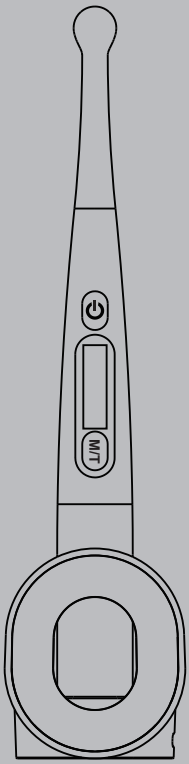
HeptaLux

Curing Light

Instruction Manual



CE

Please read this manual before operating.

Contents

Guilin YIKESHI Medical Instrument Co., Ltd. is a high-tech enterprise for research, development, and production dental equipment. With a focus on quality. Product range includes: ultrasonic scalers, curing lights, apex locators and ultra-surgery, loupes, endo motors etc.

1. Introduction

1.1 Features:

1.1.1 Eight working modes: Normal, High, Turbo, Ortho, Soft, Pulse, Check and Transillumination.

1.1.2 Optimally collimated beam output, reduces optical loss.

1.1.3 Light source design provides excellent intra-oral access.

1.1.4 Constant light intensity. The curing effect is not affected by power level.

1.1.5 Charging base with integrated radiometer.

1.2 Principle and Application

1.2.1 Electromagnetic radiation is used to solidify the light-sensitive resin by brief irradiation at a specific frequency.

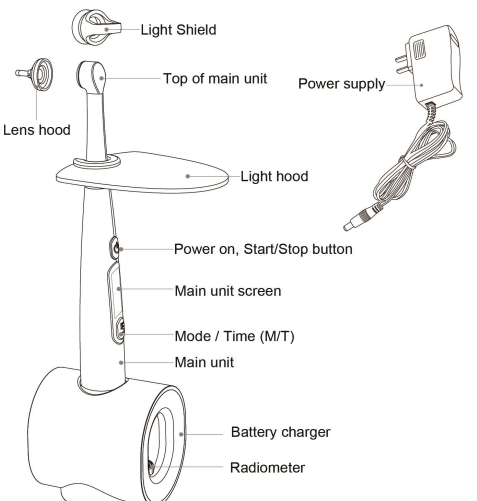
1.2.2 This product is used for dentistry where it catalyses the curing process of restorative materials by illumination in the visible or near UV or IR range, depending on the function.

1.2.3 The Check mode uses violet light to irradiate the teeth, creating fluorescence in the presence of dental caries or plaque.

1.2.4 Designed for use by professionally trained and qualified dentist, dental hygienists or dental assistants.

2. Product Performance Structure and Components

The curing light comprises a light emitting diode (LED), light hood, charging base, battery, battery charger, main unit.



3. Basic Technical Specifications

3.1 Size of main unit: 23mm × 23mm × 216mm

3.2 Net weight of main unit: 108g

3.3 Applied parts of the equipment: Top of main unit, Focus Cure lens

3.4 Power Supply:.

3.4.1 Rechargeable Lithium battery and battery charger

Battery model: 18500,

Battery capacity: 2000mAh

Charger:

Input: 100-240V~ 50/60Hz 0.4A Max

Output: DC 5V 1A

The charger complies with IEC 60601-1 and IEC 60601-1-2.

3.5 Light source:

3.5.1 10W high power LED

3.5.2 Wave length: 385nm~860nm

3.5.3 Class 2

3.5.4 Quick Test Method: Turn the device on, wait a few seconds for the function to be selected, then a quick press of the power button should turn the LED on.

3.5.5 The curing light's wavelength is matched to dental resin materials which are in common use, such as those made by 3M® and Dentsply®.

3.5.6 Operating wavelength 440 nm to 490 nm (blue light): not less than 250 mw/cm2 .

3.5.7 Environmental conditions:

Temperature: +5°C to +40°C

Relative humidity: 30%~75%

Atmospheric pressure: 70kPa to106kPa

3.6 Safety classification

3.6.1 Protection type against electrical shock: Class II

3.6.2 Protection degree against electrical shock: Type B

3.6.3 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0),can't be waterproofed.

