing the correct hemisphere.

In the graph, click within the vertical electrode track strips until the electrode track you plan to manipulate appears circled in the Bengun representation at the bottom right.

In the **Step Size** field, enter a positive value, maximum 1 millimeter.

Do the following:

- In the toolbar of the Workspace, click **Drive In** to drive the electrode down one step towards the target (clicking **Drive Out** drives the electrode up one step away from the target).
- From the remote control, turn the thumb wheel to the right to drive the electrode down towards the target (turning it to the left drives the electrode up away from the target).

> **Note:** The further you rotate the thumb wheel, the quicker the distance of the step is covered. Using the thumbwheel replaces the slider in the **Drive Speed** area of the Settings dialog box (see section ***0***, step ***0***).

Each drive movement appears in the **Trajectory** area.

Adjust the scale of the **Trajectory** graph as required by doing the following:

a. Right-click and drag to move the scale up and down.

Left-click and drag to zoom in and out within the scale.

To make identifying areas easier, use the **Colors** bar, as follows:

a. Select a color.

Highlight an area in the electrode track strip.

4.15. MONITORING ACTIVITY

The following procedure describes how to perform online monitoring of the electrophysiological activity derived from the Drive Headstage and the modules. This

monitoring is used for target localization. Monitoring activity is generally performed in conjunction with manipulating the Headstage, described in ***4.14***, at each recording site.

To monitor electrophysiological activity:

- See section ***4.15.1*** for monitoring any of the following channels:
  - **EEG**: Electroencephalography signals
  - **EMG**: Electromyography signals
  - **ECOG**: Electrocorticography signals
  - **Micro SPK**: Spike filtered continuous signals from the micro tip
  - **Micro RAW**: Raw continuous signals from the micro tip
  - **Micro SEG**: Spike filtered segmented signals from the micro tip
  - **Macro LFP**: LFP filtered continuous signals from the macro tip
  - **Macro RAW**: Raw continuous signals from the macro tip
  - **Analog In**: 12 bit analog input
- See section ***4.15.2*** for monitoring Digital input and Port signals from and external digital input system
- See section ***4.15.1.6*** for monitoring segmentation spike sorting from the micro tip.

4.15.1. Monitoring Channels

This procedure describes how to monitor channels during the target localization process.

To monitor a channel:

From the **Windows List** button  , select a channel Workspace window.

The window appears (***Figure 98***), with each channel in the window appearing in its own graph.

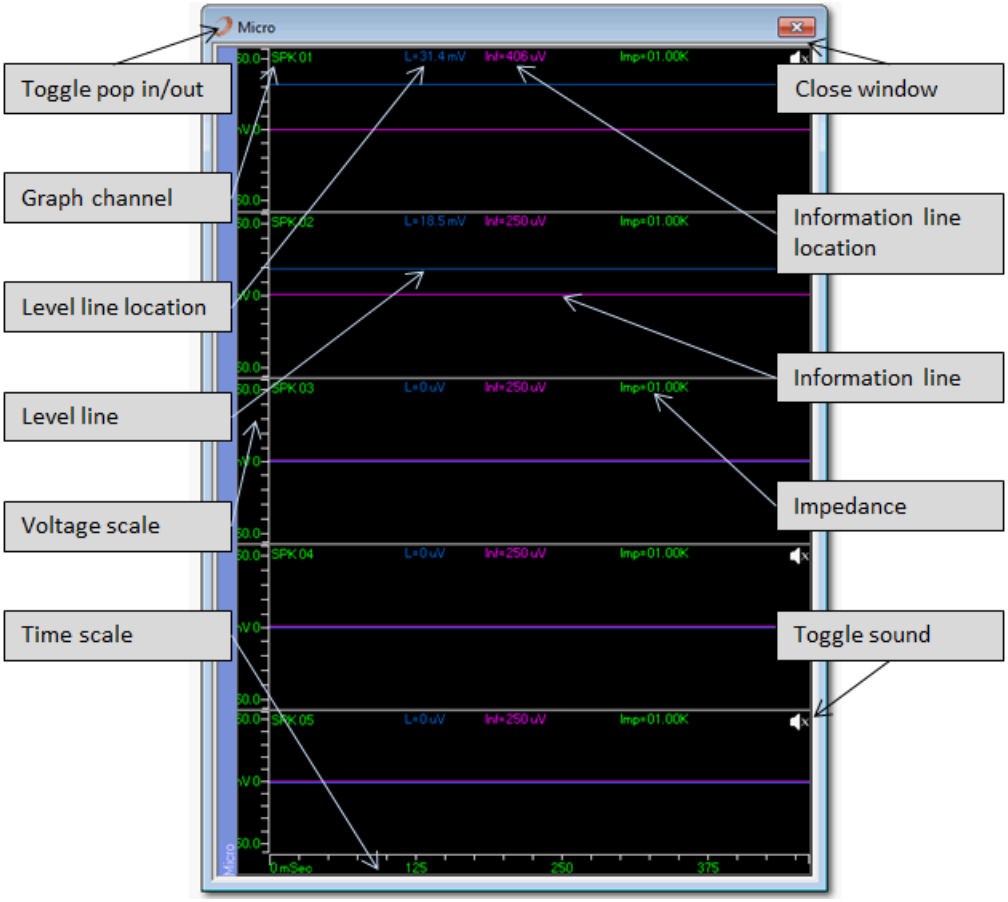


Figure 98: Channel Workspace Window

To change the theme of display, on the top left of the UI, select the desired display, i.e., signal background to be black or white.

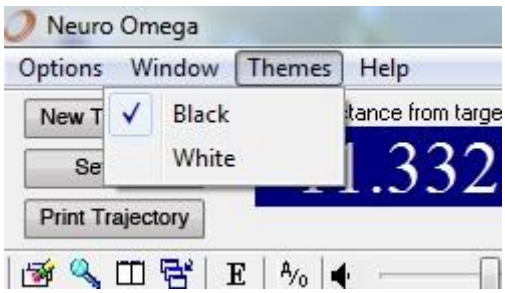


Figure 99: select theme

For each graph, do any of the following:

- Impedance is listed in the upper right corner. To refresh the impedance value, in the toolbar, click **Imp**, and then click **Recalculate**, as described in section ***4.13***.
- Adjust the channel voltage or time scales, as described in section ***4.15.1.1***.
- Listen to a channel sound, as described in section ***4.15.1.2***.
- Ground a channel, as described in section ***4.15.1.3***.

- Change the channel name, as described in section 4.15.1.4.
- Make use of the information line by clicking the line and dragging it up or down, as described in section ***4.15.1.4***.
- Apply a recording reference to the contact, as described in section ***4.15.1.6***.
- Make use of the level line by clicking the line and dragging it up or down.

> **Note:** The level line is relevant for monitoring micro segmentation spike sorting, as described in section ***4.15.3.2***, and monitoring spikes in the spikes raster window, as described in section ***4.15.4***.

4.15.1.1. Adjusting Channel Scales

This procedure describes how to adjust the voltage scale and time scale of the graphs in a Workspace window.

To adjust a graph scales:

Adjust the voltage scales of a Workspace window by doing the following:

- To zoom in, drag up on the scale.
- To zoom out, drag down on the scale.
- To offset the voltage access, right-click and drag up to move up, and down to move down.
- Do the following:

  i. Right-click anywhere in the window, and then select **Set Group Scales**.

  The Set Group Scales dialog box appears.

In the Voltage Scale area, enter the absolute voltage level for the graphs in microvolts, and then click OK.

The scales change accordingly.

Adjust the time scale of a Workspace window by doing the following:

- To zoom in, drag rightward on the scale.
- To zoom out, drag leftward on the scale.
- Do the following:

  i. Right-click anywhere in the window, and then select **Set Group Scales**.

  The Set Group Scales dialog box appears.

In the Time Scale area, enter the duration that the graphs should cover, in milliseconds, and then click OK.

The scales change accordingly.

4.15.1.2. Toggling a Channel's Sound

This procedure describes how to toggle a channel sound on and off. The volume for the sound is controlled on the keyboard, or through the operating system sounds.

To toggle a channel sound on and off:

- From the channel graph, at the upper right corner of the channel, toggle the speaker icon:
  -  indicates the sound is off.
  -  indicates the sound is on.
- From the remote control, do the following:

  a. Press the **Micro-Macro** button to select either micro or macro.

Press the **Channel** button to select the channel.

Press the **Sound** button to turn the sound on or off.

Note: Only one channel sound can be on at a time. Toggling on the sound of one channel toggles off the channel that was previously on.

4.15.1.3. Grounding a Channel

This procedure describes how to ground a channel. This is helpful, for example, when the channel is especially noisy, and the noise enters the other channels.

To ground a channel:

In the graph of the applicable channel, right click, and then select **Ground**.

The channel is grounded. Data still comes in, but it is with low noise because the channel is grounded at the first amplifier.

Note: To disconnect the ground and return data streaming in the graph, right click again, and then clear **Ground**.

4.15.1.4. Changing a Channel Name

This procedure describes how to change a channel name. This is helpful, for example, to label a channel according to the electrode anatomical location.

To change a channel name:

In the graph of the applicable channel, right click, and then select **Set Name**.

Type the new name of the channel in the **Channel New Name** box, and click **OK**.

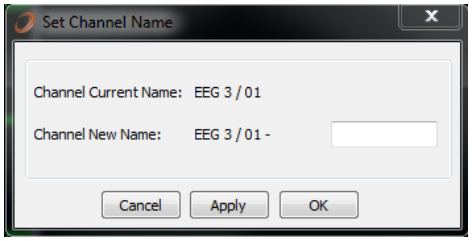


Figure 100: Set Channel Name

4.15.1.5. Using the Information Line

This procedure describes how to use the information line (see ***Figure 98***) in channel graphs (informational only). It enables the user to measure the amplitude of the signal. It is a displayed figure only and has no effect on segmentation.

To use the information line:

Drag the information line up or down along the graph.

The amplitude value of the information line appears at the top of the graph.

4.15.1.6. Applying a Recording Reference to a Contact

This procedure describes how to apply a recording reference to a contact in a channel graph as a means of reducing the amount of noise. This is known as flexible referencing.

Consider the following while using the flexible referencing function:

- In general, use an electrode that is lacking in action potential activity as the reference contact.
- All signal types for a specific contact are affected, as referencing is done by means of simple substation on the raw signal before any filtration. This includes RAW, SPK, LFP, SEG, EMG, ECOG and EEG.
- Do not use a contact as a reference that is already referencing another contact.
- Make sure to use reference contacts that are in close vicinity of the referenced contact.

To apply a recording reference to a contact:

In the channel graph to which you want to apply a reference, right-click, and then select **Set Group Reference**.

Select the contact to use as the reference, and then click **OK**.

The following occurs:

- The **Set Group Reference** dialog box closes.
- The selected contact begins serving as reference.
- In the channel graphs, for each channel, the channel referencing appears, followed by the channel referenced (***Figure 101***).

Figure 101: Macro LFP 01 Referencing Macro LFP 02

4.15.2. Monitoring Digital Input Channels

This procedure describes how to monitor digital input channels.

To monitor digital input channels:

From the **Windows List** button  , select a digital input Workspace window.

The window appears (***Figure 102***), with each input bit in the window appearing in its own graph.

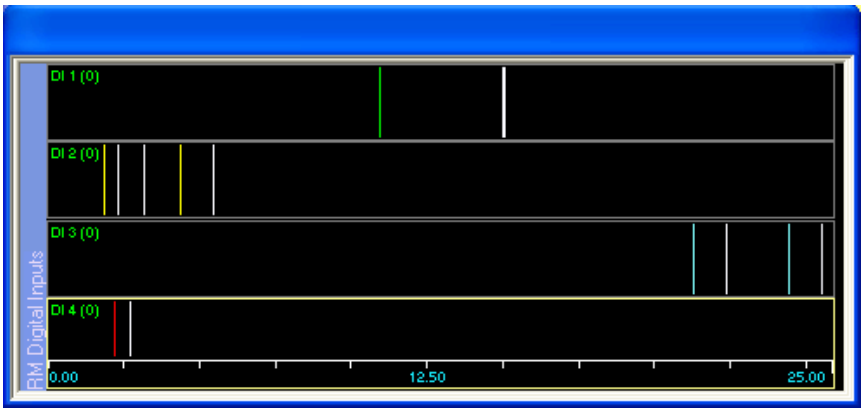


Figure 102: Single-Bit Digital Input Display

For each input bit:

- A colored tic mark indicates the change to active high (1).
- A white tic mark indicates the change to active low (0).

- The last status of every channel is also displayed by the channel label.

For each input bit, do any of the following:

- Adjust the bit's time scales, as described in section ***4.15.1.1***.

4.15.3. Monitoring Micro Segmentation Spike Sorting

This procedure describes how to monitor micro segmentation spike detections. This is done, by first defining templates to catch the spikes based on the threshold level (level line), and then monitoring the spikes sorted in individual windows per template.

Most of the spike sorting procedure is performed in the main segmentation window, as described in section ***4.15.3.1***.

To monitor the micro segmentation spike detections by template:

Set the threshold level line, and then define the spike sorting templates, as described in section ***4.15.3.2***.

For each template, define the template variation, as described in section ***4.15.3.3***.

For each template, add Include Windows, as described in section ***4.15.3.4***.

Monitor the spike segments per template, as described in section ***4.15.3.5***.

4.15.3.1. Main Segmentation Window Navigation

The main segmentation window (*Figure 103*) is divided into three parts:

- **Online sorting graph**, in which the templates are defined from the spikes passing the threshold
- **Template histogram**, containing a histogram of a template when selected
- **Template graphs**, one for each template and one for all spikes passing the threshold

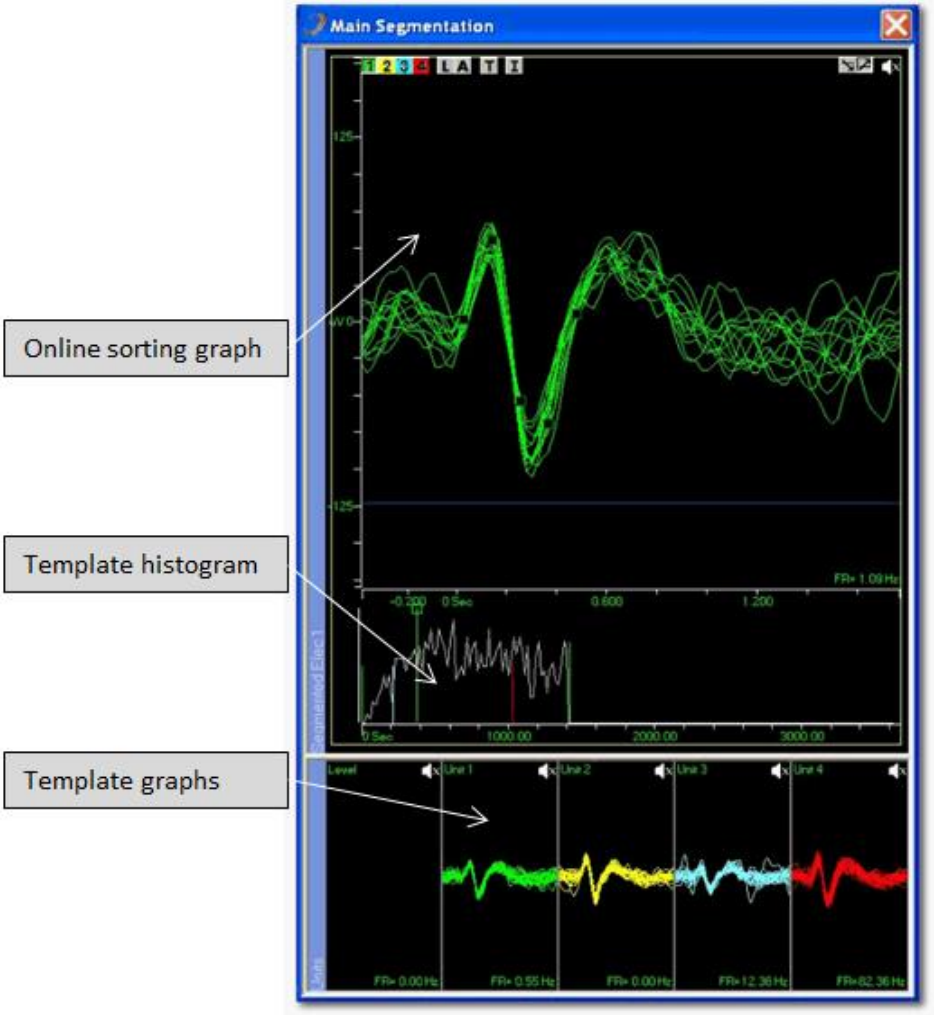


Figure 103: Main Segmentation Dialog Box

The online sorting graph toolbar (*Figure 104*) contains the following tools:

Figure 104: Online Sorting Graph Toolbar

- 1 (**Template 1**): When selected, only spikes matching template 1, its template points, its window discriminator if active, and its histogram are displayed, in addition to all unsorted spike segments.
- 2 (**Template 2**): When selected, only spikes matching template 2, its template points, its window discriminator if active, and its histogram are displayed, in addition to all unsorted spike segments.
- 3 (**Template 3**): When selected, only spikes matching template 3, its template points, its window discriminator if active, and its histogram are displayed, in addition to all unsorted spike segments.

- (**Template 4**): When selected, only spikes matching template 4, its template points, its window discriminator if active, and its histogram are displayed, in addition to all unsorted spike segments.
- (**Level**): When selected, only unsorted spikes are displayed. No template points, window discriminator, or histogram are shown.
- (**All Segments**): When selected, all spike segments are displayed, whether sorted into a template or left unsorted. No template points, window discriminator, or histogram are shown.
- **(Define Templates)**: Freezes the spike segments, and commences template definition mode.
- (**Inclusion Windows**): Adds the first **Include** window, used for fine tuning the spike selection, or removes all **Include** windows.
- (**Crossing**): Determines whether crossing is on the up or down.
- (**Sound**): Toggles sound on or off.

When a template is selected, the firing rate (FR) of that template is displayed at the bottom right corner of the online sorting graph. When is selected, the firing rate of the unsorted spikes is displayed. When is selected, the combined firing rate of all spikes is displayed.

4.15.3.2. Defining Spike Sorting Templates

This procedure describes how to define spike sorting templates. This is the first step in ***Monitoring Micro Segmentation Spike Sorting.***

Note: Spike sorting templates are not saved across different trajectories.

To define the spike sorting templates:

From the **Windows List** button , select the micro segmentation window.

The micro segmentation window appears (see ***Figure 98***), with each channel in the window appearing in its own graph.

In the graph of the channel whose spikes you want to monitor, do one of the following:

- If you want to sort the spikes crossing the level line in the rising direction, select the up arrow .
- If you want to sort the spikes crossing the level line in the falling direction, select the down arrow .

Note: If the down arrow does not automatically appear, select the up arrow first - and it appears.

Set the threshold level for the spikes by dragging the level line up or down the voltage scale.

From the **Windows List** button, select the main segmentation window.

The main segmentation window appears, with the online sorting graph displaying in white the spikes passing the threshold set in step ***0***.

