CE 2460

SIGER

SIRAY / SIRAY PLUS

Dental X-ray Unit

Operating Manual

Zhuhai Siger Medical Equipment Co., Ltd.

Foreword

Please read this manual carefully before using this product, and keep it handy for future use. You must strictly follow the operating procedures to use this product and maintain it properly.

OPERATOR or the RESPONSIBLE ORGANIZATION shall read these instructions for use as the training or the knowledge required for using this equipment.

Paragraphs marked with "**Warning**" or "**Caution**" shall be read and executed carefully to avoid injuries to operators and patients or damage to the equipment.

If any fault occurs to the equipment during use, please contact the local dealer or the company in time.

Contents

Chapter 1 Product Description

1.1 Model and specifications:

SIRAY, SIRAY PLUS

1.2 Clinical benefit

The Dental X-ray Units is a kind of intraoral dental radiography and cooperates with an intraoral image receiver to take X-ray photography for periapical, periodontal bone levels, maxilla and mandible （including: premolar, anterior teeth, molars）in adult patient then to provide clear and accuracy of critical information for diagnosis caries, the detection of periapical lesions and the display of periodontal lesions in general dental practice. It can provide patients with a painless, noninvasive dental examination and help dental doctors diagnose, treat, and evaluate the presence of teeth disease, so that patients can get targeted treatment.

1.3 Intended use:

Dental X-ray Units is used for X-ray photography of teeth for adult patient, and cooperates with an intraoral image receiver to obtain images for clinical diagnosis. It is limited to dental clinic or dental hospital clinical for diagnosis, is limited to trained and qualified dentists or dental technicians.

- **Contraindications**

X-ray radiation is prohibited in pregnant women and children. X-ray irradiation is strictly prohibited for patients and operators with pacemakers and other implantable electronic equipment.

- **Medical condition**

Used for X-ray photography of teeth

- **Side-effect**

Low levels of radiation exposure

- **Patient target group**

a) Population: adult
b) Age: above 18 years old

- **Intended user**

The equipment is used by Trained and qualified dentist or dental technician.

User profile:

a) Education

At least 18 years old – 9 years intensive reading experience (school).

b) Knowledge

Read and understand ‘westernized Arabic’ numerals when written in Arial font.

Read this manual before use.

c) Language understanding

Can understand English language in the User Manual and displayed on touch screen console.

d) Permissible impairments

Mild reading vision impairment or best-corrected visual acuity to log MAR 0.5 (6/19 or 20/63) or better.

e) Experience:

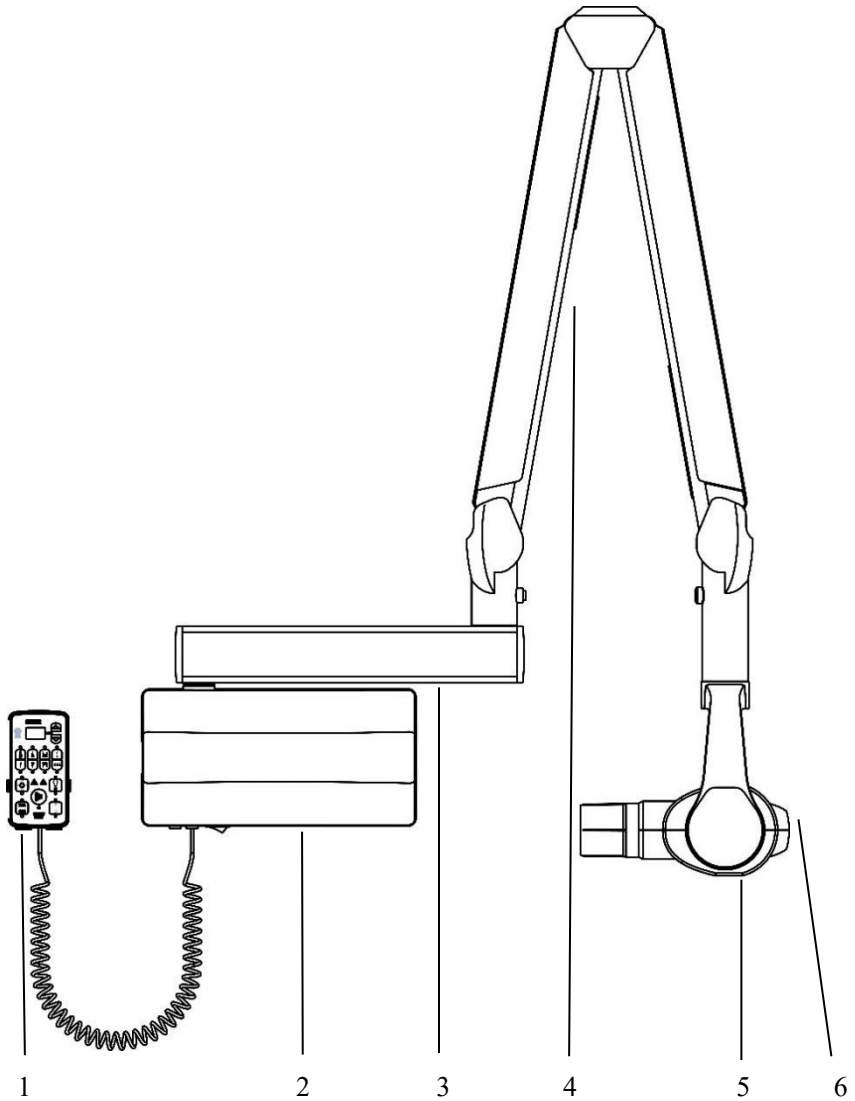
Fully trained by Siger for the dental X-ray unit.

Having experience using similar medical devices.

1.4 Structure:

A diagnostic dental x-ray system designed for permanent fixture in one location to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for general purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. The sensor is placed in the mouth, the purpose being to visualize a limited region in detail.

The dental X-ray unit is composed of an X-ray tube head, a control box, a frame (cross arm and telescopic arm), and is divided into a wall-mounted dental X-ray unit (SIRAY) and floor-mounted dental X-ray unit (SIRAY PLUS) according to its structure and installation method. The following is the panoramic view of the equipment:

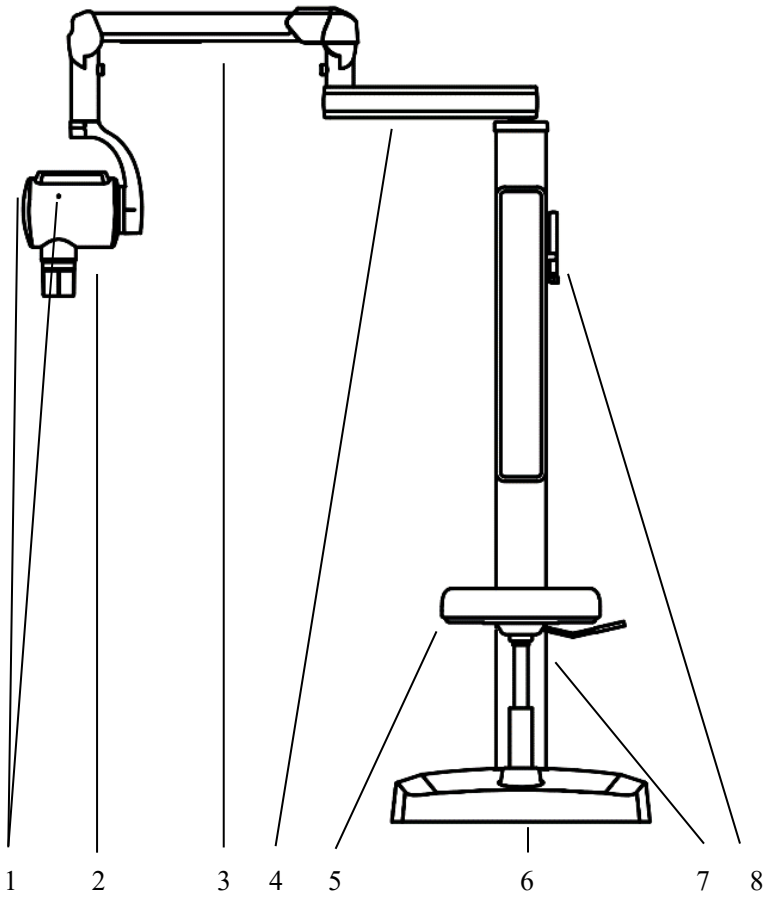


Wall-mounted dental X-ray unit (SIRAY)

Name of main parts

1	Operating panel	4	Telescopic arm
2	Control box	5	X-ray tube assembly
3	Cross arm	6	Focus (Same as SIRAY PLUS)

Maximum load：the Control box is 20.4 kg，the Cross arm is 16 kg，the Telescopic arm A is 8.8 kg，the Telescopic arm B is 5.5 kg.



Floor-mounted dental X-ray unit (SIRAY PLUS)

Name of main parts

1	Focus	5	Seat
2	X-ray tube assembly	6	Control box (inside the base joint cover)
3	Telescopic arm	7	Column
4	Cross arm	8	Operating panel

1.5 Working principle

Dental X-ray Unit is an AC power device adopted the traditional technology; no novel technology adopted. A diagnostic dental x-ray system designed for permanent fixture in one location to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for generalpurpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. The sensor is placed in the mouth, the purpose being to visualize a limited region in detail.

1.6 Technical parameters

X-RAY EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY （SIRAY, SIRAY PLUS) IEC 60601-2-65:2012+A1:2017+A2+2021. X-RAY TUBE ASSEMBLY(SIR-GT-01), IEC 60601-2-28: 2017.

1.6.1 Nameplate

SIRAY nameplate (affixed on the control box).

SIRAY PLUS nameplate (affixed behind the column).

1.6.2 The technical parameters

The technical parameters of this medical equipment are listed in the following table:

Safety class	I	Tube voltage	60 kV/65 kV/70 kV
Protection Type	Type B applied part Applied part is Seat	Tube current	2 mA/7 mA
Equipment operating mode	Intermittent-loading continuous-operations	Load cycle	1/30
Degree of protection against ingress of water and particulate matter	IP20	Total filtration of X-ray tube assembly	≥2 mm Al (70 kV)
Power supply voltage	AC230 V	Inherent filtration for X-ray tube	≥1 mm Al (70 kV)
Main fuse tube	T10 AL250 V/Φ5X20	Half-value layer	About 1.5 mm Al at 70 kV
Input power during radiation	Input power at7mA: 760 VA; Input power at 2mA: 140VAC	Radiation leakage rate	Less than 0.25 mGy/h at a distance of 1m
Power frequency	50/60 Hz	Loading time adjustment range	0.020～2.000s. The grading number is selected according to R'10 number system
Ray focus	0.4 mm	Distance between the focus of the circular output load surface mouth of the snoot and the skin	22 cm
Anode angle	12.5 °	The output radiation field of the circular output load surface mouth of the snoot	Φ5.5 cm (actual size A should satisfy: 5 cm≤A≤6 cm)
Mass of SIRAY	25 kg	Mass of SIRAY PLUS	84 kg
Apparent resistance	0.2 Ω	Accuracy of LOADING FACTORS	Voltage:±10% Current:±20% Loading time:±5%
Accuracy of RADIATION output	0.9%	Generator	100 k～200 kHz
Supply mains over-current releases	10A	Additional filtration	1mm Al (70 kV)

Applied parts for SIRAY PLUS are seat, and no applied parts for SIRAY.

PFC and three-phase-bridge rectifier circuit is used in the design of the circuit to ensure the duty cycle. Therefore, the unit is not a one peak or a two-peak high-voltage generator. The radiation time is not

affected by the pulse of the grid.

1.6.3 The technical parameters of the X-ray Tube

Model: D-045.

Manufacturer Name: Canon Electron Tubes & Devices Co., Ltd.

Serial No.: Refer to the nameplate

Class: Class B of Type I.

⚠ WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth.

An overheating signal will occur during long exposures. When the tube is over heated which the temperature of the tube exceeds 60°C, the temperature sensor will send an overheat signal to the MCU. The MCU will cut off the voltage and current output to the tube, and the operation panel will display the error code “H3”. The MCU will control the cooling time of the tube. The re-exposure can only be performed after the cooling time is reached. When an abnormality occurs in the main MCU, the standby MCU will cut off the voltage and current output to the tube in real time.

Therefore, it ensures that the oil that cools the X-ray tube does not expand due to the heat, resulting in failure of the seal and oil leakage.

General Data

Electrical:

Circuit:

High Voltage Generator ..... Constant Potential High-voltage Generator

Grounding ..... Center-grounded

Nominal X-ray Tube Voltage ..... 70 kV

Nominal Focal Spot Value 0.4

Nominal Anode Input Power (at 1.0s) (See Rating Charts) ..... 585 W

Nominal Radiographic Anode Input Power ..... 600 W

Exposure Duty Cycle ..... 1:30 or More

(Exposure Time: Interval Time)

Note) Test Condition:70kV 3.2mA

Mechanical:

Dimensions:

Overall Length ..... See Dimensional Outline

Maximum Diameter ..... See Dimensional Outline

Target:

Anode Angle ..... 12.5 degrees

Material .....Tungsten

Inherent Filtration ..... At least 1.0 mm Al

X-ray Coverage ..... φ 70 mm at SID 200 mm

Weight ..... Approx.100 g

Cooling Method ..... Oil immersed (60℃ Max.) and convection oil cooling.