3.6.4 Operation mode: short time run equipment.

3.6.5 Safety in the presence of flammable aesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

4. Installation

4.1 The top of main unit can rotate 360 degrees.

4.2 Install disposable sleeve on the main unit, use the Lens Hood to secure the sleeve.

⚠ **WARNING:**

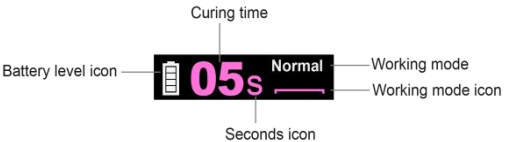
The disposable sleeves are single patient use only. Discard used disposable sleeves in standard waste after each patient.

4.3 Slide the sleeve over the unit and use the Lens Hood to secure the sleeve to the top of the unit.

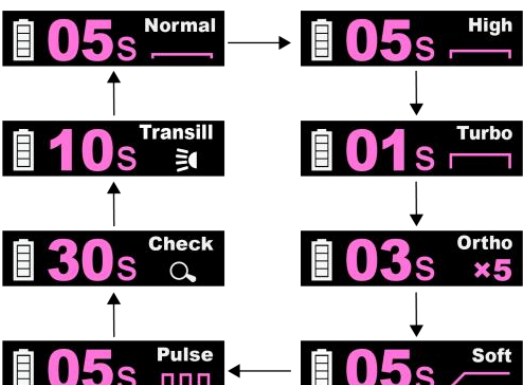
4.4 When the battery needs to be charged, use the supplied mains charger, connect to the USB C socket of the charging base.

5. Operation

5.1 Main unit screen display



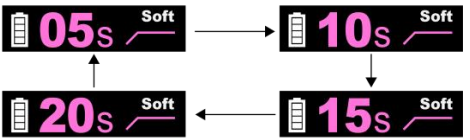
5.2 Working mode setting



Schematic diagram of working mode setting interface

Quick-press the “M/T” button to select the working mode. Eight working modes: Normal, High, Turbo, Ortho, Soft, Pulse, Check and transillumination. Because the curing time differs depending upon mode, when switching modes, the curing time will adjust automatically.

5.4 Curing time setting one-second press



Schematic diagram of curing time setting interface

One-second press the “M/T” button to change the curing time. Different working modes have different curing times.

5.5 Quick mode guide

Mode	Curing time (Seconds)	Light intensity(mW/cm2)
Normal	5, 10, 15, 20	1000-1200
High	3, 5	1800-2000
Turbo	1, 3	3000-3200
Ortho	3*5, 3*10	3000-3200
Soft	5, 10, 15, 20	1000-1200
Pulse	5, 10, 15, 20	1000-1200
Check	30, 60	/
Transill	30、60	/
Working mode setting	Press and release “M/T” button quickly to cycle to next working mode.	
Curing time setting	Press and hold “M/T” button 1 second and release. Curing light will cycle to next curing time.	

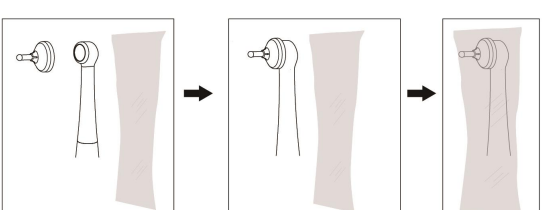
5.6 Quick Curing Guide: Recommended curing times for optimal results. Exposure times may need to be adjusted for composite reactivity, shade, distance to the composite, and depth of composite layer if it is over 2mm.

Curing Times in Seconds				
Mode	**Normal, Soft, Pulse**	**High**	**Turbo**	**Ortho**
Per 2mm Layer	1×10S	2×3S	1×3S	/
Final Cure	2×10S	2×3S	2×3S	/
Ortho Metal & Ceramic Brackets	/	2×5S	2×3S	2×3S

5.7 Use Focus Cure Lens: The magnetic Focus Cure Lens provides pinpoint curing of small composites and is helpful for tack curing veneers and all porcelain crowns.

For veneers, the Turbo mode with a 1-second curing time allows for point curing the centre of a veneer with the ability to then clean up the uncured excess around the margins, then cure the entire restoration using the full-sized curing lens.

