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Natus Photic Stimulator

User & Service Manual

Publisher's Notice

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Natus Photic Stimulator

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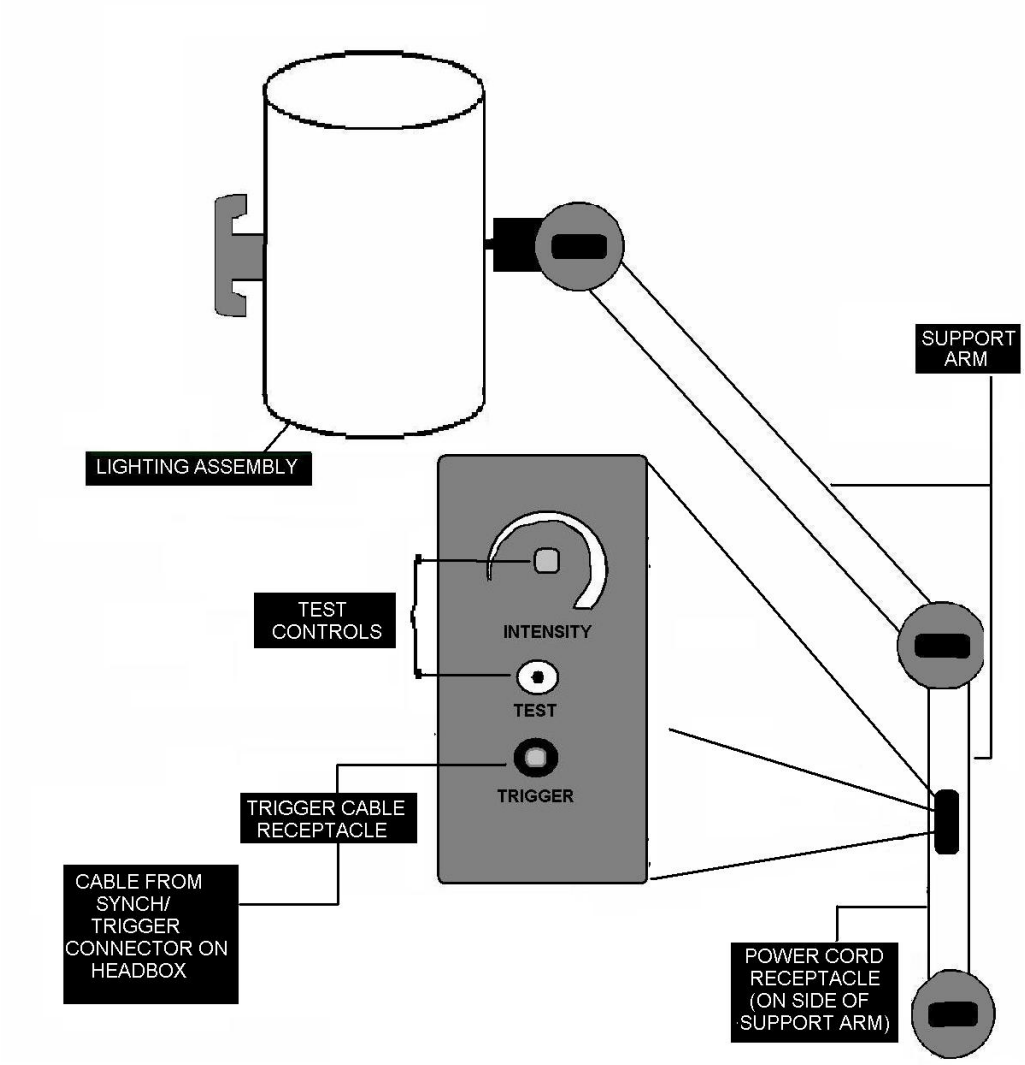
Introduction



The Natus Photic Stimulator is a powerful, portable option that can enhance and expand neurologic testing. Driven by the Natus NeuroWorks™ software from laptop or desktop computers, it supplies intense flashes of light. Its components consist of an arm-mounted light assembly, a light source, an intensity control, a test button, and a Trigger-in receptacle for a cable from a headbox. The arm-mount has three adjustment knobs along its length to give the unit flexibility and versatility.

