

uDR266i

Digital Medical X-ray Imaging System

System Operator Manual

uDR System Operator Manual Digital Medical X-ray Imaging System

uDR 266i

uExceed R002

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Foreword

This manual provides instructions on safety information, functions, site planning, installation, and maintenance of the system.

Applicable products

This manual applies to the following products:

Product name	Product model	Software version
Digital medical X-ray imaging system	uDR 266i	R002

Audience

- Users of the uDR system.
- UIH training and customer service engineers.
- UIH marketing personnel.
- Authorized distributors of UIH.

Revision records

Date	Description
2020-05	First edition
2021-01	Second edition

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1 Introduction

1.1 About this manual	1-2
1.2 About this system	1-5
1.3 Clinical use	1-6
1.4 Personnel qualifications	1-7
1.5 Terms, acronyms and abbreviations.....	1-8

2 Safety

2.1 Safety signs and symbols	2-2
2.2 Basic safety specifications.....	2-6
2.3 System safety features	2-7
2.4 Precautions for examination and diagnosis	2-8
2.5 Personal safety	2-10
2.6 System safety	2-21
2.7 Environmental protection	2-25
2.8 System messages	2-26
2.9 Service life	2-27

3 System components

3.1 System overview.....	3-2
3.2 Definition of coordinate axes and directions	3-5
3.3 X-ray tube - collimator assembly	3-6
3.4 Digital flat panel detector carrier assembly	3-18
3.5 Motion control buttons	3-21
3.6 Console system	3-22
3.7 DAP meter	3-27

4 System operations

4.1 Normal workflow	4-3
4.2 Stitching workflow (optional)	4-8
4.3 System startup and shutdown	4-10
4.4 Positioning of the U-arm	4-12
4.5 Positioning of the X-ray tube-collimator assembly	4-14
4.6 Position of flat panel detector carrier assembly	4-16
4.7 Collision protection	4-18
4.8 Use of the wireless digital flat panel detector	4-19
4.9 Light field adjustment of the collimator	4-22

Table of Contents

4.10 Use of the console system	4-23
4.11 Exposure operation	4-25

5 Optional accessories

5.1 Principle.....	5-2
5.2 Mobile radiographic table	5-3
5.3 Stitching stand.....	5-5
5.4 Additional filter plate	5-8

6 Technical reference for system operation

6.1 Overview	6-2
6.2 Site requirements	6-3
6.3 Transportation and storage	6-5
6.4 Installation and tune-up	6-6

7 Maintenance, repair, and disposal

7.1 Installation and repair.....	7-2
7.2 Periodic maintenance.....	7-3
7.3 Professional maintenance	7-6
7.4 Disinfection and cleaning	7-10
7.5 Disposal.....	7-13

8 Technical data

8.1 Configuration difference	8-2
8.2 Working conditions	8-3
8.3 Performance indexes	8-4
8.4 Major components.....	8-6
8.5 Mechanical movement	8-9
8.6 X-ray field range	8-10
8.7 Electromagnetic interference requirements.....	8-11

Index

Figure 2-1	Potential collision areas on mobile radiographic table	2-11
Figure 2-2	Potential collision areas on X-ray tube-collimator assembly	2-11
Figure 2-3	Potential collision areas on FPD assembly	2-11
Figure 2-4	Emergency stop switch on the control console	2-13
Figure 2-5	Emergency stop switch on U-arm	2-13
Figure 2-6	Emergency stop switch on U-arm (FPD carrier side).....	2-13
Figure 2-7	Warning sign for the collimator.....	2-19
Figure 2-8	System status bar in image processing system	2-26
Figure 3-1	System components in the scanning room	3-2
Figure 3-2	System components in the operation room.....	3-3
Figure 3-3	Definition of coordinate axes and directions	3-5
Figure 3-4	X-ray tube assembly XRR-3331X	3-7
Figure 3-5	Filament emission feature curve	3-9
Figure 3-6	Maximum rated value table of the XRR-3331X	3-10
Figure 3-7	Heating and cooling feature curves of XRR-3331X	3-11
Figure 3-8	Heating and cooling feature curves of anode of XRR-3331X	3-11
Figure 3-9	X-ray tube assembly E7876X.....	3-12
Figure 3-10	Maximum rated value table of the E7876X	3-13
Figure 3-11	Filament emission feature curve	3-14
Figure 3-12	Heating and cooling feature curves of E7876X.....	3-15
Figure 3-13	Collimator structure	3-15
Figure 3-14	Angle indicator	3-17
Figure 3-15	Structure of the detector carrier	3-18
Figure 3-16	Structure of the wireless digital flat panel detector.....	3-19
Figure 3-17	Structure of the control console	3-24
Figure 4-1	Vertical movement of the U-arm	4-12
Figure 4-2	Rotation of the U-arm around the horizontal axis.....	4-13
Figure 4-3	Manually rotating the X-ray tube - collimator assembly	4-14
Figure 4-4	SID adjustment.....	4-15
Figure 4-5	Infrared induction device	4-18
Figure 5-1	Mobile radiographic table	5-3
Figure 5-2	Stitching stand.....	5-5
Figure 5-3	Additional filter plate position	5-8
Figure 6-1	Room layout (unit: mm).....	6-3
Figure 6-2	System installation flowchart.....	6-6

List of Figures

Table 2-1	Warning symbols	2-3
Table 2-2	Prohibition symbols	2-3
Table 2-3	Instruction symbols	2-4
Table 2-4	Equipment category and description.....	2-4
Table 2-5	Electronic and electrical safety	2-4
Table 2-6	label	2-5
Table 3-1	Indicators of the wireless digital flat panel detector	3-19
Table 3-2	Configuration of the image processing system	3-23
Table 3-3	Control buttons on the control console	3-25
Table 4-1	Workflow	4-3
Table 6-1	List of installation tools	6-7
Table 7-1	Component maintenance time table	7-6
Table 7-2	List of hazardous materials	7-13
Table 8-1	System configuration difference.....	8-2
Table 8-2	Maximum output power.....	8-4
Table 8-3	Nominal power	8-4
Table 8-4	Voltage and combination of tube of maximum output power	8-4
Table 8-5	Changes of maximum output power with the tube current (mA)	8-4
Table 8-6	X-ray tube assembly E7876X	8-7
Table 8-7	X-ray tube assembly XRR-3331X	8-7
Table 8-8	Cable specification	8-12
Table 8-9	Emission	8-14
Table 8-10	Enclosure Port	8-14
Table 8-11	Proximity fields from RF wireless communications equipment	8-14
Table 8-12	Input a.c. power Port.....	8-15
Table 8-13	Signal input/output parts Port.....	8-15

List of Tables

1 Introduction

1.1	About this manual	1-2
1.1.1	Text conventions	1-2
1.1.2	Applicable scope	1-3
1.1.3	Instructions	1-3
1.1.4	Laws and regulations	1-3
1.1.5	Related documents	1-4
1.2	About this system	1-5
1.3	Clinical use	1-6
1.3.1	Intended use	1-6
1.3.2	Application scope	1-6
1.3.3	Contraindication	1-6
1.4	Personnel qualifications	1-7
1.5	Terms, acronyms and abbreviations	1-8
1.5.1	Terms	1-8
1.5.2	Acronyms and abbreviations	1-9

1.1 About this manual

This manual applies to the digital medical X-ray imaging system developed by Shanghai United Imaging Healthcare Co., Ltd. ("UIH" for short). Operators must observe safety instructions in this manual during operation and understand application functions of the system. Do not use this system for any purpose other than the intended use.

This manual describes the intended use, basic composition, software and hardware functions, and routine operation procedures of this system. It also provides safety knowledge and technical reference information required for the normal operation of the system, so as to instruct users to complete operations safely and effectively.

Before operating the system, users or operators must carefully read through this manual and pay special attention to all information in the safety section so as to effectively and safely complete a series of operations. Do not use this system for any purpose other than the intended use.

This manual is only valid to the software version in compliance with relevant regulations and the latest release note. This manual describes system features in detail, including its functions, options and all accessories. It aims to provide convenience for you and may be updated in future versions. UIH reserves the right to change information in this manual at any time without prior notice.

The original language of this manual is Chinese. This manual is created, maintained, and authorized by UIH, and delivered together with products.

Personnel involved in this manual are described as follows.

Related personnel	Description
Responsible organization	Organization responsible for the use and maintenance of the digital medical X-ray imaging system. A responsible organization can be a hospital, clinicians, or non-medical staff.
Operator	Personnel authorized to operate the equipment.
Patient	A patient who undergoes X-ray examination.
UIH customer service engineer	UIH installation, maintenance, and repair personnel.

1.1.1 Text conventions

This manual complies with a series of related text conventions, which can help you better understand, quickly search for, and read related information.

- Parallel main items are indicated by the symbol "■".
- Single step operations are identified by the symbol "►" and steps of a multi-step operation are identified by sequential numbers.
- Sub-items or coordinate items in a table are identified by the symbol "◆".
- In the electronic version of this manual, hyperlinks to relevant information are provided for further cross referencing.
- The user interface elements (for example button-tips, window titles, and menu texts) are identified in bold font.

- Keys of the keyboard are identified by the symbol "<>".

Expression of a single help information item:



Help information of the system.

Expression of multiple help information items:



- ◆ Help information 1 of the system.
- ◆ Help information 2 of the system.

1.1.2 Applicable scope

- This manual describes all the configurations, components, assemblies, functions, and optional accessories of the related system; your system may not have all the functions.
- This manual is applicable to the uDR configuration. For the configuration difference, see "[Configuration difference](#)" on page 8-2.
- This system may be delivered with other operator manuals due to configuration differences. Please also refer to safety instructions, operation guidelines and daily maintenance descriptions in these manuals.

1.1.3 Instructions

- Any similarities between hospital or patient names used in this manual and the actual names of current organizations or persons are purely coincidental.
- Configuration names involved in this manual (for example, names of the drive, network node, or database) may be different from those in the actual clinical environment.
- All photos, diagrams, snapshots, and images in this manual are used as examples only. The actual system appearance and software UI shall prevail.
- Graphical representations in this manual may be different from the actual situations due to configuration differences, system configuration updates, as well as hardware/software upgrade. The actual system appearance and software UI shall prevail.
- The snapshot capture may lead to image detail loss; therefore, images in this manual do not represent the actual image quality.
- All data in this manual is typical values unless specific tolerance values are provided.
- Values displayed on the UI of the image processing system in this manual have no clinical significance. You should use protocol default values or values recommended by experienced application experts.

1.1.4 Laws and regulations

This medical equipment complies with regulations regarding the medical equipment marketing issued by China Food and Drug Administration.

If there are relevant laws and regulations covering the use of the system, operators have to observe such laws and regulations.

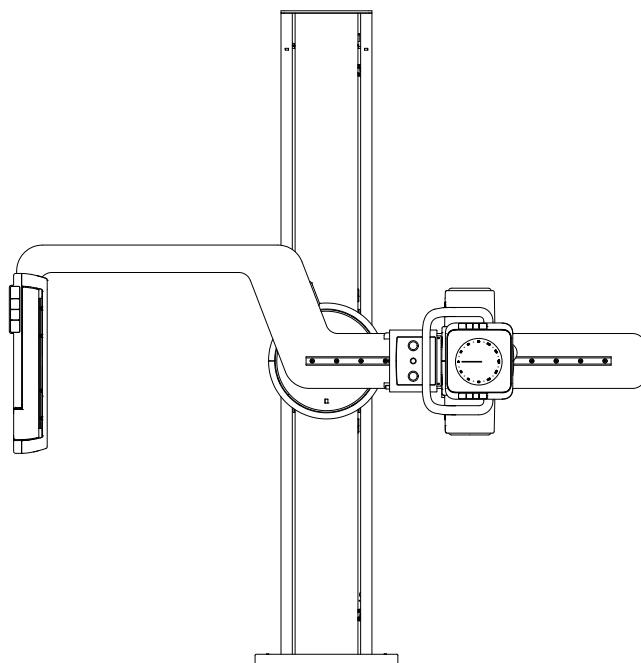
1.1.5 Related documents

This system is delivered with the onlinehelp.

1.2 About this system

This system has the following features:

- The system supports rapid imaging, excellent image quality, and convenient image adjustment.
- The system is designed with considerable predefined protocols applicable to clinical radiography and supports protocol customization.
- The motor-driven motion of U-arm positioner and the on/off of collimator bulb can be remotely controlled in the operation room.
- The system supports the radiography for many patient positions. By pressing the relevant key, you can set the system to be ready for vertical position, lying position, and specific position as indicated by the protocol.
- The system supports stitch check.



1.3 Clinical use

1.3.1 Intended use

The System is intended for radiography of the human body to acquire X-ray images for medical imaging diagnosis.

1.3.2 Application scope

- Suitable for the radiography of the skull, spinal column, chest, abdomen, extremities, and other anatomic sites of subjects at all ages who need radiography.
- Suitable for radiological examination in all the large, medium and small-sized hospitals.

1.3.3 Contraindication

Exposure must be performed within the exposure dose scope required by the technical instructions. There is no specific contraindication. However, for radiation-sensitive population (such as pregnant women, children and infants), you must be very familiar with the examination indications.

1.4 Personnel qualifications

Personnel using the system must get familiar with basic knowledge about medical imaging and system operations, including the radiographic examination procedure, and basic principles and characteristics of imaging. Users must undergo strict training, read through this manual in detail, and observe local regulations so as to safely and effectively operate this system. User training must cover the basic technical knowledge of this system and system safety operations. Users must be familiar with potential dangers and safety guideline principles. In addition, users are required to read through and comprehend the content of the operator manual.

WARNING

Operation permission

- ◆ Users who failed the training on how to safely and efficiently use the system are forbidden to operate the system. Having unqualified personnel to operate this system may lead to system damage, personnel injury or misdiagnosis.
- ◆ This system can only be operated by trained personnel with required professional knowledge, such as trained physicians, radiologists, or technicians.

1.5 Terms, acronyms and abbreviations

1.5.1 Terms

Term	Description
X-ray tube current	Refers to the electron-beam current that strikes an X-ray tube target. It is generally represented with average milliamperere (mA).
X-ray tube voltage	Refers to the potential difference between the anode and cathode of an X-ray tube. It is generally represented with peak kilovolt (kV).
X-ray tube assembly	Refers to a tube assembly composed of an X-ray tube sleeve and a tube core.
X-ray tube - collimator assembly	Consists of an X-ray tube assembly and a collimator system.
Exposure mode	X-ray exposure is determined by three high-voltage parameters: X-ray tube voltage (kV), X-ray tube current (mA), and exposure time (ms). Different controllable parameters or combinations of the high-voltage parameters with the Automatic Exposure Control (AEC) technique can form different exposure modes.
Acquisition system	Consists of an emission source, a receiver, and auxiliary equipment on the ray path. The emission source can be a high voltage generator, X-ray tube assembly, or collimator. The receiver is a wireless digital flat panel detector. The auxiliary equipment is an AEC ionization chamber.
Ionization radiation	Composed of either or both of direct and indirect ionizing particles. Generally, ionization radiation does not include ultraviolet radiation.
Current-time product	Refers to the electricity quantity generated when an X-ray tube is loaded during X-ray diagnosis. It is equal to the product of the average of X-ray tube current (in milliamperere) and the loading duration (in seconds) and is usually expressed in milliamperere seconds (mAs).
Centering	The center of an X-ray beam is vertical to the center of the wireless digital flat panel detector.
Radiation protection	Refers to the requirements, measures, means, and methods used to protect human beings from ionization radiation or to minimize the hazards of ionization radiation.
Additional filtration	Refers to the equivalent filtration generated by an additional filter plate and other removable substances between the X-ray source and the patient (or a given plane).
High voltage generator	Refers to a combination of components that control and generate X-ray energy. It usually consists of the high voltage transformer assembly and controller assembly.
Inherent filtration	Refers to the equivalent filtration generated by irremovable substances that a radiation beam passes through before being emitted from an X-ray tube - collimator assembly or its components.
Focus	Refers to a point on the anode on which electrons are focused.

Term	Description
Wireless digital flat panel detector	Includes a photoconductor, which records incident X-rays and converts them into digital images.
Manual	Refers to human-driven U-arm positioner movement.
Auto	The motor-driven U-arm positioner moves to a specified location.
Automatic exposure control	Refers to an operation method for obtaining an ideal exposure dose in a pre-selected position by automatically controlling one or more loading factors in the X-ray generator.

1.5.2 Acronyms and abbreviations

Acronym and abbreviation	Full name (English)
AEC	Automatic Exposure Control
DICOM	Digital Imaging and Communications in Medicine
DR	Digital Radiography
PDU	Power Distribution Unit
RHA	Rotation around Horizontal Axis
RIS	Radiology Information System
SID	Source to Image Receptor Distance
SOD	Source to Object Distance

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2 Safety

2.1	Safety signs and symbols	2-2
2.1.1	Definition of safety level	2-2
2.1.2	Safety symbols and labels	2-2
2.2	Basic safety specifications	2-6
2.3	System safety features	2-7
2.4	Precautions for examination and diagnosis	2-8
2.4.1	Image orientation	2-8
2.4.2	Keep the patients visible	2-8
2.4.3	Indoor lighting	2-8
2.4.4	Prerequisite for diagnosis and treatment	2-8
2.4.5	Patient constant-contact components	2-9
2.4.6	Emergency procedure	2-9
2.5	Personal safety	2-10
2.5.1	System motion safety	2-10
2.5.2	Emergency stop switch	2-12
2.5.3	Patient positioning safety	2-14
2.5.4	Mechanical safety	2-14
2.5.5	Electrical safety	2-16
2.5.6	Radiation safety	2-17
2.5.7	Laser protection	2-19
2.5.8	Fire safety	2-19
2.5.9	Explosion safety	2-20
2.6	System safety	2-21
2.6.1	Equipment compatibility	2-21
2.6.2	Electromagnetic compatibility	2-22
2.6.3	Transportation protection	2-23
2.6.4	Electrostatic protection	2-24
2.7	Environmental protection	2-25
2.7.1	Handling of hazardous substances and components	2-25
2.7.2	Product disposal	2-25
2.8	System messages	2-26
2.9	Service life	2-27

2.1 Safety signs and symbols

2.1.1 Definition of safety level

This manual involves four levels of safety warning signs:

Before operating this system, users must read through and get familiar with all safety information involved in this manual, strictly observe safety information marked with the words "Danger", "Warning", "Caution", and "Note", and keep in mind various safety measures to prevent safety accidents.

"Danger", "Warning", "Caution", and "Note" are defined as follows in laws and regulations:

"Danger": Failure to follow these instructions will cause serious injury or death.

"Warning": Failure to follow these instructions may cause serious injury or death.

"Caution": Failure to follow these instructions may cause moderate or minor personal injury or potential damage to the equipment or other properties.

"Note": Provides additional information to notify users of the potential risk for personnel safety or property protection directly or indirectly.

This chapter mainly describes the operation safety information of the system in the following format:

DANGER

Safety information — risk factors and results.

- ◆ Safety information — preventive measures.

WARNING

Safety information — risk factors and results.

- ◆ Safety information — preventive measures.

CAUTION

Safety information — risk factors and results.

- ◆ Safety information — preventive measures.

NOTICE

Safety notes to be followed.

2.1.2 Safety symbols and labels

The following table describes safety symbols and labels used in this system.

Table 2-1 Warning symbols

Symbol	Description	Usage and position
	Warning: ionization radiation	This symbol indicates the existence of radiation on the equipment. ◆ Surface of the X-ray tube cover
	Warning: hazardous voltage	This symbol indicates there is hazardous voltage on the component. ◆ Surface of the X-ray tube cover and internal side of the system cabinet
	Warning: high surface temperature	This symbol indicates that the component surface is very hot. ◆ Surface of the X-ray tube cover
	Warning: watch your hands	This symbol indicates that the component may hurt your hands. ◆ Surface of the U-arm column and cross arm
	Warning: watch your feet.	This symbol indicates that the component may hurt your feet. ◆ Surface of detector carrier
	Warning: laser beam	This symbol indicates the existence of laser equipment. ◆ Collimator surface
	General warning sign	This symbol indicates a position to which the warning symbol needs to be pasted. ◆ Surface of the system cabinet
	Laser beam description	This symbol indicates a description of the laser beam in the laser equipment. ◆ Near the laser light of the collimator

Table 2-2 Prohibition symbols

Symbol	Description	Usage and position
	No trampling	Component surface
	Maximum load capacity: 15 kg MAX LOAD 15KG	This symbol indicates that the maximum load on the component is 15 kg. ◆ Surface of detector carrier

Symbol	Description	Usage and position
	Weight limit: 150 kg	This symbol indicates that the maximum load on the component is 150 kg. ♦ Mobile radiographic table

Table 2-3 Instruction symbols

Symbol	Description	Usage and position
	Refer to the operation instructions (mandatory requirements).	This symbol indicates that operators must refer to the operation instructions. ♦ Close to positions in which prompts are provided for users

Table 2-4 Equipment category and description

Symbol	Description	Position
	Type-B applied part	This symbol indicates that the electric shock prevention level is Type B. ♦ Surface of detector carrier
	WEEE directive Recycling trash can sign	This symbol indicates that the equipment contains materials that may endanger the environment once disposed improperly. ♦ surface of U-arm positioner

Table 2-5 Electronic and electrical safety

Symbol	Description	Position
	Protective earth	This symbol indicates any terminal connected to the external protective earth conductor. This terminal is used to prevent electric shocks in case of misoperations. ♦ Connection point of the protective earth conductor
	Caution: ESD	This symbol indicates that an electrostatic sensitive device is connected to the system. ♦ Host

Table 2-6 label

Symbol	Description	Position
 Shanghai United-Imaging Healthcare Co.,Ltd. No.2258 Chengbei Road,Jiading District, Shanghai, 201807, P.R. China Device Name:  0123 Model:  (01) GTIN: (240) Material No.: (21) Serial No.:   January 2018 Made in China	System label	Lower left of the stand
 Shanghai United-Imaging Healthcare Co., Ltd. No.2258 Chengbei Road,Jiading District, Shanghai, 201807, P.R. China Input Voltage: Input Frequency: Standby Power: Momentary Power: Operation Mode: Continuous operation with intermittent loading	Input power label	Rear of movable radiographic table

2.2 Basic safety specifications

Strictly observe safety instructions in the manual when using this system.

Always abide by the following installation and operation instructions for medical equipment:

- If the system encounters any electrical or mechanical fault, stop using it.
- This system can only be used with other equipment, components, assemblies, and spare parts provided and tested by UIH. UIH will take no responsibility for any faults, losses, or personal injuries caused by the use of equipment, components and assemblies that are not provided or tested by UIH.
- If this system needs to be connected to other equipment, components or assemblies, but no available technical data shows that the system can be safely used with them, you must consult the manufacturer to ensure that the safety of patients, operators, or environment is not affected.
- This system needs to be correctly operated and routinely repaired and maintained, just as other technical equipment. For details ,see "[Maintenance, repair, and disposal](#)" on [page 7-1](#).
 - ◆ UIH takes responsibility for the safety features of the product only when the repair, maintenance, and alternation are performed by UIH or the personnel expressly authorized by UIH.
 - ◆ UIH will take no responsibility for any faults, damage, or personal injuries incurred by the improper operation or maintenance of this system..
- If the system fails to work normally, contact UIH Customer Service Center.
- Do not remove or modify the safety circuits in any way and never remove the product cover or cables, unless there are relevant instructions in this manual.
- Do not touch a patient and the non-medical electrical equipment around the patient at the same time to prevent electric shocks. The non-medical electrical equipment includes the host and the monitor of the image processing system, and barcode scanner.

Liquid ingress prevention

This medical equipment meets the requirements for Class IPX0 and has no protection against liquid ingress.

NOTICE

The system is not waterproof. Keep the system away from water and keep it dry.

2.3 System safety features

- Based on the type of protection against electric shocks: Class I equipment.
- Based on the degree of protection against electric shocks: Type-B applied part.
- Based on the degree of protection against liquid ingress: equipment without protection against liquid ingress.
- Based on the safety level when flammable anesthetic gas is mixed with air, oxygen, or nitrous oxide: equipment that cannot be used in such an environment.
- Based on the operating mode: Equipment supporting intermittent loading continuous operating mode.
- Input voltage and frequency of the equipment: 3N~, 380 V/400V/440V AC, 50 Hz/60 Hz.
- Input power of the equipment:
 - ◆ The input power of the 65 kW high voltage generator is 120 kVA.
 - ◆ The input power of the 50 kW high voltage generator is 95 kVA.
- Based on whether the equipment has applied parts that can prevent defibrillation discharge effect: equipment without the applied parts that can prevent defibrillation discharge effect.
- Based on whether the equipment has signal input/output parts: equipment with signal input/output parts.
- Based on whether the equipment is permanently installed: permanently installed equipment.

2.4 Precautions for examination and diagnosis

2.4.1 Image orientation

- Operators should ensure that the image orientation on the monitor or film is correct.
- When "free flat panel" is selected on the acquisition system, operators should confirm the image orientation. For the selection of the acquisition system, see the *Software Operator Manual*.

WARNING

Image flip

- ◆ Image flip may make operators confused about the up, down, left and right orientations of an image, which can cause misdiagnosis.
- ◆ Operators should use the flip function correctly, interpret images, and take responsibility for results inferred from images.

WARNING

Attaching left and right labels

- ◆ Incorrect attaching of left and right labels is a potential factor of misdiagnosis. Examiners are required to fill out the left and right labels correctly.
- ◆ If necessary, examiners can use lead letters or similar tools during acquisition.

2.4.2 Keep the patients visible

During the examination, make sure the operator can observe the patient constantly, and the patient can hear the voice of the operator through the audio.

2.4.3 Indoor lighting

Avoid mirror reflection of windows, lamps, and lattices in the operating position on the monitor.

2.4.4 Prerequisite for diagnosis and treatment

The image processing system monitor cannot be used for diagnosis. Please send images to the diagnostic workstation or film them.

Checking the image quality

The quality of images acquired by the system deteriorates with the time due to the aging and normal wearing of main system components. Therefore, the image quality should be checked routinely after system installation to ensure diagnosis.

NOTICE

Only qualified personnel are allowed to check the image quality to ensure that the image quality is up to the image quality standard for clinical diagnosis.

