MD CE 0197

Master Ray Dental X-Ray Generator Instruction Manual

Please carefully read this manual before operating.

ZMN-SM-967 V1.0-20240606

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 device correctly and safely.

Contents

1. Product introduction

1.1 Product introduction

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

Features of this device:

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

1.2 Model

Master Ray

1.3 Configuration

Device configuration is detailed in packing list.

1.4 Software title and version

Master Ray V1

1.5 Structure and components

This product is mainly composed of X-Ray tube, control system, exposure handbrake, Wireless exposure hand brake, battery, power adapter, lanyard (non-removable), Backscatter Shield (Optional) and beam limiting device.

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 device safety classification

1. Type of operation mode: Non continuous operation mode(2:120)
2. According to the type of electric shock prevention:

When charging, it is connected to the power supply network and belongs to Class II ME device;

When operating, it is not connected to the power supply network and belongs to internal power supply ME device.

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 device (IPX0)
5. Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: device 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, 1.1A
2. Internal power supply: DC 10.8V
3. Types of radiation: X-ray
4. Electric power:
Maximum power: 0.14kw (70kV, 2mA, 0.1s)
Nominal electric power: 0.14kw (70kV, 2mA, 0.1s)
5. Tube voltage: tube voltage output is fixed at 70kV, error ±10%
6. Tube current: tube current output is fixed at 2mA, error ±20%
7. 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)
8. X-ray tube
a) X-ray tube model: D-045
b) Focal spot: 0.4mm
c) Target angle: 12.5°;
d)Target material: Tungsten
e) Total filtration: 1.5mmAl/70 kV
f) Permanent filtration: 1.2mm Al/70kV
g) Additional filtration: 0.3mmAl/70 kV
9. Distance from focal spot to skin: 20~23cm
10. Output radiation field: Φ5.9cm±0.1cm
11. Product specifications
Dimension: 240mm×161mm×143mm
Weight: 2.1KG
12. Battery specification: 18650×3 10.8V 2500mAh 27Wh R
13. Exit field sized: Φ5.9cm±0.1cm
14. Reference LOADING conditions: 70kV, 2mA, 2s, loading interval 2s/120s, 29 exposures per hour.
15. Radiation output stated :the variation coefficient under the function less than 5%.
16. Under the reference condition (70kV, 2mA, 2s) of this device, the leakage radiation value of the accessible surface (excluding the X-ray outlet) shall not exceed 0.05mGy/h. Leakage radiation loading factor: 2s/120s.
It is recommended to entrust a qualified testing institution to conduct a status test for items 5, 7, 8.a) and 16 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

Applicable: Hospital or dental clinic.
Inapplicable: Not suitable for use in operating rooms, MRI, CT and other environments where HF surgical device is present.
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 device, such as an apron and thyroid collar.

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. Matters Needing Attention

3.1 The Master 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 Master 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 Master 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 device 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 device 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 device nearby may be affected during the use. There is a risk of malfunction of nearby device.
3.17 Due to electromagnetic compatibility, the use of other device 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 Master Ray Dental X-Ray Generator;

B. Device specific features and instructions: The Master 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

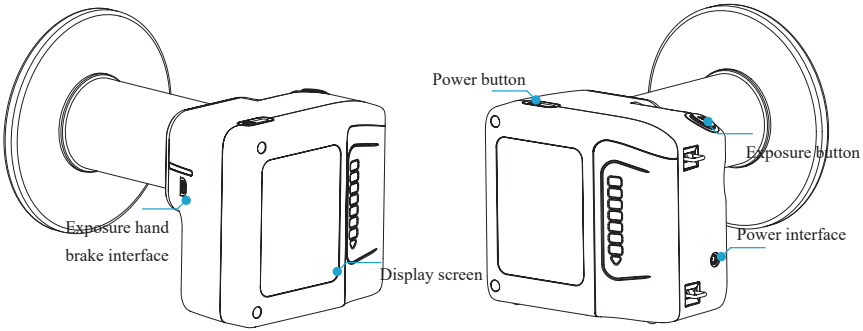


Figure 1 Schematic diagram of dental X-Ray Generator

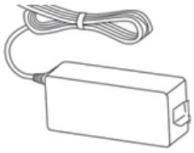
When remotely controlling the device's exposure via a hand brake cable,

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.

