

CuringPen-E
Dental Curing Light USER MANUAL
Changzhou Sifary Medical Technology Co.,Ltd.

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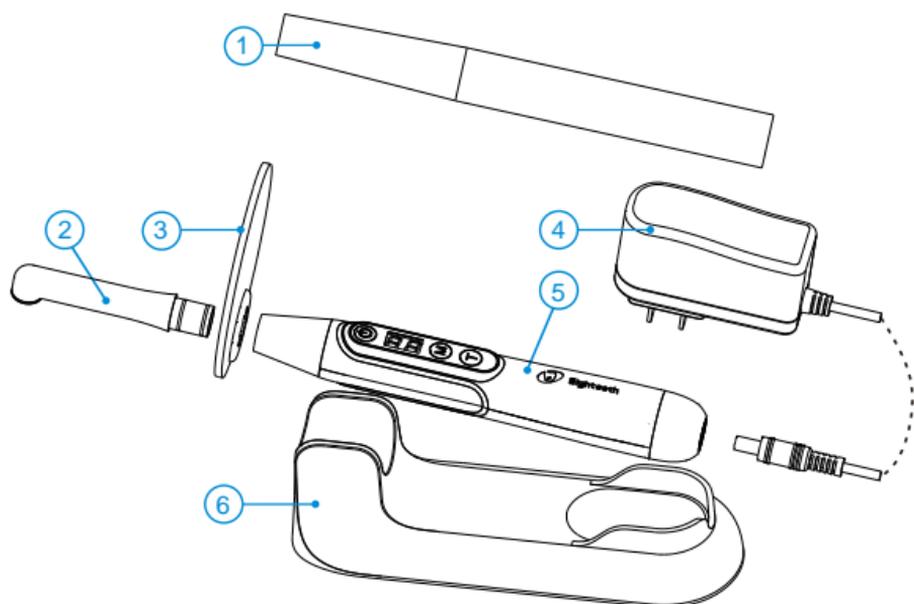
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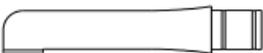
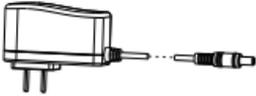
1.Scope of CuringPen-E

1.1 Parts Identification

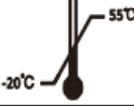
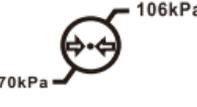
- ① Disposable sleeve
- ② Light source head
- ③ Protective light shield
- ④ Adapter
- ⑤ Handpiece
- ⑥ Base



1.2 Components and accessories

<p>Handpiece (1pcs)</p>  A handpiece with a white body and a black grip section. It features three circular buttons on the grip and a small logo.	<p>Light source head (1pcs)</p>  A long, thin, cylindrical component with a slightly wider base and a small protrusion at the tip.
<p>Disposable sleeves (100 pcs)</p>  A long, thin, cylindrical component with a slightly wider base and a small protrusion at the tip.	<p>Adapter (1pcs)</p>  A rectangular component with a small protrusion on one side and a small hole on the other.
<p>Base (1pcs)</p>  A U-shaped component with a small protrusion on one side and a small hole on the other.	<p>Protective light shield (1pcs)</p>  A long, thin, cylindrical component with a slightly wider base and a small protrusion at the tip.
<p>Manual(1pcs)</p>	

2. Symbols Used

 Warning	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 NOTE	Additional information, explanation of operation and performance.
	Serial number
	Catalogue number
	Manufacturer
	Date of manufacture
	Class II equipment
	Type B applied part
	Direct current
	Dispose of in accordance with the WEEE directive
	Keep dry
	Do not reuse
	Consult instructions for use
	Authorized Representative in the European Community
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer's LOGO
	Lot number

3. Before Use

3.1 Scope of application

CuringPen-E is intended to cure dental resins and composites.

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

3.2 Contraindications

Do not use the device for non dental procedure.

Safety and effectiveness have not been established in pregnant women and children.



Warning

Read the following warnings before use:

1. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
2. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
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, portable or mobile RF communication devices and do not use this system near the active HF Surgical Equipment in the hospital. Please charge at least 3 hours before first use. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
4. Protective light shield and a disposable sleeve are compulsory during treatment.
5. If irregularities occur in the device during treatment, switch it off. Contact the agency.
6. No modification of this equipment is allowed. Never open or repair the device yourself, otherwise, void the warranty.