The system can be connected to a DICOM-compliant film printer that produces images of the DX type.

2.4.5 Patient constant-contact components

The armrests and front cover of detector carrier are frequently touched by patients. Therefore, maintain and clean them periodically. For details, see "[Disinfection and cleaning](#)" on page 7-10.

2.4.6 Emergency procedure

- Due to the complexity of the whole system, the possibility of sudden system function failures cannot be completely ruled out in clinical use.
- When a system function fails, a relevant system message is displayed on the image processing system monitor. Rectify the fault as prompted. For details, see "[System messages](#)" on page 2-26.

⚠ WARNING**System fault**

- ◆ Some system function faults cannot be rectified within a short period of time, resulting in the examination delay or suspension. Therefore, appropriate emergency procedures should be established to cope with such cases.

2.5 Personal safety

2.5.1 System motion safety

Assemblies of the digital medical X-ray imaging system move at a certain speed. Therefore, exercise caution when operating such assemblies.

When system components crush or collide with personnel during system motion, mechanical damage or personnel injuries may be incurred.

- System components can ascend, descend, rotate and move. Ensure that you and any third party are out of the scope of the system motion path before operating the system.
- System components can be moved only when their motion will not pose a hazard to patients, operators, or any third party and there is no obstacle on their moving paths.

Hazard of crushing

The armrest components are mainly used to determine the correct positions of patients. Patient should hold the armrests tightly during positioning.

Pay attention to the hazard of crushing around moving components during patient positioning.

- Pay attention to the gap between moving components and surrounding fixed objects to prevent the hazard of finger crushing.
- Before moving system components, ensure that patients do not grasp the edge of any assembly that may be bumped.

Abnormal motion

If a system component moves abnormally, for example, if the detector carrier moves upwards in the case of no manual operation, press the nearest emergency stop switch immediately (see "[Emergency stop switch](#)" on page 2-12). The emergency stop switch can be released only after the cause for the abnormal motion is pinpointed and eliminated. If the problem persists, contact UIH Customer Service Center.

Collision protection

Collision protection areas are applicable to all motor-driven components. In the motor-driven motion process, when the X-ray tube - collimator assembly enters the collision protection area, the motor-driven motion slows down, and stops moving when the X-ray tube - collimator assembly reaches the electronic position limit.

Potentially dangerous crushing and collision areas

The following figure shows the potentially dangerous areas of crushing and collision that may pose to patients and operators.

- The motion of the X-ray tube - collimator assembly may lead to personnel injuries in specific areas.
- When a Mobile radiographic table is configured, ensure that no obstacle is present within the movement range of the X-ray tube - collimator assembly and the table top.

- Ensure that the knees of sitting personnel are not below the system components that can move vertically.

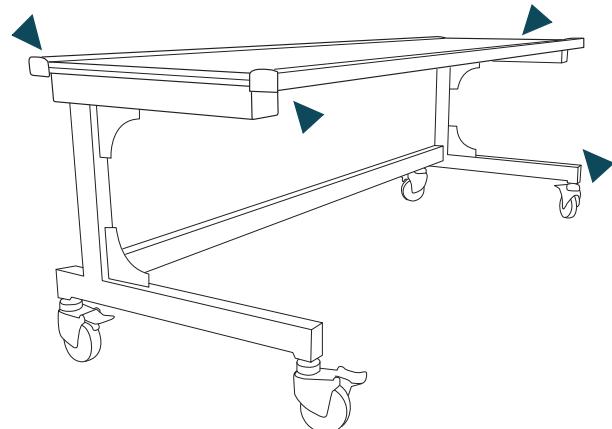


Figure 2-1 Potential collision areas on mobile radiographic table

⚠ WARNING

Hazard of crushing

- ◆ Patients should place their hands and feet on the table top when lying on the mobile radiographic table, to prevent crushing.

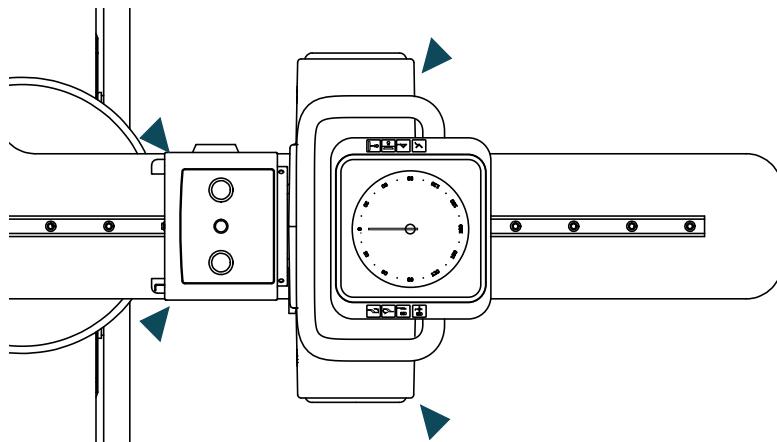


Figure 2-2 Potential collision areas on X-ray tube-collimator assembly

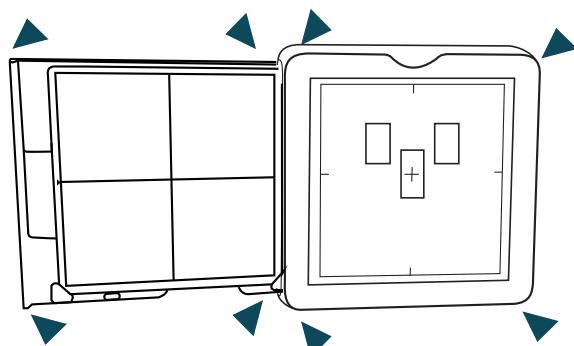


Figure 2-3 Potential collision areas on FPD assembly

⚠ WARNING**Hazard of crushing**

- ◆ Patients should place their hands and feet on the table top when lying on the mobile radiographic table, to prevent crushing.
- ◆ Ensure that components move at a low speed carefully when they are close to potentially dangerous crushing and collision areas, to prevent crushing.

2.5.2 Emergency stop switch

If an arising emergency endangers the safety of patients, operators, or the system, press the nearest emergency stop switch immediately.



2.5.2.1 Function

⚠ WARNING**Unexpected motion**

- ◆ Collision or injuries may be caused to patients or operators, and system assemblies may be damaged when the system is activated accidentally, the equipment moves in the case of no operations, or the equipment fails to be stopped. In this case, press the nearest emergency stop switch immediately.

NOTICE

The function of the emergency stop switch needs to be checked every day.

■ Stop triggering

- ◆ If the emergency stop switch is pressed, exposure is disabled and only manual motion operations can be performed.
- ◆ Exposure can be restored only after the emergency stop switch is rotated clockwise for release.
- ◆ Information about triggered stop is displayed on the image processing system monitor.

■ Stop cancellation

- ◆ The emergency stop switch cannot be released unless the cause for a system exception is identified and eliminated.

NOTICE

The system motion function will fail within the first 5 seconds after the emergency stop switch is released. This is normal during system restart and the system motion function becomes normal 5 seconds later.

2.5.2.2 Position

There is an emergency stop switch on the control console of the operation room.

There are two emergency stop switches on the U-arms in the scanning room.

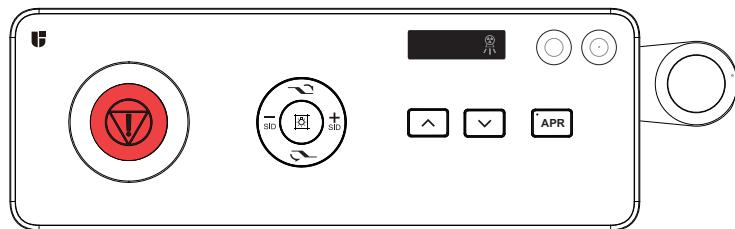


Figure 2-4 Emergency stop switch on the control console

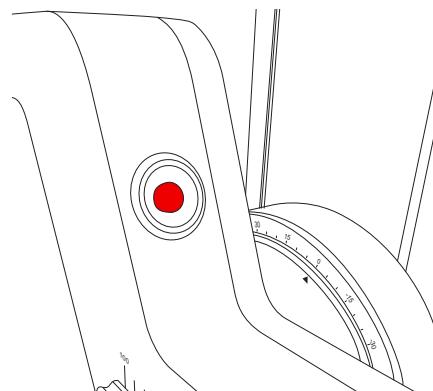


Figure 2-5 Emergency stop switch on U-arm

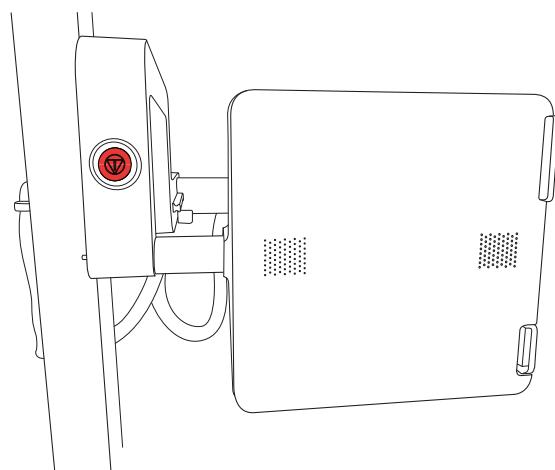


Figure 2-6 Emergency stop switch on U-arm (FPD carrier side)

2.5.3 Patient positioning safety

The maximum allowable patient load of mobile radiographic table is 150 kg.



- It is important to evenly distribute patient weight on the top of the mobile radiographic table. Otherwise, there will be risks of material deformation and personnel injury.
- The patient weight includes objects attached to a patient, such as electronic equipment, artificial limbs, implants, and plaster bandages. An example of uneven distribution of the patient weight: A 150 kg patient sits at one end of the table top.
- The damaged top of the mobile radiographic table is potentially risky to patients. The collision of the table top with other hard objects will lead to cracks.
- If the table top has been damaged, contact UIH Customer Service Center immediately to check, repair, or replace the top of the mobile radiographic table.

2.5.4 Mechanical safety

This section describes information about mechanical safety involved in the operations performed on the equipment, including basic protection, positions of possible collision and crushing during equipment motion, as well as methods of suspending equipment motion in case of any emergencies.

2.5.4.1 Patient safety during examination

- Remove objects within the motion scope of the equipment to avoid collision.
- Unless otherwise specified, do not operate the equipment when the cover plate or panel is removed.
- Ensure that the actual load on the mobile radiographic table does not exceed its normal load capacity (150 kg). Otherwise, equipment damage or patient injuries may be incurred.
- Ensure that the actual load on the armrest above the detector carrier does not exceed its normal load capacity (15 kg). Otherwise, equipment damage or patient injuries may be incurred.
- Ensure that operators make visual and verbal communication with patients during the entire examination.

NOTICE

- ◆ Keep fingers, hands, and tools away from areas indicated by safety signs.
- ◆ Avoid having body parts or clothing stuck or caught in the moving components of the system.

NOTICE

This system can be operated only by qualified personnel who receive professional training.

When operating the equipment, operators have the responsibility of observing and correctly instructing the patient position, and taking proper protective measures to ensure patient safety.

NOTICE

Ensure that the equipment does not collide with patients or other equipment during operation.

2.5.4.2 Repair and maintenance safety

- All screws must be tightened thoroughly but cannot be over-tightened. The tightening must comply with torque values in relevant standards.
- Do not remove the cover or cables of the system at will unless otherwise stipulated in the manual.

NOTICE

Ensure that screws are correctly connected. Incorrect screw connection may cause physical damage or property loss. All screw connections must be consistent with the descriptions in the document.

- When performing heavy load work, be sure to wear protective device (such as safety shoes and gloves) to avoid physical injuries when heavy goods are carried or lifted.
- Heavy or tricky objects must be moved mechanically or carried by sufficient people and should be handled as slowly as possible during transportation.
- Do not move the system when it is in operation. Shut down the system, cut the power off completely, and ensure all the peripheral components (such as the monitor, mouse, keyboard, and cables) are disconnected before transportation.
- If a cable is pulled, twisted or worn during the system motion, stop the motion immediately and adjust the motion pattern. If this problem persists, contact the UIH Customer Service Center.

2.5.4.3 Special mechanical safety

- A patient may be caught between the top of the mobile radiographic table and the X-ray tube - collimator assembly.
 - ◆ Ensure that no patient is caught between the top of the mobile radiographic table and the X-ray tube - collimator assembly when the mobile radiographic table is positioned or the X-ray tube - collimator assembly is moved downwards.

- ◆ When the X-ray tube - collimator assembly is rotated around the horizontal axis, ensure that no patient get stuck between the column of the X-ray tube - collimator assembly and the table top.
- A patient may be caught between the detector carrier and the ground.

Ensure that no patient is stuck between the detector carrier and the ground when the detector carrier is moved downwards.

WARNING

Fingers jammed

- ◆ Do not hold the arm of the X-ray tube - collimator assembly to adjust the position of the X-ray tube - collimator assembly. Otherwise, your fingers may be jammed. Use the handle on the X-ray tube - collimator assembly. For details, see "["X-ray tube - collimator assembly" on page 3-6](#)".

2.5.5 Electrical safety

- Electrical safety tests must be performed on the equipment in accordance with local safety ordinances or as required to ensure the equipment safety.
- Before installation or commissioning, ensure that all protective earth devices are correctly connected to prevent dangerous voltage leakage. All external metal parts must be connected to protective earth devices. Adopt washers to fasten the screws used for external metal parts and protective earth, or use dedicated protective earth devices.
- Check the leakage current, grounding resistance, overload protection, and grounding terminals during maintenance and care. To avoid the risk of electric shocks, cut off the power before repairing and maintaining the equipment.
- The high voltage generator can generate dangerous high voltage. Perform operations in strict accordance with specifications during operation and repair. Otherwise, operators or others may be exposed to extreme danger.
- The equipment is incapable of preventing liquid from going inside. Therefore, do not spill any liquid over the equipment to ensure operation safety of the equipment.
- Immediately shut down the system after use and cut off the power.

WARNING

In any emergency situation where system risks or failures endanger the safety of patients, operators, or the system, press the emergency stop switch immediately.

- There is still voltage on the high voltage generator when the system is powered off. Wait about 5 minutes before cleaning, sterilizing, and repairing the equipment so that energy storage components discharge electricity thoroughly.
- Do not use the equipment when it encounters any electrical or mechanical failure, and do not use the equipment when the protective circuit and protective facility is removed.

2.5.6 Radiation safety

Operators should be fully aware of the risk of excessive exposure to X-rays. Incorrect use of X-rays may cause personal injuries.

2.5.6.1 Routine protection

⚠ WARNING

The equipment must be used in an X-ray shielding room that complies with national laws and regulations.

In most cases, three measures can be taken for radiation protection:

■ Time protection

The longer the radiation duration is, the greater the absorbed dose will be. Therefore, shorten the exposure time as much as possible. All personnel should minimize the duration at radiated sites.

■ Distance protection

Keep all personnel (except patients) away from the radiation source.

■ Shielding protection

Ensure that the main protective layer is adequately shielded, to prevent operators and the public from exposure to the main X-ray beam and scattered X-rays. The main protective layer includes the protective shield of the wall, window, door, and control panel. Determine the correct shielding thickness based on expected operation parameters of the X-ray system.

Operators should perform image processing in the operation room. If an operator needs to get in close contact with a patient, the operator should use protective devices that meet the national and local radiation protection requirements, such as lead screens, lead gloves, aprons, and thyroid retainers, so as to minimize the hazard of exposure to radiation.

Wear a radiation dose monitor or use a pen-shaped radiation dosimeter to check the personal radiation dose.

Radiation protection for patients

To reduce or avoid excessive radiation exposure of patients in the scanning room, observe related radiation protection regulations:

- ◆ To protect patients from radiation hazards, use other radiation protection accessories in addition to the existing devices of the system, such as the collimator and additional filter plates.
- ◆ Generally, the minimum light field is used for centering.
- ◆ Use a gonad shielding plate or a lead-lined rubber hood to protect the gonads from radiation during image acquisition.
- ◆ Select the correct measurement field for the ionization chamber for the examination. Otherwise, patients may be exposed to unexpected or excessive radiation.
- ◆ Always keep the distance between the X-ray beam and the skin as long as possible, to minimize the dose absorbed through the skin of patients.

- ◆ Keep the examination time as short as possible to reduce the total radiation dose.
- ◆ Put the ROI close to the wireless digital flat panel detector, to reduce radiation and optimize the image quality.
- ◆ Do not place any object on the exposure path between a patient and the wireless digital flat panel detector. Otherwise, the image quality is reduced and the dose of the radiation exposed to patients is increased.
- ◆ Do not remove or alter any safety circuit that prevents the accidental triggering of X-rays.

 **WARNING**

Additional radiation

- ◆ Ensure that the X-ray tube is aligned with the flat panel before exposure, to prevent a patient from receiving additional radiation when no diagnosis image is acquired.

Radiation protection for operators

To reduce or avoid excessive radiation to operators, observe related radiation protection regulations:

- ◆ Avoid direct exposure to X-ray beams during working. If this is unavoidable, take proper protective measures.
- ◆ If you need to stay in the scanning room during the examination, wear protective clothing and gloves.
- ◆ Keeping a long distance is the most effective method of radiation protection. Stay away from the radiation object and X-ray tube assembly as far as possible if you need to stay in the scanning room during the examination.
- ◆ Minimize the duration of your stay in the scanning room.
- ◆ You can wear a dose tester to measure the received radiation dose.

2.5.6.2 X-ray protection

Any object in the path of the main beam can generate secondary radiation (scattered rays). The intensity of secondary radiation depends on the energy and intensity of the main beam as well as the number of atoms in the materials of the object struck by the main beam. Some impacts of X-ray radiation are accumulative. Therefore, take protective measures to avoid direct exposure to the main beam at any time.

Ensure that all maintenance personnel and operators receive strict training and well understand the hazards of radiation. The staff responsible for the equipment must know about the safety requirements for X-ray operations. Read through the manual carefully so as to completely understand all the safety and operation requirements.

- Ensure that there are only necessary personnel in the scanning room before exposure. Do not perform X-ray exposure until all unnecessary personnel leave the scanning room.
- Ensure that the shield door of the scanning room is completely closed before exposure. UIH take no responsibility for injuries caused by X-ray exposure in the event that no shield door switch is installed.
- Ensure the greatest validity of each X-ray exposure. Repeated X-ray exposure will increase the X-ray dose received by a patient.

⚠ CAUTION
Radiation protection <ul style="list-style-type: none"> ◆ Before each X-ray exposure, take all necessary measures to protect against radiation.

2.5.7 Laser protection

The collimator generates one low-energy red laser beam, which is used to align the X-ray tube assembly with the wireless digital flat panel detector. Lasers are generated each time the laser light of the collimator is turned on. The laser dimmer can be manually turned on or off. You can turn off the laser light to avoid the laser contact with eyes.



Figure 2-7 Warning sign for the collimator

⚠ CAUTION
It is prohibited to look into the laser beam without protection. It can cause eye damage and even blindness if you looking into the laser beam for more than 15 seconds.

2.5.8 Fire safety

The fire in or around the system may lead to great property damage, and result in burn, crash, and gaseous poisoning of patients and operators.

- Electrical equipment and cables on fire may be charged when the electrical equipment catches fire. In this case, cut off power immediately to prevent fire spread and electric shocks during fire extinction.
- Ensure that fire extinguishers are easily accessible, and operators are skilled in using them.
- Ensure that the physicians and patients are clear about the escape path.
- Fire protection safety facilities should be designed in the planning or building of the equipment room.

Fire extinguisher

All operators of the system should be fully aware of how to use fire extinguishers, and receive the training on how to use fire extinguishers and other fire extinguishing equipment as well as training on local fire prevention regulations.

Conductive liquid entering the running operator console circuits will result in short circuits and cause the equipment to be on fire. Therefore, do not place any liquid or food on the console or other components.

If the system cannot be shut down for a special reason or the power supply cannot be cut off due to other needs, operators must select a non-conductive extinguishing agent to quench fire while the power is on, for example:

- Carbon dioxide fire extinguisher
- 1211 fire extinguisher
- Difluoro dibromomethane fire extinguisher

⚠ WARNING

Hazard of electric shocks

- ◆ It is prohibited to put out fire with water when the power is not cut off. Otherwise, there will be a risk of electric shocks.

⚠ WARNING

Fire hazard

- ◆ Only dedicated electrical or chemical fire extinguishers can be used. In case of electrical fire, water or other liquid fire extinguishers may lead to serious or even fatal personal injuries.
- ◆ Vents cannot be covered during equipment running.
- ◆ Do not use flammable or explosive disinfection sprays as the generated vapor may flame, leading to serious personal injuries or equipment damage.
- ◆ The conductive liquid that infiltrates the system may short-circuit components and result in electric leakage and fire. Therefore, do not place any liquid or food on any components of the system.

2.5.9 Explosion safety

⚠ WARNING

Explosion hazard

- ◆ Do not use this system in an area with the explosion risk.

- Detergent and disinfectant (including those used on the patient's body) may generate explosive gas mixtures. Therefore, observe related safety regulations and refer to "[Disinfection and cleaning](#)" on page 7-10.

2.6 System safety

2.6.1 Equipment compatibility

The system described in this manual shall not be used in combination with other software or devices, unless such software or device is verified compatible and is approved by UIH. Otherwise, UIH will not assume any responsibilities for the losses incurred.

Only UIH or a third party authorized by UIH has the right to alter the system. And these alterations should be in compliance with relevant laws and regulations.

NOTICE

Signal input and output parts can only be connected to devices specified for the system. For example, it is not allowed to connect any third-party monitor and computer to the equipment.

⚠ WARNING

- ◆ The assembly, extension, readjustment, modification, or maintenance of the equipment should all be performed by the maintenance personnel authorized by the manufacturer.
- ◆ Users are prohibited to replace the system components without permission. If replacement is required, contact UIH Customer Service Center.

If the digital medical X-ray imaging system needs to be connected to other systems, components, or assemblies, but no technical data shows such connections are safe, users must consult UIH to ensure that doing so will not endanger the safety of patients, operators, and the environment. Before using a third-party component in the system, obtain the compatibility license from UIH, and refer to operation instructions and technical specifications of the third-party products.

⚠ WARNING

Reduced system security level

- ◆ If auxiliary equipment does not meet safety requirements of this equipment, the safety level of the system may be lowered. Original accessories of the system or third-party accessories approved by UIH must be used.
- ◆ Any failing component in the system may lower the safety level of the system. In this case, stop the system immediately and contact UIH Customer Service Center.

⚠ WARNING

Compatibility

- ◆ The use of hardware/software assemblies that are not approved by UIH or tampered may damage the system.
- ◆ UIH provides follow-up services only when users use software/hardware approved by UIH and reach written agreements with UIH.

Signal input/output interface

Only the equipment tested and approved by UIH can be connected to the system to ensure the operating safety of the system.

Equipment connected to the system through interfaces must pass relevant standard certification, for example:

- Information technology equipment must pass the GB 4943 certification.
- Medical electrical equipment must pass the GB 9706.1 certification.

2.6.2 Electromagnetic compatibility

Electromagnetic Compatibility (EMC) refers to the ability of a device or system to function properly as required in its electromagnetic environment, without generating electromagnetic interference intolerable to any device in its environment. Therefore, EMC includes two aspects: on one hand, the electromagnetic interference generated by the device in the environment during normal operation cannot exceed a certain limit; on the other hand, the device is immune to electromagnetic interference existing in the environment to a certain extent, — known as Electromagnetic Susceptibility (EMS).

The system complies with the electromagnetic compatibility (EMC) standards of relevant medical electrical equipment in the YY0505 standard. This standard defines the radiation level allowed by the equipment and the capability of the equipment to resist external electromagnetic interference.

Special measures should be taken for medical electrical equipment to ensure electromagnetic compatibility. Portable and mobile RF communication equipment, such as mobile phones, may affect the normal operation of the medical electrical equipment in some cases. It may lead to death, serious injuries, or clinical misdiagnosis. Therefore, do not take RF communication equipment (even it is powered off) to the scanning room.

Strong magnetic substances are not allowed near the system. Otherwise, the system may be interfered by the magnetic field and incorrect output signals are incurred. Using other cables and accessories in the system may result in the EMC failure.

According to the design, electronic equipment that meets electromagnetic compatibility requirements will not fail due to electromagnetic interference under normal operating conditions. However, if a high-frequency transmitter with high transmit power transmits radio signals near the equipment, there is a possibility that electromagnetic incompatibility may be incurred.

Though some high-frequency transmitters, such as mobile phones or similar mobile radio devices, comply with electromagnetic compatibility regulations, the radio signals generated by them may still affect the normal running of the system if they are used near the equipment with a relatively high transmit power. Therefore, it is prohibited to use such radio devices near this equipment to eliminate the possibility of interference.

Under special circumstances, some high frequency transmitter can disorder the operation of the system, resulting in accidental injuries to patients or operators. Therefore, the communication using any radio device is not allowed. This principle applies even if the device is in "standby" mode.

For detailed technical data of electromagnetic interference, see "["Electromagnetic interference requirements" on page 8-11](#)".

NOTICE

Use the equipment in the specified electromagnetic environment. Otherwise, the equipment may fail to work properly.

NOTICE

Portable and mobile RF communication devices may affect normal operation of the equipment. Use the equipment in a recommended electromagnetic environment.

⚠ WARNING

The equipment or system should not be adjacent to or stacked together with other equipment. If required, observe and verify that it can operate properly under its configuration.

⚠ WARNING

Unapproved accessories, transducers, and cables (except transducers and cables sold by the equipment or system manufacturer as spare parts of internal components) might result in radiation emission increase or interference immunity reduction of the equipment or system.

⚠ WARNING

The use of unapproved accessories, transducers, or cables together with the equipment or system might result in electromagnetic emission increase or interference immunity reduction of the equipment or system.

⚠ WARNING

Electromagnetic compatibility

- ◆ Shut down other electronic devices within the designated operation area.

2.6.3 Transportation protection

Before transportation, cut off the power of the equipment and then pack it. Make sure that all peripheral components (including the monitor, mouse, keyboard, and cable) are disconnected and transported safely.

Ensure that packing cases are securely fastened during transportation to avoid internal damage caused by shaking.

