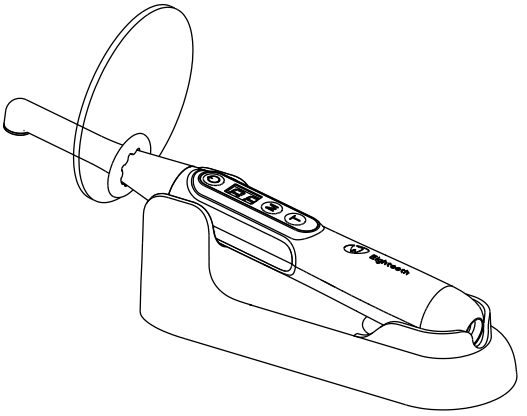


CuringPen-E

Dental Curing Light USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

Version: S03
IFU-6535021
Issued: 2022.03.30
Size: 180mm×87mm

Content

1.Scope of CuringPen-E

1.1 Parts Identification

① Disposable sleeve

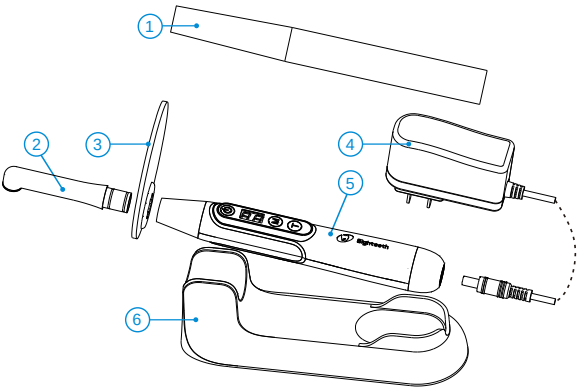
② Light source head

③ Protective light shield

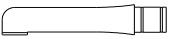
④ Adapter

⑤ Handpiece

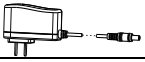
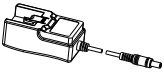
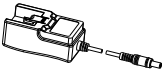
⑥ Base



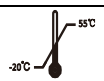
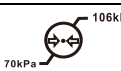
1.2 Components and accessories

Handpiece (1pcs) 6551021 	Light source head (1pcs) 6551020 
Disposable sleeves (100 pcs) 6531034 	Base (1pcs) 6551022 
Protective light shield (1pcs) 6551005 	Manual(1pcs) 6535021

For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	Adapter (1pcs) 6516007 	/
American standard	Adapter (1pcs) 6516008 	American standard power plug (1pcs) 6316008 
Multi-standard	Adapter (1pcs) 6516008 	British standard power plug (1pcs) 6316006 
		Australian standard power plug (1pcs) 6316007 
		Argentina standard power plug (1pcs) 6316011 

2. Symbols Used

	**If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.**
	**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**
	**Medical Device**

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.

The Turbo Mode (P3) must only be used for direct restorations in the posterior region (Class I & II). Do not use the Turbo Mode in cases of deep cavities (caries profunda).

3.2 Contraindications

Materials, the polymerization of which is activated outside the wavelength range of 380 – 515 nm (no materials known to date).If you are not sure about certain products,please ask the manufacturer of the corresponding material.

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 the light emission window cannot be optimally placed in relation to the composite restoration, the restoration must be polymerized using a conventional method. If soft tissue exposure to the curing light cannot be avoided, the Turbo Mode must not be used, as exposure may result in damage of the soft tissues.

6. If irregularities occur in the device during treatment, switch it off. Contact the agency.

7. 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

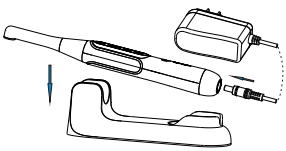
Make sure the light source head align to the slots of the protective light shield, plug them together.

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.

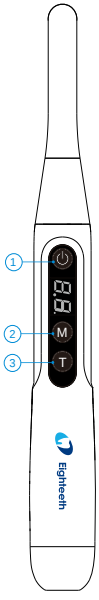


NOTE

- **Only the original adapter can be used.Otherwise, the device may be damaged.**
- **The round connector of the adapter must be pluged 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,the screen lights up with green letters and numbers indicating it is on. **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:

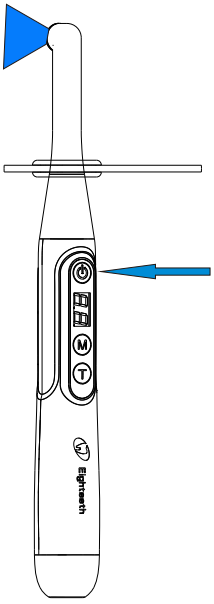
light intensity mode	time selection(sec)
P1 Normal Mode	05,10,15,20,25,30,35,40
P2 High Power Mode	01,03,05,10
P3 Turbo Mode	01,03,05
P4 Pulse Mode	05,10,15,20
P5 Ramp Mode	05,10,15,20

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.

