MD

CE 0197

Mini Ray Dental X-Ray Generator
Instruction Manual

Please carefully read this manual before operating.

ZMN-SM-479 V1.0-20231220

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 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

Contents

1 Product introduction

1.1 Product introduction

This device is a portable dental X-ray generator 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 Indication for Use

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

1.4 scope

The device is an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. The device is used by doctors in medical institutions such as hospitals and clinics for both adult and pediatric patients.

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 cathode 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, battery, power adapter, Backscatter Shield(optional) and beam limiting device.

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 be-

longs 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 ±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, the grade is adjustable, and the grade is selected according to the R10 numerical system; with deviation ±5% or ±20ms which is larger
8. Filtration
a. Permanent Filtration:1.0 mmAl/70kV
b. Additional Filtration: 0.6 mmAl/70kV
c. Total filtration: 1.6mmAl/70kV
9. X-ray tube
a. X-ray tube model: KL11-0.4-70
b. Focal spot: 0.4mm
c. Target angle: 12°
d. Permanent Filtration: 1.0mmAl/70kV
10. Distance from focal spot to skin: 20.5±0.5cm
11. Distance from focus to imaging: 20~23cm
12. Output radiation field: Φ5.9cm±0.1cm
13. Product specifications
Dimension: 338mm×112mm×247mm
Weight: 2.2KG
14. Battery specification: 18650×3 10.8V 2500mAh 27Wh R
15. Exit field sized: Φ5.9cm±0.1cm

16. Reference LOADING conditions: 70kV, 2mA, 2s, loading interval 1s/60s, 59 exposures per hour.

17. Radiation output stated: the variation coefficient under the function less than 5%.

18. 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℃ ~ 40℃
Relative humidity: 30% ~ 75%
Atmospheric pressure: 70kPa ~ 106kPa

1.12 Transportation and storage condition

Storage temperature: -20℃ ~ 55℃
Transportation temperature: -20℃ ~ 55℃
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 generator 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 Generator no less than 2 meters.

3.1.4 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.

3.1.5 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 generator.

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 generator, it is quite important to use the charger provided by the device. The power line of the dental X-ray generator can only be replaced by the same type of line.

3.1.8 Due to the electromagnetic compatibility of X-ray generator, other device nearby may be affected during use of the generator. 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

Fault	Reason	Solution

E01	Press and hold the exposure button for less than 1 second during the preparation phase, or release before the exposure ends	Press the exposure button once and use it after the warning disappears
E02	The temperature of device is too high	Device is cooled down before use
E03	The voltage of device is too high	Restart the device, if the fault still exists, please contact the manufacturer
E04	The device current is too large	Restart the device, if the fault still exists, please contact the manufacturer
E05	The battery is low	Plug in the power adapter and charge it before use

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.

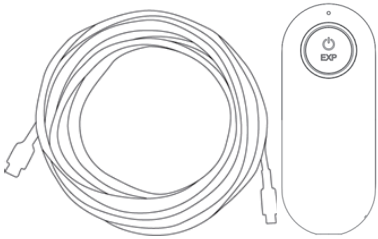
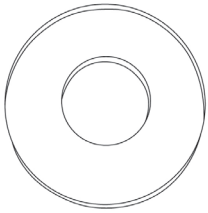
7) Children and pregnant women must consult with a doctor before X-ray exposure.

4 Product installation and function description

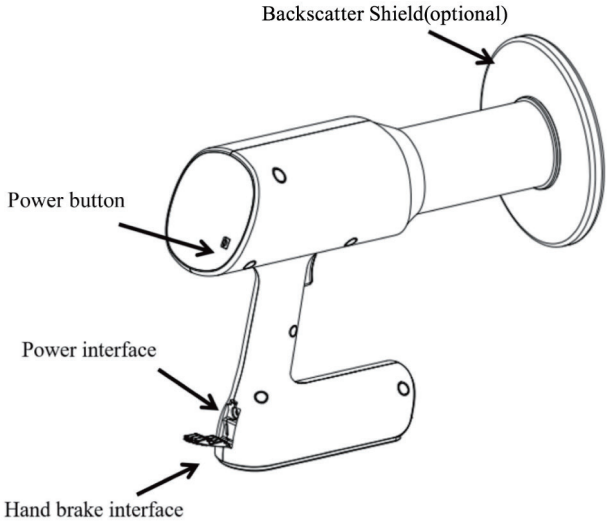
4.1 Components

Table 1

NO	Item	Quantity
1	Power adapter	1
2	Connection cable of hand brake	1
3	Exposure hand brake(optional)	1
4	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.
 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 handheld 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



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.

