Red-Light Wand

User Manual

1. Product Name

Red-Light Wand

2. Models and Specifications

SW-A01 and SW-A02

3. Structure

The Red-Light Wand consists of a handle, a wand body, a position regulator, and a USB data cable. Figure 1 shows the structure of the Red-Light Wand.

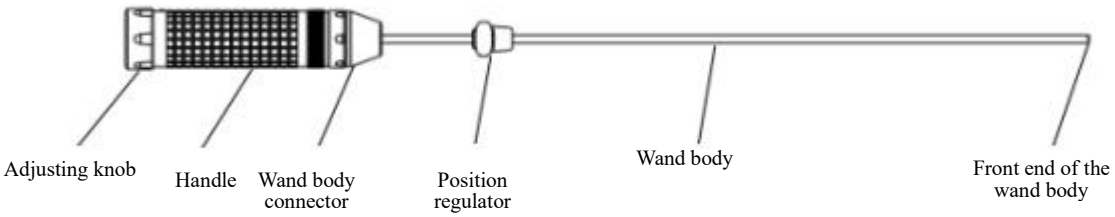

Figure 1 Structure of the Red-Light Wand

4. Working Principle

The Red-Light Wand uses red LED light as its light source and is powered by a built-in lithium battery. The LED lamp is lit to generate red light and illuminate the front end through optical fiber.

5. Scope of Application and Intended Use

The Red-Light Wand is intended to provide a source of pilot light during placement of a tracheal tube on a patient who needs tracheal intubation.

6. Functions

The Red-Light Wand visualizes the process of introducing a tracheal tube into the patient's airway based on the principle of light transmission of human neck soft tissue, providing visual indication for blind exploration of tracheal intubation.

7. Performance

7.1 Appearance

(1) All parts of the Red-Light Wand are assembled completely and fixed securely.

(2) The surface of the Red-Light Wand is free of defects, such as burrs, dents, and scratches.

(3) Dimensions: The working length of the wand body is 345 mm ± 15 mm and its diameter is

4.5 mm ± 1 mm.

7.2 Handle

(1) The Red-Light Wand has a built-in rechargeable lithium battery, with charging input ≤ 5 VA.

(2) The Red-Light Wand provides an adjusting knob for power-on, power-off, and stepless dimming intensity adjustment.

7.3 Wand body

(1) The Red-Light Wand is rated as IPX7 for waterproof performance and can be immersed for disinfection.

(2) Maximum light intensity of the Red-Light Wand model SW-A01 (golden) at the front-end optical outlet of the wand body: ≥17,000 lx.

(3) Maximum light intensity of the Red-Light Wand model SW-A02 (black) at the front-end optical outlet of the wand body: ≥7,000 lx.

7.4 Position regulator mobility

The static friction force between the position regulator and the wand body is greater than 5N and less than 50N.

7.5 Electrical safety

The Red-Light Wand meets the electrical safety requirements of IEC 60601-1:2005+A1:2012 and IEC 60601-2-18:2009.

7.6 Electromagnetic compatibility

The Red-Light Wand meets the electromagnetic compatibility requirements of IEC 60601-1-2:2014.

7.7 Description of classification

(1) Classification of the Red-Light Wand based on protection against electric shock: internally powered equipment, class II.

(2) Classification of the Red-Light Wand based on the degree of protection against electric shock: type B.

(3) Classification of the Red-Light Wand based on the degree of protection from harmful liquid penetration: IPX0 for the handle part and IPX7 for the wand body part.

(4) For details about how to disinfect and sterilize the Red-Light Wand, see chapter 11 "Preventive Inspection, Servicing, and Maintenance" in this user manual.

(5) Classification of the Red-Light Wand based on the safety level when it is used in the presence of flammable anesthetics mixed with air or with oxygen or nitrous oxide: Non-AP/APG type.

(6) Classification of the Red-Light Wand based on its operating mode: continuous operation.

8. Instructions for Installation and Use

8.1 Power supply

The Red-Light Wand has a built-in, non-removable, and rechargeable lithium battery as its internal power.

