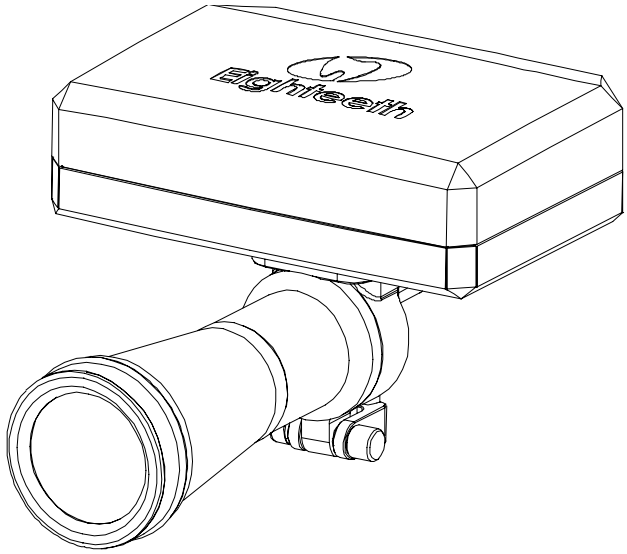
Eighteeth

Wireless Z

CE



Surgical Headlight USER MANUAL

Changzhou Sifary Medical Technology Co., Ltd.

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Version: 03
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1. Wireless Z Components

1.1Parts Identification

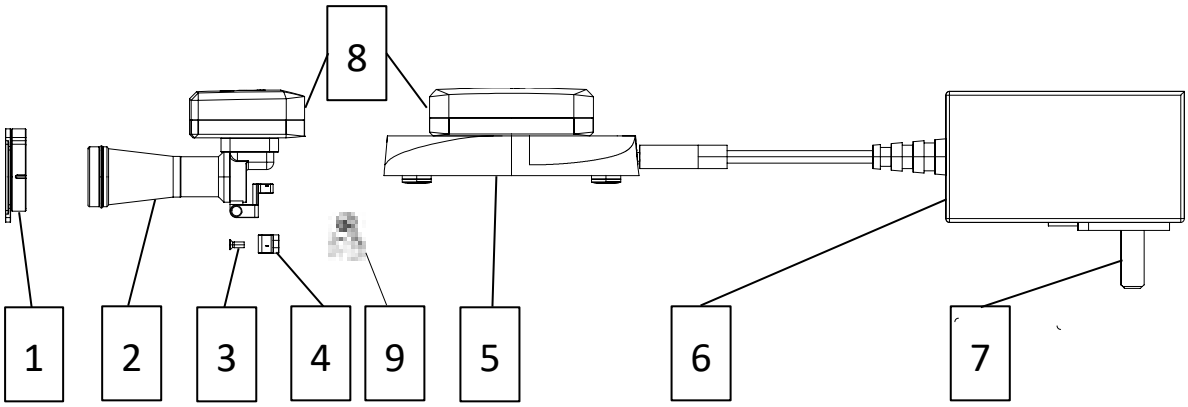


Fig.1

①Filter

②Headlight

③Screw

④Dovetail joint assembly

⑤Battery Recharger

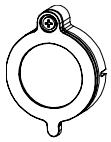
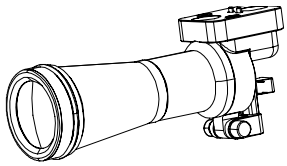
⑥Adapter

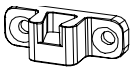
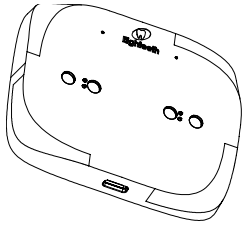
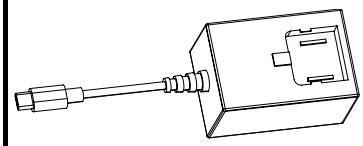
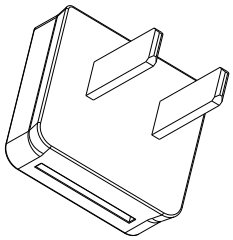
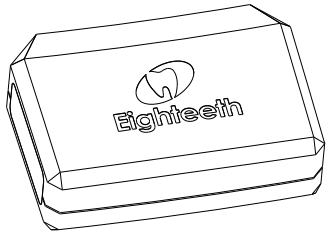
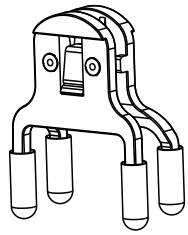
⑦Plug

