TABLE OF CONTENTS

PROTEKTOR32 – INTRAOPERATIVE NEUROPHYSIOLOGICAL MONITORING ............ 6

Indications for Use ........................................................................................................... 6

Protocols ......................................................................................................................... 6

SAFETY INFORMATION ...................................................................................................... 7

Critical Warnings and Cautions ...................................................................................... 7

General Warnings ........................................................................................................... 7

General Cautions ............................................................................................................. 11

Audio/Visual Stimulation Warnings ............................................................................... 11

Protektor32 with the Electro-Surgical Units (ESU) – Guidelines ................................. 12

Output Waveforms ......................................................................................................... 12

Electrostatic Discharge (ESD) handling procedures and warnings ......................... 13

PROTEKTOR32 SAFETY AND STANDARDS CONFORMITY ......................................... 14

Essential Performance .................................................................................................... 14

Standards Compliance and Normative References Information ............................ 14

Declaration of Compliance for IEC 60601-1-2 .............................................................. 17

Table 4 - Immunity Test Levels - Enclosure Port ......................................................... 17

Table 5 – Immunity Test Levels – Input A.C. Power Port ............................................ 17

Table 7 – Patient Coupling Port ...................................................................................... 18

Table 8 – Immunity Test Levels - Signal Input / Output Parts Port ......................... 18

Table 9 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment .... 19

Declaration of Compliance for FCC ............................................................................... 20

REGULATORY SYMBOLS ................................................................................................ 21

PROTEKTOR32 SYSTEM CONFIGURATION ................................................................... 23

Protektor Headbox ......................................................................................................... 24

Protektor32 Headbox Features ...................................................................................... 24

USING THE TCMEP STIMULATOR WITH PROTEKTOR32 ....................................... 28

Safety Information ......................................................................................................... 28

Contra-Indications and Exclusions ............................................................................. 28

Protocol for Elicitation of TcMEPs .............................................................................. 28

TcMEP Warnings and Cautions .................................................................................... 29

Stimulation limitations of the TcMEP modality ......................................................... 30

Pulse Train Safety Limits .............................................................................................. 30

Current Density ............................................................................................................ 31
Instructions for Use

XLTEK Protektor32

RECOMMENDED USER PERFORMED MAINTENANCE ................................................................. 33
Routine System Maintenance ................................................................................................. 33
General User Performed Maintenance .................................................................................. 33
Maintenance Warnings ......................................................................................................... 33
Environmental Conditions ................................................................................................. 34
Waste Management ............................................................................................................. 34
PROTEKTOR32 SOFTWARE / EPWORKS ......................................................................... 35
Setting Up Tests .................................................................................................................. 35
Create a Basic Test .............................................................................................................. 35
DATA ACQUISITION .............................................................................................................. 50
Types of Recordings ........................................................................................................... 50
Live Data Recording Window Overview ............................................................................ 50
Acquisition Toolbar ............................................................................................................ 51
Stimulators Window ........................................................................................................... 51
Groups Window .................................................................................................................. 51
Waveform Window ............................................................................................................ 51
Waveform Display Mode – Menu Options ......................................................................... 53
Using Markers .................................................................................................................... 55
Measuring Waveforms with Cursors ................................................................................ 56
Impedance Check ............................................................................................................... 57
EEG / SPECTRAL WINDOWS ............................................................................................... 59
EEG Live Window ............................................................................................................... 59
EEG Review Window .......................................................................................................... 59
Reviewing EEG Data .......................................................................................................... 59
EEG Review Window Overview ......................................................................................... 60
Spectral Window: CSA and DSA EEG ............................................................................. 61
Quadrant-DSA Window ...................................................................................................... 63
Spectral Review Windows ................................................................................................. 64
REVIEWING A STUDY ........................................................................................................... 65
Timebar ............................................................................................................................... 66
Timebar Overview ............................................................................................................... 66
Log Book ............................................................................................................................. 68
Trending Window Overview .............................................................................................. 69
History Window Overview ................................................................................................. 70
History Window – All Traces ............................................................................................. 70
REPORTS ............................................................................................................................... 72

natrus.
Creating Generic Reports ................................................................. 72

REMOTE MONITORING ....................................................................... 73

Before You Begin ............................................................................ 73

XLTEK Portals .................................................................................. 73

  LocalPortal .................................................................................... 73
  RemotePortal .................................................................................. 73

Multiple Connections ..................................................................... 74

Additional Information and Terms .................................................. 74

TOOLBAR BUTTONS ........................................................................ 76

ACCESSORIES ................................................................................ 77
Protektor32 – Intraoperative Neurophysiological Monitoring

Indications for Use

The Protektor32 system, composed of both hardware and software, is intended to be used for intraoperative neurological Monitoring. The instrument uses EEG, EP, EMG and Transcranial Stimulation techniques (TcMEP) to provide the healthcare professionals with information to help assess a patient’s neurological status during surgery.

The TcMEP mode is intended for intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

The EPWorks software, an integral part of the system, is intended to allow a medical professional to manually configure stimulation and acquisition parameters and to manually create EEG, EP, EMG and TcMEP protocols according to their own requirements. The intended use for each of the software’s outputs is as follows:

- The EEG, EP, and EMG waveforms are intended to help the user assess a patient’s neurological status during surgery.
- Simple waveform parameters (e.g., amplitude, latency), and user-defined Fast Fourier Transform (FFT) displays (CSA, DSA) are intended to help the user analyze the EEG and EP waveforms.

This device is intended to be used by qualified medical practitioners, trained in Electroencephalography, Evoked Potentials and Electromyography, who will exercise professional judgment when using the information.

Protocols

As stated by the America Academy of Neurology (2008) “[...] the quality, extent and type of monitoring [...] is exquisitely reliant on the rigors of the monitoring procedure and protocols, and the clinical expertise of the monitoring physician.” All things considered, Intraoperative neurophysiological monitoring depends on the collection of data that will be judiciously interpreted by the trained professional to identify neurological changes due to operative manipulations.

The Protektor32 offers flexibility to accommodate user needs for intraoperative monitoring. It provides an easily accessible interface to quickly set up protocols when performing the following intraoperative monitoring procedures:

- **Central Sulcus Mapping:** A method for intraoperative determination of the central sulcus using SSEP and/or Motor Evoked Potentials.
- **Pedicle Screw Stimulation:** A method or technique for monitoring pedicle screw placement and performed by applying stimulation of the “pedicle screw” and recording the evoked EMG activity from the muscles innervated by the spinal nerve roots at risk.
- **Direct Nerve Stimulation:** A method used to evaluate damaged nerves. It is based on the possibility to record and analyze a type of evoked potential (EP) called Nerve action potential (NAP) which is a the total electrical potential that develops and travels within a nerve after its constituent nerve fibers have been stimulated- either physiologically or physically- to a level above their threshold.

The above reflects TcMEP protocols only as they relate to the intended use of the Protektor32.
Safety Information

The Protektor32 System is intended for use ONLY by qualified individuals who have received training on this device. Read carefully this manual and make sure you fully understand all warnings and cautions, and the procedures to follow before operating the Protektor32 system.

For TcMEP specific warnings and cautions, refer to the section “Using the TcMEP Module on Protektor 32” in this manual.

Critical Warnings and Cautions

⚠️ The Protektor32 is intended for use ONLY by qualified individuals who have received training on this device. This user/service manual should be read and understood fully before commencing use of the product.

⚠️ Use of the Protektor32 high-current stimulator for transcranial stimulation can cause bite-related injury. It is imperative that effective preventative measures be implemented BEFORE using the device for this purpose.

General Warnings

⚠️ It is the responsibility of the institution where the Protektor32 unit is installed to ensure that the requirements of IEC60601.1.1-M92 - Collateral Standard: Safety Requirements for Medical Electrical Systems are fulfilled in the particular installation.

Non-medical electrical equipment (printers and computers) complying with the appropriate IEC or ISO safety standards may be directly connected to the Protektor32 serial and network ports for data-transfer functions only if both the Protektor32 and the equipment are outside of the patient environment and no patient-applied parts are connected to the patient.

For further details on how to comply with this standard regarding non-Xltek supplied printers or VGA monitors, please consult the standard or contact Xltek Technical Support at 1-800-303-0306 or OTS@natus.com.

⚠️ WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠️ Connecting electrical equipment to a MULTIPLE SOCKET OUTLET (MSO) effectively leads to creating a MEDICAL ELECTRICAL (ME) SYSTEM and the result can be a reduced level of safety. For the requirements that are applicable to an ME SYSTEM, please refer to IEC 60601-1 Ed. 3.1.

⚠️ Connection of a patient to high-frequency surgical equipment (electrocautery) and to an electromyograph or evoked response equipment simultaneously may result in burns at the site of the electrical stimulator or biopotential input part electrodes and possible damage to the electrical stimulator or biological amplifiers.
<p>| ! | Operation in close proximity (for example 1 m) to shortwave or microwave therapy equipment may produce instability in the electrical stimulator output. |
| ! | The device is <strong>NOT</strong> intended to operate in the vicinity of strong sources of potential electromagnetic interference such as MRI or CT. |
| ! | <strong>Electrostatic Discharge (ESD) Precaution</strong>: Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures. Connectors marked with the ESD protection symbol should not be touched. |
| ! | All wires to/from the patient must <strong>NOT</strong> contact any of the conductive parts of the device including earth. |
| ! | Preventive maintenance is required every six months. This should include chassis and patient leakage current measurements at a minimum. |
| ! | The device is not protected against defibrillation. All wires to/from the device should be removed before using a defibrillation. |
| ! | Do <strong>NOT</strong> use this device in the presence of implanted electronic devices unless a specialist medical opinion has been obtained. |
| ! | Do <strong>NOT</strong> place the stimulation electrodes such that the stimulation current will be trans-thoracic (crossing the area of the chest and thorax.) |
| ! | The Protektor32 headbox carries ordinary classification for the level of protection against ingress of liquids (IPX0). It is not drip or splash proof. |
| ! | The Protektor32 headbox requires a properly grounded electrical outlet. The internal isolation transformer must not be bypassed under any circumstances. |
| ! | Stimulating electrodes must be large enough so that the current density is always less than 2 mA r.m.s./cm². Current densities exceeding 2 mA r.m.s./cm² may require special attention of the operator. For example, if the stimulus is stimulating at 100 mA at 10 Hz, with a duration of 1 ms, then the stimulus electrode must be at least 0.5 cm². For a detailed description and calculations of the stimulation parameters needed to achieve less than 2 mA rms / cm² refer to section <strong>Using the TcMEP Module on Protektor32</strong>. |
| ! | When an electrode with a small surface area is used (such as a needle electrode), the current density rises. |
| ! | Current density in TcMEP mode is dependent on the stimulation strength (voltage) and number of pulses. If the stimulation parameters are different from those detailed in the table and the voltage is greater than these thresholds, it may cause skin burns. |</p>
<table>
<thead>
<tr>
<th>Warning</th>
<th>Patient movement may occur during stimulation, leading to inadvertent neural injury. Take adequate steps to avoid stimulation when patient movement could cause injury.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>The Protektor32 shall be used ONLY with legally-marketed electrodes in the country where in use. For instance, in the United-States use ONLY FDA-approved, legally-marketed electrodes. In Canada use ONLY Health Canada-approved legally-marketed electrodes.</td>
</tr>
<tr>
<td>Warning</td>
<td>Hazardous voltages are exposed when the lid of the Protektor32 headbox is removed.</td>
</tr>
<tr>
<td>Warning</td>
<td>This system is NOT AP or APG rated. DANGEROUS: Explosion hazard. Do not use in the presence of flammable anesthetics.</td>
</tr>
<tr>
<td>Warning</td>
<td>Do not turn on the system until all cable connections have been made and their integrity checked.</td>
</tr>
<tr>
<td>Warning</td>
<td>The proper use of this device for its intended purpose can only be assured once all instructions have been read and understood. If there are any questions regarding the operation of this device, please contact your Xltek representative at once.</td>
</tr>
<tr>
<td>Warning</td>
<td>The sale, distribution or use of this device is restricted to, by or on order of a licensed medical practitioner.</td>
</tr>
<tr>
<td>Warning</td>
<td>The Protektor32 headbox is a Type BF device. According to the IEC 60601-1 standard, a BF device is an applied part isolated from other parts of the equipment to such a degree that no current greater than a set level flows if an unintended voltage is connected to the patient. This set level of current is the maximum patient leakage current allowable in a single fault condition. All of the patient connections of the Protektor32 headbox are electrically isolated. However, these connections are not intended for direct cardiac contact.</td>
</tr>
<tr>
<td>Warning</td>
<td>Electrical Shock Hazard. Do not connect electrode inputs to earth ground. The patient headbox contains warning symbols to remind you that the connections are intended for isolated patient connections only.</td>
</tr>
<tr>
<td>Warning</td>
<td>Remove all unused power cables from the vicinity of the Protektor32 system.</td>
</tr>
<tr>
<td>Warning</td>
<td>Connect all patient electrodes to fully electrically isolated physiological devices only. Connection to any other device or external outlet may result in personal injury.</td>
</tr>
<tr>
<td>Warning</td>
<td>The Protektor32 headbox accepts only touch-proof style electrode inputs. Do not attempt to use any other style of patient electrode input.</td>
</tr>
<tr>
<td>Warning</td>
<td>No equipment other than devices connected to the Protektor32 may be powered by an isolation transformer. The current rating of the transformer must be sufficient to operate all of the devices powered by it. Refer to the current ratings of each individual device.</td>
</tr>
</tbody>
</table>
### Instructions for Use

