PORTABLE X-Ray UNIT

OPERATING MANUAL

Overall Drawing of Portable X-Ray Unit

Contents

Thank you for your purchase YKY-S Series Portable X- ray unit. This manual describes the technical performances, usage, maintenance and servicing and precautions etc. in detail. Therefore, **please make sure to read through this manual carefully before you use this unit.**

Introduction to Products

1. Applicable scope

This unit is applicable to oral cavity of human which is to be photographed by X- ray for medical diagnosis.

2. Characteristics of products

This unit is small in volume, light in weight and good in protection. It uses high frequency generator technology (Generate X-Ray of higher utilization rate while removing redundant harmful rays) and operates with numerical control functions. This product is used to diagnose dental diseases of ordinary outpatients by imaging in oral cavity clinic. This product is easy to carry when going out to visit patients. The unit has constant tube voltage of 60KVP and tube current of 1.5mA.

3. Equipment category

Based on electric shock protection, this product belongs to category II. Its internal power supply has type B applications.

This equipment is non-liquid-proof device.

4. Main parts of the product

This unit mainly consists of X-Ray tube head and controller.

Performance of Products

- Tube voltage: 60kVp±10%
- Tube current: 1.5mA±20%
- Nominal power: 0.09kw 60kv 1.5mA 0.2s
- The range for loading time: 0.2s~2.0s with error ±(10%+1ms)
- Indexing value of loading time: 0.1s

Technical Parameters

1. Working conditions of X- ray unit

(1) Ambient temperature: 10℃~40℃;

(2) Relative humidity: 30%~75%

(3) Atmospheric pressure: 70Kpa-106Kpa

(4) Kept away from corrosive substances or objects;

2. Transportation and storage conditions

(1) Range of ambient temperatures: -40℃~70℃

(2) Range of relative humidity: 10%~100%

(3) Range of atmospheric pressure: 50Kpa~106Kpa

3. Requirements for power supply

(1) Capacity of battery: 2600mAh Voltage of battery: 14.8~16.8V

(2) Charging conditions: single phase AC 100V-240V 50/60Hz

(3) Charging voltage: 16.8V charging current: 1A

4. Other technical parameters

(1) Focus: 0.7mm

(2) Focal spot to skin distance: 110mm

(3) Inherent filtration: 0.5mmA1

(4) Exposure time: 0.05s~2.0s

(5) X-Ray emission: <0.25mGy/h

(6) Operating mode: intermittent loading, continuous operating

(7) Weight of body: net weight 2.0Kg, gross weight 5.0Kg

(8) Overall dimensions: 170×150×155(mm)

About Electromagnetic Compatibility

The portable dental X-Ray unit YKY-S must be operated in the environment that complies with YY0505-2012 electromagnetic compatibility criteria. This portable dental X-Ray unit YKY-S is designed in accordance with requirements of YY0505-2012 about electromagnetic radiation and electromagnetic interference resistance of medical electronic equipment.

The portable and mobile radio frequency communication devices may affect the normal use of the portable dental X-Ray unit YKY-S. If these devices have strong radio frequency radiation and are positioned close to the unit, it is possible to increase such electromagnetic interference. Therefore, it is recommended that these mobile phones, wireless phones or other similar communication devices should be kept away from the unit when it is working.

Warning: the portable dental X-Ray unit YKY-S may increase X-Ray emissions or decrease its resistance capability against electromagnetic interference if it uses the accessories or cables other than those provided by the manufacturer along with the unit.

Table 201 Guide and Declaration of Manufacturer – provisions for cables

SN	Name	Cable length (m)	Shielded or not	Manufacturer	Model/ specifications	remarks
1	Power lines	1	No	Qingdao Yakang Electronic Medical Equipment Co., Ltd.	HXY-168V1071A	--
2	Exposure line	2.5	No	Qingdao Yakang Electronic Medical Equipment Co., Ltd.	KD2-24	--

Warning: The use of the accessories, transducers or cables that are not designated by manufacturer may result in increase of X-Ray emissions or decrease of resistance to electromagnetic interference.

Table 202 Guide and Declaration of Manufacturer – Electromagnetic Emission

<table>
<tr><th colspan="3">Guide and Declaration of Manufacturer – Electromagnetic Emission</th></tr>
<tr><td colspan="3">The portable dental X-Ray unit YKY-S is designed to be used by the buyer or users in the following electromagnetic environment:</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment –guide</td></tr>
<tr><td>Radio frequency emission GB4824</td><td>1 group</td><td>The portable dental X-Ray unit YKY-S is designed for its own functions only, therefore, its radio frequency emission is very low and has little interference to electronic equipment around it.</td></tr>
<tr><td>Radio frequency emission GB4824</td><td>Category B</td><td rowspan="3">The portable dental X-Ray unit YKY-S is applicable to use in all facilities which include household facilities and public low voltage power grid directly connected to the house.</td></tr>
<tr><td>Harmonic emission GB17625.1</td><td>Category A</td></tr>
<tr><td>Voltagefluctuations/flicker emission GB17625.2</td><td>Compliance</td></tr>
</table>

Warning: The portable dental X-Ray unit YKY-S shall not be used when it is close to other equipment or stacked on other equipment. If necessary, it should be verified that the unit could work normally in such conditions.

