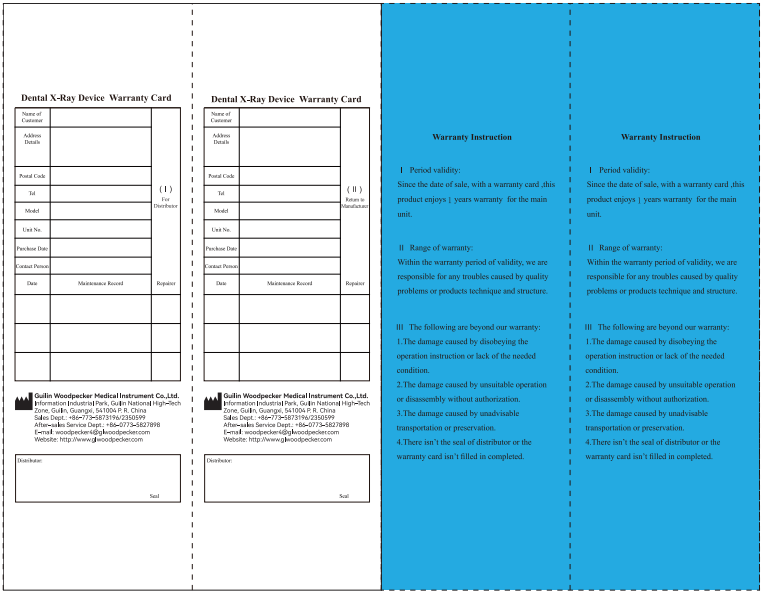
文件名/NAME	Smart Ray 牙科 X 射线机英文说明书	代码/CODE	14.02.21.012
尺寸/SIZE	130×190mm, 出血 6mm	版本/REV.	V1.0
材质/MATERIAL	120g 铜版纸		
装订&注释/ bind (books etc) &NOTES	骑马订； 保修卡正反面印刷需对应。	印刷颜色/COLORS	4X4 CMYK
修订日期/DATE	2024 年 01 月 17 日		

请勿打印此页，仅供参考。/DO NOT PRINT THIS PAGE,REFERENCE ONLY.

保修卡正反面



Dental X-Ray Device 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
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E-mail: woodpecker4@gliwoodpecker.com
Website: http://www.gliwoodpecker.com

Distributor:

Seal

Dental X-Ray Device 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
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E-mail: woodpecker4@gliwoodpecker.com
Website: http://www.gliwoodpecker.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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WOODPECKER®

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Smart Ray Dental X-Ray Generator Instruction Manual

Please carefully read this manual before operating.

ZMN-SM-906 V1.0-20240117

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 before use to ensure that you can correctly and safely use the device.

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1 Product Introduction

1.1 Product introduction

This device is a portable Dental X-Ray Generator, which is used to photograph teeth and obtain dental image information. The device can only be used by professional dentists in hospitals or clinics.

Features of this device:

1) Small, light, convenient for doctors to carry;
2) High-quality and efficient user interface, making exposure easier;
3) Low radiation, high efficiency, providing good user experience.

1.2 Model

Smart Ray

1.3 Configuration

Device configuration is detailed in packing list.

1.4 Software Name and Version

Smart Ray V1

1.5 Structure and Composition

This product consists of X-Ray combined machine head, X-Ray tube, power adapter, lithium battery, beam limiter, landyard (non-removable), wired hand brake (optional) and wireless exposure hand brake (optional).

1.6 Intended use

This product is used for X-Ray photography of teeth to obtain images for clinical diagnosis.

1.7 Device Safety Classification

1. Type of operation mode: Non continuous operation mode (2:120).
2. Type of protection against electric shock: Class II equipment when charging, Internal power supply equipment when using.
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:
Power adapter model: UES48-150320SPA1
Power input: 100-240V~ 50/60Hz 1.1A
2. Internal power supply: DC 10.8V

3. Power adapter output: DC 15.0V 3.2A
4. Type of radiation: X-Ray
5. Electric power
Maximum output electric power: 0.14kw (70kV, 2mA)
Nominal electric power: 0.14kw (70kV, 2mA, 0.1s)
6. Tube voltage: tube voltage output is fixed at 70kV, error ±10%
7. Tube current: tube current output is fixed at 2mA, error ±20%
8. Loading time: the exposure loading time adjustment range is 0.02s ~ 2s, multiple exposure time settings adjustable according to R'10 numerical system; with deviation ±5% or ±20ms (whichever is greater)
9. X-Ray tube
X-Ray tube model: KL11-0.4-70
Focal spot: 0.4 mm
Target angle: 12°
Total filtration: 1.5mmAl/70 kV
Permanent filtration: 1.0mmAl/70 kV
Additional filtration: 0.5mmAl/70 kV
10. Distance from focal spot to skin: 20~23cm
11. Output radiation field: Φ5.9cm±0.1cm.
12. Product specifications:
Dimension: 240mm×161mm×143mm
Weight: 2.2KG
13. Battery specification: 18650×3 10.8V 2500mAh 27Wh R.
14. Exit field size: Φ5.9cm±0.1cm.
15. Reference LOADING conditions: 70kV, 2mA, 1s, loading interval 1s/60s, 59 exposures per hour.
16. Radiation output stated: the variation coefficient under the function less than 5%.
17. Under the reference conditions (70kV, 2mA, 1s), the leakage radiation value of the contactable surface (excluding the X-Ray outlet) is not more than 0.25 mGy/h. Leakage radiation loading factor: 2s/120s.

1.9 Operation environment

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

1.10 Transportation and Storage Conditions

Ambient 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 device.

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.

Note: This product is not intended for use in operating rooms, MRI, CT and other environments with high frequency surgical equipment.

1.14 Technical Specification of 433MHz

Characteristic	Description
Operation Frequency Range:	433.050 to 434.790 MHz
Operation frequency:	Host: 433.92MHz receiver Remote control: 433.92MHz transmitter
Type of modulation:	FSK
Channel number:	1 channel
Rx category	2
Antenna Type:	PCB Layout Antenna
Antenna Gain:	2.0 dBi for Host, 1.15 dBi for Remote control (Provided by the Client)

2 Contraindication

Not found yet.

