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Natus Photic Stimulator

User & Service Manual



Publisher's Notice



105706X Rev K Natus Photic Stimulator User & Service Manual

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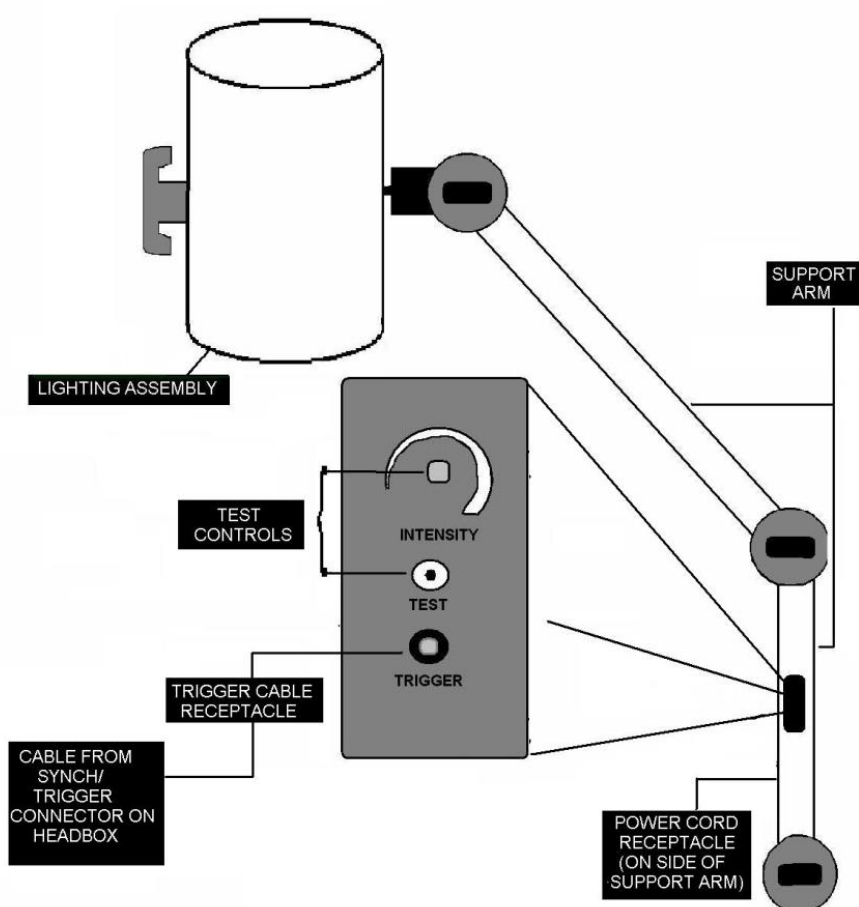
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Intended Use

The photic stimulator is used by trained medical staff in a medical environment to apply photic flashes to the patient during neurophysiology studies such as EEG, where it is used as an activation to test photosensitivity related to epilepsy. Trigger pulses applied to the input of the photic stimulator generate photic flashes at specific frequencies, typically in the range of 0.5Hz to 60Hz. The photic stimulator is intended for use on mobile or fixed systems, and with patients of all ages. The Photic Stimulator can also be used along with Evoked Potential devices for stimulating Visual Evoked Potentials.

System components



Connected to Natus Neurology hardware and driven by the Natus application software from laptop, desktop, or All-In-One computers, the Natus Photic Stimulator 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.



Using the Manual

This manual describes the theory, features, set up, operation and maintenance of the Natus Photic Stimulator. It also provides information on specifications, troubleshooting and getting help.

Please follow the instructions carefully.










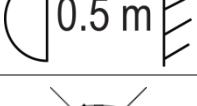
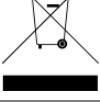

Manual Conventions



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.
<i>Italic</i>	Italic text is used for captions.


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.

