XLTEK EEG32U

User and Service Manual

Publisher's Notice

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XLTEK EEG32U

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ISO 13485 Certified

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Introduction

The ***XLTEK*** **EEG32U** amplifier offers advanced signal acquisition capabilities for accurate data acquisition with 1kHz sampling rates and 16 bit analog-to-digital data conversion. The highest signal-to-noise ratios and fast recovery from saturation for stable baselines are available with the **EEG32U**. This rugged device was designed with extensive clinical input to meet the workflow and application needs of the basic EEG Lab.

EEG32U features include:

- USB connectivity to XLTEK Desktop or Laptop
- 32 referential channels
- Patient-event switch interface
- Photic-stimulator interface for EEG applications

WARNING: We strongly recommend that you read the **Warnings and Cautions** section of this manual before operating this amplifier.

Product Intended Use

The **EEG32U** Amplifier is intended to be used as an electroencephalograph to acquire, display, store and archive electrophysiological signals. The amplifier should be used in conjunction with ***Natus*** NeuroWorks™ software to acquire scalp electroencephalographic (EEG) signals.

The **EEG32U** Amplifier is intended to be used by trained medical professionals, and is designed for use in clinical environments such as hospital rooms and epilepsy monitoring units. It can be used with patients of all ages, but is not designed for fetal use.

Essential Performance

Essential performances of the EEG32U amplifier are identified in the standard IEC 60601-2-26:2012. Essential performance relates to the quality of the signal recorded from the amplifier. Specific essential performances are:

(1) accuracy of signal reproduction
(2) dynamic range and differential offset voltage
(3) input noise level
(4) frequency response
(5) common mode rejection

The definition of these essential performances can be found in the standard.

Using the Manual

This manual describes the theory, features, set up, operation and maintenance of the **EEG32U** amplifier. It also provides information on specifications, troubleshooting and getting help.

When reviewing the procedures, we recommend you read the entire section first, before beginning a sequence. Please follow the instructions carefully.

Manual Conventions

Various symbols and typographical conventions are used throughout the manual. The following table illustrates them and describes their meanings and functions.

Symbol/ Convention	Description/Function
	This symbol denotes a warning or important information that should not be missed. Read all warnings and cautions carefully before starting the system for the first time.
	A note that contains important supplemental information.
Bold	Names of control keys, function keys, options, and labels are shown in bold. Bold text is also used to emphasize important names or ideas.
Italic	Italic text is used for captions.

Specifications: EEG32U Amplifier

Specification	Value(s)
Analog Specifications Channels	
Referential Channels	32
Differential Input Impedance	≥ 100 MOhms
Common Mode Input Impedance	≥ 50 MOhms
Common Mode Rejection Ratio	-≥ 110 dB @ 60 Hz
Channel Bandwidth	0.1 Hz to 400 Hz
Input Noise (peak to peak)	3.0 µV @ 0.1Hz~70 Hz bandwidth
Input Noise (RMS)	0.65 µV @ 0.1Hz~70 Hz bandwidth
EEG Channel Hardware Gain	125
Maximum Differential AC Input Before Clipping (Referential)	± 20 mV
Maximum Operational DC Input Voltage Electrode Offset	± 1000 mV
Input Bias Current	≤ 20 pA
Channel Crosstalk	≥ 70 dB
Photic Stim Interface	
Photic Stim Output	1 (TTL level, active high)
Photic Stim Input	1 (TTL level, active high)
User Interface	
Push Buttons	1 (Impedance Check)
Event Switch Connection	1 on board
LED Indication	68 on board.
Digital Specifications	
Sampling Frequency	256, 512 and 1024 Hz
Sampling Resolution - EEG Channels	16 bits
Sampling Quantization - EEG Channels	600 nV

Specification	Value(s)
Modes of Operation	
Power Consumption	<1 W @ 5 V
Impedance Check	< 2.5, < 5, < 10, < 25 KOhms
Channel Test Signal	Programmable Sine: 16-32 Hz, 158-10110 µV peak-to-peak Square: 0.25-0.5 Hz, 50-6400 µV peak-to-peak
Host Interface	
USB 2.0	USB 2.0 Full Speed (12Mbit/sec).
Amplifier Mechanical	
Interface Cable	USB 2.0 cable, maximum 3m
Approximate Size	160 mm (l) x 97mm (w) x 29mm (d)
Environmental Conditions for Use	
Operating Environmental Limits	Temperature: 10° to 40°C
	Relative Humidity: 30%-75%
	Atmospheric Pressure: 700 hPa-1060 hPa
Transport and Storage Temperature Range	- 25°C to 60°C
Transport and Storage Humidity Range	10-95%, including condensing
Transport and Storage Atmospheric Pressure Range	500 hPa to 1060 hPa

EEG32U Safety and Standards Conformity

Standards of Compliance and Normative References

32 Channel Electroencephalograph (EEG) Headbox; model EEG32U; rated 5Vdc,0.2A

1. Type of protection against electric shock: Class II
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 **EEG32U** and its accessories have been designed to comply with the following national and international standards.

