

Dental X-Ray Unit YR03341 **Operation User's Manual**

Thank you very much for purchasing our Dental X-Ray Unit YR03341.

Please read the "Operating Instructions" and "Warranty" before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the "Warranty" at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.



OUR SERVICES

Benefits and Support

In Kalstein France, we take care of the full satisfaction of our customers, that is why we provide value-added services of the highest level based on our experience.



Online Inductions and Trainings

In any part of the world, receive your induction or training from our specialized team of engineers



Quick Response

Our work team is always available to response all your consults or questions, in order to support you in any situation.





#Letsgivemore 💗

Thanks to your purchase, a donation will be made to a non-profit foundation that fights against breast cancer and helps most vulnerable communities.



Technical Support

Enjoy of personalized advice for the correct preventive and corrective maintenance of your equipment, thanks to Kalstein's manuals and articles, special catalogues and video tutorials.





Delivery Logistics

We take care of all the necessary logistics for the dispatch of your goods, whether is by sea, land or.air.



Kalstein Worldwide

With more than 25 years growing with our customers, Kalstein's multiformat and modern content, is now present in more than 10 countries and increasing.





DENTAL X-RAY UNIT





INTRODUCTION

Manufacturer Declaration

We appreciate you kindly select our dental X-ray unit very much. Please read the operation manual carefully before using the unit so that you could learn all the details about technical specification, installation, operating methods maintenance and the transportation.

The preparation of this manual according with GB/T14436-93 <The general industrial product guarantee files>, GB/T9969-2008 <industrial product specification conditions> and other relevant standards, our company has the instruction of non-public publishing copyright, any person or company shall not to copy or translated into another language the whole or any section of this manual without the written consent of our company.

After-sales service responsibility

Our company only responsible for the performance and reliability of the instrument under the following circumstances:

- Assembly, debug and repair personnel authorized by our company.
- Related electrical equipments according with national standards.

Using the device according to the operation manual

! Note: This device is not treatment device.

Warning: This device needs to be use by trained professional or medical institutions





SAFETY GUIDELINES

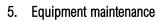
- 1. Before working and testing, you must according with the safety instruction:
 - Please make sure the machine connects with the power correct, check the equipment work carefully
 - Please make sure equipment connect the ground correct.
 - Please make sure the power supply
- 2. In addition, you also must according with the requirements of national special provisions (for example: Occupational Safety and Accident Prevention Regulations).
- Note: During using process, you should make the distance from the focus to skin as long as possible.
 - 3. The equipment placement and storage place should be paid attention to the following:
 - Please do not use and save in inflammable and explosive places.
 - Please do not use and save in pressure, temperature, humidity, over the allowed scope environment.
 - Please do not use and save in the water place.
 - Please avoid slope instability, vibration and impact (including handling).
 - Please note that the frequency of the AC power source and allow current and voltage.
 - Keep well ventilated, avoid direct sunlight.

4. Equipment installation

You must according with the technical data to finish all installation tasks.

When finished the installation and before turning on the equipment, you must be sure all the protective grounding line which the manufacturer provided linked normally.

In order to take clearly dental x-rays films and not disturb other electrical equipment using, please link the wiring from the electric meter separately for dental X-ray machine, and the single wire diameter > 1mm² (like air conditioning wiring).







Because the equipment includes the user's operation and diagnosing patients, therefore must be maintained, checked, diagnosed equipment maintenance every year, mechanical transmission parts must be clean, lubrication and maintenance regularly, ensure the equipment safety. And this equipment involved in high voltage electrical control components, should check the safety of its insulation, grounding device reliability.

6. Products warning statement explain (oblique arm):

Warning: Before finished the installation and removal the tube head, you must push the balance arm to the highest place, to avoid the arm up and hurt person.

Explanation: Because the oblique arm elastic strongly, to prevent injury to people, please accordance with the warning of the instructions in strictly, if make any accidents caused by incorrect operation, we will not take any responsibility.

7. The Symbol Instruction

NO.	SYMBOL	INSTRUCTION	NO.	SYMBOL	INSTRUCTION
1	A	May cause an electric shock, damage of high voltage components or debugging test points	7	I	Fragile with care
2		Turn on the switch will produce radioactive rays.	8	11	Up
3	Δ	Caution	9	X	Stacking layer limit
4	0	Power off	10	#	Dryness
5		Power on	11	★	В Туре
6	•	Protective earth			

8. Electromagnetic compatibility

- 8.1 It may cause electromagnetic interference to other devices by air or by connecting cables. EMC refers to the ability of the device to suppress the electromagnetic interference of other devices without causing similar electromagnetic interference to other devices. The product design according with YY0505-2012 class 1, type A standard.
- 8.2. Guidelines and manufacturer statements. Comply with the following EMC electromagnetic compatibility radiation and electromagnetic immunity declaration. see table 1, table 2.



