Digital Mammography System

User Manual

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Product Information

First of all, thank you for the purchase of HEDY Medical Co. Ltd. products! Before using the equipment, please read this manual carefully, so that you can use the equipment correctly. This manual is random file of the device, please put it together with the device, and review the operating procedures and safety requirements of the manual.

Product performance structure and composition: detector, high-volt generator (Spellman VMX), X-ray tube assembly， collimator, gantry, console, generator cabinet, image acquisition workstation and the control box.

Intended use: the MXR-550 digital mammography system generates digital mammographic images that can be used for screening and diagnosis of breast cancer.

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Preface

Statement

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Contents contained in this manual are subject to change without prior notice.

Manufacturer's Responsibility

The manufacturer should be responsible for the safety, reliability and performance of this machine only under the following conditions:

- The assembling operation, extension, readjustment, improvement and maintenance are done by the qualified personnel approved by the manufacturer.
- The related electrical devices conform to national standards.
- The machine is used according to the conditions and requirements described in this manual.
- All maintenance related parts and the supporting accessories, consumables must be the original or approved by the manufacture.

The manufacturer is not responsible for the following conditions:

- Equipment failure caused by natural disaster or force majeure.
- Product safety problems caused by the installation, maintenance, and change of equipment without the authorization or permission of the manufacturer.
- Equipment failure or personal injury caused by improper operation or the user does not comply with the instructions of the manufacturer or its agents and the maintenance of the equipment.

User Notice

Before using this device, please fully understand the following:

- To ensure operation safety and long-term stable performance of the system, it's strongly recommended reading this manual to get a full knowledge on the function, operation and

maintenance before operating the system.

- Pay special attention to contents of “Warning”, “Caution” and “Note” in this manual.
- This manual is random file of the device, please put it together with the device, and review the operating procedures and safety requirements of the manual.

Warranty

The warranty period of the product shall be subject to the sales contract. The product’s warranty period is beginning with the “Acceptance Date” on the attached "The warranty card". "The warranty card" is an effective proof to calculate the warranty period, in order to protect your rights and interests, please keep it to prepare for the check of room service. If you lost the "equipment warranty card" of the products, the warranty period begin with the date of delivery of equipment. The manufacturer guarantee to the user, it is free of charge for failure repair and replacement of damaged parts in the warranty period, and this guarantee applies only to the failure of the specified operating equipment in accordance with the manual. After the warranty period, the manufacturer will continue to provide paid maintenance services.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part which serial number is not able to be identified clearly.
- Others not caused by instrument or itself.

When problems occur in the warranty period, please inform the manufacturer. Explain the type, number, date of purchase and the nature of the problem.

The life cycle of the system

This system contains environmentally dangerous components and materials (such as PCBs, electronic components, used dielectric oil, lead, batteries, etc.), which, at the end of the life-cycle of the system, becomes dangerous and will be considered as harmful waste according to the international, domestic and local regulations.

The manufacturer recommends contacting an authorized representative of the manufacturer or an authorized waste management company to remove this system once the life-cycle of the system comes to an end.

Chapter1 Safety Information

This chapter describes the security considerations, and the general preventive measures associated with the system and patients.

1.1 Classification of the Safety

MXR-550 digital mammography system with X has the following safety classification:

- According to the State Food and Drug Administration medical management belongs to the class II medical devices.
- The shock proof type: class I equipment.
- Prevent electric shock: B type application part.
- Prevent harmful liquid level: IPX0.
- Protection under the use of mixed gas with flammable，air, nitrous oxide and oxygen cases: Not in a mixture of flammable gas and air or the use of anesthesia and the mixture of oxygen or Nitrous Oxide.
- Power connected form: non detachable power supply cord.
- Operation mode: intermittent loading continuous operation.
- Recommended disinfection, sterilization method: according to the requirements of the manufacturers to classify.

1.2 Safety Signs

1.2.1 Warning Level

The following messages can be read throughout this manual, they are supposed to be paid special attention to.

 **DANDER!**	A **DANDER** label applies to information that may cause severe personal injury, even death if neglected.

 **WARNING!**	A **WARNING** label applies to information that may cause severe personal injury or actual property loss if neglected.

 **CAUTION！**	A **CAUTION** label applies to information that may cause mild personal injury or property loss if neglected.

NOTE！	A **NOTE** label applies to information on installation, operation or maintenance, which is very important but poses no risk potential.

Note: A **Note** used to provide some detailed explanation or message.

1.2.2 Equipment Labeling and Safety Symbols

symbol	detailed description	symbol	detailed description
	Type B applied part (on medical equipment)		General warning sign
	Warning, radioactive material or ionizing		Refer to the instruction manual/booklet
	Warning, crushing hazard: hand		Caution, risk of electric shock
	Non-ionizing radiation		Emergency stop
	Protective earth (ground)		Earth (ground)
	"OFF" for a part of equipment		"ON" for a part of equipment

	Alternating current (ac) symbol		Serial number
	big focus		small focus
	Date of Manufacture		Manufacture information
	Environmental protection use period (10 years)		European community representative
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer or an authorized waste management company for information concerning the decommissioning of your equipment.		

1.3 Safety Information

In order to ensure the safety of patients and operators, when using this system the following safety precautions must be strictly observed.

 **WARNING!**	1. This system can only be used by qualified professionals or in the used under the guidance of qualified professionals. 2. When you need to connect the equipment to any other manufacturer's equipment, please call the manufacturer to confirm its rationality. The manufacturer will not bear any responsibility for the damage caused by the connection to other equipment without permission of the manufacturer. 3. Please confirm that it meets the GB9706.15 standards, and the need to re check the leakage current of the whole system and other safety performance indicators, to avoid the possibility of damage caused by the system due to leakage current. 4. All other devices, which connected to the device by signal input and output, are required to meet the requirements of GB/IEC. the

	manufacturer does not assume any responsibility, if the use of external equipment for customers without authorization does not comply with the requirements of GB/IEC, resulting in abnormal data and even the damage to the equipment, 5. The unspecified components should not be added to the system

 **DANDER!**	1. The hazard of electric! According to the 93/42/EEC medical device act, the system is equipped with EMC filter. If there is no proper grounding, it will cause the electric shock to the user. 2. The hazard of electric! Do not remove the housing or panels, generator chassis have used to generate and control the X-ray of the high-voltage circuit, the high voltage of these circuits can be fatal. There is no component or regulator that can be maintained by the operator, only by the trained and qualified personnel to contact the internal components of the device. 3. The hazard of electric! In the operation process of system, must ensure that the system grounding connects the ground, and the connection of the cable must be in the system when the system is off, otherwise it will cause electric shock. 4. The hazard of electric! Do not use this system in the presence of flammable gases or flammable liquids (such as narcotics), or there is a risk of explosion. 5. This system is not water-proof. Do not use this system in any place where water leakage may occur. If any water is sprayed on or into the system, electric shock may result.

NOTE！	Must be in line with the requirements of the environment and power requirements of the system, otherwise it will not meet the normal performance of the product.

 **WARNING!**	1. Any patient does not allow contacting the control unit of the system. 2. Do not attempt to remove or replace any parts, must be professional maintenance personnel for maintenance. 3. Do not attempt to change the system software, which may cause damage

	to the system function and the loss of the image, and prohibit the use of any software provided by the company. 4. In the process of printing, saving and transmitting data, it is forbidden to turn off the power supply; otherwise it will lead to the loss of the information of the process. 5. Before cleaning the machine, be sure to unplug the power cable. When the system fails, it may cause electric shock.

 **CAUTION！**	1. This manual does not introduce the clinical examination technology, must be based on professional training knowledge and clinical experience to choose the right technology. 2. During operation, the improper power down may cause the hard disk data damage or system failure.

 **WARNING!**	Users should be responsible for providing communication tools between the operator and the patient.

1.4 Electromagnetic Compatibility (EMC)

This equipment complies with IEC 60601-1-2 Edition 2 EMC standard for medical devices. This equipment generates, uses, and can radiate radio frequency (RF) energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with radiated emissions as per CISPR11 Group 1 Class A standard limits.

Detailed requirements and recommendations about power supply distribution and installation are listed in the Pre-Installation section of the Service Documentation shipped with your system.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the Operator (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- Reorient or relocate the affected device(s);
- Increase the separation between the equipment and the affected device;
- Power the equipment from a source different from that of the affected device;

- Consult the point of purchase or manufacturer customer service department for further suggestions.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.

All interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference. Do not use devices which intentionally transmit RF Signals (Cellular Phones, Transceivers, or Radio Controlled Products) in the vicinity of this equipment as it may cause performance outside the published specifications. Recommended separation distances are detailed in the Pre-Installation section of the Service Documentation shipped with your system. Keep the power to these types of devices turned off when near this equipment.

The medical staff in charge of this equipment is required to instruct technicians, patients, and other people who may be around this equipment to comply fully with the above requirement.

Further data and recommendations for meeting Electromagnetic Compatibility (EMC) requirements for a typical installation are given in the Pre-Installation section of the Service Documentation shipped with your system. Note that the magnetic field of an MRI device located nearby may cause a risk of interference. Magnetic field amplitude limits are specified in the Pre-Installation section of the Service Documentation shipped with your system.

 **CAUTION！**	Normal operation of the system may interfere with the use of the medical electronic system near the radio transmitter. In the system installation room, it is forbidden to use devices which can produce radio wire, such as cell phones, radio transceivers, and wireless remote control toys.

1.5 Operational Safety

For patients and operating personnel safety, in the use of this system, please follow the following safety precautions:

 **WARNING!**	1. In order to use this device continuously, please save the manual and the device together, and review the operation procedures and safety requirements of the manual. 2. Operators must comply with the safety and radiation protection provisions of X-ray equipment to avoid radiation damage to the operator or patients. 3. The operator should always be responsible for ensuring the safety of the patient. The operator should monitor patients by visual observation, correct patient location and use of the protective equipment provided by the equipment.

	4. The equipment can only be used by trained qualified professional personnel or in qualified professional personnel to guide the use of. 5. The patient must stay away from the movement of the system's components. 6. When there is any electrical or mechanical failure of the equipment, the equipment shall not be forced to use.

 **CAUTION！**	1. Do not put any object on the device, to prevent the restriction of ventilation at the top. 2. Careful examination before operation to ensure that patients and other devices do not interfere or collide.

NOTE！	When the equipment work in emergency situations need to stop the mechanical movement, can press the emergency stop switch, the electronic mechanical movement will stop immediately.

 **DANGER!**	Before cleaning and maintenance of equipment, be sure to turn off the power.

1.6 Radiation Protection

It is harmful to health to Exposure to X radiation, so we should take protective measures to avoid exposure under the main beam. Some of the effects of X - ray radiation are accumulated, which may be expressed in a few months or years. For the operator, the best safety criterion is "avoid direct exposure to the main beam at any time".

Lead shielding is an effective protective measure. In order to minimize the risk of exposure to radiation, you should use protection device such as lead screen, lead gloves, apron, thyroid retainer and so on, and the protection device shall meet the national and local requirements for radiation protection.

 **WARNING!**	1. Before using the equipment, make sure that the X ray tube is placed in a normal working position, and the X ray beam is pointing to the detector. 2. Make sure that all necessary protective measures are taken before exposure.

	3. Operators must comply with the safety and radiation protection provisions of X-ray equipment to avoid radiation damage to the operator or patients. 4. Before using the equipment, The operator should be familiar with the requirements for radiation dose and has received training on the operation of the system. 5. The operator should make the distance of the focus to the skin as large as possible, to reduce the absorbed dose of the patient. 6. Select the appropriate technical parameters for each program to reduce the exposure of the X-ray and generate the best diagnostic image effect. 7. When patients need to support, take appropriate protective measures. 8. Because the X-ray is harmful to the human's body, operator should take the corresponding fixed position measures for special subject in the examination. The sensitive parts for possible exposed by the X-ray of patients should be protect. 9. All personnel should be as far as possible to reduce the time in the X-ray field. 10. Repeated exposure to the same patient at high frequency is prohibited.

NOTE！	All body parts exposed to radiation exposure should be measured, and the exposure dose must not exceed the acceptable tolerance.

1.7 Fire Safety

 **WARNING!**	● Only use the electric fire extinguisher or the chemical fire extinguisher. Water or other liquid extinguishers may result in serious or even fatal injuries to personnel. ● Ensure that the radiator of collimator, when once the light is on, ensure that the vents are not covered by other objects.

1.8 Environmental Protection

According to the requirements of safety and environmental protection, manufacturers design and manufacture X-ray equipment. This device will not cause any harm to people or the environment, if

you did not take apart any cover of the product, or always use the equipment properly.

Under the condition of rules allow, if the use of material may cause damage to the environment, it must be handled in the right way.

 **WARNING!**	1. The waste generated by X-ray equipment can’t be treated with industrial or household waste together. 2. Handling of waste generated by X-ray equipment in the right way in accordance with the requirements of the local environmental protection regulations. 3. Reusable materials can be recycling used to reduce the environmental pollution by the qualified waste disposal company.

Please contact the manufacturer's service, or proper disposal of the method according to the local garbage collection facilities.

FOR YOUR NOTE

Chapter2 Product Presentation

2.1 Overview

Digital mammography system (MXR-550) is a breast X-ray radiography equipment, which is development and produce by HEDY Medical Device Co., Ltd. It is mainly composed of high-volt generator, generator cabinet, X-ray tube assembly, collimator, detector, C-arm, console and breast image acquisition workstation, which can be used for the diagnosis of radiography in medical units.

The main characteristics of the system are as follows:

- Consistency and ease of use, meet different location radiography, convenient to handover the radiography mode.
- Has the function of self-protection and patient protection.
- Power on self-test, error indication.

In addition, the system supports the wheelchair model, which can normal operate to the wheelchair patients.

2.2 The Range of Application and Contraindications

The range of application: specialized in human breast tissue radiography, access to tissue imaging for clinical diagnosis.

Contraindications: /

2.3 Environmental Requirement

- **Work environment**

Temperature: 10℃~40℃.

Relative Humidity: 30%~75%.

Atmospheric Pressure: 700～1060hPa.

- **Storage environment**

Temperature: 5℃~40℃.

Relative Humidity: 20%~85%.

Atmospheric Pressure: 700～1060hPa.

2.4 System Structure

2.4.1 Gantry

The main components of gantry are C-arm and column, as shown below:

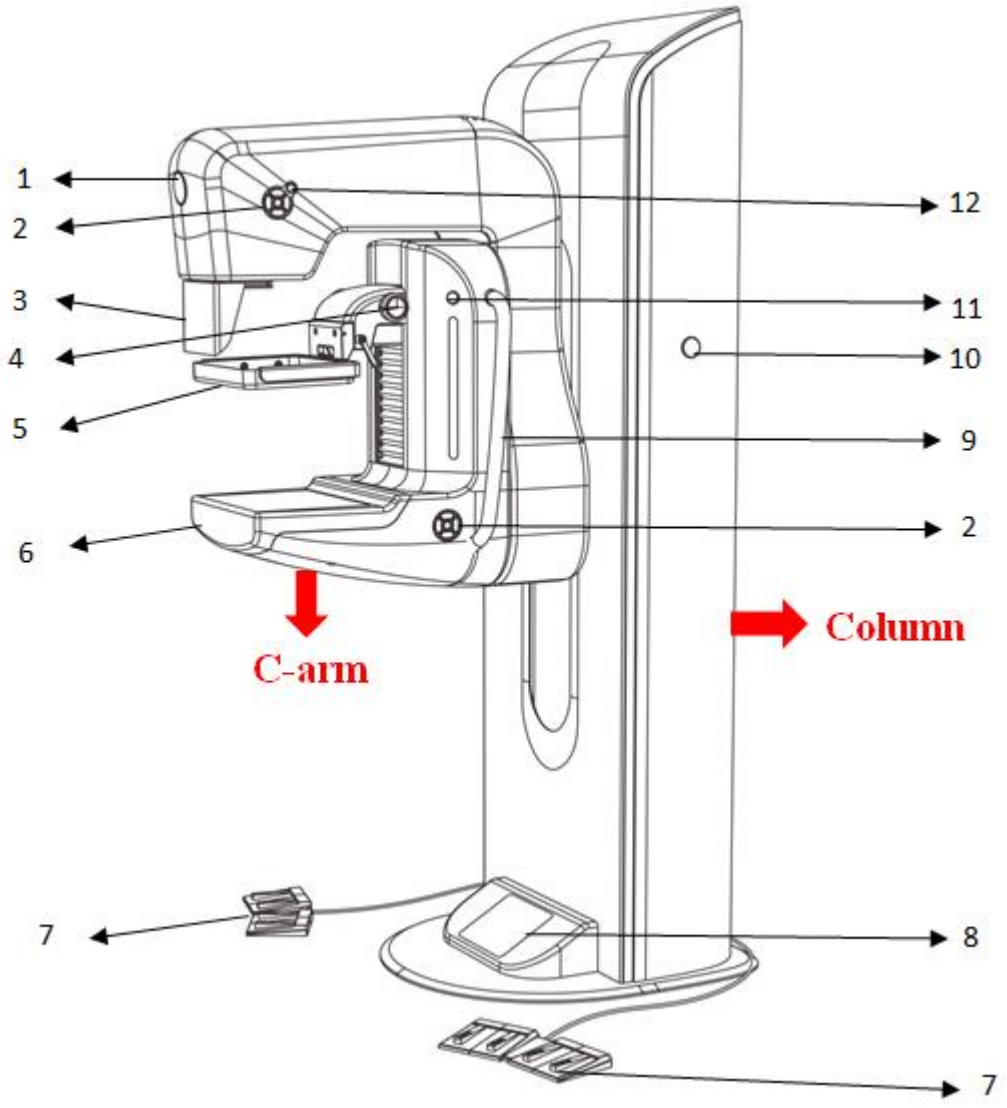


Figure 2-1

No.	Part name	No.	Part name
1	The X-ray tube subassembly	7	Footswitches
2	C-Arm movement control buttons	8	The LCD display
3	Face protection shield	9	The Patient Handles

4	The Compression Handwheels	10	The Emergency Off switch
5	The Compression Device	11	The Fast Compression release button
6	The Patient platform	12	The collimator light button

Tube subassembly: The tube assembly consists of tube and collimator.

Face protection shield: Face protection shield is mounted on the front of the X-ray tube and it can prevent the patient from the head into the X-ray region.

The Patient platform: Including digital detector and reciprocating filter two part. The system can realize two kinds of radiography mode with filter or automatic out of filter. (System reserved buttons to achieve automatic out of filter operation).

The LCD display: Located in the lower part of gantry, display normally shows the following information:

- Breast compression thickness
- Angle of rotation.
- Compression force.
- Compression mode (Ordinary radiography model, Enlarged compressed mode and enlargement factor).
- The current checking view.

The Patient Handles: The patient's hand may be positioned on the handle as required, for greater comfort and to optimize access to the breast, especially for lateral and oblique view.

The collimator light button: When the collimator light is off, turn it on by pressing this button. The light turns off automatically after the delay time of the software setting.

Note: All the button, rotary knob and the handle are symmetrically distributed on both side of the gantry.

2.4.2 Generator Cabinet

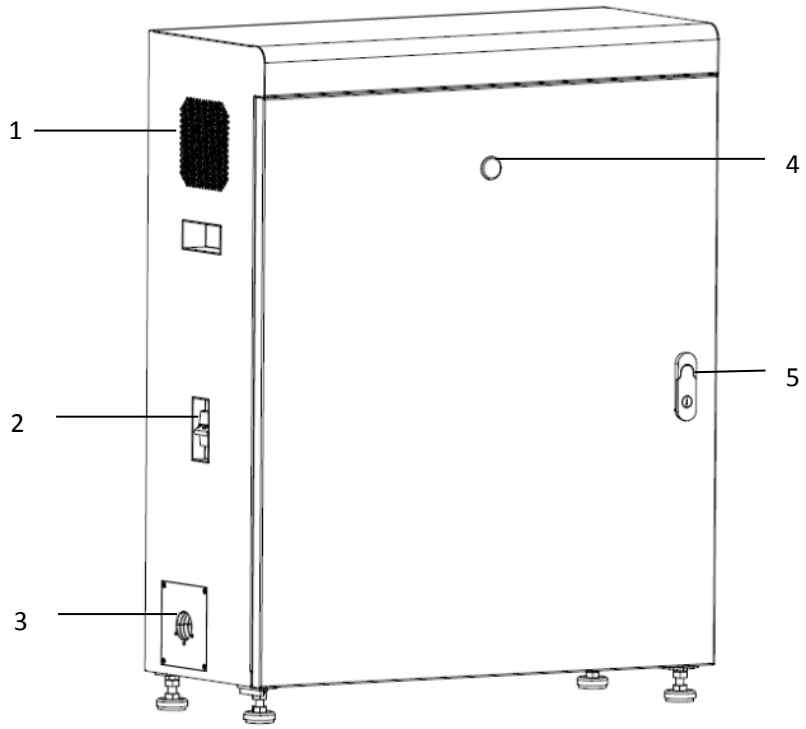


Figure 2-2: generator cabinet

No.	Part name	No.	Part name
1	Louver	4	Status indicator light
2	Air switch	5	Cabinet lock
3	Outlet hole	/	/

Function description is as follows:

Status indicator light: The light turns on when the generator cabinet starts to work.

Air switch: “OFF” disconnected the connection between the generator cabinet and the net power supply; “ON” connected to the net power supply.

The generator cabinet has power supply board, high voltage generator, the electric part and so on.

Five minutes after power off, you can open the high-volt generator on the generator cabinet.

2.4.3 Console (optional)

The independent console placed in the examination room, convenient the operation of doctor. And the protective shield on the console can protect the operator from X- ray exposure. You can also

choose to configure the scan code gun.

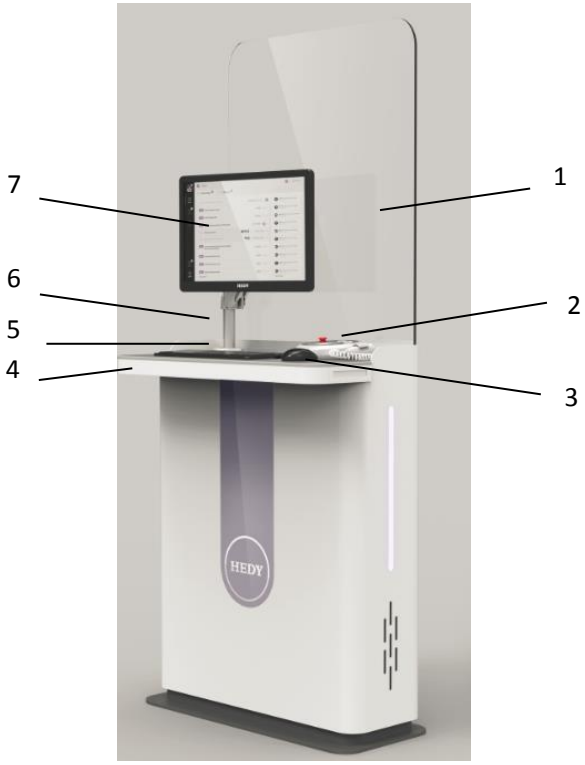


Figure 2-3: console

No.	Part name	No.	Part name
1	Ray protection shield	5	Keyboard
2	Control box	6	File storage area
3	Mouse	7	Monitor
4	Burning device	/	/

2.4.4 Image Acquisition Workstation

The image acquisition workstation includes a host computer, a monitor, an alphanumeric keyboard, and a mouse. The workstation computer is installed with image processing system to achieve management over patients and images.

Image acquisition workstation has the following functions:

- Using Patient login and information management of standard DICOM.
- Using digital detector for image acquisition.

- Image display and processing.
- Using DICOM 3.0 standard transfers the image to image acquisition workstation.
- Burning the image into DVD disc.
- Output the image to the film printer.
- System configuration and calibration.

NOTE！	1. Check the system clock of the computer periodically, to ensure the accurate checking time of the patient. 2. The computer should be installed with antivirus software before network connection to prevent network viruses from attacking the DROC software.

NOTE！	The monitor in the Image acquisition workstation for display images, its resolution should not be less than 1280 × 1024, the contrast should not be less than 1000: 1. Otherwise it will affect the diagnosis.

 **WARNING!**	1. Suddenly lose power or hard disk operation is not standard, may cause the system data loss. 2. Please don't install other software in the computer system, or the operating system may collapse cause data loss.

2.4.5 Exposure Device

This equipment has two exposure devices, control box and exposure handbrake. There have a brief description below.

2.4.5.1 Control Box

Figure 2-4: control box

No.	Part name	Function
1	Automatic positioning keys	The equipment runs automatically to the pre-set location.
2	**ON** button(with indicator light)	Press to turn the equipment ON
3	**OFF** button	Press to turn the equipment OFF
4	Press release button	Press to make the paddle immediately rose to 120mm or more, automatic pressure release.
5	Compression plate automatic release function selector switch	Press this button, release the paddle automatically after the exposure
6	Emergency stop switch	Press to cut off the gantry and high voltage generator power supply at the same time
7	Exposure button(with indicator light)	Press to exposure; green light: preparation orange light: exposure
8	Buzzer	Sound an alarm when the boot after self-checking, exposure and error

2.4.5.2 Exposure Handbrake

The button in top of the exposure handbrake has three states, respectively is: close, preparation, and exposure. Details see the table below:

States	Sample Pictures	Description
OFF		There is no pressure on the top of the button, the exposure handbrake in the "off" state.
Prepare		When the button is part of the press as the "ready" state, the system will improve the rotor speed and heating filament, prepare and make sure the system is ready to exposure. If the button is released, it returns to OFF position.
Expose		When fully pressed the button on the exposure handbrake ， it is "expose" state.

NOTE！	For exposure, directly press the handbrake fully can also be exposed without preparation.

2.5 Attenuation equivalent

The attenuation equivalent of the components in the X-ray beam (30kV, 0.3mm aluminum of half value layer).

Components	Attenuation equivalent (mm Al)
Magnification table (1.5 or 1.8)	0.1
Carbon fiber plate	0.2
Paddle	0.1

Chapter3 Installation and Testing

3.1 Room Requirements

3.1.1 Room Space Requirements

- Installation area: 2.6m×2.5m.
- Operation room area: 1.5 m×2.5m.
- Room height: ≥2.5m.
- The door height: ≥2.0m.
- The door width: ≥1.0m.

3.1.2 Room Floor Requirements

1) The floor should be smooth cement floor or tile floor, must be stable and flat, and concrete thickness 150 mm or more.
2) The room should install air conditioners and dehumidification equipment in advance, completes the moisture-proof, waterproof, rat-proof measure and equipped with appropriate lighting and power socket.

3.1.3 Room Environmental Requirements

1) Environment temperature: 10℃～40℃;
2) Relative humidity: 30%～75%;
3) Barometric pressure: 700～1060hPa.

3.1.4 Power Condition

Hospital network power supply needs to meet the conditions:

1) Voltage：Single phase AC220V;
2) Mains frequency: 50 Hz;
3) Source resistance: ≤0.5Ω;
4) The instantaneous power input: ≥10kVA;

5) Current release characteristic: 220VAC, 50A.

NOTE！	If the network power supply of the room is not stability enough, higher than the rated voltage or low voltage condition need to configure the regulated power supply. If often blackout, need to configure the UPS power supply. The output of UPS power supply need to meet with the power requirements of machine, the rated power output suggest 30% larger than the machine rated power input.

3.1.5 Protection Requirements

The protection requirements of the room need to meet the national radiological protection standards, recommended the following protective measures:

1) Examination room brick wall is 370 mm thick (equal to 2 mm lead equivalent), concrete wall thickness should be in above of 200 mm.

2) The lead glass between exam room and operator room thickness > 1.5 mm lead equivalent, vision acuity 0.25 ㎡, the height glass center distance: 1200 mm.

3) Ceiling of 1.0 mm lead equivalent.

4) Exam room of ground floor, for protective treatment of the ceiling of the examination room with 2 mm leads equivalent protection. To the second floor above, just for ground protection processing, with 2 mm lead equivalent protection.

5) When the exam room is on the first floor (regardless of bungalow or buildings), the external windows should be adopted 1.0 mm lead equivalent of lead glass or covered by 240mm brick wall.

3.1.6 Wiring

There have line hole between exam room and operator room. If it is the ground hole, the wall of exam room must have 500 mm long, 100 mm wide, 50 mm high board holes, with 2 mm lead leather cover surface.

3.1.7 Radiation Hazard Warning Sign

Outside the exam room must have marked the radiation hazard warning signs and lights. When the indicator lights up, close the room door, and others without permission shall not enter.

3.2 Installation Preparation

3.2.1 Unpacking and Unloading

1. Notes

1) Ensure the transit of packing-case from the car to install room, have not steps and large slope.

2) Due to the equipment frame, need to trailer handling.

3) Be careful and steadily to transfer the detector, avoid damage to the detector by jounce.

4) Please according to the installation's order transfer the packing-case, if the space of installation room is small.

5) There needs at least two skilled workers in the whole process of transport.

2. Before spilt open a case, make sure the total number of cases and check the boxes for damage phenomenon, if found to have damaged phenomenon, immediately notify the carrier or agent.

3.2.2 Installation Tools

No.	Name	No.	Name
1	socket wrench(21 sets)	9	monkey wrench
2	Allen wrench(9 sets)	10	flathead screwdriver
3	Phillips screwdriver	11	multimeter
4	diagonal cutting pliers	12	nipper pliers
5	percussion drilling	13	gradienter
6	oil pen	14	plumb bob
7	flexible rule	15	cable ties
8	gerny	16	cutter knife

3.3 Installation Instructions

3.3.1 Installation Process

Install the gantry→ install the platform of radiography→ install the X-ray source component→ install the generator cabinet →install image acquisition workstation.

3.3.2 Installation Steps

1. Install the gantry

Install the gantry to the specified location, aim at the playing mounting hole in advance, fixed the gantry on the ground with supplied screw.

 **WARNING!**	The installation staff must be careful when transfer the equipment, avoid injuring or crushed or cause equipment damage.

2. Install the platform of radiography (detector and grid)

1) Adjust the C-arm to proper position for ease of detector installation.

2) Install the cooling fan in the detector support platform, pay attention to the direction of the installation of the cooling fan.

3) Place the detector on the supporting platform, adjust to the proper location, fixed the detector on the platform with supplied screw.

4) Install detector protection on both sides of supporting platform to prevent the friction between the detector and grid.

5) Connect the power cord, signal lines, cable to the detector and settle the circuit. Install grid in the grid bracket, check the movement of grid after connected to power supply.

6) After the installation, put the shell outside-in into the radiography platform, buckle with the shell of C-arm.

NOTE！	The detector is a valuables that should be taken lightly, and be careful to fall.

NOTE！	The detector surface can’t load more than 1kg.

3. Install the X-ray source component

1) Connect the power cord between the generator cabinet and the gantry. Press the height adjustment knob to make the C-arm has a proper location for ease of the X-ray source component installation.

2) Take out the tube and collimator from the packing-case; Then remove the flange on the collimator and install it on the outlet window of tube, fixed it with supplied screw.

3) Place the tube on the tube mounting plate, make the outlet window of tube straight down, pay attention to the corresponding mounting holes and fixed the tube with supplied screw.

4) The connection between collimator and tube can refer to below:

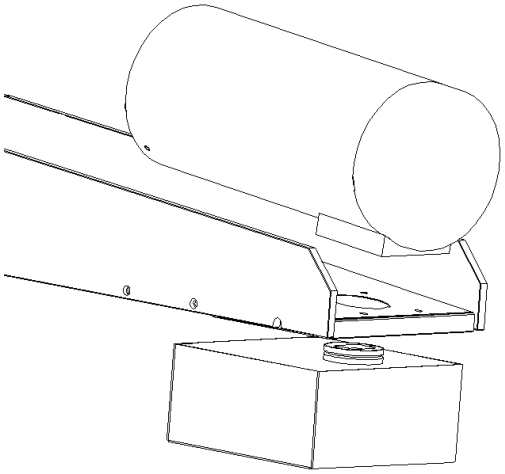


Figure 3-1

5) Connect the tube high voltage cables and the stator filament connector.

6) Cover the X-ray tube assembly with the outer cover.

4. Install the generator cabinet (contain high-volt generator)

1) Transport the generator cabinet and high-volt generator to the designated location, tear down the packing cases.

2) Rotating anode connection: the tube rotating anode connected to the TB2 terminal of high-volt generator.

3) High voltage cable connection: clean up the high-voltage pothead with absolute alcohol or 95% alcohol, coated with high voltage silicon grease. Then inserted one end of high-voltage cable into the high pressure slot of high-volt generator and lock, and the other end insert high pressure slot of tube and lock.

4) High-volt generator network power supply connection:

- Net power input interface: TB1-1 (This system uses single-phase 220 v ac power supply as the main power supply).
- Ground wires: TB1-1.

- Single-phase ac wire: TB1-2, TB1-3.

5) Connect the power supply cord and signal line between the generator cabinet and the equipment, finally connect the room power supply.

NOTE!	The high-volt generator box should not tilt more than 20 ° above in the process of transport.

 **WARNING!**	The generator can provide enough power even to destroy the tube, so the users should limit the maximum exposure to X-ray tube within the range of rating. Manufacturer does not assume any due to incorrect use of the generator of the responsibility for the damage to the X-ray tube.

NOTE!	Before connection, be sure that the switch of Network power supply is broken.

5. Install image acquisition workstation

1) Take the computer host, display screen, mouse, keyboard out of the packing;

2) Connect the mouse and keyboard to the corresponding interface on the host back;

3) Connect the host to the network interface of hospital with cable;

4) Connect the video display wires to the back of the host;

5) Connect the monitor power cord to the power supply.