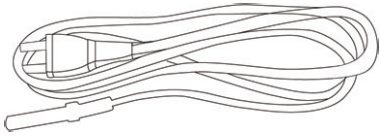
4.2 Accessories installation

4.2.1 Packaging Accessories

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

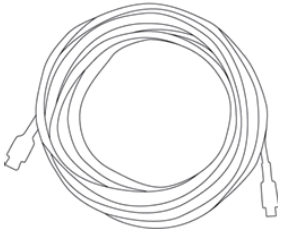


Power adapter



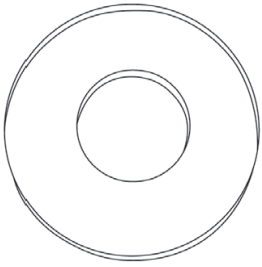
Power adapter connecting cable

Wired exposure hand brake (optional)



Hand brake connecting cable (Optional)

Wireless exposure hand brake (optional)



Backscatter Shield (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:

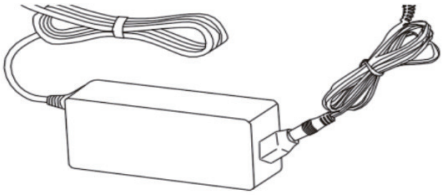


Figure 2 Power adapter

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

4.2.3 Exposure handbrake

Figure 3 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:

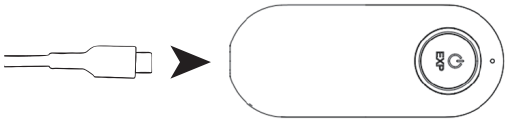


Figure 4 Exposure hand brake connecting cable

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

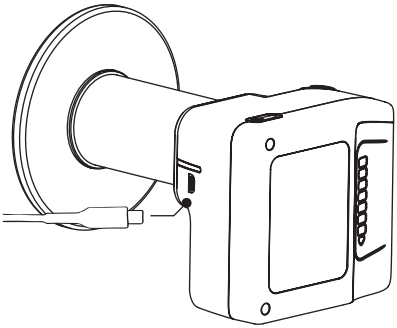


Figure 5 Connect exposure hand brake to host

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

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

④ The Hand brake connecting cable is 8 meters long.

4.2.4 Wireless exposure hand brake

Figure 6 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 Backscatter Shield

The backscatter shield is used to prevent backward scattered radiation, providing additional protection for the operator, with a lead equivalent of 0.3mmPb.

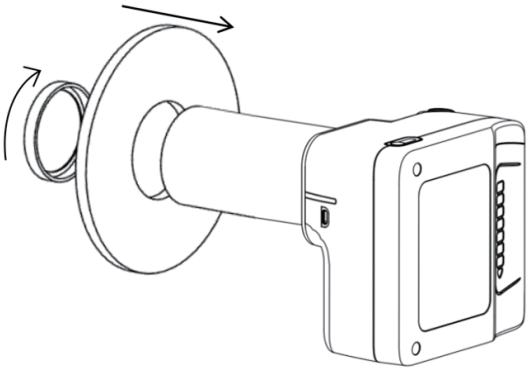


Figure 7 Backscatter Shield

Note: Please avoid dropping the Backscatter Shield, as it may cause damage.

4.3 Available Accessories

The Product is HAND-HELD or can be installed on fixed bracket.The fixed bracket need to be purchased. The safe load capacity of the fixing bracket needs to be 8kg.

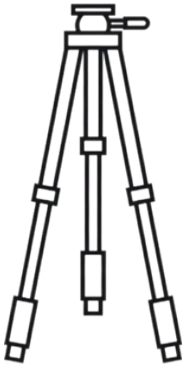


Figure 7 fixed support

4.4 Functions of the control panel

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

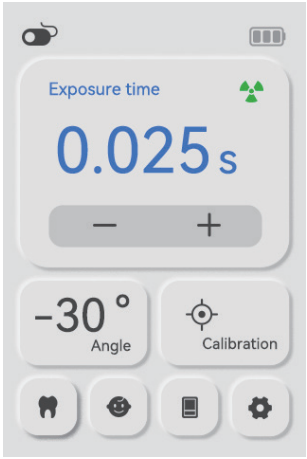


Figure 8 Control panel

Table 1

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/ child

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 exposure angle
8		Display of X-ray exposure time
9		X-ray machine exposure status (gray: Not ready, green: Ready)
10		Time setting of X-ray exposure , “-” decreases time of exposure , “+” increases time of exposure