NOTICE

To ensure personal safety, wear proper safety equipment such as safety shoes and protective gloves during unpacking or equipment installation.

2.6.4 Electrostatic protection

Electrostatic discharge can damage electronic components of the system, resulting in system malfunctions. When operating electrostatic sensitive devices, take antistatic measures. Service personnel must wear protective clothing, protective shoes, and ESD wrist straps to prevent static electricity from damaging electrostatic sensitive devices and incurring potential injuries to operators.

⚠ WARNING

Electrostatic hazard

- ◆ When performing operations related to circuit boards, wear antistatic facilities to prevent the generated static electricity from damaging to the circuit boards or hurting people.

2.7 Environmental protection

2.7.1 Handling of hazardous substances and components

In order to make the system performance meet the regulatory requirements, UIH has to use some materials that may be harmful to the environment, and such materials must be scrapped and disposed in a proper way.

Related components of the system must be recycled according to relevant laws and regulations or properly disposed by authorized personnel by using the method of the local waste collection stations. It is prohibited to dispose of this medical diagnosis system together with general industrial or domestic waste.

Handling of damaged wireless digital flat panel detectors

The wireless digital flat panel detector may be damaged when operated abnormally. As a result, harmful thallium-contained particles may spill out. If the damaged wireless digital flat panel detector is not properly handled, it may harm people's health and cause environmental pollution.

NOTICE

Do not use a damaged wireless digital flat panel detector. Otherwise, thallium-contained particles may spill out and environmental pollution or personnel injuries may be caused.

Collect spilled particles and store them in a sealed container. After collection, contact UIH Customer Service Center to return the spilled particles to UIH.

2.7.2 Product disposal

The service life of the system is 10 years. Conduct daily maintenance on the system according to this manual. If the operation period is much longer than the service life and normal operation frequency, you may need to conduct extra checks and repair in addition to daily maintenance. Please inform UIH Customer Service Center in advance when necessary.

Medical equipment is a type of special product. After the product reaches its service life, it needs to be recycled and disposed in accordance with relevant laws and regulations. Users should contact UIH Customer Service Center for recycling after the product lifecycle expires. Handle harmful substances in an appropriate manner.

UIH allows you to dispose of the system in a proper way. Reusable components can be recycled by certified waste processing companies to help reduce environmental pollution.

2.8 System messages

System messages are displayed on the operation UI of the image processing system in the operation room.

Based on the influence on the system, system messages are classified into three levels:

Message level	Description	Image processing system	
		Icon	Position
Message	Indicates information showing various normal states of the system, such as the position of U-arm positioner, and current parameters of the generator.		Status bar, message list, prompt dialog box
Warning	Indicates information showing that system errors may be caused or low-risk events may be triggered. Such information does not need your confirmation.		Status bar, message list, prompt dialog box
Error	Indicates that the system is in the error status. You are required to handle such errors or contact UIH Customer Service Center for handling.		Status bar, message list, prompt dialog box

■ Message status bar

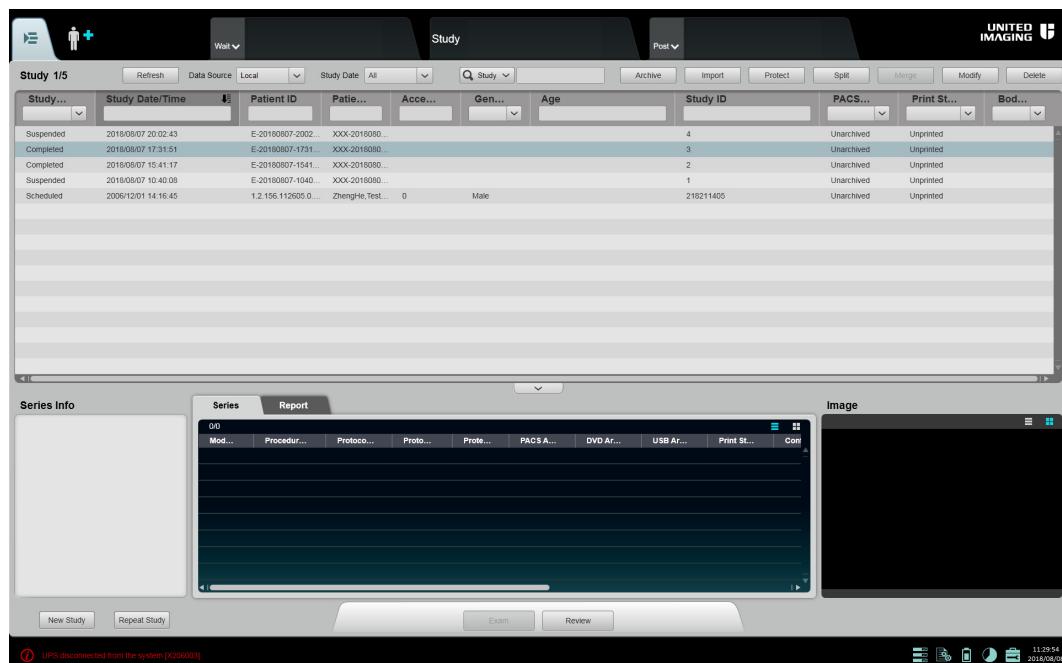


Figure 2-8 System status bar in image processing system

■ System status list

Click the system status bar to list history messages of the system.

■ Prompt dialog box

The prompt dialog box will pop up on the UI of the image processing system for some system messages.

- ◆ Click **OK**, and perform operations as prompted. If the prompt dialog box persists after prompted steps are performed, contact UIH Customer Service Center.

2.9 Service life

The expected service life of this product is 10 years.

Please contact UIH Customer Service Center for the disposal of this product at the end of its service life.

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3 System components

3.1	System overview	3-2
3.1.1	System components in the scanning room	3-2
3.1.2	System components in the operation room	3-3
3.2	Definition of coordinate axes and directions	3-5
3.3	X-ray tube - collimator assembly	3-6
3.3.1	X-ray tube assembly	3-6
3.3.2	Collimator	3-15
3.3.3	Angle indicator	3-16
3.4	Digital flat panel detector carrier assembly	3-18
3.4.1	Wireless digital flat panel detector	3-19
3.4.2	Wireless digital flat panel detector tray	3-20
3.5	Motion control buttons	3-21
3.6	Console system	3-22
3.6.1	Image processing system	3-22
3.6.2	Control console	3-24
3.6.3	Exposure hand switch	3-26
3.7	DAP meter	3-27

3.1 System overview

This section describes the structure of the digital medical X-ray imaging system.

3.1.1 System components in the scanning room

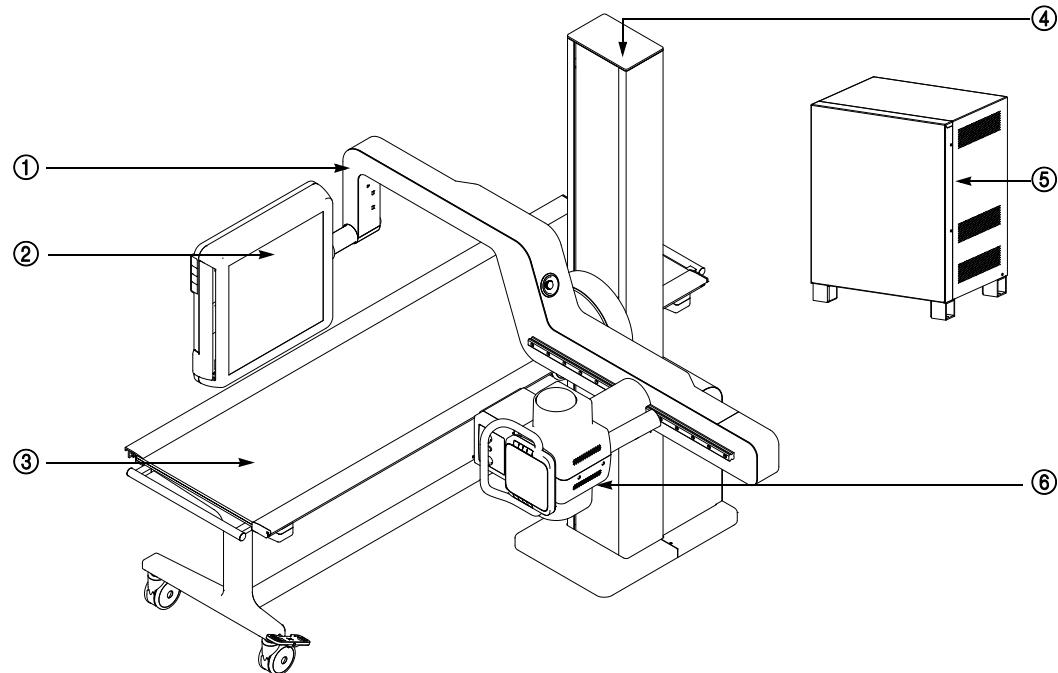


Figure 3-1 System components in the scanning room

- | | |
|--|-------------------------------------|
| 1. U-arm | 4. U-arm column |
| 2. Wireless digital flat panel detector assembly | 5. System cabinet assembly |
| 3. Mobile radiographic table | 6. X-ray tube - collimator assembly |

No.	Component name	Description
1	U-arm	<ul style="list-style-type: none"> The U-arm is connected to the X-ray tube - collimator assembly at one end and the wireless digital flat panel detector assembly at the other end. The U-arm can rotate around the horizontal axis. The U-arm supports the movement of the X-ray tube - collimator assembly. <p>The U-arm supports the movement of the wireless digital flat panel detector assembly.</p>
2	Wireless digital flat panel detector detector carrier assembly	<ul style="list-style-type: none"> This assembly, located at one end of the U-arm, is composed of the wireless digital flat panel detector carrier and wireless digital flat panel detector. Motion control buttons can be used to control the motion direction of the wireless digital flat panel detector.

No.	Component name	Description
3	Mobile radiographic table	The mobile radiographic table carries a patient to be examined.
4	U-arm column	The U-arm column provides support for the U-arm so that the U-arm can vertically move along the guide rails of the column.
5	X-ray tube - collimator assembly	This assembly, located at the one end of the U-arm, is composed of an X-ray tube assembly, a collimator, and an angle indicator.
6	System cabinet assembly	The system cabinet assembly integrates a high voltage generator and a power distribution unit.

3.1.2 System components in the operation room

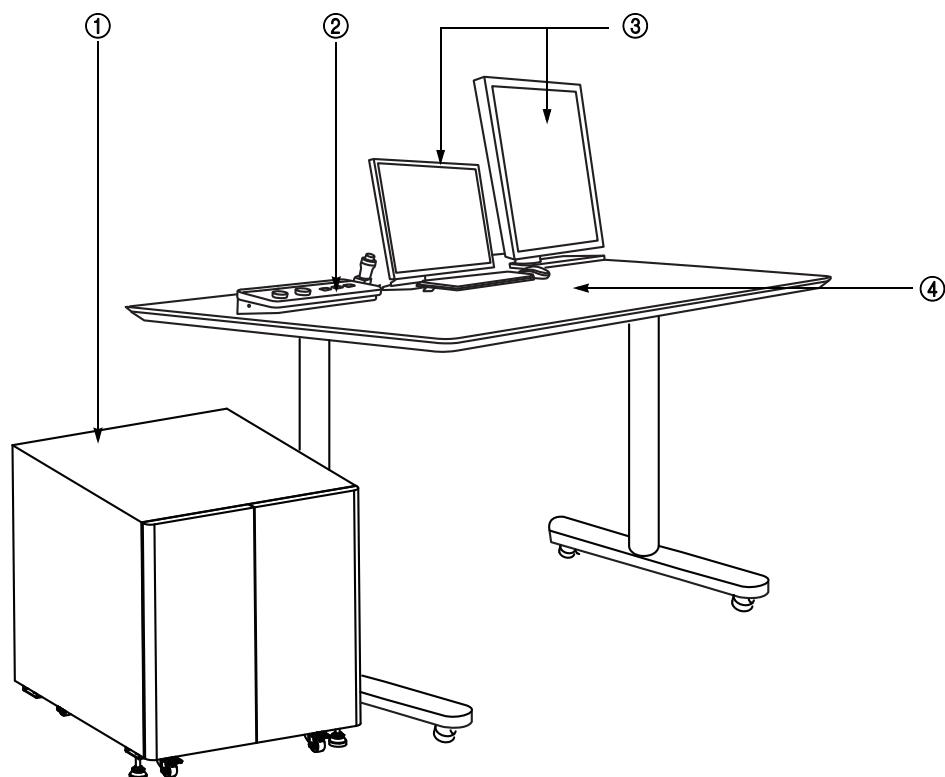


Figure 3-2 System components in the operation room

No.	Component name	Description
1	Image processing system workstation assembly	<ul style="list-style-type: none"> ◆ Host cabinet, workstation host ◆ This assembly supports a range of image processing operations from patient registration to filming.
2	Control console	The control console consists of a control console and an exposure hand switch. It can complete system power-on/off, motion control, and exposure operations.

No.	Component name	Description
3	Monitor	The monitor consists of an image processing system monitor and a diagnostic monitor (optional).
4	Keyboard and mouse	The keyboard and mouse are used to assist with the operations on the image processing system.

NOTICE

Do not issue the same motion instruction to the system from the scanning room and operation room at the same time.

3.2 Definition of coordinate axes and directions

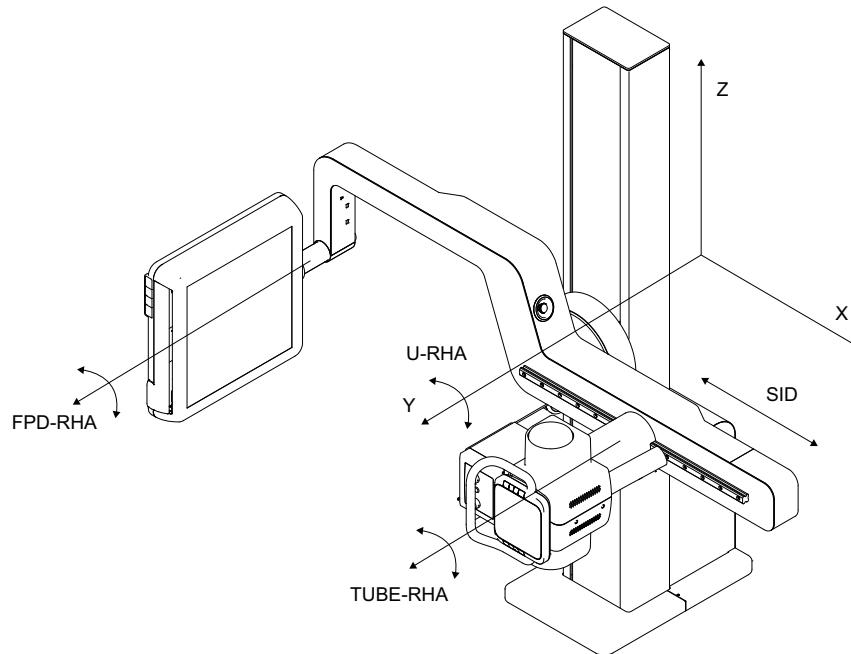


Figure 3-3 Definition of coordinate axes and directions

Name	Description
X-axis	The X-axis is vertical to the Z-axis and is parallel to the ground and the cross arm of the U-arm.
Y-axis	The Y-axis is vertical to the Z-axis and the cross arm of the U-arm, and is parallel to the ground.
Z-axis	The Z-axis is vertical to the ground and the positive direction is vertically upward.
FPD-RHA	The detector carrier uses the cantilever of detector carrier as the center and rotates leftward and rightward around the horizontal axis (Y-axis in the figure).
U-RHA	The U-arm rotates leftward and rightward around the horizontal axis (Y-axis in the figure).
TUBE-RHA	The X-ray tube assembly, using the tube focus as the center, rotates leftward and rightward around the horizontal axis (Y-axis in the figure).
SID	The X-ray tube assembly moves relative to the detector carrier along the U-arm.

3.3 X-ray tube - collimator assembly

The X-ray tube - collimator assembly is composed of an X-ray tube assembly, a collimator, and an angle indicator.

3.3.1 X-ray tube assembly

This system supports two X-ray tube assembly models: XRR-3331X (tube sleeve: XH-121; tube core: XRR-3331) and E7876X (tube sleeve: XH-121; tube core: E7876). The structure and performance of the two models are described as follows.

WARNING

Burn hazard

- ◆ The temperature of the X-ray tube assembly will rise under extreme conditions. Do not touch the X-ray tube sleeve to prevent burns.

WARNING

Additional load

- ◆ It is prohibited to add additional loads to the X-ray tube - collimator assembly. Otherwise, system components may be damaged and the fall of additional loads can cause personal injuries.

3.3.1.1 X-ray tube assembly XRR-3331X

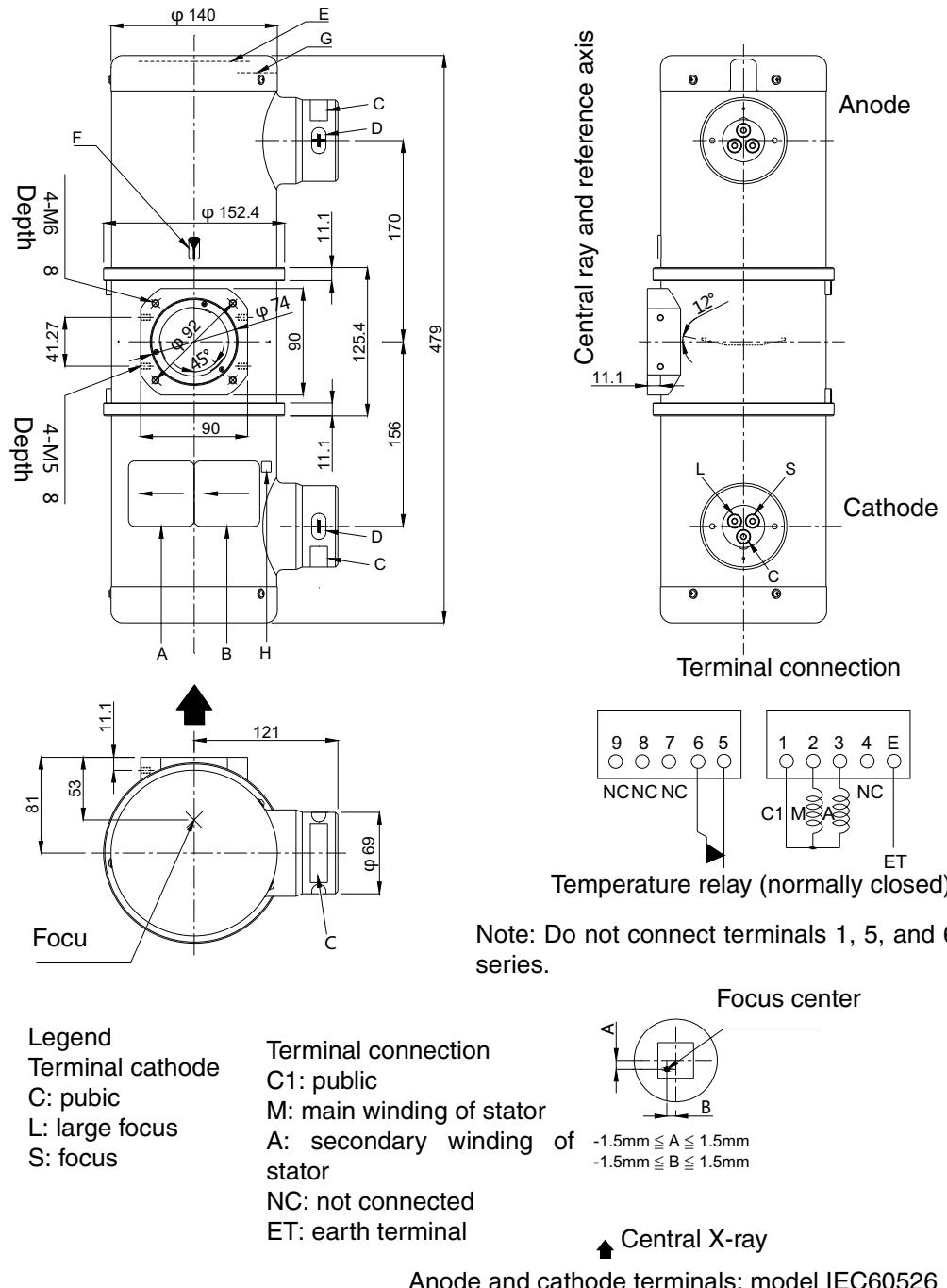


Figure 3-4 X-ray tube assembly XRR-3331X

Features of the X-ray tube assembly XRR-3331X:

- Inherent filtration of the X-ray tube: 0.9 mm Al @ 75 kV
- Nominal voltage of the X-ray tube: 150 kV
- Standard loading conditions: 150 kV, 3.4 mA
- Rated value of the rotating anode motor

Parameter	Startup		Running	
Power frequency (Hz)	180	60	180	60
Input power (W)	1100	910	83	83
Voltage ^a	220	130	60	40
Current	5.7	7.8	1.6	2.3
Minimum acceleration ^b	1.2	0.8	-	-
Capacitor (μ F)	6	44	6	44
Minimum braking time ^c (s)	3/90 V (DC)			

- a. The voltage imposed each time cannot exceed 110% of the specified values above.
 - b. The startup time provided in the table above is the time required for increasing the speed from 0 to a high speed.
 - c. This time is applicable to the highly rotated state.
- For the emission feature of the cathode filament, see the feature curves in the following figure.

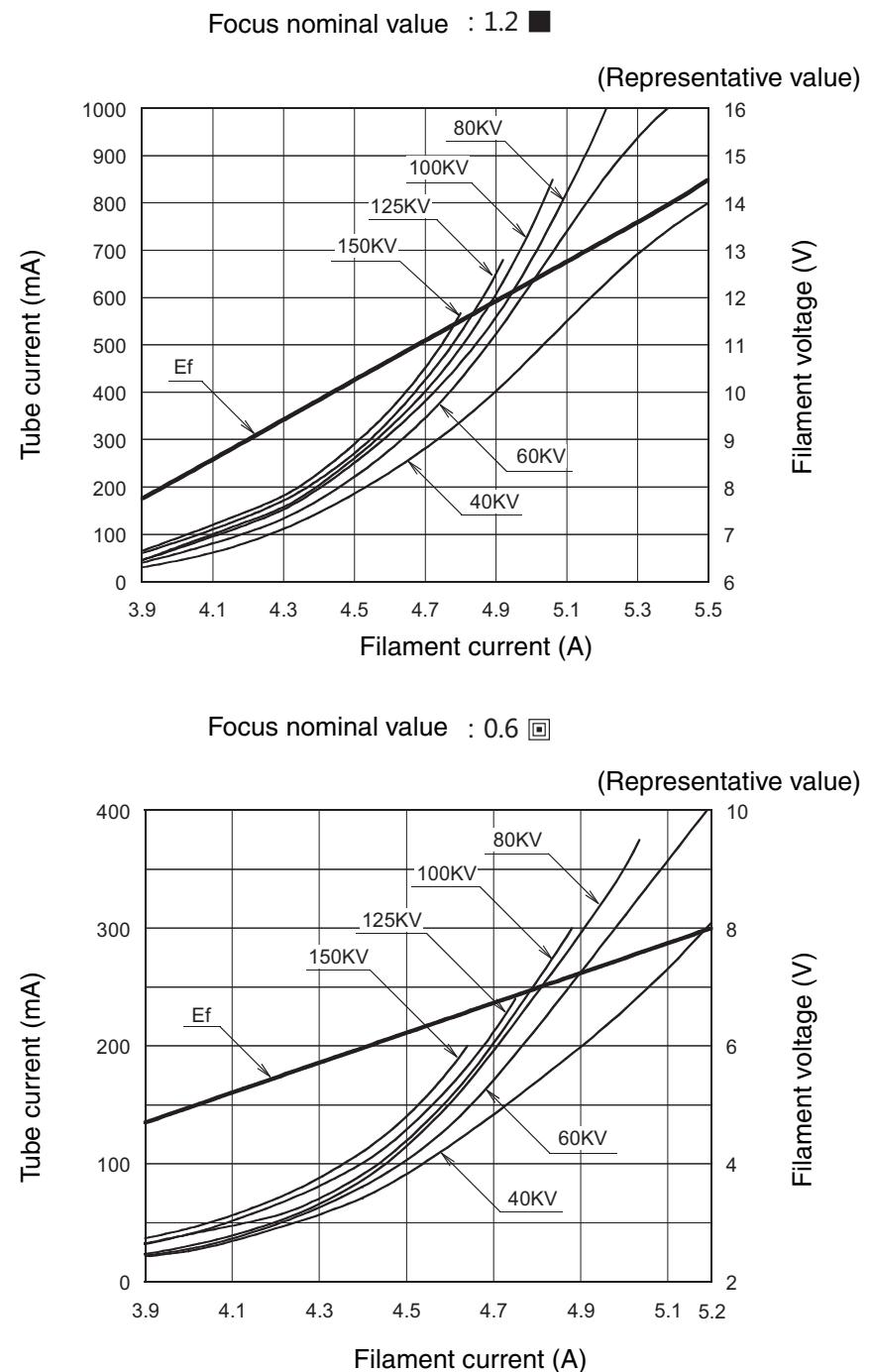


Figure 3-5 Filament emission feature curve

■ Maximum rated value table of the XRR-3331X (stator drive frequency: 50 Hz)