Lithium battery specifications of the SW-A01 model (golden): 3.6 V DC, 3450 mAh

Lithium battery specifications of the SW-A02 model (black): 3.6 V DC, 2200 mAh

⚠Warning: Do not disassemble or replace the lithium battery by yourself; otherwise, you will bear responsibilities resulting from product damage caused by self-replacement.

8.2 Connection for charging

To charge the Red-Light Wand, connect the USB data cable to the USB interface at the end of the handle and connect the other end of the USB data cable to a power adapter. Be sure to power off the Red-Light Wand when charging it. Figure 2 shows the charging connection diagram.

You should purchase the power adapter on your own. Please use a power adapter (output: 5 V) that is from a formal manufacturer and meets the requirements of IEC 60601-1:2005+A1:2012.

⚠Note: The USB interface is only used for charging.

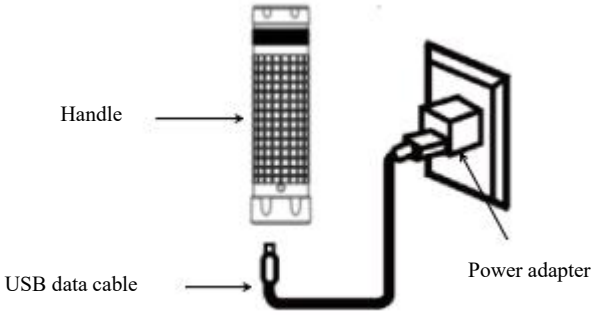

Figure 2 Charging connection diagram

8.3 Indicator light

When the indicator light on the side of the handle is YELLOW, the Red-Light Wand is being charged. When the indicator light is GREEN, charging is complete or the Red-Light Wand is in use after power-on. When the indicator light is flashing YELLOW, the Red-Light Wand has insufficient power and must be charged right away.

8.4 Wand body connection

Connect the wand body to the handle and rotate the wand body clockwise to fasten it.

8.5 Power-on/off and light intensity adjustment

Rotate the adjusting knob at the tail end of the handle clockwise to power on the Red-Light Wand and increase the light intensity, which reaches the maximum level when the adjusting knob can no longer be rotated. Rotate the adjusting knob counterclockwise to reduce the light intensity and power off the Red-Light Wand.

8.6 Wand body removal

After the Red-Light Wand is powered off, rotate the wand body counterclockwise to separate the handle from the wand body.

8.7 Preparation before intubation

(1) Disinfection of the wand body: Rinse clean the wand body and then dry it. Immerse the wand body in 0.55% ortho-phthalaldehyde disinfectant for at least 5 minutes, and then take out the wand body, rinse it clean with flowing sterile water, and dry it by using sterile gauze before use. Alternatively, disinfect the wand body by following the immersion disinfection procedure formulated by the hospital. Do not disinfect the wand body by using strong acid and alkali disinfectants.

(2) Select a tracheal tube of corresponding specifications, and apply lubricant evenly to the front end of the Red-Light Wand, the front end of the tracheal tube, and the airbag.

(3) Place the Red-Light Wand into the tracheal tube. When the front end of the Red-Light Wand is about 1 cm away from the Murphy hole of the tracheal tube, fix the Red-Light Wand through the position regulator. Do not extend the front end of the wand body beyond the Murphy hole of the tracheal tube. It is recommended that the Red-Light Wand be bent by 100–135° at a distance of 5.5–7.5 cm from its front end. Then, shape and fix the tracheal tube.

See the following figures.

Bent part	
Bending angle	

⚠Warning: When the Red-Light Wand is working at a temperature approximating to its highest operating temperature, the temperature on the wand surface will exceed 41°C under the illuminant of the Red-Light Wand. The patient's oral tissue may be injured after long-time direct contact with the wand surface at such a high temperature. Therefore, minimize the duration of direct contact between the patient's mouth and the Red-Light Wand under this circumstance.

(4) Intubation

Place the tracheal tube into the patient's mouth by following the method and procedure formulated

by the hospital.

9. Contraindications

⚠The contraindications for using the Red-Light Wand include foreign bodies in the upper airway, tumors, polyps, abscess of the posterior pharyngeal wall, and fragile tissues in the intubation pathway.