3.4 Testing Instructions

3.4.1 Machine Testing

In the machine testing process, must strictly carry out the following requirements:

1. It’s not allowed to put sundries in any part of the equipment. If you need to set test instrument, you should put protective film on the parts and the detector is not allowed to set test instrument directly.

2. Before starting, first to verify the correctness of the connection position throughout; when the equipment running, ensure the movement within the scope of barrier-free.\

3. During the exposure, irrelevant person shall not stay in the exam room, and the door of it must be closed.

4. Open the detector power supply before ten minutes of the test; the system will cut off the power supply during disassembly.

5. Don't allow install other software on the host workstation, does not allow for has nothing to do with the production of other actions.

NOTE!	1. Before leaving the factory, the equipment has made the machine testing by the professional person (including mechanical movement and imaging chain characteristics of testing), the user need not again for equipment testing. 2. The installation and testing of the equipment must be handled by the authorized professionals.

3.4.2 Calibration

The detector settings may be subject to changes in the external environment (eg temperature fluctuations, humidity, vibration). Therefore, the detector must be calibrated periodically. The calibration process is as follows:

1. Double click on the new DASA installer file to launch installation.

Figure 3-2

2. Click on install.

3. Click on close to exit the installation.

4. Launch DASA application. DASA is located in “C:\Pegasus\bin” directory.

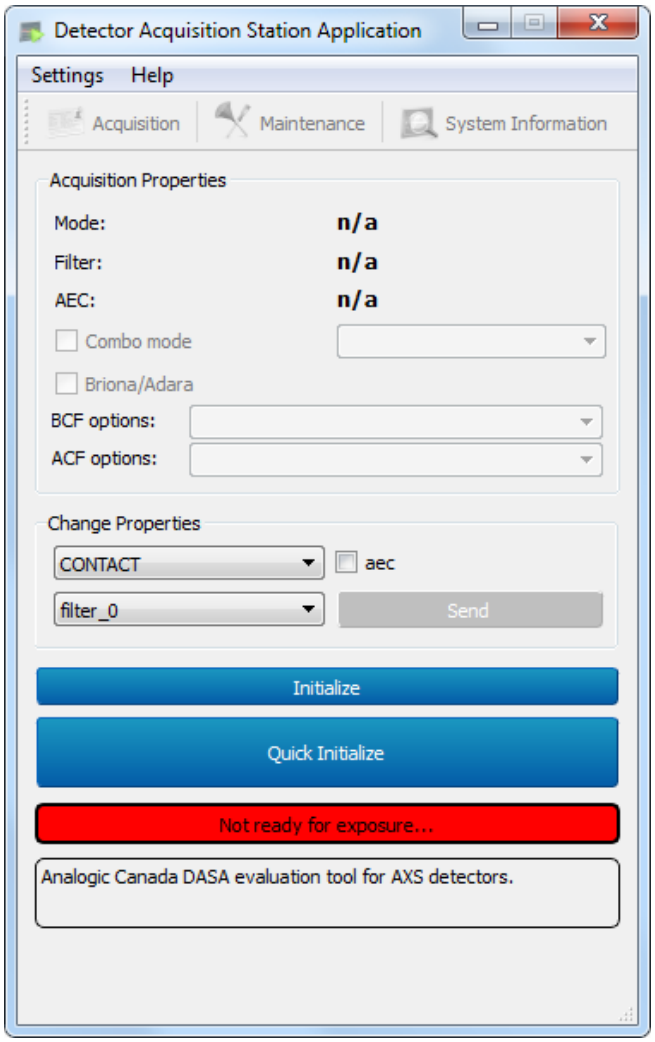


Figure 3-3

5. Click on Initialize.

This command will perform several tasks such as:

a. Initiate communication between Host and the Detector;

b. Perform a Startup calibration(this makes sure that the detector images are stable);

c. Perform Initial Electronic Offset (EO) Acquisition for every enabled Contexts. This step performed on first installation or if the Eos been erased from the disk. Eos are saved in “C:\Pegasus\temp” directory.

Once the Initialization is completed, DASA should look like this.

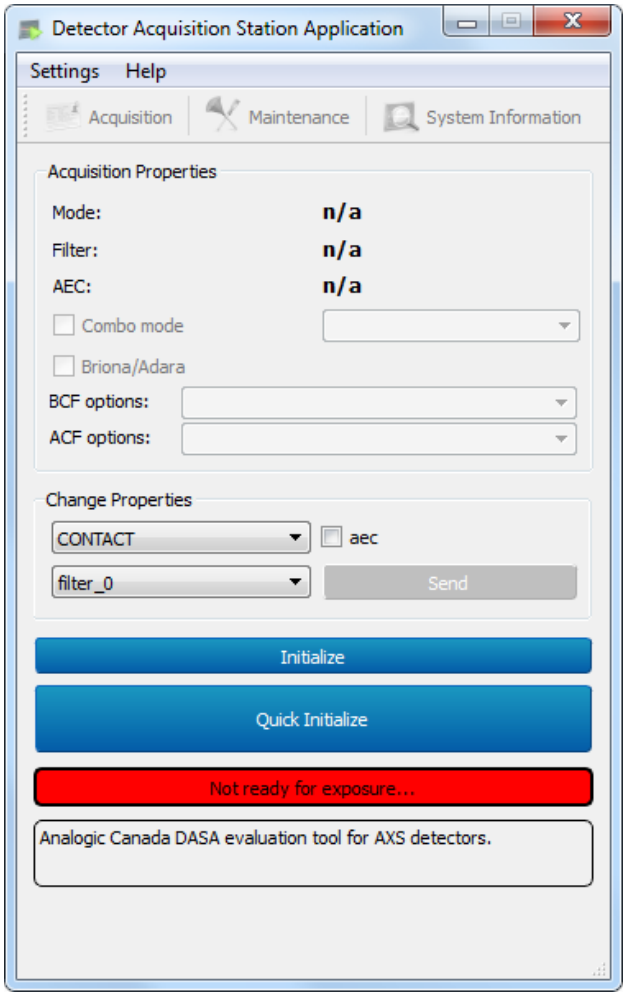


Figure 3-4

6. Calibration

In this section, we will calibration Contact and Tomo1 context to handle 1 filter each.

7. Contact

DASA Acquisition Properties window shows the current state.

Figure 3-5

Currently, the system is in Contact context, the first filter is selected and the AEC mode is disabled.

a. To calibrate, click on the Maintenance tab.

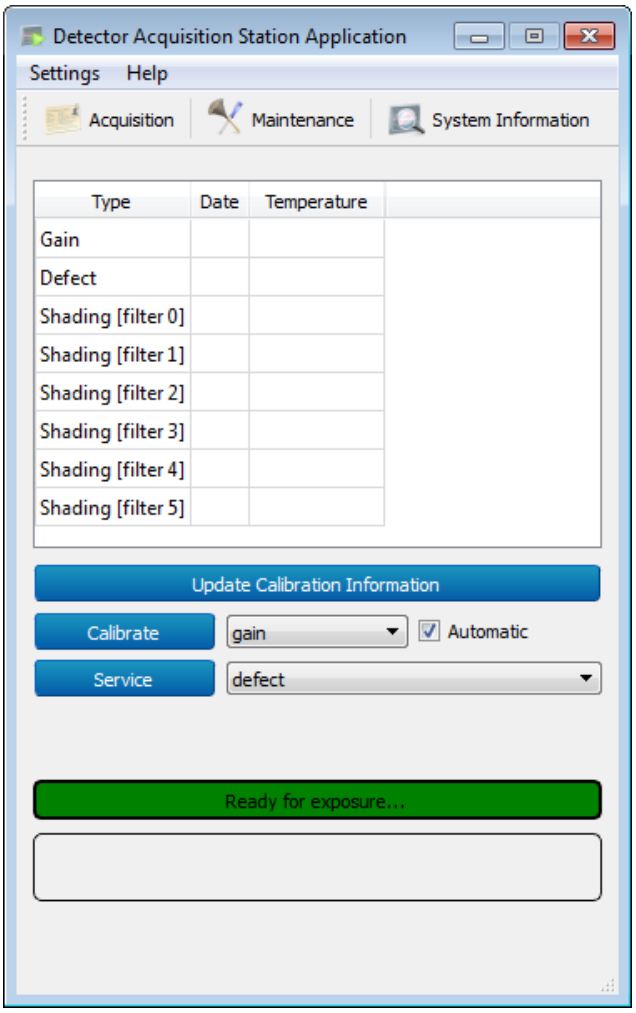


Figure 3-6

b. Select gain and click on calibrate. This operation will take about 2 minutes to complete.

c. Click on “Update Calibration Information” to confirm that the Gain calibration has just been updated.

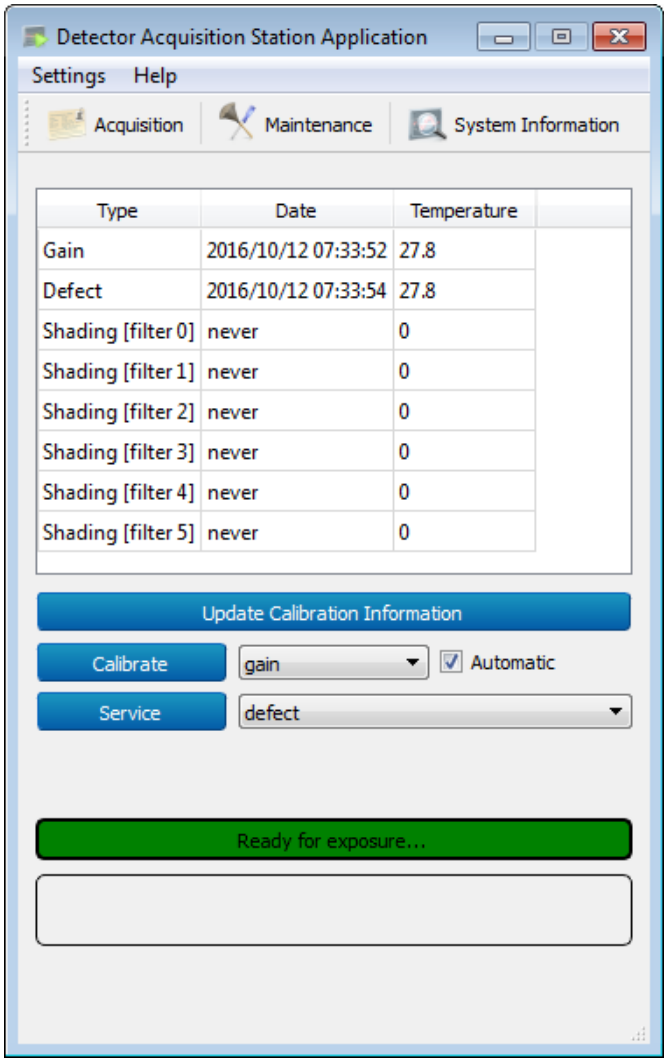


Figure 3-7

Notice that the Gain calibration also updates the Defect Table.

d. Select “Shading” from the drop down menu and click on “Calibrate”.

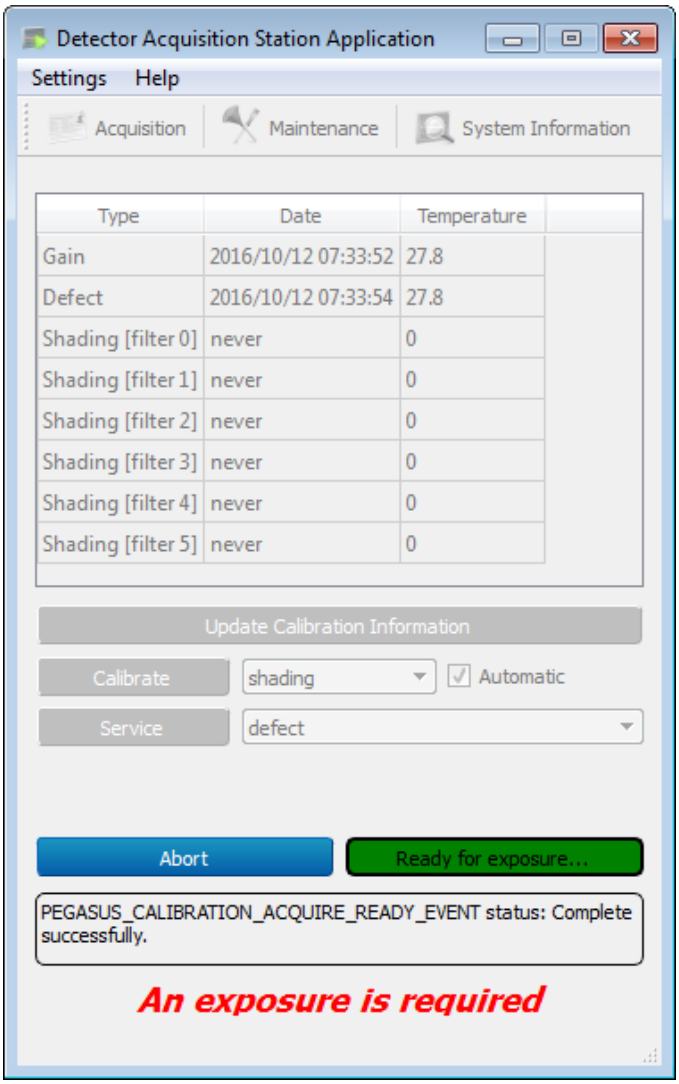


Figure 3-8

e. At this point, a X-Ray exposure is required. Only one exposure is required.

Here, we will be using the following parameters:

- Mo-Mo
- 28kV, 200mAs
- 4cm PMMA on collimator
- No grid and no bucky.

Once exposed, the computing will take about 1 minute to complete. According to the above method, it is possible to deal with artifacts caused by human factors.

Click on “Update Calibration Information” to confirm that the Shading for filter_0 calibration has just been updated.

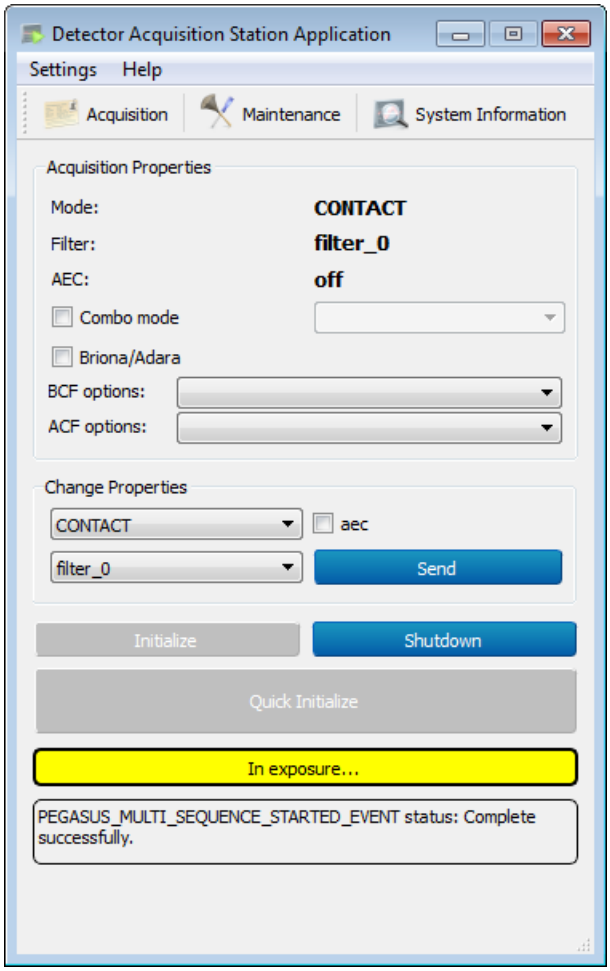
Type	Date	Temperature
Gain	2016/10/12 07:33:52	27.8
Defect	2016/10/12 07:33:54	27.8
Shading [filter 0]	2016/10/12 07:39:56	28.6
Shading [filter 1]	never	0
Shading [filter 2]	never	0
Shading [filter 3]	never	0
Shading [filter 4]	never	0
Shading [filter 5]	never	0

Figure 3-9

Notice that the shading calibration don't update the defect table.

f. To update the defect table using X-Ray, the defect calibration can be performed by selecting "defect" in the drop down menu and clicking on "Calibration". We recommend using the same exposure conditions as for the Shading Calibration.

g. To validate the calibration process, expose the detector in the same condition used for the shading to obtain a Flat Field image.



The images are saved in “C:\Pegasus\temp”.

The image will be displayed on the right side of DASA. We will introduce the viewer later.

The calibration is a success when you obtain a Flat Field image.

NOTE!	After the calibration of the detector, it must be detected by the factory engineer for dot and line defects. To ensure that the line defect width ≤ 4 pixels, the dot defect ≤ 2 ×2 pixels.

3.4.3 Trial Operation

End of testing, exposure by using test card or body model as test objects, to judge whether the machine is normal.

Chapter4 Operation Instructions

4.1 Start up

1. Open the total brake power of room.
2. Check the emergency stop switch status of system.
3. Press the shift knob on the control box, the system is in a power-up state, including (image acquisition workstation, high-volt generator, the machine and detector, etc.).
4. Open the printer.
5. Check to see if the dongle has been good, if not, inserted the dongle to USB interface in the host, start the image processing software.

4.2 X-ray Tube Preheating Process

If the lack of tube preheating process, it will affect the regular exposure effect of tube. Perform the preheating process of tube will prolong the service life of the X-ray tube. When the user turns on the equipment every day and the selected tube under the condition of long time unused, perform the preheating process of tube according to the following steps.

1. Close the blades of collimator completely.
2. Select the exposure parameter: 30 kV, 50 mA, 500 ms.
3. Make sure there are no personnel by radiation.
4. Each time exposure operation, a total of 3 times interval of 30 s.

 **WARNING!**	Before the effectively exposure operation, please make sure that the tube fully preheat.

4.3 Examination Operation

Typical of the examine procedure as shown below:

1. Choose the paddle according to the details of examine.
2. When necessary, can install the face protection shield.
3. Adjust the C-arm to the required angle.
4. Adjust the C-arm to the correct height.

5. Check whether the green light on the generator cabinet or the display on the gantry lights up.
6. Check to see if the dongle has been plugged correctly, double-click the desktop icon or in the start menu to open the image processing software.
7. User login: operators on first select the user interface, enter the correct password landing or fingerprint, can use the system;
8. Medical record entry and selection: choose existing medical records or entry medical record information such as name, ID, etc.;
9. Check the patient information: operator determine the patient and the examine view of patient, and then let the patient into the exam room and check according to the patient's application form to the patient ensure accurate patient’s information.
10. Mammary gland placement on breast radiography platform or Magnification table.
11. Using pressure foot or manual compression/decompression knob to adjust the paddle, and the Stress and thickness of the mammary gland display on the screen display
12. Ensure correct mammary gland oppression. Using the collimator light to check the skin folds in the process of oppression.
13. Ensure that only breast exposure in the wild.
14. Set the exposure parameter in the examine interface of the image acquisition workstation.
15. Exposure. Press the exposure key or press the handbrake switch to “Prep” position to X-ray tube. Continue to press the button or press the hand brake switch completely until the "Exp" position, X-ray exposure, and keep pressing in the process of exposure. In the process of exposure, exposure indicator will light.
16. At the end of the exposure, loosen the button or handbrake button.
17. After the exposure, manual or automatic release pressure immediately to ensure the patient’s breast is free.
18. If the dose calculation function is enabled, the user can read out the calculated dose value of the glands in the main screen.
19. Accept or reject: after the exposure (or collection), the system will automatically appear image, and then select the appropriate grayscale curve type. According to the image quality to refused or receive the image
20. Image post-processing: exposure conditions and the size of the X-ray image doesn't suitable, cutting and adjusting the window width and window level, to balance adjustment of image gray-scale, make the X-ray images to achieve satisfactory effect.
21. Print film: according to the different situation choose single and multiple image printing.
22. Send the images: click the “send” button to send the image into the image management center for the diagnosis of physicians diagnose;

Repeat the above procedures if you need to continue to exposure.

The equipment should be used in a well-ventilated environment, during the normal use, the equipment in a natural air convection way to radiate heat.

NOTE!	To ensure the image uniformity, the tube should be perpendicular to the detector when exposure. Otherwise the resulting image is uneven around, affecting the quality of the captured image.

 **WARNING!**	If you loosen the exposure handbrake did not reach the time set by the inspection procedures, may interrupt the exposure accidental, the acquired images are not normal diagnosis.

4.4 Shutdown the System

1. Press the OFF button on the control box, shut off the computer and machine.
2. Shut down the printer according to the printer operator manual.
3. Close the generator cabinet power supply.
4. Close the total brake power of room.

4.5 Special Operations

4.5.1 Remote Cloud Diagnosis

Adopt world-class innovative data compression and transmission technology, through the connection between the other computer, tablet, mobile phone and other intelligent device and the host image acquisition workstation, can realize remote image transmission, diagnosis and other operations, the construction of the hospital, hospital cloud consultation platform, the implementation across the hospital, the basic-level hospitals and consultation expert point, at any time and place, cross-platform real-time communication, interactive operation of cloud consultation system. Promote the Remote consultation diagnosis rate and utilization rate, has great effect for integration of the optimize allocation of medical.

4.5.2 Magnification Radiography

The magnification radiography always adopts two different projection views. Dedicated point pressure device can give more effective oppression to the part of the breast; expand the overlapping structure to make the lesions showed better.

Use increase 1.5 or 1.8 times the Magnification table (optional). After installed the Magnification table, the system can automatically detected on the table and into the radiography model. The subsequent operation is reference 4.3 radiography amplification content.

1. Installing the Magnification table

1) The installation of brackets of Magnification table

Remove the sealing device on the installation interface of bracket, push the bracket into the reserved card slot and then the bracket will be automatically locked in place.

2) The installation of Magnification table

Hold the handle on the Magnification table, put the Magnification table on the breast radiography platform and aim at mounting holes, and then push the Magnification table until it will be automatically locked in place.

2. Removing the Magnification table

Press the button on the breast of Magnification table, pulling the platform out from the breast radiography platform at the same time.

NOTE!	As soon as the magnification table is mounted, the grid is automatically retracted from the field of the collimator and the small focal spot is selected.

4.6 Mechanical Movement

The mechanical movement of the system including C-arm movement and the paddle movement, the system has the software limit, electrical limit and mechanical limit function, can lock the mechanical movement in a specific location.

 **WARNING!**	Check whether there is any obstacles in the equipment moving distance before the movement of the equipment, always take care of the C-arm action in the movement to avoid hitting nearby person or equipment.

4.6.1 C-arm Movement

There are two kinds of C-arm movement, one is the vertical movement along the column, and the other is C arm for rotary motion.

4.6.1.1 Vertical Movement

Range of movement: 630mm ~ 1440mm, deviation: ±5%

Operation mode: there are motion control button on both side of C-arm compressor bracket and the tube to adjust the C-arm to the required height and angle.

Figure 4-1：Motion control button

C-arm upward movement: keep pressing the  button to rise up the C-arm.

C-arm descending movement: keep pressing the  button to bring down the C-arm.

4.6.1.2 C-arm Rotation Movement

Range of C-arm rotation angle: clockwise + 195 °to anticlockwise 155 °. As shown in the above figure of the motion control button to control the rotation of the system.

Automatic positioning function buttons  : Equipment has the function of automatic positioning, can run automatically to the preset position. There are two ways which configured in software to touch off:

- Keep pressing until running in place.
- After inching (keep 2s), the C-arm run in place automatically. (When stress ≥30 N, the key function is prohibited)

when you select one or more views in the image acquisition software, manually press and hold the button, the system automatically run to the selected first position; If itself in the position, do not do any response; After arrived in the first place, hold down the button again, the system automatically run to the next position of the selected; Filmed in turn until all positions.

C-arm clockwise rotation movement: keep pressing the  button to continuous adjusting C-arm clockwise rotation angle.

C-arm anticlockwise rotation movement: keep pressing the  button to continuous adjusting C-arm counterclockwise rotation angle.

When the C-arm arrives in angle 90 °, 0 °, 90 °, there was a short pause of C-arm movement, keep pressing the rotation button to carry on.

Rotating of C-arm has self-protection function: When the C-arm after the overall height to a certain degree, make sure the tube dose not hit the ground, and in any state, the tube shell high from the ground should be 100mm (±10mm) above the safe distance.

In the non-safe range, if you want to rotate the C-arm, firstly let the C-arm upward to the safe distance, and then rotating the C-arm.

NOTE!	**When the paddle is stress(≥30N), the C-arm lifting and rotation motion is locked.**

4.6.2 The Movement of Paddle

Range of movement: the range of up and down movement of the paddle is: 245mm, deviation is ±10%. When reach the setting limit position, the paddle shall not continue to exercise.

Operation mode: manual regulation and electric control.

Manual regulation: Use the adjusting knob on the both side of the gantry to adjust the position of the paddle, manual compression or decompression operation, rotating the hand wheel clockwise to bring down the paddle, rotating the hand wheel counterclockwise to rise up the paddle.

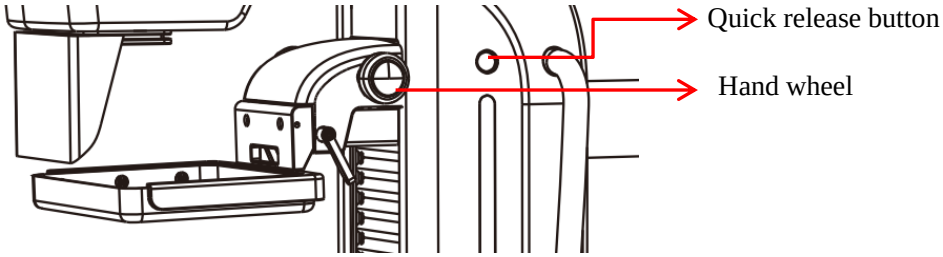


Figure 4-2

Electric control: Use electric method for control of the paddle. Equipment is equipped with two pairs of pedal switch to electric pressure and release stress, directly using the corresponding foot switch to control paddle move up and down. There are two sets of combination pedal switch (a total of eight switches), symmetrical distributed in the both side of the column.

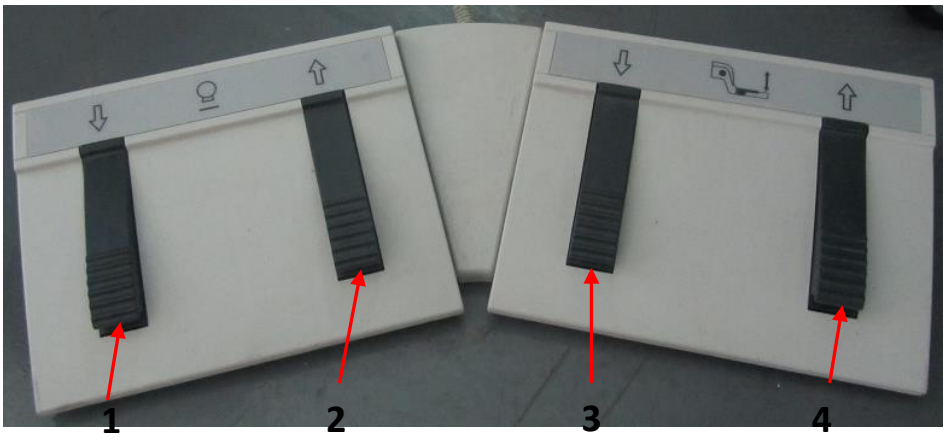


Figure 4-3: pedal switch

No.	Name	Function
1	C-arm descending motion control pedal switch	Depress this pedal switch, bring down the C-arm, support for fine-tuning and continuous adjustment.
2	C-arm upward movement control pedal switch	Depress this pedal switch, rise up the C-arm, support for fine-tuning and continuous adjustment.
3	paddle descending motion control pedal switch	Depress this pedal switch, bring down the paddle, support for fine-tuning and continuous adjustment.
4	paddle upward movement control pedal switch	Depress this pedal switch, rise up the paddle, support for fine-tuning and continuous adjustment.

The electric control of the paddle is as follows:

Descent process: after the stress reaches 30N, the paddle began to slow until the preset stress. The initialize the default values of the electric oppression is more than 70N, and the values can be set by the rotary knob on the oppression system. Use more pressure if necessary, the user can adjust it by the knob manual function.

Rising process: The paddle upwards at a constant speed, and has limited device in the highest.

In the case of already under the compression state, if you want to oppress again, hit the paddle descending motion control pedal switch twice and then to oppression.

NOTE!	**1. Electric oppression and manual compression has the largest stress limit, when more than the threshold stress no longer increases.** **2. Put the foot switch to proper place, in order to avoid the unexpected start-up by the patient and operator.** **3. In an emergency of equipment failure or operator error etc., press**

	the emergency stop button to stop all the movement of the system. **4. In the case of a power outage, use the manual way to reduce pressure.**

Compression paddle loading and unloading

Loading: Push the paddle into the oppressive system card slot, paddle will automatically lock in place, at the same time, system can automatically identify the paddle specifications.

Unloading: remove the locking of paddle, at the same time, pull out the paddle in the oppressive system.

4.6.3 Adjust the collimator light field

1. Control the collimator indicator light

- **Manual control**

In the both sides of the C-arm has a collimator indicator light button to control the indicator light. Press the button to lighten the indicator light and the light will keep up 30 seconds. Press the button again to turn off the light.

- **Intelligent control**

In the oppression, the collimator indicator light will automatically turn on when the paddle moves down and the light will keep up 30 seconds. Manually press the collimator indicator light button on the C-arm to turn off the light.

Collimator indicator lamp: when the paddle in the process of moving down, the collimator indicator lamp will light up automatically and continuously put out after 30 s.

2. Adjust the collimator light field

According to the detected platform, the collimator light field will automatically switch to the corresponding size. Click on the compression release button, the collimator light filed will automatically down to minimum size(0×0 ㎝).

In the case of using normal radiography platform, collimator light filed size is 24 cm x 30 cm, SID is 660 mm, deviation is + / - 5%.

In the case of using 1.5 times Magnification table, collimator light filed size is 16 cm x 20 cm, SID is 440 mm ,deviation is + / - 5%.

In the case of using 1.8 times Magnification table, collimator light filed size is 13.3 cm x 16.7 cm, SID is 366.7 mm ,deviation is + / - 5%.

There has a ruler under the collimator, pull it out and measure the distance between the focus to the paddle.

Chapter5 DROC Instructions

Summarize

The DROC has been installed in the image acquisition workstation before they leave the factory. Through the DROC, the user can process the system settings, DR examine, browse the images, picture processing, film printing and record operation and so on.

5.1 User Login

Before start the system, first check the power supply and hardware whether open and normal work, and then open the DROC according to the following steps:

First step: start the system.

After start the computer, double-click the DR icon on the desktop or click DR item in the beginning program, the login interface will popup.

Second step: user login.

There are two ways of login: one is through the user name and password authentication to log in, the other is fingerprint verification login.

1. Login by user name and password authentication

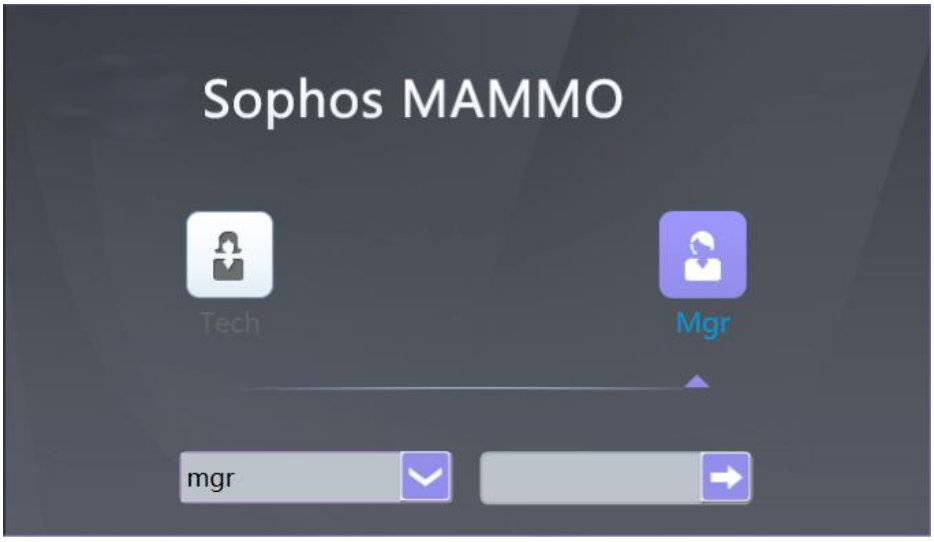


Figure 5-1： Login window

1) Choose login user's identity in the login window.

The two ICONS in the login window represent the two kinds of identities: Tech (technician) identity, Mgr (system manager) identity. The default initial user of the system is manager, and the manager user can have only one. All the newly created users are technicians.

Identity name	User name	Password
Mgr	mgr	mgr

After selected the login identity, the last login user name (If present) will be automatically displayed on the user name text box.

2) Enter the password to login.

Enter the correct password in the password textbox, click the arrow button on the right of textbox or press the enter key on the keyboard to login.

Note: when enter the password, there are not display related information of characters and not to paste the characters.

NOTE!	The passwords are case sensitive. There are five chances to input the wrong password for the same user; beyond would freeze the user accounts for 5 minutes.

2. Fingerprint login.

Click the "fingerprint login" button on the login interface into the fingerprint of landing interface. Software automatically detect fingerprint device connection state, in the condition of fingerprint device connected, according to the steps on the interface indicates, user can use the registered fingerprints to log in.