⑧Battery box

⑨Universal headlamp mounting clip(Optional)

1.2Components and Accessories

Filter(1pc)	Headlight (1pc)	Screw (2pcs)
		

Dovetail joint assembly (1pc) 	Battery Recharger (1pc) 	Adapter (1pc) 
Plug (1pc) 	Battery box (2pcs) 	Universal headlamp mounting clip （Optional） (1pc) 

2. Symbol Instruction

	Caution
	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	Lot of manufacture
EC REP	Authorized Representative in the European Community
Eighteeth	Manufacturer's LOGO
	Follow instructions for use
	Class II equipment
MD	Medical device
	Direct current
CE	CE Marking

3. Foreword

3.1 Scope of Application

Wireless Z 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 professional healthcare facility environment, such as hospital environment and clinics by qualified 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 surgical headlight, 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 move off the battery box when the light source is in use. If move it please turn off the light firstly.

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 and clinics .

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.
17. Do not place the device in a position that is difficult to disconnect.

4. Installation

4.1 Connect Charging box to the Adapter

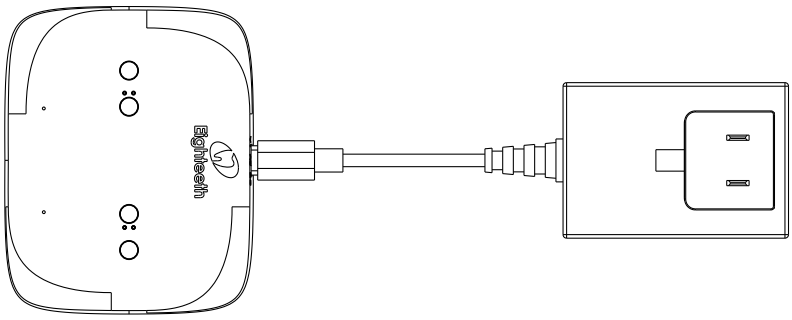


Fig.2

As Figure 2 shows, use the attached adapter's cable with Type-C interface, insert it into the only Type-C socket located in the side of the charging box (Fig.3). After connecting the adapter to the power supply, the charging indicator of the charging box will light up with red and green alternate sparkle lights, indicates that the charger box is ready for working.

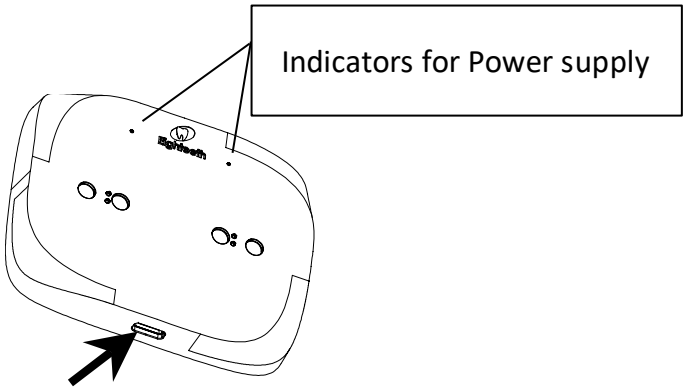


Fig.3

4.2 Install the battery box to LED light source

The Battery box and the LED light source is connected by magnetism, when connected, the two PINs in LED socket touch the two conductive copper columns located at the lower of the battery box, the battery and

the LED are connected and it is ready to work.

Please notice the corresponding direction between the magnetic pillars. See Fig.4.1.