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

5.1 Preparation before exposure

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

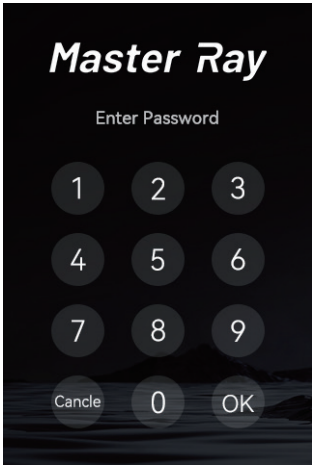


Figure 9 Password input interface

2. Check the battery of the device to ensure the normal operation of the device;

3. Select the human body, tooth position and the device mode;

4. Adjust the exposure time. The system has a default exposure time, or adjust the exposure time as required;

5. Prepare film or image plate scanner (IP image plate) or Digital Intraoral X-ray Imaging System (sensor).

5.2 Exposure images

1. A high-quality device 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 device of image receptor is facing the tooth;

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 finished and the image is taken successfully, remove the device of image receptor from the patient's mouth.

5.3 Exposure angle

5.3.1 Photograph angle reference values

Keep the patient in the correct sitting position and adjust the correct exposure 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 2

Tooth position	X - ray inclination direction	Angle of inclination
Maxillary incisor position	Downward	+42°
Maxillary single canine position	Downward	+45°
Maxillary bicuspid and first molar	Downward	+30°
Maxillary second and third molars	Downward	+28°
Mandibular incisor position	Upward	-15°
Mandibular single canine position	Upward	-18°~-20°
Mandibular bicuspid and first molar	Upward	-10°
Mandibular second and third molars	Upward	-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 device, tooth positions and human bodies are selected, the control panel automatically displays the exposure time.

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 3 Exposure time reference

Device	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) Receiving device Mode

Click the device selection icon shown in the box in Figure 10 to enter the device interface as shown in Figure 11. Select the required device of image receptor, and the corresponding area of the device is displayed in blue. After the selection is successful, it will automatically exit to the interface in Figure 10, and the device selection icon will change to the corresponding device icon.

Figure 10 Click the device selection icon

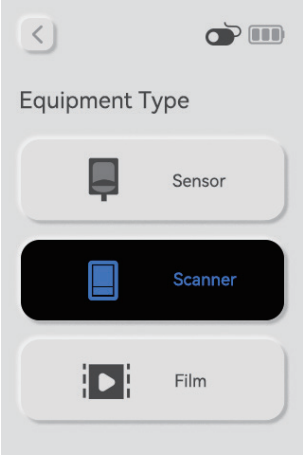


Figure 11 device selection interface

2) Human Body Mode

After selecting the device mode, select human body mode. Click the human body selection icon shown in the box in Figure 12 to button 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 12 Click the human body selection icon

Figure 13 Child

Figure 14 Adult

3) Tooth Position Mode

Click the tooth position selection icon shown in the box in Figure 15, enter the interface of the tooth position as shown in Figure 16. 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 15, and the tooth position selection icon will change to the corresponding tooth position icon.

Figure 15 Control panel

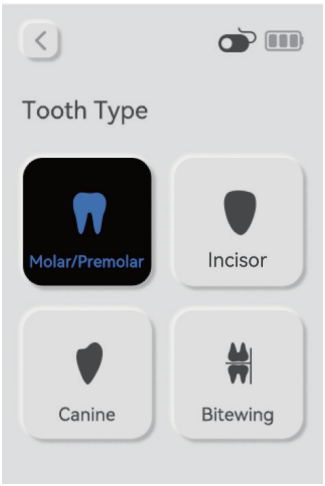


Figure 16 Tooth position selection interface

5.4.2 Setting function

Click the settings icon framed in red in the Figure 17 to enter the setting interface, where you can set different languages, restore factory settings and view device information such as host software version and screen software version, as shown in Figure 18. Restore factory settings can restore the exposure time in all modes to factory default values.

