



Lifelines
neuro



photic

Stimulator



USER MANUAL

Imagine EEG Anywhere



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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.

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.

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Trademarks

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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: the manufacturer has a policy of continual product improvement; hence the equipment specifications are subject to change without notice.

Check with Lifelines or your distributor if a software update is available.

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 line with modern computing practice, it is advisable that continual protection against viruses, Trojans, malware, adware etc. is provided on the PC used for installation and the surrounding systems. Please note the following recommendations which should be supported by your internal IT/Computing department procedures and practices:

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 or automatic if desired but at a time when the system is not being used.
3. All programs offering auto-update features, including Windows, should be set to manual or automatic if desired but at a time 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.

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1 System Overview

1.1 Warnings & 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.

1.2 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*

* Special recycling required, do not dispose of in landfill. When this equipment has reached the end of its useful life, it must be disposed of in an environmentally-friendly way. Waste electrical and electronic equipment (WEEE) requires special procedures for recycling or disposal. This includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of such equipment. Contact your local distributor for information concerning this.

Storage and transport symbols

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

1.3 The system and its parts

The Photic Stimulator is a high performance solid-state flash stimulator used in the fields of Electroencephalography (EEG) and Visual Evoked Potentials.

The system comprises the following components:

Component	Part Number
Photic Stimulator	1237
Photic USB Cable	1241
Photic User Manual	1240
Photic Setup S/W	1247
Photic Arm	1246
Customer registration form	1032
Optional components:	
Photic USB Splitter Cable	1243
Photic Ext. Trig Cable (Hirose connector)	1242
Photic Pwr+Ext. Trig I/P Cable (D-26HD)	1254*
Photic Pwr+Cntrl+Ext. Trig I/P Cable (D-26HD)	1265*
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 USB + Trig Cable (USB & BNC)	1261#
Photic Trigger Output Cable (Jack)	1248
Photic Trigger Output Cable (Touchproof)	1251

NOTE: * Both these cables are superseded by the '1269' cable.
#This cable is superseded by the '1269' + '1270' cables.

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

1.4 Specifications and safety

Electrical Safety and EMC

The system has been certified and complies with the following standards

Standard	Description
IEC 60601-1	Standard for medical electrical equipment, general requirements.
UL60601-1:2003	USA standard for medical electrical equipment, general re-quirements.
CAN/CSA 22.2 No 601.1 M90	Canadian standard for medical electrical equipment, general requirements.
IEC 60601-1-2	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
<i>*Note: Compliance is provided by the PC.</i>	

Classification	
Degree of protection against electrical shock:	No patient-applied parts, no accessible metalwork
Type of protection against electrical shock:	Class II device
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.

1.5 Description of the components

The Photic Stimulator

The Photic Stimulator is a device for generating short-duration flashes of white light by means of a solid-state LED (light emitting diode). The flashes are controlled from a host PC and typically occur over a repetition rate of between 1 and 60Hz.

Photic stimulation is used as a clinical routine in the field of Electroencephalography (EEG) and Visual Evoked Potentials. The visual stimulation is used to produce electrical responses in the brain of the patient. These signals are monitored and recorded by a separate piece of equipment. In EEG studies where epilepsy is typically being diagnosed, Photic stimulation is used to assess the patient's photosensitivity, i.e. sensitivity to flashing lights.

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. Note the Cautions at the beginning of this document.

Refer to **Figure 1** for the system setup.

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 in order to observe any physiological effects during the test. Other persons are excluded from the area.

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 XP, Windows Vista, Windows 7, 8 or 10 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 60950-1 for safety reasons.

Optional Interface Cables

The following, optional, interface cables can be used to interface the Photic Stimulator to 3rd party EEG equipment.