Warnings and Cautions

Important Safety Information

⚠	This equipment/system is intended for use by Healthcare professionals ONLY. Please read this section before installing any of the hardware. Refer to this section when you operate, transport, store, or re-install 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. XLTEK is not responsible for any injury or damage that may result from inadequate, poorly constructed, or unapproved transports, carts, or operating surfaces.
⚠	Never use equipment that has parts missing or equipment that might contain loose parts inside of it (that is, inside an enclosed portion of the equipment). If you suspect a piece of equipment has missing or loose parts, contact XLTEK.
⚠	Never place powered equipment (that is, equipment that operates with an electric power source) on any flammable surface. Avoid this whether the equipment is active or not.
⚠	A risk of explosion is possible if you use this device in the presence of flammable anesthetics.
⚠	Reliable grounding requires hospital-grade receptacles and power cord.
⚠	Always perform a leakage current test and compare to allowable standards BEFORE connecting the patient to monitoring equipment NEVER connect a multiple portable socket outlet to the isolation transformer output receptacles. Additional cord connected equipment may increase leakage currents and present a hazard. XLTEK strongly recommends that you do not open the Photic Device. It contains no serviceable parts. If you must open the device, disconnect the line cord before you do so.
⚠	**Electrostatic Discharge (ESD) Precaution:** 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. 
⚠	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 reorienting or relocating the equipment or shielding the location.
⚠	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 equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
	**Fast transients precautions (EFT) Precautions:** In environments where parasitic electrical noise interferes with intermittent photic stimulation (IPS) there is no risk of misinterpretation of EEG waveforms. The visual stimulation is confirmed by the technologist performing the test. In addition the accompanying EEG (Electroencephalograph) amplifier's signals will also be contaminated past the point where any clinical signal interpretation is possible. Trained electroencephalographic physicians and technologists are well equipped to identify and disregard signals that are obscured by environmental noise.

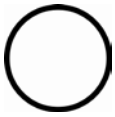
NOTE: XLTEK designates no non-medical equipment for use with the Photic Stimulator system. No supporting documentation for such devices is necessary.

The Photic Stimulator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile RF communications equipment can affect the functionality of the Photic Stimulator.

Description of Symbols

Symbols and warning labels on equipment can simplify language differences and give users instant comprehension of warnings and markings in a restricted space.

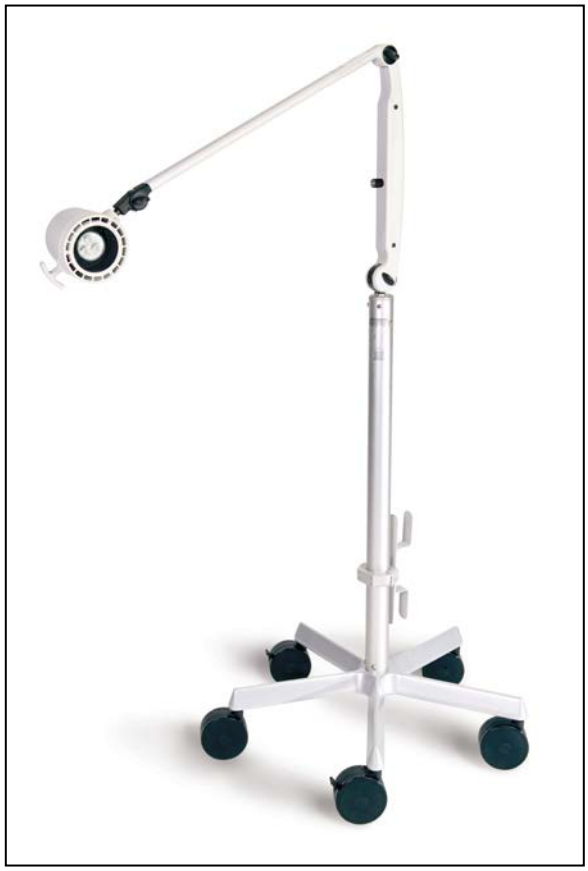
	**ATTENTION:** **Warnings and Cautions**
	Consult Accompanying Documents
	Protective Earth (Ground)
	Type B equipment
	Type BF Equipment
	Dangerous Voltage
	Alternating Current
	Power On
	Power Off
	**EU only**: Do Not Dispose as Unsorted Municipal Waste
	CE Mark
	Class II Equipment (non-grounded enclosure)
	Electrostatically Sensitive Device (ESD)

Specifications

WARNING: Reliable grounding requires hospital-grade receptacles and power cord.