Tube Holding…..... Holding the glass envelope of the anode end and cathode end, or the screw of the anode shank.

Absolute Maximum and Minimum Ratings

(At any time, these values must not be exceeded.)

Maximum X-ray Tube Voltage ..... 70 kV

Between Anode (or Cathode) and Ground .....35 kV

Minimum X-ray Tube Voltage ..... 50 kV

Maximum X-ray Tube Current (See Rating Charts) ..... 12 mA

Filament Characteristics:

Maximum Filament Current ..... 3.0 A

Filament Frequency Limits ..... DC or AC (Sine Wave) 0 ~ 20 kHz

Thermal Characteristics:

Anode Heat Content ..... 7 kJ (10 kHU)

Maximum Anode Heat Dissipation ..... 210 W (300 HU/s)

Maximum Radiographic Exposure Time ..... 3.2 s

Environmental Limits

Operating Limits (In Dielectric Oil):

Oil Temperature .....10~ 60℃

Oil Pressure ..... 70~ 140 kPa

Shipping and Storage Limits:

Temperature ..... -40 ~ 70 ℃

Humidity ..... 10 ~ 90 %

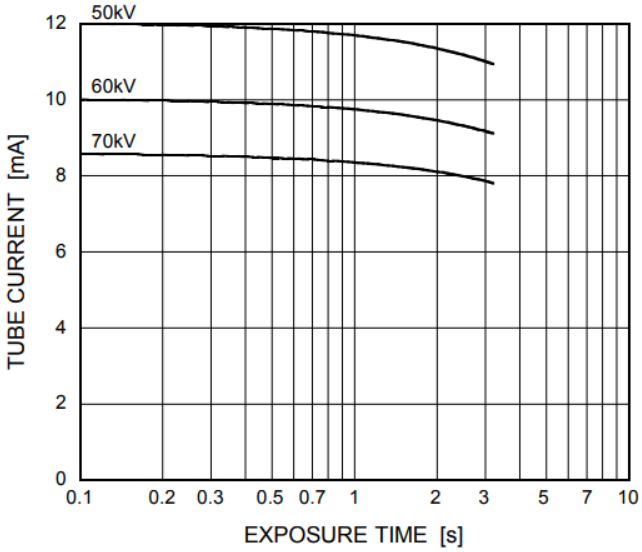
(No Condensation)

Atmospheric Pressure .....50 ~ 106 kPa

Maximum Rating Charts
(Absolute maximum rating charts)

Constant Potential High-voltage Generator

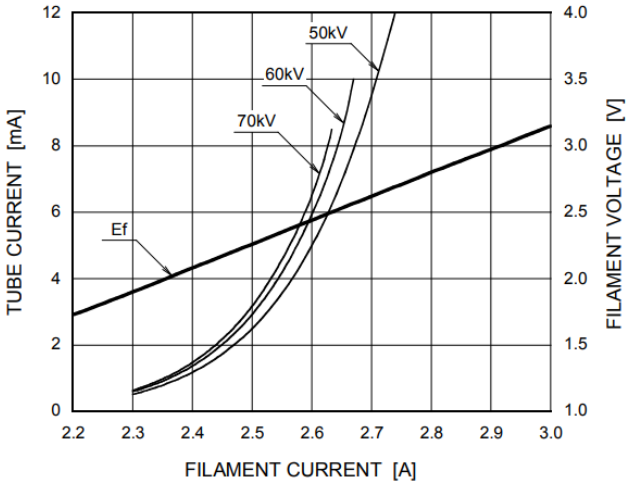
Nominal Focal Spot Value: 0.4



Emission & Filament Characteristics

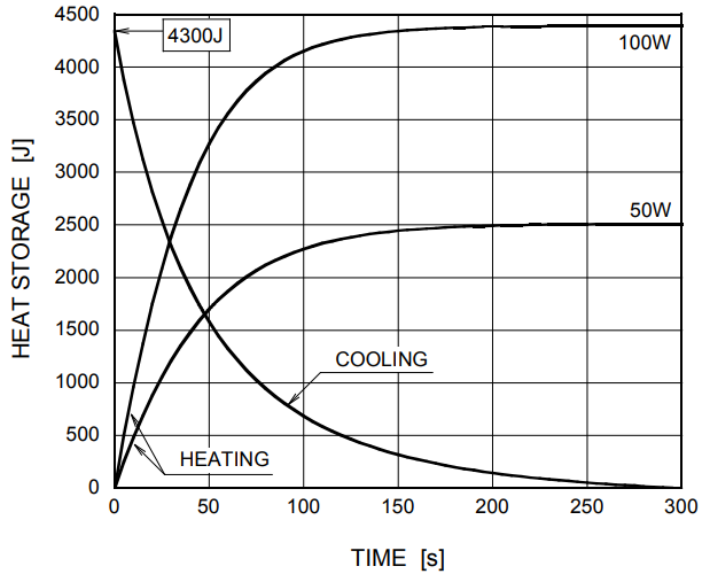
Constant Potential High-voltage Generator

Nominal Focal Spot Value: 0.4



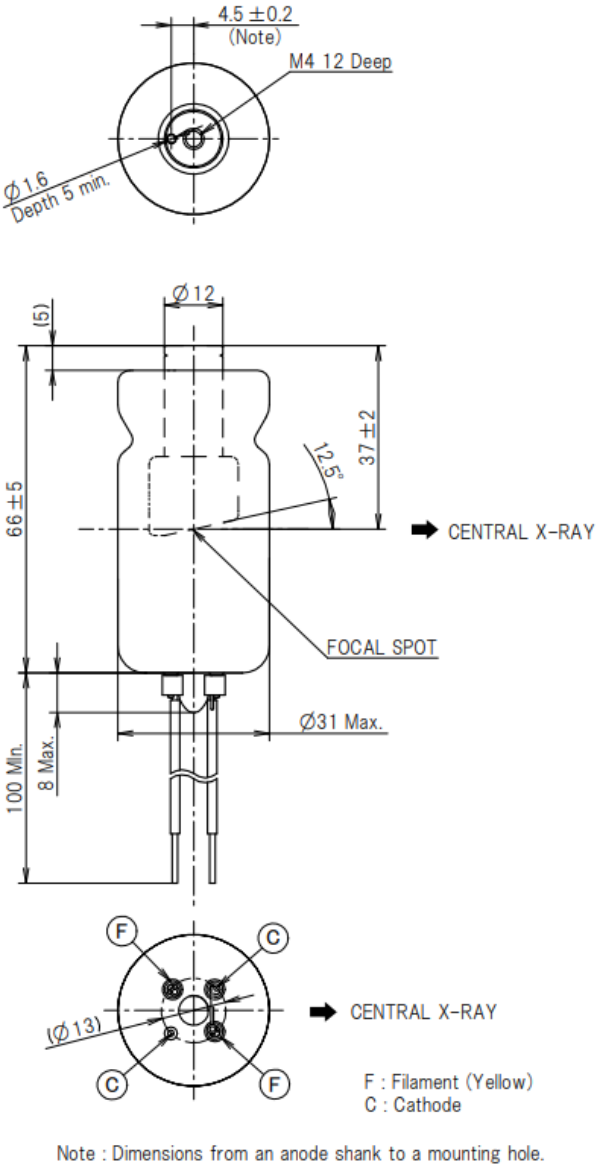
This graph indicates typical characteristics.

Anode Heating / Cooling Curve



Dimensional Outline

Unit: mm



Note : Dimensions from an anode shank to a mounting hole.

1.7 Precautions, warnings and tips

- **Safety precautions**

When using this equipment, be sure to follow the basic safety precautions listed below to reduce the risk of equipment damage, fire, electric shock, personal injury and other hazards:

*Follow all warnings and instructions given on the equipment and in the accompanying text document. If any operating instructions conflict with the safety information, pay attention to the safety information as you may have misinterpreted the operating instructions. If you cannot resolve the conflict, contact a professional service person for help.

* Please turn off the equipment's main power before maintenance and cleaning.

* Do not place the equipment on unstable floors, carts or racks as the equipment may fall and cause damage.

* Do not place the equipment near radiators or heaters.

* Do not use the equipment in the presence of any flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.

* Do not place or hang heavy objects on the equipment.

* Do not use wires that do not comply with the requirements of the equipment. Otherwise, its performance may be compromised or a fire or an electric shock may even be caused.
* Do not push anything into the equipment through the housing or the opening on the housing, because this may touch a dangerous voltage position and thereby cause a fire or an electric shock. Do not spill any liquid on the equipment.
* Do not use with the patient while parts of the equipment are serviced or maintained.
* Do not position the equipment too difficult to operate the disconnection from the supply mains.
* To avoid the risk of electric shock, do not disassemble the equipment without prior authorization. If you need to repair the equipment, please contact professional technical service personnel.
* Opening or removing the cover may expose you to dangerous voltages or other dangers. Improper assembly may cause electric shocks during subsequent use of the equipment.
* In the event of the following cases, turn off the main power switch and ask professional service personnel for help:
    (1) Any part of the power cord, plug, or connecting cable is damaged or frayed.
    (2) Unknown liquid is spilled into the equipment or the circuit of the equipment.
    (3) The performance of the equipment suddenly changes significantly. The equipment still cannot work normally after being operated according to the instructions.
* Please adjust only the controls mentioned in the operation instructions. Incorrect adjustment of other controls may result in equipment damage.
* Avoid using the equipment during thunderstorms. Thunderstorms may cause a lightning strike. If possible, turn off the main power during a thunderstorm.
* Do not use a damaged or loose plug. Insecure plug connections may cause electric shocks or sparks, which will lead to fires.
* Grounded plugs and sockets must be used. Poor grounding may result in electric shocks or equipment damage.
* If any oily liquid is found leaking from the equipment, stop using the equipment immediately and contact the manufacturer.
* Users are reminded that exposure and use of the equipment need to be restricted in accordance with local radiological protection laws.

⚠ **Warning:** When a patient has a cardiac pacemaker or hearing aid, the possible influence of the dental x-ray unit on it shall be taken into account.

⚠ **Warning:** This equipment may only be used by authorized and trained individuals. The manufacturer is not liable for any incorrect operation, negligence or inapplicability.

⚠ **Warning:** When the exposure is finished and you leave work, the main power must be turned off.

⚠ **Warning:** Users need to provide means for audio and visual communication between the operator and the patient.

⚠ Warning: Do not replace equipment components (except fuses) without authorization to avoid unacceptable risks.

⚠ Warning: Equipment cannot be used in OXYGEN RICH ENVIRONMENT.

- **Notes on this manual**

The notes contain the information on all optional components of the fixed type SIRAY PLUS and the wall-mounted type SIRAY, so some of the information may not apply to your machine.

This manual provides information on the operations and maintenance of the dental X-ray unit. All information provided is valid until the publication of this manual. The company reserves the right to modify the specifications or design of the equipments at any time without prior notice to the user.

Without the prior written permission of our company, this manual shall not be altered, disseminated, re-published or sold in any form or by any means (such as the electronic, mechanical or graphic means).

our company reserves the right to interpret and change all the information in this document.

⚠ **Caution:** The guaranteed content shall be invalid in the event of non-compliance with any of the following alerts:

(1) Observe the terms described in the instructions.

(2) The equipment must only be used according to the contents of this manual.

(3) The indoor power cord installed shall be a three-core power cord of 1 square millimeter or more.

(4) If the power cable needs to be replaced, replace the power cable with one that carries sufficient flow （for SIRAY PLUS）

(5) The equipment shall be installed according to the requirements.

(6) Any maintenance, modification or correction operations related to access to the inside of the equipment must be performed by an engineer of our company.

(7) The X-ray tube assembly will accumulate heat during long running or multiple exposures in a row. Please be careful that the X-ray tube assembly is not covered.

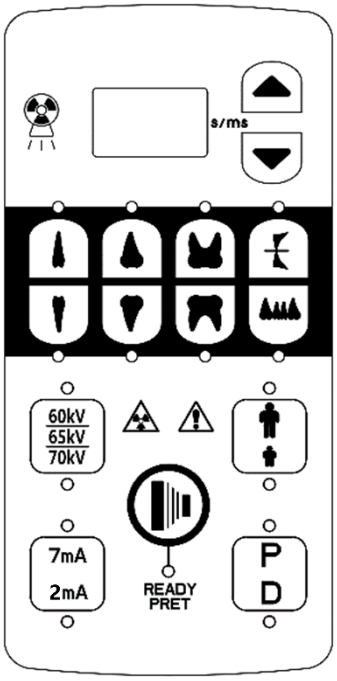
(8) Any accessories and used equipments must be replaced by our company Otherwise the performance and safety of the dental X-ray unit will be affected.

