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桂林市啄木鸟医疗器械有限公司
Guilin Woodpecker Medical Instrument Co., Ltd.

MD

Mini Ray Dental X-Ray Device Instruction Manual

Please carefully read this manual before operating.
ZMN-SM-1121 V1.2-20260109

Guilin Woodpecker Medical Instrument Co., Ltd.

Preface

Thank you for purchasing the Dental X-Ray Device produced by Guilin Woodpecker Medical Instrument Co., Ltd. Woodpecker is a high-tech enterprise researching, developing, producing, and dental products sales company. Please read the full text of the instruction manual carefully to ensure that you can use the device correctly and safely

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1 Product introduction

1.1 Product introduction

This device is a portable Dental X-Ray Device used to photograph teeth and obtain dental image information.

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

Mini Ray

1.3 Scope of application

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

1.4 Contraindications

Pregnant women and young children should not be exposed to the environment for a long time when the product works.

1.5 Principles of operation

X-rays are emitted when high voltage is supplied to the X-ray tube assembly, which frees electrons from the cathode. They hit the Anode to produce X-rays. The device acquires images by emitting X-rays continuously on the human teeth.

1.6 Configuration

The device configuration is detailed in the packing list.

1.7 Software title and version

Mini Ray V1.0

1.8 Structure and components

This product is primarily comprised of an X-Ray tube, control system, exposure handbrake(optional), battery, power adapter, beam limiting device, Wireless exposure hand brake(optional), Backscatter Shield(optional).

1.9 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.

1.10 Primary technical parameters

1. Power adapter input:
Power adapter model: UES24LCP-150160SPA
Power input: 100-240V~ 50/60Hz 800mA

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 $\pm 10\%$
6. Tube current: tube current output is fixed at 2mA, error $\pm 20\%$
7. Loading time: the exposure loading time adjustment range is 0.02s~2s, the grade is adjustable, and the grade is selected according to the R10 numerical system; with deviation $\pm 5\%$ or $\pm 20\text{ms}$ which is larger
8. Filtration
 - a. Total filtration: $\geq 1.5\text{mmAl}$
 - b. Permanent filtration: 0.8mmAl
 - c. Additional filtration: 0.7mmAl
9. X-ray tube
 - a. X-ray tube model: KL11-0.4-70
 - b. Focal spot: 0.4mm
 - c. Target angle: 12°
10. Distance from focal spot to skin: $20.5 \pm 0.5\text{cm}$ (Please use the X ray alignment aid to ensure the distance between the focus and the skin is 20cm.)
11. Output radiation field: $\Phi 5.9\text{cm} \pm 0.1\text{cm}$
12. Product specifications
Dimension: 338mm $\times$ 112mm $\times$ 247mm
Weight: 2.2KG
13. Battery specification: 18650 $\times$ 3 10.8V 2500mAh 27Wh R
14. Exit field sized: $\Phi 5.9\text{cm} \pm 0.1\text{cm}$
15. Reference LOADING conditions: 70kV, 2mA, 2s, 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 condition (70kV, 2mA, 2s) of this device, the Leakage radiation value of the accessible surface (excluding the X-ray outlet) is not exceed 0.05mGy/h. Leak radiation loading factor: 2s/120s

1.11 Operation environment

Environment temperature: $10^\circ\text{C} \sim 40^\circ\text{C}$
 Relative humidity: 30% ~ 75%
 Atmospheric pressure: 70kPa ~ 106kPa

1.12 Transportation and storage condition

Storage temperature: $-20^\circ\text{C} \sim 55^\circ\text{C}$
 Transportation temperature: $-20^\circ\text{C} \sim 55^\circ\text{C}$
 Relative humidity: 10% ~ 93%
 Atmospheric pressure: 70kPa ~ 106kPa

2 Contraindication

Not found yet.

3 Warnings and Safety Instructions

This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. It is important

to read this user manual carefully and strictly abide by all warnings and cautions stated with in it.

3.1.1 This device is designed and manufactured to ensure maximum safety of operation. Operate and maintain it in strict compliance with the safety precautions and operating instructions .

3.1.2 The Dental X-Ray Device shall never be used in the presence of flammable anesthetic gas, pure oxygen or nitrogen oxide to avoid any risk of explosion.

3.1.3 The Mini 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. Patients and operators are advised to wear radiation protector (For example, the protective device has, protective clothing, protective baffle, protective mask, etc.) when taking X films. Try to use the Exposure hand brake to control the device and the distance from the Dental X-Ray Device no less than 2 meters.

3.1.4 Dental X-Ray Device 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.

3.1.5 The equipment complies with the IEC 60601-1 standard. Only peripheral equipment conforming to IEC 60950-1 can be connected to it so as to avoid any risk of failure of the Dental X-Ray Device.

3.1.6 Company specializes in the production of medical device. We are responsible for the safety of the device only when the maintenance, repair and modification of the device is 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. Please do not attempt to disassemble or modify the device. Unauthorized disassembly and modification may cause abnormal operation or direct damage to the device.

3.1.7 In order to ensure safe and correct operation and use of the Dental X-Ray Device, it is quite important to use the charger provided by the device. The power line of the Dental X-Ray Device can only be replaced by the same type of line.

3.1.8 Due to the electromagnetic compatibility of X-ray device, other device nearby may be affected during use of the device. There is a risk of malfunction of nearby device. During use, device sensitive to electromagnetic compatibility should be kept away;

3.1.9 Due to electromagnetic compatibility, the use of other device may interfere with that product's operation. During use, it should be kept away from the electromagnetic interference environment;

3.1.10 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.

3.1.11 After 30 minutes of inactivity, the device will automatically shut down. If you need to put the device back in the box for storage, please confirm that the device has been turned off.

The back scatter shield protects users from back scatter radiation that they might be exposed to during X-ray exposure. Operating the device with the back scatter shield allows the users to be exposed to less radiation compared to when operating without. If damaged or defective, contact your service representative for replacement.

3.2 Warnings and Safety Instructions

3.2.1 Safety Instructions

Table 1

Fault	Reason	Solution
 Warning: Please long press to expose, short press to exit this page	Hold down the exposure button for less than 1s	Please long press to expose, short press to exit this page
 Warning: High temperature!	The temperature of equipment is too high	Wait for the device to cool down. The warning will automatically disappear after the cooling is completed.
 Warning: High voltage!	The voltage of equipment is too high	Restart the device, if the fault still exists, please contact the manufacturer
 Warning: Overcurrent warning!	The equipment current is too large	Restart the device, if the fault still exists, please contact the manufacturer
 Warning: Insufficient battery, please charge!	Low batter power	Plug in the power adapter and use it after charging
 Please connect the locator	Location services have been enabled, but no positioning module has been detected.	Restart the device
 Auto exposure will activate 2 seconds after locating is complete. Use with caution!	Automatic Exposure Safety Notice	/
 Auto exposure	Auto Exposure Warning Activated	/

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.

