

CuringPen

LED Curing Light USER MANUAL

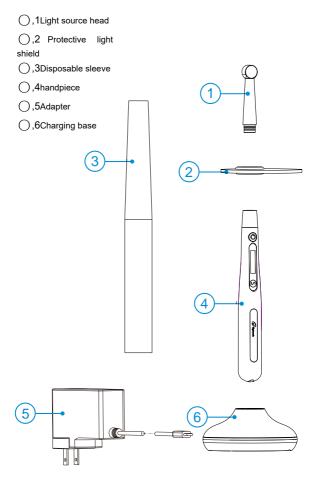
Changzhou Sifary Medical Technology Co.

Content

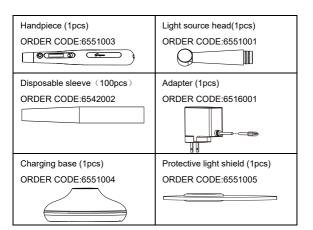
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1.Scope of CuringPen

1.1 Parts Identification



1.2 Components and accessories



1.3 Optional accessories



2. Symbols Used

_			
Warning	If the instructions are not followed properly,		
	operation may lead to hazards for the product or the user/patient.		
A	Additional information, explanation of		
NOTE	operation and performance.		
SN	Serial number		
REF	Catalogue number		
***	Manufacturer		
سا	Date of manufacture		
	Safety class II device		
	Type B applied part		
===	Direct current		
7	WEEE(Waste of Electrical and Electronic		
	Equipment)Directive Marking		
	Store in a dry place		
	Consult instructions for use		
EC REP	Authorized Representative in the European Community		
-20°C -55°C	Temperature limitation		
20%	Relative humidity		
106 kPa	Transport and storage pressure conditions:70 kPa - 106 kPa		
Eighteeth	Manufacturer's LOGO		

3. Before Use

3.1 Scope of application

Suitable for the purpose of curing dental resins and composites or detecting caries.

This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel

3.2 Contraindications

Do not use the device for non-endodontic dental procedures.

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



Warning

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.
- 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 .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.
- 6. 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 alignment the slots of handpiece, plug them together until it "click" securely into place.



The light source head can be 360 degrees rotated without take off, make it easy to watch the LCD in treatment

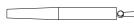


WARNING

- After connecting the light source head and the handpiece, pull it gently to make sure the connection is good.
- Make sure the assembly is connected properly, otherwise might cause unexpected fault, even hurt the patients

4.2 Install the disposable sleeve

Take a disposable sleeve and gently insert it into the handpiece from the light source head.



4.3 Install the protective light shield

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





WARNING

- Disposable sleeve must be discarded after 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 could be used. Put the handpiece all the way into the charge base, the charge state will show on the screen.



Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop

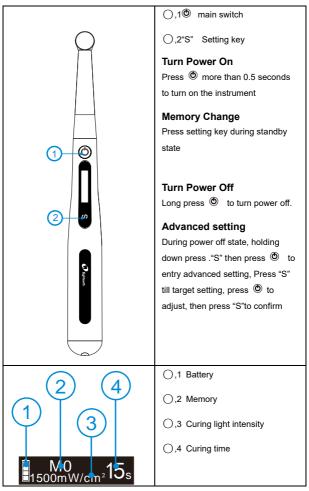


NOTE

 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



6.Setting

6.1 Selecting memory

0.1 Selecting i	Memory Change		
≜ MO 15	There are 6 built-in memor	ry programs, namely	
M0 _{1500mW/cm²} 15 _s	M0, M1, M2, RAMP, PULS	E, Detect. Press setting	
	key to change the memory	during standby state	
	Light intensity setting	1	
Curing Power 1500lnW/cm ²	The memory programs of M0, M1 and M2 can be customized to 2300mW/cm², 1500mW/cm² or 1000mW/cm². 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 time setting menu.		
	Detect memory programs are built-in,		
	and the user cannot modify the		
	settings.		
	Curing Time setting		
	In the curing time setting n	nenu, press "S" to	
	select different times. The time selection is		
	different under different lig	ht intensity:	
Curing Time	light intensity(mW/cm²)	time selection(sec)	
05Sec	2300	01,02,03	
	1500	05,10,15,20	
	1000	05,10,15,20	
	1000 600	05,10,15,20 10,15,20,25	
	1000 600 Long press "S" or short pre	05,10,15,20 10,15,20,25 ess to exit the setting.	
	1000 600	05,10,15,20 10,15,20,25 ess to exit the setting.	