4. Setting up the CuringPen-E

4.1 Install the light source head

Make sure the light source head align to the slots of the handpiece. Push gently until there is a “click” sound which indicates that the light source head is securely installed into the handpiece.



The light source head can be 360 degrees rotated without being taken off, which makes it easy to watch the LCD during the treatment.



Warning

- Only the original light source head can be used. Check the light source head and handpiece before

- installation. Do not use damaged light source head and handpiece.
- After installing the light source head, pull it gently to make sure the connection is good, otherwise, it may cause unexpected fault, even hurt the patients.

4.2 Install the disposable sleeve

Apply a disposable sleeve over the entirety of the light source head

and handpiece before beginning a procedure.



4.3 Install the protective light shield

Make sure the light source head align to the slots of the protective light shield, plug them together.

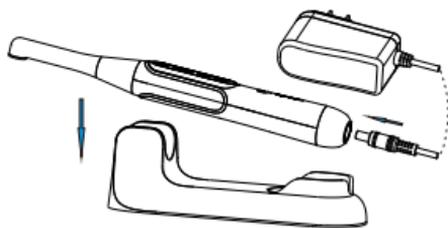


Warning

- Disposable sleeves must be discarded after each use.
- The light source head, protective light shield, Base and handpiece should be cleaned and disinfected after each treatment.

4.4 Plug the adapter

Plug the round connector of the adapter into the charging hole at the rear of handpiece, and then the buzzer makes beeps twice, and then the display symbol of charging cycle will show on the screen, and then place the handpiece on the Base.

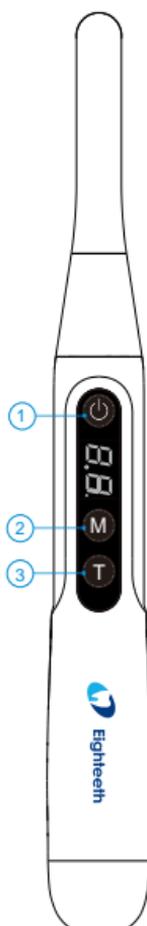


NOTE

- Only the original adapter can be used. Otherwise, the device may be damaged.
- The round connector of the adapter must be plugged into the charging hole at the rear of handpiece in the right way.

5. Use Interface

5.1 Panel key



①  Main switch

② "M" Mode key

③ "T" Time key

Turn Power On

Press  more than 0.5 seconds to turn on the device.

Mode Selection

Press setting key in standby state to select the operating mode.

Time Selection

Press setting key in standby state to select the seconds.

Start / Stop Light Intensity Output

In standby state, press  to start the output of light intensity, and press  to stop the output.



The icon shows **P2** working mode



The icon shows **03** seconds

6.Setting

6.1 Selecting memory mode

Memory mode setting

There are 5 built-in memory programs, namely P1 Normal Mode,P2 High Power Mode,P3 Turbo Mode,P4 Pulse Mode,P5 Ramp Mode. Press setting key to enter the mode setting menu.In the menu,press setting key gently again to change the memory.

Curing Time setting

In the curing time setting menu, press "T" to select different times. The time selection is different under different light intensity:

light intensity mode	time selection(sec)
P1 Normal Mode	05,10,15,20,25,30,35,40
P2 High Power Mode	01,03,05,10
P3 Turbo Mode	01,03,05
P4 Pulse Mode	05,10,15,20
P5 Ramp Mode	05,10,15,20