3.2.2 Warnings

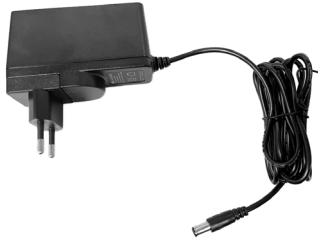
- 1) Do not use this device while charging.
- 2) Do not service and maintain the device during operation.
- 3) This device has residual radiation, it is recommended to add protection.
- 4) Dropping the device may cause damage to the product. If it is dropped or suspected of unknown damage.
- 5) Please contact the manufacturer to check the device, and do not attempt to disassemble it for repair.
- 6) Please use an image receiver that meets the Woodpecker operational 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, affecting clinical judgment.
- 7) Children and pregnant women must consult with a doctor before X-ray exposure.

4 Product installation and function description

4.1 Components

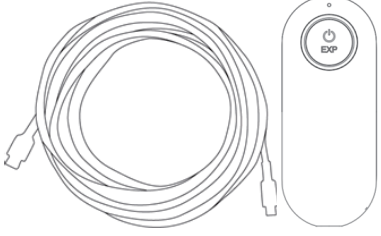
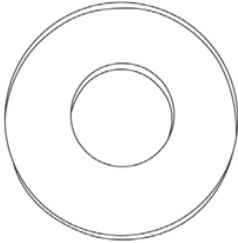
Table 2

NO	Item	Quantity
1	Power adapter	1
2	Connection cable of hand brake(optional)	1
3	Exposure hand brake(optional)	1
4	Wireless exposure hand brake(optional)	1
5	Backscatter Shield(optional)	1



Power adapter

Please use the provided power adapter to charge the device . Using other non-matching power sources may lead to device damage due to differences in voltage. And do not position me device to make it difficult to plug off the adapter.

 Exposure hand brake(optional)	Using a Connection cable of hand brake and hand brake, the device can be connected to enable control of exposure from a safer distance. This helps minimize the operator's radiation exposure from the X-ray device, thereby enhancing safety measures.
 Wireless exposure hand brake	Using a Connection cable of hand brake and hand brake, the device can be connected to enable control of exposure from a safer distance. This helps minimize the operator's radiation exposure from the X-ray device, thereby enhancing safety measures.
 Backscatter Shield(optional)	Using a Backscatter Shield can help reduce the scattered radiation from the X-ray device to some extent. When performing long-term hand held X-ray exposure work, it is recommended to install a Backscatter Shield to minimize the potential X-ray hazards.

4.2 Drawing of the exterior of the device

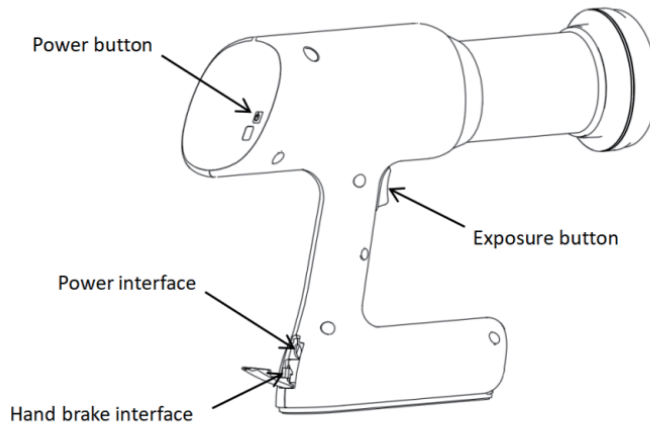


Figure 1 Schematic diagram of Dental X-Ray Device

Note: The Hand brake interface can only be connected to the hand brake using a hand brake cable and cannot be connected to other USB devices.

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 use the matching specifications of the fixing bracket to fix. The load capacity of the fixed bracket should be greater than 3KG.

4.2.1 Installation area

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

4.2.2 Power adapter installation

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



Figure 2 power adapter

[Note] Only the power adapter and power connector provided with the device can be used.

4.2.3 Hand brake(optional)

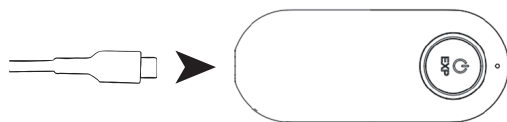


Figure 3 Exposure hand brake connecting cable
Connect the other end of the hand brake connecting cable to the host:

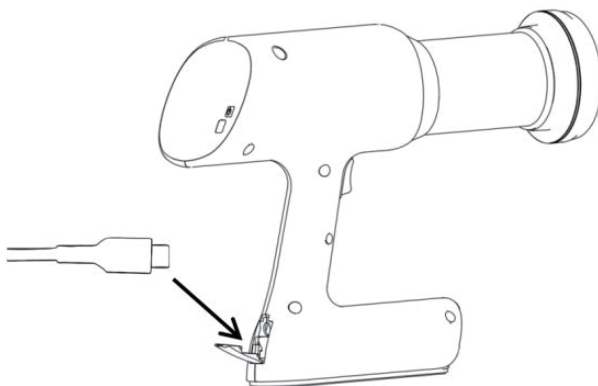


Figure 4 Exposure handbrake connection device
Note: ① wired connection mode: Long press the button of exposure hand brake, the exposure starts light on.
4.2.4 Functions of the control panel
See Table 1 for the functions of the buttons on the control panel.

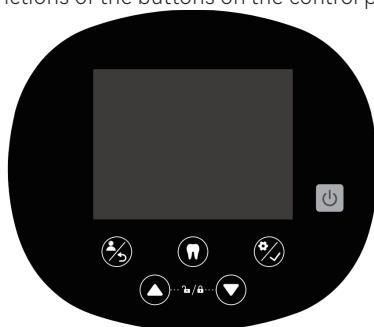


Figure 5 Operation panel

Table 3

S/N	Icons	Function
-----	-------	----------

1		Standby button
2		Time setting of exposure in the main interface/switch icons in the other interface/Lock function
3		Select Human Body /Return button
4		Selection of tooth position button
5		Access the settings interface / Switch pages / Function confirmation button

4.2.6 User Main Interface

See Table 2 for the functions of the icons on the User Main Interface.