Table 1 – Safety Standard of Compliance and Normative References

CAN /CSA-C22.2 No. 60601-1: 08(R2013) + C2:2011 ANSI/AAMI ES60601-1:2005/(R)2012 + C1:2009/(R)2012 and A2:2010/(R)2012 IEC 60601-1:2005 + C1:2006 and C2:2007, Third Edition CENELEC EN 60601-1:2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010, Edition 3.0	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366:2007, Edition 1.0	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-26:2012, Edition 3 CENELEC EN 60601-2-26L2003, Edition 2	Medical electrical equipment – Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 80601-2-61:2011, Edition 1	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Table 2 – EMC Standard of Compliance and Normative References

IEC 60601-1-2, Edition 4.0, February 1, 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– collateral standard: electromagnetic compatibility – requirements and tests

IEC 61000-4-2:2008, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3 ed 3.0 with A1:2007+A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2012, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2014, ed 3.0	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6 ed 2.0 with A1:2004 + A2:2006	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004, ed 2.0	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:2014, ed 4.0	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2013, ed 3.0	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11 ed 5.0 with A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

Declaration of Compliance for IEC 60601-1-2

Table 1 - Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The EEG32U is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG32U should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The EEG32U 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
RF emissions CISPR 11	Class A	The EEG32U 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 - Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The EEG32U is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG32U should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV, 100Khz for power supply lines ±1 kV, 100Khz for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods 40% dip for 5 cycles	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EEG32U requires continued operation during power mains interruption, it is recommended that the EEG32U be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC supply voltage prior to application of the test level.			

Table 3 - Electromagnetic Immunity– for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The EEG32U is intended for use in the electromagnetic environment specified below. The customer or the user of the EEG32U should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EEG32U, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \times \sqrt{P}$ 150kHz to 80MHz $d=1.2 \times \sqrt{P}$ 80MHz to 800MHz $d=2.3 \times \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site[1] should be less than the compliance level in each frequency[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EEG32U is used exceeds the applicable RF compliance level above, the EEG32U should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the EEG32U.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1,720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1,845						
1,970						
2,450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5,500						
5,785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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.

Warnings and Cautions

General Warnings

NOTE: It is recommended that all data be stored using redundant storage capabilities. This can help to minimize data loss in the event of a failure of the primary drive.

!	Proper use of this device depends on careful reading of all instructions and labels that come with or on the system.
!	The EEG32U headbox is classified as an IPX0 – ordinary degree of protection against ingress of water according to IEC 529. The EEG32U is not water proof.
!	Inaccurate measurements may be caused by incorrect application or use.
!	Only qualified personnel should operate this equipment.
!	Only use the **EEG32U** amplifier in conjunction with approved devices and accessories. Use of cables other than those specified or sold by the manufacturer on the equipment, may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2007
!	The computer and the peripherals used with the EEG32U headbox and the NeuroWorks EEG system must either be approved by ***XLTEK*** and supplied as part of an IEC 601 approved system or it must be approved to IEC 950 or similar and kept outside of the patient environment (that is, the area within 1.5 meters of the patient laterally and within 2.5 meters of the floor in the area occupied by the patient).
!	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
!	Turn off the system power before cleaning. Prevent detergent solution or cold sterilization agents from seeping into the electronics of the system. Be careful around all connectors and edges. Do not use abrasive agents.
!	The accessories of this device may include several kinds of disposable, sterile needle electrodes. These needles may be labeled as **STERILE**. The EEG32U is not sterile and cannot be made sterile.

	The sale, distribution, or use of this device is restricted to, by, or on order of a physician.
	**WARNING:** Third-party software installed on the acquisition computer may interfere with the operation of the Natus software. Please consult Natus Technical Support before installing third-party software on the computer.
	This device does not contain any hazardous components; therefore, no special precautions are required for their disposal.
	**WARNING:** No modification of this equipment is allowed.
	The EEG32U system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the amplifier should be observed to verify normal operation in the configuration in which it will be used.
	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 EEG32U System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electrical Warnings and Cautions

	***XLTEK*** systems are intended for connection to a properly grounded electrical outlet only.
	The EEG32U is an electrically isolated, electrically floating device. The computer that is part of the system should be attached to a properly grounded electrical outlet.
	Conductive parts of electrodes and their connectors are not to contact other conductive parts and earth.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** connect electrode inputs to earth ground. The patient headbox contains warning symbols reminding you that the connections are intended for isolated patient connections only. Connecting an earth ground might result in electrocution.
	**ELECTRICAL SHOCK HAZARD:** Do **NOT** turn on the system power until all cables have been connected, verified and visually inspected for any damage. Failure to inspect the cables may result in electrocution. Verification of electrical safety should be performed routinely.