For all porcelain crowns, place the curing light on the buccal and lingual surfaces and Focus Cure using Turbo mode for approximately 2 seconds each, clean up the uncured resin around the margins, then cure the entire restoration using the full-sized lens.



5.8 Caries detection using Check Mode

Select the Check mode, when purple light irradiates caries or dental plaque, it will produce orange red fluorescence when detecting surface caries or dental plaque. This is easier to see usung the safety glasses.

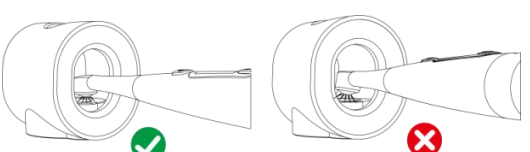
⚠WARNING:

Check mode is not suitable for curing resin-based materials.

5.9 Measuring the light intensity

The integrated radiometer allows the light intensity (mW/cm2) to be measured easily and quickly while the charging base is connected.

To measure the light intensity, place the top of main unit, without disposable sleeve, flush into the marked recess on the upper side of the charging base. Then activate the light and read the value displayed on the screen. Measurement accuracy is in the range of +/–10%.



⚠ CAUTION:

If the top of main unit is placed obliquely, there will be obvious deviation in the measured light intensity value. The integrated radiometer measures a 10mm light source. If the measured light source diameter is not 10 mm (8mm is common), it will read incorrectly. Different manufacturers have different standards for this measurement. It should therefore, only be used for measuring the Xpedent curing lights.

5.10 When operating, Slide a new sleeve over the unit and use the Lens Hood to secure the sleeve to the top of the unit.

Select the correct mode and time, aim the LED at the target position, press the power button until it “beeps”, the curing activates according to the selected mode, and the screen shows countdown to zero.

The selected work is now finished and the screen returns to the selected program.

5.11 During operation, the light can be turned off by pressing the power button until it beeps.

5.12 At the end of a working cycle, the next working cycle can be started immediately by quick pressing the button. If the main unit gets hot, turn off the device until it cools; Not suitable for more than 10 continuous cycles of operation.

5.13 When low power is detected, the battery level icon on main unit screen displays 0 power and flickers, or "Low Battery!" is displayed; recharge required.

5.14 To charge, connect the charger to the charging base and insert the main unit. Flashing lights on the charging base indicate the unit is charging; when all lights are on and not flashing, the battery is fully charged.

5.15 When finished, discard the sleeve and clean the top of the main unit with calico ensure the lens remails clean.

5.16 The unit will turn off automatically after two minutes without use; press power button to resume operation.

5.17 The effective light intensity of this unit is much higher than a Halogen Lamp; the solidification depth for composites resin will not less than 4mm after 10 seconds.

⚠ **WARNING:**

Use a disposable sleeve before using the equipment on the patient.

6. Precaution

6.1 Please recharge the battery for at least 4 hours before first time usage.

6.2 As is the case with all high-performance lights, the high light intensity can result in heat build-up. Prolonged exposure of areas near the pulp and soft tissues may result in irreversible damage. Therefore, this curing light must only be operated by trained professionals.

6.3 Do not expose soft oral tissues at close proximity for more than 10 seconds in any mode. If longer curing time is required, use multiple shorter curing cycles to avoid heating soft tissue, or use a dual-cure product.

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

6.5 Never aim the light directly at unprotected soft tissues, as this may cause injury or irritation. Do not aim the light at eyes. Light reflected from the tooth surface may also injure eyes. Use the eye protection light hood supplied with the unit or suitable, light filtering safety glasses. The curing light is classified as a Risk Group 2 device according to IEC 62471.

6.6 Check mode will not cure for curing resin-based materials.

6.7 During operation, the light should be aimed straight at the resin to ensure curing.

6.8 Use the original Light Shield to avoid blue light damage to eyes. Never aim the light directly at eyes.

6.9 Only the original charger should be used; other USB C chargers are not EMC cleared and may cause damage.

6.10 Charge the battery in a cool, ventilated environment. Please ensure the charger is plugged in correctly.

6.13 The instrument creates a little electromagnetic interference. Do not use in environments susceptible to electromagnetic interference. Avoid use in locations with strong electromagnetic interference.

