

Diagnostic X-Ray Equipment

Operation manual Technical manual





User Registration

Please verify the model and serial number of this X-ray machine at the back of the instrument, and fill in the following form. If there are any errors, please contact your distributor and inform the distributor the model and serial number of this instrument.

| Product Name: | |
|-----------------------|--|
| Product Model: | |
| Serial Number: | |
| Date of Manufacturer: | |

Software Version for Release: RAY-P-01-00

Before operating this equipment, please read carefully all safety cautions and instructions for operation in this manual. This manual will help you understand the functions of Runyes Diagnostic X-ray Equipment as much as possible.

Please follow the instructions for the correct use, and maintenance.

Please keep this manual for future reference.

If an error occurs during the operation of this equipment, please contact the local distributor for assistance. We will provide you with high-quality service and assistance.

Maximum service life: 8 years.

Diagnostic X-Ray Equipment

| Table Contents | 1. Overview |
|--|--|
| | |
| 1.Overview | 1.1 Applicable Range and Location The X-ray machine is suitable for X-ray imaging of teeth for clinical diagnosis. It is primarily used in medical institutions such as hospitals and clinics. |
| 2.Technical Data | The diagnostic X-ray equipment is suitable for X-ray photography to obtain images for clinical diagnosis. The main applicable locations are medical institutions such as hospitals and clinics. |
| 3.Check List - Before Using The Equipment | 1.2 Structural Components |
| 4.Product Composition | This equipment consists of an X-ray tube head, control system, battery, adaptor, beam limiting device,and stand. |
| 5.Basic Information Of Software | 1.3 Classification Electrical Shock Protection Type: Class I while charging; internal power supply while operating Degree of Electrical Shock Protection: Type B applied partNon-AP/APG type equipment |
| 6.Procedure Of Taking X-rays | Degree of Liquid Ingress Protection: IPXO (non-liquid-tight enclosure) Operating Mode: Intermittent loading, continuous operation |
| 7.Error Codes | 1.4 Responsibility of the User |
| 8.Safety | User' notice: Follow the operating and maintenance instructions provided in this manual. The manufacturer and its agents are not liable for any accidents caused by improper use or maintenance. |
| 9.Cleaning and Disinfection | |
| 10.Maintenance And Inspection | Immediately notify the health authorities and the manufacturer in the event of accidents related to this equipment or any performance changes that may result in death, personal injury, or health hazards to patients or operators. |
| 11.X ray Tube Characteriscs | Product model and serial number are required in the feedback report provided to the manufacturer. Users can obtain the information from the technical tag. |
| 12.Tube Assembly And Equipment Dimension Diagram | |
| 13.Accessories list | |

14.Waste Disposal Process

1.5 Warnings And Precautions

The use and operating location of the equipment are crucial, as radiation safety requirements vary in different countries and regions, and the equipment should be properly shielded. The user is responsible for ensuring compliance with local safety requirements.

This X-ray machine may generate ionizing radiation that can be harmful to health if not controlled properly. Therefore, it is recommended that only trained personnel operate this machine in accordance with existing laws and regulations.

Although this machine complies with electromagnetic compatibility specifications, it is still advised not to use the machine in locations with external electromagnetic interference (e.g., high-power devices or radio transmitters can interfere with the electronic circuits of the system).

Users must not open the equipment casing on their own. In the event of equipment malfunctions, please contact the manufacturer or qualified service personnel to avoid the risk of high-voltage electric shock.

Replaceable parts of the equipment, such as batteries, adaptors, and handheld exposure devices, must be used with the original factory accessories. Users should not replace them arbitrarily.

Authorized service personnel from our company can provide drawings and component information.