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 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 Backscatter Shield

After removing the device, please install the shielding Backscatter Shield as shown in the figure below:

clamp the Backscatter Shield into the limit tube, and then tighten the sleeve ring clockwise

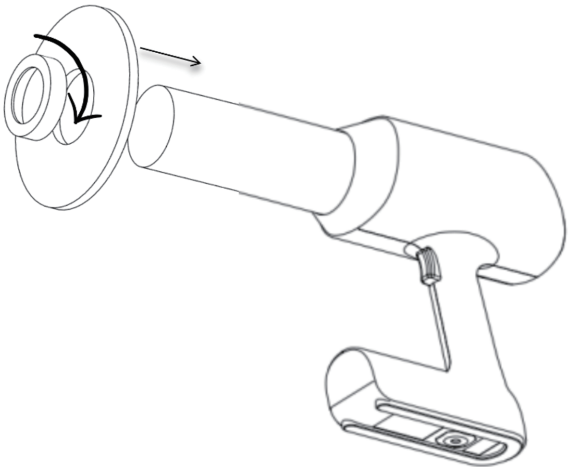


Figure 3 Backscatter Shield

4.2.4 Hand brake

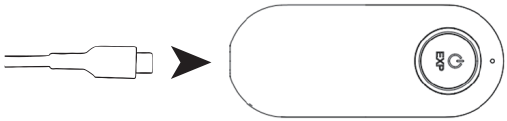


Figure 4 Exposure hand brake connecting cable

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

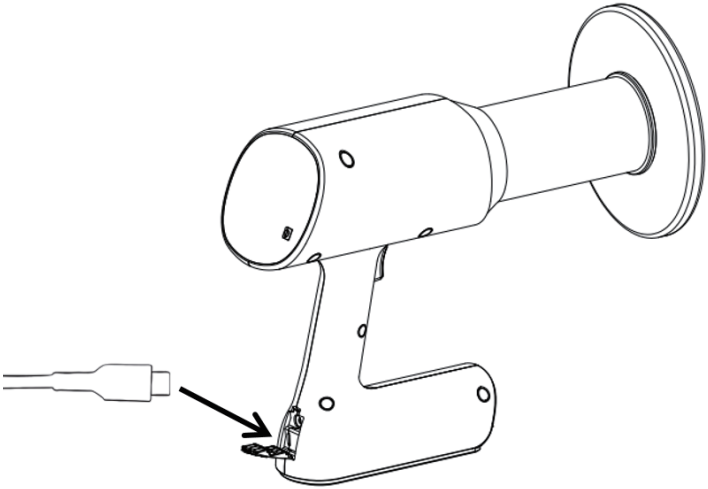


Figure 5 Exposure handbrake connection device

Note: ① wired connection mode: Long press the switch of exposure hand brake, the exposure starts light on.

4.2.5 Functions of the control panel

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

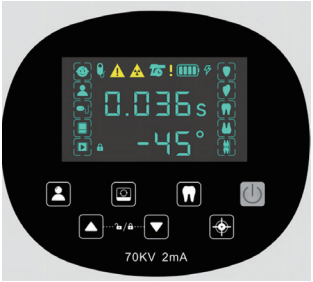


Figure 6 Control panel

Table 1

S/N	Icons	Function
1		Standby button

2		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.
3		Time setting of X-ray exposure, “▼” decreases time of exposure , “▲” increases time of exposure
4		When you click the Calibration button, the displayed Angle returns to zero.
5		device of image receptor for Digital Intraoral X-ray Imaging System
6		image plate scanner (IP image plate)
7		Film
8		Selection of human body: The patients shot include adults/ children
9		Children
10		Adults
11		Selection of tooth position : selection of tooth position shot.
12		Incisors
13		Canines
14		Molars/Premolars
15		Bitewing
16		Low power identifier/Battery power/ Charge identifier
17		Angle display
18		Display of X-ray exposure time
19		Indication of X-ray exposure status
20		Fault warning indication
21		Device cooling countdown
22		Connection mode: Wired connection mode of the exposure handbrake

4.2.6 Description of Effective Occupied Area

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

not be less than 200cm.