USB Splitter Cable	The allows the Photic to be used at full power by using 2 USB ports. Most USB ports can supply the full-power, intermittent current required by the unit and a USB splitter cable is not normally required. Refer Section 3.2 for details.
Ext. Trigger Input Cable (D-26HD connector)	This cable allows the Photic to be triggered from a TTL-type signal derived from an external piece of equipment. It is fitted with a D-26 High-density plug suitable for connection to the USBIFB. Power is supplied from an available USB port. Adapter cables are available to convert the D26 connector to a BNC for trigger input or MiniDIN for trigger output (see below). For details of this mode of operation, refer 3.2 .
D-26HD BNC Adapter	This cable is used with the cable above to convert from the D-26HD trigger input to a standard BNC connector
D-26HD MiniDIN Adapter	This cable is used with the cable above to convert from the D-26HD trigger output to a MiniDIN connector.
Ext. Trigger Input Cable (Hirose HR212-10P-8P connector)	This cable allows the Photic to be supplied by 15V and triggered from the Viasys V32 system.
Ext. Trigger Input Cable + USB control (USB and BNC connectors)	This cable allows the Photic to be triggered from a TTL-type signal whilst being simultaneously powered and controlled from USB. This allows the intensity and duration for the external triggering to be controlled from the USB interface.
Trigger Output Cable	<p>This allows the Photic to trigger an external amplifier or other piece of equipment. It provides a precise pulse output synchronised to the flash output and is connected to one of the Trackit's or R40's Auxiliary inputs located on the PCU. It is available with a 3.5mm jack plug or 2-pin touchproof.</p> <p>Note: Restrictions on signal output connections. The trigger output cable described above is fully isolated in the Photic to type BF standards so it can be connected to type BF amplifier inputs.</p>

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 Assembly instructions for third-party products will be found in their packing cases. It is recommended that these instructions 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, which is not supplied by Lifelines, must be certified to IEC 60950-1 for safety reasons.

EEG amplifier

The patient will be connected to an EEG amplifier during the EEG examination, and 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 and so when used simultaneously with other patient-connected equipment, for example a cardiac pacemaker or other electrical stimulator, it is unlikely that a safety hazard will arise. However 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 procedures apart from occasional cleaning and checking for wear and 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 by the use of QAC-based disinfectants. Wipes are recommended in order to prevent the ingress of any liquid into the equipment. Suitable products include Mikroqid Sensitive Wipes (Schülke & Mayr GmbH), Microbac forte (Paul Hartmann AG), Distel Wipes (Tristel Ltd.), Mikro-Kill disinfectant wipes (Medline Industries, Inc.), Sani-Cloth HB



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

When the device has reached the end of its operating life, it should be disposed of in accordance with local waste regulation authority that is typically within the local government office.

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.