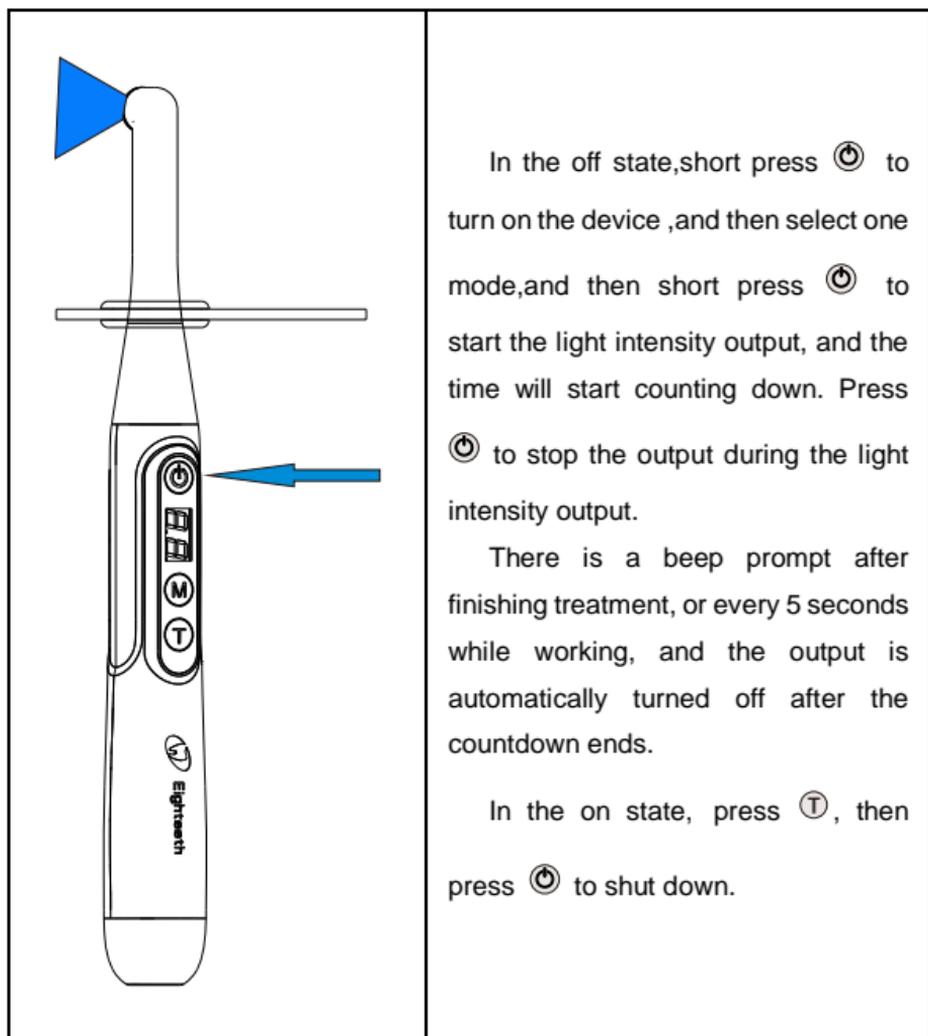


NOTE

- The light intensity of P1 to P5 memory modes are built-in, and the user cannot modify the settings.

7.Operation

7.1 Handpiece operation



In the off state, short press  to turn on the device, and then select one mode, and then short press  to start the light intensity output, and the time will start counting down. Press  to stop the output during the light intensity output.

There is a beep prompt after finishing treatment, or every 5 seconds while working, and the output is automatically turned off after the countdown ends.

In the on state, press , then press  to shut down.



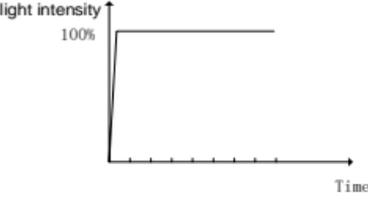
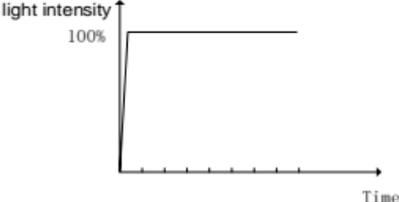
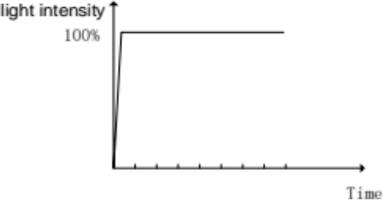
Warning

- When the device is working, do not directly illuminate the eyes, otherwise it will cause injury.
- Do not directly illuminate the skin, otherwise high temperature burns may occur.
- Before using, please try it outside the oral cavity to ensure that there is no problem with the function of the device.
- Do not disassemble the light source head during treatment.

**NOTE**

- To prevent the lamp from injuring patients by overheating, after the device is used continuously 300 seconds at P2 High Power Mode and P3 Turbo Mode, it will be prohibited to use the highest light intensity output within 60 seconds.
- When using, the light should be directly irradiated onto the curing dental resins and composites to avoid improper exposure.
- The disposable sleeve and protective light shield are highly recommended.
- If there is any abnormal functioning, stop using the device and report to the distributor.
- Gloves are compulsory during treatment.
- Always disinfect the handpiece and light source head after each treatment.