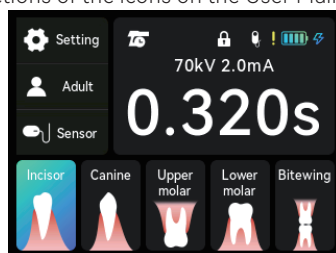


Figure 6 Screen panel

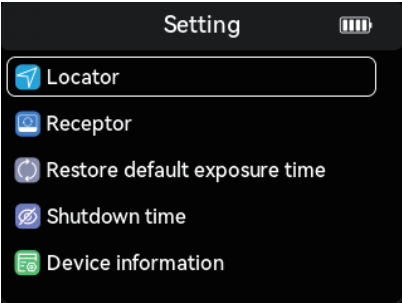
Table 4

S/N	Icons	Icons' meaning and usage
1		Lock indication. Press and hold the “△” and “▽” buttons at the same time to unlock/lock the generator. The generator cannot be operated in the locked state.
2		Adults
3		Children
4		Incisors
5		Canines

6		Upper Molars
7		Lower Molars
8		Bitewing
9		Device of image receptor for Digital Intraoral X-ray Imaging System
10		Image plate scanner (IP image plate)
11		Film
12		Low power identifier/Battery power/ Charge identifier
13		Display of X-ray exposure time
14		Connection mode: Wired connection mode of the exposure handbrake
15		Heat dissipation countdown

4.2.7 User setting interface

Table 5 Icon Meaning

Secondary Heading	Function
 ① Locator ② Receptor ③ Restore default exposure time ④ Shutdown time ⑤ Device information	①: Setting the Locator function and Auto exposure function ②: Select the desired image receiver device ③: Restore default exposure time ④: Preset idle shutdown time ⑤: Device information

Secondary Interface

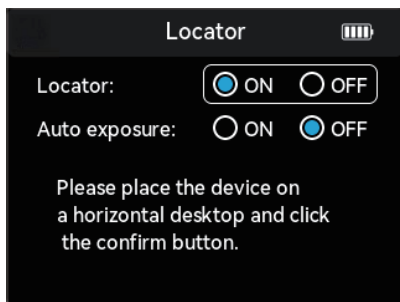


Figure 7 Locator interface

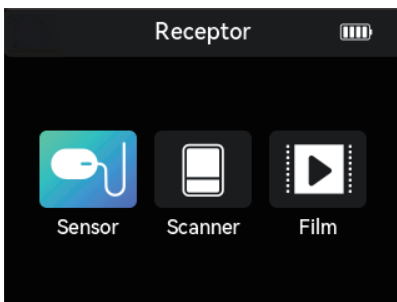


Figure 8 Receptor interface

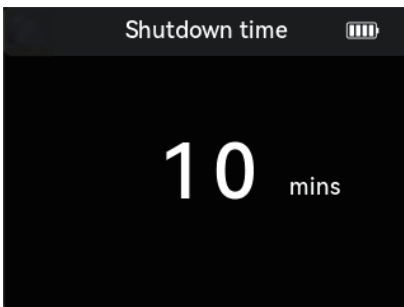
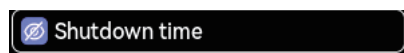


Figure 9 Shutdown time interface

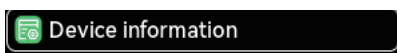


Figure 10 Device information interface

5 Operating instructions

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.
2. Press at the same time to unlock the device, and after the unlock-ing is completed, the icon turns off, and the device can be operated.
3. Check the battery of the device to ensure the normal operation of the device.

Note: When there is only one battery indicator light and the red light is flashing, use the battery charger to charge the battery immediately.

4. Select the human body, tooth position and the device mode.

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

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

7. If using the positioning function, follow these steps to prepare for exposure:

- Installing the magnet, the side marked with the symbol  should face outward, away from the sensor.
- Put on the Sensor Protective Sleeve (with magnet) and Disposable Protective Sheath.

5.2 Exposure images

1. High-quality image receptor device (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 will face the tooth.

2. Move the Dental X-Ray Device to the teeth on the patient's face and adjust the position of the device and the patient according to the angle displayed on the screen.

3. Ensure that the light cone of the device of image receptor is perpendicular to the position of the IP image plate, press the X-ray device exposure button. The exposure key should be pressed for the whole process until the "beep" sound prompt of the beeper occurs.

4. When the exposure is finished and the image is successfully taken, remove the image receptor device 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 Device. 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 6

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

Warning: During the loading exposure process, do not move the device to avoid blurring the image due to the movement of the device and image receiving device.

5.4 Software Operation Instructions

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

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.

The photograph time reference values are as follows:

Table 7

	Digital Sensor		Scanner		Film	
	Child	Adult	Child	Adult	Child	Adult
Incisor	0.16	0.20	0.20	0.25	0.50	0.63
Canine	0.20	0.25	0.25	0.32	0.63	0.80
Upper Molar	0.32	0.50	0.40	0.63	0.80	1.25
Lower Molar	0.25	0.32	0.32	0.40	0.80	1.00
Bitewing	0.32	0.40	0.40	0.50	0.80	1.00

Notes: The exposure time set in each mode is recommended by the manufacturer, and the time can be adjusted in each mode.

1) Device Mode

Press the  button indicated by the arrow into the Setting Interface, as shown in Figure 11 and Figure 12, and press the  button to select the "Receptor", and press the  button again into the Receptor Interface, as shown in Figure 13. In Figure 13, press the  button to select the sensor, scanner, and film. Whether choose to press the  button to return to the Setting interface or press the  button to return directly to the main interface, the selected parameters will be saved.