3 Precautions

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

3.2 The Smart 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.

3.3 Operators must be fully acquainted with industry safety recommendations, established maximum permissible doses, and local jurisdiction requirements for use.
3.4 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 beam limiter.
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 backscatter shield.

3.5 Do not enable the Smart Ray until patient and operator are positioned and ready for the exposure, preventing interruption and inadvertent exposure of anyone to X-Rays.
3.6 Do not hold the beam limiting equipment close to the skin for the exposure time.
3.7 When selecting and using sensors, preference should be given to models that allow the backscatter shield to remain at the outer end of the beam limiter for maximum operator protection.
3.8 An exposure can be terminated for any reason by prematurely releasing the pressed exposure hand brake or exposure button.
3.9 Do not operate if the beam limiter is broken!
3.10 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.
3.11 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 device itself.
3.12 The device 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.
3.13 Our company is specialized in the production of medical devices. We are responsible for the safety of the device only when the maintenance, repair and modification 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.
3.14 Other safety information can be found in each chapter of this instruction manual. Please read the whole manual carefully and be familiar with the operation method of Dental X-Ray Generator. The following are precautions during operation.

1) The device shall be used according to the method specified by the manufacturer, otherwise the device will be damaged and endanger the safety of patients. The manufacturer would not be responsible for the harm caused by the improper use.
2) The Dental X-Ray Generator shall not be used in the environment with flammable anesthetic gas, pure oxygen or nitrogen oxide to avoid any risk of explosion.

3) Patients and operators need to wear radiation protection appliances when taking X-Rays.

4) Dental X-Ray Generator and its accessories are designed and developed to ensure the highest degree of safety and performance. Using accessories not provided by the original factory may cause risks to patients, users or the device itself.

3.15 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 device. The power cord of the Dental X-Ray Generator can only be replaced by the cord of same type.

3.16 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.

3.17 Due to electromagnetic compatibility, the use of other equipment may interfere with our product.

3.18 After use, you should press the power button and confirm that the device has been turned off, otherwise it will lead to the consumption of battery power.

3.19 After 10 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.

3.20 Pediatric Use

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 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 device 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 Smart Ray Dental X-Ray Generator;

B. Device specific features and instructions: The Smart Ray Dental X-Ray Generator provides the following specific design features and instructions that enable safer use of our device with pediatric patients:

4 Product Installation and Function Description

4.1 Schematic Diagram of the Whole Machine

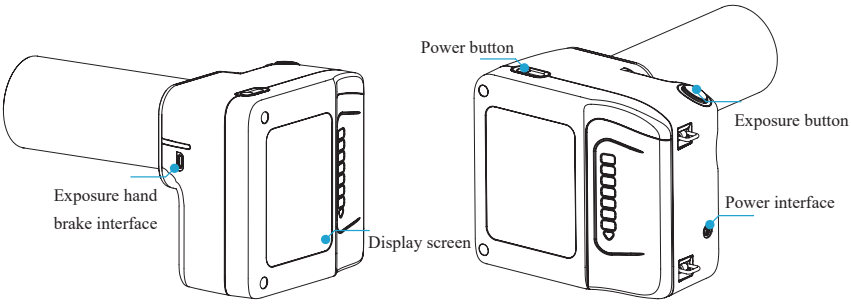


Figure 1 Schematic diagram of Dental X-Ray Generator

When remotely controlling the device's exposure via a hand brake cable, a fixed bracket can be used to secure the X-Ray device. The fixing port of the device is a standard 1/4-20 UNC screw, please se the matching specifications of the fixing bracket to fix.The load capacity of the fixed bracket should be greater than 8KG.

4.2 Fitting Installation

4.2.1 Packaging Accessories:

Take out all the components from the box, and be careful not to drop or damage the device.

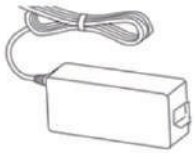


Figure 2 Power adapter

Figure 3 Power adapter connecting cable

Figure 4 Wired exposure hand brake (optional)

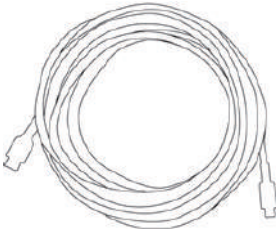


Figure 5 Hand brake connecting cable(optional)

Figure 6 Wireless exposure hand brake (optional)

4.2.2 Power Adapter Installation

Take out the power adapter and power cord from the box, and connect the power cord and power adapter as shown in the following figure:

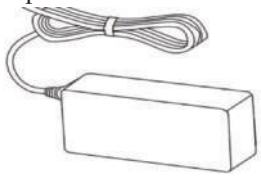


Figure 7 Power adapter installation

[Note] Only use the power adapter and power cord provided with this device.

4.2.3 Exposure handbrake

Figure 8 Exposure hand brake

① wired connection: Take out the exposure handbrake and the connecting wire, and connect one end of the connecting wire to the end of the exposure handbrake:

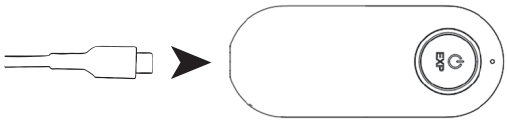


Figure 9 Exposure hand brake connecting cable

Connect the other end of the handbrake cable to the host:

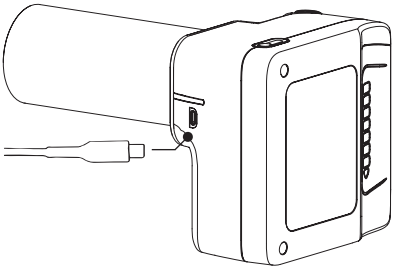


Figure 10 Connect exposure hand brake to host

② Long press the switch of exposure hand brake, the exposure starts light on.

③ When the host is ready, press the switch to expose.It functions the same as the exposure switch of the host.

④ The Hand brake connecting cable is 8 meters long.

4.2.4 Wireless exposure hand brake

Figure 11 Wireless exposure hand brake

The wireless exposure hand brake and the host have been matched before delivery, and no further matching operation is required.It functions the same as the exposure button of the host. It has a remote control distance of 3.5 meters.

4.2.5 Control Panel Function

See Table 1 for the functions of each icon on the control panel.

