

Surgical Headlight USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd.

P/N: IFU-5035010

Version: 03

Issued:2023.03.18

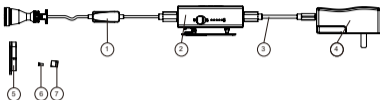
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1. Lux-SFT Components

1.1 Parts Identification



① Headlight and touch switch assembly

② Battery box

③ USB cable




④ Adapter









⑤ Filter components

⑥ Screw










⑦ Dovetail joint assembly











1.2 Components and Accessories

<p>Filter components (1pcs)</p> 	<p>Headlight and touch switch assembly (1pcs)</p> 	<p>Dovetail joint assembly (1pcs)</p> 
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<p>Battery box (1pcs)</p> 	<p>Adapter (1pcs)</p> 	<p>USB cable (1pcs)</p> 
<p>Screwdriver (1pcs)</p> 	<p>Inner packing box (1pcs)</p> 	<p>Outer packing box (1pcs)</p> 
<p>Cleaning Cloth (1pcs)</p> 	<p>Screws (2pcs)</p> 	<p>USER MANUAL (1pcs)</p>
<p>Certificate (1pcs)</p>	<p>Warranty card (1pcs)</p>	

2. Symbol Instruction

	General warning sign.
	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
	Serial number
	Dispose of in accordance with the WEEE directive
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Catalogue number

	Manufacturer
	Date of manufacture
	Lot of manufacture
	Authorized Representative in the European Community
	Manufacturer's LOGO
	Follow instructions for use
	Class II equipment
	Medical device
	CE marking
	Output indicator of battery box



Input indicator of battery box

3. Foreword

3.1 Scope of Application

Clinically, Lux-SFT Surgical Headlight is worn on the doctor's head for the lighting of the parts for diagnosis and examination of patients.

This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contraindications

None



WARNING

Please read the following warnings carefully before use:

1. Please confirm if the package is complete before open it. After opened, please check and confirm the components are correct.
2. Before the first use and after each use, please clean the Surgical Headlight with a microfiber cloth attached in the package.
3. The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls and do not use this system near the active HF Surgical Equipment in the hospital. 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 ultrasonic scaler, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

4. Make sure that the device is completely dry, do not store it in the humid condition and be sure away from any liquids.

5. Please use the attached original adapter, and do not use the device when charging.

6. Please do not pull off the power cable when the light source is in use.

7. Please do not look directly at the light source when the Surgical Headlight is working to avoid burning your eyes.

8. Please do not charge, use and store this device at high temperatures.

9. Do not use organic solvent or other corrosive detergent to clean the device.

10. Never open or repair the device by yourself, otherwise, void the warranty.

11. If the liquids leak from the lithium battery box, it means that the lithium battery is leaking, please shut off the device and stop using it immediately, then contact the local distributor for help.

12. This device is only intended to be used by the professionals (such as the doctors or nurses) in hospital environments, clinics or dental

offices.

13. The lithium battery in the battery box cannot be replaced. Any replacement will damage the battery and cause danger.

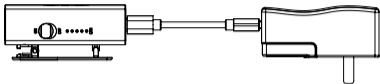
14. This device is not waterproof, please do not immerse or spray any components into or with detergents and other liquids. Also, it cannot be sterilized by autoclave.

15. Please dispose of the Surgical Headlight according to the local environmental protection laws and regulation for scrap of the device.

16. Please deal with the disposable waste generated during cleaning and disinfection according to the local environmental protection laws and regulation.

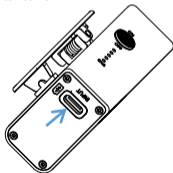
4. Installation

4.1 Connect to the Adapter



Use the attached cable with Type-C interface, insert it into the “Input” socket located in the lower part of the lithium battery box. After connecting the adapter to the power supply, the charging indicator of the lithium battery box will light up.

Please note that: Before the first use, we strongly recommend that the lithium battery box should be fully charged. When charging, please push the power switch to “OFF”.



4.2 Connect to the LED Light Source and the Touch Pad Switch



Under the non-charging condition, insert the Type-C interface at the end of the LED light source and the touch pad switch into the “Output” socket which located on the upper side of the lithium battery box. Please push the power switch to “OFF” before doing this.



5. Operation

5.1 Lithium Battery Box Charging

When charging, the charging indicator will light red. The 4 white battery capacity indicators, each corresponding to 25% volume of battery capacity. When the charging indicator turns from red to green, and the 4 white battery capacity indicators all turn on white, it means that the lithium battery box is fully charged. (Note: Please turn off the power switch when charging!)