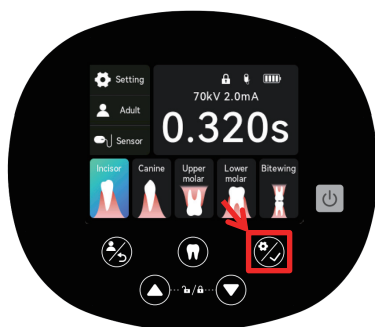


Figure 11

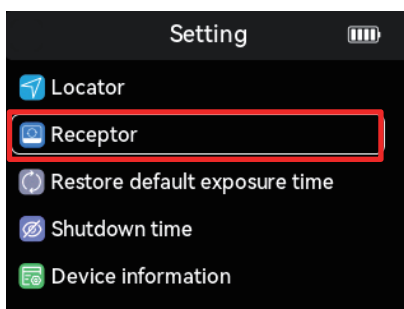


Figure 12

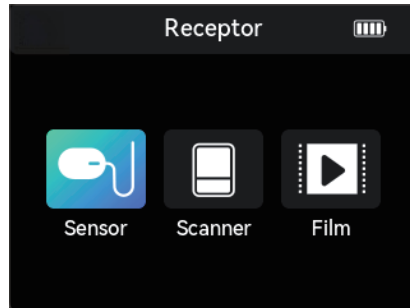


Figure 13

2) Human Body Mode

After selecting the device mode, select the human mode. Press the  button indicated by the arrow at the first position in Figure 14 to toggle between Adult mode and Child mode. Select different human body modes according to the age of the patient, and the corresponding options will be displayed in the human body mode area at the second position after successful selection.



Figure 14

Table 8 Human Body Mode

Icons	Mode
	Adult Mode
	Child Mode

3) Tooth Position Mode

Press the  button indicated at arrow in Figure 15, you can select the tooth type to be photographed at points shown in Figure 15 on the interface, and the border of the corresponding tooth area will light up. After successful selection, the tooth type background changes from black to blue.

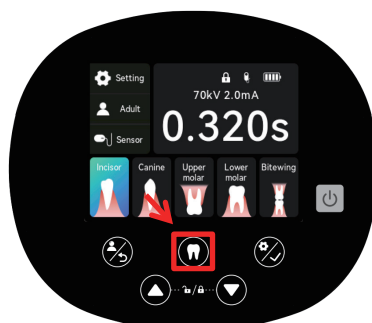


Figure 15

5.4.2 Setting of exposure time

If there is required to change the exposure time, Press the  button and the exposure time can be adjusted from 0.02 seconds to 2 seconds.

5.4.3 Exposure location icon

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.

5.4.4 Image receiving device

The image receiving device can be: Imaging Plate, sensor 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.

Table 9

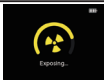
Name	Country	Brand	Model
IP image plates	France	ACTEON	IMAGING PLATE
Dental image plates scanner	China	Woodpecker	i-Scan
Digital intraoral X-ray imaging system	China	Woodpecker	i-Sensor H2

5.4.5 Exposure

When the Locator is "OFF":

Short press the exposure button to enter the pre-exposure interface, Long press the exposure button of Dental X-Ray Device to carry out exposure. See Table 10 for different states of exposure icons on the screen.

Table 10

Exposure icon	State
	Heat dissipation countdown
	Exposing
	Finish

3. Upon completion of device usage, the device can be powered off by pressing the shutdown button, or alternatively, it can be left idle, and the device can be set to switch off automatically after 60 minutes as shown in Figure 17(The shutdown time can be set from 5 minutes to 60 minutes, with each adjustment increment being 5 minutes).

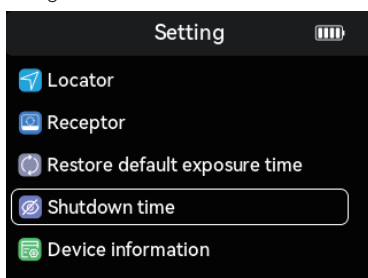


Figure 16

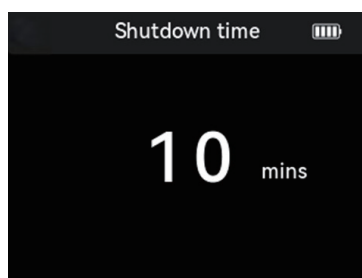


Figure 17

When the Locator is "ON":

1. First, Place the magnet, the Sensor Protective Sleeve, and the disposable protective sleeve in that order over the sensor, then insert the sensor into the patient's oral cavity.(Note: Magnets have north and south poles,with symbol should face outward, away from the sensor.)
2. Press the standby button to turn on the device. (Note: Keep away from magnetic objects when turning on the device.)
- 3.Select the tooth position to be imaged.
4. Short press the exposure button to enter the pre-exposure interface, the "Out of range" will be displayed on the screen (press the  button to return to the main interface).

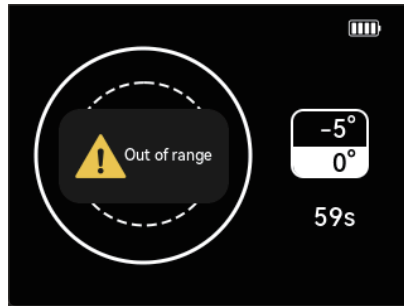


Figure 18

5. Adjust the exposure angle of the generator to align with the recommended angle. When the angle is displayed in green, it indicates that the exposure angle is aligned.

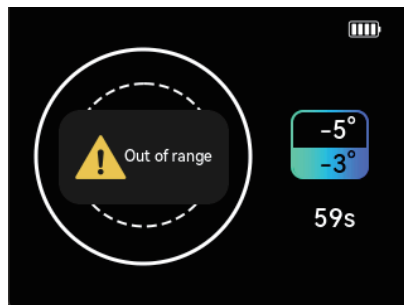


Figure 19

6. Move the generator closer to the sensor with the magnet. Observe the screen and adjust the X-ray output port to align with the sensor center. When the screen appears as shown in Figure 20 this indicates that the sensor center is aligned with the X-ray port center.

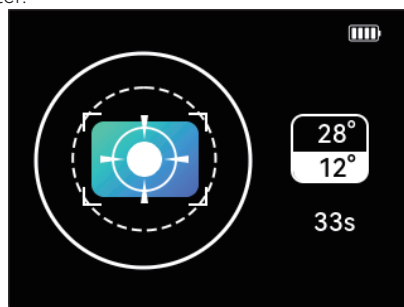


Figure 20

7. When the sensor center is aligned with the X-ray port center and the exposure angle reaches the recommended angle, as shown in Figure 21. Press and hold the exposure button. The display shows "Exposing" as shown in Figure 18. After the "beep" sound ends, the exposure is complete. The display shows "Finish" and returns to

the main interface.