Chapter 2 Equipment Operation Instructions

⚠ **Warning: Before proceeding in accordance with the contents of this chapter, please confirm that the installation and commissioning are completed properly according to the equipment installation and maintenance manual.**

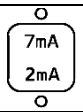
2.1 Description of the operating panel and operation keys

2.1.1 Illustration of the operating panel



2.1.2 Description of buttons and symbols

Icon	Name	Function
	Maxillary Anterior	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Maxillary Canine	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Maxillary Molar	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Biting Fin / Biting Wing	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Mandibular Anterior	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Mandibular Canine	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Mandibular Molar	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	Multi-tooth	When this button is pressed, the corresponding exposure indicator and the ready-for-exposure indicator will be lit constantly, and then the exposure can be proceeded.
	The Exposure button	When the Exposure button is pressed and held, the exposure will proceed and the exposure indicator will be lit (yellow) constantly. After the exposure is completed, the indicator will go out.
	X-ray exposure indicator	When the Exposure button is pressed and held, the exposure will proceed and the exposure indicator will be lit (yellow) constantly. After the exposure is completed, the indicator will go out.
	Ready-for-exposure indicator	The ready-for-exposure indicator used jointly with the operating procedure.

	Patient Figure	Press the patient size button to toggle between the two choices, Large size and Small size, with the corresponding indicator lit constantly.
	Mode	“Film”, “PSP” or “Digital Program” can be selected. Non-lit indicator indicates that “Film” is selected. Lit indicator indicates that “PSP” or “Digital Program” is selected.
	Voltage	60 kV/65 kV/70 kV voltage selection. When you select 60 kV, the above indicator light is always on; When you select 65 kV, two indicator lights are always on; When you select 70 kV, the following indicator light is always on.
	Current	7 mA or 2 mA, with the corresponding indicator lit constantly.
	Exposure Time	Adjusts the exposure time
	Display	Display the voltage, current, exposure time, cumulative exposure times and error codes； When the exposure time is displayed, the time more than 0.2 s (including 0.2 s) takes s as unit, and the time less than 0.2 s takes ms as unit.
	Radiation Warning	Sign
	Caution	Sign

2.2 Setting and display of parameters

2.2.1 Turn on the equipment

After checking the installation and making sure that there are no problems, plug in the power and turn on the power switch. The power-on indicator is lit. After the self-test is completed, the operating panel will display the parameters set for the last operations.

2.2.2 Setting of a program mode

Press and hold the Mode button  for 5 seconds until you hear three buzzes and then the equipment will enter the program mode setting state and the Ready-for-Exposure indicator will go out.

The program is selected with the Exposure Time button  and shown on the display. Program definitions are:

Film Exposure Speed P1, Sensor P2, Film Type Selection P3, Buzzer Volume P4, Cumulative Exposures P5, and Restore Factory Settings P6, cycled in sequence.

After the setting is completed, hold and press the Mode button  for 5 seconds until you hear three buzzes (or after no operation for 10 seconds), the equipment will exit the program setting state and the Ready-for-Exposure indicator will be lit constantly.

2.2.2.1 Choose a film exposure speed

In the program mode setting state, when “Film Exposure Speed” P1 is selected, you can press the Mode button  to enter the Film Exposure Speed Selection mode and use the Exposure Time button  to make a choice among three speeds: F, E and d.

2.2.2.2 Choose a sensor

In the program mode setting state, when “Sensor” is selected P2, you can press the Mode button [P D] to enter the Sensor Selection mode and use the Exposure Time button to make choice between one sensor: Ordinary 6En.

2.2.2.3 Film type selection

The reserved function.

2.2.2.4 Choose a buzzer volume level

In the program mode setting state, when “Buzzer Volume” P4 is selected, you can press the Mode button [P D] to enter the Buzzer Volume Selection mode and use the Exposure Time button to make a choice from nine volume levels: 0, 1, 2, 3, 4, 5, 6, 7 and 8.

2.2.2.5 Cumulative exposure times

In the program mode setting state, when “Exposure Speed” P5 is selected, you can press the Mode button [P D] to enter the Cumulative Exposure Times Display mode and use the Exposure Time button to adjust the displayed values of the ones, tens, hundreds, thousands, ten-thousands and hundred-thousand digits respectively.

2.2.2.6 Restore Factory Settings

In the program mode setting state, when “Exposure Speed” P6 is selected, you can press the Mode button [P D] to enter the Restore Factory Settings mode and use the Exposure Time button to select On or OFF to confirm whether to restore factory settings. Restoring factory settings will not clear the cumulative exposure times.

2.3 Operations of the manual button panel and function button memory settings

2.3.2 Setting of tooth position buttons (8 buttons in total)

Setting a tooth position button: Adjust the tooth position, mode, patient figure, voltage, current and exposure time to the required parameters. Press and hold the corresponding tooth position selection button for about 5 seconds until you hear a prompting sound, then the current parameters will be stored for the corresponding tooth position button.

Operations of a tooth position button: Select the corresponding tooth position selection button according to the shooting requirements and then the corresponding indicator will be lit constantly.

2.3.3 Operations of the Mode button

Press the Mode button [P D] to select “Film,” “PSP” or “Digital Program,” and then the corresponding indicator will be lit constantly (the indicator will not be lit in when the film mode is selected).

2.3.4 Operations of the Patient Size Selection button

Press the patient size button to toggle between the two choices, large size and small size. With the corresponding indicator lit constantly.

2.3.5 Operations of the Voltage button

Press the Voltage button to choose “60 kV” “65 kV” or “70 kV,” When you select 60 kV, the above indicator light is always on; When you select 65kV, two indicator lights are always on; When you select 70 kV, the following indicator light is always on.

2.3.6 Operations of the Current button

Press the Current button to choose “7 mA” or “2 mA,” and then the corresponding indicator will be lit constantly.

2.3.7 Operations of the Exposure Time Button

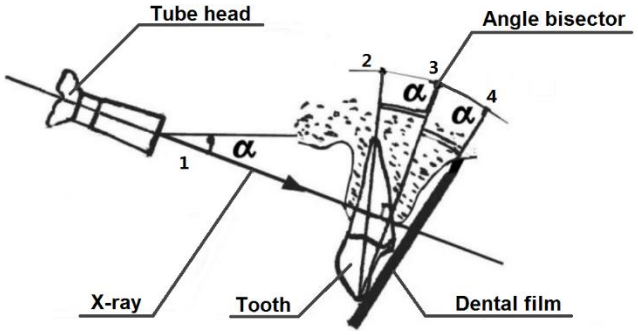
Press the Exposure Time button to choose the exposure time and then the display will show the corresponding exposure time. Press or to increase or reduce the exposure time.

2.3.8 Operations of the Exposure Button

After selecting the parameters for each item, press and hold the Exposure button. Then the exposure will proceed, the exposure indicator will be lit (yellow) constantly and the buzzer emits a “beep.” The exposure button can be released only when the exposure indicator goes out and the buzzer stops sounding.
In the event of an emergency, the exposure can stop when the Exposure button is released.

2.4 Place the dental film

After adjusting the exposure time, voltage and other parameters, place the dental film in the mouth while asking the patient to press it with his/her index finger. Adjust the cone of the tube head until its end surface is about 10 mm from the skin and its axis (i.e., the X-ray) is perpendicular to the bisector of the angle between the long axis of the tooth and the film, as shown in the following figure:



See the following table for details of the average X-ray tilt angles for projecting the maxillary and mandibular teeth according to the desired angles of the teeth:

Tooth Position		Number	X-ray Tilt Direction	X-ray Tube Tilt Angle
Maxillary	Incisor	1, 2	Downward	+42°
	Unicuspid tooth	3	Downward	+45°

	Bicuspid tooth and the first molar	4, 5, 6	Downward	+30°
	The second and third molars	7, 8	Downward	+28°
Mandibular	Incisor	1, 2	Upward	-15°
	Unicuspid tooth	3	Upward	-18~20°
	Bicuspid tooth and the first molar	4, 5, 6	Upward	-10°
	The second and third molars	7, 8	Upward	-5°

The numbers and layout of all teeth:

Maxillary	8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8
Mandibular	8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

2.5 Safety protection function

After the exposure is finished, the dental X-ray unit is in the natural cooling protection state and the time window is displayed as the countdown. At this time, pressing the controller exposure button, the dental X-ray unit will not work. After the cooling is completed and the equipment restores to the last set working state, the ready-for-exposure indicator lit (green), the equipment can do a new task.

During an exposure, in the event of an emergency, the exposure can stop when the Exposure button is released.

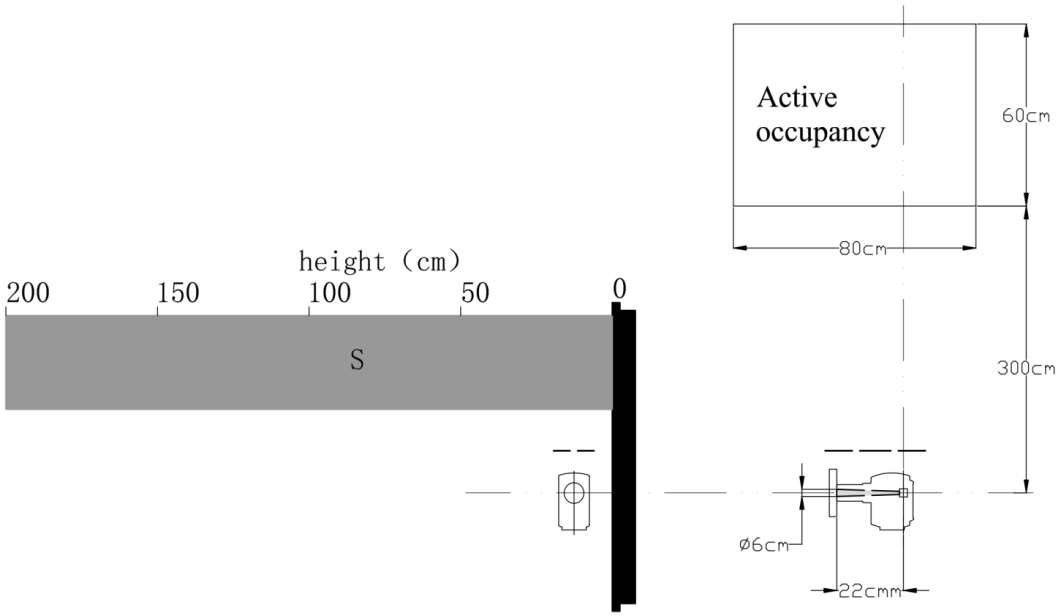
2.6. Precautions

Radiation protection:

(1) When the photosensitizer dose is sufficient, the distance from the focus to the skin shall be increased as much as possible so that on the one hand, X-ray radiation on the patient can be reduced and on the other hand, image distortion can be reduced, It also reduces the effect of scattered radiation on the image receiver.

(2) No other unrelated persons (such as the child's parents, or other patients, etc.) should be present in the examination room during loading.

(3) During the loading process, the operator shall operate 3 meters away from the tube head and shall not stand in the X-ray radiation direction. The operator must use a protective equipment and wear protective clothing. If the local health sector has stipulated that it is necessary that an engine room and relevant protective facilities shall be provided, it shall be carried out according to the provisions of the local health department. The information of important area which is occupied by the operator is shown in the figure below:



(4) In the event of an unexpected emergency, e.g., when the power switch is turned on or the Exposure button is pressed, the exposure indicator is lit constantly or the buzzer keeps buzzing, the power switch shall be turned off immediately to prevent radiation or machine damage.

(5) Test method of radiation dose when the equipment is working: when it is running under nominal voltage of X-ray tube with the maximum input energy equivalent to the specified 1h, at 1m from the focus point, and the average air Kerma rate is not exceed 1.0 mGy/h within any area of 100 cm^2 (the main linear size is no longer than 20 cm). The adjustment of exposure time of the equipment can affect the amount of radiation of the operator.

(6) After the exposure is complete, there is residual radiation, do not open the door of the examination room and take off protective equipment or protective clothing for 30 seconds to avoid unnecessary exposure.

(7) If the operator is operating the equipment outside the clinic room, it is recommended to install an external interlocking device with visible indication at the external interlocking device interface to prevent the equipment from starting to emit X-ray radiation and to enable the equipment to stop X-ray radiation. The external interlocking device interface is on the Control handle.

Safety and use:

(1) In areas with unstable power supplies, a voltage regulator shall be provided, and the capacity of the voltage regulator shall be no less than 2 kVA.

(2) For details of the applicable conditions of various types of dental film, see the applicable conditions of various types of dental film in the following table.

Use conditions for various types of dental film:

No.	Dental Film Type	The Set Parameters of the Dental X-ray Unit			Development Method and Development Time	
		kV	Mode		Light Room	Darkroom
			2 mA	7 mA		
1	Film	60 or 70			3 minutes or more	3 minutes or more
2	Sensor	60 or 70	D	D		
3	PSP	60 or 70	P	P		

Radiation leakage:

The radiation produced by the equipment is x-rays, which are essentially electromagnetic radiation.

Patient radiation dose:

If the user wants to periodically measure and follow the radiation dose consistency, it can be measured in the following way.

Position the beam limiting device of the Equipment on the radiation detector(not supplied with the Equipment)，the radiation detector must be calibrated.