During the examination, there should be someone constantly monitoring the patient's condition in the operating room to ensure their safety. Patients should be instructed to remove glasses, removable dentures, watches, hairpins, or any other items that may enter the imaging area to avoid creating false images. 1.6 lable Instruction

| No. | lcon | Description | No. | lcon | Description |
|-----|-------------|-------------------------------------|-----|------|---------------------------|
| 1 | ★ | TYPE B APPLIED PART | 6 | Ţ | Fragile, handle with care |
| 2 | \triangle | Follow instructions for use | 7 | Ť | Keep dry |
| 3 | -@- | x-ray focus position | 8 | m | Date of manufacture |
| 4 | Ċ | Power switch | 9 | SN | Serial number |
| 5 | A | X-rays,beware of ionizing radiation | | | |

2. Technical data

2.1 Technical specification Charger Input: 100~ 240V Frequency: 50/60Hz Power: 30VA Internal Power Supply: 14.87 Power Supply Internal Resistance: $\leq 2\Omega$ Main Unit Input Voltage: 19V= Ray Type: X-ray Ray Direction and Distribution: diameter of 60mm from beam limiting device Dose Rate: 2mGy/s X-ray Tube Model: XD10F-0.2/70 Target Material: Tungsten Target Angle: 15° X-ray Focal Spot: 0.4mm Tube Voltage: 70kV±10% Tube Current: 2mA+20% Loading Time Adjustment Range: 0.04s-2.0s, Error ±(10%+1ms), adjustment mode selected according to R'10 coefficient. Nominal Power: 0.14kW (70 kV, 2mA, 0.1s) Factor Combination Leading to Maximum Output Power Load: 70 kV, 2mA Inherent filtration: 1.0mmAI/70kV. YY/T0062-2004 Additional filtration: 0.5mmAl/70kV, YY/T0062-2004 Total filtration: 1.5mmAl/70kV, YY/T0062-2004 Half-Value Layer: ≥1.6 mmAl at 70kV Load Cycle: 1/15 Leakage Radiation Loading Factor: Exposure for 1 second, pause for 15 seconds Leakage Radiation Rate: ≤0.25mGy/h at 1 meter (70kV, 2mA, 1s, loading interval of 1s/15s) Total Weight: 2Kg Weight of Tube Assembly: 1.1kg

2.2 Beam Limiting Device Focus-to-skin distance: 20.5cm±0.5cm Output radiation field: Circular, φ6cm±0.5cm

2.3 Control System Microprocessor-controlled Selection of Pediatric (Small), Adult (Large), and Animal Wheel types Equipped with a handheld switch with a 3m spiral cable The handheld switch can be installed at a remote location

2.4 Working Environment Requirements Operating temperature: 10°C-40°C Relative humidity: 30%RH to 75%RH Atmospheric pressure: 700hPa to 1060hPa

2.5 Transportation and Storage Conditions Storage temperature: -20°C to 55°C Transportation temperature: -20°C to 55°C Relative humidity: ≤93%RH Atmospheric pressure: 700hPa to 1060hPa

Note: The X-ray machine should be stored in an indoor environment with good ventilation and noncorrosive air. It should not be thrown, dropped, or subjected to severe vibrations during use or transportation.

3. Check List--Before Using The Equipment

3.1 Checklist - Before Use
Before use, ensure your familiarity with radiation protection measures and read this manual carefully.
Ensure that the film meets the working requirements and is ready for use.
Ensure that the film is compatible with the developer/fixer solution.
Ensure that the developer/fixer solution is within its expiration date and at the appropriate temperature and concentration.
Ensure that the film is within its expiration date and do not use expired films.
If using other imaging equipment, ensure that the imaging equipment is in normal working condition.
Ensure that the device has sufficient battery power.

4. Product Composition

4.1 Product Diagram





2: Power switch

4: Display screen

6: Charging interface 8: Exposure button

- Beam limiting device
 Handheld exposure switch interface
- 5: Function key buttons
- 7: Battery compartment

4.2Console and Handheld Exposure Switch



One end of the exposure hand switch cable is connected to the device interface at position 3, and the other end is connected to the exposure switch.

 \triangle Note: The handheld exposure switch should not be connected to any other devices!

