

iHelmet Hair Growth System

(Model: LTD160Pro)

User Manual

(Version: V1.0)



Manufacturer information:

Company name: Slinph Technologies Co., Ltd.

Company address: Room 211, Building B 1970 Cultural and Creative Industrial Park,
Shenzhen, China

NOTE: This manual is only used to operate this electronic device; the company will not bear the consequences caused by this instruction manual for other purposes and responsibilities. This manual contains proprietary information, protected by copyright, and all rights reserved. Without our prior written consent, it should not be allowed to copy any part of this manual or translation.

Considering the needs of the technical improvement or file update, the company reserves the right to revise the content in these operating instructions for correction, and if the change does not involve the sold device safety without prior notice.

Due to technical update or the special requirements of users, under the condition of the instrument performance is not affected, the standard of some parts is different with this manual, please pay attention.



Warning: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: 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.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

RF exposure compliance statement:

This device has been evaluated to meet the general RF exposure requirement it can be used in portable exposure condition without restriction.

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Requirement of Use

Content on this page will tell you when using our devices must pay careful attention to the operation steps, avoiding abnormal operation, may this germinal helmet or the risk of personal injury.

Our company state that users must read the requirement of use before usage and operate according to the requirement of use. The company does not bear the duty of safety, reliability and performance guarantee that because users do not operate this device as this page required and use, maintain, store the device according to the iHelmet growth system manual which cause the any anomalies or person and machine risk injury .We also will not maintain freely such failures. So before usage, you must read carefully the content of this page and the user manual.

If your iHelmet is not functioning properly, discontinue using your device and contact a Slinph. Customers service Specialist +86 755 83461353 or service@slinph.com to service or replace your unit.



Warning: Do not attempt to repair any portion of the iHelmet Hair Growth System. This appliance has no user-serviceable parts. If a malfunction occurs, contact a Slinph customers service Specialist +86 755 83461353 or service@slinph.com.

1 Safety and Regulatory

1.1 Introduction

iHelmet is recommended for men and women experiencing mild or moderate hair loss on the scalp. Before first use, remove the helmet from the packaging. Place the helmet on your head in a comfortable position and press the ON/OFF switch. Download APP from Apple APP Store or Android APP markets , operate the App and touch the “Light” key in the App, then the mobile phone connects automatically the helmet through Bluetooth. The device will then turn on and you'll hear an audible beep.

The treatment is simple and easy. Just make sure you are sitting up in a comfortable chair, couch or even sitting up in bed. You should feel no warmth or pain as iHelmet is a cold laser. Once about 30 minute treatment is finished, a “treatment completed” will sound and you know the treatment is done. Take off the device and place it back into the original box for storage.

iHelmet uses a proximity sensor to ensure that the device is in close contact with the scalp at all times. If you take off the iHelmet, treatment will be paused until you put the iHelmet back onto your head within 3 minutes. Once the pause time exceeds 3 minutes, the iHelmet will be shut off automatically.

iHelmet is designed to be used every other day, for 16 weeks. Do not worry if you miss a treatment in this schedule, you just need to keep going forward with the next treatment in the schedule. Users should start to see a change in their hair within 4-6 months of use, generally an improvement in the density of the hair. After the initial 16 week period, you can use the iHelmet as often as needed to maintain the growth.

Carefully read all instructions and warnings before operating your iHelmet Hair Growth System.

The iHelmet may be used solely for the purpose described in this manual.

If the sensor in your iHelmet is not functioning properly, please stop use and contact Slinph, Inc. Customers service Specialist +86 755 83461353 or service@slinph.com to service or replace your unit through the company's operation.

1.2 Contraindications

- The iHelmet Hair Growth System cannot be used by children under 18 years old.
- Do not use the iHelmet Hair Growth System if you are taking medications which make you sensitive to sun or light. Do not use this device if you have any condition which makes you sensitive to light.
- Do not use this device if you have sensitive skin or if you have experienced previous sensitivity to this specific wavelength of light (650nm).
- Do not use the iHelmet Hair Growth System if you have cancer on your scalp.