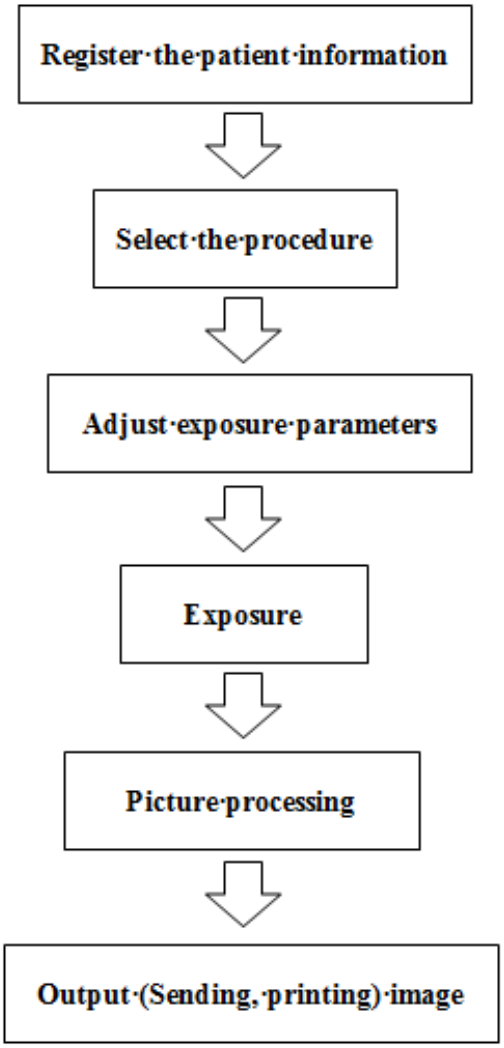
Figure 5-2

Note: fingerprint login applies only to technician user, manager user only through user name password to login.

3. System initialization

After the initialization, enter the DROC main interface.

The main process of DROC acquisition image is as follows:



5.2 Patient Registration and Management

After successfully login, the Work station software jumped to [work list-new] interface.

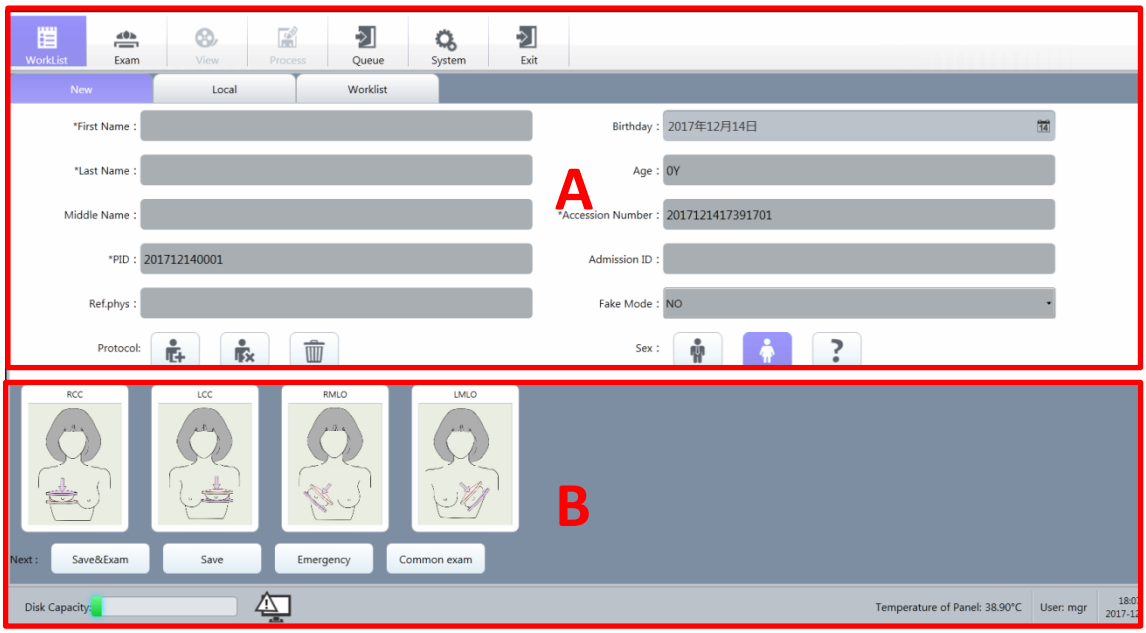


Figure 5-3

A	The patient information registration area
B	The selected procedure display area

In the "Work list" interface of the DROC, user can register for the patient through the following several ways:

1) Local registration: directly enter the patient's information to the "work list" interface of the work station software to register.

2) Remote registration: looking for work list to register. Searching the patients in login list of the hospital HIS/RIS system, confirm the selected as the current examination of the patient. The re-visiting patients may also directly to look for the previously saved personal information, confirm the selected as the current examination of the patient.

3) Emergency registration: the system automatically generates the patient ID, name, the accession number and procedure, and the information will be displayed in the patient registration area. This function can provide a quick examine channel for emergency patients and physical examination people.

5.2.1 Local Registration

In the system main interface that [work list-new] interface, you can see the patient's information registration area as shown in the figure below:

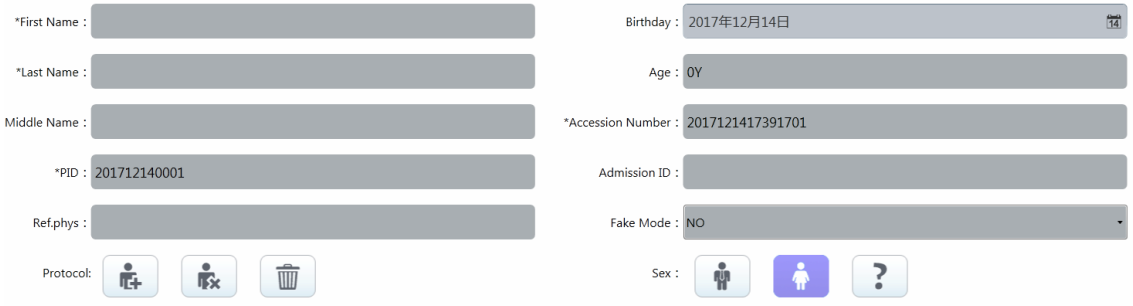


Figure 5-4

The first step: Fill in the patient information

（1） Directly fill in the patient information in the inspection information area. (Fields marked with * are required)

- Patient name: including the first name, last name and middle name, case sensitive.
- PID: the PID is automatically generated by the system, and composed of the current date/time and four free numbers.
- RefPhysician: the physician responsible for the patient’s examination.
- Date of birth: the patient’s date of birth.
- Age: directly fill in the age or the date of birth; the age can be obtained automatically calculated according to patient’s birthday.
- Accession number: the patient’s registration number, in accordance with PID number.
- Admission Id: the number of patients to see a doctor.
- Ethnic Group: the race of the patient.
- Sex: from left to right is male, female and other. The default setting is "female".

（2） Sweep code identification

In addition to manually fill in information of the patient, the user can scans the bar code on the patient medical records, the software can automatically identify and search the patient information.

The second step: Selected the procedure

Click the [add view] button  in the interface, switch to the view interface.

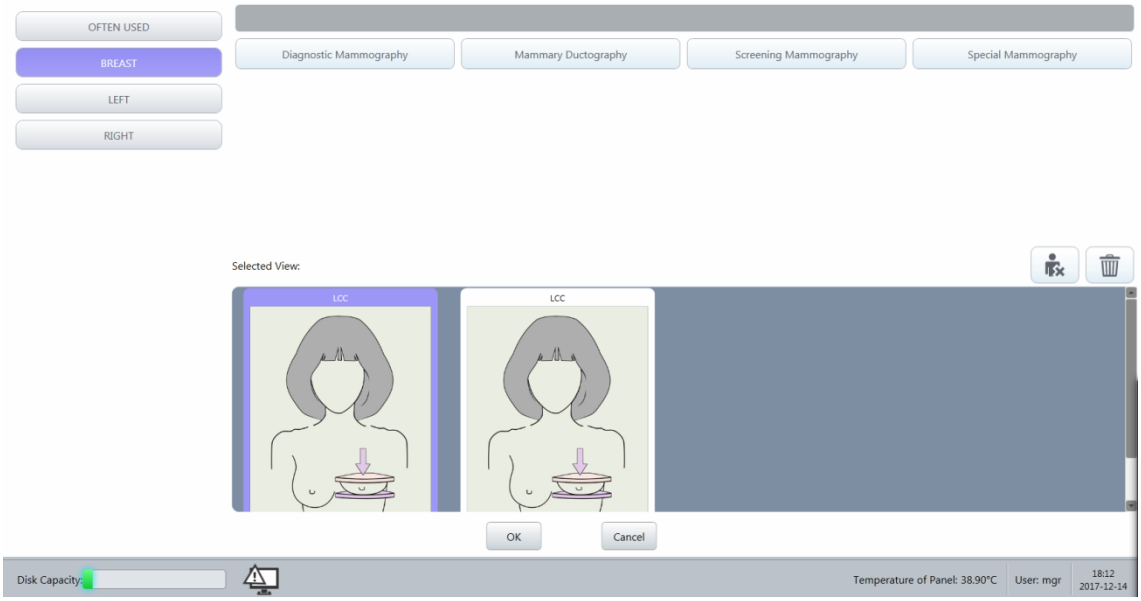


Figure 5-5

Click the item on the left of the interface to choose the patient’s procedure, and then click the [confirm] button to save the procedure to the [new] interface.

Click the  button, delete the selected procedure.

Click the  button; remove all the procedure in the area.

The third step: after the complete new patient information input, can perform the following actions:

Click the [save and check] button, switch to the examination interface, and the patient's information will be saved to the local work list at the same time.

Click the [save] button, the patient's information will be saved to the local work list, and the information on the [new] interface will be deleted for the next patient.

5.2.2 Remote Registration

Remote registration is register by searching "remote work list". Searching the patients in login list of the hospital HIS/RIS system, confirm the selected as the current examination of the patient.

Click the [remote work list] button on the [work list] interface, switch to the interface of remote work list. Import the patient's record from the RIS server, displayed in the remote work list, as shown in the figure below:

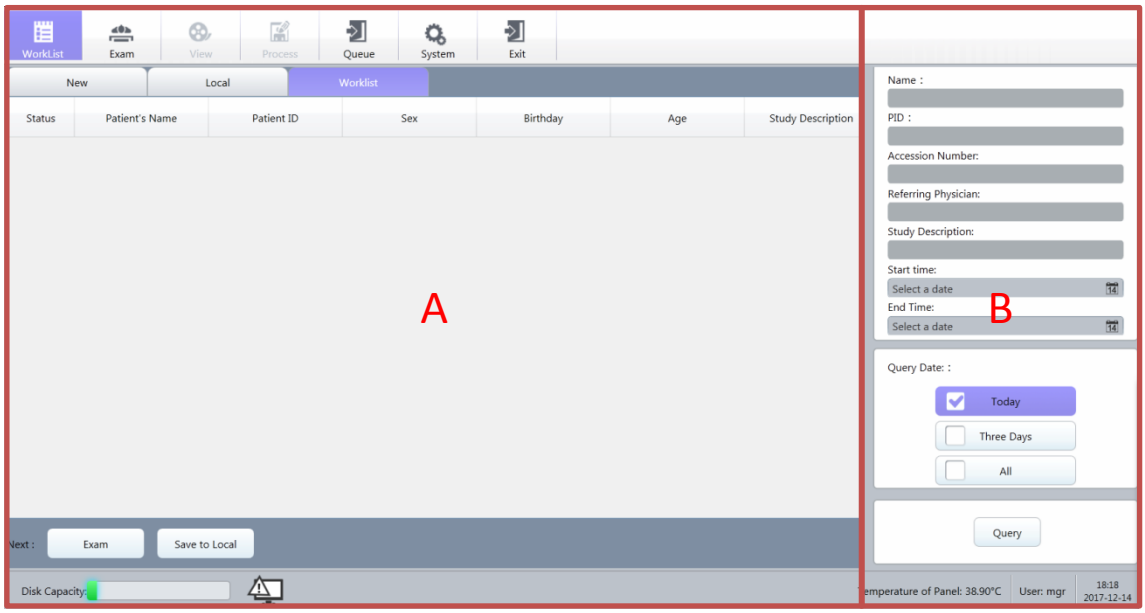


Figure 5-6: remote work list

A	The patient list area
B	Query function area

The remote work list support precise query and fuzzy query. The fuzzy query depends on whether the remote server database support fuzzy queries and support wildcards (in most cases the default value is no. *).

Precise query steps: input complete field information in the query textbox, check the time bucket and then press the enter key on the keyboard or click the query button.

The user can also directly check the time bucket of examination to screen the patient and the information of eligible patients will be displayed in the patient list area. At this time you can choose the patient in the list to register, click the [check] button and switch to the examination interface; click the [save to the local] button to save the patient's information to the local worklist.

The patient record retrieved from remote list will filter the remote records which had been saved in the local worklist, in order to prevent the repeated examination.

5.2.3 Emergency Registration

For large flow centralized patient examination or emergency cases, requirements quickly enter the patient information, you can use the emergency registration function, and the system will

automatically generate accession number directly into the examination interface.

Click the [emergency] button on the bottom side of the [new] interface, the system will automatically generate the patient ID, name, gender, age, and the examine view, directly into the image acquisition interface:

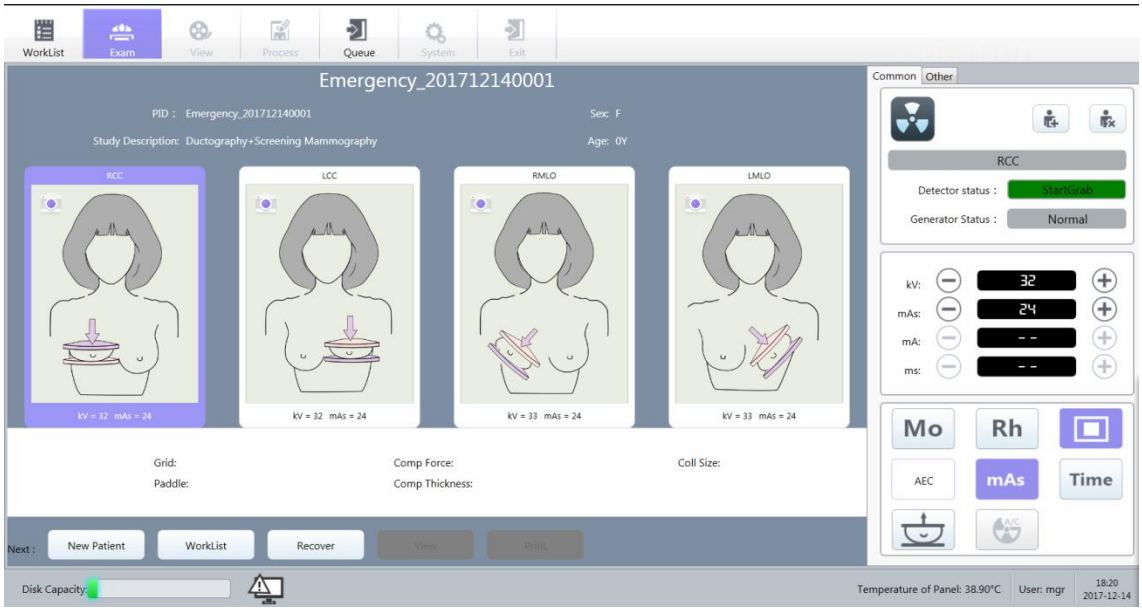


Figure 5-7

Note:

- **The emergency prefix name and the default procedure can be configured.**
- **The default emergency patient's age is NA, and the gender default O.**

5.3 The Patient Information Management

In the system [work list-local] interface, users can query, modify, delete, protect and export the patient's information.

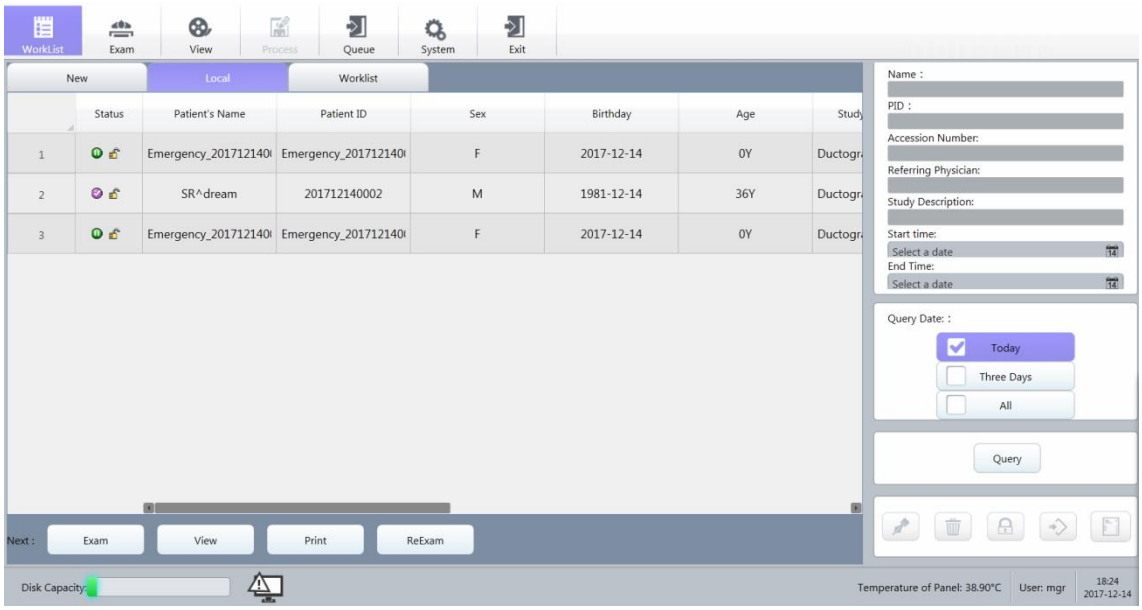


Figure 5-8

There are three kinds of state is used to identify check status of each record in the local wordlist.

ICON	DESCRIPTION
	New registered state of patients, have not grab image.
	Pending state of the patients, shows that the patient to check for interrupt (have not grab image or get part of the image)
	The completion state of the patients, shows that the examination of patient has finished (all the image of patient have grabbed completely, or the examination have been suspended).

For newly registered patients and pending state patient, user can enter the examination by click the record the list at any time, perform or continue to perform image acquisition work.

5.3.1 Query the Patient Information

When the list record is large, the user can quickly find out the target patients through the query function, as shown in the figure below:

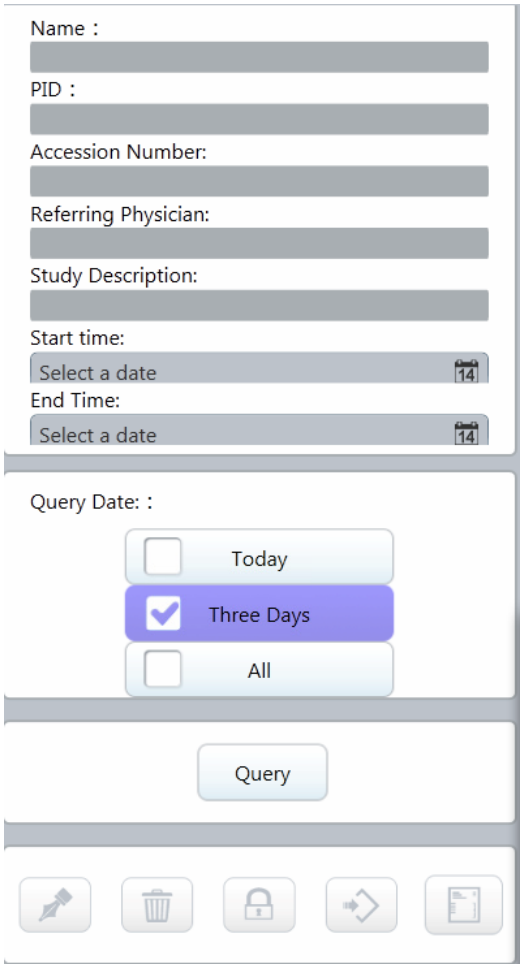


Figure 5-9

The system support precise query and fuzzy query: input complete or part of the field information in the query textbox, check the time bucket and then press the enter key on the keyboard or click the query button.

If there have match the query conditions of patients, the patient's information will listed in the local worklist, and then you can find out the target patient. If there have not match query conditions of patients, the list is empty.

Note:

- **If one of the imports is empty, shows that the field information of query record can be any content.**
- **In precise query, input name must add ^ symbol.**
- **The query is case-insensitive.**

In addition, user can directly check the query time to queries in different periods of the patient record.

5.3.2 Modify the Patient Information

The user can modify the patient's information of emergency patient or wrong registration, the patient information will not resume after modification.

In the local worklist, select one patient's record, click the edit button  in the toolbar at the right corner of the interface, switch to modify the patient information interface.

After modify the corresponding information, click the [reset] button, return to the original information; click the [sure] button to save the change; click the [cancel] button to cancel the change and close to modify the patient information interface.

5.3.3 Delete the Patient Information

In the local worklist, select one or more of the patient's record, and click the [delete] button  in the toolbar at the right corner of the interface, you can delete the patient's information.

State:

- **Only managers have permission to delete, technician users can't do this.**
- **The protected records are not be deleted until cancel the protection.**
- **If the records have part of the image, perform delete operation will default to transfer the images to the cache area.**
- **In addition, user can complete the patient data delete operation through automatic disk management on the system configuration.**

5.3.4 Protect the Patient Information

The protect button  has a combination of protection and cancellation protection function.

If the selected record is in the protect state, click the button to cancel the protection; if not, click the button to protect it (protection states real-time display in the local worklist).

5.3.5 Export the Patient Image Information

Completed examination of the patient, whose images follow these steps to export:

First step: in the local worklist, selected one of patient record in a complete state, click on the [export] button  in the toolbar at the right corner of the interface.

Second step: set parameters, click [Browse] select the exported directory, the destination folder must

be empty. The user can set the export file formats, file naming, and burner address and click on [next] button to start the export.

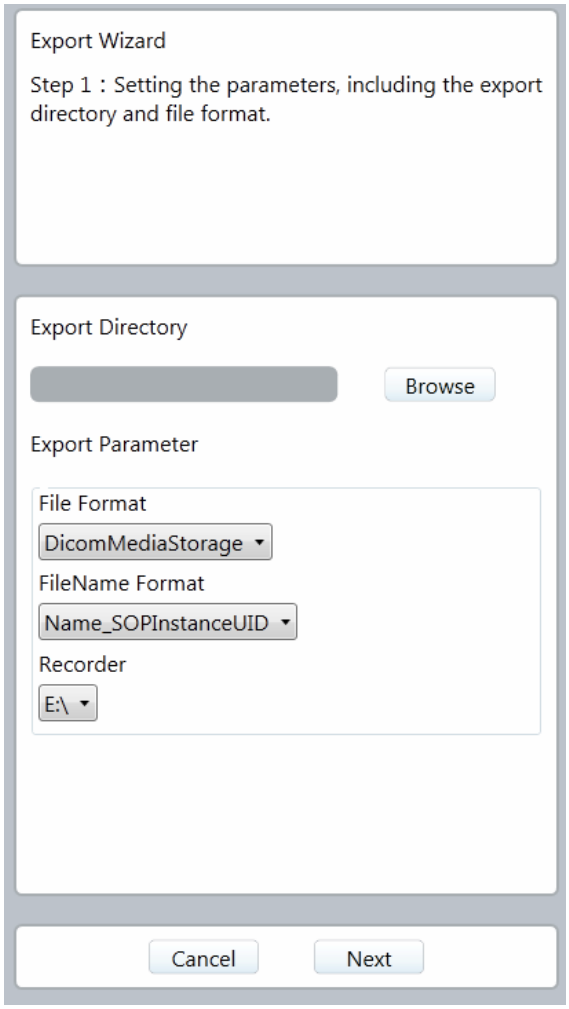


Figure 5-10

Select the export file format to DIOCM format, a mini image browsing tools will be burn into the disc when the burn. Put the already-burned CD into the CD drive, mini image viewing tool will automatically open the DIOCM image. Other formats, burn the exported file when the burn.

Third step: The progress of the export. Progress bar shows the current ordinal export images, you can click the [Cancel] button to abort the current export, the destination folder retain all the images before cancel.

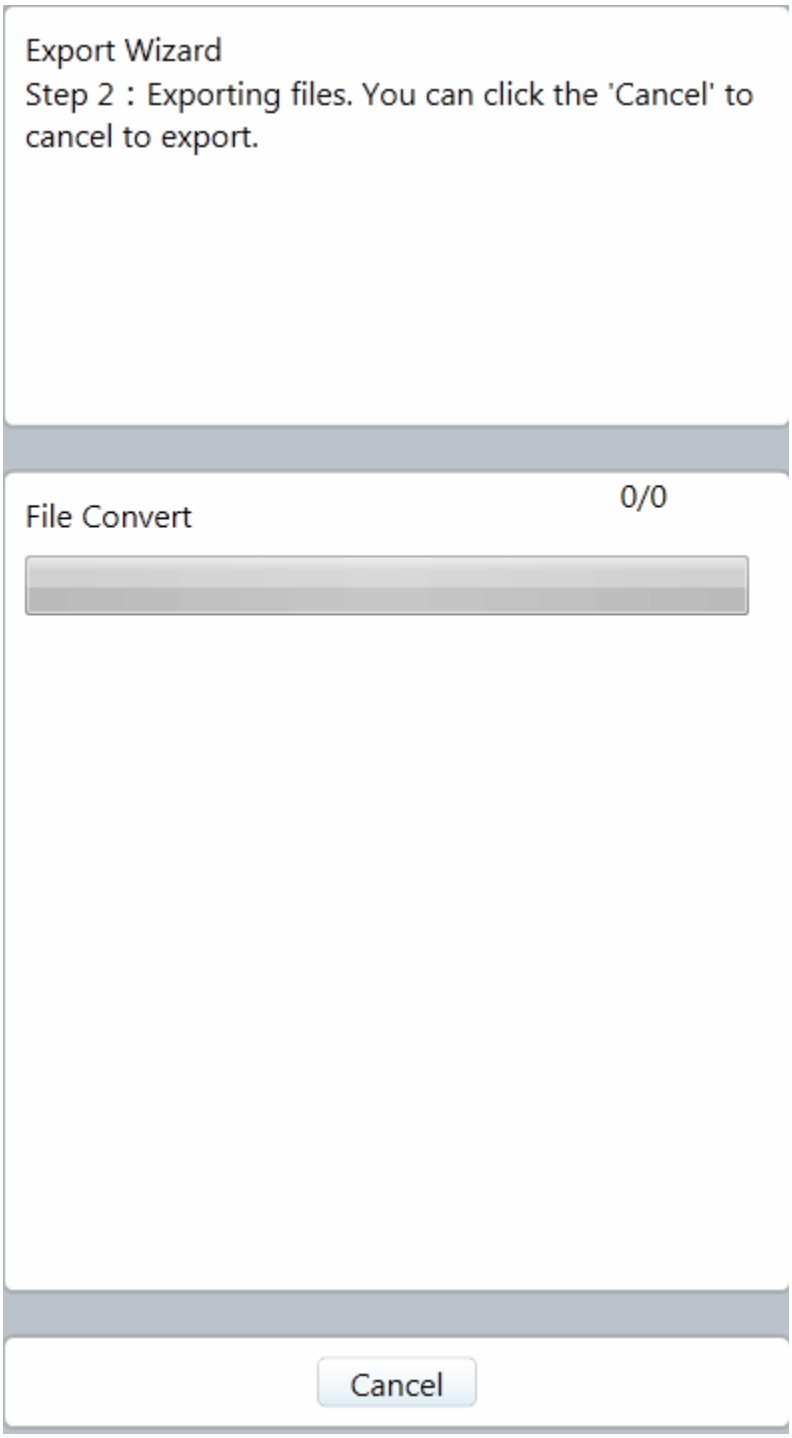


Figure 5-11

Fourth step: all of the images can be burn to disk after export. If there is no CD/DVD burner or not installed appropriate drive in the PC, will not be able to burn. At this time click the [finish] button, prompted whether to empty folders: “OK”-the folder is emptied, the "Cancel"-saved the corresponding images to a folder and create a DICOMDIR.

In the case does not empty the folder, you can see the following files (contain the image and the DICOMDIR file) in the folder.

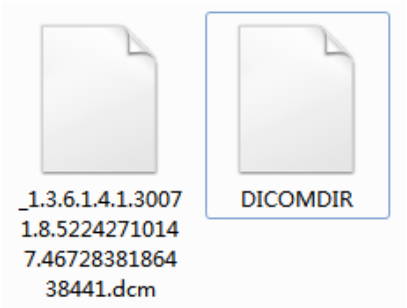


Figure 5-12

5.4 Examination Exposure

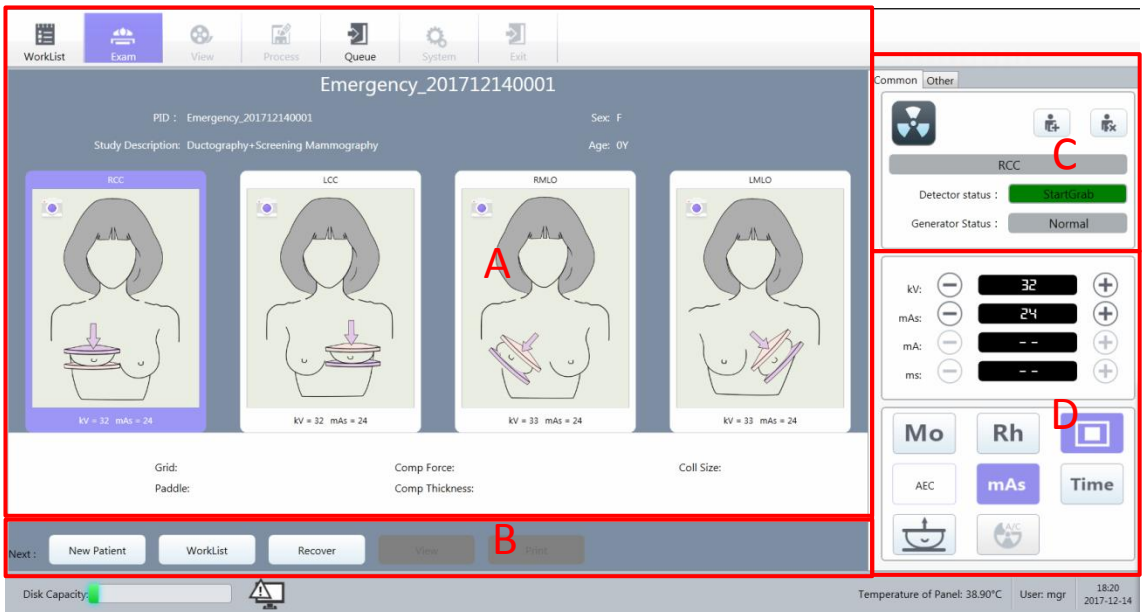


Figure 5-13

AREA	DESCRIPTION	AREA	DESCRIPTION
A	Displays patient information, radiography shooting positions, grid states, size of the paddle, compression strength and thickness and the size of collimator.	C	Displays the current position of radiography, and the states of some of the equipment。
B	Next action button zone	D	Exposure's parameter settings area

There are two ways into the examination after patient registration: one way is direct examination of new patients in [worklist-new] interface, including new patient registration and emergency registrations, which is described in the steps above. The other way is loaded the patients from local/remote worklist into the examination interface.

There are four conditions to load the patient into the examination interface from the local/remote worklist.

1. Single record loading for the patient with multi records

For the patient with multi records, you can select a new registration or pending state's record,

double-click it, and then the procedure will be loaded into the examination interface.

2. Multiple records loading for the patient with multi records

For the patient with multi records, you can select more than one new registration or pending state's record, click the [check] button at the bottom side of interface, and then all the selected records will be loaded into the examination interface.

3. All records loading for the patient with multi records

For the patient with multi records, you can select a new registration or pending state's record, click the [check] button at the bottom side of interface, and then all the selected patient’s records will be loaded into the examination interface.

Note: all the selected records must be the new registered or pending state.

5.4.1 Select View of Radiography

After entering the examination interface, the selected view of radiography is displayed in area A that is shown in the above figure. The system default exposure in order from left to right, you can also click priority exposure radiography view to exposure.

If the view has been image acquisition, image display box display the image thumbnails.

5.4.2 Adjust Exposure Parameters

Before the exposure action, you can adjust exposure parameters in the examination interface, as shown in the following figure:

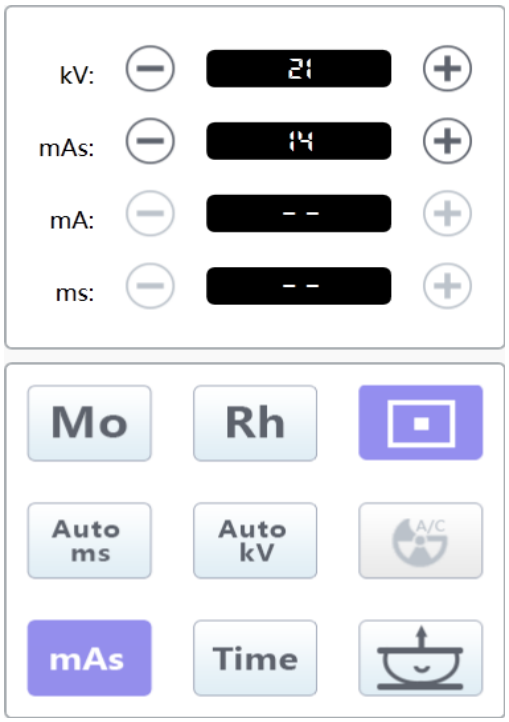


Figure 5-14

Icon	Description
Mo	Press the icon to choose the Mo filtration
Rh	Press the icon to choose the Rh filtration
	Press it to switch large/small focus
Auto ms	Semi-automatic mode, can adjust the kV value
Auto kV	The fully automatic mode, do not need to adjust the parameters
	Press to reset the high-volt generator
mAs	mAs models, can adjust the kV and mAs value
Time	Time models, can adjust the kV, mA and ms value

	Press to make the paddle automatically releases

Auto exposure mode: the system to provide four kind of exposure modes (Auto - kV, Auto - ms, mAs model, Time model), from automatic to manual Settings exposure conditions, to ensure the best image quality.