5.Basic Information Of Software

5.1 Basic Operation Functions Body type selection Position selection Exposure time adjustment X-ray exposure

5.2 Testing Battery power detection X-ray tube voltage detection

5.3 Functional SafetyDuring the exposure countdown, pressing any key other than the exposure button will exit the standby state.Releasing the hand during exposure will terminate the exposure.

5.4 Software Release Version RAY-P-01-00

4. Procedure of Taking X-ray Films and Equipment Operation

6.1 Power On

a. Preparation: Insert the battery pack into the device.

b. Power on: Press the power switch button for 1 second to turn on the device. The LCD screen lights up, and a beep sound indicates power-on.

c. Check: Check the battery power to ensure the device can function properly.

d. Mode selection: Adult/Child, Teeth Position.

e. Exposure time: The system has default time settings, but users can adjust the shooting time as needed.

f. Imaging: Place the film or sensor within the imaging area of the patient's teeth position, press the exposure button to emit X-rays, and a beep sound indicates the exposure.

g. Cooling: After the shooting is completed, the device enters a cooling countdown and standby mode, preparing for the next shot.

h. Power off: Press the power switch button, the display screen turns off, and a beep sound "beep, beep" indicates the power-off.



6.2 Symbols and Meanings in the Display Panel





| Symbols | Details | Symbols | Details |
|-------------|---|--------------|-----------------------|
| L | The device is cooling down | Ð | Low power |
| | Ready | | Battery power display |
| | Under exposure (Warning: ionizing radiation) | • D J | Charging |
| \triangle | Warning symbol | | Lock |
| | Upper teeth foretooth | İ | Adult mode |
| | Upper molar tooth | ń | Children mode |
| | Upper posterior tooth | | lower tooth foretooth |
| | Bitewing | T | Lowr molar tooth |
| 8.8.8 | Exposure time | | Lowr posterior tooth |
| Up | Increase exposure setup time | X | Bitewing |
| Down | Decrease exposure setting time | Mode | Adult/child choice |
| Teeth | Tooth selection | | |
| | |] | |

6.3 Patient Position

Ensure the patient maintains the correct sitting position, then place the film or digital imaging device, and take necessary precautions. Adjust the angle and position between the X-ray generator and the patient.

a/Parallel line technology



The film or digital sensor is placed in the mouth or on a film holder. The film or sensor is parallel to the long axis of the teeth.

Diagonal technology



The film or digital sensor should be placed inside the mouth or on a film holder, and positioned parallel to the long axis of the teeth.

c/X-ray inclination average angle when shooting upper and lower teeth

| Tooth | X-ray tilt direction | X-ray tube tilt angle |
|---------------------------------------|----------------------|-----------------------|
| Maxillary incisor | Tilt Towards foot | +429 |
| Maxillary uni-cuspid | Tilt Towards foot | +45º |
| Maxillary bicuspids and first molars | Tilt Towards foot | +30º |
| Maxillary second and third molars | Tilt Towards foot | +28º |
| Mandibular incisor | Tilt Towards head | -15º |
| Mandibular uni-cuspid | Tilt Towards head | -18º~-20º |
| Mandibular bicuspids and first molars | Tilt Towards head | -10º |
| Mandibular second and third molars | Tilt to the head | -5º |

6.4 Exposure Methods:

There are two exposure methods for the user:



1.Press the exposure button on the device, and wait for a 60-second countdown to appear on the display, indicating that it is ready for exposure.

2. Press the exposure button on the device or the exposure button on the handbrake to perform exposure. During exposure, the yellow indicator light on the hand controller will illuminate, and the X-ray symbol on the screen will light up, accompanied by a "beep" sound as a reminder.

Note: If it is the first time using a new machine, please set the exposure time to 0.1s for exposure testing. After the machine exposes correctly, you can then select other values for exposure.

6.5 Charging And Battery Maintenance

6.5.1 Charging:

a. Turn on the device's power switch.

b. Connect one end of the charger to the device charging port and the other end to the power outlet $(100-240V^{50}/60Hz)$.

c. When the device is connected to the charger, a charging icon will appear on the display, accompanied by a "beep beep" sound as a reminder.

d. When charging is complete, the battery level will be displayed as full.

e. Disconnect the power supply and the charger to complete the charging process. f. The charging time for a single charge is approximately 3 hours.