5.2 Control

Push the power switch to "ON", slightly touch the touch pad switch (t < 0.3s), the LED light source will be turned on to the maximum brightness, slightly touch the pad again, the LED light source will be turned off. When the LED light source is on, continuously touch the pad, the brightness will increase or decrease, and the adjustment range is between 1%Max and Max.

5.3 Working Indicators

When the lithium battery box is fully charged and the LED light source is working, the 4 battery capacity indicators are all on. Each battery capacity indicator corresponds to 25% volume of battery capacity, one turning off means that the battery capacity is reduced by 25%. When only one battery capacity indicator is on, please charge the lithium battery box in time.

5.4 Device that can be used together

This Lux-SFT Surgical Headlight can be used together with Eighteenth Surgical Binocular Loupes, so as to provide an integrated vision system. Mount the Surgical Headlight to the Surgical Binocular Loupes as the following steps:

- Take out the two screws and the dovetail groove connector from the package;
- Mount the connector to the position reserved on the loupes;
- Tighten the screws and insert the LED light source into the groove;
- Adjust the angel of the LED light source to position the light spot to the proper view field.

6. Maintenance

Disassemble the LED light source from all components of the Surgical Headlight and the Surgical Binocular Loupes before cleaning and disinfection.

Use a microfiber cloth attached in the package or cotton stick to wipe the lens for cleaning and disinfection by dipping in the 75% alcohol slightly. Please note that you'd better wash and dry the cloth before use.

Do not use organic solvent or any other corrosive detergent to clean and disinfect the device, especially for the lens and the cable. Do not use excessive alcohol.

Keep the original packaging required for return/maintenance shipment and contact your local authorized distributor.

7. Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

Faults	Possible causes	Solutions
Touch Pad no response	When the touch pad is covered by water or stain, etc., it may cause the internal controller failure, and then no response occurs.	Power off, clean the touch pad by dry clean cloth, then power on and try again.
LED Light Source intensity changes automatically	When the device is working stably, there are unreasonable factors interfered, causing the controller to restart automatically.	Power off, then power on and try again.
LED Light Source does	The LED cable is broken, resulting in	Replace the cable by professionals.

not work	open circuit.	
	The cable interface is loose.	Please check whether the interface contact has become dark due to oxidation. If the color changes, please use 75% ethyl alcohol with microfiber cloth to clean it, then try to use it again after drying. Otherwise, please contact your local distributor.
	Low power causes the system to start low voltage protection.	Recharge the battery.

	Interface short circuit.	Please check the touch pad, the battery and the cables to confirm whether there are other metal objects entering, which may cause a short circuit.
Low initial brightness of LED Light Source	LED aging or internal circuit aging due to long-term use.	Please contact your local distributor.
Unable to charge	The adapter is damaged.	Replace the adapter.
	The cable for charging is broken.	Replace the cable.
	The controller interface is damaged.	Please contact the local distributor and professionals.

8. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	Lux-SFT
Package Dimensions	22.1*16.2*7.2 cm
Internal Battery	Lithium ion battery, 3.6V, 3350mAh
Adapter Input	100-240V ~ 50/60Hz, 0.2A
Input	5V $\overline{\text{---}}$ 1A
Output	DC 6.0 200mA (max)
LED Light Input	DC 6.0 200mA (max)
Electrical Safety Class	Charging: Class II; Operating: Internally powered
Color Temperature	3000K~6700K
Color Rendering Index (CRI)	≥ 90
Illuminance	10000 \pm 20%lux 35cm
Operating Time	Continuous operation for ≥ 8 h at maximum brightness
Operating Conditions	Use: in enclosed spaces Ambient temperature: 0°C ~ 40°C Relative humidity: < 80%, no condensation at 0°C

	Operating altitude: <5000m above sea level
Transport and Storage Conditions	Ambient temperature: -20 °C ~ +55°C Relative humidity: 20% ~ 80% Atmospheric pressure: 70kPa ~ 106kPa

9. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Lux-SFT is intended for use in the electromagnetic environment specified below. The customer or the user of the Lux-SFT should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environments-Guidelines
RF emissions CISPR 11	Group 1	The Lux-SFT 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 Lux-SFT is suitable for use in all

<p>Harmonic emissions IEC61000-3-2</p>	<p>Class A</p>	<p>establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
<p>Voltage fluctuations/flicker emissions IEC 61000-3-3</p>	<p>Complies</p>	