6.2	Advanced	setting

O.E Advanced Setting		
	During power off state, holding down press "S" then press ® to entry the	
	"Auto power off time" setting.	
Auto Off	It can be set to 1min, 5min, 10min or	
5 min	15min.	
	Press (5) to change setting, press "S" to	
	enter the next setting "Volume" volume	
	setting mode.	
	In the volume setting menu, press "S" to	
	select different settings. It can be set to	
Volume	"Off", "low", "mid" or "high".	
mid	Press (to change setting, press "S"	
	to enter the next setting "Hand" hand	
	setting mode.	
	The right hand and the left hand can be	
Hand	set in the "Hand" setting menu, Press 🏻	
Right	to change setting, press "S" to enter the	
	next setting.	
	The last item is the firmware version,	
I 1	and the handpiece shuts down	
- 1	automatically within 1 s after the version	
	information is displayed.	

7.Operation

7.1 Charge



Displays the present remaining amount of the battery.

Less than 15% remains, please charge.



NOTE

 If the power if less than 15%, must be recharged within 30 days, otherwise the battery will be damaged.



Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop Fully charged will take about 4 hours, depending on residual battery power and battery state.

It can be recharged 300-500 times, depending on the operating conditions of the device.



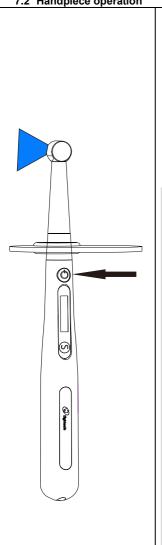
NOTE

 When changing, other function will forcibly stop, take from charge base, press main switch, the last function will recall.



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. 7.2 Handpiece operation



After the handpiece main unit is turned on, press o to start the light intensity output, and the time will start counting down. Press any key to interrupt 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.



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.



NOTE

- After the device is used continuously for 10 times at 2300mW/cm2, it will be prohibited to use the highest light intensity output within 1 minute, Used to prevent the lamp from overheating
- When using, the light should be directly irradiated onto the curing dental resins and

composites to avoid improper exposure. The disposable protective cover and protective light shield are highly recommended.	
When the device is in standby mode, it will automatically shut down when it reaches the set time. The factory default setting is 5 minutes	



WARNING

- 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 lamp during treatment.



NOTE

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

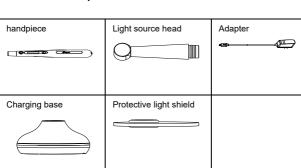
7.3 Operation mode Standard mode In these three modes, the light intensity can be set to 2300mW/cm2, 1500mW/cm2 or 1000mW/cm². Wavelength: 385nm-515nm When opressed, the setting light intensity is output M0、M1、M2 immediately, and the sound is prompted every 5 seconds. 100% Ramp Mode Light intensity: 1000mW/cm². Wavelength: 385nm-515nm When @ pressed, the light intensity gradually increases to 1000mW/cm2 in the first 5 seconds, and then continues to output 1000mW/cm2, prompting the sound every 5 seconds. RAMP light intensity **PULSE Mode PULSE** Light intensity: 1000mW/cm²

Wavelength: 385nm-515nm When opressed, the output light intensity is 1000mW/cm² and flashes once every 1 second, prompting the sound every 5 seconds. light intensity **Detecting mode** Light intensity: 600mW/cm² Wavelength: 385nm-410nm Light intensity 100% When @ pressed, he setting light intensity is output immediately, and the sound is prompted every 5 seconds. Detect This mode is only suitable for detecting dental calculus, caries, cracks, etc. WARNING **Detect Mode cannot be** used to cure dental resins and composites,

otherwise there is a risk of incomplete curing.

8.Maintenance

Disinfection components



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



WARNING

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

Disposable components

Disposable sleeve (100pcs)



WARNING

- Please discard it after use and do not use it again.
- The product has been disinfected with ethylene oxide, so there is no need to disinfect it before use.