Table 1 Electromagnetic emission

Guide and manufacturers declaration—Electromagnetic emission

Dental X-ray machine is expected using in the following provisions of the electromagnetic environment, buyers or users shall ensure that using it in the electromagnetic environment.

asers share ensure that using it in the electromagnetic environment.							
Emission test	Conformity	Electromagnetic environment, guide					
RF emission GB 4824	Class 1	Dental X-ray machine in order to finish its expected function must launch electromagnetic energy. Nearby electronic equipment may be affected.					
RF emission GB 4824	Type A	Dental X-ray machine is suitable for the household or not residential low-voltage supply network of public and not all the					
Harmonic emission GB 17625.1	Inapplicability	facilities used in the direct connection.					
Voltage fluctuation/launch GB 17625.2	Inapplicability						





Table 2 Electromagnetic immunity

Guide and manufacturers declaration—Electromagnetic immunity

Dental X-ray machine is expected using in the following provisions of the electromagnetic environment, buyers or users shall ensure that using in the electromagnetic environment.

Immunity test	IEC 60601 Electrical level	According with level	Electromagnetic immunity—Guide
Electrostatic discharge GB/T 17626.2	±6kV Contact discharge ±8kV Air discharge	±6kV ±8kV	The ground should be wood, concrete or ceramic tile, if the ground covered with synthetic material, the relative humidity should be at least 30%.
Electrical transient bursts GB/T 17626.4	±2kV For the power cord ±1kV For the input/output line	±2kV ±1kV	Network power supply should have a typical commercial or the quality of medical environment.
Surge GB/T 17626.5	±1kV Wire to wire ±2kV Wire to ground	±1kV ±2kV	Network power supply should have a typical commercial or the quality of medical environment.
	< 5%UT for 0.5 cycles (up the UT, > 95% sag) 40%UT for 5 cycles (up	<5% UT	Network power supply should have a typical commercial or the quality of medical environment. If dental X-ray
interruption and the voltage change	UT, 60% sag) 70% UT, for 25 cycles	40%UT	machine user needs to run continuously during power outage, then recommend the
GB/T 17626.11	(up the UT, 30% sag) < 5%UT for 5 seconds	70% UT	dental X-ray machine adopts uninterruptible power supply or batteries.
	(up the UT, > 95% sag)	<5% U T	
Power frequency magnetic field (50/60Hz) GB/T 17626.8		3 A /m	Power frequency magnetic field should have in a typical commercial or hospital environment level of power frequency magnetic field characteristics of the typical place.

Note: $U\tau$ Refers to the communication network voltage before applying test voltage.

Installation must notice:

- Install the equipment as far away from other electrical equipment as possible.
- Adjust the position between this equipment and other equipment/ installation. Angle could reduce electromagnetic interference.
- Changing Other Equipment wiring position can be reduce the electromagnetic interference.



- Changing other equipment power path can be reduce the electromagnetic interference.
- Specified electromagnetic compatibility environment see table 3 and table 4.

Table 3 Electromagnetic immunity

Guide and manufacturers declaration—Electromagnetic immunity

Dental X-ray machine is expected using in the following provisions of the electromagnetic environment, buyers or users shall ensure that using in the electromagnetic environment.

Immunity	IEC 60601 Electrical level	According	Electromagnetic immunity—Guide
test		with level	
The radio frequency transmission GB/T 17626.6	3V (effective value) 150 kHz ∼ 80 MHz	3V (effective value) 150 kHz ~ 80 MHz	Using portable and mobile radio frequency communication equipment close to any part of the dental X-ray machine should not more than recommended separation distance, including the cables. The distance by the transmitter frequency and the corresponding formula $ \begin{array}{c} \text{The recommended separation distance} \\ \text{d=1.} \ 2\sqrt{p} \\ \text{(see table 4)} \\ \text{d=1.} \ 2\sqrt{p} \\ \text{800MHz} \sim \text{800MHz} \\ \text{d=2.} \ 3\sqrt{p} \\ \text{800MHz} \sim 2.5 \text{GHz} \\ \end{array} $
The radio frequency radiation GB/T 17626.3	3V/m 80 MHz ~ 2.5 GHz	$3V/m$ 80 MHz \sim 2.5 GHz	In the formula: P——According to the manufacturer provide the transmitter maximum rated power output, unit is watts(W); d——The recommended separation distance, the unit is meter(M). Fixed type strength of the transmitter based on electromagnetic survey ^a to determine, each frequency range ^b should be less than the level. May appear interference near the following mark symbol of the equipment

Note I: In the frequency of 80 MHZ and 800 MHZ, using the formula of high frequency.

Note Π : These guides may not be suitable for all situation, electromagnetic propagation by buildings, objects, and the effect of absorption and reflection of the body.

- a. Stationary transmitter, such as: wireless (cellular/cordless) phones and ground mobile radio station, amateur radio, AM and FM radio and television broadcasting, etc., the field intensity in theory can predict. For the evaluation of fixed RF transmitter electromagnetic environment, electromagnetic site survey should be taken into account. If measured dental X-ray machine field strength is higher than the place of the above applicable radio frequency (RF) in line with the level, the dental X-ray machine should be observed to verify their works. If the observed abnormal performance, the supplementary measures may be required, such as to readjust direction or location of dental X-ray machine.
- b. Through 150 KHZ ~ 80 MHZ frequency range, the field strength should be lower than 3 V/m.