6.14 This product should be used by trained, qualified dental professionals in a hospital or at a professional medical site.

6.15 To avoid electromagnetic interference, the device should be installed at a medical site which is EMC compliant.

⚠ **WARNING:**

Over-heating: The duty cycle of the equipment is 20 Seconds, on - 20 Seconds off, if the curing light works for 40s continuously, the device may start to overheat.

7. Cleaning, Disinfection and Sterilisation

The reprocessing instructions for the handpiece and base are different from the Lens Hood, the Focus Cure Lens and the Light Shield. The electrical nature of the Handpiece and charging base makes them unsuitable for autoclave or washer disinfector automated reprocessing. The Single Patient Sleeve is therefore used to simplify the process and ensure no damage to the electrical components.

7.1. Instructions for Cleaning and Disinfecting HeptaLux handpiece and charging base

⚠ **Warnings**

1) The HeptaLux Focus Cure Lens, Light Shield and Lens Hood should be removed and reprocessed separately as outlined below.

2) The handpiece and charging base are not sterilisable by autoclave or washer disinfector.

3) These are non-critical items according to Spalding, so Intermediate-level disinfection is appropriate.

4) Do not immerse in liquid.

5) Do not autoclave.

6) Do not clean in an automated washer/disinfector.

7) Disconnect the power supply from the charging base prior to cleaning.

Device life

Device life is determined by wear and damage due to use; cleaning is unlikely to affect device life

Device can be cleaned for up to 5000 times

Point of use

Remove disposable sleeve and discard. Clean with disposable alcohol-based wipe designed for cleaning medical devices. Start reprocessing within 1 hour of use.

Charging base should be cleaned as soon as reasonably practical after being exposed to body fluids, or touched by contaminated hands or a contaminated HeptaLux handpiece

Cleaning and Disinfection: Automated

Do not use automated washer/disinfectors for cleaning HeptaLux handpiece or charging base. Component damage will occur

Cleaning: Manual

The HeptaLux handpiece and charging base are to be cleaned by scrubbing with an alcohol based disposable wipe designed for cleaning medical devices. Remove all visible dirt, pay particular attention to crevices, but do not penetrate the casing. Discard used wipes responsibly

Allow the device to air dry.

Disinfection: Manual (Intermediate-Level)

To disinfect, repeat the cleaning process with particular attention to difficult to access areas, such as around buttons

Allow the device to air dry.

Wipe the devices with a sterile, clean, lint-free cloth dampened with distilled water to remove any residual chemicals

Packaging.

No particular requirements.

Sterilisation

Sterilisation is not recommended and has not been validated

Do not subject components to Steam or liquid chemical sterilisation will damage the product

Drying

Dry the devices with a sterile, clean, lint-free cloth. Fully air dry before storage

Maintenance

Inspect to ensure that all soil has been removed

Inspect all components for visual damage; damaged or warn components should be replaced

7.2 Instructions for Cleaning, Disinfecting and accessories including Light Hood, Light Shield and Focus Cure

⚠ Warnings

These instructions are for use ONLY for the accessories. The handpiece and charging base should be disinfected according to the procedures in the “Instructions for Cleaning and Disinfecting HeptaLux handpiece and charging base” section above

The Light Shield, Lens Hood and Focus Cure should be removed and cleaned and sterilised as outlined below. The HeptaLux handpiece and charging base are not sterilisable by autoclave

Steam autoclaving sterilisation is appropriate and validated for the Light Shield, Light Hood and Focus Cure

Do not allow the device to exceed 137 °C/279 °F

Limitations on reprocessing

Repeated reprocessing has minimum effect on these accessories. End of life is normally determined by wear and damage due to use.

Accessories can be reprocessed up to 60 times.

Cold liquid immersion disinfection/sterilisation, chemical vapor sterilisation, and dry heat sterilisation methods have not been tested or validated for efficacy and are not recommended for use.

Point of use

Remove protective sleeve and Lens Hood or Focus Cure, and discard sleeve. Remove Light Shield.