<table>
<thead>
<tr>
<th>Warning Icon</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Possible interference with signals may occur in certain situations (for example, poor grounding in circuitry and close proximity to other instrumentation such as an MRI).</td>
</tr>
<tr>
<td>!</td>
<td>The accessories of this device may include several kinds of disposable, sterile electrode needles. These needles are labeled as STERILE and the method of sterilization is documented on the packaging. These electrodes should not be used if the sterile packaging has been tampered with.</td>
</tr>
<tr>
<td>!</td>
<td>The computer (desktop PC or laptop) connected to the Protektor32 headbox has a cooling fan. Keep this area unobstructed to prevent overheating.</td>
</tr>
<tr>
<td>!</td>
<td>When the Protektor32 comes to the end of its operating life, it should be disposed of in accordance with local waste disposal regulations.</td>
</tr>
<tr>
<td>!</td>
<td>Do not place more than 10lbs in the accessory bin on the Protektor32 Cart.</td>
</tr>
<tr>
<td>!</td>
<td>Multiple Portable Socket Outlets (MPSO) shall not be placed on the floor.</td>
</tr>
<tr>
<td>!</td>
<td>Additional MPSO or extension cord shall not be connected to the system.</td>
</tr>
<tr>
<td>!</td>
<td>Do <strong>NOT</strong> connect items which are not specified as part of the system.</td>
</tr>
<tr>
<td>!</td>
<td>Do <strong>NOT</strong> touch any Protektor32 accessible metal parts and the patient simultaneously.</td>
</tr>
<tr>
<td>!</td>
<td>Do <strong>NOT</strong> connect non-medical equipment, which has been supplied as a part of the system, directly to the wall outlet when the system is supplied via MPSO with a separating transformer.</td>
</tr>
<tr>
<td>!</td>
<td>Do <strong>NOT</strong> connect electrical equipment which, has not been supplied as a part of the system, to the MPSO.</td>
</tr>
<tr>
<td>!</td>
<td>Connection of a patient to high-frequency surgical equipment (electrosurgical unit) and to an electromyograph or evoked response equipment simultaneously may result in burns at the site of the electrical stimulator or biopotential input part electrodes and possible damage to the electrical stimulator or biological amplifiers. To minimize the potential for such issues, read and follow the section of this manual labelled: “Guidelines for the use of Protektor32 with Electro-Surgical Units.”</td>
</tr>
<tr>
<td>!</td>
<td>Corruption/loss of data over network due to unplugging the network cable or data interruption during data transfer/hardware failure/ corrupt software.</td>
</tr>
<tr>
<td>![Warning Icon] Do not install any other software than the EPWorks Software. Natus assumes no responsibility when the equipment is not used as described in this manual.</td>
<td></td>
</tr>
<tr>
<td>![Warning Icon] Never touch the patient while connecting or disconnecting any connectors.</td>
<td></td>
</tr>
<tr>
<td>![Warning Icon] 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 Protektor32 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</td>
<td></td>
</tr>
</tbody>
</table>

## General Cautions

| ![Warning Icon] It is recommended that the stimulator probe be disinfected between patients with 70% isopropyl alcohol. This is not a method of sterilization if the stimulator is used invasively. |
| ![Warning Icon] Turn off all system power and disconnect the power cord from the system and the wall before attempting to clean the unit. The Protektor32 headbox can be wiped clean with a soft, damp cloth using non-conductive distilled water, electrically non-conductive inert surfactants or an Xltek-approved cold sterilizing agent. It is important to dry off the units quickly. Avoid letting liquid seep into any of the internal electronics of the system. Do not use any abrasive cleaner on the system. |
| ![Warning Icon] Inspect all cables and connections (especially the power cord) often for signs of fraying or other damage. Do not operate the Protektor32 headbox if you suspect damage to any of the cables or the power cord. |
| ![Warning Icon] Do not leave any cables attached to the Protektor32 headbox when transporting the unit. This may cause connections to become loose or malfunction during operation of the unit. |
| ![Warning Icon] Do not turn on the power to the Protektor32 headbox immediately after bringing it in from a cold environment to one at room temperature. Allow the unit to assume the ambient environmental temperature (i.e. one hour warm up). |
| ![Warning Icon] The isolated switch mode power supply is intended for connection only to a 110V, 120V, 220V or 240V external (wall) outlet. |

## Audio/Visual Stimulation Warnings

| ![Warning Icon] Only the Telephonics Model TDH-39P headphones and ear inserts (TIPS) provided have been approved for use with your Protektor32. Patient isolation in accordance with IEC60601-1 is dependent on the approved parts. |
**Instructions for Use**

Only equipment approved to **IEC950, IEC 60601-1** or a similar safety standard may be connected to the VGA port on the Protektor32. The final system must be configured to meet the requirements for safety of medical systems prescribed by IEC60601-1-1.

Exposure to excessive sound can cause temporary and even permanent hearing loss.

Long-term exposure to excessive light can cause temporary and even permanent changes in visual acuity.

Patient electrical isolation is ensured when all peripherals (headphones, printer, goggles, monitor) attached to the Protektor32 are **Xltek**-approved. The final system configuration must meet the requirements of **IEC60601-1** for safety of medical systems.

If you choose to attach a VGA display other than the model supplied by **Xltek**, it **MUST** either meet IEC60601-1 or the leakage current requirements for your jurisdiction.

---

**Protektor32 with the Electro-Surgical Units (ESU) – Guidelines**

Follow the safety guidelines below to ensure proper use of Protektor 32 with the Electro-Surgical Unit. Failing to follow these guidelines may result in skin burns to the patient, and/or damage to the Protektor 32 unit.

1. When ESU is active, keep the ESU pencil away from the Acquisition box and stimulation electrodes.
2. Use as large as possible patient ground electrode connected to the Protektor32 ground input.
3. Do not place Protektor32 ground electrode(s) in close proximity to the ground return electrode for the ESU. Do not connect the ESU ground electrode to the Protektor32 ground.
4. Ensure that the dispersive pad for the ESU has a good electrical contact with the patient. Although certain ESUs have a mechanism for checking the quality of contact, always visually inspect the dispersive pad to ensure that it is properly applied.

Do not activate the electro-surgical unit for extended periods of time, unless the ESU electrode is in direct contact with the patient.

---

**Output Waveforms**

The output waves from the Protektor32 are required to electrically stimulate the patient and evoke a response. These waves have no D.C. component and are limited to ±400V and 100 mA on the standard electrical stimulators, ±500V and 1500mA on the TCEMEP stimulator, and ±10V and 40mA on the surgical probe stimulators. Since there is no D.C. component to the output, there are no specific precautions which need to be taken with regard to a D.C. component.

If the load impedance exceeds the voltage limit for a given current, the stimulation output is attenuated in proportion to the resistance. Typical loads would be in the range of 500 Ohms to 10 kOhms. The
stimulation pulse duration ranges from 0.05 ms to 1.0 ms. Pulses are repetitive up to a maximum frequency of 500 Hz.

**Electrostatic Discharge (ESD) handling procedures and warnings**

Before performing any setup or placement procedures, it is recommended that all clinical staff read and/or are trained on the precautions outlined in this section.

| ![WARNING] | **WARNING:** Be sure to take the appropriate Electrostatic Discharge (ESD) precautions. Disconnect the cables before moving, cabling, or performing any set up procedures. |

Some semiconductor (solid state) devices can be easily damaged by static electricity. Such components are commonly called Electrostatically Sensitive Devices (ESD). Do not touch the accessible conductive parts for the Connectors marked with the ESD symbol.

Follow these techniques to help reduce the incidence of component damage caused by static electricity:

- Immediately before handling any product components assemblies, drain the electrostatic charge from your body by touching a known earth ground.
- Minimize body motions when handling unpackaged replacement ESDs. Motions such as brushing clothes together or lifting your foot from a carpeted floor can generate enough static electricity to damage the product components.
- Avoid carpets in cool, dry areas. If provided, leave the product components in their anti-static packaging until ready to be installed.
- Take care when connecting or disconnecting cables. When disconnecting a cable, always pull on the cable connector or strain-relief loop, not on the cable itself.

| ![WARNING] | **WARNING:** A damaged cable can cause a short in the electrical circuit. Prevent damage to the connectors by aligning connector pins before you connect the cable. |

| ![WARNING] | **WARNING:** Misaligned connector pins can cause damage to system components at power-on. |
Protektor32 Safety and Standards Conformity

Essential Performance
The potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of EMG DIAGNOSTIC EQUIPMENT are:

- Minimum noise on a waveform or artifacts or distortion in an image and any error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis
- Free from the display of incorrect safety-related indications
- Free from the production of unintended or excessive stimulation output
- Free from the production of unintended or excessive patient applied parts surface temperature

Standards Compliance and Normative References Information
Intraoperative Neuromonitoring device, Model Protektor32, transportable / mobile (when mounted on cart), rated: 24Vdc, 2A. For use with external power supply (Jerome Industries; model WSL524MC; rated 100–240Vac, 50/60Hz, 140VA; Xltek P/N 005307)

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: Type BF
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-40°C, 30-75% rH, 700-1060hPa

The Protektor32 and its accessories have been designed to comply with the following national and international standards.

