MD

CE 0197

Ai Ray Dental X-Ray Generator Instruction Manual

Please carefully read this manual before operating for the first time

ZMN-SM-911 V1.1- 20240509

Guilin Woodpecker Medical Instrument Co., Ltd.

Preface

Thank you for purchasing the Dental X-Ray Generator produced by Guilin Woodpecker Medical Instrument Co., Ltd. Woodpecker is a high-tech enterprise researching, developing, producing and selling dental products, and it owns a sound quality control system. Please read the full text of the instruction manual carefully to ensure that you can use the equipment correctly and safely.

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1. Product introduction

1.1 Product introduction

This equipment is a portable Dental X-Ray Generator, which is used to photograph teeth and obtain the dental image information.

Features of this equipment:

1) Small, light, easy for doctors to carry;

2) High quality and efficient user interface, making shooting easier;

3) Low radiation and high efficiency, providing good user experience;

1.2 Model

Ai Ray

1.3 Configuration

Equipment configuration is detailed in packing list.

1.4 Software title and version

Ai Ray V1

1.5 Structure and components

This product is mainly composed of X-Ray tube, control system, exposure handbrake, battery, power adapter and beam limiting equipment.

1.6 Intended use

This Dental X-Ray Generator is indicated for use only by a trained and qualified dentist or dental technician both adult and pediatric subjects as an extra oral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

1.7 Equipment safety classification

1. Type of operation mode: Continuous operation with intermittent loading

2. Type of protection against electric shock: Class II equipment

3. Degree of protection against electric shock: The Beam limiter is B Type applied part

4. Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)

5. Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment can't be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.8 Primary technical parameters

1. Power adapter input: ~100-240V 50/60Hz 1.5A

2. Internal power supply: DC 10.8V

3. Types of radiation: X-ray

4. Electric power:
Maximum power: 0.21kw(70kV, 3mA, 0.1s)
Nominal electric power: 0.21kw(70kV, 3mA, 0.1s)
5. Tube voltage: tube voltage output is fixed at 70kV, error ±10%
6. Tube current: tube current output is fixed at 3mA, error ±20%
7. Loading time: the exposure loading time adjustment range is 0.04s~1s, the grade is adjustable, the grade is selected according to R10 numerical system; with deviation ±10% or ±20ms.
8. X-ray tube
a) X-ray tube model: KL11-0.4-70
b) Ray focus: 0.4mm
c) Target angle: 12°
d) Total filtration: 1.5mmAl/70 kV
e) Minimum permanent filtration: 1.0mm Al/70kV
f) Additional filtration: 0.5mmAl/70 kV
9. Distance from focus to skin: 20~23cm
10. Nominal dose output at the end of the beam limiting tube(20cm): ≥3.41mGy/s
11. Output radiation field: Φ6.0cm±0.1cm
12. Product specifications Dimension: 114mm×363.8mm×245.6mm, Weight: 2.4KG
13. Battery specification: 10.8V 2500mAh
14. Exit field sized: Φ6.0cm±0.1cm
15. Reference LOADING conditions: 70kV, 3mA, 1s, loading interval 1s/90s, 39 exposures per hour.
16. Radiation output stated: the variation coefficient under the function less than 5%.
17. Under the reference condition (70kV, 3mA, 1s) of this equipment, the leakage radiation value of the accessible surface (excluding the X-ray outlet) shall not exceed 0.05mGy/h.
It is recommended to entrust a qualified testing institution to conduct a status test for items 5, 7, 8.a) and 17 once a year that ensure the device functions properly across the entire range of patient sizes in which the device may be used.

1.9 Operation environment

Environment temperature: 10℃ ~ 40℃
Relative humidity: 30% ~ 75%
Atmospheric pressure: 70kPa ~ 106kPa

1.10 Transportation and storage condition

Storage temperature: -20℃ ~ 55℃
Transportation temperature: -20℃ ~ 55℃
Relative humidity: 10% ~ 93%
Atmospheric pressure: 70kPa ~ 106kPa

1.11 Intended user

The user should be a physician with skilled radiology experience, professional radiology medical background, passing the oral X-ray technology and safe use operation training organized by the local relevant authority, and training by the authorized local distributor designated by the manufacturer on the operation method and safety precautions of this equipment.

1.12 Intended patients

Patients with hard tissue lesions, endodontic lesions, periapical lesions and periodontal disease of the teeth.

1.13 Intended environment

Hospital or dental clinic.

This X-ray unit must only be operated by trained personnel in a controlled setting. Within such a setting, ensure that only the patient is in the direct beam of the x-ray, and that any ancillary personnel are a minimum of 2m away from the patient. If it is necessary for any ancillary personnel to be closer than 2m, these personnel should stay out of the direct beam and wear personal protective equipment, such as an apron and thyroid collar.

2. Contraindication

Not found yet.

3. Matters Needing Attention

1.The Ai Ray was designed to be used in both clinical settings (e.g., a dental office) and controlled settings where transportation or use of other X-ray devices might be prohibitive due to the device's size and/or mobility.

2.The Ai Ray provides a high degree of protection from unnecessary radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation. It is important to restrict use and follow all applicable government radiation protection regulations. Pregnant women should not be exposed to X-rays unless necessary. Proper safety precautions should be taken to minimize dose to the fetus.