5 Operating instructions

The user of the medical generator 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 unlocking 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).

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 generator 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 generator exposure button. The exposure key should be pressed for the whole process until the "di" sound prompt of the beeper occurs.
4. When the exposure is finished and the image is 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 Generator. The photograph angle reference

values are as follows (The following values are only reference values, the operator can adjust the angle according to the actual situation to ensure that the beam limiting tube and the image receiving device remain vertical.):

Table 3

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

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 generator, which visually displays the operation interface, so that the operator can better use the generator.

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:

	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	0.25	0.32	0.32	0.40	0.80	1.00
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

Click the generator selection icon indicated by the arrow, as shown in Figure 7, and select the desired image receiver generator, as shown in Figure 8. From top to bottom are sensor, scanner, and film. The corresponding generator area is shown in blue.

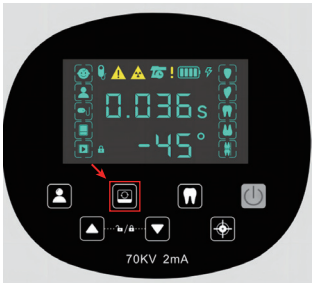


Figure 7

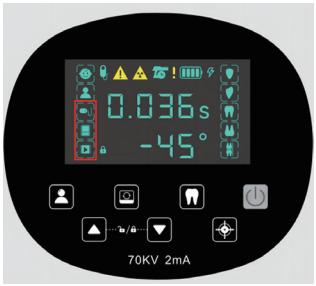


Figure 8

2) Human Body Mode

After selecting the generator mode, select the human mode. First, click the human body selection icon indicated by the arrow at the first position in Figure 9, and button back and forth between adult and child modes at the second position. 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 after successful selection.

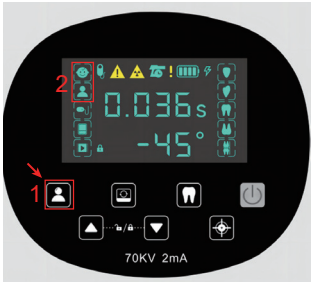


Figure 9

Table 4 Human Body Mode

Icons	Mode
	Adult Mode
	Child Mode

3) Tooth Position Mode

Click the tooth position selection icon indicated at arrow 1 in Figure 10, you can select the tooth type to be photographed at 2 points shown in Figure 10 on the interface, and the border of the corresponding tooth area will light up. After successful selection, the box will frame the icon corre-

sponding to the tooth position.

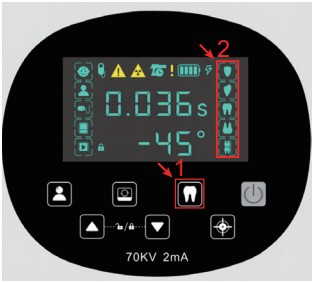


Figure 10

5.4.2 Setting of exposure time

If there is required to change the exposure time, Click the “▲” or “▼” 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 generator, 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 generator 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 generator, otherwise it may result in incomplete images.

Note: When exposure, make sure that the beam limiting tube is vertical to the image receiving generator, 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.

Figure 11

5.4.4 Exposure

1. Long press the exposure button of dental X-Ray generator to carry out exposure. See Table 5 for different states of exposure icons on the screen.
2. Long press the exposure button on the exposure handbrake to carry out exposure. During exposure, the exposure indication light of the exposure handbrake will be on. See Table 5 for different states of the exposure icon on the screen.
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 will automatically power off after approximately ten minutes.

Table 5

Exposure icon	State
	Heat dissipation countdown
	Being exposed

5.4.5 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 6

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

5.5 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.