<table>
<thead>
<tr>
<th>Table 1 – Safety Standard of Compliance and Normative References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IEC 60601-1:2012 (Ed. 3.1)</strong></td>
</tr>
<tr>
<td><strong>CSA C22.2 No. 60601-1:2014-03</strong></td>
</tr>
<tr>
<td><strong>EN 60601-1:2006 + A1:2013</strong></td>
</tr>
<tr>
<td><strong>IEC 60601-2-40:1998 (Ed. 1.0)</strong></td>
</tr>
<tr>
<td>Standard</td>
</tr>
<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>IEC 60601-1-6: 2010 (Ed. 3.0) + A1: 2013</td>
</tr>
<tr>
<td>IEC 62366:2007 (Ed. 1.0) + A1: 2014</td>
</tr>
<tr>
<td>Standard</td>
</tr>
<tr>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>IEC 60601-2-40:2016 (Ed. 2.0) – Clauses 201.17 and 202</td>
</tr>
<tr>
<td>IEC 61000-4-2:2008 (Ed. 2.0)</td>
</tr>
<tr>
<td>IEC 61000-4-3:2010 (Ed. 3.2)</td>
</tr>
<tr>
<td>IEC 61000-4-4:2012 (Ed. 3.0)</td>
</tr>
<tr>
<td>IEC 61000-4-6:2013 (Ed. 4.0)</td>
</tr>
<tr>
<td>IEC 61000-4-8:2009 (Ed. 2.0)</td>
</tr>
<tr>
<td>IEC 61000-3-2:2018 (Ed. 5.0)</td>
</tr>
<tr>
<td>IEC 61000-3-3:2013 (Ed. 3.0)</td>
</tr>
<tr>
<td>CISPR 11:2010 (Ed. 5.0) + A1</td>
</tr>
</tbody>
</table>
Declaration of Compliance for IEC 60601-1-2

Table 3 - Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Protektor32 uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The Protektor32 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td><strong>Warning:</strong> This equipment/system 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 Protektor32 or shielding the location.</td>
</tr>
</tbody>
</table>

Table 4 - Immunity Test Levels - Enclosure Port

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard or Test Method</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge</td>
<td>IEC 61000-4-2</td>
<td>± 8 kV contact</td>
</tr>
<tr>
<td></td>
<td></td>
<td>± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td>
</tr>
<tr>
<td>Radiated RF EM Fields</td>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 MHz – 2,7 GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 % AM at 1 kHz</td>
</tr>
<tr>
<td>Proximity Fields from RF Wireless Communications Equipment</td>
<td>IEC 61000-4-3</td>
<td>See “Enclosure Port Immunity to RF Wireless Communications Equipment” Table below</td>
</tr>
<tr>
<td>Rated Power Frequency Magnetic Fields</td>
<td>IEC 61000-4-8</td>
<td>30 A/m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50 Hz or 60 Hz</td>
</tr>
</tbody>
</table>

Table 5 – Immunity Test Levels – Input A.C. Power Port

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Electrical Fast Transients / Bursts

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
|            | IEC 61000-4-4       | ± 2 kV  
|            |                     | 100 kHz repetition frequency |

### Surges

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IEC 61000-4-5</td>
<td>± 0,5 kV, ± 1 kV</td>
</tr>
</tbody>
</table>

### Surges

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IEC 61000-4-5</td>
<td>± 0,5 kV, ± 1 kV, ± 2 kV</td>
</tr>
</tbody>
</table>

### Conducted Disturbances

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
|            | IEC 61000-4-6       | 3 V  
|            |                     | 0,15 MHz – 80 MHz  
|            |                     | 6 V in ISM bands between  
|            |                     | 0,15 MHz and 80 MHz  
|            |                     | 80 % AM at 1 kHz |

### Voltage Dips

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
|            | IEC 61000-4-11      | 100% dip; 0,5 cycle  
|            |                     | At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  
|            |                     | 100% dip; 1 cycle  
|            |                     | and  
|            |                     | 30% dip; 25 cycles (50Hz)  
|            |                     | Single phase: at 0° |

### Voltage Interruptions

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IEC 61000-4-11</td>
<td>100% dip; 250 cycles (50Hz) /300 cycles (60 Hz)</td>
</tr>
</tbody>
</table>

### Table 7 – Patient Coupling Port

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
| Electrostatic Discharge | IEC 61000-4-2 | ± 8 kV contact  
|                      |                     | ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
| Conducted Disturbances Induced by RF Fields | IEC 61000-4-6 | 3 V  
|                      |                     | 0,15 MHz – 80 MHz  
|                      |                     | 6 V in ISM bands between  
|                      |                     | 0,15 MHz and 80 MHz  
|                      |                     | 80 % AM at 1 kHz |

### Table 8 – Immunity Test Levels - Signal Input / Output Parts Port

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
</table>
| Electrostatic Discharge | IEC 61000-4-2 | ± 8 kV contact  
|                      |                     | ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air |

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Basic EMC Standard</th>
<th>Immunity Test Levels – Professional Healthcare Facility Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical Fast Transients/Bursts</td>
<td>IEC 61000-4-4</td>
<td>± 1 kV</td>
</tr>
<tr>
<td>Phenomenon</td>
<td>Basic EMC Standard</td>
<td>Immunity Test Levels – Professional Healthcare Facility Environment</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>--------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Conducted Disturbances Induced by RF Fields</td>
<td>IEC 61000-4-6</td>
<td>100 kHz repetition frequency</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 V</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0,15 MHz – 80 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 V in ISM bands between</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0,15 MHz and 80 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 % AM at 1 kHz</td>
</tr>
</tbody>
</table>

Table 9 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

<table>
<thead>
<tr>
<th>Test frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Service</th>
<th>Modulation</th>
<th>Maximum Power (W)</th>
<th>Distance (m)</th>
<th>IMMUNITY TEST LEVEL (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380 – 390</td>
<td>TETRA 400</td>
<td>Pulse modulation 18 Hz</td>
<td>1,8</td>
<td>0,3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430 – 470</td>
<td>GMRS 460, FRS 460</td>
<td>FM ± 5 kHz deviation 1 kHz sine</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
<tr>
<td>710</td>
<td>704 – 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse modulation 217 Hz</td>
<td>0,2</td>
<td>0,3</td>
<td>9</td>
</tr>
<tr>
<td>810</td>
<td>800 – 960</td>
<td>GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse modulation 18 Hz</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
<tr>
<td>870</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>930</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,720</td>
<td>1,700 – 1,990</td>
<td>GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25, UMTS</td>
<td>Pulse modulation 217 Hz</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
<tr>
<td>1,845</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,970</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2,450</td>
<td>2,400 – 2,570</td>
<td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation 217 Hz</td>
<td>2</td>
<td>0,3</td>
<td>28</td>
</tr>
</tbody>
</table>
### Declaration of Compliance for FCC

**Note:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

**Warning:** Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
Regulatory Symbols
A number of symbols appear on the various components of the Protektor32 system. Please consult the table below for their meanings and significance.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td><strong>ATTENTION:</strong> Consult Accompanying Documents</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Consult Accompanying Documents</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Consult Operating Instructions</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Protective Earth (Ground)</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Type BF Equipment</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Dangerous Voltage</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Alternating Current</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>Direct Current</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Electrostatically Sensitive Device (ESD)</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="symbol" alt="Power On" /></td>
<td>Power On</td>
</tr>
<tr>
<td><img src="symbol" alt="Power Off" /></td>
<td>Power Off</td>
</tr>
<tr>
<td><img src="symbol" alt="CE Mark" /></td>
<td>CE Mark</td>
</tr>
<tr>
<td><img src="symbol" alt="Canadian Standards Association" /></td>
<td>Canadian Standards Association (indicates safety approval by)</td>
</tr>
<tr>
<td><img src="symbol" alt="TUV Safety Tested and Production Monitored" /></td>
<td>TUV Safety Tested and Production Monitored</td>
</tr>
<tr>
<td><img src="symbol" alt="Made in Canada" /></td>
<td>Made in Canada</td>
</tr>
<tr>
<td><img src="symbol" alt="EU only: Do Not Dispose as Unsorted Municipal Waste" /></td>
<td>EU only: Do Not Dispose as Unsorted Municipal Waste</td>
</tr>
</tbody>
</table>
Protektor32 System Configuration

Device styles/models may vary from those shown above.

<table>
<thead>
<tr>
<th>Legend</th>
<th>Description</th>
<th>Legend</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Stimulator Pods</td>
<td>M</td>
<td>Medical Grade Power Supply</td>
</tr>
<tr>
<td>B</td>
<td>Low Current Stimulator Pods</td>
<td>N</td>
<td>Isolation Box</td>
</tr>
<tr>
<td>C</td>
<td>TCeMEP Pod</td>
<td>O</td>
<td>PC/Laptop</td>
</tr>
<tr>
<td>D</td>
<td>Acquisition Pods</td>
<td>P</td>
<td>External Triggers</td>
</tr>
<tr>
<td>E</td>
<td>Oximeter</td>
<td>Q</td>
<td>Acquisition Head Box</td>
</tr>
<tr>
<td>F</td>
<td>Goggles</td>
<td>R</td>
<td>Stimulator Head Box</td>
</tr>
<tr>
<td>G</td>
<td>Cautery Detector</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>Headphones or Ear Inserts</td>
<td>1</td>
<td>Communication Cable</td>
</tr>
<tr>
<td>I</td>
<td>VGA Monitor**</td>
<td>2</td>
<td>VGA Cable</td>
</tr>
<tr>
<td>J</td>
<td>Power Cable (MAINS)</td>
<td>3</td>
<td>DC Power Cable</td>
</tr>
<tr>
<td>K</td>
<td>Isolation Transformer</td>
<td>4</td>
<td>Power Cable</td>
</tr>
<tr>
<td>L</td>
<td>Printer**</td>
<td>5</td>
<td>USB Data Cable</td>
</tr>
</tbody>
</table>

**VGA monitor and Printer are optional.

Applied Parts include electrodes for EEG and EMG data acquisition, goggles for visual stimulation, headphones for auditory stimulation, electrical stimulators, and pulse oximeter.
Note: Use only Xltek approved cables and accessories with this device.

Protektor Headbox

The Protektor32 headbox contains a complete data acquisition system that has built-in amplifiers, A/D Converters, Digital Signal Processors, CPUs, and storage devices.