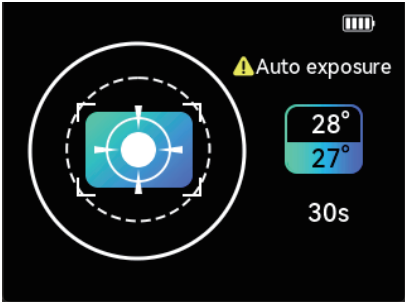


Figure 21



Figure 22

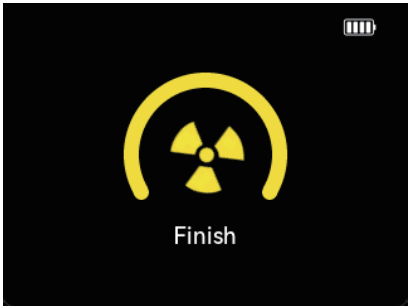


Figure 23

Table 11

	The outer circle indicates the positioning recognition range.
	The inner circle indicates the X-ray port range. Positioning and exposure must be within the inner circle.
	Black background with white characters indicates the recommended exposure angle for the selected tooth position
	White background with black characters indicates the current angle of the device

Note: It is recommended to select the tooth position to be exposure, adjust the tilt angle of the generator, and then move closer to the patient's exposure area before exposing. (If you feel that the recommended exposure angle cannot provide an accurate image, you can select an appropriate angle based on the actual clinical situation for alignment and exposure. This will not affect the positioning function of the imaging.)

5.4.6 Locator interface:

Press the  button to enter the setting interface.

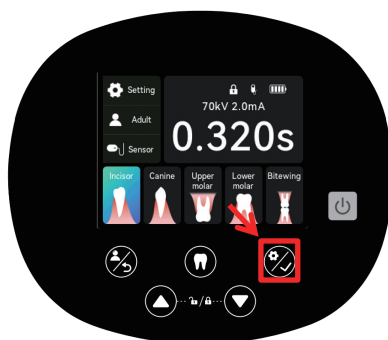


Figure 24

Press the  button to select the “Locator” and press the  button to enter the “Locator” interface.

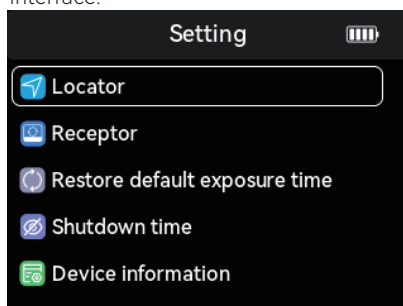


Figure 25

Press the  button switches between “Locator” and “Auto exposure” as shown in Figure 26 and Figure 27. The default parameters are as follows: the “Locator” is set to on, and the “Auto exposure” is set to off.

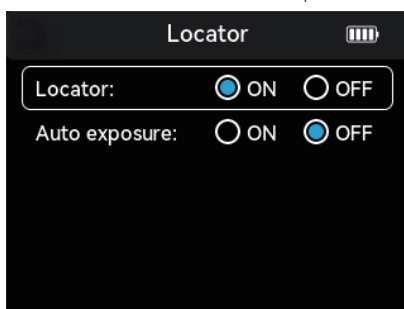


Figure 26

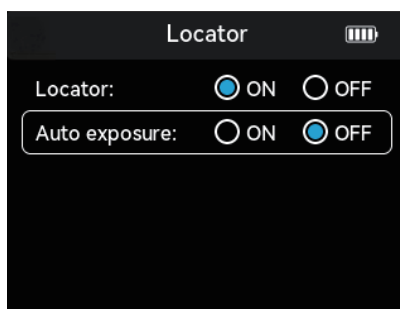


Figure 27

1.Locator

(1) Press the  button to select “Locator” in the Locator interface, from large frames to small frames, If the positioning function is working properly, a posi-

tioning calibration prompt will be displayed below,as shown in Figure 28. If the positioning function malfunctions, a warning “Please connect the locator” will be displayed below, as shown in Figure 29.

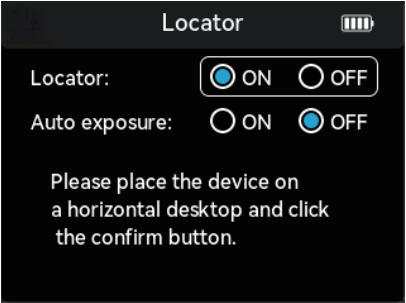


Figure 28

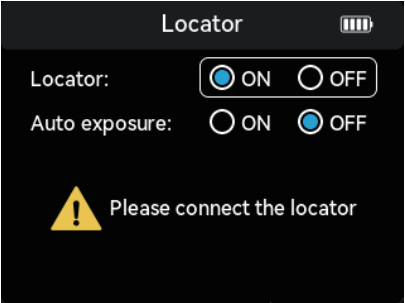
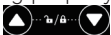


Figure 29

(2) When the positioning function is working properly and place the device horizontally on a flat surface, then press the  button to select the “ON”, press the  button again, a progress bar indicating calibration in progress will appear below, as shown in Figures 30. If the calibration is successful, the progress bar will complete and the system will return to the main interface, as shown in Figure 31. When the option status is “OFF”, there will be no prompts.

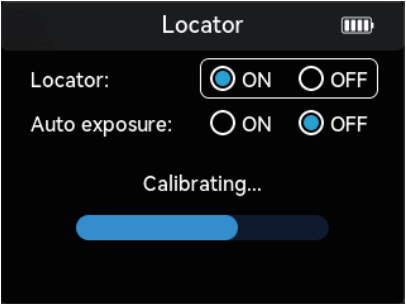


Figure 30

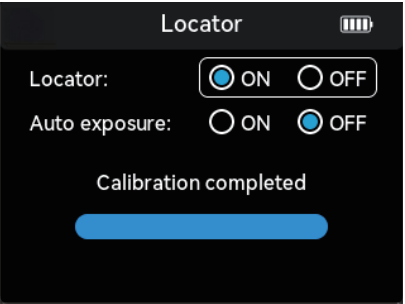


Figure 31

2.Auto exposure

Press the  button to select “Auto exposure” in the Locator interface, from large frames to small frames, and Warning Notice will appear below, as shown in Figures 32. This function carries a high risk of danger. When preparing the interface, ensure there is no strong magnetic interference around the device, as this may cause accidental exposure. It is recommended to approach the subject before entering the preparation interface.



Figure 32

Note: This feature can only be enabled when location services are on and working properly.

5.4.7 Positioning Angle Calibration

For testing and maintenance purposes only, calibration is not required under normal conditions.

- First, Place the device on a level surface and keep it stationary.
- Second, Short press exposure button to enter the Pre-exposure interface, and press the  button, when the current angle of the device turns 0°, it indicates successful calibration.