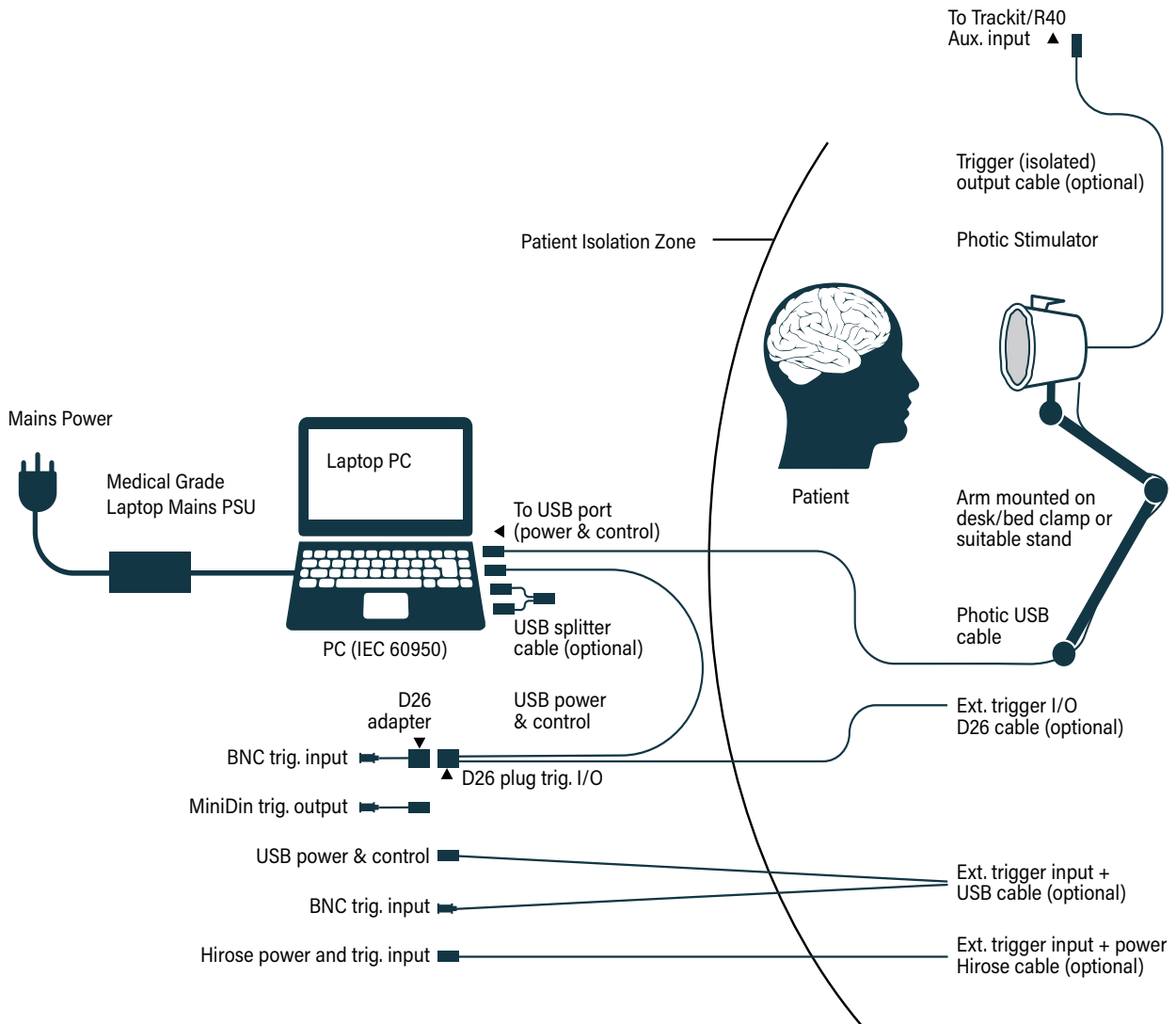


Figure 1: Connecting the Photic Stimulator

List of parts	List of optional parts
Photic Stimulator	Interface cables - various
Photic USB Cable	Trigger Input Cables - various
Photic User Manual	Trigger Output Cable - various
Photic Setup S/W	
Photic Arm	

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 is over a USB connection. The general arrangement is shown in Figure 1 above. 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

This is a 'dumb' operating mode where the unit is triggered by a TTL-like signal. This is most useful when the unit is being used to replace 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 11. There are two operating modes available, depending on the voltage of the external power supply:

- 12 - 15V is detected by the Photic and in this mode the pulse width of the incoming trigger signal determines the flash pulse width. In this way, it is possible to control the intensity.
- 5V is detected by the Photic and in this mode 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

This allows the unit to be powered and controlled over USB but also externally triggered from the BNC connector. This enables the intensity and duration to be controlled over USB for the external trigger input. When the USB control turns on its own flash repetition rate, this takes priority over the external trigger input. When turned off, the external source is enabled again.

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 Recorder 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. 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 XP, Vista Windows 7, Windows 8 & 8.1 and Windows 10.

The Photic Stimulator is connected to the host PC USB port. Over 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

The USB drivers will be found on the installation CD. Upon first connection of the Photic to the PC USB port, at the Windows prompt, browse to the folder CD Drive:\USB Drivers. From there, Windows will find the correct drivers for the version of Windows being used.

To install the main program, follow the instructions in the Readme file on the CD.

4.2 Overview

When the program is launched, 3 types of flash stimulation are provide: Manual, Sweep or Complex. Select the option as required and the control panel to the left will change appropriately.

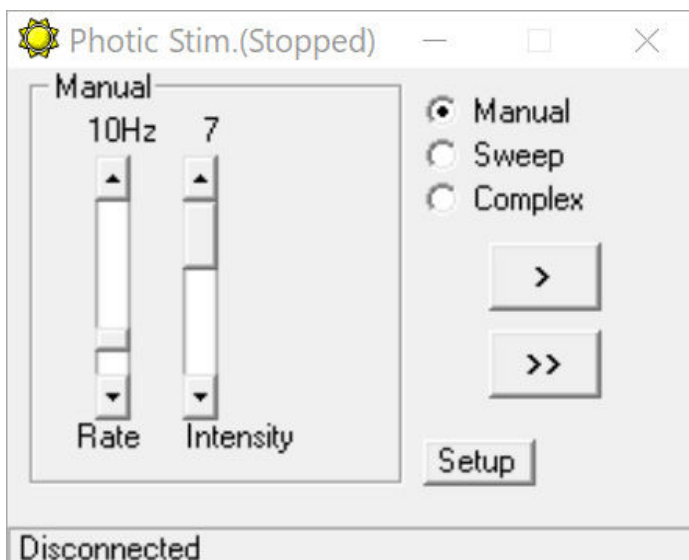


Figure 3: Photic not connected (Manual Stimulation)

The Status Bar information at the bottom of the window displays “Disconnected” if no Photic is found connected to the PC.