At a point when the spikes separate into groups, from the online sorting window toolbar, click **T**.

The following occurs:

- The online sorting graph freezes.
- Template definition mode commences.
- The window cursors appear, color coded to correspond to the four templates (***Figure 105***).

Figure 105: Color Coded Window Cursors

- Saving options appear at the bottom of the graph (***Figure 106***).

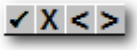


Figure 106: Template Definition Saving Options

The following options are available:

- Change which template point is placed on the template in the time axis by using the left (<) and right (>) buttons.
- Manually move the template points.
- After all templates have been defined, click ✓ to save.
- If necessary, click X to cancel.

The window cursor provides an automatic approximation of template points. The approximation is based on the signals falling within the window cursor.

Define each template as required by performing steps ***0***-***0***.

Move the corresponding window cursor to the segments comprising the template in the following ways:

- Drag the window cursor.
- Enlarge the window cursor by dragging one or both of its horizontal ends.

Note: Verify that the position of the window cursor includes the desired spikes. The actual position of the window cursor along the XY axis does not matter.

As the window cursor is moved over the spikes, the spikes are automatically marked with the template points.

Note: To see the template points of a previously-set template, click the template's window cursor.

By default, the system puts the first template point at the level crossing line. If necessary, perform manual adjustments as described under Figure 105.

The following happens:

- The online sorting graph displays iterating segments for all templates. Spikes falling under a template are displayed in the template color.
- In the template graphs, the spikes are sorted according to template. For example, Template 1 appears in the Unit 1 graph, and the Level graph contains all those spikes not falling under any template.

Continue with ***4.15.3.3*** to define the template threshold for each template.

4.15.3.3. Defining the Template Variation

This procedure describes how to define the template variation for a spike sorting template defined in section ***4.15.3.2.*** It is the second step in ***Monitoring Micro Segmentation Spike Sorting.***

The threshold of a template is the similarity a spike must be to the template, in which a low threshold catches more spikes, and a high threshold, less.

The template threshold is defined using the template histogram (***Figure 107***), which displays a distribution of spike variability.

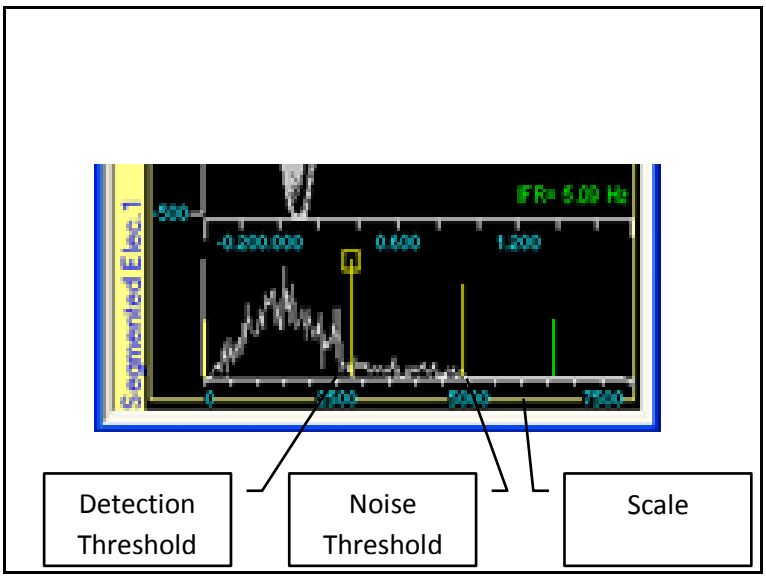


Figure 107: Template Histogram

Spike variability is the sum of the squared differences (SSQ) between a segment and the template, as follows:

- The more similar a spike is to the template, the closer to 0 on the X axis the spike distance appears.
- The time scale portrays the absolute spike variability in the SSQ value.
- The detection threshold defines how similar a spike must be to be considered a template match.
- The noise threshold defines how much of the histogram to display beyond the detection threshold.

To define the variation for a template:

From the toolbar of the online sorting graph, select a template (see ***Figure 104, page 144***).

Only that template spikes appear in the graph; below it, the graph the template histogram appears (see ***Figure 107***).

Do the following:

a. Drag the X axis to include more or less spike distances. Including more spike distances allows you to set the threshold more accurately.

Drag the noise threshold along the Y axis. The farther it is to 0, the fewer spike variability on the histogram, as more are defined as noise.

Drag the detection threshold along the Y axis. The closer it is to 0, the fewer spike variability are defined as matches.

Changes made, take effect immediately, but may not be visible for a few seconds.

4.15.3.4. Adding Include Windows

This procedure describes how to add Include Windows to the online sorting graph. This is the third step in ***Monitoring Micro Segmentation Spike Sorting.***

An Include Window fine-tunes the accuracy of the template, and is helpful in a situation when a group of spikes matches a template, yet the group's tail differs before or after the template area. When added, spikes are only matched to a template if they pass through the Include Window as well.

Up to three Include Windows can be added for each template.

To add Include Windows to a template:

From the toolbar of the online sorting graph, select a template (see ***Figure 104***).

Only the present template spikes appear in the graph. Below it, the template histogram appears (see ***Figure 107***).

From the toolbar of the online sorting graph, click  .

An Include Window, which looks like another window cursor, appears on the level line.

Move the Include Window to the spikes comprising the template in the following ways:

- Drag the Include Window.
- Enlarge the Include Window by dragging one or both of its horizontal ends.

Note: Verify that the position of the window cursor includes the desired spikes. The actual position of the window cursor along the XY axis does not matter.

To add another Include Window, do the following:

a. Right-click on the online sorting graph, and then select **Include >** an Include Window.

Another Include Window appears on the level line.

Repeat step 0 to move the Include Window to the desired position.

To remove an Include Window from a template, right-click on the online sorting graph, select **Include**, and then clear the Include Window.

Note: To turn off the Include Window, click I.

4.15.3.5. Monitoring the Spike Templates

This procedure describes how to monitor the spikes as they fall into the templates. It is the final step in *Monitoring Micro Segmentation Spike Sorting*.

To monitor the spike templates:

- In the online sorting graph or the corresponding template graph, toggle the spikes of a template to appear or disappear by right-clicking, and then selecting or clearing the template.
- To adjust the voltage scales of all of the template graphs, do the following:

  a. In any of the template graphs or the online sorting graph, right-click, and then select **Set Group Amplitude**.

  The **Set Group Scale** dialog box appears (***Figure 108***).

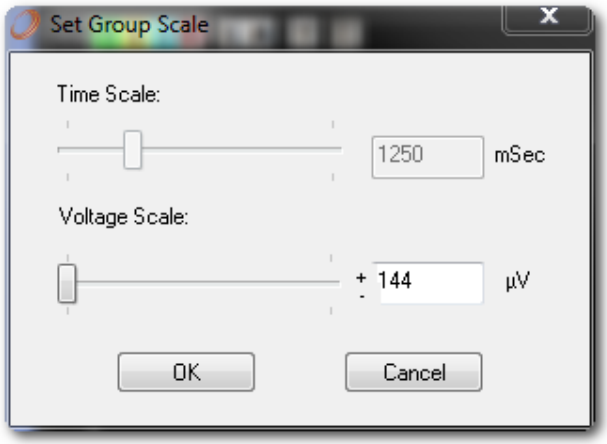


Figure 108: Set Group Scale Dialog Box

Adjust the **Voltage Scale**, and then click **OK**.

The voltage scale is adjusted.

4.15.4. Monitoring Spikes in the Spikes Raster Graph

This procedure describes how to monitor micro segmentation spike detections in a fixed time, in a spikes raster representation. Spikes determined by the threshold set by the level line in the micro segmentation window, or a spike sorting template as defined in

section ***4.15.3.2***, compose the raster. One line in the spikes raster graph represents a spike or template match.

> **Note:** The selected spikes raster graph displays only one channel at a time.

To monitor the spikes raster graph:

Do one of the following:

- If you want the spikes raster graph composed of spikes determined by a spike sorting template, then do the following:
  i. Define the template as described in section ***4.15.3.2***.

Define the template threshold, as described in section ***4.15.3.3***.

Continue with step 0.

- If you want the spikes raster graph composed of spikes determined by the level line in the micro segmentation window, then continue with step ***0***.

From the **Windows List** button, select the micro segmentation window.

The micro segmentation window appears (see ***Figure 98***), with each channel in the window appearing in its own graph.

In the graph of the channel whose spikes you want to monitor, do one of the following:

- If you want the raster composed of spikes crossing the level line in the rising direction, select the up arrow.
- If you want the raster composed of spikes crossing the level line in the falling direction, select the down arrow.

> **Note:** If the down arrow does not automatically appear, select the up arrow first, and it appears.

Set the threshold level for the spikes composing the raster by dragging the level line up or down the voltage scale.

From the **Windows List** button, select the spikes raster window.

The spikes raster window appears (***Figure 109***).

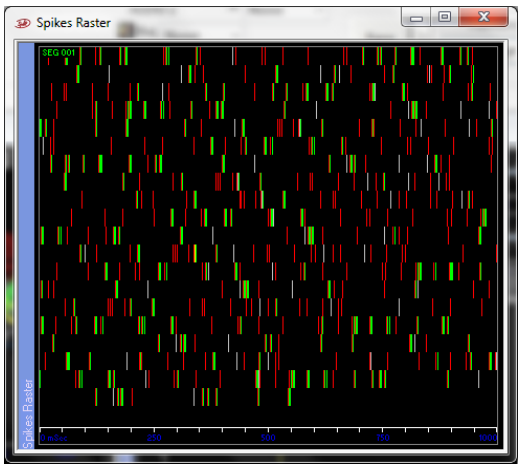


Figure 109: Spikes Raster Window

The level line is white, while the templates match the colors of the template match windows.

Right-click in the graph area, and then verify that **Level Line** is selected.

Right-click again in the graph area, and then select **Options**.

The **Raster Options** dialog box appears (***Figure 110***).

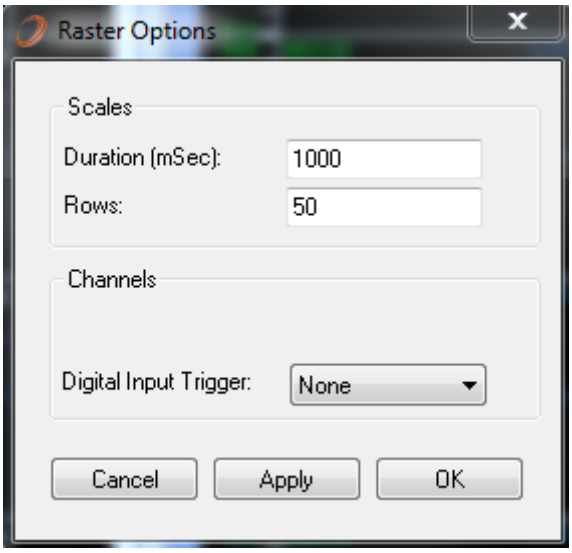


Figure 110: Raster Options Dialog Box

Do the following:

- In the **Scales** area, in the **Duration** field, type the amount of time (in milliseconds) for the spikes to appear in one row, in a first-in first-out method.

Note: You can change the duration also in the graph itself, by dragging the time scale at the bottom.

- In the **Rows** field, type the amount of rows that can appear on the screen at one time, in a first-in first-out method.
- From the **Digital Input Trigger** dropdown, select the digital input to use as the trigger, as follows:
  - When the digital signal changes state from 0 to 1, this is marked in the raster with an **X**.
  - When the digital signal changes state from 1 to 0, this is marked in the raster with an **O**.

Note: See section *2.12* for connecting an external digital input system.

Do one of the following:

- Click **Apply** to apply your settings while keeping the **Raster Options** dialog box open.
- Click **OK** to apply the settings and close the **Raster Options** dialog box.

4.15.5. Monitoring Spikes in the Interspike Interval (ISI) Graph

This procedure describes how to monitor micro segmentation spike detections, which are repeated in a certain frequency; i.e. firing rate, in a bins drawing. Spikes determined by the threshold set by the level line in the micro segmentation window, or a spike sorting template as defined in section ***4.15.3.2***, compose the graph. Bins drawing in the graph represents a spike or template match of a certain firing rate.

Note: The selected Interspike Interval graph displays only one channel at a time.

To monitor the ISI graph:

Do one of the following:

- If you want the ISI graph composed of spikes determined by a spike sorting template, then do the following:
  i. Define the template as described in section ***4.15.3.2***.

Define the template threshold, as described in section ***4.15.3.3***.

Continue with step 0.

- If you want the ISI graph composed of spikes determined by the level line in the micro segmentation window, then continue with step ***0***.

From the **Windows List** button, select the micro segmentation window.

The micro segmentation window appears (see ***Figure 98, page 138***), with each channel in the window appearing in its own graph.

In the graph of the channel whose spikes you want to monitor, do one of the following:

- If you want the ISI composed of spikes crossing the level line in the rising direction, select the up arrow.
- If you want the ISI composed of spikes crossing the level line in the falling direction, select the down arrow.

Note: If the down arrow does not automatically appear, select the up arrow first, and it appears.

Set the threshold level for the spikes composing the raster by dragging the level line up or down the voltage scale.

From the **Windows List** button, select ISI window.

The Interspike Interval window appears (***Figure 109***).

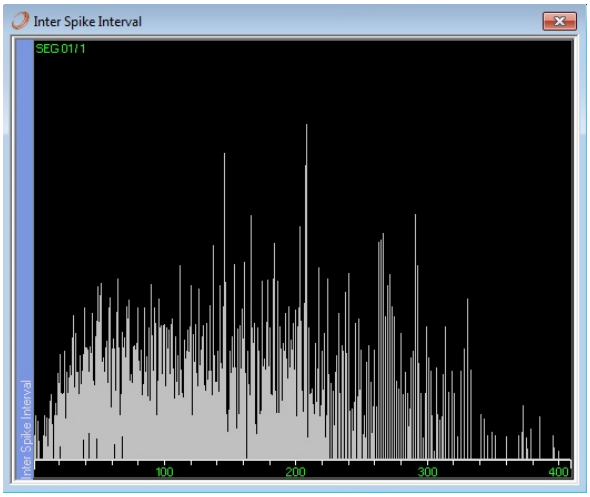


Figure 111: ISI Window

The level line is white, while the templates match the colors of the template match windows.

4.15.6. Monitoring EEG signals in Color Density Spectral Array Graph.

This procedure describes how to monitor Fast Fourier Transform (FFT) of the EEG signal, which is calculated for a selected period of time, in a color density drawing. Color is determined by the amplitude – blue color for the smallest values and red color for the

biggest. Y axis represents time; X axis represents frequency range of the EEG channel (according to the channel filters). Spectral edge line can be added to the graph.

Notes:

- The Color Density Spectral Array graph displays only one channel at a time.
- The calculated data of the Color Density Spectral Array is not saved.

To monitor the Color Density Spectral Array graph:

From the **Windows List** button , select **Color Density Spectral Array** window.

The **Color Density Spectral Array** window appears (Figure 112).

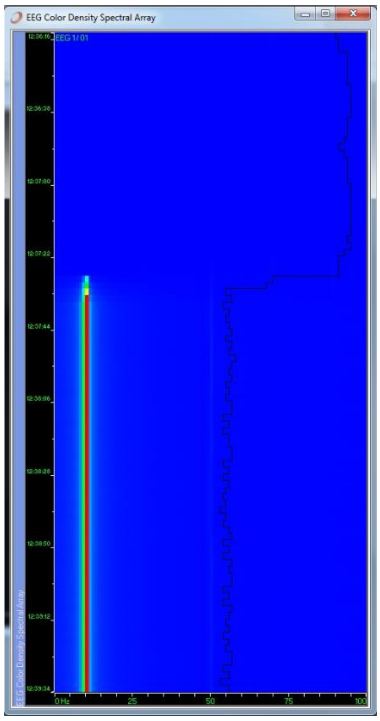


Figure 112: Color Density Spectral Array Window

The level line is white, while the templates match the colors of the template match windows.

Right-click in the graph area, and then select **Options**.

The **Color Density Spectral Array** dialog box appears (Figure 113).

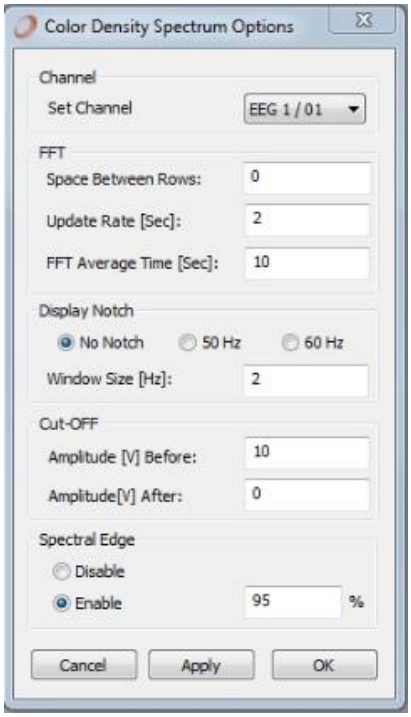


Figure 113: Color Density Spectral Array Dialog Box

Do the following:

- In the **Channels** area, from the **Channel** dropdown list, select the channel you want to monitor.
- In the **Space Between Rows** field, type the distance between rows in Pixels.
- In the **Update Rate** field, type the time in seconds for updating the row in the display.
- In the **FFT Average Time** field, type the time in seconds for calculating the average of the FFT.
- From the **Display Notch** field, choose 50 Hz or 60 Hz to remove the unselected notch from the display.
- In the **Window Size** field, type the band width value of the notch in Hz.
- In the **Amplitude** field, type the maximum value allowed to be displayed (and calculated in the FFT average) in the **Before** field, and type the replacement of these values in the display in the **After** field.
- From the **Spectral Edge** section, set an edge to display the percentage of power under the displayed frequency.

Notes:

- When the chosen function entails clearing data or changing channel (for example, choosing a different channel, or changing the Cut-OFF settings), the outcome is not reversible – all previous calculations will be lost.

4.16. OPRA

OPRA (Online Pattern Recognition Algorithm) is a tool that provides visual feedback on neural activity throughout the trajectory. It appears in an electrode track of the **Trajectory** graph from the moment you create the new trajectory, and appears in a printed trajectory. Changes in neural activity and signal energy are estimated by two functions: the energy of the recorded signal and the spike firing rates. As these increase, the OPRA bar changes from white (no activity) to red (increased activity).

The OPRA process is as follows:

OPRA takes a two-second snapshot at each new depth while you drive the trajectory (data must be logged for this to occur – see section ***0***)

Based on the snapshot, OPRA calculates the increase in neural activity.

OPRA provides visual feedback in the electrode track of the trajectory in the **Trajectory** graph.

OPRA is calculated at each site with the root mean square of the spike signal at that site. The first five sites are used a reference for the track. Each electrode is calculated individually. Using OPRA can "help the surgical team assess in real-time the location of the STN in the trajectory." Particularly, "the entry into and exit from the STN can be predicted."*

4.16.1. Assessing OPRA Feedback

This procedure describes how to assess OPRA feedback in the Trajectory graph.

