
Roray Dental X-Ray System User Manual

Foshan Roson Medical Instruments Co., Ltd.

V1.0

Introduction

Dear customer,

Thank you for selecting our production!

- In order to use the product correctly, please read the users' manual carefully before use the equipment.
- The equipment is only for the qualified professional technician trained or qualified professionals (such as a dentist) in the hospital or clinic to use.
- The equipment belongs to the radioactive equipment, the operator should operate the equipment according to the users' manual, the equipment shall not be used for other purposes except for medical photography.

The following identifiers are used on the equipment, their meanings are as follows:

Symbol	Description	Symbol	Description
~	AC	==	DC
	Warning		Dangerous warning for ionizing radiation
	Follow the operating instruction		The symbol is prohibited to discard the electronic equipment casually, according to the regulations, the equipment should be disposed according to the local legal requirements, after the useful life.
	Protective ground		Type B application section
	X-ray emit or imminent emit		Standby
	Dangerous Voltage		

Catalogue

CHAPTER 1	OVERVIEW.....	5
1.1	PRODUCT BASIC INFORMATION.....	5
1.2	MANUFACTURER INFORMATION.....	6
CHAPTER 2	PRODUCT DESCRIPTION.....	7
2.1	TECHNICAL SPECIFICATION.....	7
2.1.1	PRODUCT TECHNICAL SPECIFICATION.....	7
2.1.2	PRODUCT BASIC SAFETY FEATURES.....	8
2.1.3	X-RAY TUBE TECHNICAL SPECIFICATION.....	9
2.1.4	PRODUCT SOFTWARE.....	10
2.2	WARNINGS AND CAUTIONS.....	10
2.2.1	WARNINGS.....	10
2.2.2	CAUTIONS.....	11
2.2.3	ELECTRIC SAFETY.....	11
2.2.4	X-RAY PROTECTIVE SAFETY.....	12
CHAPTER 3	PRODUCT OPERATION INSTRUCTION.....	13
3.1	PRODUCT OVERALL LAYOUT.....	13
3.1.1	THE HOST VIEW.....	13
3.1.2	THE BATTERY COVER OF THE HOST BASE VIEW.....	13
3.2	OPERATION PANEL DESCRIPTION.....	14
3.2.1	OPERATION PANEL.....	14
3.2.2	PRODUCT OPERATING DESCRIPTION.....	14
3.3	MATTERS NEEDING ATTENTION IN THE PROCESS OF USE.....	22
CHAPTER 4	INSTALLATION, MAINTENANCE AND MAINTAIN.....	23
4.1	PRODUCT INSTALLATION.....	23
4.1.1	ZONE OF SIGNIFICANT OCCUPANCY.....	23
4.1.2	POWER ADAPTER CONNECTION.....	23
4.1.3	EXPOSURE SWITCH INSTALLATION.....	24
4.2	EQUIPMENT MAINTENANCE.....	24
4.2.1	GENERAL PRINCIPLE.....	24
4.2.2	CLEAN.....	24

4.3 PRODUCT MAINTENANCE.....	25
4.3.1 DAILY MAINTENANCE.....	25
4.3.2 CLEANING AND MAINTENANCE THAT CAN BE PERFORMED BY AUTHORIZED TECHNICIANS.....	25
4.3.3 MAINTAIN AND MAINTENANCE CYCLE.....	25
4.4 NORMAL WORKING AND TRANSPORTATION STORAGE CONDITIONS.....	25
4.4.1 NORMAL WORKING CONDITION.....	25
4.4.2 TRANSPORTATION AND STORAGE CONDITIONS.....	26
4.4.3 WASTE DISPOSAL.....	26
CHAPTER 5 COMMON TROUBLESHOOTING AND OTHERS.....	27
5.1 FAULT DIAGNOSIS AND RESOLUTION.....	27
5.1.1 FAULT CODES AND TROUBLESHOOTING METHOD.....	27
5.1.2 CIRCUIT DIAGRAM OF THE PRODUCT.....	28
5.2 QUALITY GUARANTEE.....	28
5.2.1 MANUFACTURER'S RESPONSIBILITY.....	28
5.2.2 GUARANTEE CONTENT.....	28
5.3 PRODUCT OPERATING LIFE AND MANUFACTURE DATE.....	29
5.4 EQUIPMENT LIST.....	29
CHAPTER 6 ELECTROMAGNETIC COMPATIBILITY.....	30

Chapter 1 Overview

1.1 Product Basic Information

Product Name: Dental X-ray System

Working principle: The high voltage generator provides high voltage to both ends of the X-ray tube filament and metal target in the internal X-ray source assembly, a large number of electrons are generated on the cathode filament of the X-ray tube and move at a high speed in the vacuum tube, impact the metal target to generate the X-ray. The X-ray penetrate the different tissue densities of the body, such as teeth and muscles after pass through the X-ray window and beam tube, the X-ray which carry image information through body tissue, are passed through image receiving devices such as phosphor sheets, film or digital image receivers, to show different densities of human tissue images.

Application Range: used for the teeth to taking an X-ray photography, with an intraoral image receiver, images are obtained for the clinical diagnosis.

Structural composition: the product consists of the host (including the X-ray tube, controller and rechargeable battery), beam limiting tube, power adapter, stand and exposure switch.

Product model: Roray

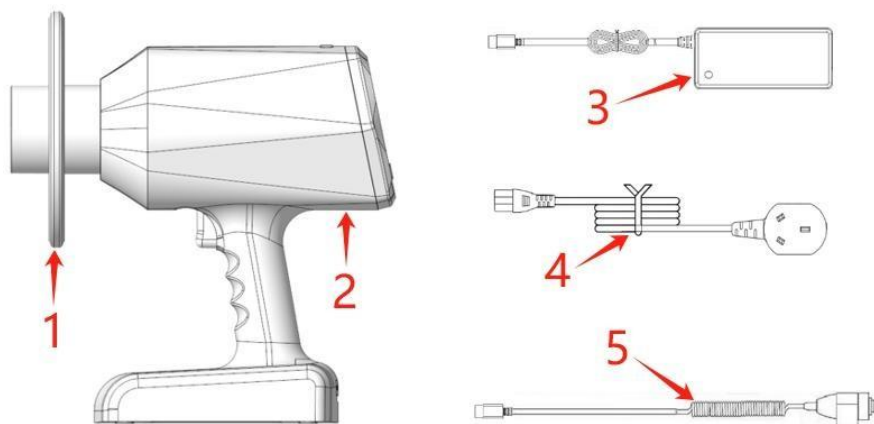


Figure 1-1 Roray Main Constituent Element

1—Protection plate (optional), 2—Host, 3—Adaptor, 4—Power Cable, 5—Exposure Switch (optional)

Contraindication: the patients and operators with cardiac pacemakers are prohibited, pregnant women exposed to X-ray is prohibited, X-ray irradiation should be used with caution in children.