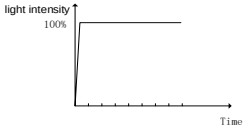
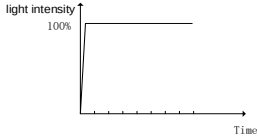
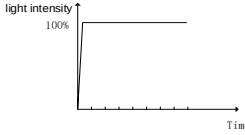
Warning

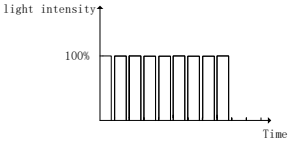
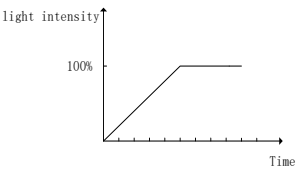
- **When the device is working, do not directly illuminate the eyes, otherwise it will cause injury.**
- **Do not directly illuminate the skin, otherwise high temperature burns may occur.**
- **Before using, please try it outside the oral cavity to ensure that there is no problem with the function of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

NOTE

- **To prevent the lamp from injurying 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

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

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 pluged into the charging hole at the rear of handpiece in the right way.**

- **If pluging 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

8.1 Foreword

For hygiene and sanitary safety purpose, the handpiece, light source head and protective light shield must be cleaned and disinfected even if the disposable sleeve is used. They should be cleaned and disinfected before each usage to prevent any contamination. This concerns the first use as well as the subsequent uses. Comply with your national guidelines, standards and requirements for cleaning and disinfection.

Reprocessing procedures have only limited implications to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.

In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

8.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Do not use bleach or chloride disinfectant materials.

8.3 Disinfection components

Disinfection components		
Handpiece	Light source head	Protective light shield
		

Warning

Before first use, after each use and whenever there is a risk of

contamination, disinfect the above components.

Reprocessing Instructions

Preparation before cleaning:

Immediately after using, remove the used disposable sleeve. Disconnect all plug connections. Put the handpiece, light source head and protective light shield in container for transportation.

Warning

Make sure that used sleeves are disposed of as infected waste which is potentially biologically hazardous.

Transportation:

Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

Cleaning

Wipe the handpiece, light source head and protective light shield surface with a cloth moistened in Ethanol (70 to 80vol%), until the components are free of visible soils. Repeat this step with a new gauze soaked in Ethanol (70 to 80vol%), if necessary.

Dry the components with compressed air.

Disinfection

Wipe he handpiece, light source head and protective light shield surface with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80vol%) at least 2min, repeat for 5 times.

Remove any chemical residues by wiping the components clean and dry with a sterile cloth.

NOTE

1.Do not use disinfectants other than Ethanol (70 to 80vol%) for disinfection.

2.Make sure no liquid penetrates the handpiece and light source head, otherwise, it will damage the internal parts.

3.Adapter and base should be cleaned and disinfected with a cloth moistened in Ethanol (70 to 80vol%) before first use and after each use.

Warning

1.Do not disinfect the handpiece and light source head in an autoclave or other sterilization container.

2.Do not soak or immerse any part of the handpiece and light source head in liquid.

Storage:

Store the components in a clean and dry place for the next treatment.

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 reachs 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/cm² P2:2000±15%mW/cm² P3:3000±15%mW/cm² P4:1200±15%mW/cm² P5:1200±15%mW/cm²
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

This product has no essential performance.

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-E** 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.
RF emissions CISPR 11	Class B	The **CuringPen-E** is suitable for use in professional healthcare facility environment.
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	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV	Line to line: ±0.5kV, ±1kV	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 form 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-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.

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 **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**
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 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be usedno closer to any part of the **CuringPen-E**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended minimum separation distances** Refer to table "Recommended minimum separation distances"
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	Refer to table "Recommended minimum separation distances"	Complies	

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+A1:2020. 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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation 217Hz	2	0.3	28

		LTE Band 1, 3, 4, 25; UMTS				
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

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.

3. 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 CuringPen-E, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

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

EC REP
Caretechion GmbH
Tel: +49 211 2398 900
Add: Niederrheinstr. 71, 40474 Duesseldorf, Germany
Email：info@caretechion.de