To assess OPRA:

At each recording site, in the Trajectory graph, select the electrode track for which to assess OPRA feedback.

OPRA feedback appears for the electrode track (***Figure 114***).

* This process is described at length in *Real-Time Refinement of Subthalamic Nucleus Targeting Using Bayesian Decision-Making on the Root Mean Square Measure*, by Moran, Bar-Gad, Bergman, and Israel.

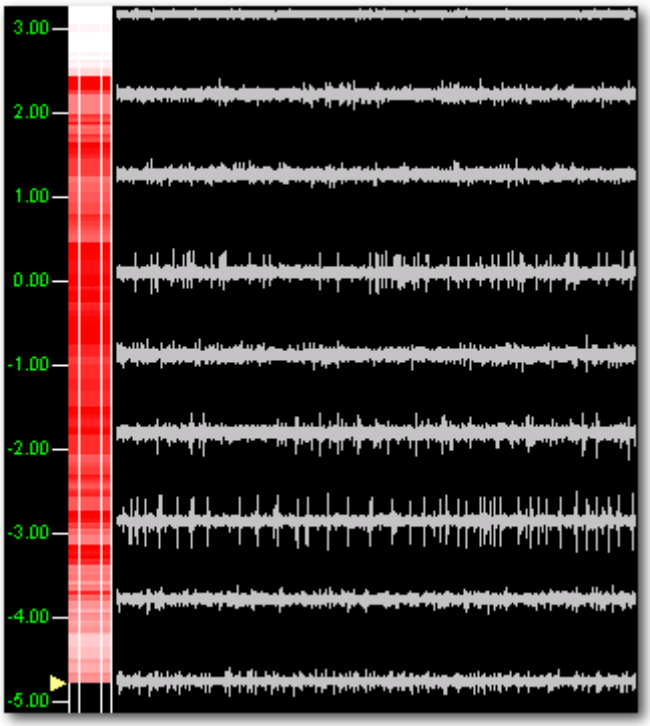


Figure 114: OPRA Feedback Appearing in the Trajectory Graph

Assess the OPRA feedback, as follows:

- If the OPRA representation is white, this indicates low neural activity.
- If the OPRA representation is red, this indicates high neural activity.

Right click on the OPRA display window, chose Trajectory Map Review (figure 152). Trajectory map, will display signals recorded at each site (figure 153), with option to select to display which electrode, duration, and amplitude.

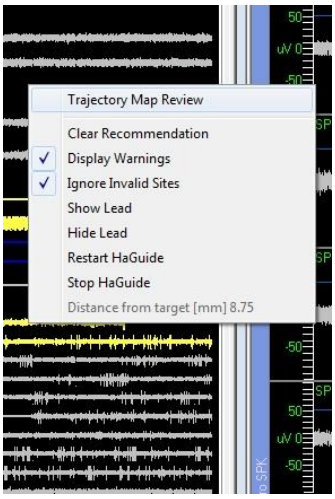


Figure 115: OPRA options

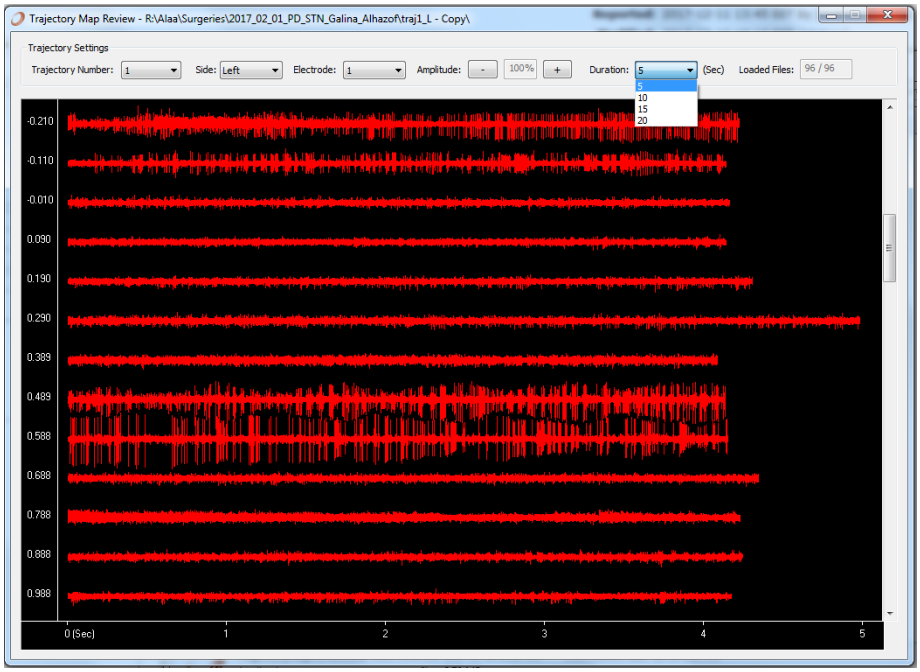


Figure 116: Trajectory Map Review

4.16.2. OPRA Best Practices

For best use, do the following:

- Create the new trajectory only after everything else (electrodes, cables, assembly) has been prepared, as setting up can interfere with the OPRA calculation.
- Create the new trajectory after completing the impedance check as described in section ***4.13.***
- Move the threshold for spike sorting outside the noise, so that the firing rate is not calculated from the noise, as OPRA takes the firing rate into account.
- Ensure that **Save in Each Site** is selected, as described in section ***0.***

4.17. USER EVENTS

The following procedures describe methods for inserting placeholders in the log file, at each recording site, for subsequent review:

- Marking Events from the **Events Control Panel**, as described in section ***4.17.1***
- Marking Events while in the Events Definition table, as described in section ***4.17.2***
- Adding remarks, as described in section ***4.17.3***

Before the operation, define the events you expect to encounter during the experiment, as described in section ***4.7***. During the operation, have the Events Control Panel open to mark these events.

All event values are stored in user-defined digital port number 21, while remarks are stored in Stream Format. The default log file location is under the patient reference in the surgeries data folder on C:\.

> **Note:** New events are not saved across patients.

4.17.1. Marking Events from the Events Control Panel

This procedure describes how to mark events on the **Events Control Panel**. The events appear in the log files for review.

This is the simpler way of marking events. The other way is from the **Events Definition** table, as described in section ***4.17.2***.

To mark events:

From the toolbar, click **E** **Events Properties**.

The **Events Control Panel** appears (see ***Figure 86***). The panel contains a number of predefined events for convenience.

To mark an event, in the **Predefined Events** area, do one of the following:

- Select an event button.
- From the dropdown list, select an event.

Click **Send**.

The event is marked in the log file.

4.17.2. Marking Events from the Events Definition Table

This procedure describes how to mark events while already in the **Events Definition** table. This is helpful if you have edited events (see section ***4.7.2***) during monitoring. The events appear in the log files for review.

The simpler way to mark events is from the Events Control Panel, as described in section ***4.17.1***.

From the **Events Definition** dialog box (see ***Figure 87, page 118***), select the event you want to send for logging, and then click Send.

The event is marked in the log file.

4.17.3. Adding Remarks

This procedure describes how to add remarks, which are text comments. The remarks are stored in the log file in a stream format.

To add remarks:

From the toolbar, click **Events Properties**.

The **Events Control Panel** appears (see ***Figure 86***); the panel contains a number of predefined events for convenience.

Click **Mark**.

The following happens (***Figure 117***):

- The text field is enabled.
- The **Mark** button changes to **Cancel**.
- After entering text in the **Remarks** field, the **Send** button activates.

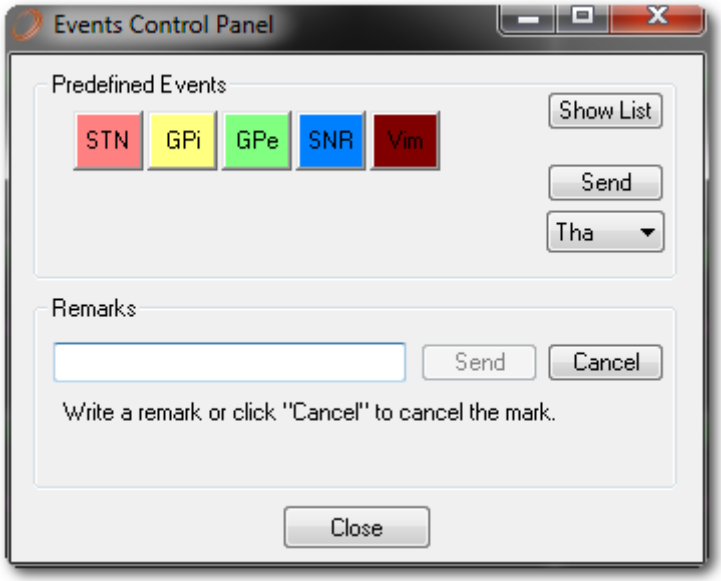


Figure 117: Events Control Panel, Remarks Enabled

If you want to cancel the remark, click **Cancel**.

Enter your remark, and then click **Send**.

In the log file, the timestamp of the message is from when the user clicked **Mark**.

4.18. TRAJECTORY PRINTING

The following procedures describe printing the trajectory, which is useful for review:

- ***Printing the Selected Track***

❖ *Printing an Active*

The printout can be saved and attached to the patient file, or viewed later to compare all the depths together. OPRA (see section ***4.16***) is also shown in the dots on the depth locations.

4.18.1. Printing the Selected Track

This procedure describes how to print the selected recording site in the Trajectory graph for review.

To print the trajectory:

Double-click anywhere on the trajectory graph (***Figure 84***).

The **Print Trajectory** dialog box appears (***Figure 118***), containing a version of the **Trajectory** graph, as follows:

- Each row of the graph describes the activity of one recording site.
- The recording sites are divided into pages of ten to a page.

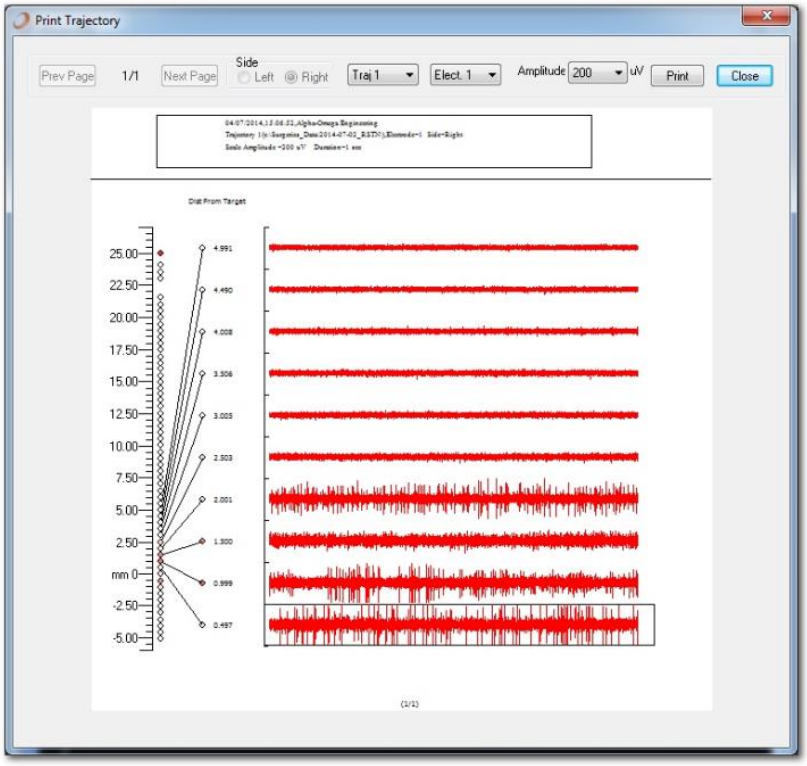


Figure 118: Print Trajectory for a Selected Track

Prepare the print job by selecting, from the **Amplitude** dropdown list, the amplitude, in millivolts, of the traces that you want to appear in the print job.

Click **Print**.

The trajectory is printed.

4.18.2. Printing an Active Track

This procedure describes how to print any of the active tracks for review.

To print the trajectory:

From the toolbar, click **Print Trajectory**.

The **Print Trajectory** dialog box appears (***Figure 119***), containing a version of the **Trajectory** graph, as follows:

- Each row of the graph describes the activity of one recording site.
- The recording sites are divided into pages of ten to a page.

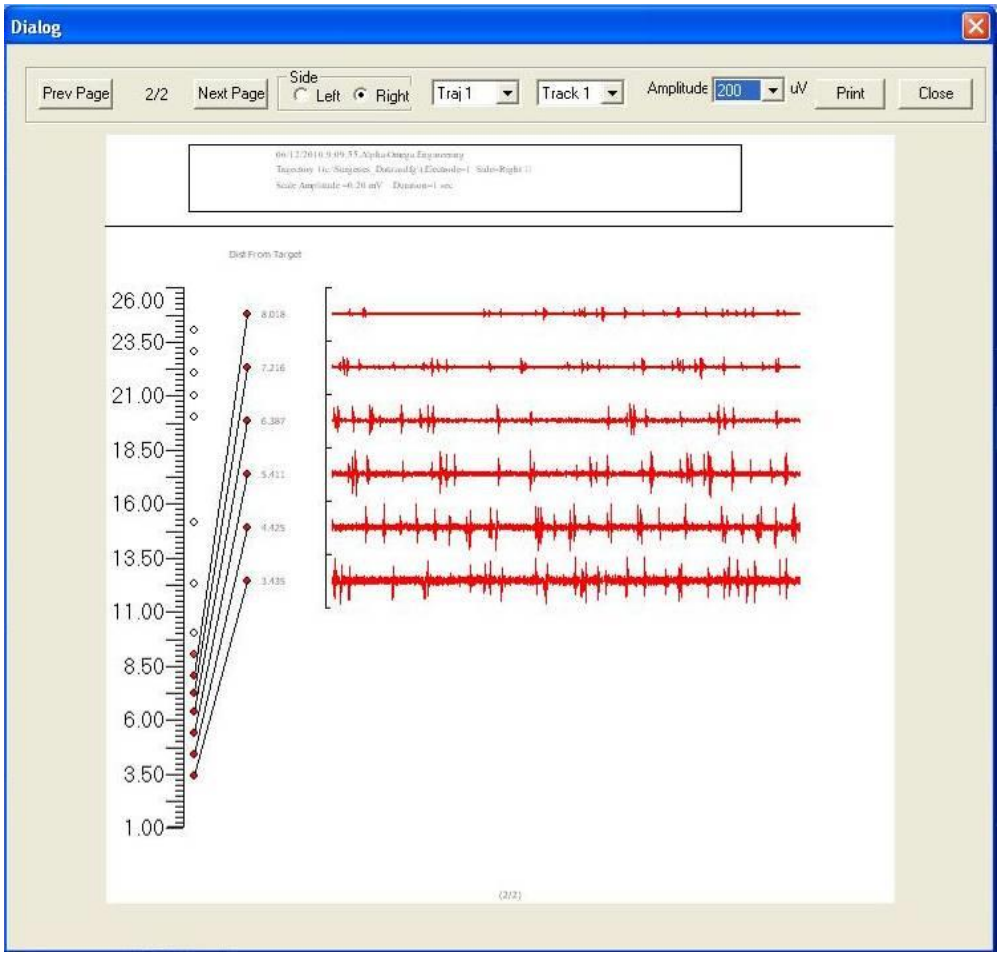


Figure 119: Print Trajectory Dialog Box

Prepare the print job by doing any of the following:

- Click **Prev Page** or **Next Page** to open the page of recording sites you want to print.
- In the **Side** area, select the hemisphere of the trajectory you want to print.

- From the **Trajectory** dropdown list, select the trajectory (left or right) you want to print.
- From the **Track** dropdown list, select the track of the trajectory that you want to print.
- From the **Amplitude** dropdown list, select the amplitude of the traces that you want to appear in the print job, in millivolts.

Click **Print**.

- The trajectory is printed.

4.19. SAVING DATA TO THE LOG FILE

This procedure describes how to save the current data set from the site to the log file during monitoring, for later review. Settings for saving automatically are located in the **Settings** dialog box, as described in section ***4.9***.

Note: The default file location is under the patient reference in the surgeries data folder on C:\.

To save manually:

Do any of the following:

- From the toolbar, click **Save**.
- From the remote control, press the **Save** button.

The following happens when saving is activated, either automatically or manually:

- In the **Trajectory** graph:
  - Creates a one-second-trace segment (left pane of the laptop screen)
  - Displays OPRA (see section ***4.16***)
- Save the continuous data to the log file

Note: You can save manually even when you have configured automatic saving.

4.20. STIMULATION

Perform stimulation after successfully determining placement (see section ***4.1***, step ***0***). The workflow for stimulation is as follows:

Set up stimulation for the channel, including defining the waveform, the amplitude, and the return channel, as described in section ***4.20.1***.

Apply the stimulation, as described in section ***4.20.2***.

Monitor the stimulation with the current monitor, which displays the real injected current value, as described in section ***4.20.3***

4.20.1. Setting Up Stimulation

This procedure describes how to set up stimulation, which is necessary before applying stimulation to the patient. Stimulation setup includes selecting a specific electrode, selecting a defined stimulation pulse or waveform, and defining duration and frequency, among other things.

To set up stimulation:

From the toolbar, from the **Stim Channel** dropdown list, select the channel through which to send the stimulation.

From the toolbar, select **Stim Setup**.

The **Stimulation Setup** dialog box appears (***Figure 120***).

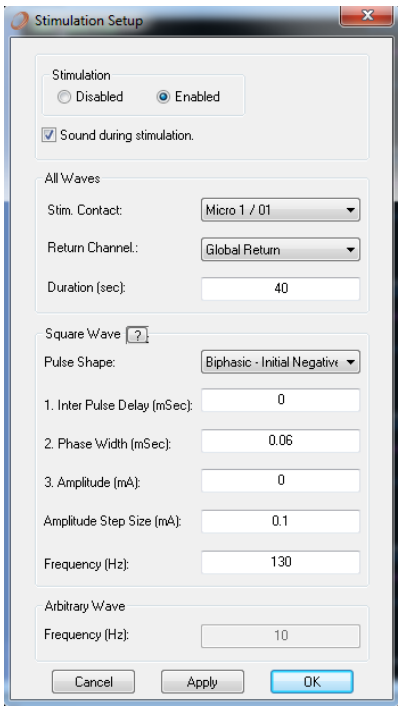


Figure 120: Stimulation Setup Dialog Box

In the Stimulation **Setup** dialog box, do the following:

- Verify that **Stimulation** is **Enabled**.
- For a beep to sound for the duration of the stimulation, select **Sound during Stimulation**.

Note: The beep is not as loud as the recorded signal; turn the volume up to louder to hear this.

- In the **All Waves** area define the following:
  - **Stim. Contact:** is the required stimulation contact. From the Dropdown box, select any contact available for stimulation.
  - In the **Return Channel** dropdown list, select the channel through which to return the stimulation (see section 4.20.2, step 0) by doing one of the following:
  - If you plan to apply the stimulation from a micro channel, select another micro channel or a macro channel.
  - If you plan to apply the stimulation from a macro channel, select another macro channel.
  - If you plan to apply the stimulation from an EMG channel, select another EMG channel.
  - If you plan to apply the stimulation from an EEG channel, select another EEG channel.
    - If you plan to apply the stimulation from an ECOG channel, select another ECOG channel.