Table 203 Guide and Declaration of Manufacturer – Resistance to electromagnetic interference

<table>
<tr><th colspan="4">Guide and Declaration of Manufacturer – Resistance
to electromagnetic interference</th></tr>
<tr><td colspan="4">The portable dental X-Ray unit YKY-S is designed to be used by the buyer or users in the following electromagnetic environment:</td></tr>
<tr><th>Rest on resistance to interference</th><th>IEC 60601 test level</th><th>Compliant level</th><th>Electromagnetic environment – guide</th></tr>
<tr><td>Static dischare GB/T 17626.2</td><td>±6kV,
contact discharge
±8kV,
air discharge</td><td>±6kV,
contact discharge
±8kV,
air discharge</td><td>The floor should be made of wood or concrete or ceramictiles. Ifthe floor is covered with synthetic materials, the relative humiditymust be 30% at least.</td></tr>
</table>

Electric fast transient impulse train, GB/T 17626.4	±2kV, for power line, ±1kV, for input/ output lines	±2kV, power lines ±1kV, input/output lines	The grid power source should-have quality sufficient for use in typical commercial or hospital environment.
Surge GB/T 17626.5	±1kV, differential mode voltage ±2kV,common mode voltage	±1kV, line to line ±2kV,line to line	The grid power source should-have quality sufficient for use in typical commercial orhospital environment.
Voltage dip, short interruption and changesof voltage forpowerinput line GB/T 17626.11	<5% U_T, last for 0.5 cycles, (at U_T, >95% dip) 40% U_T, last for 5 cycles, (at U_T, >60% dip) 70%U_T, last for 25 cycles, (at U_T, >30% dip) <5% U_T, last for 5s, (at U_T, >95% dip)	<5%UT (fall>95%UT)0.5 cycles 40%UT (fall 60%UT)5 cycles, 70%UT (fall 30%UT)25 cycles <5%UT (fall>95% UT), 5s	The grid power source should-have quality sufficient for usein typical commercial orhospital environment. If the users ofde-vice or system need to continue to operateit during power out-age, it is recommended to use UPS or battery as power supply.
Power frequency magneticfield (60Hz) GB/T 17626.8	3A/m	3A/m	The power frequency magnet-icfield should have the level ap-plicable to such typical sites as commercial sites and hospitals.
Notes: U_T refers to AC grid voltage before test voltage is imposed.			

Table 204 Guide and Declaration of Manufacturer – Resistance to electromagnetic interference

Guide and Declaration of Manufacturer – Resistance to electromagnetic interference			
The portable dental X-Ray unit YKY-S is designed to be used by the buyer or users in the following electromagnetic environment:			
Rest on resistance to interference	**IEC 60601 test level**	**Compliant level**	**Electromagnetic environment – guide**

Radio frequencyconduction GB/T17626.6 Radio frequencyradiation GB/T 17626.3	3V(effectivevalue) 150kHz-80MHz 3V/m 80MHz-2.5GHz	3V(effectivevalue) 3V/m	The portable and mobile RF communication devices shall not be closer to any parts (including cables) of the portable dental X-Ray unit YKY-S than recommended. The recommended distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Wherein: P- max. rated output power of transmitter provided by transmitter manufacturer (in Watt) d- recommended distance (in meters)[b] The field intensity of fixed type radio frequency transmitter is determined based on the survey of electromagnetic site. Each frequency range [d] should be lower than compliant level. There may be interference around the equipment that is marked with the following sign: 

Note 1: The formula of higher frequency range is used for 80MHz and 800MHz.

Note 2: This guide may not be applicable to all conditions. The electromagnetic transmission may be affected by buildings, objects or human body because they may absorb or reflect the electromagnetic waves.

a. The field intensity of fixed type transmitters (including wireless (cellular or cordless) telephones, ground mobile radio station, amateur radio, amplitude modulation, frequency modulation radio broadcast or TV broadcast etc.) can not be accurately known. In order to evaluate electromagnetic environment of fixed type radio frequency transmitters, a survey on the electromagnetic sites is required. If the field intensify measured in the site where the portable dental X ray unit YKY-S is located is higher than compliant level, observation should be made to this unit to verify if it could work normally. If it is found the unit can not work normally, additional measures may be required, for example, adjust the orientation or position of this unit.

b. In the range of 150kHz – 80MHz, field intensify shall be lower than 3V/m.

