photic Stimulator

MADE IN BRITAIN

USER MANUAL

lifelines® neuro

Imagine EEG Anywhere

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Doc No:	51331-006
Part No:	1240
Issue:	3.0
Date:	November 2024

Customer Responsibility

The Photic Stimulator is reliable only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and inserts. A defective system should not be used. Parts that may be broken or missing or those that are clearly worn or contaminated should be replaced immediately with new original replacement parts that have been manufactured by or are available from Lifelines.

The owner of this system has the sole responsibility for any malfunction resulting from improper use or maintenance, or repair done by anyone other than a qualified Lifelines representative and for any malfunctions caused by any parts that have been damaged or modified by anyone other than a qualified Lifelines representative.

The owner of this system has the sole responsibility for the connection of this product to other systems which do not satisfy the electrical safety requirements of standards IEC 60601-1 and IEC 60601-1-2 for medical devices.

NOTE: Any serious incident that has occurred in relation to the Photic Stimulator should be reported to the manufacturer and, where applicable, the competent authority of the EU Member State in which the user and/ or patient is established.

Disclaimers & Warranties

The information in this section is subject to change without notice.

Except as stated below, Lifelines makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Lifelines shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this material.

Lifelines shall warrant its products against all defects in material and workmanship for one year from the date of delivery.

Misuse, accident, modification, unsuitable physical or operating environment, improper maintenance or damage caused by a product for which Lifelines is not responsible will void the warranty.

Lifelines do not warrant uninterrupted or error-free operation of its products.

Lifelines or its authorised agents will repair or replace any products that prove to be defective during the warranty period, provided that these products are used as prescribed in the operating instructions in the user's and service manuals.

No other party is authorised to make any warranty to assume liability for Lifelines products. Lifelines will not recognise any other warranty, either implied or in writing. In addition, services performed by someone other than Lifelines or its authorised agents or any technical modification or changes of products without Lifelines prior, written consent may be cause for voiding this warranty.

Defective products or parts must be returned to Lifelines or its authorised agents, along with an explanation of the failure. Shipping costs must be prepaid.

Lifelines manufactures hardware and software to be used on or with standard PC-compatible computers and operating software. Lifelines, however, assumes no responsibility for the use or reliability of its software or hardware with equipment that is not furnished by third-party manufacturers accepted by Lifelines at the date of purchase.

All warranties for third-party products used within the Photic Stimulator system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

Trademarks

Microsoft and Windows are registered trademarks of the Microsoft Corporation. All other trademarks and product names are the property of their relevant owners.

Responsibility of manufacturer

The manufacturer and distributor consider themselves responsible for the equipment's safety, reliability and performance only if:

- any peripheral equipment to be used with the Photic Stimulator is supplied by third-party providers recommended by the manufacturer;
- assembly operations, extensions, readjustments, modifications, or repairs are carried out by person authorised by the manufacturer;
- the electrical installation of the relevant room complies with the appropriate requirements;
- the equipment is used by a healthcare professional and in accordance with the instructions for use.

NOTE: Equipment specifications are subject to change without notice.

NOTE: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

Software and Virus Protection

Lifelines takes all reasonable steps to ensure that its software is virus-free. In addition, continual system protection against viruses, Trojans, malware, adware etc. is recommended. Please note the following:

1. Virus protection software should be installed on every computer at risk of infection. This software should have a resident (online) shield and provide email scanning if appropriate.
2. Virus scanning should be set to manual mode. If set to automatic, only allow scanning when the system is not being used.
3. All programs offering auto-update features, including Windows, should be set to manual. If set to automatic, only allow updates when the system is not being used.
4. Adopt formal departmental or organisational procedures to ensure the integrity and safe operation of the medical equipment and supporting systems.

Contents

1 System Overview

1.1 General description

Intended Use

The Lifelines Photic Stimulator is intended to be used for photic stimulation in the field of electroencephalography.

Intended User

The intended user of the device is a healthcare professional who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice.

General description

The Photic Stimulator generates short-duration flashes of light by means of a solid-state LED (light emitting diode) to produce electrical responses in the brain of the patient. The flashes are controlled from a host PC at a rate of between 1 and 60Hz.

The Photic Stimulator is not in contact with the patient and the luminous energy produced is not capable of creating a health hazard to the patient.

Refer to Figure 1 for the system setup.

Clinical Benefit

Photic stimulation is routinely included in electroencephalographic (EEG) recordings to elicit epileptiform abnormalities and is used to assist in the assessment, diagnosis and classification of neurological disorders, such as epileptic syndromes.

Intended patient population

Paediatric to adult. The patient profile has no influence over the Photic stimulation. The patient has no interaction with the device.

1.2 Warnings and Cautions

	Warning sign indicates a situation or procedures that may be dangerous for the patient and/or user.		**Caution** sign indicates a situation or procedures that may cause equipment damage or its improper usage.

	The Photic Stimulator must only be used by a healthcare professional, within a hospital or clinical setting, who has the training and knowledge to undertake EEG examinations and is familiar with EEG equipment and practice. This user manual must be read in its entirety before the equipment is used.
	There is a small risk that photic stimulation can induce a seizure in photosensitive patients. For this reason, photic stimulation should only be carried out with strict adherence to an approved photic stimulation protocol. The methods used in the protocol should maximize the probability of eliciting abnormal responses in patients with photosensitive epilepsy, while minimising the chances of inducing such a response in others or of precipitating a seizure during testing. Bystanders should be excluded from the treatment area.
	Do not modify this equipment without the authorization of the manufacturer.
	The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment
	The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system 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 Photic, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

Contraindications

1. Patients whose known or possible diagnosis does not include epilepsy.
2. Patients with an established history of electroclinical events to photo sensitivity.
3. Patients with known epilepsy who have been seizure-free for some time.

1.3 Explanation of symbols

Symbol	Description
	Follow operating instructions
	Attention consult accompanying documentation
	Input/output connection
	Output connection
	Off On
	Manufacturer
	European Representative
	Special recycling required*
	Medical Device

* Do not dispose of in landfill. This product includes printed circuit boards, electronic components, wiring and other elements of electronic devices. When this equipment has reached the end of its useful life, follow all local laws and regulations for the proper recycling or disposal of such equipment. Contact your local distributor for information.