Charging adapter

6.5.2 Battery Maintenance:

a. When the machine is not in use, turn off the power switch to save energy.

b. Please use the charger provided by the manufacturer for charging.

c. If it is not used for a long time, separate the battery from the device, and also charge it once every three months.

d. The battery level should be kept above 20%.

e. Avoid high-level and prolonged single charging exceeding 12 hours.

6.6 Locking Device Exposure

To prevent accidental operation, the device has a locking function:

Lock exposure: When the Mode key is pressed followed by the Teeth key, an icon will appear in the upper right corner of the display, indicating that the device's exposure function is locked. Other functions can still be operated, but the device cannot perform exposure when the exposure button is pressed.

Unlock: Press the Mode key and Teeth key again to close the icon in the upper right corner of the display, indicating that the lock is released, and the device can perform exposure normally.

6.7 Viewing Cumulative Dose

The device has a function to view the cumulative exposure dose. When the Mode key is pressed, followed by the UP key, the screen will display the accumulated dose that the device has been exposed to, measured in uGy or mGy or kGy. To exit the dose viewing mode, press the Mode key and the UP key again.

6.8 Exposure Time Setting

When the default exposure time of the device does not meet the user's current imaging needs, the user can adjust the exposure time for each tooth position. Setting method: Select the desired position, use the UP or DN key to adjust the exposure time. After adjusting the desired exposure time, simultaneously press the UP and DN keys for 3 seconds. The system will emit two beeps as a confirmation that the current exposure time has been saved.

Restoring the default exposure time of the device: If the user wants to restore the device to its factory default exposure time, simultaneously press the UP and DN keys for 10 seconds. The device will emit a long beep sound, indicating that the system has restored the factory default exposure time.



Charging plug

7.Error Instructions And Error Codes

| Error indication | Error info | Solution | |
|---------------------|------------|-------------------------------------|--|
| Device exception | | Re-expose or view the exposure code | |
| Low battery | | Please charge on time | |

| Error indication | Error info | Solution |
|---------------------|--|---|
| E01 | Exposure terminated | Press and hold the exposure button until the exposure finish |
| E02 | Retain | |
| E03 | High voltage warning | Restarting the device to expose, If still fails, please contact the dealer |
| E04 | The voltage of the X-ray tube is too high | Restarting the device to expose, If still fails, please contact the dealer |
| E05 | The current of the X-ray tube is too low | Restarting the device to expose, If still fails, please contact the dealer |
| E06 | The voltage of the X-ray tube is too low | Restarting the device to expose, If still fails, please contact the dealer |
| E07 | Anode current feedback failure | Check the connection between the control panel and the ball tube or contact the dealer |
| E08 | Anode voltage feedback failure | Check the connection between the control panel and the ball tube or contact the dealer |

Note: when an error code appears, press the UP and DOWN keys for 3 seconds to close the error code.



8. Safety

■ Only trained and authorized technicians are allowed to open the chassis and access the circuit boards.

The device's power must be turned off before cleaning or disinfecting the equipment.

■ Water and other liquids must not penetrate the interior of the device, as they may cause short circuits or corrosion.

The device should not be used in flammable gas or vapor environments.

■ Only trained and qualified personnel are allowed to operate the device and must comply with existing regulations regarding radiation protection.

■ When taking X-rays, both the patient and operator must wear protective equipment, and the distance between the operator and the X-ray source component should be ≥ 2 meters.

Ensure that the device is attended by someone.

■ The machine contains components that must be discarded in accordance with existing regulations.

■ Contraindications: Pregnant women and children should avoid prolonged exposure to the working environment of the product.

9. Cleaning And Disinfection

9.1 Cleaning

Disconnect the power connection before cleaning.