	**ELECTRICAL SHOCK HAZARD:** Do **NOT** service the system. Refer servicing to qualified personnel only. Do **NOT** use repaired components without proper testing.
	The computer attached to the EEG32U should use a three-wire power cord with a hospital grade plug. For grounding reliability, only connect the device to a hospital grade or hospital-only receptacle. Inspect the power cord often for fraying or other damage. Do **NOT** operate the system with a damaged power cord or plug.
	If there is an isolation transformer with the system, do **NOT** place the isolation transformer on the floor. Only plug XLTEK recommended components into the isolation transformer.
	Do NOT connect non-medical equipment which has been supplied as part of the system directly to the wall outlet when the system is supplied, via MPSO, with a separating transformer.
	Do NOT connect electrical equipment which has not been supplied as a part of the system to the MPSO.

Patient Environment Warnings and Cautions

NOTE: The patient environment is defined as the area within 1.5 meters of the patient laterally and within 2.5 meters of the floor in the area occupied by the patient.

	Connect all patient electrodes to fully electrically isolated physiological devices only. Connecting patient electrodes to any other device or external outlet may result in personal injury.
	The patient headbox accepts only touch-proof style electrode inputs. Do **NOT** attempt to use any other style of patient electrode input.
	To prevent cabling entanglement/strangulation, ensure no loose cables are accessible to the patient.
	No parts of the ME equipment shall be serviced or maintained while in use with a patient.
	Patient connections are **NOT** intended for direct cardiac contact.
	Do **NOT** touch any earth-grounded components of the EEG32U amplifier and the patient simultaneously.

	Do not use the EEG32U amplifier in the vicinity of MRI or CT systems.
	Do not use the EEG32U amplifier with HF surgical equipment.
	Do not allow loose electrodes to contact metal parts.
	The **patient event switch** attached to or on the **EEG32U** or other XLTEK device is not intended for critical patient-safety-related incidents.
	Do **NOT** use the XLDetect montage with custom channel labels.
	As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Transportation Warnings

	Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.
	**TIPPING HAZARD:** During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

Conducted Immunity Warnings

	In environments where parasitic electrical noise interferes with the electrical biologic signal, there is no risk of misinterpretation of EEG waveforms or ancillary data. Any abnormal pattern or out of range value is confirmed by trained medical professionals performing the test. In addition to ancillary data, the accompanying EEG (Electroencephalograph) amplifier's signals will also be contaminated past the point where any clinical signal interpretation is possible. Trained electroencephalographers and technologists are well equipped to identify and disregard signals that are obscured by environmental noise.

Procedures and Warnings

Electrostatic Discharge (ESD) Handling

Before performing any setup or placement procedures, read the precautions outlined in this section.

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: 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: Misaligned connector pins can cause damage to system components at power-on.

Conducted Immunity Procedures and Warnings

Conducted immunity is defined as the ability of an electronic product to tolerate the influence of electrical energy from other electronic products or electromagnetic phenomena.

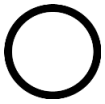
The electrical energy from other electronic devices located in nearby equipment are usually propagated through the connecting cables. The functionality of some Semiconductor devices and high sensitivity amplifiers (EEG, EMG ECG) may be affected by induced parasitic signals.

This effect could be described as noise and/or channel saturation on the EEG waveforms, which are coupled together with off the scale values for auxiliary sensors.

Follow these techniques to help identify the sources, and to increase the immunity towards parasitical noise:

- Verify the power supply and all portable multiple socket-outlets are off the floor and in a dry location.
- If parasitic noise is present on the EEG waveforms, try to identify possible culprits by disconnecting nearby equipment from the common power source.
- Lay out the interconnection cables as far as possible from the cables being used by nearby equipment.
- Verify the Power cord integrity. Do not use portable multiple socket outlets that are not properly grounded.
- Do not use power outlets without a protective ground
- When isolation transformers are used, ensure that the Medical System is properly grounded.

