

Operator's Manual
Veterinary Portable X-ray Unit
VetiGen P50/VetiGen P58



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IMPORTANT!

The device is veterinary use only.

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- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray Animal Medical authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

NOTE:

This equipment must be operated by skilled/trained clinical professionals.

 WARNING

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

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Mindray Animal Medical's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray Animal Medical or repairs by people other than Mindray Animal Medical authorized personnel.

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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Important Information

- It is the customer's responsibility to maintain and manage the device after delivery.
- The warranty does not cover the following items, even during the warranty period:
 - Damage or loss due to misuse or abuse.
 - Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
 - Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
 - Damage or loss due to use of the device outside the region where the device was originally sold.
 - Damage or loss involving the device purchased from a source other than Mindray Animal Medical or its authorized agents.
- This device shall not be used by persons other than fully qualified and certified medical personnel.
- DO NOT make changes or modifications to the software or hardware of this system.

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- In no event shall Mindray Animal Medical be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by Mindray Animal Medical.
 - The purpose of this system is to provide physicians with data for clinical diagnosis. The physician is responsible for the results of diagnostic procedures. Mindray Animal Medical shall not be liable for the results of diagnostic procedures.
 - Important data must be backed up on external memory media.
 - Mindray Animal Medical shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
 - This manual contains warnings regarding foreseeable potential dangers, but you shall also be continuously alert to dangers other than those indicated. Mindray Animal Medical shall not be liable for damage or loss resulting from negligence or ignorance of the precautions and operating instructions described in this operator's manual.
 - If a new manager takes over this system, be sure to hand over this operator's manual to the new manager.

About This Manual

This operator's manual describes the operating procedures for this system. To ensure safe and correct operation, carefully read and understand the manual before operating the system.

NOTE:

- If you find that the contents of the multi-language manuals are NOT consistent with the device or the English manuals, refer **ONLY** to the corresponding English manuals.
 - The accompanying manuals may vary depending on the specific device you purchased. Please refer to the packing list.
-

Meaning of Signal Words

In this manual, the signal words  **DANGER**,  **WARNING**,  **CAUTION**, **NOTE** and **TIP** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
 DANGER	Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.
 WARNING	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.
TIP	Important information that helps you to use the device more effectively.

Software Interfaces in this Manual

Depending on the software version, preset settings and optional configuration, the actual interfaces may be different from those in this manual.

Conventions

In this manual, the following conventions are used to describe the buttons on the control panel, items in the menus, buttons in the dialog boxes and some basic operations:

- **Bold font** indicates buttons on the control panel, items in menus, on the soft menu or buttons in dialog boxes.
- Select **Bold font**: select the corresponding item on the touch screen.
- **Bold font** > **Bold font**: select a submenu item following the path.

Operator's Manuals

The content of the operator manual, such as screens, menus or descriptions, may be different from what you see in your system. The content varies depending on the software version, options and configuration of the device.

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1 Important Information

1.1 Safety Precautions

Please observe the following precautions to ensure animal and operator's safety when using this device.

DANGER

Do not operate this device in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol, because there is danger of explosion.

WARNING

- **Contraindication:** Pregnant animal should avoid the examination by this device as much as possible. If there is any justified reason for them to conduct the examination, take protective actions as much as possible.
 - **Target users:** This device is only intended for use by radiography specialists who have been trained by Mindray Animal Medical or the agent and have read through the operator's manual.
 - **Intended use environment:** The main application site is medical institutions.
 - The service personnel not trained and authorized by Mindray Animal Medical are prohibited from opening the enclosure or panel of the equipment; otherwise, short circuit or electric shock may occur.
 - The service personnel not trained and authorized by Mindray Animal Medical are prohibited from replacing all fuses in this device; otherwise, short circuit or electric shock may occur.
 - To ensure device safety, do not connect a portable multi-jack socket to the device.
 - The device can only be connected to a power grid with protective grounding; otherwise, electric shock may occur.
 - Do not use this device with a high-frequency electrosurgical unit (ESU), high-frequency treatment equipment, or defibrillator; otherwise, the animal may suffer electric shock.
 - To ensure device safety, do not use other peripherals or accessories than those provided or designated by Mindray Animal Medical.
 - Signal output and input can only be connected to specified devices.
-

- It is not allowed for the operator to have contact with other animals and the electronic parts (such as the input/output terminal of the signal) of other devices that are connected to the device. Otherwise, it may produce the electrical shock to the animal.
 - Before maintaining or repairing the device, cut off the power supply of the entire system.
 - Do not install irrelevant software on this device; otherwise, it may cause the device breakdown and data loss.
 - Avoid abnormal power failure during operation. Otherwise, data loss or startup failure may occur.
-

** CAUTION**

- Check that this device operates properly before using the device.
 - Keep away from venous catheters, urethral catheters, and other catheters connected to the animal while using the device.
 - This manual does not describe clinical inspection techniques. Operators must select the proper inspection technique based on their professional knowledge and clinical experience.
 - When using iodine-containing contrast medium, strictly observe the instructions of the product.
 - Periodically maintain the equipment during the service life. When the service life ends, stop using the equipment.
 - Turn off the input power switch before cleaning this equipment to avoid electric shock.
 - If you want to connect the power plug of this device and that of the external device connected to this device to a socket, ensure that the socket is a wall socket with protective grounding and meets the requirements of the rated power identification plate. Use of a multi-functional socket may affect grounding and make the leakage current exceed the safety limit. Be sure to use the power cable delivered with the device.
 - Do not connect and disconnect the device peripherals in the electrified state. This operation can only be performed by professional personnel.
 - Do not use a USB memory device (e.g., a USB flash drive, removable hard disk) which has unsafe data. Otherwise, system damage may result.
 - Radio waves can cause the device to work abnormally.
 - If this device is used near radio transmitting equipment, radio waves may interfere with the normal operation of the device. Do not use or take any devices transmitting RF signals (such as cellular phones, transceivers and radio controlled products) in the room placing the device.
 - If any equipment that may generate radio waves is near the device, immediately shut down the equipment to ensure normal operation of the device.
 - If the mains supply is unstable and may affect the proper operation of the device, it is recommended to use an uninterruptible power supply.
 - Adjust the size of the beam limiting device before pressing the Prep/ Expose button, to protect the animal from absorbing excessive X-ray radiation.
 - Data may be lost if the device is powered off or encounters abnormal power failure during image acquisition.
 - Always keep the device dry. Avoid transporting this device quickly from a cold place to a warm place; otherwise condensation or water droplets may form allowing a short circuit and possible electric shock.
 - If the system is powered off improperly during operation, it may result in data damage of the system's hard disk or system failure.
-

- Avoid abnormal power failure during operation. Otherwise, data loss or startup failure may occur.
-

NOTE:

- Accessory equipment (analog or digital) connected to the device must comply with the relevant IEC standards (e.g., IEC 62368-1 audio/video, information and communication technology equipment safety standard and IEC 60601-1 medical equipment standard). Furthermore, all configurations must comply with the standard IEC 60601-1. It is the responsibility of the person, who connects additional equipment to the signal input or output ports and configures a medical system, to verify that the device complies with the requirements of IEC 60601-1. If you have any questions regarding these requirements, consult the Customer Service Department or your local distributor.
 - The device is not waterproof. Avoid water splash on the surface of the equipment or water ingress inside the equipment. In the case of water splash, consult the Customer Service Department or your local distributor.
 - Do not turn off the device power supply when data is being printed, saved, and transmitted; otherwise, the operation cannot be completed properly and file information may be lost
 - Do not shut down the device forcibly; otherwise, the disk data may be corrupted or the device may malfunction.
 - While the device is running, the operator should keep the animal within its field of view and pay consistent attention.
 - To avoid scald, do not touch the enclosure of the X-ray tube or beam limiting device during long-term inspection.
 - Keep the body parts of the animal away from the moving assemblies of the system to avoid animal injury resulting from system movement.
 - Keep venous catheters, urethral catheters, and other catheters connected to the animal away from moving devices.
 - Check the clock of the system periodically, to ensure the accurate examination time of the animal.
 - To dispose of the device or any part, contact the Customer Service Department or your local distributor. The manufacturer is not responsible for any system content or accessories that have been discarded improperly.
 - The service life of this device is ten years. Dispose of the device when its service life is reached. Follow local regulations regarding the disposal of such product.
 - Contact the Customer Service Department or your local distributor to provide the circuit diagram, component list, legends, and calibration rules if necessary.
-

1.2 Radiation Protection

The radiation protection of this system complies with IEC 60601-1-3 (for medical electrical equipment).

This device is equipped with a high-performance protective device that provides effective X-ray radiation protection and causes no harm under normal usage. However, the device cannot provide full protection, nor does it force the operator to take sufficient measures to protect the operator or others from direct or secondary radiation due to negligence, ignorance, or accidents.

Exposure to X-ray radiation may be damaging to health, and some of the effects of X-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for the X-ray operator is to avoid exposure to the primary beam at all times. An effective protective measure is the use of lead

shielding. To minimize dangerous exposure, use such items as lead screens, lead impregnated gloves, aprons, thyroid collars, and so on.

Choose appropriate technical parameters for each program to reduce the exposure dose of X-ray to the lowest level, and reach the best effect of imaging for diagnose. Carefully check the digital display and confirm the selected technical parameters before exposure. Pay special attention to the position of the decimal point in the value of current time product.

** WARNING**

Do not use this device to conduct repeated exposure on the same animal at a high frequency.

** CAUTION**

- During X-ray radiography, use lead impregnated clothes, boards, or other dedicated protective devices to protect the animal's sensitive parts (such as gonad), the operator, or the animal's helper.
 - During X-ray radiography, other personnel than the animal and its helper are prohibited from entering the X-ray beam area, or they should keep a distance of at least 3 m from the area.
 - The operator should use protective tools and wear protective clothes adapted to the workload if the operator has to work in the device area during X-ray radiography.
-

It is necessary to monitor the radiation quantity received by the device operator to identify insufficient or incorrect radiation protection measures and potential serious radiation exposure. Such monitoring provides valuable cross-check information to determine whether the adopted safety measures are proper. The most effective means to determine the properness of existing protective measures is to use instruments (such as a personal radiation measurement device) to detect the radiation dosage. Radiation measurement should be performed on all the body parts of the operator that are exposed to radiation. The measurement results cannot exceed the acceptable range.

When using the device, abide by the local regulations and restrictions on radiation protection. Before operating the device, the professional personnel should be familiar with the exposure dosage against Ionizing Radiation and for the Safety of Radiation Sources and have received training in the device operation.

