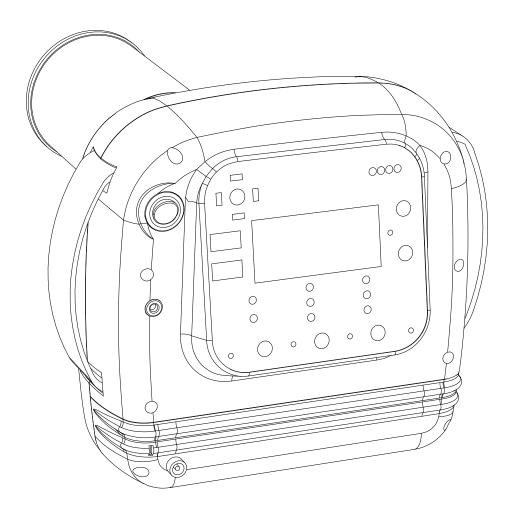
Portable X-ray System

XR-01



USER'S MANUAL

Rolence Enterprise, Inc.

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I. CERTIFICATE OF WARRANTY

1.1 Range and terms for warranty

Rolence guarantee this product without any expense for the malfunction or disorders occurred under standard transportation and operation within 1year from installation.

1.2 Requirements on After service call

When the malfunction or disorder appeared, stop operating and check again the related article of this "User's Manual".

Before your calling, please put off this equipment and check for the model name, serial No. and purchasing date.

Rolence Is not responsible for indirect harm.

Rolence cannot warrant for defect or harm after warranty period.

1.3 Development Policy

Rolence pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation this manual should not be regarded as an infallible guide to current specifications. We reserve the right to make changes without prior notice.

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II. GETTING STARTED

2.1 Intended Use

The XR-01 Portable X-Ray System is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and child subjects

▲ CAUTION!

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

2.2 Principle of Operation

Rolence Portable X-Ray system XR-01 is designed for use in radiography to find hidden dental structures, malignant or benign masses, bone loss, cavities and other areas of dental diagnosis. The controlled x-ray beam penetrates oral structures at different levels, which depending on varying anatomical densities, and then exposures onto image receiver such as film or digital sensor to form a radiography image.

2.3 Compliance

The owner/operator is responsible for verifying continued compliance exposure rates, leakage radiation, alignment of the useful beam, and the calibration of kVp and mAs. Annual verification by a qualified service technician may be required by federal law. Compliance with applicable statutory and regulatory requirements is the responsibility of the owner/operator. Consult local, state, and/or federal agencies regarding specific requirements and regulations applicable to the use of this type of medical electronic equipment.

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2.4 Cleaning

Ensure the adaptor is unplugged before attempting to clean. To make sure that power is off while cleaning. Use a non-alcohol based disinfectant only wipes or a cloth dampened with liquid or spray. The system is not designed to be subjected to any kind of sterilization procedure and not designed to be used to sterilize anything else.

⚠ WARNING !

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Do not modify this equipment without authorization of the manufacturer.

2.5 Symbols

Symbols used in this publication and used mark on the equipment have the following meanings.



Symbols

X-Ray Source Assembly, Emitting

Description



Symbols

Electrical Shock Hazard

High Voltage

Description



Warning; Radioactive material or ionizing radiation



Consult Accompanying Documents



Attention, Consult Accompanying Documents



Consult Accompanying Documents



WEEE Mark



Type B Applied Part

WARNING

Warning is given in situations and circumstances in which a serious hazard for the patient or user can be happened.

CAUTION

Cautions are given in situations or circumstances in which the equipment can possibly be damaged, or a threat of minor personal injury can be happened.

NOTE

Notes are given in situations requiring special attention to operate this equipment.

III. SAFETY

3.1 Electrical Safety

⚠ WARNING !
Electrical circuits inside the equipment use voltages which are capable of
causing serious injury or death from electric shock.
To avoid this hazard, operators should never remove any of the cabinet
covers.

Observe the following safety procedures to avoid electric shock or serious injury to operators and patients and to avoid system malfunction.

- Under no circumstance should the safety interlocks in the system be bypassed, jumped, or otherwise disabled.
- Under no circumstance should the system or assembly covers be removed by anyone other than a Rolence trained service representative.
- Do not place food or beverage containers on any part of the equipment. They can trip over and introduce conductive substances into the electrical circuitry.

\triangle WARNING !

This system is not waterproof. Water, soap, or other liquids, if allowed to drip into the equipment, can cause electrical short circuits leading to electric shock and fire hazards. If liquids should accidentally spill into the system electronics, do not connect the power cord to a supply connection or turn the system on until the liquids have dried or evaporated completely.