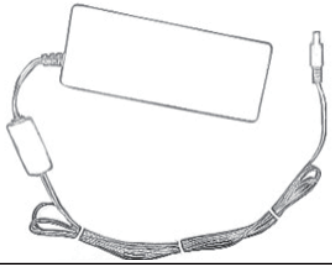
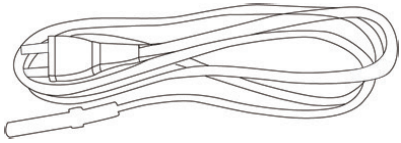
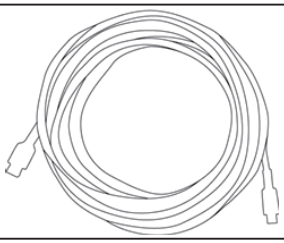
3.Operators must be fully acquainted with industry safety recommendations, established maximum permissible doses, and local jurisdiction require-

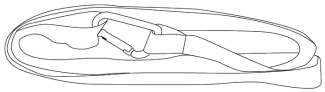
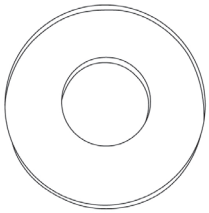
ments for use.
4. Optimal operator protection from radiation backscatter exists when the following measures are taken:
a. the backscatter shield is positioned at the outer end of the collimator cone.
b. the backscatter shield is close to the patient.
c. the patient tilts his or her head when needed to accommodate exposures.
d. the operator remains within the significant zone of occupancy immediately behind the device shield.
5. Do not enable the Ai Ray until patient and operator are positioned and ready for the exposure, preventing interruption and inadvertent exposure of anyone to X-rays.
6. When selecting and using sensors, preference should be given to models that allow the backscatter shield to remain at the outer end of the collimator cone for maximum operator protection.
7. An exposure can be terminated for any reason by prematurely releasing the depressed trigger .
8. Do not operate if the backscatter shield or collimator cone is broken!
9. The Dental X-Ray Generator shall never be used in the presence of flammable anesthetic gas, pure oxygen or nitrogen oxide to avoid any risk of explosion.
10. Dental X-Ray Generator and its accessories have been designed and developed to ensure the highest level of safety and performance. The use of accessories not provided by the original manufacturer may pose a risk to patients, users or the equipment itself.
11. The equipment complies with the IEC 60601-1 standard. Only peripheral equipment conforming to IEC 60950-1 can be connected to it so as to avoid any risk of failure of the Dental X-Ray Generator.
12. Our company is specialized in the production of medical equipment. We are responsible for the safety of the equipment only when the maintenance, repair and modification of the machine are carried out by our company or by our authorized dealers, and the replacement parts are our Woodpecker accessories and operated according to the operating instructions.
13. Other safety information can be found in each chapter of this instruction manual. Please read the whole manual carefully.
14. In order to ensure safe and correct operation and use of the Dental X-Ray Generator, it is quite important to use the charger provided by the equipment. The power line of the Dental X-Ray Generator can only be replaced by the same type of line.

15. Due to the electromagnetic compatibility of X-ray generator, other equipment nearby may be affected during the use. There is a risk of malfunction of nearby equipment.
16. Due to electromagnetic compatibility, the use of other equipment may interfere with the our product.
17. After use, you should press the power switch and confirm that the device has been turned off, otherwise it will lead to the consumption of battery power.
18. After 30 minutes of inactivity, the device will automatically shut down. If you need to put the device back in the box for storage, please confirm that the device has been turned off.

4. Product installation and function description

Table 1

	
Power adapter	Power cord
	
exposure hand brake(optional)	Connection cable of exposure hand brake(Optional)

	
Lanyard	Backscatter Shield

4.1 Schematic diagram of the whole machine

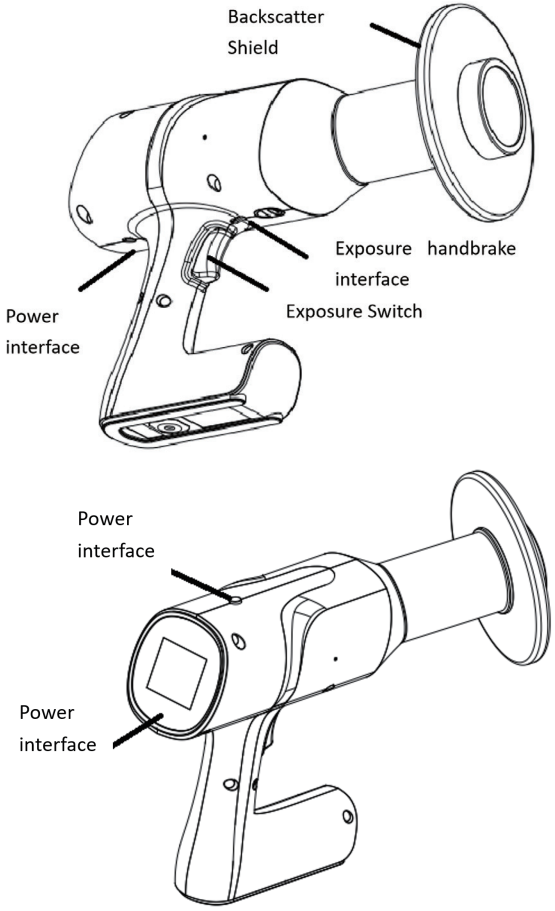


Figure 1 Schematic diagram of Dental X-Ray Generator (Left is the back

and right is the front)

4.2 Accessories installation

Take out all the parts from the packing box. Be careful not to drop or damage the equipment.

4.2.1 Power adapter installation

Take out the power adapter and power line from the packing box and connect them as shown in the figure.

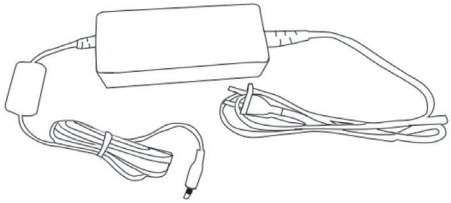


Figure 2 Power adapter

[Note] Only the power adapter and power line provided with the equipment can be used.