Warnings:

Before applying stimulation refer to the electrodes specifications for maximum allowed charge density. The applicable stimulation electrodes are any commercially available 1.17mm diameter or above strip and grid electrodes. The applicable grid and strip stimulation electrodes must have been cleared by the relevant regional authorities (i.e. Food Drug Administration, FDA for the US, CE for Europe).

- Select **Global Return** for the current to return through the global stimulation return. In the Drive Headstage, this is shorted to ground. In the Headbox modules, there is an individual connector (see section 2.11).

Note: You may not return the stimulation by the same channel through which it was applied.

Warnings:
In the following specific use cases, while performing peripheral nerve or cortical stimulation, the stimulation current may return through the Microelectrodes' contacts (Micro and Macro).
The current could reach high charge density which may cause tissue harm.
Use case 1:
In case of:
1. Using only one EMG/ECoG channel and;
2. Microelectrode is connected to the patient and;
3. EMG/ECoG "Global stimulation return" connector is not properly connected and;
4. EMG/ECoG "reference" connector is not properly connected.

Use case 2:
In case of:
1. Using only one EMG/ECoG channel and;
2. Microelectrode is connected to the patient and;
3. EMG/ECoG channel is not properly connected and;
4. EMG/ECoG "reference" connector is not properly connected

Indicators of an improper connection:
Indicator 1 - EMG/ECoG recording will show very high noise, (above 5 [mV])
Indicator 2 - EMG/ECoG electrode impedance will be high, (above 500 [kΩ])
Advise on action to be taken by the user:
Before performing peripheral nerve or cortical stimulation verify the following:
1) EMG/ECoG "Global stimulation return" is connected properly (visual check)
2) EMG/ECoG "Reference contact" is connected properly (see Indicator 1 above)
3) EMG/ECoG channel is connected properly (see Indicator 1 above)
4) Perform impedance check (see Indicator 2 above)

- **Duration:** is the duration of one stimulation season.

Note: When applying stimulation, stimulation lasts for as long as you press the stimulation button, unless the value in the **Duration** field is less.

- In the **Square Wave** area, from the **Pulse Shape** dropdown list, select one of the waveforms:
  - **Biphasic - Asymmetric**
  - **Biphasic – Initial Negative**
  - **Biphasic – Initial Positive**
  - **Monophasic – Initial Negative**
  - **Monophasic – Initial Positive**

Note:
- If you selected the **Biphasic** waveform from the **Pulse Shape** dropdown list, each phase has this duration (one positive and one negative).

- The question mark beside **Square Wave** can be clicked to show the shape and parameters of the selected **Pulse Shape**

- In the **Inter Pulse Delay** field, type the length of time between pulses in milliseconds.
- In the **Phase Width** field, type the duration of the phase in milliseconds.
- In the **Amplitude** field, type the pulse phase amplitude of the stimulation in milliamps.
- In the **Amplitude Step Size** field, type the step size of the amplitude of the stimulation in milliamps.
- In the **Frequency** field, type the frequency of the stimulation in Hertz.

Do one of the following:

- To implement setup and close the **Stimulation Setup** dialog box, click **OK**.
- To implement setup and leave the **Stimulation Setup** dialog box open, click **Apply**.

Define how the evoked potentials upon stimulation are viewed in the evoked potentials window (as required), as described in section ***4.21***.

4.20.2. Applying Stimulation to the Patient from the Toolbar

This procedure describes how to apply stimulation to the patient from the toolbar, and monitor the stimulation.

To apply stimulation to the patient from the toolbar and monitor the stimulation:

Do the following:

- To select the channel from which to send the stimulation:
  i. From the toolbar, from the **Stim Channel** dropdown list (see ***Figure 81***), select a channel.

, page 49), press the **Micro-Macro** button to select either micro or macro, and then press the arrow buttons to select the channel.

- To adjust the current amplitude of the stimulation if necessary (in milliamps):

i. From the toolbar, in the **Stim Amplitude** field, click the **Up** and **Down** buttons.

From the remote control, press the **+** and **-** buttons.

To apply the stimulation, do the following:

a. From the toolbar, click and hold down **Stim**.

From the remote control, press and hold down the **Stimulation** button.

Stimulation is applied to the patient for as long as you hold down the button, unless the value entered in setting up the stimulation (see section ***4.20.1***) is less.

Monitor the stimulation using the **Current Monitor** window, which displays the real injected current value, as described in section ***4.20.3***

4.20.3. Monitoring Stimulation in the Current Monitor Window

This describes how to monitor stimulation in the Current Monitor window, which displays the real injected current value.

To monitor stimulation using the Current Monitor window:

From the **Windows List** button  , select the **Current Monitor** window.

The Current Monitor window appears (***Figure 121***), in which the height of the bar is relative to the stimulus strength, colored as follows:

- When the bar is green, stimulation is working correctly.
- When the bar is purple, the measured stimulation value is below the requested value by 30% or more.

Figure 121: Current Monitor Window

Note: For safety reasons, if the measured value is above the requested value by more than 30%, the system stops the current and the Current Monitor displays purple.

4.21. DEFINING AND MONITORING THE EVOKED POTENTIAL

This procedure describes how to define the potentials evoked upon stimulation are viewed in the evoked potentials window, and then monitor the potentials during stimulation.

The Evoked Potential tool is useful for visualizing the effects of stimulation in one area upon another area recorded by a channel, primarily LFP. The tool creates time-locked averages to the stimulus event.

To define and monitor the evoked potential:

From the **Windows List** button , select the Evoke Potential window.

The **Evoke Potential** window appears (***Figure 122***).

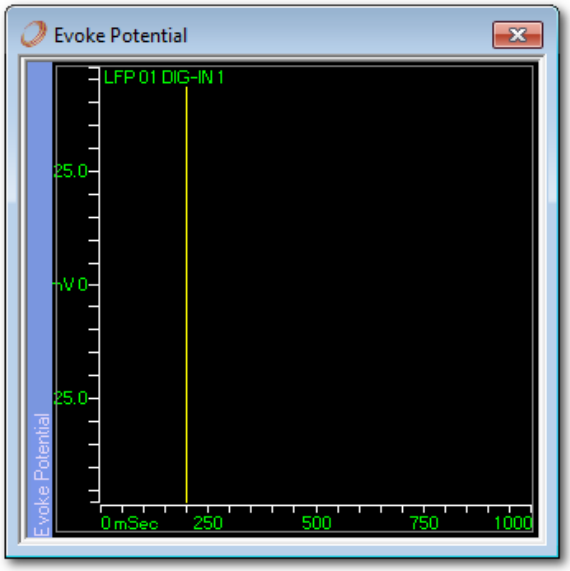


Figure 122: Evoke Potential Window

Right-click in the graph area, and then select **Options**.

The **Options** dialog box appears (***Figure 123***).

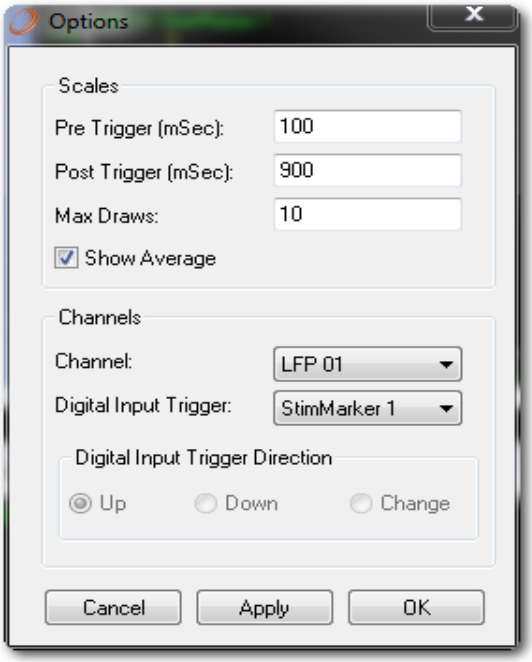


Figure 123: Evoked Potentials Options Dialog Box

Do the following:

a. In the **Scales** area, type the amount of time (in milliseconds) in the **Pre Trigger** field to display before the trigger; and in the **Post Trigger** field,

after the trigger. The total amount of time must be less than 1000 milliseconds.

In the **Max Draws** field, enter the number of snapshots appearing in the **Evoke Potential** window around the time-locked event. There is always this number of traces in the window, with the newest one cycling in and the oldest cycling out, working in a first in first out basis.

Select the **Show Average** option to show the calculated average of all the snapshots defined in the **Max Draws** field. This is helpful when many stimulus events are occurring per second, as an effect may only appear with the average.

In the **Channels** area, from the **Channel** dropdown list, select an **LFP** or **SPK** channel.

From the **Digital Input Trigger** dropdown list, select a trigger for the tool to start creating the time-locked averages:

i. Select a digital input trigger.

The **Digital Input Trigger Direction** area becomes active (***Figure*** 124).

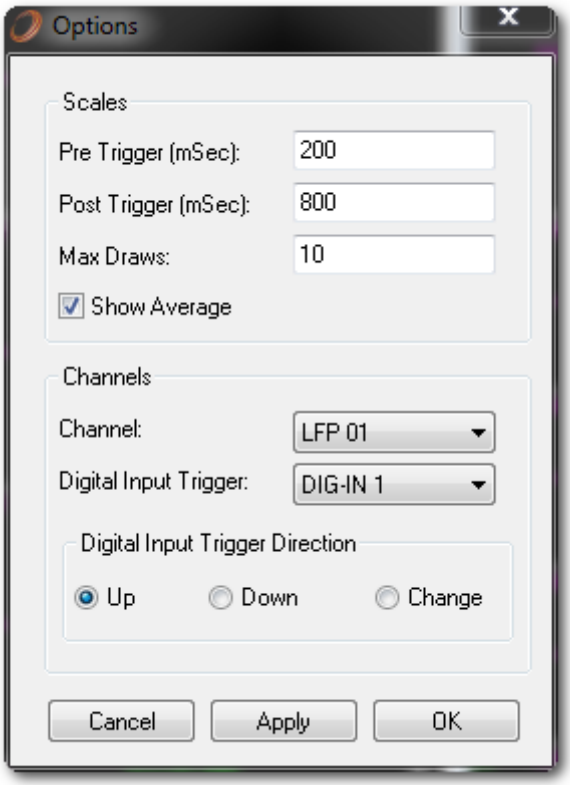


Figure 124: Evoked Potentials Options with DIG-IN Selected

Select a **StimMarker** trigger.

The **Digital Input Trigger Direction** area becomes inactive.

If you selected a digital input trigger, then in the **Digital Input Trigger Direction** area, select one of the following:

- **Up**: The digital input must be in the high state to trigger the tool.
- **Down**: The digital input must be in the low state to trigger the tool.
- **Change**: The tool is triggered regardless of digital input state.

Do one of the following:

- Click **Apply** to apply your settings while keeping the **Evoked Potentials** dialog box open.
- Click **OK** to apply your settings and close the **Evoked Potentials** dialog box.

Do any of the following:

- To reduce the total amount of time displayed in the graph, drag the time scale to the right.
- To expand the voltage scale, drag up on the scale.
- To contract the voltage scale, drag down on the scale.
- To clear the screen for a fresh start, right-click in the graph area, and then select **Clear**.

During stimulation, from the **Windows List** button  , select the evoked potential window.

The Evoke Potential window appears (***Figure 125***), displaying signals based on the stimulation in real time. Above the signals a colored line appears, displaying the average of all the signals.

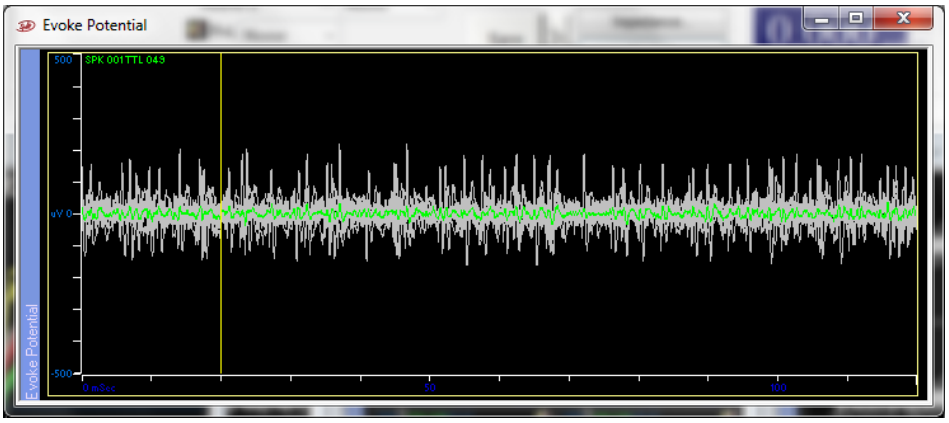


Figure 125: Active Evoked Potential Window

Adjust the channel voltage or time scales, as described in section ***4.15.1.1***.

4.22. DEFINING AND MONITORING THE PERISTIMULUS HISTOGRAM (PSTH)

This procedure describes how to define the Peristimulus Histogram upon stimulation or Digital input trigger, and then monitor the sorted spikes in response.

The PSTH tool is useful for visualizing the effects of stimulation or digital input in one area upon another area recorded by a channel, for SPK channels. The tool creates time-locked averages to the stimulus or trigger event.

The **PSTH** is divided into two sections:

- **Lower part:** is the part that shows raster of line crossing or template matching with every trigger i.e. digital input or stimulation marker. The yellow line is synchronized with the given trigger.
- **Upper part:** draws a histogram of the averages of the sorted spikes.

To define and monitor the PSTH:

From the **Windows List** button  , select the ISI window (refer to section 4.6.1 in order to create window).

The **PSTH** window appears (***Figure 122, page 171***).

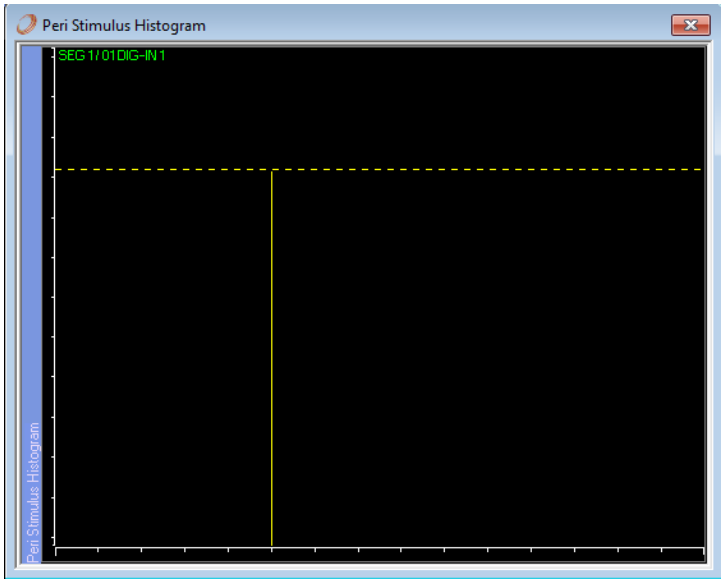


Figure 126: PSTH Window

Right-click in the graph area, and then select **Options**.

The **Options** dialog box appears (***Figure 123, page 171***).

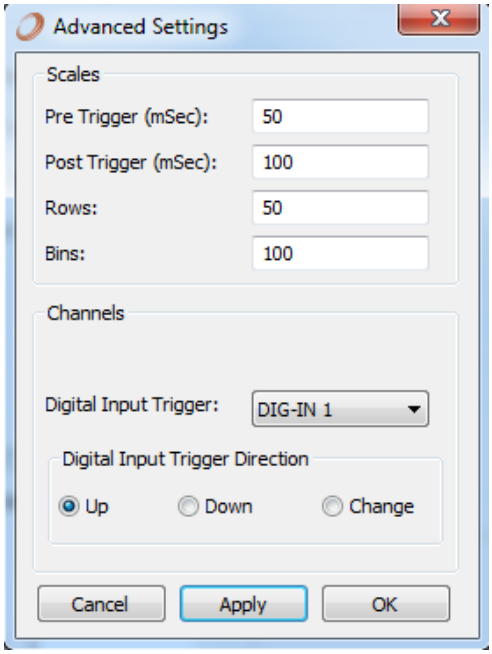


Figure 127: Evoked Potentials Options Dialog Box

Do the following:

a. In the **Scales** area, type the amount of time (in milliseconds) in the **Pre Trigger** field to display before the trigger, and in the **Post Trigger** field after the trigger. The total amount of time must be less than 1000 milliseconds.

In the **Rows** field, enter the number of raster rows in the **PSTH** lower part of the window. There is always this number of rows in the window, with the newest one cycling in and the oldest cycling out, working in a first in first out basis. The amount of rows must be between 1 -100.

In the **Bins** field, enter the number of bins that can be drawn on every row in the **PSTH** lower part of the window. The amount of bins must be between 1 -100.

From the **Digital Input Trigger** dropdown list, select a trigger for the tool to start creating the trigger-locked averages:

i. Select a digital input trigger.

The **Digital Input Trigger Direction** area becomes active.

Select a **StimMarker** trigger.

The **Digital Input Trigger Direction** area becomes inactive.

If you selected a digital input trigger, then in the **Digital Input Trigger Direction** area, select one of the following:

- **Up**: The digital input must be in the high state to trigger the tool.
- **Down**: The digital input must be in the low state to trigger the tool.
- **Change**: The tool is triggered regardless of digital input state.

Do one of the following:

- Click **Apply** to apply your settings while keeping the **PSTH** dialog box open.
- Click **OK** to apply your settings and close the **PSTH** dialog box.

Do any of the following:

- To reduce the total amount of time displayed in the graph, drag the time scale to the right.
- To clear the screen for a fresh start, right-click in the graph area, and then select **Clear**.

During stimulation, from the **Windows List** button , select the **PSTH** window.

The **PSTH** window appears (***Figure 125***), displaying signals based on the triggering in real time.