Main feature: the product is a high frequency dental X-ray equipment, rated tube voltage is 65kV DC, rate tube current is 2.5 mA, the inverter X-ray control method is adopted, for chemical film and digital sensor diagnostics to obtain high quality dental images, the power supply of the X-ray system is 14.4V DC, powered by a rechargeable battery pack.

1.2 Manufacturer information

Manufacturer: Foshan Roson Medical Instruments Co., Ltd.

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Ver: V1.0

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Chapter 2 Product Description

2.1 Technical specification

2.1.1 Product technical specification

Serial number	Name		Parameter value
1	Power Adapter	Input Voltage	Uniphase AC 100~ 240V
		Supply Frequency	50/60Hz, ± 1 Hz
		Input Power	330W
2	Output Power		37.8W
3	Charge voltage		DC 25.2V
4	Charge current		1.5A
5	Nominal value of the focal point		0.4mm
6	Anode angle		15°
7	Available maximum tube voltage at 2.5mA		65kV
8	Maximum output electric power		162.5W
9	Maximum loading factor combination		65kV、2.5mA、2s
10	Repeatability of radiation output		No more than 0.05
11	Tube voltage (The deviation is within the range of $\pm 10\%$)		65kV
12	Tube current (The deviation is within the range of $\pm 20\%$)		2.5mA
13	Running mode		Discontinuous operation, maximum excitation (open) time : minimum excitation (close) time = 1: 30
14	Total filtration of X-ray tube assembly		> 2.5 mm Al
15	Intrinsic filtration of X-ray tube assembly		0.75mm Al
16	Additional filtration		1.5mm Al
17	Half-value layer		≥ 1.5 mm Al (65kV)

18	Leakage radiation	$\leq 0.25\text{mGy/h}$ (65kV、2.5mA、2s)
19	Adjustment range of the loading time	0.02 ~ 2.00s, adjustable by R10 coefficient
20	Distance of the Focal point to skin (The deviation is within 0~5%)	215mm $\pm$ 3mm (long) 164mm $\pm$ 3mm (short)
21	X-ray field size at the end of beam limiting tube	round, Φ 53mm $\pm$ 3mm (long) round, Φ 54mm $\pm$ 3mm (short)
22	Nominal electric power	0.16kW (65kV、2.5mA、0.1s)
23	Available maximum tube current at 65kV	2.5mA
24	Inverter frequency of the high voltage generator	80kHz

2.1.2 Product basic safety features

- (1) Safety category: Class I or internal power supply class, does not work while charging.
- (2) Classified by electric shock protection type: Type B application section.
- (3) Classified by the degree of protection against fluid intake: Common equipment.
- (4) Classified by the manufacturer's recommended disinfection and sterilization methods: As required by the manufacturer to carry out.
- (5) Classified by the degree of safety for use with flammable anesthetic gases mixed with air or with oxygen or nitrous oxide: Non AP/APG type.
- (6) Classified by operation mode: Discontinuous operation, Maximum excitation (open) time: Minimum excitation (close) time = 1: 30.
- (7) The product has no application part with protection against defibrillation discharge effect.
- (8) Whether the equipment has a signal output or input part: No.
- (9) The product is a common equipment.
- (10) Permanent or non-permanent installation equipment : Non-permanent installation equipment.
- (11) Radiation type: Ionizing radiation.
- (12) Radiation property: X ray.
- (13) Radiation distribution: The X-ray radiates from the positive direction of 6cm circle in the window of the limited beam barrel when used.

2.1.3 X-ray tube technical specification

Serial number	Name	Parameter value
1	The X-ray tube model	XD10DF-0.2/70
2	Nominal value of the focal point	0.4mm
3	Target material	Tungsten
4	Maximum working tube voltage	70kVP
5	Anode angle of the X-ray tube	15°
6	Intrinsic filtration	0.75 mm Al
7	Filament current	2.0 A
8	Filament voltage	2.35~3.35 V

The emission characteristics of X-ray tubes are shown in Figure 2-1.

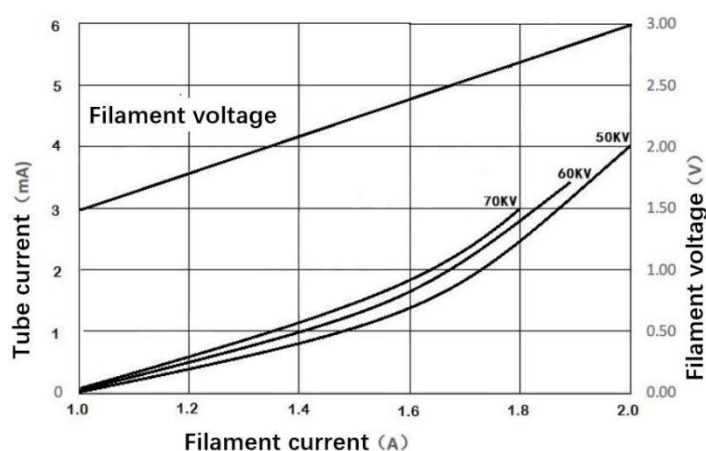


Figure 2-1 Filament emission characteristics of X-ray tube

The X-ray tube load characteristics are shown in Figure 2-2.