4.2.2 Exposure handbrake

Figure 3 Exposure hand brake

Note: wired connection mode: Long press the switch of exposure hand brake, the exposure starts light on.

4.2.3 Functions of the control panel

See Table 1 for the functions of the icons on the control panel.

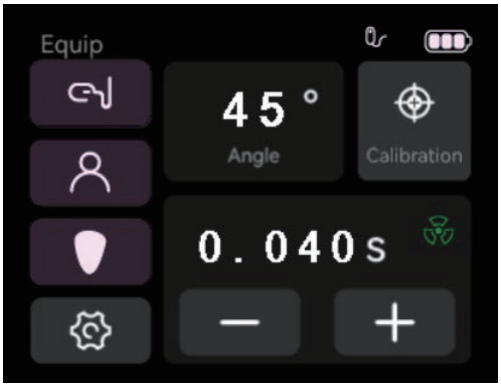


Figure 4 Control panel

Table 2

S/ N	Icons	Function
1		Selection of equipment: equipment of image receptor for Digital Intraoral X-ray Imaging System, film and image plate scanner (IP image plate)
2		Selection of human body: The patients shot include adults/ children
3		Selection of tooth position : selection of tooth position shot.
4		Connection mode: Wired connection mode of the exposure handbrake
5		Battery power: display of battery power
6		Setting function
7		Display of shooting angle
8		Display of X-ray exposure time
9		Indication of X-ray exposure status (normal (no color): not ready, green color: ready, yellow color: being exposed)
10		Time setting of X-ray exposure , “-” decreases time of exposure , “+” increases time of exposure
11		Click the calibration button to reset the displayed angle to zero

4.2.4 Description of Effective Occupied Area

The operator should designate any valid occupied area in the place of use, the floor size should not be less than 60cm×60cm, and the height should not be less than 200cm.

5. Operation instruction

The user of the medical device must comply with the requirements of the relevant operating regulations and relevant regulations of the medical de-

partment, and is limited to the use of trained doctors or technicians using in hospital environment.

5.1 Preparation before shooting

1. Turn on the Dental X-ray power switch, the LCD screen lights up, accompanied by a beeper "di" sound prompt, enter the password: 1234;

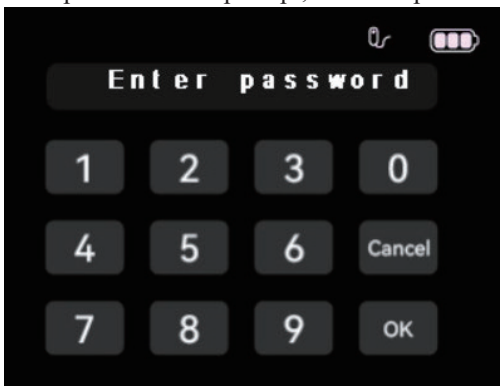


Figure 5

2. Check the battery of the equipment to ensure the normal operation of the equipment;
3. Select the human body, tooth position and the equipment mode;
4. Adjust the exposure time. The system has a default exposure time, or adjust the shooting time as required;
5. Prepare film or image plate scanner (IP image plate) or Digital Intraoral X-ray Imaging System (sensor).

5.2 Shooting images

1. A high-quality equipment of image receptor (film or IP image plate or sensor) in a sealed protective bag will be put in the patient's mouth, parallel to the longitudinal axis of the tooth. The effective surface of the equipment of image receptor is facing the tooth;
2. Move the Dental X-Ray Generator to the teeth on the patient's face and adjust the position of the equipment and the patient according to the angle displayed on the screen;
3. Ensure that the light cone of the equipment of image receptor is perpendicular to the position of the IP image plate, press the X-ray machine shooting switch; the exposure key should be pressed for the whole process until the "di" sound prompt of the beeper occurs;
4. When the exposure is finished and the image is taken successfully, remove the equipment of image receptor from the patient's mouth.

5.3 Shooting angle

5.3.1 Photograph angle reference values

Keep the patient in the correct sitting position and adjust the correct shooting angle of the Dental X-Ray Generator. The photograph angle reference values are as follows(The following values are only reference values, the operator can adjust the angle according to the actual situation to ensure that the beam limiting tube and the image receiving device remain vertical.):

Table 3

Tooth position	X - ray tilt direction	Angle of tilt
Maxillary incisor position	Downtilt	+42°
Maxillary single canine position	Downtilt	+45°
Maxillary bicuspid and first molar	Downtilt	+30°
Maxillary second and third molars	Downtilt	+28°
Mandibular incisor position	Uptilt	-15°
Mandibular single canine position	Uptilt	-18°~ -20°
Mandibular bicuspid and first molar	Uptilt	-10°
Mandibular second and third molars	Uptilt	-5°

5.4 Software Operation Instructions

This chapter introduces the front panel of the Dental X-Ray Generator, which visually displays the operation interface, so that the operator can better use the machine.

5.4.1 Mode function

When different modes of the equipment, tooth positions and human bodies are selected, the control panel automatically displays the exposure time.

1. Equipment Mode

Click the icon of equipment selection in the arrow indication in Figure 6 to enter the equipment interface as shown in Figure 7. Select the required equipment of image receptor, and the corresponding area of the equipment is displayed in blue. After the selection is successful, it will automatically exit to the interface in Figure 6, and the device selection icon will change to the corresponding device icon.

Figure 6

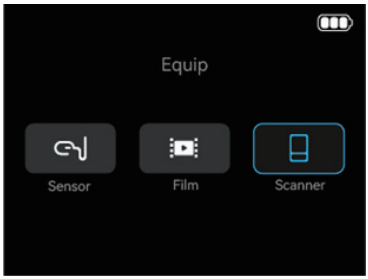


Figure 7

2. Human Body Mode

After selecting the equipment mode, select human body mode. Click the human body selection icon indicated by the arrow in Figure 8 to switch back and forth between adult and child modes. Different human body models can be selected according to the age of the patient. After the selection is successful, the human body model area will display the corresponding options.