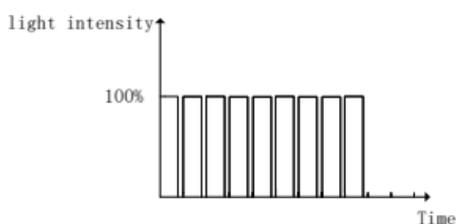
7.2 Operation mode

<p>P1</p>	<p>Normal Mode</p> <p>Light intensity :1200mW/cm²</p> <p>Wavelength: 380nm-515nm</p> <p>When  is pressed, the set light intensity is output immediately. There is a beep prompt after finishing treatment, or every 5 seconds while working.</p> 
<p>P2</p>	<p>High Power Mode</p> <p>Light intensity: 2000mW/cm²</p> <p>Wavelength: 380nm-515nm</p> <p>When  is pressed, the set light intensity is output immediately. There is a beep prompt after finishing treatment, or every 5 seconds while working.</p> 
<p>P3</p>	<p>Turbo Mode</p> <p>Light intensity: 3000mW/cm²</p> <p>Wavelength: 380nm-515nm</p> <p>When  is pressed, the set light intensity is output immediately. There is a beep prompt after finishing treatment.</p> 

P4**Pulse Mode**Light intensity: 1200mW/cm²

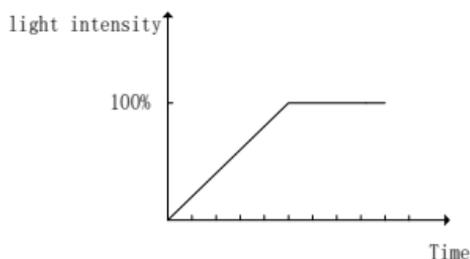
Wavelength: 380nm-515nm

When  is pressed, the set light intensity is output immediately and flashes once every 1 second. There is a beep prompt after finishing treatment, or every 5 seconds while working.

**P5****Ramp Mode**Light intensity: 1200mW/cm²

Wavelength: 380nm-515nm

When  is pressed, the light intensity gradually increases from 0mW/cm² to 1200mW/cm², and then continues to output 1200mW/cm². There is a beep prompt after finishing treatment, or every 5 seconds while working.



7.3 Charge



When the “E0” low battery prompt appears on the screen, it means the battery is exhausted, please charge it in time. How to plug the adapter is described in the Chapter 4.4 Plug the adapter.



During charging, the charging indication “  ” appears on the screen dynamically. When the battery is fully charged, the indication “  ” appears on the screen statically.

It takes about 3 hours for full charge, depending on residual battery power and battery state.

It can be recharged 300-500 times, depending on the operating conditions of the device. If there is a significant decline in battery power, please report to the distributor, so as not to affect the curing effect.



NOTE

- When the "E0" low battery warning shows on the screen, the device must be recharged within 15 days, otherwise the battery may cause irreparable damage due to long periods of low power.
- If the device flickers on the screen in standby mode, it indicates that the battery is less than 20%, so please charge it in time.
- Only the original adapter can be used. Otherwise, the device may be damaged.
- The round connector of the adapter must be plugged into the charging hole at the rear of handpiece in the right way.

- If plugging the adapter while the device is working, other functions of the device will forcibly stop, and then the device will enter charging status.
- When the device is not used for a long time, please change the device at least once a month.
- The device automatically enters the shutdown state after 120 seconds without operation. Please press  to restart the device.



Warning

- Do not change the battery, only trained technician or distributor can change the battery, the electronic parts will be damaged if use a wrong battery or install with a wrong way.

8.Maintenance

Disinfection components

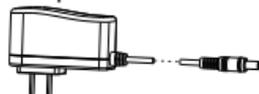
Handpiece



Light source head



Adapter



Base



Protective light shield



Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80vol%) at least 2 mins, repeat for 5 times.



Warning

- Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%).
- Do not use too much ethanol as it's going into machine and damage the components inside.

Disposable components

Disposable sleeves (one box of)



Warning

- Please discard the disposable sleeve after each use and do not use it again.

9.Error Warning

E0	When the indication "E0" blinks on the screen, it means the battery is exhausted, please charge it in time. If the error warning persists, please contact your local distributor.
E1	When the indication "E1" blinks on the screen, it indicates that the light source head has failed. Please stop using and contact your local distributor.
E2	When the indication "E2" blinks on the screen, please stop using and contact your local distributor.
EH	When the indication "EH" blinks on the screen, it indicates that the number of continuously using High light intensity mode reaches the limit. Please stop the device working for 60 seconds before continuing to use it.