Put the battery box into the socket located in Light source along the direction, See Fig.4.2. The finished assembling shows in Fig.4.3.

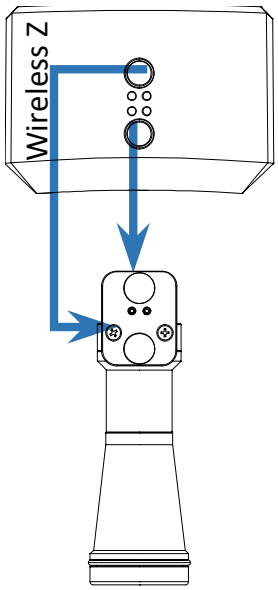


Fig.4.1

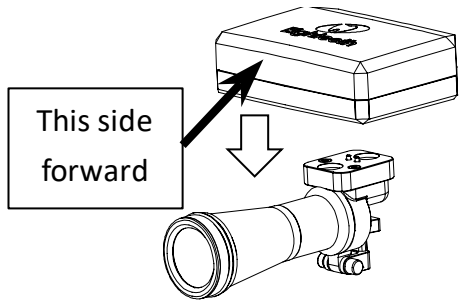


Fig.4.2

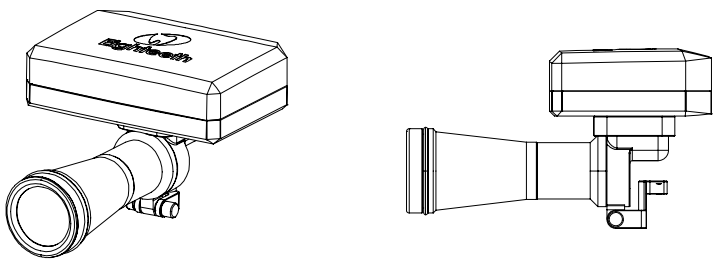


Fig.4.3

WARNING

Put the battery box into the socket of LED light source along the contrary direction compared with Fig.4.1 &4.2, only one pair of pillars will be attracted because of the magnetism, the battery will not be conducted and Wireless Z will not work. As a potential result, the battery box will easily drop down and cause hazards to the patients during

operation.

The battery box can be easily move off from the LED light source because of their magnetic connection. When the battery power is out of power, the user can move it off quickly and recharge it for next use.

4.3 Filter Installation

One set of Orange (UV-Free) filter is attached in the Wireless Z package for the direct composite restoration (dentistry). If necessary, the user can put the filter into the tube from the front of the Led Light source. See Fig. 5

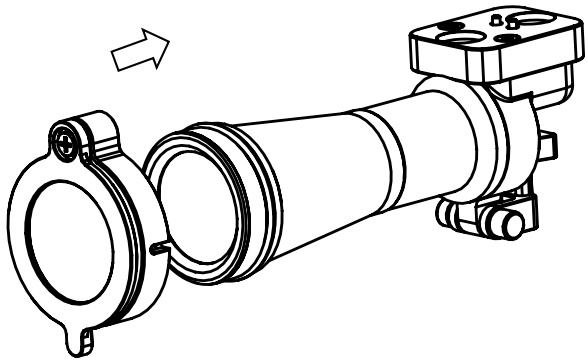


Fig.5

4.4 Dovetail joint installation

Wireless Z is designed to use with Eighteeth® *Brilliance*™ & *Brilliance*™ *48°* Loupes.