Exposure Index

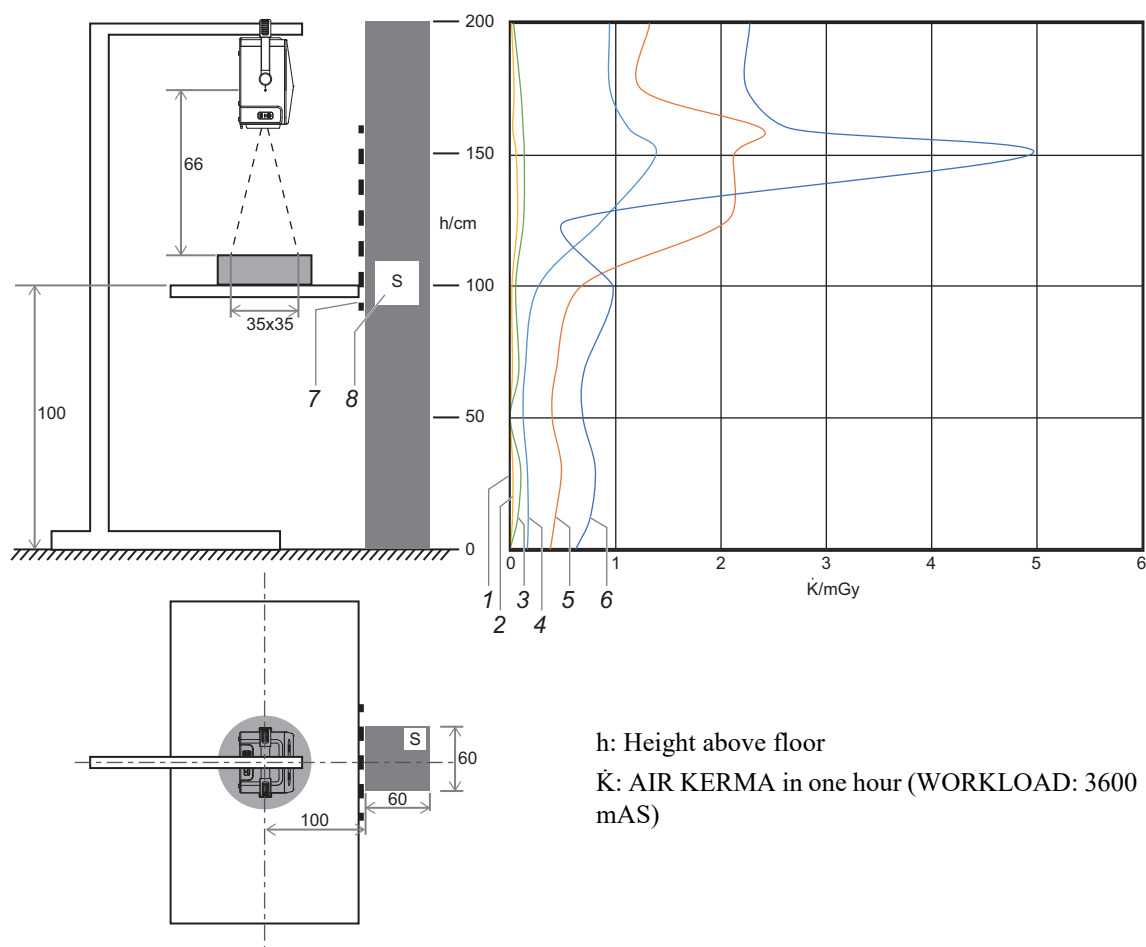
Exposure Index (EI): provides dose indication by calculating the gray value of the image, and the range is 0 to 11000. The lower the EI value, the smaller the radiation exposure.

While acquiring necessary clinical information, reduce EI value as much as possible by reducing mAs and projecting area.

1.3 Designated Important Occupied Area

If you take the X-ray unit from the specified place to the position of the animal, ensure a free radiation space as shown in the following figure before performing the X-ray examination. Any significant zone of

occupancy specified in this subclause should has a floor area of no less than 60 cm x 60 cm and a height of no less than 200 cm. Wear appropriate lead clothes to protect yourself from radiation leakage.



1.	70 kV with protective device
2.	100 kV with protective device
3.	125 kV with protective device
4.	70 kV without protective device
5.	100 kV without protective device
6.	125 kV without protective device
7.	Protective Device (Lead Apron)
8.	Significant zone of occupancy (S)

1.4 Parts that can be used within animal environment

- X-ray tube support device and X-ray source assembly
- High voltage generator
- Footswitch
- Handswitch

2 Product Overview

2.1 Intended Use

It is clinically indicated for digital radiography of the chest, abdomen, bone and soft tissue for animals.

2.2 Safety Classification

Basis of Classification	Type
According to the type of protection against electric shock	Class I
According to the degree of protection against electric shock	No applied part
According to the degree of protection against harmful ingress of water	Enclosed type equipment that does not prevent ingress of liquids
According to the recommended disinfection and sterilization method	/
According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
According to the operation mode	The equipment works in continuous operation
Whether the equipment has the application part that protects against defibrillation release effect	The equipment has no application part that protects against defibrillation discharge effect
Permanently installed or non-permanently installed	Non-permanently installed
According to the installation and use	Portable equipment
Mains supply overvoltage category	Class II

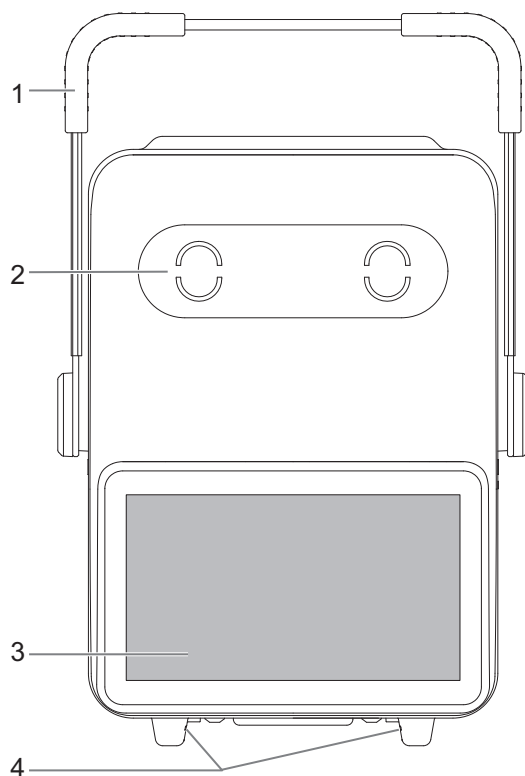
2.3 Device Configuration

- Main unit
- Power cord

- Accessories: see the packing list.

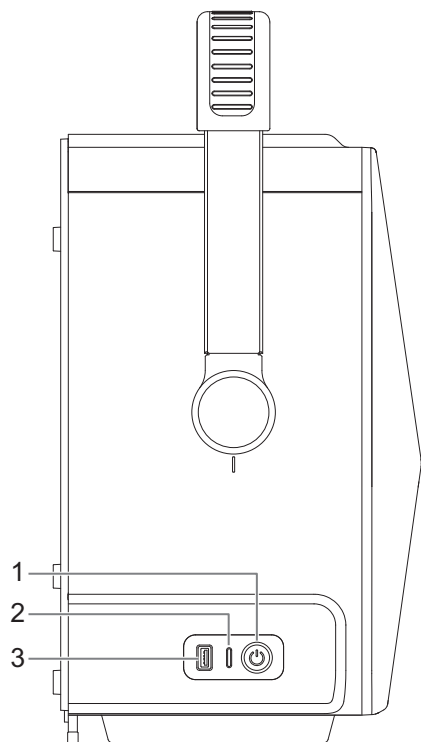
2.4 Introduction to Each Unit

Figure 2-1 Front view



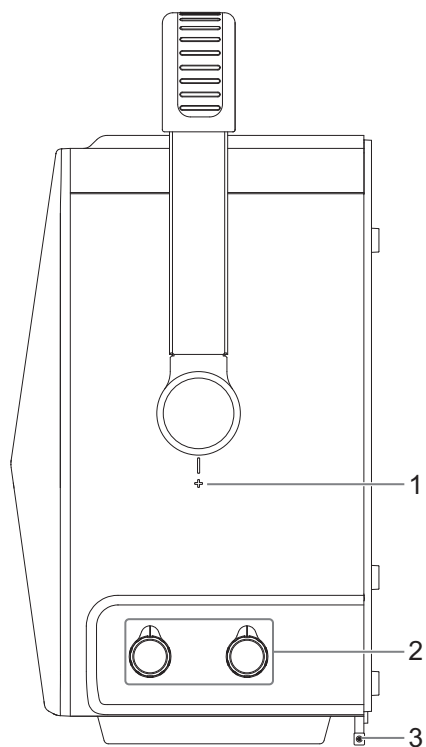
No.	Name	Description
1.	Handle	Used to fix the device.
2.	Exposure indicators	Indicates the device exposure status.
3.	Touch screen	Screen-touching operator-system interface or control.
4.	Accessory slots	Used to install a DAP instrument to measure the dose area product of exposure.

Figure 2-2 Left view



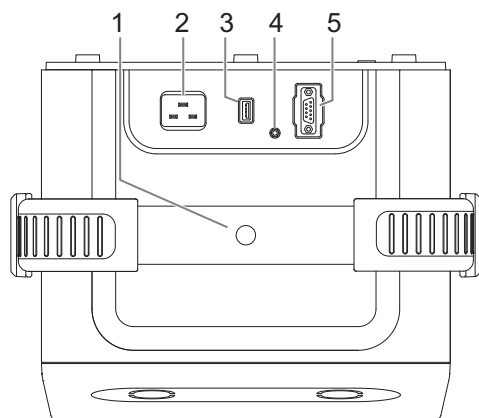
No.	Name	Description
1.	Power button	Power on/off the device.
	Indicator	Indicates the startup status of the device.
2.	AC power indicator	Lights on when AC power is connected.
3.	USB port	For device upgrade use only.

Figure 2-3 Right view



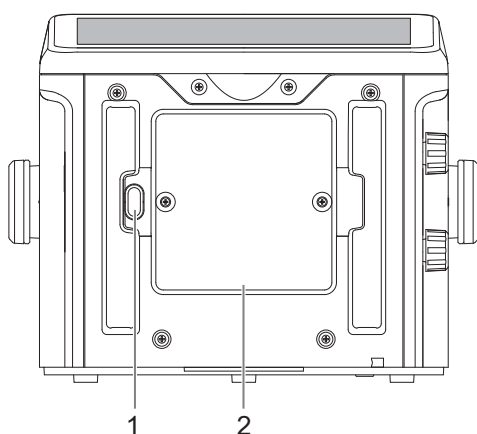
No.	Name	Description
1.	Focal spot position mark	Indicates the position of the focal spot.
2.	Lateral/longitudinal light field adjusting knobs	Rotate the knob to adjust the size of the light field.
3.	Measuring tape	Used to measure the actual SID value.

Figure 2-4 Top view



No.	Name	Description
1.	Fixing hole	Used to fix the device.
2.	AC power inlet	Used to connect the AC power cord.
3.	USB port	Used to connect the image acquisition workstation computer.
4.	Grounding terminal	Reserved.
5.	Input/output port	Used to connect the handswitch, footswitch, shielding door signal, and external lamps.

Figure 2-5 Bottom view



No.	Name	Description
1.	Auto BTM module	Used to automatically measure the animal body thickness.
2.	Beam limiting leaves	Adjust the size of the radiation field by using the lateral/longitudinal light field adjusting knobs.

Exposure Status Indication

The exposure indicator displays the exposure status.

Figure 2-6 Exposure indicator

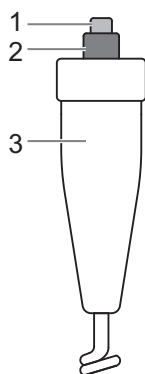


Status	Exposure Indicator
Exposure is allowed	Lights in white
Preparing for exposure	Blinks in green
Exposure preparation is completed	Lights in green

Status	Exposure Indicator
Exposing	Lights in yellow

2.5 Exposure Handswitch

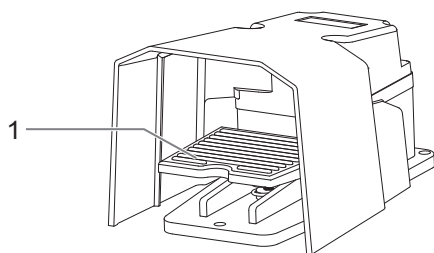
Figure 2-7 Exposure handswitch



No.	Name	Description
1.	Prepare button	• OFF: OFF position is when no pressure is applied to the button on the head of the handswitch.  • PREPARE: PREPARE is the middle position on the handswitch. When it is partially pressed, the system starts the X-ray tube and is ready to make an exposure. If the button is released, it returns to the OFF position.  • EXPOSE: When the button on the exposure handswitch is fully pressed, it is in the EXPOSE position. 
2.	Expose button	
3.	Handle	Used to hold the handswitch.

