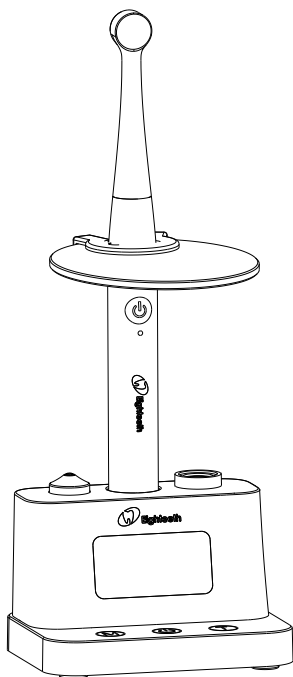




CuringPen-X



CuringPen-X

Dental Curing Light USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

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Size: 176mmx88mm

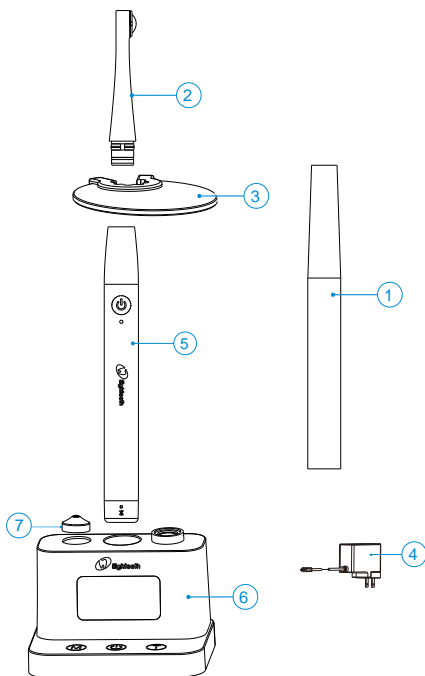
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1.Scope of CuringPen-X

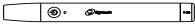





1.1 Main composition of product

Dental Curing Light is composed of Handpiece, Light source head, Base, Adapter, Disposable sleeve, Magnetic head and Protective light shield.

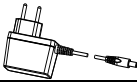
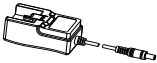

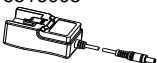





- ① Disposable sleeves
- ② Light source head
- ③ Protective light shield
- ④ Adapter
- ⑤ Handpiece
- ⑥ Base
- ⑦ Magnetic head




















1.2 Components and accessories

Handpiece(1pc) 	Light source head (1pc) 	Base (1pc) 
Disposable sleeves (100 pcs) 	Protective light shield (1pc) 	Magnetic head (1pc) 

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
	Country of manufacture + 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
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer's LOGO
	Lot number
	Medical Device

3. Bofore Use

3.1 Product description

The CuringPen-X is designed to polymerize all photo-activated dental materials in the wavelength range of 380~515nm per ISO 10650:2018. It is a cordless pen-style, LED light polymerization device, and 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 Intended purpose

The CuringPen-X is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 380~515nm waveband of visible light.

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.

3.3 Contra-indications

Do not use the device for non-dental procedure.

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



Read the following warnings before use:

- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- 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.
- Protective light shield and a disposable sleeve are compulsory during treatment.
- 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 and Orthodontic Mode must not be used, as exposure may result in damage of the soft tissues.

- If irregularities occur in the device during treatment, switch it off. Contact the agency.
- No modification of this equipment is allowed. Never open or repair the device yourself, otherwise, void the warranty.
- Repair work must only be carried out by qualified SERVICE PERSONNEL. Sifary will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.
- Only the original light source head, protective light shield, and adapter can be used.

4. Setting up of the CuringPen-X

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.



- 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.
- Disposable sleeves must be discarded after each

- 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.

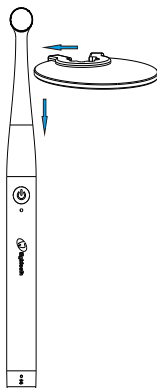
4.3 Install the disposable sleeve

Apply a disposable sleeve over the entirety of the light source head and handpiece before beginning a procedure.



4.4 Install the protective light shield





Align the gap in the shade plate with the thin position of the light source head, and push gently towards the end after clamping the light source head until the shade is fixed on the main engine.