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Safety

3.2 Electrical Fire

The user should develop an emergency procedure for the area in which the system is used that includes the following safety measures:

- Turn the system off and unplug the main power cable from the outlet.
- Evacuate everyone from the area.
- Call for help.
- Use only a fire extinguisher of a type approved for electrical fires.

The use of the wrong type of fire extinguisher presents electrical shock and burn hazards. To avoid these hazards, a fire extinguisher which has been approved by the appropriate local, state, and federal codes must be available in the room where the equipment is being used.

3.3 Electromagnetic Compatibility Statement

This generating equipment, used and related to radio frequency energy, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in particular installation. If this equipment does cause harmful interference to other device, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by on or more of the following measures.

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
 Consult the manufacturer or field service technician for help.

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3.4 Radiation Safety

3.4.1 General

\triangle WARNING !

This x-ray unit may be dangerous to patient and operator unless safe exposure values are used and correct operating procedures are observed.

This X-Ray tube assembly produces ionizing radiation when energized. Hence, when, used, it can be better that the authorized operators wear X-ray Protective devices like X-Ray protective apron, glove or thyroid cover, etc.

It is imperative that the owner designates areas suitable for safe operation and service of the system and operator ensure that it is used only in these designated areas.

It is the responsibility of the owner to ensure that all personnel wear protective clothing and radiation monitoring devices while using this system.

▲ NOTE !

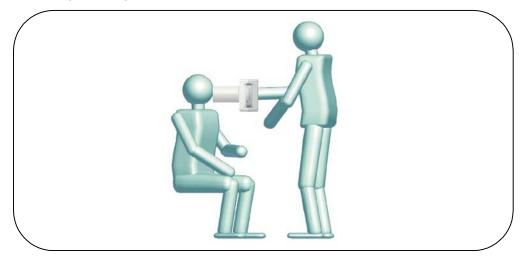
The beam limiting device(Collimator cone) is lined with Pb because of leakage radiation.

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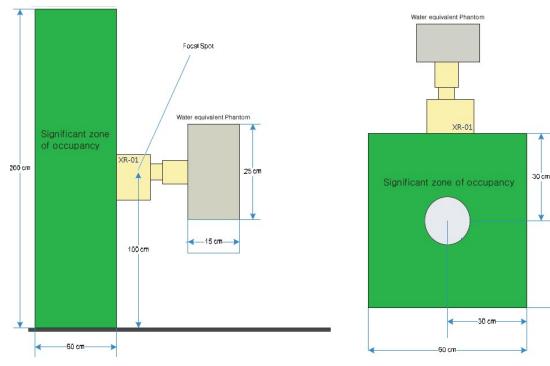
3.4.2 Handheld

Rolence XR-01 Portable X-Ray can be used handheld equipment; it is convenient for use anytime anywhere.



3.4.3 Significant zones of occupancy

Please establish significant zone of occupancy as following and puts individual defense tool such as apron in this area and face in radiography.



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60 cm

3.4.4 Leakage and Scatter Measurement Information

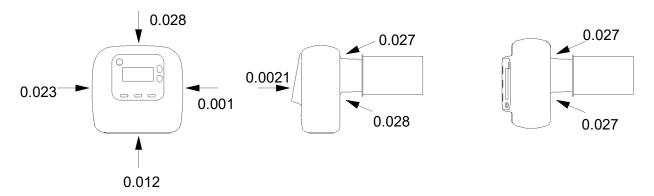
Annual Occupation Dose Limits

Туре	Occupational Dose Limit
Total effective dose equivalent	50 mSv
Lens of the eye	150 mSv
Skin	500 mSv
Hands and feet	500 mSv

Specified in 10 CFR 20.1201 and 10 CFR 20.1208

Leakage

The inherent shielding of XR-01 was sufficient to eliminate leakage radiation. The measurement was performed at 10 mm from the device surface at 9 points as follows: (Unit: mGy/hour)



According to FDA guidance "Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use" and IEC 60601-1-3 standard, leakage radiation shall not exceed 0.88 mGy/hour and 0.25 mGy/hour respectively. All shipped XR-01 have been inspected strictly with leakage limit 0.04 mGy/hour, which is 6.25 times than IEC regulations.

Scatter

The vertical and horizontal significant zone have been established by internal design verification. The estimated annual dose to operators who stay in safety zone is approximately 1 mSv if maximum exposure time is assigned for each exposure.

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3.5 Storage and Transportation Environment

Avoid the following environments for storage or transportation;

- Where the equipment is exposed to water vapor.
- Where the equipment is exposed to direct sunlight.
- Where the equipment is exposed to dust.
- Where the equipment is exposed to high humidity.
- Where there is a ventilation problem.
- Where the equipment is exposed to a salty atmosphere.
- Where the equipment is exposed to chemicals or gas.