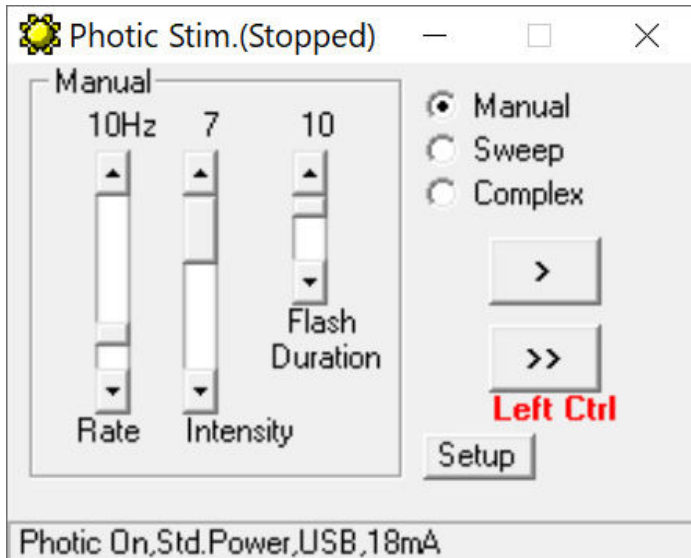


Figure 4: Photic connected (Manual Stimulation)

When a Photic is found connected to the PC, the Status Bar information displays either “Photic On” or “Photic Off” depending on the state of the On/Off switch at the rear of the unit. With no Photic connected or when no flash stimulation is in progress, the Title Bar will display “Photic Stimulator (Stopped)”. The status bar also shows the power source (USB) and the operating current (in mA).

With a Photic connected and flash stimulation in progress, the Title Bar displays “Photic Stimulator (Running)”, as shown below:

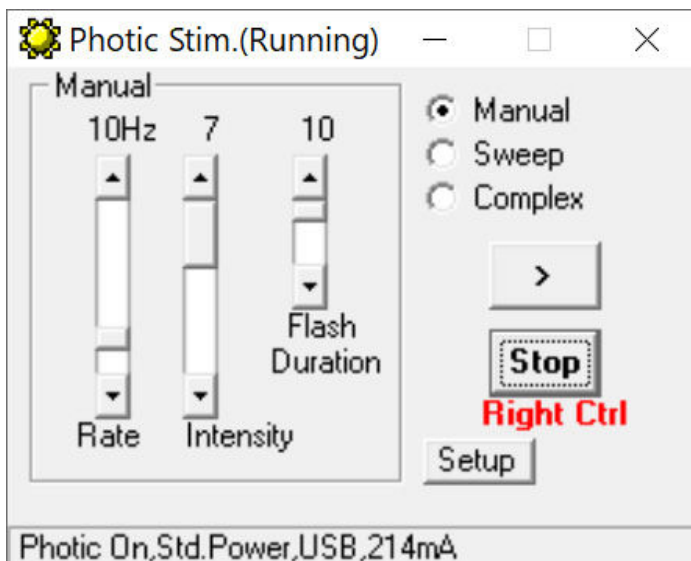


Figure 5: Photic connected and running (Manual Stimulation)

4.3 Manual Stimulation

Manual Stimulation allows for simple, manual control of the Photic flash rate, intensity and duration, as shown in Figure 5 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

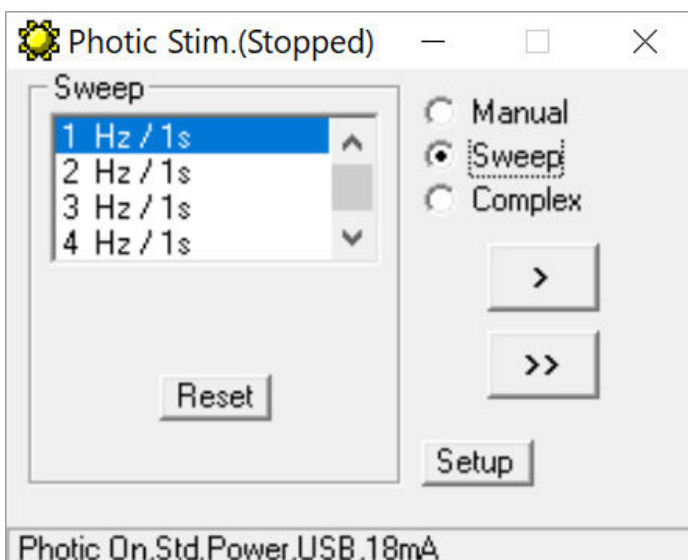


Figure 6: Sweep Stimulation

This allows a sweep of ascending flash repetition rates to be delivered. The Start Frequency, Stop Frequency and the Dwell Time for each 1Hz increment can be set and the Intensity. The list displays each frequency increment with the current active step highlighted. Select any step to start at or click on the Reset button to start back at the beginning.