Table 205 Recommended Distance between portable and mobile RF communication devices and portable dental X-Ray unit YKY-S

Recommended Distance between portable and mobile RF communication devices and portable dental X-Ray unit YKY-S			
The portable dental X-Ray unit YKY-S may be used in the electromagnetic environment wherein the RF radiation is properly controlled. Based on max. rated output power of communication devices, the buyer or users may maintain the recommended min. distance between portable and mobile RF communication devices (transmitters) and the portable dental X-Ray unit YKY-S to avoid electromagnetic interference.			
Max. rated output power of transmitter /W	Distances corresponding to different frequencies of transmitters /m		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For those max. rated output powers of transmitters not listed above, the recommended distance d (in meters) could be determined by use of formula indicated in the corresponding column of *frequency of transmitter*. Herein, P refers to max. rate output power of transmitter provided by transmitter manufacturer (in watt). Note 1: The formula of higher frequency range may be used for 80MHz and 800MHz. Note 2: This guide may not be applicable to all conditions. The electromagnetic transmission may be affected by buildings, objects or human body because they may absorb or reflect the electromagnetic waves.			

Description of basic safety and basic performances

The portable dental X-Ray unit should have sufficient resistance capability against electromagnetic interference to ensure its performance will not be lowered in the resistance tests stated in YY0505.

There is no risk of safety accidents.

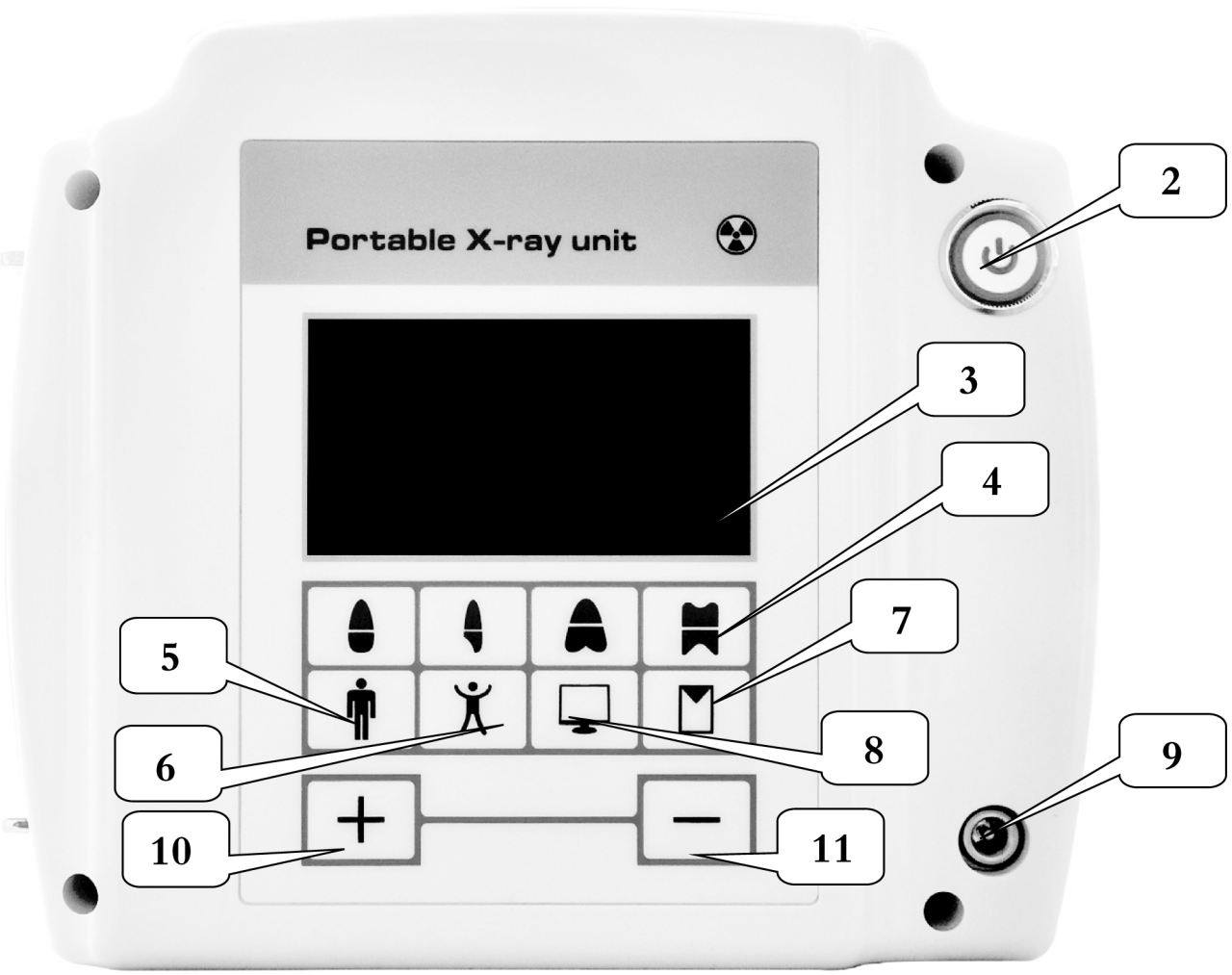
The buttons on the panel could work normally. There is no error code in the image. It could expose normally without error prompts. There are no abnormal events during charging.