Storage and transport symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Temperature limits		Fragile		Keep dry
	Relative humidity limits		Barometric pressure limits		

1.4 The Photic and its parts

The Photic comprises the following components:

Component	Part Number
Photic Stimulator	1237
Photic USB Cable	1241
Photic Setup S/W	1247
Photic Arm	1246
Optional components:	
Photic Ext. Trig Cable (Hirose connector)	1242
Photic Pwr+Cntrl+Ext. Trig I/O Cable (D-26HD)	1269
Photic D-26 BNC Adapter Cable	1260
Photic D-26 MiniDIN Adapter Cable	1270
Photic NK Trigger Cable 5m	1309
Photic Trigger Output Cable (Jack)	1248
Photic Trigger Output Cable (Touchproof)	1251
Photic D-26 Xltek 32U Adaptor Cable 5m	1330
Photic D-26 Xltek Trex Adapter Cable	1331
Photic D-26 Xltek Brain Monitor Adaptor Cable 0.5m	1332
Photic D-26 Dantec Focus Adapter Cable 0.2m	1333
Photic D26 to Twin BNC Adapter Cable 0.2m	1334

NOTE: Part numbers may be preceded by 'L14' on labelling or packaging.

Photic USB Connection Cable

The PC connection cable connects from the Photic Stimulator RJ45 connector to a USB port on the host PC.

⚠ The Photic must only be used with the USB cable provided with the unit.

Arm

The arm allows the unit to be conveniently positioned in front of the patient.

Setup software

The Trackit Plus software and stand-alone Photic setup software runs under Microsoft Windows 10 and Windows 11 on the host PC and is used to setup and trigger the Photic Stimulator.

Host PC (not supplied by Lifelines)

The host PC must be certified to IEC 62368-1 or IEC 60950-1 for safety reasons.

Optional Interface Cables

Refer to Appendix 2 details of optional interface cables, which can be used to interface the Photic Stimulator to 3rd party EEG equipment.

Isolated Trigger Output Cables

The isolated trigger output cable triggers an external amplifier or other piece of equipment. It provides an output pulse synchronised to the flash output and is intended to connect to the Trackit's or R40's Auxiliary input. It is available with a 3.5mm jack plug or 2-pin touchproof connector.

> **NOTE:** The isolated trigger output connector in the Photic is Type BF isolated to allow connection to Type BF amplifier inputs.

2 Installation and Maintenance

The following section must be read and understood before the equipment is switched ON.

⚠	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

The function or safety of the equipment could be impaired if it has been subjected to unfavourable conditions in storage or in transit. If at any time function or safety is thought to be impaired, the instrument should be taken out of operation and secured against unintended use.

The manufacturer should be contacted (details on page ii) for assistance, if needed, in setting up, using or maintaining the equipment; or to report unexpected operation or events.

The assembly of the system and any modifications during its service life require evaluation to the requirements of IEC 60601-1.

2.1 Checks for completeness and integrity

1. Remove the equipment from the packaging case(s).
2. Use the parts list to check that all ordered items have been received.
3. It is recommended that assembly instructions for third party products be filed with Photic Stimulator technical reference materials.
4. Check for signs of damage that may have occurred during transit or storage. If any damage is found, do not use the instrument; contact your distributor.

2.2 Environmental parameters for operation

The operational and storage/transportation environmental conditions are as follows:

Operational		Storage and transport	
Temperature	+10°C to +40°C (+50°F to +104°F)	Temperature	-10°C to +50°C (14°F to +122°F)
Relative humidity	25% to 95% non-condensing	Relative humidity	10% to 95% non-condensing
Atmospheric pressure	700 hPa to 1060 hPa	Atmospheric pressure	500 hPa to 1060 hPa

⚠	Do not obstruct any cooling slots. Position the instrument so that air flows freely.

2.3 Power supply connections

Power requirements	5V DC (USB) provided by host PC **OR** 12-15V (provided by 3rd party EEG system)
Power consumption	Maximum peak power consumption 2.5W (single USB port), 5W (two USB ports) or 3.0W @ 12V (direct connection).

Leakage current

This instrument is designed to comply with IEC 60601-1, the international standard for medical electronic equipment, which specifies the permissible levels of leakage current from individual products. A potential hazard exists in the summation of leakage currents caused by connecting several pieces of equipment together. Because this instrument can be used in conjunction with standard electronic devices, the total leakage current should be tested at regular intervals.

2.4 Use with other equipment

Host PC

The host PC, if not supplied by Lifelines, must be certified to IEC 62368-1 or IEC 60950-1 for safety reasons.

EEG amplifier

The Photic's isolated trigger output can connect to an input channel of the amplifier to provide a marker pulse of the flash frequency.

Other patient-connected equipment

The Photic Stimulator has no patient-applied parts so it is unlikely that a safety hazard will arise when used simultaneously with other patient-connected equipment. Always consult the documentation supplied with the other patient-connected equipment to ensure that all hazards, warnings and cautions are considered before the equipment is used together.

2.5 Interference

The Photic Stimulator will continue to operate in the presence of radio frequency magnetic fields (RF) and the effects of electrostatic discharges (ESD) and other interference, in accordance with the requirements of EN60601-1-2.

⚠	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 Photic Stimulator, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.
⚠	When in close proximity to the Photic Stimulator, do not use mobile phones, transmitters, power transformers, motors, or other equipment that generates magnetic fields. Refer to the Appendix for more information.
⚠	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix.

2.6 Maintenance and cleaning

The Photic Stimulator contains no user-serviceable parts. The system uses solid-state components and requires no routine testing or maintenance apart from occasional cleaning and checking for wear or damage to all parts including the accessories.

All the outer surfaces of the Photic Stimulator system may be cleaned using a soft cloth moistened with water and detergent. Each item may also be cleaned using a low-pressure air line or a vacuum cleaner.

Disinfection of the equipment can be carried out using QAC-based disinfectants. Wipes are recommended to prevent the ingress of any liquid into the equipment.

⚠	Do not allow any liquid to enter the case of any instrument or connector. Do not use acetone on any of the instruments.

2.7 Disposal of equipment

This unit includes printed circuit boards, electronic components, wiring and other elements of electronic devices. When this equipment has reached the end of its useful life, follow all local laws and regulations for the proper recycling or disposal of such equipment. Contact your local distributor for information.