1.3 Adverse Reactions

Low Level Laser Therapy as used in the iHelmet has been designated NSR (Non-Significant Risk) by most of the world wide regulatory bodies. Read the Warnings and Precautions section below for additional risks.

1.4 Warnings and Precautions

To reduce the risk of electrical shock, that may result in injury or death:

- Not operate the iHelmet in close proximity to anything marked with the above logo for electromagnetic frequency (i.e., cellular tower).
- Do not place or store the helmet where it can fall or be pulled into a tub or sink.
- Never use the laser helmet when your hair is wet.
- Never leave the iHelmet Hair Growth System plugged into the electrical outlet while unattended. This could cause an electrical hazard that may result in an injury.
- Use the USB charge power with the DC5V, 2A.
- Never operate the iHelmet if it has a damaged cord or helmet. See the User Assistance section below for instructions on returning the device to iHelmet.
- Keep the cord away from hot surfaces. Contacting a hot surface with the cord or a plug can cause the device to malfunction and produce an electrical shock.
- Only use the iHelmet Hair Growth System according to the user guide that is provided. We do not recommend any other use.
- Do not stare directly at the laser light or its reflection off a mirrored surface.
- Do not use the Laser Helmet as a head protection device or for any athletic activities.
- Please keep the laser away from children and pets.
- Do not directly stare at the beams or observe it through certain optical elements (for example, eye loupes, magnifiers and microscopes), or it will pose an eye hazard.
- The iHelmet Hair Growth Helmet is made to use on the human scalp only. Use it on other parts of the body is not advised.
- Do not point or shine the iHelmet lights at others, pets, etc.

- Do not attempt to adjust or modify the iHelmet in any way. Use of this device or procedures other than those specified in this manual can result in injury.
- Battery is only replaced by service personal. Do not attempt to replace the battery by non-trained person, the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD
- Applied part temperature.
- Be careful to strangulation due to cables and hoses, particularly due to excessive length.
- The equipment is to be put into service according to the EMC information provided in this manual Portable and mobile RF communication equipment might affect the equipment on potential electromagnetic or other interference and advice on how to avoid or minimize such interference.
- "Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure"

2 Indications for Use

The iHelmet Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa-V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.

Ludwig Classifications of Female Pattern Baldness

Ludwig Women's Hair Loss Scale						
						Approved
I - 1	I - 2	I - 3	I - 4	II - 1	II - 2	
						Not Approved
III	Advanced	Frontal				

Norwood Hamilton Classifications of Male Pattern Baldness

							Approved
IIa	III	IIIa	III vertex	IV	IVa	V	
							Not Approved
I	II	Va	VI	VII			

Fitzpatrick Classification of Skin Types

Skin type	Type 1	Type 2	Type 3	Type 4	Type 5	Type 6
Skin color	Pale, white skin	White Skin	White skin	Light brown or olive skin	Brown skin	Dark brown or black skin
Reaction to Sun Exposure	Always burns, never tans	Burns easily, tans minimally	Burns minimally, tans easily	Burns minimally, tans easily	Rarely burns, tans easily and darkly	Rarely burns, always tans, deeply pigmented
	Approved				Not Approved	

3 Device Description

iHelmet Hair Growth System consists of laser diodes that are spread throughout the helmet. The device uses diode lasers to cover the entire area of the head that is normally covered with hair, and this unique design allows the treatment of the entire scalp without manual movement. The device will pause automatically treatment if the sensor detects that the head is not in close proximity to the sensor, and will resume again once close enough. At the end of the treatment, an audible tone beeps to indicate the treatment is over and then the iHelmet automatically shut off.