For normal operation, you must keep away from the place with a Strong vibration and maintain the following range of temperature and humidity.

Usable range of temperature and Relative humidity

- Temperature : -5°C ~ 40°C
- Humidity : 30% ~ 75% RH
- Atmosphere : 700 ~ 1060hPa
- •

For storage and transportation condition, you must maintain the following range of temperature and humidity and atmosphere.

- Temperature : -10°C ~ 70°C
- Humidity : 10% ~ 90% RH
- Atmosphere : 500 ~ 1060hPa

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IV. PRECAUTION

▲ NOTE !

The system should be used only by personnel possessing relevant qualifications, including adequate training in radiation protection.

▲ NOTE !

Radiation safety training requirements vary from country to country. Please consult with your local Radiation/Health authority for more details.

⚠ NOTE !

Read carefully the following this manual.

4.1 Radiation Safety Precaution

- 4.1.1 Before operation, make sure User's Manual and maintenance schedules are observed. X-ray must only be operated by trained personnel in a controlled setting otherwise X-ray may be dangerous to patient, operator or ancillary people.
- 4.1.2 Pregnant women are generally advised to avoid X-rays to minimize the chances of causing any harm to the fetus unless necessary.
- 4.1.3 Personal exposure monitoring device and radiation protection equipment must be provided to operators. Maximum permissible whole-body or partialbody radiation dose of operator in accordance with local regulations shall be established. The record shall be checked before each operation.
- 4.1.4 Backscatter shield is designed to protect operators from scatter radiation. Make sure to install backscatter shield properly by following step before operation.
 - a) Check the backscatter shield and collimator before each operation. Do not operate if any of them is broken.
 - b) Keep Backscatter shield on the outer side of the collimator cone as close as possible to the patient.
 - c) Operator stays within the significant zone of occupancy. (see 3.4.3 for more details)

- 4.1.5 Never stand in the direct line of the primary X-ray beam. If patient needs assist, give caregiver personal protective equipment such as an apron to wear or to stand behind a barrier.
- 4.1.6 For reducing radiation exposure to operator and help ensure stability while taking radiographic images, the use of a tripod is recommended as possible.

4.2 Caution when user starts to use

- 1. Before Operating, read carefully the User's Manual and follow direction while setting.
- 2. Before Operation, check accessories.
- 3. Before turning Power on, check whether battery should be fully charge.

⚠ NOTE !
Remove the power cord before using, XR-01 is not functional while charging.

4.3 Checking Before Operating

- 1. Observe carefully on the whole system and the patient.
- 2. When there is problem with the system or the patient, keep the patient in safety, stop operating the system and make relevant disposition.

4.4 System Malfunction

Observe carefully on the whole system and the patient. When there is problem with the system or the patient, keep the patient in safety, stop operating the system and make relevant disposition. In case of malfunction, do not attempt to operate the system until it has been checked out by a qualified service technician.

4.5 Inspection

- 1. Make inspection for system and part periodically.
- 2. In case it is used after quite a long time of recess, confirm its status from an expert of this equipment or manufacturer.
- 3. Wash periodically with neutral detergent very carefully.
- 4. Do not use erosive detergent of fluid.

V. COMPOSITION

5.1 Composition

This system is composed of main body and accessories as follows. **Main**

- XR-01 Portable X-Ray
- Beam limiting Device

Accessories

- AC/DC Adaptor
- Power Cord
- Hand Switch
- Carrying Box
- Back Scatter Shield (Optional)

5.2 AC/DC Adaptor

- Model Name : GSM60A24-P1J
- Manufacturer : Mean Well Enterprises Co., Ltd.
- Rated Input : 100-240Vac, 50-60Hz, 1.4-0.7A
- Rated output : 24Vdc/2.5A, 60W MAX

\triangle WARNING !

Recharge with the recharge unit supplied by Rolence.

Use it only for the XR-01, otherwise it may occur malfunction or disorder.

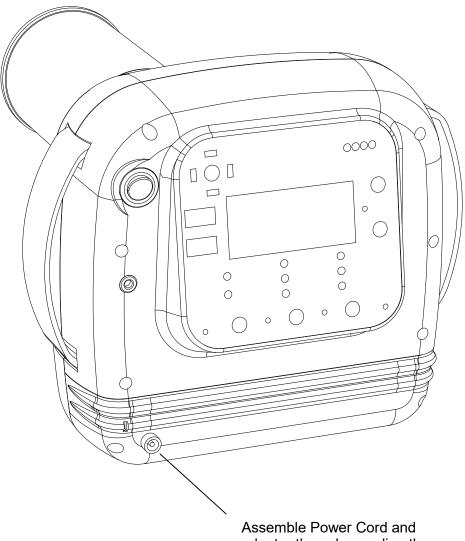
5.3 Battery

⚠ WARNING !