3 Connections for Photic Stimulator setup

3.1 Overview

Below is an overview diagram showing the principal components when connected to a PC during system set up. The Photic Stimulator is typically placed 30 cm in front of the patient's eyes. The operator would normally stand in front of the patient to observe any physiological effects during the test. Other persons are excluded from the area.

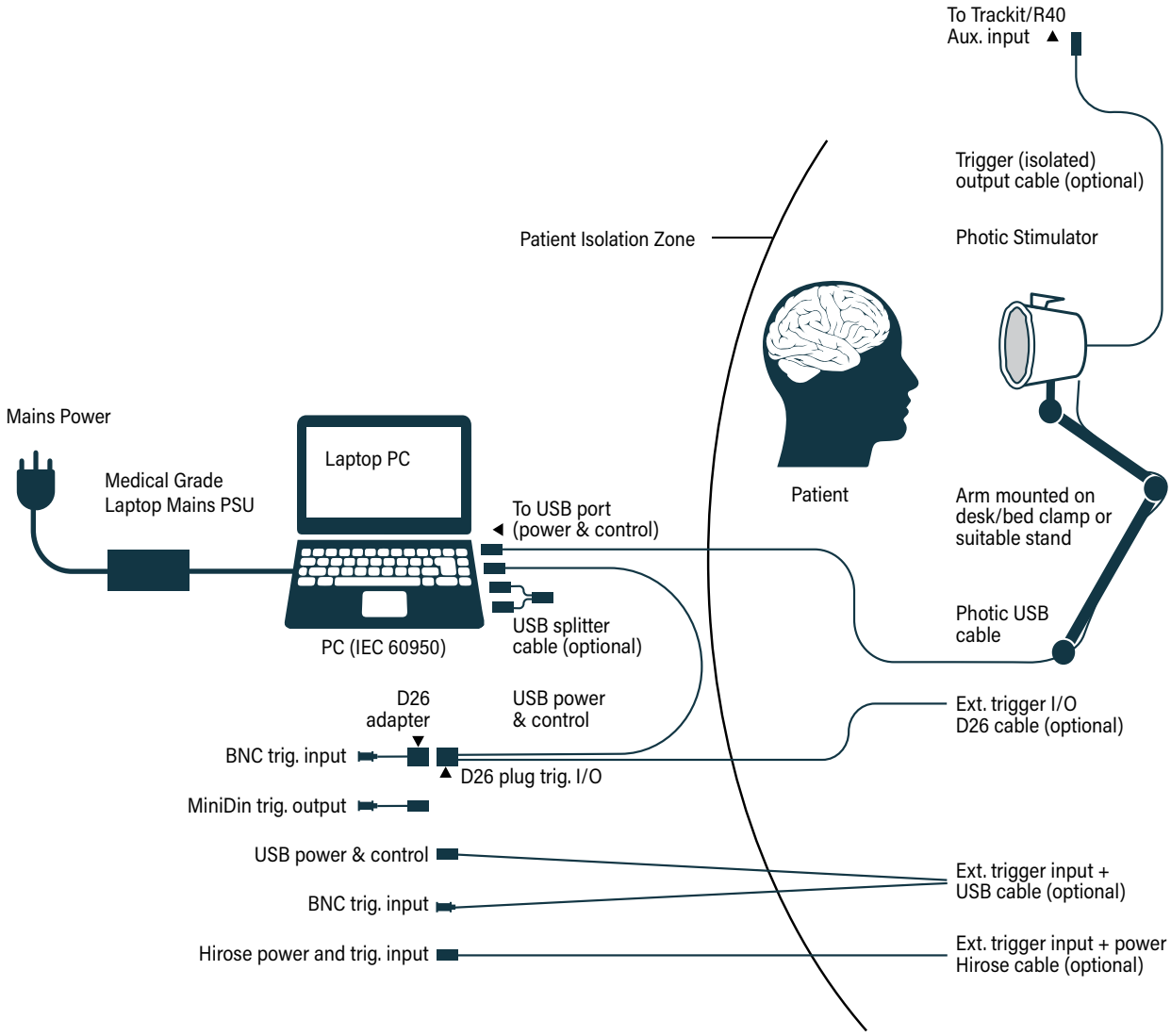


Figure 1: Connecting the Photic Stimulator

3.2 Connecting the Photic Stimulator

The Photic Stimulator may be used in the following different modes:

USB Interface

This is the normal mode whereby power and control are over a USB connection.. The Photic Stimulator USB Cable connects from the Photic's RJ45 connector to the Host PC USB port.

⚠	The Photic must only be used with the USB cable provided with the unit.

External Power + External Trigger Interface

In this operating mode, the unit is triggered by a TTL-like signal. This typically used when the unit is replacing an older piece of equipment that uses a similar trigger arrangement. Cables are available offering BNC trigger input, D-26HD and Hirose - see table *"Optional Interface Cables" on page 27*. There are two operating modes available, depending on the voltage of the external power supply:

- 12 – 15V is detected by the Photic. The pulse width of the incoming trigger signal determines the flash pulse width to control the intensity.
- 5V is detected by the Photic. The pulse width of the incoming trigger signal is ignored and the flash pulse width is fixed at 10ms.

NOTE: In V3 and later of the Photic firmware it is possible to setup an internal flash memory parameter to control the default intensity and duration (not for the PWM case) for external trigger inputs. This parameter is setup once over the USB interface and is then used thereafter at every switch on. Refer to section 4 for details.

NOTE: In V4 and later of the Photic firmware it is possible to setup an internal flash memory parameter to control the default intensity and duration, including the PWM 12V case, for external trigger inputs. This parameter is setup once over the USB interface and is then used thereafter at every switch on. Refer to section 4 for details.

USB + External Trigger combined

The Photic can be powered and controlled via USB, with external triggering through the BNC connector. USB control manages intensity and duration for the external trigger input. If the USB flash repetition rate is active, it takes priority; otherwise, the external trigger is enabled.

External Trigger Output (isolated)

This signal is provided on a 2-pin Type 249 touchproof connector on the Photic unit. It provides a synchronisation trigger pulse to the Trackit or R40 EEG Amplifier or similar equipment to generate the Photic 'tick' marks in the recording. The Trigger Output cable connects from this socket to one of the Aux. Inputs on the Trackit or R40 Amplifier.