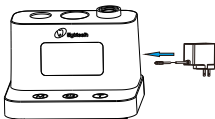




use.

- The light source head, protective light shield, base and handpiece should be cleaned and disinfected after each treatment.

4.2 Plug the adapter

The base power indicator icon  blinks, indicating that the power is very low and should be charged in time. Insert the USB port of the power adapter into the USB charging port of the base, the charging symbol  is displayed in the upper right corner of the base screen, and the power indicator icon is displayed  dynamically. When the base is charged, the power indicator icon is stationary and the state of full charge  is displayed.

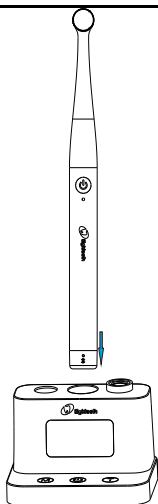


Gently place the handpiece into the charging hole on the base. If the handpiece power indicator  blinks and the handpiece power indicator icon blinks, the handpiece is being charged. When the charging is complete, the handpiece power indicator is steady green, and the handpiece power indicator icon  stops blinking.



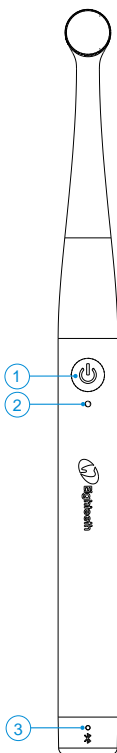
- Only the original adapter can be used. Otherwise, the device may be damaged.
- The round connector of the adapter must be plugged into the charging hole at the rear of handpiece in the right way.


4 Setting up of the CuringPen-X



5.User interface

5.1 Handpiece buttons and indicators




① Switch button 



② Power indicator

③ Bluetooth status indicator


Power on

In the off state, press , the machine makes a "beep" prompt tone, and vibrates, the power indicator lights up, complete the boot and enter the standby state.

Output and turn off the light intensity

In standby, press  to start the light intensity output. When the machine is output, press  to turn off the light intensity output.

Power Off

In the standby state, long press , the machine makes a "beep" prompt tone, and vibrates, the power indicator goes off, and the shutdown is complete.

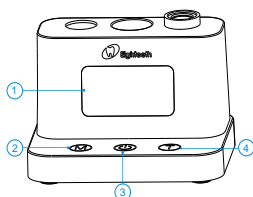
Electric quantity

Power indicator ② green means power higher than 50%, yellow means power 15%~50%, red means power below 15%, red light blinks means power below 10% should be charged in time.

Bluetooth connection status

Bluetooth status indicator ③ Blue: the handpiece is connected to the base; Blinking: The connection is ongoing; Off: The connection is disconnected.

5.2 Base buttons and the main screen of the display



- ① Display
- ② "M" Mode select button
- ③ "Power" Switch key
- ④ "T" Time select key

Power On

In the off state, long press

Power, the machine will make a "beep" prompt tone, the display will display the startup animation and enter the main interface, boot is complete.

Mode selection

Tap the "M" mode selection button to select the corresponding working mode.

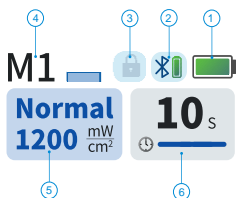
Time selection

Tap the "T" time selection button to select different light intensity output time or number of cycles.

Power Off

In the startup or standby state,

long press Power, the machine will sound "drip" prompt tone, the display will be off, complete shutdown.



- ① Base power
- ② Bluetooth connection status and handpiece power
- ③ Anti-false touch lock
- ④ Working mode
- ⑤ Light Intensity
- ⑥ Light intensity output time

6.Settings

6.1 Set the working mode and light intensity output time

Dental Curing Light CuringPen-X has 8 built-in working modes.



Tap the "  " mode selection button to select the corresponding working mode. Tap the "  " time selection button to select different light intensity output time, different working modes and optional time are as follows:

Table 1 Different working modes and optional time

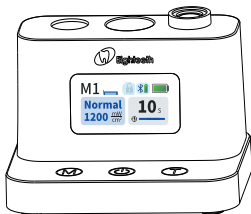
Modes	Optional time
M1 Standard Mode	5s、 10s、 15、 20s、 40s
M2 Bright Light Mode	3s、 5s、 10s
M3 Turbo Mode	1s、 3s
M4 Orthodontic Mode	Irradiate 3s, extinguish 2s for one cycle; Optionally 3 cycles, 5 cycles, 8 cycles
M5 Pulsed Mode	5s、 10s、 15s、 20s
M6 Progressive Mode	5s、 10s、 15s、 20s
M7 Detection Mode	30s、 60s
M8 Detection Mode	60s、 180s、 300s



- The output light intensity in all working modes of M1-M8 is set and cannot be modified by the user.