The measurement result of patient radiation was described with the entrance surface dose (ESD). The method to measure the ESD is to test the dose directly from 22cm away from the focus and within the area of 6cm, without reference object. The ESD is shown in the following table:

Time of exposure(s)	DOSE（mGy）					
	70 kV		65 kV		60 kV	
	2 mA	7 mA	2 mA	7 mA	2 mA	7 mA
0.080	0.233	0.585	0.207	0.518	0.176	0.440
0.100	0.293	0.712	0.264	0.634	0.219	0.526
0.125	0.367	0.888	0.324	0.778	0.277	0.665
0.160	0.471	1.120	0.417	0.989	0.359	0.852
0.200	0.590	1.400	0.519	1.230	0.443	1.050
0.250	0.738	1.730	0.650	1.520	0.560	1.310
0.320	0.947	2.200	0.829	1.940	0.720	1.670
0.400	1.190	2.750	1.048	2.420	0.900	2.080
0.500	1.480	3.420	1.303	3.010	1.117	2.580
0.630	1.870	4.300	1.651	3.780	1.419	3.250
0.800	2.380	5.440	2.092	4.790	1.799	4.120
1.000	2.970	6.810	2.611	5.980	2.253	5.160
1.250	3.710	8.500	3.258	7.460	2.817	6.450
1.600	NA	10.900	NA	9.540	NA	8.240
2.000	NA	13.600	NA	11.900	NA	10.300

Note
Dose accuracy: +/- 50% (mGy)
To obtain the dose in mGy.cm^2, multiply values in the tables by the exposed surface

2.7 Exposure values

The first time you turn on the dental x-ray unit, the default exposure values are displayed.

These values can also be customized according to actual use. The recommended exposure values are shown in the table below:

Exposure Time Table(s)									
mA/ kV	Teeth Position / Reception Type	Large size				Small size			
		D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed	D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed
7mA ,70kV	Maxillary Canine	0.100	0.125	0.160	0.320	0.063	0.080	0.100	0.200
	Maxillary Anterior	0.125	0.160	0.200	0.400	0.080	0.100	0.125	0.250
	Maxillary Molar	0.160	0.200	0.250	0.500	0.100	0.125	0.160	0.320
	Biting Fin / Biting Wing	0.125	0.160	0.200	0.400	0.080	0.100	0.125	0.250
	Mandibular Canine	0.100	0.100	0.125	0.250	0.063	0.063	0.080	0.160
	Mandibular Anterior	0.125	0.125	0.160	0.320	0.080	0.080	0.100	0.200
	Mandibular Molar	0.125	0.125	0.160	0.320	0.080	0.080	0.100	0.200
	Multi-tooth	0.125	0.160	0.200	0.400	0.080	0.100	0.125	0.250

	Teeth Position / Reception Type	Large size				Small size			
		D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed	D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed
7mA, 65kV/2mA, 70kV	Maxillary Canine	0.160	0.200	0.250	0.500	0.100	0.125	0.160	0.320
	Maxillary Anterior	0.200	0.250	0.320	0.630	0.125	0.160	0.200	0.400
	Maxillary Molar	0.250	0.320	0.400	0.800	0.160	0.200	0.250	0.500
	Biting Fin / Biting Wing	0.200	0.250	0.320	0.630	0.125	0.160	0.200	0.400
	Mandibular Canine	0.160	0.160	0.200	0.400	0.100	0.100	0.125	0.250
	Mandibular Anterior	0.200	0.200	0.250	0.500	0.125	0.125	0.160	0.320
	Mandibular Molar	0.200	0.200	0.250	0.500	0.125	0.125	0.160	0.320
	Multi-tooth	0.200	0.250	0.320	0.630	0.125	0.160	0.200	0.400
	Teeth Position / Reception Type	Large size				Small size			
		D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed	D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed
2mA, 65kV	Maxillary Canine	0.250	0.320	0.400	0.800	0.160	0.200	0.250	0.500
	Maxillary Anterior	0.320	0.400	0.500	1.000	0.200	0.250	0.320	0.630
	Maxillary Molar	0.400	0.500	0.630	1.250	0.250	0.320	0.400	0.800
	Biting Fin / Biting Wing	0.320	0.400	0.500	1.000	0.200	0.250	0.320	0.630
	Mandibular Canine	0.250	0.250	0.320	0.630	0.160	0.160	0.200	0.400
	Mandibular Anterior	0.320	0.320	0.400	0.800	0.200	0.200	0.250	0.500
	Mandibular Molar	0.320	0.320	0.400	0.800	0.200	0.200	0.250	0.500
	Multi-tooth	0.320	0.400	0.500	1.000	0.200	0.250	0.320	0.630
	Teeth Position / Reception Type	Large size				Small size			
		D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed	D (Digital Sensor GEN)/ P (PSP)	F-speed	E-speed	D-speed
2mA, 60kV	Maxillary Canine	0.320	0.400	0.500	1.000	0.200	0.250	0.320	0.630
	Maxillary Anterior	0.400	0.500	0.630	1.250	0.250	0.320	0.400	0.800
	Maxillary Molar	0.500	0.630	0.800	1.250	0.320	0.400	0.500	1.000
	Biting Fin / Biting Wing	0.400	0.500	0.630	1.250	0.250	0.320	0.400	0.800
	Mandibular Canine	0.320	0.320	0.400	0.800	0.200	0.200	0.250	0.500
	Mandibular Anterior	0.400	0.400	0.500	1.000	0.250	0.250	0.320	0.630
	Mandibular Molar	0.400	0.400	0.500	1.000	0.250	0.250	0.320	0.630
	Multi-tooth	0.400	0.500	0.630	1.250	0.250	0.320	0.400	0.800

Chapter 3 Installation, Commissioning and Maintenance of the Dental X-ray Unit

3.1 Installation conditions

Installers and maintenance personnel must meet the following requirements:
a) Education
At least 18 years old – 9 years intensive reading experience (school).
b) Knowledge
Read this manual before use.
c) Language understanding:
Can understand English language in the User Manual and displayed on touch screen console.
d) Permissible impairments
Mild reading vision impairment or best-corrected visual acuity to log MAR 0.5 (6/19 or 20/63) or better.
e) Experience:
Training by Siger or fully trained for dental X-ray unit.
Having experience installing and maintaining similar medical devices.

⚠ **Caution: The installation of this equipment must be completed by the Manufacturer's professional personnel or personnel trained and authorized by the Manufacturer.**
If you need to install, please contact the manufacturer/distributor. Contact information for manufacturers is on the last page.

⚠ **Caution: After the first installation:**
Turn on the power to check whether all the indications and prompts of the operating panel are normal.
Adjust the loading factor to the minimum (60 kV, 2 mA, 0.02 s) for exposure. Check whether all the indications and prompts of the operating panel are normal and whether the exposure of the equipment is normal. You can use the equipment when all of its functions are normal.

Note: If you need to use the lowest current, the shortest time (2 mA, 0.02 s) for exposure, then you must first continuous exposure 5 times, until the X-ray tube assembly temperature is stable, the X-ray output dose will be stable.

This equipment shall be placed in a clean, dry, ventilated and shaded place. Retain enough space around the equipment for routine maintenance.

Do not install and use the equipment in the following places:

(1) Humid, dusty or poorly ventilated places or places in direct sunlight;
(2) places where changes in high temperatures or high humidity often occur, e.g., places near air conditioners and heaters;

⚠ **Caution: Improper installation may damage the equipment!**
Determine the installation location according to the overall layout of the clinic room, lighting, use convenience and other specific circumstances. The machine shall be placed in a clean, dry, ventilated and cool place to keep it in a good operating environment. Ensure that the contact surface with which the mounting base contacts must be flat, horizontal and solid. The wall load which is installed the equipment shall be no less than 25 Kg and the floor load shall be no less than 85 Kg.
The equipment shall be transported to the desired installation site according to the method specified on the outer packaging box.

Equipment packaging can be removed.

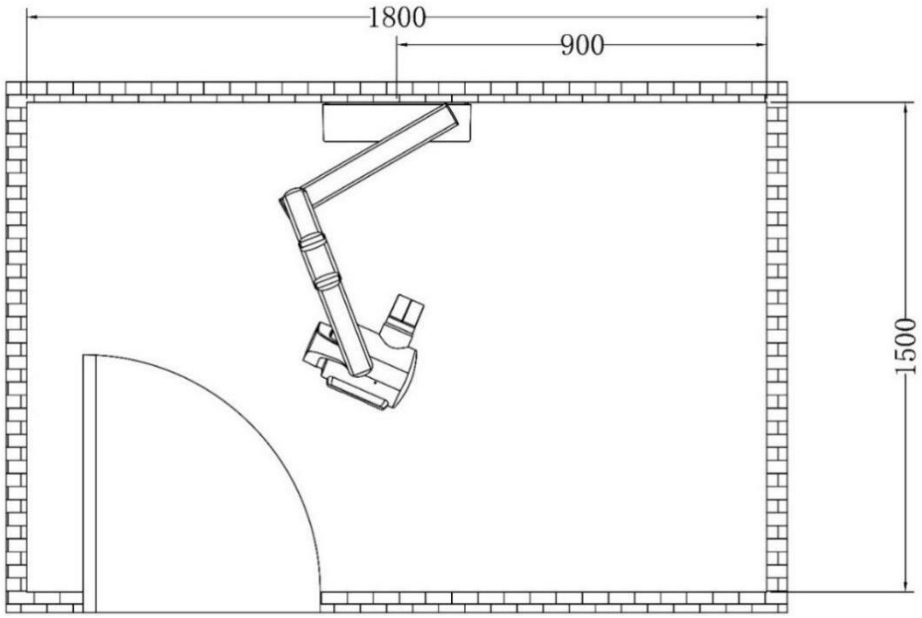
Take out the packing list and check the configuration and accessories to see if they are intact. If you have any doubts, please contact the Manufacturer in time.

3.2 Equipment installation method

3.2.1 Installation of wall-mounted dental X-ray unit (SIRAY)

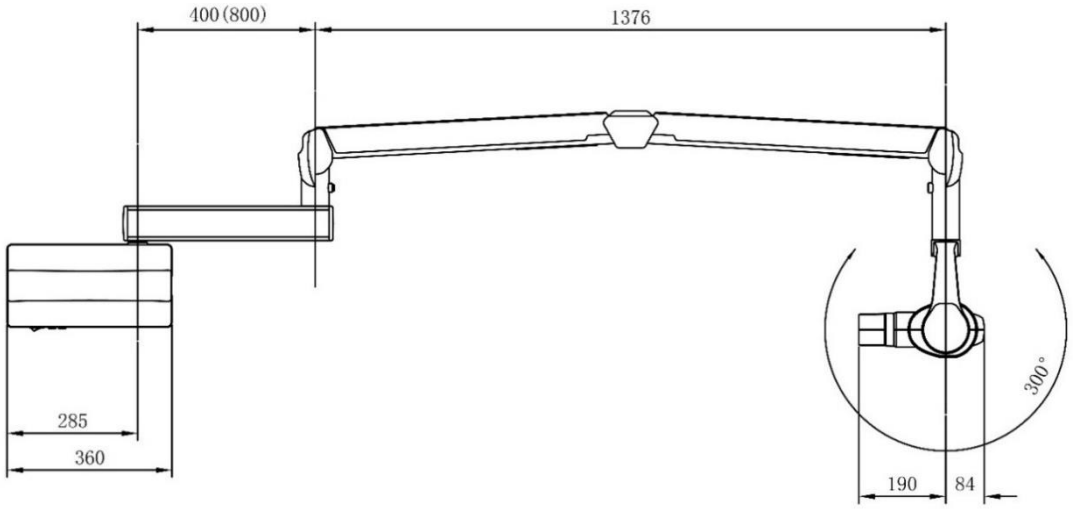
Dimensions of the X-ray room: 2 meters（or 2.4 meters） in length, 2 meters（or 2.4 meters） in width and 2.4 meters in height.