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

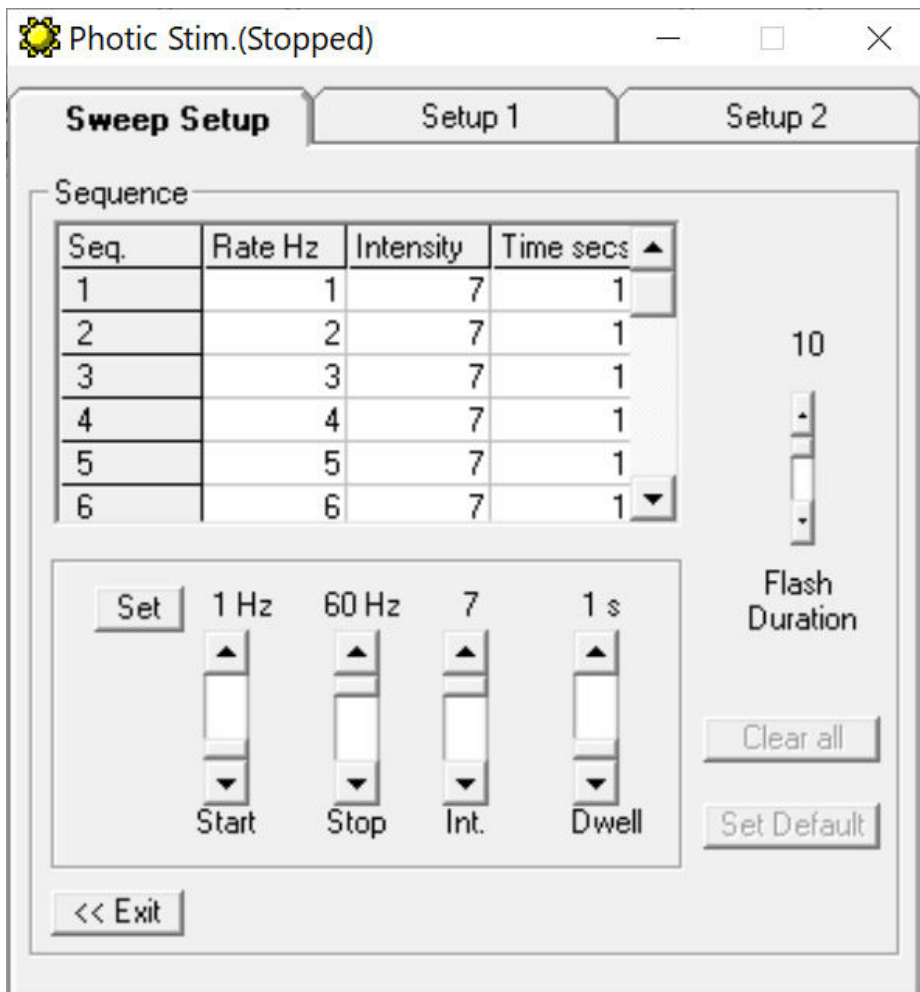


Figure 7: Sweep Stimulation setup

This allows the Start Frequency, Stop Frequency 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 setting up. This will save the settings and revert to the control panel.

4.5 Complex Stimulation

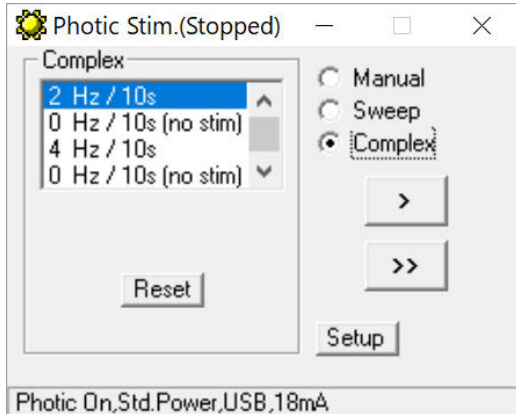


Figure 8: Complex Stimulation

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. Programming a 0 for rate indicates a gap of defined length with no flash stimulation. 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. Gaps are displayed as 0 Hz. When the end of the Complex pattern is reached the program automatically reset back to the beginning.