Symbol	Description
	ATTENTION: Consult Accompanying Documents
	Consult Accompanying Documents
	Protective Earth (Ground)
	Type B equipment
	Type BF Equipment
	Dangerous Voltage
	Alternating Current
	Power On
	Power Off
	Keep the Photic Lamp 0.5 meters away from walls. The Photic Arm can rotate, which may potentially damage the Strobe Lamp.
	EU only: Do Not Dispose as Unsorted Municipal Waste
	CE Mark





	Class II Equipment (non-grounded enclosure)
	Electrostatically Sensitive Device (ESD)

Warnings and Cautions






	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.
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There are no known contraindications. The photic stimulator is used at the discretion of the medical professional.

Natus Photic Stimulator shall **NOT** be used in the following conditions:

	Check areas of use to avoid using the system in the presence of flammable gases.
	Natus systems are not AP or APG rated. DO NOT USE a Natus system in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
	To ensure the validity of signals, do not operate the device near any sources of electromagnetic interference.
	Do NOT operate the system in case of damaged AC power cord or ungrounded metal contacting damaged power cord.

Other warnings and cautions:

	Natus strongly recommends that you do not open the Photic Device. It contains no serviceable parts. If you must open the device, disconnect the power cord before you do so.
	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.
	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 NATUS.
	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.
	Reliable grounding requires hospital-grade receptacles and power cord. Do not use power outlets without a protective ground.

	Position the equipment so that the detachable mains cord is readily accessible for disconnection.	
	Always perform a leakage current test and compare to allowable standards BEFORE connecting the patient to monitoring equipment	
	Do not use portable multiple socket outlets that are not properly grounded.	
	When an isolation transformer is used, make sure that the Medical System is properly grounded.	
	NEVER connect a portable multiple-socket outlet to the isolation transformer output receptacles. Additional cord-connected equipment may increase leakage currents and present a hazard	
	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 (Ed. 3.0).	
	Verify the power supply and all portable multiple socket-outlets are off the floor and in a dry location.	
	Natus recommends proper cable management and storage to ensure stability of the device.	
	Do not use the equipment adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the equipment to verify normal operation in the configuration in which it will be used.	
	<p>Electrical Fast Transients (EFT) are defined as short bursts of energy that are propagated through the power cord. The EFT source is usually located in nearby equipment or machinery.</p> <p>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.</p>	



NOTE: NATUS 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.

ESD 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.

Specifications

Standard Specifications		
Support arm	52 in. (1320.8 mm) total	
Frequency of flash	Maximum 60 Hz	
Duration of flash	1ms	
Light intensity	Adjustable via Intensity control (12-position control: 11 settings; 1 Off) Intensity measured at 30cm distance, position 12: <ul style="list-style-type: none"> • Minimum: 22000 lux • Maximum: 75000 lux Typically an intensity of 39000 lux is observed in measurements on Natus Photic Stimulator.	
Input requirements	TTL Positive Pulse; 100 μ s @ 1 mA	
Mains input	100-240VAC 50/60Hz, 1 A (1A-0.5A)	
Protection against electric shock:	Class I	
Flammability	UL 94V-0	
Environmental Conditions for Use		
Operating Environmental Limits	Temperature Range	10° C to 40° C
	Humidity Range	30% to 75% RH
Transport and Storage Limits	Temperature Range	-25° C to 60° C
	Humidity Range	10%- 90%RH non-condensing
Condensation		
Recovery Time after condensation to operations specifications	24 hours	

Environmental Conditions

- Select a room with properly grounded power sources.
- Do not use or store the 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 Conditions for use' section of this manual.

Unpacking

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

- Photoc Stimulator (p/n 10440)
- Interface cable for Photoc Stimulator, 20ft (p/n 003771)
- Table clamp (p/n 585-PS2001C)
- User & Service Manual



NOTE: The Photoc Stimulator should be used only with cables that are supplied or approved by NATUS.

Product Images

- Photic stimulator and roll stand (roll stand not included):



- Photic Arm:



- Intensity control, Test, Trigger In:



Cable Option List

Interface cables are available with the specific end connector for the following devices:

Natus PN	Description
003771	Interface cable for Xltek
003632	Interface cable for Protektor
012788	Interface cable for Grass (Comet PLUS)
W6473H	Interface cable for Trex
019174	Interface cable for Nicolet v-series amplifiers

Installation and Operation



WARNING: Never place the photic device on the floor.

