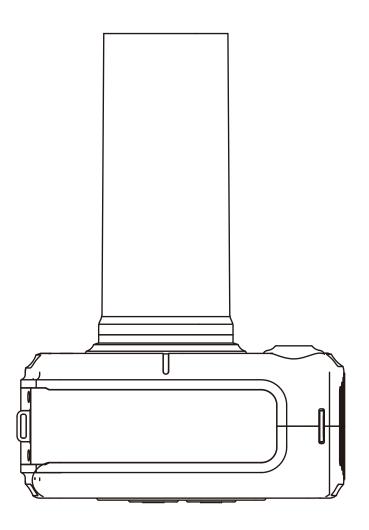


# VeRay Portable Dental X-ray User Manual



Guilin Refine Medical Instrument Co., Ltd.

RF-DXR-M001-1.1

#### 1. Introduction

Thank you, for purchasing VeRay Portable Dental X-Ray. This manual contains installation, operation, and maintenance instructions; that should only be performed by a service technician experienced in these procedures.

#### 1.1 Intended Use

The unit is an advanced high frequency field dental x-ray device rated at 60kV DC and 2 mA tube current, with inverter X-ray control methods for producing diagnostic high quality, tooth and maxillary bone images, for both chemical film and digital sensors. The unit operates on a 22.2VDC supplied by a rechargeable Li-Polymer battery pack. When x-rays are taken the device can either be handheld, or mounted on a tripod.

	Caution	This device is only intended for use by authorized or qualified personnel. Please, read the user's manual before use.	
Reference certain that all of the user's manuals precautions are strictly at Type B Applied Part provides the lowest degree of patient provides th		In order to protect the unit against damage, and ensure proper and safe usage, please, make certain that all of the user's manuals precautions are strictly adhered to.	
		Type B Applied Part provides the lowest degree of patient protection of all the types of applied part and is not suitable for direct cardiac application.	

#### 2. Safetv Marks

Please, observe the following safety requirements:

Do not exceed x-ray dosage necessary for image diagnosis.

Intended only for use by qualified personnel.

Do not allow the patient to touch the device.
 Do not leave device unattended around patients

Do not leave device unattended around patients.

• If device seems defective, please, contact your authorized dealer.

• It is prohibited to tamper with the structure of the device

• Avoid usage in the following conditions:

a. Around flammable material or explosive gas. b. Where it is damp or moist

c. Direct Sunlight. d. Poor ventilation areas

e. Dusty areas. F. Humid places. g. Salty places

Keep the device in the conditions listed below:

● For safe-keeping; temperature -40 °C - 70°C , humidity 10%- 90%RH

● During usage; temperature -10 °C - 40°C , humidity 30% - 70%RH

• For optimum conditions; temperature 10 °C - 30°C, humidity 40%- 60%RH

#### 1) Storage

Do not store the device where it is damp, salty, or in dusty locations.

These conditions may cause operating problems.

lacktriangle Do not store device in places where the temperature fluctuates drastically. Do not place the device in direct sunlight.

• Do not store device near or around flammable material, or explosive gases.

Do not keep the battery-pack long with charger connected.

• Do not keep the digital sensor with the main body connected. The digital sensor is very sensitive

device so it has to be kept in the separate keeping case for it.

Don't do exposure the unit when you are connecting the charger and under charging.

#### 2) Caution

• Do not expose device to the extreme shock or vibration.

Do not place device in/on a dusty, dirty, or inclined place.

• Prior to use of the sensor, keep the sensor covered with disposable cover for it without fail.

Do not jerk the connection cable between the charging desk device and the charger

#### 3) Reference

Check condition of the battery-pack and device before usage.

Use the device according to the procedure for operation.

Use the device in a ventilated area.

• Use only the charger provided with this product.

• Ensure the battery charger is unplugged before attempting to clean. Keep the unit clean by using clean dry piece of cloth. Only use non-alcohol based disinfectant wipes, or dampened with liquid or spray.

## 4) Guarantee

This product is warranted for one year for its quality from the date of purchase.

• In case it is hard to recognize the warranty period, the warranty is applicable three months after it was manufactured.

• For the case of defects of the products itself or improper workmanship, the product will be either repaired free of charge or exchanged according to the status of the product.

• Even within the warranty period, if the damage is caused by failure of the user, the repair free of charge is not applicable.

In case attached level for sealing is removed or has such an indication, repair free of charge and

warranty are not applicable.

 $\ lacktriangledark$  The repair done at the place other than designed A/S Center is excluded from warranty.

 The service period will not be extended for the product which was repaired with charge or free of charge.