Figure 12 Control panel

Table 1

No.	Icon	Function
1		The exposure hand brake is connected by wire.
2		Battery charge display
3		Exposure status of Dental X-Ray Generator (gray: not ready, green: ready)
4	0.025 s	The display of Dental X-Ray Generator exposure time
5	− +	X-Ray exposure time setting: "-": reduces exposure time "+": increases exposure time
6	-30 ° Angle	The display of exposure angle
7	Calibration	When the calibration button is clicked, the displayed angle returns to zero.
8		Tooth type selection: Molars/premolars, cusps, incisors, bite wings.
9		Group selection: Adult/Child
10		Equipment selection: Sensor/scanner/film
11		Settings

5 Operating Instructions

Users of this device must meet the requirements of relevant operating specifications and relevant laws and regulations of the medical department, and only use it by trained doctors or technicians in hospital environment.

5.1 Preparation before exposure

1. Check the battery capacity of the device to ensure that it can work normally;

2. Press the power-on button to turn on the Dental X-Ray Generator, accompanied by the prompt beep sound. Press the designated area briefly for 1 second, wait for “Smart Ray” to change from white to green, and the lock icon will change to unlock icon, and then release your hand to enter the main interface;

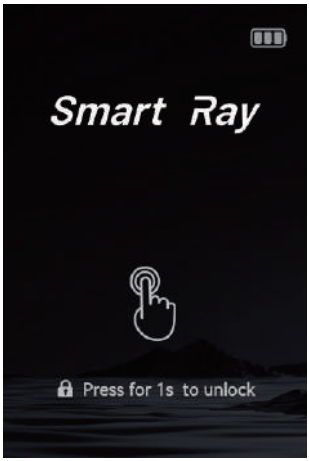


Figure 13 Power-on lock screen interface

3. Select the group, tooth type and equipment mode to be photographed;

4. Adjust the exposure time, the system has the default exposure time, and the exposure time can also be adjusted as needed;

5. Prepare film or IP imaging plate or digital imaging equipment (sensor).

5.2 Exposure

1. Put a good quality image receiver (IP imaging plate/sensor/film) in a sealed protective bag and put it in the patient’s mouth, parallel to the longitudinal axis of the teeth. The effective surface of the image receiver faces toward the teeth;

2. After short press/long press the exposure button to enter the pre-exposure mode, move the Dental X-Ray Generator to the position of the patient’s teeth, and adjust the positions of the Dental X-Ray Generator and

the patient according to the angle displayed on the screen;

3. Ensure that light beams of the Dental X-Ray Generator is perpendicular to the position of the image receiver, press the exposure button of the Dental X-Ray Generator, and keep pressing the exposure button until the beep sound stops and the exposure is over;

4. When the exposure is completed, the image is successfully acquired. Take out the image receiver from the patient's mouth.

5.3 Exposure Angle and Time

5.3.1 Reference Value of Exposure Angle

Keep the patient in a correct sitting position and adjust the correct exposure angle of the Dental X-Ray Generator. The reference values of the exposure angle are as follows:

Table 2

Tooth type	X-Ray inclination direction	Angle of inclination
Maxillary incisor	Downward	+42°
Maxillary canine	Downward	+45°
Maxillary bicuspids and first molars	Downward	+30°
Maxillary second and third molars	Downward	+28°
Mandibular incisor	Upward	-15°
Mandibular canine	Upward	-18°~-20°
Mandibular bicuspids and first molars	Upward	-10°
Mandibular second and third molars	Upward	-5°

5.4 Software Operating Instructions

This chapter introduces the control panel of the Dental X-Ray Generator, and intuitively displays the operation interface, so that the operator can use the device better.

5.4.1 Mode Function

After selecting different equipment, tooth type and group modes, the control panel will automatically display the exposure time.

Table 3 Exposure time reference

Equipment	Body	Tooth Position	Time

Sensor	Adult	Incisor	0.200s
		Canine	0.250s
		Molar/Premolar	0.320s
		Bitewing	0.400s
	Child	Incisor	0.160s
		Canine	0.200s
		Molar/Premolar	0.250s
		Bitewing	0.320s
Scanner	Adult	Incisor	0.250s
		Canine	0.320s
		Molar/Premolar	0.400s
		Bitewing	0.500s
	Child	Incisor	0.200s
		Canine	0.250s
		Molar/Premolar	0.320s
		Bitewing	0.400s
Film	Adult	Incisor	0.630s
		Canine	0.800s
		Molar/Premolar	1.000s
		Bitewing	1.000s
	Child	Incisor	0.500s
		Canine	0.630s
		Molar/Premolar	0.800s
		Bitewing	0.800s

1. Equipment Mode

Click the equipment selection icon shown in the box, as shown in Figure 14, and select the required image receiver, as shown in Figure 15. From top to bottom, there are sensor, scanner and film, and the selected equipment will be displayed in blue on a black background.

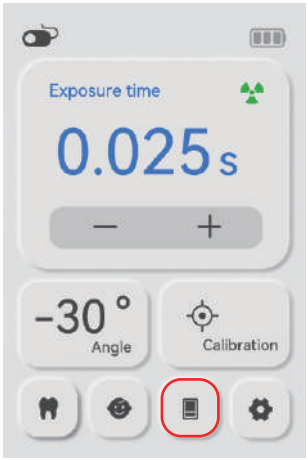


Figure 14 Control panel

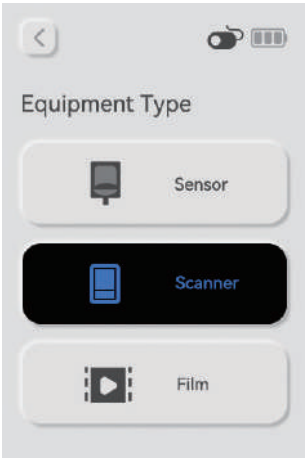


Figure 15 Equipment selection interface

2. Human Body Mode

After selecting the equipment mode, you should select the group mode. Click Figure 16 first, and then click the group selection icon to button back and forth between adult/child mode. You can select different group modes according to the patient's age. After successful selection, the corresponding option will be displayed in the group mode area.

Figure 16 Control panel

Figure 17 Child

Figure 18 Adult

Note: When setting the exposure parameters, please consider the patient's age, body size, and clinical indication, etc.

3. Tooth Type Mode

Click the tooth type selection icon shown in Figure 19 to display the interface as shown in Figure 20, and select the tooth type to be photographed. After successful selection, the icon will be displayed in blue on black background.