Use the battery supplied by Rolence.

The user is responsible for any malfunction from usage with another battery.

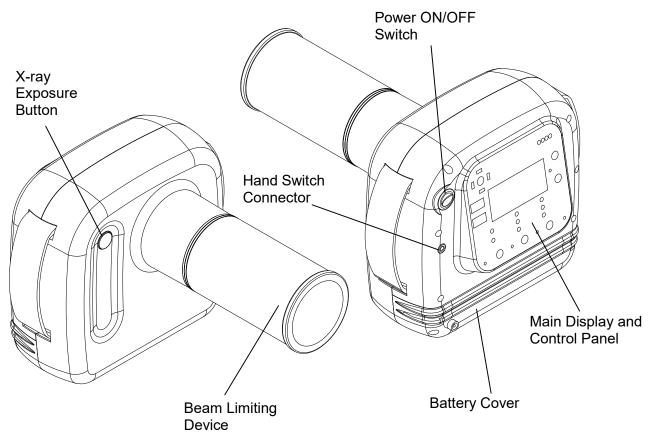
- Model Name : 7S1PXRP001(Li-Polymer Type)
- Manufacturer : Rolence Enterprise Inc.
- Voltage : 25.2Vdc
- Capacity : 2900mAh
- Recharge Battery -



adapter then charge directly

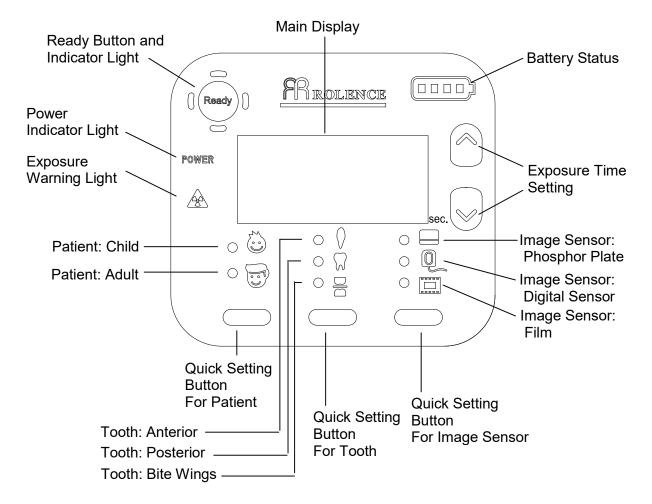
- 1. Assemble Power Cord and Adapter then charge directly.
- 2. If powered, the LED indicator light on with green.
- 3. The LED indicator shows orange light if recharging.
- 4. The LED indicator shows green light if recharge complete.

VI. EXPLANATION OF EACH PART



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6.1 Main Display and Control Panel

- 1. Power Indicator Light: Light on when power on.
- 2. Main Display: Display current exposure time or error code when error happens.
- 3. Battery Status: Display the remaining battery power. Low battery when all 4 blocks disappear.
- 4. Exposure Time Setting: Manually adjust the exposure time, press "up" button to increase, "down" button to decrease. (0.01sec / step)
- 5. Quick Setting Button For Patient: Use the default time setting for each kind of patient.
- 6. Quick Setting Button For Tooth:
 - Use the default time setting for each kind of tooth.
- 7. Quick Setting Button For Image Sensor: Use the default time setting for each kind of image sensor.

8. Ready Button and Indicator Light:

Press the "Ready Button" to disable the safety lock before starting exposure. Indicator light shows green light when safety lock disabled, press any button will re-enable the safety lock with green light disappear.

Indicator light shows orange light when cooling or initiate, User is unable to control the XR-01 in this moment.

9. Exposure Warning Light: Yellow light when generating X-Ray with buzzer rings.

VII. OPERATION

⚠ NOTE !

Before using XR-01, Please clean to surface contact to patient (see section 2.3)

Before operation, please make sure the radiation protection measures indicated in section 4.1 are satisfied.

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS MANUAL.

7.1 Power ON

When power switched on, the XR-01 need 5sec to initiate.

In initiate process main display shows 0.00 and the ready indicator lights on in orange, user is unable to control XR-01 until the ready indicator turns off and initiate complete.

After the initiate or exposure is complete, user should at least complete one exposure within 3 minutes. Otherwise the system automatically turns off and buzzer rings, user should turn off the power switch for saving battery. Or then turn power on again for next operation.