Automatic exposure system (AEC) through a small dose of exposure, get the standard parameter values by the algorithm. To prevent excessive radiation output, setting the maximum exposure time of less than 200 mas.

The DROC will default for exposure parameters of each view, which under each model and each procedure. In general, use the system default settings. You can also according to the need to click the plus or minus button on either side of the display window, manually modify the exposure parameter Settings.

5.5 Handbrake Exposure

 **WARNING!**	If you do not take proper protective measures or do not strictly follow the practice, the x-line system is harmful to the patient and the operator!

1. Check the states of detector before exposure

There has a detector states indicator bar in the technical parameter area.

Green indicator bar: shows the detector free to exposure.

Yellow indicator bar: shows that the detector is ready to work and need to wait a few seconds to expose.

Red indicator bar: shows that the detector is in the exposure state.

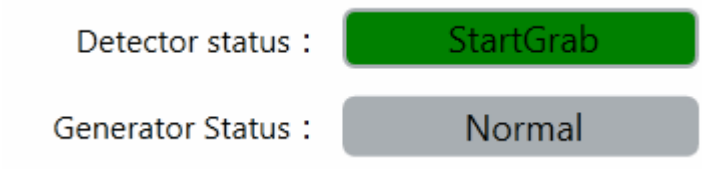


Figure 5-15: detector states indicator bar

2. Press the exposure handbrake and hold for a few seconds, starting the exposure, and the buzzer sounded a short sound. After the buzzer ring at least three times, release the handbrake, the exposure ends.

Note: If the detector has not been used for more than a pre-determined length of time, the detector will enter "sleep" State with energy-saving.

If the heat capacity of the tube exceeds the maximum allowed range, the x ray tube and generator are in unavailable until the heat down to a normal range. At this point, the message will appear.

5.6 Processing Images

Directly into the image processing interface after exposure, and displays a preview image, as shown in the following figure:

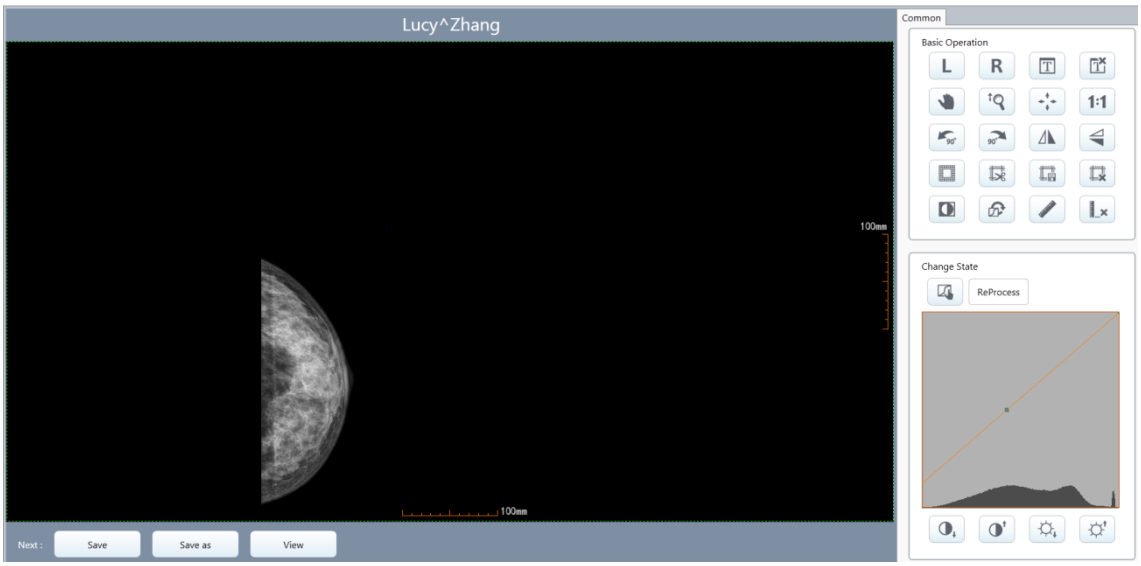


Figure 5-16: Image processing interface

In the image processing interface, users can:

1. Add image tags	2. Add note
3. move image	4. Change the size of images displayed
5. Rotate or flip images	6. Crop the image
7. Invert the colors of display image	8. Restored image
9. Adjust ESA curve	10. Adjust the brightness and contrast of an image
11. Accept image	12. Reject image

These are briefly described of features in the following.

◆ **Add image tags**

Every image can add up to two view marker, respectively left and right tag information, as shown in the figure below:

Figure 5-17: left and right tag

Click the left or right icon to mark the tag to the image and the same tag can't be added repeat. Click on the image tag, press and hold the left mouse button to drag the icon to the appropriate location. The Added tags and images will be sent to the DICOM output devices.

◆ **Add note**

Figure 5-18: add note icon

Click on the icon, list of notes appear, the default list options are "Test", "No Use" (the notes can be configured in the system configuration). An image can add up to three notes, and the note can be

repeated. The Added notes and images will be sent to the DICOM output devices and when accessing a local image again in the DROC, image thumbnails can also preview these notes.

- **move image**

When the image is magnified, attention part is no longer within the display area, you can click the "drag" icon and the mouse becomes a hand. And then in the display area, press and hold the left mouse key to drag the image to the appropriate location.

Figure 5-19: drag icon

- **Change the size of images displayed**

There are three icons to change the size of images displayed.

Figure 5-20

Pictured above from left to right is the "zoom" icon, the "covered window" icon and the "original size" icon.

Zoom: click this icon, the style of mouse becomes a magnifying glass, press and hold the left mouse button, upward sliding to shrink the image and down sliding to magnify image.

Covered window: system default in adaptive dimension display images, after zoom the image, you can click this icon to bring the image back to the covered window size.

Original size: Click the icon, the image displayed in original size, you can press the left mouse button and drag the observation of fine structure in the image.

Note: In the original state, can only observe images, cannot do operations such as cropping or add tags.

- **Rotate or flip images**

Rotate the images

Figure 5-21

Pictured above from left to right are: Rotated counterclockwise 90 ºor clockwise 90 °. Recommend that after rotated the image, adding tags to indicate the direction of rotation of the image.

Flip the images

Figure 5-22

The flipped image is the original image horizontally mirrored. As shown in the previous figure, left and right or up and down flip images.

- **Crop the image**

If the valid content in the image only a portion of the whole image, you can choose to save or print the effective part.

Figure 5-23

Pictured above from left to right are: rectangular cutting icon, custom size cutting icon, save the trim icon and remove the trim box icon. The user can do the following operation:

Rectangular cutting: click the rectangular cutting icon, press and hold the left mouse button, drag the mouse to get a rectangle clipping box.

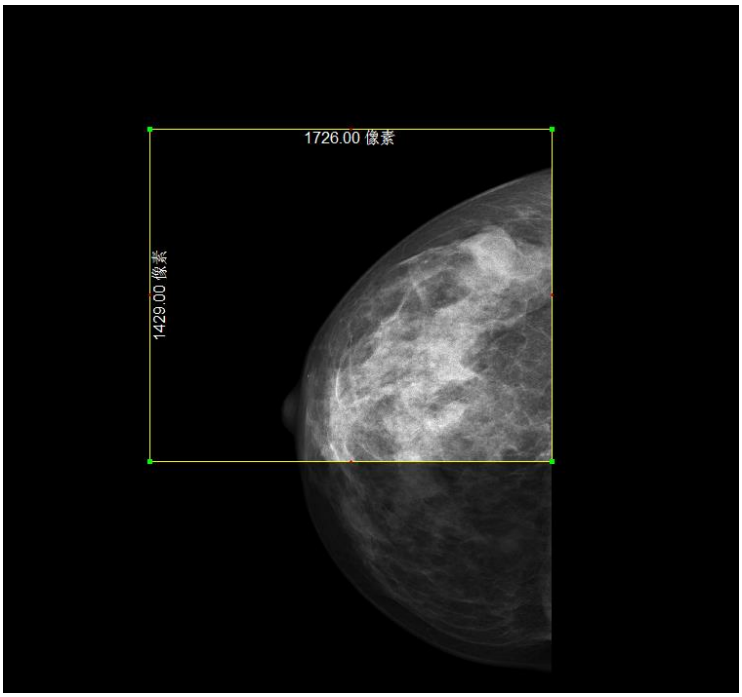


Figure 5-24

Custom size cutting: click the custom size cutting icon, and then select one size of clipping box to crop the image.

- **Invert the colors of display image**

Figure 5-25

It is better to observe the texture structure of the image after inverse-color processing.

- **Restored image**

Figure 5-26

Click the icon to reset all operations on the image, and restore to the default image.

- **Adjust ESA curve**

- Change the State of ESA curve

Click the [change state icon]  , and then select the needed curve.

The curve of the common state set by the system is as follows:

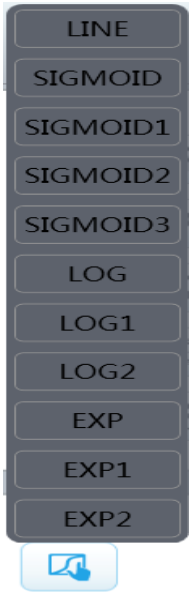


Figure 5-27

- Modify the curve of the image

Drag the square handle on the ends of the curve respectively, until get satisfactory images.

◆ **Adjust the brightness and contrast of an image**

Figure 5-28

As shown in the image above, adjust the contrast and brightness icon from left to right are: reduced contrast, increase contrast, reduce brightness, increase the brightness. Press and hold the left mouse button upward sliding to reduce image contrast/brightness and down sliding to increase image contrast/brightness.

◆ **Accept image**

Figure 5-29

Click the [accept] button to accept the image. And then return to the examination interface. Position of image thumbnails instead of the original figure appears in the display area.

◆ **Reject image**

Sometime may need to abandon the current image (For example, patients move during the exposure process).

Click on the [rejection] button, reason for rejection list appears, as shown in the following figure:

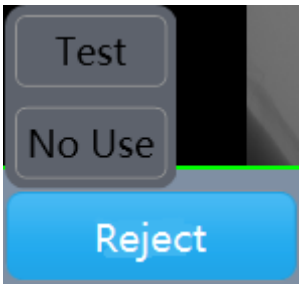


Figure 5-30

Select one from the list, the system automatically returns the examination interface, current exposure procedure without change.

Note: Reason for rejection can be configured. Rejected images will still be stored in the local database, as one of the technicians filming the statistical basis of the data.

5.7 Sending Images

After patient exposure is accepted, the system will automatically send it to the default archive nodes, users can also send it to the sending interface manually.

There are two ways to enter the sending interface: one way is that click the bottom side [read] button or top-side read icon in the examination interface. The other way is select the image of patient records from the local worklist and then click the bottom side [read] button or top-side read icon.

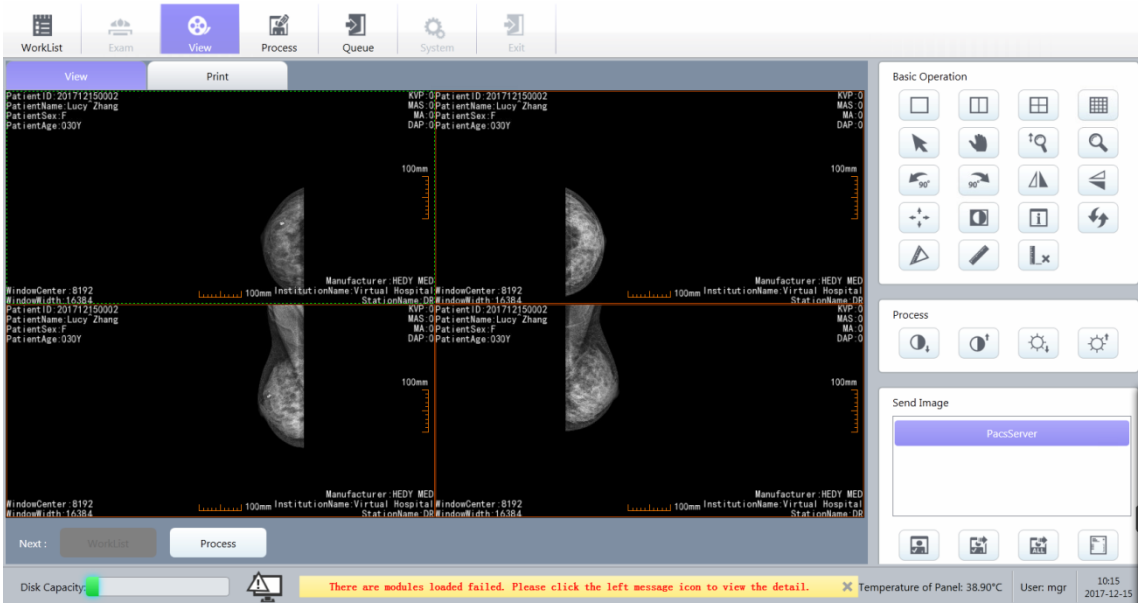


Figure 5-31: sending interface

To view and process image (optional): Before you send it, you can review the image and simple handling. This handles function button in the interface contrast and image processing interface are as follows:

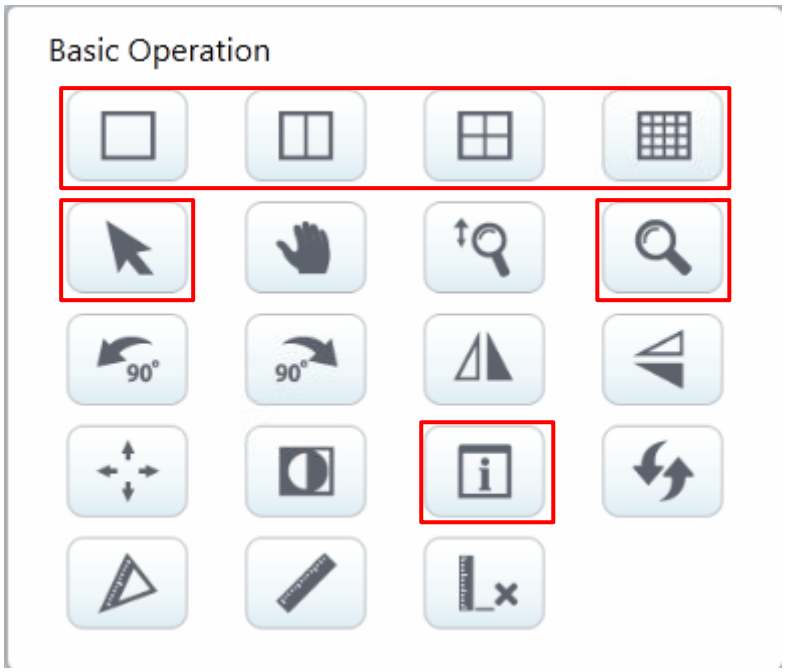


Figure 5-32: basic operation

Sending interface has different buttons with a red circle, from top to bottom as follows: formatting buttons, restoring the cursor button, the magnifying glass button, DICOM information button below describes each button in turn function.

Formatting buttons: You can change the layout of the image display, respectively, for each page 1x1, 1x2, 2x2, 4x4 sites.

Restoring cursor buttons: During the process of image viewing, you can restore the mouse cursor and cancel the function of drag or magnifying glass.

Magnifying glass button: You can use the magnifying glass to observe the local image.

DICOM information button: To view a single image with the detailed DICOM information.

Other function buttons on the can refer to the image processing part.

The steps of sending images:

The first step: select image: in the sending interface, click on the image needs to be sent, then click the [select/deselect images] button to select the image.

The second step: select a send node: Sent by a send node lists all available target nodes, you can select up to 3 nodes as send destinations.

The third step: send: Click [send selected images] button, the selected images are sent to the target node.

If you send all images for this patient, you can simply select the sending node, click on the [send all images] button.

Whether it is sent automatically or manually, if the sending fails, the system will automatically try again, if still no success, try again up to three times.

The send status can be viewed in the send queue.

5.7.1 Print the Image

For patients already had collected images, users can print out the images in the print interface and the system will not automatically print.

There are two ways to enter the print interface: one way is that click the bottom side [print] button or top-side read icon in the examination interface. The other way is select the image of patient records from the local worklist and then click the bottom side [print] button or top-side print icon.

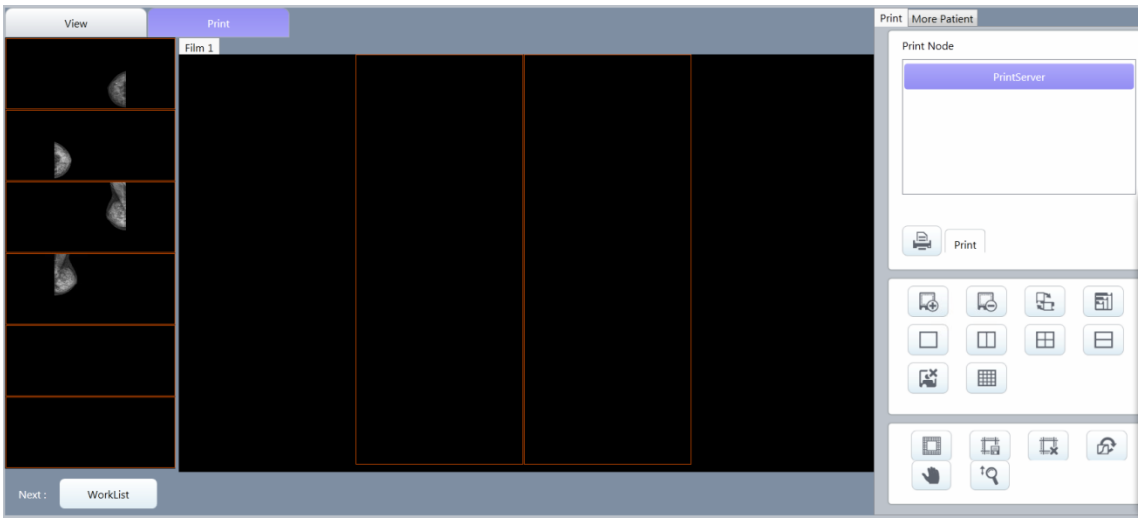


Figure 5-33: Image print interface

In the print interface, you can set the printing film, choose the print node and then print pictures of patients.

1. Set the printing film

Add/delete film:

Figure 5-34

Under normal circumstances, by default there is only one piece of film in the film display, you can press any increased demand for films.

Adjust the direction of the film:

Figure 5-35: Direction button

Choose the right film direction to more rational use of space on the film. Film direction, there are two options: vertical and horizontal, click on the direction button to switch the film direction.

Adjust film sizes:

Figure 5-36: Film sizes

Click on the [film sizes] button, appears a small list, which lists several standard film sizes to choose from.

Select a film format:

Figure 5-37: Film format

Buttons shown in the figure, from left to right are:

1×1: Film only arranged in an image. In the printing device, which does not support multiple images, this value is the default value.

1×2: Two images side by side in the film-layout.

2×2: Four images in the film arranged in a 2x2.

2×1: Tow images in the film arranged up and down.

Add/reduce film images:

Figure 5-38: Add and reduce image button

After setting the film format, select images from the image list and drag it to the appropriate region of film. If the image already exists in the region, the dragged image will overwrite it.

Increase the image by [Add image] buttons. Select the images you want to print, click on the [Add image] button, the images can be automatically added to the blank area of the film. If the current film has been booked, the system will automatically generate a new film. This method will not overwrite the original image in the film.

It is similar to the operation of deleted image and added image.

2. Select Print node: print node lists all printers configured on your system. You can select a printer as the output destination.
3. Printing: select print node, click on the [print] button to print out all the films currently on the specified printer. If printing fails, the system will automatically try again, if still no success, try again up to three times. Print status can be viewed in the print queue.

5.7.2 Send and Print queues

There are Send queue and print queue, you can choose from the following select query.

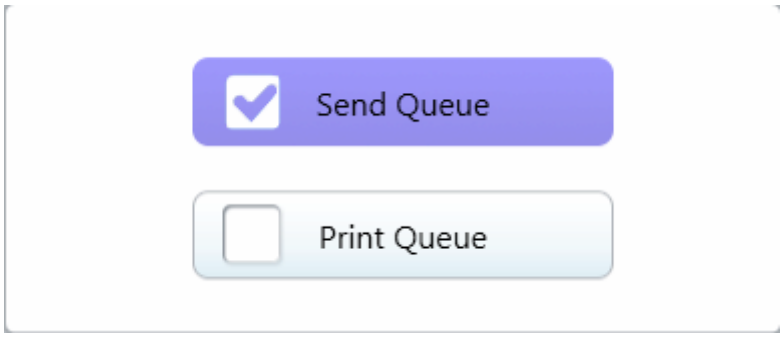


Figure 5-39

- **Send queue**

After the examination of patient, the image is automatically sent to the default node, which generated a new record in the send queue.

The records include: patient's name, identification, priority, state of sent, number of sent, destination and the date of image generation.

There are four status of sending, respectively are 【NEW】【INPROGRESS】【COMPLETED】 and [FAILED]. The record failed to send can perform retry operations, resend will not add a new record, sending a number of cumulative.

Similar to the local and remote worklist, queue support queries sent records of different time periods:

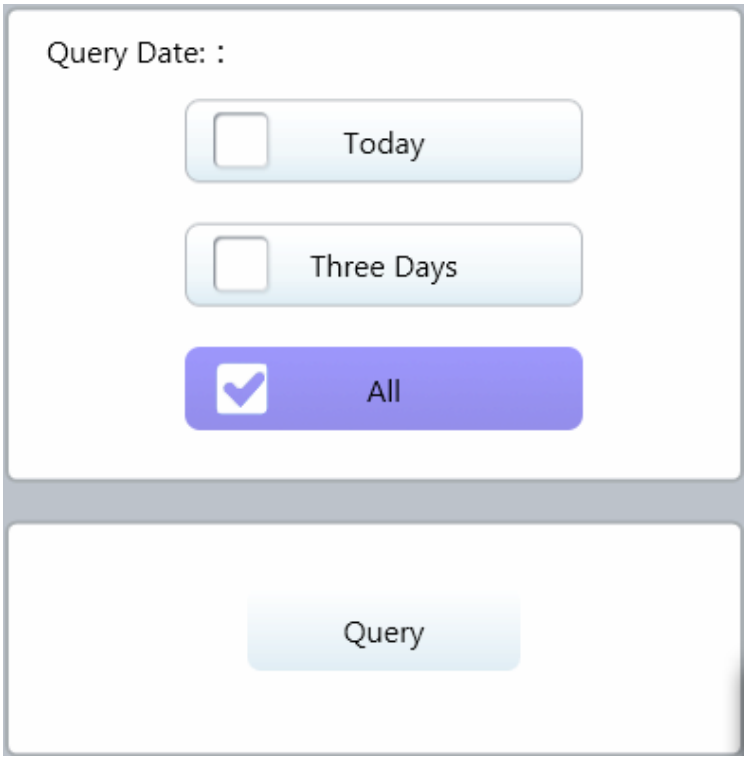


Figure 5-40

Each record in send queue you can save 7 days, expires will be cleared automatically. Allows you to manually delete records within a time limit, delete can be selected one by one or batch removed.

- **Print queue**

System will not automatically print images of patients, if necessary, the user can manually print. When you do print a new record will be generated in the print queue. Records include: patient's name, identification ， priority ， state of print ,number of print, destination,

The function of print queue is similar to the send queue.

5.8 System Configuration

System configuration features include: common and advanced features. Common features include: system information, user management and statistics; Advanced features include: emergency setting, procedure, APR, networking, hardware, system, etc.

Note: Different user rights, you can perform system configuration actions are different. Manager can perform all management functions on the system configuration, but technician has a part of permissions in the common features module.

5.8.1 Common Features module

5.8.1.1 System Information

Select [system information] on the common menu bar, the system name, copyright and version information will be displayed in the interface. Software version: 0.1.

The algorithm version information of the original data processing of the device is 0.0.6.0.

5.8.1.2 User management

Select [user management] on the common menu, the interface that is displayed will vary according to the different user permissions.

The user management interface of manager:

	User ID	User Name	User Level
1	1	mgr	administrator

Figure 5-41:User management interface Ⅰ

Managers can see a list of all users, add technicians, edit and modify the name and password of all users, delete others, and so on.

The user management interface of technicians:

	User ID	User Name	User Level
2	2	Tech	Technician

Figure 5-42:User management interface Ⅱ

Technicians can only see a list of current user's information， and edit their own user name and password.

Below from the Angle of the manager to introduce its permissions operation:

1. Create new user

Click the "new" button on the underside of the user management interface, appears a new user interface, as shown in the following figure:

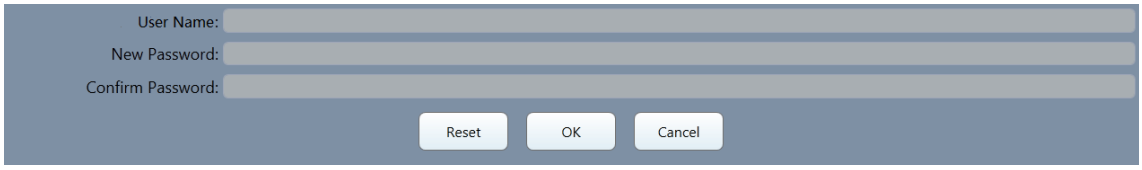


Figure 5-43: New user interface

After you enter the user name ， password and confirm the new password, click on the [OK] button, the system pop up a confirmation box “Do you want to register log in fingerprint”, Click on the "OK" button to enter the registered user login the fingerprint interface, click on the "Cancel" button the complete text of the new user registration.

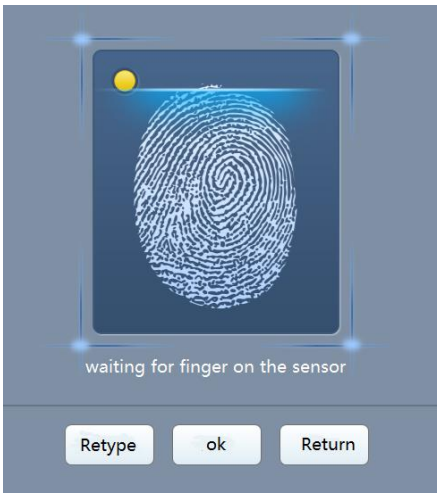


Figure 5-44

New user put his finger on the fingerprint device, fingerprint registration successfully after the fingerprint device scan the finger and generate the fingerprint features, as shown in the following figure:

Figure 5-45

Click the [OK] button, the fingerprint information was successfully registered, at the same time a new user is added.

Click on [re-enter] button, again to login the fingerprint registration.

Click the [back] button, interface returns to the new user interface.

Note: All of the new users are technicians, only have technician permissions.

2. Edit user information

Select the user to edit, and click the [Edit] button, editing interface appears, as shown in the following figure:

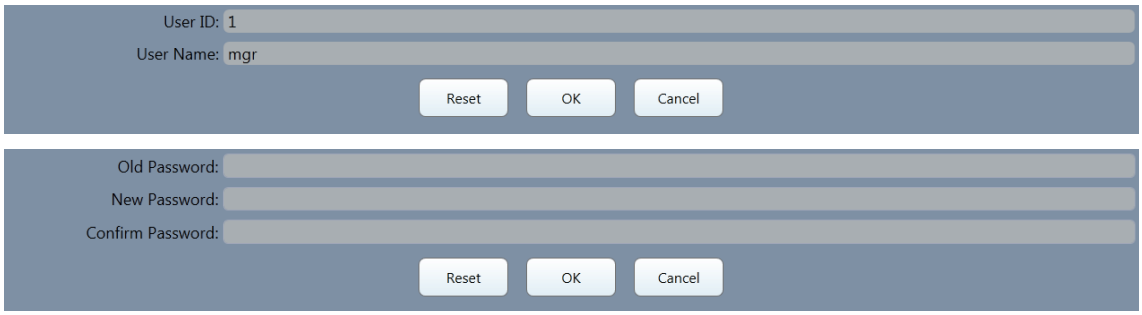


Figure 5-46: Editing interface

In this interface, users can edit the user name and password.

After editing is complete, click the [OK] button, the user name and password has been modified; click on the [Reset] button, and empty input information; click the [Cancel] button, the current operation was aborted.

3. Delete a user

In the user management interface, select the user you want to delete, click on the [Delete] button and then confirm the operation in the confirmation box, specifying a user is deleted.

5.8.1.3 Statistics

Statistical sets different users permissions:

Manager users can use the statistical functions to view and export all user work and statistical information on the overall operation of the system, as well as the statistics for all doses;

Technician users can only view and export current user dose statistics.

Below from the angle of the manager to introduce its permissions operation:

1. Work statistics

Work statistics can serve as an important basis for judging quality of user work.

Manager can specify a user ID, or time period as filters to query the user's work records; in the case do not specify query criteria, query for all users by default, as shown in the following figure:

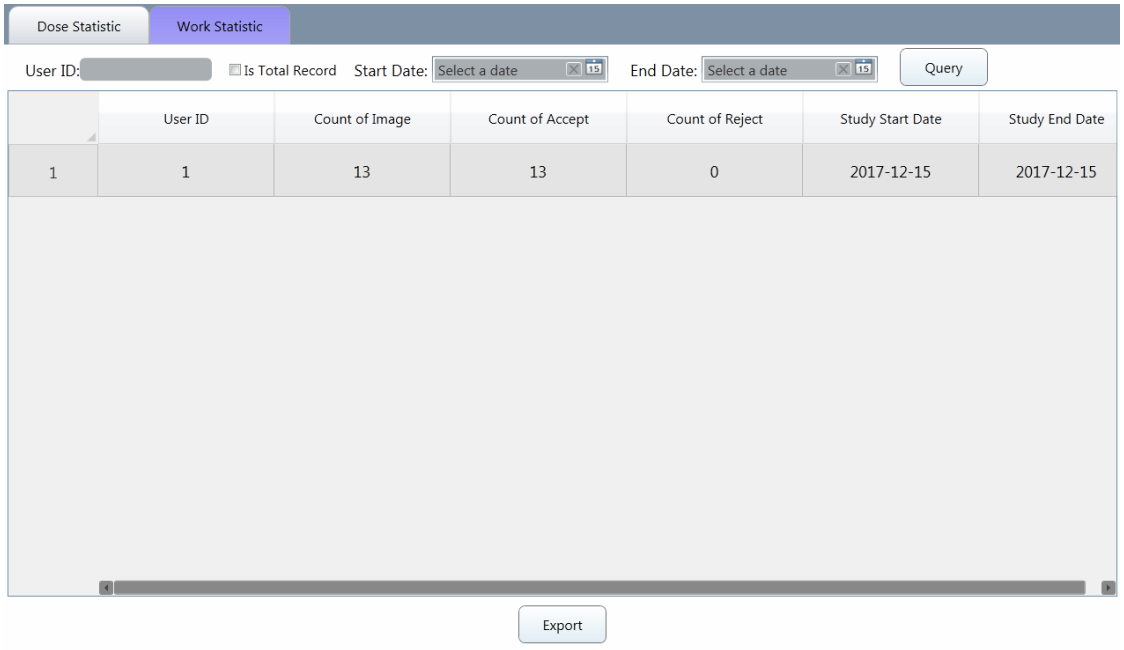


Figure 5-47: Work statistics

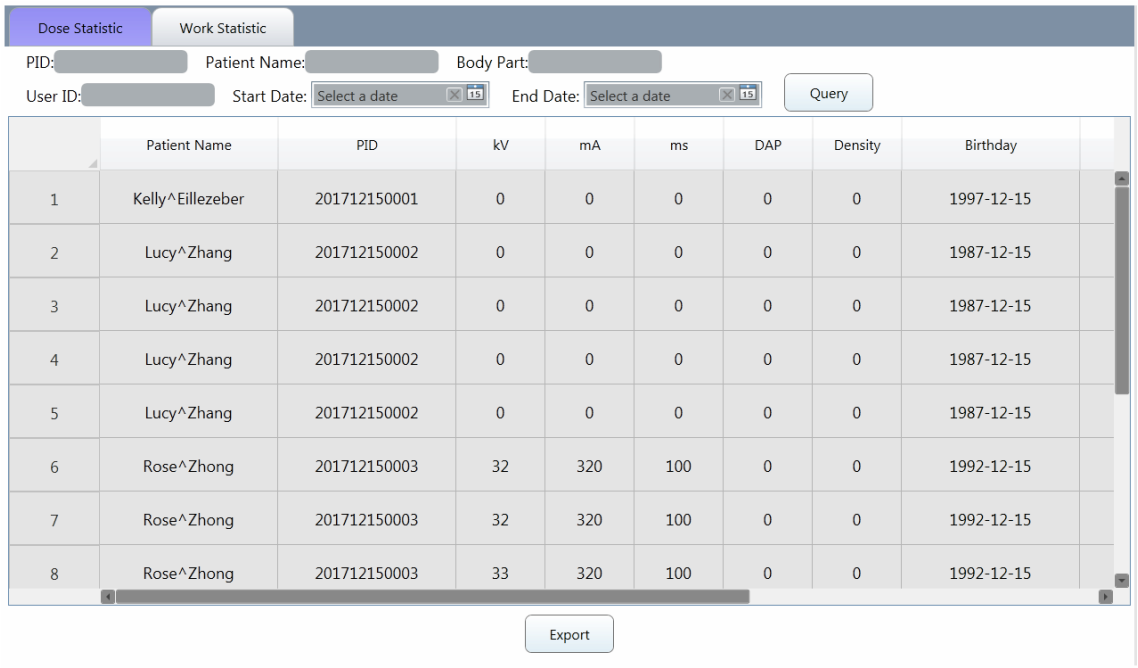
Work statistics including user identification, total exposure image, accept the image number, refused to image number and the date range, which records the users work situations in a particular time period. Check the 【machine】, you can see the situations of overall work of the system.