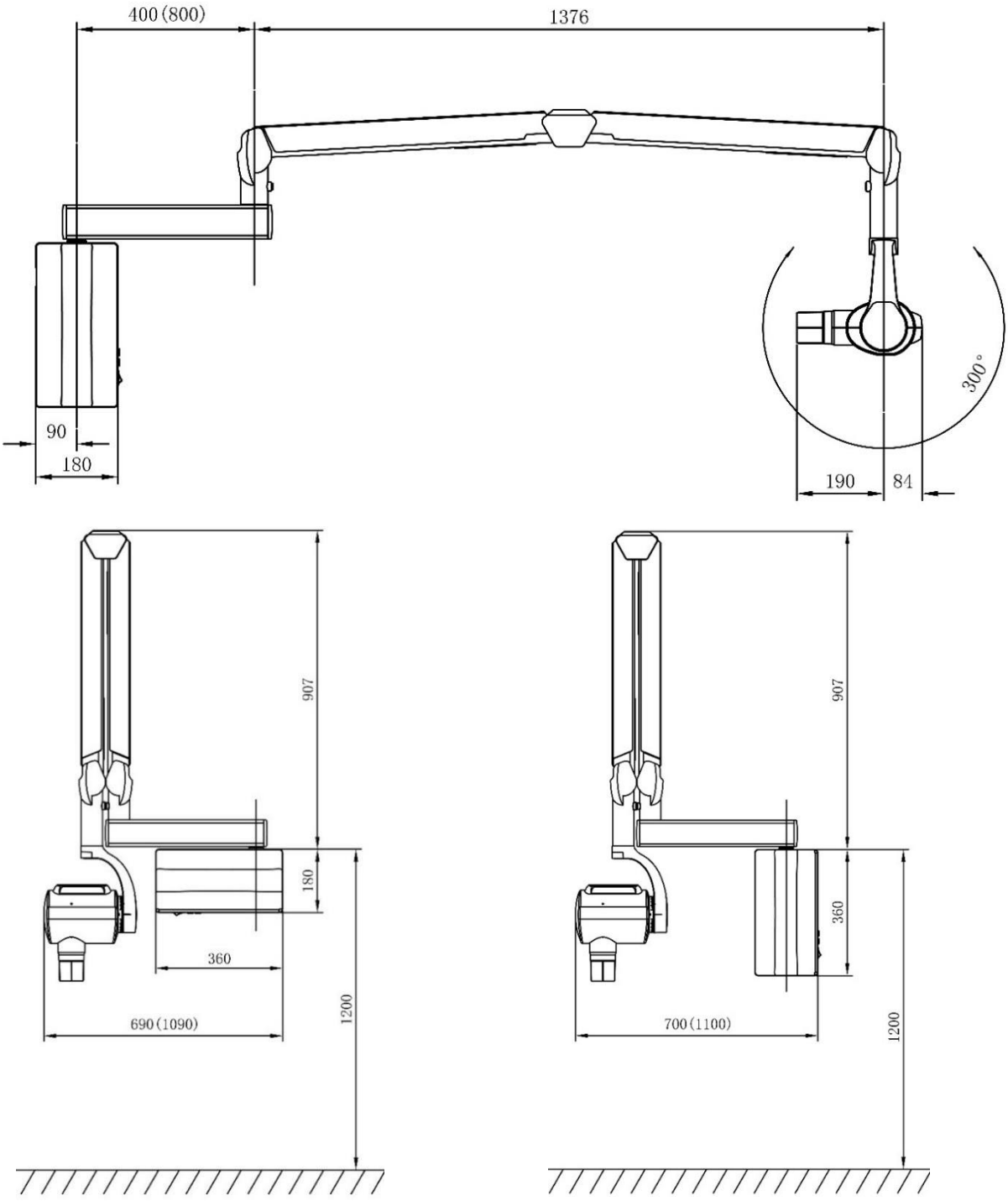
Unit: mm



The following figure shows the dimensions of the unfolded equipment. It is designed to be of safe dimensions that will not cause equipment bumps.

Unit: mm

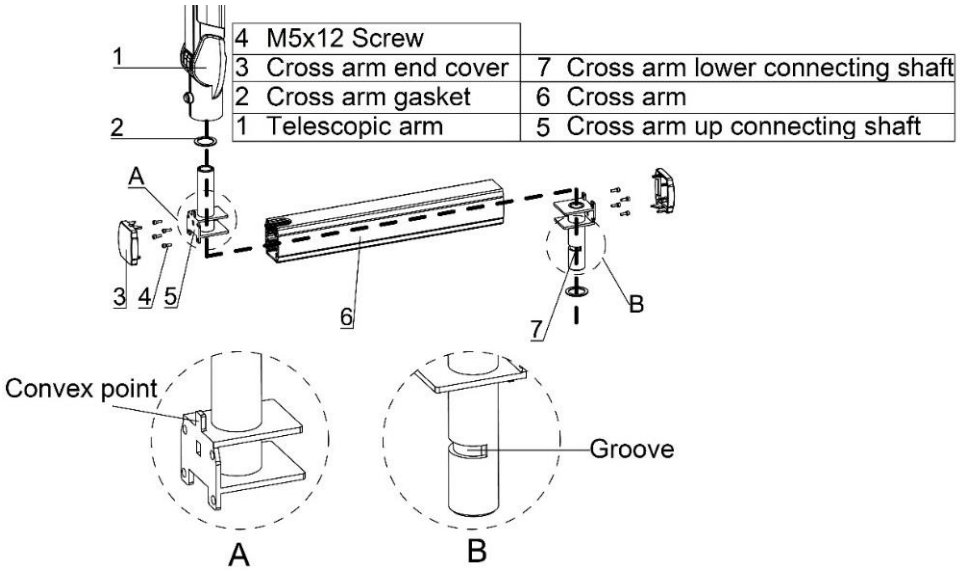




The power supply is 230 V with a ground wire and the wire diameter is no less than 1 mm^2. Power supply voltage: 230±10% VAC; power supply frequency: 50/60 Hz.

3.2.1.1 Installation of cross arm and telescopic arm

As shown in the thick dash line of the figure, pass the thread of cross arm separately through cross arm up connecting shaft, cross arm body and cross arm lower connecting shaft as well as cross arm gasket. Install the cross arm up connecting shaft and cross arm lower connecting shaft on the cross-arm body with M5x12 screw. Then install the telescopic arm on the cross arm up connecting shaft, and finally install cross arm end cover.

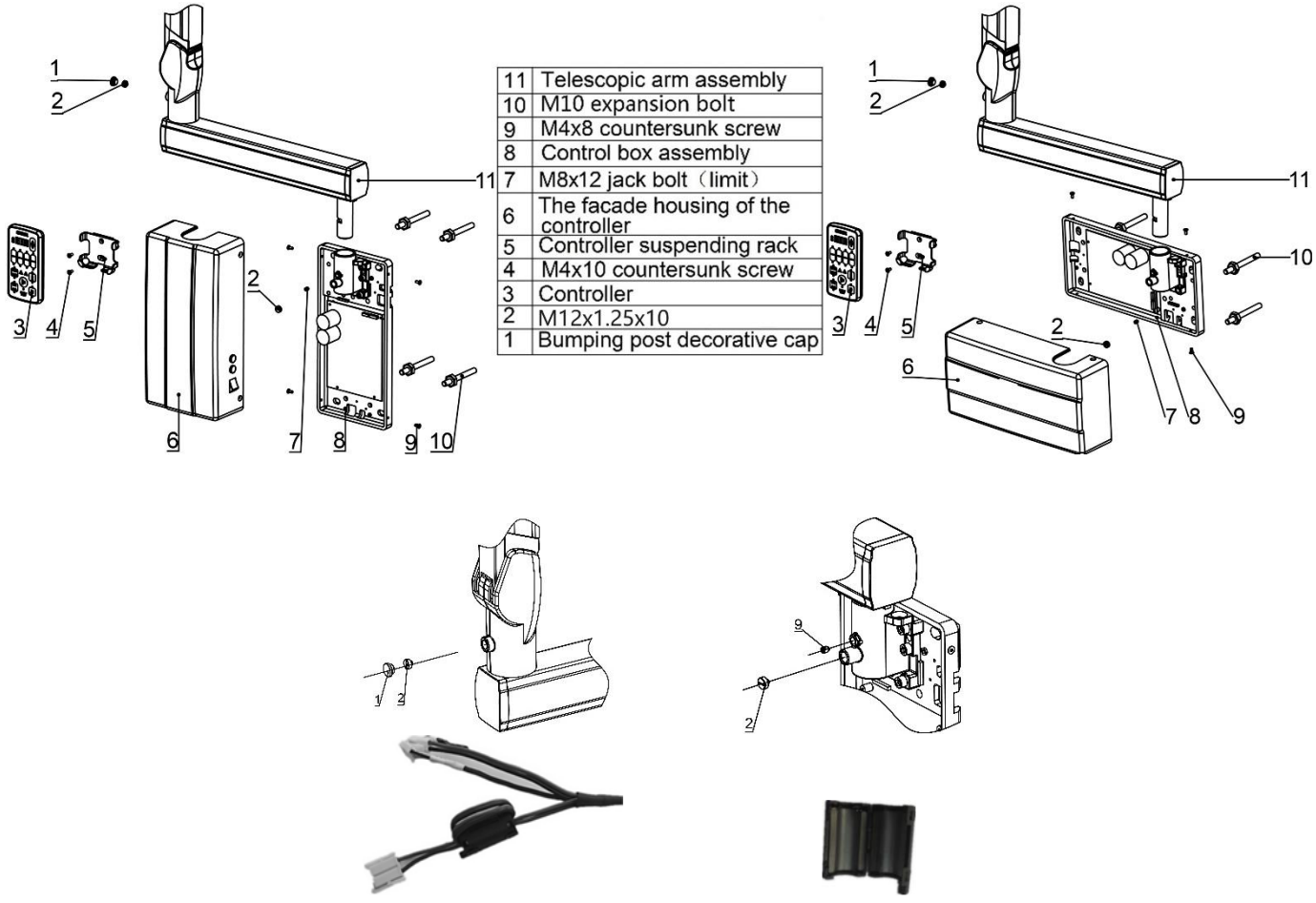


3.2.1.2 Installation of the control box and telescopic arm assembly

First, fix the bottom plate of the control box to the wall with M8 expansion bolts, then observe horizontal bubble and keep it level.

Install the telescopic arm assembly on the cross-arm fixer and tighten limit screws. Then separately install damping block, spring, damping adjusting nut and bumping post decorative cap.

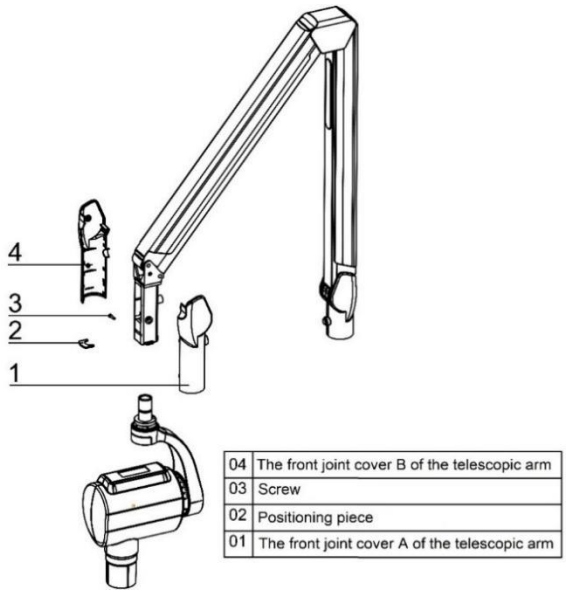
Wrap the two longest wires in the telescopic arm around the magnetic ring twice and fasten, finally connect the wire plug of telescopic arm wire with the corresponding connector on the circuit board in the control box, fix it well and install the ground wire.



3.2.1.3 Installation of the tube head

Remove the front joint cover of the telescopic arm.

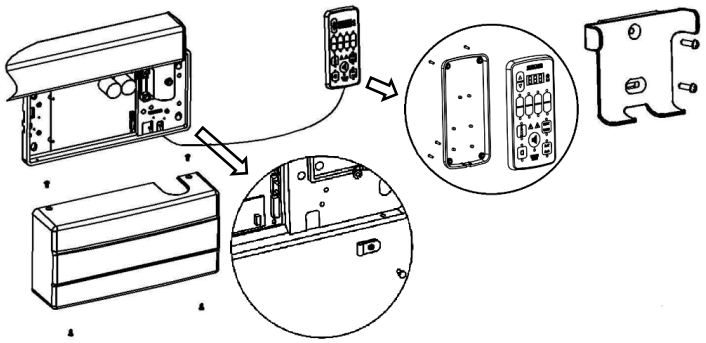
Insert the cable connected to the tube head into the telescopic arm. Insert the flange of the bending arm of the tube head into the corresponding hole on the front connector of the telescopic arm. Install and fix the positioning pieces and tighten the screws. Then connect the cable plug of the tube head to the cable plug of the telescopic arm and fix them, and install the front joint cover of the telescopic arm.



04	The front joint cover B of the telescopic arm
03	Screw
02	Positioning piece
01	The front joint cover A of the telescopic arm

3.2.1.4 The Installation of Operating Panel (Installed outdoors)

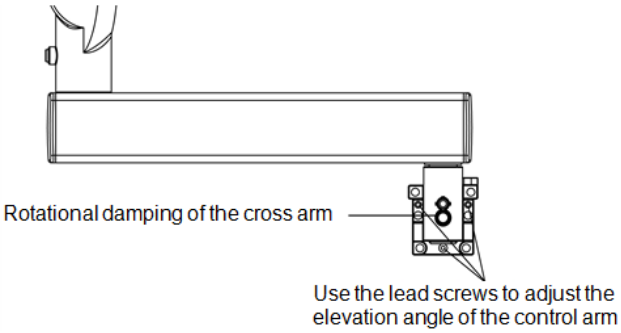
If the operation panel is installed outdoors, the connecting line of the operating panel needs to be replaced from the spring connection line to straight connection line. Open the cover of the control box and operating panel, remove the spring connecting line, connect the control box and operating panel's circuit board with the straight connection line, install the cover of the control box and operating panel, and finally move the operating panel hanger to the appropriate position to install it.