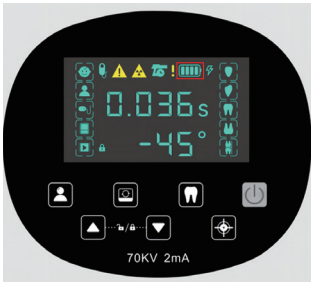
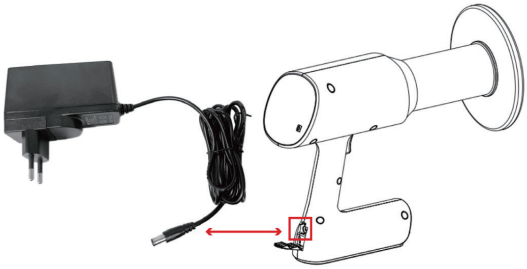


Figure 12

(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).



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 recharging 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 generator 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 generator is turned on for 30 minutes and not operated, the power

saving mode is activated and the generator automatically powers off. All displays are turned off on the control panel and the generator must be powered back on to resume normal operation in power saving mode.

5.5.2 Battery Maintenance

1) When the generator 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 generator;

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

Table 7

Design feature important to pediatric imaging	Page number reference in Instructions for use
Output radiation field	P.2
Reference LOADING conditions	P.3
Mode function	P.13
Exposure Control	P.15

Table 8

Testing information	Page number reference in Instructions for use
Image receiving generator requirment	P.15
Radiation and Protection	P.27

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 generator 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 generator should be disconnected from the power supply.

6.1 Cleaning

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

Dry the device with a clean, dry and soft cloth.

6.2 Maintenance

Immerse a piece of clean dry gauze in 70% -80% ethanol disinfectant, and then wipe the disinfected parts twice with soaked dry gauze.

Dry the device naturally or with a clean, dry and soft cloth.

Caution: Do not use the following methods of disinfection

Do not use organic solvents or corrosive cleaning products to clean the dental X-ray generator.

Do not spray detergent directly on the dental X-ray generator.

Do not use organic solvent or corrosive disinfectant to disinfect the dental X-ray generator.

Do not spray disinfectant directly on the dental X-ray generator.

7 X-ray tube characteristics

Filament voltage: 2.4-3.0V

Maximum filament current: 2.9A

Filament frequency: DC/ AC sine wave (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 13
Maximum rated value: as shown in Figure 14
Thermal characteristics: see Figure 15
Filament and emission characteristics: see Figure 16