Reprocess the accessories as outlined below. Reprocess handpiece and charging base as outlined in the “Instructions for Cleaning and Disinfecting HeltaLux Handpiece, Charging Base” section above

It is recommended that the device be reprocessed as soon as is reasonably practical following use

Cleaning and Disinfection: Automated For Lens Hood, Light Shield and Focus Cure

Thermal disinfector: Manufacturer’s specification according to DIN EN ISO 15883. Cleaning program (A0 value > 600 or, at least 1 min at 90 °C/194 °F) as indicated by the manufacturer in the operating instructions

Follow manufacturer’s recommendation for use of detergent and neutraliser, observing concentrations and contact times

Cleaning: Manual For Lens Hood, Light Shield and Focus Cure

As an alternative to automated cleaning and disinfection, accessories have to be cleaned by scrubbing with hot water and a pH-neutral, phosphate-free cleaning solution

Immerse accessories in the detergent solution. Clean with a soft brush

Rinse under running potable water

Dry with a lint-free single use cloth

7.9 Storage

7.9.1 Store in a clean, dry, ventilated, non-corrosive environment with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;

7.9.2 After sterilisation, the product should be packaged in a medical sterilisation bag or a clean sealing container and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

7.10 Transportation

1) Prevent excessive shock and vibration during transportation, and handle with care;

2) It should not be mixed with dangerous goods during transportation.

3) Avoid exposure to sun or rain or snow during transportation. The cleaning and disinfection of main unit are as follows.

a) Before each use, wipe the surface of the machine with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

b) After each use, wipe the surface of the device with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe.

Repeat the wipe for at least 3 times.

8. Contraindication

8.1 The curing-light is contraindicated for use in patients prone to photo biological reactions (including patients with solar urticaria or erythropoietic protoporphyria) or those currently undergoing treatment with photo sensitizing pharmaceuticals.

8.2 The heart disease patients, pregnant women and children should be cautious to use the curing light.

9. Daily maintenance

9.1 The disposable sleeve helps prevent cross contamination and helps keep dental composite material from adhering to the surface of the lens and main unit.

9.2 Cleaning the housing: wipe the housing surfaces with a cloth lightly moistened with ethanol for disinfection (ethanol 70 to 80 vol%). Do not clean with highly aggressive disinfecting solutions (e.g. solutions based on orange oil or with an ethanol content of more than 40%), solvents (e.g. acetone), or pointed instruments, which may damage or scratch the housing surfaces.

9.3 Routinely check the lens for cured dental resins. If necessary, use a non- diamond dental instrument to carefully remove any adhered resin.

9.4 This equipment does not include the self-maintainable spare parts. The maintenance of this equipment should betaken by the appointed professional or special repair shop.

9.5 Please use accessories which are designed and supplied by our company, contact the local dealer or our company to buy. Itmes supplied by other manufacturers may not work properly and may cause damage to the curing light.

9.6 The accessory of the product should be cleaned by clean water or sterilised liquid. Do not soak.

9.7 Please clean the resin remained on the top of the main unit after using to avoid reducing product function or lifespan.

9.8 If the main unit is not used for a long time, charge the lithium battery every six months to prevent degradation after long-term storage.

10.Troubleshooting

Faults	Possible causes	Solutions
No Display. No response.	1. Battery is out of power. 2. Battery is protected. 3. Faulty of battery.	1. Charge. 2. Please put the curing light into the pedestal to charge, 3. Please contact our special repair shop or us.
The main unit can't be charged.	1. The main unit is not properly inserted into the charging base. 2.The charger is not connected well. 3. The charging point is dirty. 4. Using the wrong charger 5. Faulty of charger.	1. Insert the screen front of the main unit and the screen front of the charging base in the same direction. 2. Reconnect the charger. 3. Clean by the alcohol. 4. Use the original charger. 5. Please contact our special repair shop or us.
Main unit screen displays "Low battery!"	Battery is out of power.	Charge.
Main unit	LED source of top of	Replace the top of

screen displays "LED Error!"	main unit is broken.	main unit with a new one, please contact our special repair shop or us.
Light intensity is weak.	1. There is resin on the lens of top of main unit. 2. Lens damage.	1. Clean the resin. 2. Replace the lens assembly with a new one, please contact our special repair shop or us.
Effective duration of the battery become short.	The capacity of the battery decreased.	Replace the battery with a new one, please contact our special repair shop or us.