⚠The Red-Light Wand should be used with caution on patients with an obvious abnormal neck structure, obesity, and neck scars.

10. Precautions

10.1 Precautions for use

(1) Read the instructions for use carefully and completely before using the Red-Light Wand.

(2) Before use, check the outer surface of the Red-Light Wand for unintended sharp edges, protrusions, or rough surfaces which may cause harm. If such defects are present, replace the Red-Light Wand.

(3) Take care to avoid direct eye contact with the luminous area when using the Red-Light Wand.

(4) Do not modify the Red-Light Wand arbitrarily.

(5) Place the Red-Light Wand into a tracheal tube with qualified medical equipment certification.

(6) Rinse and disinfect the wand body before initial use and after surgery. The wand body can be disinfected by immersing it in disinfectant. Do not disinfect the wand body by using strong acid and alkali disinfectants.

(7) Do not disinfect or sterilize the Red-Light Wand under high temperature and pressure.

(8) Do not bend the wand body continuously for many times in a short period of time to prevent the wand body from breaking.

(9) Prevent liquid penetration into the USB interface at the tail end of the handle.

(10) If the Red-Light Wand is suspected to encounter any functional errors during use, stop using it immediately, mark the errors, and contact the authorized after-sales service promptly.

(11) Do not discard the scrapped lithium battery and main unit randomly. The disposal of waste and residues should conform to local laws and regulations.

(12) Do not heat or burn the lithium battery.

(13) The Red-Light Wand can be used only by professional medical staff.

(14) Do not replace parts by yourself or use components and accessories from other manufacturers; otherwise, you will bear responsibilities resulting from product damage caused by self-replacement. If the Red-Light Wand is faulty and repair is required, contact

the after-sales service. When replacing the LED indicator light, power off the Red-Light Wand and wait until the surface temperature of the Red-Light Wand is reduced to normal temperature before the maintenance personnel can carry out the maintenance or repair of the product.

(15) Use only the maintenance parts and components provided by Shenzhen Century Weichuang Medical Technology Co., Ltd. Use of maintenance parts and components from other manufacturers may void the warranty.

(16) Do not disassemble the Red-Light Wand by yourself. To perform adjustment, repair, and replacement, contact the supplier, after-sales service, or Shenzhen Century Weichuang Medical Technology Co., Ltd.

10.2 Stop using the Red-Light Wand under any of the following circumstances:

(1) The outer surface of the wand body is damaged, discolored, or fractured.

(2) The wand body does not light on after power-on, and the Red-Light Wand is still unusable after charging.

10.3 Electronic interference

The Red-Light Wand has passed testing in compliance with applicable standards. However, other electrical medical equipment may cause interference to the Red-Light Wand and the Red-Light Wand may also interfere with other electronic equipment during use. If interference is present, it is recommended that you increase the physical distance between the Red-Light Wand and other electrical medical equipment.

11. Preventive Inspection, Servicing, and Maintenance

11.1 Preventive inspection

Before use, turn on the switch of the Red-Light Wand and ensure that the optical fiber at the front end of the wand body lights on.

11.2 Cleaning, servicing, and servicing period

Handle: Before initial use and after surgery, disinfect the handle by wiping it with a piece of cloth soaked with 75% alcohol (ensure that the handle is disconnected from the power adapter). Dry it before use or storage.

Wand body: Before initial use and after surgery, clean and disinfect the wand body by using the disinfection method described in section 8.7. Sterilization is not required.

11.3 Instructions for safe use and maintenance of the lithium battery

(1) Store and use the lithium battery within the specified temperature and humidity ranges.

(2) Unplug the power adapter promptly when the lithium battery is fully charged to prevent overcharge.

(3) Do not keep discharging the battery until the Red-Light Wand is powered off.

(4) Do not knock, crush, heat, or burn the handle to prevent the lithium battery from being

damaged.

(5) It is recommended that the lithium battery be charged once every three months when the Red-Light Wand is unused for a long time, to prevent faults caused by battery self-discharge.

11.4 Maintenance

Keep the Red-Light Wand away from dust and protect it from shaking and impact.