Guidance and manufacturer's declaration – electromagnetic immunity

The **Lux-SFT** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Lux-SFT** should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environments-Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 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 transients/ bursts IEC 61000-4-4	$\pm 2\text{kV}$ 100kHz repetition frequency	$\pm 2\text{kV}$ 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: $\pm 0.5\text{kV}$, $\pm 1\text{kV}$ Line to earth: $\pm 0.5\text{kV}$,	Line to line: $\pm 0.5\text{kV}$, $\pm 1\text{kV}$ Line to earth: $\pm 0.5\text{kV}$,	Mains power quality should be that of a typical commercial

	$\pm 1\text{kV}, \pm 2\text{kV}$	$\pm 1\text{kV}, \pm 2\text{kV}$	or hospital environment.
Voltage dips IEC 61000-4-11	<p>0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0°</p>	<p>0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0°</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptio

<p>Voltage interruptions IEC 61000-4-11</p>	<p>0% U_T; 250/300 cycle</p>	<p>0% U_T; 250/300 cycle</p>	<p>ns, it is recommended that devices be powered from an uninterruptible power supply or battery.</p>
<p>Rated Power frequency magnetic field IEC 61000-4-8</p>	<p>30 A/m 50Hz or 60Hz</p>	<p>30 A/m 50Hz or 60Hz</p>	<p>Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial</p>

			or hospital environme nt.
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Note: U_T : rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz

Guidance and manufacturer's declaration – electromagnetic immunity

The **Lux-SFT** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Lux-SFT** should assure that it is used in such an environment.

Proximity magnetic fields	IEC 61000-4-39 test level	Compliance level	Electromagnetic environment – guidance
Proximity magnetic fields	65A/m 134.2kHz Pulse modulation 2.1 kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	7.5A/m 13.56MHz Pulse modulation 50 kHz	7.5A/m	

Guidance and manufacturer's declaration – electromagnetic immunity

The **Lux-SFT** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Lux-SFT** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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<p>Conducted disturbance s induced by RF fields IEC 61000-4-6</p>	<p>3 V 0.15 MHz – 80 MHz, 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz</p>	<p>3 V</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Lux-SFT, including cables, than the recommended separation distance calculated from the equation applicable</p>
<p>Radiated RF EM fields IEC 61000-4-3</p>	<p>3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz</p>	<p>3V/m</p>	<p></p>

<p>Proximity fields from RF wireless communication equipment</p> <p>IEC 61000-4-3</p>	<p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>	<p>Complies</p>	<p>to the frequency of the transmitter .</p> <p>Recommended minimum separation distances</p> <p>See the RF wireless communication equipment table in "Recommended minimum separation distances"</p>
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Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **Lux-SFT** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **Lux-SFT** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27

450	43 0- 47 0	GMR S 460 FRS 460	FM \pm 5 kHz devia tion 1 kHz sine	2	0.3	28
710	70 4- 78 7	LTE Ban d 13, 17	Pulse mod ulati on 217H z	0.2	0.3	9
745						
780						
810	80 0- 96 0	GSM 800/ 900, TETR A 800, iDEN 820,	Pulse mod ulati on 18Hz	2	0.3	28
870						
930						

		CDMA A 850, LTE Band 5				
172 0	17 00 - 19 90	GSM 1800 ; CDMA A 1900 ; GSM 1900 ; DECT; LTE Band 1, 3,	Pulse mod ulation 217H z	2	0.3	28
184 5						
197 0						

		4, 25; UMT S				
245 0	24 00 - 25 70	Blue toot h, WLA N, 802. 11 b/g/ n, RFID 2450 , LTE Ban d 7	Pulse mod ulati on 217H z	2	0.3	28
524 0	51 00 -	WLA N 802. 11	Pulse mod ulati on	0.2	0.3	9
550 0						

578	58	a/n	217H			
5	00		z			



- Use of accessories and cables other than those specified or provided by the manufacturer of **Lux-SFT** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **Lux-SFT** and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
DC Power Cable (USB Cable)	1.00	Yes	/
Headlight Cable Section A	0.62	NO	/
Headlight Cable Section B	0.80	NO	/

- Use of **Lux-SFT** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **Lux-SFT** and the other equipment should be observed to verify that they are operating normally.
- **Lux-SFT** has no ESSENTIAL PERFORMANCE.

10. Statement

Service Life

The service life of Lux-SFT series products is 6 years.

Maintenance

MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Please deal with them according to the local environmental protection laws and regulation.

Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to Changzhou Sifary Medical Technology Co., Ltd. The industrial design, inner structure, etc., have claimed for several patents by Sifary, any copy or fake product must take legal responsibilities.



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