File export: click the [Export] button at the bottom of the interface, you can save the current report in Excel format to your local machine, exported files can be edited.

2. Dose statistics

By looking at the data of dose statistics, users can know more about the exposure dose for the patient during the exposure process and the image status after exposure and so on.

Manager users can input patient ID, patient's name, procedure, user ID, or select a time period to query patient dose statistics logging (supports accurate query and fuzzy query); in the case do not specify query criteria, query for all users by default, as shown in the following figure:



	Patient Name	PID	kV	mA	ms	DAP	Density	Birthday
1	Kelly^Eillezeber	201712150001	0	0	0	0	0	1997-12-15
2	Lucy^Zhang	201712150002	0	0	0	0	0	1987-12-15
3	Lucy^Zhang	201712150002	0	0	0	0	0	1987-12-15
4	Lucy^Zhang	201712150002	0	0	0	0	0	1987-12-15
5	Lucy^Zhang	201712150002	0	0	0	0	0	1987-12-15
6	Rose^Zhong	201712150003	32	320	100	0	0	1992-12-15
7	Rose^Zhong	201712150003	32	320	100	0	0	1992-12-15
8	Rose^Zhong	201712150003	33	320	100	0	0	1992-12-15

Figure 5-48: Dose statistics

Dose statistics reports include patient information (name, PID, date of birth), exposure parameters (kV, mA, ms, AGD, Gland thickness), exposed procedure (procedure, the procedure description), image information (image annotations, image state) and user identity information.

The radiation dose has the following relationship with ESAK.

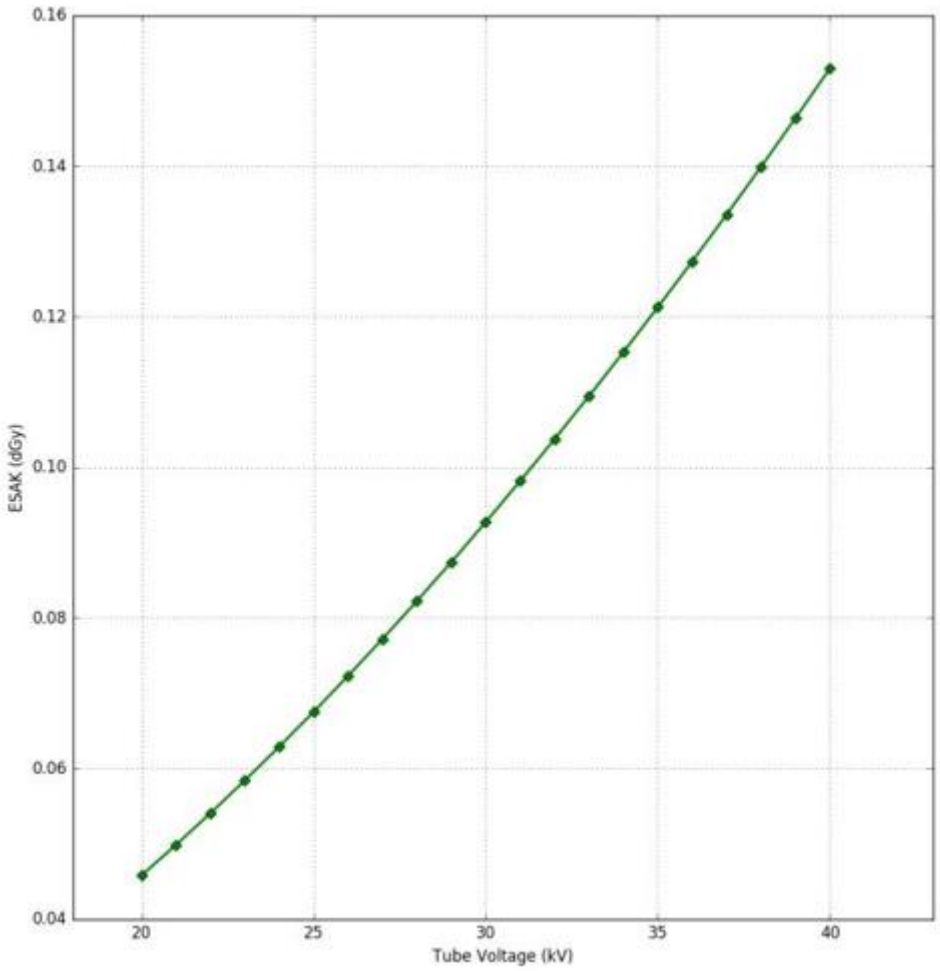


Figure 5-49

The curve is obtained by changing the tube voltage under the following conditions.

- MO-MO
- 100mAs
- Gland thickness 4mm
- HVL 0.374mm

Note:

- **Dose statistics included all records of exposure, including rejected images records.**
- **The accuracy of AGD ≤0.01dGy.**
- **Technician users can query and output the dose statistics information under the current user identity.**

File export: click the [Export] button at the bottom of the interface, you can save the current report in Excel format to your local machine, exported files can be edited. A single dose of patient information can be printed on labels to the film.

5.8.2 Advanced Features Module

Only manager users can access this module, you can view and modify information in emergency settings, procedure settings, APR parameter settings, network parameter settings, and other related data.

5.8.2.1 Emergency Settings

Click on the [Advanced-Emergency setting], emergency settings interface appears, as shown in the following figure:

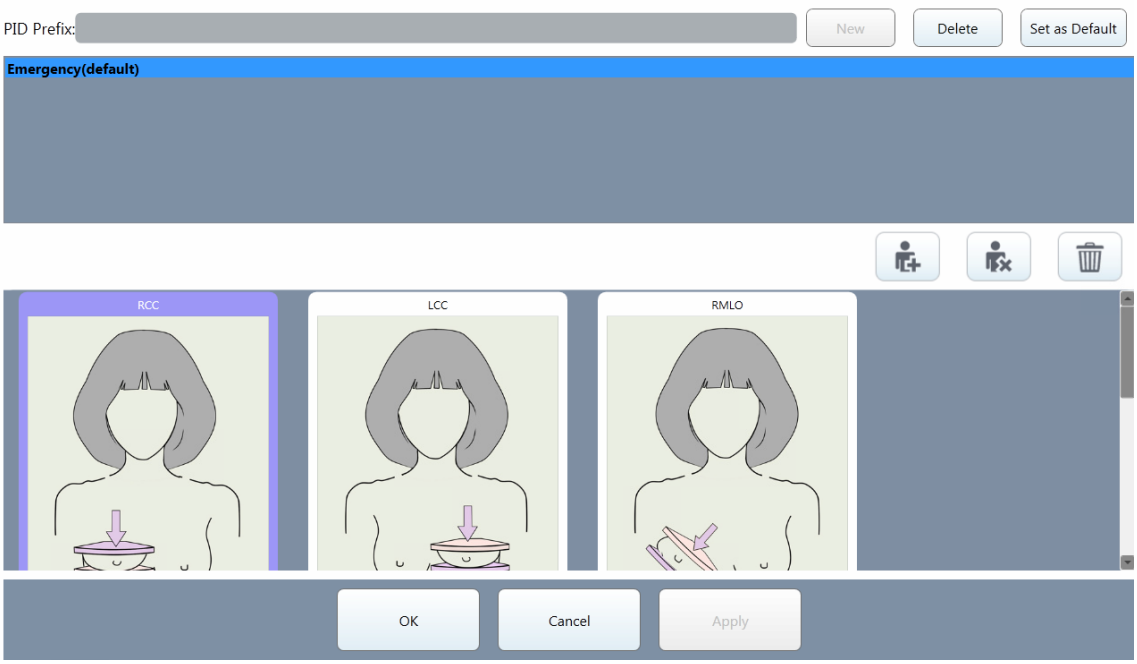


Figure 5-50：Emergency settings

On this interface, users can add and remove emergency items, modify emergency procedures and set the default emergency items.

1 Add emergency items

The first step: set the prefix name

In the PID Prefix text box, enter the prefix names of new emergency items, as shown in the following figure:

Figure 5-51： Prefix name

Click on the [new] button to add it successfully in the list, add after the success of the list as shown below:

Figure 5-52

The second step: set up new emergency procedure

Click on the  button to switch to the procedure interface.

Select the regular procedure and then click the [OK] or [Apply] button at the bottom of the interface to save or confirm the new emergency procedure.

2 Modify the existing emergency procedure

Click to select the one of the emergency item you need to modify and the currently selected procedure displayed at the lower of the interface. Manager modify the existing emergency procedure by the [add procedure]  button, [delete procedure]  button and the [empty procedure]  button.

After the modifications are complete, you can click [OK] or [Apply] button to save the current changes.

3 Delete the emergency items

Click to select deleted items in the emergency list, and then click on the [delete] button behind the PID Prefix text box to delete the selected item.

4 Set the default emergency item

Select an emergency item from the list, click on the [set as default] button behind the PID Prefix text box to set the selected item as the default.

5.8.2.2 Procedure configuration

Click on the [Advanced-Procedure], procedure configuration interface appears:

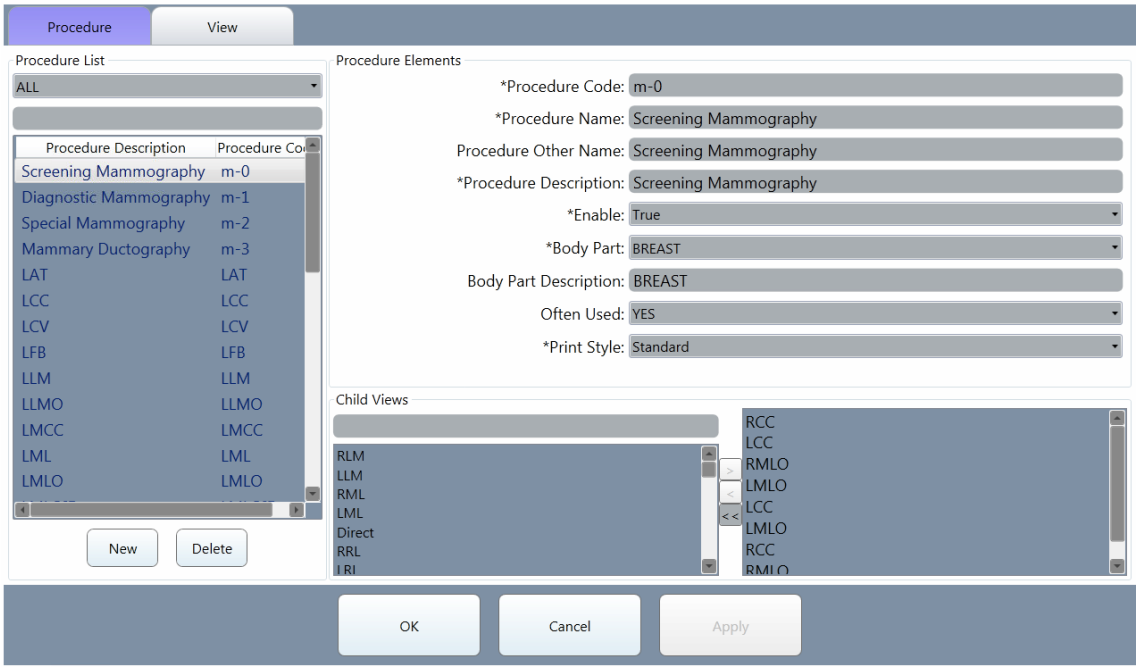


Figure 5-53： Procedure

In this interface, you can configure the examination item, which include the configuration Procedure setting.

1. Procedure configuration

As shown in the picture above, Procedure configuration consists of Procedure list and procedure elements. These information users can view, add, edit, and delete operations.

To view the procedure:

In the drop-down box, select the type of procedure list, optional types are: OFTEN USED、ABDOMEN、LOWER LIMB、SKULL、SPINE、THORAX、UPPER LIMB、ALL.

The selected type of procedure appears in the procedure list, which include the information of procedure description and procedure code.

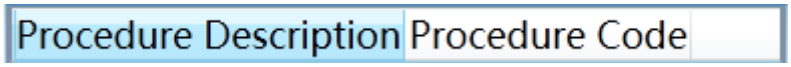


Figure 5-54

Select one of procedure from the list, the corresponding procedure information appears on the right.

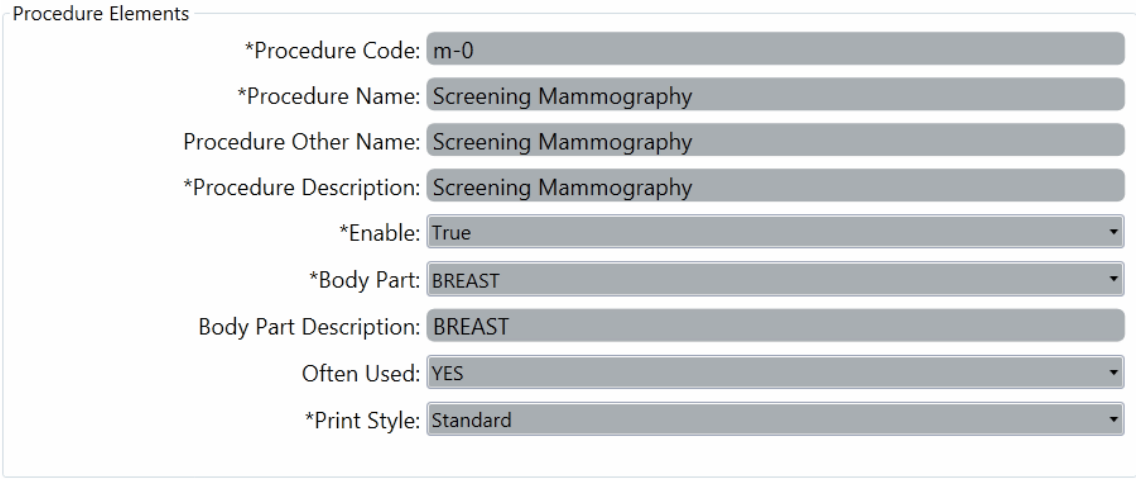


Figure 5-55: Procedure element

Additional procedure:

The first step: click the [new] button at the bottom of the list, the information of procedure list and procedure elements will be empty.

The second step: choose child views. As shown in the figure， left area is for all the views and the right area is for the selected views, the operator button on the middle area.

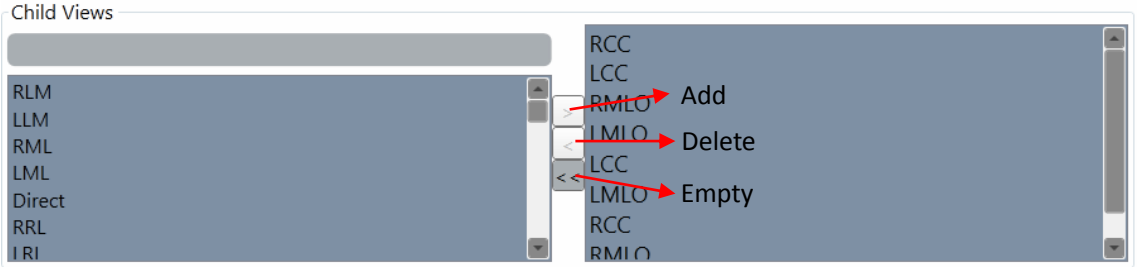


Figure 5-56: Child views

Select one or more of the views on the left area, click on the [Add] button to add this view. In order to avoid repeat to add the same view, adding view will be removed from the left area. There are similar actions to delete or empty views in the selected views area.

The third step: fill in the procedure elements (Fields marked with * are required). After completed the procedure elements, click on the [OK] or [Apply] button to save the new information.

Edit existing procedure:

If you need to modify existing procedure refer to the Add method.

Delete procedure:

Select the procedure needs to be removed from the list, click on the [Delete] button in the list bottom.

Then confirm the operation to remove the procedure from the procedure list.

2. views configuration

As shown in the picture below, views configuration consists of view list and view elements. The view information can also be view, add, modify, and delete operations, which refer to the procedure configuration.

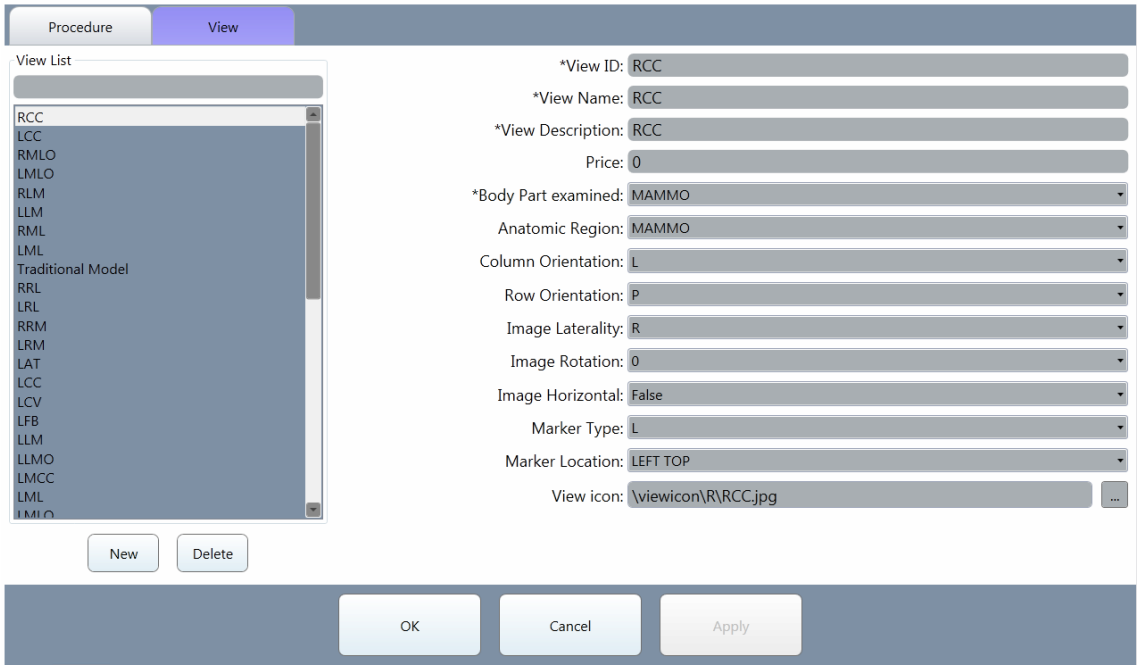


Figure 5-57: views configuration

5.8.2.3 APR

Select the [Advanced-APR], APR parameter settings interface appears. This interface consists of two parts: the view list on the left side and the parameters configuration on the right.

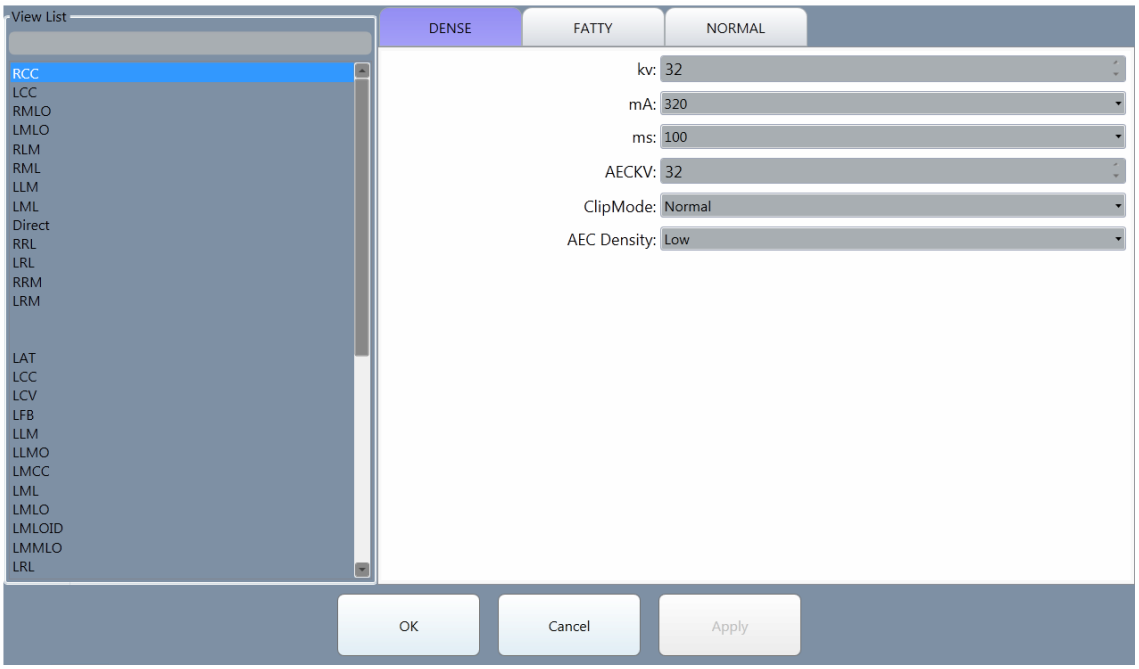


Figure 5-58: APR interface

In this interface, user can view and modify the examination parameters (include kV, mA, AEC kV, Clip Mode, AEC Density). Users can change parameter values， after the modifications are complete, click on the 【OK】 or 【Apply】 button at the bottom side of interface to save the changes.

5.8.2.4 Network configuration

Select the [Advanced-Network], there is a network configuration interfaces. Network configuration consists of four modules: remote worklist, remote worklist tag, archive, printers.

1. Remote Worklist

Users obtain the RIS remote patient registration records by configuring the remote worklist information. In this interface, users can set the connected devices information and remote worklist property mapping.

Connected device information settings:

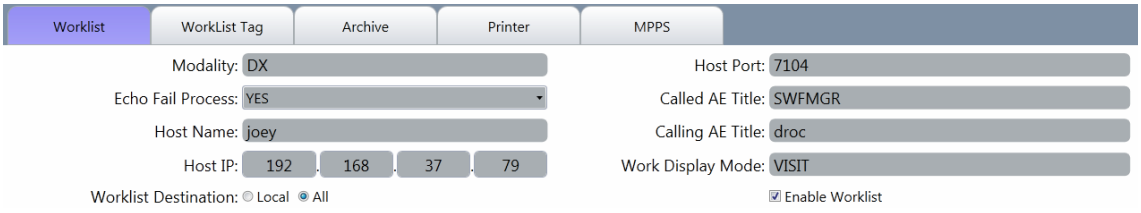


Figure 5-59: Connected device information

Remote worklist property mapping:

Remote worklist property mapping includes: worklist fields, DICOM group number and element, the parent group and element.

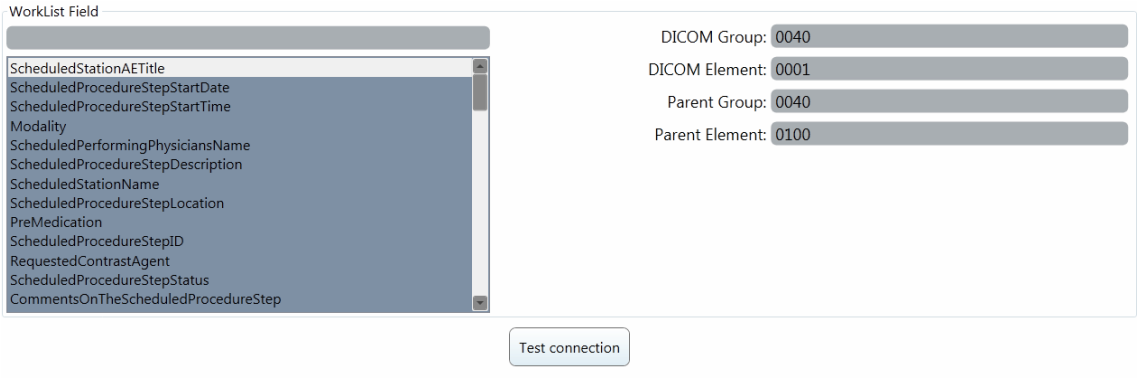


Figure 5-60: Remote worklist property mapping

When the RIS system through remote worklist service for registration, users need to configure remote server parameters in this interfaces. About remote working list can refer to the DICOM standard related knowledge.

2. Worklist Tag

Remote worklist tag used as a remote annotation is saved to the local record, so as not to repeat the search. The optional fields are as follows, you can check one or more configuration identifier.

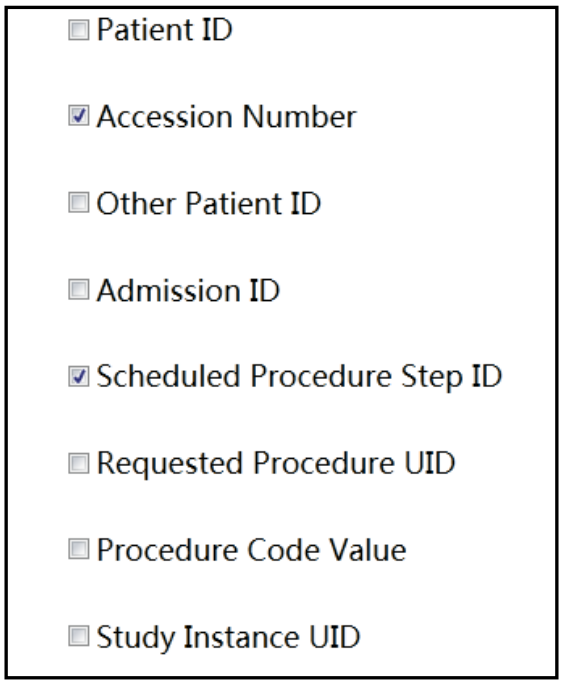


Figure 5-61： Configuration identifier

3. Archive

There are archive list and the configuration information of each archive node. User can view and modify the information of the current archive node, can also add or remove nodes.

For data storage, you need to configure a PACS server parameters, related knowledge about DICOM storage can refer to the DIOCM standard.

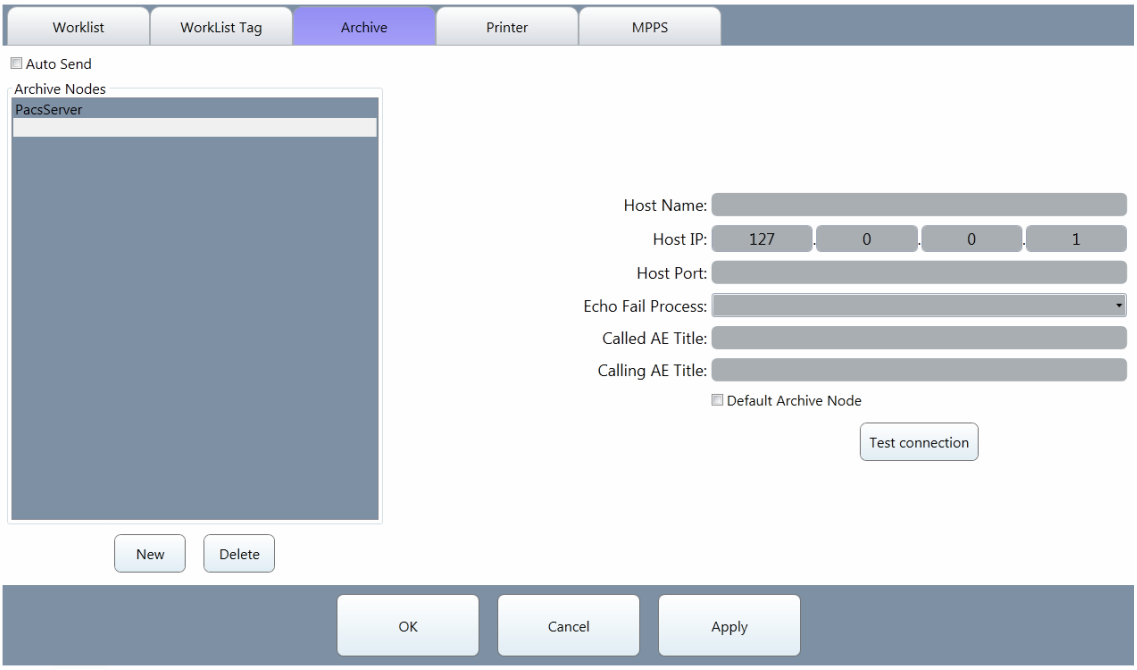


Figure 5-62: Archive interface

- To view the node information

Select the node you want to view in the node list, display the specific configuration information in the configuration information area.

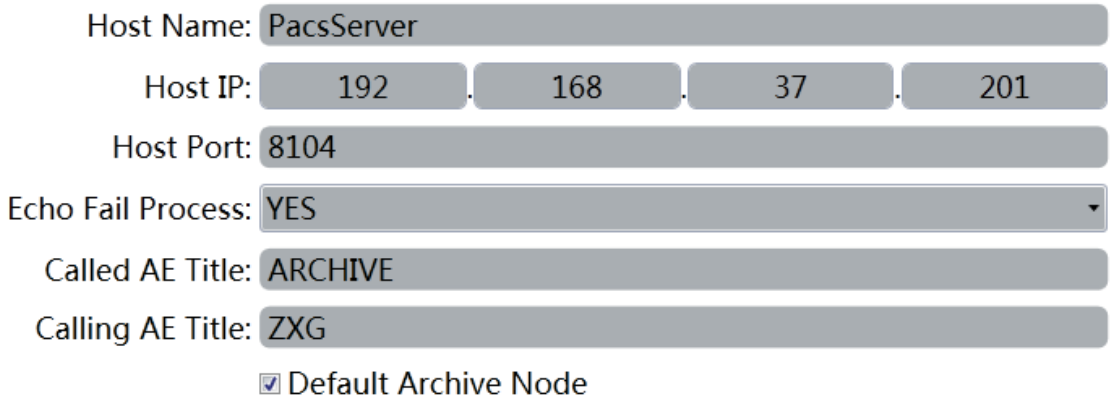


Figure 5-63: Archive node information

- Add node

Click the [new] button at the bottom of node list, all the configuration information except the Host IP will be empty. The Host IP is 127.0.0.1.

After completed the node configuration information, you can check the [Default Archive Node] to make the new node as the default archive node.

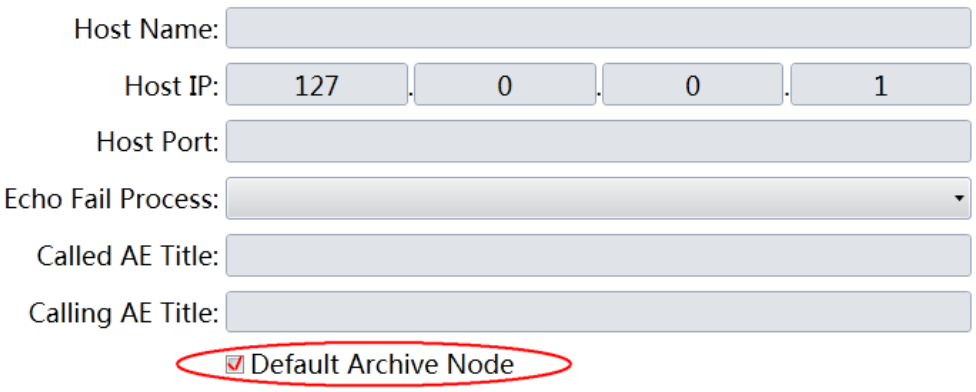


Figure 5-64

Click the [Apply] or [OK] button to save the new node.

- Modify the node information

Information if you need to modify existing storage nodes, refer to the new method.

- Delete node

Select the node you want to remove from the node list, and click the [Delete] button to remove node from the list.

4. Printer

Printer configuration parameters included: print node list, node configuration information and film size supported.