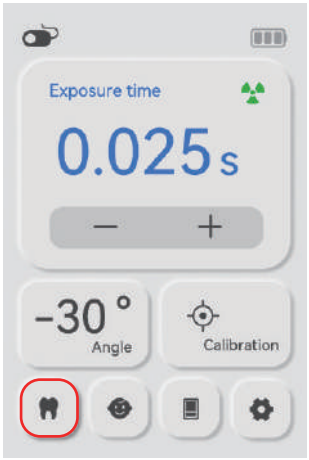


Figure 19 Control panel

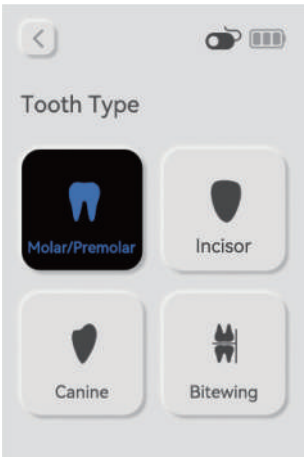


Figure 20 Tooth type selection interface

5.4.2 Settings

Click the settings icon framed in red in the Figure 21 to enter the setting interface, where you can set different languages, restore factory settings and view equipment information, as shown in Figure 22. Restore factory settings can restore the exposure time in all modes to factory default values.

Figure 21 Control panel

Figure 22 Settings interface

5.4.3 Exposure Time Setting

If you want to change the exposure time, click the "-" or "+" button to adjust the exposure time from 0.02 seconds to 2 seconds. After adjustment, it is automatically saved as the default time in the current mode.

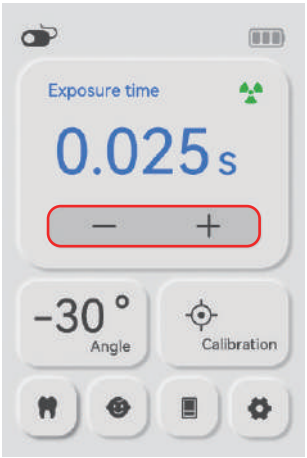


Figure 23 Exposure time setting

5.4.4 Exposure Guidance

As an intra-oral dental X-Ray system, the Master 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 exposure, the operator should hold the device, aim the output port of the beam limiter at the patient's part where the image needs to be acquired, and shoot at a distance of 0-3cm from the skin of the patient's exposure part.

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

Note: When exposure, 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 exposure, 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. After confirming the selected group, tooth type, device, and exposure time, press/hold the exposure button or other exposure button to enter the pre-exposure interface when the device ready state indicator icon is green.

Ready state icon	State
	Not ready
	Ready

2. In pre-exposure interface, the pre-exposure countdown and real-time angle will be displayed on the screen (you can return to the main interface through the back button on the screen).

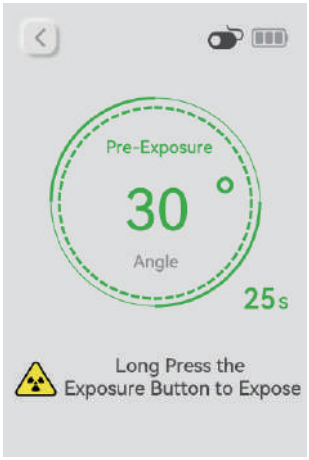


Figure 24 Pre-exposure interface

3. In the ready state, long press the exposure button or other exposure buttones, and the device will make exposure and give a prompt on the screen with a long beep sound.

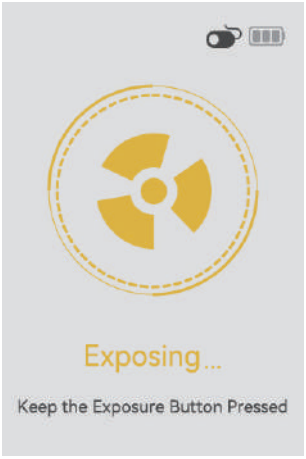


Figure 25 Exposing interface

4. The beep sound stops and the completion interface pops up, indicating that the exposure has been completed.

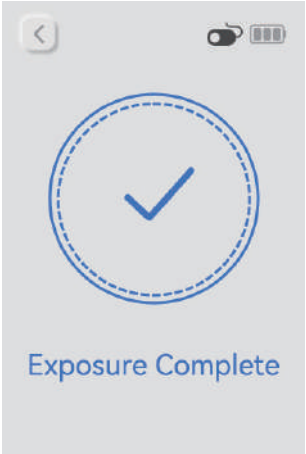


Figure 26 Interface of exposure completion

5. A period of cooling is required after the exposure is completed.

Figure 27 Cooling countdown interface

5.4.6 Image Receiver

The image receiver may be: imaging plate, sensor. The quality of the captured image should be at least 1080PPI. As a medical device, X-Ray image receiver should meet the relevant requirements of local medical devices.

5.5 Use of Battery

5.5.1 Battery Parameters

Model: 18650*3 10.8V 2500mAh 27Wh R

Specifications: 10.8V 2500mAh

5.5.2 Charging

1. The battery indicator icon of the remaining power will be showed on the screen. When it is running out of battery power, the battery needs to be recharged.
2. Connect one end of the charger to the charging port of the device and the other end to the power supply network (100-240V ac, 50/60Hz);
3. When charging, the charging icon displayed by the device will turn green, and when charging is completed, the charging icon will be full;
4. On the screen lock interface, the charging icon will turn green, and when the charging is completed, the charging icon will be full;
5. Please disconnect the power supply and charger when charging is complete;
6. The single charging time is about 1 hour.

5.5.3 Battery Maintenance

1. When the device is not in use, turn off the power button to save electricity;
2. Use the charger provided by the original factory for charging;
3. When the battery is not used for a long time, it should be separated from the device and charged every three months;
4. Keep the battery icon displaying at least one grid. In case of insufficent remaing battery, charge the battery immediately;
5. Avoid long-term single charging for more than 12 hours.
6. Avoid exposing the battery to high temperature or fire, and avoid direct sunlight when storing.