4.4.1 Install Dovetail joint to *Brilliance™* Loupes

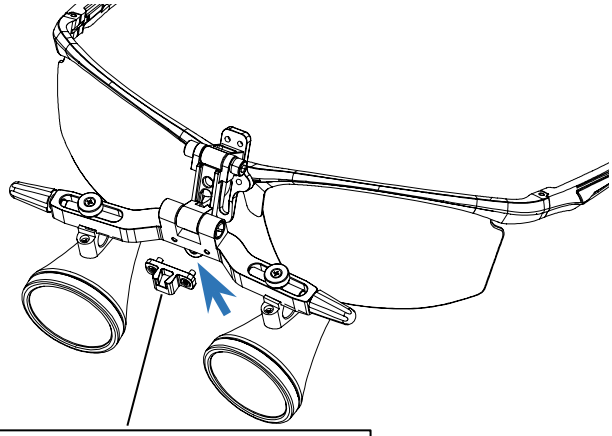


Fig. 6.1 Dovetail joint

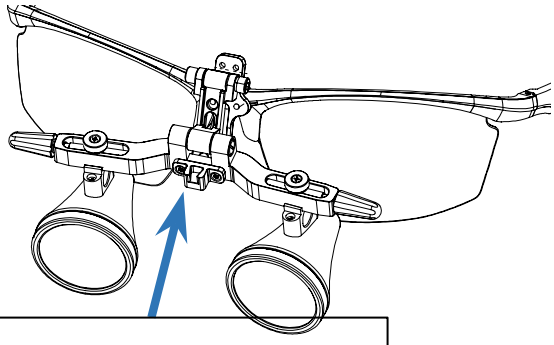


Fig. 6.2 Dovetail joint assembled

Fig.6

If you combine Wireless Z with *Brilliance™* loupes, please assembly dovetail joint into the *Brilliance™* loupes' overarm, use the attached T4 screw driver to tighten 2 screws with the joint. And this dovetail joint is used to connect the Wireless Z in future. See Fig. 6.

4.4.2 Install Wireless Z to *Brilliance™ 48°* Loupes

Brilliance™ 48° Loupes is attached with Headlight mount which has

dovetail joint inside, see Fig.7:

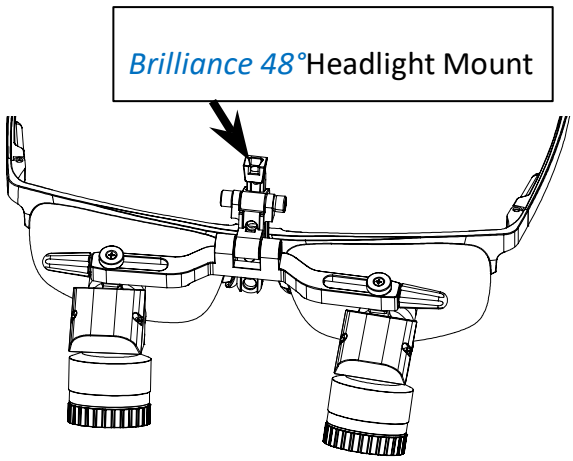


Fig.7

When connect Wireless Z to *Brilliance™ 48°* Loupes, the dovetail joint attached with Wireless Z is not necessary. The headlight mount is attached specially for *Brilliance™ 48°*. It just need mount the Wireless Z into the headlight dovetail socket of *Brilliance™ 48°*. See Fig.8.