Protektor32 Headbox Features

- Up to 32 Analog Input Channels (differential or referential).
- 2 Independent Electrical Stimulators, --each with eight switchable output ports, and 2 low-current probe ports.
- 1 Auditory Stimulator.
- 1 Visual stimulator.
- 2 Bi-directional external triggers
- Full Bandwidth Acquisition (60 kHz sampling).
- Simultaneous Multi-Channel EP, EMG, and EEG.
- Ultra-Low-Noise Amplifiers
- Connects to Laptop or Desktop
- Small and light enough to be carried into the OR
- Switch Matrix
- Stim Pods
- Breakout Box

The Protektor32 headbox can be connected to other equipment through a communications port; two external trigger input/outputs; and a cautery detection port.
Connecting Protektor Headbox
The instructions which follow demonstrate how to connect the Protektor32 headbox to a laptop or desktop computer.

⚠️ Position the equipment so that the detachable mains cord is readily accessible for disconnection.

1. Plug the power cord into the Isolation Box.

![Figure 1: Power Connected to Headbox Power Connection](image1)

2. Connect the Isolation–Acquisition cable into the Isolation box and to the Acquisition box.

![Figure 2: Isolation-Acquisition cable connected to Isolation Box](image2)

3. Connect the Acquisition box to the Stimulator box using the Acquisition – Simulator cable:

![Figure 3: Acquisition box connected to Stimulator box](image3)
Instructions for Use

4. Connect the USB cable between the Isolation box and the Laptop / Desktop PC.

5. Connect the Acquisition / Stimulator pods to the acquisition and stimulator boxes.

Examples of detachable pods

Detachable Stimulating Pod

Acquisition Pod

Example of Pod holder with cable clip
Using the TcMEP Stimulator with Protektor32

The TcMEP stimulator with Protektor 32 provides a mode of operation that delivers single or train stimuli at a rate up to a few pulses per second.

Safety Information

Contra-Indications and Exclusions

Contra-indications and exclusion criteria for Protektor32 Transcranial Stimulation mode:

- Subjects with a history of head injury, stroke, epilepsy, seizures or other neurological impairment.
- Subjects with a history of cerebral aneurysm.
- Subjects with any type of implanted biomedical device (for example, a pacemaker).
- Subjects with metal plates or fragments in their head.

Protocol for Elicitation of TcMEPs

Place the stimulating electrodes on the patient’s scalp according to your laboratory protocols for stimulating electrode locations. Several different configurations of stimulating electrodes have been reported, including stimulation between C3 and C4 [Calancie et al. 1998, 2001; Jones et al. 1996] using the International 10-20 standards for EEG electrode placement. Next, place recording electrodes according to the location(s) from which you wish to record.

The ultimate decision of how to use the TcMEP modes (including stimulating electrode placement, recording electrode placement, and type of electrodes) is up to the user. We refer the user to published, peer reviewed papers where detailed descriptions of different protocols to perform TcMEP are available.

NOTE: In order to avoid false positive warnings to the surgical team, it is imperative that there is a thorough understanding that substantive alterations in anesthesia delivery, or mean arterial blood pressure, can account for deviations from TcMEP intra-operative baselines.

References:

## TcMEP Warnings and Cautions

<table>
<thead>
<tr>
<th>Warning</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulating electrodes must be large enough so that the current density is always less than 2 mA r.m.s./cm². Current densities exceeding 2 mA r.m.s./cm² may require special attention of the operator. For example, if the stimulus is stimulating at 100 mA at 10 Hz, with a duration of 1 ms, then the stimulus electrode must be at least 0.5 cm².</td>
<td></td>
</tr>
<tr>
<td>When an electrode with a small surface area is used (such as a needle electrode), the current density rises.</td>
<td></td>
</tr>
<tr>
<td>Current density in TcMEP mode is dependent on the stimulation strength (voltage) and number of pulses. If the stimulation parameters are different from those detailed in the table and the voltage is greater than these thresholds, it may cause skin burns. For a detailed description and calculations of the stimulation parameters needed to achieve less than 2 mA rms / cm² refer to the Table 4 appearing below.</td>
<td></td>
</tr>
<tr>
<td>Patient movement may occur during stimulation, leading to inadvertent neural injury. Take adequate steps to avoid stimulation when patient movement could cause injury.</td>
<td></td>
</tr>
<tr>
<td>Due to the high current density and risk of patient burns, corkscrew and needle electrodes with low surface areas, such as those 13 mm long and 0.4 mm in diameter should not be used for stimulation with the TcMEP stimulator.</td>
<td></td>
</tr>
<tr>
<td>Cortical stimulation may not be appropriate for use on patients with a history of skull fracture or neurosurgical procedures to the head. Skull defects could provide high local current densities.</td>
<td></td>
</tr>
<tr>
<td>Cortical stimulation may induce seizures and memory problems in those with a history of epilepsy and other disorders with predisposition to seizures (e.g. alcoholism). Ensure that necessary medical precautions are taken in case of such an episode.</td>
<td></td>
</tr>
<tr>
<td>Otherwise unexplained intra-operative seizures and possible arrhythmias are indications of cease use of the TcMEP stimulator.</td>
<td></td>
</tr>
<tr>
<td>The TcMEP stimulator outputs must be connected to the stimulating electrodes only. Unintentional misconnection of the outputs to ground electrodes could result in current being dangerously applied to organs other than the cerebral cortex.</td>
<td></td>
</tr>
<tr>
<td>Studies by Calancie et al. relied upon to demonstrate safety and effectiveness of the device employed threshold level monitoring to increase patient safety by minimizing energy delivered.</td>
<td></td>
</tr>
<tr>
<td>When using the electrical stimulator many times over a long period, check the moisture and the paste on the stimulation electrodes periodically. When electrical stimulation is conducted over an extended period of time, the moisture and the paste on the stimulation electrodes dry out; as a result, if the electrical stimulation continues with it dried out, the point that is being stimulated with high current density will get hot and may cause a burn.</td>
<td></td>
</tr>
</tbody>
</table>
When both a high-frequency surgical instrument and the electric stimulator are used for the patient at the same time, there is a possibility that burns will result where the electrode is applied or damage to the electrode used. Remove the electrode when you use a high-frequency surgical instrument.

The output of the electric stimulation parts might be unstable when a shortwave or microwave therapeutic instrument is close to the electrode. Turn off the power of the electrical stimulator when using a microwave therapeutic instrument.

### Stimulation limitations of the TcMEP modality

1. Energy limitation per pulse
   - 50mJ per pulse on a 1000 Ohm Load (Safety requirement according to IEC60601-2-40 – collateral standard)
2. Energy limitation per time period
   - Maximum = 100mJ per second distributed in maximum 9 pulses on a 1000 Ohm load.

### Pulse Train Safety Limits

To prevent excessive delivery of stimulation to the patient, Protektor32 is set-up with specific conditions for the relationship between the output voltage and number of pulses of stimulation. The Total energy delivered to the patient by the Protektor32 TcMEP stimulator depends on the number of pulses per train and the selected stimulation voltage.

The calculated energy the device will deliver to the patient is depicted in the following figure:

![Energy Limitation vs. Allowable Settings](image)

*Figure 6. Energy limitation vs. Allowable settings*

**Energy Limitation vs. Allowable Settings**

Settings outside the ranges depicted in the figure are not allowed by the device. If the set value is exceeded, the Protektor32 function for limiting output is triggered.
Current Density

When using TcMEP mode you must be aware of the Current density. Current density is dependent on the stimulation strength (voltage) and number of pulses. In order to achieve current densities less than 2 mA rms/cm² you can use the parameter settings-setup appearing in Table 4.

Table 4: Maximum voltage - number of pulses combinations to achieve less than 2 mA rms/cm².

| Maximum voltage settings per pulse setting per electrode configuration to avoid current densities above 2mA RMS/cm² |
| Pulses per second | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| One EEG disc electrode (0.9cm²) |
| Voltage Settings [V] | 255 | 180 | 147 | 127 | 114 | 104 | 96 | 90 | 85 |

DISPOSABLE SILVER EEG DISC ELECTRODES - Diameter of cup: 10 mm; Height of cup: 3 mm; Surface area = 90 mm² (Part #105191 in the Natus Neurodiagnostic Accessories Catalogue)

⚠️ If you use settings-setups combinations exciding those detailed in Table 4 above, stimulation may result in skin burns and will require special attention of the operator.

\[
t = \text{Pulse Duration} \quad \text{Fixed at 50us} \\
i = \text{Interpulse Interval (pulse rate)}
\]

Note: Num Priming Pulses + Num Test Pulses cannot exceed 9 total.
Min Repetition Time
(1 second)
Recommended User Performed Maintenance

Routine System Maintenance
In a solid state system, with no moving parts, there is no need for routine maintenance. However, if you still wish to test the system, input a 1 mV, 1 Hz square wave using a calibrated signal generator. The waveform displayed on screen should appear as a square wave with appropriate amplitude and frequency. It is important to note that the current filter settings may distort the waveform.

General User Performed Maintenance
To keep the Protektor32 system in good working condition, follow a regular schedule of preventive maintenance. Regular user performed maintenance does not involve access to the interior of the Protektor32 headbox and components. For service problems that require corrective maintenance and/or internal component service, call Xcite Technical Support at 1-800-303-0306, or contact your local Xcite representative.

Periodically check cable connections and electrodes for damage and wear. Inspect cables for bent pins. Replace frayed or worn cables. Also, regularly inspect and clean all system components, including:

- Connectors and jack ports
- Electrodes and accessories
- Stimulator / Acquisition / Isolation Boxes and cables

**NOTE:** Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of system components.

Maintenance Warnings

| ! | Do not service or maintain this equipment while in use with the patient. |
| ! | Disconnect the Protektor32 headbox and breakout box from the computer before wiping. Disconnect all cables. Use a lint-free cloth. Do **NOT** use cleaners on any system component. |
| ! | Be careful not to allow any fluid to seep into the internal electronic components of the headbox or breakout box. |
| ! | Do **NOT** leave the headbox or breakout box attached to the computer when transporting the unit. |
| ! | Do **NOT** use petroleum-based or acetone solutions, or other harsh solvents, to clean the device. |
Environmental Conditions

<table>
<thead>
<tr>
<th>Operating Environmental Limits</th>
<th>Temperature: 10° to 40°C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relative Humidity: 30%–75%</td>
</tr>
<tr>
<td></td>
<td>Altitude: Up to 4600 meters above sea level</td>
</tr>
<tr>
<td></td>
<td>Atmospheric Pressure: 500 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Transport and Storage Limits</td>
<td>Temperature Range: -40°C to 70°C</td>
</tr>
<tr>
<td></td>
<td>Humidity Range: 10%–100%, including condensation</td>
</tr>
<tr>
<td></td>
<td>Atmospheric Pressure Range: 500 hPa to 1,060 hPa</td>
</tr>
<tr>
<td>Electrical Ratings of Isolation Box, Acquisition Box, and Stimulator Box with Protektor32 Cart</td>
<td>24Vdc/ 2A</td>
</tr>
<tr>
<td>Isolation Transformer Maximum Output Power</td>
<td>P/N 006979: 100VAC-50/60Hz, 8.7/4.35A (850VA), 115(120)/230(240)VAC-50/60Hz, 8.7/4.35A (1000VA)</td>
</tr>
<tr>
<td></td>
<td>P/N 010758: 120VAC-60Hz, 7.50A (900VA)</td>
</tr>
</tbody>
</table>

Waste Management

Waste Electrical and Electronic Equipment Compliance.