Table 4 The recommended separation distance between portable and mobile radio communication equipment or system

. . .

The recommended separation distance between portable and mobile radio communication equipment and the dental x-ray machine

Dental X-ray machine is using expected in the radiofrequency radiation harassment controlled electromagnetic environment. Communications equipment based on maximum rated power output, the purchaser or the user can through the following recommended by maintaining a portable and mobile radio communication equipment (transmitter) and the minimum distance between dental X-ray machine to prevent electromagnetic interference.

The maximum	Corresponding to different frequency transmitter isolation distance					
rated power output	M					
of the transmitter	150 kHz ∼ 80 MHz	80MHz~800MHz	800MHz~2.5GHz			
w	d=1. 2√p	d=1. 2√p	d=2.3√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			

To the table not listed transmitter maximum rated power output and recommended isolation distance is d, unit meters (M), determine by the available transmitter frequency corresponding column, here P is provided by the manufacturers transmitter maximum rated output power, unit watts (W).

Note I: In the frequency of 80 MHZ and 800 MHZ, using the formula of high frequency.

Note II: These guides may not be suitable for all situation, electromagnetic propagation by buildings, objects, and the effect of absorption and reflection of the body.

Notice: The product cable as the following table:

NO.	Name	Length(m)	Shielding or no
1	Power cable	3	no
2	Connected cable	2.8	no



- The product installation and using shall ensure the above electromagnetic compatibility environment to make sure equipment operation normally.
- Do not use this equipment near the strong radiation source, otherwise may interfere with the equipment normal work.
- Please purchase and use the equipment accessories and cables sold by the manufacturer, otherwise it may increase the equipment or system launch or the reduce the immunity result. Should not be close to
- or stacked with other devices, if it must be close or stacked, it should be observed to be able to work normally in the configuration.
- In the case of electromagnetic interference, it should be capable of achieving its basic performance. Its basic performance includes:
 - --The normal work of each part and various preset parameters do not change randomly.
 - --The operation mode of the equipment is not changed randomly, no error alarm reported. Product working principle

High voltage generator provide high voltage on both ends of the X-ray tube filament and a metal target, X ray tube cathode filament produced a large number of electrons in a vacuum tube high-speed movement, hit the metal target, to produce x-rays.

In hospital when using dental X-ray take image, X-ray generator emit x-rays through the body teeth, muscle groups such as density, will be through the body's tissues with image

information of X rays by dental medical film image receiver, show the density of different tooth tissue images, used for clinical diagnosis.

2. Product main structure

Dental X-ray machine consist by x ray tube head, console, frame, it is the fixed X-ray machine.

3. Main performance

Tube voltage 60/70kVp

Tube current 8mA

Exposure time 0.01s 9.99s. Step number according to the priority of R '10 series.

4 Device Type





According to the protection of the risk of electric shock, this equipment belongs to class I type B applied part.

Application

- 1. The scope of application: dental X-ray machine get the human oral cavity image by x ray photography used for medical imaging diagnosis.
- 2. The scope of using: Need trained oral dentists or technician to use. For adults and children's Diagnosis.

Product performance

- 1 Conditions of operation:
 - 1.1 Atmospheric pressure: 70Kpa~106Kpa
 - 1.2 Environmental temperature:+10°C~+40°C
 - 1.3 Relative humidity:30%~75%
- 2 Condition of transportation and store:
 - 2.1 Environmental temperature: -40°C~+70°C
 - 2.2 Relative humidity:10%~100%
 - 2.3 Atmospheric pressure:50KPa~106KPa
- 3 **Power supply:** Voltage: Single phase AC

220V±22V;50/60Hz±1Hz Power capacity: >1.1kVA Power resistance: <2 Ω

- 4. Specifications:
 - 4.1 Tube voltage: 60/70kVp
 - 4.2 Tube current: 8mA
 - 4.3 Power: 0.339kW
 - 4.4 Earth Leakage Current

Normal state: ≤0.5 mA Single failure state≤1 mA 4.5

The way of running: Break load; continuous operation

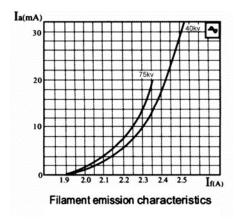
4.6 Loading time: $0.01 \sim 9.99$ s, follows R'10 series

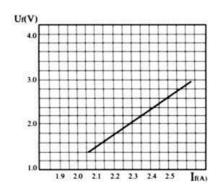
4.7 X-ray glass:



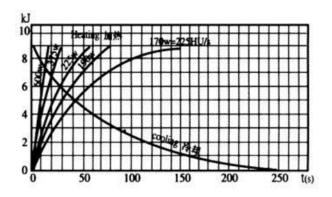
	Focus			Fuse		nominal	Anode
	value		Current	voltage V	Working	anode input	thermal
Normal		Target					
			А		frequenc	power	capacity
voltage KV		angle					
					у	kW	KJ
					HZ		
85	1.5	12°	2.5	2.8±0.7	50~60	1.4	9