When the battery storage is less than the minimum dose, the main display shows E00 and user is unable to control XR-01

User should recharge the battery with recharge unit and adaptor supplied by Rolence.

7.2 Adjustment of Exposure time

- 7.2.1 The XR-01 has fixed tube voltage and tube current at 60 kV, 2.0 mA. Only exposure time is adjustable from 0.01-2 seconds.
- 7.2.2 Adjust exposure time by pressing Exposure Time Setting "up" button to increase, "down" button to decrease. (see section 6.1)
- 7.2.3 Pre-set exposure factors is provided as Table 7.2.5. Exposure time may vary from different imaging sensors, film speeds, brands, types, patient size, and distance to patient.
- 7.2.4 Pediatric considerations

The XR-01 is designed for both adult and children. However, the preset exposure factors is not applied for every patient, especially for children. Pediatric population or smaller patient may be more sensitive to X-ray exposure. We recommend dentist consider the patient's age, size and health history before X-ray examination. Also, protective thyroid collars and aprons should be used whenever possible. About safe imaging of pediatric patients, you can find more details from following websites:

1. Image Gently

http://www.imagegently.org/

2. FDA Guidance

https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/Medic allmaging/ucm298899.htm

Operation

7.2.5 Pre-set exposure time

Item		Part	Exposure Time
		Anterior	0.27 sec
	Adult	Posterior	0.32 sec
Phosphor		Bite Wings	0.34 sec
Plate		Anterior	0.15 sec
	Child*	Posterior	0.26 sec
		Bite Wings	0.27 sec
		Anterior	0.20 sec
	Adult	Posterior	0.27 sec
Digital		Bite Wings	0.29 sec
Sensor	Child*	Anterior	0.15 sec
		Posterior	0.22 sec
		Bite Wings	0.24 sec
		Anterior	0.50 sec
	Adult	Posterior	0.65 sec
Film		Bite Wings	0.68 sec
		Anterior	0.31 sec
	Child*	Posterior	0.50 sec
		Bite Wings	0.55 sec

7.3 Exposure

- 1) Set the exposure time.
- 2) Sight the cone for the area you want to get the image.
- 3) Push "Ready" button to disable the safety lock.
- 4) "Ready indicator light" turns on in green.
- 5) If not start X-Ray exposure in 30sec, XR-01 goes back to safety lock mode and green ready light turns off.
- 6) Press down "X-Ray Exposure Button" continuously to start exposure process.
- 7) When "X-Ray Exposure Button" was pressed, exposure warning light turns on and buzzer rings.
- 8) 3 seconds after the "X-Ray Exposure Button" was pressed, the XR-01 start generating X-Ray, until the set exposure time.
- 9) Push "X-ray Exposure Button" until the end of exposure period. Once the Exposure Button was released, the exposure stop immediately.

10) When X-ray exposure is finished, yellow LED turns off and buzzer stops ringing.

11) After exposure the cooling time is required and orange light turns on, it takes 30 times of exposure time + 5 seconds to cool down the tube assembly. User cannot exposure it till the cooling process finished.

▲ NOTE !

In order to get the best image from the equipment, please exposure the Xray with distance determined by its cone. And avoid touching the patient with the cone or backscatter shield.



7.4 Battery recharging and operation time

△ WARNING !

When you use ordinary adaptor, the battery can be damaged. You should use its own adaptor supplied by Rolence.

\triangle WARNING !

This battery is exclusive for XR-01.

You cannot use any other battery for this equipment.

When life span of battery is finished, you should change it with the same Battery supplied by Rolence.

7.4.1 Specification of Battery

This adopted Lithium-Polymer battery which is very safe. Its specification won't be changed after long time of disuse.

7.4.2 Operation Time

The remaining extent of battery is shown on right-upper side on Main Display. If the battery is not sufficient, you cannot acquire the best image.

Keep the battery charged enough. When the remaining extent of battery is lower than the minimum, the electricity is automatically shut off in order to protect any damage for the equipment.

The charging time(from empty to full) is about 4 hours.

Please charge the battery for about 12hours when the first using of the equipment. It is recommended to fully recharge the battery every three months while in long-term storage to ensure that no low battery becomes damaged. Fully recharge the battery every 3 months to prevent low-battery damage for long-term storage.

7.5 Periodic Check

We recommend to check this equipment annually. Only qualified people can check this equipment according to the Regulations of the country.