12. Conditions and Methods of Storage and Transportation

12.1 Environmental conditions for normal use:

(1) Ambient temperature: 5–40°C

(2) Relative humidity: ≤ 80%

(3) Atmospheric pressure: 86–106 kPa

12.2 The Red-Light Wand should be stored in a well-ventilated indoor environment free of corrosive gases, and should be stored and transported under the following conditions:

(1) Ambient temperature: –20°C to +55°C

(2) Relative humidity: ≤ 93%

(3) Atmospheric pressure: 50–150 kPa

13. Date of Manufacture and Shelf Life

Date of manufacture: See the product label.

Shelf life: 2 years

Shelf life of the wand body: It is recommended that the wand body be replaced after it is bent for 100 times (or depending on the actual condition of the product).

14. Configuration List

Item	Quantity	Item	Quantity
Handle	1	Position regulator	1
Wand body	1	USB data cable	1
User Manual	1 copy		

15. Graphs, Symbols, and Acronyms and Abbreviations

	Attention. See the document delivered with the equipment.		Manufacturer
	Applied Part: Type B		Double insulation

	Date of manufacture		Up
	Manufacturer’s batch code		Protect from rain
	Shelf life		Number of stacking layers
	Humidity limit		Temperature limit
	Separate handling of scrapped electrical and electronic equipment in conformance to local laws and regulations		Atmospheric Pressure Symbol indicates upper and lower limits of the atmospheric pressure for this device.
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

16. Instructions for Waste Disposal

Send the product that has reached the end of its shelf life to an appropriate place for environmentally-friendly handling. Disposal of waste and residues should conform to relevant national laws and regulations.

17. Registrant, Manufacturer, and After-Sales Service

Name: Shenzhen Century Weichuang Medical Technology Co., Ltd.

Domicile, manufacturing, or after-sales service address: #601 of the 1st plant , Jinli Science and Technology Park, Nanbu Community, Longtian Street, Pingshan District, Shenzhen, Guangdong, China.

Tel: 0755-28990035 and 28990036

Fax: 0755-28990035-8003

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18. Description of User Manual Preparation

This user manual includes instructions for use and technical instructions.

19. Date of User Manual Preparation

19/07/2019

Appendix: EMC Information

Note:

- The Red-Light Wand (models: SW-A01 and SW-A02) meets the EMC requirements of the IEC 60601-1-2:2014 and IEC 60601-2-18:2009 standards.
- Install and use the Red-Light Wand based on the EMC information in the document that is delivered with the Red-Light Wand.
- Portal and mobile RF communication equipment may compromise the performance of the Red-Light Wand (models: SW-A01 and SW-A02), so prevent strong electromagnetic interference when using the Red-Light Wand, for example, keeping the Red-Light Wand away from mobile phones and micro ovens.
- For details about the guidelines and the manufacturer's statement, see the appendix.

Warning:

- The Red-Light Wand (models: SW-A01 and W-A02) should not be used in proximity to or stacked with other equipment. If it must be used under such a condition, be sure to observe and verify that it can work properly with its used configuration.
- The Red-Light Wand (models: SW-A01 and SW-A02) may experience increased emission or reduced electromagnetic susceptibility when it is used with other accessories and USB data cables than those sold by the Red-Light Wand manufacturer as spare parts for the internal components of the Red-Light Wand.

Cable information

No.	Name	Cable Length (m)	Shielded?	Remarks
1	USB data cable	1.0	No	/

Guidelines and Manufacturer's Statement – Electromagnetic Emission		
The Red-Light Wand (models: SW-A01 and SW-A02) is intended to be used in the following specified electromagnetic environments. Buyers or users of the Red-Light Wand should ensure that it is used in such electromagnetic environments.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidelines**
RF emission IEC CISPR 11-2010	Group 1	The Red-Light Wand (models: SW-A01 and SW-A02) uses RF energy only for its internal functions. Therefore, the Red-Light Wand has extremely low RF emission and an extremely low possibility of interfering with nearby electronic equipment.
RF emission IEC CISPR 11-2010	Class B	The Red-Light Wand (models: SW-A01 and SW-A02) is suitable for use in all facilities, including domestic facilities and public low-voltage power supply networks that are directly connected to domestic residence.
Harmonic emission IEC 61000-3-2:2018	Not applicable	
Voltage fluctuation and flicker emission IEC 61000-3-2:2018	Not applicable	