The Trigger Output from the Photic is isolated and suitable for connection to type BF equipment. The signal is approximately 75mV in amplitude with a pulse width the same as the currently set flash duration. An alternative cable is available fitted with a 2-pin touchproof connector for use with an EEG amplifier without an 3.5mm Aux connector, such as the Trackit T4A.

External Trigger Output (non-isolated)

This signal is provided on a connector at the host-end of the Photic interface cable. It is a TTL type signal and is used to provide a synchronisation trigger output pulse to the PC.

3.3 Switching on

The Photic Stimulator has an on/off switch located on its rear panel. When off, the flash output is stopped immediately. The state of the switch is communicated back to the host PC if using a USB connection.

4 Photic Stimulator Setup Software

Photic setup and control software is supported on Microsoft Windows 10 and Windows 11.

Using the USB connection, the software allows the user to define parameters such as flash repetition rate, intensity and duration as well as run simple, sweep or complex trains of stimulation.

NOTE: The screenshots shown in the following sections are for illustrative purposes only and may not be exact representations of the actual product.

4.1 Installation

Windows will automatically install the required USB drivers after connecting the Photic to the PC for the first time.

To install the main program, follow the instructions in the Readme file provided with the software.

4.2 Overview

The Photic program provides connection status and running status in the Status bar and Title Bar, as shown in the table below. The status bar also shows the power source (USB) and the operating current (in mA).

Three types of flash stimulation are available: Manual, Sweep or Complex. Select the option as required and the control panel to the left will change appropriately.

Connection	Mode	Status bar text	Title Bar text
Photic not connected to PC	N/A	Disconnected	Photic Stim (Stopped)
Photic Connected	Switch Off	Photic Off	Photic Stim (Stopped)
	Switch On, Stim inactive	Photic On	Photic Stim (Stopped)
	Switch On, Stim active	Photic On	Photic Stim (Running)

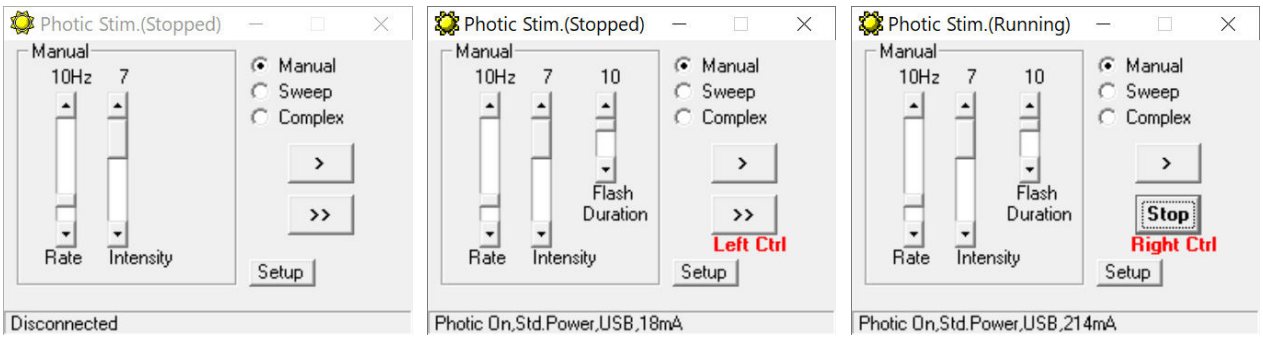


Figure 2: Photic Control Panel

4.3 Manual Stimulation

Manual Stimulation allows for simple, manual control of the Photic flash rate, intensity and duration, as shown in Figure 2 above.

Rate

Use the slider control to vary the repetition rate from 1 Hz to 60 Hz.

Intensity

Use the slider control to vary the intensity over the range 7 (max) to 1 (min) in 7 steps.

Duration

Use the slider control to vary the flash duration from 1 to 10ms.

The Auto function over-rides the selected duration and automatically adjusts the duration depending on the repetition rate. At low frequencies, the duration is lengthened and at high frequencies it is shortened, according to the Duty Cycle set (refer below for details). If the Auto function is selected, the Duration control is not accessible.

Single Flash (>)

Click on the > button to produce a single flash.

Go/Stop (>>)

Click on the '>>' button to start/stop the flash stimulation. The designated keyboard short-cut keys can also be used to start and stop the flash stimulation (refer to Configuration below). The assigned key is shown in red text below the ">>" button.

4.4 Sweep Stimulation

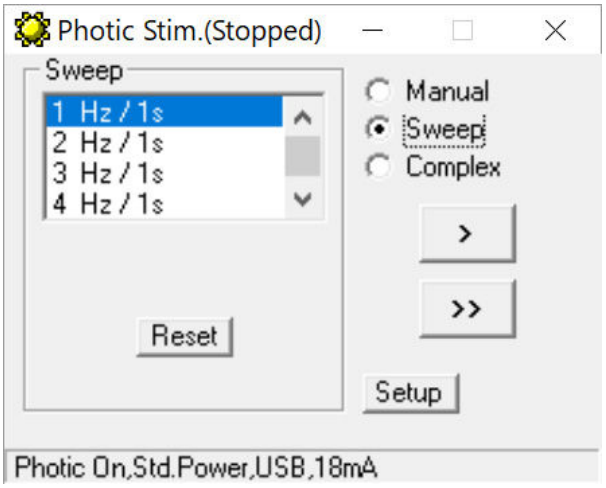


Figure 3: Sweep Stimulation

This allows for a sweep of ascending flash repetition rates and intensities based on start and end values. The list displays each frequency increment with the current active step highlighted. Select any step to start there or click on the Reset button to start back at the beginning.

To set the parameters for the Sweep, click on the Setup button.