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

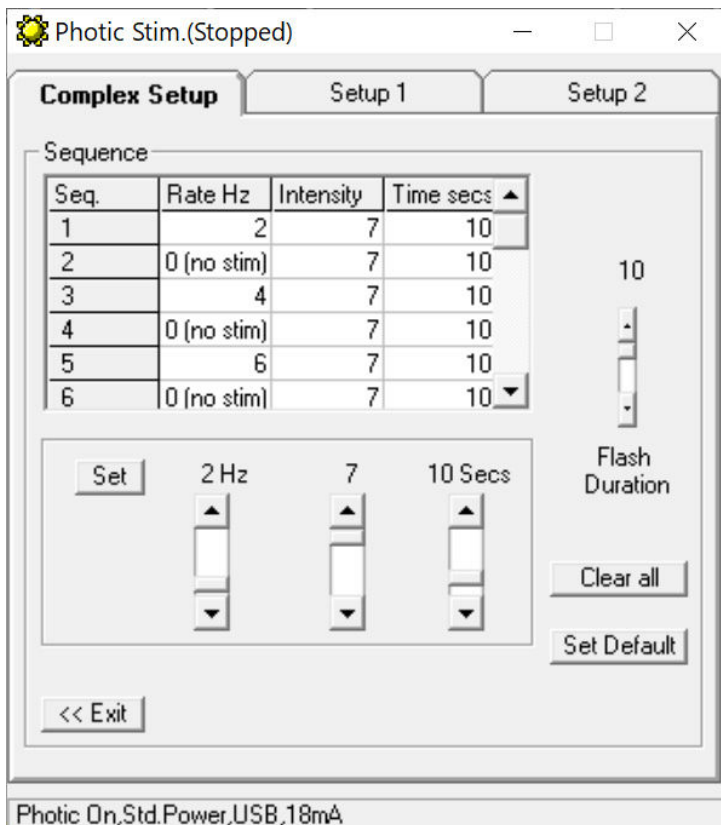


Figure 9: Complex Stimulation setup

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 setting up. This will save the settings and revert to the control panel.

4.6 Setup 1

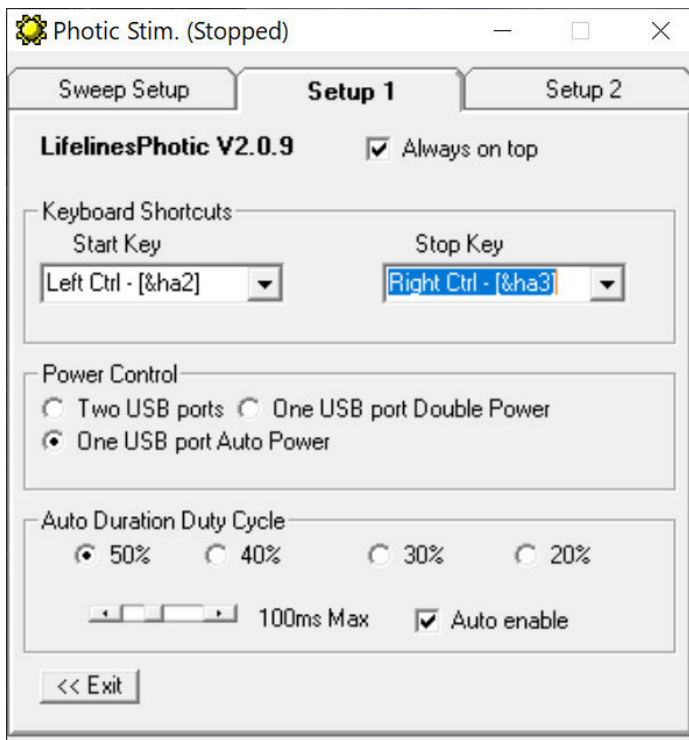


Figure 10: Setup 1

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, of course, 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 from the unit at high repetition rates when combined with high intensities and with maximum flash duration selected.

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

At the maximum flash duration and using 1 USB port means that the intensity is not less than 4 up to the maximum repetition rate of 60Hz. This level of reduction is small and only comes into effect at extremes of operating conditions and using the limited power availability from 1 USB port, as detailed.

To maintain the maximum intensity at the maximum repetition rate, use 2 USB ports with the optional USB splitter cable (p/n 1243).