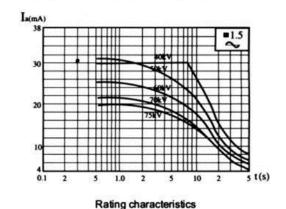




Filament characteristics



Anode heating and cooling characteristics



4.8 X-ray source components

- 4.8.1 Maximum continuous heat dissipation: 170 W
- 4.8.2 Maximum heat capacity: 12700 HU
- 4.8.3 Angle of X-ray tube anode target face shaft of the benchmark: 12 $^{\circ}$
- 4.8.4 The tolerance of focus position to the shaft of the benchmark ≤ 1 mm.
- 4.8.5 X-ray source components total filtration: ≥2.5 mmAl

 Non-removable material 0.5mmAl, Detachable material 2mmAl
- 4.8.6 X-ray source components weight: 7.5 kg
- 4.8.7 High voltage transformer





High voltage transformer: 1:226

Nominal power: 339 W

4.8.8 The largest wild: 3.14 x 26² (mm²)

4.8.9 Leak radiation: < 0.25 mGy/h (conditions for 60 kV, 8 mA)

4.8.10 Around vertical axis rotation: 360 $^{\circ}$

4.8.11 Around horizontal axis corner: 270 $^{\circ}$

4.8.12 X-ray source components adjustable range: 700 mm

4.9 The distance from focus to skin: 210mm

4.10 Activity arm horizontal turning angle: ≥±40°

4.11 Activities arm up-down range: ≥400 mm

4.12 Current: 5 A/10A

4.13 Insurance tube type: RF1-20-5 A /10A 250 V, 5 A/10A

4.14 Weight: 30 Kg

4.15 Service life 6 years

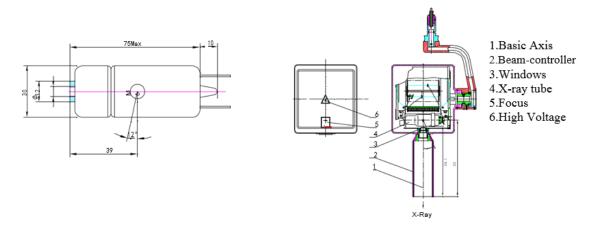




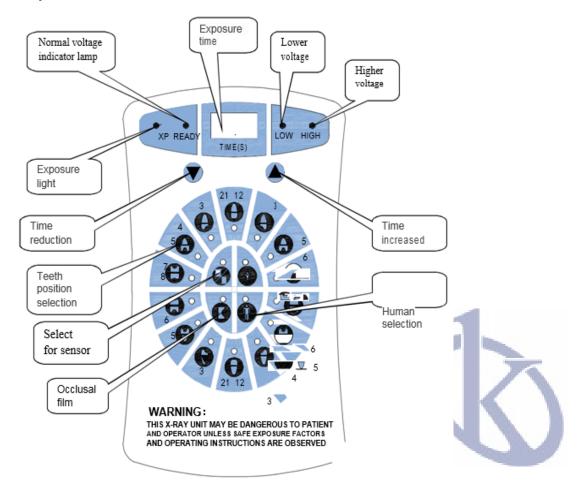
The main structure

1 X-ray tube outside drawing

2 Combined head inside and outside structure



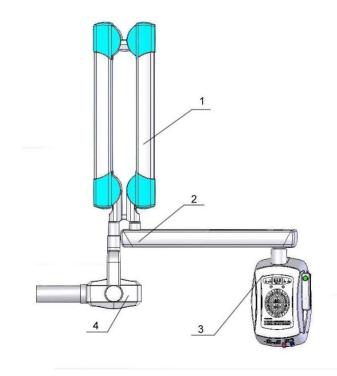
3 Control panel keyboard





4 Device outside drawing

- 1. Balance arm components
- 2. Horizontal arm
- 3. Central controller
- 4. X-ray generator



Installation and Debugging

1.X-ray machine room selection.

Dental X-ray machine room should fully consider the protection and safety of the adjacent room and the surrounding area, and the room should have sufficient area of using. The wall of the room should have the protective thickness of 2mm lead equivalent, and the other side wall should have 1mm lead equivalent protection thickness. The room in the multi-storey building, the ceiling, the floor should be considered as the corresponding side wall, pay attention to the protection and safety of the adjacent room. The doors and windows of the room must be properly set and have the same protective thickness as the wall. The layout of the room should be reasonable, not to pile up the sundry that is not related to the diagnostic work. There should be ionizing radiation signs outside the room and install a smart work indicator light.



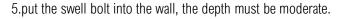


2. Installation of machine

Before installation of machine, please must according the user manual packing list to check each part (The installation of the machine must complete by two people.)