Figure 17 Click the setting icon

Figure 18 Settings interface

5.4.3 Setting of exposure time

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.

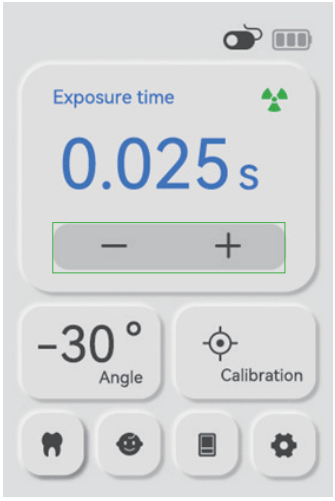


Figure 19 Setting of exposure time

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 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 exposure site.
Note: The device should be kept still when exposure, otherwise the captured image will be blurred or dislocated, 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.

Table 4

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 20 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 21 Exposing interface

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

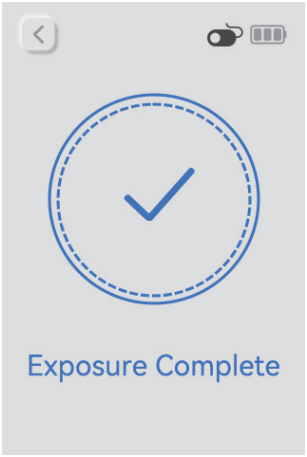


Figure 22 Interface of exposure completion

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

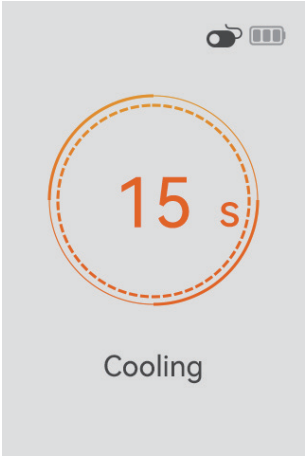


Figure 23 Cooling countdown interface

5.4.6 Image receiving device

Recommended image-receiving devices include: DÜRR and ACTEON Imaging Plate, Woodpecker and VATECH sensors. 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

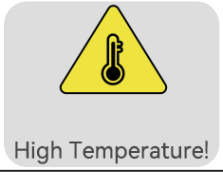
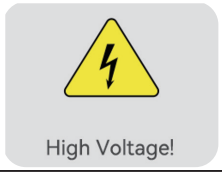
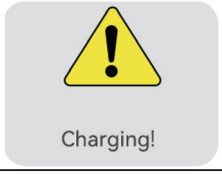
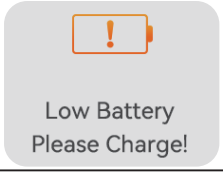
5.5.1 Battery Parameters

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

Table 5 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 not eliminate the fault, please contact the distributor to return the device to the manufacturer for handling. Do not try to open the casing 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. Maintain maintenance

Note: Maintenance and servicing of the device 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 device or affect the safety performance of the device.
Before the first use of this device, 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

Dental X-ray generator is for multiple use and suitable for manual cleaning and disinfection.The main unit enclosure surface will come in contact with the operator's hands. The following steps are for cleaning and disinfecting the enclosure.
(1) Wet the soft cloth completely with purified water, and wipe the enclosure 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.

(2) Wet the clean soft cloth completely with 75% alcohol, wipe the enclosure surface for 3 times. Wipe for 30 s each time.
(3) Wet the clean soft cloth completely with sterile water, wipe the surface of the enclosure thoroughly for 3 times. Wipe for 30 s each time, to remove the residual disinfectant on the surface.
(4) Use a dry water absorbent sterile cloth to wipe off the residual water on the enclosure.
Caution: Do not use the following methods of disinfection
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 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
Filament frequency: DC/ AC (0-20kHz)
Nominal anode input power: 600W (0.1s)
Target material: Tungsten
Anode heat capacity: 4500J
Maximum anode heat dissipation: 110W
Overall dimension and wiring: as shown in Figure 24
Maximum rated value: as shown in Figure 25
Thermal characteristics: see Figure 26
Filament and emission characteristics: see Figure 27

