LIGHTMED

Enlightening Vision

Operator's Manual

Wireless Footswitch

Operator's Manual

For The

Wireless Footswitch

CE 2460
Directive 93/42/EEC
Doc. No.: DC6400
Rev. No.: 01

Operator's Manual for the Wireless Footswitch

Clinicians and/or Doctors should ensure that they are adequately knowledgeable of the operation or training prior to using the Wireless Footswitch.

This Operator's Manual should be studied and understood before proceeding to operate the equipment on patients.

This Operator's Manual contains confidential and proprietary information of the Manufacturer.

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Document Title: Operator's Manual for the Wireless Footswitch

Document Number: DC6400

CAUTION!

NCC 警語

取得審驗證明之低功率射頻器材,非經核准,公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻器材之使用不得影響飛航安全及干擾合法通信;經發現有干擾現象時,應立即停用,並改善至無干擾時方得繼續使用。
前述合法通信,指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

FCC CAUTION

FCC Label Compliance Statement：
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:(1)this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
To assure continued FCC compliance：
1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment
2. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Table of Contents

Section 1 Introduction

This manual is intended to provide the Operator with an overview of the operation and safety requirements for the Wireless Footswitch. This manual is not intended to provide instructions on actual treatment procedures, and it is expected that users will have undertaken training prior to using the equipment.

Caution has been taken into consideration in the preparation and revision of this Manual. However, there is no guarantee that all information written here will be accurate. The information provided in this Manual is subject to change without notice.

Only approved or authorized accessories may be used with this footswitch. The Manufacturer and Distributor organization shall not be held liable or responsible for damages or injury caused as a result of using unapproved accessories.

All maintenance and service work must be carried out by authorized and trained Service Technicians and only those procedures outlined in the Operator's and Service Manual are allowed. Any service work carried out by unauthorized persons will void all warranties.

No circuit diagrams or component part lists are to be provided for this wireless footswitch. If you require any technical documentation that is not provided in this manual, please contact the Manufacturer or your local distributor, in writing, with your reasons for requesting them and only then a copy of the Service Manual may be provided.

Before using the Wireless Footswitch, the operator should read this manual carefully and pay attention to the sections of safety, operation, and maintenance.

Section 2 Safety

This footswitch has been designed and tested to function in a safe and correct operation when used as indicated in this manual. Do not use this footswitch without reading and completely understanding this Operator's Manual.

2.1 Product Classifications

The LIGHTLas 532/577/810 Photocoagulator Laser is classified as:

- Class IV laser product as specified in the standards IEC 60825-1 (2007) as well as USA 21 CFR 1040.10 and 1040.11.
- Class I type B electromedical equipment as specified in the IEC 60601-1 standard.
- Class II device according to the FDA CFR 21 regulations.
- Class II type B medical device according to the MDD 93/42/EEC (as amended by 2007/47/EC).

The LIGHTLas 532/577/810 Photocoagulator Laser has been designed to comply with the following standards:

Standards	LIGHTLas 532/577/810
Laser	• IEC 60825-1:2007 • EN 60825-1:2007 • USA 21 CFR 1040.10, 1040.11 (1997) • IEC 60601-2-22:2007+A1:2012 • EN 60601-2-22: 2013
Electrical	• IEC 60601-1 2005+CORR.1:2006+CORR.2:2007+A1:2012 • EN 60601-1: 2006+A1:2013 • EN 60601-1-2: 2015 • IEC 60601-1-2 :2014 • USA UL 2601 • JIS T1001 (1992) and T1002 (1992)
Others	• MDD 93/42/EEC (as amended by 2007/47/EC) • EN 60601-1-6:2010 • IEC 60601-1-6 :2010 • EN 62366 :2008 • IEC 62366:2007 • ISO 15223-1:2016 • ISO 14971:2012 • ISO 13485:2016

2.2 Warnings and Precautions

The following warnings and precautions apply to the Wireless Footswitch and should be observed by all users at all time:

- **DO NOT** try to service or repair the footswitch other than what is included in this manual. Service should only be performed by authorized and trained technicians.
- **ALWAYS** use the wireless footswitch module when the battery is sufficiently charged.
- **ALWAYS** perform laser treatments when the wireless footswitch connection is stable.
- **DO NOT** use the Footswitch if the ambient temperature is outside the range of 15 to 30°C, which is the rated operating temperature limits where the Footswitch can be guaranteed to operate without any interruptions. Outside this range of temperature, it is possible for the Footswitch to generate an error condition where a message is displayed, and the Footswitch goes into disconnect mode until the internal temperature returns to normal limits. Only then the Footswitch can be used again but the error condition may reoccur unless the rated temperature comes within limits.