2.1 The installation of the controller ledger

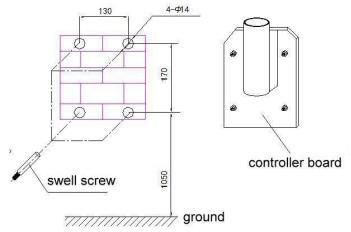
- 1.The wall must withstand more than twice the weight of the machines (the net weight id 30kg).
- 2.open the packing, take out the controller, dismount the above cover of the controller, and then take the controller board as template.
- 3.put the controller board from the floor 1050mm and pull the position of the drill hole on the wall.
- 4.drill hole (the diameter of the hole is 14mm) Two horizontal holes must be in horizontal line, if skew too large, the machine is difficult to work normally.

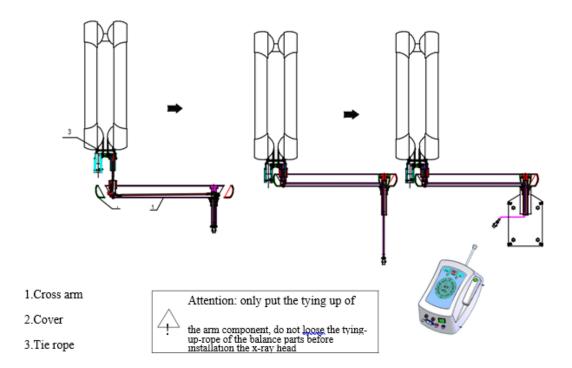


6.fix the controller board on the wall and fix up the nuts.

2.2The installation of the arm

- open the packing and loose the tying up of the arm component, take of the covers of 2 sides of the cross arm, put the cylinder of the arm end into the hole of component balance and pull out the redundancy cables from the other end of the arm.
- 2 put the other end (with plug) of the arm into the hole of the board.
- 3 connect the plug with the socket (lie in controller)
- 4 buckle the controller into the board and aim at the spiral nail hole tightly.

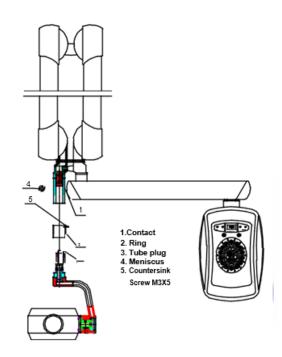




2.3 Installation of X-ray head

Installation of X-ray head (must be done by two person)

- (1) Take off screw 5, up the ring 2, then remove the meniscus 4.
- (2) put No.3 into No.1, make tie-in and tie-tank in order
- (3) put two parts of No.4 separately into tie-in and tie-tank
- (4) make connection order and fasten No.5 bolt
- (5) screw beam-controlled device
- (6) connect power cable and timer
- (7) connect grounding cable, connect green-yellow part of cable to grounding nut of controller; the other end is connecting ground.
 - (if there is accident caused by bad grounding, our company shall not be responsible for that)







WARNING: 1. DON'T WITHDRAW HAND FROM X-RAY HEAD BEFORE FINISHMENT OF INSTALLATION.

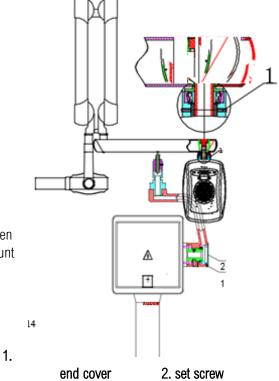
2. GOOD GROUNDING MUST BE ENSURED.

2.4 Horizontal arms adjustment

1. The horizontal arm can move circularly as using. If it is wrong, you could adjust the screw to meet your need.

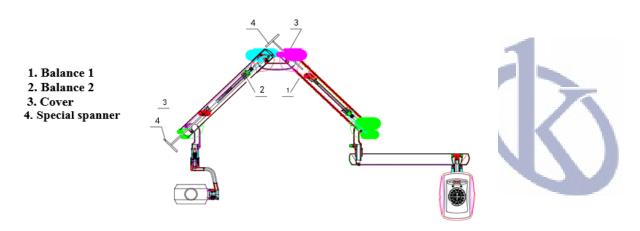
2.5 Adjustment of x-ray generator

The x-ray generator can be rotated freely and self-locking, if it is so flexible that cannot self-locking, you can fix 1. if it is not flexible you can loosen 1. if still cannot meet the requirement, you can demount 2, and add some Oil between axle and surface.



2.6 Balance's adjustment

The x-ray generator can stop at any position when being used, if not, you can make it through adjustment.



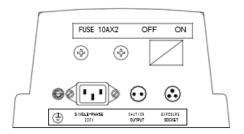


- (1) Adjustment of balance 1:
- a. Demount the cover of balance 1. Method to demount push up the cover. If it is not moved, please put a wood chip board at the lower edge of the cover, then to beat the board lightly.
- b. Pull the balance 1 to about 45°, from the hole we can see there is a hexagonal nut inside, put the special spanner into the nut, then clockwise to increase the pull.
- (2) Adjustment of balance 2:
- a. Demount the cover of balance 2. others operation is the same as balance 1.