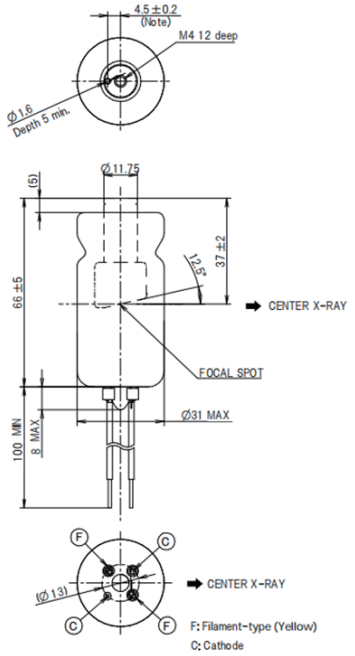


Figure 24 Mechanical dimension machine wiring

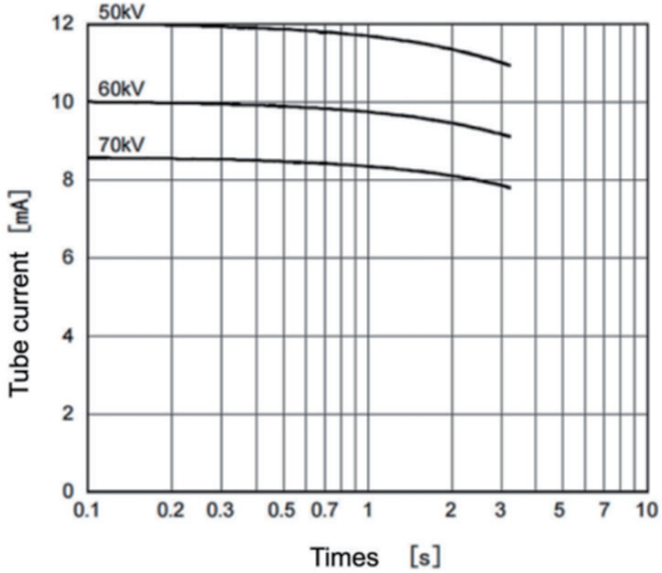


Figure 25 Maximum rating diagram

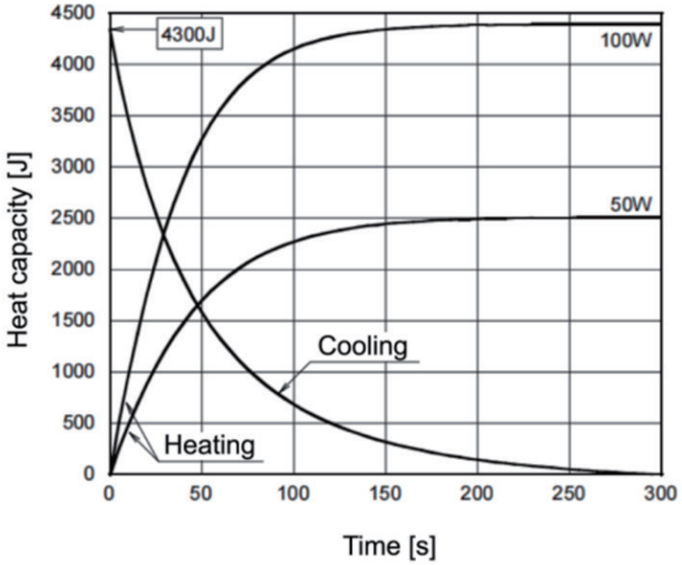


Figure 26 X-ray tube anode heating and cooling curve

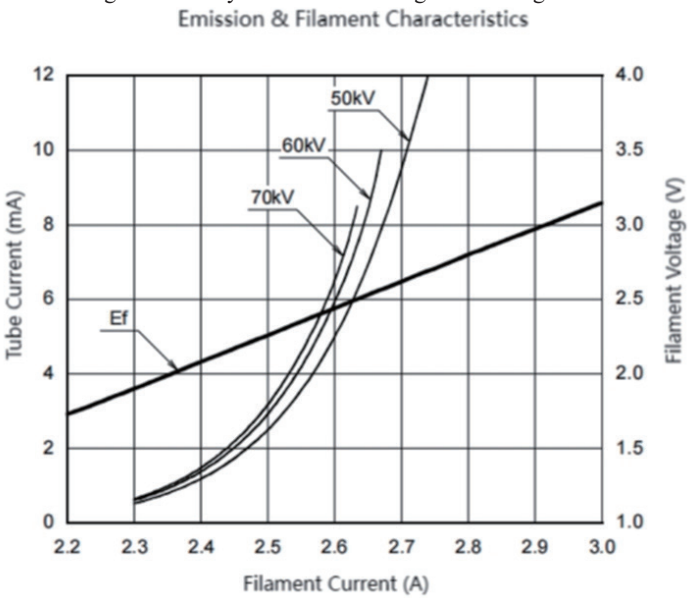


Figure 27 Filament and emission characteristic curve

9. Dimension Drawing of X-Ray Tube Assembly

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

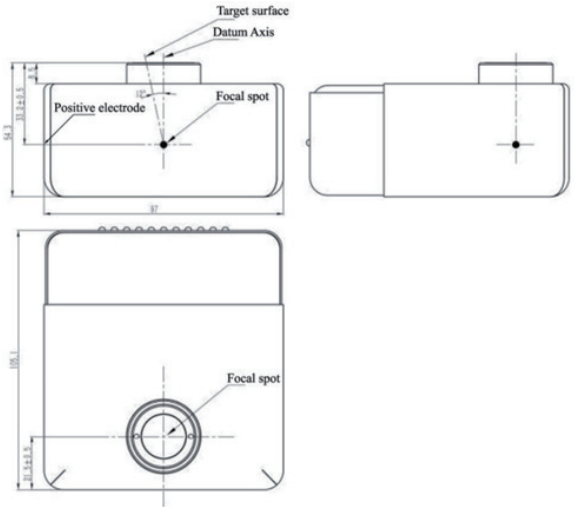