VIII. Maintenance Plan

8.1 Daily Maintenance

- 1. Review this user's manual periodically to ensure operator's understanding of intended use.
- 2. Routine clean of the XR-01 is essential. Use non-acetone base disinfectant to wipe the exterior surface of the XR-01.
- 3. A periodically review process of personnel training is essential to be established. Make sure the process is meet local, national regulatory requirement.
- 4. Periodically review the section 3.4 to keep sufficient awareness of radiation protection issues.

8.2 Battery Maintenance

- 1. Battery must be charged before initial use.
- 2. Battery's capacity decreases naturally over its lifespan which is usually be between 1~2 years.
- 3. For long-term storage battery, as battery would lose the charge over time, recharging the battery every 3 months is strongly recommended.
- 4. Remove the charger from the unit after fully charged..

8.3 Annual Maintenance

- 1. **Power on** the device to check the power button is working properly and green power indicator and four orange indicators at left top side should illuminate.
- 2. Check the increase and decrease buttons work properly by pressing them and see if time setting changes accordingly.
- 3. Set exposure time as 1.00 sec and press READY. Verify the button moves freely. Verify XR-01 could enter READY state (READY LED illuminates). Initial an exposure by pressing "X-ray exposure button" and release it to verify that exposure terminates right away by release of "X-ray exposure button".
- 4. Verify the audible signal is heard.
- 5. Verify the backscatter shield is not cracked and firmly attached to the collimator cone.

8.4 Calibration check (optional)

1. XR-01 is calibrated according to strict standard. All parameters are set in factory and didn't be adjusted by users. However, calibration checks performed by qualified and experienced technician is required in some countries/locations.

2. Test items and descriptions

Test Item	Acceptance Limits	Remark
kVp Accuracy	60 kV ± 10%	
Timer Accuracy	Set time ± 10%	Measured during the entire exposure, reference to 75% raise/fall.

8.5 Maintenance Log sheet

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
		Date	Date	Date	Date	Date	*1
1.	Power button						
2.	Time selection buttons						
3.	X-ray exposure button						
4.	READY state]
5.	Exposure termination						
6.	Exposure warning signal						
7.	Exposure termination						
8.	Calibration check (if needs)						
	For ensuring XR-01 w ommended.	/orks proper	ly, schedulin	g a five year	s inspection	by Rolence	is strongly

IX. HELP MESSAGE

9.1 Error Code

If there's any error happens on this equipment, it shows the following error code in order to clarify the problem.

Error Code	Class of Error	Counter plan	
E00	Low Battery The battery power is insufficient to generate X-Ray	Recharge Battery	
E01	Filament Fail The filament is broken Unable to heat up the filament	Contact Rolence	
E02	Over Heat The inner temperature of tube assembly is over 60°C	 Stop operation After 2 hours, check If same message, contact Rolence 	
E03 Insufficient exposure Exposure terminates if operator re the depressed trigger prematurely		 Check the exposure parameters Reinitiate the exposure. 	

X. DISPOSAL



In the EU the "crossed-out wheeled bin" symbol indicated that this product shall be disposed by disassembled and delivered to authorized operator for satisfying European Directive 2002/96/EC and 2003/108/EC. XR-01 system is mad of materials including iron, aluminum, lead, copper, plastics, electronic components and dielectric oil in the x-ray tube assembly tank. It must be disposed of according to local requirements. DO NOT dispose of any part of XR-01. Please contact with authorized representative or Rolence Enterprise Inc. for disposal or recycling.

XI. TECHNICAL DATA

11.1 Basic Technical Specifications

11.1.1 Classification / Spec	
Compliance Electrical classification	Internally Power
(Battery)	Туре В
Electrical classification	Class II
(AC/DC Adaptor)	Туре В
MDD(93/42/EEC):Annex IX	Class Ilb
	IP0; do not operate under
IPX specification	wet conditions
11.1.2 Mode of operation	Intermittent operation

For use in environments where no flammable anesthetics and/or flammable cleaning agents are present; non-alcohol based disinfectant only-wipes or cloth dampened with liquid/spray

11.1.3 Complied Standards

Exposure time range

- IEC/EN 60601-1	- IEC/EN 60601-1-2
- IEC/EN 60601-1-3	- IEC/EN 60601-1-6
- IEC/EN 60601-2-65	
11.1.4 X-Ray Exposure Control	

0.01sec~2.0sec manually adjustment(0.01s / steps)

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11.1.5 X-ray Tube Assembly kV range 60kV(fixed) mA range 2.0mA(fixed) 1:30 + 5sec Exposure duty cycle **Total filtration** 1.6mmAl Maximum output power 120W Maximum Leakage technique factors 60kV X 4mAs 11.1.6 Beam Limiting Device Туре Round Type Source to Skin Distance 20cm X-ray field size Ø60 11.1.7 Battery 7S1PXRP001(Li-Polymer Type) Model Name Manufacturer Rolence Enterprise Inc. Nominal Voltage 25.2Vdc Capacity 2900mAh 11.1.8 AC/DC Adaptor Model Name GSM60A24-P1J Manufacturer Mean Well Enterprises Co., Ltd. Rated Input 100~240Vac, 50~60Hz, 1.4~0.7A Rated output 24Vdc/2.5A, 60W Max