If all the above solutions have been completed, the machine still cannot work normally. Please contact our special repair shop or us.

11. Storage and transportation

11.1 The equipment should be handled carefully and lightly, kept away from vibrations or direct sunlight and kept in a dry, cool and ventilated place.

11.2 Store separately from articles that are combustible, toxic, caustic, or explosive.

14.3 Acceptable Humidity is 10%～93%, atmosphere pressure is 70kPa~106kPa and temperature -20℃ to +55℃ .

11.4 Excess impact or vibration should be prevented during transportation. Handle with care.

11.5 Do not transport with dangerous goods.

11.6 Avoid exposure to sunlight or precipitation.

12. After service

Please refer to the warranty card for the warranty period and conditions.

13. Environmental protection

There are no harmful factors in our product. Deal with it based on the local law.

14. Symbol instruction

	Check the random file		Appliance compliance WEEE directive
	Follow Instructions for Use		Power on, Start/Stop button
	Type B applied part	IPX0	Ordinary equipment
	Date of manufacture		Manufacturer
	Class II equipment		Used indoor only
	Optical radiation	CE	CE marked product
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		
M/T	Mode / Time setting button, quick press adjustment working mode, long press adjustment curing time		
	Humidity limitation for storage		
	Atmospheric pressure for storage		
	Temperature limitation for storage		

15. EMC - Declaration of conformity

The device has been tested and approved in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be adversely effected by electromagnetic interference. Avoid using the device in high electromagnetic environments.

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The device use 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.</td></tr>
<tr><td>RF emissions CISPR11</td><td>Class B</td><td rowspan="4">The device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">Guidance & Declaration — electromagnetic immunity</td></tr>
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</table>

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 transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4- 11.	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device require continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible

	(30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	cycles <5% UT (>95 % dip in UT) for 5 sec	power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Guidance & Declaration - Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1- 2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSUR E PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended operation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur In the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz end 800 MHz. the higher frequency			

range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device is recommended below, according to the maximum output power of the communications equipment.

Rated aximum output power of transmitter W	Separation distance according to frequency of transmitter /m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,5GHz d=2.3×P1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by

absorption and reflection from structures, objects and people.

16. Statement

The manufacturer reserves the right to modify the product without further notice. The pictures are only for reference. The final IP rights belong to GUILIN YIKESHI MEDICAL INSTRUMENT CO. , LTD. The industrial design, inner structure, etc, patents pending by YIKESHI, any copy or fake product may result in legal action.

Warranty Card

Name of Customer		
Address Details		
Postal Code		(I) For Distributor
Tel		
Model		
Machine ID		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Yikeshi Medical Instrument Co.,Ltd.
D-8,Guilin National High-tech Zone Information Industrial Park, Chaoyang Road,Qixing District,Guilin,Guangxi,541004,P.R.China
Postal Code: 541004
Tel: 0086 0773 5805522
Fax: 0086 0773 5805522
Email: sales@xpediency.cn
Website: www.xpedent-intl.com

Distributor:

Seal

Warranty Card

Name of Customer		
Address Details		
Postal Code		(II) Return to Manufacturer
Tel		
Model		
Machine ID		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Yikeshi Medical Instrument Co.,Ltd.
D-8,Guilin National High-tech Zone Information Industrial Park, Chaoyang Road,Qixing District,Guilin,Guangxi,541004,P.R.China
Postal Code: 541004
Tel: 0086 0773 5805522
Fax: 0086 0773 5805522
Email: sales@xpediency.cn
Website: www.xpedent-intl.com

Distributor:

Seal

Warranty Instruction

I Period validity

Terms of service: We offer 12 months warranty repair to the equipment based on the date of sale on the warranty card, and charged maintenance for the life of the product.

II Range of warranty

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

III The following are beyond our warranty

1. The damage caused by disobeying the operation instruction or lack of the needed condition.

2. The damage caused by unsuitable operation or disassembly without authorization.

3. The damage on product that caused by users' unexpected drop or impact to product.

4. The damage caused by unadvisable transportation or preservation.

5. There isn't the seal of distributor or the warranty card isn't filled in completed.

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XPEDENT®

EC REP

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Capelle aan den IJssel, The Netherlands

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