Figure 28 Dimensions of X-Ray tube Assembly

9.2 Electrical Connection Diagram of X-Ray Tube Assembly

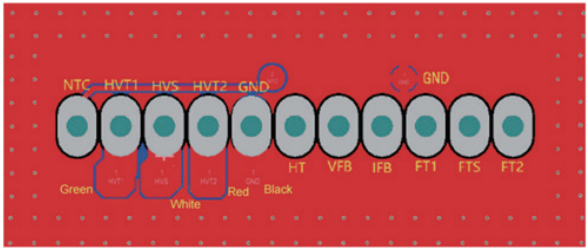


Figure 29 Electrical Connection Diagram of X-Ray Tube Assembly

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

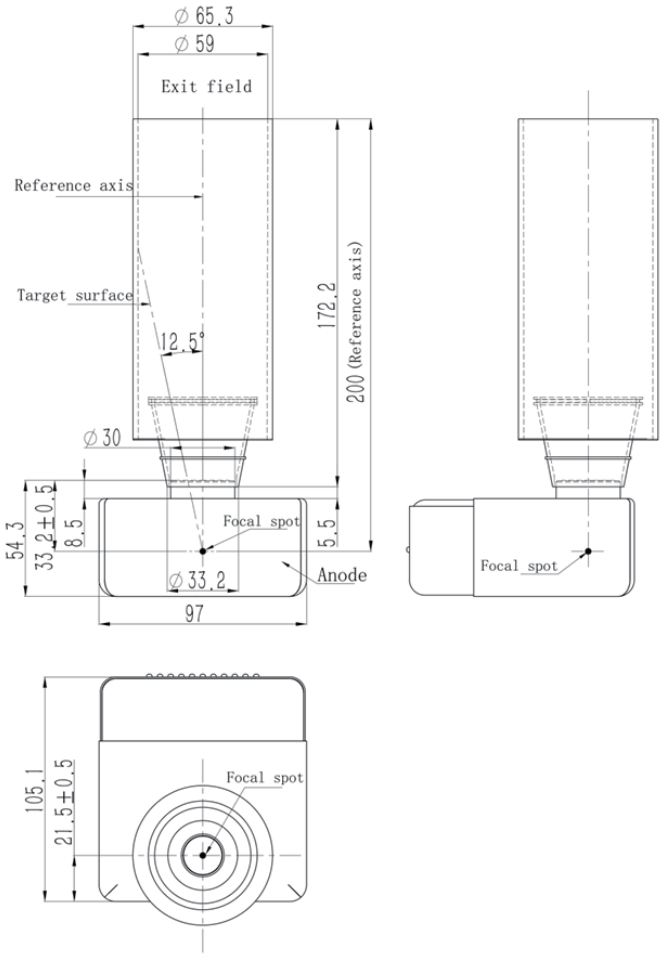


Figure 30 Dimension drawing of X-Ray source assembly

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: Master Ray-01
(4) X-Ray tube assembly target angle: 12.5°