3.1 Specification

Devices Name	iHelmet Hair Growth System
Model	LTD160Pro
Electrical Requirement	
Power Supply	Internal lithium battery: 3.7Vdc, 3000mAh Charging by specified power adaptor: 5Vdc, 2A max.
Continue Operating Hours	The battery can continuously operate 1 hour maximum after full charge.
Typical Operation Time	The device uses high quality laser diodes and LED's that are rated to exceed 10,000 hours of usage.
Output Specification	
Waveform	Visible red laser
Wavelength	650nm±10nm
Amounts of Laser Diodes	LTD88Lite: 88 LTD36Air: 36 LTD160Pro: 160
Energy of per Laser	4~5mW
Classification according to IEC60825-1	Class 3R
Beam Divergence	Parallel: 10±2° Perpendicular: 19±4°

Treatment Time	Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks
Operation Mode	Maximum 35 min. on, interval 48 hours
Treatment Area	LTD88Lite: 220.61 cm ² LTD36Air: 86.3 cm ² LTD160Pro: 338.42 cm ² Mathematically Max. derived
Irradiance (power per area)	LTD88Lite: 2.3533 mW/cm ² LTD36Air: 2.0857 mW/cm ² LTD160Pro: 2.3639 mW/cm ² Mathematically Max. derived
Fluence	LTD88Lite: 4.1883 J/cm ² LTD36Air: 4.3801 J/cm ² LTD160Pro: 4.9642 J/cm ² Mathematically Max. derived
Additional Feature	
Dimension	266mm x 196mm x 135mm (L x W x H)
Weight	LTD88Lite: about 550g LTD36Air: about 500g LTD36Air: about 600g
Environment for Operation	Temperature: 15~30°C Humidity: 30~80% RH Atmosphere range: 80~110kPa
Environment for Storage	Temperature: -20~65°C Humidity: 0~80% RH Atmosphere range: 50~110kPa