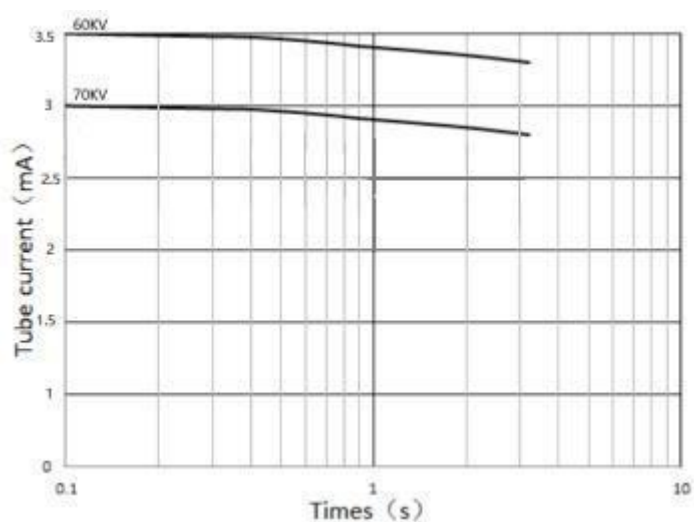


Figure 2-2 Load characteristics curve

Heating and cooling characteristics of the anode are shown in Figure 2-3.

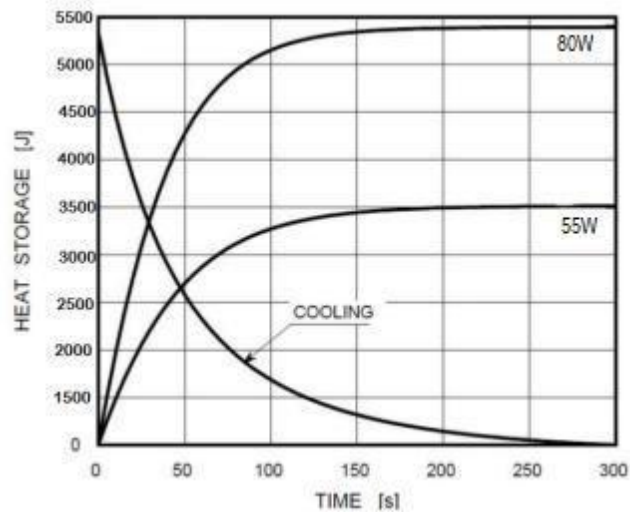


Figure 2-3 Heating and cooling characteristics of the anode

The X-ray tube dimension is shown in Figure 2-4.

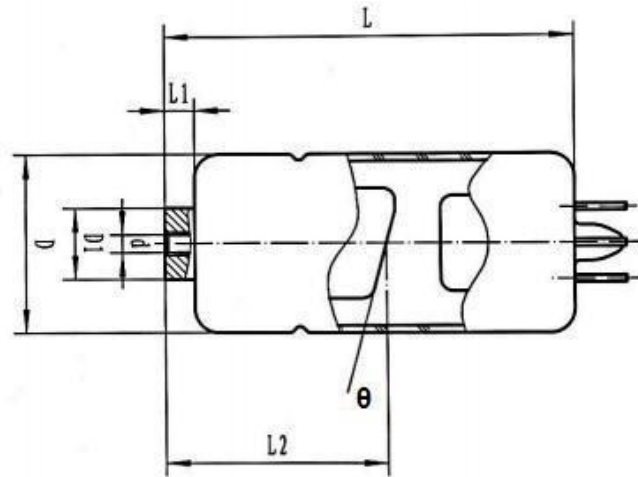


Figure 2-4 Dimension

L	L1	L2	D	D1	d
$68 \pm 2\text{mm}$	$4.5 \pm 1\text{mm}$	$37 \pm 0.5\text{mm}$	$\Phi 30 \pm 0.1$	$\Phi 12 \pm 0.1$	M4

2.1.4 Product software

Software name: The control software of the dental X-ray system

Release version: V1.0

2.2 Warnings and cautions

2.2.1 Warnings

⚠Warning: To avoid the risk of electric shock, the product must be connected to the power supply network with protective grounding when charging.

⚠Warning: The users' manual instructs product operators to operate the product safely. The product should only be used by persons with the necessary radiological knowledge and training, the manufacturer is not responsible for any improper operation, negligence or improper use.

⚠Warning: The power supply of the host must be turned off when the exposure is over.

⚠Warning: When taken an X-ray photography for tooth, the medical staff should always monitor during exposure.

⚠Warning: Ionizing radiation.

⚠Warning: Do not place the equipment on the position that is difficult to operate the disconnecting device. The equipment uses a flexible wire with a mesh power plug as a breaking device.

⚠Warning: Modification of the product is not permitted.

2.2.2 Cautions

- In order to use the product correctly, please read the users' manual carefully before use the equipment.

- The equipment is only for the qualified professional technician trained or qualified professionals (such as a dentist) in the hospital or clinic to use.

- The equipment belongs to the radioactive equipment, the operator should operate the equipment according to the users' manual, the equipment shall not be used for other purposes except for medical photography.

- The equipment should not be used when there is any electrical or mechanical fault.

- The protective circuit and protective facilities of the equipment shall not be removed to make the equipment work with electricity.

- The equipment must not be used in a humid, flammable, or explosive environment.

- Any modification to the equipment shall be approved by our company or its authorized maintenance personnel.

- Ensure that there is no risk to the patient or the operator when replace the components of the equipment, if necessary, consider contacting our maintenance personnel.

Any improper operation of the equipment will cause damage to the equipment, regular inspection and maintenance is also necessary.

2.2.3 Electric safety

- Ensure the voltage and current meet the power requirements of the product.

- There is no flammable or explosive gas leakage in the room where the equipment is located.

-
- Ensure the battery charger is unplugged before cleaning, cleaning should be carried out in the case of the equipment is power off, only use non-alcohol sanitizer wipes or cloths dampened with liquid or spray.
 - X-ray system and the included battery charger is not suitable for any type of disinfection.
 - Turn off the X-ray System after use.