2.6 Footswitch

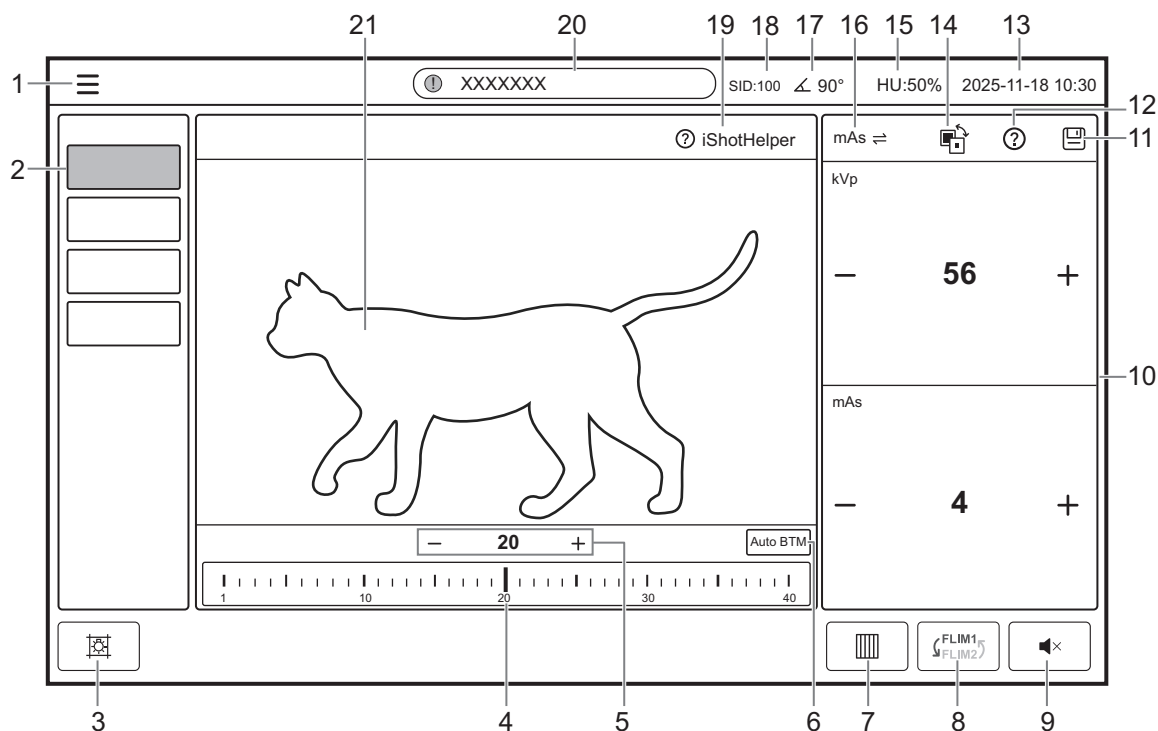
Figure 2-8 Footswitch



No.	Name	Description
1.	Expose button	Used to control the exposure.

2.7 Main Screen

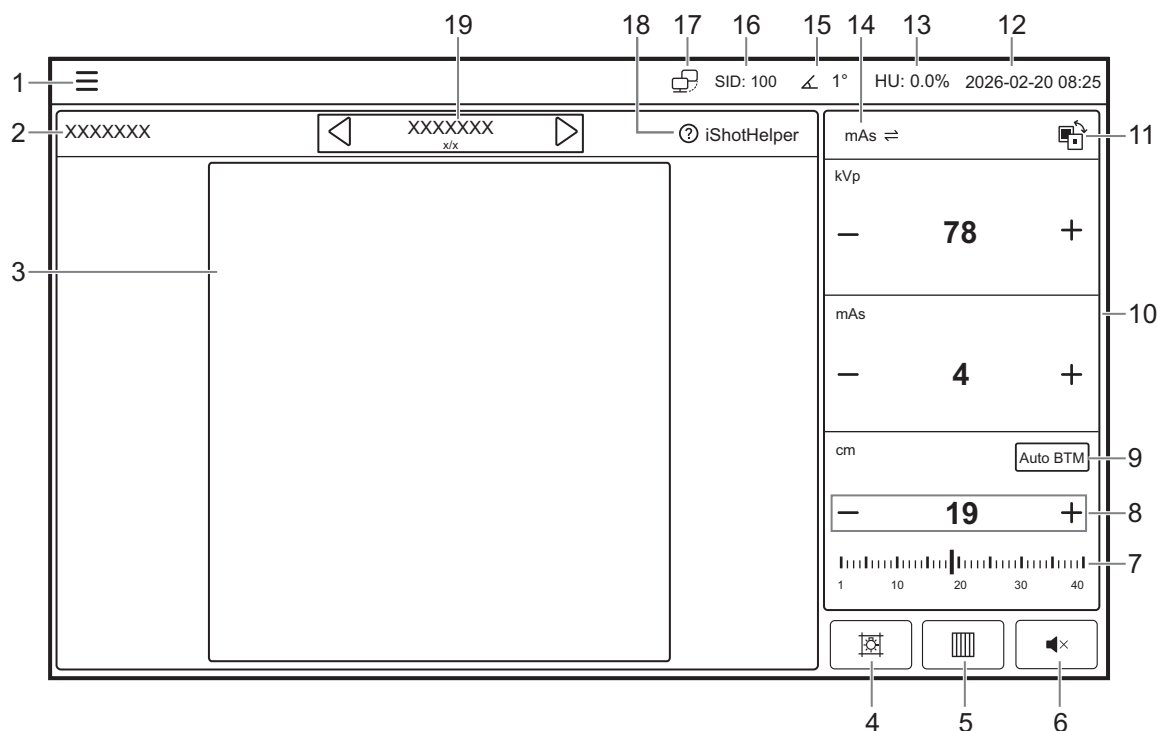
Figure 2-9 Startup initial screen (VetiGen mode)



No.	Name	Description
1.	Setup button	Enter/exit setup screen.
2.	Animal type selection area	Select animal type and the corresponding examined body part.
3.	Light field button	Tap to turn on/off the light source indicator.

No.	Name	Description
4.	Body thickness adjusting slider	Drag to adjust the body thickness value quickly.
5.	Body thickness adjustment button	Tap +/- to adjust the body thickness value.
6.	Auto BTM button	Tap to enable/disable automatic body thickness measurement.
7.	Grid switch button	Tap to enable/disable the grid function.
8.	Image receptor switch button	Tap to switch the image receptors.
9.	Volume On/Off button	Tap to turn on/off the alarm tone, touch screen tone, and exposure prompt tone.
10.	Exposure parameter panel	Tap +/- to adjust the exposure parameters.
11.	Parameter save button	Tap to save the parameters as the default settings for the current body part at the current thickness value.
12.	Parameter adjustment help button	Tap to view parameter adjustment instructions.
13.	Date/Time	Displays the current date and time of the device.
14.	Focal spot button	Tap to switch between large focal spot and small focal spot.
15.	Anode heat content	Displays the current heat content value of the X-ray tube assembly.
16.	mAs/mAms mode switch button	Tap to switch between different exposure parameter modes.
17.	Handle angle	Displays the installation angle of the device when the vertical ground is used as a reference.
18.	SID Value	Displays the currently SID value of the selected image receptor.
19.	iShotHelper button	Tap to view the diagrams of the animal positioning.
20.	Alarm message area	Displays the alarm message. Tap Reset to close the dialog box and reset the device. The alarm message will be cleared after the reset. TIP: If the resetting fails or no Reset button in the alarm message area, contact the Customer Service Department or your local distributor.
21.	Examined body part setting area	Select the body part of the current animal to be radiographed.

Figure 2-10 Startup initial screen (VetiGen+VetiPad mode)



No.	Name	Description
1.	Setup button	Enter/exit setup screen.
2.	Animal information area	Displays the current animal information.
3.	Image display area	Displays the acquired image of the current body part.
4.	Light field button	Tap to turn on/off the light source indicator.
5.	Grid switch button	Tap to enable/disable the grid function.
6.	Volume On/Off button	Tap to turn on/off the alarm tone, touch screen tone, and exposure prompt tone.
7.	Body thickness adjusting slider	Drag to adjust the body thickness value quickly.
8.	Body thickness adjustment button	Tap +/- to adjust the body thickness value.
9.	Auto BTM button	Tap to enable/disable automatic body thickness measurement.
10.	Exposure parameter panel	Tap +/- to adjust the exposure parameters.
11.	Focal spot button	Tap to switch between large focal spot and small focal spot.
12.	Date/Time	Displays the current date and time of the device.
13.	Anode heat content	Displays the current heat content value of the X-ray tube assembly.
14.	mAs/mAms mode switch button	Tap to switch between different exposure parameter modes.

No.	Name	Description
15.	Handle angle	Displays the installation angle of the device when the vertical ground is used as a reference.
16.	SID Value	Displays the current SID value of the selected image receptor.
17.	Connection status indicator	Displays the connection status between the device and the DROC.
18.	iShotHelper button	Tap to view the diagrams of the animal positioning.
19.	Examined body part	Displays the current examined body part. Tap the left/right button to select the desired body part to be radiographed.

2.8 Symbols and Warning Labels

The symbols and warning labels of this device in order to call your attention to potential hazards.

Their meanings are explained as follows:

Symbol	Description
	Refer to instruction manual/booklet
	AC (Alternating current)
	Stand-by
	Protective earth (ground)
	Serial number
	Date of manufacture
	CE marking
	Exposure pedal of the footswitch
IPX1	Protected against vertically falling water drops
	General warning sign
	Warning, electricity

Symbol	Description
	Warning, radioactive material or ionizing
	Warning; Crushing of hands
	Centre of gravity
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
1 类激光产品 最大输出: 2.5mW 发射波长: 850nm GB 7247.1-2012 CLASS 1 LASER PRODUCT Maximum output: 2.5mW Emitted wavelength: 850nm IEC 60825-1:2014	Class 1 laser product
 激光窗口 LASER APERTURE	Caution for laser aperture

3 Preparation before Use

3.1 Installation

WARNING

- Read and understand the safety precautions before positioning the device to ensure the safety of both the operator and the device.
 - Install the device properly to prevent damage caused by drop, impact, strong vibration or other mechanical force.
 - Install the device in a location easy to observe, operate and maintain.
-

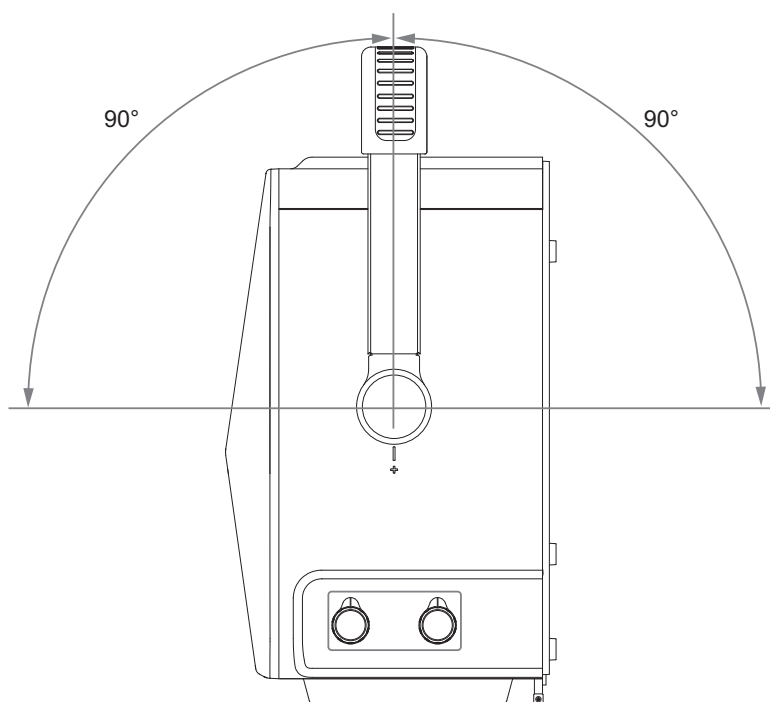
NOTE:

- Please purchase the bracket by yourself. Make sure the bracket specifications meet the installation requirements of the equipment before purchasing. If you have any questions, contact the Customer Service Department or your local distributor
 - Do not hang items other than those specified on this device.
-

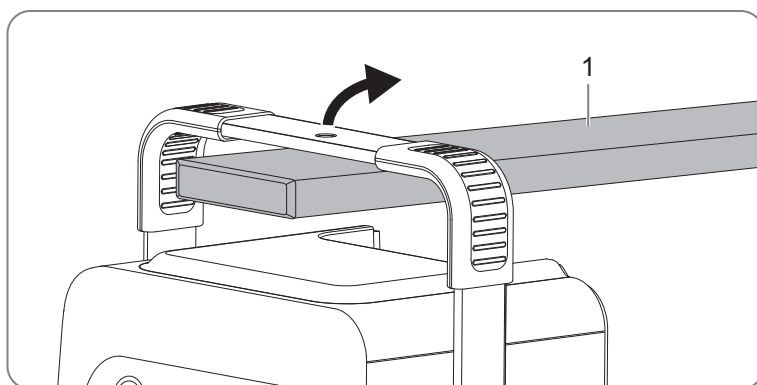
Perform the following procedure:

1. Adjust the handle angle.

The maximum adjustable range of the handle is 90°. Adjust the handle to a proper angle before installation.

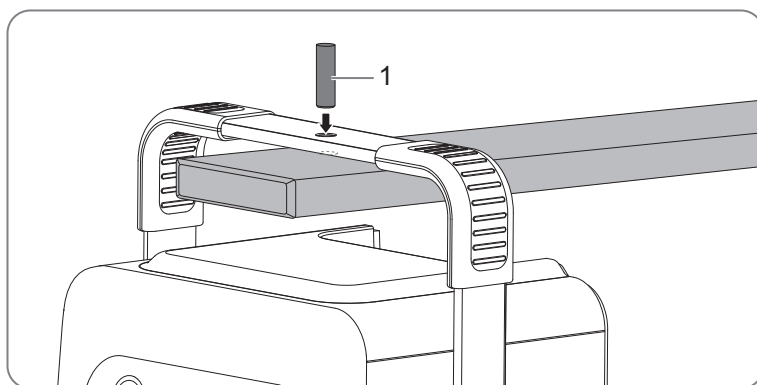


2. Install the device in the suspension position of the device bracket, and align the fixing hole on the handle with the fixing hole on the device bracket.



- | | |
|----|---------------------------------------|
| 1. | Device bracket (purchased separately) |
|----|---------------------------------------|

3. Use the bolt to fix the handle to the device bracket.



- | | |
|----|-----------------------|
| 1. | Bolt (diameter 13 mm) |
|----|-----------------------|

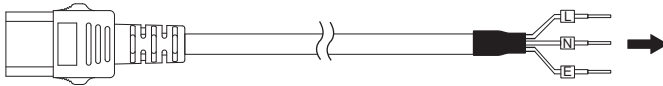
3.2 Connecting the Power Cord

WARNING

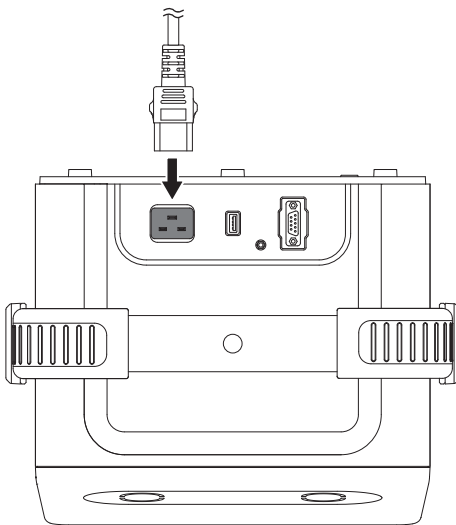
- Before connecting the power cord, you need to purchase a legally marketed power plug. Use the power plug in the conditions specified in this manual. It is recommended to use the power plug that meets the safety certification requirements (such as CE, or UL).
 - The installation must be performed by qualified professionals under the guidance of the Customer Service Department or your local distributor.
 - Before connecting the power cord, check and ensure that the mains supply specifications are consistent with the rated power supply specifications of the device.
-

Perform the following procedure:

1. Assemble the power cord to the power plug (purchased separately)

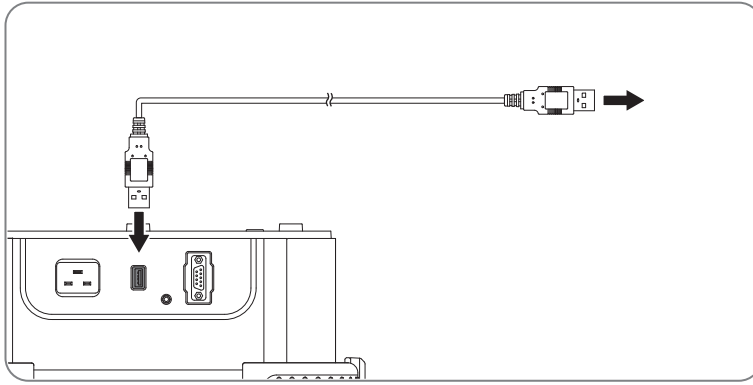


2. Connect one end of the power cord to the AC power inlet of the device and the other end to the mains supply.



3.3 Connecting the Image Acquisition Workstation Computer

Connect the device to the image acquisition workstation computer by using the supplied USB cable.

**NOTE:**

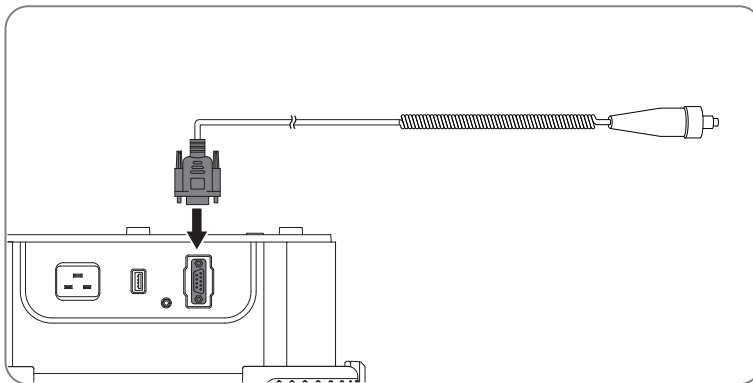
- After connection, bind the USB cable to avoid accidental drag and frequent shaking.
- If you need to change the USB cable or buy a new one, contact the Customer Service Department or your local distributor.

3.4 Connecting the Exposure Handswitch

Select one of the following methods to connect the exposure handswitch as required.

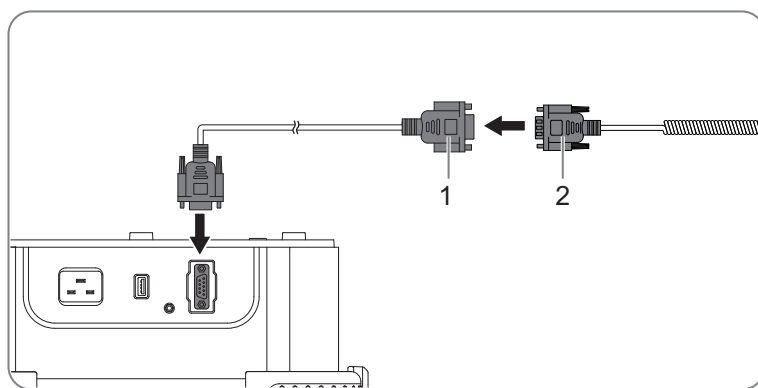
Connecting directly to the device

Connect the exposure handswitch to the input/output port of the device.



Connecting with handswitch extension cable

Perform the following procedure:

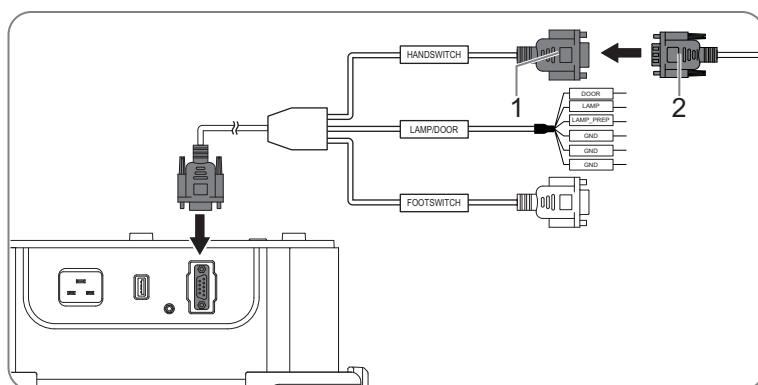


1.	Handswitch extension cable
2.	Exposure handswitch connector

1. Connect the handswitch extension cable to the input/output port of this device.
2. Connect the exposure handswitch to the handswitch extension cable.

Connecting with the 1-to-3 splitter cable

Perform the following procedure:

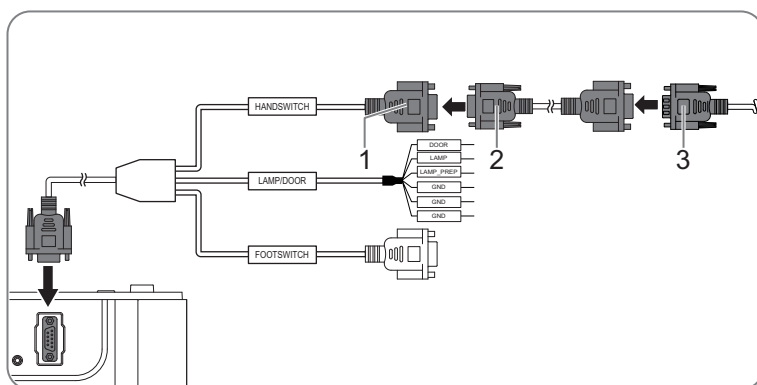


1.	1-to-3 splitter cable
2.	Exposure handswitch connector

1. Connect the 1-to-3 splitter cable to the input/output port of this device.
2. Connect the exposure hand switch to the handswitch connector of the 1-to-3 splitter cable.

Connecting with the 1-to-3 splitter cable and handswitch extension cable

Perform the following procedure:

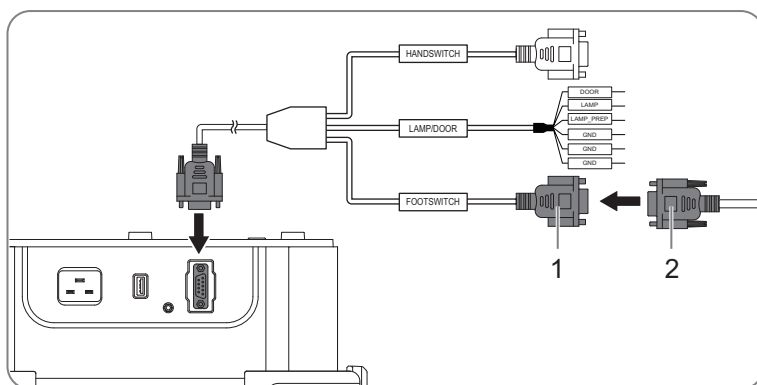


1.	1-to-3 splitter cable
2.	Handswitch extension cable
3.	Exposure handswitch connector

1. Connect the 1-to-3 splitter cable to the input/output port of this device.
2. Connect the handswitch extension cable to the handswitch connector of the 1-to-3 splitter cable.
3. Connect the exposure handswitch to the handswitch extension cable.