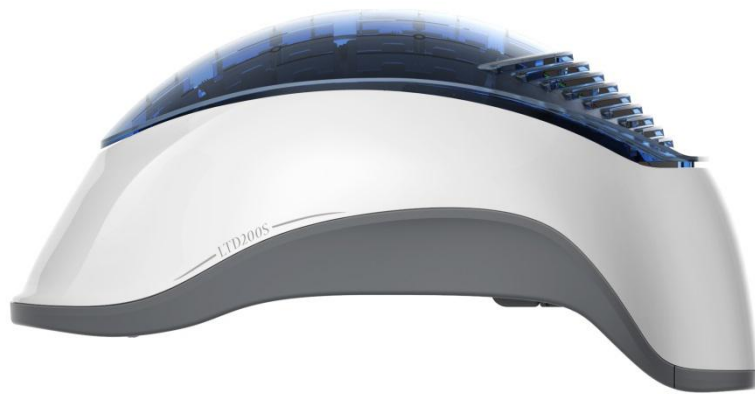
3.2 Device Components



Picture 3-1: Front view



Picture 3-2: Back view



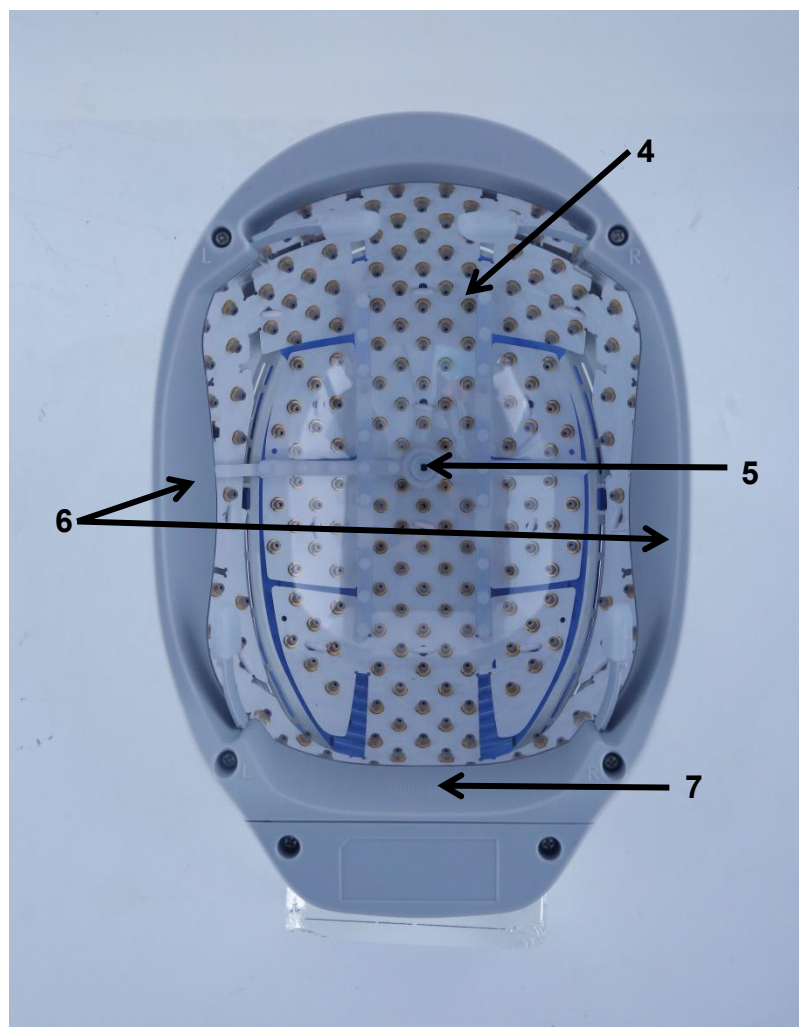
Picture 3-3: Side view



Picture 3-4: Oblique view



Picture 3-5: Top view



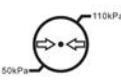
Picture 3-6: Bottom view

Number	Description
1	Logo indicator light
2	Mini USB
3	Power button which contains two color indicator light green/orange
4	Laser diode
5	Temperature and humidity sensor
6	Infrared detection chip
7	Trumpet

3.3 Label & Symbols(Need to be updated)

Labels on device		
No.	Symbols	Description
1		Refer to instruction manual/ booklet
2		Symbol for "ATTENTION, CONSULT ACCOMPANYING DOCUMENTS".
3		Symbol for "SERIAL NUMBER". This symbol shall be accompanied by the manufacturer's serial number.
4		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture.
5		Symbol for "MANUFACTURER". This symbol shall be accompanied by the name and the address of the manufacturer.
6		Please dispose of the device in accordance with the legal obligation in your area
7		Type BF Applied Part.

Labels on device		
No.	Symbols	Description
8	IP22	Protected against solid foreign objects ≥ 12.5 mm and against vertically falling water drops when enclosure tilted up to 15°
9		Warning: laser radiation. The warning signs stick on beside of Trumpet.
10		Visible laser radiation avoid direct eye exposure, Laser product is Class 3R. Laser wavelength is 650nm, power is 5mW, continuous radiation . The warning signs stick on beside of Trumpet.
11		Laser aperture. The warning signs stick on beside of Trumpet.

Labels on Package		
No.	Symbols	Description
1		Fragile, handle with care
2		Keep dry
3		This way up
4		Recommended storage temperature and limits -20°C - 65°C
5		atmosphere limitation 50KPa~110KPa
6		humidity limitation 0%-80%

3.4 Packing List



List	Quantity
iHelmet Device	1
Accessory box	1
Certificate	1
User Manual	1
Warranty card	1
Quick guide	1
Mini USB line	1
Silicone slices	4
Portable bag	1

4 Operation

4.1 Before Treatment

Take out all parts of the iHelmet Hair Growth System from the box and ensure they are all accounted for.