1. Secure the photic device on a platform, table, cart, or other raised surface. 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
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. Depending on the amplifier hardware, connect the mini-din 6-pin male end of the appropriate interface cable to the photic stimulator:
 - Use the cable with PN 003771 on NeuroWorks EEG systems with **Brain Monitor, EEG32U, EMU40EX, or Natus Quantum.**
 - Use the cable with PN 012788 on NeuroWorks EEG systems with **Grass Comet-PLUS** headbox. 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.
 - Use the cable with PN W6473H on NeuroWorks EEG systems with **Xitek TrexHD** headbox.
 - Use the cable with PN 019174 on NeuroWorks EEG systems with **Nicolet V-32 or V-44** headbox.



NOTE: Refer to the User & Service manual of the corresponding amplifier hardware for more information about how to connect the interface cable.



NOTE: Refer to the User manual from the EEG software Platform for more information about how to control the Natus photic stimulator.



NOTE: Use the **Test** button to troubleshoot the device.

Recommended User Performed Maintenance








To keep the Natus Photoc Stimulator in good working condition, follow a regular schedule of user performed maintenance. Regular maintenance performed by the user does not involve access to the interior of the stimulator and components. For service problems that require corrective maintenance and/or internal component service, call Natus Technical Support at **1-800-303-0306** or OTS@natus.com, or contact your local Natus representative.

Periodically check cable connections 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
- Accessories

The Natus Photoc Stimulator and its components should not be immersed in water or any other fluid. To clean, use a damp cloth or cleaning/disinfecting products such as isopropyl alcohol, PDI “Sani Wipes AF3”, PDI “Sani-Cloth Plus”, Metrex CaviWipes, or AIC Wedge Wipes to wipe all surfaces, cables and accessories.

Recommendations

	Disconnect the power cord and all cables from the unit before cleaning. Use a lint-free cloth. Do not use cleaners on any system component.
	Take care not to allow any fluid to seep into the internal electronic components of the system.
	Do NOT autoclave, pressure sterilize, or gas sterilize this unit.
	Do NOT soak or immerse the unit in any liquid.
	A cleaning solution of 70% isopropyl alcohol is recommended.
	Use cleaning solution sparingly. Excessive solution can flow into the unit and cause damage to internal components.
	Do NOT use petroleum-based or acetone solutions, or other harsh solvents, to clean the unit.

Safety & Standards Conformity

Safety Standards

This device complies with the following electrical safety standards:

IEC 60601-1:Ed. 3.1 - General Requirements for Basic Safety and Essential Performance

IEC 60601-1-6:Ed. 3.1 – Collateral Standard: Usability

IEC 60601-2-40:Ed. 2.0 - Particular Requirements for the Safety of Electromyographs and Evoked Response

EMC Standards

IEC 60601-1-2:2007 (Ed. 3.0) - Electromagnetic Compatibility (EMC) Requirements and Tests

- CISPR 11 B Conducted and CISPR 11A Radiated Emissions
- EN 61000-3-2 and EN 61000-3-3 Harmonics and Voltage Fluctuations
- EN 61000-4-2 Electrostatic Discharge Immunity
- EN 61000-4-3 Radiated Immunity
- EN 61000-4-4 Transients Immunity
- EN 61000-4-5 Surges Immunity
- EN 61000-4-6 Conducted Immunity
- EN 61000-4-8 Magnetic Fields Immunity
- EN 61000-4-11 Voltage Dips and Interruptions

Declaration of Compliance for IEC 60601-1-2:2007 (Ed. 3.0)


IEC 60601-1-2:2007 Table 1 – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class A	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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

IEC 60601-1-2:2007 Table 2 – Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Natus Photoc Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Natus Photoc 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	±6 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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±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	10 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 (Ed. 3.0) Table 4 – Electromagnetic Immunity
for Equipment and Systems that are not Life-Supporting**

Immunity and Compliance Levels			
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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	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 $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 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: 
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.			
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.			

IEC 60601-1-2:2007 (Ed. 3.0) Table 6 – Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Natus Photic Stimulator			
<p>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.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
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.



A Total Service Solution

Standing behind every Natus 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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