Support arm	52 in. (1320.8 mm) total
Frequency of flash	Maximum 60 Hz
Light intensity	Adjustable via Intensity control (12-position control: 11 settings; 1 Off)
Input requirements	TTL Positive Pulse; 100 μs @ 1 mA
Mains input	100-240VAC 50/60Hz, 1 A (1A-0.5A) Protection against electric shock: Class I

Product Images



Photic Arm: Intensity control, Test, Trigger In

Unpacking

When you unpack your Natus Photic Stimulator, make sure the following items are included:

- Photic Stimulator (p/n 10440)
- PCI to Photic Stimulator 20ft Cable (p/n 003771)
- Protektor to Photic Stimulator Cable (p/n 003632)
- User & Service Manual

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

Cable Option List

The 20ft cables are available with the specific end connector for the following devices:

Xltek PN	***Description***
003771	PCI to Photic Stimulator Cable
003632	Protektor to Photic Stimulator Cable
012788	Photic Stimulator – Grass Amplifiers Cable
W6473H	Trex Cable for LED Photic Stimulator
580-PHTCB1	Photic Stimulator – Netlink Cable
580-PHTCB3	Photic Stimulator – XL Cable

Installation and Operation

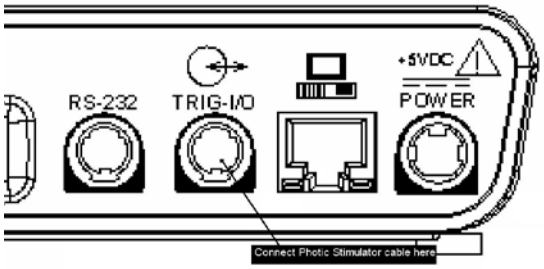
WARNING: Never place the photic device on the floor.

1) Place the photic device on a platform, table, cart, or other raised surface. Never place the photic device on the floor.
2) Plug the photic device only into a power outlet marked and verified as Hospital Grade.

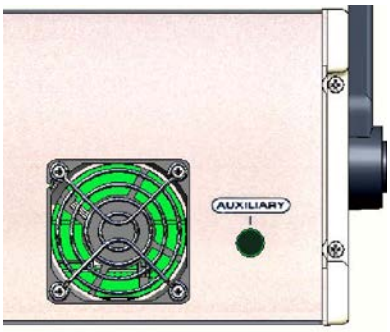
NOTE: Acceptable 'Hospital Grade' power outlets must be labeled as such.

3) On the **XLTEK Connex, Brain Monitor, Brain Monitor ICU, EEG32U or EMU40 headbox**, connect the mini-din 6-pin male end of trigger cable (XLTEK part number 003771) to the Photic connector.
4) On the **XLTEK Trex headbox**, connect the Hirose connector of trigger cable (XLTEK part number W6473H) to the Photic connector.
5) On the **XLTEK PCI computer-headbox interface card (used with EEG32, EMU40, EMU128FS, Mobee and Hyppo headboxes),** connect the mini-din 4-pin male end of trigger cable (XLTEK part number 003771) to the matching connector on the PCI card.

6) On the **Netlink or Netlink ICU headbox**, connect the mini-din 4-pin male end of trigger cable (BLSC part number 580-PHTCB1) to the Trig I/O connector.



7) On the **Netlink LTM or XL headbox**, connect the Lemo 6-pin connector of trigger cable (BLSC part number 580-PHTCB3) to the Auxiliary connector.



8) On the **Gamma headbox**, connect the phone plug of trigger cable (BLSC part number 580-PHTCB2) labeled “Strobe Out” to the phone jack on back panel of computer labeled “Strobe”.

9) Use the photic device per the instructions in the NeuroWorks User & Service Manual (part number 101886X).

10) On the **Grass Comet-PLUS amplifier**, connect the 2.5 mm sub-mini phone connector to the “Trigger” output and the 3.5mm mini phone connector to the “DC1” input on the back of the amplifier system.

OR

11) Use the Test button to troubleshoot the device.

Recommended User Performed Maintenance

Cleaning

No special cleaning is required for this device. Ordinary, ‘house-keeping’ type cleaning to prevent the accumulation of dust or debris is adequate.

Inspection

No special inspection procedures are required for this device.

Maintenance

This device has no serviceable parts and requires no scheduled maintenance.

