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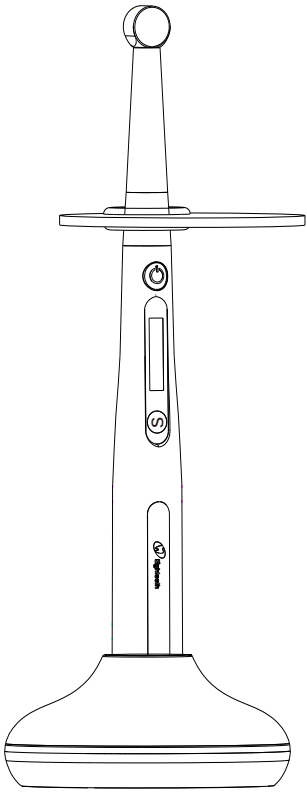


CuringPen

Dental Curing Light USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

Version: 05
IFU-6535001
Issued: 2023.04.20
Size: 210mm×90mm

Content

1.Scope of CuringPen

1.1 Parts Identification

① Light source head

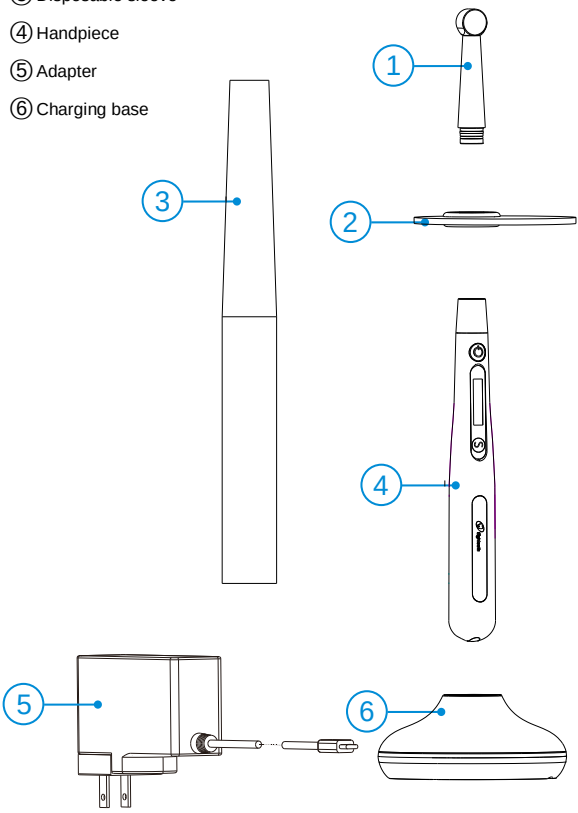
② Protective light shield

③ Disposable sleeve

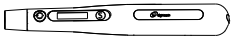
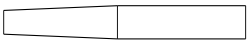
④ Handpiece

⑤ Adapter

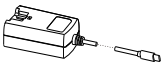
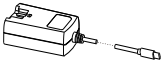
⑥ Charging base



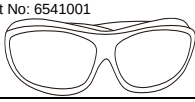
1.2 Components and accessories

Handpiece (1pcs) Part No: 6551003 	Light source head (1pcs) Part No: 6551001 
Disposable sleeve (100pcs) Part No: 6542002 	Charging base (1pcs) Part No: 6551004 
Protective light shield (1pcs) Part No: 6551005 	

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

Standard	Adapter	Power plug
European standard	Adapter (1pcs) Part No: 6016018 	/
American standard	Adapter (1pcs) Part No: 6516003 	American standard power plug (1pcs) Part No: 6016011 
Multi-standard	Adapter (1pcs) Part No: 6516003 	British standard power plug (1pcs) Part No: 6016009 
		Australian standard power plug (1pcs) Part No: 6016010 
		Argentina standard power plug (1pcs) Part No:6016014 

1.3 Optional accessories

Light curing depth test board (1pcs) Part No: 6503011 	Protective light glasses (1pcs) Part No: 6541001 

2. Symbols Used

	General warning sign
	Caution
	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
	Authorized Representative in the European Community
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer's LOGO
	CE marking
	Batch code
	Medical device

3. Before Use

3.1 Scope of application

CuringPen 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.