3.5 Connecting the Footswitch

Perform the following procedure:



1.	1-to-3 splitter cable
2.	Footswitch connector

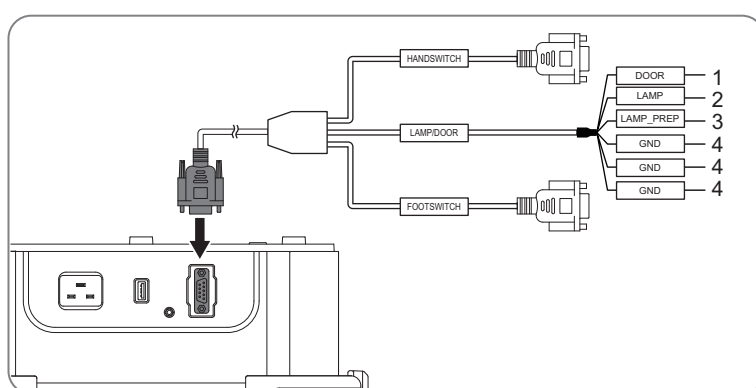
1. Connect the 1-to-3 splitter cable to the input/output port of this device.
2. Connect the footswitch to the footswitch connector of the 1-to-3 splitter cable.

3.6 Connecting the Shielding Door Signal and Indicators

⚠ WARNING

- The installation must be performed by qualified professionals under the guidance of the Customer Service Department or your local distributor.
- The rated voltage of one lamp is 12 V $\pm$ 5%, and the rated current of each lamp cannot exceed 0.5 A.
- When connecting the cables, protect them from a short circuit and separate them with insulating tape to ensure the correct positive and negative poles.

Perform the following procedure:



1.	Shielding door signal cable terminal (marked as DOOR)
2.	Startup signal cable terminal (marked as LAMP)
3.	Exposure preparation signal cable terminal (marked as LAMP_PREP)
4.	Grounding terminals (GND)

1. Connect the 1-to-3 splitter cable to the input/output port of this device.
2. Connect according to the marks on the terminals:
 - Shielding door signal cable terminal (DOOR) and grounding terminal (GND): used to monitor the status signals of the shielding door on this device. If the device is already enabled Door Access Control (For detailed operations, see the Setup chapter), the device will not be allowed to perform exposure before the shielding door is closed.
 - Startup signal line terminal (LAMP) and grounding terminal (GND): used to output the startup signal of this device after startup.
 - Exposure preparation signal cable terminal (LAMP_PREP) and ground terminal (GND): used to output exposure preparation signal.

3.7 Startup

CAUTION

To ensure safe and effective device operation, you must perform daily maintenance and checks. If the device begins to function improperly, immediately shut down the device and contact the Customer Service Department or your local distributor. If you use the device in a persistent improperly functioning state, you may harm the animal or damage the device.

NOTE:

Before device startup, ensure that the room is maintained in the operating environment specified by this manual for 10 minutes.

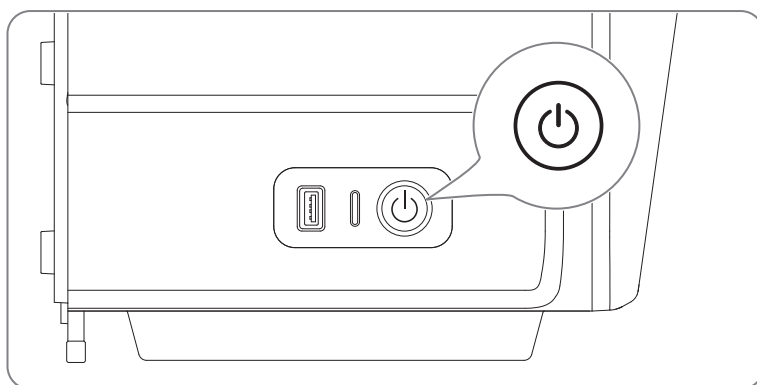
3.7.1 Checking before Powering On

Check before the device is powered on:

- The temperature, relative humidity and atmospheric pressure meet the requirements of the operating conditions.
- There is no condensation.
- There is no distortion, damage or dirt on the device and peripheral devices.
- If any dirt is found, cleaning shall be performed, see the device maintenance chapter.
- There are no loose screws on the touch screen and control panel.
- There is no cable damage (e.g., power cord). Maintain secure connections to the device at all times.
- Ensure that all connections are free from damage and remain clear of foreign object blockages.
- There are no obstacles around the system and its air vent.
- The entire exposure environment and field must be clean.

3.7.2 Powering On the Device

Press  to power on the device.



3.7.3 Powering Off the Device

WARNING

- Data may be lost if the device is powered off or encounters abnormal power failure during the exposure process.
 - If the device cannot be powered off normally, press and hold the power button for more than 6 seconds to shut down the device forcibly.
-

NOTE:

Do not shut down the device during saving, sending, or upgrade of board programs.

When the device is powered on, press  to power off the system.

4 Setup

The Setup function is designed to set the configuration parameters of operating the device and maintaining user workflow setup data.

CAUTION

When the preset data is changed, be sure to save the preset data according to the methods described in this chapter. The manufacturer is not responsible for the loss of preset data.

Perform the following procedure:

1. Tap  to enter the setup menu.
2. Tap to select different tabs, and use different screen controls to set parameter options and parameter values.
3. Tap **Save** and then tap  to exit the setup menu. The device will operate according to the changed parameters.

Directly tap  to exit the setup menu, and the parameter changes will not be saved.

4.1 Device Management

System Information

Item	Description
Tube Type	Displays the tube model.
Power	Displays the power of the device.
Product Name	Displays the device model.
Product SN	Displays the device SN.
Input voltage	Set the voltage according to the voltage of the local mains supply.

Collimator Setup

Item	Description
On time for collimator light (s)	Set the shutdown delay timer for the collimator indicator.
Auto-on condition for collimator light	Set the trigger condition for the collimator indicator to turn on automatically.

Security Control

Item	Description
Door Access Control	Set to enable/disable the function of shielding door status detection. When this function is enabled, the device will detect the shielding door status before exposure: - Exposure is forbidden when the shielding door is not closed. - Exposure is permitted when the shielding door is closed.
Warning light	Set to enable/disable external warning lights.

Tube training

Item	Description
Start Mode	Set the start mode of tube training.
Start exposure countdown(s)	Displays the remaining time before exposure starts.
Tube training status	Displays the tube training result.

SID and sensor

Item	Description
Film1 SID cm	Set the SID value (range: 30 – 120) of image receptor 1.
Film2 SID cm	Set the SID value (range: 30 – 120) of image receptor 2.
Auto BTM calibration	Tap  on the main screen to select the image receptor to be calibrated, and then tap this button to start the Auto BTM calibration. After the calibration is completed, the SID value of the selected image receptor is automatically updated and directly saved. TIP: - Prior to calibration, ensure that there are no visible reflections or materials on the image receptor. - Do not forcibly interrupt the calibration process; otherwise, calibration may fail.

Item	Description
Angle calibration	Tap to start calibration of the angle sensor. After the calibration, the current angle () is 0°. TIP: Do not forcibly interrupt the calibration process; otherwise, calibration may fail.

4.2 Basic Setup

Date and time

NOTE:

Ensure that the current exam date and time are the same as the device date and time.

Perform the following procedure:

1. Tap the text box.
The device automatically displays the soft keyboard.
2. Tap the numeric keys to set the date and time.
3. Tap OK to confirm the settings.
 - Tap  to clear the input box.
 - Tap  to delete the characters on the left of the cursor.
 - Tap  to exit the soft keyboard.
4. Tap **Save** to save the date and time.

Work Mode Setup

Item	Description
Instrument mode	To set the exposure mode of the system: • Standalone mode The device can be performed exposure directly. • System mode The device can be performed exposure only after receiving the exposure command from the image acquisition workstation.
Work mode	Select the work mode. Demo mode is used for customer service training or marketing to perform simulated exposure.

Item	Description
Screen saver	Set whether to enable the screen saver function. After the screen saver function is enabled, the screen automatically enters the screen saver state without any operation within 15 minutes. Tapping the touch screen or triggering the exposure procedure automatically exits the screen saver state.

Touch screen

Item	Description
Touch Experience	Test the touch control function.
Touch check	Calibrate the touch screen.
Color Test	Test the touch screen color display.
Multi-gray Test	Test the multi-gray display of the touch screen.

4.3 System Language

Perform the following procedure:

1. Select the check box before the desired language.
2. Tap **Save**.

The screen language automatically switches to the selected language.

4.4 Data Management

- **Last Exposure Result**
Tap **Read** to view the time and parameters of the last exposure.
- **Exposure Count**
Tap **Read** to view the cumulative exposure times.

4.5 Help Manual

Tap to view the quick operation instructions.

4.6 Version Information

This screen displays the device software version and other versions of devices.

The information varies depending on the device configurations and version.

5 Basic Operations

5.1 X-ray Field Size Adjustment

Use the collimator to adjust the size of the X-ray field.

NOTE:

- Do not turn on the indicator of the beam limiting device repeatedly, and do not keep the indicator on for a long time, to avoid damaging the indicator due to overheat.
 - Do not turn on the indicator of the beam limiting device for a long time; otherwise, the enclosure area around the indicator may overheat and the indicator service life may be reduced.
 - Minimize the radiation area of the animal by adjusting the collimator only for a minimum area required for the purpose of diagnosis.
-

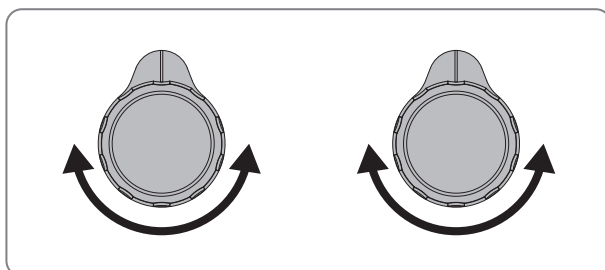
Perform the following procedure:

1. Tap the light field button on the main screen to turn on the light source indicator.

It is off after a delay of 90 seconds (default). You can press the light field button to turn on the indicator as needed.

Tap the light field indicator () on the touch screen to turn on or off the indicator.

2. Aim the light field at the animal's lesion, and adjust the light field size based on the selected field specifications by rotating the lateral () /longitudinal () light field adjustment knobs.

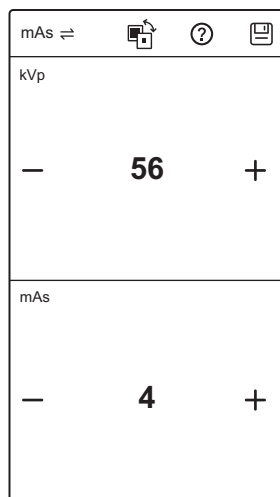


5.2 Exposure Parameters Adjustment

NOTE:

- Adjust exposure parameters correctly based on the corresponding body part of the selected animal type.
- Do not perform exposure until proper exposure parameters are selected for the animal.

The device sets default parameters for each radiographed body part. You can adjust the default parameters based on the animal's conditions.



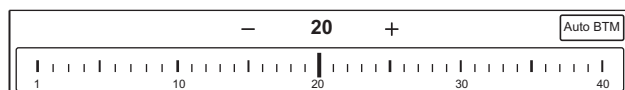
Adjusting the exposure dose

Tap $\rightleftharpoons$ to switch the exposure parameter modes, and then tap +/- to adjust the parameter value.