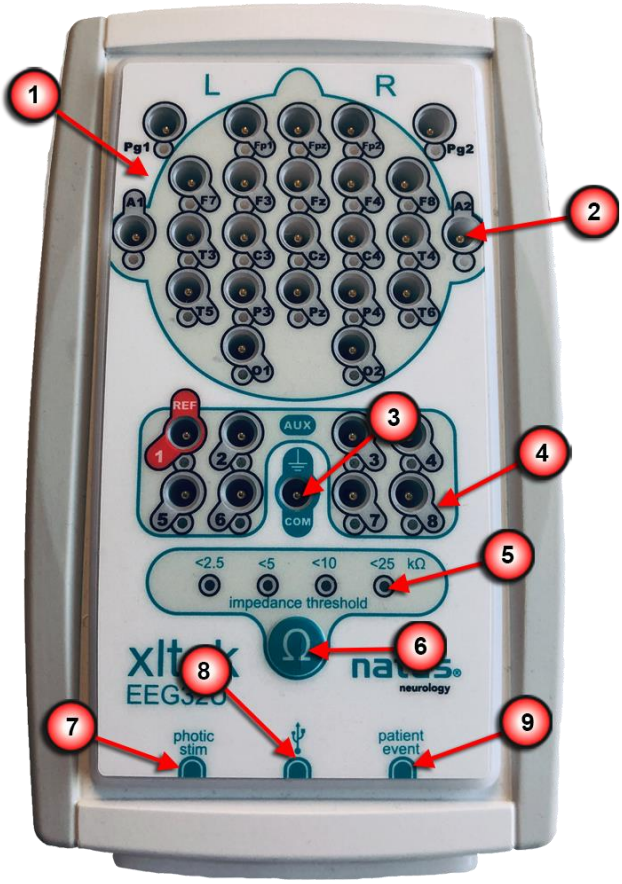
Description of Symbols

Symbol	Description
	**ATTENTION:** **Consult Accompanying Documents**
	Consult Accompanying Documents
	Protective Earth (Ground)
	Type BF Equipment
	Dangerous Voltage
	Alternating Current
	Direct Current 5VDC 0.2A
	Power On
	Power Off
	**EU only**: Do Not Dispose as Unsorted Municipal Waste
	CE Mark
	Class II Equipment (non-grounded enclosure)

Symbol	Description
	ESD Sensitive or Static Sensitive
	Manufacturer Information
REF	Reference Number. This is the part number for the device.
C ETL US LISTED Intertek 4010802 MEDICAL ELCTRICAL EQUIPMENT	The ETL mark is a safety symbol that shows the product was independently tested and certified to applicable U.S. and Canadian product safety standards.
Segurança INMETRO UL BR OCP-0029	InMetro Mark
MADE IN CANADA FABRIQUÉ AU CANADA	Made in Canada

Product Images

EEG32U Headbox



EEG32U Headbox

1	Standard 10-20 Channel Inputs
2	Impedance LEDs
3	Patient Ground
4	Additional Referential Inputs
5	Impedance Threshold LEDs
6	Impedance Button
7	Photic Stim Connection
8	USB Connection
9	Patient Event Connection

Unpacking

When you unpack your EEG32U, make sure the following items are included:

- EEG32U headbox
- USB 2.0 cable
- Patient event switch

Optional Accessories:

- EEG accessory kit

NOTE: The EEG32U amplifier should be used only with cables, transducers, electrodes, sensor, and switches that are supplied or approved by XLTEK.

Setting Up

NOTE: In the event of a power failure, the current recording will resume using the last programmed settings upon the restoration of power.

The EEG32U amplifier is designed to work with an ***XLTEK*** computer system running XLTEK Database (XLDB) and NeuroWorks software.

Placement of the Operator and Patient

It is expected that the operator of the system will stand or sit in front of the computer, but not continuously. The patient is typically lying in a bed located beside the system cart or amplifier and is in no way supported by the equipment.

At no point should the system be leaned against or rested upon. Refer to the *Transport System Specifications and Maintenance* section for placement, details, and cautions for the different cart transportation options.

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

Beginning a study

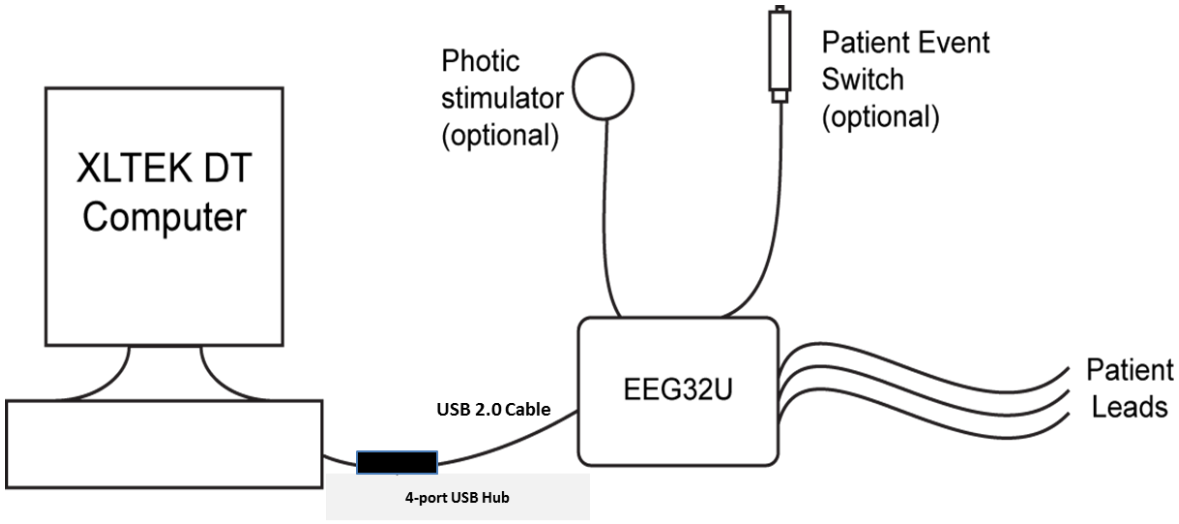
Once the equipment has been installed by your Natus qualified representative and a patient has been connected to the EEG32U system, a new EEG study can be started. For details on beginning a new EEG study, consult the *NeuroWorks* manual directly.