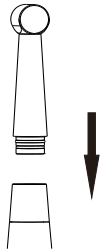
Read the following warnings before use:

- **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. 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 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.**

4. Setting up the CuringPen

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.

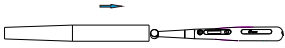


The light source head can be 360 degrees rotated without being taken off, which makes it easy to watch the LCD during the treatment.

- **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.**
- **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.**

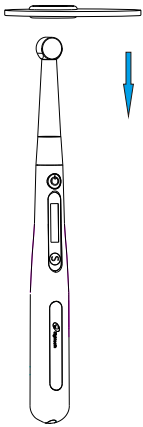
4.2 Install the disposable sleeve

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.

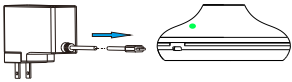


- **Disposable sleeves must be discarded after each use.**
- **The light source head, protective light shield and handpiece should be cleaned and disinfected after each treatment.**

Avoid direct exposure of the lamp to the eyes during working.

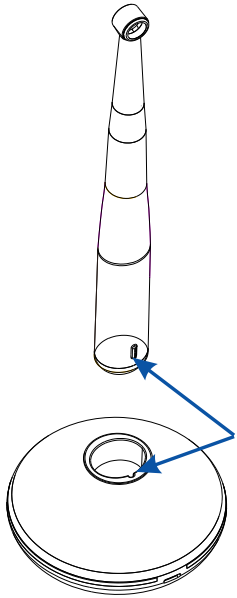
4.4 Charging

Plug the USB of adapter into the charge base, and plug the other end into a power outlet, the Power LED on charge base will light up (green).



- **Only the original adapter can be used.**

Put the handpiece all the way into the charge base, the charge state will show on the screen.

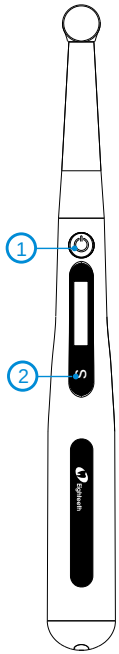


The charging indication appears on the screen, and flashes slowly while charging. When the battery is fully charged or in a state near full charge, the flash will stop.

- **Put the handpiece into the charge base in the right direction, otherwise the handpiece will not be recharged.**

5.Use Interface

5.1 Panel key



①⏻ Main switch

②"S" Setting key

Turn Power On

Press ⏻ more than 0.5 seconds to turn on the device.

Memory Mode Selection

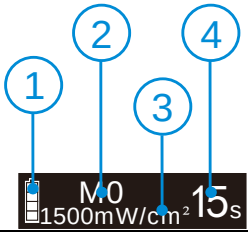
Press setting key in standby state to select the memory mode.

Start / Stop Light Intensity Output

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

Turn Power Off

Long press ⏻ to turn power off.



① Battery

② Memory mode

③ Curing light intensity

④ Curing time

6.Setting

6.1 Selecting memory mode

Memory mode change

There are 6 built-in memory programs, namely M0, M1, M2, RAMP, PULSE, Detect. Press setting key to change the memory during standby state.

Light intensity setting

The memory modes of M0, M1 and M2 can be customized to 2300mW/cm^2, 1500mW/cm^2 or 1000mW/cm^2. Long Press “S” to enter the light intensity setting menu, then press “S” to change or press main switch to confirm and exit.

On the light intensity setting menu, long press “S” to enter the curing time setting menu.

- **The light intensity of RAMP, PULSE and Detect memory modes are built-in, and the user cannot modify the settings.**

Curing Time setting

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

light intensity(mW/cm²)	time selection(sec)
2300	01,02,03
1500	05,10,15,20
1000	05,10,15,20
600	10,15,20,25

Long press “S” or short press ⏻ to exit the setting interface. The current memory mode automatically saves the setting parameters.

6.2 Advanced setting

In power off state, holding down press “S” then press ⏻ to enter the “Auto Off” setting.