2.2.4 X-ray protective safety

Ensure to take precautions against X-ray before each exposure, keep the following in mind:

- Wear protective clothing, wear protective goggles during the X-ray examination.
- Dose exposure should be as low as possible during the X-ray examination permissive condition.
- Human skin should be as far away from X-ray sources as possible, when diagnostic requirements are met.
- The radiation exposure and absorbed radiation dose are inversely proportional to the square of the distance from the radiation source, the farther away you are from the source, the lower the dose you receive. The operator should be 3 meters away from the X-ray tube head.
- The X-ray Generated by the equipment has certain harm to human body. Besides operate the X-ray system properly to ensure it normal operation, it is more important to pay special attention to the protection of human body against X-ray, so as to minimize the harm of X-ray operators and patients. Such as the equipment room should have protective equipment and measures (such as lead plates), and the operator must use protective equipment (such as lead glasses) and wear protective clothing (such as lead caps, lead aprons, and lead gloves). The operator must operate in an occupied area when approaching patients for radiological examination.

Chapter 3 Product operation instruction

3.1 Product overall layout

3.1.1 The host view

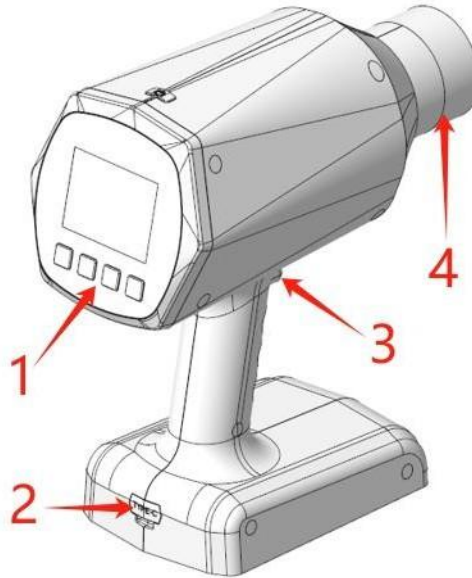


Figure 3-1 The host view

Figure 3-1 functional descriptions:

Serial number	Position	Name	Functional descriptions
1	“1”	Operation panel	See the details below 3.2.
2	“2”	Adapter or exposure switch connection port	Open the cover and put the adapter charging cable into the connection port, realize internal battery charging, or put the exposure switch cable into the connection port, realize exposure switch connection.
3	“3”	Exposure switch	Press the exposure button to activate the X-ray exposure.
4	“4”	Beam tube	Provide X-ray emission field dimension.

3.1.2 The battery cover of the host base view

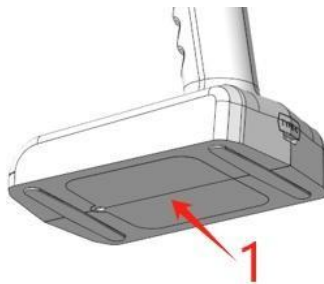


Figure 3-2 The battery cover of the host base view

Figure 3-2 functional descriptions:

Serial number	Position	Name	Functional descriptions
1	“1”	Battery cover	Open the battery cover to replace the battery.

3.2 Operation panel description

3.2.1 Operation panel

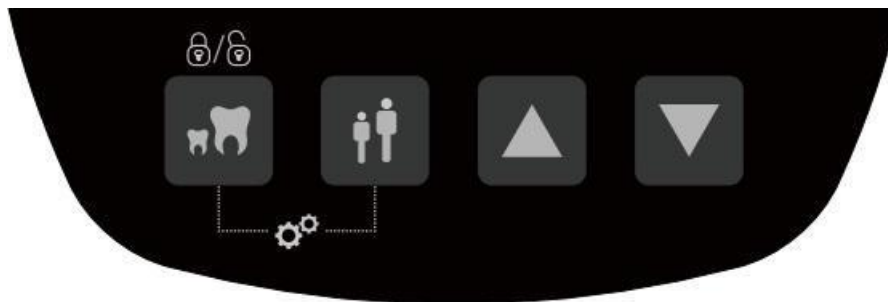


Figure 3-3 Operation panel

Figure 3-3 functional descriptions:

Serial number	Keypad	Name	Functional descriptions
1		Power On/Off button	Turn on or turn off the equipment power supply
2		Patient body type selection button	Select body type large/small
3		Up button	Increase loading time
4		Down button	Decrease loading time
5		Teeth type selection button/Child lock button	Select teeth type/Lock or Unlock

3.2.2 Product operating description

(1) Product power ON/OFF

Power ON: press the power On/Off button, system power on, the buzzer sounded, the screen light up, ensure that at least one grid of power is available before start up the equipment.

Power OFF: press the power On/Off button, the buzzer sounded, turn off the equipment.

Enter the main interface:

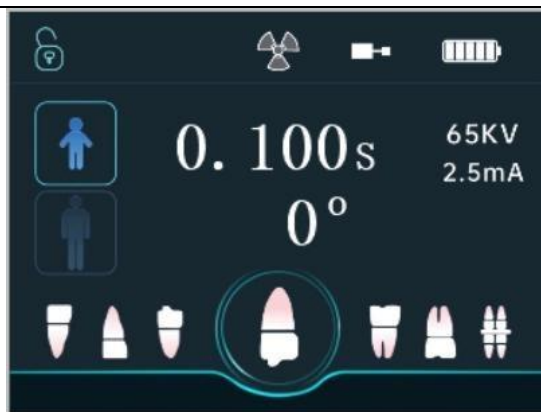


Figure 3-4 Main interface

Figure 3-4 functional descriptions:

Serial number	Symbol/Value	Name	functional descriptions
1		Tooth	Display the selected tooth type
2		Standby/Exposure	Indicate Standby/Exposure state
3		Battery capacity	Display the battery capacity state
4		Patient	Display the selected patient type
5		Exposure tube voltage	Display the fixed exposure tube voltage
6		Exposure tube current	Display the fixed exposure tube current
7		Exposure time	Display the setting exposure time
8		Receptor	Display the receptor that receipt X-ray
9		Angle	Display the photograph angle
10		Child lock	Lock or unlock

(2) Body type large/small selection button



Select the type of patient , please press the patient body type selection button , the selection will display the corresponding blue symbol on the screen.

(3) Teeth type selection button



Select the tooth type, please press the teeth type selection button, the selection will display the corresponding tooth type symbol on the screen, as shown in Table 1-1.