Adjusting the body thickness value

TIP:

The body thickness measured by **Auto BTM** may fluctuate at ± 1 cm, which is a normal phenomenon.



- Tap +/-, or drag the slider to adjust the body thickness.
- If Auto BTM module is configured, tap **Auto BTM** to enable the auto body thickness measurement.

Saving exposure parameters

Tap  to save the parameters as the default settings for the current body part at the current thickness value.

5.3 SID Value Setting

After installing or adjusting the location of the device or the image receptor, the SID value of the image receptor needs to be configured.

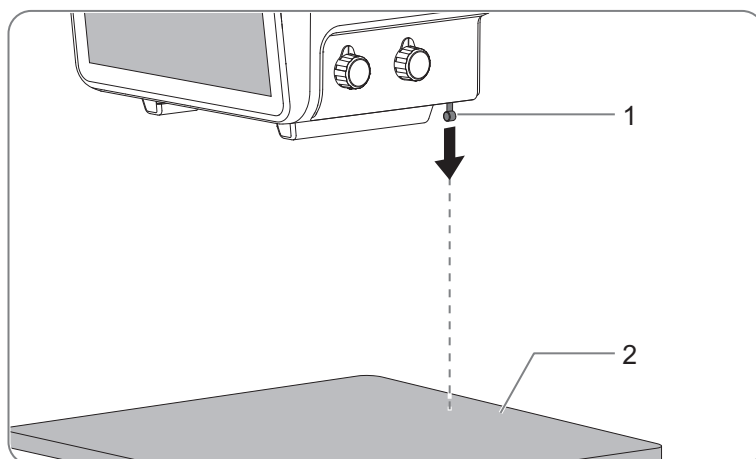
NOTE:

- Before setting the SID value, ensure that the light field of the collimator is vertically aligned with the image receptor.
 - If you have any questions about the device installation or adjustment, contact the Customer Service Department or your local distributor
-

Perform the following procedure:

1. Pull down the measuring tape vertically to measure the SID.

Figure 5-1 SID value measurement



1.	Measuring tape
2.	Image receptor

2. Tap  on the main screen, and then select **Device Management > SID and sensor**.
3. Tap +/- to adjust the SID value of the selected image receptor.
4. Tap **Save** to complete the settings.

5.4 Exposure Operations

NOTE:

If you want to switch to another exposure method before the current exposure is completed, terminate the ongoing exposure operation first.

5.4.1 Exposure Handswitch Operation

Perform the following procedure:

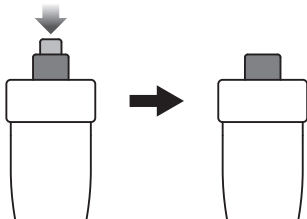
1. Verify that the animal is ready for performing exposures.
2. Hold the handswitch.



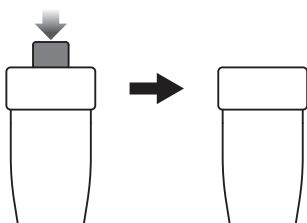
3. Apply pressure to the button to start exposure.

Exposure is stopped when the button on the head of the handswitch is released at any time during the exposure process.

1. Press the button to the PREPARE position to enter the expose prepare status.



2. Press the button fully to the EXPOSE position to start expose.

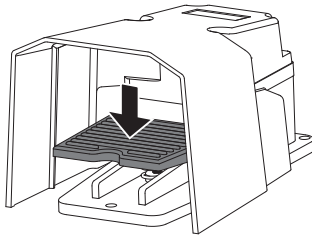


4. Release the expose button after the exposure is completed.

5.4.2 Footswitch Operation

Perform the following procedure:

1. Verify that the animal is ready for performing exposures.
2. Do one of the following to perform the exposure:



- Depress and hold the pedal until exposure is complete and then release.
- Or:
 - a. Depress the pedal to enter exposure preparation status and release.
In exposure preparation status, the device does not respond to handswitch operations. This status lasts for 20s.
 - b. Depress the pedal again until the exposure is complete and then release.

5.5 Starting an Exposure

Perform the following procedure:

1. On the main screen, select the animal type and the corresponding body part to be examined.
The default exposure parameters are loaded.
2. Tap  to switch to the desired image receptor.
3. Position the animal according to the selected body part.
4. Adjust the range of the light field according to the selected position.
5. If a grid is configured, tap  to enable the grid function.
6. If necessary, use the parameter adjustment controls to adjust the exposure parameters and body thickness.

If using the Auto BTM function, the device automatically adjusts the exposure parameters according to the obtained body thickness value.

7. Use the handswitch or footswitch to perform the exposure.

6 Periodic Maintenance

CAUTION

Failure to perform periodic inspection and maintenance may cause the working conditions to deteriorate without the user's knowledge and thus result in equipment faults, damage, and even injury.

To ensure the performance and safety, you should perform periodical checks for the device. A periodic maintenance and repair program must be established to ensure continuous safe performance of the device. It is the user's responsibility to check the device status and perform preventive inspection of the device.

There are two levels of maintenance. One level is maintenance by the user or operator, and the other level is maintenance by professional X-ray maintenance personnel.

6.1 Operator's Tasks

WARNING

- After startup, do not perform cleaning or maintenance of any component of the device. Be sure to shut down the device and disconnect the mains supply before cleaning or maintenance. Disconnect the cables between all the operated components and the device during cleaning, maintenance, and inspection.
- Ensure that no water or other liquids enter the device, to avoid electrical system short circuit or component corrosion.
- Because some substances of cleaning agents are harmful to the human body, the concentration of such substances in air cannot exceed the upper limit specified by relevant rules and regulations. Strictly observe the use instructions provided by the manufacturers of such cleaning agents.
- After cleaning and disinfection, fully ventilate the room and then power on the device. Residual flammable gases in the room may cause fire and explosion when the device is powered on.
- Do not use any other cleaning agents or solvents because they may darken the painting or smudge printed text.

- Do not directly clean the surface of the device with a cleaning spray, because the spray mist may seep into the device, damage electronic components, and form a combustible mixture of air and water vapors, posing a safety hazard.
 - Do not remove any shelf cover. Do not remove or handle the internal components of the device.
THESE ACTIONS COULD CAUSE SERIOUS BODILY INJURY AND/OR DEVICE DAMAGE.
-

NOTE:

- After the device has not been used for more than 2 weeks, you are recommended to perform 1 to 2 exposures at a level less than 100 kV first to avoid abnormal discharge of the X-ray tube and impact on the service life of the X-ray tube. Do not use the high kV level for exposure directly.
 - After the device has not been exposed for more than 1 month, complete the tube training according to the instructions to avoid abnormal discharge and affecting the service life of the tube core. It will take about 15 minutes.
 - Check and clean the interfaces regularly to keep them clean and prevent foreign objects from entering.
-

Perform the following procedure:

1. Power off the device and cut off the power supply to the device.
2. Check whether the cables between the main components of the device are connected properly.
3. Clean regularly.

You are advised to clean the device and all contaminated parts twice per day, and the duration of cleaning the same part each time does not exceed 3 minutes, especially for the parts in contact with animals. Soak a soft cloth in ethanol (75%) or isopropanol (70%) solution. Then use it to clean the enclosure and surface of the device. After cleaning, use a soft cotton cloth to dry the touch screen immediately, and wipe off the contrast agent stains (if any) as soon as possible.

6.2 Service Tasks

NOTE:

- After the device is used for 1 year, contact the Customer Service Department or your local distributor to recalibrate the X-ray tube to ensure mA accuracy.
 - After the device is not in use for more than 1 month, contact the Customer Service Department or your local distributor to perform the X-ray tube training.
 - Regularly check the leak-tightness of the oil tank in the high-pressure generator (recommended (once per 12 months)).
-

If you find abnormal sound, operation failure, device damage, or X-ray out of control during use, contact the Customer Service Department or your local distributor.

Only service engineers trained on medical X-ray equipment can perform maintenance and repair of this device.

The device manufacturer recommends that initial device maintenance be performed after 1 month and before the third month following device installation and operation. In normal cases, maintenance should be performed every 12 months based on the device operation status.

If many animals are examined every day (for example, 125 animals per day) after system installation, the maintenance cycle should be shortened. For example, perform full maintenance every 6 months.

7 Specifications

7.1 Technical Specifications

WARNING

Do not use this device in conditions other than those specified.

Item		Value
Power supply	Voltage	AC single-phase power, 100-240V AC
	Frequency	50/60Hz±1Hz
	Input power	≤2 kVA
Electric power	Output power	5 kW
	Nominal electric power	5kW (50mA, 100kV, 0.1s)
	Maximum output power	5kW (63mA, 80kV)
Load factor regulating range	Tube voltage/kV	40 kV–125 kV. Deviation ≤±8%
	Tube current/mA	12.5 mA–100 mA. Deviation ≤±20%
	Loading time/ms	1.6 ms–8000 ms. Deviation ≤±(10%+1 ms)
	Current-time product/mAs	0.16 mAs–160 mAs. Deviation ≤±(10%+0.2mAs)
Operating conditions	Relative humidity	20%–85%, non-condensing
	Atmospheric pressure	62 kPa–106 kPa
	Ambient temperature	10°C–40°C
Storage and transportation conditions	Relative humidity	10%–90%, non-condensing
	Atmospheric pressure	50 kPa–106 kPa
	Ambient temperature	-20°C–60°C

Item		Value
Physical specifications	Dimensions (WxDxH, excluding the handle and footpads)	395mm x 285mm x 245 mm (Tolerance: ± 20 mm)
	Weight	≤ 16 kg

7.2 Specifications of X-ray Tube (KL10-0.6/1.8-125SB)

7.2.1 General Data

Electrical

- Circuit
 - High voltage generator: constant potential high-voltage generator
 - Grounding mode: center-grounded
- Nominal voltage of the x-ray tube: 125 kV
- Nominal focal spot value
 - Large focus: 1.8
 - Small focus: 0.6
- Nominal anode input power (at 0.1s)
 - Large focus: 5300 W
 - Small focus: 1270 W
- Exposure duty cycle
 - Large focus: At least 1:60 (Exposure time: Interval time)
 - Small focus: At least 1:60 (Exposure time: Interval time)

Mechanical

- Dimensions
see **7.2.6 Dimensional Outline.**
- Target
 - Anode angle: 15°
 - Target: Tungsten
- Inherent filtration: At least 0.65 mmAl at 75 kV
- Weight (about): 1.0 kg
- X-ray coverage: 430mm x 430 mm at SID 909 mm
- Cooling method: Oil immersed (60°C max.) and convection oil cooling
- Tube holding: holding the glass envelope of the anode end and cathode end, or the screw of the anode shank.

7.2.2 Absolute Maximum and Minimum Ratings

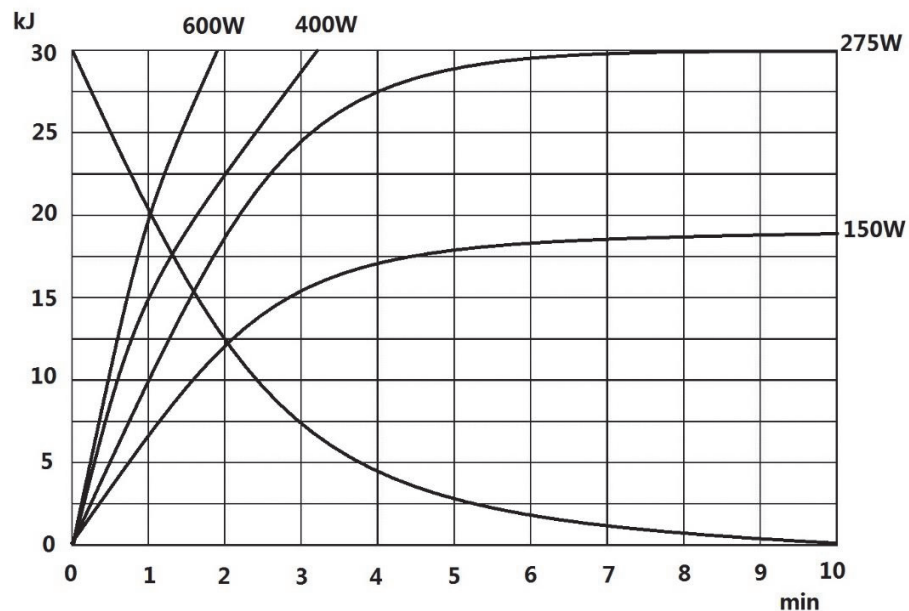
At any time, these values must not be exceeded.