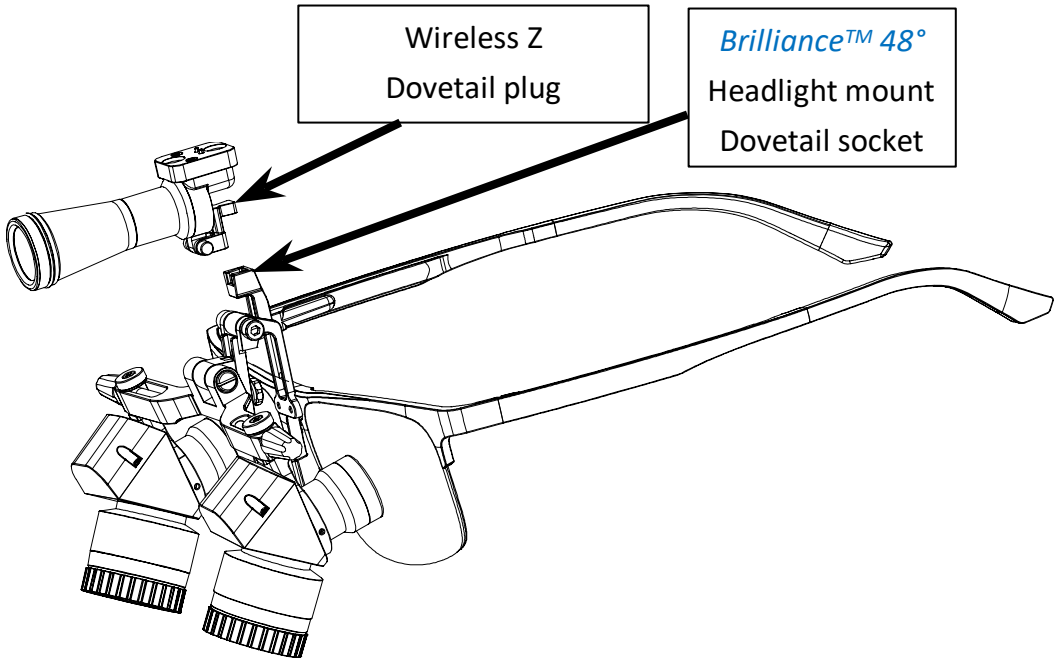


Fig.8

4.4.3 Connect Wireless Z to other brands' Loupes

Wireless Z can be connected to other brands' Loupes by using Universal headlamp mounting clip.

The dovetail joint of the headlamp and the general headlamp mounting clamp are connected according to the requirements of schematic Fig 9, and then the universal headlamp mounting clamp that connects the dovetail joint is fixed on the magnifying glass of other friendly brands, and the requirements of the schematic diagram should be met after the installation is completed.

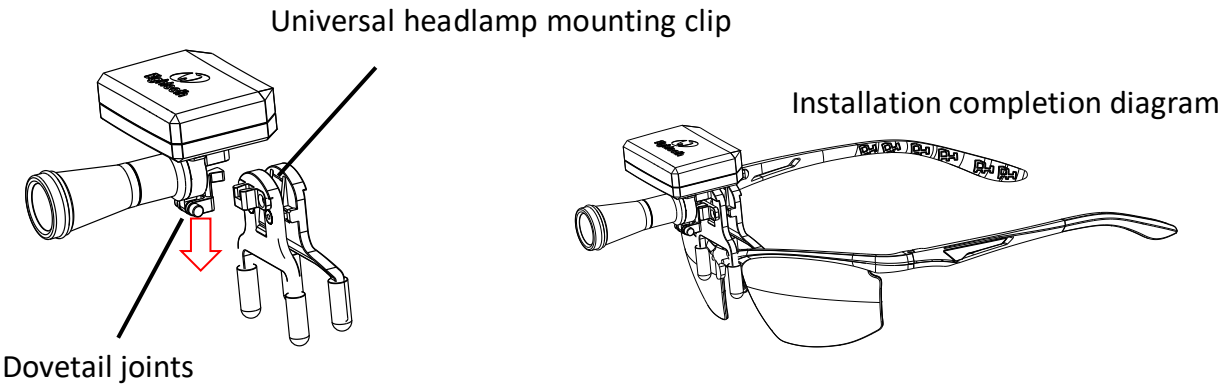


Fig.9

WARNING :

Because of improper connection between Wireless Z and other brands' Loupes Frames, it will cause Wireless Z drop down and broken, or drop onto the patients face and lead hazards.

5. Operation

5.1 Lithium Battery Box Charging

Before using the battery box for the first time, please turn on the battery switch (ON open / OFF closed) and fully charge the battery; Does not work while charging.

After connecting the adapter to the power supply, the charging indicators of the charging box will light up with red and green alternate sparkle lights, indicates that the charger box is ready for working.