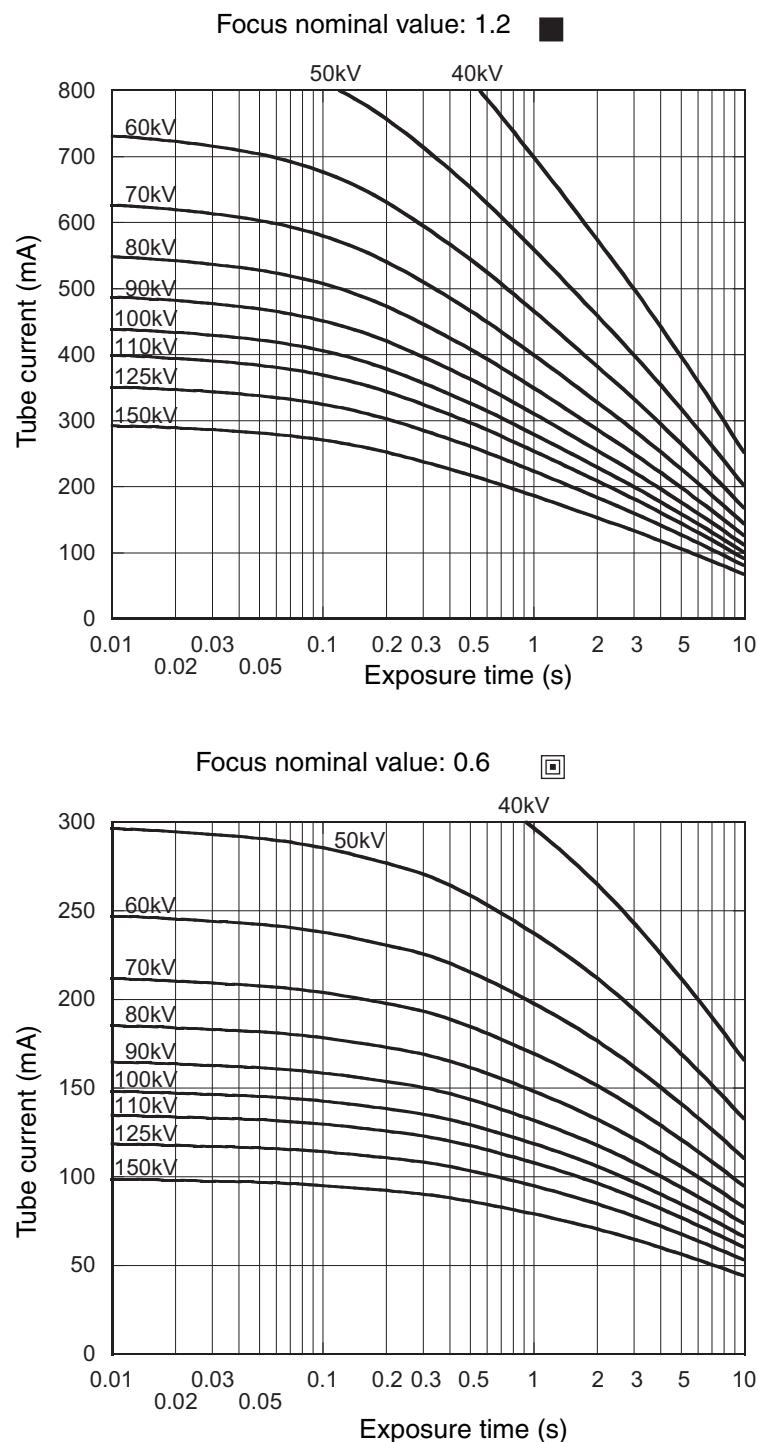


Figure 3-6 Maximum rated value table of the XRR-3331X

- Heating and cooling feature curves of the X-ray tube assembly (the average input power is imposed to the anode in the following figure)

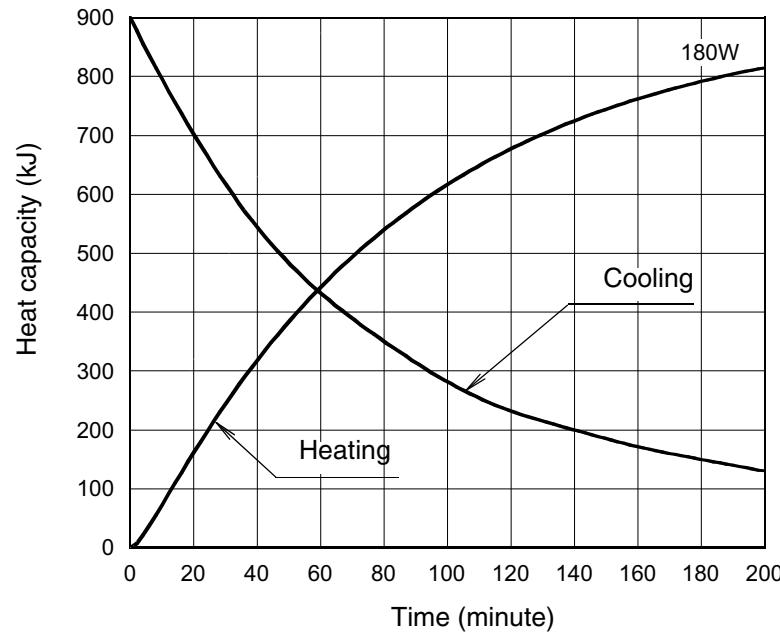


Figure 3-7 Heating and cooling feature curves of XRR-3331X

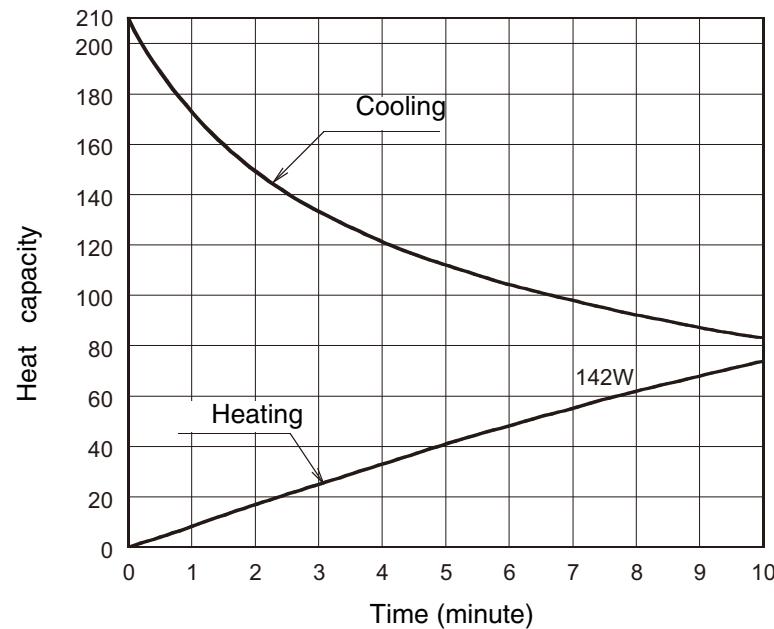


Figure 3-8 Heating and cooling feature curves of anode of XRR-3331X

3.3.1.2 X-ray tube assembly E7876X

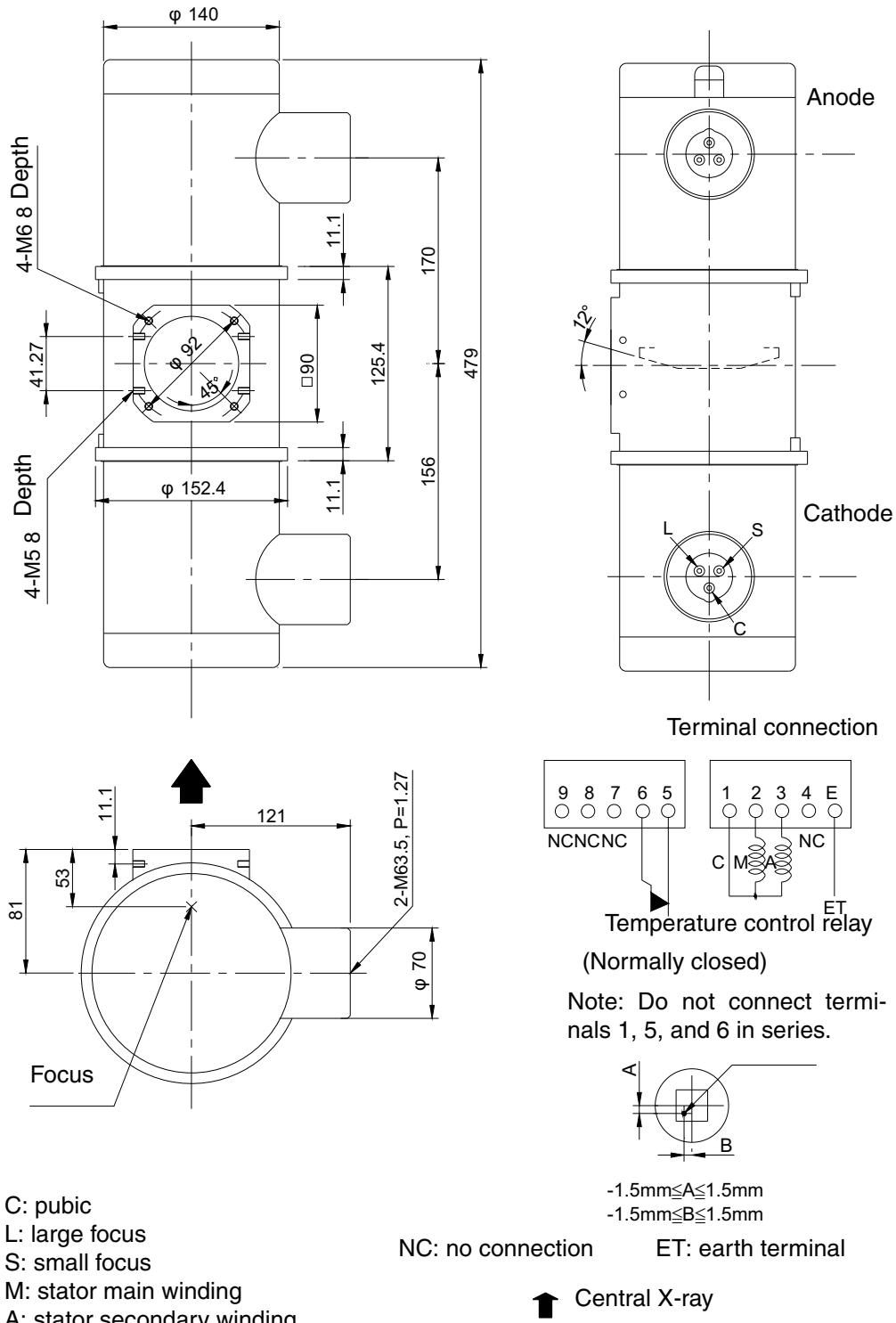


Figure 3-9 X-ray tube assembly E7876X

Features of the X-ray tube assembly E7876X:

- Inherent filtration of the X-ray tube: 1.5 mm Al @75 kV

- Nominal voltage of the X-ray tube: 150 kV
- Standard loading conditions: 150 kV, 3.4 mA
- Rated value of the rotating anode motor

Parameter	Startup		Running	
Power frequency (Hz)	50	60	50	60
Input power (W)	1450	1450	80	80
Voltage ^a (V)	240	240	58	58
Current (A)	6.5	6.5	1.5	1.5
Minimum acceleration ^b (s)	0.6	0.6	-	-
Capacitor (μ F)	24	24	24	24

- a. The voltage imposed each time cannot exceed 110% of the specified values above.
- b. The maximum acceleration and deceleration time can be up to 110% of the specified values above.

- Maximum rated value table of the E7876X (stator drive frequency: 50 Hz)

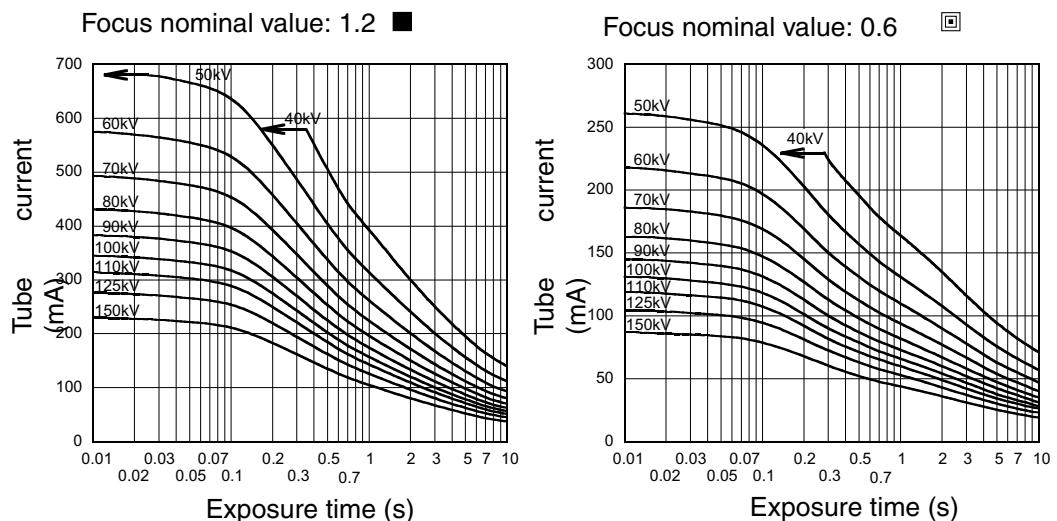


Figure 3-10 Maximum rated value table of the E7876X

- For the emission feature of the cathode filament, see the emission feature curves in the following figure.

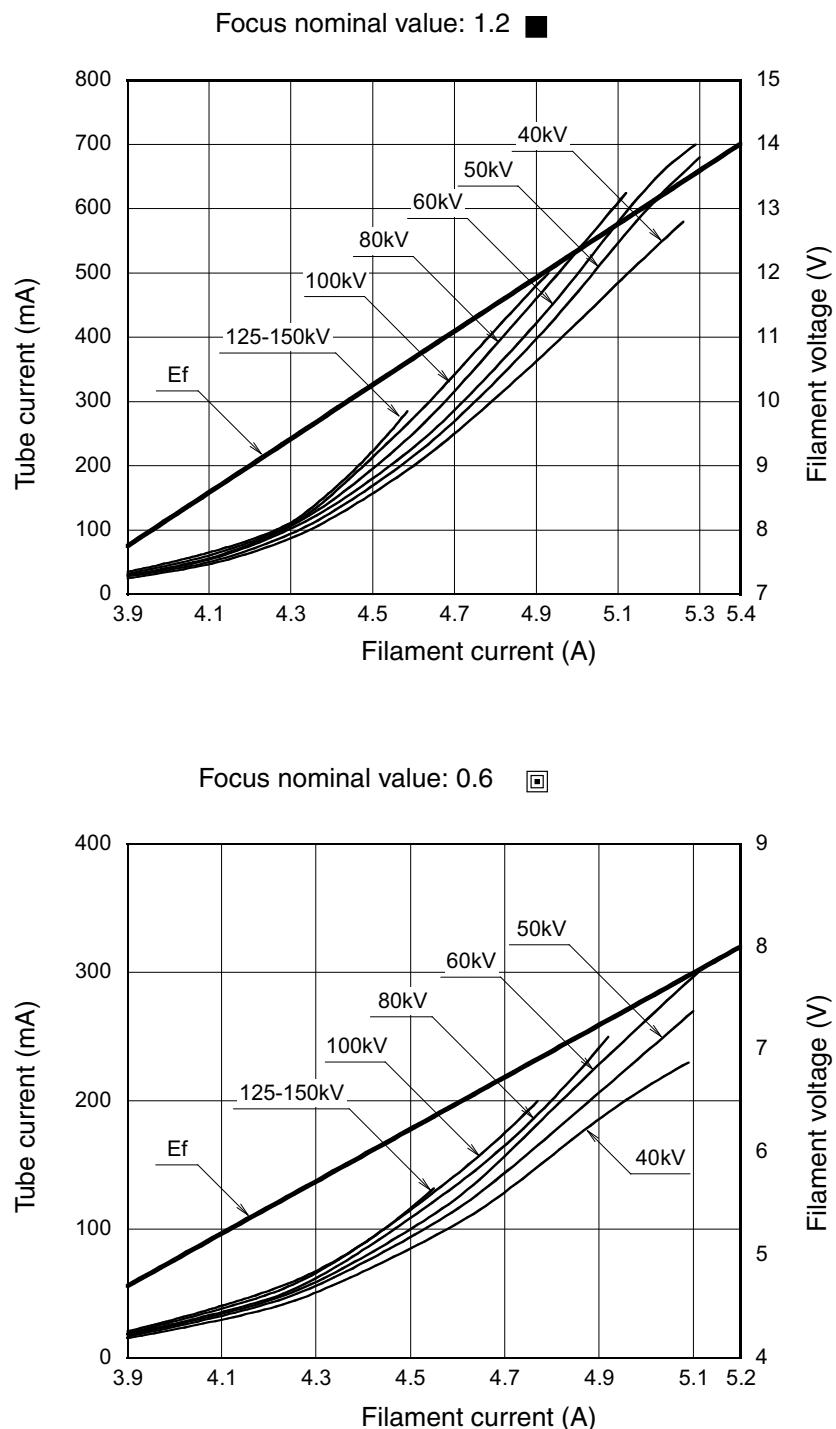


Figure 3-11 Filament emission feature curve

- Heating and cooling feature curves of the X-ray tube assembly

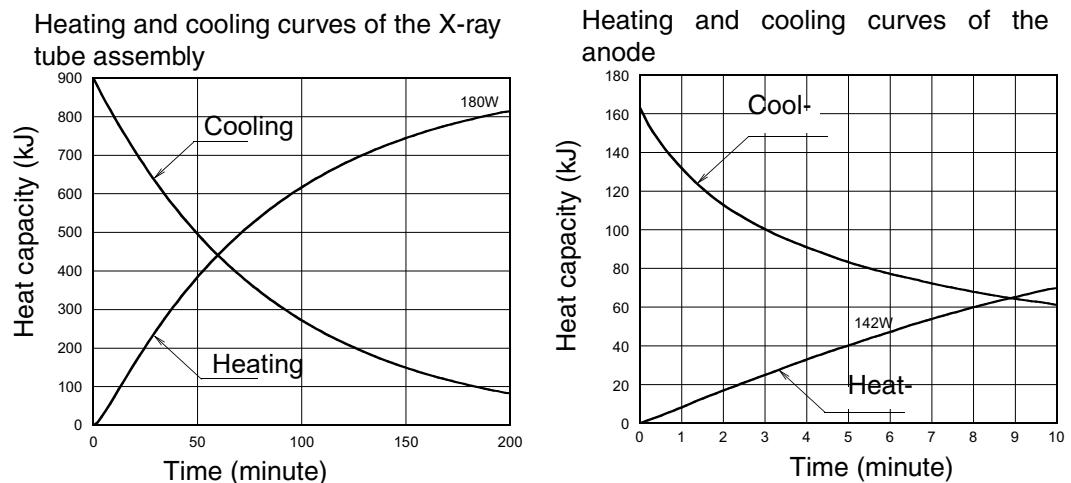


Figure 3-12 Heating and cooling feature curves of E7876X

3.3.2 Collimator

The following figure shows the components of the collimator.

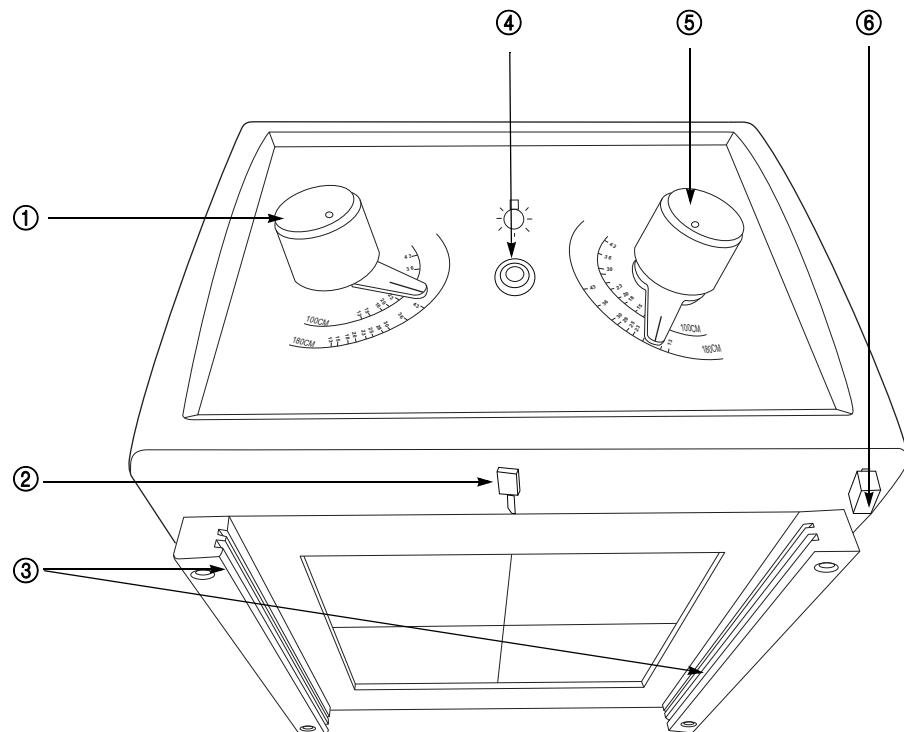


Figure 3-13 Collimator structure

- | | |
|---|---|
| 1. Horizontal adjustment knob for light field | 4. Light field positioning light switch |
| 2. Laser positioning light and dimmer | 5. Vertical adjustment knob for light field |
| 3. Additional filter plate slot | 6. Tape measure |

- Light field adjustment knobs are used to adjust the light field scope of the collimator in horizontal and vertical directions.

- The laser positioning light is used to indicate the position of the X-ray field centerline and is turned on with the switch-on of the light field positioning light.
- The dimmer is used to switch off the laser positioning light.
- The light field positioning light switch is used to turn on and turn off the light field positioning light.
- The additional filter plate slot is used to accommodate the additional filter plate.
- The tape measure is used to accurately measure the distance from the focus of the X-ray tube to the surface of the wireless digital flat panel detector.

 **WARNING**

Burns caused by laser light

- ◆ If the laser positioning light is on for a long time, the light box and light bulb will become hot. Do not touch the light box to prevent burns.

 **WARNING**

The laser light may hurt eyes.

- ◆ Do not look into the laser beam without protection as it may cause eye damage and even blindness if the time lasts more than 15 seconds.
- ◆ Use the slide cover to shield the laser lamp during examination, to protect patients' eyes.

3.3.3 Angle indicator

The angle indicator is used to display the angle of the X-ray tube - collimator assembly and motion control buttons on both sides are used to control the motion of system components.

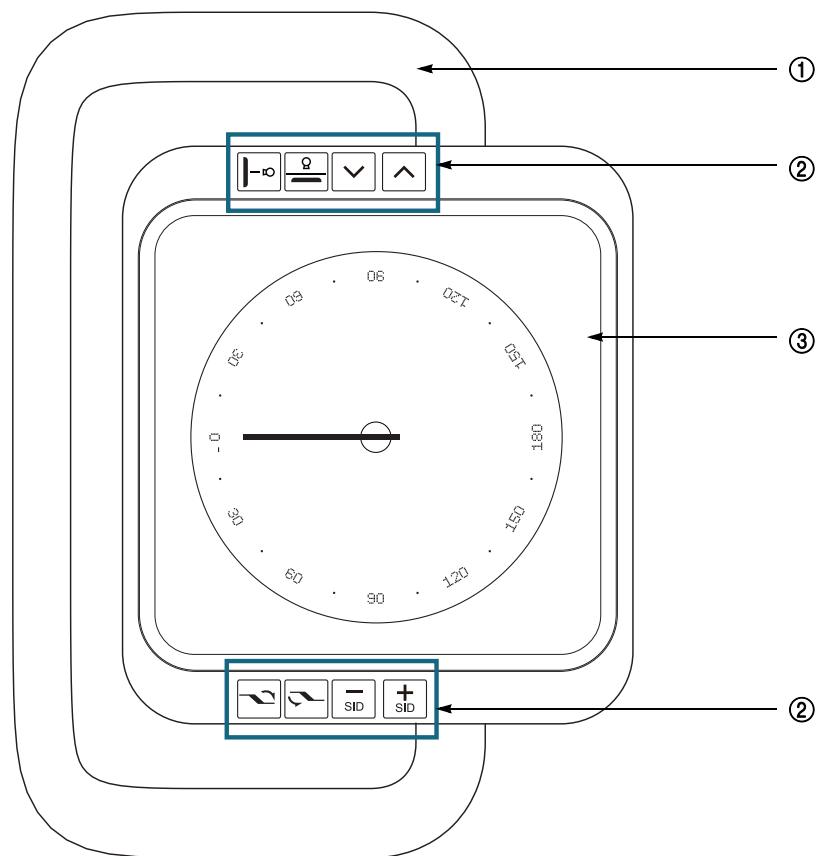


Figure 3-14 Angle indicator

- 1. Handle
- 2. Motion control buttons
- 3. Angle display screen

NOTICE

The direction indication of the motion control buttons on the X-ray tube - collimator assembly is based on that the X-ray tube - collimator assembly rotates 0 around the horizontal axis (RHA). When the X-ray tube - collimator assembly rotates around the horizontal axis (RHA), interpret the direction correctly.

3.4 Digital flat panel detector carrier assembly

The following figure shows the main components of the detector carrier.

The aluminum equivalent of the top of the detector carrier assembly is not greater than 1.2 mm Al.

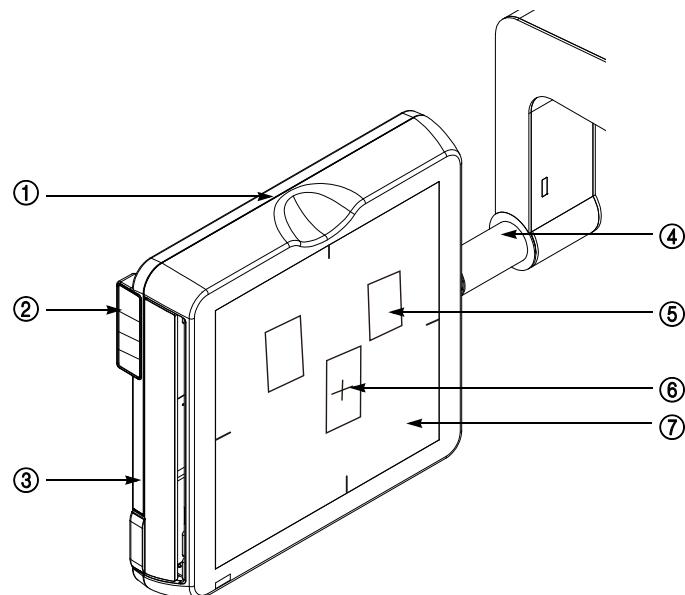


Figure 3-15 Structure of the detector carrier

- | | |
|--|---|
| 1. Jaw slot | 5. Measurement field for the ionization chamber |
| 2. Motion control panel | 6. Center cross line |
| 3. Wireless digital flat panel detector tray | 7. Effective imaging area |
| 4. Cantilever of detector carrier | |

- The wireless digital flat panel detector is placed in the tray.
- The center cross line is used to check whether the focus of the X-ray tube assembly is aligned with the center of the detector.
- The measurement field for the ionization chamber is the sensing area of automatic exposure control. You can select from the three measurement fields or use their combinations.
- The detector carrier handle at the rear of the cantilever of the detector carrier is used to unlock the locked detector carrier.