(5) Total filtration: 1.5mmAl/70kV
(6) Permanent filtration: 1.2mmAl/70kV
(7) Nominal value of focal spot: 0.4 mm

11. Radiation and Protection

11.1 Radiation

1) dose area product

The dose area product is shown in the figure below. The dose 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). A mannequin is used to represent the patient in the test. Setting parameters such as receiving device, human body, dental position and exposure time will change the exposure time, resulting in the change of the dose received by the patient. When adjusting parameters, appropriate parameters should be set so that the patient can receive the appropriate dose. Too low dose will affect the imaging quality, which may result in repeated exposure, while too high dose will cause the patient to receive unnecessary radiation.

Table 6 Test conditions (20cm away from the focal spot of the tested tube)

Exposure time (ms)	Dose value (μGy)	Area (mm^2)	Dose area radiation ($\mu Gy*mm^2$)
20	45	2387	107415
25	58	2387	138446
32	75	2387	179025
40	96	2387	229152
50	122	2387	291214
63	152	2387	362824
80	192	2387	458304
100	240	2387	572880
125	298	2387	711326
160	381	2387	909447
200	473	2387	1129051
250	588	2387	1403556
320	748	2387	1785476
400	930	2387	2219910
500	1182	2387	2821434
630	1484	2387	3542308
800	1876	2387	4478012
1000	2342	2387	5590354
1250	2928	2387	6989136
1600	3745	2387	8939315
2000	4678	2387	11166386

2) Dose indication

Under the condition of 70kV, 2mA, the distance between the test point and the focal spot 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.

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 scattered 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 0.05mGy/hr, as stipulated by IEC regulations, to pass the product shipment test successfully.

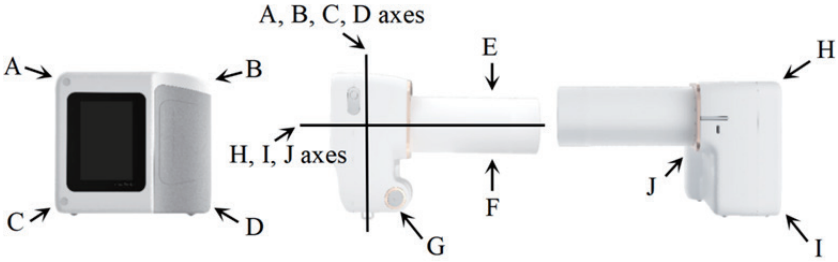


Figure 31 Leak radiation test site

2) 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 focal spot should be kept about 10cm away from the effective occupied

area, as shown in the following figure:

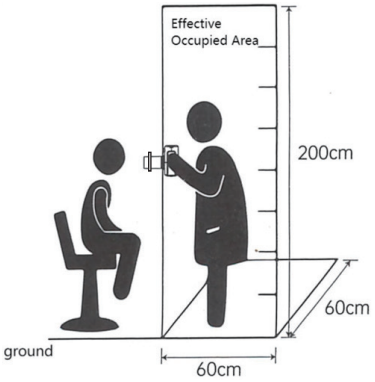


Figure 32 Effective occupied area

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:

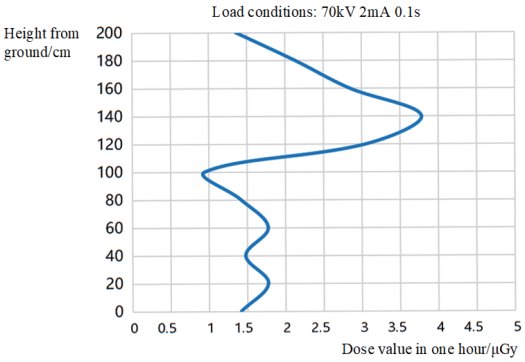


Figure 37 Distribution of Stray Radiation

When measuring the scatter radiation, the focal spot is 1meter above the ground and 0.2 meter outside the middle of limited occupied area, STRAY RADIATION not exceed 0.05 mGy in one hour.