9.Error Warning

Low Battery	The battery is too low. Charge it immediately
Fault: Blue Error	Blue LED broken, contact your distributor.
Fault: Blue Overload	Blue LED overload, contact your distributor.
Fault: Violet Error	Violet LED broken, contact your distributor.
Fault: Violet Overload	Violet LED overload, contact your distributor.
<u> </u>	The temperature of the light source head is higher than expectation, turn the power off or waiting more than 1 minutes 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 ch
The second is not	The battery is run down. Charge the battery.		ар 7.1
The power is not turned on.	The time to press the main switch is too short.	Press the main switch more than 0.5 seconds.	5.1
	Use a wrong adapter.	Use the original adapter.	1
The Power LED does not light up when charging.	There is no electricity in the outlet.	Check the connection.	1
	The adapter is not connected.	Check the connection.	1
the handpiece does not display the charging interface while charging	Put the handpiece into the charge base in the wrong direction.	Check the direction.	4.4
	The charge base broken.	Using adapter connect to handpiece directly, and contact your distributor.	1
	Charge pin of charge base unable to rebound.	Remove debris which between move part and base of the charge pin.	1
No output	Handpiece broken	Contact your distributor	1
No sound	Beep volume set to off	Set beep volume to low, mid or high.	1
140 oodiid	Handpiece 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 x 11cmx 8cm±1cm	
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	385nm-515nm	
Electrical safety class	Class II	
Applied part	В	
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 B	The CuringPen is suitable for use in all establishments,	
Harmonic emissions IEC61000-3-2	Class A	including domestic establishments and those	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

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	IEC 60601	Compliance	Electromagnetic
test	test level	level	environment -
			guidance
Electrostatic	+/- 8 kV	+/- 8 kV contact	Floors should be
discharge	contact		wood, concrete or
(ESD) IEC 61000-			ceramic tile. If
4-2	+/- 2 kV, +/-	+/- 2 kV, +/- 4 kV,	floors are covered
	4 kV, +/- 8	+/- 8 kV, +/- 15 kV	with synthetic
	kV, +/- 15 kV	air	material, the
	air		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% 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; 25/30 00	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 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

30 A/m	30 A/m	Power frequency	
50Hz or	50Hz or 60Hz	magnetic field	
60Hz		should be at	
		levels	
		characteristic of a	
		typical	
		location in a	
		typical	
		commercial or	
		hospital	
		environment.	
	50Hz or	50Hz or 50Hz or 60Hz	

Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz

Guidance and manufacturer's declaration – electromagnetic immunity

The **CuringPen** is intended for use in the electromagnetic environment specified below. The customer or the user of the **CuringPen** should assure that it is used in such an environment.

	IEC 60601 test	Compliance	Electromagneti	
Immunity test	level	level	c environment -	
			guidance	
Conducted dis-	3 V	3 V	Portable and	
turbances	0.15 MHz – 80		mobile RF	
induced by RF	MHz, 6 V in ISM		communications	
fields	bands be-tween		equipment	
IEC 61000-4-6	0.15 MHz and		should be	
	80 MHz, 80 %		usedno closer to	
	AM at 1 kHz		any part of the	
			CuringPen,	
			including cables,	
			than the	
			recommended	
		3V/m	separation	
			distance	
Radiated RF EM	3 V/m, 80 MHz –	30/111	calculated from	
fields	2,7 GHz, 80 %		the equation	
IEC 61000-4-3	AM at 1 kHz		applicable to the	
			frequency of the	
			transmitter.	
Proximity fields		Complies		
from RF				

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

Recommended minimum separation distances

Nowadays, many RF wireless equipments 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 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipments and the **CuringPen** as recommended below.

Test frequenc y (MHz)	Band (MHz)	Service	Modulati on	Maximu m power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulati on 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 modulati on 217Hz	0.2	0.3	9
810 870	800-960	GSM 800/900,		2	0.3	28

		TETRA				
930		800,				
		iDEN	Pulse			
		820,	modulati			
		CDMA	on			
		850,	18Hz			
		LTE				
		Band 5				
1720		GSM				
1845		1800;				
		CDMA				
		1900;				
		GSM	Pulse			
	1700-	1900;	modulati	2	0.3	28
1970	1990	DECT;	on	2	0.3	
1970		LTE	217Hz			
		Band 1,				
		3,				
		4, 25;				
		UMTS				
		Bluetoot				
	2400-	h,				
		WLAN,	Pulse			
		802.11	modulati			
2450	2570	b/g/n,	on	2	0.3	28
	2570	RFID	217Hz			
		2450,	217HZ			
		LTE				
		Band 7				
		WLAN	Pulse			
5240	5100-	802.11	modulati	0.2	0.3	9
02.10	5800	a/n	on	0.2	0.0	
			217Hz			
5500						
5785			I	I		

13.Statement

Service Life

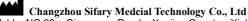
The service life of CuringPen series products is 3 years.

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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