Method of using

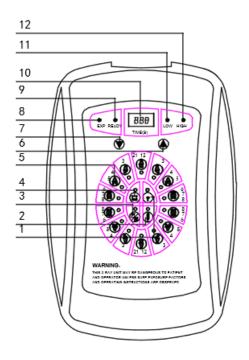
- 1. Power supply voltage confirmation: 220V±22V.
- 2. Insert one end of the power cord into the power socket behind the lower end of the column. (see picture 1)
- 3. Place the end of the ground wire with the end of the forklift to the ground string at the lower end of the column and tighten the nut, and the other end is connected to the ground. See picture 1)
- 4. Plug the exposure switch into the exposure socket below the console. (see picture 1)
- 5. Reconfirm the power supply voltage is 220V±22V, plug in the power cord, turn on the power switch, the power indicator is bright, the digital tube light is bright, indicating that the machine has been energized.
- 6. Panel function (see picture 2): set the operation panel according to the patients.





Picture 1

- 1. Button for child
- 2. Button for adult
- 3. Button for occlusal film
- 4. Select for sensor
- 5. Select tooth: select the number 1-8 for tooth lighting lamp means selected tooth
- 6. Increase exposure time
- 7. Decrease exposure time
 - 7.Film placed and shooting location
 - 7.1 Teeth arranged diagram

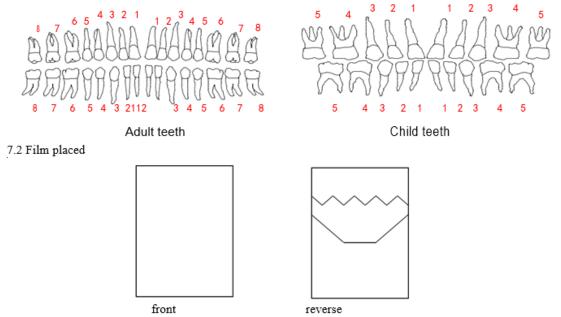


Picture 2

- 8. Exposure indicator lamp
- 9. Normal voltage indicator lamp
- 10. LED display
- 11. Lower voltage indicator lamp
- 12. Higher voltage indicator lamp







Put the film into mouth, film front close to the inside of teeth which want to image, use the thumb hold the film reverse, to make sure closely.

7.3 Shooting location

7.3.1 Patients posture: patient sit on the chair.

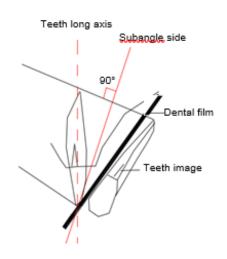
Maxillary and mandible incisor: lip is parallel to the ground.

Maxillary molar: ear- nose line (the line between upper external auditory canal and the nose) parallel to the ground.

Mandible molar: ear- mouth line (the line between upper external auditory canal and the mouth) parallel to the ground.

7.3.2 Film and X-ray direction relation

a) Film and x ray direction position as the figure below, X-ray along the center line by teeth point to the film. Note horn line and the center line position, if the centerline position deviation from the correct position (center line and Angle is less than or greater than 90 °), then take a fake image, may shorter or longer than the actual teeth.





b) When shooting, the suggestion of the patients and the cone position (for adults' example) Mandible shooting: the cone aimed at the parts of shooting.

Maxillary shooting: (6-7-6-7) teeth position, cone aimed at the edge of zygomatic.

(4-5-4-5) teeth position cone aimed at the front of the zygomatic; (3—3) teeth position cone aimed at the side of the nose.

- (2-2) teeth position cone aimed at the tip and the midpoint of the side of the nose.
- (1-1) teeth position, Cone aimed at the nasal tip.

Notice: when exposure, the patient should always be

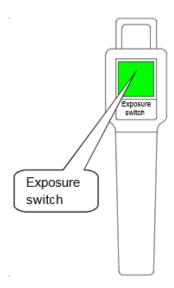
monitored outside the room to ensure the patient's safety.

8 Choose the exposure time selection

According to the teeth position press the corresponding button, digital tube display exposure time Immediately.

9 Exposure

Press the switch (or remote-control switch) to exposure, with buzzer. When finish, take out the film from the patients oral cavity.



During the exposure, need to press the button

all the time, it will stop on time automatically.

10 Developing

a. light room film

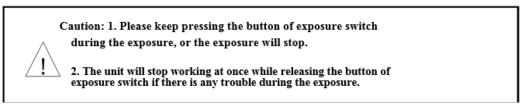
Put 3 or 4ml solution by the injector to the tooth-bag, take out the film to wash with clear water after pressing about 2 - 5min with hand.

b. dark -room film

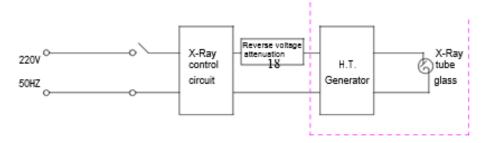


Tear the tooth-bag in dark room, take out the film by clam, put it into the developing solution, take out the film after 3 or 5min to wash it with clear water. then put the film into the fixer solution about 3 or 5min, wash it with clear water again.