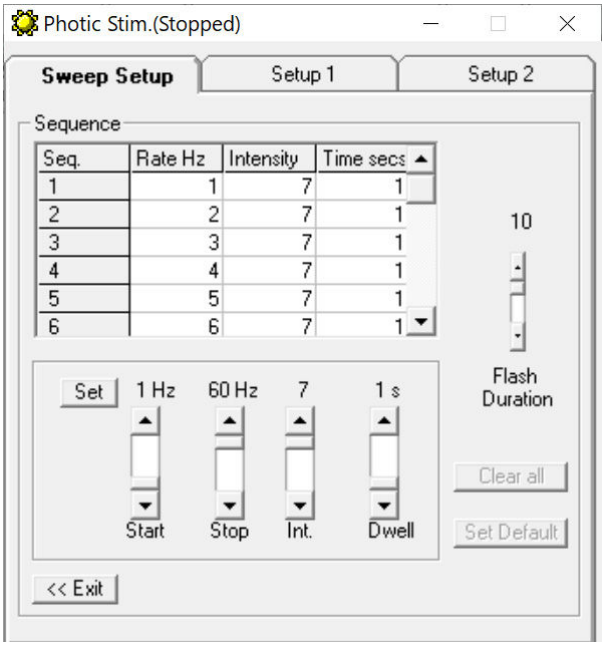


Figure 4: Sweep Stimulation setup

This allows the Start Frequency, Stop Frequency, Intensity and Dwell time to be set. Click on the Set button to calculate the full sweep parameters and fill in the table. The Flash Duration control will be available if Auto Duration has not been set, as described above. Click on Exit when finished to save the settings and revert to the control panel.

4.5 Complex Stimulation

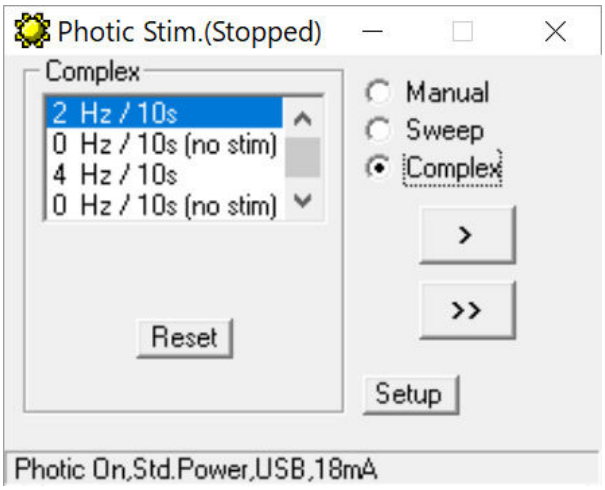


Figure 5: Complex Stimulation

This allows complex trains or sequences of flashes including gaps to be delivered. Up to 64 individual sequence steps can be programmed for Rate, Intensity and Step Time. The list displays each step in the sequence with the current active step highlighted. Select any step to start at or click on the Reset button to start back at the beginning. When the end of the Complex pattern is reached the program automatically stops and resets back to the beginning.

To set the parameters for the Complex, click on the Setup button.

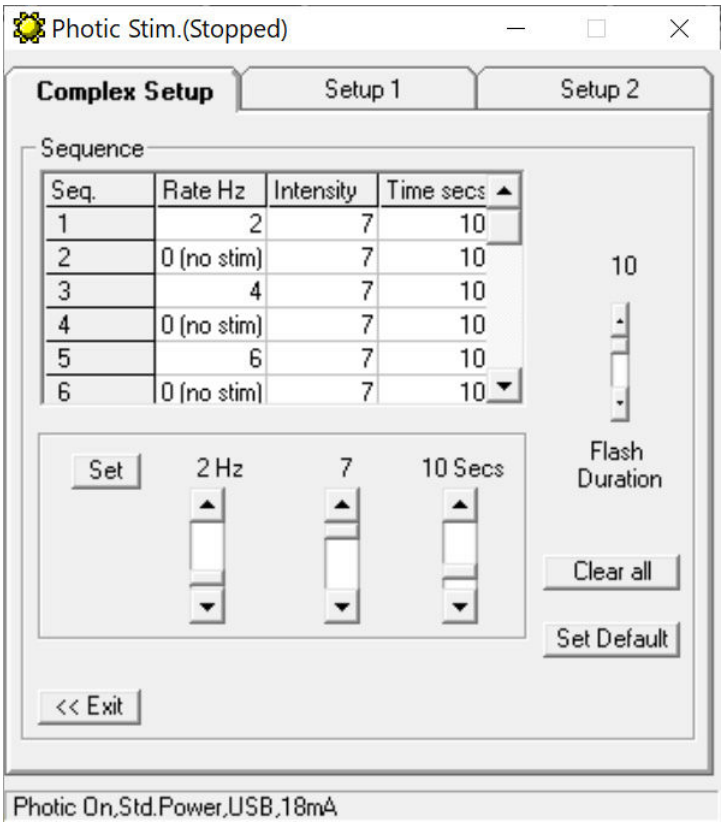


Figure 6: Complex Stimulation setup

Click on a sequence step in the table and adjust its parameters using the slider controls below. To set these new values, click on the 'Set' button. To program a gap, set the frequency to 0. To end the sequence, enter 0 for the Rate and Time. The Flash Duration control will be available if Auto Duration has not been set, as described above. Click on Exit when finished to save the settings and revert to the control panel.

4.6 Setup 1

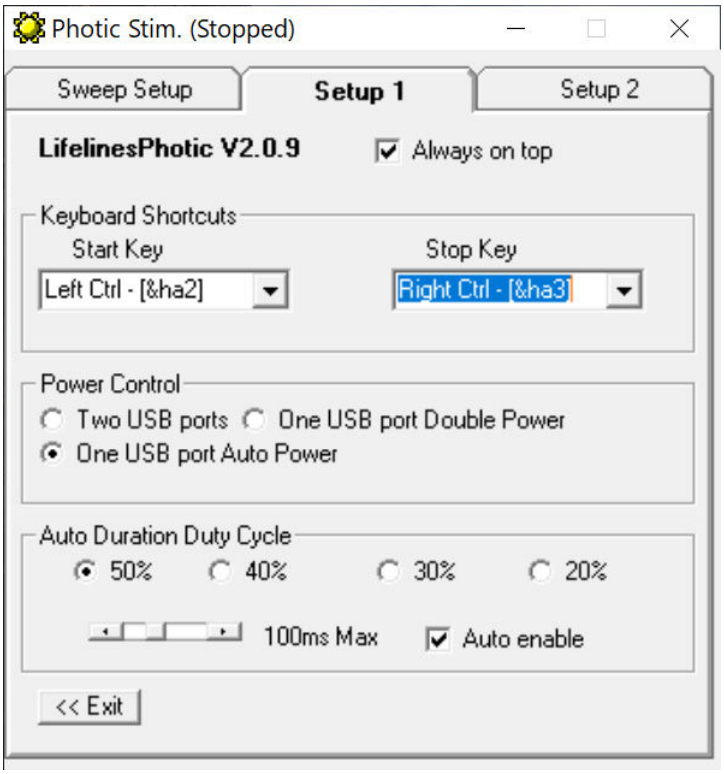


Figure 7: Setup 1

This is the first of two setup screens to configure the photic light's functions and communication. The software version is displayed at the top.