Powering Down the System

Utilize the following steps to ensure your system is powered down completely and safely.

1. Close any active studies in the *NeuroWorks* software.
2. Shut the computer down; ensuring to follow the proper shut down procedure.
3. Unplug the USB cable from the EEG32U.

Connecting to a Computer



Hardware Connections for an EEG32U Amplifier

To connect the EEG32U to the XLTEK computer:

1. Use the supplied USB 2.0 cable (026620 – 3m USB 2.0 A/B Cable - Black (9.8ft)) to connect the EEG32U headbox to the 4 port USB hub (026274 – 4 port Industrial USB Hub; 026275 – 12VDC power supply).
2. Use the second USB 2.0 cable (W8194X – USB 2.0 Hi-Speed Gold Cable 6ft) from the USB hub (026274 – 4 port Industrial USB Hub; 026275 – 12VDC power supply) to connect to the desktop or laptop computer.
3. Insert the Patient Event Switch into the Patient Event input on the headbox.
4. If a Photic Stimulator is needed, insert the Photic Stimulator into the Photic Stimulator connection on the base unit.
5. When you are ready to run a study, connect the patient leads and transducers to the Brain Monitor.

WARNING: The Patient Event Switch jacks are not isolated from the computer. Only an ***XLTEK*** Patient Event Switch may be plugged into these inputs.

Note: Do not connect any other type of equipment to the USB hub. Connecting any additional equipment will invalidate the safety certification for this product.

Testing the EEG32U Amplifier

The EEG32U amplifier is fully assembled, tested and calibrated prior to being shipped to you. The following sections describe some tests you can perform to verify the performance of the EEG32U amplifier.

Calibration and Verification

There is no need to calibrate the NeuroWorks Software or the EEG32U headbox. All calibration is done at the factory before the system is shipped. To verify that the EEG32U headbox system is correctly calibrated, perform the following procedure:

1. Connect the **EEG32U** headbox to an ***XLTEK*** acquisition station and turn the system on.
2. Start **XLTEK Database** (XLDB).
3. To start a new study, click **New**.
4. Choose **Edit > Settings > Acquisition**.
5. In the Acquisition tab, set the **Reference Electrode** to **Common**.
6. Design a bipolar montage using pairs of the channels to be verified. For example, to verify C3, C4, O1 and O2, use a montage with C3-C4 and O1-O2.
7. Apply a sine wave of 50 microvolts, peak-to-peak amplitude, 10 Hz to all channels of the group using a signal generator. Ensure that there is a 50 Ohm load on the generator output if the generator is designed to deliver the specified level into this load.
8. Set the **LFF** filter to 0.1, the **HFF** filter to OFF, and the **Notch** filter to OFF.
9. Verify that no sine wave is greater than 50 microvolts peak-to-peak. The accuracy of the gain is +/- 1%.

NOTE: For more information on setting up a montage, consult the online Help.

Channel Test

While you are working in the NeuroWorks live recording screen, a channel test may be performed to verify the integrity of the signal processing from the amplifier input through to the display. A channel test applies a test signal to all channels. This allows you to examine the waveforms on the screen to see if all of the channels are functioning.

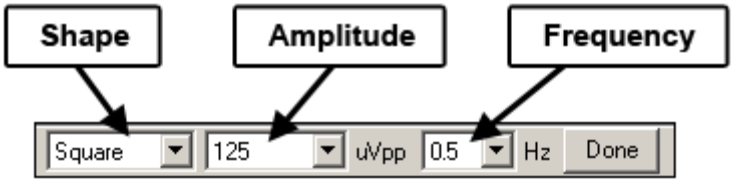
NOTE: A channel test does not validate the connection from the patient electrode to the amplifier input.

To Run a Channel Test

1. In NeuroWorks EEG, choose **Edit > Settings**. The **Edit Settings** box appears.
2. To open the **Acquisition** dialog box, click the **Acquisition** tab.
3. Select Common in the **Reference Electrode** list box and click **OK**.
4. Choose **Controls > Channel Test Signal**. The **Channel Test** control bar appears above the waveform window.
5. Use the Channel Test toolbar to select the desired wave **shape**, **amplitude**, and **frequency**.
6. To stop the channel test, click **Done**.