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 is the mode whereby the flash duration is proportional to the repetition rate according to a set duty cycle. In this way, the intensity is increased at low frequencies. Duty Cycle can be set to 20, 30, 40 or 50% with a maximum flash duration selectable between 50 and 200ms. This latter setting 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

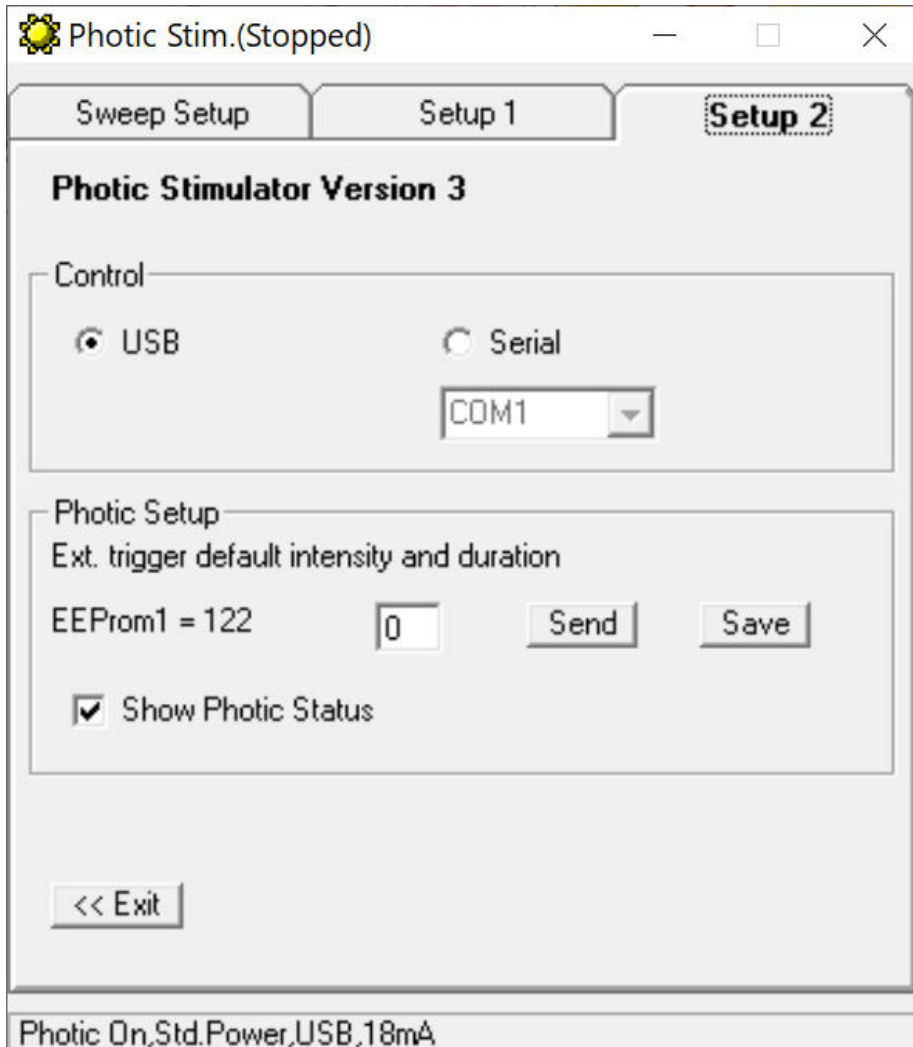


Figure 11: Setup 2

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. Normally deselected.

Also here, is the option to set 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 is 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.

So for example to set Intensity 7 and Duration 10, the value to enter would be $112 + 10 = 122$.

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

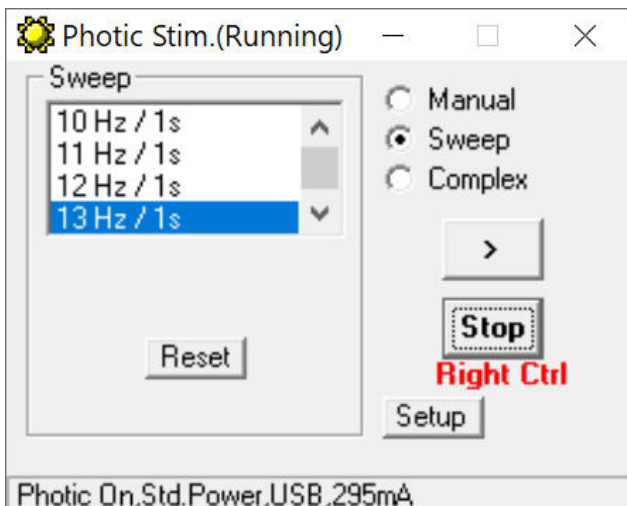


Figure 11: Shutdown Procedure

- 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 \pm 2.5%
Intensity control	7 steps linear control
Flash duration control	1 – 10ms duration fixed or auto duty cycle, 200ms max Internal accuracy \pm 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, >25 μ s 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)