Warning: The working environment temperature of iHelmet must be 15 ~ 30 degree Celsius

4.2 Open the iHelmet

Push the ON/OFF switch for more than 0.5 sec first (picture4-1 and picture 4-2).



Picture 4-1



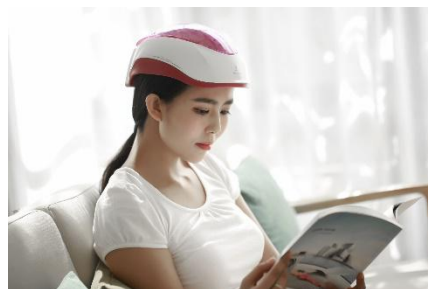
Picture 4-2

4.3 Place the iHelmet

Place the iHelmet on top of the head with the logo facing forward (picture 4-3 and picture 4-4).



Picture 4-3



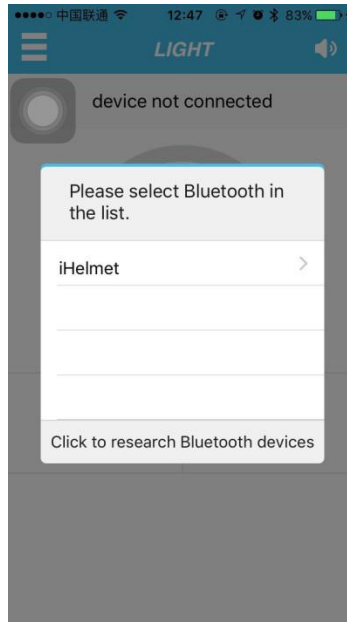
Picture 4-4

4.4 Connect the iHelmet to the system

- 1) Open the iHelmet APP in the mobile phone; Press the “Light” key at the bottom menu of main page, the iHelmet device will automatically connect with mobile phone through Bluetooth.
- 2) The 20~35 minute timer (the treatment time setting by mobile phone APP) immediately begins once the connection is successfully completed.



Warning: Before using the iHelmet APP, User should download the iHelmet APP from APP STORE or market for iOS or Android system. If the helmet is connected with the APP for the first time, User should enter the password “1234” when the Bluetooth connection is building (picture 4-5). After the first connection, the password is not necessary for the next time. The pass word is not needed for the iOS APP even the connection is the first time.



Picture 4-5

4.5 Treatment

Look for the rest time blue circle for the treatment in the “Light” page (picture 4-6). This lets you know that the treatment has started and the rest time of the treatment.

In the treatment, the temperature in the part contact with scale will be up 41°C and may be in maximum to 43°C. The device will contact the patient safely operating as the manual suggested and the operation time is 20-25 min.



Picture4-6

**Warning:**

- 1) When used as instructed, the LED on the ON/OFF switch will light up during your treatment. Once the treatment has begun, the timer will count down the treatment time and the Lasers will be powered on. When the treatment is finish you will hear a beep to indicate the end of the treatment, at which point all the lasers will turn off.
- 2) If you take off the helmet while the treatment is still going on, the treatment will pause and will not start up until the helmet is put back onto your head within 3 minutes. The helmet will be turn off if the pause time exceeds 3 minutes.
- 3) Do NOT look directly at the laser lights while they are on. Please check the unit to see if the light on the ON/OFF switch illuminates, and if not, then contact Slinphat the serial number provided in the Troubleshooting section of this manual. Do not look directly at the lasers. If you have any issue or problem which is noticed with the device, please contact Slinph to ask for service.

4.6 The Sign of the end of the Treatment

When the session is finished, you will hear a beep and the helmet will be turned off automatically.



Warning: The helmet cannot be continuously used twice or more within [48 hours](#).

4.7 After Treatment

- 1) Once your treatment is finished, you can remove the helmet. Store your iHelmet back in the original box, or in a cool dry location.

2) If you stop using your iHelmet helmet, the improvement in your hair that was initially observed can start to decrease over time.