11, please turn the power switch after exposing.



PRINCIPLE INTRODUCTION



Turning on the power supply, path after transformation, the circuit makes the high voltage generator get electric, the high voltage supply X-ray tube, produce x-rays.

FAILURE AND MAINTENANCE

- The power indicator light is not bright—make sure the power switch turned on, check whether the power plug into the socket completely (Contacts are in good condition), and then check the loop or fuse whether cutout.
- 2. When press the exposure switch (or remote control), the indicator is not bright, no Buzzer sound check whether the power light is bright (if not, see tip 1)
- 3. The film is too light or too dark or uneven density make sure power indicator is not bright, the exposure indicator and buzzer sound normal (if not, see tips 1, 2), when exposing, make sure press the switch all the time, until finish exposure and it may stop automatically.
- 4. Exposure time more than setting time- console exposure indicator or buzzer sound doesn't stop automatically, loosen the switch, turn off the power, check the failure.



- 5. Console exposure indicator or buzzer sound at any time without press the switch-- turn off the power, check the failure.
- 6. If there is noise or heat from the tube without exposure, turn off the console and cut down all the power. Check the failure.
- 7. If the fuse is blown, use a screwdriver to turn the fuse counterclockwise to replace the fuse.
- 8. When there is a failure, please do not disassemble, should write "have fault!" The note is attached to the device and contact with the company local maintenance department or the company.

! Notice: The fault X-ray tube head shall be returned to the company and the user do not disassemble it.

9. Product warranty

!

- 1) The company ensure according with the qualified raw materials and process to produce the equipment, if provide the problem belong to the manufacturing process and materials fault report in normal using or maintains, will repair or replace the hardware.
- The company will irresponsible to the following situation and directly, indirectly or eventually damage or delay:
- component is tear, stretching, debugging.
 - not by company authorized personnel repair or change the device;
- damage caused by abnormal use.
 - replaced or be removed the product labels or marks.
 - user's improper operation

•

3) Product warranty 1 year from the date of sold.

ATTENTION MATTERS

- 1. In order to security operation, must set up a good grounding wire.
- 2. Because of small X-ray machine is limited by the heat capacity, suggest intermittent operation.



- 3. The machine will produce X-ray in the exposure process and using for a long term, may a harm to human body, the operator should be operating in an effective area and must be equipped with protective equipment such as lead room lead protective screen. (see attached figure)
- 4. In order to make the absorbed dose in patients as low as possible and reasonable, must installed the cone which contained in the tools bag and far from the tube when shooting.
- 5.In order to make the absorbed dose of the patient as low and reasonable as possible, when exposure must install the cone, and far away from the head when operation.
- 6 When using correctly found any accidents please turn off the power apply immediately. Stop using until qualified.
- 7. each X-ray equipment equipped each one with the following specifications of the additional filtration board: 1.0/0.5 mm aluminum.
- 8. firstly, remove the tube head and then other parts.
- 9. After using the machine, put the tube head to the balance place, use 75% medical rubbing alcohol to disinfect the cone part.
- 10. Make sure clean the machine surface with dry cloths every week, check the connector.
- 11. Pay attention to machine maintenance, check the indicator light, display, knobs, switches, remote control work; X-ray source component whether leak oil; when X-ray exposure, whether has abnormal sound; Mechanical parts whether loose screw.
- 12. The machine's capacity rated is 1.1 kW, please choose the power supply or grid greater than 1.5 kW. If the machine using the same power with the higher medical equipment (such as the ECG machine) will produce AC interference to other devices.
- 13. When using in the power supply instability area, must pay attention to adjust the supply voltage, in case of damage the machine.
- 14. The electromagnetic compatibility (EMC) related matters need to attention:
 - The instrument is in conformity with IEC60601-1-2 medical electronic equipment electromagnetic compatibility standards and/or system. But more than IEC60601-1-2 standard limit or level of electromagnetic environment, will have a harmful interference on device, or destroy its performance, therefore, if the device is not



having the function, please make sure to identify and eliminate disadvantageous before using.

The follows are some of the interference sources and remedies:

- 1) there is strong electromagnetic interference near the device. Such as radio, substation, X-ray machine, CT scans, microwave/high frequency equipment, and mobile phones, etc.:
- a) far away from the source, such as mobile phones.
- b) if there is a high-power equipment interference such as radio, please put to another place.
- 2) other interference from other equipment by electric knife line and radio frequency interference and/or systems: Identify the cause of interference, remove the possible interference sources. If not, please change to use other power supply.
- 3) direct or indirect electrostatic discharge effect:
 - a) before using, make sure all the operators and patients contact equipment and/or system no direct or indirect electrostatic energy.
 - b) a wet room can effectively reduce the interference
- 4) the radio receiver (such as television and radio) electromagnetic interference: try to keep the device far from radio receivers.

If the above methods can't solve the problems, please contact the company's after-sales service or designated maintenance station.