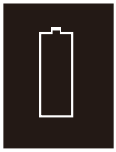
It can be set to 1min, 5min, 10min or 15min.

Press ⏻ to change setting, press “S” to enter the next setting- “Volume” setting mode.

	In the volume setting menu, press “S” to select different settings. It can be set to “Off”, “low”, “mid” or “high”. Press ⏻ to change volume setting, press “S” to enter the next setting- “Hand” setting mode.
	The right hand and the left hand can be set in the “Hand” setting menu. Press ⏻ to change setting, press “S” to enter the next setting.
	The last item is the firmware version, and the handpiece shuts down automatically within 30s after the version information is displayed.

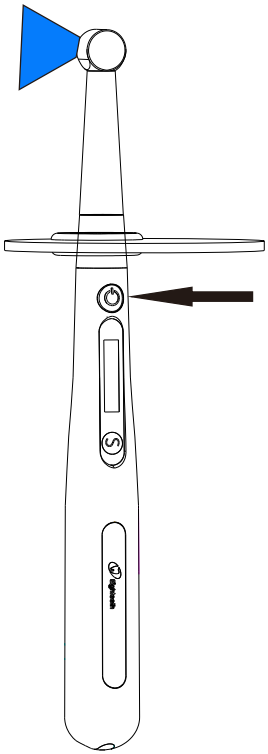
7.Operation

7.1 Charge

	Display the present remaining amount of the battery. Less than 15% remains, please charge. ● **If the power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be irrecoverably damaged.**
	During charging, the charging indication appears on the screen and flashes slowly. When the battery is fully charged or in a state near full charge, the flash will stop. It takes about 4 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. ● **When charging, other functions will forcibly stop. When removed from the charging base, press main switch, the last function will recall.** ● **When the device is not used for a long time, please change the device at least once a month.** ● **Only the original adapter can be used.**

● **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.**

7.2 Handpiece operation



Turn on the device and select one mode. Press ⏱ to start the light intensity output, and the time will start counting down. Press any key to stop the output during the light intensity output.

There is a beep every 5s while working, and the output is automatically turned off after the countdown ends.

- **When the device is working, do not directly illuminate the eyes, otherwise it will cause injury.**
- **The maximum surface temperature of the light source can reach 55 ℃ or higher during use, do not directly illuminate the skin, otherwise high temperature burns may occur.**

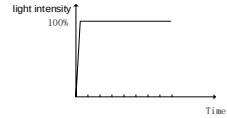
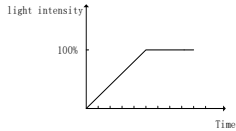
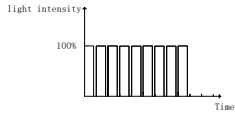
- **To prevent the lamp from overheating, after the device is used continuously for 10 times at 2300mW/cm^2, it will be prohibited to use the highest light intensity output within 1 minute.**
- **When using, the light should be directly irradiated onto the curing dental resins and composites to avoid improper exposure.**

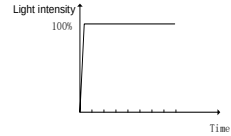
	• **The disposable sleeve and protective light shield are highly recommended.**
	When the device is in standby mode, it will automatically shut down when it reaches the set auto off time. The factory default setting is 5 minutes.

- **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.**

- **If there is any abnormal functioning, stop using the device and report to the company.**
- **Gloves are compulsory during treatment.**
- **Always clean the handpiece and light source head after each treatment.**

7.3 Operation mode

M0、M1、M2	**Standard mode** In these three modes, the light intensity can be set to 2300mW/cm², 1500mW/cm² or 1000mW/cm². Wavelength：380nm-515nm When ⏻ is pressed, the set light intensity is output immediately, and there is a sound prompt every 5 seconds. 
RAMP	**Ramp Mode** Light intensity: 1000mW/cm²。 Wavelength: 380nm-515nm When ⏻ pressed, the light intensity gradually increases to 1000mW/cm² in the first 5 seconds, and then continues to output 1000mW/cm². There is a sound prompt every 5 seconds. 
PULSE	**PULSE Mode** Light intensity: 1000mW/cm² Wavelength: 380nm-515nm When ⏻ is pressed, the output light intensity is 1000mW/cm² and flashes once every 1 second. There is a sound prompt every 5 seconds. 