- Nominal voltage of the X-ray tube: 125 kV
- Minimum X-ray tube voltage: 40 kV
- Maximum X-ray tube current

- Large focus: 100 mA
- Small focus: 25 mA
- Maximum filament current
 - Large focus: 3.5 A
 - Small focus: 3.5 A
- Filament voltage (at maximum filament current)
 - Large focus: 6.5 V–7.2 V
 - Small focus: 2.5V–3.1V
- Thermal characteristics
 - Anode heat content: 30 kJ (42 KHU)
 - Maximum anode heat dissipation rate: 275 W
- Wiring length: 100 mm

7.2.3 Thermal Characteristics

Figure 7-1 Thermal Characteristics



7.2.4 Maximum Rating Charts (Absolute Maximum Rating Charts)

Figure 7-2 Small focus

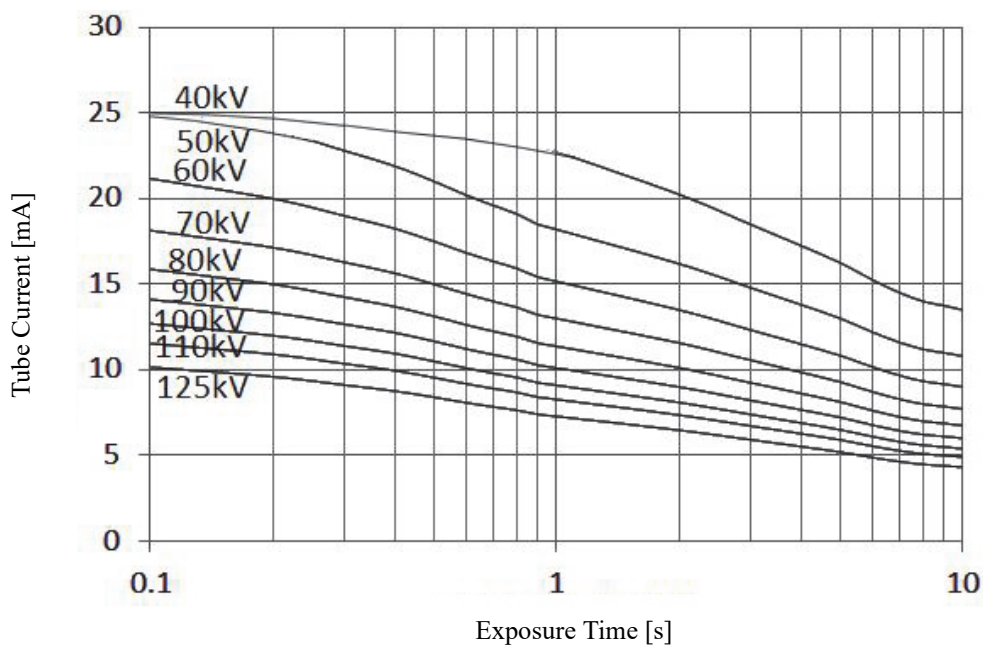
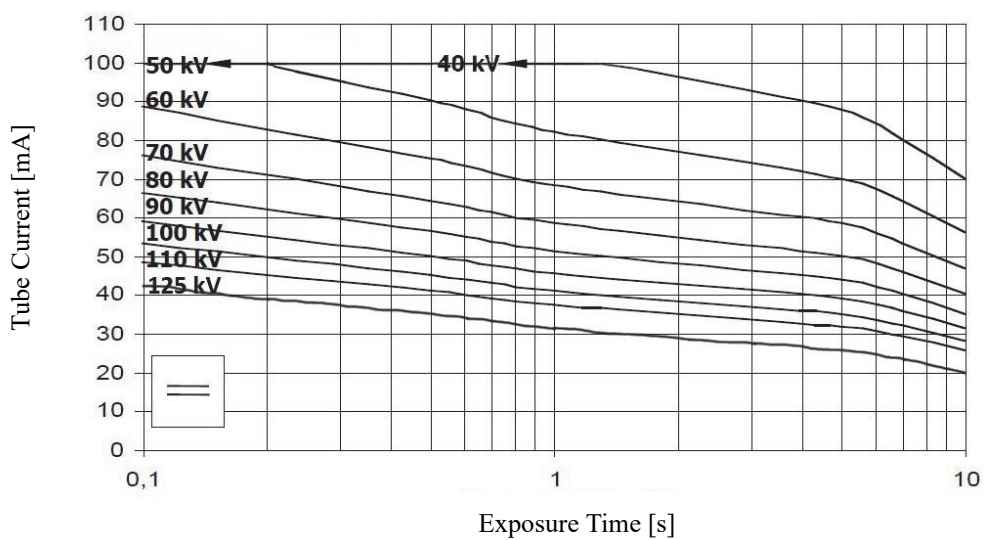


Figure 7-3 Large focus



7.2.5 Emission Characteristics

Figure 7-4 Small focus

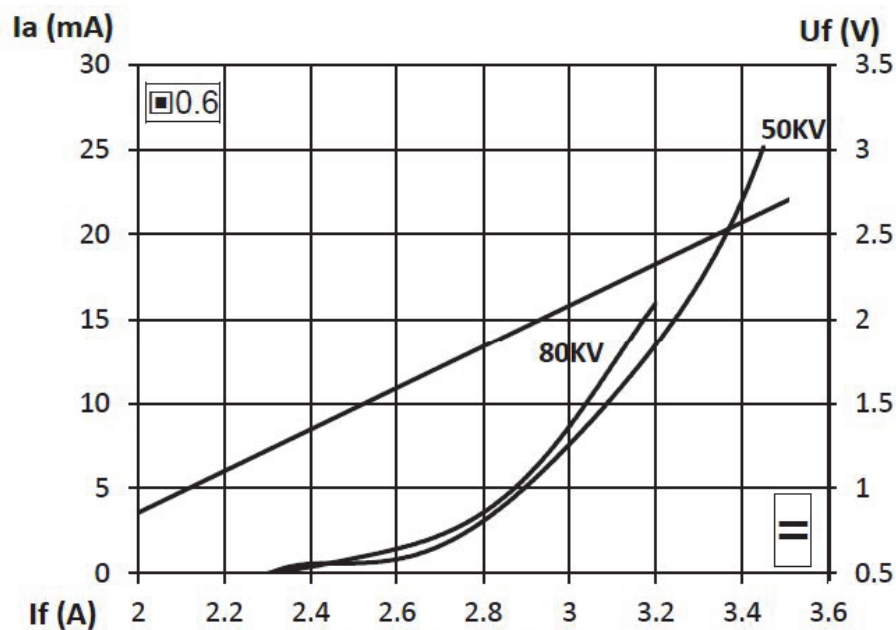
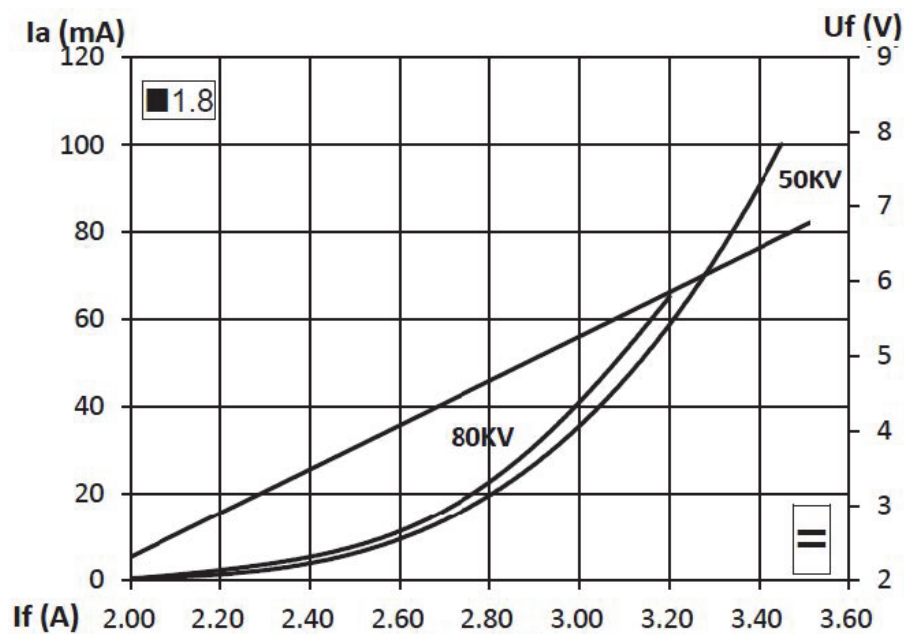
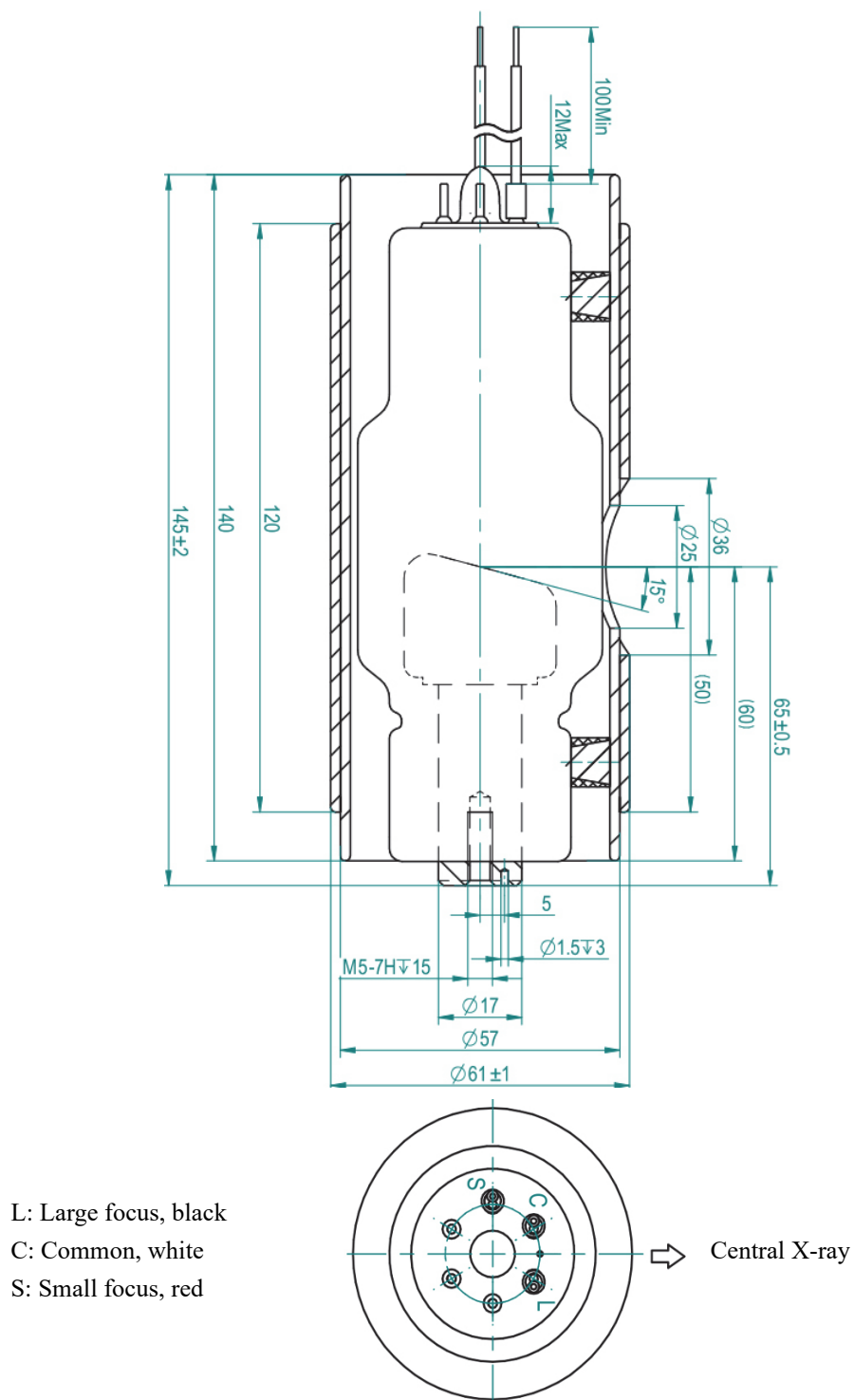