3.2.2 Equipment commissioning method

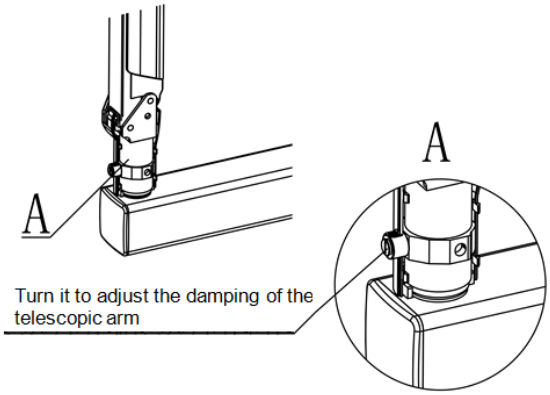
3.2.2.1 Commissioning of the cross arm

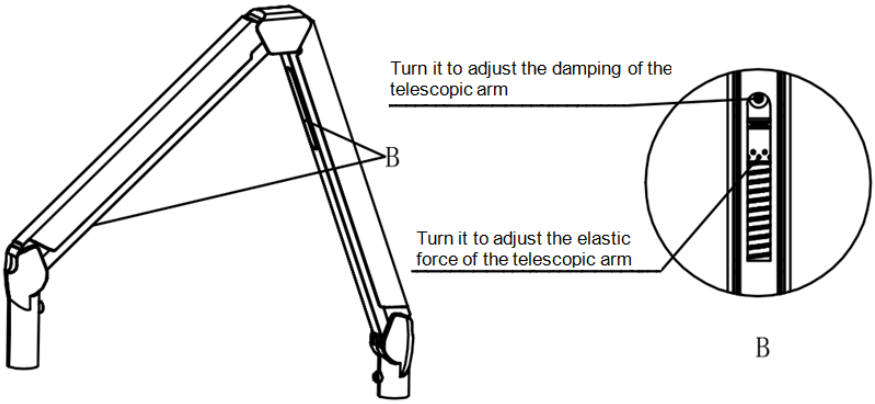
Check whether or not the horizontal bubble of the holder, which is connected to the cross arm of the control box is horizontal. If it is not horizontal, loosen the M8x12 limit lead screws and adjust the cross-arm holder to the desired position. Tighten the lead screws.



3.2.2.2 Commissioning of the telescopic arm

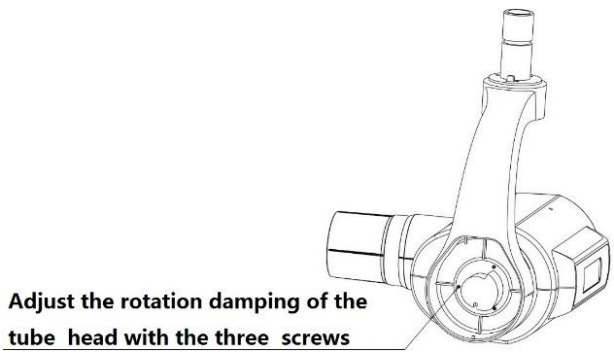
Check whether or not the strength of the telescopic arm is appropriate. If it is too large or too small, remove the decorative cover and adjust the damping and elastic force of the telescopic arm to the required strength, and then install the decorative cover.





3.2.2.3 Commissioning of the tube head

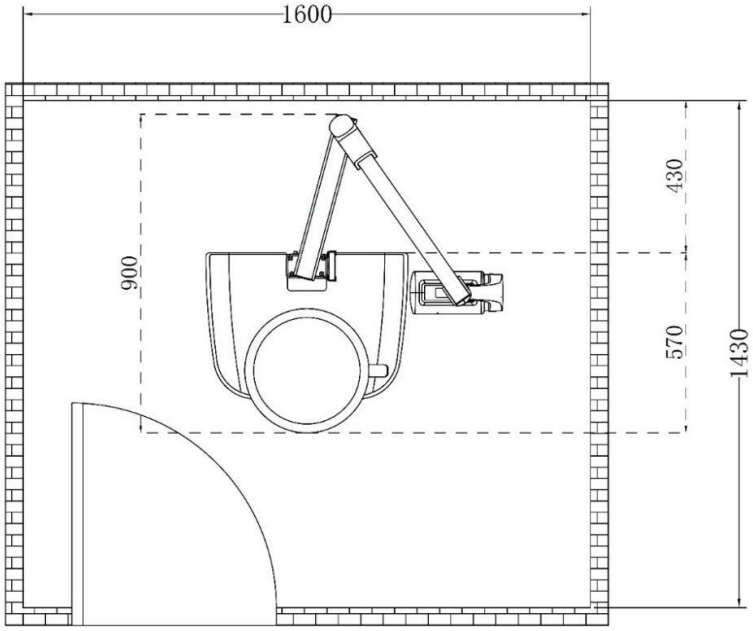
Check whether or not the strength of the bending arm of the tube head is appropriate. If it is too large or too small, remove the arm cover and adjust the damping and elastic force of the telescopic arm to the required strength, and then install the arm cover.



3.2.3 Installation of floor-mounted dental X-ray unit (SIRAY PLUS)

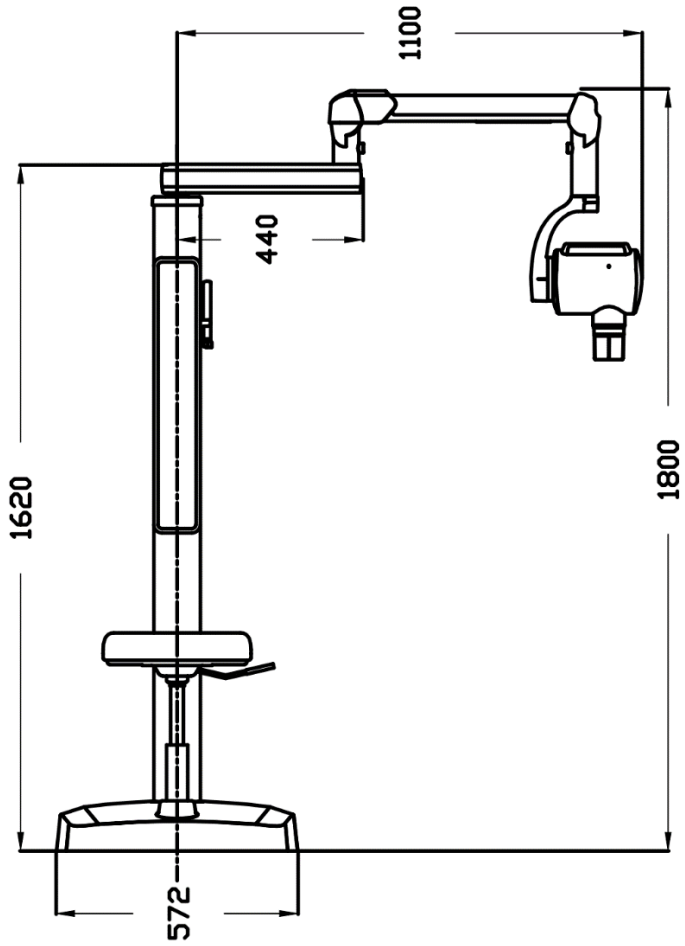
Dimensions of the X-ray room: 1.6 meters in length, 1.43 meters in width, and 2.2 meters in height.

Unit: mm



The following figure shows the dimensions of the unfolded equipment. It is designed to be of safe dimensions that will not cause equipment bumps.

Unit: mm



Installation of floor-mounted dental X-ray unit dimension drawing

3.2.3.1 Installation method

Fix the base plate components with Φ10 expansion bolt on the floor and make sure keep it horizontal.

Check whether the main control board installed on the base plate is loose.

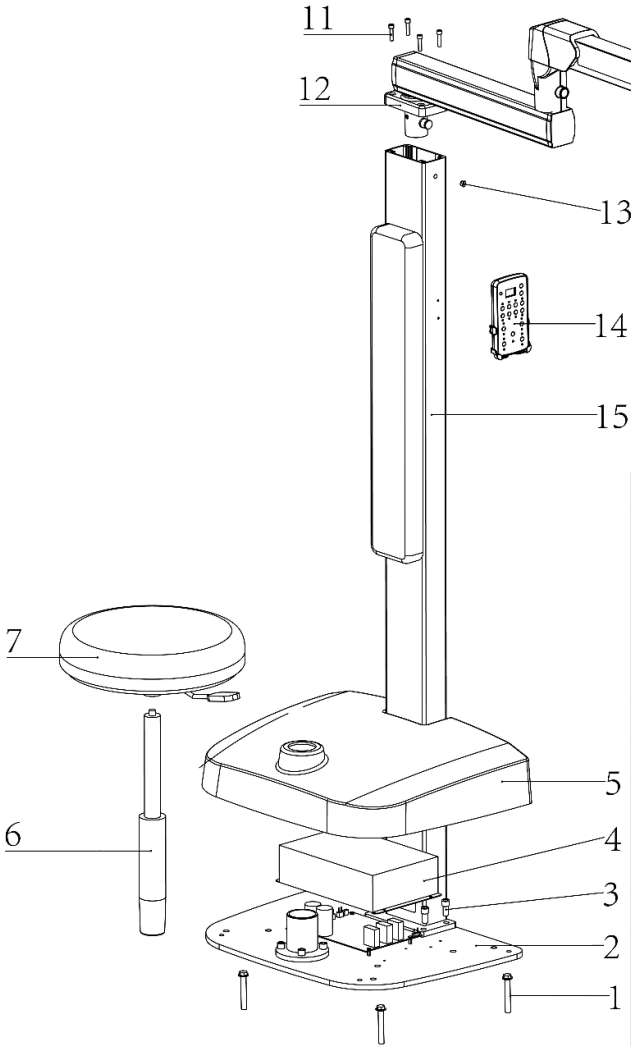
Install the column on the base plate with 4 M10x20 screws. Insert the wire which in the arm assembly into the column assembly, install the arm assembly on the column with M6x40 screws, and install all wires in the column on the socket corresponding to the main control board.

The PCB shielding cover and base plate cover are respectively mounted on the base plate.

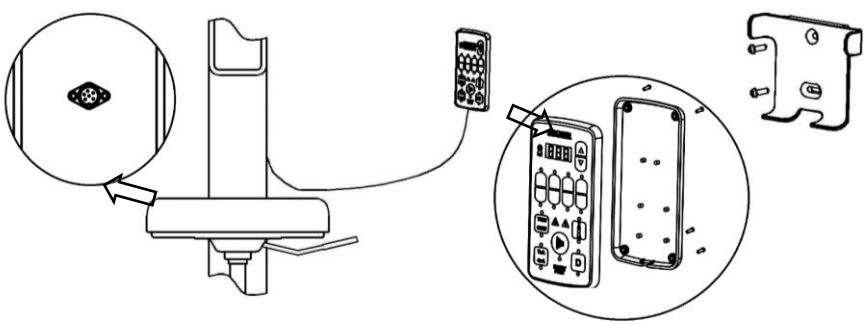
Insert the air spring into the air spring hole and insert the seat cushion on the air spring.

Connect and fix the plug of the X-ray tube head and the plug of the arm body assembly, fix the locating plate, and install the front connector cover.

Install the control box assembly on the column with 2 M4x10 screws and connect the wire and power cord of the control box assembly.

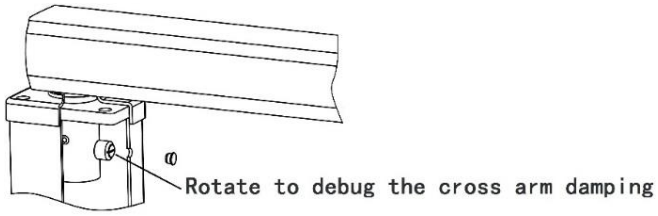


15	Column Assembly
14	Control Box
13	Blanking Cap
12	Rotary Arm Assembly
11	M6x40 Screw
10	Front Connector
9	Locating Plate
8	Tube Head Assembly
7	Cushion
6	Air Spring
5	Base Plate Cover
4	PCB Shielding Cover
3	Screw M10×20
2	Base Plate Assembly
1	Φ10 expansion



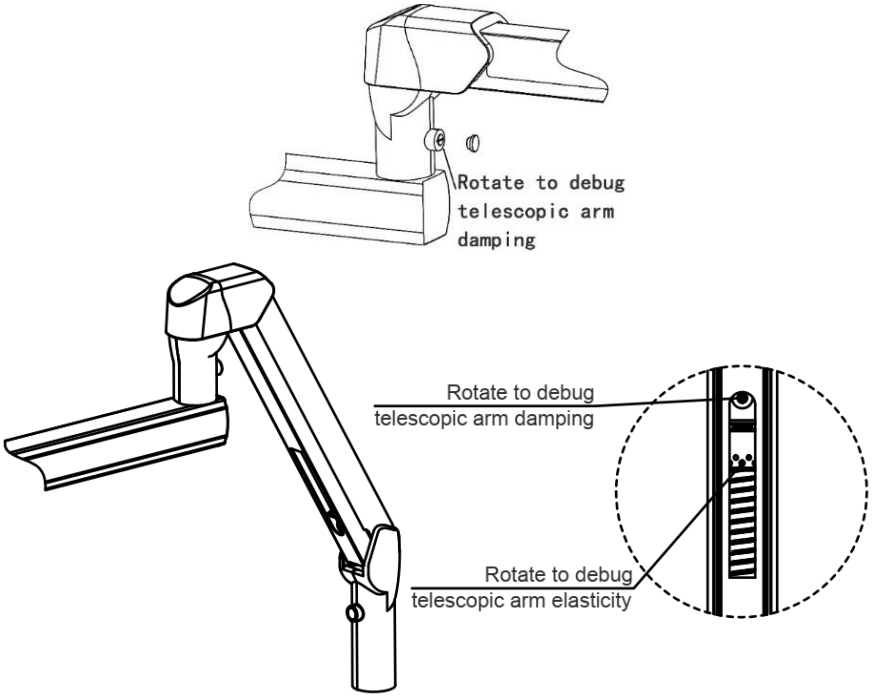
3.2.3.2 Debug the Cross Arm Damping

The structure is similar as shown below. It's same as debugging method for the cross-arm damping of a wall-mounted dental X-ray machine. Please refer to 3.2.2.1.