#### 2.1 Cleaning

Ensure the battery charger is unplugged before attempting to clean. Make sure the power on the unit is off while cleaning. Only use a non-alcohol based disinfectant wipe or cloth dampened with liquid or spray. The unit and its accompanied battery charger, are not designed to be subjected to any kind of sterilization procedure.

This unit may be dangerous to the operator and patient unless safe exposure factors and operating instructions are observed.

Keep in mind that the optimal radiation to the operator exists within a cone-shaped area immediately

behind the backscatter shield (the so-called zone of significant occupancy). All personnel authorized to operate the equipment should be fully acquainted with safety recommendations and established maximum permissible doses and follow all guidelines dictated by your in-house radiation protection program in regard to patients and operators who are pregnant or expect to become pregnant. In implementing a radiation protection program, please consult any state, provincial, and local regulations governing radiation protection and the use of x-ray equipment. Ensure proper registration and compliance with any such regulation.

Do not operate the unit until patient and operator are positioned and ready for exposure, diminishing the likelihood of interruption and preventing inadvertent exposure of anyone to x-rays. Do not attempt an exposure if anyone is positioned immediately behind the patient (in line with the direction of x-ray emission). An exposure can be prematurely terminated for any reason by abruptly releasing the trigger button.

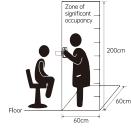
## Zone of significant occupancy

Requiring presence of an operator, provide with at least one significant zone of occupancy which has a floor area of not less than 2'(60cm)  $^\star$  2'(60cm), and a height of not less than 6.5'(195mm).

The type of radio examinations the significant zone of occupancy is designated to be user.

Location of the significant zone of occupancy including the positions of its boundaries relative to clearly recognizable features of the x-ray equipment.

Identity of the removable protective devices for use with the x-ray equipment and information on their application and use.



#### 3. Warranty

Warranty: Guilin Refine Medical Instrument Co., Ltd, warrants that all parts shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one year from the date of delivery to the customer unless otherwise specified in writing.

Guilin Refine Medical Instrument Co., Ltd shall not be liable for any damage, injury, or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damage, injury or loss, the product was (1) damaged or misused; (2) repaired, altered or modified by persons other than Guilin Refine Medical Instrument Co., Ltd (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by an authorized dealer. Guilin Refine Medical Instrument Co., Ltd, obligation for breach of this warranty or for negligence of otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part. This warranty shall be void on any product on which the serial number has been altered, defaced or removed.

# 4. Quality control procedure

It kV, mAs measured with a one-year period.

Measuring the deviation is  $\pm 5\%$ , the measurement points are as follows.

It is measured with an Oscilloscope 60 kV 0.5 s (2 mA) Test Benchmark

kV Check Point (TP 6) = 6 V (Oscilloscope) = 60 kV

mA Check Point (TP 9) = 4 V (Oscilloscope) = 2 mA

### Chapter I. Application

This unit is the portable dental wireless X-ray system with high frequency inverter control.

# Composition.

Main body: a. X-ray generator. b. X-ray exposure cone. c. High capacity battery .

# Accessories

Battery charger: 1 ea. Neck strap: 1 ea. Hand strap: 1 ea. User's Manual: 1 ea.

# Chapter II. Specifications

### 1. Main body

## 1) X-ray generator

(1) Tube Voltage 60 kV (Fixed) (2) Tube current 2 mA (Fixed)

2) X-ray Control device

(1) Main power Battery 22.2 V DC, Adaptor 25.6 V DC. (2) Exposure time 0.01 - 2.00 sec (Manual 56 steps) 3) X-ray Exposure

(1) Type Round style. (2) Output Radiation Field 60 mm. (3) SSD(standard) 200 mm 4) X-rav tube

(1) Type Stationary anode X-ray tube. (2) Tube Model KL11-0.4-70 (3) Tube Focus 0.4 mm. (4) Anode heat capacity 4500 J

(5) Maximum Tube Voltage 70 kV. (6) Target Angle 12 ° (7) Total filtration Basic filtration 0.8 mm Al. Additional filtration 1.0 mm Al (8) Cooling system Oil Cooling

#### 2. Battery

1) Type Li-ion Polymer. 2) Voltage 22.2 V DC. 3) Capacity 950 mAh

# 3. Charger

1) Input 100 - 240 V AC, 50 - 60 Hz. 2) Output voltage 25.2 V DC

3) Output current 1 A.