4.8 Charging

- 1) After completion of treatment, low electricity will be a voice prompt "Low battery, please charge!"
- 2) When the device is switched on, if detected low electricity, it will be a voice prompt "Low battery, please use iHelmet again after charge!" at the same time, the orange indicator light in the power button will flash at 1 Hz frequency. Low power cannot be started the treatment.
- 3) Charging display: When charging, the green indicator light in device button is shining with "breathing light", the green indicator light is normally on charging full.
- 4) Electric quantity display: The device cannot display the electric quantity, but beginning the treatment after connected the APP, it will show the battery in the APP, such as the Picture 4-7 show:



Picture 4-7



Warning:

- 1) Keep the Charger and mini USB line away from water.

- 2) The device cannot work when charging.

5 Maintenance

5.1 Cleaning Instructions

Clean the inside of the iHelmet (the side where the lasers reside) with a soft, dry cloth after using. Do not use any abrasive cloths. Do not use any chemicals such as acetone, soap or detergents. Do not submerge in water.

Please check the device normally on/off before every use.



Warning:

- 1) DO NOT use Acetone or any other cleaning agents on the iHelmet. Acetone and other cleaning agents will damage the unit causing the warranty to be voided.
- 2) Always disconnect the iHelmet hair growth system from its power source before attempting to clean it. Before cleaning your device, make sure that it is turned off.
- 3) Before operation, volatilize the cleaning solvent and flammable solution used for the device.

5.2 Maintaining Your Device

The iHelmet is engineered to operate for many years when cared for properly. If you must clean the device, please see above for cleaning instructions.



Warning: Do not attempt to repair or service the iHelmet at home. If any problems arise that may require service, contact Slinph immediately.

- a schedule of maintenance necessary to keep the product in compliance; for example: Inspect optical output power at least once a year; inform supplier to change the light source if there is obvious power decline.

5.3 Storing Your Device

Keep your iHelmet stored in a dry place with a temperature range between -20 to 65 degrees Celsius. This device stored in an area with the humidity that is 30% to 80%. Keep your iHelmet out of direct sunlight and away from hot surfaces or devices that emit heat. The iHelmet cannot be kept in close proximity to chemicals of any kind.

It is suggested that the battery should be optimized when storage for two months, otherwise the running time of battery is significantly shortened. And it is suggested that when user stop to use iHelmet more than 1 month should keep charging one time per month. Keep battery stored in a dry place.

5.4 Disposing Your Device

It is important to note that a portion of the iHelmet's components can be recycled, but it is illegal for you to dispose of them where you live. Check with a government agency for their protocols for disposing electronic devices.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

5.5 Life Expectancy

The life expectancy of the iHelmet is based on independent testing done via the IEC 60068 international standard. The iHelmet uses high quality laser diodes that are rated to exceed 8,000 hours of usage. Based on the independent testing and the rating for the diodes and the other electronic components, the life expectancy of the iHelmet is 5 years of regular use. In the life of the device, you can replace the battery, but need to return to factory, use a certified battery or buy if from qualified authorized store. It is recommended that you read this entire instructional guide thoroughly before attempting to operate the iHelmet.

6 Frequency Asked Questions

(1) Q: My iHelmet will not turn on

A: Check whether the helmet device is out of power. Make sure the green light is on the ON/OFF switch. If the helmet is out of power, charge the device until the light on the ON/OFF switch normally on green.

(2) Q: My iHelmet is turning on, but the laser is not visible

A: Operate the iHelmet APP, touch the "Light" key in the main page, the helmet will connect to the APP through Bluetooth. Once the connection is built, the laser will be visible.

(3) Q: My iHelmet will not turn off

A: The helmet will turn off within 10 sec after the treatment is completed. Press the ON/OFF switch at least for 1 sec.

(4) Q: My iHelmet will not turn off

A: The helmet will turn off within 10 sec after the treatment is completed. Press the ON/OFF switch at least for 1 sec.