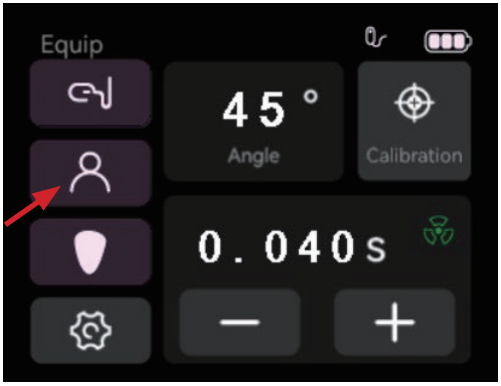


Figure 8

Table 4 Human Body Mode

Icons	Mode
	Adult Mode
	Child Mode

Note: Please use caution when configuring the X - ray by considering the patient's age, size, body habitus, and clinical indication when verifying exposure time settings. Technique Factor time settings can be adjusted by the operator.

Table 5 Exposure time reference

Equipment	Mode		Time
Digital Sensor		Adult Mode	0.250s
		Child Mode	0.200s
Film		Adult Mode	0.800s
		Child Mode	0.630s
Phosphor Plate		Adult Mode	0.320s
		Child Mode	0.250s

3. Tooth Position Mode

Click the tooth position selection icon indicated by the arrow in Figure 9, enter the interface of the tooth position as shown in Figure 10. Select the tooth type to be shot, and the corresponding area of the tooth is displayed in blue. After the selection is successful, it will automatically exit to the interface in Figure 9, and the tooth position selection icon will change to the corresponding tooth position icon.

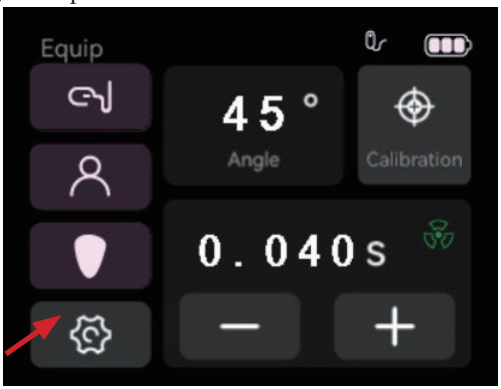


Figure 9

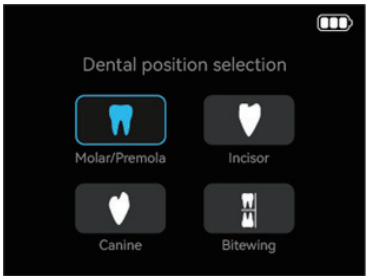


Figure 10

5.4.2 Setting function

Click the setting icon indicated by the arrow in Figure 11 to enter the setting interface. Different languages and factory modes can be set as shown in Figure 12. After the setting is successful, it will automatically exit to the Figure 11 interface.

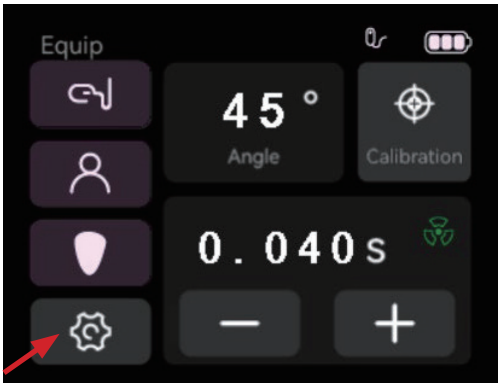


Figure 11

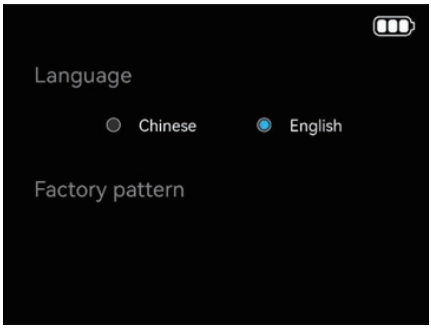


Figure 12

5.4.3 Setting of exposure time

If there is required to change the exposure time, click the "±" button to adjust the exposure time from 0.04 second to 1 second.

5.4.4 Shooting location icon

As an intra-oral dental X-ray system, the Ai Ray can be easily positioned. This high degree of flexibility makes it easy to take exposures while the patient is reclined, lying completely on their back, or sitting upright. Ensure the patient is protected by using an apron.

When shooting, the operator should hold the device, aim the output port of the beam limiting cylinder at the part of the patient that needs to shoot the image, and shoot at a distance of 0-3cm from the skin of the patient's shooting site.

Note: The device should be kept still when shooting, otherwise the captured image will be blurred or dislocated, which will affect the observation effect.

Note: When shooting, make sure that the center of the beam limiting tube

is aligned with the center of the image receiving device, otherwise it may result in incomplete images.

Note: When shooting, make sure that the beam limiting tube is vertical to the image receiving device, otherwise the captured image will be blurred and the image observation effect will be affected. It is recommended to use the "Image Plate Positioning Bracket" to assist in positioning.

Note: When the device must be angled and the operator cannot be completely within the protection zone, ensure operator protection through the use of proper safety measures, such as the use of an apron.

Note: Both digital imaging sensors and film and phosphor plate speeds can vary somewhat in their characteristics and could require different exposure settings to meet density preference.

5.4.5 Exposure

1. Long press the exposure switch of Dental X-Ray Generator to carry out exposure. See Table 4 for different states of exposure icons on the screen.

2. Long press the exposure button on the exposure handbrake to carry out exposure. During exposure, the exposure indication light of the exposure handbrake will be on. See Table 5 for different states of the exposure icon on the screen.