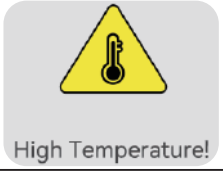
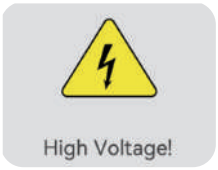
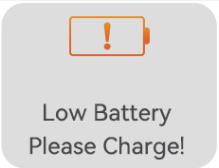
Note: If the user needs to replace the battery, he/she should contact the company or its authorized distributors to replace it, otherwise the company will not be responsible for the serious consequences.

6 Troubleshooting

This device can prompt seven kinds of known faults. In case of abnormality, the screen displays the characters of fault codes of the types shown in Table 4 below, and the buzzer gives an alarm prompt:

Table 4 Fault Prompt

Faults	Causes	Solutions
	Press and hold the exposure button in the pre-exposure interface for less than 1s.	Short press the exposure button again, or click the back button on the screen, and wait for the warning to disappear before using it normally.

	In the process of exposure, release the exposure button without waiting for the completion of exposure.	Short press the exposure button again, or click the back button on the screen, and wait for the warning to disappear before using it normally.
	Device temperature is too high	Use the device after cooling.
	Tube voltage is too high	Restart the device. If the fault still exists, please contact the manufacturer.
	Exposure when charging	Normal exposure after unplugging the power adapter.
	Excessive current	Restart the device. If the fault still exists, please contact the manufacturer.
	Low battery	Plug in the power adapter and reuse the device after charging.

If the above methods can't eliminate the fault, please contact the distributor and return the device for handling. Do not try to open the shell of this device and repair it yourself.

6.1 Notes

1) Do not use this device when charging.
2) No maintenance is carried out during the operation of the device.

3) The device has residual radiation, so it is suggested to increase protective measures.

4) The dropping of device may cause product damage. If the device falls or is suspected of unknown damage, please contact the manufacturer to check the device, and do not try to disassemble it for maintenance.

5) Please use the image receiver that meets the company's operation requirements. If use the image receiver with low resolution or the one that does not meet the relevant requirements of local medical devices, the image quality may be affected, image blur may occur and finally affects the clinical judgment.

6) Children and pregnant women must consult a doctor before exposure.

7 Cleaning and Maintenance

Note: In the process of use, it is forbidden to maintain the device. The power adapter, power cord, exposure hand brake, hand brake connecting wire and battery of this device are all replaceable parts. If they are damaged, please contact an authorized dealer or manufacturer that complies with local regulations to repair or replace the parts, otherwise it may damage the device or affect its safety performance. Before using this device for the first time, a complete cleaning procedure must be performed. Before each cleaning and disinfection, the power supply of the Dental X-Ray Generator should be cut off.

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 Maintenance

a) Wet the clean soft cloth completely with 75% alcohol, wipe the surface for 3 times. Wipe for 30 s each time.

b) 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.

c) Use a dry water absorbent sterile cloth to wipe off the residual water on the test sample.

Note: Do not use the following disinfection methods

a) Do not use hard tools to clean, so as not to cause wear and tear;

b) Do not use organic solvents or corrosive cleaning products to clean Dental X-Ray Generator;

c) Do not spray cleaning agent directly on the Dental X-Ray Generator;

d) Do not use organic solvents or corrosive disinfectants to disinfect Dental X-Ray Generator;

e) Do not spray disinfectant directly on the Dental X-Ray Generator.

8 X-Ray Tube Specifications and Characteristics

Filament voltage: 2.4-3.0V
Maximum filament current: 2.9A
Filament frequency: DC/AC (0-20kHz)
Anode nominal input power: 600W (0.1s)
Target material: Tungsten
Anode heat capacity: 4500J
Anode maximum heat dissipation: 110W
Overall dimensions and wiring: As shown in Figure 28
Maximum rating: As shown in Figure 29
Thermal characteristics: As shown in Figure 30
Filament and emission characteristics: As shown in Figure 31

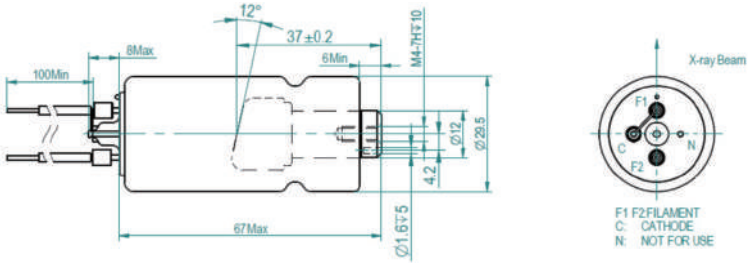


Figure 28 Overall dimensions

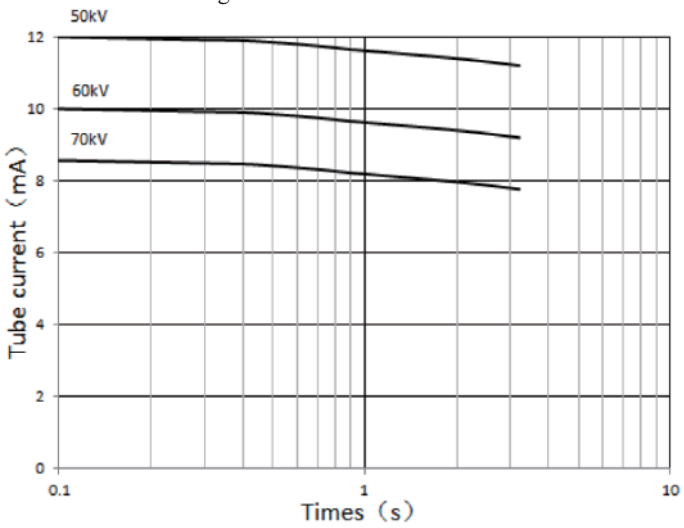


Figure 29 Maximum rating table (single)