Detect	**Detect mode** Light intensity: 600mW/cm² Wavelength: 380nm-515nm  When ⏻ is pressed, the set light intensity is output immediately, and there is a sound prompt every 5 seconds. ⚠ ● **This mode is only suitable for detecting dental calculus, caries, cracks, etc.** ⚠ ● **Detect Mode cannot be used to cure dental resins and composites, otherwise there is a risk of incomplete curing.**

8.Maintenance

Disinfection components

handpiece	Light source head	Adapter
		
Charging base	Protective light shield	
		

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

- **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 sleeve（100pcs）

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

9.Error Warning

Low Battery	The battery power is too low. Charge it immediately.
Fault: Blue Error	Blue LED is broken. Contact your distributor.
Fault: Blue Overload	Blue LED is overloaded. Contact your distributor.
Fault: Violet Error	Violet LED is broken. Contact your distributor.
Fault: Violet Overload	Violet LED is overloaded. Contact your distributor.
	The temperature of the light source head is higher than expectation. Turn the power off or wait more than 1 minute to let it cold down.

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. Contact your distributor.

Problem	Cause	Solution	Ref. chap
The power is not turned on.	The battery is out of power.	Charge the battery.	7.1
	The time to press the main switch is too short.	Press the main switch more than 0.5 seconds.	5.1
The Power LED does not light up when charging.	Use a wrong adapter.	Use the original adapter.	/
	There is no electricity in the outlet.	Check the connection.	/
	The adapter is not connected.	Check the connection.	/
The handpiece does not display the charging interface while charging	Put the handpiece into the charging base in the wrong direction.	Check the direction.	4.4
	The charging base broken.	Using adapter connect to handpiece directly, and contact your distributor.	/
	Charge pin of the charging base is unable to rebound.	Remove debris which between move part and base of the charge pin.	/
No output	Handpiece is broken.	Contact your distributor	/
No sound	Beep volume is set to off.	Set beep volume to low, mid or high.	/
	Handpiece is broken	Contact your distributor	
Insufficient light intensity	There are resin or other contaminants on the surface of the lamp lens.	Cleaning the lamp head residue	

11.Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd.
Model	CuringPen
Dimensions	22cm×11cm×8cm±1cm(package)
Weight	730g ±10%
Power supply	Lithium ion battery: 3.7V, 1600mAh, ±10%
Charger power supply	AC 100-240 V, ⎓ ±10%
Charger power output	5V ⎓ 1A
Power Frequency	50/60Hz，±10%
Charger nominal power input	5VA
Light intensity	2300mW/cm² 1500mW/cm² 1000mW/cm² 600 mW/cm²
Wavelength	380nm-515nm
Electrical safety class	Class II
Applied part	B (Light source head)
Operation mode	Intermittent operation 15mins. 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** 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** 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 A	The **CuringPen** is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The **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**
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 earth: ± 0.5kV, ± 1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ± 0.5kV, ± 1kV, ±2kV	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% U_T; 0.5 cycle at 0°, 45°, 90°, 135°,180°,225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0° 0% U_T; 250/300 cycle	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles sine phase at 0° 0% U_T; 250/300 cycle	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
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			

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.

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** 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 dis-turbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be usedno closer to any part of the **CuringPen**, 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	See the RF wireless	Complies	**Recommended minimum**

communication equipment IEC 61000-4-3	communication equipment table in "Recommended minimum separation distances"		**separation distances** See the RF wireless communication equipment table in "Recommended minimum separation distances"

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** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **CuringPen** 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	1700-1990	GSM 1800;	Pulse modulation	2	0.3	28

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

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

Cable information:

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

- Use of **CuringPen** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **CuringPen** 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**, 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 series products is 3 years. It is recommended that the equipment be checked and repaired at the dealer once a year.

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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