Table 6

Exposure icon	State
	Not ready
	Being exposed
	Ready

5.4.6 Image receiving device

Recommended image-receiving devices include: ACTEON Imaging Plate, Woodpecker Scanner and Woodpecker sensors:

Table 7

Name	**Country**	**Brand**	**Model**
IP image plates	France	ACTEON	IMAGING PLATE
Dental image plates scanner	China	Woodpecker	i-Scan

Digital intraoral X-ray imaging system	China	Woodpecker	i-Sensor H2

The quality of the captured image should be at least 1080PPI. As a medical device, the X-ray image receiver should meet the relevant requirements of local medical devices.

5.5 Charging and battery maintenance

5.5.1 Charging

1. Connect one end of the charger to the charging port of the equipment and the other end to the power supply of the network (100-240V, 50/60Hz);
2. When charging, the equipment displays the charging icon, and when charging is finished, the battery is charged fully;
3. Disconnect the power supply and the charger when the charging is complete;
4. A single charge takes about 1 hours.

5.5.2 Battery maintenance

1. When the machine is not in use, the power switch should be turned off to save electrical energy.
2. Please use the original charger to charge.
3. Keep the electrical energy more than 20%.
4. High position and single charge over 12 hours should be avoided.
5. Avoid exposing the battery to high temperature or fire, and avoid direct sunlight when storing the battery.
6. If you find that the battery life cannot meet the needs of use, please contact the manufacturer and authorized dealers in time to replace the new battery.

5.5.3 Pediatric Use: Summary

Introduction: Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height,measurements, which approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female.

Exposure to ionizing radiation is of particular concern in pediatric patients because:

1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients);

2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients;
3) younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.
A. References for pediatric dose optimization: The following resources provide information about pediatric radiation safety for Ai Ray Dental X-Ray Generator;
B. Device specific features and instructions: The Ai Ray Dental X-Ray Generator provides the following specific design features and instructions that enable safer use of our device with pediatric patients:

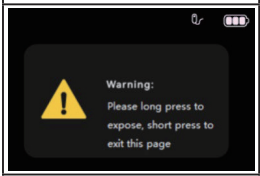
Table 8

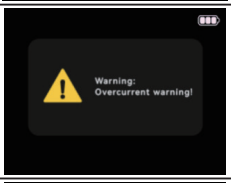
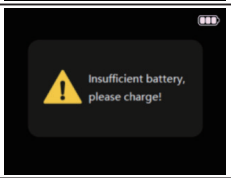
Design feature important to pediatric imaging	Page number reference in Instructions for use
Output radiation field	P.2
Reference LOADING conditions	P.2
Mode function	P.12
Automatic Exposure Control	P.15

Testing information	Page number reference in Instructions for use
Image receiving device requirment	P.15
Radiation and Protection	P.31

6. Troubleshooting

Table 9

Fault	Reason	Solution
	Hold down the exposure key for less than 1s	Plea long press to expose, short press to exit this page
	The temperature of equipment is too high	Equipment is cooled down before use

	The voltage of equipment is too high	Restart the machine, if the fault still exists, please contact the manufacturer
	The equipment current is too large	Restart the machine, if the fault still exists, please contact the manufacturer
	Low battery power	Plug in the power adapter and use it after charging

If the above methods can not eliminate the fault, please contact the distributor to return the equipment to the manufacturer for handling. Do not try to open the casing of this equipment and repair it yourself.

7. Maintain maintenance

Note: Maintenance and servicing of the equipment is prohibited during use.

The power adapter, power cord, exposure handbrake and handbrake connecting wire, and battery of this device are replaceable components. If they are damaged, please contact an authorized dealer or manufacturer to replace accessories that comply with relevant EU regulations. Disassemble the machine for repair or replace the components, otherwise it may cause damage to the equipment or affect the safety performance of the equipment.

Before the first use of this equipment, a complete cleaning procedure must be followed. The Dental X-Ray Generator should be disconnected from the power supply before cleaning and disinfection each time.

7.1 Cleaning

Wet the soft cloth completely with purified water, and wipe the test sample surface thoroughly for 2 times. After each wipe, replace the clean soft cloth. If there are still visible stains, wipe repeatedly until there are no visible stains.Then wipe the surface with a clean soft cloth until there is no water stains.

7.2 Disinfection

1. Wet the clean soft cloth completely with 75% alcohol, wipe the surface for 3 times. Wipe for 30 s each time.
2. Wet the clean soft cloth completely with sterile water, wipe the surface of the test sample thoroughly for 3 times. Wipe for 30 s each time, to remove the residual disinfectant on the surface.
3. Use a dry water absorbent sterile cloth to wipe off the residual water on the test sample.

Caution:

a. Do not use the following methods of disinfection.
b. Do not use organic solvents or corrosive cleaning products to clean the Dental X-Ray Generator.
c. Do not spray detergent directly on the Dental X-Ray Generator.
d. Do not use organic solvent or corrosive disinfectant to disinfect the Dental X-Ray Generator.
e. Do not spray disinfectant directly on the Dental X-Ray Generator.