6.2 Advanced Settings

Press and hold down the M mode selection button to enter the setting screen. Tap the "M" button to switch to the function you want to set, tap the "⏻" button to select the setting parameters, and tap the "⌂" button to return to the home page. After no operation on the setting screen for 30 seconds, the system will automatically return to the home page.



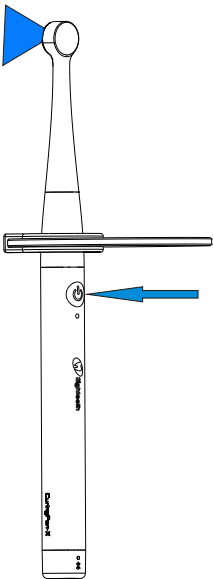


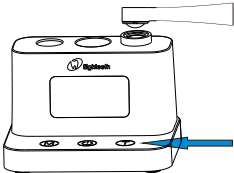
- ① Base volume (low, medium, high, silent)
- ② Handle volume (low, medium, high, silent)
- ③ Handle pairing (yes, no)

Tap "⌂", select yes, and tap "⏻" to enter handle pairing. Place the host in the base, hold down the host switch button for 2s to start pairing. After the pairing is successful, the pairing success screen will be displayed, and automatically return to the standby screen after 2s.

- ④ Anti-miscontact lock (close anti-miscontact lock, time anti-miscontact, mode anti-miscontact and time mode joint anti-miscontact)
- ⑤ Language (Chinese, EN)
- ⑥ Screen brightness (low, medium, high)
- ⑦ Base automatic shutdown time (5 minutes, 10 minutes, 30 minutes)
- ⑧ Handle automatic shutdown time (3 minutes, 5 minutes, 10 minutes)
- ⑨ Version Information
- ⑩ Restore factory Settings

7.Operations

7.1 Machine operation

	<p>7.1.1 Light intensity output</p> <p>After the base is powered on, select a working mode and light intensity output time. After the handpiece is powered on and Bluetooth is connected, press  start light intensity output to start the countdown. During the output of light intensity, press  to turn off the output of light intensity. When the light intensity output ends, the machine will make a "beep" prompt sound and vibrate.</p> <p>If you do not need to change the working mode and light intensity output time, the handpiece can be used directly.</p>
	<p>7.1.2 Light intensity detection</p> <p>When the light intensity needs to be detected, long press the "T" button to enter the light intensity detection interface, place the Light Source head on the metering port, and keep it as parallel as possible. At this time, the current light intensity value will be displayed on the screen.</p>



- When the light intensity is being output by the device, do not

directly illuminate the eyes, otherwise it will cause injury.

- Do not directly irradiate the skin, otherwise high temperature burns may occur.
- Try it outside your mouth to make sure the device is functioning properly before using it for treatment.
- Do not disassemble Light Source head during treatment to avoid accidents.
- In the process of use, the maximum surface temperature of the Light Source head can reach 60°C , at this time do not touch the Light Source head, so as to avoid burns.




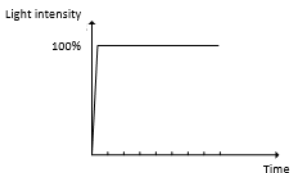
- During the use of the device at one time, after the cumulative use time reaches 60 seconds in M3 super strong mode, the output light intensity will be prohibited to prevent patients from being burned by excessive temperature of the Light Source head. After 60 seconds, the device can continue to be used.
- When using, ensure that the surface of the Light Source head is clean and the light should be directly illuminated on the light curing material to avoid the effect of curing when there is dirt on the surface of the Light Source head or improper irradiation position.
- A disposable sleeves and a protective light shield must be used.
- Stop using this device when any abnormality occurs.