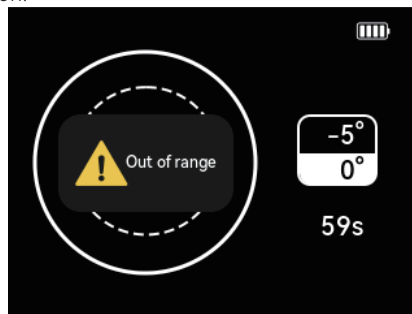


Figure 33

5.5 Using and Maintaining The Battery

5.5.1 Using The Battery

(1) The battery level indicator for remaining power is displayed on the right side of the control panel. When there is only one bar of power, the battery needs to be charged.

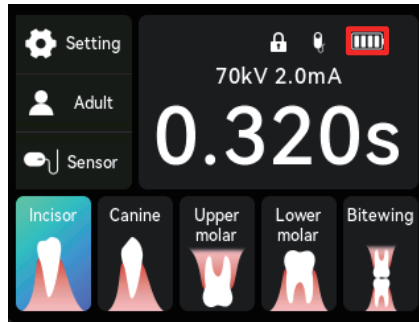


Figure 34

(2) Charging

- a. Connect one end of the charger to the charging port of the device and the other end to the power supply of the network (100-240V, 50/60Hz).

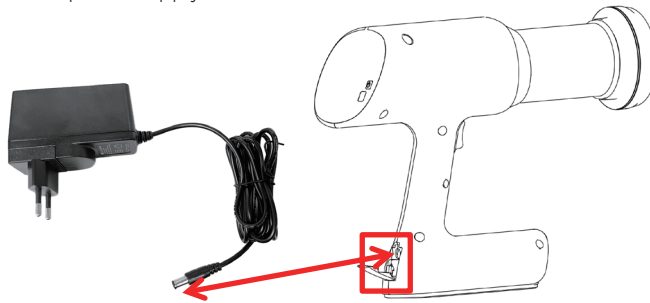


Figure 35

- b. When charging, the device displays the charging icon, and when charging is finished, the battery is charged fully.
- c. Disconnect the power supply and the charger when the charging is complete.
- d. After the discharge is completed, a single charge takes about 2 hour to fully charge the battery.

(3) Battery Use Cycle

The battery is a consumable part. Gradual degradation is expected, so re- charging should be done more frequently. When the battery life is reduced to half or less than a new battery, please contact your service representative for a new battery to check how to replace the battery.

(4) Battery Replacement

To replace the battery, contact an authorized dealer or manufacturer for replacement accessories that comply with local regulations. Disassemble the device to repair or replace parts, otherwise it may cause damage to the device or affect the safety performance of the device.

(5) Power saving mode

If the device is turned on for 30 minutes and not operated, the power saving mode is activated and the device automatically powers off. All displays are turned off on the control panel and the device must be powered back on to resume normal operation in power saving mode.

5.5.2 Battery Maintenance

(1) When the device is not in use, the power button should be turned off to save electrical energy.

(2) Please use the original charger to charge.

(3) Keep the power above one bar.

(4) High voltage charging and a single charge of over 12 hours should be avoided.

(5) Avoid exposing the battery to high temperature or fire, and avoid direct sunlight when storing the battery.

5.5.3 Pediatric Use: Summary

Introduction: Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height, measurements, which approximately correspond to that of an average 12 year old or a 5th percentile adult female.⁴⁴)

Exposure to ionizing radiation is of particular concern in pediatric patients because: 1) for certain organs and tumor types, younger patients are more radio sensitive 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; and 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 Mini Ray Dental X-Ray Device;

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

Table 12

Design feature important to pediatric imaging	Page number reference in Instructions for use
Output radiation field	P.2
Reference LOADING conditions	P.2
Mode function	P.12
Exposure Control	P.14

Table 13

Testing information	Page number reference in Instructions for use
Image receiving Device requirement	P.14
Radiation and Protection	P.31

6 Cleaning and 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 parts. If damaged, contact an authorized dealer or manufacturer for replacement parts that comply with local regulations. Disassemble the device to repair or replace parts, otherwise it may cause damage to the device or affect the safety performance of the device.

Before using this device for the first time, a complete cleaning procedure must be

performed. Before each cleaning and disinfection, the Dental X-Ray Device should be disconnected from the power supply.

6.1 Cleaning

1. Wipe the shell of the product and the head of the X-ray device with non-abrasive materials (gauze and soft cloth) dipped with detergent, and pay attention not to allow liquid to flow into the device.
2. Dry the device with a clean, dry and soft cloth.

6.2 Maintenance

1. Immerse a piece of clean dry gauze in 70% -80% ethanol disinfectant, and then wipe the disinfected parts twice with soaked dry gauze.
 2. Dry the device naturally or with a clean, dry and soft cloth.
- Caution: Do not use the following methods of disinfection
3. Do not use organic solvents or corrosive cleaning products to clean the Dental X-Ray Device.
 4. Do not spray detergent directly on the Dental X-Ray Device.
 5. Do not use organic solvent or corrosive disinfectant to disinfect the Dental X-Ray Device.
 6. Do not spray disinfectant directly on the Dental X-ray Device.

7 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)