If you are still experiencing problems with your iHelmet after using this troubleshooting guide, please contact Slinph to service or replace your unit.

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7 Service

If the sensor in your iHelmet is not functioning properly, discontinue using your device and contact Slinph. Customers service Specialist +86 755 83461353 or service@slinph.com to service or replace your unit.



Warning: Do not attempt to repair any portion of the iHelmet Hair Growth System. This appliance has no user-serviceable parts. If a malfunction occurs, contact a Slinph Customers service Specialist +86 755 83461353 or service@slinph.com

We will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel.

8 Warranty

To Obtain Warranty Service Please Complete These Two Easy Steps:

1. Contact Slinph Support to receive an RMA number.

Call or e-mail Slinph Support to describe the problem and request a return merchandise authorization (RMA) number. You will need to provide the unit's serial number, your return shipping address and an email address/phone number.

Phone: +86 755 83461353.

Email: service@slinph.com

2. Once you have received submitted your RMA request, Slinph will issue a prepaid return label with your RMA number and instructions to ship the unit back to us to be

served. You must include the RMA number on the outside of the package. If you do not include your RMA number as requested, it could cause your return process to be delayed.

No. 211-212, Building B,
1970 Cultural and Creative Industrial Park,
Ping'an Road, Longhua New District, Shenzhen 518107 China

9 Safety, EMC & Biocompatibility Requirement

9.1 Safety Requirements

This device uses on medical electric device for safety performance is tested according to IEC 60601-1: 2005/(R) 2012 And A1:2012. The device is type I, the power net of the power supply should have the secured Protective Earth connection.

9.2 EMC Requirements

This device complies with Medical EMC Standard IEC 60601-1-2:2014.



Warning: Keep away from water. Contact with water may result in an electrical shock.

To reduce the risk of hazard by electric shock:

- 1) Do not use while bathing.
- 2) Do not place or store your iHelmet where it can fall or be pulled into a tub or sink.
- 3) Do not expose your iHelmet to running water, or drop into water or any other liquid.
- 4) If your iHelmet falls into water, unplug it immediately from the power outlet.
- 5) If using your iHelmet near water, the use of an electrical outlet protected by a Ground Fault Circuit Interrupter is recommended.
- 6) Do not dispose of your iHelmet in a fire or store in high temperatures greater than 65°C. Power supply cannot be separated during use. Do not position the equipment in a manner that will make it difficult to plug or remove the power cord.

Guidance and manufacturer's declaration – electromagnetic emissions
--

The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) is intended for use in the electromagnetic environment specified below. The customer or the user of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) 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	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) is intended for use in the electromagnetic environment specified below. The customer or the user of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) 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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment or typical home environment
Surge	± 1 kV line(s) and	Not Applicable	Mains power quality should be

IEC 61000-4-5	neutral		that of a typical commercial or hospital environment or typical home environment
Voltage dips, short 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 5s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment or typical home environment. If the user of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) requires continued operation during power mains interruptions, it is recommended that the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment or typical home environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) is intended for use in the electromagnetic environment specified below. The customer or the user of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro), including cables, than the recommended separation distance

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.6GHz	10 V/m 80 MHz to 2.6GHz	calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,6 \text{ GHz}$ 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, ^ashould 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 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 iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) is used exceeds the applicable RF compliance level above, the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro). b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the MODEL ST261			
The iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iHelmet (Model: LTD88Lite, LTD36Air, LTD160Pro) 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. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

- a. 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 ACCOMPANYING DOCUMENTS.
- b. Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

9.3 Biocompatibility Requirements

The user indirect contacting material used for the sensing catheter component of the device is biocompatible for its intended use. Complies with biocompatibility standards ISO 10993-5:2009 (Cytotoxicity) and ISO 10993-10:2010 (Irritation and Sensitization).