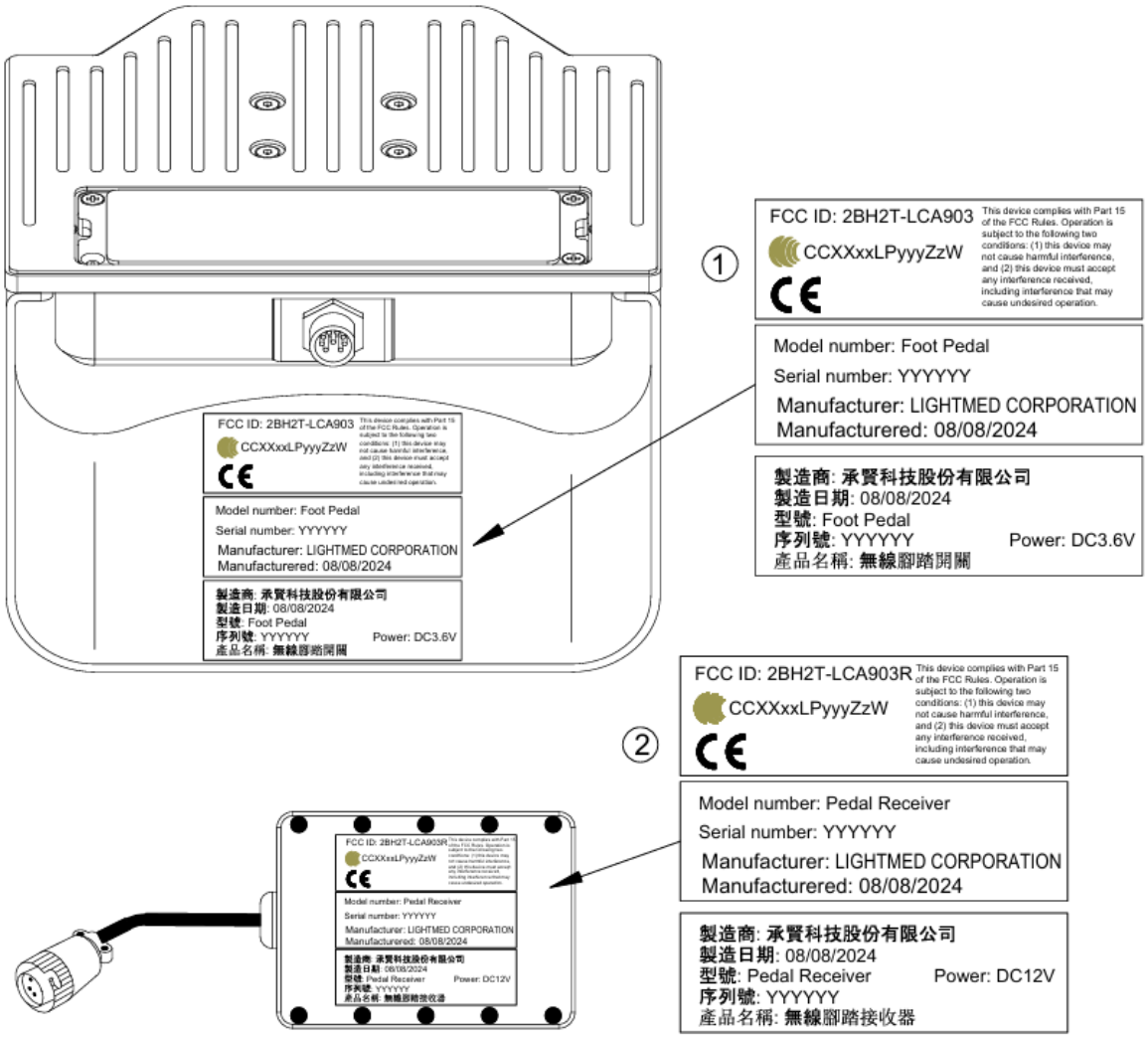
2.3 Electrical Hazards

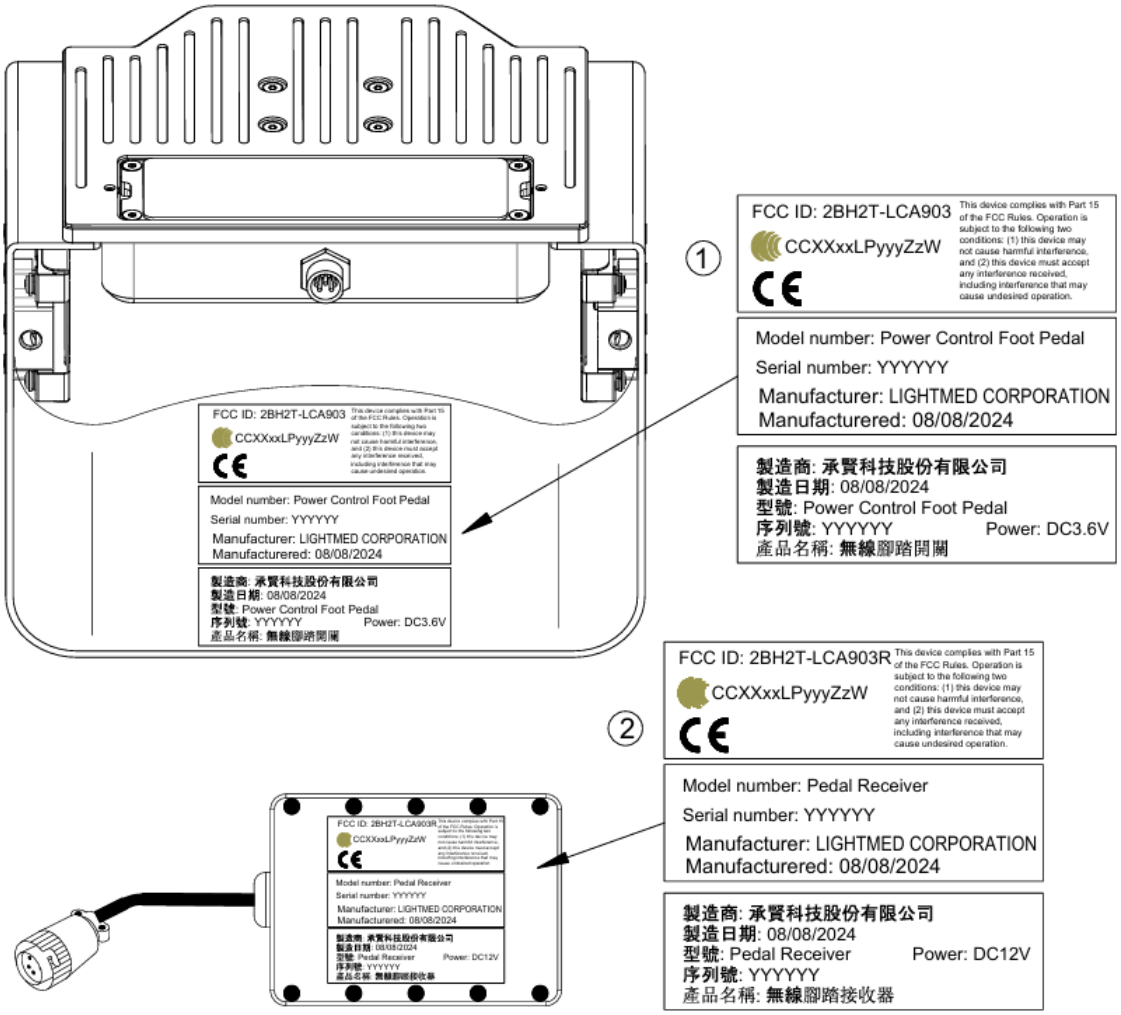
The wireless footswitch is designed to meet international standards for medical equipment. This wireless footswitch system is designed to operate using batteries.

WARNING! Ensure the battery is charged, the beeper is not sounding, and the connection is stable without any disconnection issues before starting the treatment.

The operator or user does not need to remove any cover or housing after installing the battery.

2.4 Wireless Footswitch Labels





Item	Description
FCC ID	FCC Label Compliance Statement This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. To assure continued FCC compliance-15.21: e 1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment. 2. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm

	between the radiator & your body.
CE	Conformité Européene or European Conformity. Indicates Manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety, and environmental protection legislation as per **93/42/EEC, Article 17.**