Channel Test Signal Control

The Channel Test Signal control in NeuroWorks EEG turns on the channel test signal according to the last settings saved and displays the Channel Test Signal toolbar. The toolbar has controls for shape, amplitude and frequency.



Channel Test Signal Toolbar

Available Channel Test Signal Settings

Shape	Sine or Square
Amplitude	Sine wave amplitude can be 79, 158, 316, 63**2**, 1264, 2527.5, 5055 and 10110 µV peak to peak. Square wave amplitude can be 50, 100, 200, 400, 800, 1600, 3200, and 6400 µV peak to peak.
Frequency	Sine wave frequency can be 16, 32 or 64 Hz. Square wave frequency can be 0.25, 0.5 or 1 Hz

Impedance Check

An Impedance Check is performed to ensure that the electrode contact with the patient is satisfactory. You can perform an impedance check at any time during a study. The impedance check will exhibit high accuracy only if at least six patient leads plus Common electrode are connected.

To Activate an Impedance Check

Do one of the following:

- On the keyboard, press the **minus** (-) key on the number pad.
- Choose **Controls > Impedance Check**.
- Press the **Impedance button** on the headbox, hold it for at least 2 seconds and then release

Running an Impedance Check

When an impedance check is initiated, the software scans all channels (in auto scan mode). You can monitor the contact of a single channel by locking onto it and then adjusting the electrode contact to acceptable impedance levels. LEDs on the EEG32U show red light for a channel that failed impedance check and green for channels that passed it.

To…	**Do this…**
Start the impedance check	Choose **Controls > Impedance Check**
Lock onto a channel	Click **Lock Channel**. Then, make adjustments to the electrode connection until satisfactory levels are achieved
Proceed to a full impedance check	Click **Release Lock**
End the impedance check	Click **End**

Save the impedance check as part of the study	Click **End and Start Recording**

Interpreting an Impedance Check

An impedance check displays bar graphs that show the impedance of each electrode connection. A **green** bar indicates the reading is below the threshold. A **red** bar indicates the reading is above the threshold. To set the impedance threshold, click one of the **Threshold** buttons in the **Threshold Group** box on the right side of the **Check Impedance** screen. To read a numerical value for the impedance in kOhms, double click on the headbox picture on the screen after closing Impedance Check. This brings up a table that lists the impedances for all channels that were checked.

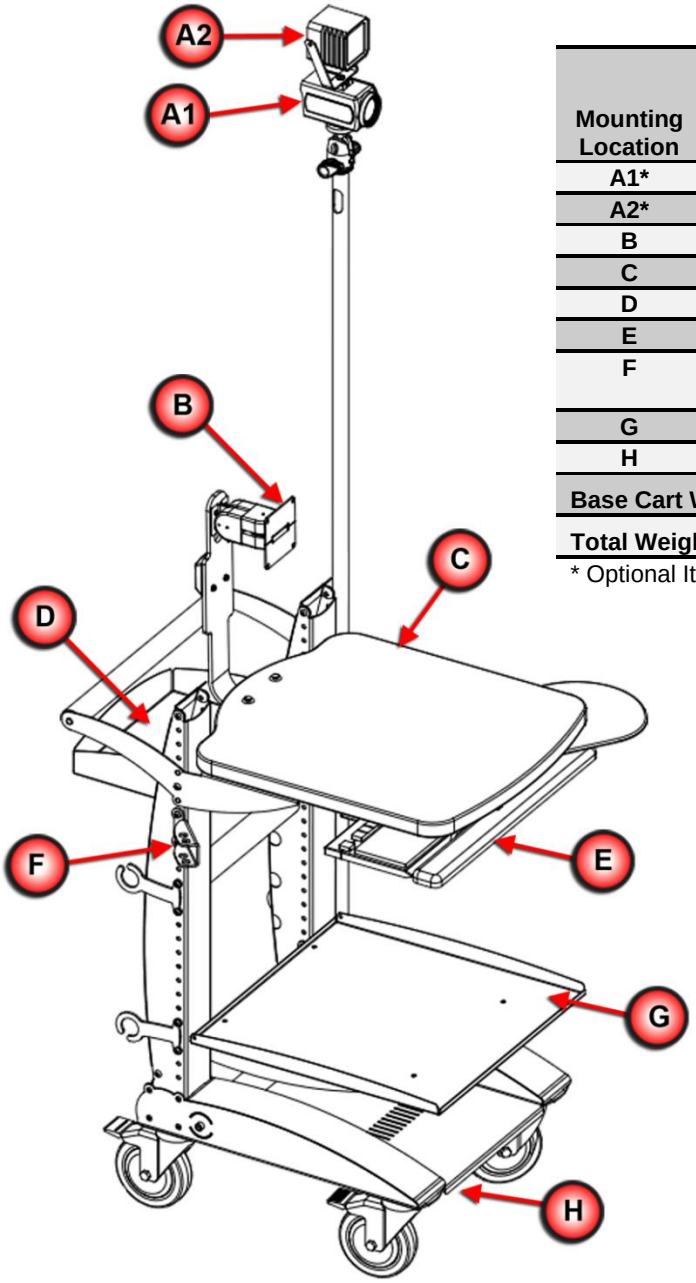
NOTE: If the impedance check is run with a **Protocol**, the threshold is determined in the **Action** settings in the **Protocol** tab of the **Edit > Settings** box. Otherwise, the threshold is determined by manually clicking the option buttons in the Threshold section of Impedance Check dialog box.