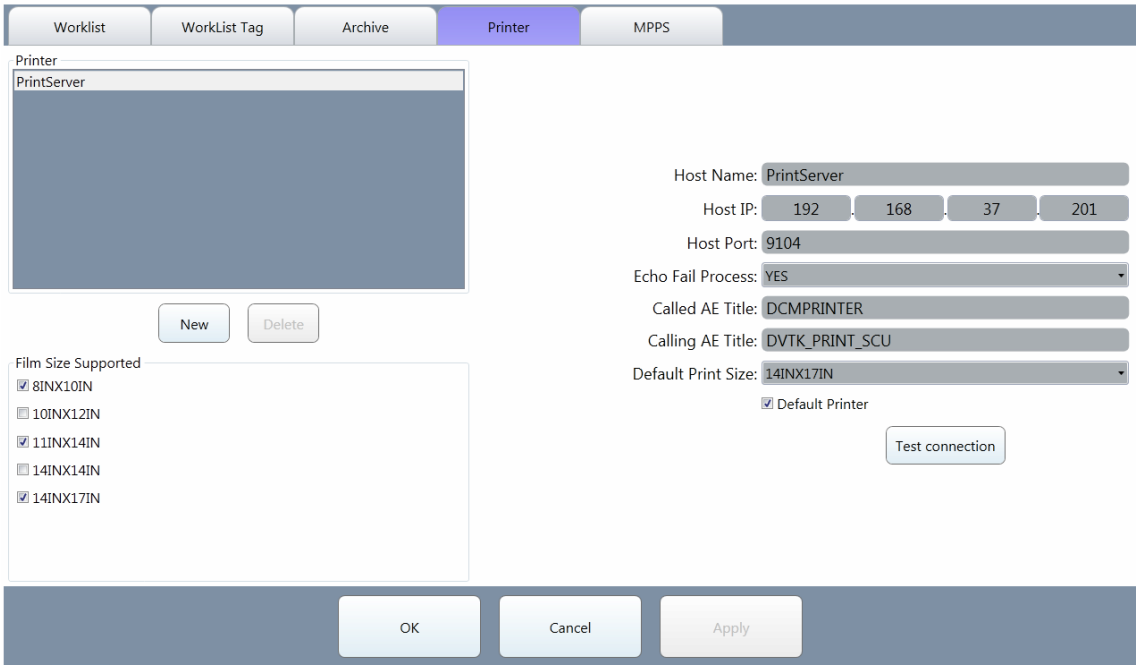


Figure 5-65: Printer configuration

You need to set the DICOM printer parameter for printing function. Related configuration, you can refer to the archive node configuration methods. The film size supported as shown in the following figure：

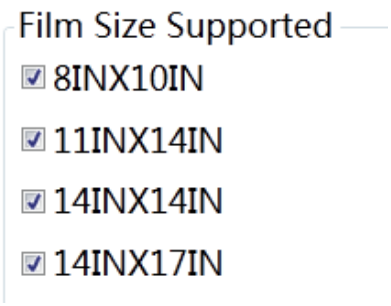


Figure 5-66: Film size supported

About DICOM Print knowledge can refer to the DICOM standard.

5. MPPS

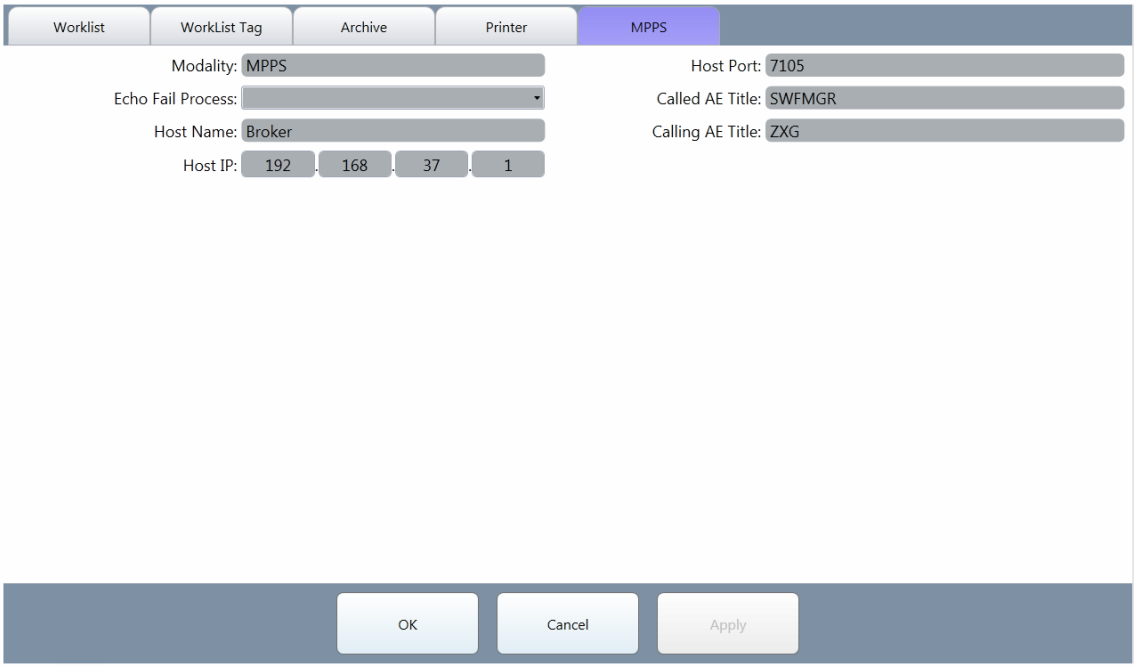


Figure 5-67

5.8.2.5 Hardware configuration

Select [Advanced-Hardware], hardware configuration interface appears. Hardware configuration including high-volt generator, detector, DAP and CAN Bus configuration.

1. High-volt generator

User can view the property information of high-volt generator, such as serial, work, different high-volt generator of the listed properties are different.

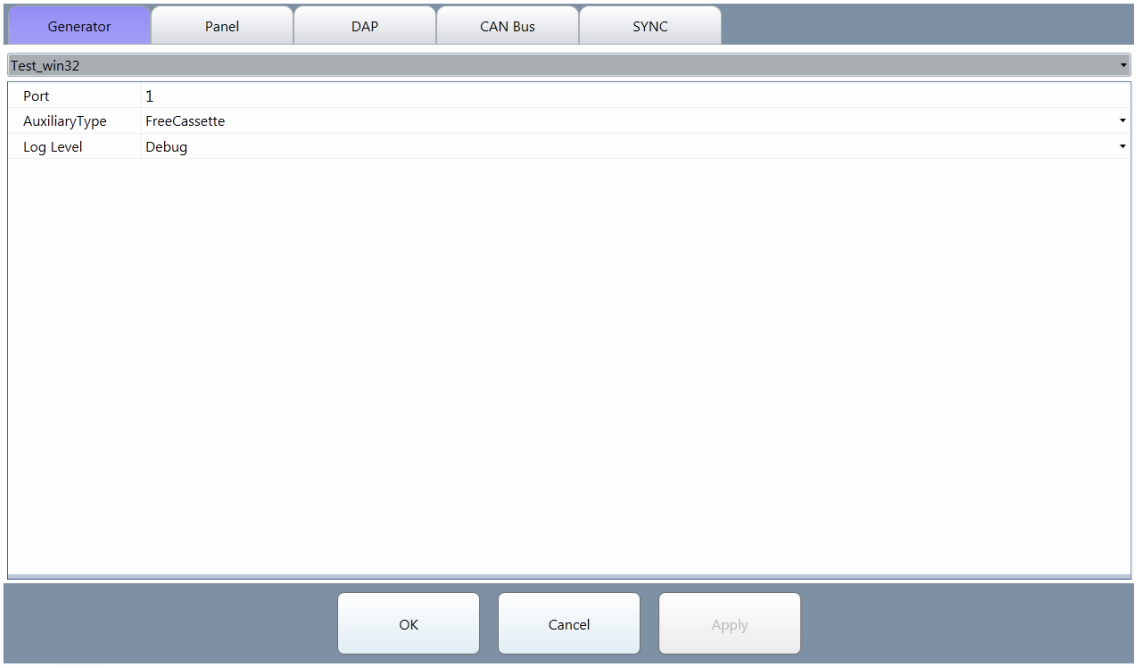


Figure 5-68: High-volt generator,

2. Detector

User can view and edit the property information of detector. Above the list of properties you can set up a virtual drive, virtual disk size, and whether to enable double-detectors:

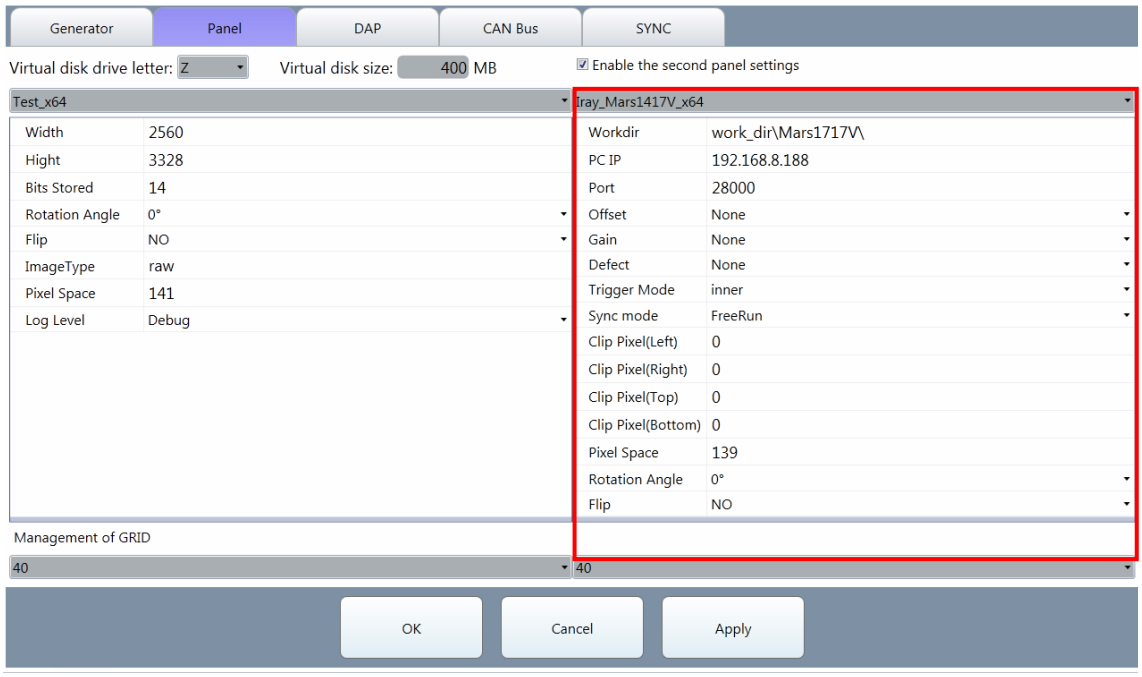


Figure 5-69: Detector configuration

After completed the editing, click the [Apply] or [OK] button to save the new settings.

3. DAP

Users can set the DAP's interface parameters in this interface.

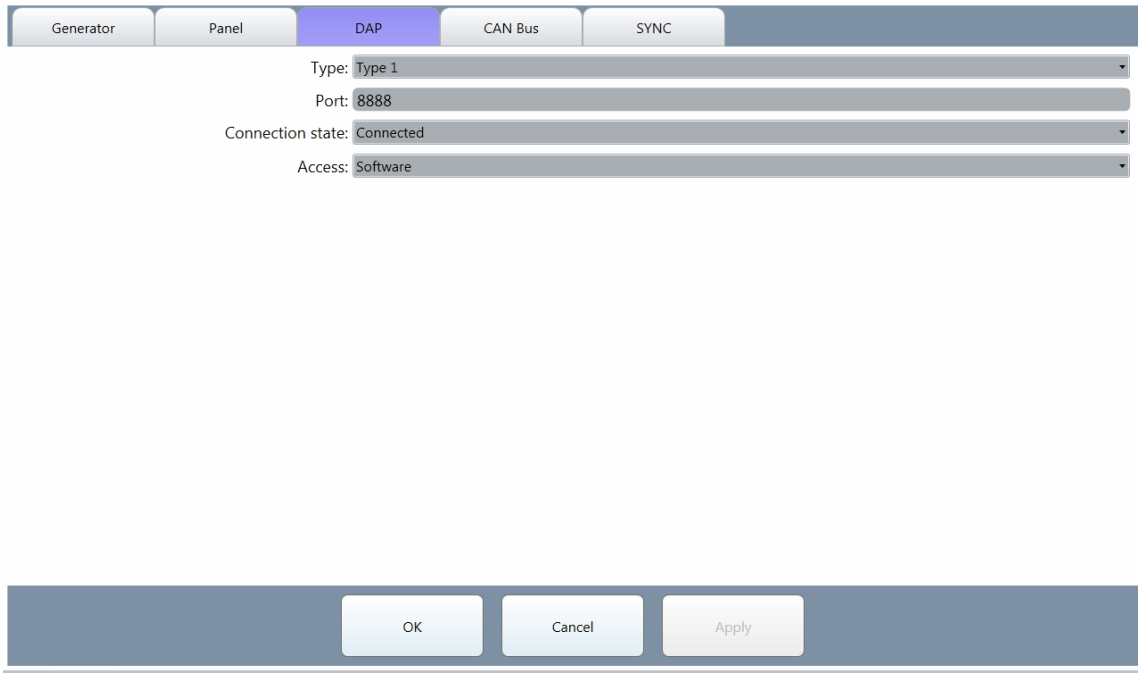


Figure 5-70: DAP configuration

4. CAN Bus Configuration

Users can set the CAN model, the technical parameters of the equipment, as shown in the following figure:

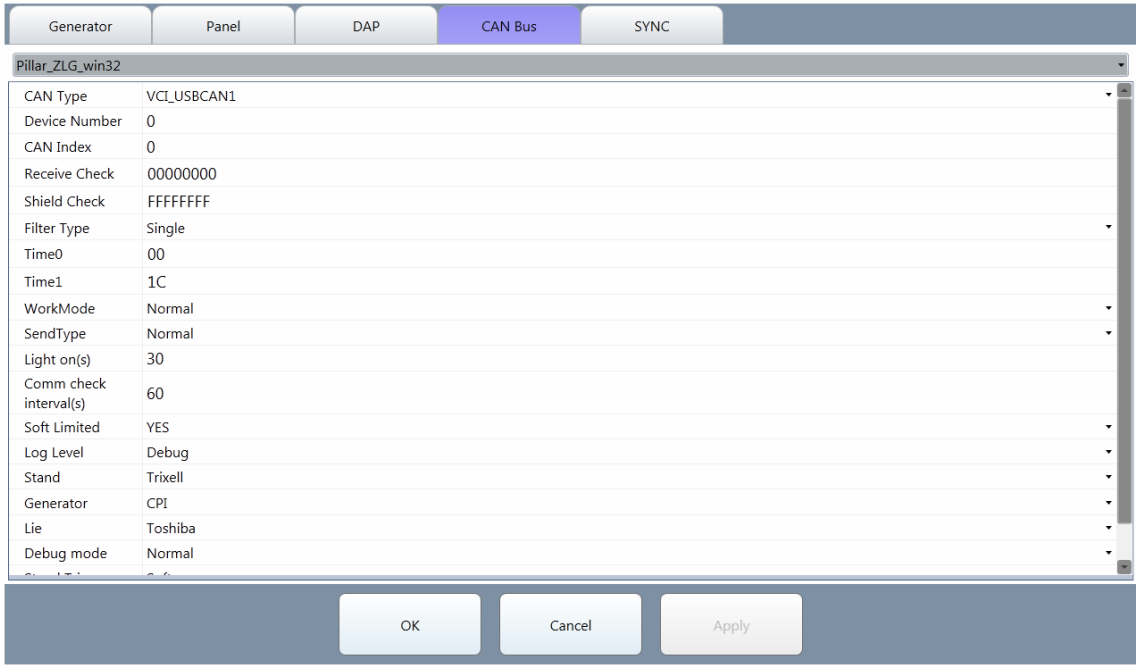


Figure 5-71:4. CAN Bus Configuration

Click [Apply] or [OK] button to save the new configuration.

5. SYNC Configuration

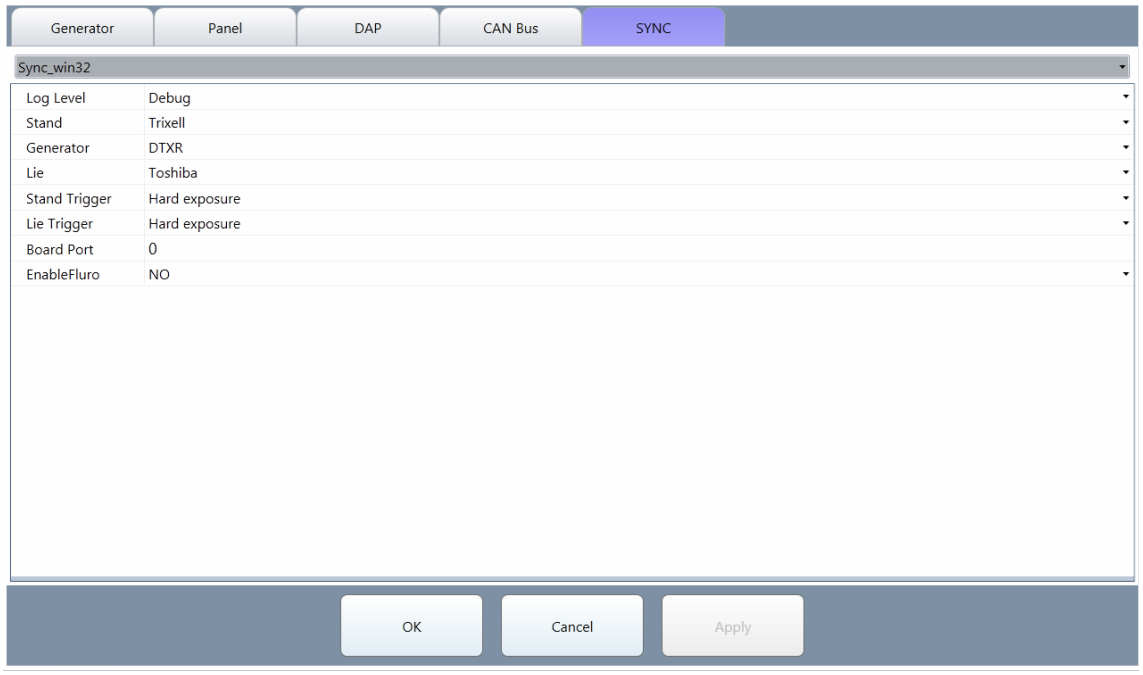


Figure 5-72

Click [Apply] or [OK] button to save the new configuration.

5.8.2.6 System Configuration

Select the [advanced-system], a system configuration interface appears. System configuration includes image annotation, reason for rejection, image processing settings and other settings.

1. Image annotation configuration

All the comments will be list in the image comments list. You can add new annotations or delete existing annotations to the list.

1) Add new annotations

Enter the comment text in the text box, and then click the [new] button at the right of text box to add a new comment.

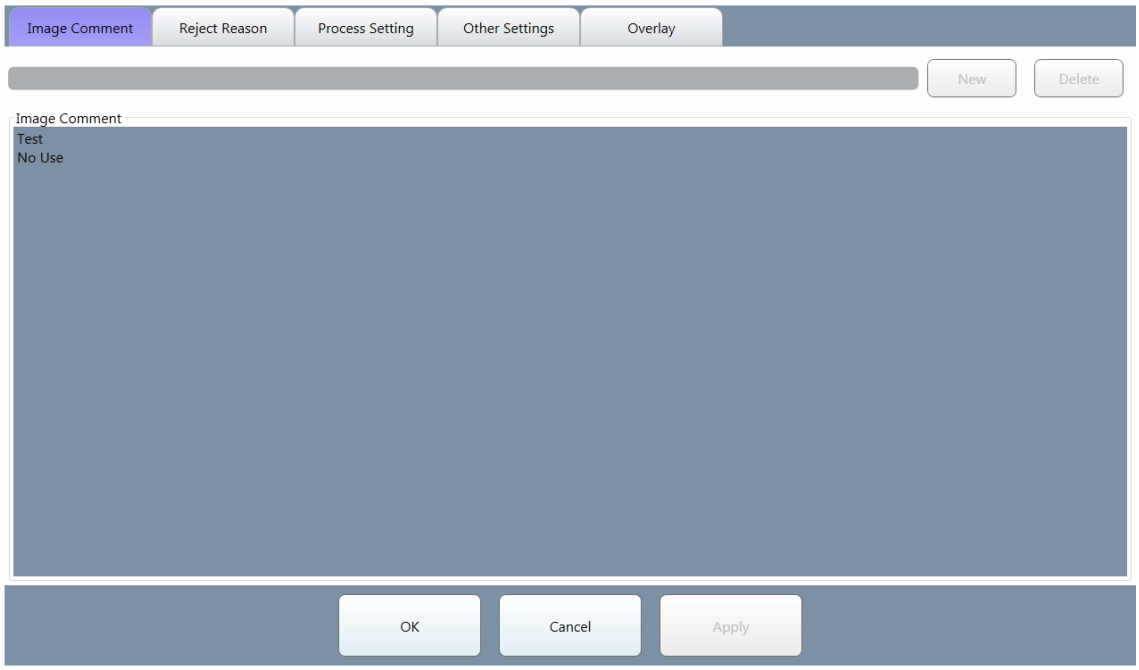


Figure 5-73: Add new annotations

2) Delete existing annotations

Select the comment you want to delete, click on the right side of the text box [delete] button you can delete the comment.

2. Reason for rejection

Reason for rejection and image annotation sets are similar, and can add and remove reasons for refusal in the same way.

3. Image processing settings

Users can select a configured image processing parameters through each drop down box.

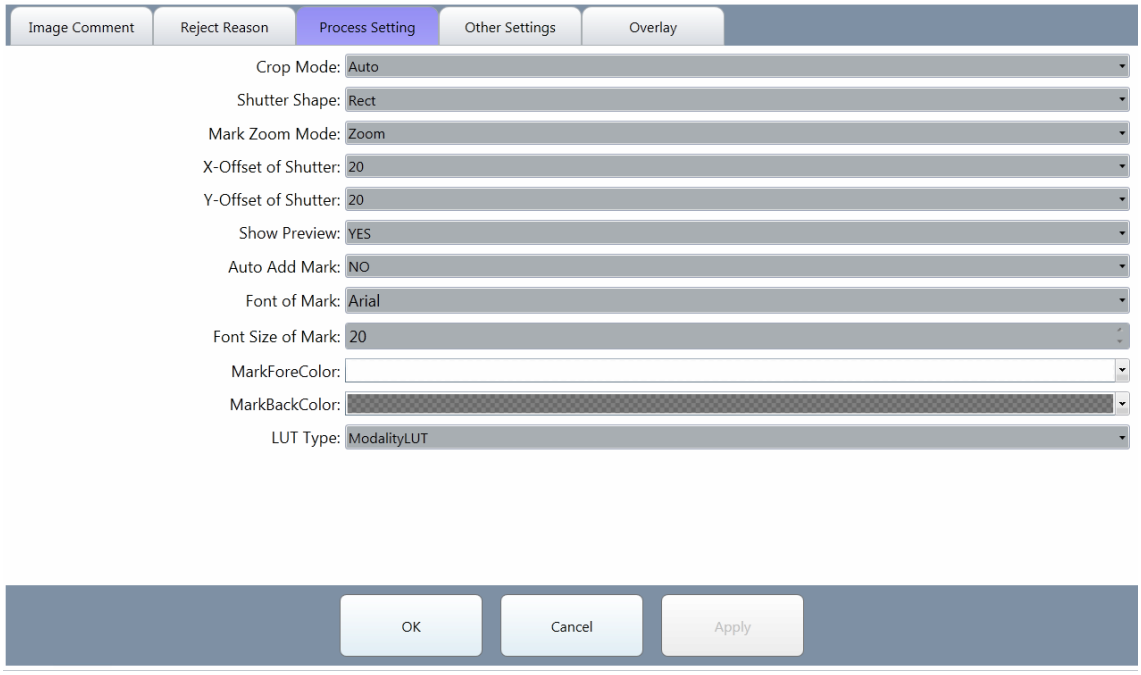


Figure 5-74: Image processing settings

4. Other settings

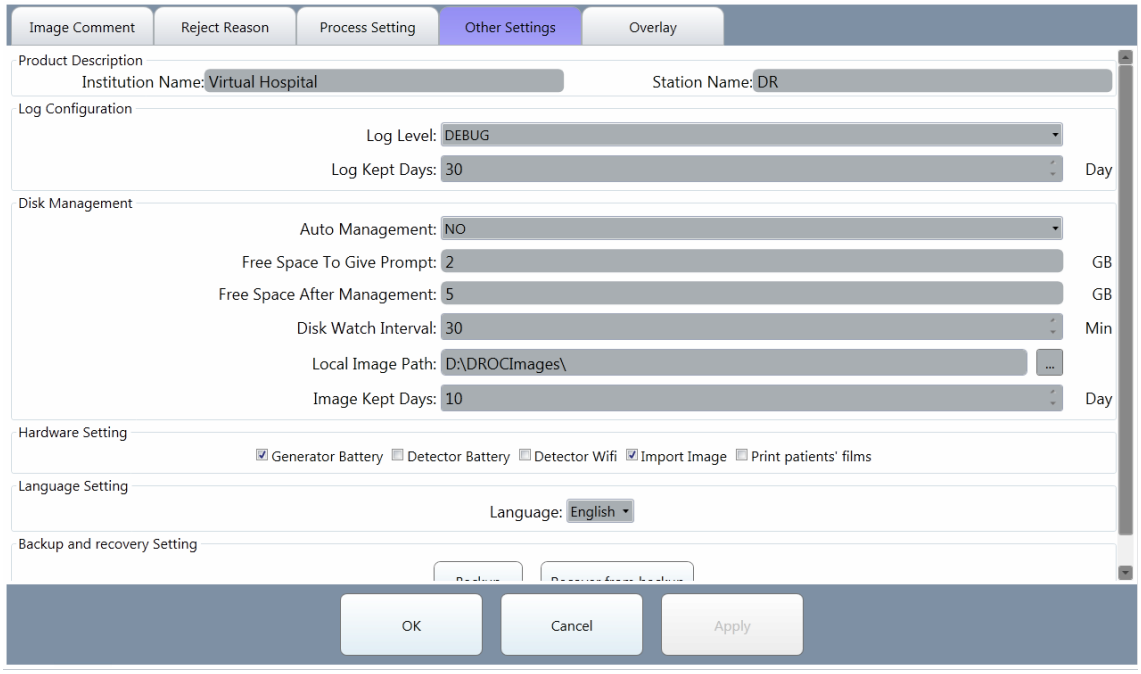


Figure 5-75: Other settings

Product Description: include the institution name and station name.

Log Configuration： Set the log level and retention time. Default settings for DEBUG level and kept for 30 days.

Disk Management： Set the disk management space and time interval, and sets the path for local image storage and storage time (Storage time default is 10 days).

Hardware Setting： You can configure high-volt battery, detector batteries and detector WIFI.

System Language Setting： You can choose Chinese or English.

Reset Factory Setting： Click it to back to factory default settings.

Click on the [Apply] button to save the current changes.

Click on the [OK] button to save and close the current interface.

Click on the [Cancel] button, it returns system information interface without saving changes.

5. Overlay

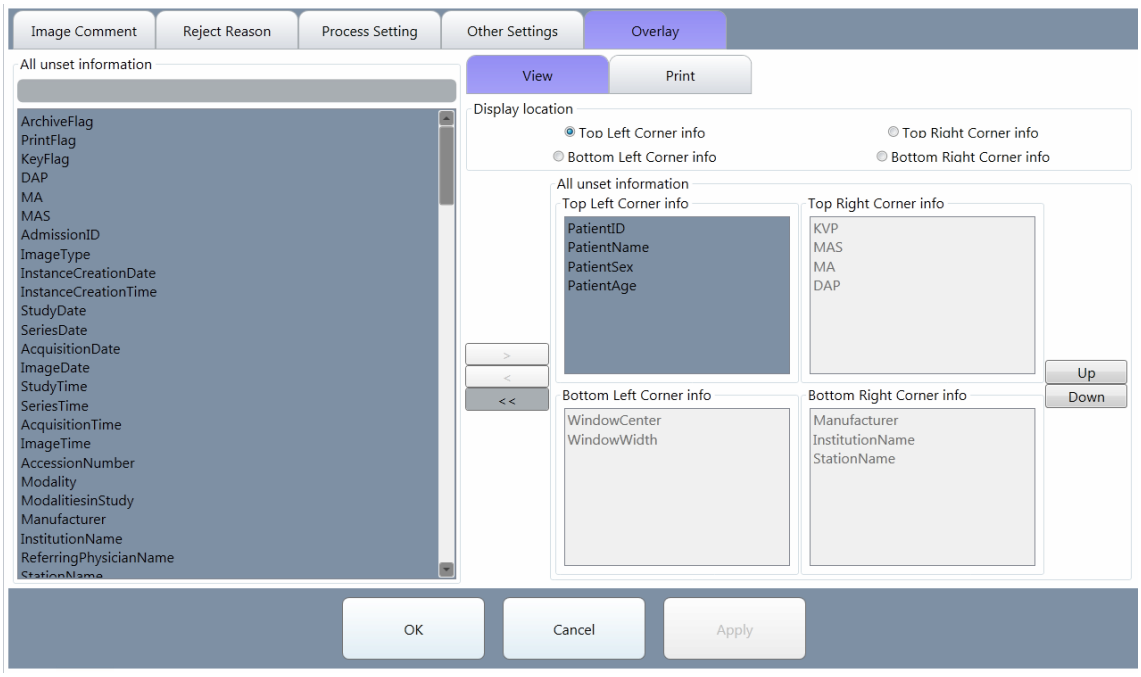


Figure 5-76

Click on the [Apply] button to save the current changes.

Click on the [OK] button to save and close the current interface.

Click on the [Cancel] button, it returns system information interface without saving changes.

5.9 Exit the System

When a check is on, you cannot perform an exit, you need to turn off all checking.

In a new patient interface or local/remote worklist interface, click on the top-side exit icon and popup exit interface:

Figure 5-77: Exit interface

Login again:

Click on the [login again] button, pop-up confirmation cancellation prompt box, after confirmed it, the interface switches to the login interface.

Shutdown:

Click on the [shutdown] button, pop-up confirmation shutdown prompt box, after confirmed it, the computer shut down.

Exit:

Manager user clicks on the [exit] button, pop-up to confirm the exit prompt box, after confirmed it, the system shut down.

To prevent technicians user to change system configuration, technician users are not allowed to exit the system.

FOUR YOUR NOTE

Chapter6 Planned Maintenance

This chapter describes planned maintenance procedures which must be performed regularly to maintain safe and effective operation of the equipment.

Maintenance has two aspects, one is routine maintenance by the user or operator, and the other is professional maintenance by an authorized service personnel.

6.1 Routine Maintenance

6.1.1 The Whole Machine Maintenance

Be sure to do the following user's routine maintenance:

1) Ensure the room is clean, dry and ventilation, avoid high temperature and direct sunlight.
2) Wipe all the moving parts of slide surface frequently to avoid dust and inclusions.
3) Check the risk warnings and labels are all in good condition.
4) Check whether the shell, buttons and handle can be operated normally, whether there are any damages, and any missing parts.
5) Check whether there is abnormal sound when the X-ray generator components exposure.
6) Check whether there is any wear, corrosion or oil shortage on the bearing, the user can coated with new lubricating oil when necessary.
7) Check to make sure all wires are fixed, there is no loss or damage.
8) Check to ensure that the system can run smoothly when all the moving parts are within the scope of moderate exercise.
9) Ensure the equipment’s power supply, pay attention to understand power supply situation, measure and adjust the power supply.
10) Check whether grounding protection of the whole machine and each part is good.
11) Check for error logs in the Window, remove the log files after the analysis is completed.
12) Run the Windows defragmenter when pieces of authentication system are more than 5%.
13) Check the old image’s storage directory (make a list and before removal the list, confirm whether the user still need to use and whether it has been filed).
14) Make the system setting’s archive file on a floppy disk.
15) Cleaning/Disinfection

 **CAUTION！**	**Except cleaning some patients commonly used components in checking process, power off and unplug the system before cleaning/disinfection the equipment.**

The commonly used components are as follows: Compression plate, breast radiography platform or Magnification table, patients handle and mask type shield.

- **Cleaning**

Before each inspection, clean and sterilize the components those are applicable and close to the patient. Such as clean the compression plate, the steps are as follows:

1. Shift out the three-dimensional compression plate.
2. Use a damp cloth or pads to clean parts, wet gauze with water or lukewarm household detergent solution.
3. After cleaning, install the three-dimensional compression plate.

NOTE！	**Don't clean the system with abrasive, organic solvent cleaner (probably the cleaner has chemical reaction on the metal) and the solubility of the detergent cleaner (e.g., gasoline and stain remover, etc.).**

 **CAUTION！**	**Don't splash equipment! Don't let cleaner into the equipment.**

- **Disinfection**

We recommend that the surface disinfection using isopropyl alcohol, due to phenol and its composites disinfectant can decompose chlorine, and has certain corrosion effect, therefore is generally not recommended.

Disinfection spray is not recommended according to general principle, because spray mist may seep into the system, this means that the system security can no longer guarantee (break circuit, and formation of combustible air water vapor mixture).

 **WARNING！**	**As is known to all, some components of disinfectant are harmful to health, the disinfectant concentration in air shall not exceed the legal value, and we recommend using a strict control of manufacturer's products.**

6.1.2 Tube Maintenance

Periodical inspection:

- Whether the insulating oil of the tube components leakage or not.
- Whether the function of the temperature control switch is normal or not.
- High voltage line connection parts: line plug clamps are loose or not; the condition of the insulation silicon grease leakage and the coating.
- Whether there is abnormal noise or vibration when the X ray tube anode turns.

6.1.3 Professional Maintenance

The mechanical structure and electrical components inside the equipment need to be maintained by our authorized medical professionals.

We suggest that the system maintained after install and operate over a period of time (1 month to three months). After that, according to the system’s running state, maintain every 12 months.

If the patients is up to 50 everyday, shorten the maintain time to every 6 months.

Otherwise, there are simple Quality Control test which ensure that the system is operating to its design

standards and provides a high level of mammographic quality by our service engineers.