10.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. Please contact your distributor.

Problem	Cause	Solution
The power is not turned on.	The battery is out of power.	Charge the battery.
	Handpiece is broken.	Contact your local distributor.
The device flickers on the screen in standby mode.	The battery is out of power.	Charge the battery.
The power LED does not light up when charging.	There is no electricity in the outlet.	Check the connection.
	Use a wrong adapter.	Use the original adapter.
	The adapter is damaged.	Contact your local distributor.
	Handpiece is broken.	Contact your local distributor.
No sound.	Handpiece is broken.	Contact your local distributor.
Insufficient light intensity.	There are resin or other contaminants on the surface of the lamp lens.	Cleaning the lamp head residue.
"E0" error warning.	The battery power is too low.	Charge the battery.
"E1" error warning.	The circuit of the light source head is open.	Check the circuit of the light source head.If the error warning persists ,please contact your local distributor.

"E2" error warning.	The circuit of the light source head is short.	Contact your local distributor.
	Handpiece is broken.	Contact your local distributor.
"EH" error warning.	The number of using High light intensity mode reaches the limit.	Keep the device from working for 60 seconds before continuing.

11. Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co.,Ltd
Model	CuringPen-E
Dimensions	19cm×16.5cm×7.5cm±1cm
Weight	660g±10%
Power supply	Lithium ion battery: DC 3.7V, 1400mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	5V  1A
Power Frequency	50/60Hz, ±10%
Charger nominal power input	0.2A
Light intensity	P1:1200±15% mW/cm^2 P2:2000±15% mW/cm^2 P3:3000±15% mW/cm^2 P4:1200±15% mW/cm^2 P5:1200±15% mW/cm^2
Wavelength	380nm-515nm
Electrical safety class	Class II
Applied part	B
Operation mode	Intermittent operation 5mins. ON / 1min. OFF
Operation conditions	Use: in enclosed spaces Ambient temperature: 5°C ~ 40 °C Relative humidity: <80% Operating altitude < 3000m above sea level Atmospheric pressure: 70kPa ~ 106kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa ~ 106kPa

12.EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The CuringPen-E is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The CuringPen-E 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. The CuringPen-E is suitable for use in professional healthcare facility environment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The CuringPen-E is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen-E 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 ± 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	± 2 kV 100kHz repetition frequency	± 2 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: ± 0.5 kV, ± 1 kV Line to earth: ± 0.5 kV, ± 1 kV, ± 2 kV	Line to line: ± 0.5 kV, ± 1 kV Line to earth: ± 0.5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% UT; 0.5 cycle at 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT; 250/300	0% UT; 0.5 cycle at 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0° 0% UT;	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 from an uninterruptible power supply or a battery

	cycle	250/300 cycle	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	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 **CuringPen** is intended for use in the electromagnetic environment specified below. The customer or the user of the **CuringPen** 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 between 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 CuringPen , including cables, than the recommended separation distance calculated from the equation applicable to the
Radiated RF EM fields		3V/m	

IEC 61000-4-3 Proximity fields from RF wireless communication equipment IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	frequency of the transmitter. Recommended minimum separation distances See the RF wireless communication equipment table in "Recommended minimum separation distances"
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Recommended minimum separation distances

Nowadays, many RF wireless equipment 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 **CuringPen-E** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **CuringPen-E** 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	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787			0.2	0.3	9

12 EMC Tables

745		LTE Band 13, 17	Pulse modulation 217Hz			
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- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400- 2570	Bluetooth , WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

**Warning**

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

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	1.2	No	/

2. Use of **CuringPen-E** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **CuringPen-E** and the other equipment should be observed to verify that they are operating normally.

13.Statement

Service Life

The service life of CuringPen-E series products is 5 years.

Maintenance

MANUFACTURE 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. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

Rights

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Changzhou Sifary Medical Technology Co., Ltd

Add: NO.99, Qingyang Road, Xuejia County, Xinbei District,
Changzhou City, 213000 Jiangsu, P.R. China

Tel: +86-0519-85962691

Fax: +86-0519-85962691

Email:Info@sifary.com

Web: www.sifary.com



Caretechion GmbH

Tel: +49 211 2398 900

Add: Niederrheinstr. 71, 40474 Duesseldorf, Germany

Email: info@caretechion.de

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