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Natus Photic Stimulator

User & Service Manual

Publisher's Notice

REF

105706X Rev M

Natus Photic Stimulator User & Service Manual

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EC REP

CE

℞ ONLY

Issued in December 2018.

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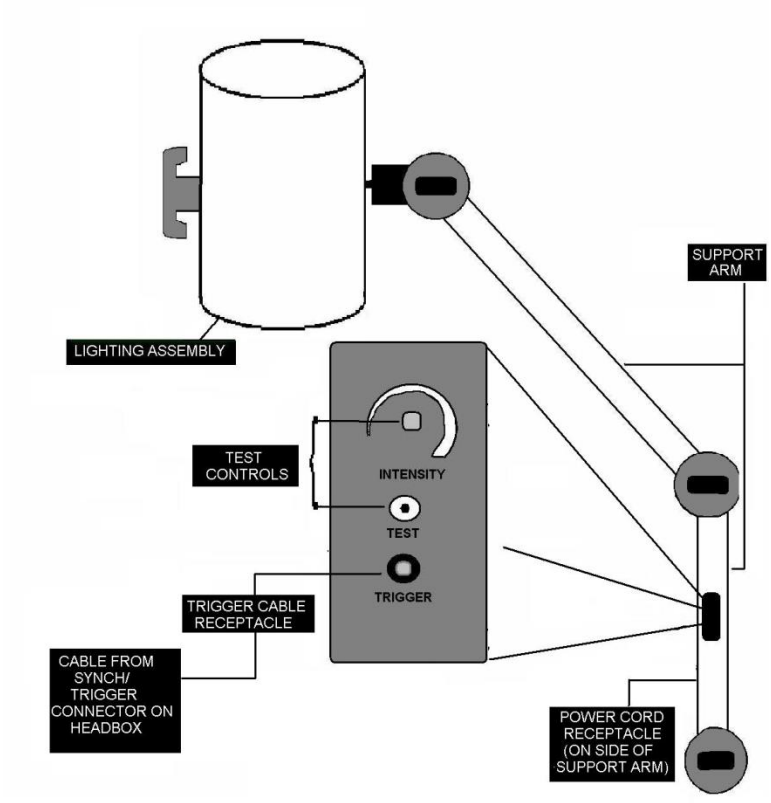
Intended Use

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 photo-sensibility 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.

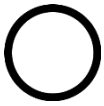
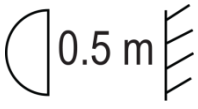
Manual Conventions

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.
Italic	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

Symbol	Description
	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.

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.
	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 Natus Photic Stimulator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	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 accessories, transducers or cables other than those specified or sold by the manufacturer on the equipment could 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 (Ed. 4.0).
	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.

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

NOTE: 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.

NOTE: 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: • 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 µs @ 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 Photic Stimulator, make sure the following items are included:

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

NOTE: The Photic 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 Xltek **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 Photic 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 Photic 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

Essential Performance

In normal operational mode, essential performance is defined as the following:

Observe photic flash. Photic flash pattern can become random and/or irregular under immunity testing, as long as it recovers after stimulus is removed.

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

ANSI Z80.36-2016 for Ophthalmics – Light Hazard Protection for Ophthalmic Instruments

EMC Standards

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
CISPR 11 ed 5.0 with A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement
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
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

Declaration of Compliance for IEC 60601-1-2:2014 (Ed. 4.0)

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	

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

Table 4 - Immunity Test Levels - Enclosure Port

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

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

Phenomenon	Basic EMC Standard	Immunity Test Levels – Professional Healthcare Facility Environment
Electrical Fast Transients / Bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line (Differential Mode)	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges Line-to-ground (Common Mode)	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage Dips	IEC 61000-4-11	100% dip; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 100% dip; 1 cycle

Phenomenon	Basic EMC Standard	Immunity Test Levels – Professional Healthcare Facility Environment
		and 30% dip; 25 cycles (50Hz) Single phase: at 0°
Voltage Interruptions	IEC 61000-4-11	100% dip; 250 cycles (50Hz) /300 cycles (60 Hz)

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

Phenomenon	Basic EMC Standard	Immunity Test Levels – Professional Healthcare Facility Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical Fast Transients/Bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges Line-to-Ground (Common Mode)	IEC 61000-4-5	± 2 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

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

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 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 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 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 217 Hz	2	0,3	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5,500						
5,785						

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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P/N 105706X, Rev M