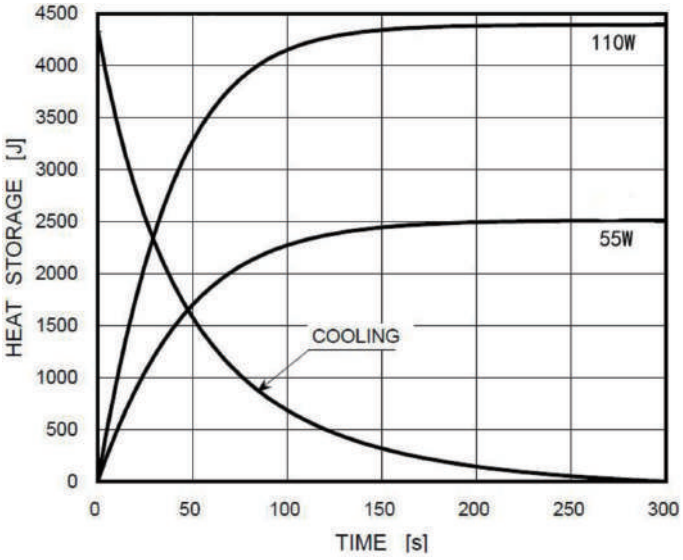


Figure 30 Anode heating and cooling curve of X-Ray tube

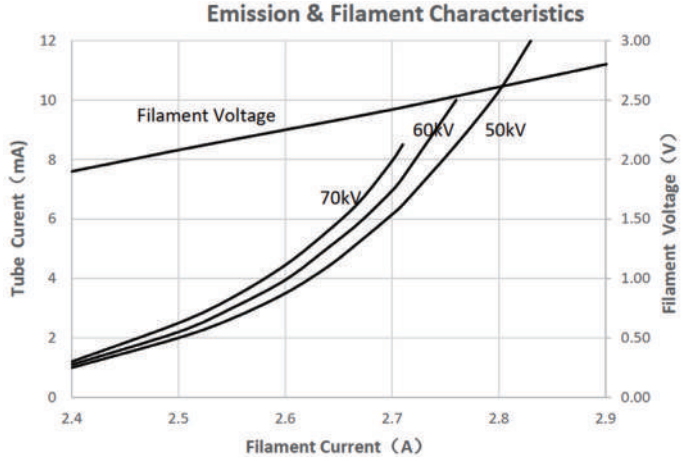


Figure 31 Filament and emission characteristic curve

9 Dimension Drawing of X-Ray Tube Assembly

9.1 Reference Axis, Dimensions, High Voltage Polarity of X-Ray Tube Assembly

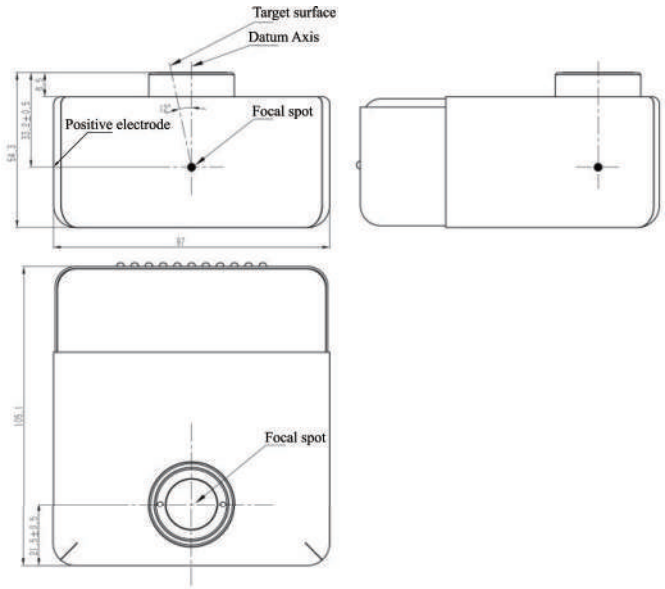


Figure 32 Dimensions of X-Ray tube Assembly

9.2 Electrical Connection Diagram of X-Ray Tube Assembly

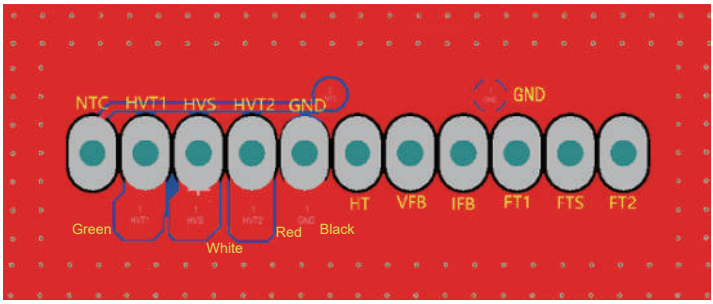


Figure 33 Electrical Connection Diagram of X-Ray Tube Assembly

HVT1 High voltage transformer terminal 1
HVT2 High voltage transformer terminal 2
NTC Temperature sampling resistor terminal
HVS High voltage transformer power supply
GND Power supply ground
HT Terminal of temperature protector
VFB High voltage feedback
IFB Current feedback
FT1 Terminal 1 of filament transformer
FTS Filament transformer power supply

FT2 Terminal 2 of filament transformer

10 X-Ray Source Assembly

10.1 X-Ray Source Assembly Dimensions

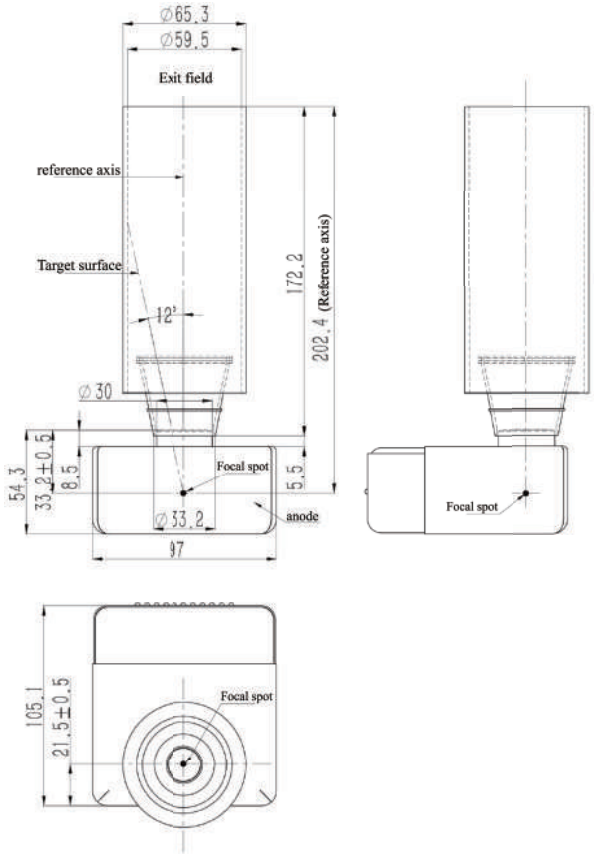


Figure 34 Dimension drawing of X-Ray source assembly

10.2 X-Ray Source Assembly

(1) Manufacturer: Guilin Woodpecker Medical Instrument Co., Ltd.
(2) Address: Guilin National High-tech Zone Information Industrial Park
(3) X-Ray source assembly model: Smart Ray-01
(4) X-Ray tube assembly target angle: 12°
(5) Total filtration: 1.5mmAl/70kV
(6) Permanent filtration: 1.0mmAl/70kV
(7) Nominal value of focal spot: 0.4 mm

11 Radiation Protection

11.1 Radiation

1) Dose area radiation

Dose area radiation is shown in the following figure. You can look up the dose area corresponding to X-Ray radiation received by human body in the table and find out the value at the corresponding time (ms).