Environmental Specifications

Temperature

Operating: 10 to 40° C

Storage and transportation: -20 to 70° C

Humidity

Operating: 30% to 75% RH

Storage and transportation: 10%- 90%RH non-condensing

Condensation

Recovery Time after condensation to operations specifications: 24 hours

Flammability

UL94 HB
UL94V-O

EMC Specifications

IEC 60601-1-2:2007 Electromagnetic Compatibility (EMC) Testing
CISPR 11 B Conducted and CISPR 11A Radiated Emissions
EN 61000-4-2 Electrostatic Discharge Test
EN 61000-4-3 Radiated Susceptibility Test
EN 61000-4-4 Transient Susceptibility Test
EN 61000-4-5 Surge Susceptibility Test
EN 61000-4-6 Conducted Immunity Test
EN 61000-4-8 Magnetic Fields Test
EN 61000-4-11 Voltage Fluctuations Test
EN 61000-3-2 and EN 61000-3-3 Dips and Flicker Test
RE 101 Magnetic Emissions Test

Safety Standards

This component complies with the following electrical safety standards:

UL 60601-1

CAN/CSA C22.2 No. 601-1-M90

IEC 60601-1-2:2007 Electromagnetic Compatibility (EMC) Testing

Environmental Conditions

- Select a room with properly grounded power sources.
- Do not use or store your equipment in places where chemicals are stored or where there is a potential for gas leakage.
- Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperature, poorly ventilated areas and dusty, saline or sulfuric air.
- Verify the selected site maintains a relative humidity between 30% and 75% (without condensation).
- Verify all conditions meet the requirements listed in the Environmental Specifications section of this manual.

Room Topography

- Place all equipment on an even, level surface. Avoid the potential for mechanical shock or possible vibrations during setup system operation or when relocating the equipment.
- Verify the power supply and all portable multiple socket-outlets are off the floor and in a dry location.

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: 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 or pins for the Connectors marked with the ESD symbol unless ESD precautionary procedures are used.

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.

Electrical Fast Transient (EFT) Procedures and Warnings

Electrical Fast transients are defined as short bursts of energy that are propagated through the power cord. The EFT source is usually located in the nearby equipment or machinery such as motors switching equipment light switches, etc.
The functionality of Some Semiconductor devices and high sensitivity amplifiers (EEG, EMG ECG) may be affected by EFT.

For higher levels of EFT - the effect could be described as noise on the EEG waveforms or visible variance in the stimulating pattern.

Follow these techniques to help identify the sources and reduce the effect of the EFT:

- Verify the power supply and all portable multiple socket-outlets are off the floor and in a dry location.
- Verify the Power cord integrity, do not use portable multiple socket outlets that are not properly grounded.
- Do not use the power outlets without a protective ground
- When isolation transformers are used, make sure that the Medical System is properly grounded.
- If the effect of the EFT is present on EEG waveforms and visual stimulators try to identify the nearby possible equipment by disconnecting it from the common power source

Declaration of Compliance for IEC 60601-1-2:2007

IEC 60601-1-2:2007 Table 1 Requirements

<table>
<tr><td colspan="3">The Natus Photic Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Natus Photic Stimulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Natus Photic Stimulator is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: 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 equipment or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

IEC 60601-1-2:2007 Table 2 Requirements:

The Natus Photic Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Natus Photic Stimulator 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	±6 kV contact ±8 kV air	±0.3 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	± 0.5kV was applied and unit still flickered.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 UT = 100Vac & 240 Vac	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 %UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 60601-1-2:2007 Table 4 Requirements:

<table>
<tr><td colspan="4">The Natus Photic Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6

Radiated RF IEC 61000-4-3</td><td>3 Vrms 150 kHz to 80 MHz

3 V/m 80 MHz to 2,5 GHz</td><td>3 Vrms

1 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = [\frac{3,5}{V_1}]\sqrt{P}$

$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz

$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]

Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">a) 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

IEC 60601-1-2:2007 Table 6 Requirements:

Recommended separation distances between portable and mobile RF communications equipment and the Natus Photic Stimulator

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** M		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.35	0.70
0.1	0.37	1.11	2.21
1	1.17	3.50	7.00
10	3.69	11.07	22.14

Note: Table 6 above is for a field strength (E_1) of 1V/m and V_{rms} (V_1) of 3V.

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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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