3.2.3.3 Debug the Telescopic Arm Damping

The structure is similar as shown below. It's same as debugging method for the telescopic arm damping of a wall-mounted dental X-ray machine. Please refer to 3.2.2.2.



3.2.3.4 Commissioning of the tube head

The same as the commissioning method of the tube head of the wall-mounted type. See 3.2.2.3 for details.

⚠**Warning:**

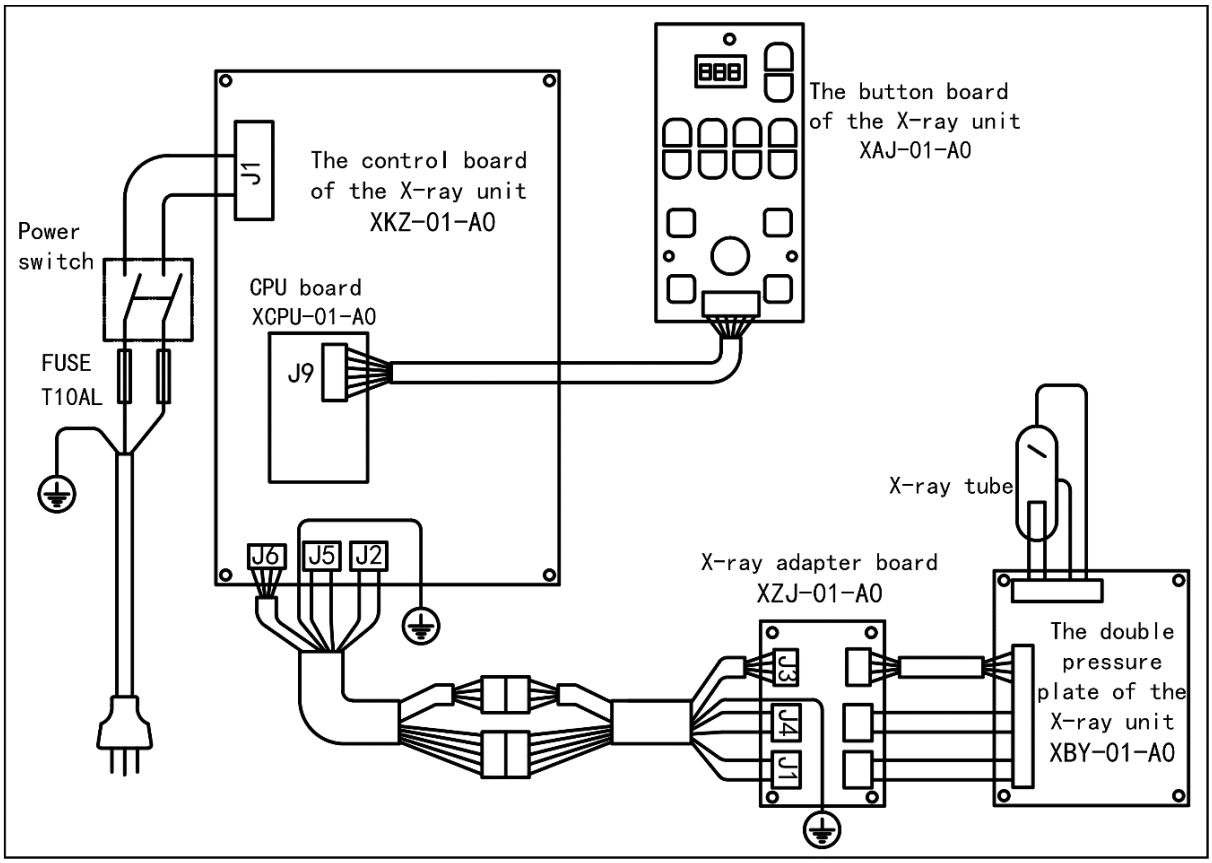
Do not position me equipment to make it difficult to operate the disconnection equipment.

The manipulator cannot suspend objects.

⚠**Caution:** The user after installation check whether the mechanical structure is strong.

3.3 Electrical schematic

Any operation involving maintenance of the equipment interior must be performed by a qualified engineer who shall determine the damaged parts according to the Fault Code Table when repairing the equipment, and replace the parts provided by the company. You can contact the after-sales department of our company for technical guidance. During maintenance, you can contact our company to obtain the electric schematic diagram and other relevant data.



3.4 Maintenance of the equipment

⚠ **Caution: The correct maintenance method can extend the life of the equipment!**

The X-ray generator (X-ray tube head) shall not vibrate and bump violently while being used.

When the fuse is broken, replace it with the fuse of the original model after troubleshooting.

The seat and backrest do not require special maintenance. It is recommended to wipe them with a towel whenever a patient is treated.

The equipment's external components (e.g., the mouth of the cone) that often contact with doctors, nurses or patients must be wiped with 75% alcohol once every day.

⚠ **Caution: When cleaning the surface of the dental X-ray unit, disconnect the main power.**

⚠ **Caution: Do not use abrasives or acidic cleanser.**

⚠**Caution: The user should carry out the following inspections monthly:**

- Visually check whether all visible labels are in good condition;
- Check that the power cord is properly connected to the power outlet and visually inspect the cable for damage. If the cable is damaged, it should only be replaced by authorized service technicians;
- Check whether the visual exposure indicator goes on during exposure.
- Verify that the buzzer emits sound during the exposure;
- Check whether the exposure button must be pressed continuously within the exposure period;
- When the exposure button is release prematurely, check whether the exposure is terminated;
- Check all the functions of the operating panel according to Sections 2.2 and 2.3.

3.5 The normal operations, transportation and storage conditions for the machine.

Normal Operations		Transportation and Storage	
Ambient temperature	+10℃～+40℃	Ambient	-20℃～+55℃

		temperature	
Relative humidity	30%~75%	Relative humidity	≤93%
Atmospheric pressure	70 kPa～106 kPa	Atmospheric pressure	50 kPa～106 kPa

3.6 Waste disposal

If the equipment is too old, even after proper maintenance and repair, it can no longer meet the expected operating specifications of the manufacturer, then the equipment cannot be used and should be scrapped in time. All provisions concerning waste disposal shall be observed. At a minimum, the X-ray source modules and the electronic circuit related components of the equipment shall be regarded as non-environmental protection waste. Disposed in accordance with the local laws and regulations or the rules of the hospital.

Chapter 4 Common Troubleshooting and Other Matters

4.1 Common fault analysis and maintenance

Error messages are divided into two categories. One category is Use Error (H) and the other System Error (E). Use errors can be quickly processed.

Display Content	Error Cause	Solution
E1	Abnormal self-test during boot-up	Contact the maintenance department
E2	Communication error	Contact the maintenance department
E3	The filament signal line is not connected or shorted	Contact the maintenance department
E4	The tube voltage signal line is not connected or shorted	Contact the maintenance department
E5	The tube current signal line is not connected or shorted	Contact the maintenance department
E6	The temperature signal line is not connected or shorted	Contact the maintenance department
E7	Low tube voltage	Contact the maintenance department
E8	Low tube current	Contact the maintenance department
H1	The Exposure button fails to bounce up	Check the button
H2	Exposure is interrupted before the time expires	Re-exposure
H3	High temperature of the tube head	Wait until the tube head is cool

4.2 Replacement of the fuse tube

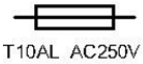
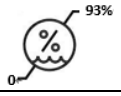
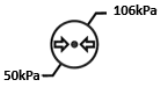
After turning off the main power switch, find the fuse holder on the facade housing of the control box, use a medium slotted-screw driver to unscrew the fuse cap, place a new fuse, and then do operations in reverse to the above operations.

Fuse	Specification
Main fuse	T10 AL250 V/Φ5X20

4.3 The equipment's service life:

This equipment has an expected service life of eight years. See the nameplate for the production date.

4.4 Graphics and symbols used for the equipment

	It appears alone if other contents are shown in the user manual.		When appearing together with “**Caution**”, it means important information for users or service personnel.
	When appearing together with “**Warning**”, it means that failure to follow the Manual may cause personal injury or damage to the equipment and its components.		Fuse mark.
	“No wet” sign.		"Fragile" sign.
	"Up" sign.		Storage humidity limit sign.
	Storage temperature limit sign.		Storage Atmospheric Pressure limit sign.
	Stacking limit by 6.		Stacking limit by 3.
	Means “See the accompanying document”.		It is the sign meaning “Do not discard an electronic equipment freely”. According to the regulations, after the expiration date, the equipment shall be disposed of according to the local legal requirements to avoid polluting the environment and injuring the user.
	“Grounding” sign.		Class: Class B of Type I.
	“On” sign.		“Off” sign.
IP20	Waterproofness grade sign.		Radiation warning sign.
	X-ray source device: transmitter.		Manufacturer.
	Date of manufacture.	CE 2460	CE mark.
EC REP	European Authorized Representative.		Hazardous voltage.
	No stepping.	1mm Al	X-ray filter plate.
	Mind your hands.		

Chapter 5 Electromagnetic Compatibility

⚠ Caution:

- The dental X-ray machine meets the relevant electromagnetic compatibility requirements of the standard IEC60601-1-2.
- The user shall install and use the equipment according to the information provided in the accompanying

document.

- Portable and mobile RF communication equipments may influence the performance of the dental X-ray machine. When using the equipment, avoid strong electromagnetic interference, e.g., in the vicinity of mobile phones, microwave ovens, etc.
- See Annex for details of the guidelines and the manufacturers' statements.

⚠ Warning:

- The dental X-ray machine shall not be placed near or stacked with other equipment when it is used. Otherwise, you shall observe and verify whether it runs properly with the operating settings thereof.
- Use of the cables other than the cables that are delivered by the dental X-ray unit manufacturer as spare parts for internal components may result in an increase in the emission of the dental X-ray machine or a reduction in its immunity.

Annex:

Guidelines and the manufacturer's statement − electromagnetic emission		
The dental X-ray unit is intended for use the electromagnetic environment specified below. The customer or the user of dental X-ray unit should assure that it is used in such an environment:		
Emissions test	**Compliance**	**Electromagnetic environment - guideline**
RF emission CISPR 11	Group 1	The dental X-ray unit uses RF energy only for its internal function. Therefore, its RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The dental X-ray unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Compliant	
Voltage fluctuation / fliker emissions IEC61000-3-3	Compliant	

Guidelines and the manufacturer's declaration − electromagnetic immunity			
The dental X-ray unit image intensifier is intended for use in the electromagnetic environment specified below. The customer or the user of the dental X-ray unit image intensifier should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test**	**Compliance Voltage**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC61000-4-2	Contact: +8 kV Air: +2, +4, +8, +15 kV	Contact: +8 kV Air: +2, +4, +8, +15 kV	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	The input a.c. power ports: ±2 kV The input d.c. power ports: ±2 kV Signal input/output ports: ±1 kV	The input a.c. power ports: ±2 kV The input d.c. power ports: ±2 kV Signal input/output ports: ±1 kV	Mains power quality should be that of a typical commercial or hospital environments.
Electrical surge IEC61000-4-5	Input power ports: +0.5, +1.0 kV Signal input/output: +2.0 kV	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environments.
Voltage dips, short interruptions and voltage variations on power supply	0.5 cycles for > 95% (sync angle (degrees):0, 45, 90, 135, 180,225, 270, 315)	0.5 cycles for > 95% (sync angle (degrees):0, 45, 90, 135, 180,225, 270, 315)	Mains power quality should be that of a typical commercial or hospital environments. If the user of the dental X-ray unit image Intensifier requires continue operation during power mains interruptions, it is recommended that the

input lines IEC61000-4-11	1 cycle for >95% U_T (sync angle (degrees):0) 25 (50Hz)/30 (60Hz) cycles for 30% U_T (sync angle (degrees):0) 250 (50Hz)/300 (60Hz) cycles for >95% U_T (sync angle (degrees):0)	1 cycle for >95% U_T (sync angle (degrees):0) 25 (50Hz)/30 (60Hz) cycles for 30% U_T (sync angle (degrees):0) 250 (50Hz)/300 (60Hz) cycles for >95% U_T (sync angle (degrees):0)	dental X-ray unit image Intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the dental X-ray unit image Intensifier further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration − electromagnetic immunity			
The dental X-ray unit is intended for use in the electromagnetic environment specified below. The customer or the user of the dental X-ray unit should assure that it is used in such an electromagnetic environment:			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment − guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	Same as the left	Portable and mobile RF communications equipment should be used no closer to any part of the dental X-ray unit, including cables, than the recommended separation distance calculated form the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$
Radiation RF IEC61000-4-3	Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz	Same as the left	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an			

electromagnetic site survey should be considered. If the measured field strength in the location in which the dental X-ray unit is used exceeds the applicable RF compliance level above, the dental X-ray unit should be observed to verify normal operate. If abnormal performance is observed, additional measures may be necessary, such as re-adjust or relocating the dental X-ray unit.