15. The environmental protection

To protect the environment, the products produced the using film packaging bags, lotion residue, should not be discarded, should pay attention to the collection, unified handling. Products in use at the end of useful resources, iron, copper, lead, glass, plastic, etc., has the very high recycling value, can be regenerated, by the product recycling, to prevent and reduce the pollution of the environment.



MAINTENANCE

The equipment should be inspected and tested by professional technical personnel on a regular basis in terms of performance index, grounding, dose and safety protection.

- 1. The equipment shall be installed in clean and non-corrosive gas room. When working, the environment of the room shall be satisfied:
 - Atmospheric pressure: 70Kpa~106Kpa
 - Environmental temperature: +10°C~+40°C
 - Relative humidity:30%~75%
- 2. When after using, turn off the switch, use 75% medical rubbing alcohol to disinfect the cone part.

Note: when disinfecting, the cleaning cloth should be fully wrung out; After the sterilization, the machine room should be fully ventilated before starting the equipment again

3. Daily maintenance.

!

After work, should keep the equipment clean, pay attention to the equipment without anomalies, the power cord (including earth), light display accurate, photographic effect, if there are any problems timely repair in case of serious problem of development.

Note: check the hanging parts of the equipment before each use to avoid danger

4. The equipment maintained regularly.

Maintenance cycle: quarterly.

Maintenance content:

!

- Use soft, non-woven fabric to clean the surface of the equipment.
- Check all connectors for good contact.
- Check whether the indicator light and switch work are normal
- X ray tube components whether leak oil.
- When X-ray tube components exposed, there is no abnormal sound
- Whether the mechanical part of each fixed screw has a loose phenomenon.
- Apply lubricating oil to the cross arm connecting parts.





- 5. Long-term maintenance. Park environment:
 - Environmental temperature: +10°C∼+40°C
 - Relative humidity:30%~75%
 - Atmospheric pressure: 700hpa~1060hpa

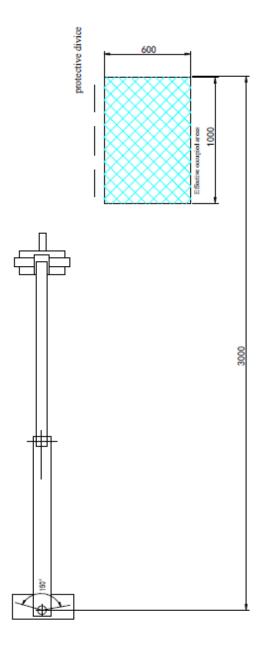
Mechanical maintains:

- ✓ Apply lubricating oil to the connecting parts of the cross arm regularly to keep the frame rotating flexibly.
- ✓ Electrical maintenance
- ✓ Turn on the machine for one hour on a regular basis.
- ✓ After turning on the machine, take exposure to keep the equipment working normally.
- 6. The device is not used for more than 2 weeks; it must be preheated for 5 minutes and then operate according to the operating instructions.





XIII EFFECTIVE OCCUPIED AREAS





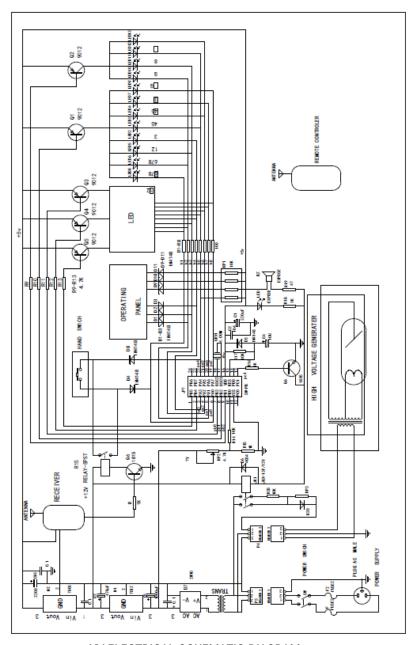
Effective occupied areas



PACKING LIST

1	Packing case (carton box)	1	
2	Cross arm components	1	
3	The tube head components (carton)	1	
4	central controller (carton)		
5	Accessory bag(I)	1	
	Built-in: (1) Special spanner for adjusting balance	1	
	(2) wrench	1	
	(3) flat screwdriver	1	
	(4) cross screwdriver	1	
	(5) cone	1	
	(6) aluminum 1.0/0.5 mm filter		
	(7) fuse 5A/10A		
	(8) Swell bolt M10x80	4	
6.	Accessory bag(II)		
	Built-in: (1) cord	1	
	(2) ground line	1	
	(3) exposure switch	1	
	(4) remote control	1	
7	Operation manual	1	





XV ELECTRICAL SCHEMATIC DIAGRAM





All rights reserved ® KALSTEIN France S. A. S., Optimum Business Center 450 Rue Baden Powell,
• 34000 Montpellier, France.
TIf: +33 467158849 / +33 680760710/ +33 663810023 https://kalstein.eu
KALSTEIN FRANCE, S. A. S