The aluminum equivalent of the wireless digital flat panel detector detector carrier is not greater than 0.5 mm Al.

The rectangles in solid line are the effective imaging areas of the wireless digital flat panel detector. An effective imaging area of the wireless digital flat panel detector is 427 mm × 427 mm. To reduce unnecessary radiation, the light field cannot be out of the effective imaging area of the wireless digital flat panel detector. For details, see "[Radiation safety](#)" on page 2-17.

3.4.1 Wireless digital flat panel detector

The wireless digital flat panel detector receives X-rays emitted from the X-ray tube assembly, and converts them into to digital images to be displayed on the image processing system monitor, so as to assist technicians or physicians with the diagnosis.

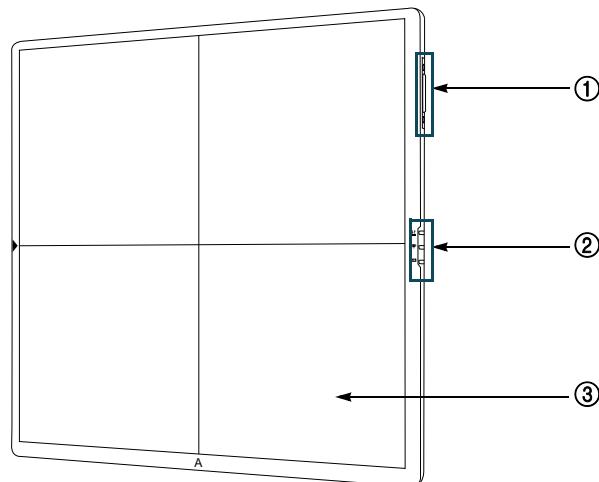


Figure 3-16 Structure of the wireless digital flat panel detector

- | | |
|------------------|---|
| 1. Charging port | 3. Wireless digital flat panel detector panel |
| 2. Indicator | |

An effective imaging area of the wireless digital flat panel detector is 427 mm × 427 mm. To reduce unnecessary radiation, the light field should not be out of this area. For details, see "["Radiation safety" on page 2-17](#)".

NOTICE

- ◆ Although this equipment and some mobile RF communication devices comply with the radiation application requirements, the wireless digital flat panel detector can be still interfered by other devices, including portable and stationary RF communication devices.
- ◆ The RF range of the wireless digital flat panel detector is 2.4 GHz or 5 GHz. Operators must ensure that there are not many other wireless devices operating within the above RF range; otherwise, the transmission of remote control signals may be interrupted.

The wireless digital flat panel detector has three indicators, which indicate the data transmission status, wireless network signal status, and battery level status separately.

Table 3-1 Indicators of the wireless digital flat panel detector

Icon	Description	Icon	Description
	Data transmission		Wireless network signal

Icon	Description	Icon	Description
	Battery level		

3.4.2 Wireless digital flat panel detector tray

The handle of the wireless digital flat panel detector tray is located in the upper part on one side of the detector carrier and is marked with "PULL". Pull the handle outward to pull out the wireless digital flat panel detector tray, and then put the wireless digital flat panel detector inside. The battery bay indicators on both sides of the detector carrier are on.

3.5 Motion control buttons

There are motion control panels on the angle indicator and wireless digital flat panel detector detector carrier. Motion control buttons on the panels can be used to control the motion of the U-arm and assist with the positioning.

For positions of the motion control buttons, see "[Angle indicator](#)" on page 3-16 and "[Structure of the detector carrier](#)" on page 3-18.

Button icon	Name	Function
	Upward movement of the U-arm	After this button is pressed, the U-arm moves upward along guide rails of the column. After this button is released, the motor-driven motion is stopped.
	Downward movement of the U-arm	After this button is pressed, the U-arm moves downward along guide rails of the column. After this button is released, the motor-driven motion is stopped.
	One touch ready for vertical position	After this button is pressed, the U-arm positioner moves to the standard vertical position.
	One touch ready for lying position	After this button is pressed, the U-arm positioner moves to the standard lying position.
	SID increase	After this button is pressed, the SID distance increases.
	SID decrease	After this button is pressed, the SID distance decreases.
	Clockwise rotation of the U-arm	After this button is pressed, the U-arm rotates around the central axis clockwise. After this button is pressed, the motor-driven rotation is stopped.
	Counterclockwise rotation of the U-arm	After this button is pressed, the U-arm rotates around the central axis counterclockwise. After this button is pressed, the motor-driven rotation is stopped.

3.6 Console system

The console system is used to control the system power-on/off in the operation room, to set the system positioning and display the positioning status, and to trigger exposure.

The console system consists of the following system components:

- Image processing system assembly

The image processing system assembly includes the system host, mouse, and keyboard.

- Monitor

The console system is equipped with a standard high-resolution color monitor so as to help operators accomplish task operations conveniently and rapidly. An optional diagnostic monitor can be configured for further diagnostic assessment.

- control console

In the operation room, operators can press buttons on the control console to complete power-on/off, system motion, and exposure motion operations.

3.6.1 Image processing system

The UIH image processing system supports the complete workflow from patient registration, patient administration, exam, viewing, image processing, to filming. Operators can quickly switch among different applications by using navigation buttons at the bottom of the display UI. Multiple applications for different patients can run concurrently.

- Patient registration

Implements the registration, modification, and storage of patient information, and supports emergency registration in case of emergencies.

- Patient administration

Provides a full set of patient data management solutions for users, and supports the following operations: data archiving, transmission, import, deletion, protection, modification, merging, and splitting.

- Exam

Provides a full set of patient examination solutions for users, implements the selection and adjustment of the acquisition system, patient age group, patient type and position, and exposure mode, and displays the system status on the examination UI, including the exposure dose, SID, centering status, grid status, and flat panel status.

- Viewing

Provides image browsing, view, comparison, measurement, annotation, window width/level adjustment, zoom, pan, local amplification, and rotation; adopts the multi-level viewing window design for the image display area, and allows physicians to conduct a contrast diagnosis using multiple sequences.

- Filming

Provides the image browsing, processing, and typesetting functions, and supports electronic film archiving and fast filming.

3.6.1.1 System configuration

Table 3-2 Configuration of the image processing system

Item	Configuration
Memory	No less than 8 GB
Hard disk	No less than 1 TB
Power	500 W
Keyboard	USB interface. Both Chinese and English are supported.
Mouse	USB interface
Operating system	Windows embedded standard 7 64-bit
Monitor	<ul style="list-style-type: none"> ◆ Size: no smaller than 21.5 inches ◆ Resolution: no smaller than 1920 × 1080 ◆ Brightness: no smaller than 170 cd/m² ◆ Dual monitors are supported. ◆ An optional 21.3-inch diagnostic monitor can be configured.

WARNING

Hardware compatibility

- ◆ The use of any non-original accessory may reduce the display effect or cause incomplete or even incorrect display, affecting the diagnosis.

■ Language

- ◆ The UI of the image processing system can be configured to use Chinese or English.
- ◆ In this manual, all menus, UI, buttons, and prompts are in English.

■ Copyright

The system and user software are copyrighted.

■ DICOM compliance

The image processing system software complies with the DICOM 3.0 standard.

■ Third-party software

Only the software authorized by UIH for this system can be used.

CAUTION

Network connection

- ◆ Connecting the system to an unknown network is in violation of authorized access, which may result in the risk of data leakage.
- ◆ When adding functions or modifying the current configuration, ensure that all necessary preventive measures are taken for the network security of the current level.

WARNING

Counterfeit software and hardware

- ◆ Using counterfeit software or hardware may lead to system failures and impose a threat to patients or the equipment.
- ◆ UIH will take no responsibility for the use of hardware and software not approved by UIH.

■ Virus scan

Refer to the *Software Operator Manual*.

■ Data protection

Personal data is under data protection. Be sure to observe related relevant laws and regulations.

3.6.1.2 Equipment connection

The equipment can be connected to external conventional printers, laser printers, and barcode scanners. The printers must support DICOM 3.0. The Motorola LS2208 barcode scanner is recommended.

3.6.2 Control console

Users can use the control console to implement system power-on/off, control of system movements, and exposure operations.

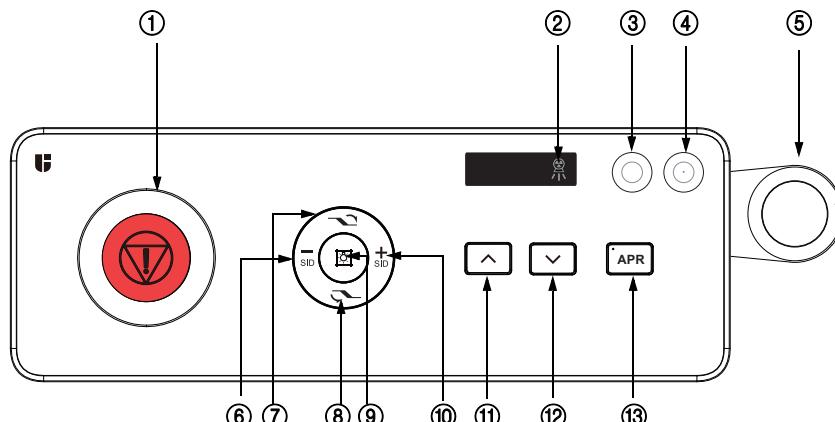


Figure 3-17 Structure of the control console

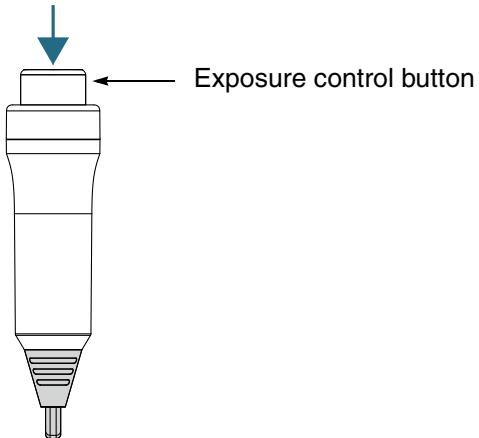
1. Emergency stop switch
2. X-ray radiation indicator
3. One-key power-off button
4. One-key power-on button
5. Exposure hand slot
6. SID decrease
7. Clockwise rotation of the U-arm
8. Counterclockwise rotation of the U-arm
9. Light field positioning light switch
10. SID increase
11. Motor-driven upward movement button of the U-arm
12. Motor-driven downward movement button of the U-arm
13. One-key APR
14. Service switch (at the rear of the control console, not displayed in the figure)

Table 3-3 Control buttons on the control console

Icon	Name	Function
	Emergency stop switch	After this switch is pressed, the motor driving operation is cut off, and the motor-driven motion of the system is stopped. Release this switch only after confirming that the system is in the normal state.
	X-ray radiation indicator	The yellow indicator turns on during exposure.
	One-key power-on button	After this button is pressed, the system starts up.
	One-key power-off button	After this button is pressed, the system is shut down.
	Light field positioning light switch	After this switch is pressed, the light field positioning light of the collimator is turned on/off.
	Clockwise rotation of the U-arm	After this button is pressed, the U-arm rotates around the central axis clockwise. After this button is pressed, the motor-driven rotation is stopped.
	Counterclockwise rotation of the U-arm	After this button is pressed, the U-arm rotates around the central axis counterclockwise. After this button is pressed, the motor-driven rotation is stopped.
	SID decrease	After this button is pressed, the SID distance decreases.
	SID increase	After this button is pressed, the SID distance increases.
	Motor-driven upward movement button of the U-arm	When this button is pressed and held down, the U-arm moves upward. When it is released, the movement is stopped.
	Motor-driven downward movement button of the U-arm	When this button is pressed and held down, the U-arm moves downward. When it is released, the movement is stopped.
	One-key APR	After this button is pressed, the U-arm positioner is driven to move to the position specified in the protocol.
	Service switch	The service switch, located at the rear of the control console, is used to enable/disable the flat panel calibration function.

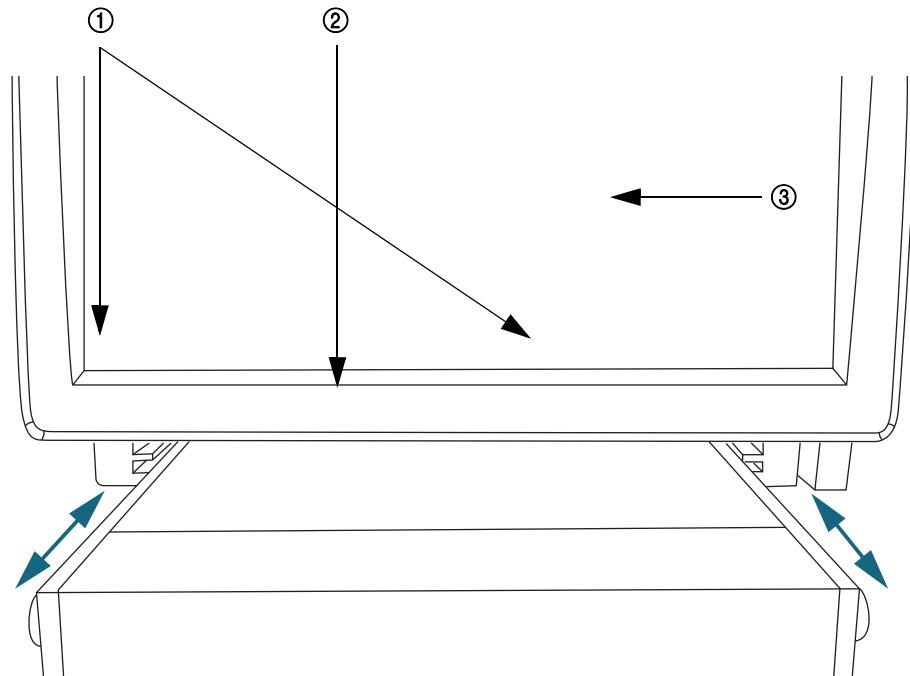
3.6.3 Exposure hand switch

The exposure handle switch is integrated into the control console and is used to control the exposure.



3.7 DAP meter

DAP meter is used to auto-calculate the total dose value of different exposures which realizes the detection of accumulating dose area product.



- 1. DAP meter slot
- 2. DAP meter
- 3. Collimator

■ Installation

1. Align both sides of the meter with the collimator slot.
2. Plug the meter into the slot from the front side of the collimator and parallel push the meter inward till the stop position.
3. Insert the wiring of the additional filter into the socket behind the collimator.

■ Removal

1. Disconnect DAP meter and collimator.
2. Horizontally and slowly pull the meter outward from the collimator slot.
3. Put the DAP meter safely into the storage device.

NOTICE

If the DAP meter is not installed, the accumulative DAP value displayed in the system status area on the Exam interface will be 0.

■ Check and maintenance

DAP meter should be equipped with a metering device to check and maintain the accuracy of dosimetric. The accuracy range of dosimetric is from -35% to +35%.

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4 System operations

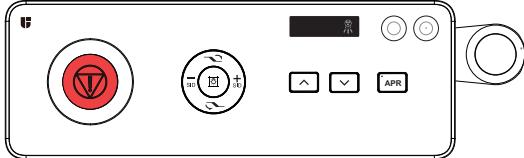
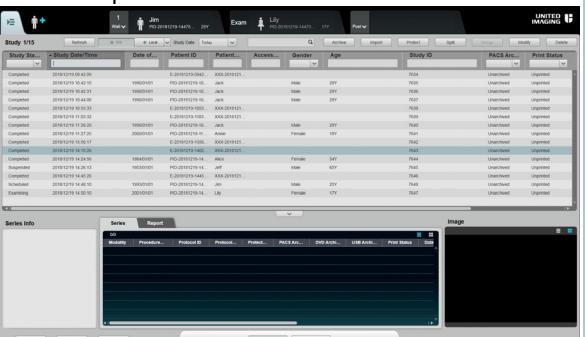
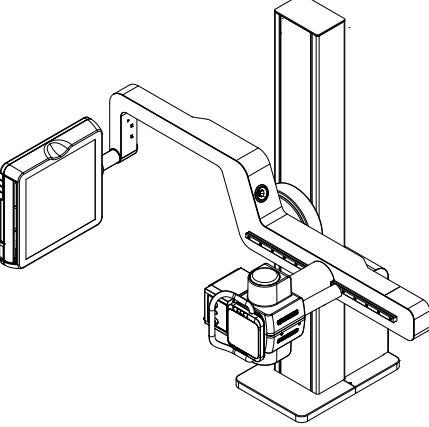
4.1	Normal workflow	4-3
4.1.1	One-key system power-on	4-4
4.1.2	Patient input	4-5
4.1.3	System position adjustment	4-5
4.1.4	Patient positioning	4-5
4.1.5	Check before exposure	4-6
4.1.6	Exposure	4-6
4.1.7	Image preview	4-6
4.1.8	Advanced post processing of images	4-7
4.1.9	Filming	4-7
4.1.10	Patient leave	4-7
4.2	Stitching workflow (optional)	4-8
4.2.1	Patient preparation	4-8
4.2.2	Stitching stand preparation	4-8
4.2.3	U-arm positioner preparation	4-8
4.2.4	Patient positioning	4-8
4.2.5	Exposure	4-9
4.2.6	Image stitching	4-9
4.2.7	Image post-processing	4-9
4.3	System startup and shutdown	4-10
4.3.1	System status	4-10
4.3.2	Check before system startup	4-10
4.3.3	System startup	4-10
4.3.4	System shutdown	4-10
4.3.5	Shutdown cancellation	4-11
4.4	Positioning of the U-arm	4-12
4.4.1	Vertical movement of the U-arm	4-12
4.4.2	Rotation of the U-arm around the horizontal axis	4-12
4.5	Positioning of the X-ray tube-collimator assembly	4-14
4.5.1	Rotation around the horizontal axis	4-14
4.5.2	SID adjustment	4-14
4.6	Position of flat panel detector carrier assembly	4-16
4.7	Collision protection	4-18
4.8	Use of the wireless digital flat panel detector	4-19
4.8.1	Installation	4-19
4.8.2	Disassembly	4-20
4.8.3	Charging	4-20
4.8.4	Precautions	4-20
4.9	Light field adjustment of the collimator	4-22

4.10	Use of the console system	4-23
4.10.1	Startup/Shutdown of the image processing system	4-23
4.10.2	Use of the control console	4-23
4.10.3	Use of the mouse	4-23
4.10.4	Use of the keyboard	4-24
4.11	Exposure operation	4-25
4.11.1	Use of the exposure hand switch	4-25
4.11.2	Automatic exposure control	4-25

4.1 Normal workflow

This section describes the normal clinical application workflow. For more details, see relevant chapters and the *Software Operator Manual*.

Table 4-1 Workflow

Step	Diagram	Reference
Start the system.		For more information about system power-on/off, see "System startup and shutdown" on page 4-10.
Load a patient for examination or register a new patient.	<ul style="list-style-type: none"> Select a patient in the exam list.  Go to the patient registration interface to register a new patient.  	For more information, see the <i>Software Operator Manual</i> .
Adjust the position of U-arm positioner.		For more information about the position, see "System operations" on page 4-1.

Step	Diagram	Reference
Conduct a check before exposure.		For more information, see the <i>Software Operator Manual</i> .
Perform exposure.		For more information about exposure, see "Use of the mouse" on page 4-23.
Preview the image.		For more information, see the <i>Software Operator Manual</i> .
Process and film the image.		For more information, see the <i>Software Operator Manual</i> .

4.1.1 One-key system power-on

- ▶ Press the <ON> button on the control console to start system components and the image processing system software.

4.1.2 Patient input

For existing patients:

1. Select a patient to be examined from the patient list on the {Patient Administration} interface.
2. Click **Exam** to go to the {Exam} interface.

For new patients:

1. Enter patient information on the {Patient Registration} interface.
2. Select and add a protocol.
3. Click **Exam** to go to the {Exam} interface.

4.1.3 System position adjustment

1. Confirm that the scanning room meets the patient exam requirements. For example:
 - ◆ The patient accessible components are cleaned.
 - ◆ Required optional accessories are ready.
2. Adjust the position of U-arm positioner in the scanning room, determine the SID, and set exposure parameters.
3. Adjust the position of the detector carrier.
4. If necessary, turn on the light field positioning light on the collimator.

⚠ CAUTION

Injuries to eyes

- ◆ Do not look into the laser beam without protection as it may cause eye damage and even blindness if the time lasts more than 15 seconds.

⚠ WARNING

Collision injuries

- ◆ Before any component is moved, make sure that the component will not collide with or crush operators and patients.

4.1.4 Patient positioning

- Check the radiation protection, and cover the necessary radiation protector on the patients.
 - You can instruct patients to position themselves from both the scanning room and operation room.
1. Instruct a patient to sit down, lie down, or stand up according to the radiographic requirements for the selected site.
 2. Determine whether external support is needed, for example a nurse, other technicians, parents of young patients, or relevant auxiliary equipment for patients.

3. If no external support is needed, instruct the patient to position himself/herself in the direction preset in the exam protocol.
4. Move the wireless digital flat panel detector close to the projection site of the patient as much as possible.
5. Adjust the projection site and the light field position to make the site to be examined in the center of the light field as much as possible.

4.1.5 Check before exposure

1. Click **Exam** to go to the {Exam} interface.
2. Adjust exposure parameters when necessary.
 - ◆ Adjust patient information and exposure parameters on the image processing system in the operation room.
 - ◆ Check whether the acquisition system information on the image processing system is consistent with the position information.
 - ◆ Confirm or adjust the patient position.

NOTICE

Operators should confirm whether exposure parameters meet clinical requirements before exposure. If not, make necessary adjustment.

3. Check whether the exposure indicator (OK ring)  on the image processing system monitor is on.

4.1.6 Exposure

When the exposure indicator is on, use the exposure hand switch to perform exposure.

1. Press the exposure hand switch to the first-stage position to prepare for exposure.
2. Fully press the exposure hand switch till you hear the exposure prompt tone.
3. Release the button on the exposure hand switch 2 seconds after the end of exposure prompt tone, to complete the exposure.

4.1.7 Image preview

1. A previewed image is generated a few seconds later. Then, the final image is displayed in the **image display area** on the {Exam} interface of the image processing system. Check the image quality, check whether the image meets the clinical needs, and determine whether to "accept" or "reject" the image.
2. If necessary, use an image processing tool to edit the image on the {Exam} interface, for example, add comments or adjust the window width/window level.

4.1.8 Advanced post processing of images

1. Click the **Review-Filming** tab to go to the {Review-Filming} interface.
2. Adjust the page layout for the image on the {Review-Filming} interface if necessary.
3. Adjust the image noise, tissue equalization, and contrast on the {Review-Filming} interface if necessary, to ensure the image quality.

4.1.9 Filming

1. After determining the image to be printed, configure printing settings in the printing setup area on the left side of the {Review-Filming} interface.
 - ◆ The settings include the printing direction, image display mode, and printing size.
2. After completing the settings, select the copies, and click **Print** to start printing.

4.1.10 Patient leave

After the patient examination ends, ask the patient to leave the scanning room to prepare for the next examination.

For more specific operations on the image processing system, see the *Software Operator Manual*.

4.2 Stitching workflow (optional)

This system can be configured with an optional stitching software package. In combination with a stitching stand, this system can complete the acquisition of images to be stitched, image stitching, and image post-processing. Contact UIH Customer Service Center to add the stitching function to your system.

4.2.1 Patient preparation

1. Create and register a patient.
2. Enter patient information.
3. In **Protocol Area** on the **Patient Registration** interface, select the stitch protocol under the {Stitch} procedure.
4. After completing patient registration, go to the {Exam} interface.

4.2.2 Stitching stand preparation

1. Move the stitching stand to the fixing groove.
2. Press the dead lever of the stitching stand to push the stitching stand into the fixing groove.
3. Fasten the stitching stand.

For detailed operations, see "[Placement of the stitching stand](#)" on page 5-6.

4.2.3 U-arm positioner preparation

1. Move the X-ray tube - collimator assembly in the scanning room to adjust the distance between the X-ray tube and the patient.
 - ◆ Adjust the distance from the X-ray tube - collimator assembly to the wireless digital flat panel detector to 180 cm.
2. Adjust the height of the X-ray tube - collimator assembly to the middle position of the stitching area.
3. Adjust the wireless digital flat panel detector to the proper position.
4. Rotate the X-ray tube - collimator assembly around the horizontal axis, adjust the incident angle, and adjust the light field range by using light field control buttons on the collimator.
 - ◆ The light field needs to cover the wireless digital flat panel detector.

4.2.4 Patient positioning

1. Instruct the patient to stand on the base of the stitching stand and stay close to the back plate.
2. Adjust the armrest of the stitching stand to a proper position suitable for the patient position.

-
3. Instruct the patient to complete required positioning.

4.2.5 Exposure

1. On the **Exam** interface of the image processing system in the operation room, adjust exposure parameters for each frame image.
2. Press the exposure hand switch to the first-stage position to prepare for exposure.
3. Fully press the exposure hand switch to start the acquisition of every frame image.

After the acquisition of the first frame image is completed, make adjustment and select the protocol for the next frame image. Repeat the U-arm positioner positioning and exposure operation till all images are acquired.

4.2.6 Image stitching

On the **Stitching interface**, **stitch the images manually**.

1. Adjust and confirm the sequence of images to be stitched.
2. Drag the stitching sequence to the **image display area**. Then, image stitching is automatically completed.
3. Manually adjust the image obtained after stitching.