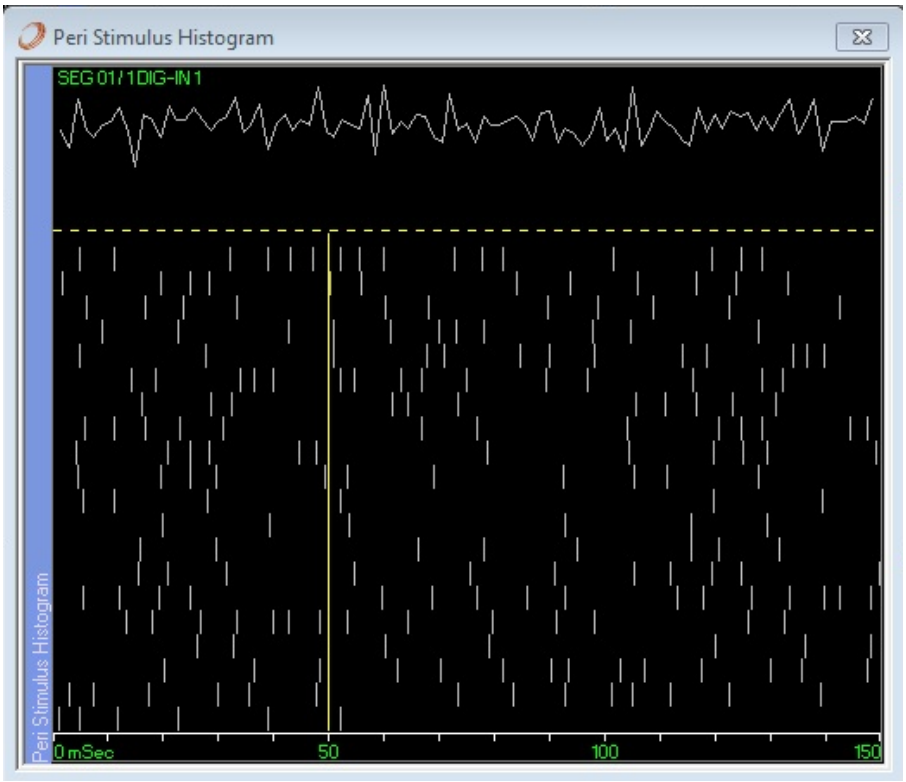


Figure 128: Active PSTH Window

Adjust the channel time scales, as described in section ***4.15.1.1***.

4.23. OPERATION OF THE NEURO OMEGA PLAYER MODE

Neuro Omega Player gives the option to replay and recreate the surgery.

- Replay all the surgery files or a chosen files on a computer, Offline Mode

> **Warnings:**
> Neuro Omega Player must not be used while Neuro Omega software is used.

4.23.1. Player Offline Mode

Powering the Player On.

This procedure describes how to power on the Neuro Omega Player in offline mode.

Power on the computer and double click the Main Player shortcut.

The Patient window appears (Figure 129).

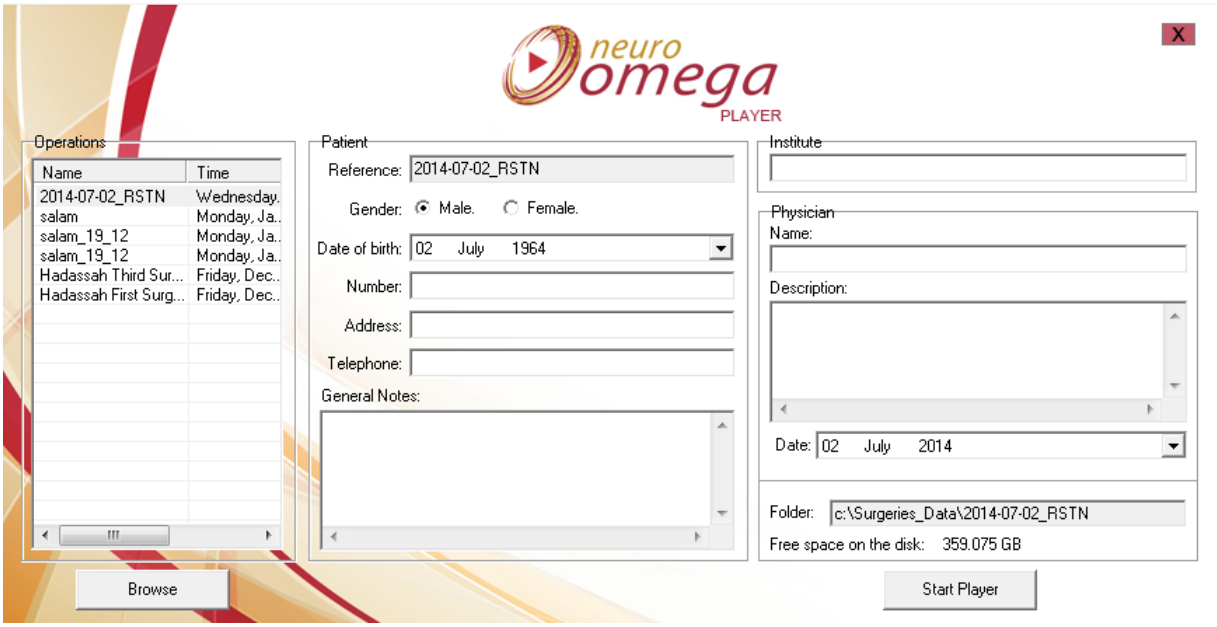


Figure 129: Patient window

Choosing operation

This procedure describes how to choose operation data in order to recreate the surgery.

To choose new surgery

Click on the **Browse** button and choose a surgery file from the window.

To choose an existing file

From the **Operations** area, click the chosen file name.

The patient data is updated.

Click Start Player.

Neuro Omega Player Interface

The Neuro Omega Player interface is made of the following components:

- **Toolbar**: See section ***4.6.1*** for more information.
- **Workspace**: See section ***4.6.2*** for more information.
- **Trajectory Graph**: See section ***4.6.2.1*** for more information.
- **System Diagnostics**: See section ***4.6.4*** for opening system diagnostics.
- **Playlist (**Figure 130, page 180)
- **Slider Bar (**Figure 131, page 180)

Playlist

The playlist has two columns

- In case of a trajectory playlist, one column is for the distance from target and the other one for the total recording time.
- In case of a general playlist, one column is for the file name and the other one for the total recording time.

The Playlist contains the following buttons:

- **Open/hide playlist button**  : Opens or hides the playlist from the interface.
- **Browse button**  : Opens a window to choose files to run by name.
- **Combobox**  : Switches between playlists; only the selected playlist is shown.

Two ways to play a file

- Double clicking the file in the playlist will open it and run it.
- Double clicking the OPRA pane will start playing the closest recorded file to the clicked "Distance from target".

Slider Bar

The Slider Bar comprises the following components:

- **Time indicator**  **:** Shows the total time of the current played playlist entry and the progress time of the presently played playlist entry.

- **Speed button**  : gives the option to change the speed of the running file .
- **Repeat button**  **:** gives the option to repeat only the running file automatically or not to repeat , or to repeat the whole playlist .
- **Stop button**  **:** stops the running file.
- **Play button**  **:** plays or resumes to play the selected file .
- **Pause button**  **:** Pause the played file.
- **Previous/next button**  : enables the user to Select/Open/Play the previous/next playlist entry.
- **Indicates the playing progress**  **.**

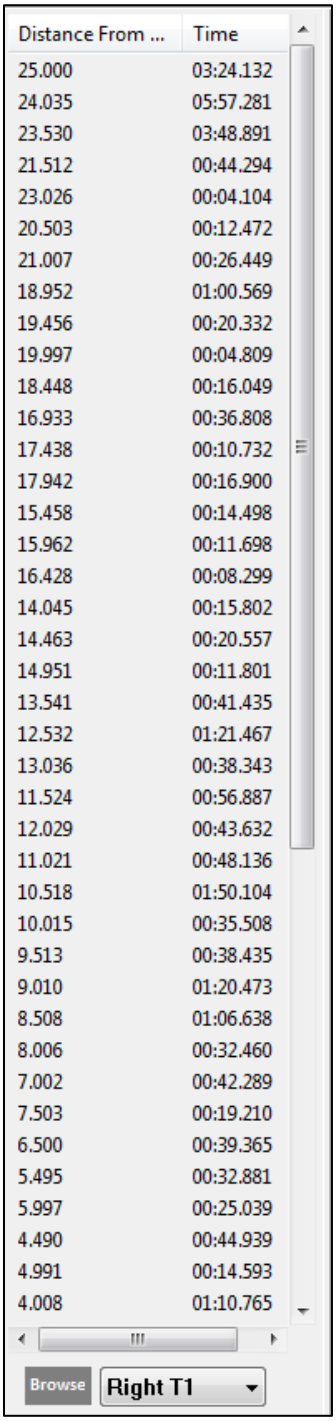


Figure 130: Playlist

Figure 131: Slider Bar

Replay Software Display

- **Distance from target** is updated according to the running file.

- **Step Size** is updated according to the running file.
- **Settings button** opens a window that includes the same data saved, related to the recording setup.
- While running a file with stimulation, the **Stim button** turns red and the Stim contact and amplitude are updated.
- If the running file includes impedance check, the **Imp button** turns red, and by pressing the button, a window with the result appears.
- **Stim Setup button** opens a window that includes the same data saved, related to the stimulation setup.

4.24. DRY RUN: DBS ELECTRODE HANDLING

> **Note:** This section does not apply for the MER Headstage

This procedure describes how to handle the DBS electrode.

Move the recording electrode to the exact depth in which you have determined to implant the DBS electrode, and then disconnect the electrode connections (***Figure 132***).

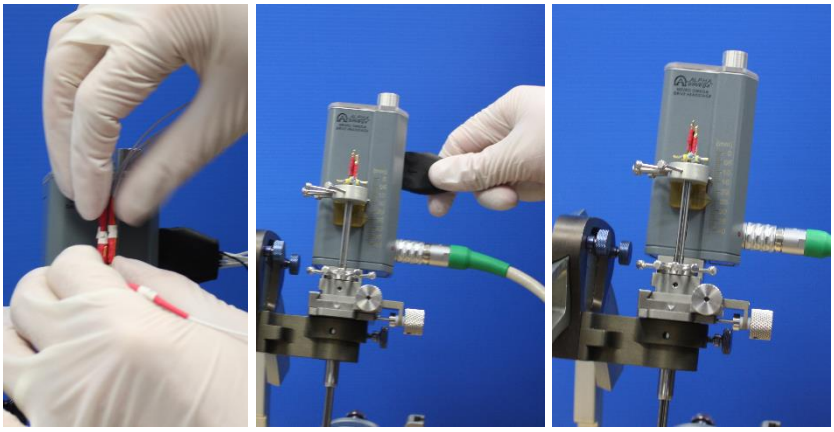


Figure 132: Disconnecting the Electrodes

Loosen the retaining screws on the electrode holder, and then remove all of the electrodes (Figure 133).

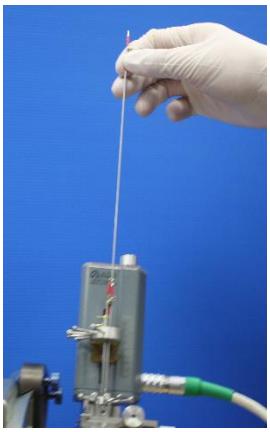


Figure 133: Removing the Electrodes

Remove the electrode holder (Figure 134), leaving the cannula connected to the Bengun.

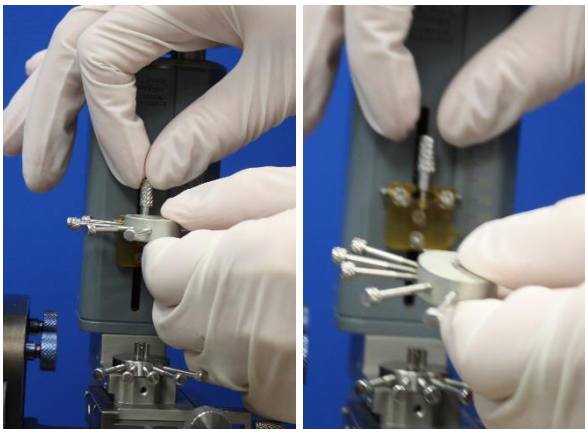


Figure 134: Removing the Electrode Holder

Attach and secure the DBS holder socket to the Drive Headstage. It attaches and locks in the same place and the same way as did the electrode holder (Figure 135).

Figure 135: Attaching the DBS Holder Socket

Connect the DBS holder to the ruler and secure screw (Figure 136).

Figure 136: Connecting the DBS Holder to the Ruler

Thread the DBS electrode into the clamps of the DBS holder, through the depressed area to prevent the DBS from being pinched by the clamps (Figure 137).

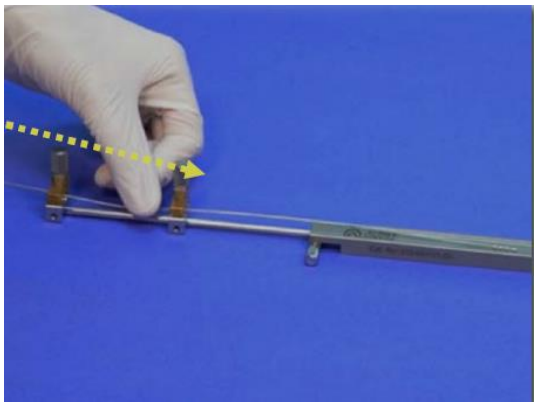


Figure 137: Threading the DBS into the DBS Holder

The 237 marker is where the micro-tip was (Figure 138)

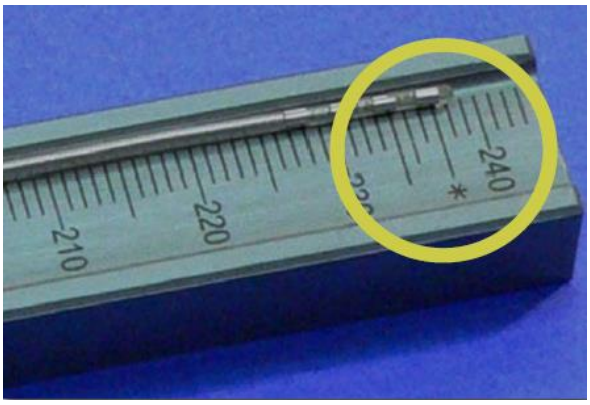


Figure 138: the 237 Marker

Note: The placement of the strips provides different options for stimulation during the patient programming phase.

On the DBS holder, while slightly pushing the DBS electrode downward, lock the clamps onto the DBS electrode, to hold the DBS electrode in place (Figure 139).

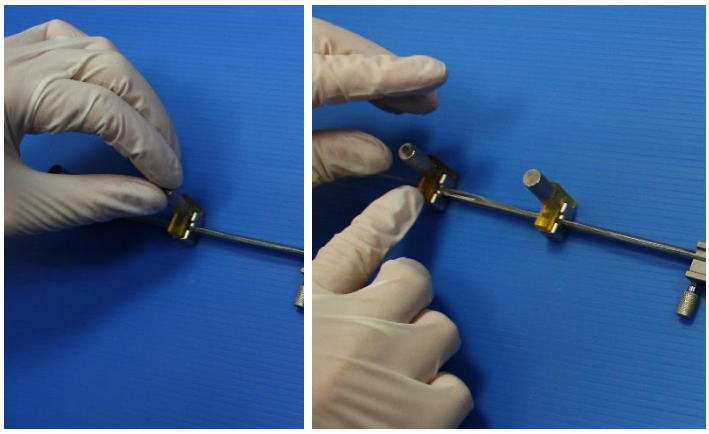


Figure 139: Locking the Clamps onto the DBS

Remove the DBS holder from the ruler (Figure 140).

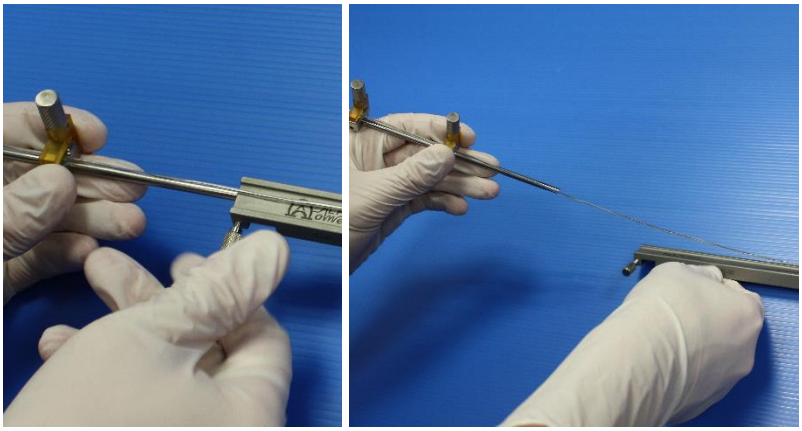


Figure 140: Removing the DBS Holder from the Ruler

The DBS electrode is now measured to the correct length.

Bring the DBS holder to the Drive Headstage Assembly (Figure 141).

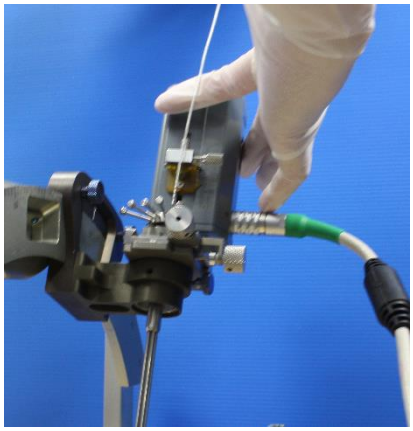


Figure 141: Threading the DBS into the Cannula

CHAPTER 5. ADVANCED CAPABILITIES

5.1. ADVANCED OVERVIEW

More advanced capabilities are as follows:

- Defining filtering and sampling properties, described in section 5.2.
- Defining options for the log files generated by the system during recording, described in section ***5.3***.
- Editing a contact channel, described in section ***5.5***.

> **Note**: Some advanced capabilities involve external systems. Connecting these systems is described in section ***2.12***.

5.2. FILTERING AND SAMPLING PROPERTIES

Channel properties are used to see and set the different digital filter values and sampling rates for different signal types, where possible, for the signals coming from the electrodes. It also allows turning the acquisition on or off for certain signal types.

You can control the filtering and sample properties of the following contacts:

- For Micro, see section ***5.2.1***.
- For Macro, see section ***5.2.2***.
- For EEG, see section ***5.2.3***.
- For EMG, see section ***5.2.4***.
- For ECOG, see section 5.2.5

You can also change a channel name, as described in section ***5.2.5***.

5.2.1. Controlling Micro Filtering and Sampling Properties

This procedure describes how to control filter settings, grounding, referencing, and sampling properties, for editing channels derived from the micro contact.

To control micro filtering and sampling properties:

1. Press **CTRL+SHIFT+M** to open the system menu.
2. Select **Options → Micro Settings**.

   The **Channels Settings (Micro)** dialog box appears (***Figure 142***), displaying relevant information on all of the channels derived from the micro contact type.