Transport System Specifications and Maintenance

Refer to the corresponding *Instructions for Use* for all system components prior to use. This should include, but is not limited to: cameras, computers, stimulators, and software.

NOTE: Transportation System setup and installation should be performed by Natus qualified personnel only.

XLTEK Trolley Specifications



Mounting Location	Default Equipment	Equipment Weight [lbs]	Maximum Load [lbs] (including equipment)
A1*	Video Camera	1	3
A2*	IR Illuminator	2	2
B	Monitor Mount	10	10
C	Work Surface	0	10
D	Storage Bin	0	10
E	Keyboard Tray	3	5
F	Natus Photic Stimulator Mount	5	5
G	Tray for Acquisition DT	20	50
H	Isolation Transformer	22	60
Base Cart Weight		**100**	
Total Weight		**163**	**255**

* Optional Items

Maintenance

1. Regularly inspect the trolley to ensure that casters, bolts, equipment mounting and shelf fasteners are secured tight at all times.
2. Regularly inspect all wires and cables for cuts and damages.
3. Regularly inspect all electrical plugs to ensure they are securely inserted into their mating receptacles.

Warnings and Cautions

WARNING: Only use XLTEK approved equipment on the trolley/cart. Non-approved equipment may compromise the function and safety of the system.

Make sure that any platform, table, cart, or other surface used during the operation, transport, or temporary or permanent storage of the system and its components is adequate, sturdy, and safe. Natus is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces. Natus is not responsible for any injury or damage that may result from improper cable storage during transport.

WARNING: Do not tilt the trolley/cart more than 10° incline as this will compromise the stability of the trolley/cart.

TIPPING HAZARD: During transport, the user should guide the cart using both hands, ensuring the wheel base is aligned so that a single caster leads in the direction of motion. Failure to lead the cart with one wheel could result in a tipping hazard when ascending or descending steps or thresholds.

Electrical Input and Isolation Transformer Details

EU	
Electrical input	200-240V AC, 2.24A @ 50 Hz
Isolation Transformer	Powervar ABC500-22MED
North America	
Electrical input	120V AC, 3.10A @ 60 Hz
Isolation Transformer	Powervar ABC300-11MED

Maintenance, Cleaning, & Disposal

To keep the EEG32U headbox system in good working condition, follow a regular schedule of preventive maintenance. Regular preventive maintenance does not involve access to the interior of the EEG32U headbox and components. For service problems that require corrective maintenance and/or internal component service, call the Natus Technical Support at **1-800-303-0306** or **OTS@natus.com**, or contact your local ***XLTEK*** 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
- Headbox and headbox cable
- Electrodes and accessories

The EEG32U amplifier and its components should not be immersed in water or any other fluid. To clean, use a damp cloth to wipe all surfaces.

Taking basic care of the system and avoiding extreme physical abuse helps prolong the lifespan of the headbox.

Recommendations

	Disconnect the EEG32U headbox 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 attached to the computer when transporting the unit.
	Do **NOT** autoclave, pressure sterilize, or gas sterilize this amplifier.
	Do **NOT** soak or immerse the amplifier in any liquid.
	A cleaning solution of 70% isopropyl alcohol is recommended.
	Use cleaning solution sparingly. Excessive solution can flow into the amplifier and cause damage to internal components.
	Do NOT use petroleum-based or acetone solutions, or other harsh solvents, to clean the amplifier.

Disposal

At the end of the expected service life, when disposing of the EEG32U amplifier and its components, it is recommended that federal, state, and local laws be followed for proper disposal of printed circuit boards, plastics, and metal parts. For disposal of non-Natus accessories, please follow the instructions provided with these items.

Troubleshooting

If the acquired waveforms are flat, do not appear, or do not appear correctly (or as expected), try shutting down the computer for at least 10 seconds. Then set up the test again from the beginning. Shutting down and starting over resets the headbox and sometimes solves the problem. If you are still experiencing problems, consult the checklist below.