Anode heat capacity: 4500J

Maximum anode heat dissipation: 110W

Overall dimension and wiring: as shown in Figure 36

Maximum rated value: as shown in Figure 37

Thermal characteristics: see Figure 38

Filament and emission characteristics: see Figure 39

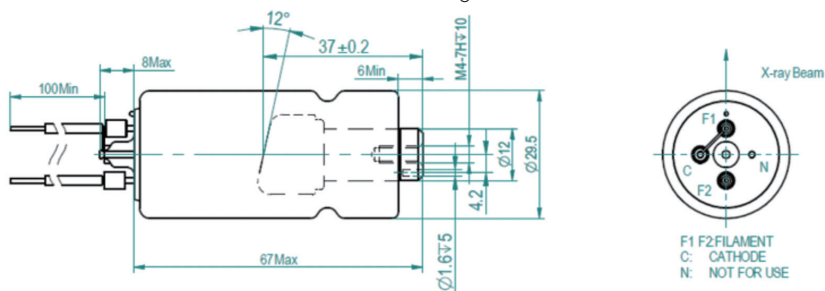


Figure 36 Mechanical dimension device wiring

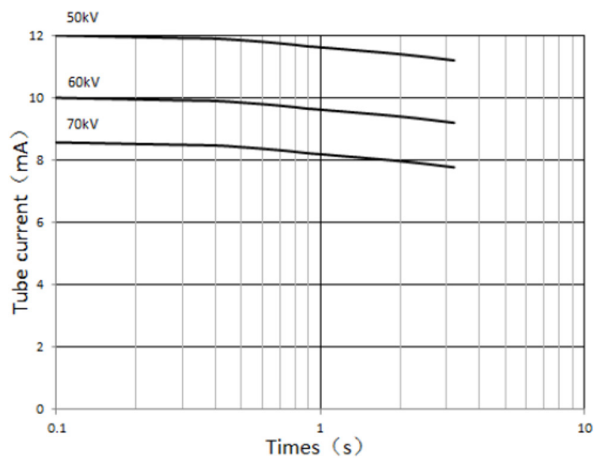


Figure 37 Maximum rating diagram

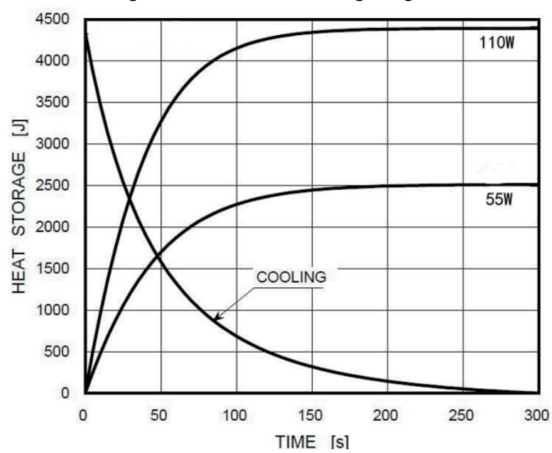


Figure 38 X-ray tube anode heating and cooling curve

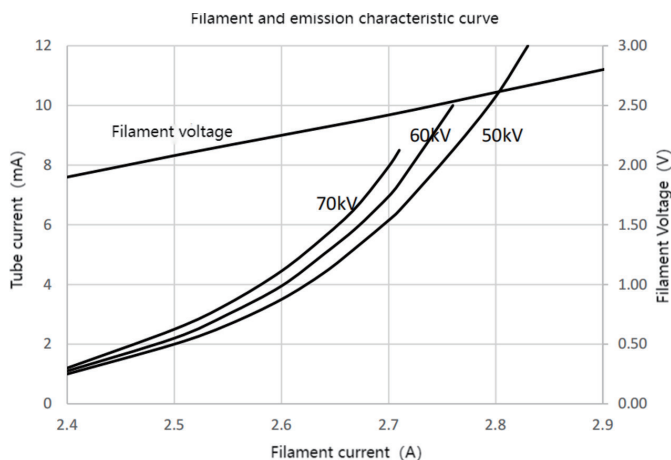


Figure 39 Filament and emission characteristic curve

8 Storage, maintenance, and transportation

8.1 Storage/ maintenance

- 1) The device shall be handled with care, away from an uneven or vibrating 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°C ~ + 55°C . Inspect the device for scratches, wear and other mechanical scratches or damage after each use.

8.2 Transportation

- 1) Avoid excessive shock and vibration during transportation, and handle with care to avoid inversion.
- 2) It shall not be transported with toxic, corrosive, flammable and explosive substances.
- 3) Avoid sun exposure or rain and snow immersion during transportation.

9 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 14

Part	Toxic or harmful substances or elements					
	(Pb)	(Hg)	(Cd)	(Cr ⁶⁺)	(PBB)	(PBDE)
Power adapter	○	○	○	○	○	○

Main unit	○	○	○	○	○	○
Mechanical elements, including bolts, nuts, washers, etc.	○	○	○	○	○	○

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

×: Indicates that the content of the toxic substance in at least one of the homogeneous materials of the part exceeds the limit requirement specified in SJ/T-11363-2006. (This product meets EU RoHS environmental protection requirements; there is currently no mature technology in the world to replace or reduce the content of lead in electronic ceramics, optical glass, steel and copper alloy.) According to the “Administrative Measures on the Restriction of the Use of Hazardous Substances in Electric and Electronic Products” and the “Regulations on the Administration of the Recycling and Disposal of waste Electrical Appliances and Electronic Products” and related standards, please observe the safety and precautions of the products, and please recycle or dispose this product according to the methods in local laws and regulations after use.

10 After-sales service

Commencing from 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.

At the same time, the maintenance of the circuit diagram, parts list and other information are provided by the company to help maintenance personnel to repair parts; Please ensure that the information used is complete before repair.

11 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 15

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

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

11.1 Guidance and manufacturer’s declaration-electromagnetic emission

Table 16

Guidance and manufacturer's declaration–electromagnetic emission		
The Dental X-Ray Device 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 Device 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. The Dental X-Ray Device 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.
RF emission CISPR 11	Group B	
Harmonic emission IEC 61000-3-2	Group A	
Voltage fluctuation/ flicker emission IEC 61000-3-3	Complies	

11.2 Guidance and manufacturer's declaration–electromagnetic immunity**Table 17**

Guidance and manufacturer's declaration–electromagnetic immunity			
The Dental X-Ray Device 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	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge(EDS) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±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 SIP/SOP lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV line to line ±0.5kV, ±1kV, ±2kV line to ground	±0.5kV, ±1kV line to line ±0.5kV, ±1kV, ±2kV 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	$<5\% U_T$ $(>95\% \text{ dip in } U_T)$ for 0.5 cycle $<5\% U_T$ $(>95\% \text{ dip in } U_T)$ for 1 cycle $70\% U_T$ $(30\% \text{ dip in } U_T)$ for 25/30 cycles $<5\% \text{ dip in } U_T)$ for 5 sec	$<5\% U_T$ $(>95\% \text{ dip in } U_T)$ for 0.5 cycle $<5\% U_T$ $(>95\% \text{ dip in } U_T)$ for 1 cycle $70\% U_T$ $(30\% \text{ dip in } U_T)$ for 25/30 cycles $<5\% \text{ dip in } U_T)$ for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dental X-ray Device requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T refers to the AC mains voltage prior to application of the test level.			