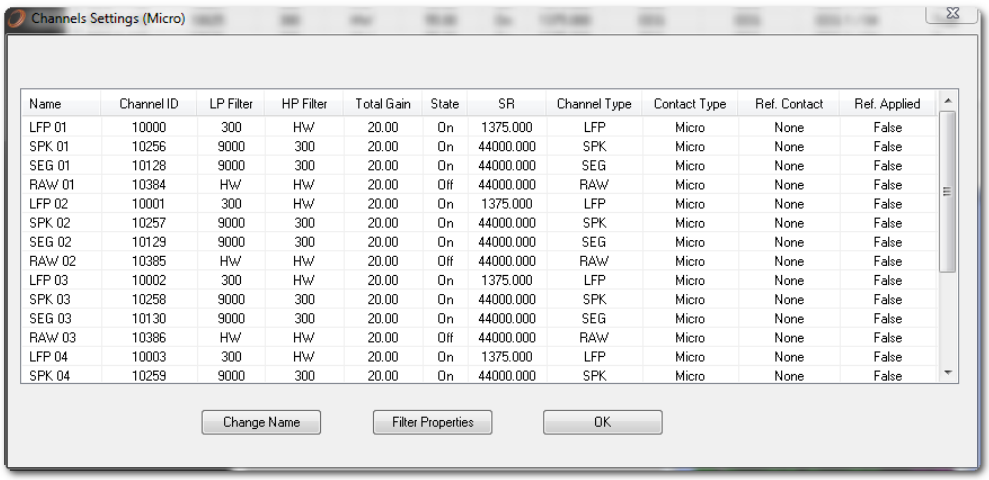


Figure 142: Channel Settings Dialog Box (Micro)

3. Select the channels whose properties you want to edit, and then click **Filter Properties**.

   The **Filter Properties (Micro)** dialog box appears (Figure 143)

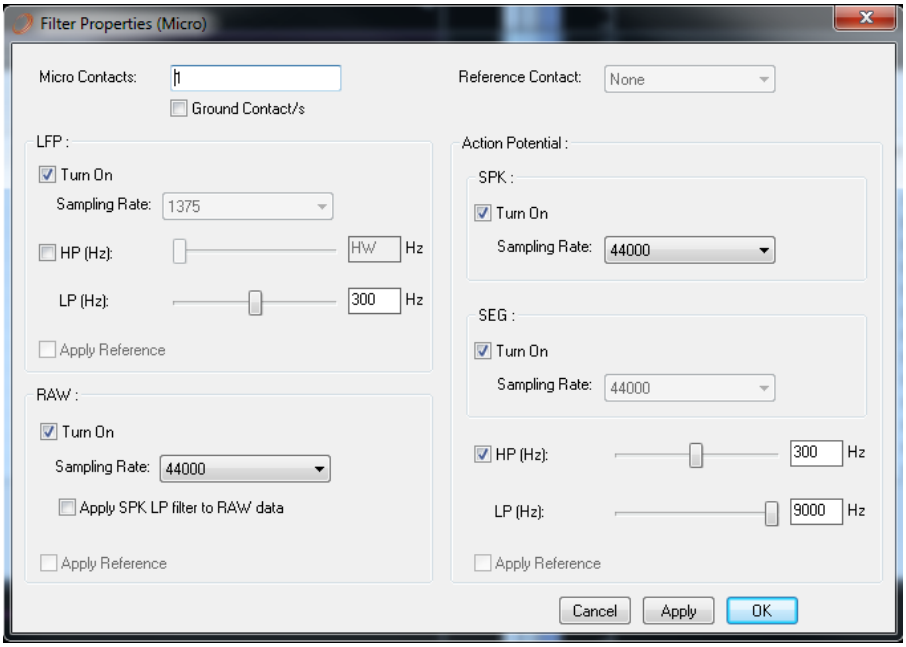


Figure 143: Filter Properties Dialog Box (Micro)

4. Do the following:

    a. In the **Micro Contacts** field, enter the contacts you want to edit; either a single contact number or a range of contacts separated by a comma. For example, selecting electrodes 1, 3, 4, 5, and 7 is done by specifying 1, 3-5,

7. It is also possible to pre-select electrodes from the **Channels Properties** window.

5. In the **Reference Contact** dropdown list, select the contact to be used as the reference in recording. See section ***4.15.1.6*** for more information on flexible referencing.
6. Select **Ground Contact/s** if you want the contacts entered in **Micro Contacts** grounded. See section ***4.15.1.3*** for more information on grounding a contact.
7. In the **LFP** area, do the following:
    i. Select **Turn On** to enable the acquisition of LFP signals.

    View the **Sampling Rate** field, which shows the LFP signal sampling rate.

    From the **HP (Hz)** slider bar, select the high pass filter for the LFP signals. If the checkbox is not selected, it will be only HW filters.

    From the **LP (Hz)** slider bar, select the low pass filter for the LFP signals.
8. In the **RAW**: This section is related to the raw continuous signals.
    i. Select **Turn On** to enable the acquisition of raw signals.

    From the **Sampling Rate** dropdown list, select the raw signal sampling rate.

    Select **Apply SPK LP filter to RAW data** if you want the system to apply the SPK LP filter to the RAW data before.
9. In the **SPK** area of the **Action Potential** area, do the following:
    i. Select **Turn On** to enable the acquisition of SPK signals.

    From the **Sampling Rate** dropdown list, select the SPK signal sampling rate.
10. In the **SEG** area of the **Action Potential** area, do the following:
    i. Select **Turn On** to enable the acquisition of segmented signals.

    View the **Sampling Rate** field, which shows the segmented signal sampling rate, which is the full sampling rate of the system.
11. From the **HP (Hz)** slider bar, select the high pass filter for the SPK and SEG signals. If the checkbox is not selected, it will be only HW filters.
12. From the **LP (Hz)** slider bar, select the low pass filter for the SPK and SEG signals.
13. Do one of the following:
    a. Click **Apply** to apply the new settings.
14. Click **OK** to apply the new settings and close the dialog box.

5.2.2. Controlling Macro Filtering and Sampling Properties

This procedure describes how to control filter settings, grounding, referencing, and sampling properties, for editing channels derived from the macro contact.

To control macro filtering and sampling properties:

1. Press **CTRL+SHIFT+M** to open the system menu..
2. Select **Options > Macro Settings**.

   The **Channels Settings (Macro)** dialog box appears (***Figure 144***), displaying relevant information on all of the channels derived from the macro contact type.

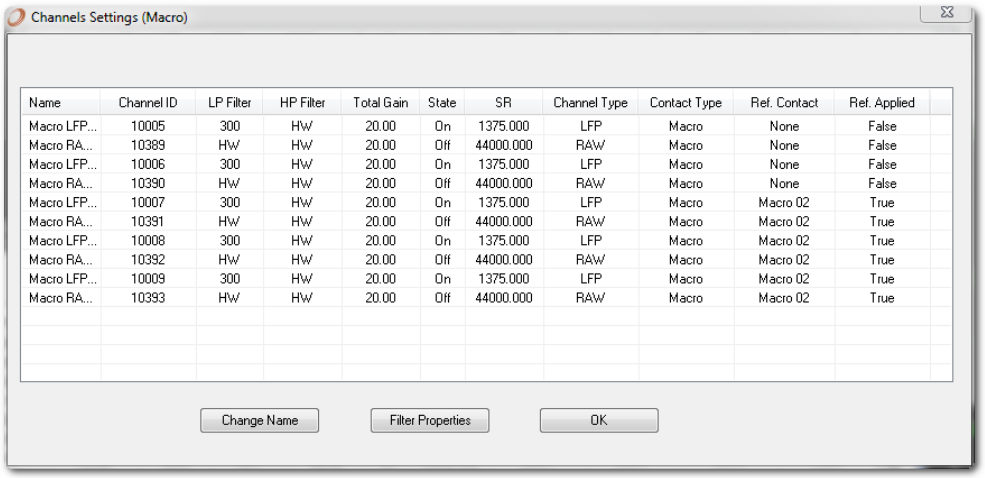


Figure 144: Channel Settings Dialog Box (Macro)

3. Select the channels whose properties you want to edit, and then click **Filter Properties**.

   The **Filter Properties (Macro)** dialog box appears (***Figure 145***).

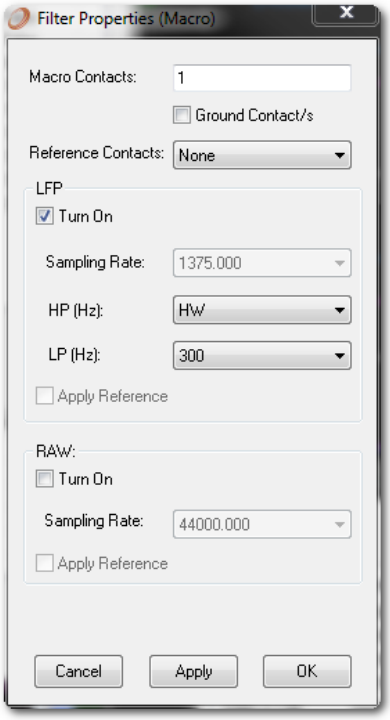


Figure 145: Filter Properties Dialog Box (Macro)

- Do the following:
  - In the **Macro Contacts** field, enter the contacts you want to edit, either a single contact number or a range of contacts separated by a comma. For example selecting electrodes 1, 3, 4, 5, and 7 is done by specifying 1, 3-5, 7. It is also possible to pre-select electrodes from the **Channels Properties** window.
  - In the **Reference Contact** dropdown list, select the contact to be used as the reference in recording. See section ***4.15.1.6*** for more information on flexible referencing.
  - Select **Ground Contact/s** if you want the contacts entered in **Macro Contacts** grounded. See section ***4.15.1.3*** for more information on grounding a contact.
  - In the **LFP** area, do the following:
    - Select **Turn On** to enable the acquisition of LFP signals.
    - View the **Sampling Rate** field, which shows the LFP signal sampling rate.
    - From the **HP (Hz)** dropdown list, select the high pass filter for the LFP signals.
    - From the **LP (Hz)** dropdown list, select the low pass filter for the LFP signals.
  - In the **RAW**: This section is related to the raw continuous signals.

- Select **Turn On** to enable the acquisition of raw signals.
- From the **Sampling Rate** dropdown list, set the raw signal sampling rate.

4. Do one of the following:
   - Click **Apply** to apply the new settings.
   - Click **OK** to apply the new settings and close the dialog box.

5.2.3. Controlling EEG Filtering and Sampling Properties

This procedure describes how to control filter settings, grounding, referencing, and sampling properties, for editing channels derived from the EEG contact.

To control EEG filtering and sampling properties:

1. Press **CTRL+SHIFT+M** to open the system menu.
2. Select **Options → EEG Settings**.

   The **Channels Settings (EEG)** dialog box appears (***Figure 146***), displaying relevant information on all of the channels derived from the micro contact type.

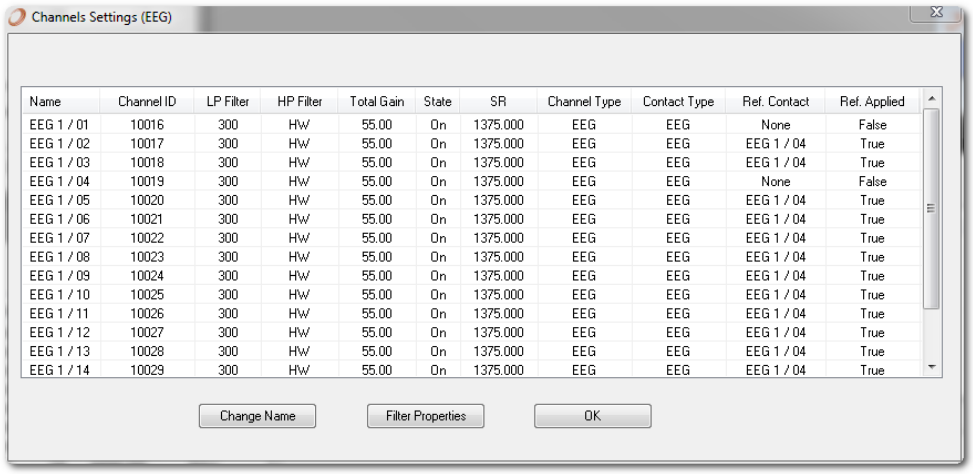


Figure 146: Channel Settings Dialog Box (EEG)

3. Select the channels whose properties you want to edit, and then click **Filter Properties**.

   The **Filter Properties (EEG)** dialog box appears (Figure 147).

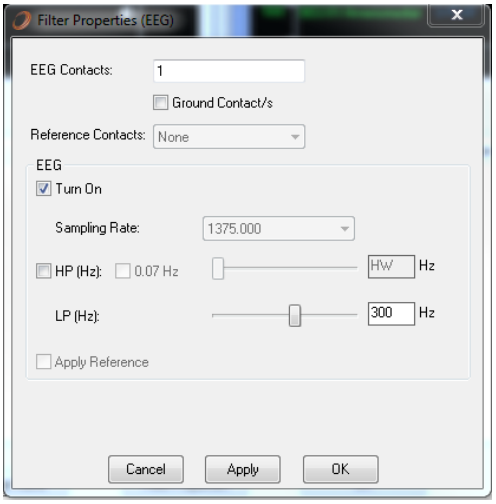


Figure 147: Filter Properties Dialog Box (EEG)

4. Do the following:
    - In the **EEG Contacts** field, enter the contacts you want to edit; either a single contact number, or a range of contacts separated by a comma. For example, selecting electrodes 1, 3, 4, 5, and 7 is done by specifying 1, 3-5, 7. It is also possible to pre-select electrodes from the **Channels Properties** window.
    - In the **Reference Contact** dropdown list, select the contact to be used as the reference in recording. See section ***4.15.1.6*** for more information on flexible referencing.
    - Select **Ground Contact/s** if you want the contacts entered in **EEG Contacts** grounded. See section ***4.15.1.3*** for more information on grounding a contact.
    - In the **EEG** area, do the following:
        - Select **Turn On** to enable the acquisition of EEG signals.
        - View the **Sampling Rate** field, which shows the EEG signal sampling rate.
        - From the **HP (Hz)** slider bar, select the high pass filter for the EEG signals. If the checkbox is not selected, it will be only HW filters.
        - From the **LP (Hz)** slider bar, select the low pass filter for the EEG signals.
5. Do one of the following:
    - Click **Apply** to apply the new settings.
    - Click **OK** to apply the new settings and close the dialog box.

5.2.4. Controlling EMG Filtering and Sampling Properties

This procedure describes how to control filter settings, grounding, referencing, and sampling properties, for editing channels derived from the EMG contact.

To control EMG filtering and sampling properties:

6. Press CTRL**+SHIFT+M** to open the system menu.
7. Select **Options → EMG Settings**.

   The **Channels Settings (EMG)** dialog box appears (***Figure 148***), displaying relevant information on all of the channels derived from the micro contact type.

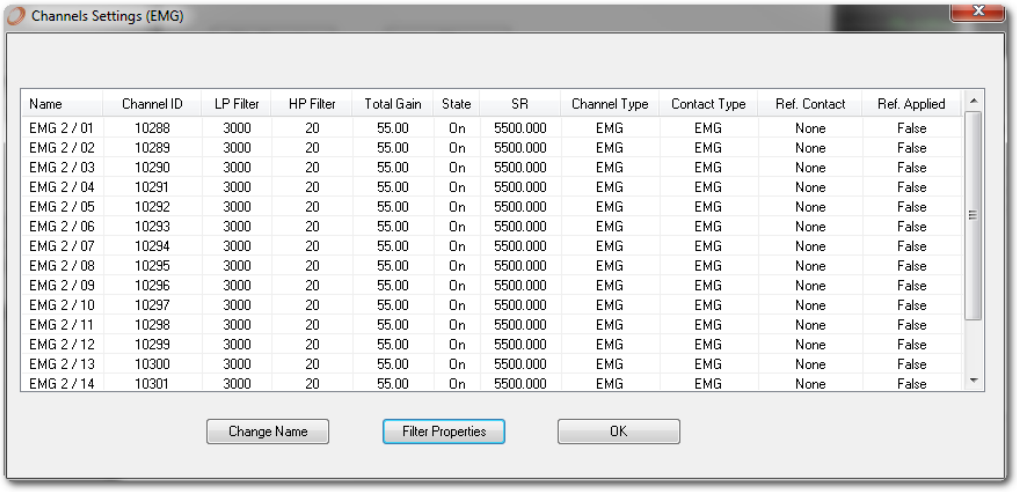


Figure 148: Channel Settings Dialog Box (EMG)

8. Select the channels whose properties you want to edit, and then click **Filter Properties**.

   The **Filter Properties (EMG)** dialog box appears (Figure 149).

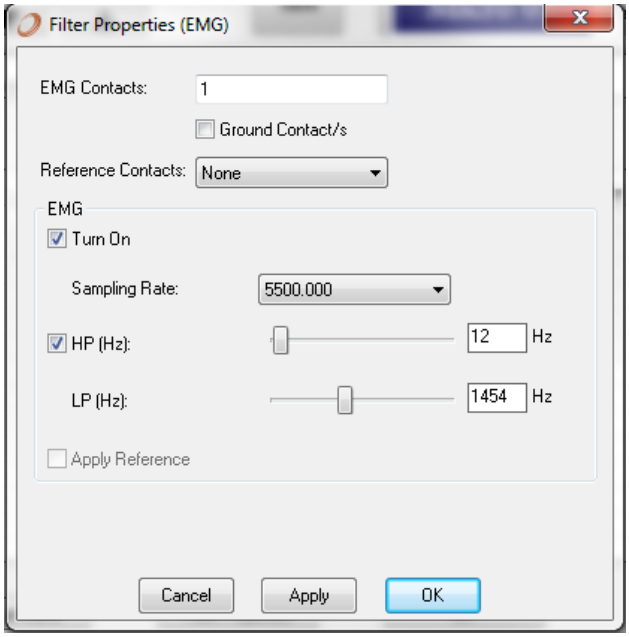


Figure 149: Filter Properties Dialog Box (EMG)

9. Do the following:
    - In the **EMG Contacts** field, enter the contacts you want to edit, either a single contact number or a range of contacts separated by a comma. For example selecting electrodes 1, 3, 4, 5, and 7 is done by specifying 1, 3-5, 7. It is also possible to pre-select electrodes from the **Channels Properties** window.
    - In the **Reference Contact** dropdown list, select the contact to be used as the reference in recording. See section ***4.15.1.6*** for more information on flexible referencing.
    - Select **Ground Contact/s** if you want the contacts entered in **EMG Contacts** grounded. See section ***4.15.1.3*** for more information on grounding a contact.
    - In the **EMG** area, do the following:
        - Select **Turn On** to enable the acquisition of EMG signals.
        - From the **Sampling Rate** dropdown list, set the EMG signal sampling rate.
        - From the **HP (Hz)** slider bar, select the high pass filter for the EMG signals. If the checkbox is not selected, it will be only HW filters.
        - From the **LP (Hz)** slider bar, select the low pass filter for the EMG signals.
10. Do one of the following:
    - Click **Apply** to apply the new settings.
    - Click **OK** to apply the new settings and close the dialog box.

5.2.5. Controlling ECoG Filtering and Sampling Properties

This procedure describes how to control filter settings, grounding, referencing, and sampling properties, for editing channels derived from the ECoG contact.

To control ECoG filtering and sampling properties:

1. Press **CTRL+SHIFT+M** to open the system menu.
2. Select **Options > ECoG Settings**.
3. Choose the configuration wanted :
   - ECoG Micro HF
   - ECoG Micro LF
   - ECoG Macro HF
   - ECoG Macro LF
4. Select the channels whose properties you want to edit, and then click **Filter Properties**.

The **Filter Properties (ECoG)** dialog box appears.