Do not dispose of this product in the unsorted municipal waste stream. Dispose of the product according to the local regulations.
Protektor32 Software / EPWorks

Setting Up Tests

A) Before You Begin

1. Ensure that the headbox is connected to the computer and turned on.
2. Open EPWorks by double-clicking the EPWorks icon on the Windows® desktop.
3. Click File > New. The Study Information window will appear.
4. Type the patient's first and last name into the designated text boxes. (You can fill in more information now, or you can reopen the Study Information window to fill in more information later by clicking on the EPWorks toolbar.)
5. Click OK. The Test Directory window will open. (See illustration below).

![Test Directory Window](image)

*Test Directory Window. The tests appearing on this image are for illustration purpose only.*

The Study Information button on the EPWorks toolbar opens the Study Information window so you can add or edit information.

The Settings button on the EPWorks toolbar opens the Edit Test window so you can input or change the test settings or switch to a new test.

Create a Basic Test

1. From Test Directory, open the Edit Test window by clicking the Create... button.
2. Click the New... button and select the number of channels that the test requires.
   - EP-16: Runs only on the EP-16 headbox;
   - Protektor: Runs only on the Protektor headbox.
3. To set up electrode locations, click an electrode Location cell. Type in a name to label the location—e.g., “C-3” in the E3 electrode location cell, or “C-4” in the E4 electrode location cell—and press the Enter key. The location label is automatically placed on the headbox input map.
4. Enter a name for the test, e.g., Master Electrode, in the Test Definition text box. Note that tests are grouped in alphabetical order.
5. Click Save, to save the test with the new name.
B) Edit Text Window Tabs – Configuring a Basic Test

The following tests can be configured from the Edit Test window tabs:

- Electrodes
- EEG Montage
- Channels (Amplifier Inputs)
- Electric Stimulators
- AV/External Stimulators
- Timelines
- Groups
- Traces
- Markers
- Layouts
- Reporting

Test Directory – New Test

New Test...
Acoustic Nerve
Bilateral SSEP Lower Interleaved
Bilateral SSEP Upper Interleaved
Clinical Auditory EP
Clinical Visual EP
Four Channel Mapping
Four Extremity Interleaved SSEP
Hardware Channel Test
Hardware Electrical Stim
L3-4 L5-S1 Free Run
L3-4 Free Run
L3-4 Triggered
L5-S1 Free Run
L5-S1 Triggered
Posterior Fossa Protocol
C) Electrodes Tab

To make any required modifications to the electrode locations:

1. Click the Electrodes tab;
2. Enter your changes (e.g., add muscles or special electrodes)
3. Click Save.
D) EEG Tab

The EEG tab allows you to set up channels and filters for an EEG montage. Standard 10-20 locations defined in the Electrodes settings are automatically placed on the EEG tab head map.

To use the head map to set up a Differential Channel:

1. On the EEG tab head map, locate the pointer over the desired Input 1 location. Pressing the left mouse button, move the pointer to the desired Input 2 location and release. A red arrow is drawn between the locations. A new channel is added to the EEG table listing Input 1, Input 2 and default settings for the new channel.
2. Repeat Step 1 until you have added the required channels to the test.
3. To select the remaining settings for the new channel, right-click column headings or individual cells and select values for LFF, HFF, Notch, Color, Gain, and Quadrant from the pop-up menus.
4. Click OK to save.

To use the EEG table to set up a Differential Channel:

1. Click the Add button. An empty channel with a red background will appear in the table.
2. Right-click the Input 1 cell of the new channel and select an EEG electrode location from the pop-up menu.
3. Right-click the Input 2 cell of the new channel and select an EEG electrode location from the pop-up menu.
4. Repeat Steps 1 to 3 until you have added the required channels to the test.
5. Select the remaining settings for the new channel by right-clicking column headings or individual cells and select values for LFF, HFF, Notch, Color, Gain, and Quadrant from the pop-up menus.
6. Enter a name for the montage in the Name text box above the head map.
To use the head map to set up Referential Channels:

1. Click a location on the headmap to select Input 1. A new channel will appear in the EEG table with Input 1 set accordingly.
2. Repeat Step 1 until you have added the channels you require to the test.
3. To select the remaining settings for the new channels, right-click column headings or individual cells to select values for LFF, HFF, Notch, Color, Gain, and Quadrant from the pop-up menus. See the topic EEG Channel Settings for more information.
4. Click OK to save.

Note that if a referential channel already exists, it will not be added to the table when you click that location in the head map.

To use the EEG table to set up referential channels:

1. Click the Add button that is located to the right of the EEG table. An empty channel with a red background will appear in the table.
2. Right-click the Input 1 cell of the new channel and select an EEG electrode location from the pop-up menu.
3. Repeat Step 1 until you have added the required channels to the test.
4. To select the remaining settings for the new channels, right-click column headings or individual cells to select values for LFF, HFF, Notch, Color, Gain, and Quadrant from the pop-up menus. See the topic EEG Channel Settings for more information.
5. Click OK to save.

Setting Up Channels for Custom EEG Locations

Before you set up a channel for a custom EEG electrode location, you need to assign a custom EEG location in the Electrodes tab. Once this is done, the custom location appears in the pop-up menu when you right-click an Input 1 cell in the EEG tab.

To set up a channel for your custom EEG electrode location:

1. Click the button to add a new channel to the montage.
2. Right-click the Input 1 column cell and select the custom EEG location you want from the pop-up menu.
3. Repeat Step 1 to add the required custom channels to the test.
4. To select the remaining settings for the new channels, right-click column headings or individual cells to select values for LFF, HFF, Notch, Color, Gain, and Quadrant from the pop-up menus. See the topic EEG Channel Settings for more information.
5. Enter a name for the montage in the Name text box above the head map.
6. Click OK to save.

Custom EEG locations can also be used to set up the EEG montage; however, note that they will not appear on the EEG tab head map.
E) Channels Tab

To specify the electrodes you will be using in each channel:

1. Click the Channels tab. -- Each pair of electrodes that is added here will use one of the available channels on the headbox. -- Click Append to add a new channel to the Inputs table.
2. To choose an active electrode for the channel, right-click the cell in the Active column, and select an active electrode from the menu displayed.
3. To choose a reference electrode for the channel, right-click the cell in the Reference column and select an electrode location from the menu. Repeat Steps 3 and 4 until you have all of the required inputs for your montage.

To invert waveforms -- e.g., Left Erbs point to Right Erb’s point, and then Right Erb’s point to Left Erb’s point -- so that they will deflect upwards on the active window. To do so, you must add another input channel.

4. The amplifier gain is set in the Input Range column of the Inputs tab. To set the same input range for all of the input channels, right-click the Input Range column heading and select a value. To set different gains for different channel types, right-click a cell in the Input Range column and select a value.

For most EP recordings, an amplifier gain of ±50 - ±100 µV is generally acceptable. If too much noise is present, however, an amplifier input range of ±500 µV is advisable for EMG recordings.

5. Reject Threshold is the level at which the input (amplifier) rejects unwanted signals (e.g., from Bovie knife and bipolar cauterizers). To set the Reject Threshold, right-click the column heading or individual cells and select a value from the menu. Note that you may select a level below the Input Range, but not above. To adjust your Reject Threshold up, you must increase your Input Range.

6. To enable your speaker for EMG sound, right-click cells in the Sound column and select Off, 25, 50, 75 or 100% as desired.
7. To set the auto squelch or speaker so as not to respond below a certain level, and avoid 60 Hz hum, right-click the cells in the **Squelch** column and set a squelch threshold.
8. Click **Save**.

F) Electric Stimulators Tab

To set up the Electric Stimulators:

1. Click the **Electric Stimulators** tab.
2. To add the stimulators you want, click the **Add** button and select stimulator from the drop-down menu. Repeat until you have added all the stimulators that are needed for the test.
3. Click each cell in the **Name** column and type a name for each stimulator (e.g., “Left PTN” or “Right PTN”).
4. To select a mode of stimulation, right-click the cells in the **Mode** column and select from single pulse, repetitive pulse, triggered, free run and averaged. Note that the selected mode determines which options are available in the remaining columns.
5. To set the maximum intensity of the stimulator output, right-click the cells in the **Maximum Intensity** column and select from the available intensities (Maximum available intensity 100 mA (milliamps)).
6. To set the duration of the stimulation, right-click the cells in the **Pulse Duration** column and select from 0.05 ms, 0.1 ms, 0.2 ms, 0.3 ms, 0.5 ms, 1 ms.
7. To set the stimulus rate, right-click the cells in the **Pulse Rate** column, and select the desired rate.
8. The remaining columns allow you to set **Pulse/Train** and **Train Rate**.
9. Click **Save**.
G) AV/Ext Stimulators Tab

The AV/Ext Stimulators tab is used to set stimulation parameters for the internal Auditory/Visual stimulators and/or the external Trigger In/Out ports.

1. Use the Stimulator pull-down menu to select the type of stimulator hardware that will be used for the test. You can select either Headphones or TIPs (ear inserts).

   ! If you select tips for recording a 0.9ms stim delay will be removed from the waveform latency

2. In the Auditory section, select the type of Ipsilateral Sound that will be used for the test: Click, Pip or Tone. Depending on which option you select, you will need to refine your selection further. These are your options:

<table>
<thead>
<tr>
<th>Stimulus Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| Click         | Alternating: Select to make the click sound alternate between the rarefaction and condensation waveform type. This default setting is used most commonly during auditory stimulation.  
Rarefaction: Select to use a waveform that is in inverse proportion to the condensation waveform type.  
Condensation: Select to use a waveform that is in inverse proportion to the rarefaction waveform type. |
| Pip           | If Pip is selected, then you must type a value into the Rise/Fall Time [ms] text box. |
| Tone          | If Tone is selected, then you must type a value into the Duration [ms] text box. |
3. Select a **Contralateral Sound**. This setting allows you to select which type of stimulation to use in the ear that is opposite to the ear that is being monitored.

- **Masking Tone**: A contralateral sound used for auditory stimulation raises the threshold of audibility for the ipsilateral sound by the presence of another (masking) sound.
- **Noise**: The contralateral sound used for the test lowers the threshold of audibility for the ipsilateral sound by the presence of another random, discordant sound.
- **Silence**: No contralateral sound is used for the test if Silence is selected.

4. In the **Visual** section, set the stimulator unit for **Pattern Reversal** or **Goggles**.

- **Stimulator**: Use the Stimulator pull-down menu to select the type of stimulator hardware that will be used for the test. You can choose either Goggles or Monitor. All of the settings below are for Monitor only.
- **Modality**: The Modality pull-down menu allows you to select the visual pattern that will be used for the visual stimulation. You can choose from Stripes or Quadrants (a checker-board pattern).
- **Color**: You can specify the color of the stimulation pattern. Choose from Black, Red, Blue or Green. This feature is only available when Monitor is selected as the visual stimulator.
- **Acquire On**: Use the Acquire On pull-down menu to specify which colors will trigger the acquisition of EP data: Both, White or Color. This feature is only available when Monitor is selected as the visual stimulator.
- **Rate [Hz]**: Type a value into the Rate [Hz] text box to set the rate of the visual stimulation in Hertz.
- **Flash**: Select this box to display a gray pattern in between two quadrant/stripe patterns on the monitor.