Table 1-1

Teeth type							
Description	Upper canine tooth	Lower molar tooth	Upper molar tooth	Wing bite teeth	Lower front tooth	Upper front tooth	Lower canine tooth

(4) Standard exposure time

Preset standard exposure time as shown in Table 1-2.

Table 1-2

Patient type	Receiver type							
Child	Sensor	0.1	0.125	0.2	0.32	0.08	0.08	0.1
Adult	Sensor	0.25	0.2	0.32	0.4	0.16	0.16	0.25
Child	Scanner	0.125	0.16	0.25	0.4	0.1	0.1	0.125
Adult	Scanner	0.32	0.25	0.4	0.5	0.2	0.2	0.32
Child	Film	0.2	0.25	0.4	0.63	0.16	0.16	0.2
Adult	Film	0.5	0.4	0.63	0.8	0.32	0.32	0.5

(5) Photograph angle

The patient keeps a correct seated position, sit on a chair upright, adjust the photograph angle of the X-ray machine, the reference values of the photograph angle as shown in Table 1-3.

Table1-3

Tooth	X-ray direction	Recommend angle
	Tilt down	+45°
	Tilt up	-5°

	Tilt down	+30°
	Tilt down	+5° ~ +8°
	Tilt up	-25°
	Tilt down	+45°
	Tilt up	-20°

(6) Exposure time

Change the exposure time, please press the Up button  to increase the exposure time, or press the Down button  to decrease the exposure time.

(7) Exposure operating steps

- 1) Firstly set the exposure conditions you want to take photographs.
- 2) Fix the sensor to the opposite side to be exposed, then connected to the device in the exposure section.

- 3) Press the exposure button  .

- 4) When the Exposure start, the exposure ready symbol“”display on the screen , then the exposure symbol“”display on the screen. Meanwhile, the buzzer sounded.

- 5) After taken photographs, the screen display standby symbol“”, the next exposure can be made.

- 6) If battery pack charged fully, can take about 800 photographs. (exposure condition is 0.2 s interval 120 s)

7) The battery capacity are 3 grids or less than 3 grids, please charge before exposure.

(8) Battery charge

The battery capacity display at the top right corner on the screen. It will influence image if the battery capacity is low. Therefore, you must always check the battery state. If the battery capacity is low, The battery symbol“”display on the screen, make sure to charge the battery. It takes about two hours to charge, Turn off the equipment when the battery is charging.

(9) Mode Function

Press the combination buttons ( + ), enter the setting interface to set modes, are shown in figure 3-5.

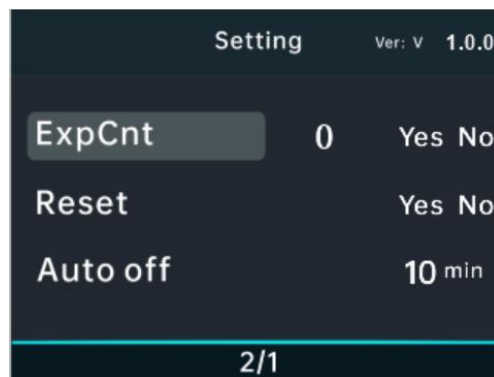


Figure 3-5 Setting interface

1) ExpCnt

Record the exposure count.

In the mode setting interface, press the Up button  or Down button  select the ExpCnt, then press the patient body type selection button , the non-selectable state  behind ExpCnt change to the selectable state , press the Up button  or the Down button  again, the  behind ExpCnt change to  at the

same time, press the patient body type selection button  to clear the exposure number,

finally press the teeth type selection button  shortly to exit the setting interface and return to the main interface.

2) Reset

Restore factory defaults.

In the mode setting interface, press the Up button  or Down button  select the Reset, then press the patient body type selection button , the non-selectable state  behind Reset change to the selectable state , press the Up button  or the Down button  again, the  behind Reset change to  at the same time, press the patient body type selection button  to restore factory defaults, return to the main interface automatically after the factory defaults is restored.

3) Auto off

If the equipment is not operated within the Auto off time , the equipment turn off automatically, to prevent unnecessary power consumption.

In the mode setting interface, press the Up button  or Down button  select the Auto off, then press the patient body type selection button , the time behind Auto off change to the adjustable state, such as , press the Up button  or the Down button  again, to set the Auto off time, press the patient body type selection button  again, the time behind Auto off change to the un-adjustable state, such as , save the Auto off time, finally press the teeth type selection button  shortly to exit the

setting interface and return to the main interface.

4) Sleep

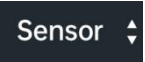
If the equipment is not operated within the sleep time, it will go into sleep mode automatically.

If you want to change the sleep time, please press the combination buttons ( + ) to enter the setting interface, then set the sleep time.

In the mode setting interface, press the Up button  or Down button  select the Sleep time, then press the patient body type selection button , the time behind Sleep time change to the adjustable state, such as , press the Up button  or the Down button  again, to set the Sleep time, press the patient body type selection button  again, the time behind Sleep time change to the un-adjustable state, such as , save the Sleep time, finally press the teeth type selection button  shortly to exit the setting interface and return to the main interface.

5) Receptor

The user can choose a receptor between the sensor , the scanner  and the film  to receipt the X-ray.

In the mode setting interface, press the Up button  or Down button  select the Receptor, then press the patient body type selection button , the sensor or the scanner or the film behind the Receptor change to the adjustable state, such as , press the Up button  or the Down button  again, set the appropriate receptor, press the patient body type selection button  again, the appropriate receptor change to the un-adjustable state, such as , save the appropriate receptor, finally press the teeth type selection buttons  shortly to exit the setting interface and return to the main interface.

6) Language

In the language setting interface, press the Up button  or Down button  to select the Language option, then press the patient body type selection button ; the Chinese, English, Spanish and Russian options (figure 3-6) under the Language entry will change to the adjustable state. For example, press the Up button  or the Down button  again to set the appropriate language, then press the patient body type selection button  again to confirm and switch to the selected language. Finally, press the teeth type selection button  shortly to exit the setting interface and return to the main interface.