Guidelines and Manufacturer's Statement – Electromagnetic Susceptibility			
The Red-Light Wand (models: SW-A01 and SW-A02) is intended to be used in the following specified electromagnetic environments. Buyers or users of the Red-Light Wand should ensure that it is used in such electromagnetic environments.			
Electromagnetic Susceptibility Test	**IEC 60601 Test Level**	**Coincidence Level**	**Electromagnetic Environment – Guidelines**
Electrostatic discharge IEC61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be wood, concrete, or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient IEC61000-4-4	±2 kV pair power cable ±1 kV pair I/O cable	Not applicable	Not applicable
Surge IEC61000-4-5	±1 kV differential mode voltage	Not applicable	Not applicable

	±2 kV common mode voltage		
Voltage dip, short-term interruption, and voltage variation on power input cables IEC61000-4-11	< 5% U_T, lasting 0.5 cycles (On U_T, voltage dip > 95%) 40% U_T, lasting 5 cycles (On U_T, 60% voltage dip) 70% U_T, lasting 25 cycles (On U_T, 30% voltage dip) < 5% U_T, lasting 5s (On U_T, voltage dip > 95%)	Not applicable	Not applicable
Power frequency magnetic field (50/60 Hz) IEC61000-4-8	3 A/m	3 A/m, 50/60 Hz	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidelines and Manufacturer's Statement – Electromagnetic Susceptibility			
The Red-Light Wand (models: SW-A01 and SW-A02) is intended to be used in the following specified electromagnetic environments. Buyers or users of the Red-Light Wand should ensure that it is used in such electromagnetic environments.			
Electromagnetic Susceptibility Test	**IEC 60601 Test Level**	**Coincidence Level**	**Electromagnetic Environment – Guidelines**
RF conduction IEC61000-4-6 RF radiation IEC61000-4-3	3 V (valid value) 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V (valid value) 3 V/m	Portable and mobile RF communication equipment should not be used closer to any parts, including cables, of the Red-Light Wand (models: SW-A01 and SW-A02) than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency. **Recommended isolation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80–800 MHz

			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where: P : the maximum rated output power of the transmitter provided by the transmitter manufacturer, in the unit of watts (W) *d:* the recommended isolation distance, in the unit[b] of meters (m) The field strength of a fixed-type RF transmitter is determined by surveying the electromagnetic field[c] and should be lower than the coincidence level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the symbol. 
Note 1: From 80 MHz to 800 MHz, the higher frequency range applies. Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by absorption and reflection by buildings, objects, and human bodies.			
a: Fixed-type transmitters, such as base stations for wireless (cellular or cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, have field strengths that cannot be predicted accurately in theory. Survey of electromagnetic sites should be considered for evaluating the electromagnetic environments of fixed-type RF transmitters. Observe and verify that the Red-Light Wand (models: SW-A01 and SW-A02) works properly if the environment where the Red-Light Wand is used has field strength higher than the preceding applicable RF coincidence level. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the orientation or position of the Red-Light Wand. b: In the whole frequency range of 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.			

Recommended Isolation Distance Between Portable and Mobile RF Equipment and the Red-Light Wand

The Red-Light Wand (models: SW-A01 and SW-A02) is intended to be used in electromagnetic environments with controlled RF radiation disturbance. According to the maximum rated output power of communication equipment, buyers or users of the Red-Light Wand (models: SW-A01 and SW-A02) can prevent electromagnetic interference by maintaining the following recommended minimum distance between portable and mobile RF communication equipment (transmitter) and the Red-Light Wand.

Maximum Rated Output Power of the Transmitter (W)	**Isolation Distance (m) Corresponding to Different Frequencies of the Transmitter**		
	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 the maximum rated output power of the transmitter not listed above, the recommended isolation distance *d*, in meters (m), can be calculated by the formula in the corresponding transmitter frequency column, where *P*, in watts (W), is the maximum rated output power of the transmitter provided by the transmitter manufacturer.

Note 1: From 80 MHz to 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by absorption and reflection by buildings, objects, and human bodies.