[b] Over the frequency range150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the dental X-ray unit

The dental X-ray unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the dental X-ray unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the dental X-ray unit as recommend 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**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 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

For transmitter rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimate using the equation applicable to the frequency of transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Reporting System of Serious Events

Please contact with manufacturer and local competent authority as below table once any serious incident related with the oxygen concentrator occurs.

Country	Contact information	Website
Belgium	**MDD AIMDD - IVDMD** Head of Vigilance Division: Th. Roisin **MDD AIMDD Vigilance: C. Driesmans** tel: +32 2 528 4418 **IVDMD Vigilance: J. Poels** tel: +32 2 528 4449 E-mail: vigilance.meddev@fagg-afmps.be **FAMHP- Federal Agency for Medicines and Health Products** Place Victor Horta 40, box 40, B - 1060, Brussels, fax:+32 2 528 4120	https://www.afmps.be/fr
Bulgaria	Executive Director of BDA: **Bogdan Kirilov, M.Pharm.** Head of Division 'Medical devices': **Todor Darakchiev** **Bulgarian Drug Agency** 8 Damyan Gruev Str., BG - 1303 Sofia, tel:+359	https://www.bda.bg/bg/

Country	Contact information	Website
	2 890 34 83, fax:+359 2 890 34 34 E-mail: todor.darakchiev@bda.bg, bda@bda.bg - Web site	
Ceska Republika / Czech Republic	**Ivana Justová** **State Institute for Drug Control** Šrobárova 48, 100 41 Prague 10, Czech Republic, tel: +420 272 185 794, fax: +420 272 185 764 E-mail: urgent@sukl.cz, ivana.justova@sukl.cz	/
Hrvatska / Croatia	Krunoslav Kranjcec, Agency for Medicinal products and medical devices Ksaverska cesta 4, 10 000 Zagreb, tel: +385 1 4884 327, fax: +381 1 4884 110 E-mail: medpro@halmed.hr, Krunoslav.kranjcec @halmed.hr	https://www.halmed.hr/?ln=en
Danmark / Denmark	**Danish Medicines Agency** Axel Heides Gade 1, DK - 2300 - Kobenhavn, tel: +45 44 88 9595, fax: +45 44 88 9599 E-mail: med-udstyr@dkma.dk, Web sites: www.medicinskudstyr.dk	https://laegemiddelstyrelsen.dk/en/devices/
Deutschland / Germany	**AIMDD, MDD - Dr. Ekkehard Stößlein** - tel: +49 228 207 5384 **IVDMD - Prof. Dr. Rüdiger Siekmeier** - tel: +49 228 207 5360 **Federal Institute for Drugs and Medical Devices** Kurt Georg Kiesinger Allee 3, D - 53175 Bonn, fax: +49 228 207 5300 E-mail: medizinprodukte@bfarm.de **IVDMD** **Dr. Markus Funk** - tel: +49 6103 77 3115 **Jochen Halbauer -** tel: +49 6103 +77 3114 **Paul Ehrlich Institute**, Section Pharmacovigilance 2 Paul-Ehrlich-Strasse 51-59, D - 63225 Langen, fax: +49 6103 77 1268 E-mail: pharmacovigilance2@pei.de	https://www.bfarm.de/DE/Home/_node.html https://www.pei.de/DE/home/home-node.html
Eesti / Estonia	**Sofia Ratusnaja** - tel: +372 744 7425 **Health Board, Medical Devices Department** 1a Põllu st., EE - Tartu 50303 E-mail: mso@terviseamet.ee -	https://www.terviseamet.ee/en/medical-devices
Ireland / Eire	**Health Products Regulatory Authority** Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IE - Dublin 2 E-mail: devicesafety@hpra.ie	https://www.hpra.ie/
Ellada / Greece	**Eleni Papaioannou, MD** - tel: +30 213 20 40542, fax: +30 210 65 49585 E-mail: vigilancematerial@eof.gr **National Organization for Medicines** 284 Mesogion Ave, GR- 15562 Holargos, Athens	/
España / Spain	**Carmen Abad** **Carmen Valls** - tel: +34 91 822 5255, fax: +34 91 822 5289 **Agencia Espaňola de Medicamentos y Productos Sanitarios** C/ Campezo 1, Edificio 8, ES - 28022 Madrid	https://www.aemps.gob.es/

Country	Contact information	Website
	E-mail: psvigilancia@aemps.es	
France	**Emilie Alliez** - tel: +33 1 55 87 33 46, fax: +33 1 55 87 37 02 **Agence nationale de sécurité du médicament et des produits de santé (ANSM)** 143-147 boulevard Anatole France, FR - 93285 Saint Denis Cedex E-mails: Exclusively for correspondence between authorities: medicaldevicesvigilance@ansm.sante.fr Other purposes: materiovigilance@ansm.sante.fr	http://www.afssaps.fr/
Italia / Italy	**Vigilance on Medical Devices** **Head of Unit 5 - Dr.ssa Lucia Lispi** - tel: +39 06 5994 2055 E-mail: dgfdm@postacert.sanita.it, vigilance@sanita.it, l.lispi@sanita.it **MDD AIMDD Vigilance - Dr.ssa Antonella Campanale - Dr.ssa Daniela Minella** tel: +39 06 5994 3038, +39 06 5994 3069 E-mail: dgfdm@postacert.sanita.it, vigilance@sanita.it, a.campanale@sanita.it; d.minella@sanita.it **Head of Unit 4 - Dr.ssa Antonella Colliardo - tel: +39 06 59943968.IVDMD Vigilance - Dr.ssa Maria Gabriella Cividino - Dr.ssa Maria Elena Russo** tel: +39 06 59943785, +39 06 59942516 E-mail: dgfdm@postacert.sanita.it, mg.cividino@sanita.it; me.russo@sanita.it; a.colliardo@sanita.it Ministry of Health, Directorate General of Medical Devices and Pharmaceutical Services Via Giorgio Ribotta 5, IT - 00144 Roma	/
Kypros / Kibris / Cyprus	**Ioannis Argyropoulos** – tel: +357 22 605785 **Cyprus Medical Devices Competent Authority** Prodromou 1 & Chilonos 17 Corner, CY - 1449 Nicosia, fax: +357 22 468427 E-mail: cymda@mphs.moh.gov.cy	/
Latvija / Latvia	Medical Device Evaluation Department - tel: +371 67 078 466, tel: +371 67078466 State Agency of Medicines, 15 Jersikas street, LV - 1003 Riga E-mail: info@zva.gov.lv	/
Lietuva / Lithuania	Director: **Nora Ribokiene** - tel: +370 5 261 51 77, fax: +370 5 212 73 10 **The State Health Care Accreditation Agency, under the Ministry of Health of the Republic of Lithuania** Jeruzales str. 21, LT-08420 Vilnius E-mail: vaspvt@vaspvt.gov.lt	https://vaspvt.gov.lt/
Luxembourg	Ministère de la Santé, Direction de la Santé - tel : +352 247 85612 Villa Louvigny - allée Marconi, L - 2120 Luxembourg E-mail: meddevices.vigilance@ms.etat.lu	https://sante.public.lu/fr/politique-sante/ministere-sante/index.html

Country	Contact information	Website
Malta	**Malta Medicines Authority - Medical Devices Unit** **Medicines Authority** Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann SĠN 3000, Malta Tel: +356 2343 9000 E-mail: devices.medicinesauthority@gov.mt	https://medicinesauthority.gov.mt/medicaldevices
Magyarország / Hungary	**Kornel Szerdi dr.**- tel: +36 1 886 9329, fax:+36 1 269 1255 **Health Registration and Training Centre, Department of Medical Devices** 1051, Budapest, Zrínyi street 3, Hungary E-mail: amd.vig@ogyei.gov.hu	/
Nederland /Netherlands	**Sietske Eerens, Esther Klinckenberg** - tel: +31 88 120 5000, fax: +31 88 120 5001 D**utch Health and Youth Care Inspectorate, IGJ Information Office (Meldpunt)** Visitors address: Stadsplateau 1 | 3521 AZ | Utrecht, postal address: Postbus 2518 | 6401 DA | Heerlen E-mail: meldpunt@igj.nl	https://www.igj.nl/
Österreich / Austria	**Federal Office for Safety in Healthcare - (BASG) Bundesamt für Sicherheit im Gesundheitswesen** **Institute for Surveillance, Department Medical Devices Surveillance** Traisengasse 5, A-1200 Vienna, fax: +43 50555 36409 E-mail: medizinprodukte@basg.gv.at	https://www.urpl.gov.pl/pl
Polska/ Poland	**Competent Authority** **Andrzej Karczewicz** - tel: +48 22 492 11 90, **Beata Koziozemska** - tel: +48 22 492 11 68 **Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** Al. Jerozolimskie 181C, 02-222 Warsaw, fax: +48 22 492 11 99 E-mail: incydenty@urpl.gov.pl	https://www.urpl.gov.pl/pl
Portugal	**Raquel Alves** - tel: + 351 21 798 7297, tel:+351 21 798 7145, fax:+351 211 117 559 **Infarmed - National Authority of Medicines and Health Products, IP Unidade de Vigilância de Produtos de Saúde da Direção de Produtos de Saúde** Parque da Saúde de Lisboa, Av. do Brasil, nº 53, PT - 1749-004 Lisboa E-mail: dvps@infarmed.pt	https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/vigilancia-de-dispositivos-medicos
Romania	**Oana Arsenescu Georgeta Herta** tel: +40 21.222.86.52, +40 21 260.01.58, +40 21 260.01.59 fax: +40 21.222.86.83 **National Agency for Medicines and Medical Devices of Romania** 58, Sos. Nicolae Titulescu, sector 1, Bucharest E-mail: mdevice@anm.ro, georgeta.herta@anm.ro	https://www.anm.ro/
Slovenija /	**JAZMP - Agency for Medicinal Products and**	https://www.jazmp.si/en/medical-

Country	Contact information	Website
Slovenia	**Medical Devices of the Republic of Slovenia** Slovenčeva ulica 22, SI - 1000 Ljubljana - - tel: +386 8 2000 500 E-mail: info@jazmp.si, meddev.vigilance@jazmp.si	devices/vigilance-of-medical-devices/
Slovenska Republika / Slovakia	**Darina Kaminská -** tel: +421 2 50701215, **State Institute for Drug Control, Medical Devices Section** Kvetna 11, SK - 825 08 Bratislava E-mail: darina.kaminska@sukl.sk	https://www.sukl.sk/hlavna-stranka/english-version?page_id=256
Suomi / Finland	**Finnish Medicines Agency Fimea Medical Devices Unit** Mannerheimintie 166, P.O. box 55, FI-00034 FIMEA, FINLAND, tel:+358 29 522 3602 E-mail: meddev.vigilance@fimea.fi, registry@fimea.fi	https://www.valvira.fi/
Sverige / Sweden	Swedish Medical Products Agency 'Läkemedelsverket' Department of Medical Devices Box 26, SE-751 03 Uppsala, - tel: +46 18 174600, E-mail: meddev.central@lakemedelsverket.se -	https://www.lakemedelsverket.se/sv
Norway / Norge	**AIMDD, MDD IVDMD - – Raymond Ludvigsen / Bjørn Kristian Berge** **Statens legemiddelverk/ Norwegian Medicines Agency** Postboks 6167 Etterstad, N-0602 Oslo, tel: +47 22 89 77 00 E-mail: meddev-no@legemiddelverket.no	https://legemiddelverket.no/English
Iceland / Island	**Haukur Eggertsson** - tel: +354 520 2100, fax: +354 **561 2170 Icelandic Medicines Agency** Vínlandsleið 14, IS-113 Reykjavík E-mail: Haukur.Eggertsson@lyfjastofnun.is	https://www.lyfjastofnun.is/
Liechtenstein	**Martin Stricker,** tel: +423 236 73 36 **Office of Public Health** Äulestrasse 51, Postfach 684, FL - 9490 Vaduz E-mail: medical.devices@llv.li -	https://www.llv.li/inhalt/1908/amtsstellen/amt-fur-gesundheit
Turkey	**The Ministry of Health, Turkish Medicine and Medical Device Agency** **Vice Presidency of Inspectorate, Medical Device Vigilance Unit** Söğütözü Mahallesi 2176. Sokak No:5 P.K. 06520 Çankaya Ankara/ TURKEY E-mail: meddev.vigilance@titck.gov.tr	/

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E-mail: info@siger.cn
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EU Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
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