11.3 Guidance and manufacturer's declaration-electromagnetic immunity

Table 18

Guidance and manufacturer's declaration-electromagnetic immunity			
The model Mini Ray is intended for use in the electromagnetic environment specified below. The customer or the user of the model Mini Ray should assure that they are used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio	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 model Mini 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. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = [6/d] \times P^{1/2}$ 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.
Radiated RF IEC 61000-4-3	10V/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)	10V/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)	

 Notes:

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

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

Table 19

Recommended separation distances between portable and mobile RF communications equipment and the Dental X-ray Device			
The Dental X-ray Device is intended for the use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dental X-ray Device as recommended below according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter /W	Separation distance according to frequency of transmitter/ m		
	150kHz ~ 80MHz $d = 1.2 \times P^{1/2}$	80MHz ~ 800MHz $d = 1.2 \times P^{1/2}$	800MHz ~ 2.5GHz $d = 2.3 \times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

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

For the rated maximum output power of transmitters not listed in the above table, the recommended separation distance “d” (m) can be determined by the formula in the corresponding transmitter frequency column. Where “P” is the maximum output rated power of the transmitter in watts (W) provided by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the formula of higher frequency range is applied.

NOTE 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and emission from buildings, objects and human bodies.

12 Symbol instruction

The side and top surfaces of the device have the following markings:

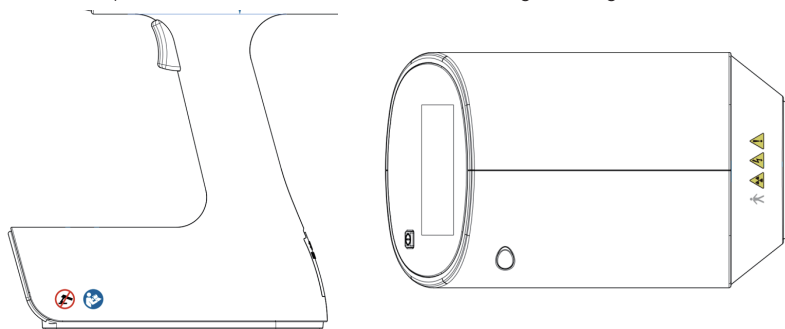
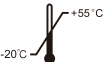


Table 20

	Manufacturer		Serial number
	Electrostatic Sensitive		Product number
	Danger! High voltage		Medical Device
	Avoid sun exposure		Date of manufacture
	Follow the manual		X-ray, beware of ionizing radiation
	Warning		Keep dry

	Type B application.		Handle with care
	Class II device	IPX0	Ordinary device
	Standby button		Recovery
	Temperature limit for storage: -20° C ~ +55° C		
	Humidity limit for storage: 10% ~ 93%		
	Atmospheric pressure for storage: 70kPa ~ 106kPa		
	WEEE mark Please deal with the waste disposal produced by the device following relevant laws and regulations.		
	Exposure and power switch of the exposure hand brake		
	Place the device on the side of the desktop as much as possible to tilt it, and try to hold it with both hands during handheld movement.		
	Exposure button of the wireless exposure hand brake		

13 Radiation and Protection

13.1 Radiation

1) Dose area product

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

Table 21

Test conditions (20.5cm from the focus of the tube)

Exposure time (ms)	Dose value (mGy)	Area (cm ²)	Dose area radiation (mGy*cm ²)
20	0.078	28.27	2.205
25	0.098	28.27	2.756
32	0.125	28.27	3.528

40	0.156	28.27	4.410
50	0.195	28.27	5.513
63	0.246	28.27	6.946
80	0.312	28.27	8.820
100	0.390	28.27	11.025
125	0.488	28.27	13.782
160	0.624	28.27	17.640
200	0.780	28.27	22.051
250	0.975	28.27	27.563
320	1.248	28.27	35.281
400	1.560	28.27	44.101
500	1.950	28.27	55.127
630	2.457	28.27	69.459
800	3.120	28.27	88.202
1000	3.900	28.27	110.253
1250	4.875	28.27	137.816
1600	6.240	28.27	176.405
2000	7.800	28.27	220.506

2) Dosimetric indications.

Under the condition of 70kV, 2mA, the distance between the test point and the focal point of the X-ray tube is 20.5cm, 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.

13.2 Protection requirements

1) Effective occupied area

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

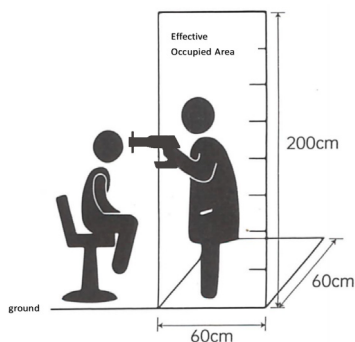


Figure 40 Effective occupied area

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:

Load conditions: 70kV 2mA 0.4s

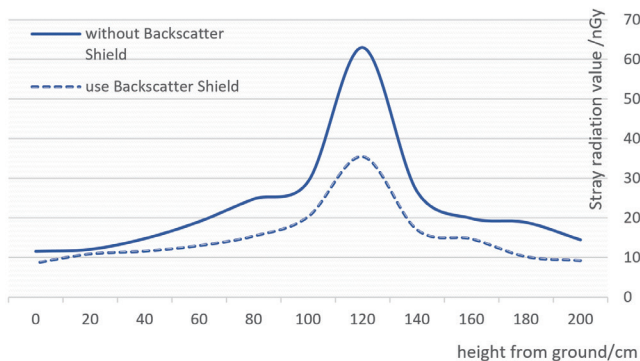


Figure 41 Stray radiation distribution diagram

When measuring the scatter radiation, the focal point is 1.15 meter above the ground and 0.1 meter outside the middle of limited occupied area.

2) Physical protection

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

14 Special description

Please refer to the product packaging label for the production date, service life: 10 years. Safety: The radiation dose for an occupational radiation worker is less than 50 mSv for whole body, less 150 mSv for the eyes and less 500 mSv for hands, skin and feet in a single year.

Performance: The image quality of subject device is excellent and is not inferior to the wall-mounted X-ray machine. Benefits: From the clinical data, such as significantly improving the self-care ability. The hand-held dental radio graph 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.

15 Disposal

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

Scan and Login website
for more information



Guilin Woodpecker Medical Instrument Co.,Ltd.

Information Industrial Park, Guilin National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China

Sales Dept.: +86-773-5873196/2350599

After-sales Service Dept.: +86-0773-5827898

E-mail: woodpecker4@glwoodpecker.com

Website: <http://www.glwoodpecker.com>

Cut along the dashed line

Dental X-Ray Device Warranty Card

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

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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		Repairer
Date	Maintenance Record	

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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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