Use a regular cotton cloth and an alkaline cleaning agent to wipe the exterior of the product and the X-ray head, following the guidelines in "WS310.1-2016 Hospital Disinfection Supply Center Part 1: Management Specifications." Be careful not to let any liquid enter the device, as it may cause mechanical damage.

After cleaning, remove the cleaning agent and ensure that no residue is left on the surface. Use a clean, dry, soft cloth to wipe it dry. Do not use abrasive materials for cleaning.

9.2 Disinfection

It is recommended to use 70%~80% (volume ratio) alcohol disinfectant solution. Soak a clean, dry gauze cloth in the disinfectant solution and then wipe the surfaces that need to be disinfected twice, with an exposure time of 3 minutes. Allow it to air dry naturally or use a clean, dry, soft cloth to wipe off any remaining disinfectant.

Note that when contaminated by patient blood, body fluids, etc., the contaminants should be removed first before cleaning and disinfection.

Alcohol is flammable, so there should be no open flames during its use.

Exercise caution when using an alcohol disinfectant solution for individuals allergic to alcohol.

After disinfection, promptly remove any residual disinfectant to avoid direct contact with patients.

10. Maintenance And Inspection

10.1 Daily Maintenance Ensure that the equipment is placed in a location accessible only to operators. Keep a clean cloth available for regular cleaning of the equipment.

10.2 Inspection

a. Daily Inspection

Check if the screen displays properly upon startup.
Verify if the buttons function correctly.
Confirm if the buzzer produces sound.
Ensure that the exposure button and indicator light are functioning normally.
b. Monthly Inspection
Check if the battery pack's usage time is normal.
c. Annual Inspection
A safety inspection of the equipment must be conducted annually.

10. X Ray Tube Characteristics

Filament voltage: 2.3-3.5V Maximum filament current: 2.0A Filament frequency limit: DC or AC (0-20kHz) Anode nominal input power: 200W (for 1 second) Anode heat capacity: 5300J

Maximum heat dissipation of anode: 80W

Overall dimensions and wiring: mechanical dimensions and wiring diagram in figure 10-1. Thermal characteristics: X-ray tube anode heating and cooling curve in figure 10-2. Filament and emission characteristics: filament and emission characteristics curve in figure 10-3.

Maximum rating: Maximum rating chart in figure 10-4.

| L.mm | L1 mm | L.2mm | Dmm | D1 mm | dmm | Target angle | Maximum mass |
|------|-------|--------|-------|---------|-----|-----------------|--------------|
| 68±2 | 4.5±1 | 37±0.5 | Φ30±1 | Φ12±0.1 | M4 | 15° | 100 |





10-2 X ray tube anode heating and cooling curve

10-3 X ray tube anode heating and cooling curve



10-4 Maximum Rating

10-1 Dimensions and wiring

12. Tube Assembly And Equipment Dimensions

12.1 Tube Assembly Reference Axis, Dimensions, High Voltage Polarity



13. Accessories list

| No. | Description | QTY | Remark |
|--------------------|--------------------------|-----|----------------|
| 1 Charging Adapter | | 1 | |
| 2 | Beam limiting Device | 1 | Line length:2m |
| 3 | Handheld Exposure Device | 1 | |

12.2 Device Dimensional Drawing



14. Waste disposal

To reduce the burden on the environment, recyclable components should be sent to recycling centers after removing hazardous substances. Disposing of the waste product is the responsibility of the recycler.

All components and elements containing hazardous substances must be disposed of in accordance with legal and environmental regulations. Necessary precautions must be taken when handling waste products to avoid injury.

△ Recyclable ▲ Recyclable after Processing

| Component/Part | Main Material | Recyclable Material | Waste Processing Center | Recycling after separating hazardous substances |
|----------------|------------------|---------------------|----------------------------|---|
| Metal Casing | ABS Aluminum | | | \bigtriangleup |
| Circuit Board | | A | | |
| Wire | Copper | \bigtriangleup | | |
| Packaging | Paper | \bigtriangleup | | |
| X-ray Tube | | | | Δ |
| Others | | | Δ | |