4) Status display of unit LED (Red: Under charging, Green: Finished charging)

# Chapter III. Unit description

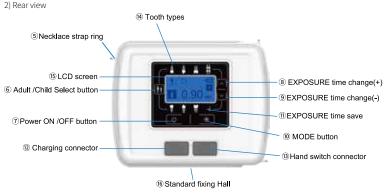
## 1. Part name of unit

1) Front view

① Status display(LED)
② X-ray Exposure cone



② X-ray EXPOSURE button



3) Side view

 ${\small \scriptsize \textcircled{17} Battery \, replacement \, cover}\\$ 

Functional explanation.

z. r arrecional explanation.	
① Status Display on the LED	LED color changing: Unit status display  Off ⇒ Turn off  Green ⇒ Standby for shot  Yellow ⇒ Exposing X-ray  Red ⇒ Unit error
② X-ray EXPOSURE button	It makes use of X-ray EXPOSURE. If you press the button 2 seconds more, it will exposure for the set time. If you release the button before 2 seconds, it occurs an unit error.
③ X-ray Exposure cone	We made the inside of cone with lead, it prevents from exposing the X-ray to the user.
④ Hand strap ring	The top and bottom rings are connected with hand strap.
⑤ Necklace strap ring	It is for connecting with necklace strap.
Adult Child Select button	If you press the button, it displays ADULT/CHILD and symbol on the LCD.
7 Power ON /OFF button	It is a button for turn on (or turn off) the unit.
Changing exposure time up (+)	When presses the button, the exposure time will be increased.
Changing exposure time down (-)	When presses the button, the exposure time will be decreased.
⑩ User's MODE button	If user want to change the set item, press the button and you can enter the set item area.
① Saving exposure time	If you press the button 2 second more, the exposure time is stored.
① Charging connector	The connector is for the purpose of charging battery
③ Hand Switch connector	The connector is for the purpose of connecting with hand switch.
(4) Tooth type of exposure object	They are buttons for selecting tooth of exposure object.
(5) LCD screen	It is displayed the unit's status and information.
<sup>®</sup> Standard fixing Hall	The hall is for the purpose of using with tripod.
17 Battery replacement cover	The cover is use for battery protection and replacement.

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#### Chapter IV. Operation

#### 1. Turn ON

- 1) When press the ON button and the unit turns on with beep sound.
- 2) LED blinks green while booting and it lights up green while standby.
- 3) When the battery is normal, there is not any sign.
- 4) When the battery is not sufficient,
- ⇒ the unit occurs with beep and the power cord shape blinks 10 times at the same time and then the power automatically turns off.
- 5) In the case of No.4) as above, you must charge it with the charger.
- 6) When you turn on the unit, LCD is changed the screen of 3 steps for 5 seconds as under.

#### ♦ Step 1

V 1.0 Company name and software version

Standby for Exposure shot

# 2. Turn OFF

If you want to turn off the unit, press the OFF button for 2 seconds.

#### 3. Set of EXPOSURE condition

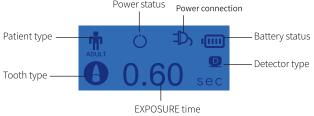
## 1) ADULT / CHILD select button

If you want to select patient type, press the ADULT/CHILD select buttons.

- It is displayed the letter and symbol on the screen.
- 2) Tooth type buttons

Basic set: Select one of 7 type buttons which you want to shot (maxillary front tooth, canine, molar and submaxillary front tooth, canine, molar)

3) LCD compositions



#### 4) Standard Exposure time

Ty Standard Exposure time								
Patient Type	Film/Digital				<b>&gt;</b>	•		<del>-</del> ‡‡-
ADULT	Film	0.50	0.60	0.90	0.35	0.40	0.50	0.95
ADULI	Digital	0.15	0.20	0.30	0.10	0.12	0.20	0.50
CHILD	Film	0.25	0.40	0.55	0.16	0.20	0.25	0.65
CHILD	Digital	0.08	0.10	0.12	0.07	0.10	0.16	0.30

#### 5) EXPOSURE time

If you want to change the EXPOSURE time, you can change 56 steps with UP/DOWN buttons

6) Saving the EXPOSURE time

Automatic saving: When you shot the unit after changing the EXPOSURE time on the AUTO mode, it is

 ${\it Manual saving:}\ When\ you\ shot\ the\ unit\ after\ changing\ the\ EXPOSURE\ time\ on\ the\ Manual\ mode, if\ you\ press$ the SAVE button 2 seconds more, the exposure time is stored.

1) At first set the exposure conditions which you want to shot.

2) Fix the digital senor or film on the opposite side which you want to expose and then contact the unit on the exposure part.

3) Press the exposure button

4) The power status symbol (1) blinks after 2 seconds.

5) When the exposure is started, the exposure symbol 🔲 is displayed on the LCD. At the same time the LED lights vellow and rings beep.

6) Please press the exposure button for finishing shot which you set the exposure time.

7) It is displayed standby symbol 🔀 for 5 seconds after finishing the shot and then you can shot next

8) If you fully charge the battery you can shot about 150 times.