Section 3 Product Specifications

3.1 General Specifications

<table>
<tr><th></th><th colspan="5">FOOTSWITCH</th><th>RECEIVER</th></tr>
<tr><td>Item</td><td colspan="6">Description</td></tr>
<tr><td>Electrical input</td><td colspan="6">12 VDC</td></tr>
<tr><td>Transport, Operating, and Storage Requirements</td><td colspan="6"><table>
<tr><th>Item</th><th>Temperature Range (°C)</th><th>Relative Humidity Range</th><th>Atmospheric Pressure (mbar)</th></tr>
<tr><td>Operating</td><td>15 to 30</td><td>30 to 85% non-condensing</td><td>800 to 1,060</td></tr>
<tr><td>Transport</td><td>-10 to 70</td><td rowspan="2">Up to 95% non-condensing</td><td rowspan="2">500 to 1,060</td></tr>
<tr><td>Storage</td><td>-10 to 55</td></tr>
</table></td></tr>
<tr><td>Dimensions</td><td colspan="5">145x165x115(H)</td><td>80x55x27(H)</td></tr>
<tr><td>Weight</td><td colspan="5">1.3kg</td><td>170g</td></tr>
</table>

Section 4 Installation

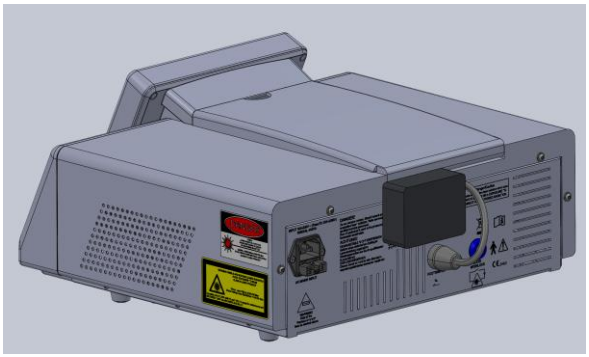
4.1 Introduction and Requirements

Battery Installation Process for Wireless Footswitch:

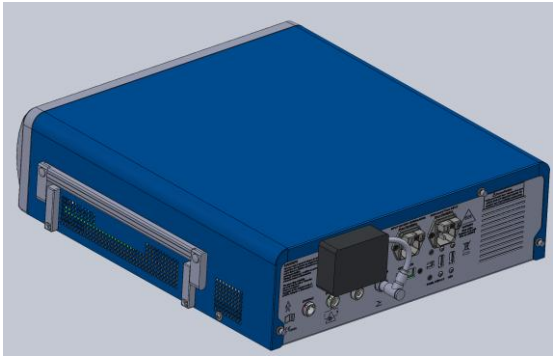
1. Using a Phillips screwdriver, loosen the four screws on the wireless footswitch.
2. Insert the specified LS-14500 battery.
3. Tighten the screws.
4. Insert the footswitch into the designated port of the specified machine.

Receiver Installation Process:

Insert the receiver into the specified machine. Refer to the diagram below for guidance.



LightLas



TruScan Pro

CAUTION! Please ensure that the battery and the corresponding port are properly installed.

4.2 Tools and Equipment

The following tools and equipment are required for the Service Engineer or installer to have in order to carry out a complete installation or uninstallation of the Wireless Footswitch. These items can also be purchased from the Manufacturer:

Item	Tools
Installation or Uninstallation	• Phillips screwdriver

Section 5 Electromagnetic Compatibility (EMC) Test

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Wireless Footswitch, is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Wireless Footswitch uses RF power only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Wireless Footswitch 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The Wireless Footswitch

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

Rated Maximum Output Power of Transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
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 1: At 80 MHz and 800 MHz, the separation distance for 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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Wireless Footswitch, is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ophthalmic laser, LIGHTLas SeLecTor Deux, requires continued operation during power mains interruptions, it is recommended that the ophthalmic laser, LIGHTLas SeLecTor Deux, be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *UT* is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The Wireless Footswitch, is intended for use in the electromagnetic environment specified below. The customer or the user of this system should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6

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

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

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

Recommended separation distance
$d = 1,2\sqrt{P}$
$d = 1,2$ 80 MHz to 800 MHz
$d = 1,2$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wireless Footswitch, is used exceeds the applicable RF compliance level above, the Wireless Footswitch, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wireless Footswitch. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Section 6 User Maintenance

The Wireless Footswitch is designed to require minimal maintenance, but attention to a few procedures will ensure optimal performance:

Initial Operation:

During the initial setup, the wireless connection between the footswitch and the receiver may take up to 15 seconds to establish. This is normal behavior, so please be patient while the system completes the connection process.

Battery Maintenance:

Low Battery Voltage: When the battery voltage drops, the green LED on the receiver will turn red, and a short beep will sound every 5 seconds. This indicates that the battery needs to be replaced soon.