4.2.7 Image post-processing

After completing the stitching, use an image processing tool to edit the image on the **Stitching interface** of the image processing system. For specific operations, see *the Software Operator Manual* delivered with the product.

4.3 System startup and shutdown

There are <ON>  and <OFF> keys  on the control console.

4.3.1 System status

This digital medical X-ray imaging system can be in either of the following states:

- Off: Indicates that all system components and the image processing system are shut down.
- On: Indicates that all system components and the image processing system are started.

4.3.2 Check before system startup

- Make sure that there is no obvious damage to the system.
- Make sure that there is no obstacle within the motion scope of moving components.

4.3.3 System startup

There is an <ON> key on the control console.

1. Press the <ON>key. The power-on indicator is on.
2. All components are energized and start up. The system runs the self-test.
3. The image processing system is started at the same time.

The system cannot be restarted within 10 seconds after shutdown. Wait for 10 seconds before restarting the system.

NOTICE

The system can start normal image acquisition within 5 minutes after cold startup.
Images with stable quality can be collected half an hour after the system startup.

4.3.4 System shutdown

Shut down the image processing system if exposure is not required within a short period of time. It is recommended that the entire system be restarted at least once every other week.

1. Press the <OFF> key on the control console.
2. The image processing system is shut down.
3. Other system components are deenergized.

If the image processing system has unfinished tasks during system shutdown, the system displays a prompt, asking you whether to skip the unfinished tasks. If you need to complete and save the unfinished tasks, do not press any button and wait patiently.

⚠ WARNING**Data loss**

- Shut down the system in strict accordance with the correct steps; otherwise, data loss may occur.

⚠ WARNING**High voltage generator damage**

- Never press the <OFF> key during exposure; otherwise, the high voltage generator may be damaged.

4.3.5 Shutdown cancellation

After pressing the <OFF> key, you can press the <ON> key within 10 seconds to cancel the shutdown. In this case, the system ignores the shutdown instruction and you do not need to log in again.

4.4 Positioning of the U-arm

You can press motion control buttons to adjust the movement position of the U-arm, to assist with patient positioning.

4.4.1 Vertical movement of the U-arm

1. Press the <Up> button  or <Down> button  . The U-arm moves vertically along guide rails of the column.
 - ◆ The vertical movement range of the U-arm is not smaller than 1320 mm.
2. When the U-arm moves to the required position, release the motion control button to stop the motion.

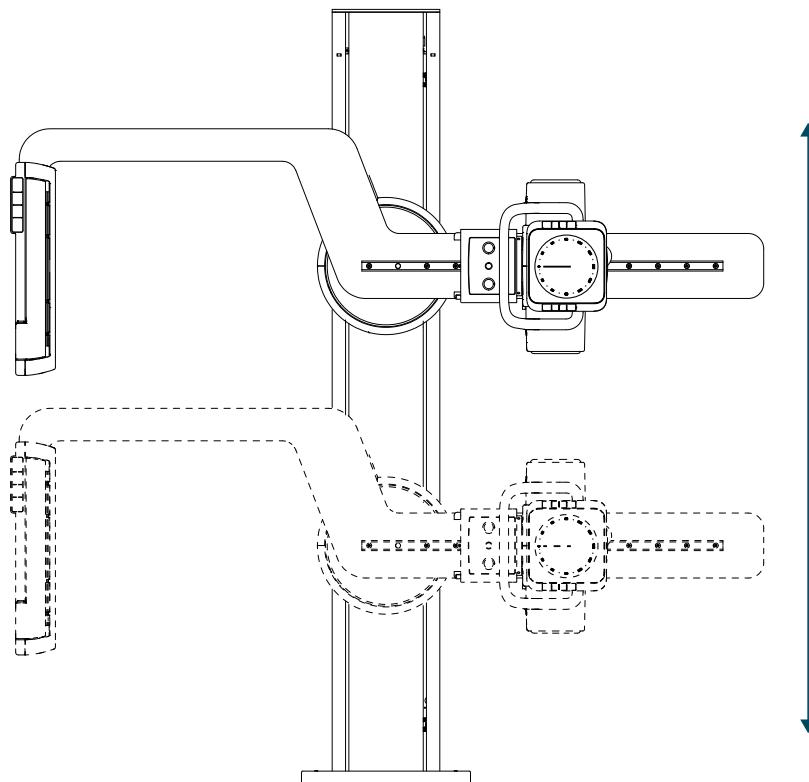


Figure 4-1 Vertical movement of the U-arm

NOTICE

If the mechanical sound akin to chain friction is generated inside the column during the vertical movement of the U-arm along the Z-axis, stop the equipment and contact UIH Customer Service Center for repair in a timely manner.

4.4.2 Rotation of the U-arm around the horizontal axis

1. Press the <Rotate Clockwise>  or <Rotate Counterclockwise> key  . The U-arm rotates around the horizontal axis, with the column as the axis.

- The rotation of the U-arm around the horizontal axis ranges from -30° to +120°.
2. When the U-arm rotates to the required position, release the motion control button to stop the rotation.

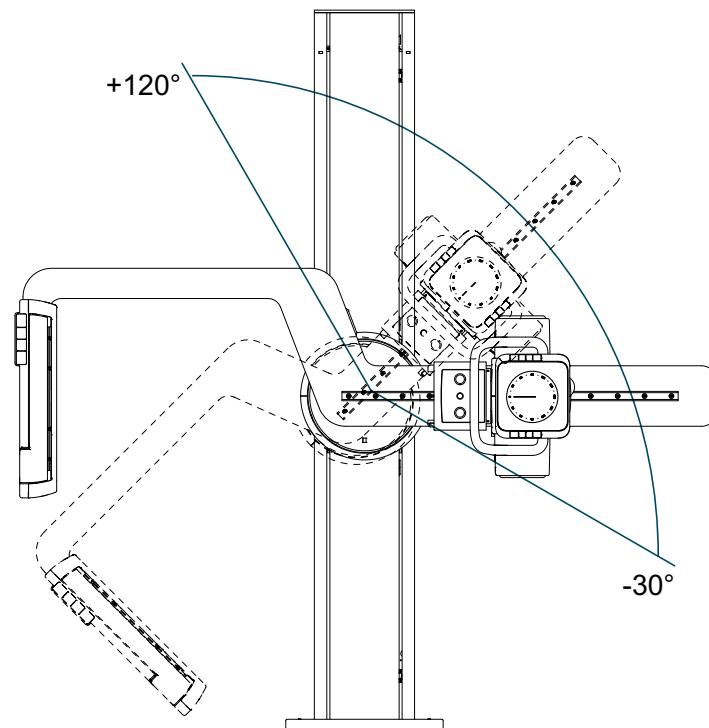


Figure 4-2 Rotation of the U-arm around the horizontal axis

4.5 Positioning of the X-ray tube-collimator assembly

Use motion control buttons to position the X-ray tube - collimator assembly. Only one button can be triggered at a time and the latter motion control button triggered at the same time is deemed invalid.

⚠ WARNING

Exposure prohibited

- ◆ Exposure is prohibited during system motion.

4.5.1 Rotation around the horizontal axis

1. Hold the mobile handle of the X-ray tube - collimator assembly with both hands.
2. Manually rotate the X-ray tube - collimator assembly around the horizontal axis to the required position and then stop the rotation.
 - ◆ The rotation of the X-ray tube - collimator assembly around the horizontal axis ranges from -120° to $+120^\circ$.

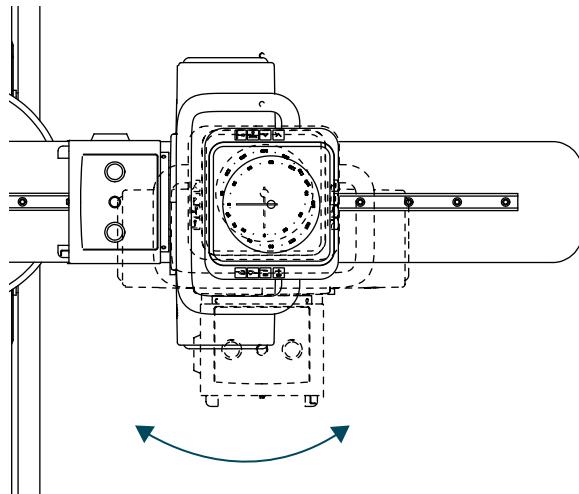


Figure 4-3 Manually rotating the X-ray tube - collimator assembly

⚠ WARNING

Hazard of crushing

- ◆ When rotating the X-ray tube - collimator assembly, pay attention to the gap between moving components and the guide groove to avoid crushing fingers.

4.5.2 SID adjustment

1. Press the <SID Decrease>  or <SID Increase> key  . The system automatically adjusts the telescopic distance from the focus of the X-ray tube to the wireless digital flat panel detector, that is, SID.

- ◆ The value of the SID ranges from 1000 mm to 1800 mm.

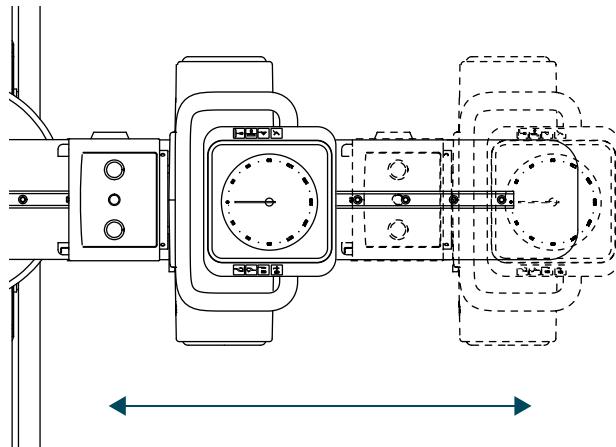


Figure 4-4 SID adjustment

2. When the X-ray tube - collimator assembly moves to the required position, release the motion control button to stop the motion.

SID measurement

Check the SID display frequently to ensure that the displayed SID value is the same as the value measured using the tape measure inside the collimator.

The collimator is equipped with a tape measure with the scale of "cm" to measure the SID.

- ◆ There is a distance of 4.27 cm between the front cover of the detector carrier and the wireless digital flat panel detector in the detector carrier. Therefore, add this distance to the value measured using the tape measure inside the collimator.

⚠ WARNING

Hazard of collision

- ◆ Before moving the X-ray tube - collimator assembly, confirm that no person or object exists in the motion path.

4.6 Position of flat panel detector carrier assembly

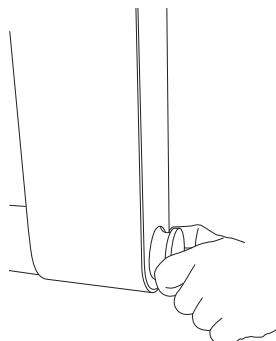
The wireless digital flat panel detector assembly can be rotated through the detector carrier handle at the rear of the assembly.

WARNING

Hazard of collision

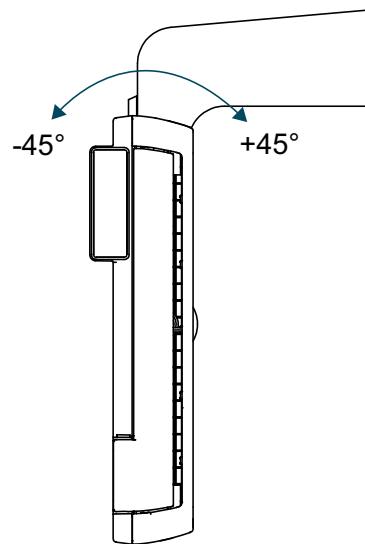
- ◆ When a patient clings to the detector carrier, especially when the patient's lower jaw is close to the jaw slot, it is prohibited to adjust the height of the detector carrier. Pay special attention to the case in which the detector carrier tracks the X-ray tube - collimator assembly.

1. Grasp the detector carrier handle tightly and pull it outward to release the mechanical lock.
 - ◆ The detector carrier handle is located on the inner side of the detector carrier.



2. Manually rotate the wireless digital flat panel detector assembly.
 - ◆ The rotation of the wireless digital flat panel detector detector carrier assembly around the horizontal axis ranges from -45° to +45°.
 - ◆ There are detents at 0°, ±15°, ±30°, and ±45° in the rotation around the horizontal axis.

3. After the wireless digital flat panel detector is rotated to the required position, press and lock the detector carrier handle to fasten the wireless digital flat panel detector assembly.



4.7 Collision protection

This system is equipped with infrared protection devices and there are two symmetrical infrared induction holes on the inner side of the U-arm.

If a patient or an operator is in the infrared induction area and blocks the induction holes during the motor-driven U-arm positioner movement, the movement is stopped to prevent accidental collision injuries.

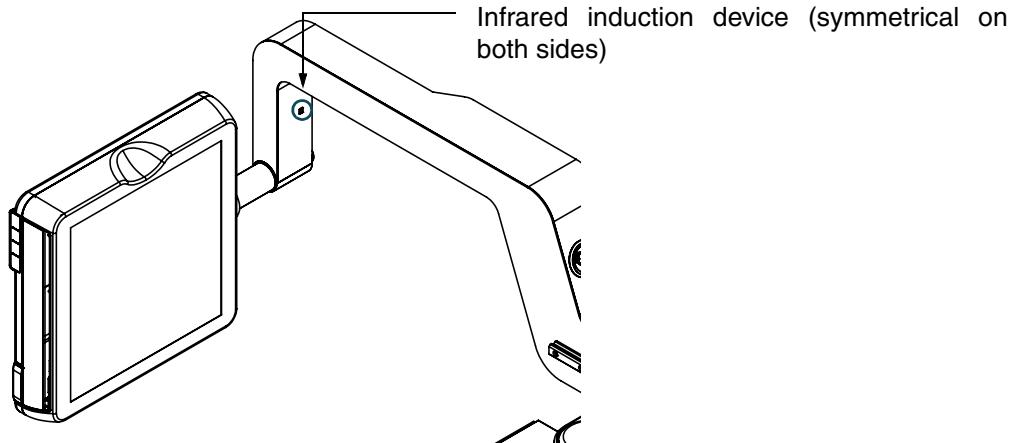


Figure 4-5 Infrared induction device

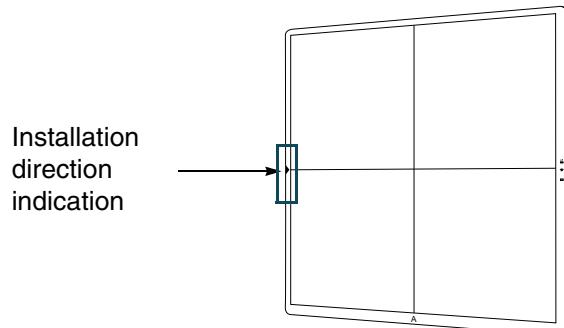
4.8 Use of the wireless digital flat panel detector

NOTICE

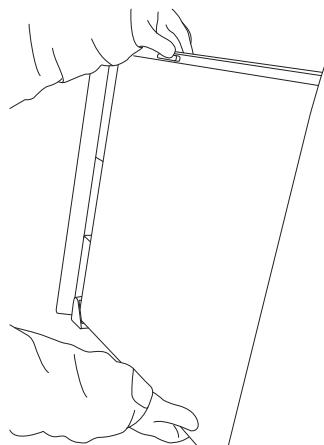
When installing or disassembling the wireless digital flat panel detector, hold the edges of the wireless digital flat panel detector tightly, to prevent damage caused by accidental falling.

4.8.1 Installation

1. Hold the handle of the wireless digital flat panel detector tray tightly.
 - ◆ The handle is marked with "PULL".
2. Pull the wireless digital flat panel detector tray outward until it is in the detent.
3. Hold up the wireless digital flat panel detector with both hands.
4. Hold the left edge of the wireless digital flat panel detector with the left hand and hold the bottom of the wireless digital flat panel detector with the right hand. Follow the arrow indication on the wireless digital flat panel detector to align it with the slot of the wireless digital flat panel detector tray.



5. Press the pole on the wireless digital flat panel detector tray with the left thumb and put the wireless digital flat panel detector into the slot from top bottom.



6. Push the tray installed with the wireless digital flat panel detector into the detector carrier till it is locked.

4.8.2 Disassembly

1. Hold the handle of the wireless digital flat panel detector tray tightly.
2. Pull the wireless digital flat panel detector tray outward slowly.
3. Grasp the wireless digital flat panel detector with the left hand tightly, and hold the bottom of the wireless digital flat panel detector.
4. Press the pole on the wireless digital flat panel detector tray with the left thumb and slowly pull the wireless digital flat panel detector upward.
5. Push the tray into the detector carrier till it is locked.

4.8.3 Charging

1. Install the wireless digital flat panel detector into the detector carrier.
2. Push the wireless digital flat panel detector and tray into the correct position of the detector carrier. The system automatically starts charging.
 - ◆ The system automatically disconnects charging after the battery is fully charged.
3. When you pull the wireless digital flat panel detector tray outward, the system automatically disconnects the charging.

4.8.4 Precautions

CAUTION

Damage of the wireless digital flat panel detector

- ◆ Exercise caution when using the wireless digital flat panel detector. Collision with any object, falling, or violent shaking may damage the wireless digital flat panel detector.
- ◆ Regardless of whether the wireless digital flat panel detector is used or temporarily placed, select a flat and clean surface to avoid crushing and bending the wireless digital flat panel detector.

CAUTION

Maintenance of the wireless digital flat panel detector

- ◆ Do not use the wireless digital flat panel detector in an environment with water. Do not splash any liquid especially chemicals on the detector. Prevent blood or other liquids of injured patients from flowing into the detector.
- ◆ When the wireless digital flat panel detector is not used, use a dedicated plastic bag to protect the detector.

⚠ CAUTION

Handling of damaged wireless digital flat panel detectors

- ◆ If a wireless digital flat panel detector is damaged, stop using it.
- ◆ The spill of a damaged flat panel detector may be poisonous. Therefore, do not touch it. Be sure to wear protective gloves to collect and place it in a sealed container.
- ◆ Contact the UIH Customer Service Center and send the damaged wireless digital flat panel detector and its spill to UIH for handling.

⚠ CAUTION

Overheating of the wireless digital flat panel detector

- ◆ If the wireless digital flat panel detector is overheated, its performance may deteriorate. Ensure that air vents are well-ventilated.

NOTICE

Do not put the wireless digital flat panel detector in a place near the heat source or fire.

4.9 Light field adjustment of the collimator

For the position of the light field adjustment knob of the collimator, see "Collimator" on page 3-15.

1. Press the <Light Field Positioning Light Switch> to turn on the light field positioning light.
 - ◆ The light field positioning light automatically turns off 30 seconds after being turned on by default.
 - ◆ Press the switch again to turn on the light field positioning light again.
2. Use the light field adjustment knob to adjust the light field.
 - ◆ Rotate the <Horizontal Adjustment of Light Field> knob on the left side of the collimator counterclockwise to enlarge the radiation field, and rotate the knob clockwise to reduce the radiation field.
 - ◆ Rotate the <Vertical Adjustment of Light Field> knob on the right side of the collimator clockwise to enlarge the radiation field, and rotate the knob counterclockwise to reduce the radiation field.

When SID is 100 cm:

- Minimum radiation field: 2 cm × 2 cm
- Maximum radiation field: 43.5 cm × 43.5 cm

Light field size measurement of the light-field positioning light

You can use any measure gauge with correct standard value to measure the size of the simulated light field. If the simulated light field size differs from the displayed radiation field size, contact UIH Customer Service Center.

WARNING

Hazard of burns

- ◆ If the light field positioning light is on for a long time, the light box and light bulb will become hot. Do not touch the light box to prevent burns.

CAUTION

Excess radiation

- ◆ When manually adjusting the collimator, pay attention to the size of the light-field. Oversized radiation field will generate excessive radiation, causing unnecessary harm to patients.

NOTICE

If the focus of the X-ray tube cannot accurately align with the center of the wireless digital flat panel detector during automatic centering and clinical use is affected, contact UIH Customer Service Center.

4.10 Use of the console system

4.10.1 Startup/Shutdown of the image processing system

4.10.1.1 Startup of the image processing system

1. Complete the system installation by following the correct installation procedure.
2. Connect the system to a power supply and turn on the switch of the image processing system monitor.
3. Press the <POWER> key on the host to start the host.

4.10.1.2 Shutdown of the image processing system

1. Click [UIH Icon] in the upper right corner of the main interface to open the drop-down list.
2. Select **Shutdown**.
3. The system is shut down.

NOTICE

You must shut down the image processing system by strictly following the procedure above to avoid system crashes.

4.10.2 Use of the control console

For detailed operation instructions of the control console, see "[Control console](#)" on page 3-24.

⚠ WARNING

Damage of the console system

- The console system is not waterproof. Keep it away from water. Do not put cups around the console system.

4.10.3 Use of the mouse

The mouse is used to control the cursor on the image processing system monitor and start related programs.

Button	Function
Left mouse button	Select an object, and start an application and function.
Right mouse button	The "context menu" pops up.
Scroll wheel	Drag the scroll bar to flip over films and to view the exam list.

- The shape of the mouse cursor or pointer displayed on the screen may vary with the current application.
- The mouse is right-handed by default. In "Control Panel" of the Windows, you can modify the mouse control mode to left-handed. Then, the functions of the left and right mouse buttons will be switched.

For more details, refer to the *Software Operator Manual*.

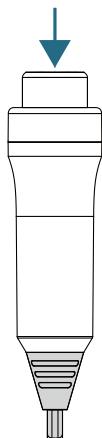
4.10.4 Use of the keyboard

You can use the keyboard to enter texts and digits when the image processing system is in use. You can also use shortcut keys or key combinations to perform certain programs. For more details, refer to the *Software Operator Manual*.

4.11 Exposure operation

4.11.1 Use of the exposure hand switch

When the system and a patient are ready, start exposure.



1. Press the exposure hand switch to the first-stage position to prepare for exposure.
2. Fully press the exposure hand switch till you hear the exposure prompt tone.
3. Release the button on the exposure hand switch 2 seconds after the end of exposure prompt tone, to complete the exposure.

WARNING

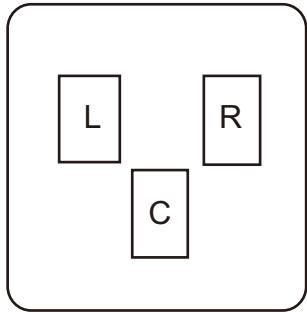
Overtemperature of the X-ray tube assembly

- ♦ Frequent triggering the exposure hand switch only to stage 1 may lead to overtemperature of the X-ray tube and shorten the service life of the X-ray tube.

4.11.2 Automatic exposure control

Automatic exposure control can automatically terminate X-ray exposure to produce images with the optimal quality.

When the detector carrier is equipped with an ionization chamber, you can use the AEC mode. Then, the system automatically selects ms and mAs and no manual adjustment is required. In AEC mode, the system provides the left (L), central (C), and right (R) measurement fields for the ionization chamber. Select at least one measurement field for the ionization chamber based on clinical requirements: L, C, R, LR, LC, RC, or LCR.



- ◆ You can select a required measurement field for the ionization chamber on the monitor in the operation room based on clinical requirements.
- ◆ When confirming the selection of one measurement field for the ionization chamber, ensure that a patient's body part to be examined is correctly within the range of the measurement field, to prevent incorrect exposure.

⚠ CAUTION

Invalid exposure

- ◆ Ensure that a patient's radiographic position covers the selected measurement field for the ionization chamber as much as possible so as not to affect the image quality due to insufficient dose received by the flat panel.

NOTICE

Select automatic exposure control in the case of centering, to prevent excessive radiation.

⚠ WARNING

Incorrect exposure

- ◆ When selecting a measurement field for the ionization chamber, make sure that the patient is within the measurement area, to prevent incorrect exposure.

⚠ WARNING

Underexposure

- ◆ Avoid radiation around the measurement field for the ionization chamber. Otherwise, X-ray radiation may be terminated in advance, resulting in underexposure.

5 Optional accessories

5.1	Principle	5-2
5.2	Mobile radiographic table	5-3
5.3	Stitching stand	5-5
5.3.1	Intended use	5-5
5.3.2	Placement of the stitching stand	5-6
5.3.3	Adjustment of the stitching stand armrests	5-7
5.4	Additional filter plate	5-8

5.1 Principle

- Your system may not have all the optional accessory functions. If you need to purchase optional accessories, contact UIH Customer Service Center.
- For the cleaning of optional accessories, see "Optional accessories" on page 7-12.

NOTICE

Only UIH original optional accessories or optional accessories approved by UIH can be used. Improper optional accessories may lower the system safety, cause injuries to patients or operators, and damage system components.

5.2 Mobile radiographic table

The mobile radiographic table is used to carry a patient to be examined and assist the patient with the examination in lying position.

Control wheels of the mobile radiographic table and move at the required position, position a patient accurately, and step on the locking pedals to lock the mobile radiographic table.

The mobile radiographic table can carry a maximum weight of 150 kg. The table top is 680 mm away from the ground and the effective radiographic size is not smaller than 510 mm × 1840 mm. The aluminum equivalent of the top of the mobile radiographic table is not greater than 0.8 mm Al.



When using the mobile radiographic table, do not collide it with other components of the system to prevent damage.

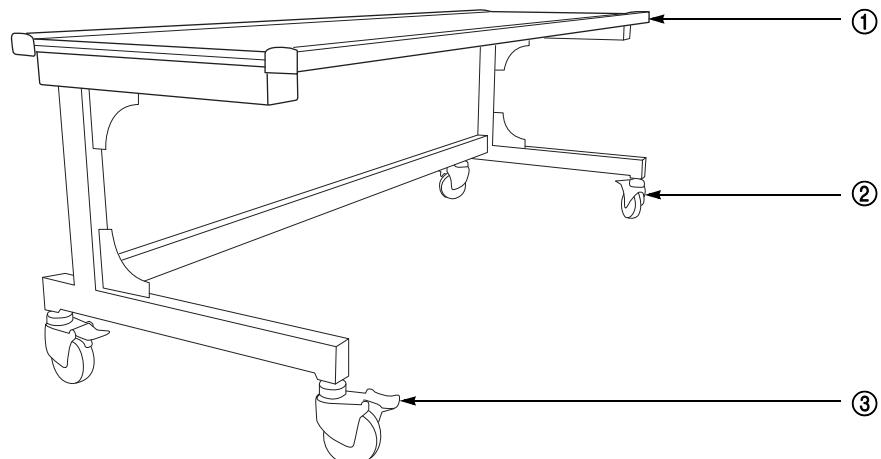
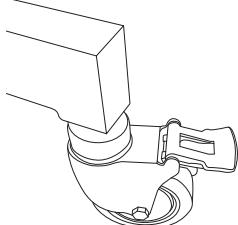


Figure 5-1 Mobile radiographic table

- | | |
|------------------------|-------------------------|
| 1. Table top | 3. Locking pedal (four) |
| 2. Mobile wheel (four) | |

No.	Name	Description
1	Table top	Supports a patient for examinations in the lying or sitting position.
2	Mobile wheel	Moves the mobile radiographic table in any direction.