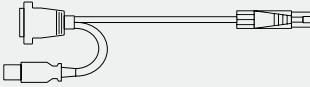
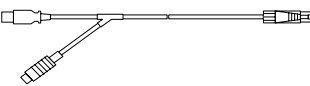
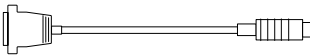
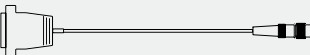

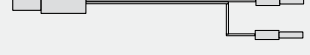

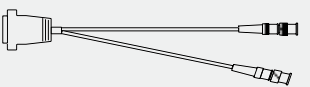
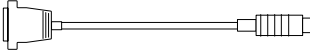


Pin 16	Gnd
Pin 18	External +ve TTL trigger input. Refer RJ45 pin 2 description above for details.
Pin 17	For the 1269 type cable External +ve TTL trigger output. Refer RJ45 pin 6 description above for details.

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

Lifelines Part No.	Description	G&B Part No.	View	Power	Control	Trig. I/P	Trig. O/P
1241	Photic Standard USB Cable 5m Provides USB power and control.	6881		USB	USB	USB	None
1242	Photic Viasys Cable 5m Provides ext. 15V power and ext. trigger input.	6882		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).	6899		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	51226		USB	USB	USB	MiniDIN
Adapters							
1270	Photic D-26 NK Adaptor Cable 0.5m Converts 1269 into MiniDIN output	6900		USB	USB		MiniDIN
1260	Photic D-26 BNC Adaptor Cable 2.5m Converts 1254 or 1265 or 1269 into BNC input	6892		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	81000476					Jack
1251	Photic Keyhole Trig O/P Cable 2.5m (touchproof) Provides a 75mV isolated tick mark for connection to Amp via touchproof plugs	81000477					T'proof
1331	Photic D-26 Xltrex Trex Adaptor Cable 5m Converts 1269 into Hirose output	51241		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	51244		USB	USB	USB or BNC	BNC
1332	Photic D-26 Xltrex Brain Unit Adaptor Cable 0.5m Converts 1269 into PS2 I/O	51242		USB	USB	USB or PS2	PS2
1330	Photic D-26 Xltrex 32U Adaptor Cable 5m Converts 1269 into PS2 I/O	51240		USB	USB	USB or PS2	PS2
1333	Photic D-26 Dantec Focus Adapter Cable 0.2m Converts 1269 into D9 I/O	51243		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 commercial and/or hospital environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
<p>RF Common mode/ Conducted Susceptibility IEC 61000-4-6</p> <p>Radiated RF Electromagnetic Fields IEC 61000-4-3</p>	<p>3 Vrms 0.15 to 80 MHz 6V in ISM Bands 3 V/m</p> <p>80 MHz to 2.5 GHz</p>	<p>3 Vrms 0.15 to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz See Note d.</p>	<p>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.</p> <p>Recommended separation distance</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.</p>			
<p>NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>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.</p>			
<p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			
<p>c The Photic Stimulator does not contain magnetic components and is not susceptible to power frequency magnetic field interference.</p>			
<p>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.</p>			

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		
	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 $d = 2.33 \sqrt{P}$
W			
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.

Version History

V1.5 (15 December 2009)

- First release

V1.6 (15 June 2010)

- Lifelines logo adjusted on page 3.
- Virus protection recommendations added, Page 5.
- Details of Light Hazard Protection according to ISO 15004 added, Page 11 and Specifications, page 32.
- Additional interface cables added, page 10.
- Additional details shown in overview diagram Fig. 1, page 18.
- Additional modes detailed, page 19 – 20.
- Setting of internal flash memory parameter for default external trigger intensity and duration added, refer 3.2 and 4.6.
- Additional connector details, page 33.
- Additional light output details in Specifications, page 32.

V1.7 (20 July 2011)

- Additional interface cables added, sections 1.2 and 1.4
- Additional connector and cable details added in Appendix 2.
- Clarification to Overview diagram in section 3 and section 3.2.
- External trigger input amplitude and duration added to Specification.

V1.8 (25 July 2012)

- Various amendments for 60601 3rd edition.

V1.9 (22 July 2014)

- Corrected CE symbol on page 3.

V1.10 (23 Jan 2017)

- Corrected address on page 3.
- Setting of internal flash memory parameter for default external trigger intensity and duration added for 12V (PWM) case. Refer 3.2 and 4.6.

V1.11 (7 Oct 2019)

- Updated EMC Declaration
- Added European Representative information
- Updated front cover.

V2.0 (11 March 2020)

- New user manual design.



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photic

Stimulator

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