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Technical Data

11.1.9 Dimension(Unit : mm) and Weight			
Main Body with Beam Limiting Cone	174 x 178 x 257	2.7kg±10%	
Main Body without Beam Limiting Cone	174 x 178 x 150	2.5 kg±10%	
AC/DC Adaptor	121 x 48 x 30	280g± 10%	
Backscatter Shield (optional)	145 x 145 x 8	0.18kg±10%	
Carrying Box	455 x 260 x 197	1.2kg±10%	

11.1.10 Environmental requirements

OperationTemperature-5°C ~ 40°CRelative humidity35% ~ 75%RHAtmosphere700 ~ 1060hPaStorage and transportation-10°C ~ 70°CTemperature-10°C ~ 70°CRelative humidity10% ~ 90%RHAtmosphere500 ~ 1060hPa

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(1) Manufacturer	Canon(D-045)
(2) Туре	Stationary
(3) Focal Spot	0.4mm
(4) Target Angle	12.5°
(5) Target Material	Tungsten
(6) Inherent Filtration	1 mmAl
(7) Cooling Method	Oil cooling
(8) Input Energy(see rating chart)	585W(at 1.0s)
(9) Maximum Tube Voltage	70kV
(10) Minimum Tube Voltage	50kV
(11) Maximum Tube Current	12mA
(12) Filament Voltage	4.0)/
(at the maximum filament current)	4.0V
(13) Maximum Filament Current	3.0A
(14) Thermal Characteristics	
Anode Heat Storage Capacity	4.3kJ
Maximum Anode Heat Dissipation Rate	100W

11. 2 X-Ray Tube Specifications and Characteristics

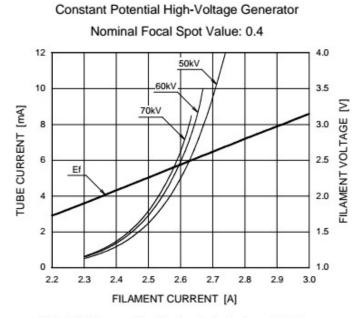
S-19-01-1500-U0001 V1.5

32

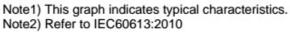
(15) Rating chart

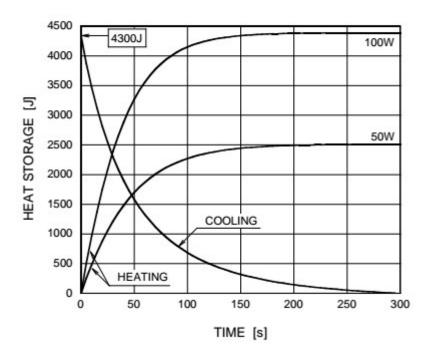
Maximum Rating Charts (Absolute maximum rating charts)

Constant Potential High-Voltage Generator Nominal Focal Spot Value: 0.4 50kV 12 60kV 10 70kV TUBE CURRENT [mA] 8 6 4 2 0 0.1 0.2 0.3 0.5 0.7 1 2 3 5 7 10 EXPOSURE TIME [s] Refer to IEC60613:2010



Emission & Filament Characteristics



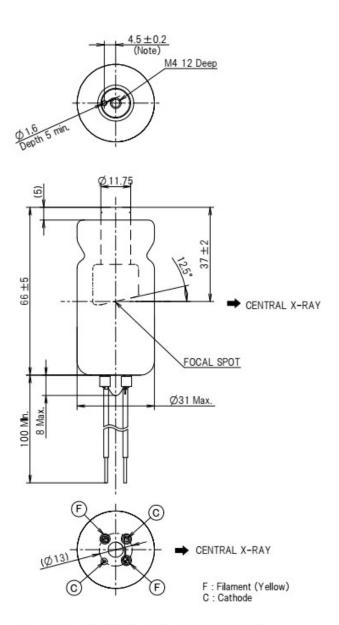


Anode Heating / Cooling Curve

(16) Dimensional Outline of X-ray Tube (D-045)