Battery Nearly Depleted: As the battery level approaches critically low, the LED will remain red, and the beeping will become continuous. This continuous warning alerts users that the system will soon stop functioning. Replace the battery or connect the footswitch cable as needed.

Battery Life: Under normal operating conditions, the battery life is approximately 10 months. Be sure to replace the battery regularly to maintain reliable operation.

Battery Installation:

Ensure the battery is installed correctly to avoid system malfunctions. Incorrect installation may affect the device's performance and reliability. For detailed instructions, contact your local distributor.
By following these maintenance steps, you can help ensure the reliable and effective operation of the Wireless Footswitch.

Section 7 European Community Information

1. Declaration of Conformity:

   LightMed Corporation declares that the Wireless Footswitch complies to the requirements of the MDD Regulation and meets, (where applicable), the Essential Requirements of Council Directive 93/42/EEC as amer pertaining to Medical Devices. National Requirements of EU Countries may not have been considered but will be implemented if and when required by the local Distributors. This includes local language translations of relative Instructions for use and labeling.

   We hereby notify appointment of Medical Device Safety Service GmbH Schiffgraben 41, 30175 Hannover, Germany to act as the European Authorized Representative as defined in Article 1, § 2(g) of the Directive 98/79/EEC

   The following standards have been applied and tested:
   - IEC 60601-1.
   - IEC 60601-1-1.
   - IEC 60601-1-2.
   - IEC 60601-1-4.
   - IEC 60601-2-22.
   - IEC 60825-1.
   - ISO 14971.

2. Warranty:

   The Wireless Footswitch conforms to the requirements of the MDD (93/42/EEC as amended by 2007/47/EC) and thereby in the EU Countries the Warranty as specified in the applicable regulations will apply. Your local Distributor will be able to confirm the details.

3. Specific German Requirements / Nationale Anforderungen in Deutschland:

   Since January 01, 1993, the User has had responsibility for accident prevention for laser equipment. According to section 5 of this rule the laser equipment manufacturer has to be registered by a responsible Notified authority and reviewed by an expert laser agent, in according to Section 6. The laser Equipment has to be verified by Technical Safety Inspection annually for the following items. The test results are to be recorded and kept in a devices appendix.

   i. Function Test including:
      - Measuring of laser output.
      - Laser-Power-Off-Testing.
      - Long-distance remote interlocking.
      - Fiber optic cable.

ii. Measuring of electrical leakage currents. According to DIN VDE 0751, Part 1, 9 (with 230 VAC/50 Hz max. 500 µA).

iii. Measurement of PE resistance (Rated value: < 0.1 Ω in appliance inlet plug < 0.2 Ω in power plug).

Der Anwender wird hiermit auf seine Pflichten aus der Unfallverhütungvordchrift LASERSTRAHLUNG (VBG93) in der Fassumg vom 01.01.1993 hingewiesen. Hierzu: Durchführungsanweisung vom Oktober 1995. Nach #5 dieser Vorschrift muss der Betrieb eiens Lasers bei den zuständigen Behörden angemeldet, und nach #6 ein sachkundiger Laserchutzbeauftragter schriftlich bestellt werden. Das Lasergerät muss einmal jährlich einer sicherheitstechnischen Kontrolle unterzogen werden (MPBetreibV,#6).

i. Funktionsprüfung:
- *Messung der Laserleistung.*
- *Laser-Not-Aus-Taster.*
- *Fernverriegelung d. Lichtleiter.*

ii. Messung des Erdableitstroms. NachDIN VDE 0751,Teil 1, Schaltbild 9 (bei 230 VAC/50Hz max. 500 µA).

iii. Messung des Schutzleiterwiderstands. (Sollwert: <0.1 Ω am Gerätestecker < 0.2 Ω am Netzstecker)

Über das Ergebnis der Prüfung ist eine Bescheinigung auszustellen, die bei den Geräteunterlagen (Medizinproduktebuch) aufbewahrt werden muss.

Section 8 Disposal

LIGHTMED endeavor to maximize reuse opportunities, providing equipment test service to ensure any reuse capacity of product. Before product disposition, you could seek professional service from manufacturer or local distributor.

WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)The European Union (EU) WEEE Directive (2002/96/EC) places an obligation on producers (manufacturers, distributors and/or retailers) to take-back electronic products at the end of their lifetime. Manufacturers, distributors, and retailers are obliged to finance the costs of recovery from municipal collection points, reuse, and recycling of specified percentages per the WEEE requirements.

To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources. You could contact local distributor for further information.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