Put the battery box onto the charging box, and the two positioning magnet posts at the bottom of the battery box are aligned with the two magnetic positioning holes of the charging box. See Fig.10

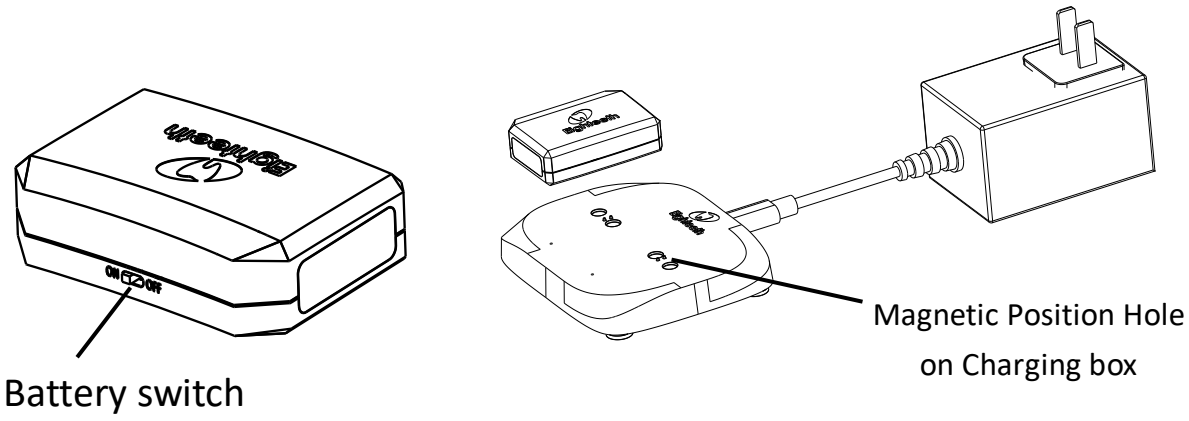
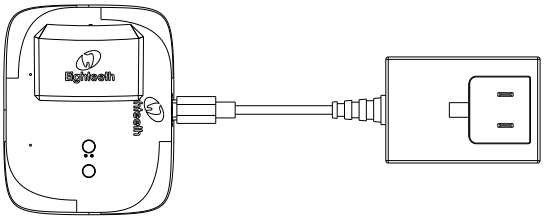


Fig.10

Caution：

Put the battery box onto the Charging box along the contrary direction compared with Fig.10, only one pair of pillars will be attracted because of the magnetism, the battery will not be conducted and charged. Please confirm their proper position and the indicator(s) on the charging box will continuously light in one color (Red or Green), thus means it is ready for charging.

Two battery boxes are standard configuration with Wireless Z, which can be charged separately as shown in Fig. 11.1, or at the same time, as shown in Fig. 11.2.



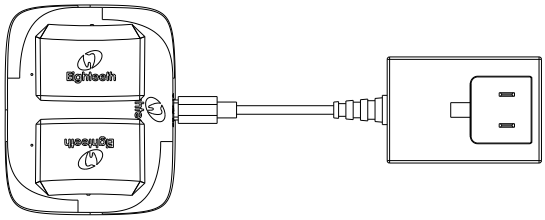


Fig. 11.1 Single Battery Charging **Fig. 11.2 Two Battery Charging**

When charging, the indicators corresponding to the charging position on the charging box (See Fig.3) will no longer flash alternately, but will continue to illuminate, and the color of the indicators will be displayed according to the battery level. When the battery is not fully charged, the indicator of the corresponding charging position on the charging case will continue to light up red, and after fully charged, the indicator light of the charging position will continue to light up green.

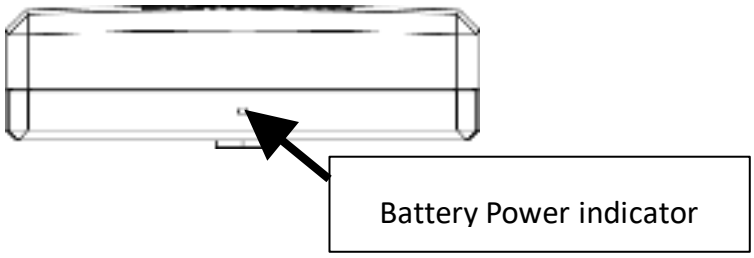


Fig. 12

In the charging state, when you touch the decorative tab on the side of the battery box (Figure 13) with your finger for a short time (t>0.5s) (once or twice), the battery indicator in the battery box will flash briefly

(1-2 times): when the battery is less than 35%, the red light flashes; when the battery is more than 35%, the green light flashes; When the battery is fully charged, and the indicator of the corresponding charging position of the charging case will also turn green. Figure 12 shows the location of the battery case power indicator.