Usage

You must clearly know about the following items in order to safely and correctly use the unit and bring it into full play.

1. Switch on and wait for 6 seconds for self-checking and then enter operating mode;

The buttons are selected as follows under the operating mode:


Portable X-ray unit
2
3
4
5
6
7
8
9
10
11

（1）Exposure button

（2）Power switch

（3）LCD display

（4）Tooth Position selection:

Simulation exposure time for four tooth models

（5）Body selection:fat (adult) person

（6）Body selection:thin(child)person

（7）Dental film inaging options

（8）Computer inaging potioons

（9）Socket for charging

（10）Fine-tuning button:Increase exposure time

（11）Fine-tuning button:Reduce exposure time

2. It is recommended to use intermittently to prolong its service life.

3. Please switch off the unit if it will be out of use for long after taking images;

Tooth photographing

1. The patient should sit uprightly while keeping head stable. Place the front face of dental film on the inner side of the tooth to be photographed and press the back side of the dental film with your hand to ensure both sides are in close contact (film holder may be used);

2. Adjust collimator cylinder to aim it at the tooth to be photographed vertically to obtain accurate and clear images;

3. Select exposure time; press the exposure button;

4. After photographing, take out dental film for washing;

5. Switch off the unit

Dental film processing

1. Lightroom film: use injector to extract 3-4ml of processing solution and inject it into dental film and press it for 1-3 mins with your hand; and then take the film out of external package and wash it with clean water;

2. Darkroom film: tear open the external package and take out dental film and use film clip to hold it and put it into processing solution and swing it lightly and hang it up and 3-5 mins later, take out and wash it with clean water and then put it into fixing solution and keep it for 3-5mins and wash it with clean water.

Maintenance and Attentions

- Use medical alcohol to sterilize and clean the end of collimator cylinder that is in contact with patients after each use;
- Do not use or store the unit in inflammable sites;
- Do not use or store it in the environment where such factors as atmospheric pressure, temperature or humidity etc. exceed the given range;
- The unit should be stored or used in the place that is well ventilated and free from direct insolation;
- The unit will generate X-Ray during exposure time, therefore, the operators must wear leaded protective clothing and protective scarf etc.
- The X-Ray output window is provided with collimator cylinder to ensure the X ray is limited within the given scope.
- In case of occurrence of any accidents during use, the operator must immediately stop the unit and cut off power supply;
- When multiple dental films to be made, the time interval must be one minute at least.
- When the unit is to be out of use for long, the unit should have sufficient battery level or be switched on regularly to check its batter level is sufficient.
- **Shall not be switched on for use when it is being charged.** It can be used only after it is fully charged.
- The unit contains such electronic components as Li battery, therefore, it should be retired in the locations designated by state for recycling.
- EMC: this unit complies with requirements of YY0505. This unit may cause interference to other devices, therefore, it should be away from other electronic devices such as mobile phones or remote controlled toys etc. when being used.
- The unit can be disassembled by professionals only. Therefore we decline any responsibilities for any non-compliant disassembly. The electric circuits will not be provided. If you have doubt, please refer to “Troubleshooting”

Troubleshooting

Faults	Items to be checked
Unable to enter operating interface Unable to start the unit	Check the battery is low; restart it after it is fully charged
The screen displays “battery low”	The battery is low and needs to be charged;
The screen displays “Error 01”	The unit is overheated and X tube filament becomes abnormal; reuse it after a while;
The screen displays “Error 02”	X tube filament becomes abnormal; restart the unit;
The screen displays “Error 03”	X tube filament becomes abnormal;
The screen displays “Error 04”	X-Ray generator becomes abnormal and battery charging is abnormal;
The buzzing exceeds the stated period during exposure	Immediately power it off and check the faults
If you have any problems that can not be solved by the methods above, please contact seller or technical department of the manufacturer.	

Packing List

1	Portable X-Ray unit	1
2	Charging cables	1