Table 5 Test conditions
(20cm away from the Focal spot of the tested tube)

Exposure time (ms)	Dose value (μGy)	Area (mm²)	Dose area radiation (μGy*mm²)
20	48	2387	114576
25	60	2387	143220
32	80	2387	190960
40	102	2387	243474
50	130	2387	310310
63	165	2387	393855
80	210	2387	501270
100	262	2387	625394
125	328	2387	782936
160	418	2387	997766
200	512	2387	1222144
250	644	2387	1537228
320	818	2387	1952566
400	1018	2387	2429966
500	1266	2387	3021942
630	1589	2387	3792943
800	2013	2387	4805031
1000	2510	2387	5991370
1250	3132	2387	7476084
1600	4003	2387	9555161
2000	4995	2387	11923065

2) Dose indication

Under the conditions of 70kV and 2mA, the distance between the test point and the focal spot of the X-Ray tube is 24cm, and the dose area radiation test is carried out. When selecting the corresponding exposure time, the deviation of the measured dose area radiation does not exceed 50% of the value in the table. Dose area radiation is equal to the air coefficient multiplied by the area irradiated by radiation.

3) Radiation residue

There will be residual radiation after using the device. To avoid unnecessary injuries, please wear protective appliances or stay away from the device when using it.

11.2 Protection Requirements

In addition to direct beams, there are two other possibilities for potential exposure from Dental X-Ray Generator:

Radiation leakage and stray radiation from patients/subjects in direct beams.

1) Leakage

The internal shielding layer of the device encases the X-Ray source assembly, and there is also shielding protection in the path of the X-Ray beam. Therefore, this device is safe to be used as a handheld device during irradiation.

To verify compliance with regulatory requirements for radiation leakage, each device is tested at 12 points on the device's casing using calibrated measuring instruments, as shown in the diagram below. The highest measurement among these 12 points must be below 0.25mGy/hr, as stipulated by IEC regulations, to pass the product shipment test successfully.

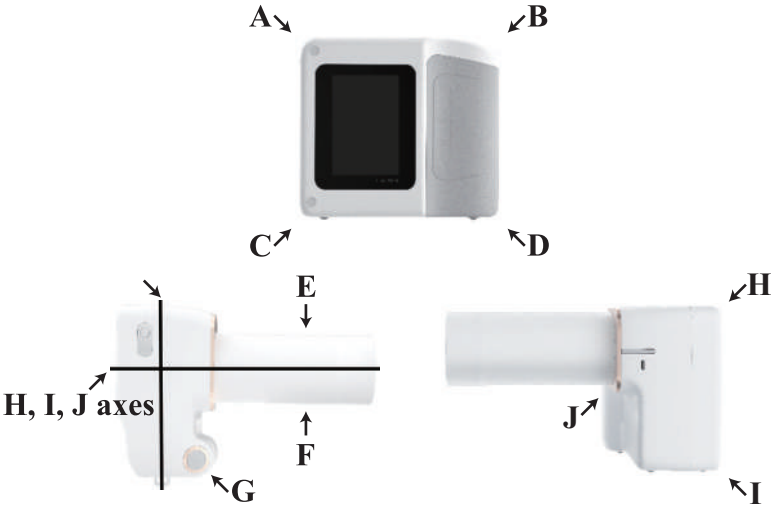


Figure 35 Leak radiation test site

2) Effective occupied area

The operator shall designate an effective occupied area in the place of use, with the floor size of 60cm×60cm and the height of 200cm. During operation, the focal spot should keep a distance of about 10cm from the effective occupied area, as shown in the following figure:

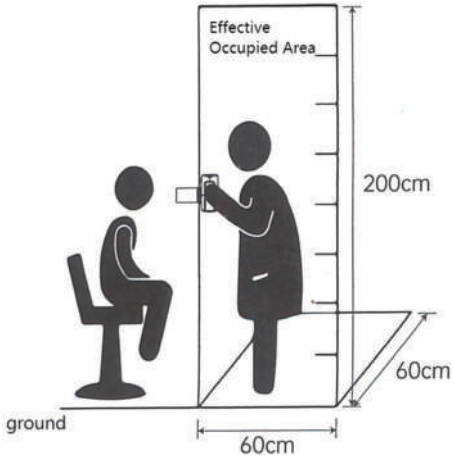


Figure 36 Effective occupied area

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 distribution map of stray radiation is as follows:

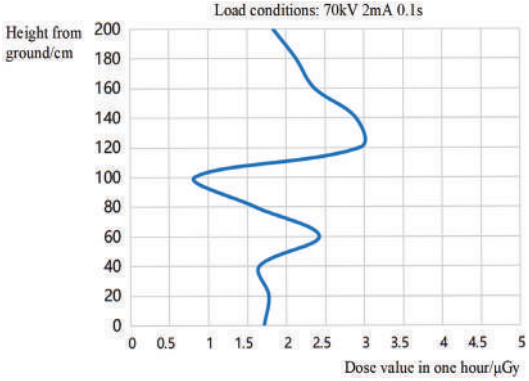


Figure 37 Distribution of Stray Radiation

When measuring stray radiation, the focal spot is 1m from the ground and 0.2m from the middle of the effective occupied area.