The 'Always on top' option sets whether the window is displayed always on top or not. The minimise window option is operational in either mode.

Keyboard Shortcuts

You can select which keyboard key will start and stop the Photic flashing. Note that this key will work regardless of whether the Photic Control application has the Windows focus or not. Select 'none' to disable the feature.

Power Control

You can select whether you are using 1 or 2 USB ports. Note that the Photic automatically detects when external power is applied.

Note that when using a single USB port, the Photic will automatically limit its power consumption to 0.5A, which is the maximum available from a single port. This will reduce the light output at high flash rates when combined with high intensities.

At the maximum flash duration, the intensity is reduced as follows:

- At > 35Hz, the maximum intensity is 6
- At > 45Hz, the maximum intensity is 5
- At > 55Hz, the maximum intensity is 4

To maintain the maximum intensity at the maximum repetition rate, use 2 USB ports with an optional USB splitter cable.

NOTE: The flash duration also affects the power consumption in a linear relationship, So, if for example, the duration is 8ms and using 1 USB port, then the intensity is reduced as follows (using a 10/8 multiplication factor):

- At > 44Hz, the maximum intensity is 6
- At > 56Hz, the maximum intensity is 5

This means that setting the duration to 6ms and using a single USB port, the maximum intensity is maintained up to the maximum repetition rate.

Many host USB ports and powered Hubs can supply the intermittent power requirements of the Photic in full power mode, so the 'One USB port Double Power" option can be selected. Strictly speaking, a USB power splitter cable allowing the connection of 2 USB ports should be used. If in any doubt, select the "One USB port Auto Power" option or manually reduce the intensity or flash duration as described above.

Auto Duration Duty Cycle

This mode sets the flash duration proportionally based on the flash rate, allowing for higher intensity at low frequencies. The Duty Cycle can be set to 20, 30, 40 or 50% with a maximum flash duration selectable between 50 and 200ms, which avoids very long flash durations at low repetition rates. The Auto Duration feature is enabled/disabled with the check box. Note that when enabled, the flash duration adjustments in other parts of the program are removed.

4.7 Setup 2

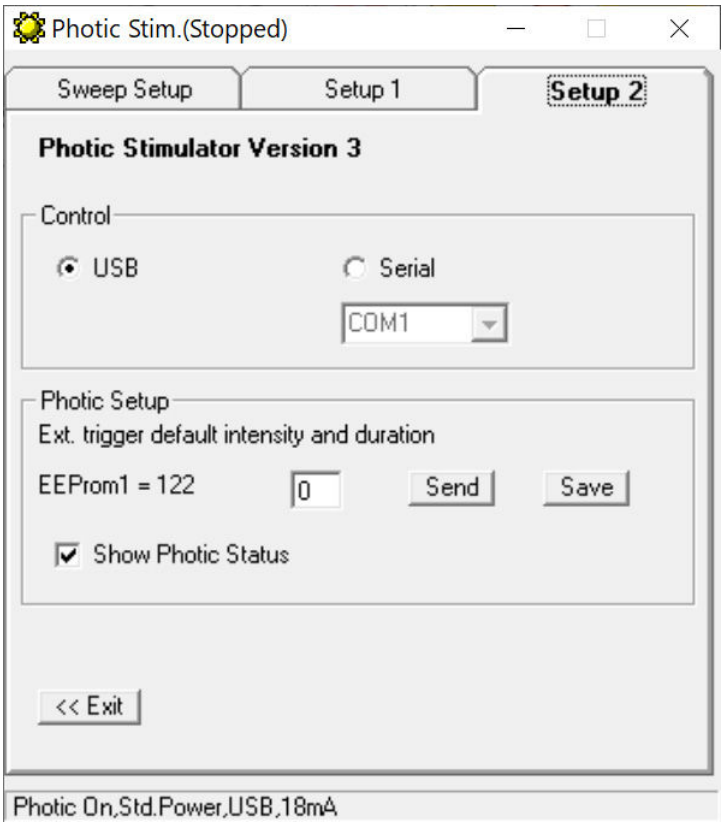


Figure 8: Setup 2

The version of the Photic's firmware is displayed at the top.

Control

Settings to allow control over USB or a Serial Port and COM number.

Photic Setup

The "Show Photic Status" option allows extended status information to be displayed in the Status Bar. This is disabled by default.

The EEProm setting configures the default flash intensity and duration when the unit is being triggered externally. This is set once over the USB interface and stored inside the Photic unit's flash memory for use at every subsequent switch-on. Note that the duration parameter is over-ridden in the PWM case as described above.

The parameter is set as follows:

Bit 7 (MS) Bit 0 (LS)

X	Int 2	Int 1	Int 0	Dur 3	Dur 2	Dur 1	Dur 0

Where:

- Int 2 – 0 represent a 3 bit binary value for the Intensity. The range is 7 (111, max) to 1 (001, min). A value of 0 = 7 max default.
- Dur 3 – 0 represents a 4 bit binary value for the duration in ms. The range is 10 ms (1010, max) to 1 ms (0001, min). A value of 0 = 10 ms max default.

The desired value is set by adding together (16 x Intensity) + Duration. This value in entered into the text box and saved in the Photic unit by clicking 'Save'. The value is automatically read back and displayed to the left to confirm.

For example to set Intensity 7 and Duration 10, enter the value 112 + 10 = 122.

NOTE: This only works for Photic units fitted with firmware V3 or later. The version is displayed at the top of the window.

NOTE: For firmware V4 or later it is also possible to override the PWM input case when 12V is applied. This is useful for situations where 12V is available, not 5V or USB, and the host software does not support the generation of a PWM trigger signal to control the intensity of the Photic unit.