8. X-ray tube characteristics

Filament voltage: 2.4-3.0V
Maximum filament current: 2.9A
Nominal anode input power: 600W (0.1s)
Target material：Tungsten
Anode heat capacity: 4500J
Maximum anode heat dissipation: 110W
X-ray source assembly maximum heat content: 6500J
Overall dimension and wiring: as shown in Figure 13
Maximum rated value: as shown in Figure 14
Thermal characteristics: see Figure 15
Filament and emission characteristics: see Figure 16

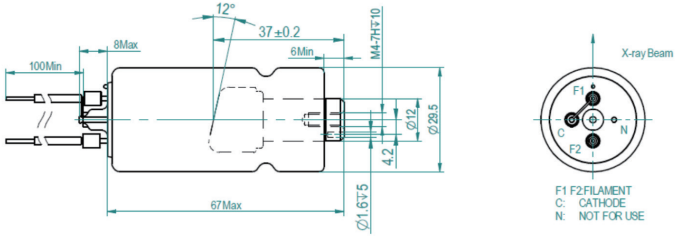


Figure 13 Mechanical dimension machine wiring

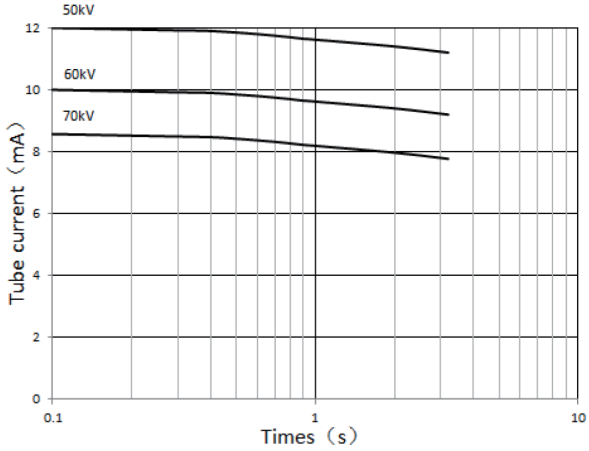


Figure 14 Maximum rating diagram

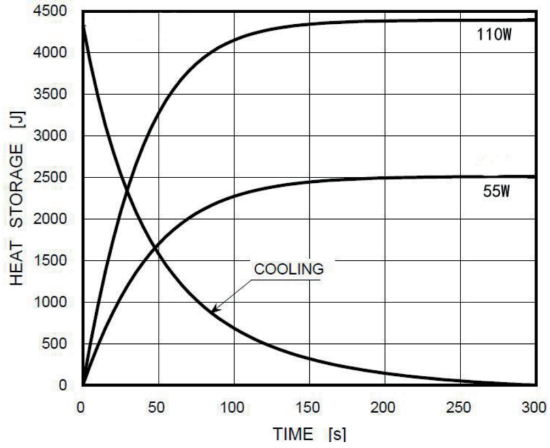


Figure 15 X-ray tube anode heating and cooling curve

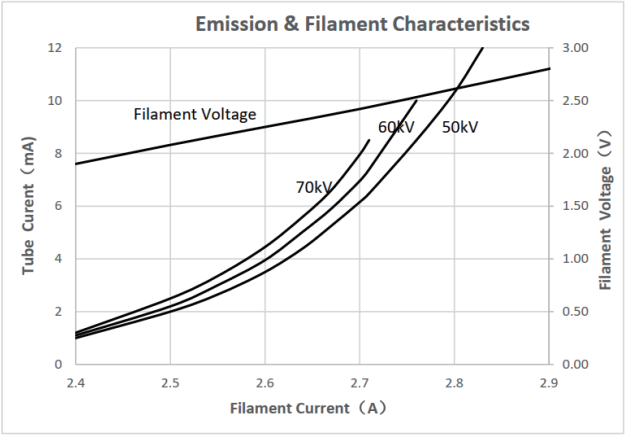


Figure 16 Filament and emission characteristic curve

9. Storage, maintenance and transportation

9.1 Storage/ maintenance

1) The equipment shall be handled with care, away from the hypocenter, and shall be installed or stored in a cool, dry and ventilated place.

2) Do not store with toxic, corrosive, flammable and explosive substances.

3) When the equipment is not used for a long time, turn off the power switch and unplug the power plug.

4) The product shall be stored in an environment with relative humidity of 10% -93%, atmospheric pressure of 70kPa ~ 106kPa and temperature of -20 °C ~ + 55 °C.

5) Inspect the equipment for scratches, wear and other mechanical scratches or damage after each use.

9.2 Transportation

1) Avoid excessive shock and vibration during transportation, and handle with care to avoid inversion;

2) It shall not be mixed with dangerous goods during transportation;

3) Avoid sun exposure or rain and snow immersion during transportation;

10. Environment protection

This equipment can't be disposed of as household waste. Therefore, this equipment should be placed in a special recycling place for waste electronic medical equipment. For more detailed information about equipment disposal and recycling, please contact the dental equipment dealer.

Table 10

Part	Toxic or harmful substances or elements					
	(Pb)	(Hg)	(Cd)	(Cr6+)	(PBB)	(PBDE)
Power adapter	○	○	○	○	○	○
Main unit	○	○	○	○	○	○
Mechanical elements, including bolts, nuts, washers, etc.	○	○	○	○	○	○

○: Indicates that the content of the toxic substance in all homogeneous materials of the part is below the limit requirement stipulated in SJ/T-11363-2006 “Marking for Control of Pollution Caused by Electronic Information Products”.

×: Indicates that the content of the toxic substance in at least one of the homogeneous materials of the part exceeds the limit requirement specified in SJ/T-11363-2006.

(This product meets EU RoHS environmental protection requirements; there is currently no mature technology in the world to replace or reduce the content of lead in electronic ceramics, optical glass, steel and copper alloy.)

According to the “Administrative Measures on the Restriction of the Use of Hazardous Substances in Electric and Electronic Products” and the “Regulations on the Administration of the Recycling and Disposal of waste Electrical Appliances and Electronic Products” and related standards, please observe the safety and precautions of the products, and please recycle or dispose this product according to the methods in local laws and regulations after use.

11. After-sales service

Since the date of sale, if the equipment fails to work normally due to quality problems, our company will be responsible for the maintenance based on the warranty card. Please refer to the warranty card for the warranty period and scope. This product does not contain self-maintained parts, and the maintenance of this equipment should be carried out by designated professionals or special repair shops.