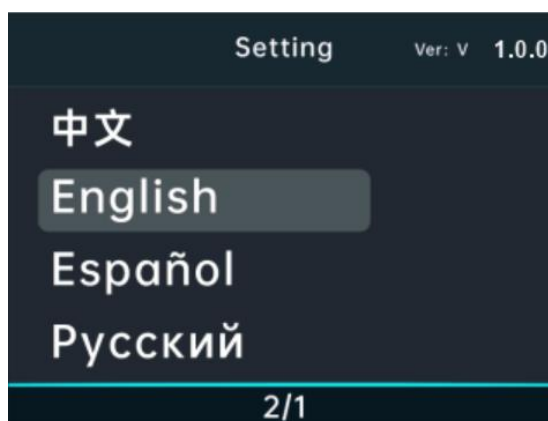


Figure 3-6 Language Setting interface

7) Main Ver

Main Ver: Software version.

(10) Child lock

Press the teeth type selection buttons  long to lock or unlock the screen. The unlock symbol  is displayed on the screen when the screen is unlocked. The lock symbol  is displayed on the screen when the screen is locked.

The exposure button on the equipment is not allowed to perform exposure operation, not allowed to adjust the exposure time, not allowed to select the patient body type, not allowed to select the tooth, not allowed to enter the setting page, and the angle is not allowed to refresh when the screen is locked.

3.3 Matters needing attention in the process of use

- (1) The X-ray image receiver will affect the image quality, the digital sensor that obtains the filing certificate of Class II medical device.
- (2) During the loading exposure, the host should be held in a steady position, should avoid the image degradation due to dithering.
- (3) The equipment should be placed in a clean and dry working room with air circulation, avoid humidity, high temperature and sun exposure.
- (4) Each button, do not exert too much force in use, to prevent dislocation, damage or poor contact, even damage.
- (5) Turn off the equipment after use in time.
- (6) X-ray system avoid collision in the case of use.

Chapter 4 Installation、Maintenance and Maintain

4.1 Product Installation

4.1.1 Zone of significant occupancy

The zone of significant occupancy is shown in figure 4-1.

The zone of significant occupancy shall be provided when the operator is required to be present, the area is no less than 60cm * 60cm, the height is no less than 200cm.

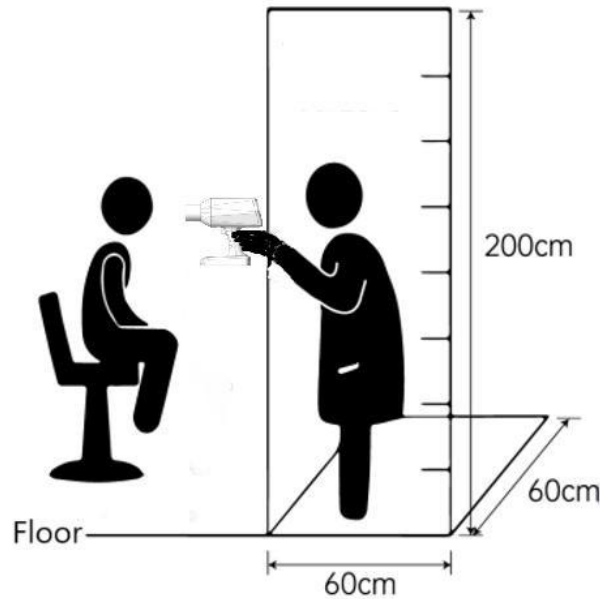


Figure 4-1 Zone of significant occupancy

4.1.2 Power Adapter Connection

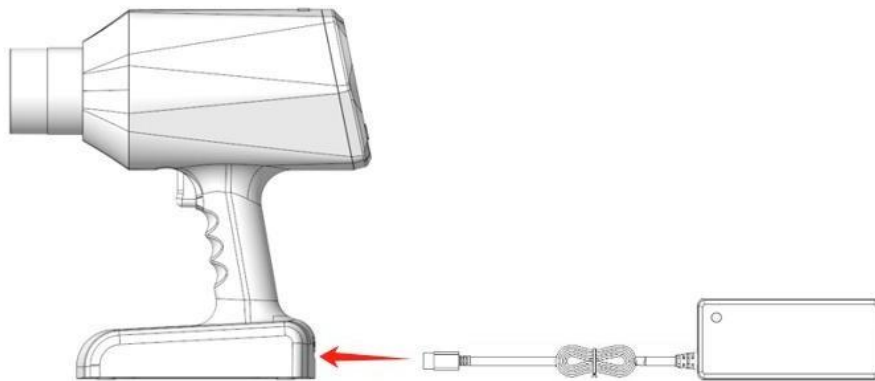


Figure 4-2 Power adapter connection

The power adapter connection is shown in figure 4-2 , put the adapter Type-C plug into the adapter connection port of the host, the adapter AC plug connect user AC100~240V to charge the battery.

4.1.3 Exposure Switch Installation

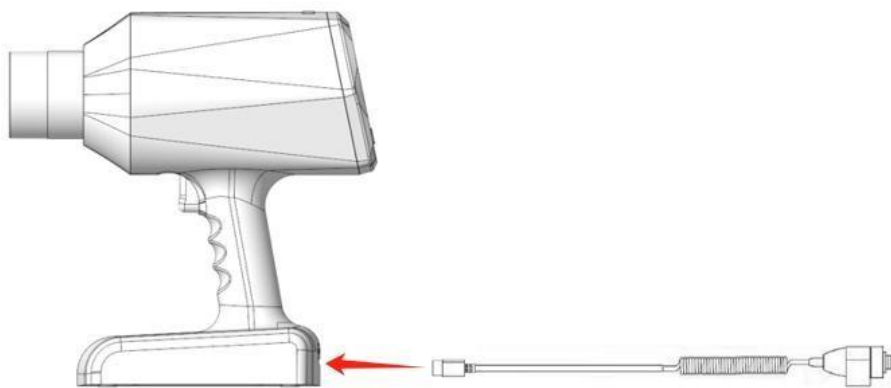


Figure 4-3 Exposure switch

The exposure switch installation is shown in figure 4-3, put the exposure switch into the exposure switch connection port.