In the above parameter, the Dur value is set to 15 to set this special mode in the Photic unit. The intensity can be set as required to 1 to 7, as above.

4.8 Shutdown procedure

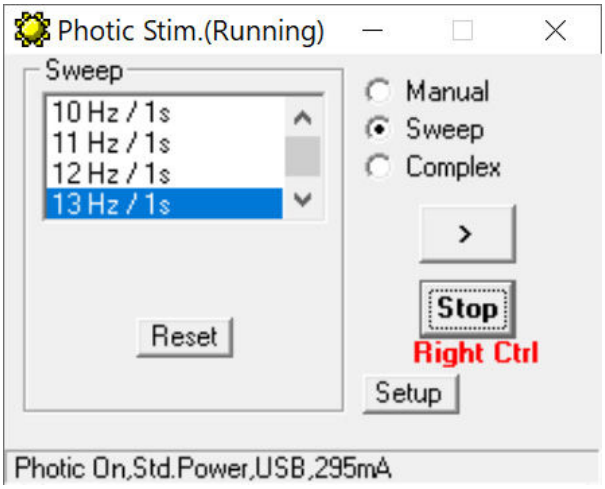


Figure 9: Shutdown Procedure

1 Click Stop.
2 Terminate the program by clicking X at top right.
3 Unplug USB cable.

Appendix 1: Photic Stimulator Specifications

Lifelines reserves the right to change product specifications at any time without notice. This is in line with the company's policy of continual product development.

Light Output	
Light source	Single hi-intensity LED and associated optics
Light aperture	100mm diameter circular
Front-filter provision	120mm diameter
Light output – Luminous power	700 lm typical, 900 lm max
Light output – Illuminance	13,000 lux peak at 30cm, 20Hz
Light output – Luminous Energy	64 lx.s max at 30cm
Light output – Irradiance	12 W/m^2 max at 30cm, 60Hz
Light output - Wavelength	425 – 700nm
Flash Repetition Rate	1 – 60 Hz or single (manual) flash Internal accuracy ± 2.5%
Intensity control	7 steps linear control
Flash duration control	1 – 10ms duration fixed or auto duty cycle, 200ms max Internal accuracy ± 2.5%
Power Input	
USB	5V, 0.5A max (1 USB Port) 5V, 1A max (2 USB Ports) 12V-15V, 0.3A (Connection to 3rd party EEG system)
Connections, ports and controls	
I/O Control RJ45 connector	RJ45 Connector providing: 1. USB data I/O and power input 2. External power input 3. External trigger input and output 4. RS232 data I/O
External trigger input	+ve pulse >3V amplitude, >25µs width
On/Off switch	Switches the flash output On or Off
External Trigger Output (2 pin Type 249 touch-proof keyhole)	Isolated 75mV output pulse for connection to type BF systems
Physical characteristics	
Weight	390g approx including mounting spigot
Size	130mm diameter x 130mm length approx.
Mounting	1. Built-in handle 2. 8mm diameter x 35mm long spigot 3. M8 x 1.25mm threaded bush

Safety and EMC standards	
The system has been certified and complies with the following standards:	
IEC 60601-1	International standard for medical electrical equipment, general requirements.
UL60601-1:2003	USA standard for medical electrical equipment, general requirements.
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	International standard for medical electrical equipment, EMC requirements, calling:
*CISPR11	Conducted Emissions, Group 1, Class B
CISPR11	Radiated Emissions, Group 1, Class B
IEC61000-4-2	Electrostatic Discharges
IEC61000-4-3	Immunity - Radiated RF Field
*IEC61000-4-4	Immunity - Transients Bursts
*IEC61000-4-5	Immunity – Surges
IEC61000-4-6	Immunity – Conducted
IEC61000-4-8	Immunity – Power frequency fields
*IEC61000-4-11	Immunity – Voltage dips, interruptions
*IEC61000-3-2	Harmonic Emissions
*IEC61000-3-3	Voltage Fluctuations/flicker

*Note: Compliance is provided by the PC

Classification	
Degree of protection against electrical shock	No patient-applied parts, no accessible metalwork
Type of protection against electrical shock Note: When unit is connected to mains power supply	Class II device Class 1 power supply
Degree of protection against harmful ingress of water	Ordinary (no protection)
Mode of operation	Continuous
Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Light Hazards

The unit has been tested and is in conformance with the following requirements for optical radiation safety:

Standard	Description
ISO 15004-2:2007	Light Hazard Protection, Group 1 instrument.

Appendix 2: Connection Details

Photic Connectors

RJ45 Connector	
Pin 1	Serial RS232 Output.
Pin 2	External +ve TTL trigger input. Note that with 12-15V power applied, the pulse width of this input signal determines the flash pulse width. With 5V applied, the flash duration is fixed at 10ms or as determined by the Photic internal flash memory parameter 1 – 10ms (which also sets the intensity from 1 - 7). With 5V applied and under USB control, the Photic can be under full USB control whilst also being able to be externally triggered (USB takes precedence). The amplitude of the external trigger signal is >3V and >25us width.
Pin 3	+ve power input, 5V or 12-15V DC
Pin 4	0V connection
Pin 5	Serial RS232 Input.
Pin 6	For Issue 3 units and later, External +ve TTL trigger output. This signal is a non-isolated TTL trigger output which can be used to generate the Photic timing 'tick' marks in the recording. The frequency and duration of the signal match that of the Photic stim.
Pin 7	USB DM signal
Pin 8	USB DP signal
Type 249 Touchproof Connector	
This connector provides an isolated signal suitable for connection to type BF equipment. The signal is approximately 75mV in amplitude with a pulse width the same as the currently set flash duration. It is normally connected to an Aux input on the Trackit.	
Pin 1	+ve output
Pin 2	-ve output

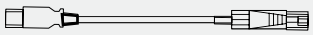
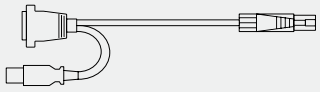
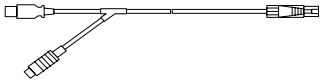
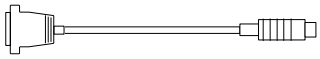
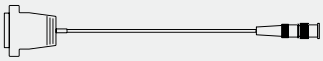
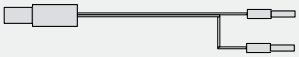
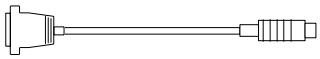
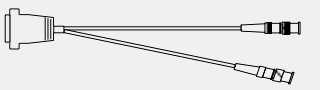
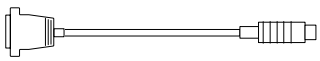
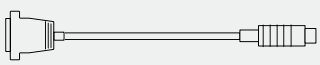
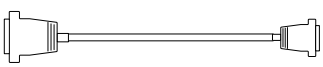
Interface Cable Connectors

D26HD Connector (26way High Density D)	
Pin 16	Gnd
Pin 18	External +ve TTL trigger input. Refer RJ45 pin 2 description above for details.
Pin 17	For the 1269 type cable External +ve TTL trigger output. Refer RJ45 pin 6 description above for details.