No.	Name	Description
3	Locking pedal	<p>Controls the motion status of the mobile radiographic table.</p>  <ul style="list-style-type: none">◆ Step on locking pedals of the four mobile wheels to lock the mobile radiographic table thoroughly. Then, the mobile radiographic table cannot be moved.◆ Raise the locking pedals of the four mobile wheels to release the mobile wheels. Then, the mobile radiographic table can move horizontally.

5.3 Stitching stand

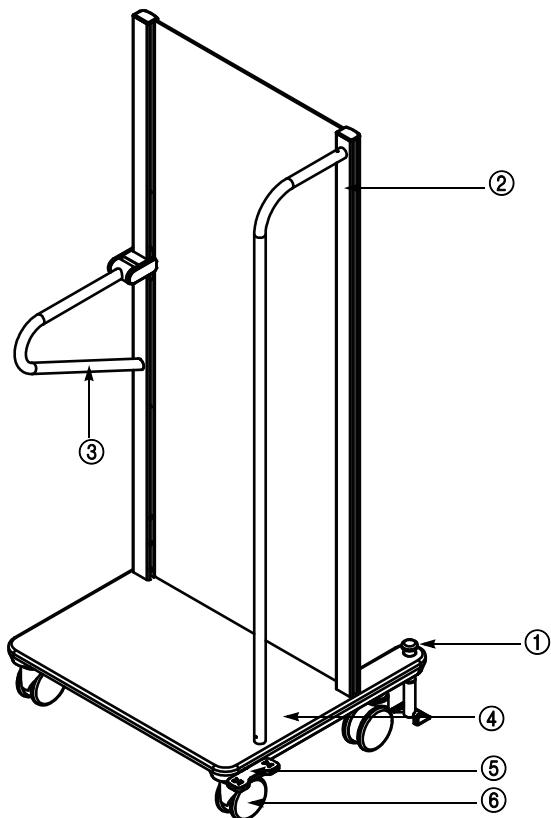


Figure 5-2 Stitching stand

- | | |
|----------------------------------|-------------------------|
| 1. Dead lever of stitching stand | 4. Stitching stand base |
| 2. Back plate of stitching stand | 5. Locking pedal |
| 3. Armrest of stitching stand | 6. Mobile wheel |



The locking pedal can be configured on either side of the stitching stand base. If any change is necessary, please contact UIH Customer Service Center.

5.3.1 Intended use

The stitching stand is used to assist patients in completing correct positioning specified in the stitching protocol.

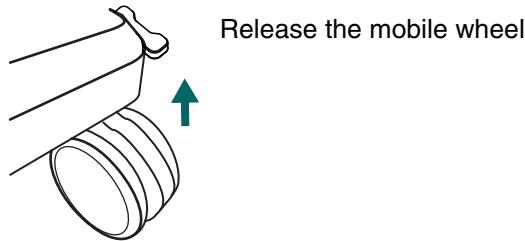
The stitching stand base can carry a maximum weight of 135 kg and each armrest of the stitching stand can bear the weight of up to 25 kg.

The aluminum equivalent of the stitching stand is not greater than 1.7 mm Al.

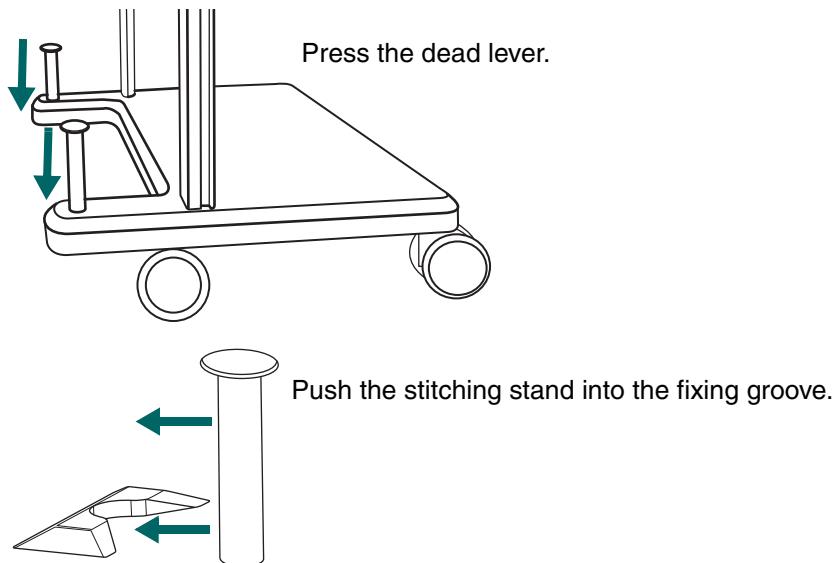
Patients should keep still during the stitching process to reduce invalid radiography and excessive radiation.

5.3.2 Placement of the stitching stand

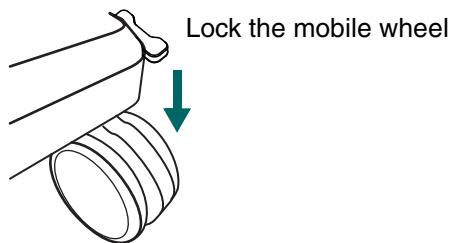
1. Move the stitching stand to the fixing groove.
 - ♦ Raise the locking pedals of the mobile wheels of the stitching stand to release the mobile wheels.
 - ♦ On the locking pedal,  indicates the unlocking state while  indicates the locked state.



- ♦ Hold the armrest of the stitching stand to move the stitching stand in any direction.
- 2. Align the dead lever of the stitching stand with the fixing groove on the ground, press the dead lever of the stitching stand, and push the stitching stand into the fixing groove.



3. Step on the locking pedals of mobile wheels to fix the stitching stand.

**NOTICE**

- ◆ Before a patient stands on the stitching stand, be sure to lock the mobile wheels of the stitching stand.
- ◆ When using the stitching stand for positioning, exercise caution to prevent equipment damage due to collision with the U-arm positioner.

5.3.3 Adjustment of the stitching stand armrests

Adjust the positions of the armrests of the stitching stand based on examination requirements.

1. Raise the armrests of the stitching stand.
2. Move the armrests vertically along the guide rails on the back plate of the stitching stand.
3. Adjust the armrests to specified positions and release the armrests.

5.4 Additional filter plate

You can use an additional filter plate to reduce exposure radiation dose, especially when performing X-ray exposure on children. You can select 0.1 mm Cu or 0.2 mm Cu additional filter plates.

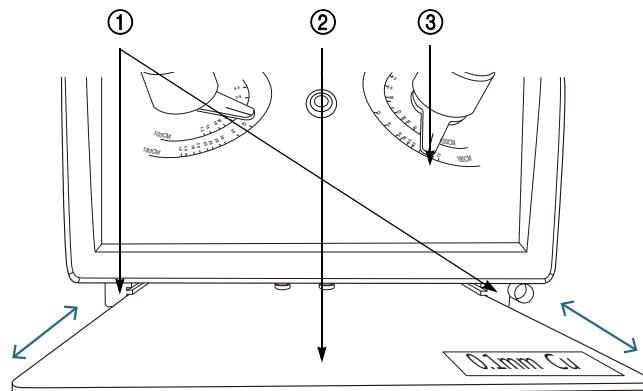


Figure 5-3 Additional filter plate position

- | | |
|---------------------------------|---------------|
| 1. Additional filter plate slot | 3. Collimator |
| 2. Additional filter plate | |

■ Installation

- ◆ Insert an additional filter plate into the slot from the front of the collimator, and push it into the stop position horizontally.

■ Disassembly

- ◆ Pull the additional filter plate out of the slot horizontally.
- ◆ Put the additional filter plate in a storage device safely.

NOTICE

Improper filtration may lower the image quality. Therefore, use additional filter plates properly.

6 Technical reference for system operation

6.1	Overview	6-2
6.2	Site requirements	6-3
6.2.1	Room layout	6-3
6.2.2	Ground requirements	6-3
6.2.3	Network requirements	6-4
6.2.4	Electrical requirements	6-4
6.3	Transportation and storage	6-5
6.4	Installation and tune-up	6-6
6.4.1	System installation process	6-6
6.4.2	Installation preparations	6-6
6.4.3	Physical installation	6-8
6.4.4	System configuration	6-9
6.4.5	System commissioning	6-10
6.4.6	End of installation	6-10

6.1 Overview

This chapter describes the preparations required for the normal operation of the system and important safety information. The preparations include site requirements, system transportation safety, system installation and tune-up, software configuration, and system performance testing.

Site requirements clarify necessary conditions required for system operation, including room layout, ground, and power distribution. For details, see "[Site requirements](#)" on page [6-3](#).

For details about the system installation process and important safety precautions, see "[Installation and tune-up](#)" on page [6-6](#). The information is used for reference only. It cannot be used as an installation guide.

Professionals authorized to install and repair the equipment should get familiar with national standards related to radiation protection and have received training on the installation and repair of this equipment.

6.2 Site requirements

6.2.1 Room layout

This system can be installed in a standard hospital room, with the area of 15 m² to 30 m². The recommended room area is 25 m².

The figure below shows the recommended room size.

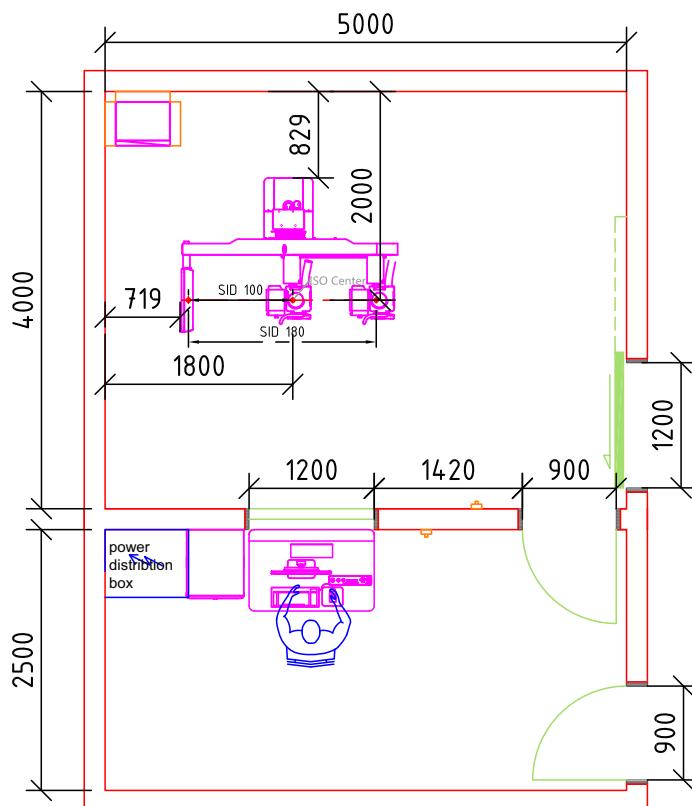


Figure 6-1 Room layout (unit: mm)

6.2.2 Ground requirements

The installation area on the ground for installation of the U-arm positioner should meet the following requirements:

- If there is a covering on the ground, for example, plastic floor, the covering must be removed before installation.
- If there is a self-leveling cement layer on the ground, the cement layer should conform to the C20/C25 strength.
- If there is a special fixture, for example, iron stand in the installation area, the fixture should meet the strength requirements for the civil structure.
- The horizontal error of the installation floor should be smaller than 5 mm.

6.2.3 Network requirements

- The system supports the TCP/IP network protocol. The images stored in the host comply with the DICOM 3.0 standard, and can be transmitted over Ethernet.
- Network interfaces provided for the system must be IEC 60603-7-compliant RJ-45 interfaces and support the 100 M to 1000 M self-adaptive function.
- If the system needs to connect to the HIS/RIS, users need to provide the IP address, AE, port, and other parameters of the PACS, Worklist workstation, and film printer to UIH.
- Network interface sockets (at least three) provided for the system should be installed in a position close to the computer system in the operation room.

6.2.4 Electrical requirements

The mains must meet the following requirements:

- Input voltage: 3N~, 380 V/400V/440V AC.
- Input frequency: 50 Hz/60 Hz.
- The internal resistance of power supply should not be greater than 0.15Ω .
- The power capacity of the high voltage generator should be not lower than 95 kVA for the entire equipment with the maximum output power of 50 kW and not lower than 120 kVA for the entire equipment with the maximum output power of 65 kW.
- A dedicated power distribution box (with appropriate power and grounding wires) is equipped and the layout of cable trays and burial of grounding wires have been completed.

NOTICE

- ◆ In addition to the power capacity, voltage frequency, and internal resistance of power supply, the power distribution system of the equipment room must be equipped with a separate grounding device, which must comply with the national standard GB 9706.1.
- ◆ A door switch cable must be connected when this equipment is installed, to ensure that personnel do not receive excessive radiation. Exposure is prohibited when the door of the scanning room is open.

Power cable requirements

No mains cable is delivered with this equipment. Select the power cable according to the following requirements:

Material	Specification		
PVC insulated copper wire (five-core) three-phase	The recommended cross-sectional area of the wire is 25 mm^2 .	Wire terminal crimping processing	The grounding cable must be yellow and green.

6.3 Transportation and storage

- Before installation, the equipment can be stored in a warehouse that meets storage conditions. Do not place the equipment outdoors or in a harsh environment.

NOTICE

Transporting and storing the equipment in an environment that does not meet requirements may cause equipment faults.

- Ensure that packing cases are secured tightly during transportation to avoid internal damage caused by shaking. Frequently check whether the cases are properly placed as requested.
- No person is allowed to pass through or stand under a heavy weight during lifting. Avoid hurting human bodies or other objects during movement.
- Do not damage the wooden packing cases when loading/unloading equipment to/from a truck by using a forklift. Keep the packing cases balanced to prevent equipment damage or personal injuries.
- The number of packing cases, products transported, and their weight may vary according to the customer configuration requirements. Detailed information is given based on the actual situation.
- Transportation and storage environment for the system:
 - ◆ Temperature range: -20°C to +55°C
 - ◆ Relative humidity: 10% to 90% (no condensation)
 - ◆ Atmospheric pressure range: 700 hPa to 1060 hPa
- Transportation and storage environment for grids
 - ◆ Temperature range: 0°C to 40°C

6.4 Installation and tune-up

NOTICE

- ◆ The equipment installation and maintenance must be performed by trained service engineers authorized by UIH. Service engineers must be aware of possible dangers in the case of improper installation or use and know how to deal with emergencies.
- ◆ During installation, service engineers should consider the reasonable space required for using the equipment and leave sufficient space for future maintenance and over-haul.
- ◆ Service engineers must wear safety shoes, anti-static clothing, and protective gloves during equipment installation.

NOTICE

The X-ray tube assembly has a filtration of 1.5 mm Al, the collimator has an inherent filtration of 1.0 mm Al, and the whole X-ray tube - collimator assembly has a filtration of 2.5 mm Al.

6.4.1 System installation process

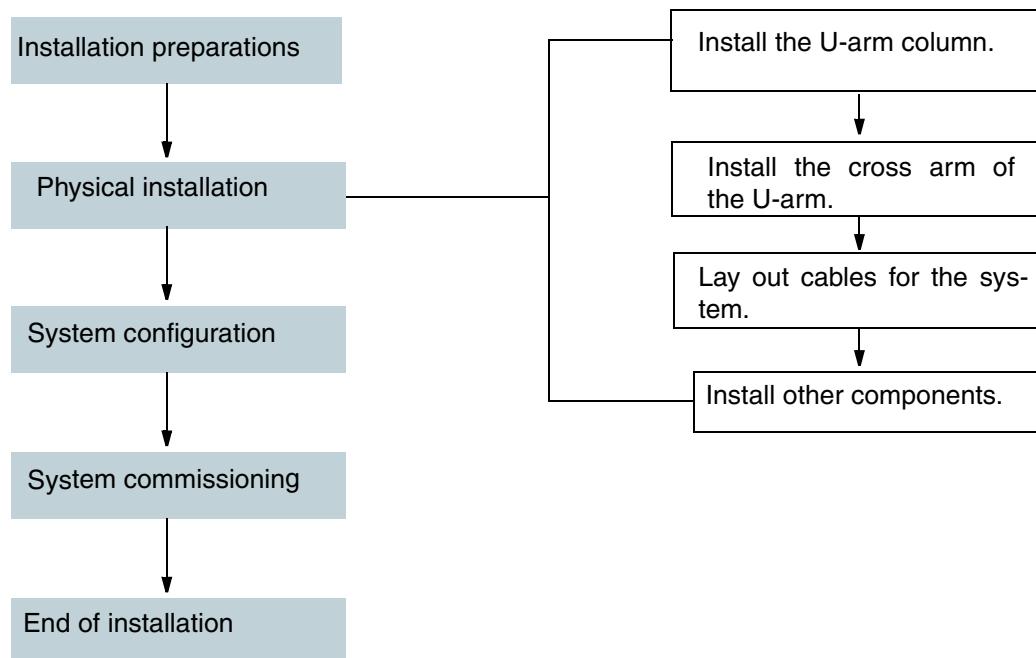


Figure 6-2 System installation flowchart

6.4.2 Installation preparations

1. Confirm that installation tools are ready.

Table 6-1 List of installation tools

Tool	Quantity
Percussion drill and ?12 mm percussion drill hammer	One set
10 N·m to 60 N·m torque wrench	One PCS
Anti-static wrist strap	One PCS
Laser level meter	One PCS
Digital angle meter	One PCS
Steel tape (5 m)	One PCS
Ratchet wrench and sleeve	One set
Rubber hammer	One PCS
Claw hammer	One PCS
Herringbone ladder	One PCS
Adjustable wrench	One PCS
Metric double open-end wrench	One PCS
L-shaped Allen wrench	One PCS
T-shaped Allen wrench	One PCS
Insulated slot type driver	One PCS
Insulated cross point screwdriver	One PCS
Utility knife	One PCS
Wire cutter	One PCS
Diagonal pliers	One PCS
Flexible magnetic pickup	One PCS

2. Unpack the equipment and check whether system components are damaged or abnormal.

NOTICE

- ◆ UIH service engineers and relevant personnel of hospitals should participate in the unpacking together, to ensure that unpacking steps are correct and the unpacking process is controllable.
- ◆ If a packing case is damaged or has other exceptions, take photos and inform UIH promptly.

3. Print the template of *System Installation and Tune-up Report* to make records.
4. Check the configuration data of the system.
5. Position the system.

6.4.3 Physical installation

6.4.3.1 Installing the U-arm

1. Transport the U-arm column to the target position according to site planning requirements, and erect the U-arm column.
2. Adjust the levelness of the column base and fasten the foundation bolts.
3. Install the U-arm.

NOTICE

Select ground screws that can be used in the loose concrete structure.
Check fixed screws between the chassis and the floor during installation.

NOTICE

The U-arm can move upward and downward. Follow steps in the system installation guide strictly during installation.

6.4.3.2 Connecting cables for the system

1. Install the operating table and host.
2. Place the system cabinet.
3. Connect system cables.
 - ◆ There are tags at both ends of each cable to mark the positions of the connection ends. Check whether markings on the tags of all cables are consistent with the cable connection positions when checking the cable layout of the system.

NOTICE

Check whether the control cable of the door switch is connected and check the signal connection status in the SVC service software.

⚠ WARNING

Ensure that the power supply of the system is cut off during installation. It is mandatory to use a protective grounding cable to ground the high voltage generator. If no separate grounding cable is connected for the high voltage generator, injuries or death caused by electric shocks may be incurred.

NOTICE

Conduct a check after connecting the rotating anode cable. Use a multimeter to measure the resistance between the common port and the operating winding (main winding) and the resistance between the common port and the starting winding (secondary winding). The resistance values must meet related tube requirements.

⚠ WARNING

Incorrect cable connections of the system will cause serious damage to the system. Make sure that the cable connections are correct.

NOTICE

Ensure that there is no short circuit among the electric power supply cathode, logic power supply cathode, and grounding PE of the system.

6.4.3.3 Installing other components

1. Install component covers.
 - ◆ Install the column cover, rear cover of the cross arm, tube cover, system cabinet cover, and flat panel detector cover.
2. Install the wireless digital flat panel detector.
 - ◆ The wireless digital flat panel detector is a precise instrument. Do not shake it violently or impose a load beyond its limits on the wireless digital flat panel detector during installation.

⚠ WARNING

Do not damage the wireless digital flat panel detector tray.

- ◆ No person is allowed to lean against the wireless digital flat panel detector tray that is pulled out.
- ◆ Do not put an object other than the wireless digital flat panel detector on the tray.

3. (Optional) Install the stitching stand.
 - ◆ Install the positioning plate of stitching stand.
 - ◆ Align the center of the stitching stand with the center of the wireless digital flat panel detector. Ensure that the rear side of the acrylic back plate of the stitching stand is 54 mm away from the outside of the wireless digital flat panel detector.

6.4.4 System configuration

1. Conduct boot checkup prior to commissioning.
2. Power on the system.
3. Configure system information.

- ◆ Configure customer information.
- ◆ Configure TCP/IP.
- ◆ Configure DICOM information.
- ◆ Configure the room height.
- ◆ Configure a wireless AP and register the flat panel detector.

⚠ WARNING

- ◆ Always abide by related safety information during commissioning and testing. Otherwise, serious personal injuries or even death will be caused.
- ◆ When the power supply is connected, do not install or remove any component of the high voltage generator. Many components of the high voltage generator still have dangerous high voltage AC even if it is turned off just now. In this case, do not touch any internal components of the high voltage generator. Wait five minutes after disconnecting the system from the mains, and then perform related operations on the high voltage generator.

⚠ WARNING

Observe radiation safety information during the operations to avoid unnecessary X-ray exposure. Ensure that there is no unnecessary person in the scanning room and the shield door is closed during exposure.

6.4.5 System commissioning

1. Calibrate the X-ray tube assembly.
2. Calibrate the wireless digital flat panel detector.
3. Calibrate the image center.
4. Check the accuracy of the image direction.
5. Calibrate the mechanical center.

The system software must be installed and commissioned by UIH customer service engineers. If necessary, please contact UIH Customer Service Center.



The calibration of the AEC function and light field must be completed by UIH customer service engineers. If necessary, please contact UIH Customer Service Center.

NOTICE

Check the image quality after completing the calibration.

6.4.6 End of installation

1. Check the unit motion.

NOTICE

Check the function and noise of the motion drive mechanism and check whether a chain breakage error is reported in the SVC service software.

2. Conduct a safety check.
3. Perform data backup.

NOTICE

Upon completion, turn the DIP switch SW3 of the motion control board (D1300) on the rear side at the bottom of the U-arm column to "OFF".

4. Clean the site and make records.

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7 Maintenance, repair, and disposal

7.1	Installation and repair	7-2
7.2	Periodic maintenance	7-3
7.2.1	User responsibilities	7-3
7.2.2	Safety check	7-3
7.2.3	Tests and inspections performed by users	7-3
7.2.4	Result recording	7-4
7.2.5	Maintenance contract	7-5
7.3	Professional maintenance	7-6
7.3.1	Maintenance of system components	7-6
7.3.2	Calibration of the wireless digital flat panel detector	7-7
7.3.3	Repair and replacement of spare parts	7-7
7.4	Disinfection and cleaning	7-10
7.4.1	Disinfection	7-10
7.4.2	Cleaning	7-10
7.4.3	Disinfection and cleaning suggestions	7-11
7.4.4	Optional accessories	7-12
7.5	Disposal	7-13

7.1 Installation and repair

The system installation, repair, and component addition or reduction must be performed in accordance with engineering standards.

UIH assumes no responsibility for the security and reliability of the system in any of the following cases:

- The installation, system expansion, realignment, modification, or repair is not performed by UIH authorized personnel.
- When the equipment malfunctions, the component that affects the system operation is not replaced with the original accessory.
- The indoor electrical installation does not comply with related national regulations.
- The system is not operated in accordance with the operator manual.

7.2 Periodic maintenance

All inspections required by laws and regulations must be performed as scheduled regularly. To ensure the safety of patients, operators, and others, it is necessary to perform inspection and maintenance regularly to maintain the safety features and normal functions of the product.

7.2.1 User responsibilities

Like other technical equipment, this medical system also requires:

- Correct operations
- Periodic inspection
- Periodic maintenance
- Timely repair

The usability and operational reliability of the system can be maintained only after these preventive measures above are taken. Users of the medical system are liable for taking these preventive measures in accordance with the accident prevention regulations, medical product laws, and other regulations. Maintenance includes the inspection performed by users as well as maintenance specified in service agreements and UIH service purchase orders or maintenance performed by personnel explicitly authorized by UIH.

7.2.2 Safety check

The safety check includes functional and operational reliability and must be performed at least once every 12 months. The safety check is part of preventive maintenance in the UIH service agree and covers the following content:

- Visually inspecting the system integrity, and checking whether there are visible damage, stains, component interference, and wear.
- Testing the necessary monitoring, safety, display, and indication system.
- Measuring safety-related output parameters.
- Checking electrical safety and the internal power supply function.
- Performing other special technical tests for specific products in accordance with the accepted engineering practice standards.
- Performing other necessary tests specified by UIH.
- Recording results and filling in test reports.

7.2.3 Tests and inspections performed by users

Users must check the X-ray system for visible defects (see the table below). If an operation failure or an exception deviated from normal operation responses occur, users must shut down the system and contact UIH Customer Service Center. The system operation can be

restored only after the fault is rectified successfully. Using faulty components may lower the system safety and expose patients or operators to unnecessary high dose radiation.