5. Click **Save**.

**H) Timelines Tab**

Timelines are used to tell EPWorks when to start gathering a new set of waveforms. You can set your timeline to be **Interleaved** or **Consecutive**. You can further modify the timeline to run continuously; to run once and never restart; or to run on intervals. A timeline is mainly used for interleaving stimuli when using two or four-limb stimulation.
To set up one or more timelines:

1. Click the **Timelines** tab.
2. To add a new timeline row to the timelines table, click **Append**.
3. To select the type of timeline, right-click the cell in the **Type** column and select **Interleaved** or **Consecutive**. **Interleaving** causes back and forth stimulation that alternates from one side to the other.
4. In the **Restart** column, set the restart property for each cell to **Never**, **Continuous** or **On Interval**....
5. Click **Save**.

I) **Groups Tab**

The **Groups** tab is used to set up collections of traces. Each group may consist of traces that are associated with a given stimulus (e.g. L(eft) Lower SSEP, R(ight) Lower SSEP). Each group can be viewed in a separate window during acquisition or review.
To set up groups for the test:

1. Click **Append**, to add a row for a new group.
2. Enter a name for the group in the **Name** column.
3. To select a signal type for the group, right-click the cell in the **Signal Type** column and select **Free Run**, **Triggered** or **Averaged**.
4. If you select the **Triggered** or **Averaged** signal type then right-click the cell in the **Trigger (Stim)** column to select from a menu of the stimulators you set earlier.
5. Use the **Stim Delay** column to set the stimulation delay for Groups set up with **Interleaved** timelines.
6. The Stim Delay button in the bottom right corner of the Groups tab is used to automatically calculate the Stim Delay settings. The Stim Delay button does not work until after the Traces tab has been set up.
7. Sweeps/Averages is the number of sweeps that are included in the whole average. Right-click the cells in the **Sweeps/Averages** column to enter your preferred setting.
8. To set a timeline for a group, right-click the cell in the **Timeline** column and select a timeline from the menu of timelines that you setup earlier in the **Timelines** tab.
9. The **Capture** column is used to set the threshold for capturing epochs of **Free Run** data. Right-click a cell in the **Capture** column to select from the following options:
   - **Start Capturing/Recording**: Use this setting to turn Capture on and off. You can also right-click a particular waveform in a Waveform window to turn Capture on and off. When Capture is turned on, there is a checkmark beside the capture value.
   - **Threshold**: is the user-defined voltage value at which, if any data point exceeds this (and does not exceed the “rejection threshold”) the data is “Captured” and displayed. Select to enter the capture threshold in µV.
   - **Chime**: is a user defined sound that will be played whenever a waveform is “Captured”. Select a sound from the Chime menu to set a sound to play every time the waveform data meets the Threshold.
10. The **Trig. Delay** column (for triggered stimulation) sets the delay in milliseconds from the time the simulation starts to the start of the acquisition. You can set the trigger delay to both positive and negative values.

11. To set the display mode, right-click a cell in the **Disp. Mode** column and select one of the these options:
   - **Replace**: Displays the number of sets of traces that are set in the **Replace Mode** option.
   - **Vertical Curve Stack**: A maximum of 50 traces are displayed consecutively in and spaced apart vertically.
   - **Overlay**: Sets of traces are superimposed (displayed with coincident origins) in the waveform window. The number of overlaid traces is set in the **Overlay Mode** option.

12. To set the number of traces displayed in **Replace Mode** or **Overlay Mode**:
   - For an individual waveform window, right-click the background of the waveform window and click the Layout tab.
   - For all waveform windows, select **Customize** from the **Tools** menu and click the **Traces** tab.

13. To set the display stack type, right-click the cell in the Disp. Stack column and select one of the following options:
   - **Trace Stack**: Organizes the traces within the group according to the channels that are part of each group.
   - **Set Stack**: Places traces together that are acquired at the same time.

14. In the **Nb. Div.** column, set the maximum number of divisions of the waveform window grid to 10, 20 or 30.

15. Click **Save**.

**J) Traces Tab**

A trace is a collection of waveforms that is acquired through the same input channels. You can define up to 32 traces for one test. The **Traces** tab allows you to define the attributes for each trace.
To set up traces to appear in the groups:

1. Click **Append** and then select a group from the menu of groups to add a trace to the test. A new row is added to the **Traces** table.
2. To give the trace a custom name, click inside the **Name** column cell and type in a name. If you do not type in a custom name, then EPWorks automatically names the trace after the input when you select an input.
3. To define which inputs will create the trace, right-click the cell in the **Input** column and select an input from the menu. (Inputs are predefined in the **Inputs** tab.)
4. The cell in the **Group** column was set when you selected a group from the **Append** button menu. (If desired, you can change the group by right-clicking the **Group** column cell.)
5. To set the low frequency filter to filter out interference below a certain value, right-click the cell in the **LFF** column and select a setting from the menu. The range of values for LFF is 0.1 Hz to 200 kHz.
6. The high frequency filter sets a circuit to pass all frequencies above a designated cut-off frequency. Frequencies below the cut-off frequency are rejected or attenuated. Right-click the cell in the **HFF** column and select a setting from the menu. The range of values for HFF is 15 Hz to 15 kHz.
7. The Notch filter minimizes and virtually eliminates the interference from nearby electrical equipment. Right-click the cell in the **Notch** column to set the Notch filter to Off, 60 Hz or 50 Hz.
8. The sensitivity setting adjusts the sensitivity, or gain, of the channels. Right-click the cell in the **Sensitivity** column and select a setting from the menu.
9. The timebase setting adjusts the display and speed of the recording on screen. Right-click a cell in the **Timebase** column and select a setting from the menu.
10. Right-click the cell in the **Color** column to set the color of the trace when it is not active (currently acquiring data). Red is the default color for active traces.
11. By default, **Chime** is set to **<none>**. Right-click the cell in the **Chime** column to select a sound from the **Chime** menu to set a sound for a specific trace.
12. When you are finished setting up traces in the **Traces** tab, click **Save**.
13. If you have set a timeline in the **Groups** tab to interleaving, you should now set the stimulation delay. To do so, click the **Groups** tab, then click the **Calculate Stim Delay** button.
14. Click **Save**.

**K) Markers Tab**

Markers and marker definitions and calculations are set up in the **Markers** tab in the **Edit Test** window. When defined, the corresponding Marker buttons appear in the toolbar window next to the **Group** menu.

**Note that:**

- Only one marker of a given type can be placed on a particular set.
- Markers can be set to mark waveforms and to calculate latency and amplitude values.
- Markers can be set for each defined group.
To Set Up the Marker Definitions Table:

1. Click the Append button to add a row to the marker definitions table.
2. Right-click the cell in the Style column and select from:
   - Amplitude
   - Cursor
   - Latency Cursor
   - Tick with Latency Value
   - Tick with Amplitude Value
   - Tick with Latency and Amplitude Values
   - Labeled Tick with Latency Value
3. Then right-click the cell in the Placement column and select from:
   - Manual
   - Peak
   - Trough
   When selecting Peak and Trough, enter the appropriate values in the From (ms) and To (ms) columns.

Note that five milliseconds on either side of the expected latency of the waveform are generally acceptable.

4. Enter the values in the From (ms) and To (ms) column’s cell to indicate when the marker begins and ends. The default value is 0 ms and 15 ms respectively.
5. To attach the marker to a specific trace, right-click the cell in the Trace column and select the trace from the menu displayed.
Note that you can set up as many markers as required for the test.

To Set Up the Calculations Table:

1. Click the Append button to add a row to the marker calculations table.
2. You can enter a name for the calculated result in the Name column. If a name is not entered, EPWorks will automatically assign a name based on the markers selected in the From and To columns.
3. Right-click the From cell to select the second marker. The result is calculated as (To - From).
4. If you plan to select Amplitude in the Type column in Step 3, then right-click the To cell to select the first marker. Note that it is not necessary to set a value in the To column, if you select Latency calculation in the Type column in Step 3.
5. Right-click the Type cell and select either Amplitude or Latency calculation type.
6. Click Save.

L) Reporting Tab

1. The Test-Specific Templates listed in the Template window are applicable to this test.
2. Click the Add button to begin creating your customized Test-specific Template.
3. This box lists the Default Template for the named test. In this example, no default has been selected from the drop-down list.
4. Click on the Global Templates button to view the list of all available Global Study and Test Templates (i.e., templates that can be used for any tests).
Data Acquisition

Types of Recordings
The following types of recordings can be performed with Protektor 32:

- Somatosenory Evoked Potentials (SSEP)
- Transcranial Motor Evoked Potentials (TcMEP)
- Visual Evoked Potentials (VEP)
- Brainstem Auditory Evoked Potentials (BAEP)
- Electromyography (EMG)
- Electroencephalography (EEG)

Live Data Recording Window Overview

In Acquisition, the History window can be viewed while live data is being recorded, thus allowing you to compare the present waveforms with those collected in previous tests.
Acquisition Toolbar

See the Toolbar Buttons chapter for the definition of the buttons.

Stimulators Window

The Stimulators Window allows you to set the duration, rate, and intensity of individual stimulators while the study is on-going.

Groups Window

The Groups window allows you to start and stop the recording of data /acquisition of data. For each group in your test, the Groups window reports the number of sweeps accepted (NA column) and the number of sweeps rejected (NR column) for the current set being acquired / recorded. To start or stop acquisition for a specific group, click the check box in the Type column. For triggered or averaged groups, you must also start the appropriate stimulator in the Stimulators window in order to acquire waveforms.
Waveform Window

The waveform window shows the results of your test in *traces* and *sets* of waveforms that are assigned to *groups*.

In recording mode, the title bar shows whether the data in the waveform window is **Live** (currently being acquired) or **Historical** (a snapshot of data that was acquired at an earlier point in the study). The Timebar displays historical data in the waveform window.

1. Title bar shows that this data is Live
2. Group menu is visible if more than one Group is assigned to the window. The Group menu is hidden if only one Group is assigned
3. Marker Buttons
4. Sett Calculations
5. Sizing Handle (used to show or hide Set Calculations)
6. Waveform Label
7. Scroll Bar (used to move window contents up/or down)
8. Sizing Handle (used to make window larger or smaller)
9. By default, a red trace is active.
10. By default a green trace is the baseline.
11. By default a blue trace is selected.
12. Trace Label.
13. Marker
15. Zoom Out/In.
**Waveform Display Mode – Menu Options**

To view or change the display mode of a group in a waveform window, right-click a trace label and select **Display Mode** from the pop-up menu.

The two main display mode categories are **Traces Stack** and **Sets Stack**. You can toggle between viewing the waveforms in **Traces Stack** or **Sets Stack** mode by clicking the first item on the **Display Mode** pop-up menu.