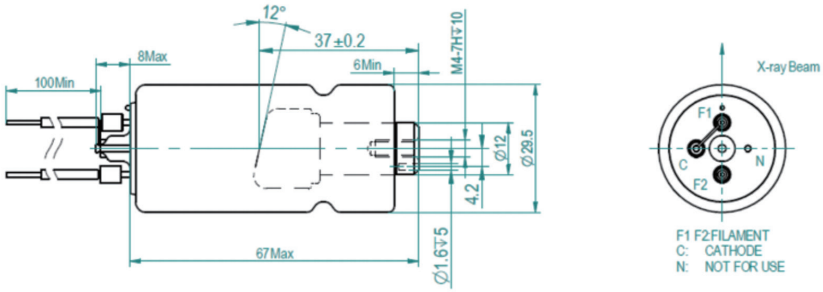


Figure 13 Mechanical dimension generator wiring

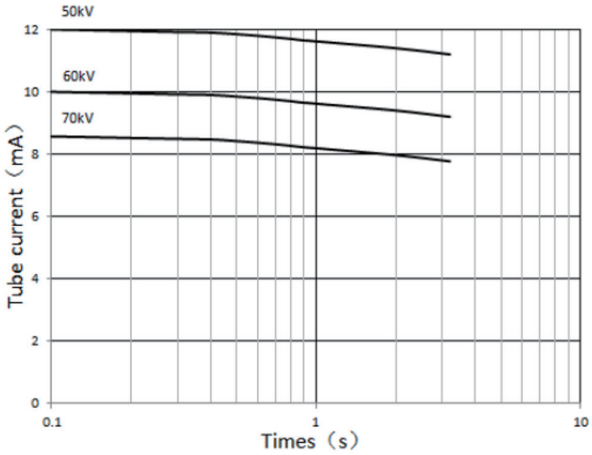


Figure 14 Maximum rating diagram

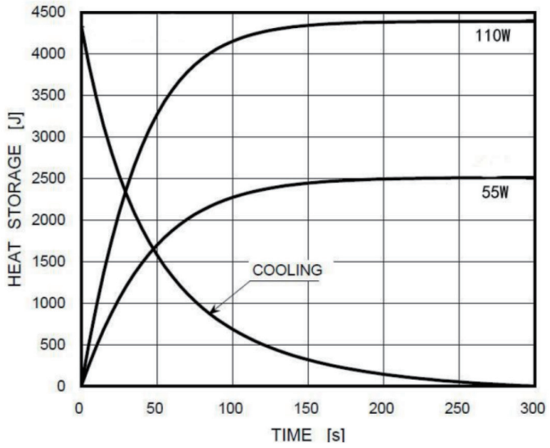


Figure 15 X-ray tube anode heating and cooling curve

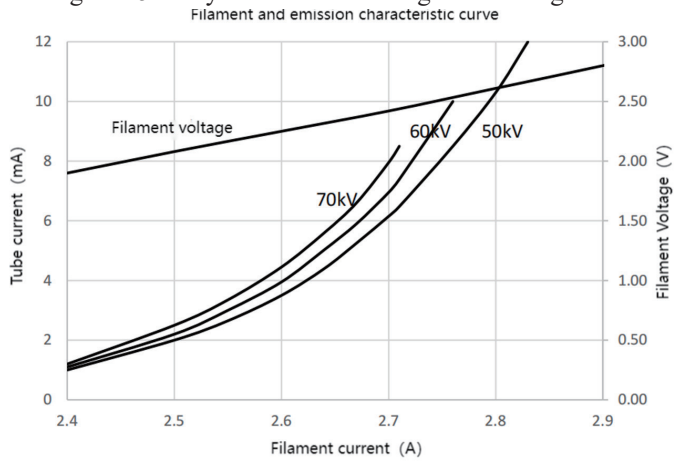


Figure 16 Filament and emission characteristic curve

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℃ ~ + 55℃.

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 9

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 war-

ranty 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 10

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 11

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 61000-3-3	Complies	

11.2 Guidance and manufacturer's declaration-electromagnetic immunity

Table 12

Guidance and manufacturer's declaration-electromagnetic immunity			
The dental X-ray generator is intended for the use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(EDS) lEC 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% 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% dip in U_T.) for 5 sec	<5% U_T (>95% dip in U_T.) for 0.5 cycle <5% U_T (>95% dip in U_T.) for 1 cycle 70% U_T (30% dip in U_T.) for 25/30 cycles <5% 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 generator requires continued operation during power mains interruptions, it is recommended that the scanner be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) 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 refers to the AC mains voltage prior to application of the test level.			

11.3 Guidance and manufacturer's declaration-electromagnetic immunity

Table 13

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 lEC 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 lEC 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 14

Recommended separation distances between portable and mobile RF communications equipment and the dental X-ray generator
The dental X-ray generator is intended for the use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the dental X-ray generator as recommended below according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter /W	Separation distance according to frequency of transmitter/ m		
	150kHz ~ 80MHz $d=1.2\times P^{1/2}$	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:

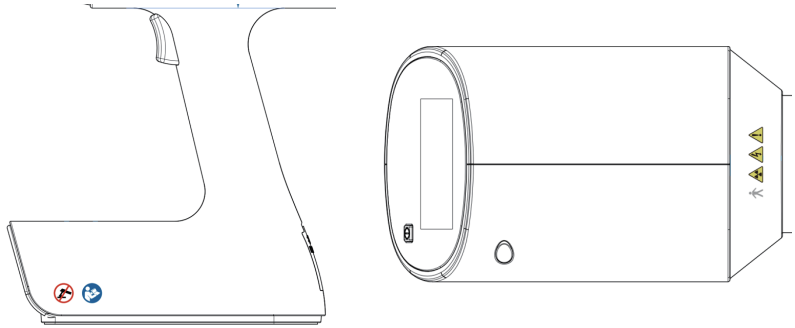
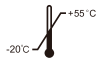
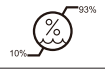
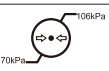