12. Electromagnetic compatibility

For this equipment, special precautions regarding electromagnetic compatibility (EMC) must be taken, and the installation and use must be performed according to the electromagnetic compatibility information specified in this manual. Portable and mobile radio frequency communication

equipment may affect this equipment. The following cables must be used to meet electromagnetic emission and anti-interference requirements:

Table 11

Name	Cable length	Shielded or not	Remark
Power adapter cable	2m	No	/
DC cable	1.5m	No	/
Connection line of exposure handbrake	8.0m	No	/

In addition to cables (transducers) sold as spare parts of internal components, the use of accessories and cables (transducers) other than those specified may result in increased emission or reduced immunity of the equipment or system.

The equipment or system should not be used close to or stacked with other equipment. If it is required to be used in this way, it should be observed to verify that it can operate normally under the configuration used.

12.1 Guidance and manufacturer's declaration-electromagnetic emission

Table 12

Guidance and manufacturer's declaration-electromagnetic emission		
The Dental X-Ray Generator is intended for the use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an electromagnetic environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emission CISPR 11	Group 1	The Dental X-Ray Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emission CISPR 11	Group B	The Dental X-Ray Generator is suitable for used in all establishments, including domestic establishments and establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission lEC 61000-3-2	Group A	
Voltage fluctuation/ flicker emission lEC 61000-3-3	Complied	

12.2 Guidance and manufacturer's declaration-electromagnetic immunity

Table 13

Guidance and manufacturer's declaration-electromagnetic immunity			
The Dental X-Ray Generator is intended for the use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an electromagnetic environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) lEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV 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 ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV 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 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T.) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 250 cycles	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T.) for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dental X-Ray Generator requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an uninterruptible power supply or a battery.

Power frequency magnetic field (50Hz) lEC 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: U_T refers to the AC mains voltage prior to application of the test level.			

12.3 Guidance and manufacturer's declaration-electromagnetic immunity

Table 14

Guidance and manufacturer's declaration-electromagnetic immunity			
The Dental X-Ray Generator is intended for the use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3Vrms 150kHz ~80MHz ISM 6V.r.m.s 3V/m 80MHz ~2.5GHz	3Vrms 150kHz ~80MHz ISM 6V.r.m.s 3V/m 80MHz ~2.5GHz	Portable and mobile RF communication equipment should be used not closer to any part of the Dental X-Ray Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz~80MHz $d = 1.2\sqrt{P}$ 80MHz~800MHz $d = 2.3\sqrt{P}$ 800MHz~2.5GHz where "P" is the maximum output rated power of the transmitter provided by the transmitter manufacturer in watts (W) and "d" is the recommended separation distance in meters (m). Field strengths of b fixed RF transmitters is determined by an electromagnetic site survey of a, and frequency range b should be less than the compliance level in each. Interference may occurs in the

			vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the formula of higher frequency range is applied. NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission from buildings, objects and human bodies.			
a. Field strengths of a 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 Dental X-Ray Generator is used exceeds the applicable RF compliance level above, the scanner should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dental X-Ray Generator. b. In the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

12.4 Recommended separation distances between RF communications equipment and dental imaging plate scanner.

Table 14

Recommended separation distances between portable and mobile RF communications equipment and the Dental X-Ray Generator			
The Dental X-Ray Generator is intended for the use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dental X-Ray Generator as recommended below according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter/W	Separation distance according to frequency of transmitter/m		
	150kHz~80MHz $d = 1.2\sqrt{P}$	80MHz~800MHz $d = 1.2\sqrt{P}$	800MHz~2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

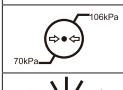
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the rated maximum output power of transmitters not listed in the above table, the recommended separation distance “d” (m) can be determined by the formula in the corresponding transmitter frequency column. Where “P” is the maximum output rated power of the transmitter in watts (W) provided by the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the formula of higher frequency range is applied. NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission from buildings, objects and human bodies.			

Notes:

Without the explicit consent of Woodpecker, unauthorized changes or modifications to the equipment may cause electromagnetic compatibility problems of this equipment or other equipment.

13. Symbol instruction

Table 15

	Manufacturer		Serial number
	Class Ⅱ equipment		Ordinary equipment
	Temperature limit for storage: -20℃ ~ +55℃		WEEE mark Please deal with the waste disposal produced by the machine following relevant laws and regulations.
	Humidity limit for storage: 10% ~ 93%		Electrostatic Sensitive devices
	Atmospheric pressure for storage: 70kPa ~ 106kPa		Danger! High voltage
	Avoid sun exposure		Date of manufacture
	Follow the manual		X-ray, beware of ionizing radiation

CE 0197	CE marked product		Warning
	Type B application.	MD	Medical Device
	Avoid tipping	REF	Product number

14. Warning

1. Do not use this device while charging.
2. Do not maintain and maintain the equipment during operation.
3. This equipment has residual radiation, it is recommended to add protection.
4. Dropping the device may cause damage to the product. If it is dropped or suspected of unknown damage, please contact the manufacturer to check the device, and do not attempt to disassemble it for repair.
5. Please use an image receiver that meets the requirements. If an image receiver with a low resolution or does not meet the relevant requirements of local medical devices is used, the image quality may be affected, resulting in blurred images, etc., affecting clinical judgment.
6. The use of the product should also comply with the relevant requirements of the local radiation safety management regulations.
7. The adapter plug can be used to disconnect from the network power supply. Don't position the device to make it difficult to operate the disconnection device.
8. The user must use the original accessories. Please contact our local dealer or the company for purchase. It is forbidden to use related accessories of other brands, so as to avoid damage to the X-ray tube and system or other dangers.
9. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

15. Radiation and Protection

15.1 Radiation

1)Dose area product

The dose area product is shown in the figure below. The dose area area corresponding to the X-ray taken by the human body can be looked up in the table to find the value under the corresponding time (ms).