4.2 Equipment Maintenance

4.2.1 General Principle

The equipment needs regular maintenance, the following suggestions are good for use and safety:

- (1) Keep the machine room clean, dry, well ventilated.
- (2) The equipment should be taken charge by special personnel, and establish management files.
- (3) In order to ensure the safety of user and patient, the equipment shall not be reformed at will, if necessary, please contact manufacturer.
- (4) The professional must be recognized by the manufacturer to inspect and repair the equipment, after the product failure.
- (5) The operator is well trained, able to complete routine inspection.
- (6) If the X-ray tube has not been used for a long time (such as more than 1 month), the X-ray tube must be loaded gradually before use, that is, the exposure time should be loaded twice successively from 0.02s→ 0.1s→ 1.0s to avoid the X-ray tube to be damage caused by excessive instantaneous loading power.

4.2.2 Clean

A soft brush or cleaning cloth should be use to clean the visible pollutant of the equipment surface, dampen the gauze with alcohol (alcoholicity 70-80 vol%) to wipe the surface.

⚠Warning : When performing the above cleaning work, the power supply of the unit must be

turned off ! And pay attention to the cleaning liquid shall be not flowed into the unit, avoid circuit leakage and short circuit, thus cause a variety of failures, even resulting in personal injury accidents.

4.3 Product Maintenance

4.3.1 Daily Maintenance

- (1) The equipment surface should be kept clean and dry, use a soft cloth dipped in a little anhydrous alcohol to scrub the surface of various residues.
- (2) Flammable liquids and gases should not approach the equipment to prevent explosion.

4.3.2 Cleaning and maintenance that can be performed by authorized technicians

Dental X-ray system is a precise and valuable medical diagnostic equipment, the user should understand the technical performance, structural principle and operating procedures of the equipment, perform the routine maintenance and maintain, to give full play to the efficiency of the equipment, extend the service life, ensure the normal operation of the equipment, ensure the safety of operators and inspected personnel.

4.3.3 Maintain and Maintenance Cycle

Time Interval	Maintenance and inspection contents
Daily Check	Check signal, display and indicate light whether normal or not. Check the buzzer whether normal or not. Check there is any abnormal sound when the high voltage generator assembly exposed. Check whether each button is loose or stuck.
Monthly Check	Check the continuous endurance about the used battery pack whether normal or not.
Annual Check	Safety checks must be carried out on the equipment to ensure the equipment run properly.

4.4 Normal working and transportation storage conditions

4.4.1 Normal working condition

- a) Environment temperature: 10°C~40°C
- b) Relative humidity: 30%~75% c)
- Atmospheric pressure: 700hPa~1060hPa
- d) Altitude: ≤ 2000m

4.4.2 Transportation and storage conditions

- a) Environment temperature: $-20\sim 55^{\circ}\text{C}$
- b) Relative humidity: $20\%\sim 80\%$
- c) Atmospheric pressure: $70\text{kPa}\sim 106\text{kPa}$

4.4.3 Waste disposal

Concerning waste disposal shall be complied with the local laws and regulations when the equipment is scrapped. The X-ray source assembly and electronic circuit (such as PCB, etc.) related parts shall be regarded as non-environmental waste products.

Chapter 5 Common troubleshooting and others

5.1 Fault diagnosis and resolution

5.1.1 Fault codes and troubleshooting method

During normal and abnormal operation, the status will be displayed on the screen. We provide common fault symptoms and suggested measures for troubleshooting. Users can refer to the solutions provided to troubleshoot the fault. If you cannot identify the cause of the fault, or if you have tried the following methods but still cannot resolve the fault, please contact us.

The error code is displayed on the screen, when any of the following faults occur. The error code content and troubleshooting methods are described in table 5-1.

Table 5-1

Error Code	Description	Recommended measure
ER0	Connection fail	Turn off and restart
ER1	Overcurrent protection or disconnection of tank line or mA, kV high	Contact the technical support
ER2	kV low	Contact the technical support
ER3	mA low	Contact the technical support
ER4	Filament driving voltage is low	Contact the technical support

If the equipment can't be turned on, or can't be exposed normally, or charging abnormally, may be the battery occur fault, you should contact our engineers to replace the battery, unauthorized personnel should not open the product shell.

If the exposure button is pressed for a shorter time than the set exposure time, the “” displayed on the screen, press the patient body type selection button or Up button or Down button to remove the “” to make an exposure.

5.1.2 Circuit diagram of the product

Any operation relating to maintenance involving access to the interior of the equipment must be performed by our Company's engineers. If Circuit diagram, drawing notes, calibration rules and other relevant data related to the maintenance of this product are required, our company will provide the data that can be provided.

5.2 Quality Guarantee

5.2.1 Manufacturer's Responsibility

The manufacturer shall be responsible for the safety, reliability and performance of the equipment in the following cases:

- (1) Assembly, debug, modify and maintenance are carried out by or authorized personal by our Company.
- (2) The electrical facilities used in the equipment meet the requirements specified in the user manual.
- (3) The operators are skilled technicians who have received training and use the equipment in strict accordance with the requirements of the user manual.

5.2.2 Guarantee content

- (1) The quality of the product is guaranteed for one year from the date of purchase.
- (2) The equipment is damaged because the user fails to comply with the above terms and conditions, or more than one year since the date of delivery of the equipment, our company will repair or replace equipment parts for the user, but will charge the cost of maintenance.
- (3) If it is difficult to identify the warranty period, the warranty shall apply after three months of manufacture.
- (4) For defects of the product or improper process, the product will be free of charge maintenance or replacement according to the state of the product.
- (5) If the damage is caused by the user's fault, it will not be repaired free of charge, even within the warranty period.
- (6) If additional grades of seals have been removed or have such instructions, they shall not be repaired and guaranteed free of charge.
- (7) Repairs performed in places other than our company or without our company's authorization are not covered by the warranty.
- (8) The service life of the product which have been free or have been repaired for free shall not be extended.

5.3 Product Operating Life and Manufacture Date

The product operating life is 5 years, the manufacture date see the nameplate of the equipment.