Time interval	Test type	Method
Look up local regulations	Stability test	-
Every day	Faulty indicator, damaged component, label, warning sign, and oil leakage	Visual check
Every day	Safety switch (emergency stop switch) for equipment motion	Visual check and sound monitoring
Every week	All cables and terminals	Visual inspection for damage or breakage
Every week	High voltage generator	Visual inspection for damage and audible inspection for abnormal sound

Some mechanical components in the X-ray system wear out during the long-term use.

Correct electromechanical settings and electronic equipment settings concern the functions, image quality, electrical safety, and radiation dose exposure to patients and medical staff.

To reduce the risks of hazards to patients and operators, UIH provides the following suggestions:

- Users should perform periodic inspection in accordance with the instructions in the table.
- UIH Customer Service Center perform maintenance on the X-ray system at least once every year. More frequent maintenance is required if the workload of the X-ray system is heavier.

⚠ WARNING	
System safety	<ul style="list-style-type: none"> ◆ Faulty components that affect the safety of the radiography system must be replaced with original accessories.

7.2.4 Result recording

The service and repair process must be recorded in medical product logs, and the record should cover the following information:

- Type and scope of work
- Details about changes to rated values or work area
- Date and signatures of persons who perform the work

7.2.5 Maintenance contract

Periodic inspection is part of the system maintenance performed by UIH Customer Service Center in accordance with the maintenance contract. Contact UIH Customer Service Center to sign a maintenance contract.

7.3 Professional maintenance

In addition to routine maintenance conducted by users, the system needs periodic professional maintenance to ensure the normal system operation and the quality of scanned images. For this, UIH has the following advice: You can reach a maintenance and repair agreement with UIH to better retain the value and safety of the equipment. All necessary maintenance, including safety inspection for hazard prevention and necessary settings for achieving the best image quality and minimum radiation dose, must be performed on a regular basis. UIH will reach an agreement with you on the maintenance interval in accordance with related regulations. If you have any question, contact UIH Customer Service Center.

7.3.1 Maintenance of system components

NOTICE

The maintenance steps and maintenance time intervals described in this manual are recommended by UIH.

The system and system components (such as motion components) need to be maintained periodically. System maintenance is performed every six months. The following table provides the required maintenance time for system components. The time required for the periodic replacement of parts (such as cables or spring mechanism) is not included in the maintenance time. The maintenance of system components is completed by UIH or specified after-sales service organizations.

Table 7-1 Component maintenance time table

Component name	Annual average maintenance time
X-ray tube assembly and collimator	120 minutes
Mobile radiographic table	60 minutes
PDU	120 minutes
Monitor	30 minutes
Wireless digital flat panel detector	120 minutes
U-arm	60 minutes
Other	120 minutes

NOTICE

- ◆ The X-ray tube should be calibrated every half a year normally.
- ◆ Preheat the X-ray tube before calibration.
- ◆ Customer service engineers need to check whether the settings of the high voltage generator are consistent with those of the X-ray tube before calibrating the X-ray tube.

NOTICE

Check and maintain the fixing mechanical limits, pulleys, slide rails, and chassis periodically.

Check whether fixed screws are loosened periodically to prevent damage.

7.3.2 Calibration of the wireless digital flat panel detector

- When the image quality deteriorates obviously, the wireless digital flat panel detector must be calibrated.
- Even if there is no obvious decline in the image quality, it is still recommended that the wireless digital flat panel detector be calibrated at an interval of 180 days.

⚠ CAUTION**Radiation safety**

- ◆ Before calibration, make sure that nobody is in the scanning room.
- ◆ If the wireless digital flat panel detector is used for a long time without calibration, the image quality may deteriorate and repeated radiography is required, resulting in unnecessary radiation.

⚠ WARNING

Radiation safety measures must be taken during inspection and calibration, to reduce the hazards of X-ray radiation to the human body. Explicit warning signs about ionization radiation should be provided below the inspection and calibration steps that require radiation protection.

For specific calibration process, refer to the *Software Operator Manual*.

7.3.3 Repair and replacement of spare parts

When the system or a component malfunctions and normal exposure is affected, stop the system immediately and contact UIH Customer Service Center for troubleshooting and repair.

Some components of the equipment wear out or are damaged during normal use. Equipment repair and component replacement must be performed by UIH or specified after-sales service organizations. Unqualified personnel are not allowed to carry out the repair. UIH assumes no liability for the loss of life or property damage caused by unauthorized repair.

⚠ WARNING

- ◆ There is still a risk of electric discharge after the high voltage generator and filter are powered off. Necessary protective measures must be taken.
- ◆ Wait for a long time after power cut for the equipment to release electricity on live parts of the equipment.
- ◆ Unauthorized personnel are strictly prohibited from removing any components of the system.

NOTICE

- ◆ Proper torque is required for fixing cables during repair.
- ◆ After components related to image quality are repaired or replaced, the system needs to be calibrated.

(i) After the X-ray tube or other components are replaced, the consistency between the AEC function and the light field needs to be re-calibrated. The calibration must be completed by UIH customer service engineers. If necessary, please contact UIH Customer Service Center.

The following table lists components that can be replaced on site:

No.	Name
1	X-ray tube assembly
2	Fuse
3	Grid
4	Flat panel detector
5	High voltage generator
6	Collimator
7	Control console
8	Computer
9	Monitor
10	Exposure hand switch

NOTICE

After the X-ray tube, high voltage generator, or the main control board of the high voltage generator is replaced, the X-ray tube needs to be re-calibrated. If necessary, please contact UIH customer service engineers.

NOTICE

Prevent clothing from getting stuck in components during repair and component replacement.

NOTICE

The spring of mechanical components needs to be checked during repair and maintenance to prevent spring failures.

The chains, wire ropes, and synchronous belts of mechanical parts need to be maintained periodically during repair and maintenance.

7.4 Disinfection and cleaning

7.4.1 Disinfection

The disinfection methods must comply with related regulations and guidance principles pertaining to disinfection and explosion protection.

WARNING

Do not use corrosive, soluble or gas disinfectant.

- Cut off all power supplies to the system before disinfection.
- Disinfect all components of the system (including optional accessories and cables) by wiping them only.
- It is not recommended to use spray for disinfection as the disinfectant may enter the system.
- If an atomizer is used for indoor disinfection, shut down the system, and completely cover the equipment with plastic cloth after the equipment cools down. Remove the plastic cloth only after the disinfectant spray in the air is completely settled, and wipe the X-ray system for disinfection.

WARNING

Use disinfectant in accordance with the manual. Using non-recommended disinfectant may cause operator injuries and system damage.

7.4.2 Cleaning

NOTICE

The use of harsh detergent, liquid, or spray may lead to electronic damage and only the recommended materials can be used for cleaning and disinfection. Prevent any cleaning liquid from flowing into the system, for example, through air vents or gaps on the outer cover.

NOTICE

- ◆ Inadequate cleaning or disinfection may make people in contact get infected. Therefore, all contaminated component surfaces and all component surfaces that patients may contact or have already contacted should be cleaned and disinfected after each examination.
- ◆ Use only water or mild household cleaning solutions during cleaning.
- ◆ Use general surface disinfectant, acetaldehyde and/or amphiprotic disinfectant during disinfection.

When selecting detergent, pay attention to the following aspects:

Use water or mild household detergent only to clean the plastic surface. Using other detergent (such as high concentration alcohol) will lead to gloss loss and crack of the materials. Do not use any corrosive, soluble detergent or polish.

Observe the following principles during cleaning:

- Cut off the power supply before cleaning the system.
- Ensure that no water or other liquid enters the system to avoid short circuits and component corrosion in the electrical system.
- For components with aluminum or glazed surfaces, wipe them only with cloth moistened with mild detergent, and then clean them with dry linen-free cotton cloth.
- Wear proper protective gloves during cleaning and disinfection.
- Clean all contaminated components and all the parts that a patient may contact or has already contacted directly or indirectly.

7.4.3 Disinfection and cleaning suggestions

System cover

It is recommended to use water, 75% medical alcohol, or mild household detergent to disinfect and clean the system cover.

Air vents or cover gap

Keep the air vents of all the components well-ventilated.

Dust

Dust deposition on the motion components may affect the motion of system components. Therefore, clean up dust at the rail junctions on a regular basis.

Angle indicator

Clean up fingerprints left on the screen periodically. Do not spray directly on the angle indicator. Wipe the angle indicator only with clean and slightly damp cloth.

Monitor and keyboard

Remove dirt immediately. You can use clean and slightly damp cloth for cleaning.

- Be sure to use slightly damp cloth without detergent for cleaning.
- Dry the monitor and keyboard with soft cotton cloth.

NOTICE

Wear proper protective gloves during cleaning and disinfection.

NOTICE

Using non-recommended detergent may lead to system damage.

NOTICE

The LCD screen is very sensitive to mechanical damage. Therefore, avoid scratches and shock. Wipe off water droplets immediately. Long-term contact with water will lead to surface discoloration.

7.4.4 Optional accessories

For optional accessories, if no specific cleaning instructions are provided in related manuals, observe the following general cleaning instructions:

- For slight contaminants, wipe them away with soft cloth moistened with a moderately warm detergent solution.
- Use cloth dipped with alcohol to wipe away the contaminants, and then use clean water for wiping.
- The best solvent to remove blood spots is cold water.
- After disinfectant is used, use clean water for wiping.

7.5 Disposal

- UIH has to use some materials that may be harmful to the environment in order to make the system performance meet the regulatory requirements. Such materials must be scrapped and disposed in a proper way. Therefore, it is prohibited to dispose of this medical diagnosis system together with general industrial or domestic waste.
- The waste of the medical device may cause certain environmental pollution and you should dispose of it properly.
 - ◆ If the detector is damaged, the overspill from it can lead to poisoning and personal injury. In this case, you should stop using the damaged detector immediately, check for any overspill, and wear the gloves to collect the detector and overspill into a sealed container and hand over it to UIH.
- UIH supports you to dispose of the system in a proper way. Reusable components can be recycled by a certified waste processing company to help reduce environmental pollution.
- Under normal operating circumstances, the expected service life of the system is ten years. If the actual operating period of the system is more than ten years, in order to ensure the system function integrity and operational safety, it is necessary to perform additional inspections and possible maintenance.

Table 7-2 List of hazardous materials

Component	Hazardous material	Quantity
X-ray tube	Lead	2.72 kg
	Oil	4 kg
Generator	Oil	10 L
Collimator	Pb	1.3984 kg
Host	Lithium battery	1 pcs
Monitor	LCD	1 pcs
Vice monitor (optional)	LCD	1 pcs
Grid	Lead	430 g

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8 Technical data

8.1	Configuration difference	8-2
8.2	Working conditions	8-3
8.3	Performance indexes	8-4
8.3.1	Electric power	8-4
8.3.2	Loading factors and control	8-4
8.3.3	Loading time	8-5
8.3.4	Current-time product	8-5
8.4	Major components	8-6
8.4.1	High voltage generator	8-6
8.4.2	Power distribution unit	8-6
8.4.3	Collimator	8-7
8.4.4	X-ray tube assembly	8-7
8.4.5	Wireless digital flat panel detector	8-8
8.4.6	Grid	8-8
8.4.7	Wireless digital flat panel detector carrier	8-8
8.5	Mechanical movement	8-9
8.6	X-ray field range	8-10
8.7	Electromagnetic interference requirements	8-11
8.7.1	Electromagnetic compatibility of the system	8-11
8.7.2	Electromagnetic compatibility of the remote control	8-12
8.7.3	EMI&EMS compliance	8-14

8.1 Configuration difference

Table 8-1 System configuration difference

Component name	Parameter	Configuration	
High voltage generator	GEN-SK (maximum output power: 65 kW)	-	√
	GEN-SK (maximum output power: 50 kW)	√	-
Wireless digital flat panel detector	Mars1717XU-VSI	√	√
X-ray tube assembly	Tube sleeve: XH-121 Tube core: XRR-3331	-	√
	Tube sleeve: XH-121 Tube core: E7876	√	-

8.2 Working conditions

Ambient conditions

- Temperature range: 10°C to 30°C
- Relative humidity: 30% to 70% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

Power supply requirements

- Input voltage: 3N~, 380 V/400V/440V AC.
- Input frequency: 50 Hz/60 Hz.
- Internal resistance of power supply: not greater than 0.15 Ω
- Power capacity for HV generator with a maximum output power of 50 kW: not lower than 95 kVA
- Power capacity for HV generator with a maximum output power of 65 kW: not lower than 120 kVA

8.3 Performance indexes

8.3.1 Electric power

Table 8-2 Maximum output power

Maximum output power	Loading conditions
50 kW	100 kV, 500 mA
65 kW	103 kV, 630 mA

Table 8-3 Nominal power

Nominal output power	Loading conditions
50 kW	100 kV, 500 mA, 0.1s
63 kW	100 kV, 630 mA, 0.1s

Table 8-4 Voltage and combination of tube of maximum output power

Maximum output power of 50 kW	Maximum output power of 65 kW
125 kV, 400 mA	130 kV, 500 mA
100 kV, 500 mA	103 kV, 630 mA
79 kV, 630 mA	81 kV, 800 mA

Table 8-5 Changes of maximum output power with the tube current (mA)

Current (mA)	200	250	320	400	500	630	800
Maximum voltage (kV)	150	150	150	125	100	79	-
Maximum output power (kW)	30	37	48	50	50	50	-
Maximum voltage (kV)	150	150	150	150	130	103	81
Maximum output power (kW)	30	37	48	60	65	65	65

8.3.2 Loading factors and control

8.3.2.1 X-ray tube voltage

The X-ray tube voltage can be adjusted in step mode in the range of 40 kV to 150 kV, with each step of 1 kV.

8.3.2.2 X-ray tube current

Select the R'10 numeral system during radiographic imaging:

- The adjustment range for HV generator with a maximum output power of 50 kW is 10 mA to 630 mA.
- The adjustment range for HV generator with a maximum output power of 50 kW is 10 mA to 800 mA.

8.3.3 Loading time

- Select the R'10 numeral system during radiographic imaging. The value ranges from 1 ms to 500 ms.
- The deviation of the radiographic loading time is not greater than $\pm(10\% + 1 \text{ ms})$.

NOTICE

It is recommended that the exposure time be longer than 10 ms. Otherwise, the image quality cannot be ensured.

8.3.4 Current-time product

- Select the R'10 numeral system during radiographic imaging. The value ranges from 0.4 mAs to 320 mAs for HV generator with a maximum output power of 50 kW and 0.4 mAs to 400 mAs for HV generator with a maximum output power of 65 kW.
- The deviation of the current-time product of the X-ray tube is not greater than $\pm(10\% + 0.2 \text{ mAs})$.

8.4 Major components

8.4.1 High voltage generator

- HV generator with a maximum output power of 50 kW

Parameter	Value
Tube voltage range	40 kV to 150 kV
Tube current range	10 mA to 630 mA
Loading time range	1 ms to 10,000 ms
Current-time product range	0.4 mAs to 1000 mAs
Output nominal power	50 kW
Maximum output power	50 kW
Input voltage	3N~, 380 V/400V/440V AC
Input frequency	50 Hz/60 Hz

- HV generator with a maximum output power of 65 kW

Parameter	Value
Tube voltage range	40 kV to 150 kV
Tube current range	10 mA to 800 mA
Loading time range	1 ms to 10,000 ms
Current-time product range	0.5 mAs to 1000 mAs
Output nominal power	63 kW
Maximum output power	65 kW
Input voltage	3N~, 380 V/400V/440V AC
Input frequency	50 Hz/60 Hz

8.4.2 Power distribution unit

Parameter	Value
Input power	380 V/400V/440V AC
Power frequency	50 Hz/60 Hz
Input power	2 kVA

8.4.3 Collimator

Parameter	Value
Collimation control	Manual
Inherent filtration	1.0 mmAl
Power input	24 V AC/DC
Maximum symmetric light field	43.5 cm × 43.5 cm (SID = 100 cm)
Minimum light field	2 cm × 2 cm (SID=100 cm)

8.4.4 X-ray tube assembly

Table 8-6 X-ray tube assembly E7876X

Parameter	Value
Model	Tube sleeve: XH-121 Tube core: E7876
Focus nominal value	Small focus: 0.6 Large focus: 1.2
Nominal tube voltage	150 kV
Maximum heat capacity of the X-ray tube assembly	975 kJ (1354 kHU)
Target angle	12°
Anode target material	Rhenium, tungsten and molybdenum alloy

Table 8-7 X-ray tube assembly XRR-3331X

Description	Parameter
Model	Tube sleeve: XH-121 Tube core: XRR-3331
Focus nominal value	Small focus: 0.6 Large focus: 1.2
Nominal tube voltage	150 kV
Maximum heat capacity of the X-ray tube assembly	900 kJ (1,250 kHU)
Target angle	12°
Anode target material	Rhenium, tungsten and molybdenum alloy

8.4.5 Wireless digital flat panel detector

Parameter	Value
Model	Mars1717XU-VSI
Acquisition matrix	3072 × 3072
Imaging area	427 mm × 427 mm
Data transmission	Wireless
Imaging medium	Cesium iodide/Amorphous silicon
Limiting resolution	3.6 lp/mm
Pixel dimension	139 µm

8.4.6 Grid

Parameter	Value
SID	130 cm
Grid ratio	8:1
Grid density	40 lines/cm

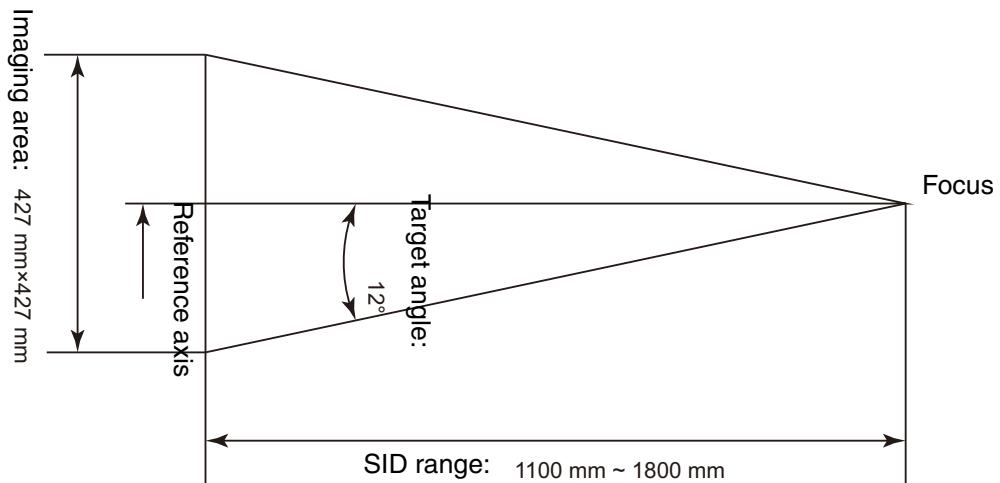
8.4.7 Wireless digital flat panel detector carrier

Parameter	Value
Maximum allowable load of the detector carrier	15 kg
Surface ray absorption ratio of detector carrier	0.5 mmAl
Grid	Stationary
Ionization chamber	Standard configuration

8.5 Mechanical movement

Description	Parameter
Lifting motion stroke of the U-arm	Not smaller than 1320 mm
Rotation of the U-arm around the horizontal axis (U-RHA)	-30° to + 120°
Rotation of the X-ray tube assembly around the horizontal axis (TUBE-RHA)	-120° to + 120°
Rotation of the wireless digital flat panel detector around the horizontal axis (FPD-RHA)	-45° to + 45°

8.6 X-ray field range



8.7 Electromagnetic interference requirements

8.7.1 Electromagnetic compatibility of the system

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

The equipment with Following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

The essential performance of this product is that, within normal condition the accuracy of loading factors is guaranteed to meet the requirements of clause 203.6.4.3.104 of IEC 60601-2-54:2009+A1:2015. The repeatability of the ray output meets the requirements of clause 203.6.3.2 of IEC 60601-2-54:2009+A1:2015, and the product has the automatic exposure control function.

WARNING

Electromagnetic compatibility — improper operation.

- ◆ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ◆ The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- ◆ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the uDR 266i, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The equipment is a large, permanently-installed system. According to chapter 8.6 of IEC 60601-1-2:2014, the test was only performed at some discrete frequencies.

- An exemption has been used and that the equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 6 000 MHz.

 **WARNING**

Electromagnetic compatibility — improper operation.

- ◆ This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation.

- Following frequencies and modulations are used to test the immunity of the equipment.

Selected Frequency (MHz)	Emitter	Frequency Range	Modulation
103.7	Radio	Business radio band	FM
433.92	Remote controller	ISM frequency	FM
446	Walkie-talkie	walkie-talkie	FM
915	Mobile phone	GSM900	Pulse
2400	Wireless router	WIFI	Pulse
5000	Wireless router	WIFI	Pulse

When the AC input voltage is interrupted, the equipment will shut down and if the power supply restored, it could be recovered by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

8.7.2 Electromagnetic compatibility of the remote control

Table 8-8 Cable specification

NO.	Name	Shielded/ Unshielded	Exposed length(cm)	Quantity	Remark
1	Network power supply wire	Unshielded	500	1	AC Power
2	Main monitor Ground cable	Unshielded	150	1	Ground
3	Secondary monitor Ground cable	Unshielded	150	1	Ground
4	Main monitor display cable	Shielded	150	1	Control
5	Secondary monitor display cable	Shielded	105	1	Control
6	Expose brake cable	Unshielded	150	1	Control
7	Secondary monitor adaptor DC-power cable	Unshielded	150	1	DC Power

NO.	Name	Shielded/ Unshielded	Exposed length(cm)	Quantity	Remark
8	high-voltage generator communication cable	Shielded	1300	1	Control
9	Control Console communication cable	Shielded	1700	1	Control
10	Cable from PC to Syscab	Unshielded	1300	1	AC Power
11	Cable from Main monitor to Syscab	Unshielded	1300	1	AC Power
12	Cable from Secondary monitor to Syscab	Unshielded	1300	1	AC Power
13	PC Ethernet communication cable 1	Shielded	1300	1	Control
14	PC Ethernet communication cable 2	Shielded	1300	1	Control
15	PC power on/off feedback cable	Shielded	1300	1	Control
16	PC Ground cable	Unshielded	1300	1	Ground
17	High-voltage rotating anode cable	Shielded	900	1	Control
18	High-voltage control cable	Shielded	900	1	Control
19	SCB Ethernet communication cable	Shielded	700	1	Control
20	SCB/MCB connect cable to Syscab	Shielded	700	1	DC Power
21	VFD connect cable to Syscab	Shielded	700	1	AC Power
22	Power distribution unit control cable	Shielded	700	1	Control
23	Frame Ground cable	Unshielded	900	1	Ground
24	High-voltage anode cable	Shielded	1300	1	High-Voltage Cable
25	High-voltage cathode cable	Shielded	1300	1	High-Voltage Cable
26	Chamber cable	Shielded	1300	1	Control

NO.	Name	Shielded/ Unshielded	Exposed length(cm)	Quantity	Remark
27	Mouse cable	Unshielded	150	1	Control
28	Keyboard cable	Unshielded	150	1	Control

8.7.3 EMI&EMS compliance

EMI Compliance Table

Table 8-9 Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment

NOTICE

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMS Compliance Table

Table 8-10 Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM field	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communica- tions equipment	IEC 61000-4-3	Refer to Table 8-11
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 8-11 Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels Professional healthcare facility environment
385	380 - 390	Pulse modulation 18 Hz, 27 V/m

Test frequency (MHz)	Band (MHz)	Immunity test levels Professional healthcare facility environment
450	430 - 470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704 - 787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800 - 960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700 - 1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400 - 2570	Pulse modulation 217 Hz, 28 V/m
5240	5100 - 5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 8-12 Input a.c. power Port

Phenomenon	Basic EMC stan-dard	Immunity test levels Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted distur-bances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage interrup-tions	IEC 61000-4-11	0% U _T , 250/300 cycles

Table 8-13 Signal input/output parts Port

Phenomenon	Basic EMC stan-dard	Immunity test levels Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted distur-bances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

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A

about the manual 1-2
about the system 1-5
acronyms and abbreviations 1-9
additional filter plate 5-8
application scope 1-6
armrest above detector carrier 5-8
automatic exposure control 4-23

C

collimator 3-15
collision protection 2-10
component replacement 7-7
configuration difference 8-2
console system 3-22
contraindication 1-6
control console 3-24

D

diagnostic monitor 5-8
digital flat panel detector
calibration 7-7
charging 4-20
disassembly 4-20
installation 4-19
structure 3-19

E

electrostatic protection 2-24
emergency stop switch 2-12
equipment compatibility 2-21
equipment repair 7-7

H

hazard of crushing 2-10

I

image orientation 2-8
image processing system 3-22
intended use 1-6

L

light field measurement 4-22
liquid prevention 2-6

M

motion control buttons 3-21

N

normal workflow 4-3

P

patient constant-contact components 2-9
patient positioning 4-5
personnel qualifications 1-7
positioning of the X-ray tube-collimator assembly 4-14
potentially dangerous crushing and collision areas 2-10

R

radiation protection
operators 2-18
patients 2-17
related documents 1-4

S

safety
basic instructions 2-6
diagnosis and treatment 2-8
electrical 2-16
emergency procedure 2-9
equipment and compatibility 2-21
features 2-7
laser 2-19
level instruction 2-2
radiation 2-17
symbols and labels 2-2
to person 2-10
X-ray protection 2-18
shutdown 4-10
SID measurement 4-15
site requirements
ground 6-3
mains 6-4
network 6-4
power cable 6-4
room dimension 6-3
startup 4-10
stitching workflow (optional) 4-8

Index

system commissioning 6-10

system components

angle indicator 3-16

collimator 3-15

detector carrier 3-18

digital flat panel detector 3-19

exposure handle switch 3-26

operation room 3-3

scanning room 3-2

system Installation 6-6

system messages 2-26

T

technical data

E7876X 3-12

image processing system 3-23

XRR-3331X 3-7

terms 1-8

text conventions 1-2

transportation and storage 6-5

U

U-arm

rotation 4-13

vertical movement 4-12

W

working conditions

ambient conditions 8-3

power supply requirements 8-3

X

X-ray tube assembly 3-6, 8-7

V02