3) Operator protection

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

12 Storage, Maintenance and Transportation

12.1 Storage/Maintenance

1) This device should be handled with care, away from the earthquake

source, and should be installed or stored in a cool, dry and ventilated place.
2) Do not mix this device with toxic, corrosive, flammable and explosive articles when storing it.
3) The device shall be stored in an environment with relative humidity of 10% -93%, atmospheric pressure of 70kPa ~ 106kPa and temperature of -20 ℃ ~ + 55 ℃.
4) Check the device for scratches, abrasion and other mechanical abrasions or damages after each use.

12.2 Transportation

1) Excessive shock and vibration should be prevented during transportation, and the device should be handled with care to avoid inversion.
2) It should not be mixed with dangerous goods during transportation.
3) Avoid exposure to sunlight, rain and snow during transportation.

13 Environmental Protection

This device cannot be disposed of as household waste, and should be placed in a special recycling place for waste electronic medical appliances. For more details about disposal and recycling, please contact your local dealer.

Table 6

Component name	Toxic and harmful substances or elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr6+)	Polybrominated biphenyl (PBB)	Polybrominated diphenyl ether (PBDE)
Power Adapter	○	○	○	○	○	○
Main unit	/	○	○	○	○	○
Mechanical components, including screws, nuts, washers, etc.	○	○	○	○	○	○

○: It means that the content of the toxic substance in all homogeneous materials of the component is below the limit requirements specified in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.
×: It means that the content of the toxic substance in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/ T-11363-2006.
(This product meets EU RoHS environmental protection requirements; At present, there is no mature technology in the world to replace or reduce the lead content in electronic ceramics, optical glass, steel and copper alloys.) According to the Administrative Measures for Restricting the Use of Hazardous Substances in Electrical and Electronic Products, the Administrative Regulations on the Recycling and Disposal of Waste Electrical and Electronic Products and related standards, please observe the safety and precautions of the products, and recycle or dispose of the products in an appropriate way according to local laws and regulations after the products are used.

14 Electromagnetic Compatibility

For this device, special precautions should be taken for electromagnetic compatibili-

ty (EMC), and it must be installed and used according to the EMC information specified in this manual. Portable and mobile RF communication equipment may have an impact on this device. The following cables must be used to meet the requirements of electromagnetic emission and anti-interference:

Table 7

Name	Cable length	Whether to shield or not	Remarks
Direct current cable	1.5m	No	/
Power adapter connecting cable	1.2m	No	/
Exposure hand brake connecting cable (optional)	8.0m	No	/

In addition to cables (transducers) sold as accessories of internal components, the use of accessories and cables (transducers) outside the regulations may lead to an increase in emission of device/systems or a decrease in immunity.

Device or system should not be used close to or stacked with other devices. If it must be used close to or stacked, it should be observed and verified that it can operate normally under the configuration it uses.

Basic performance: Under the electromagnetic interference, the product can be exposed.

1) Accuracy of loading factors (including accuracy of X-Ray tube voltage and exposure time)

2) Repeatability of radiation output

14.1 Guidelines and Manufacturer's Statements--Electromagnetic Emission

Table 8

Guidelines and manufacturer's statements-electromagnetic emission		
The Dental X-Ray Generator is expected to be used in the specified electromagnetic environment below. The buyer and/or user shall ensure that it is used in this 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	

14.2 Guidance and Manufacturer's declaration--electromagnetic Immunity

Table 9

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 ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 25/30 cycles <5% U_T (>95% dip in U_T) for 5 sec	<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 25/30 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Smart Ray requires continued operation during power mains interruptions, it is recommendedthat the model Smart Ray is 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.			

14.3 Guidance and manufacturer's declaration-electromagnetic immunity

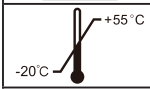
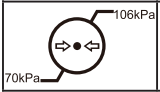
Table 10

<table>
<tr><td colspan="4">Guidance & Declaration - Electromagnetic immunity</td></tr>
<tr><td colspan="4">The models Master Ray and Smart Ray are intended for use in the electromaggnetic environment specified below. The customer or the user of the models Master Ray and Smart Ray should assure that they are used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test leve</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz
6 Vrms in ISM bands & amateur radio bands</td><td>3 Vrms
150 kHz to 80 MHz
6 Vrms in ISM bands & amateur radio bands</td><td rowspan="2">Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Master Ray and Smart Ray, including cables specified by the manufacturer. Otherwise,degradation of the performance of this equipment could result.If higher IMMUNITY TEST LEVELS than those specified in Table 9 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the following equation:
$d=(6\times P^{1/2})/E$
Where P is the maximum power in W,d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.If the Master Ray and Smart Ray complies with higher IMMUNITY TEST LEVELS for this test,the 30cm minimum separation distance may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>10 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 +A1:2020)</td><td>10 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 +A1:2020)</td></tr>
</table>

Warning:

Unauthorized changing or modification of equipment without the consent of Guilin Woodpecker Medical Instrument Co., Ltd. may lead to electromagnetic compatibility problems of this device or other equipment.

15 Symbol Description

	Manufacturer		Serial number
	Warning		Product number
	Class II equipment		Ordinary equipment
	Storage conditions, temperature range -20℃ ~ +55℃		Recovery
	Storage conditions, humidity range - 10% ~ 93%		Type B applied part
	Storage conditions, atmospheric range -70 kPa ~ 106 kPa.		Electrostatic Sensitive devices
	Avoid sunlight		Danger! High voltage
	Follow the manual		Handle with care
	Date of production		X-Rays, beware of ionization radiation.
	Exposure and power switch of the exposure hand brake		Exposure button
	Exposure button of the wireless exposure hand brake		Do not place the device on a slope greater than 5 degrees
	Medical Device		Keep dry
	Prescription device		Standby button
	WEEE mark Please deal with the waste produced by the device following relevant laws and regulations.		

16 Special Explanation

Please refer to the product packaging label for the date of production, and the period of service: 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 selfcare 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 Generator, the image quality of the handheld Dental X-Ray Generator 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 Smart Ray materials and components must be properly disposed of according to local requirements, or returned to an authorized distributor. At the end of their service life, return these items to authorized distributor for proper disposal or recycling.

18 After-Sales Service

If the device fails to work normally due to quality problems since the date of sale, our company will be responsible for the maintenance with the warranty card. Please refer to the product warranty card for the warranty period and scope. This product does not contain spare parts for self-maintenance. The maintenance of this device should be carried out by designated professionals or special repair shops.

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

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

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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.
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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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