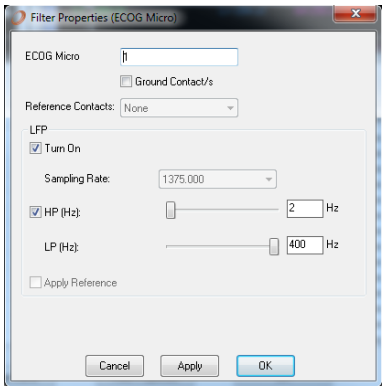


Figure 150: Filter Properties Dialog Box (ECoG)

5. Do the following:
   - In the **ECoG Contacts** field enter the contacts you want to edit, either a single contact number or a range of contacts separated by a comma. For example selecting electrodes 1, 3, 4, 5, and 7 is done by specifying 1, 3-5, 7. It is also possible to pre-select electrodes from the **Channels Properties** window.
   - In the **Reference Contact** dropdown list, select the contact to be used as the reference in recording. See section ***4.15.1.64.15.1.6*** for more information on flexible referencing.
   - Select **Ground Contact/s** if you want the contacts entered in **ECoG Contacts** grounded. See section 4.15.1.3 for more information on grounding a contact.

- In the **ECoG** area (EMG area in this example), do the following:
  - Select **Turn On** to enable the acquisition of ECoG signals.
  - From the **Sampling Rate** dropdown list, set the ECoG signal sampling rate.
  - From the **HP (Hz)** slider bar, select the high pass filter for the ECoG signals. If the box is not checked, it will be only HW filters.
  - View the **LP (Hz)** the low pass filter for the ECoG signals.

6. Do one of the following:
   - Click **Apply** to apply the new settings, while keeping the dialog box open.
   - Click **OK** to apply the new settings and close the dialog box.

5.2.6. Changing Channel Names

This procedure describes how to change the name of a channel, which is comprised, by default, of the channel and the number.

To change the name of a channel:

11. Press **CTRL+SHIFT+M** to open the system menu.
12. Select **Options**, and then the contact containing the channel whose name you want to change.

    The settings dialog box of the contact appears (see ***Figure 142, page 188*** for example).

13. Click **Change Name**.

    The **Channels Properties** dialog box appears (Figure 151).

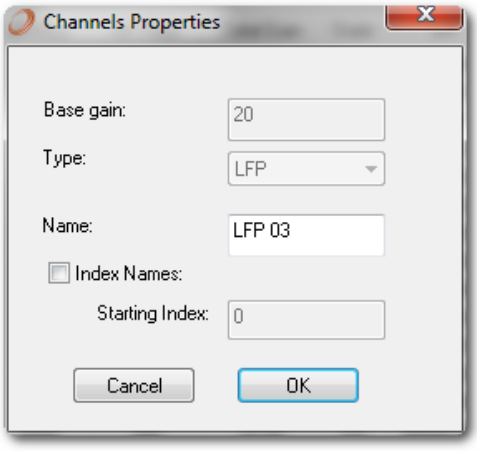


Figure 151: Channels Properties Dialog Box

14. In the **Name** field, enter the new name of the channel.
15. Select the **Index Name** option if you want subsequent channels named incrementally.
16. Click **OK**.

    Your changes are saved.

5.3. LOGGING OPTIONS

Logging options are used to define what is saved to data files and how it is saved.

Neuro Omega saves files in the *.mpx format, which is Alpha Omega's proprietary binary format. For each recording session, which starts when the Neuro Omega software opens, an *.lsx file is also saved, which is a text files that lists all the files saved in the recording session.

MapFile Convertor, which is provided with the system, allows you to convert the log file to a Matlab file or a text file, among others. See the MapFile Convertor instruction manual for details.

5.3.1. Defining Logging Options

This procedure describes how to define logging options for a channel.

To define logging options for a channel:

1. Press **CTRL+SHIFT+M** to open the system menu.
2. Select **Options → Logging Options**.

   The **Logging Options** dialog box appears (***Figure 152***).

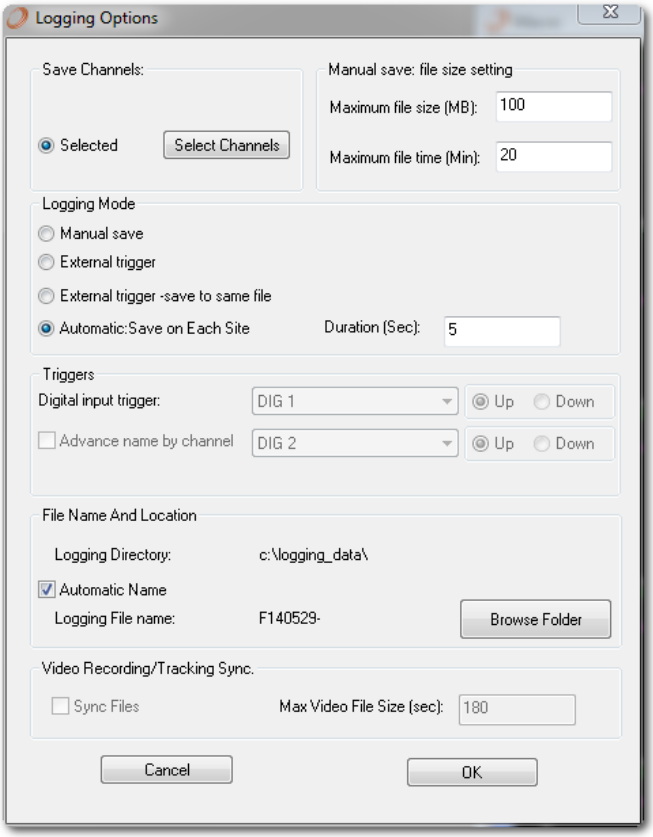


Figure 152: Logging Options Dialog Box

3. In the **Save Channels** area, select the channels you want to save, by doing the following:
4. Click **Select Channels**.

   The **Saving Channels** dialog box appears (***Figure 153***).

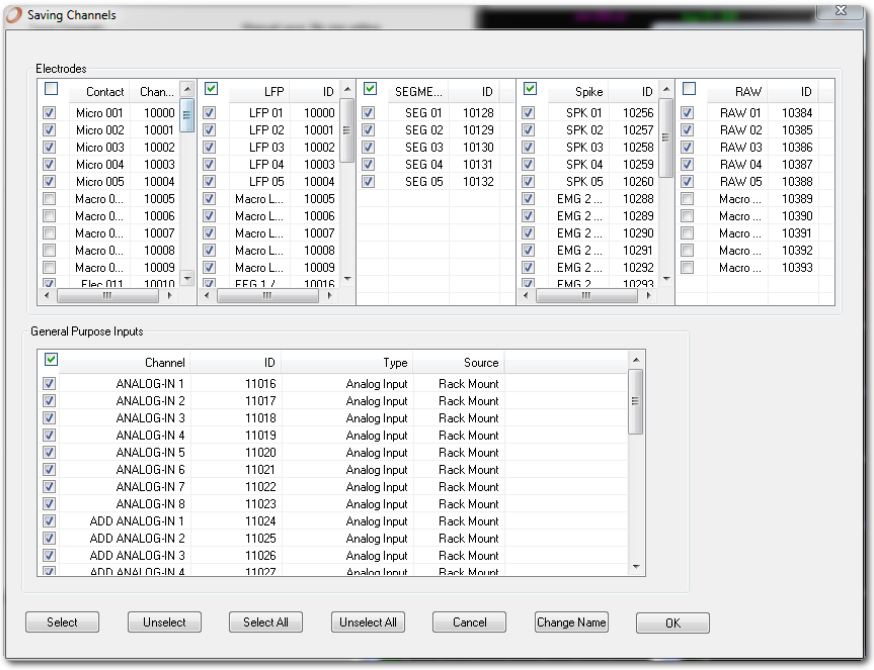


Figure 153: Saving Channels Dialog Box

5. In the **Electrodes** area, do the following:

   - In the **Contact** list, select the analog contacts that you want to save.

     The respective channels are selected in the **LFP**, **SEG**, **Spike**, and **Raw** lists.

   - In the **LFP** list, select the LFP and EEG channels that you want to save.
   - In the **SEG** list, select the SEG channels that you want to save.
   - In the **Spike** list, select the SPK (micro), and EMG channels that you want to save.
   - In the **Raw** list, select the micro and macro RAW channels that you want to save.

> **Note**: Before selecting the RAW channels to save, verify that the acquisition of raw signals is enabled. This is done when defining the micro filtering and sampling settings, as described in section ***5.2.1***.

6. In the **General Purpose Inputs** area, select the input channels that you want to save, as follows:

   - ANALOG-IN
   - ADD ANALOG-IN
   - PORT
   - UD InPort

- DIG-IN
- UD
- Stim Marker
- DIG-OUT

7. Click **OK**.

   The new settings are applied, and the **Saving Channels** dialog box closes.

8. In the **Logging Options** dialog box, in the **Manual Save** area, set the file size limit, as follows:

   - **Maximum file size** (MB): When the data file size reaches the value specified here, the file is closed and a new file is opened automatically. The new file will have the same name as the one that was closed, but with an incremental running index.
   - **Maximum file time** (min): When the lapsed time since opening the current file exceeds the value defined here, the program closes the current file and begins saving data in a new file as above. If the value in this field is 0, the program does not check the saving time.

   Note: The size limits indicated apply only when manual or automatic logging is in progress. When logging is triggered by an external trigger, these limits do not apply.

9. Select the logging mode, as follows:

   - **Manual Save**: When the user presses **Save** in the application banner, the button changes color to red and logging data begins immediately. Logging stops when the user presses the **Save** again.
   - **External Trigger**: When the user presses **Save**, the program then waits for a trigger on the specified digital input. When **Save** is pressed, it changes to the **Save Wait** mode, and the program begins logging after receiving the value 1 on the selected digital input channel, and stops saving after receiving the value 0.

     If selected, the **Triggers** area activates (***Figure 154***).

Figure 154: Triggers Area Activated

The logging by trigger behavior is illustrated in ***Figure 155***.

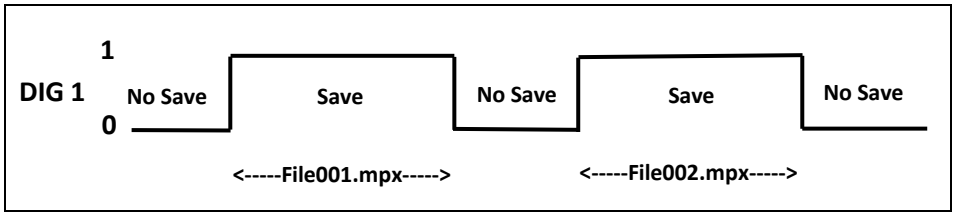


Figure 155: Logging by External Trigger Behavior

- **External Trigger – Save to Same File**: Similar to the **External Trigger** option, but data is saved into the same file. The figure below lays out the logging behavior after **Save** is pressed.

  If selected, the **Triggers** area activates (***Figure 156***).

Figure 156: Triggers Area Activated – Save to Same File

The logging by trigger behavior is illustrated in ***Figure 157***.

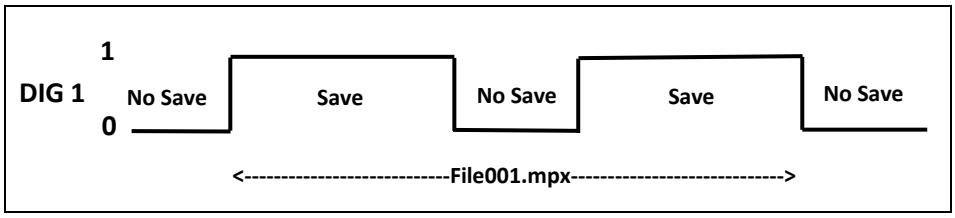


Figure 157: Logging by External Trigger Behavior – Save to Same File

10. If you selected any of the **Triggers** options in the **Logging Mode** area, complete the **Triggers** area, as described in section ***5.3.2***.
11. To change the logging filename and/or saving folder, do one of the following:

    - Select the **Automatic Name** option, click **Browse Folder**, and then select the folder in which to save the files.

      The naming convention is as follows:

      <brain hemisphere><trajectory number><trajectory depth><incremental index starting with 001>

      For example:

      RT1D1.500F0001

> **Note:** The default file location is under the patient reference in the surgeries data folder on C:\Surgeries_data.

- Clear the **Automatic Name** option, click **Browse**, and then select the file named as you want the log files named.

  The naming convention is as follows:

  <selected file><incremental index starting with 001>

> **Note:** If one or more files exist in the folder using the same name, the program automatically looks for the highest existing index and starts logging with the following index.

5.3.2. Saving Files by Digital Triggers

This procedure describes how to define the triggers for the commencement of data logging, which is a part of ***5.3.1***, and relevant when one of the trigger options is selected (step ***10***).

To control the commencement of data logging by digital triggers:

1. Connect the digital input trigger on the Input/Output panel, as described in section ***2.12***.
2. In the **Digital Input Trigger** dropdown list, select the start saving/stop saving trigger.
3. If you selected **Triggers**, then select the **Advance Name by Channel** option if you want the current file to close and a new file open every time the specified digital channel goes to active high if **Up** was selected or low if **Down** was selected.

> **Note:** The digital channel used in **Advance Channel by Name** must be different than the digital channel specified in the **Digital Input Trigger** field, and it has an effect only while logging is on.

5.4. CHANNEL ROUTING OF ANALOG OUTPUTS

The Neuro Omega system comes standard with eight analog output BNC connectors on the ADIO panel (see ***Figure 3, page 27***). It is possible to route any of the Drive Headstage or Headbox signals to any of the analog outputs. Any electrode signal sent to the analog output is amplified to a total of 4000 times, which includes the Drive Headstage gain.

You can route channels in the following ways:

- By pre-selecting the channel, as described in section ***5.4.1***
- By clicking on the channel in the Workspace, as described in section ***5.4.2***
- By defining the channel beforehand, as described in section 5.5

5.4.1. Routing a Pre-Selected Channel

This procedure describes how to select and route an analog channel for output to an external component.

To route a pre-selected analog channel for output:

1. Connect the external component receiving the output as described in section ***2.12***.
2. Connect the external component to an output port on the Input/Output panel.
3. From the toolbar, click the **Analog Output** button .

The **Analog Outputs** dialog box appears (***Figure 158***).

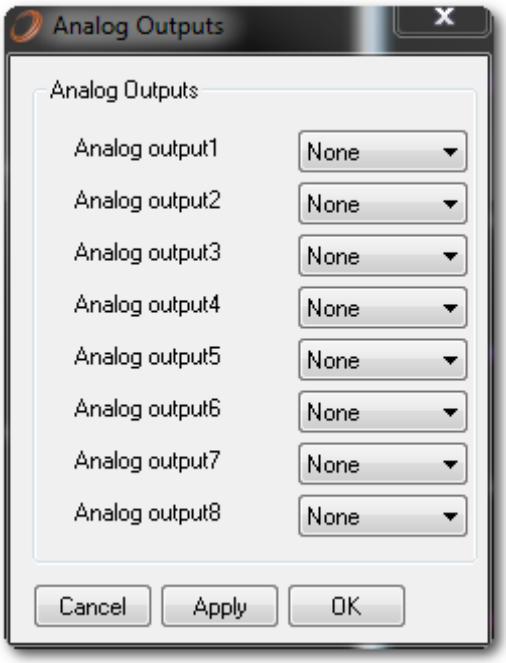


Figure 158: Analog Outputs Dialog Box

4. From the dropdown list of the output port to which you connected the external component, select the channel to route.
5. Do one of the following:

- Click **Apply** to apply the new settings.
- Click **OK** to apply the new settings and close the dialog box.

Upon receiving a signal, the selected channel outputs to the external component.

5.4.2. Routing the Channel in Focus

This procedure describes how to have the system route the analog channel currently selected in the Workspace to an external component.

To have the system route the currently selected analog channel for output:

1. Connect the external component receiving the output as described in section ***2.12***.
2. Connect the external component to an output port on the Input/Output panel.
3. From the toolbar, click the **Analog Output** button  .

The **Analog Outputs** dialog box appears (see ***Figure 158***).

4. From the dropdown list of the output port to which you connected the external component, select **Selected**.
5. Do one of the following:

- Click **Apply** to apply the new settings.
- Click **OK** to apply the new settings and close the dialog box.

6. In the Workspace, select a channel.

Upon receiving a signal, the selected channel outputs to the external component.

5.5. EDITING A CHANNEL CONTACT

This procedure describes how to edit a contact channel.

To edit a contact channel, do any of the following:

- Add or edit the window containing the contacts of any of the modules, as described in section 4.3.
- Edit filtering and sampling for any of the channels, as described in section ***05.2***.
- Edit logging options for any of the channels, as described in section ***5.3***.
- Edit impedance settings, as described in section ***5.6***.

5.6. DEFINING IMPEDANCE SETTINGS

This procedure describes how to define impedance settings, which are used to define the sine wave used to test the impedance of the recording electrodes.

To define impedance settings:

7. Press **CTRL+SHIFT+M** to open the system menu.
8. Select **Options > Impedance Settings**.

The **Impedance Settings** dialog box appears (***Figure 159***).

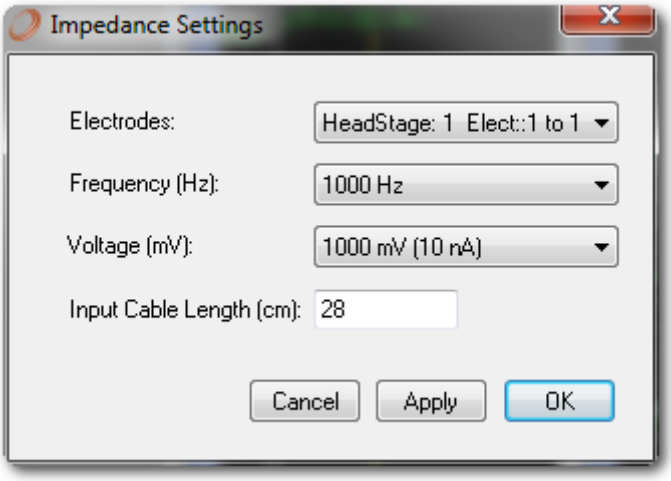


Figure 159: Impedance Settings Dialog Box

9. Do the following:

- In the **Electrodes** dropdown list, do one of the following:
  - Select which set of electrodes to set. Electrode sets are in modules of 16 channels.

> **Note: Headstage: 1** refers to the Drive Headstage, while **Headstage: 2** refers to Headbox module 1.

  - Select **ALL Electrodes** for the settings to apply to the Headstage and all of the Headboxes.
- In the **Frequency** dropdown list, select the sine wave frequency with which the impedance will be checked.
- In the **Voltage** dropdown list, select the voltage of the sine wave with which the impedance will be checked.
- In the **Input Cable Length**, define the length of the wire used before the first amplifier.

10. Do one of the following:

- Click **Apply** to apply the new settings.
- Click **OK** to apply the new settings and close the dialog box.

CHAPTER 6. GENERAL MAINTENANCE

To ensure proper operation of the Neuro Omega system, maintenance procedures must be performed at determined intervals by qualified Alpha Omega Ltd. service technicians.