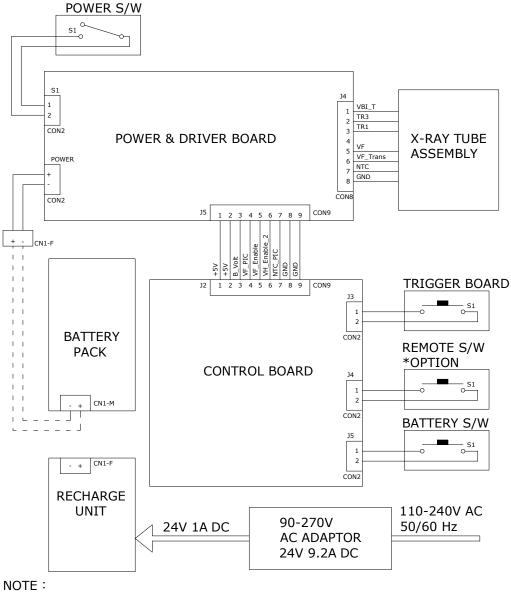
Dimensional Outline

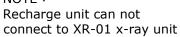
Unit: mm



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

11.3 Wiring Diagram





11.4 EMC Test Report

Worldwide Testing and Certification



TEST REPORT ELECTROMAGNETIC COMPATIBILITY (EMC)			
Panart Pafaranaa Na	040000		
Report Reference No	312080		
Supervised by (name & signature):	Juno Wong June Wing Zone Peng Zone Peng		
Approved by (name & signature):	Zone Peng Zona Peng		
Date of issue	2016-10-25		
Report issued by	Nemko Shanghai Ltd Shenzhen Branch		
Address	Unit C&D, Floor 10,Tower 2, Financial Base, Kefa Road 8#, Hi-Technology Park, Nanshan District, Shenzhen 518057, China		
Testing procedure	Supervised testing at external laboratory		
Testing location/ address	See page 7		
Applicant's name	Rolence Enterprise Inc.		
Address:	18-3, Lane 231, PuChung Rd., Chungli, 320, Taoyuan, Taiwan		
Test specification:			
Standards for EMC	EN 60601-1-2:2015		
Arrival of EUT	2016.09.19		
Test data of EUT	2016.09.20		
Test item description	Portable X-ray		
Trade Mark	R Rolence Enterprise Inc.		
Manufacturer	Rolence Enterprise Inc.		
Address	18-3, Lane 231, PuChung Rd., Chungli, 320, Taoyuan, Taiwan		
Туре	XR-01		
Serial number:	See page 7		

This report consists of 26 numbered pages including this page and shall not be reproduced except in full, without the written approval of the testing laboratory. The results are related to the equipment under test only (type-test)

The equipment complies with the requirements in the Medical Device Directive 93/42/EEC.





Rolence Enterprise Inc.

No.18-3, Lane 231, Pu Chung Rd., Chungli, Taoyuan Taiwan 32083 Phone: +886-3 463-1999 FAX: +886-3 463-1997, www.rolence.com.tw info@rolence.com.tw



CMC Medical Devices & Drugs S.L. C/ Horacio Lengo n18, C.P 29006, Málaga-Spain

Guidance and manufacturer's declaration-electromagnetic emissions

The XR-01 is intended for use in the electromagnetic environment specified below. The customer or the user of the XR-01 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions	Group1	The XR-01 uses RF energy only for its internal
CISPR 11		function. Therefore, its RF emissions are very
		low and are not likely to cause any
		interference in nearby electronic equipment.
RF emissions	Class A	The XR-01 is suitable for use in all
CISPR 11		establishments, including domestic
Harmonic emissions	Class A	establishments and those directly connected to
IEC 61000-3-2		the public low-voltage power supply network
Voltage fluctuations	Compliance	that supplies buildings used for domestic
/flicker emissions		purposes.
IEC 61000-3-3		

Guidance and manufacturer's declaration-electromagnetic immunity The XR-01 is intended for use in the electromagnetic environment specified below. The customer or the user of the XR-01 should assure that it is used in such an environment.

environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) EN 61000-4-2	+ 6 kV contact + 8 kV air	+ 6 kV contact + 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst EN 61000-4-4	+ 2kV for power supply lines	+ 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge immunity IEC 61000-4-5	0.5~+ 2kV common mode	0.5~+ 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions immunity EN 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in	Mains power quality should be that of a typical commercial or hospital environment. If the user of the XR-01 requires continued operation during power mains interruptions, it is recommended that the XR-01 be powered from an uninterruptible

	<5% UT(>95% dip in UT) for 5 s	UT) for 5 s	power supply or a battery.
Power frequency	3 A/m	3 A/m	The XR-01 contains no
magnetic field			devices susceptible to
EN 61000-4-8			magnetic fields.
NOTE UT is the a.c. mains voltage prior to application of the test level.			