Troubleshooting Checklist

☑	Ask the patient to relax.
☑	Inspect your cables.
☑	Make sure there is a tight connection between the headbox and the computer.
☑	Make sure the patient electrodes are connected to the correct channel in the headbox.
☑	Make sure the patient electrodes fit properly into the headbox (not loosely).
☑	Make sure there are no apparent breaks in the patient electrode cables.
☑	Are any of the electrodes touching? If so, they are causing a short circuit and will develop an artifact.
☑	Unplug any other devices on the same circuit such as printers, mechanical beds, vacuum cleaners, or other potential sources of interference.
☑	Install a medical grade ground to make sure your clinic has a properly grounded electrical system.
☑	Change the USB 2.0 cable. You should always have a backup USB 2.0 cable.
☑	Check the gain and timebase settings to ensure that they are appropriate for the current test. You may also want to check the LFF, HFF, and Notch filter settings. (Choose **Edit >Settings > Montage**.) • **LFF** – Filters out low-frequency interference. • **HFF** – Filters out high-frequency interference. • **Notch filter** – Minimizes electrical interference. • **Gain** – Increasing gain makes traces appear larger.

Theory of Operation:

Introduction

This section describes the theory of operation of the 32 channel EEG headbox. The initial discussion is primarily signal flow oriented. Detailed board level theory is provided later in this section.

System Overview

Features of the EEG32U System

The EEG32U headbox performs these basic functions of a digital EEG front end:

- Allows connecting patient electrodes.
- Amplifies and digitizes the electrode signals.
- Transmits the digitized waveforms to a NeuroWorks computer.
- Allows selection of reference signal.
- Provides internally generated test signals (sine and square) for user assessment of equipment performance.

Components of the Communications Link

- Digitized waveforms are transmitted to the computer using USB (universal serial bus) connection.
- Commands and replies are communicated using same USB (universal serial bus) connection.

Power Sources to the Headbox

- Power to EEG32U is supplied by a USB bus.

Circuit Board Assemblies inside the Headbox

A. Analog Board

- Handles amplification and DC removal (DC removal is similar to a low frequency filter) for 32 channels.
- Amplifiers are designed to handle signals far in excess of even abnormally high EEG, while also providing exceptional sensitivity and resolution.

B. Digital Board

- Analog to Digital converters digitize the amplified EEG signals. Signals are periodically sampled and converted to a binary number.
- The micro controller transmits the digitized signals to the computer over USB 2.0 connection.
- Contains non-volatile storage for calibration values.
- During factory calibration, the NeuroWorks computer calculates and transmits the channels gains to each digital board. Whenever a study starts, the computer uses these stored values to scale the digitized signals, channel by channel.
- Equipped with a Patient Event connector that detects an Event Switch closure and transmits it to the computer.
- Equipped with a Photic stimulator connector that allows to:
    - Transmit commands from the computer to the photic stimulator over USB 2.0 connection.
    - Transmit feedback (flash strobe marks) from the photic stimulator to the computer over USB 2.0 connection.

Getting Help

Natus is committed to providing you with support so you can operate the EEG32U headbox with ease and confidence. If you need help, follow these steps to find a solution:

Step 1: Document the Incident

Carefully document the incident. If possible, note error messages, dialog box names and what you did before the problem occurred.

Step 2: Search NeuroWorks Online Help

To open the NeuroWorks Online Help, choose Help->NeuroWorks Help.

Step 3: Restart the Computer

Often restarting the computer will solve a problem.

1. Close all applications.
2. Click the **Start** button on the Windows taskbar.
3. Choose **Shut Down** from the Start menu.
4. Select **Restart the computer** and click **Yes**.

Step 4: Shut Down the Computer

Sometimes you need to shutdown the computer completely in order to solve a problem.

1. Click the **Start** button on the Windows taskbar.
2. Choose **Shut Down** from the Start menu.
3. Select **Shut Down** and click **Yes**.
4. Turn the power off to the unit. Wait for **10 seconds**. Turn the power back on.

Step 5: Contact Technical Support

First, write down the serial number of your computer (located on the back) and the serial number of your EEG32U amplifier. Then contact your local XLTEK distributor or Technical Support at **1-800-303-0306** or OTS@natus.com.

We welcome your feedback and suggestions regarding the EEG32U amplifier and any aspect of our SleepWorks or NeuroWorks systems and software, online Help, line of accessories, and support services.

EEG Accessories & Replacement Parts

The following are compatible accessories:

Part Number	Description
W8194X	USB 2.0 Hi-Speed Gold Cable 6ft
026620	3m USB 2.0 A/B Cable - Black (9.8ft)
W6232H	Patient Event Button
105491	User and Service Manual
10440	Natus Photic Stimulator
026274	4 Port USB hub
026275	12VDC power adaptor
105546	EEG32U TROLLEY MOUNT
008556	EEG32U MOUNT
102181	EEG32U & Brain Monitor Breakout Box Roll Stand
10351	EEG32U & Brain Monitor Breakout Box Wall and Roll Stand Mounting Kit

EEG accessories which can be used with the EEG32U amplifier are available for you to browse in the Natus Neurology Accessories Catalog online at www.natus.com or call Natus Sales and Support 1-800-303-0306.

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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.

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