3) Physical protection

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

12. Storage, maintenance and transportation

12.1 Storage/ maintenance

1) The device shall be handled with care, away from the earthquake

source, 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 device is not used for a long time, turn off the power button 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 ℃ ~ + 55 ℃.

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

12.2 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;

13. Environment protection

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

Table 7

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

Table 8

Name	Cable length	Shielded or not	Remark
DC cable	1.5m	No	/
Power adapter connecting cable	1.2m	No	/
Exposure handbrake connecting cable (optional)	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 device or system.

The device or system should not be used close to or stacked with other device. 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.

14.1 Guidance and manufacturer's declaration-electromagnetic emission

Table 9

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 device.
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 61000-3-2	Complied	

14.2 Guidance and manufacturer's declaration-electromagnetic immunity

Table 10

Guidance & Declaration — electromagnetic immunity			
The models Master Ray and Smart Ray are intended for use in the electromagnetic 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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) lEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for signal Input/output lines	±2kV for power supply lines ±1kV for signal Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge lEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV 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 5/6 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 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Master Ray and Smart Ray require continued operation during power mains interruptions, it is recommended that the models Master Ray and Smart Ray be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 is the a.c. mains voltage prior to application of the test level.			

14.3 Guidance and manufacturer's declaration-electromagnetic immunity

Table 11

Guidance & Declaration - Electromagnetic immunity			
The models Master Ray and Smart Ray are intended for use in the electromagnetic 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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF lEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	Portable RF communications device (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 device 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.
Radiated RF lEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication device (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication device (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	

Warning:

Without the explicit consent of Woodpecker, unauthorized changes or modifications to the device may cause electromagnetic compatibility problems of this device or other device.
Portable RF communications device should no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.

15. Symbol instruction

	Manufacturer	SN	Serial number
	Warning	REF	Product number
	Class II equipment	IPX0	Ordinary equipment
-20℃ +55℃	Temperature limit for storage: -20℃ ~ +55℃		Recovery
10% 93%	Humidity limit for storage: 10% ~ 93%		Type B applied part
70kPa 106kPa	Atmospheric pressure for storage: 70kPa ~ 106kPa		Electrostatic Sensitive devices
	Avoid sunlight		Danger! High voltage
	Follow the manual		Handle with care
	Date of production		X-Rays, beware of ionization radiation.
EXP	Exposure and power switch of the exposure hand brake		Exposure button
	Exposure button of the wireless exposure hand brake	>5°	Do not place the device on a slope greater than 5 degrees
MD	Medical Device		Keep dry

CE	CE marked product		Standby button
	WEEE mark Please deal with the waste produced by the device following relevant laws and regulations.	EC REP	EC REPRESENTATIVE

16. Warning

16.1 Do not use this device while charging;

16.2 Do not maintain and maintain the device during operation;

16.3 This device has residual radiation, it is recommended to add protection;

16.4 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;

16.5 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.

16.6 The use of the product should also comply with the relevant requirements of the local radiation safety management regulations.

16.7 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.

16.8 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.

16.9 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.

16.10 The most unfavorable ratio of exposure time to rest time is 1/60, such as exposure of 0.5s followed by rest of 30s, or exposure of 1s followed by rest of 60s. Of the exposure times that can be set, the exposure time of 2s has the greatest effect on the temperature rise. For example, continuous exposure at the most unfavorable exposure interval of 2s/120s, from full battery to low battery warning, the maximum surface temperature of the device will exceed 41℃, but not higher than 43℃. This temperature is safe when the contact time is less than 1min.

Note: Any serious incident that has occurred in relation to the device should be reported to manufacturer and the competent authority of the

Member State in which the user and/or patient is established.

17. Special Explanation

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.

18. Disposal

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

19. After-sales service

Since the date of sale, if the device 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 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
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

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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.
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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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