5.4 Equipment List

The host, the exposure switch (optional), the adaptor, the power cable, protection plate (optional) contained in the product, one piece each.

Chapter 6 Electromagnetic Compatibility



Notice:

- The equipment conforms to the electromagnetic compatibility requirements of YY9706.102 and GB9706.265 standards.
- The user shall install and use according to the EMC information provided in the accompanying file.
- Portable and mobile radio frequency communication devices may affect the performance of the equipment, avoid strong electromagnetic interference when using, such as near mobile phones and microwave ovens, in this case, please contact our personnel for troubleshooting.
- Operate in strict accordance with the user manual of the equipment, to ensure the equipment is not interfered by electromagnetic basic working conditions.
- The guidelines and manufacturer's statement are detailed in the attachment.

Cable information provided randomly:

Name	Length (m)	Whether shield
Power cable	1.0	NO
Adapter cable	1.0	NO
Exposure switch connection cable	3.0	NO

Electromagnetic compatibility basic performance of the dental X-ray system:

1. Accuracy of loading factors
2. Repeatability of radiation output

a) Guide and manufacturer's statement—Electromagnetic emission

The customer or user of the product shall ensure the equipment is used in the electromagnetic environment described below.

Guide and manufacturer's statement—Electromagnetic emission		
The purchaser or user shall ensure the dental X-ray system is intended to be used in the electromagnetic environment specified below:		
Emission test	conformance	Electromagnetic environment—Guide

RF emission GB4824	Group 1	Dental X-ray system use radio-frequency energy only for their internal functions. Therefore its radio-frequency emission is low and there is little chance of interference with nearby electronics.
RF emission GB4824	Class B	Dental X-ray machines are suitable for using in domestic and all facilities connected directly to the domestic public low-voltage supply grid.
Harmonic emission GB 17625.1	Class A	
Voltage fluctuation / Scintillation emission GB17625.2	Conform	

b) Guide and manufacturer's statement—Electromagnetic immunity

The customer or user of the product shall ensure the equipment is used in the electromagnetic environment described below.

Guide and manufacturer's statement—Electromagnetic immunity			
The purchaser or user shall ensure the dental X-ray system is intended to be used in the electromagnetic environment specified below:			
Immunity test	IEC 60601 Test level	Coincidence level	Electromagnetic environment—Guide
ESD GB/T 17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should be wood, concrete or tile, and if the floors are covered with synthetic materials, the relative humidity should be at least 30%
Electrical transient fast pulse group	±2kV to power wire ±1kV to input/output wire	±2kV to power wire	The grid power supply should be of a quality typical for use in a

GB/T 17626.4			commercial or hospital setting
Surge GB/T 17626.5	± 1 kV wire to wire ± 2 kV wire to ground	± 1 kV wire to wire	The grid power supply should be of a quality typical for use in a commercial or hospital setting
Voltage dips, short - time interruptions and voltage changes on power input lines GB/T 17626.11	<5 % UT, continue 0.5 period (on UT, $>95\%$ temporary drop) 40 % UT, continue 5 period (on UT, 60% temporary drop) 70 % UT, continue 25 period (on UT, 30% temporary drop) <5 % UT, continue 5s (on UT, $>95\%$ temporary drop)	<5 % UT, continue 0.5 period (on UT, $>95\%$ temporary drop) 40 % UT, continue 5 period (on UT, 60% temporary drop) 70 % UT, continue 25 period (on UT, 30% temporary drop) <5 % UT, continue 5s (on UT, $>95\%$ temporary drop)	The grid power supply should be of a quality typical for use in a commercial or hospital setting. If the user of the device needs continuous operation during a power outage, it is recommended that the device use uninterruptible power supply or battery power supply
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m,50Hz	The power frequency magnetic field should have the power frequency magnetic field level characteristic of a typical site in a typical commercial or hospital environment
Note: UT is the AC network voltage before the test voltage is applied			

Guide and manufacturer's statement–Electromagnetic immunity			
The purchaser or user shall ensure the dental X-ray system is intended to be used in the electromagnetic environment specified below:			
Immunity test	IEC 60601 Test Level	Coincidence level	Electromagnetic environment–Guide
RF Conduction GB/T 17626.6 RF Radiation GB/T 17626.3	3 V (effective value) 150 kHz~ 80 MHz 3 V/m 80MHz~ 2.5GHz	3 V (effective value) 3 V/m	Portable and mobile RF communication devices should not be used closer to any part of the dental X-ray system than the recommended isolation distance, including cables. The distance should be calculated by a formula corresponding to the transmitter frequency $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ P--According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, unit is watt (W). d—Recommended isolation distance, unit is meter(m). The field intensity of a stationary RF transmitter is determined by surveying the electromagnetic field a and should be lower than the coincidence level in each frequency range b. Interference may occur near devices marked with the following symbols. 
Note 1: At 80MHz and 800MHz, the formula of higher frequency band is used.			

Note 2 : These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.

a The field strength of stationary transmitters, such as wireless (cellular/cordless) telephone and ground mobile radio base stations, amateur radio, AM and FM radio broadcasting, and television broadcasting, cannot be accurately predicted in theory. If the field intensity measured at the site of the equipment is higher than the applicable RF coincidence level, the equipment shall be observed to verify its normal operation.

b In the whole frequency range of 150KHz ~ 80MHz, the field strength should be less than 3 V/m.

c) Recommended distance for electromagnetic immunity

Dental X-ray system is designed for electromagnetic environments that can produce controlled radio-frequency interference. The user advised to maintain a minimum distance between portable and mobile RF communication devices and the device based on the rated power of the device to prevent electromagnetic interference.

Recommended isolation distance between portable and mobile RF communication equipment and this equipment			
Dental X-ray system is intended for use in electromagnetic environments where radio-frequency radiation harassment is controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and dental X-ray machines as recommended below.			
The rated maximum output power of a transmitter W	The isolation distance of the transmitter at different frequencies /m		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Rated maximum output power of transmitter not listed in the table above , recommended isolation distance d , unit is meter (m), it can be determined by the formula in the corresponding transmitter frequency column, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, unit is watt (W) .

Note 1: At 80MHz and 800MHz, the formula of higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects, and the human body.