Table 16

Test conditions (20cm from the focus of the tube)

Exposure time(ms)	Dose value(uGy)	Area(mm^2)	dose area product(uGy*mm^2)
40	136	2387	325587
50	171	2387	408177
63	214	2387	511295
80	319	2387	761930
100	342	2387	816354
125	426	2387	1017459
160	544	2387	1298528
200	684	2387	1632708
250	850	2387	2028950
320	1277	2387	3047722
400	1366	2387	3260642
500	1705	2387	4069835
630	2145	2387	5120473
800	2724	2387	6502188
1000	3400	2387	8115800

2) Dosimetric indications.

Under the condition of 70kV, 3mA, the distance between the test point and the focal point of the X-ray tube is 20cm, and the dose area product test is carried out. When choosing the corresponding exposure time, the deviation of the measured dose area product does not exceed 50% of the value in the table. The dose area product is equal to the air kerma multiplied by the area irradiated by the radiation.

3) Residual radiation.

After using this device, there will be residual radiation. To avoid unnecessary injury, please wear protective gear or stay away from the device when using the device.

15.2 Protection requirements

1) Effective occupied area

The operator should designate any effective occupied area in the place of use, the floor size is 60cm×60cm, and the height is 200cm. When using, the focus should be kept about 10cm away from the effective occupied area, as shown in the following figure:

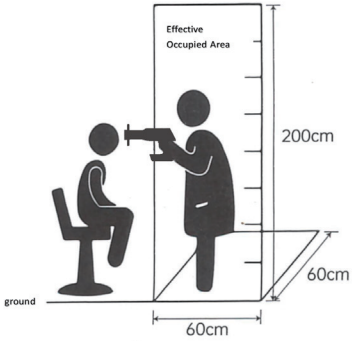


Figure 17 Effective occupied area

In order to ensure the safety of users, users should stand in the effective occupied area and test the stray radiation in the height direction of the effective occupied area. The stray radiation distribution diagram is as follows:

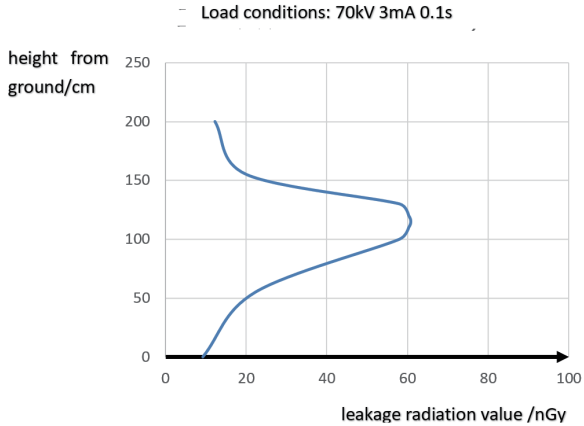


Figure 18 Stray radiation distribution diagram

When measuring the scatter radiation, the focal point is 1.15 meter above the ground and 0.1 meter outside the middle of limited occupied area, STRAY RADIATION not exceed 0.05 mGy in one hour.

2)Physical protection

During operation, it is recommended to wear protective clothing and protective glasses to reduce radiation hazards.

16. Special description

Please refer to the product packaging label for the production date, service

life: 10 years.
Safety: The radiation dose for an occupational radiation worker is less than 50 mSv for whole body, less 150 mSv for the eyes and less 500 mSv for hands, skin and feet in a single year.
Performance: The image quality of subject device is excellent and is not inferior the wall-mounted X-ray machine.
Benefits: From the clinical data, such as significantly improving the self-care ability. The hand-held dental radiograph can flexibly photograph lesions in the oral cavity. Direct action on the lesion is shown to reduce the exposure of other tissues of the patient to radiation. Compared with other dental X-ray machines, the image quality of the handheld dental X-ray machine is not inferior to other types of X-ray machines, and the radiation dose for the operator and the patient is within the limited safe dose range.

17. Disposal

Damaged or faulty Ai Ray materials and components must be properly disposed of according to local requirements, or returned to an authorized distributor. Please protect the environment, and do not improperly dispose of any part of the Ai Ray system, the handsets, the charging cradle, or the AC power supply. At end of life, return these items to authorized distributor, and proper disposal or recycling.

Scan and Login website
for more information

Guilin Woodpecker Medical Instrument Co.,Ltd.
Information Industrial Park, Guilin National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196/2350599
After-sales Service Dept.: +86-0773-5827898
E-mail: woodpecker4@glwoodpecker.com
Website: http://www.glwoodpecker.com
EC REP MedNet EC-REP C IIb GmbH
Borkstrasse 10·48163 Muenster·Germany

Cut along the dashed line

Dental X-Ray Generator Warranty Card

Name of Customer		(I) For Distributor
Address Details		
Postal Code		
Tel		
Model		
Unit No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Woodpecker Medical Instrument Co.,Ltd.
Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196/2350599
After-sales Service Dept.: +86-0773-5827898
E-mail: woodpecker4@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Dental X-Ray Generator Warranty Card

Name of Customer		(II) Return to Manufacturer
Address Details		
Postal Code		
Tel		
Model		
Unit No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Woodpecker Medical Instrument Co.,Ltd.
Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196/2350599
After-sales Service Dept.: +86-0773-5827898
E-mail: woodpecker4@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Warranty Instruction

Ⅰ Period validity:

Since the date of sale, with a warranty card ,this product enjoys 1 years warranty for the main unit.

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 caused by unadvisable transportation or preservation.

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

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