1. **Trace Label**
2. **Display Mode Menu**
   - **Display Mode**
   - **Show All Waveforms**
   - **Distribute Waveforms**
   - **Delete Waveforms**
   - **Trace Enabled**
   - **Properties**
3. **Display Mode**
   - **Sets Stack**
   - **Vertical Curve Stack**
   - **Overlay**
   - **Replace**

Click to change **Display Mode** from **Mode** from **Traces Stack** to **Sets Stack**.
**Traces Display Mode**

Waveforms are displayed sequentially in time according to the display mode of the group. A maximum of 50 traces are displayed consecutively. –See below examples of traces Stack. Note that traces can also be displayed as Sets Stack.

<table>
<thead>
<tr>
<th>Display Mode</th>
<th>Illustration</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical Curve Stack</td>
<td><img src="image1" alt="Vertical Curve Stack Illustration" /></td>
<td>Single traces</td>
</tr>
<tr>
<td>Overlay</td>
<td><img src="image2" alt="Overlay Illustration" /></td>
<td>Sets of superimposed traces.</td>
</tr>
<tr>
<td>Replace</td>
<td><img src="image3" alt="Replace Illustration" /></td>
<td>Each new acquired waveform replaces the previous one.</td>
</tr>
</tbody>
</table>
Using Markers

To place a marker on a waveform:

1. Select a Marker button.
2. Move the pointer to the desired position and click. The marker is placed on the waveform. Calculations for the marker appear in the marker calculation results section of the waveform window.
3. Repeat steps above to place as many markers as required for the test.

- To change the location of a marker, click the marker on the waveform window and hold down the left mouse button as you drag the marker to a new location on the waveform. Note that the calculation results are automatically updated as you move the marker.
- To delete a marker, click the marker to select it and then press the Delete key on the keyboard.

Marker Calculations Table

To see the marker calculations table, click the gray bar (sizing handle) and hold down the left mouse button as you drag the gray bar down.
To access the Marker Calculation options pop-up menu, right-click a cell in the marker calculations table.

- Show Absolute Marker Value
- Show Difference To Baseline
- Show Percent Difference To Baseline
- Print Table of Values

--Marker Calculations Table – Options Menu

Measuring Waveforms with Cursors

The Cursors toolbar provides a quick way to measure and compare points on a waveform. Open the View menu and select Toolbars > Cursors.

**Cursors Toolbar**

<table>
<thead>
<tr>
<th>Menu Item</th>
<th>Toolbar Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latency Difference</td>
<td><img src="image" alt="Latency Difference" /></td>
<td>Measures the time difference in milliseconds from one point on a waveform to another in the active waveform window (Inter-Peak Interval).</td>
</tr>
<tr>
<td>Amplitude Difference</td>
<td><img src="image" alt="Amplitude Difference" /></td>
<td>Measures the difference in voltage of the amplitude between two points on a waveform in the active waveform window.</td>
</tr>
<tr>
<td>Absolute Latency</td>
<td><img src="image" alt="Absolute Latency" /></td>
<td>Measures the time in milliseconds of a particular point on the waveform in the active waveform window or history window.</td>
</tr>
<tr>
<td>Absolute Amplitude</td>
<td><img src="image" alt="Absolute Amplitude" /></td>
<td>Measures the amplitude voltage of a particular point on the waveform in the active waveform window as compared to the baseline.</td>
</tr>
</tbody>
</table>

- See Protektor 32 Reference Manual for further description on the Waveform Window Properties: General Tab; Layout Tab; Misc Tab; Option Menus.

Each trace can have only one baseline waveform. A baseline waveform may belong to more than one set.

You can enable the option to run multiple stimulators in the Customize: Stimulators Tab. When running multiple stimulators, electric and external stimulators cannot run at the same time. Furthermore, no more than one external stimulator can be run at a time.

All other stimulus parameters (Audio: stimulus type, noise type, etc. and Visual: goggles vs. monitor, color, etc) must be set by opening the Edit Test window and selecting the AV/Trigger In/Out ports Tab.
To run multiple Timelines at the same time:

1. Open the Stimulators Properties window, select Customize... from the Tools menu and click the Stimulators tab.
2. Select the Enable running multiple timelines and stims option and click OK.

When you run the test, you will now be able to independently start / stop / pause / continue the timelines.

A timeline clock appears when stimulation is paused for a set interval to show when the stimulation will restart.

For information on the Timebar, Log Book, and the History window features, see the Reviewing a Study section.

Impedance Check

The impedance check can be performed at any time during a study. Note that when you check the impedance, a new Impedance Check note is inserted in the Log Book and on the Timebar.

To perform an Impedance check, follow the steps below:

1. Click the Impedance Check button on the Settings toolbar.
2. Select the impedance Threshold Value.
3. To check a single channel, select the option next to the desired channel. To check all of the channels, click the Scan All button.
4. To stop the impedance check and return to the test, click the Exit button.
EEG / Spectral Windows

EEG Live Window

The EEG Live window displays EEG data according to the currently active montage settings. Montages are set up in the Montage tab of the Edit Test window.

You can edit the channel settings temporarily in the settings option menu in the EEG waveform window. Note that channel settings made with the waveform setting option menu, do not affect the settings for the test.

EEG Review Window

The EEG Review window allows you to review all of the EEG data collected during a study.

Reviewing EEG Data

- **Toolbar**: Use the Toolbar to navigate through the recorded EEG data.
- **Notes**: Notes added during the study are shown in the EEG Review trace display.
• **Time Mark:** You can use the mouse to drag the time mark line to a particular point.

• **Time Stamp:** The Time Stamp in the title bar automatically updates to reflect the current position of the time mark line.

• **Right and Left Arrow Keys:** The right and left arrow keys on your keyboard allow you to move the trace display forward and backward.

• **Timebar:** By default, the EEG Review window is linked to the Timebar.

• When the position of the Timebar slider changes, the EEG Review window is refreshed to display data from that point in the study.

• **Lock Button:** Click the **Lock** button to toggle the link between the Timebar and the EEG Review window on and off. When the Lock button is OFF, you can double-click a note on the Timebar to jump the EEG Review window display to the time in the study where that note was applied.

### EEG Review Window Overview

1. Current time location of the Time Mark line.
2. Time Mark line can be dragged with the mouse.
3. Trace Display
4. Resizable Borders
5. Montage Channels
6. Move Handle
7. Play forward
8. Page forward
9. Stop Play
10. Page Backward
11. Play Backward
12. Select Lock to prevent this window from being linked to the Timebar Slider position.
Spectral Window: CSA and DSA EEG

Raw EEG is processed using FFT (Fast Fourier Transform) technique and displaying the EEG spectrum. The EEG frequency spectra are displayed as Power (μV^2) or Amplitude (μV) as a function of frequency.

The Spectral Window displays frequency characteristics of previously defined EEG traces in Compressed Spectral Analysis or Density Spectral Analysis formats.

The Spectra Settings of the CSA and DSA windows allow you to define their Display, Processing, and General properties. --To open the CSA/DSA Properties, right-click the background of the CSA/DSA Window and select Properties....

**Compressed Spectral Analysis (CSA) Window**

1. Montage Channel Label
2. Frequency Area
3. Time Axis
Density Spectral Analysis (DSA) Window

1. Montage Channel Label
2. Spectral Edge
3. Frequency Axis
4. Power Axis is shown in the display of color.
5. Time Axis
Quadrant-DSA Window

The Quadrant Density Spectral Analysis Window displays density spectral analysis groups in quadrants. -
- To see results in the Quadrant-DSA window, Quadrants must be set in the Edit Test -- Montage tab
window. To open the Quadrant-DSA Properties, right-click the background of the Quadrant DSA
Window and select Properties....

1. Quadrant
2. Time Axis
3. Power Axis Color
   Palette
4. Power Axis is shown
   in the display of color.
5. Frequency Axis
Spectral Review Windows

All Spectral Windows –CSA, DSA, Q-DSA– can be viewed in Review mode.

Use the Timebar to move back and forth in time as you Review your Spectral Window.
Reviewing a Study

To review a study:

1. Close all active windows by selecting Close Study from the File menu.
2. Select Review from the File menu.
3. Select a file to review from the Open dialog box.
   - If Last study directory is selected in the Review/Resume section of Customize > Options, then the most recently acquired study will appear in the File Name field of the Open dialog box.
   - If Patients main directory is selected in Customize > Options, you will need to browse for the patient file that you wish to review. Then double-click the file folder and select the patient's *.iom file (e.g., John,Smith.iom).
4. Once you have located the file you wish to review, click Open. The study file, in review mode, is then displayed.
   - To browse for a different file, click the arrow button in the Look in: list box and select the Patients directory. From the Patients directory displayed, select the file that you wish to review and click Open.
5. In Review mode, you can:
   - Use the Timebar to navigate through the study;
   - Review the notes in the Log book;
   - Review calculations in the Trending Window;
   - Review sets of traces in the History Window;
   - Review acquired EEG data in the EEG Review Window.
**Timebar**

The **Timebar** displays an overview of the entire study allowing you to review it and access its information.

Note that the Timebar feature is available in Recording and Review modes.

**Timebar Overview**

1. Note Ticks  
2. Impedance Check Tick  
3. Transition between tests  
4. Baseline Tick  
5. Slider sits at the point in the study that is shown in the waveform windows  
6. Previous Set
7. Historical Test Section (Gray) 8. Current Test Section (Yellow)
9 Live Study Section (Aqua) 10. Next Set

11. In Recording mode, the slider jumps back to live study section. In Review mode, the slider jumps to the end of the study.

**The Timebar can be linked to the following windows:**

- Waveform
- Log Book
- History
- Trending
- EEG Review

By default, all of the above windows (except History) are linked to the Timebar. To enable/disable the link, use the option menu or the Timebar toolbar button.

**The Timebar displays:**

- All tests that have been used in the course of a study including active (currently live) and inactive (historical) tests.
- All of the notes in a study.
- Baselines
- Impedance checks

When you left-click the Timebar, a watch symbol appears beside the pointer. Note that if you hold down the left-mouse button, the Timebar will not be updated until you release it.

To see an information box about any point on the timeline, roll the pointer over the area or click a point of interest.

For information on Timebar Navigation Buttons; Timebar Option Menus; Timebar Ticks; see Protektor 32 Reference Manual.
Log Book

The Log Book keeps a record of all notes that are added to the test, as well as the particular waveform, if any, that each note is associated with.

Note that the Log Book feature is also available in Recording mode.

1. Note that pertains to whole test.
2. Note that is attached to waveform.
3. Time that the note was applied.
4. For notes linked to waveforms, shows the trace label, set # and acquisition time.
5. Drag the line between headings left or right to change the width of a column.
6. Add a general note to the test by selecting from the Notes menu or creating a custom note.
7. Delete a note.
8. Open the Edit Notes dialog box to change the title, add comments or add link the note to a waveform.

1. Note that pertains to whole test.
2. Note that is attached to waveform.
3. Time that the note was applied.
4. For notes linked to waveforms, shows the trace label, set number and acquisition time.
5. Drag the line between headings left or right to change the width of a column.
6. Add a general note to the test by selecting from the Notes menu or creating a custom note.
7. Delete a note.
8. Open the Edit Notes dialog box to change the title, add comments or link the note to a waveform.
Trending Window Overview

The Trending window is used to display ordered sequences of calculations for the markers on each of your tests.