NOTE: A D26HD to BNC Adapter cable is available for trigger input and a D26HD to MiniDin for trigger output.

Hirose HR212-10P-8P Connector	
Pin 5	Gnd
Pin 6	External +ve TTL trigger input. With 15V applied from pin 1, the input pulse width determines the flash duration. The intensity is fixed at 7 or determined by the Photic internal flash memory parameter.
Pin 1	+ve power input, 15V DC

Photic Cables

Part No.	Description	View	Power	Control	Trig. I/P	Trig. O/P
1241	Photic Standard USB Cable 5m Provides USB power and control.		USB	USB	USB	None
1242	Photic Viasys Cable 5m Provides ext. 15V power and ext. trigger input.		Ext 15V	Ext PMW	Ext Hirose	None
1269	Photic USB Plus D-26 Trig I-O Cable 5m (USBIFB) or NK Provides USB power & external trigger input & non-isolated output on D26 suitable for USBIFB (I/P) or Adaptor cable (I/P or O/P) (see below).		USB	USB	USB or Ext D26	D26
1309	Photic NK Cable 5m Provides USB power/control and NK trigger output on MiniDIN connector NB. Can be used instead of 1269 + 1270		USB	USB	USB	MiniDIN
Adapters						
1270	Photic D-26 NK Adaptor Cable 0.5m Coverts 1269 into MiniDIN output		USB	USB		MiniDIN
1260	Photic D-26 BNC Adaptor Cable 2.5m Converts 1254 or 1265 or 1269 into BNC input		USB	USB	USB or BNC	
1248	Photic Keyhole Trig O/P Cable 2.5m (jack) Provides a 75mV isolated tick mark for connection to Amp via 3.5mm jack plug					Jack
1251	Photic Keyhole Trig O/P Cable 2.5m (touchproof) Provides a 75mV isolated tick mark for connection to Amp via touchproof plugs					T'proof
1331	Photic D-26 XItek Trex Adaptor Cable 5m Coverts 1269 into Hirose output		USB	USB	USB or Hirose	Hirose
1334	Photic D-26 Twin BNC Trigger I/O 0.2m Converts 1269 to twin BNC trigger I/O		USB	USB	USB or BNC	BNC
1332	Photic D-26 XItek Brain Monitor Adaptor Cable 0.5m Coverts 1269 into PS2 I/O		USB	USB	USB or PS2	PS2
1330	Photic D-26 XItek 32U Adaptor Cable 5m Coverts 1269 into PS2 I/O		USB	USB	USB or PS2	PS2
1333	Photic D-26 Dantec Focus Adapter Cable 0.2m Converts 1269 into D9 I/O		USB	USB	USB or D9	D9

Appendix 3: Manufacturer's Declaration

EMC Compatibility

This section contains specific information regarding the device's compliance with IEC 60601-1-2 and EN 60601-1-2.

	The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment.
	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided here.
	The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system 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 Photic Stimulator, including cables specified by Lifelines Ltd. Otherwise, degradation of the performance of this equipment could result.

Accessory name	Type	Length	Manufacturer
Photic USB Cable	Screened USB	5m	Lifelines
Photic Trigger Output Cable	Twin core	2.5 m	Lifelines

Guidance and Manufacturer's Declaration

Electromagnetic Emissions

IEC 60601-1-2 / EN 60601-1-2

The Photic Stimulator is intended for use in the electromagnetic environment specified below. The customer or user of the Photic Stimulator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR11/EN55011	Group 1	The 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 CISPR11/EN55011	Class B	The Photic Stimulator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. Note: Only the recommended or supplied PC must be used in the system to ensure compliance.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

IEC 60601-1-2 / EN 60601-1-2

The Photic Stimulator is intended for use in the electromagnetic environment specified below. The customer or user of the Photic Stimulator should assure that it is used in such an environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) IEC 61000-4-2	+/- 8 kV: Contact +/- 15kV: Air	+/- 8 kV: Contact +/- 15V :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 Transients/ burst IEC 61000-4-4	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Compliance is provided by the recommended PC equipment.	Compliance is provided by the recommended PC equipment.	Mains power should be that of a typical commercial and/or hospital environment. If the user of the Photic Stimulator system requires continued operation during power mains interruptions, it is recommended that the Photic Stimulator be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m See Note c.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commer-cial and/or hospital environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF Common mode/ Conducted Susceptibility IEC 61000-4-6 Radiated RF Electromagnetic Fields IEC 61000-4-3	3 Vrms 0.15 to 80 MHz 6V in ISM Bands 3 V/m 80 MHz to 2.5 GHz	3 Vrms 0.15 to 80 MHz 3 V/m 80 MHz to 2.5 GHz See Note d.	Portable and mobile RF communications equipment should be used no closer to any part of the Photic Stimulator, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** Where P is the maximum output power rating of the transmitter in watts (W) according to the 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 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 strength 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 Photic Stimulator is used exceeds the applicable RF compliance level above, the Photic Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Photic Stimulator.

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

c The Photic Stimulator does not contain magnetic components and is not susceptible to power frequency magnetic field interference.

d The conditions of intended use justify lower immunity test levels. The hazards and risk analysis associated with these lower limits have been documented in the Risk Management file.

Recommended separation distance between portable and mobile RF communications equipment and the Photic Stimulator.

IEC 60601-1-2 / EN 60601-1-2

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

If any electromagnetic interference is encountered, the patient and equipment should move to an area without interference.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
W	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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