6.1. GENERAL SAFETY INFORMATION

- Only qualified Alpha Omega service personnel can perform maintenance.
- Do not use alcohol or ammonia-based liquids for Neuro Omega system cleaning. If cleaning is necessary, it can be performed by slightly damp cloth. Disconnect the Neuro Omega system from the main power supply before cleaning.
- The Neuro Omega system should not be exposed to wet or very humid environment, see chapter 7 for technical specification.
- Consult Alpha Omega service technician about any operational problem.

6.2. POSITIONING/ VENTILATION

- Keep the Neuro Omega system away from any magnetic objects.
- Avoid exposing the Neuro Omega system to direct sunlight or other heat source.
- To prevent overheating, make sure that the ventilation openings of the Neuro Omega system monitor and main unit are not covered.
- Keep dust away from the system.

6.3. STORAGE

When storing the Neuro Omega system for 10 days or longer, disconnect the system from the mains power supply. Also see chapter 7 for technical specification.

6.4. PREVENTIVE MAINTENANCE PROCEDURE

- All sterilizable accessories must undergo a preventive maintenance procedure that will be carried out by Alpha Omega every 6 months.
- In the Neuro Omega system, a message will appear on the screen indicating that preventive maintenance is required.
- It is recommended to schedule preventive maintenance after the message appears for the first time.

CHAPTER 7. TECHNICAL SPECIFICATIONS

Specifications for the Neuro Omega system appear in the following sections:

- *General*
- *Sorting*

Drive /MER HeadstageHeadbox Modules for ECoG/EEG/EMG

- *General Purpose Analog Inputs*
- *General Purpose Analog Outputs*
- *Audio Outputs*
- *General Purpose Single Bit Digital Inputs*
- *General Purpose Digital Input 16-bit Ports*
- *General Purpose Digital Outputs*
- *Analog Digital Inputs and Outputs Pinout*

7.1. GENERAL

Parameter	Value
Operating System	Windows 7 64bit
Computer	Touch screen PC
Power	100V-240V, 50Hz-60Hz
Trolley Connectors	4 USB ports
Main Unit system connectors	■ Ethernet ports (1 GB) ■ 1 Remote port (USB) ■ 2 Audio out (3.5mm stereo)
Communication	Ethernet protocol
Peripherals	Microsoft Wireless keyboard and mouse
Number of Channels	■ Up to 10 MER channels (5 Micro and 5 Macro) Up to 112 EEG/EMG channels.

7.2. SORTING

Parameter	Value
Segmentation	■ Method: Level Threshold ■ Segment length: 96 samples at 44kHz ■ Crossing Point: 18th sample
Online Sorting	■ Method: 8 point template match ■ Templates per channel: 4 ■ Segment length: 2.15mSec (96 samples, 44kHz, template points are 5 samples apart starting in sample 18)

7.3. DRIVE HEADSTAGE/MER HEADSTAGE

Parameter	Value
Number of Electrode Physiological Inputs	10 Electrode channels with standard AO microelectrodes: ■ 5 Micro channels ■ 5 Macro channels
First Amplifier Input Impedance	100 GΩ || 2pF
Hardware Filter	0.075Hz – 10.0KHz
Gain	20
Dynamic Input range	±62.5mV
Input Type	Differential to shared reference/ground
A/D Converter Input Range	± 1.25Volts
A/D Resolution	16 bits
Input Bit Resolution	1.9uV
Sampling Rate	Micro Channel Contact: ■ Raw: 44kHz (sample per Sec) ■ Spike: 44kHz ■ LFP: 1.375kHz (fixed) Macro Channel Contact: ■ LFP: 1.375kHz (fixed)
Noise	<20µV peak-to-peak @ 10kOhm load

Parameter	Value
Software Filters Defaults	Micro Channel Contact: SPK : ■ High Pass Range: 0 – 600Hz ■ Low Pass Range: 5000 – 9000Hz LFP: ■ High Pass Range: 0 – 45Hz ■ Low Pass Range: 200 – 400Hz Macro Channel Contact: LFP: ■ High Pass Range: 2 – 45Hz ■ Low Pass Range: 200 – 400Hz
Hardware Filter	Micro Channel Contact: ■ High Pass Range: 0.07 Hz ■ Low Pass Range: 10,000Hz Macro Channel Contact: ■ High Pass Range: 0.07 Hz Low Pass Range: 10,000Hz
Stimulation Sources	2 Options: ■ 1 source for basic stimulation ■ 10 sources, 1 per channel for advanced stimulation

Parameter	Value
Stimulation Pulse	Square Pulses: Micro Channels: ■ Phase Width : 0.01ms - 0.5ms ■ Biphasic Amplitude: 0 -> ±0.1mA (up to ±50V) ■ Step size Resolution 0.001mA Frequency - up to 300Hz *Notes:* *Amplitude tolerance within 15%.* *Pulses below 40uA, the Amplitude may be up to 40% lower than the requested value.* ■ Macro Channels: ■ Phase Width : 0.01ms - 0.5ms ■ Biphasic Amplitude: 0 -> ±7 mA (up to ±50V) ■ Step size Resolution 0.001mA Frequency - up to 300Hz *Notes:* *Amplitude tolerance within 5%.* *Pulses below 400uA, the Amplitude may be up to 15% lower than the requested value.*
Stimulation Artifact	The stimulation artifact is defined as the time from the end of the stimulation pulse until the specific channel base line becomes different from the base line before the stimulation by less than +-10%. ■ Micro Stimulation: ■ Stimulation artifact on other Micro Recoding channels is up to 7mSec. ■ Stimulation artifact on other Macro Recoding channels is up to 15mSec. Macro Stimulation: ■ Stimulation artifact on other Micro Recoding channels is up to 15mSec. Stimulation artifact on other Macro Recoding channels is up to 50mSec.

Parameter	Value
Stimulation to Recording Switching Artifact	The switching artifact is defined as the time from the moment when a channel is switched from recording to stimulation or back until the specific channel base line becomes different from the base line before the switch by less than +-10% Micro Stimulation: ■ Switching artifact on other Micro Recoding channels is up to 7mSec. ■ Switching artifact on other Macro Recoding channels is up to 15mSec. ■ Switching artifact on the same channel is up to 12mSec. Macro Stimulation: ■ Stimulation artifact on other Micro Recoding channels is up to 15mSec. ■ Stimulation artifact on other Macro Recoding channels is up to 50mSec. ■ Switching artifact on the same channel is up to 13Sec. *Note:* *With Offline processing capability the Signals can be extracted out on the Same channels 1-3mSec after switching back to recording, and 200-250uSec on other recording channels*
Impedance Check	1000Hz (Micro and Macro contacts)
Headstage Size	110mm X 40mm X 50mm
Headstage Weight	220 Grams
Range (Drive Headstage)	40mm
Resolution (Drive Headstage)	10um

Operating Environment	Value
Maximum operating temperature:	41°F to 104°F, 5°C to 40°C
Humidity:	15 to 80 % RH non-condensing
Recommended operating conditions:	59°F to 95°F or 15°C to 35°C
Humidity	20 to 80%RH non-condensing
Storage temperature	-40°F to 140°F, -40°C to 60°C
Input power	±5VDC, ±12VDC

Class	II
Type	BF

7.4. HEADBOX MODULES FOR ECOG/EEG/EMG

Parameter	Value
Number of Electrode Physiological Inputs	16 per module
Input Connector	Touch proof DIN connector
First Amplifier Input Impedance	100 GΩ || 2pF
Hardware Filter	0.075Hz - 3.5kHz
Gain	55
Dynamic Input range	±23mV
Input Type	Differential (EMG) or Referential (EEG/ECoG)
A/D Converter Input Range	± 1.25Volts
A/D Resolution	16 bits
Input Bit Resolution	0.7uV
Sampling Rate at HS	44kHz Samples per Sec
Sampling Rate	■ EMG: 44ks/Sec ■ ECoG/EEG: 1.375ks/Sec (fixed) *Notes:* *Systems with more than 2 EMG/EEG Modules, the sampling rate will be 22ks/sec* ■
Software Filters	■ EMG: ■ HPF: 1-600 Hz ■ LPF: HW 3500 (fixed) ■ ECoG/EEG: ■ HPF: 0.07,2-45 Hz ■ LPF: 200-400 Hz
Noise	<20µV peak-to-peak @ 1kOhm
Impedance Check	30Hz

7.5. HEADBOX MODULES STIMULATION FOR EMG

Operating Environment	Value
Stimulation Pulse	Square Pulses: ■ Phase Width : 0.01ms - 0.5ms ■ Biphasic : 0 -> ±12 mA (up to ±50V) Optional module support ±12->±15 mA, Phase Width : 0.01ms - 0.2ms ■ Step size Resolution 0.001mA Frequency – up to 300Hz *Notes:* *Amplitude tolerance within 10%.* *Pulses width above 0.3mSec, the pulse may get overshoot of 10% and after 50uSec the amplitude will be within the normal tolerance.*
`aqz\	2 Options: ■ 1 source for basic stimulation 16 sources, 1 per channel for advanced stimulation
Stimulation Artifact	The stimulation artifact is defined as the time from the end of the stimulation pulse until the specific channel base line becomes different from the base line before the stimulation by less than +-10%. EMG Stimulation: ■ Stimulation artifact on other EMG Recoding channels is up to 25mSec.
Stimulation to Recording Switching Artifact	The switching artifact is defined as the time from the moment when a channel is switched from recording to stimulation or back until the specific channel base line becomes different from the base line before the switch by less than +-10% EMG Stimulation: ■ Switching artifact on other EMG Recoding channels is up to 3Sec. ■ Switching artifact on the same channel is up to 3Sec. *Note:* *With Offline processing capability the Signals can be extracted out on the Same channels 1-3mSec after switching back to recording, and 200-250uSec on other recording channels* *If HW filter is used, the switching artifact on the EMG Stimulation channel is up to 13Sec.*

Operating Environment	Value
Maximum operating temperature:	41°F to 104°F, 5°C to 40°C
Humidity:	15 to 80 % RH non-condensing
Recommended operating conditions:	59°F to 95°F or 15°C to 35°C
Humidity	20 to 80%RH non-condensing
Storage temperature	-40°F to 140°F, -40°C to 60°C
Input power	±5VDC
Class	I
Type	BF

7.6. General Purpose Analog Inputs

Parameter	Value
Number of Inputs	16 Channels
Input Connector	8 BNC and 8 D-type Male connector
Input Range	±5V
Gain	0.25
Hardware High Pass Filter	None
Hardware Low Pass Filter	1KHz Passive (0.7@1KHz, 0.8@500Hz)
A/D Converter Input Range	± 1.25Volts
A/D Resolution	12 bits
Input Bit Resolution	2.5mV
Sampling Rate	2.75kHz

7.7. General Purpose Analog Outputs

Parameter	Value
Number of Outputs	8 Channels
Output connector	8 BNC

Parameter	Value
Purpose	Output the signal of any of the channels
Bandwidth	DC-48kHz (Drive Headstage bandwidth is 0.075-10kHz)
Gain	Total gain - 4000
D/A Converter Output Range	± 5Volts
D/A Resolution	16 bits
Sampling Rate	44kHz

7.8. AUDIO OUTPUTS

Parameter	Value
Number of Outputs	2 Stereo
Output Connector	3.5mm Audio Jacks
Purpose	Output the signal of any of the high frequency channels
Bandwidth	DC-3.5kHz (Drive Headstage bandwidth is 0.075-10kHz)
Gain	Total gain 2000
D/A Converter Output Range	±2.5 Volts
D/A Resolution	16 bits
Sampling Rate	44kHz

7.9. GENERAL PURPOSE SINGLE BIT DIGITAL INPUTS

Parameter	Value
Number of Inputs	16 Channels
Input Connectors	4 BNC, 12 D-type Female Port
Input Type	Standard TTL
Logic Low	0V – 1.8V
Logic High	2V – 5V
Sampling Rate	44kHz
Maximum input frequency	1kHz

7.10. General Purpose Digital Input 16-bit Ports

Parameter	Value
Number of Inputs	32 Channels
Input Connectors	2x 16 D-type Female Port
Input Type	Standard TTL
Sampling Rate	44kHz
Logic Low	0V – 1.2V
Logic High	2V – 5V
Maximum input frequency	1kHz

7.11. General Purpose Digital Outputs

Parameter	Value
Number of Outputs	16 Channels
Output Connector	8 BNC, 8 D-type Female Port
Sampling Rate	44kHz
Control	Script only

7.12. Analog Digital Inputs and Outputs Pinout

The Neuro Omega has an optional Analog/Digital Input/Output package. All inputs and outputs are available on the Input/Output panel of the unit (see ***Figure 3, page 27***). Pinout details for the D-Type connectors are described in the following sections:

- ***ADD DIG-OUT Pinout***
- ***ADD ANALOG-IN Pinout***
- ***ADD DIG-IN Pinout***
- ***PORT-1 16 BIT, PORT-2 16 BIT Pinout***

The BNC connectors are numbered and logged as marked on the panel in ***Figure 160***.

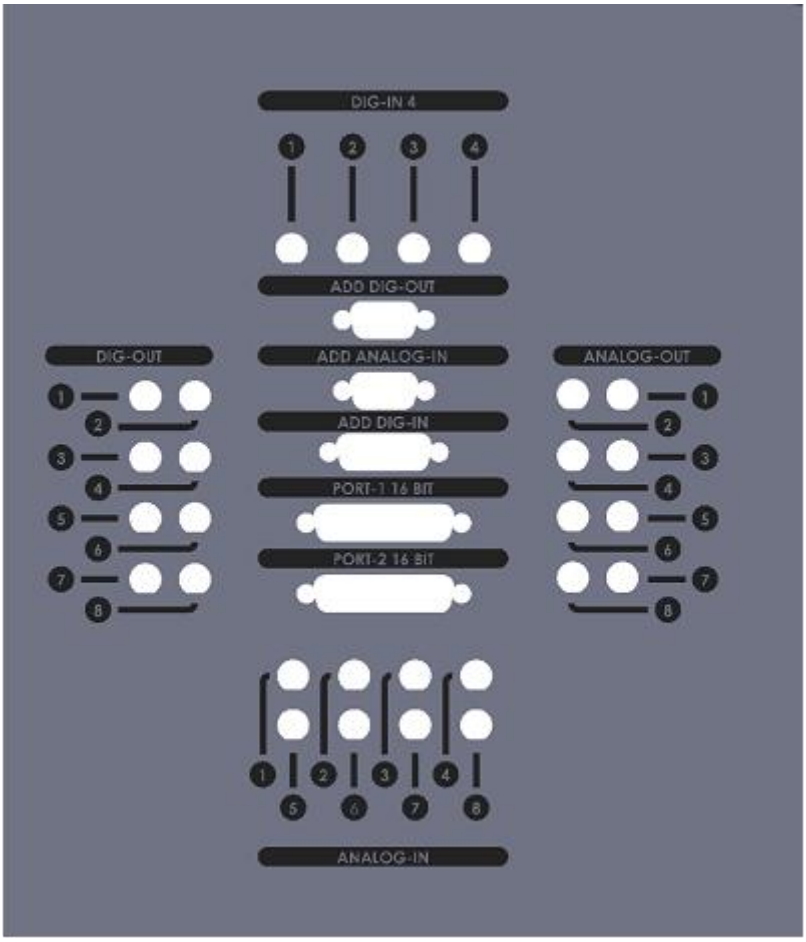
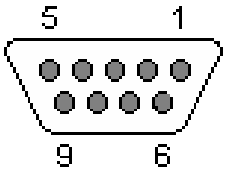


Figure 160: Input/Output Panel Diagram

7.12.1. ADD DIG-OUT Pinout

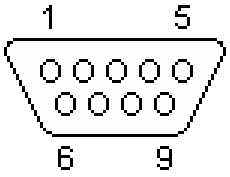
The connector type for the digital outputs is the D-Type 9-Pin Female. Pin numbers shown in the figure are the actual numbers imprinted on the connector.



Pin Number	Use	Pin Number	Use
1	D.Out 1	6	D.Out 6
2	D.Out 2	7	D.Out 7
3	D.Out 3	8	D.Out 8
4	D.Out 4	9	GND
5	D.Out 5		

7.12.2. ADD ANALOG-IN Pinout

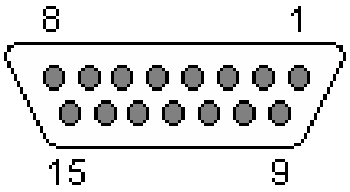
The connector type for the analog inputs is the D-Type 9-Pin Male. Pin numbers shown in the figure are the actual numbers imprinted on the connector.



Pin Number	Use	Pin Number	Use
1	A.In 9	6	A.In 16
2	A.In 10	7	A.In 15
3	A.In 11	8	A.In 14
4	A.In 12	9	A.In 13
5	GND		

7.12.3. ADD DIG-IN Pinout

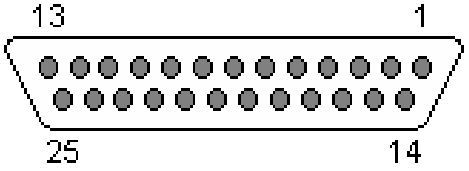
The connector type for the single bit digital inputs is the D-Type 15-Pin Female. Pin numbers shown in the figure are the actual numbers imprinted on the connector.



Pin Number	Use	Pin Number	Use
1	D.In 5	9	D.In 13
2	D.In 6	10	D.In 14
3	D.In 7	11	D.In 15
4	D.In 8	12	D.In 16
5	D.In 9	13	GND
6	D.In 10	14	GND
7	D.In 11	15	GND
8	D.In 12		

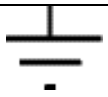
7.12.4. PORT-1 16 BIT, PORT-2 16 BIT Pinout

The connector type for the 16 bit digital inputs is the D-Type 25-Pin Female. Pin numbers shown in the figure are the actual numbers imprinted on the connector.



Pin Number	Use	Pin Number	Use
1	D.In 1	14	D.In 2
2	D.In 3	15	D.In 4
3	D.In 5	16	D.In 6
4	D.In 7	17	D.In 8
5	D.In 9	18	D.In 10
6	D.In 11	19	D.In 12
7	D.In 13	20	D.In 14
8	D.In 15	21	D.In 16
9	Strobe	22	GND
10	GND	23	GND
11	Ready	24	GND
12	GND	25	GND
13	GND		

7.13. SYSTEM SYMBOLS

No.	Symbol	Description
1		Earth (ground)
2		Type BF applied part
3		Type b applied part
4		Attention, consult accompanying documents
5	CE 0297	Conformité Européenne (European Conformity) This symbol means that the device fully complies with European Council Directive 93/42/EEC. The Numbers 0297 refers to identification of the notified body.
6		Expiration Date
7		Do Not Reuse
8	USA Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
9	LOT	Lot Number
10	REF	Catalog Number
11	NON STERILE	Non-sterile
12	STERILE R	Sterilized using irradiation
13		Do not resterilize

No.	Symbol	Description
14		Do not use if package is damaged
15		WEEE- Waste of electrical and electronic equipment
16		MANUFACTURER
17	 MM/YYYY	DATE OF MANUFACTURE (Month / Year)
18		CONSULT INSTRUCTIONS FOR USE
19	 eIFU URL is in the enclosed IFU	CONSULT INSTRUCTIONS FOR USE FOR ADDITIONAL LANGUAGES – URL link