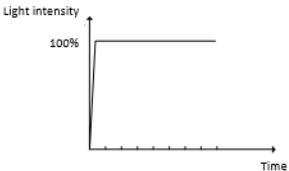

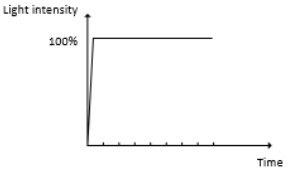

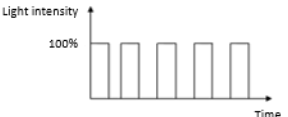
7.2 Description of working mode


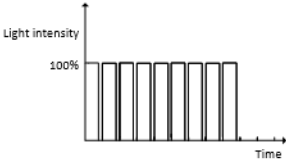

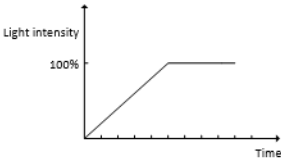

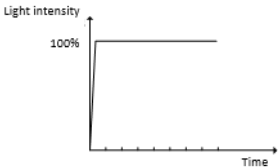
M1 Standard Mode

Output light intensity: $1200\text{mW}/\text{cm}^2$

After pressing the handpiece , the set light intensity is immediately output, and at the end of the treatment, a "beep" prompt tone will be issued, and vibration.




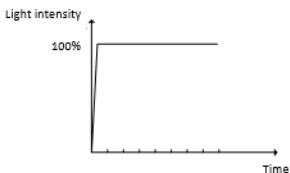
M2 Bright Light Mode	<p>Output light intensity: 2000mW/cm²</p> <p>After pressing the handpiece , the set light intensity is immediately output, and at the end of the treatment, a "beep" prompt tone will be issued, and vibration.</p> 
M3 Turbo Mode	<p>Output light intensity: 3000mW/cm²</p> <p>After pressing the handpiece , the set light intensity is immediately output, and at the end of the treatment, a "beep" prompt tone will be issued, and vibration.</p> 
M4 Orthodontic Mode	<p>Output light intensity: 3000mW/cm²</p> <p>After pressing the handpiece , the set light intensity is immediately output for 3 seconds, and then extinguished for 2 seconds, and the cycle is repeated, and at the end of the treatment, a "beep" prompt sound will be issued, and vibration.</p> 

M5 Pulsed Mode	<p>Output light intensity: 1200mW/cm²</p> <p>After pressing the handpiece , the light intensity is immediately output, flashing every 1 second, and at the end of the treatment, it will sound a "beep" prompt tone, and vibration.</p> 
M6 Progressive Mode	<p>Output light intensity: 1200mW/cm²</p> <p>After pressing the handpiece , the light intensity will gradually increase to 1200mW/cm² within the first 5 seconds, and then continue to output 1200mW/cm², and at the end of the treatment, a "beep" tone will be emitted, and vibration.</p> 
M7 Detection Mode	<p>Output light intensity: 600mW/cm²</p> <p>After pressing the handpiece , the set light intensity is immediately output, and at the end of the detection, a "beep" prompt tone will be issued, and vibration.</p> 

M8 Detection Mode


Output light intensity: 600mW/cm²

The white magnetic head is adsorbed on the Light Source head, and after pressing the handpiece , the set light intensity will be output immediately, and at the end of the detection, the "beep" prompt sound will be issued, and the vibration will be emitted.



7.3 Charge



- If the handpiece power indicator is blinking red, it indicates that the battery is less than 10% and must be recharged within 30 days, otherwise the battery may be irreparable damage due to a long period of low power.
- If the base battery indicator icon  blinks, the battery is approximately below 15% and must be recharged within 30 days, otherwise the battery may cause irreparable damage due to low power for a long time.
- If you do not use this product for a long time, please use it for at least 1 month.
- The main engine and the base are charged once.



- Non-professionals or untrained personnel are prohibited from replacing the battery. If the wrong battery is used, or installed incorrectly, the electronic components will be damaged.

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

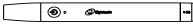


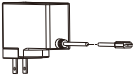



The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.

For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).

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 	Base 
Adapter 	Protective light shield 	Magnetic head 
 <p>Before first use, after each use and whenever there is a risk of</p>		

contamination, disinfect the above components.

Reprocessing Instructions

Preparation before cleaning:

Immediately after using, remove the used disposable sleeve. Disconnect the components (light source head, protective light shield) from the handpiece. Put the handpiece, light source head and protective light shield in container for transportation.