Frequency: twice a year.

Test item: the image quality/ image homogeneity/ the paddle deflection in compression.

Procedures: test by our service engineers.

6.2 Common Problems and Solutions

We provide common problems and solutions in the table below. The user can refer to the table to troubleshoot problems, or contact our medical professionals when you cannot identify the cause or unable to solve the failure.

Don't disassemble the equipment, in order to avoid wrong operation and cause damage.

No.	Problems	Solutions
1	Cannot check into the inspection interface when start DR console.	Check that the detector and the high-volt generator's power supply is on.
2	Image processing software shut down automatically after start for a while.	Ensure the dongle plugged correctly.
3	Image cannot be saved.	Check whether the storage path is changed or the hard disk space is full.
4	Image center blurring.	Ensure the warmed up time is 10 minutes enough.
5	Image noise.	Ensure the detector's cooling fan is normal.
6	Images appear more horizontal lines.	Ensure the detector's temperature is up to the temperature set.

If the device needs to be repaired or calibrated again, or it appears any other abnormal conditions during use, please cut off the power supply and contact our service personnel, describe the problem or failure in detail, the service personnel will provide door-to-door service in time.

6.3 Replace the collimator's light

The steps are as follows:

1) Power off and remove the shell of the collimator.
2) Move away the protect radiator of the light field indicator.
3) Disconnect the two power cords of the indicator.
4) Unscrew two fixed screws, remove the damaged indicator.
5) Replaced with the indicator of the same specifications, ensure the surface is clean.
6) Tighten the two retaining screws, connect the two power cord.
7) Check whether the indicate region and X-ray region is corresponding.

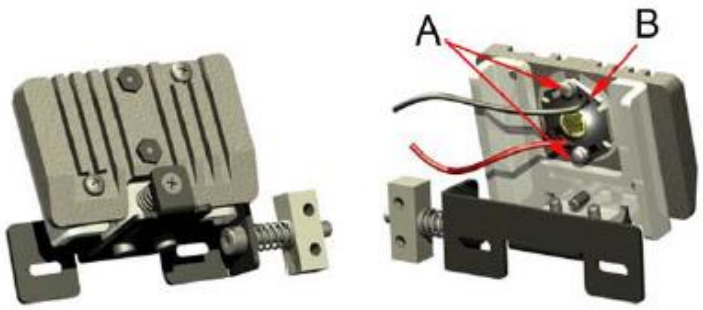


Figure 6-1

WARNING!	**Make sure the power switch is turned off, and the external power supply cord is pulled out when maintain and replace the spare parts.**

WARNING!	**Before open the shell to repair and replacement the spare parts, wait for a few minutes until the high-volt generator's capacitor complete discharged, to avoid shock hazard caused by the capacitance of the residual voltage.**

NOTE!	**In order to ensure the system's performance and the safety of operation, the replace parts must be of the same specifications as the original.**

AppendixA Maintenance Spare Parts List

No.	Material name	Specification and type
1	High voltage cable	M1, CA3, CA3, 10M
2	Power switch	400V/32A
3	Transformer	AC220 1200VA
4	Fuse	250V/30A、250V/10A
5	Fuse base	600VAC/DC,30A
6	Switching power supply (a)	INPUT:100-240VAC，1.3A OUTPUT: V1 +5V, 6.0A; V2 +12V, 2.0A
7	Switching power supply (b)	INPUT:88-264VAC, 1.8A OUTPUT: V1 +24V, 10.0A
8	AC motor	0.37kW
9	Servo motor (a)	Rated power：0.4kW Rated torque：1.27N-m Rated speed：3000 Rated current：2.6A
10	Servo motor (b)	Rated power：0.5kW Rated torque：2.39N-m Rated speed：2000 Rated current：2.9A
11	Stepper motor(a)	Phase number：2 Step angle：1.8 ° Holding torque：0.14NM Rated phase current ：0.95A

12	Stepper motor(b)	Phase number：2 Step angle：1.8 ° Rated voltage：2.7V Rated phase current：1.5A
13	Stepper motor(c)	57 planetary reduction stepper motor Reduction ratio: I=25 Efficiency：90 Rated load：25NM
14	Solid-state relay(a)	LOAD:24~220VAC 40A INPUT:5-24VDC
15	Solid-state relay(b)	LOAD:5-200VDC, 10A INPUT:5-24VDC
16	Wiring row	600V/30A
17	High-voltage generator	5KW
18	X-ray tube components(a)	300KHU
19	X-ray tube components(b)	300KHU
20	Detector	24*30CM
23	AC contactor	12V/32A

AppendixB Datasheet

B.1 System Configuration

System Part		specifications
Gantry		M-GANTRY
High-volt generator		VMX40P5X4297
Collimator		HMC-915
Console		M-CONSOLE
Detector		AXS-2430
X-ray Tube Assembly		C339V+XM15
Foot Pedal		FSL0W00000
Image Acquisition Workstation （MXRS-001）	Host	T4900
	Monitor	C14S

B.2 Power Requirement

Parameter	Specifications
Input Voltage	Single phase AC220V
Mains Frequency	50Hz
Source Resistance	≤0.5Ω
Power Capacity	≥10kVA

B.3 High-volt Generator

Parameter	Specifications
Voltage	Range: 20-40kV（step: 0.5kV） Accuracy of kV: ≤±4%
Current	Range: 10mA~160mA，Accuracy of exposure mA: ≤±5%，follow the R'20 number system, consists of the following gears: 10， 11， 12.5， 14，16， 18， 20，22， 25， 28， 32，36， 40，45， 50，56， 63，71， 80，90，100， 110， 125，140， 160
Maximum Output Power	5kW（40kV，125mA）
nominal electric power	4.8kW（30kV，160mA，0.1s）
Nominal X-ray tube current and the corresponding largest X-ray voltage	160 mA，30kV
Nominal X-ray tube voltage and the corresponding largest X-ray current	40 kV，125 mA
Nominal exposure time	Range: 0.005s~10s，Accuracy of exposure ms: ≤(10%＋1ms)，follow the R'20 number system, consists of the following gears: 0.005， 0.0056， 0.0063，0.0071，0.008，0.009， 0.01，0.011， 0.0125，0.014，0.016，0.018， 0.02， 0.022，0.025， 0.028， 0.032，0.036，0.04， 0.045，0.05， 0.056， 0.063，0.071，0.08， 0.09， 0.1， 0.1.1， 0.125， 0.14，0.16，0.18，0.2, 0.22， 0.25，0.28，0.32，0.36，0.40，0.45，0.5，0.56，0.63，0.71，0.8， 0.9，1，1.1，1.25， 1.4，1.6，1.8，2.0，2.2，2.5， 2.8， 3.2，3.6，4.0，4.5，5，5.6，6.3，7.1， 8，9，10
mAs	Range: 0.5mAs～560mAs，Accuracy of exposure mAs: ≤±2%，follow the R'20 number system, consists of the following gears: 0.5， 0.56， 0.63，0.71，0.8，0.9，1，1.1，1.25， 1.4，1.6， 1.8， 2.0，2.2，2.5， 2.8，3.2，3.6，4.0，4.5， 5， 5.6， 6.3， 7.1，8， 9， 10，11， 12.5， 14， 16， 18， 20， 22， 25，28，32， 36， 40， 45， 50，56， 63， 71， 80， 90，

	100，110， 125， 140， 160， 180， 200， 220，250，280， 320，360， 400， 450， 500， 560
Minimum mAs	0.5mAs（50ms，10mA）
AEC Shortest Irradiation Time	6.3mAs

B.4 X-ray Tube Assembly

Tube	**XM15**
Parameter	**Specifications**
Focal spot nominal value(s)	0.1mm/0.3mm
Max. anode heat storage capacity	225kJ（300kHU）
Max. continuous heat dissipation	500W
Nominal tube voltage	40kV
Anode material	Mo doped
Target angle	15°
Radiation field with housing titled at 5°	18cm a 50cm
Inherent filtration	0.5 mm Be
Additional filtration	0.03 mm Mo
Anode rotation rate	Low rate: 3000r/min； High rate: 10000r/min
Nominal input power(s) of the anode	small：1.15kW 2 kW
	large：4.8kW 9kW

Tube assembly		C339V
Parameter		**Specifications**
Leakage radiation load factor		49 kV，4mA
Additional filtration		0.03mm Mo
Weight		13kg
The rotating anode motor	Voltage	Startup: 220V，operation: 40V（50Hz）；Startup:440V，operation: 100V（170Hz）
	Current	Startup: 7.1A，operation: 1.3A（50Hz）；Startup: 5.7A，operation: 0.9A（170Hz）
	Phase shift	Startup: 3.5A，operation: 0.8A（50Hz）；Startup: 8.2A，operation: 1.4A（170Hz）
	General	Startup: 7.8A，operation: 1.5A（50Hz）；Startup: 9.2A，operation: 2.1A（170Hz）
	Condenser capacity	25-40μF（50Hz）；4.5μF（170Hz）
	Maximum speed to start up	2/min（50Hz）；1/min（170Hz）
	Input power	Startup: 1550J，operation: 60W（50Hz）; Startup: 3250J，operation: 210W（170Hz）

B.5 Collimator（HMC-915）

Parameter	Specifications
Power	24V DC，2A
Radiation field （SID=65cm（±1% SID），EN 60601-2-54）	Min.：5cm×5cm max.：24cm×30cm

Inherent filtration （x-ray beam=75kV，EN 60601-1-3 par.7.3;7.4）	The min. is 0.02mmAl（the requirement is 1mm）
Additional filtration （x-ray beam =75kV, EN 60601-1-3 par.7.5）	0.03mmMo/0.025mmRh
The illuminance in the max. SID （SID=1m, Light Field 35×35cm；EN 60601-2-54）	＞160Lux
Timer	Button/automate，30s timer
Light field indicator	LED
The biggest radiation leakage（70kV,4mA,SID=100cm, EN 60601-1-3）	＜40mRh
Light Field switch	Automate
Weight	3.6kg

B.6 Detector (AXS-2430**)**

Parameter	Specifications
Pixel unit	85μm
Effective imaging range	239.36*304.64mm
Pixel matrix	2816*3584pixels
Spatial resolution	≥7.0lp/mm
Dot and line defect	Line defect width≤ 4 pixels; Dot defect≤ 2 ×2 pixels

B.7 Gantry

Parameter	Specifications
Motion range of the C-arm	630mm～1440mm，offset: ±5%
Rotation range of the C-arm	+195 °-155 °，the division value is 1 °，offset: ±2 °
FID	660mm，offset: ±5%
Motion range of the Compression plate	245mm，offset: ±10%
Pressure range	0~300N（manual）；150~200N（automatic）

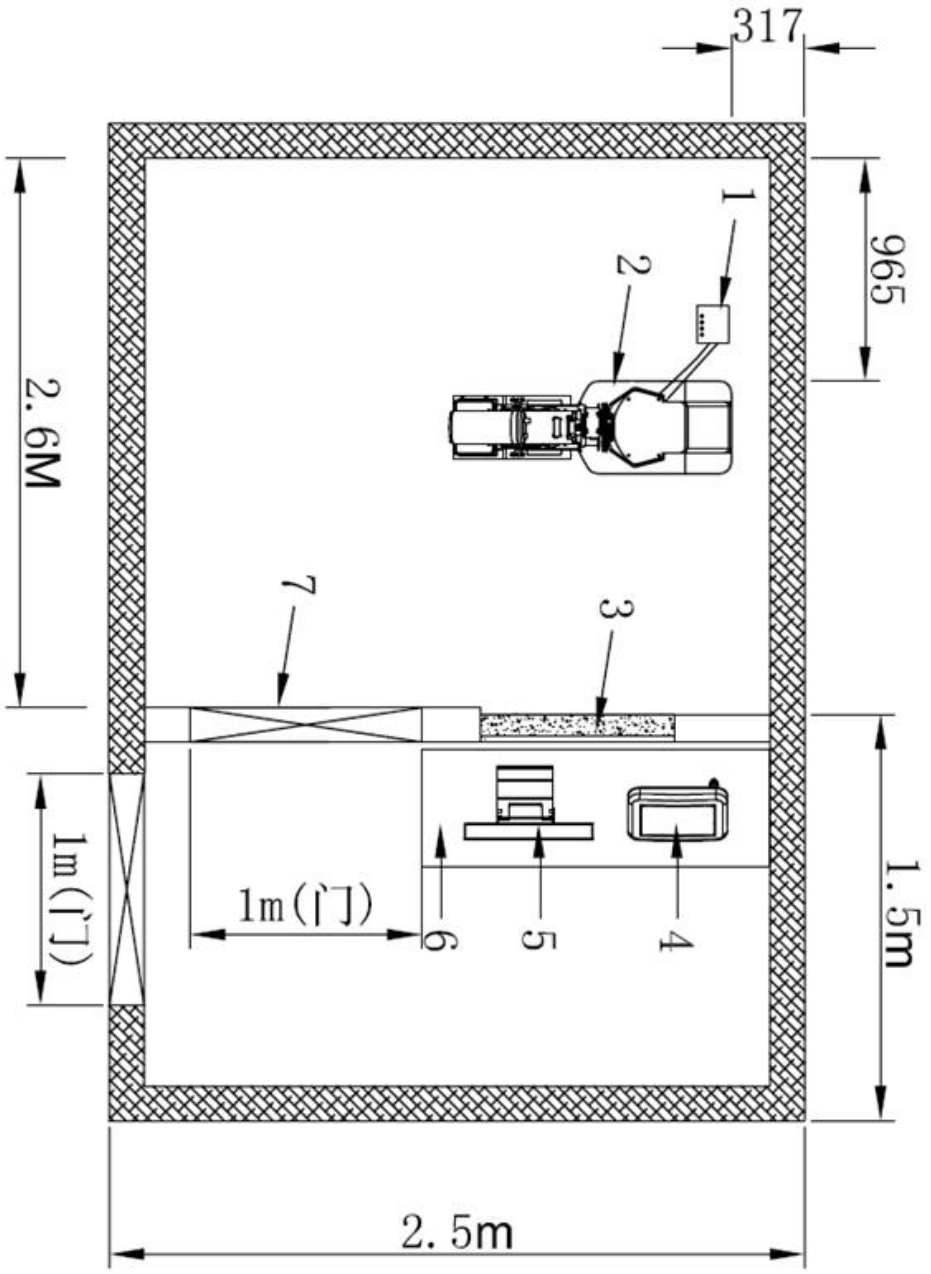
B.8 Image Acquisition Workstation

Parameter	Specifications
Monitor	19inch，resolution 1280×1024，contrast 1000:1
Memory	≥8G
Storage	≥320G
Operation system	Windows 7

B.9 Grid

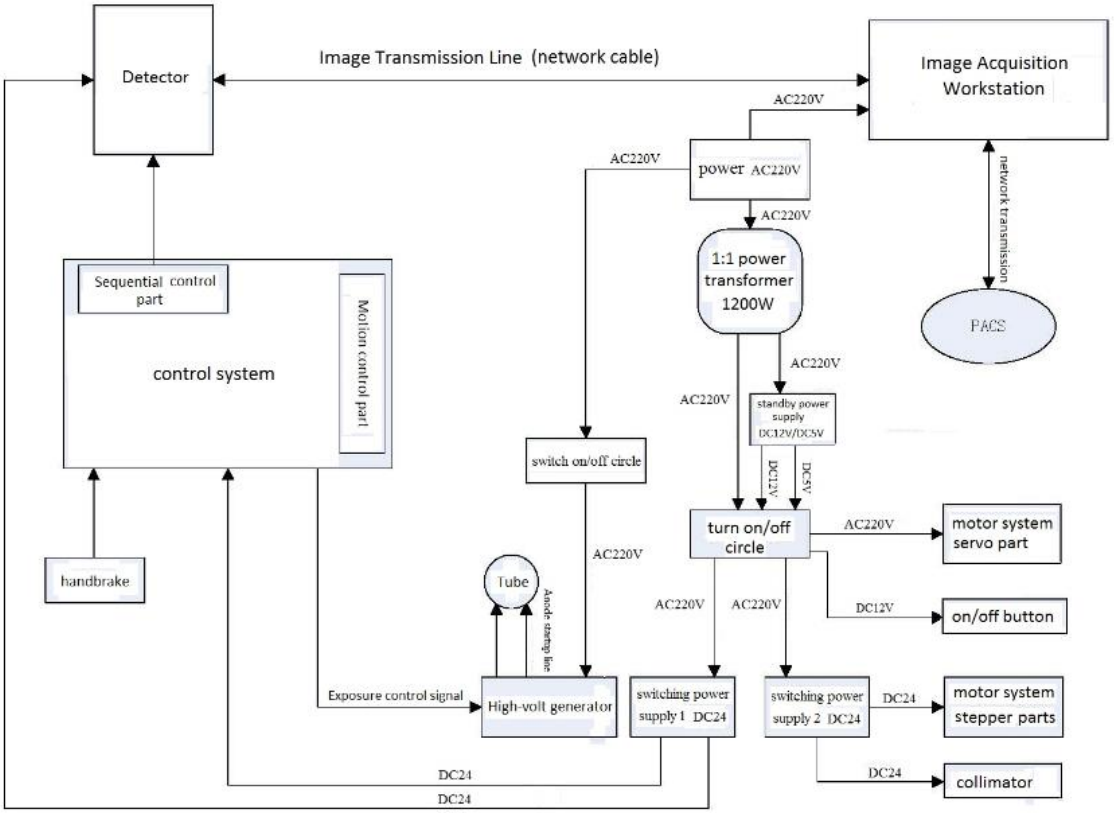
Parameter	Specifications
grid ratio	5:1
Size	338*264mm
Line Pairs	36L/cm
focal distance	66CM

AppendixC Machine Room Layout

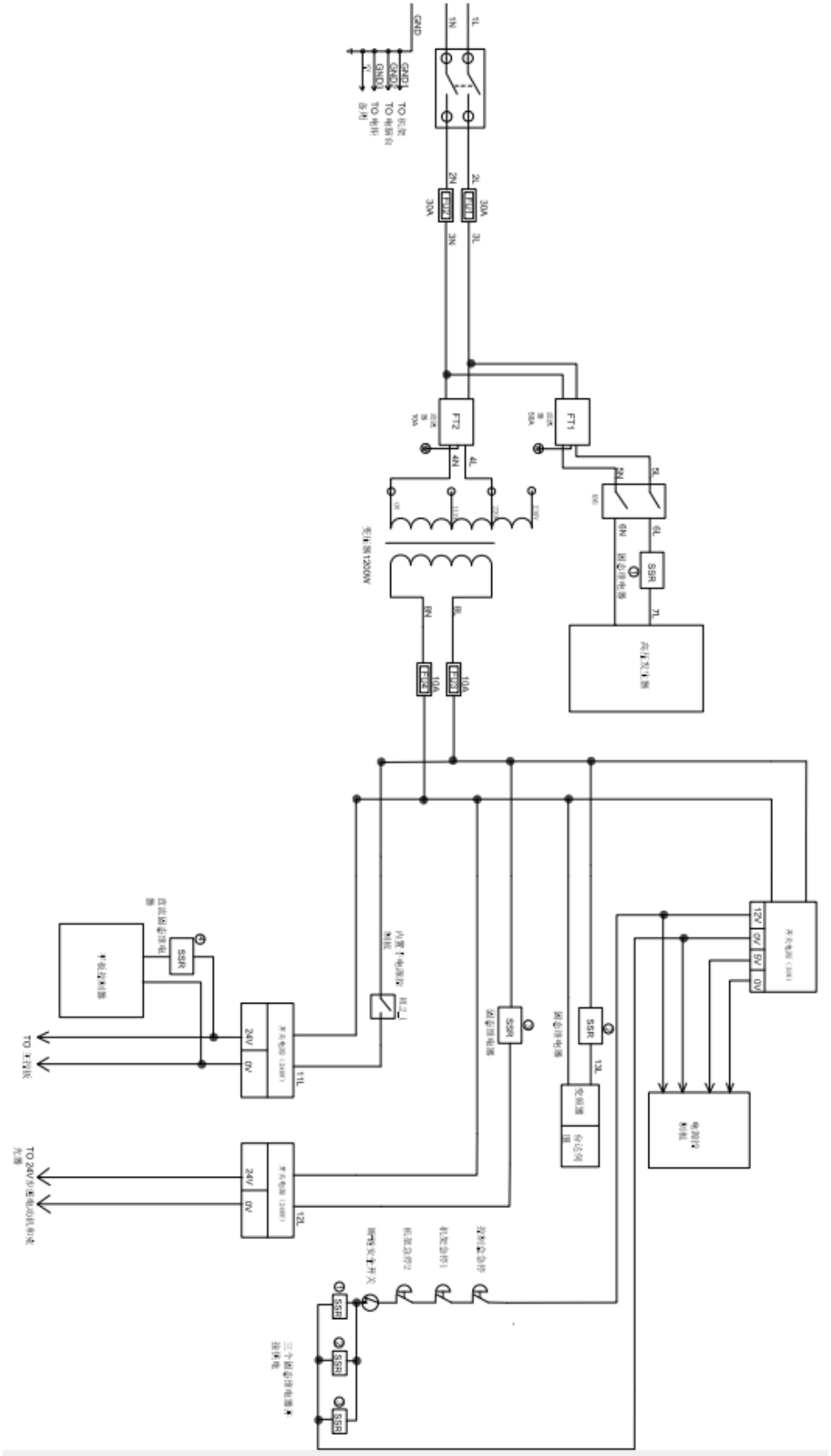


No.	Name	No.	Name
1	high-voltage generator	4	console
2	Rack	5/6	workbench
3	lead glass window	7	lead door

AppendixD The Whole Machine System Diagram



AppendixE The Whole Machine Wiring Diagram

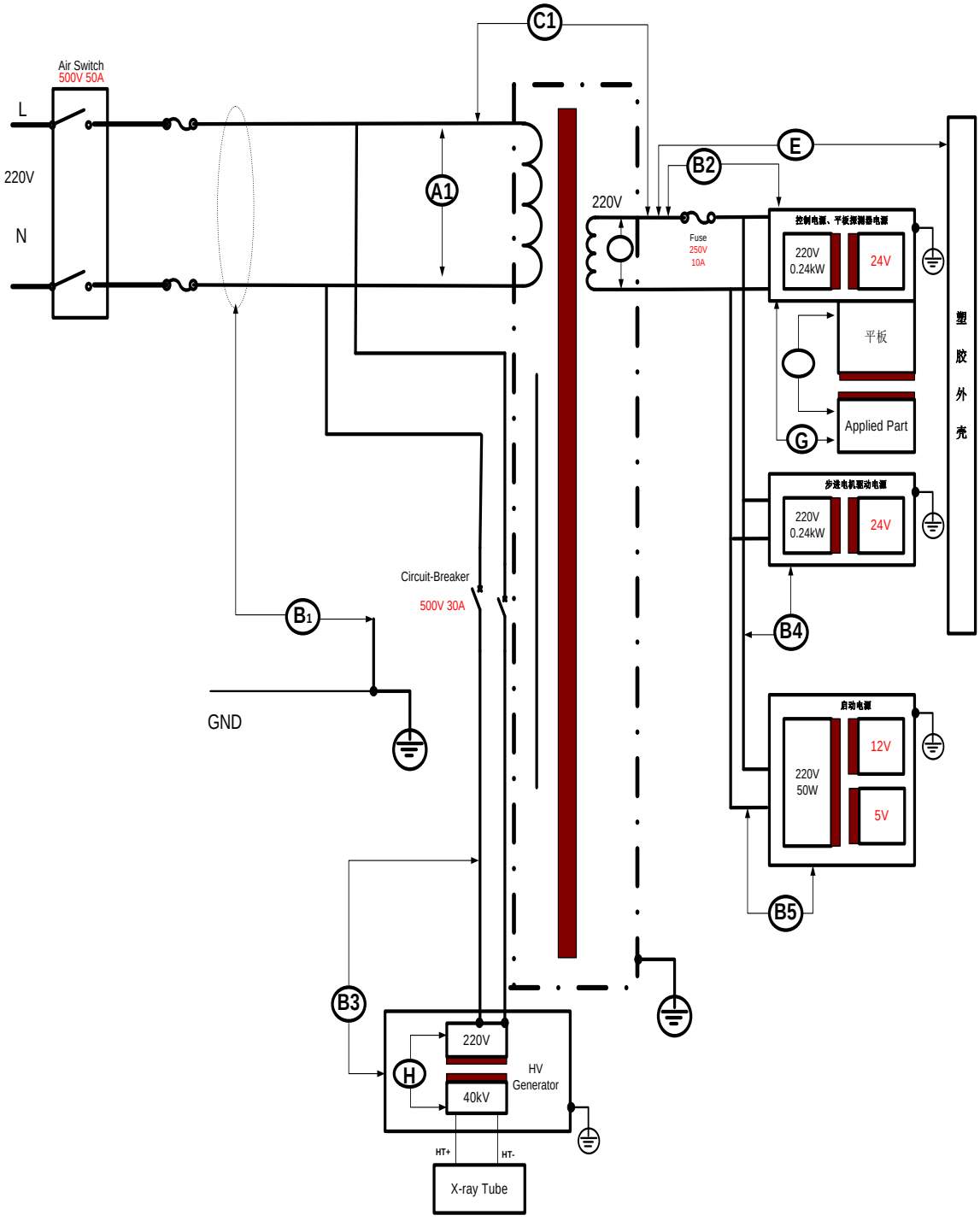


AppendixF The Basics of Insulation Diagrams

INSULATION DIAGRAM

Protection against electric shock-block diagram of system

PRODUCTION NAME: ROSA



■Class I equipment, Type B applied part

■ Permanently Installed Equipment

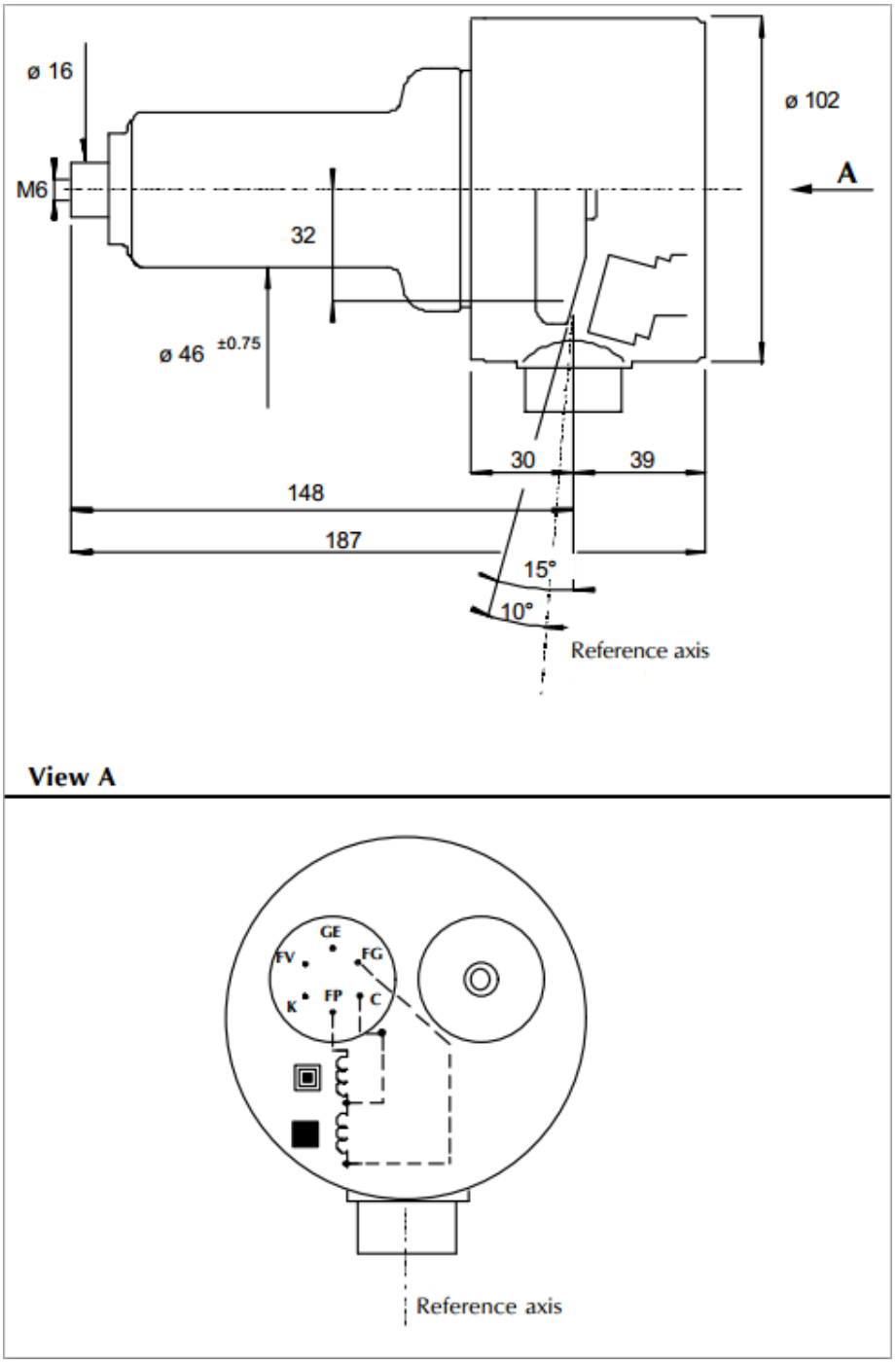
Insulation Chart									
Symbol	Insulation Type: BOP, BI, SI, DI/RI	Insulation Path	Reference Voltage (V)	Creepage Distance Required value (mm)	Electric Clearance Distance Required value (mm)	Creepage Distance Measured Value (mm)	Electric Clearance Distance Measured Value (mm)	Dielectric Strengthen (VAC)	Note
A1	BOP	A-f between（between L and N of 220V)	220	3	1.6			1500	
A2	BOP	A-f between（between L and N of 220V)	220	3	1.6			1500	
B1	BI	A-a1 (between phase line and GND)	220	4	2.5			1500	
B2	BI	A-a1 (between phase line and GND)	220	4	2.5			1500	
B3	BI	A-a1 (between phase line and GND)	220	4	2.5			1500	
B4	BI	A-a1 (between phase line and GND)	220	4	2.5			1500	
B5	BI	A-a1 (between phase line and GND)	220	4	2.5			1500	
C	DI	17g)4)	220	8	5			4000	
D1	DI	B-a	220	8	5			4000	
D2	DI	B-a	220	8	5			4000	
E	DI	B-a	220	8	5			4000	