Table 15

	Manufacturer		Serial number
	Authorised Representative in the EUROPEAN COMMUNITY		Item number
	Class II device		Ordinary device

	Temperature limit for storage: -20°C ~ +55°C		WEEE mark Please deal with the waste disposal produced by the device following relevant laws and regulations.
	Humidity limit for storage: 10% ~ 93%		Electrostatic Sensitive
	Atmospheric pressure for storage: 70kPa ~ 106kPa		Danger! High voltage
	Avoid sun exposure		Date of manufacture
	Follow the manual		X-ray, beware of ionizing radiation
	Warning	RX Only	Prescription device
	Exposure and power switch of the exposure hand brake	MD	Medical Device
	CE marked product		Type B application.
	Keep dry		Recovery
	Handle with care		Standby button
	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.		

13 Warning

13.1 Do not use this device while charging.

13.2 Do not maintain and maintain the device during operation.

13.3 This device has residual radiation, it is recommended to add protection.

13.4 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.

13.5 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 are used, the image quality may be affected, resulting in blurred images, etc., affecting clinical judgment.

13.6 If taken from one room to another, it is necessary to hold the equipment with both hands to prevent it from falling.

14 Radiation and Protection

14.1 Radiation

1) dose area product

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

Table 16

Test conditions (24cm from the focus of the tube)

Exposure time (ms)	Dose value (uGy)	Area (mm^2)	Dose area radiation ($\mu Gy*mm^2$)
20	48	2387	114576
25	60	2387	143220
32	80	2387	190960
40	102	2387	243474
50	130	2387	310310
63	165	2387	393855
80	210	2387	501270
100	262	2387	625394
125	328	2387	782936
160	418	2387	997766
200	512	2387	1222144
250	644	2387	1537228
320	818	2387	1952566
400	1018	2387	2429966
500	1266	2387	3021942
630	1589	2387	3792943
800	2013	2387	4805031
1000	2510	2387	5991370
1250	3132	2387	7476084
1600	4003	2387	9555161
2000	4995	2387	11923065

2) Dosimetric indications.

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

the focal point of the X-ray tube is 24cm, and the dose area product tost is-carried out. When choosing the corresponding exposure time, the deviaation of the measured dose area product does not exceed 50% of the valuin 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.

14.2 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:

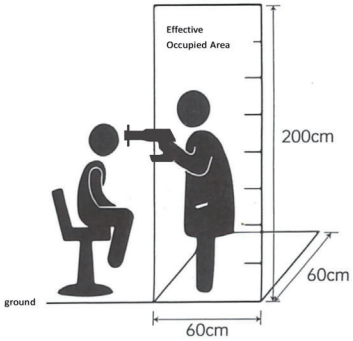


Figure 17 Effective occupied area

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

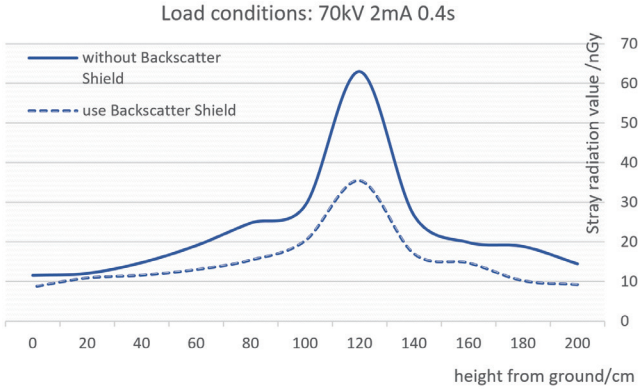


Figure 18 Stray radiation distribution diagram

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

2) Physical protection

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

15 Special description

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

Performance: The image quality of subject device is excellent and is not inferior the wall-mounted X-ray machine.Benefits: From the clinical data, such as significantly improving the selfcare ability. The hand-held dental radiograph can flexibly photograph lesions in the oral cavity. Direct action on the lesion is shown to reduce the exposure of other tissues of the patient to radiation. Compared with other dental X-ray 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.

16 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

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