1. Trending Display Configuration button: Currently set to display All Calculations. Click to narrow the display to specific groups or markers.
2. Sets number of minutes of data displayed in the graphs.
3. Graphic is set to points display type.
4. Graphic is set to vertical bars display type.
5. Reading Gap is compacted and framed by dotted blue lines.
6. Move the Scroll box left or right to view more data.
7. Status bar messages change according to the position of the mouse pointer.
8. Delimeter Bar
9. Graph Titles show Marker Label <Group Title>.
10. Red graph heading shows that graph points exceed user’s allowed level.
11. Graph points show marker calculation for each set.
12. Time Scale
13. Red triangle exceeds user’s defined levels. – i.e., “Out of Range Level”.

History Window Overview

The History window allows you to review all of the waveforms/traces that were acquired over the course of a study, including those that were deleted when the maximum number of sets for a waveform window was reached.

The waveform baseline will be shown with the most recently acquired waveform visible right above it.

Note that in Review, the History window can be enabled allowing you to compare present data with previously recorded tests.

History Window – All Traces

1. Refresh/Stop Button
2. Status Box currently shows Time Scale Start Time
3. History Display Configuration Selection Button
4. Cursor (marker) calculations are green (by default).
5. Reading Gap
6. Move the scroll box left or right to view more data
4 Time Scale Size
5 Toggle time scale units between minutes and seconds.
6 Adjust All Gains
7 Float Notes
8 Waveforms are yellow (by default).
12 Status bar messages change according to the position of the mouse pointer.
13 Move display to end of time scale.
14 Step start of time scale forward.
15 Step start of time scale back.
16 Move display to beginning of time scale.
Reports

Creating Generic Reports

Each EPWorks Report is generated using two different types of Reporting Template:

- Study Template: includes information inserted from the Patient Study – e.g., Patient Information and Case Summary.
- Test Template: includes collected data from your Patient Study – e.g., waveforms and calculation tables for each group.

After you have completed a Patient Study, click the Reporting button on the toolbar. From the Select Report Templates list, select the tests that you wish to include in your Report and click OK. Your Report will then be generated.
Remote Monitoring

Before You Begin

Before you can begin using XLTEK Portals software (i.e. LocalPortal and RemotePortal), consult your hospital or institution's IT department to configure the appropriate IP addresses, subnet masks and default gateways.

To verify that all your computers are connected and that you will be able to run XLTEK Portals software successfully, it is advisable to run Microsoft Netmeeting first.

To open Microsoft Netmeeting, go to:

Start > Programs > Accessories > Communications

To adjust your Audio and Video parameters, select:

1) Adjusting Audio Parameters for Remote Monitoring
2) Adjusting Video Parameters for Remote Monitoring

Once you have run NetMeeting successfully and adjusted your Audio and Video parameters, you are ready to start using XLTEK LocalPortals (on the Acquisition System) and RemotePortals software (on the Remote System) and begin Remote Monitoring.

XLTEK Portals

LocalPortal

LocalPortal is the XLTEK Remote Monitoring software that is run on the Local or Acquisition Station (i.e. the computer that is acquiring the patient data). This software enables data to be sent to one or more Remote Monitoring Stations (i.e. to computers that are observing the Acquisition Station).

To open the LocalPortal software, go to Start > Programs > XLTEK and select Local Portal.

It is important that you properly configure your LocalPortal software to optimize the performance of your Remote Monitoring capability.

RemotePortal

RemotePortal is XLTEK's Remote Monitoring software that is run on the Remote Station (i.e. the computer that remotely observes the Acquisition Station). The RemotePortal software enables the Remote Station to receive live waveforms (EP, free run EMG, triggered EMG, EEG) as well as historical waveforms. The software also supports the transmission of text messages.

To open the RemotePortal software, go to Start > Programs > XLTEK and select Remote Portal.

In Options, under Nickname, specify the name that the Acquisition Station will see.

When right-clicking the name of an Acquisition Station in your list, an information box with details about the case currently being acquired will appear over the Remote Portal window. To remove the information box from the screen, click on it with your mouse.
Multiple Connections

You can monitor more than one Acquisition Station by more than one Remote Station. The following configurations below are the available:

Both Local Portal (LP) and Remote Portal (RP) can run on the same station at the same time.

- RP can connect to several acquisition stations (nLP) and monitor them at the same time (one-to-many monitoring).
- LP can accept several observers (nRP) at the same time (many-to-one monitoring).
- Above three points give many-to-many monitoring where all topologies (including loops) are allowed.
- LP-nRP textual chat.

Additional Information and Terms

Bandwidth – is the total amount of EPWorks data being sent to the observer (the units are in bytes/second

- Messages – refers to how many messages per second are being sent to the observer (data is passed in messages)
- Queue – refers to how many messages are currently in the process of going across to the observer
- Remote monitoring Optimizations – These are all optimizations that can reduce system load and network load both on the acquisition system and the remote system
  - SSEP by default, not every single “intermediate” sweep is send of an averaged waveform in order to save bandwidth. The user can specify how frequently the intermediate sweeps are sent (final completed sweeps are always sent).
  - Update free run EMG every n seconds – this saves network bandwidth by sending sweeps every few seconds. The user can specify 0 and it will send the data as soon as they have it.
  - Accumulated EEG – this specifies how “smoothly” the EEG on the remote system will be displayed. The more frequently it is sent, the more the network bandwidth it will use.
- Remote Monitoring – Physician will be able to add notes directly into the patient record “log book” while connected remotely.
- Connectivity – a message will appear on both the acquisition system and the remote monitoring system if a network connection is lost and also when the connection is reestablished.
Video Microscope

A video of the microscope feed can be obtained by connecting the Protektor32 Microscope Integration Kit.

To open the microscope view click View tab and then Microscope. Once the video is displayed you will have the option to record video segments up to 10 minutes at a time. To record, click on the red record button on the bottom left of the screen. Both the start and stop time of the video clip will be displayed in the “Log Book”.

To replay the recording, double click on the video clip of interest in the “Log Book” and click the play/stop button located in the time bar on the bottom of the video.

The video image will appear if you take a screen shot.
# Toolbar Buttons

<table>
<thead>
<tr>
<th>Toolbar</th>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Controls</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Averger" /></td>
<td>Averager On/Off</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Free" /></td>
<td>Free Run Acquisition On/Off</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Trigg" /></td>
<td>Triggered Acquisition On/Off</td>
</tr>
<tr>
<td><strong>Sets</strong></td>
<td><img src="image" alt="Stop All Stimulators" /></td>
<td>Stop All Stimulators.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Delete" /></td>
<td>Delete Set and Restart Averager</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Keep" /></td>
<td>Keep Current Set.</td>
</tr>
<tr>
<td><strong>Cursors</strong></td>
<td><img src="image" alt="Latency" /></td>
<td>Latency Difference Cursor</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Amplitude" /></td>
<td>Amplitude Difference Cursor</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Absolute Latency" /></td>
<td>Absolute Latency Cursor</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Absolute Amplitude" /></td>
<td>Absolute Amplitude Cursor</td>
</tr>
<tr>
<td><strong>Customize</strong></td>
<td><img src="image" alt="Study Information" /></td>
<td>Study Information</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Create Report" /></td>
<td>Create Report</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Customize" /></td>
<td>Customize</td>
</tr>
<tr>
<td><strong>Settings</strong></td>
<td><img src="image" alt="Impedance" /></td>
<td>Impedance Test.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Edit Test" /></td>
<td>Edit Test</td>
</tr>
<tr>
<td><strong>Layouts</strong></td>
<td><img src="image" alt="Record Layout" /></td>
<td>Record Layout.</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Select Layout" /></td>
<td>Select Layout.</td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td><img src="image" alt="Sound On/Off" /></td>
<td>Sound On/Off Mute</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Increase /Decrease Sound" /></td>
<td>Increase /Decrease Sound</td>
</tr>
<tr>
<td><strong>Camera</strong></td>
<td><img src="image" alt="Current Screen Snapshot" /></td>
<td>Current Screen Snapshot</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Select Snapshot" /></td>
<td>Select Snapshot.</td>
</tr>
</tbody>
</table>
**Accessories**

Protektor32 systems can be used with the following types of electrodes:

- Disc Electrodes
- Needle Electrodes
- Corkscrew Electrodes
- Bar Electrodes
- Pedicle Screw Probe

EEG accessories which can be used with the Protektor32 amplifier are available for you to browse the Natus Neuro Catalog online at [www.natus.com](http://www.natus.com) or call Natus Sales and Support at 1-800-303-0306. The following are compatible accessories:

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>002514</td>
<td>P32 - TCMEP Pod (Cr)</td>
</tr>
<tr>
<td>002978</td>
<td>Protektor 32 - Isolation Box</td>
</tr>
<tr>
<td>002979</td>
<td>Protektor 32 - Stimulation Box</td>
</tr>
<tr>
<td>002980</td>
<td>Protektor 32 - Acquisition Box</td>
</tr>
<tr>
<td>003708</td>
<td>Probe Pod - P32 (Cr)</td>
</tr>
<tr>
<td>005030</td>
<td>P32 Cautery Detector (Cr)</td>
</tr>
<tr>
<td>005031</td>
<td>Protektor 32 Visual Stim LED Goggles</td>
</tr>
<tr>
<td>010384</td>
<td>P32 Pulse Oxi LP Cable (Cr)</td>
</tr>
<tr>
<td>006640</td>
<td>P32 POWER SUPPLY</td>
</tr>
<tr>
<td>005562</td>
<td>P32 Ear Inserts (Cr)</td>
</tr>
<tr>
<td>W8194X</td>
<td>USB 2.0 6FT HI SPEED GOLD</td>
</tr>
<tr>
<td>A1011X</td>
<td>Power Cord, Unshielded, 10ft</td>
</tr>
<tr>
<td>005032</td>
<td>P32 AUDITORY STIM HEADPHONES</td>
</tr>
<tr>
<td>005029</td>
<td>PROTEKTOR 32 TRIGGER I/O CABLE (Cr)</td>
</tr>
<tr>
<td>004878</td>
<td>PROTEKTOR 32 STRAP WITH HOOKS</td>
</tr>
</tbody>
</table>

**WARNING:** The use of accessories, transducers, or cables other than those specified or provided by XLTEK could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:** The Protektor32 headbox accepts only touch-proof style electrode inputs. Do not attempt to use any other style of patient electrode input.
<table>
<thead>
<tr>
<th></th>
<th>The Protektor32 must be used only with legally marketed electrodes in the country where in use. For instance, in the United-States use only FDA approved, legally marketed electrodes. In Canada use only Health Canada approved legally-marketed electrodes; in EU countries use only CE approved legally marketed electrodes.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All electrodes in a single patient setup should be made of the same metal. Do not use two different or dissimilar types of metals in a single setup.</td>
</tr>
</tbody>
</table>
A total service solution

Standing behind every Xltek product is Natus Medical Incorporated, an internationally respected innovator of medical products and services.

Our Neurology systems are backed up by an in-house support team staffed with technical and clinical experts, 24/7 support, remote support via WebEx or VPN, the largest clinical and technical field support network in Neuro/Sleep and customized service contracts that include preventative maintenance visits and computer upgrades.