# 5. Battery Charging and Replacement

The remained battery's capacity is displayed at the upper right corner of

If the battery's capacity is insufficient, it is effected the image. Therefore you must always check the battery.

If the battery's capacity is not enough, the power cord symbol 🗘 is blinked 10 times with beep on the LCD and then the unit automatically is turned off. It takes 3 hours for charging after automatically turn off.

2) Replacement

If you have a defective or out of life battery, please contact to Guilin



Refine Medical Instrument Co., Ltd or the purchase shop for replacement.

#### 6 "MODF" Function



If you press 2 seconds more the "MODE" button at the power on, it changes the set item screen as under. 1) Sleep Mode

- If the user does not use the unit for the sleep mode time, it automatically is changed sleep mode. When it is sleep mode, it does not operate the exposure button and the LED blinks green. If you want to change standby status, press the MODE button.
- 2) Power Save
- If the user does not use the unit for the power save time, it automatically turns off the power. It is a function which prevents unnecessary electricity from consuming.
- 3) Save Mode

It is a function for selecting automatic save or manual save

4) F / D Select

It is a function for selecting analog (chemical film) or digital method.

5) Reset It is a function for initializing with default.

6) Exp. Count It shows the total exposure number.

# 7. Changing Set value at the "MODE"

If you press 2 seconds more the "MODE" button at the power on, it changes the set item screen.



Set item	► Sleep Mode	10 Min	
	Power Save	15 Min	
	Save Mode	Manual	Set value
	F / D Select	Digital	
	Reset	No	
	Exp. Count	0	

Sleep Mode: 5 Min

Power Save: 10 Min

Save Mode: Manual

F / D Select: Digital

Reset: No

Exp. Count: 0

1) Set item movement

It moves Sleep Mode  $\rightarrow$  Reset  $\rightarrow$  F / D Select  $\rightarrow$  Save Mode  $\rightarrow$  Power Save in sequence.

(2) DOWN buttor

It moves Sleep Mode  $\rightarrow$  Power Save  $\rightarrow$  Save Mode  $\rightarrow$  F / D Select  $\rightarrow$  Reset in sequence.

2) From set item to set value movemen

Press "ADULT" button for moving from set item to set value.

3) Set value change

You can change the set value pressing UP/DOWN buttons at the set value.

			-		
	Set item	▷ Sleep Mode	▶ 10 Min	Set value	
		Power Save	15 Min		
		Save Mode	Manual		
		F / D Select	Digital		
	Set item	Reset	No		
		Neset	NO	Set value	
		Exp. Count	0		

# 4) Default and range

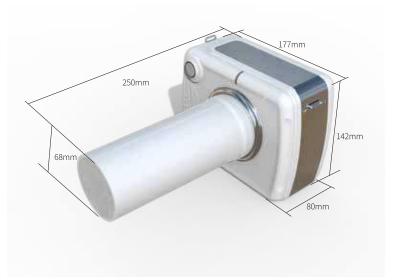
	Function	Default	Range
L			0
Sleep Mode	Power saving	10 Min	5 - 20 Min(1 minute interval)
Power Save	Auto power OFF	15 Min	5 - 40 Min(5 minute interval)
Save Mode	Automatic or Manual save	Manual	Manual / Auto
F / D Select	Film or Digital sensor	Digital	Digital / Film
Reset	Initialization	No	No / Yes
Exp. Count	Total EXPOSURE number	0	Accumulation record (Max. 99999)

# Chapter V. Error Code

When you use the unit, if you have some serious problems, the LCD appears "Error Code" and "Error Contents" on the screen. Please contact to GBTKOREA Co., Ltd or the purchasing shop.

#### Chapter VI. Unit drawing

Unit: mm



# After service and warranty instruction

- 1. Warranty: Guilin Refine Medical Instrument Co., Ltd, warrants that all parts shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one year from the date of delivery to the customer unless otherwise specified in writing.
- 2. Guilin Refine Medical Instrument Co., Ltd shall not be liable for any damage, injury, or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damage, injury or loss, the product was
- (1) damaged or misused;
- (2) repaired, altered or modified by persons other than Guilin Refine Medical Instrument Co., Ltd
- (3) not installed in strict compliance with applicable codes and ordinances; or
- (4) not installed by an authorized dealer. Guilin Refine Medical Instrument Co., Ltd, obligation for breach of this warranty or for negligence of otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part.

This warranty shall be void on any product on which the serial number has been altered, defaced or

# After service and Warranty Instruction

Name of Customer	
Address	
Post Code	
Tel	
E-mail	
Purchase Date	
Distributor	
Model	
Product No.	
Handpiece No.	
Production Date	



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