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, Base, Adapter, Magnetic head for white light and Protective light shield surface thoroughly with a cloth moistened in Ethanol (70 to 80vol%) at least 2 mins, repeat for 5 times. (Visual inspection for cleanliness of the device and its accessories. If necessary, perform reprocessing process again until the component is visibly clean.)

Disinfection

Wipe the Handpiece, Light Source head, Base, Adapter, Magnetic head for white light and Protective light shield surface thoroughly with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80vol%) at least 2 mins, repeat for 5 times.

Drying

Use a lint free cloth to wipe the surfaces.



- Do not use disinfectants other than Ethanol (70 to 80vol%) for disinfection.
- Make sure no liquid penetrates the handpiece and light source head, otherwise, it will damage the internal parts.
- Adapter and base should be cleaned and disinfected with a cloth moistened in Ethanol (70 to 80vol%) before first use and after each use.



- Do not disinfect the handpiece and light source head in an autoclave or other sterilization container.
- Do not soak or immerse any part of the handpiece and light source head in liquid.

Storage:

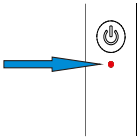
Store the components in a clean and dry place for the next treatment.

8.4 Yearly inspection

Extensive checkup for the safe and normal function of the device. Inspect all the connection components on the handpiece.

When not in use, disconnect the power adapter from the charger.

9.Error Tips


	<p>The device handpiece power indicator is red and blinking, the battery is about to run out, please charge it in time, if it still cannot be solved after charging, please contact your local dealer.</p>
<p>ERROR: Please check the light head.</p>	<p>The base screen displays "Error: Please check the light head.", the LED light head of the device is faulty, please check the light head, if it still cannot be solved after connection, please contact the local dealer.</p>
<p>Overheat Protection: Please wait 60 S before continue.</p>	<p>The handpiece's prompt tone is prolonged. When the cumulative usage time of the device in M2 high-intensity mode and M3 super-high-intensity mode reaches its limit (within a single startup), please allow the device to rest for 60 seconds before resuming use.</p>

10.Troubleshooting

When the 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-X
Dimensions	18.8cm×10cm×11.8cm±1cm(package)
Gross weight	660g±10%
Handpiece power supply	Lithium ion battery: DC 3.7V, 650mAh, ±10%
Base power supply	Lithium ion battery*2: DC 3.7V, 1400mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	5V  1A
Frequency	50/60Hz, ±10%
Charger power input	0.35A
Light intensity	M1:1200mW/cm ² M2:2000mW/cm ² M3:3000mW/cm ² M4:3000mW/cm ² M5:1200mW/cm ² M6:1200mW/cm ² M7:600mW/cm ² M8:1200mW/cm ²
Wavelength	380nm-515nm
Electrical safety class	Class II
Applied part	B
Operating mode	Intermittent operation M1-M7: 45s. ON / 18s. OFF M8: 5mins. ON / 1min. OFF
Ambient conditions	Use: in enclosed spaces Ambient temperature: 10°C~40 °C Relative humidity: 30%~75%; 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-X is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen-X should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The CuringPen-X 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-X 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-X is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen-X 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	$\pm 2\text{kV}$ 100kHz repetition frequency	$\pm 2\text{kV}$ 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: $\pm 0.5\text{kV}$, $\pm 1\text{kV}$	Line to line: $\pm 0.5\text{kV}$, $\pm 1\text{kV}$	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	<p>0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0°</p> <p>0% U_T; 250/300 cycle</p>	<p>0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°</p> <p>0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0°</p> <p>0% U_T; 250/300 cycle</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered from an uninterruptible power supply or a battery
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: U_T : rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer's declaration – electromagnetic immunity

The CuringPen-X is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen-X 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-X is intended for use in the electromagnetic environment specified below. The customer or the user of the CuringPen-X 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 between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the CuringPen-X, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
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 Refer to table "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-X 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-X 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	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						

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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						



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

Cable information:

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

- Use of CuringPen-X adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, CuringPen-X and the other equipment should be observed to verify that they are operating normally.
- 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-X, 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-X series products is 5 years. It is recommended that the equipment be checked and repaired at the dealer once a year.

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

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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