The battery box can be easily move off from the Charging Box because of their magnetic connection. When the battery power is fully charged, the user can move it off quickly from the charging box. When the battery box is in standby state, turn off the battery switch of the battery box.

5.2 Operation

After the battery box is loaded onto the LED light source battery mount as described in 4.1, shortly touch the area shown in Fig. 13on the upper the decorative tab on the side of the battery box (t>0.5s), the headlight will be turn on (MAX), and shut off by touching it again.

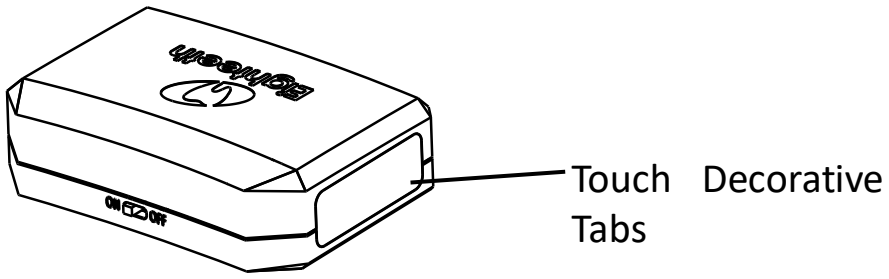


Fig. 13

The battery box has a brightness memory function, when the headlight is on, continuous touch can adjust it to a certain brightness, touch again

to turn off, and when the battery box is not removed, when you touch again, the light source lights up and returns to the brightness before the last shutdown. This feature only works on the same battery in a continuous working state.

5.3 Working Indicators

When the battery box is installed in the lamp holder and the battery switch is on (position ON), the battery power indicators (Fig. 12) will flash 3-4 times at intervals within 5 minutes from the time of loading: green light flashes when the battery power is above 35%, and red-light flashes when the battery level is below 35%;

In the working condition, when the battery power more than 35%, the green light flashes 3-4 times at intervals within 5 minutes, and when the battery level continues to decrease to below 35%, the red light will flash at intervals until the battery is exhausted, please charge is as soon as possible.

5.4 Device that can be used together

It is recommended to use Wireless Z in conjunction with the Eighteeth® Loupes, as described in clause 4.4.1-4.4.2, plug in Wireless Z, and adjust the angle of the headlight up and down to adjust the position of the illumination spot.

Wireless Z can also be used in conjunction with other brands of Loupes as described in clause 4.4.3.

6. Maintenance

6.1 Cleaning and disinfection

Wipe all external surfaces of the lens with a microfibre cloth (included in the package) or cotton swab lightly moistened with Etnanol for Disinfection (Ethanol 75%) at least 3 minutes , repeat for 5 times.

6.2 Maintenance

The surface of the lamp tube and exposed optical lens should be wiped with the attached lens cloth or medical cotton swab dipped in a small amount of 95% alcohol, and then gently wiped with the dry part of the lens cloth after drying.

When the equipment is in use, the operator is requested to use the original adapter and batteries to avoid affecting the life of the equipment. When the equipment is not in use, please ask the operator to store the equipment in a suitable environment according to the instruction manual.