FOR YOUR NOTE

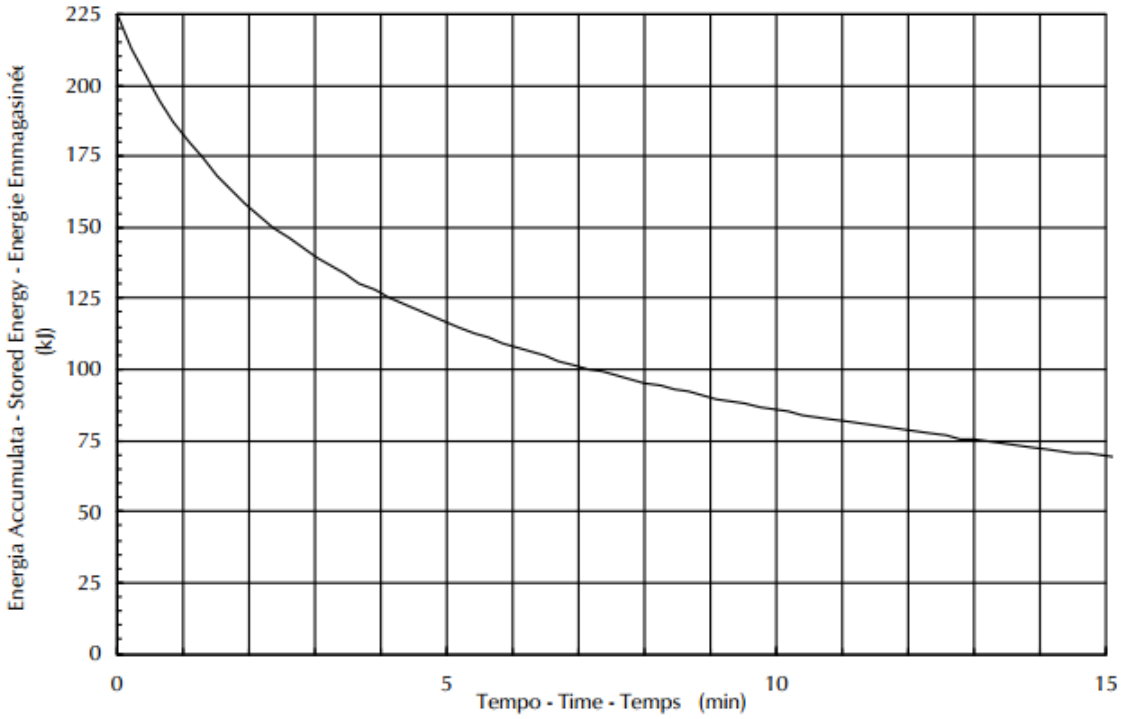
AppendixG Characteristic Curve

G.1 X-ray Tube

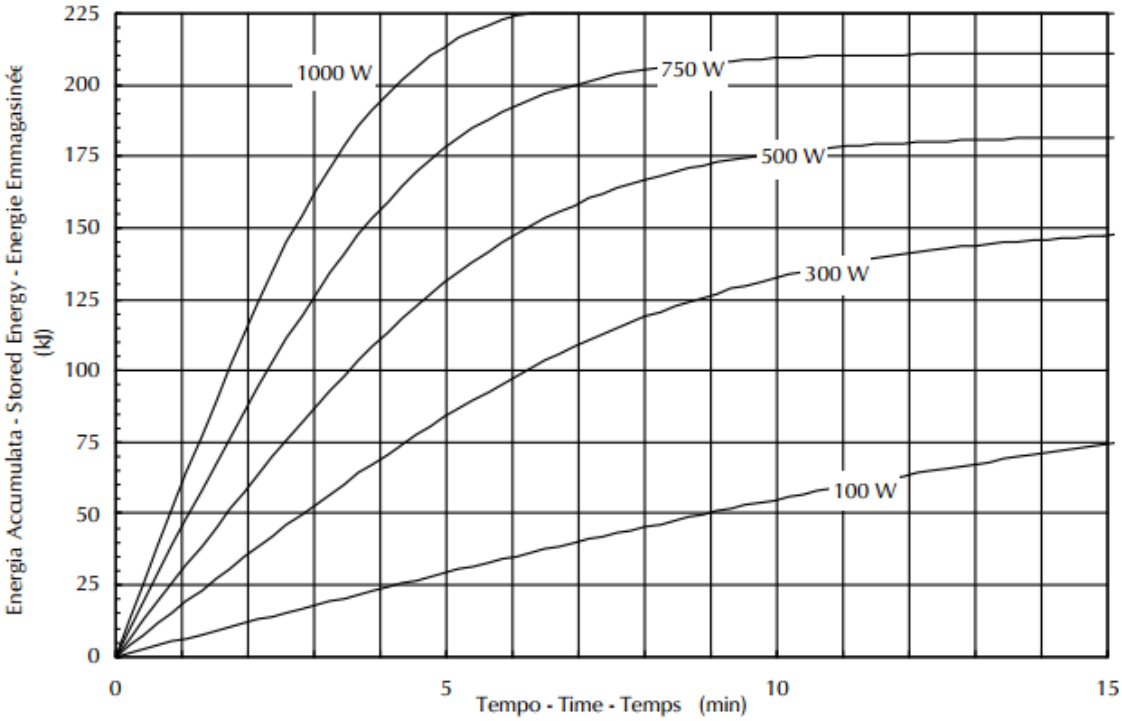
- **Dimension**



■ Anode Cooling Curve

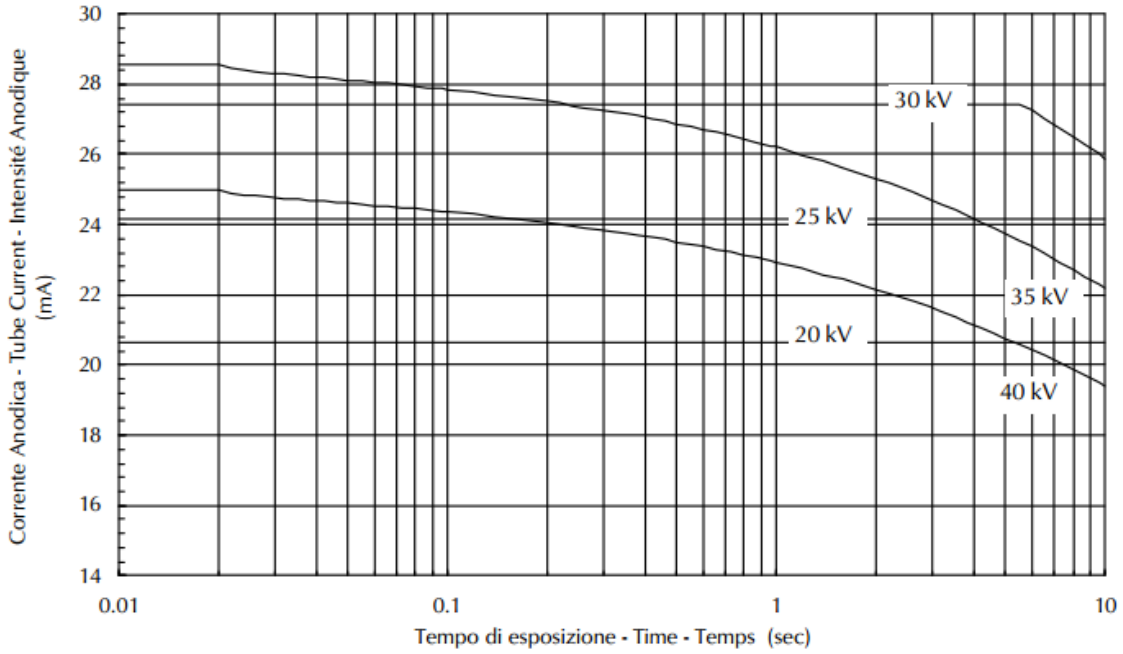


■ Anode Heating Curve

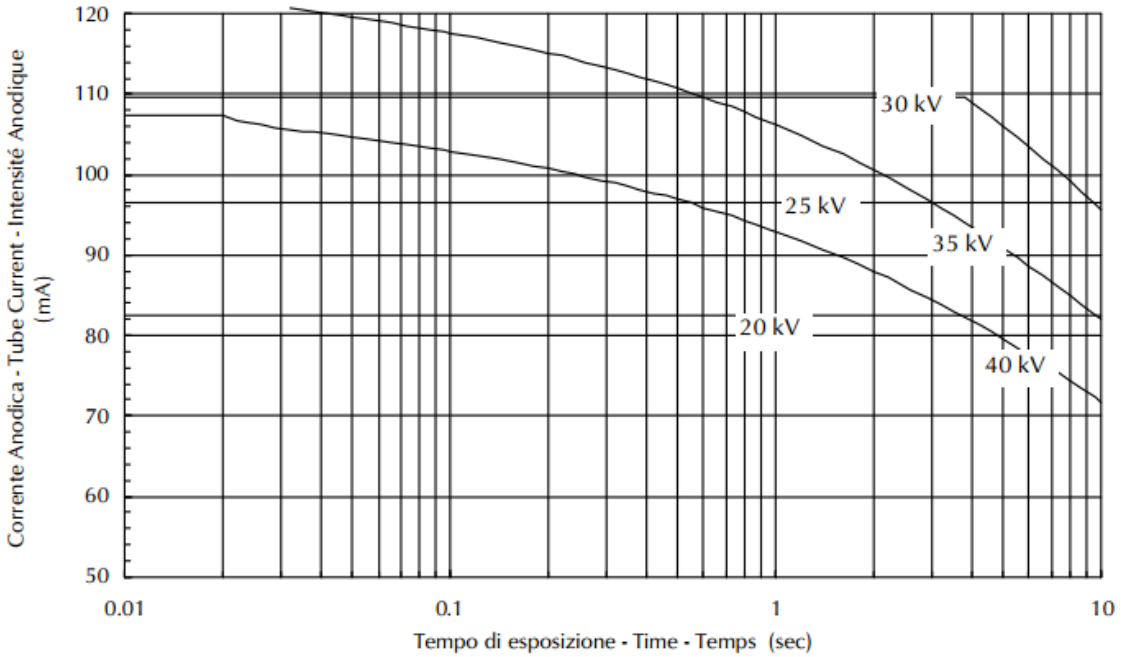


■ **Single Load Rating Curve**

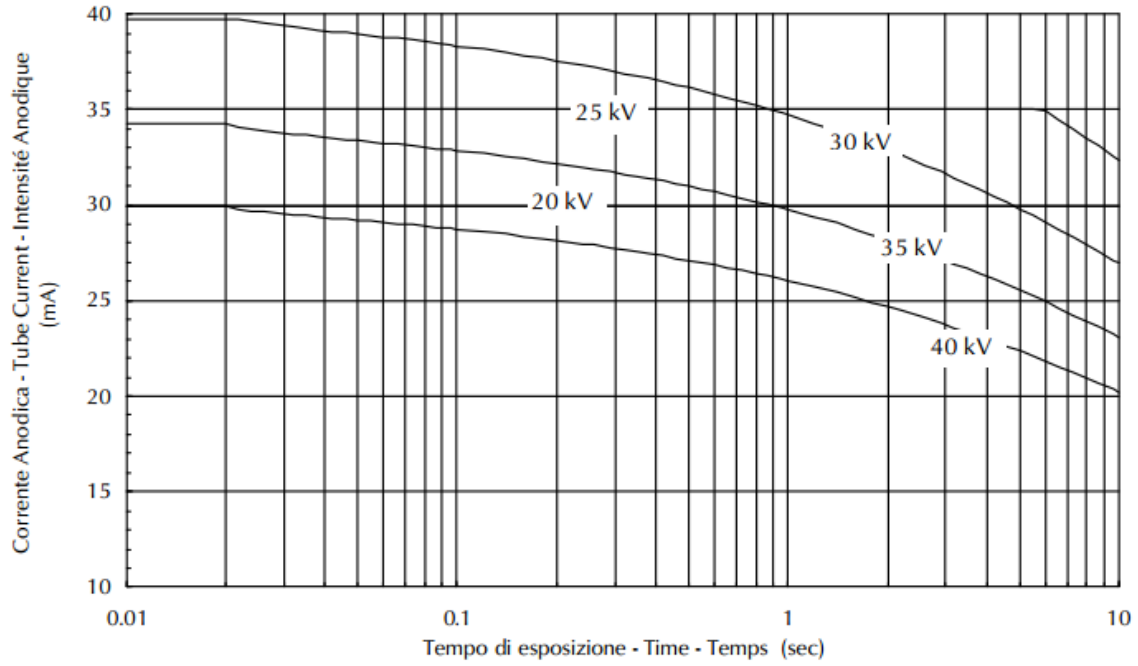
▣ 0.1 - 1 ~ - 3000 min^{-1}



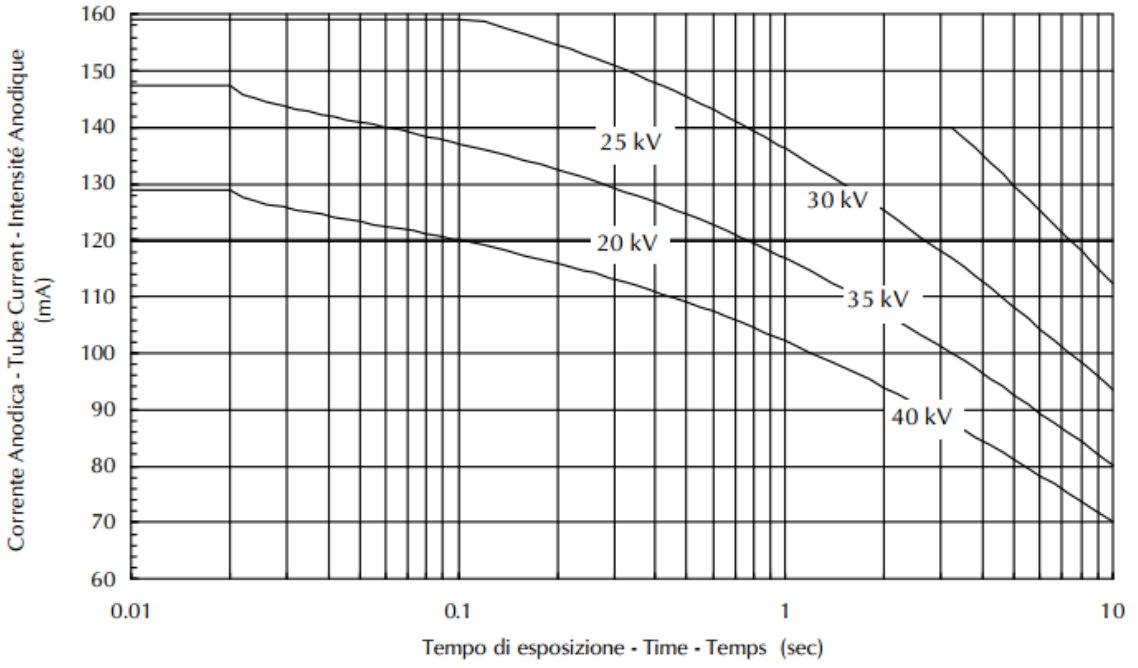
■ 0.3 - 1 ~ - 3000 min^{-1}



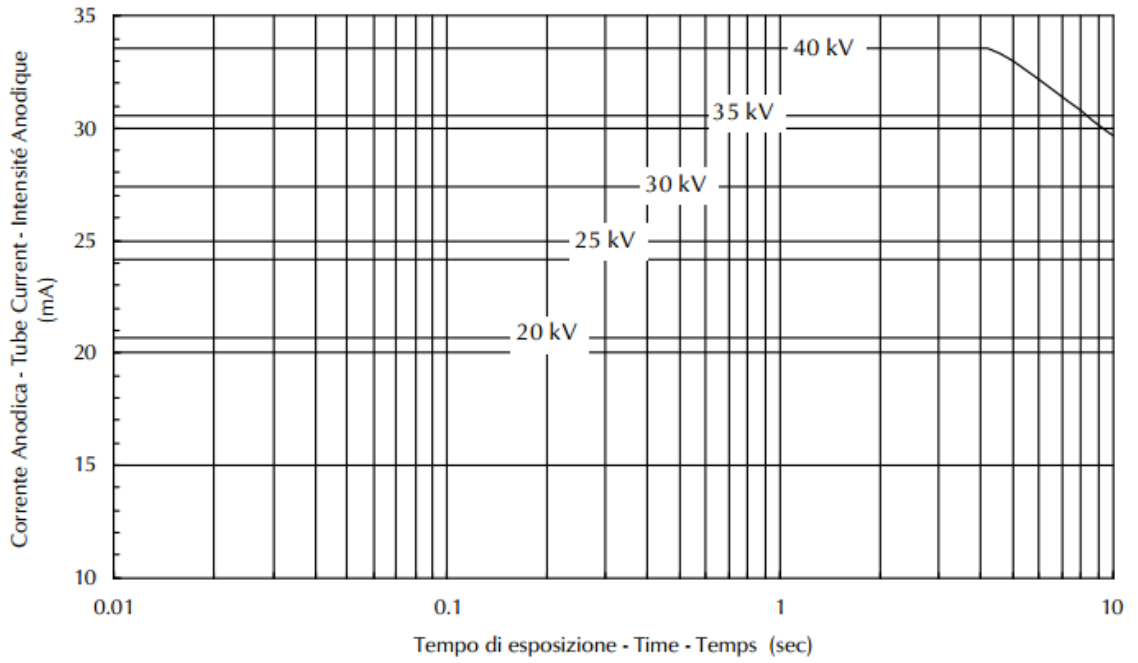
▣ 0.1 - 3 ~ - 3000 min^{-1}



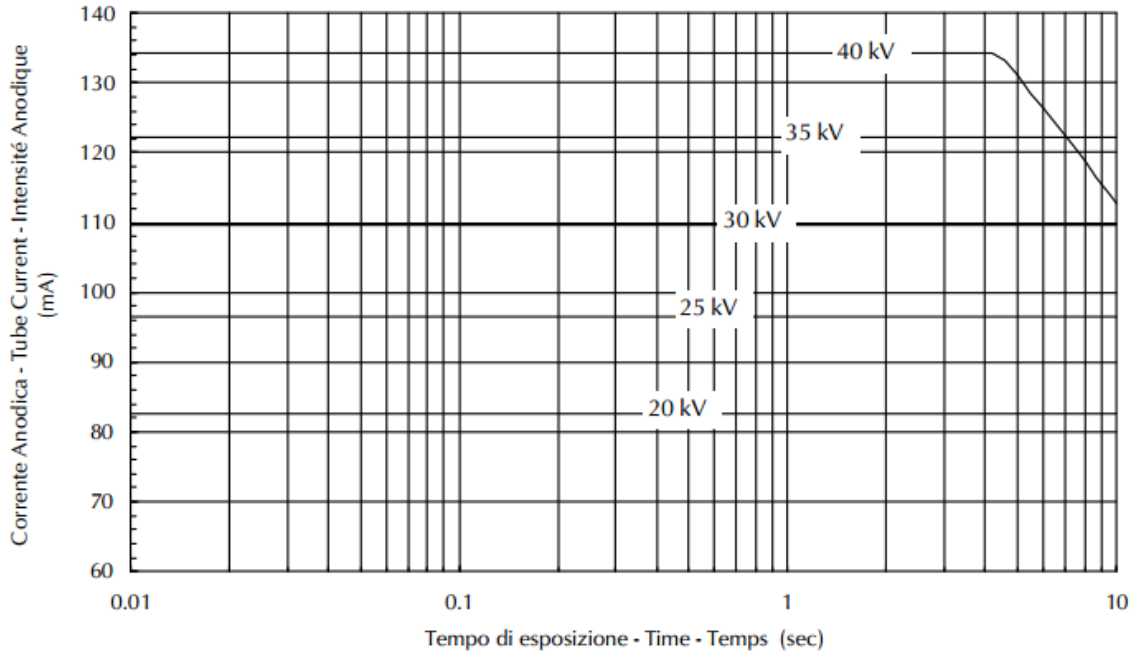
■ 0.3 - 3 ~ - 3000 min^{-1}



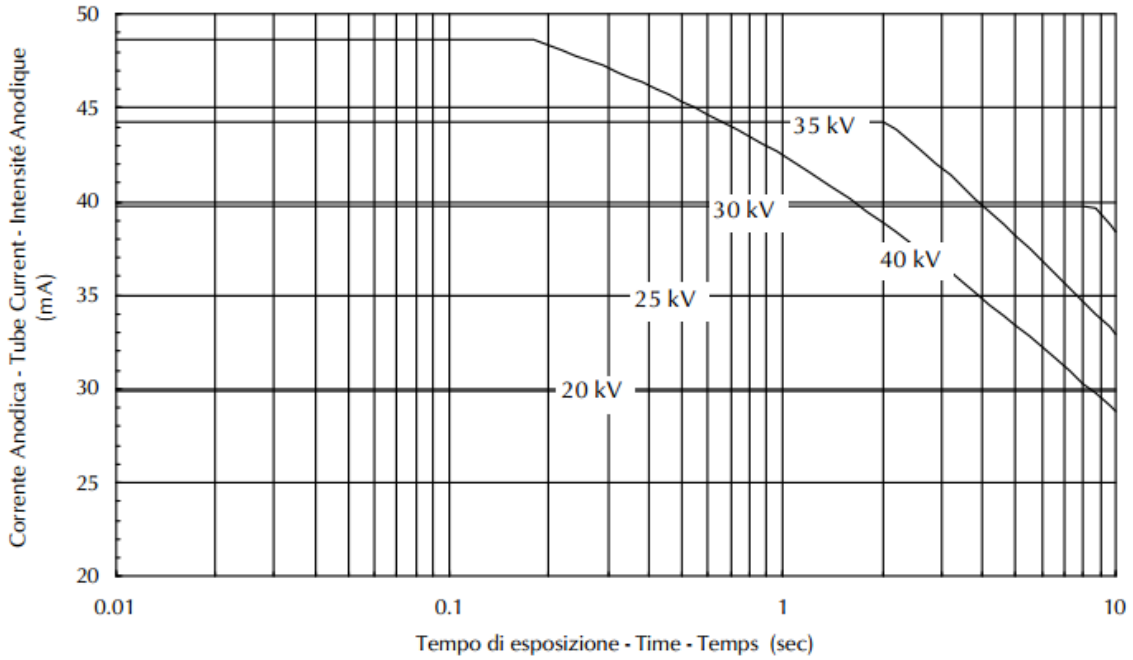
▣ 0.1 - 1 ~ - 10000 min^{-1}



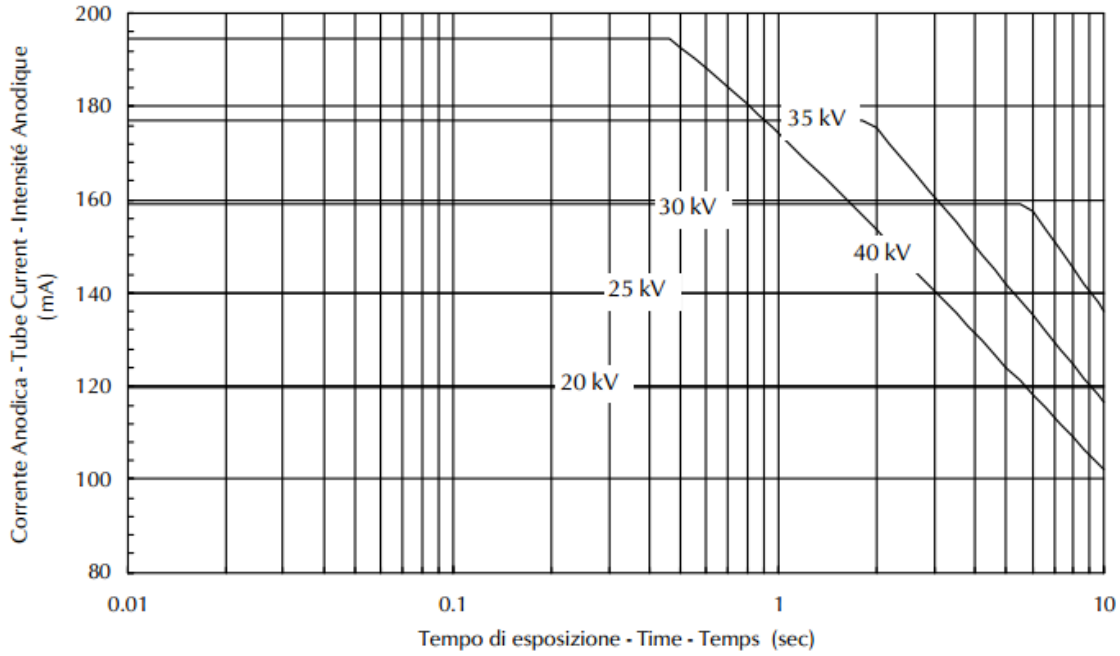
■ 0.3 - 1 ~ - 10000 min^{-1}



▣ 0.1 - 3 ~ - 10000 min^{-1}

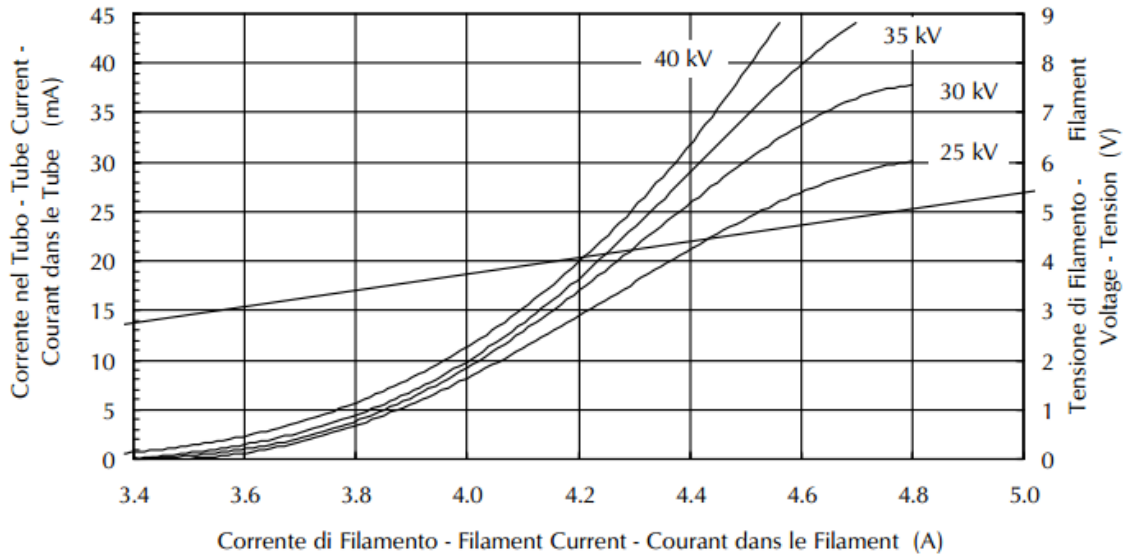


■ 0.3 - 3 ~ - 10000 min^{-1}

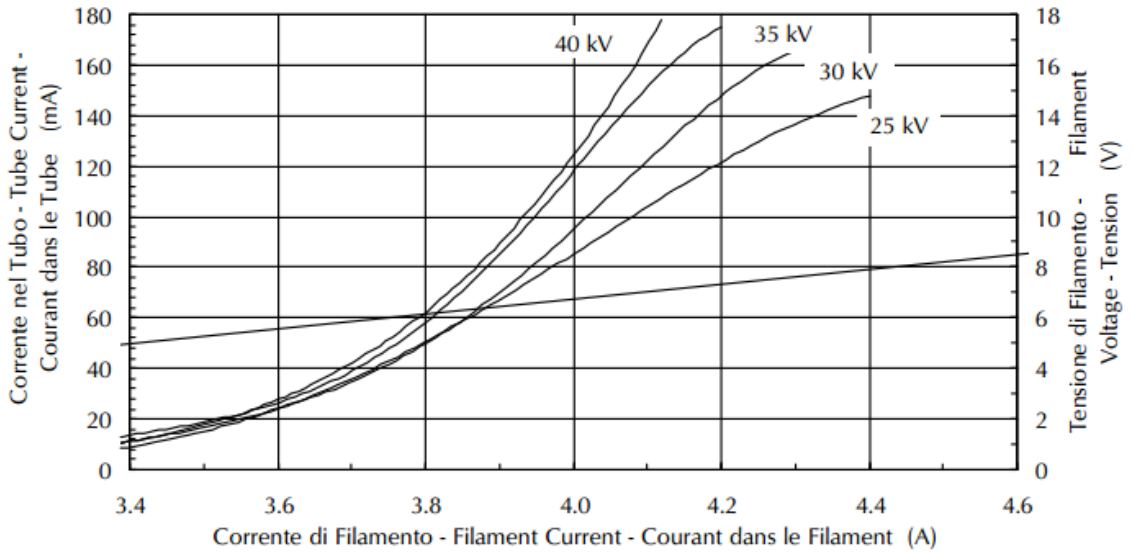


■ Cathode Emission Characteristic

▣ 0.1 - 3 ~ - (± 0.2 A)

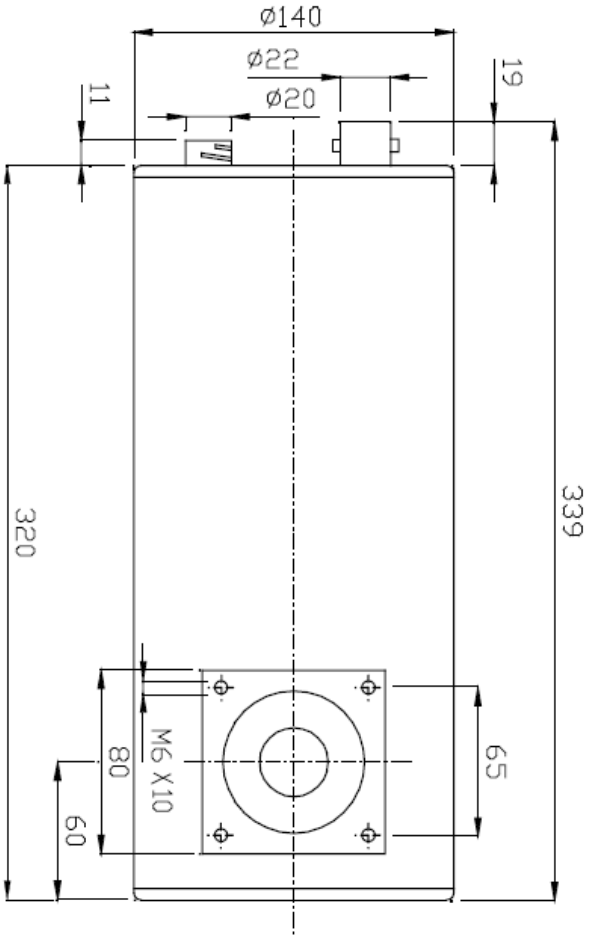


■ 0.3 - 3 ~ - (± 0.2 A)

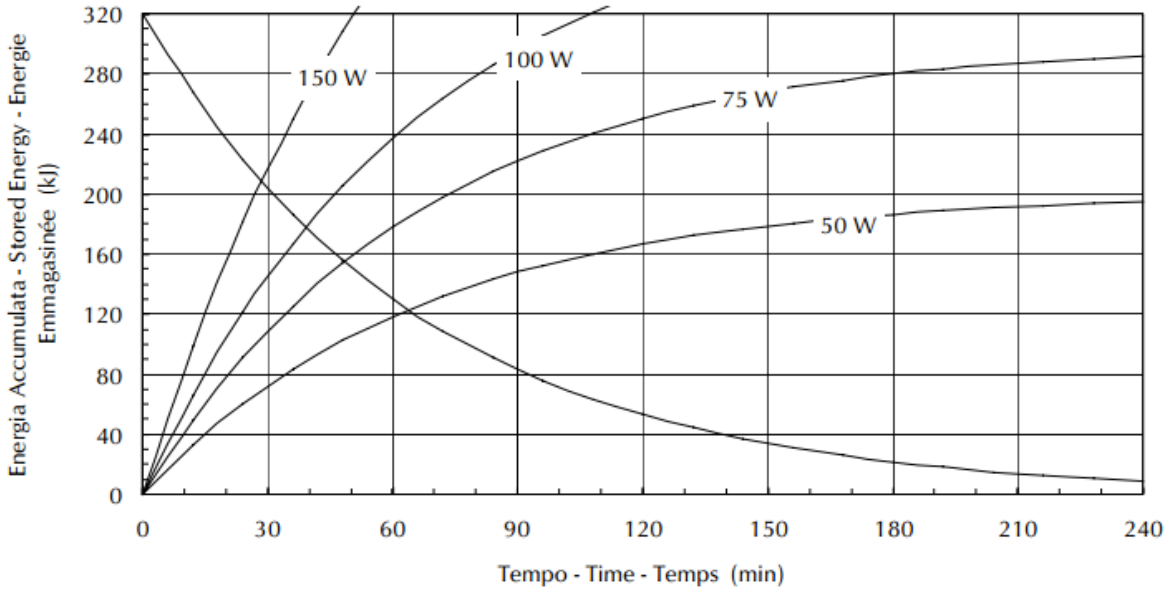


G.2 Tube-assembly characteristics curve

- **Frontal View**



- **Tube-assembly Cooling and Heating Curves**



AppendixH Harmful Material and Its Content

Component	Hazardous Substance					
	Pb	**Hg**	**Cd**	**Cr6+**	**PBB**	**PBDE**
Metal shell	o	o	o	o	o	o
Plastic shell	o	o	o	o	o	o
Detectors, x-ray tube Support device	o	o	o	o	o	o
Switch	o	o	o	o	o	o
indicator light	o	o	o	o	o	o
Display	o	o	o	o	o	o
buttons	o	o	o	o	o	o
Circuit Board	×	o	o	o	o	o
Motor	o	o	o	o	o	o
Wire rod, wire tube	o	o	o	o	o	o
X-ray tube	×	o	o	×	o	o
COLLIMATOR	×	o	o	o	o	o
DETECTOR	o	o	o	o	o	o
High-voltage generator	×	o	o	×	o	o

High voltage cable	○	○	○	○	○	○

○: Indicates that the toxic and harmful substances in the parts all homogeneous materials in the content under the limited requirements of SJ/T11363-2006.

×: Indicates that the toxic and harmful substances, at least in the part of a homogeneous material of exceeding the limits specified in SJ/T11363-2006.

AppendixI EMC Information

Accompanying Documents:

1. Instructions for use

- This system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
- Portable and mobile RF communications equipment can affect the system;

2. Technical description

- **Warning** that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the system.
- **Warning** that the device should not be used adjacent to or stacked with other equipment.
- The class A equipment is intended for use in industrial environments. Because of the conduction and radiation harassment of the MXR-550 digital mammography system, there may be potential difficulties to ensure the EMC.

3. Normative references:

Guidance and manufacturer's declaration – electromagnetic immunity			
The MXR-550 digital mammography system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV line(s) and neutral ± 2 kV line(s) to earth	±1 kV line(s) and neutral ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

4. Normative references (Continued)

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The MXR-550 digital mammography system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2,5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the model sp-3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

d=1.2√P

d=1.2√P 80MHz to 800MHz

d=2.3 √P 800MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

a

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model i7/ip-3 is used exceeds the applicable RF compliance level above, the model i7/ip-3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model i7/ip-3.

b

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

5. Normative references (Continued)

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The MXR-550 digital mammography system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The system suitable for use in all establishments, but if used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, whatever additional measures are necessary.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Inapplicability</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Inapplicability</td></tr>
</table>

Recommended separation distances between

portable and mobile RF communications equipment and the model i7/ip-3

The MXR-550 digital mammography system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E1}]\sqrt{P}$
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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

AppendixJ Abbreviations

A

AC	Alternating Current
AEC	Automatic Exposure Control
AGD	Average gland dose
APR	Anatomically Programmed Radiology

D

DICOM	Digital Imaging and Communications in Medicine
DR	Digital Radiography
DAP	Dose Area Product
DC	direct current

E

EMC	Electro Magnetic Compatibility

F

FID	Focus Image Distance

H

HIS/RIS	Radiology Information System/Hospital Information System

I

IP	Internet Protocol

K

kVA	Kilo Volt Ampere

	kHu	Kilo Heat Unit
L		
	Log	
P		
	PACS	Picture Archiving and Communications System
	PID	Patient Identification
	PCB	Printed Circuit Board
S		
	SID	Source Image Distance
	SN	Serial Number
U		
	UPS	Uninterrupted Power Source
W		
	WEEE	Waste Electrical and Electronic Equipment