 Caution：

1. **When the battery is fully charged, please take it off immediately, please do not charge it for a long time.**
2. **When the battery is discharged, please charge it immediately, it is recommended not to wait until the battery is completely discharged before charging.**
3. **If the battery is not used for a long time, it is recommended to charge and discharge once a month for performance calibration.**
4. **Please do not disassemble the lamp head privately to avoid damage to the lamp head assembly and lens.**

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 headlamp battery box totally, 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. Check whether there is any foreign object between the conductive copper pillar of the battery box and the conductive pin on the headlamp base.
LED Light Source does not work	The soldering between the LED connection cable and the Pin in the lamp barrel is broken, resulting in an open circuit	Replace the entire set of headlamp tubes

	The conductive copper pillar of the battery box is in poor contact with the conductive pin of the lamp tube base	Please check whether the interface contacts have become dark due to oxidation, if they change color, please use a cotton swab dipped in an appropriate amount of alcohol to scrub them repeatedly, dry them and then reuse them; Otherwise, please contact professional after-sales service for testing.
	Low power causes the system to start low voltage protection.	Recharge the battery.
	Interface short circuit.	Please carefully check the interface of the battery box and the lamp holder to check for short circuits caused by the entry of other metal lamps.
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 charging cable or charging case is damaged	Replace the charging cable or charging case
	The charging case or battery box interface is damaged	Please contact your local distributor.

8. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	Wireless Z
Package Dimensions	22.1*16.2*7.2 cm
Internal Battery	Lithium ion battery, 3.8V, 600mAh
Adapter Input	100-240V～50/60Hz, 0.35A Max
Input	5V ⎓ 1A
Output	DC 6.2V 200mA (max)
LED Light Input	DC 6.2V 200mA (max)
Electrical Safety Class	Charging: Class II; Operating: Internally powered
Color Temperature	3000K~7300K
Color Rendering Index (CRI)	≥90%
Illuminance	10000±20%lux 35cm
Operating Time	Continuous operation for ≥2.5h at maximum brightness
Operating Conditions	Use: in enclosed spaces Ambient temperature: 0℃～40℃ Relative humidity: ＜80%, no condensation at 0℃ Operating altitude: <5000m above sea level
Transport and Storage Conditions	Ambient temperature: -20℃～+55℃ Relative humidity: 20%～80% Atmospheric pressure: 70kPa～106kPa

9. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The Wireless Z is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Z should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environments-Guidelines
RF emissions CISPR 11	Group 1	The Wireless Z 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 Wireless Z 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 IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity
The Wireless Z is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Z 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	+/- 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 transients/bursts IEC 61000-4-4	±2kV to power cable ±1kV to input/outpout line	±2kV to power cable N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±1kV Line to earth:±2kV	Line to line:±1kV Line to earth: N/A	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips IEC 61000-4-11	＜5% UT; 0.5 cycle (on UT, >95 per cent transient drop) 40% UT; 5 cycle (on UT, 60% transient drop) 70% UT; 25 cycles(on UT, 60% transient drop) ＜5% UT; 5s(on UT, >95 per cent transient drop)	＜5% UT; 0.5 cycle (on UT, >95 per cent transient drop) 40% UT; 5cycle (on UT, 60% transient drop) 70% UT; 25 cycles(on UT, 60% transient drop) ＜5% UT; 5s (on UT, >95 per cent transient drop)	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or battery.
Rated Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a

			typical commercial or hospital environment.
Note: UT: 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 Wireless Z is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Z 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

Proximity magnetic fields	7.5A/m 13.56MHz Pulse modulation 50 kHz	7.5A/m	environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Wireless Z is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Z should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Wireless Z, including cables, than the recommended separation distance calculated from
	3 V/m, 80 MHz – 2.5 GHz, 80 %		

Radiated RF EM fields IEC 61000-4-3	AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	3V/m	the equation applicable to the frequency of the transmitter. Recommended minimum separation distances
Proximity fields from RF wireless communication equipment IEC 61000-4-3		Complies	See the RF wireless communication equipment table in "Recommended minimum separation distances"

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 Wireless Z 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 Wireless Z as recommended below.

Test frequ	Band	Service	Modulation	Maximum	Distance	Immunity

ency (MHz)	(MHz)			power (W)	(m)	test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-	GSM 1800;	Pulse modul	2	0.3	28
1845						

1970	1990	CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	ation 217Hz			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

10. Statement

Service Life

The service life of Wireless Z 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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