Figure 7-5 Large focus



7.2.6 Dimensional Outline

Figure 7-6 Dimensional outline of X-ray tube



L: Large focus, black
C: Common, white
S: Small focus, red

7.3 Specifications of X-ray Tube (DF-183SB)

7.3.1 General Data

Electrical

- Circuit
 - High voltage generator: constant potential high-voltage generator
 - Grounding mode: center-grounded
- Nominal voltage of the x-ray tube: 125 kV
- Nominal focal spot value
 - Large focus: 1.8
 - Small focus: 0.5
- Nominal anode input power (at 1.0s)
 - Large focus: 4200 W
 - Small focus: 1000 W
- Nominal anode input power
 - Large focus: 5300 W
 - Small focus: 1100 W
- Exposure duty cycle
 - Large focus: 1:60 (Exposure time: Interval time)
 - Small focus: 1:60 (Exposure time: Interval time)

Mechanical

- Dimensions
see **7.3.6 Dimensional Outline.**
- Target
 - Anode angle: 16°
 - Target: Tungsten
- Inherent filtration: At least 0.8 mmAl at 75 kV
- X-ray coverage: 430 mm x 430 mm at SID 909 mm
- Weight (about): 980 g
- Cooling method: Oil immersed (60°C Max.) and convection oil cooling
- Tube Holding: holding the insulation cylinder or the lead cylinder

7.3.2 Absolute Maximum and Minimum Ratings

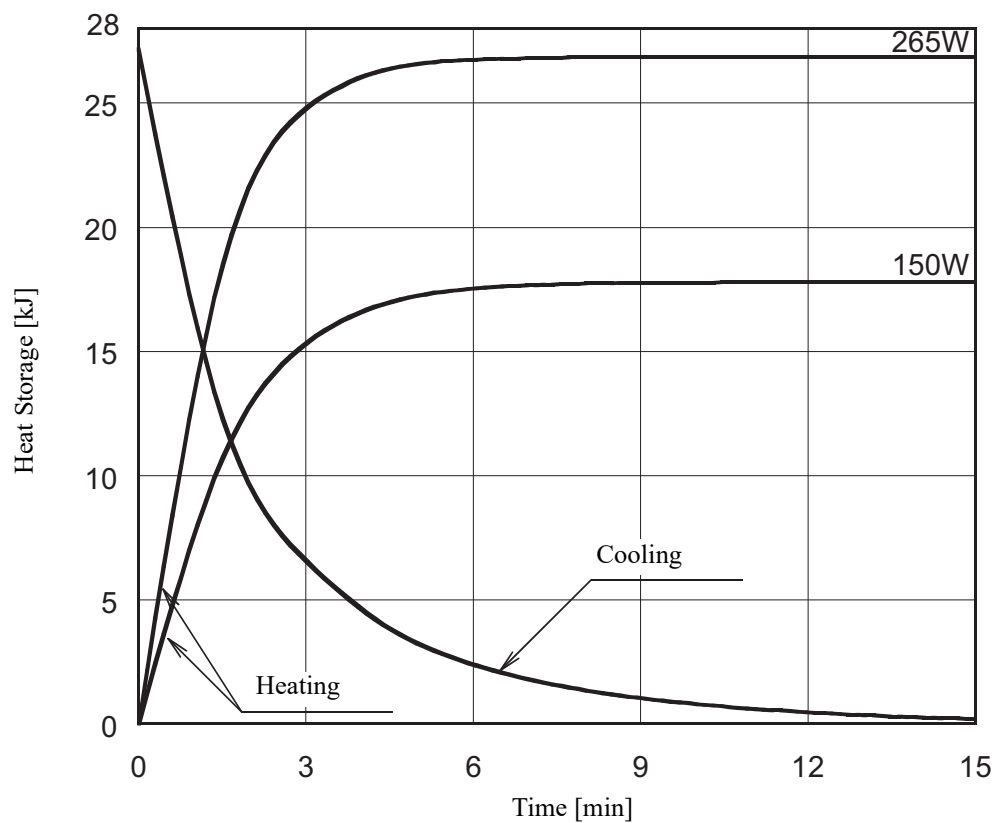
At any time, these values must not be exceeded.

- Maximum voltage of the X-ray tube: 125 kV
- Between anode (or cathode) and ground: 62.5 kV
- Minimum X-ray tube voltage: 40 kV
- Maximum X-ray tube current
 - Large focus: 100 mA
 - Small focus: 15 mA
- Maximum filament current

- Large focus: 4.6 A
- Small focus: 3.2 A
- Filament voltage (at maximum filament current)
 - Large focus: 5.4 V–6.8 V
 - Small focus: 3.8 V–5.2 V
- Filament frequency limits: DC or AC (Sine wave) 0–20 kHz
- Thermal characteristics
 - Anode heat content: 28 kJ
 - Maximum anode heat dissipation rate: 265 W
- Maximum radiographic exposure time:
 - Large focus: 10s
 - Small focus: 10s

7.3.3 Thermal Characteristics

Figure 7-7 X-ray tube assembly heating/Cooling curve



7.3.4 Maximum Rating Charts (Absolute Maximum Rating Charts)

Figure 7-8 Small focus

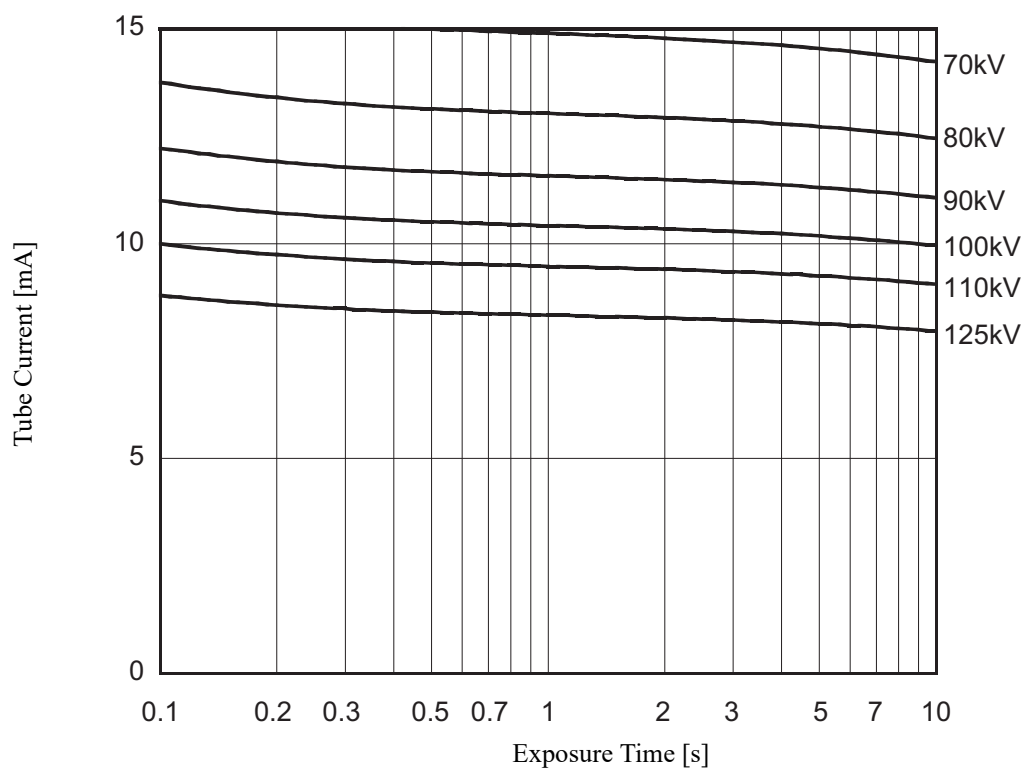
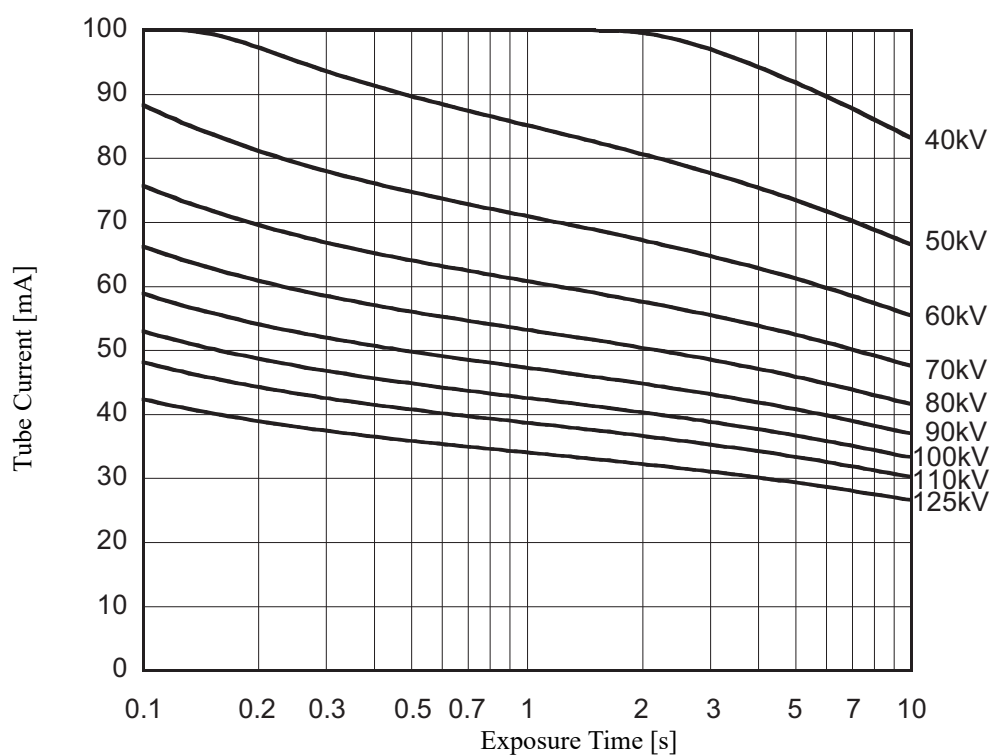


Figure 7-9 Large focus



7.3.5 Emission & Filament Characteristics (Constant Potential High-Voltage Generator)

This graph indicates typical characteristics.

Figure 7-10 Small focus (this graph indicates typical characteristics)

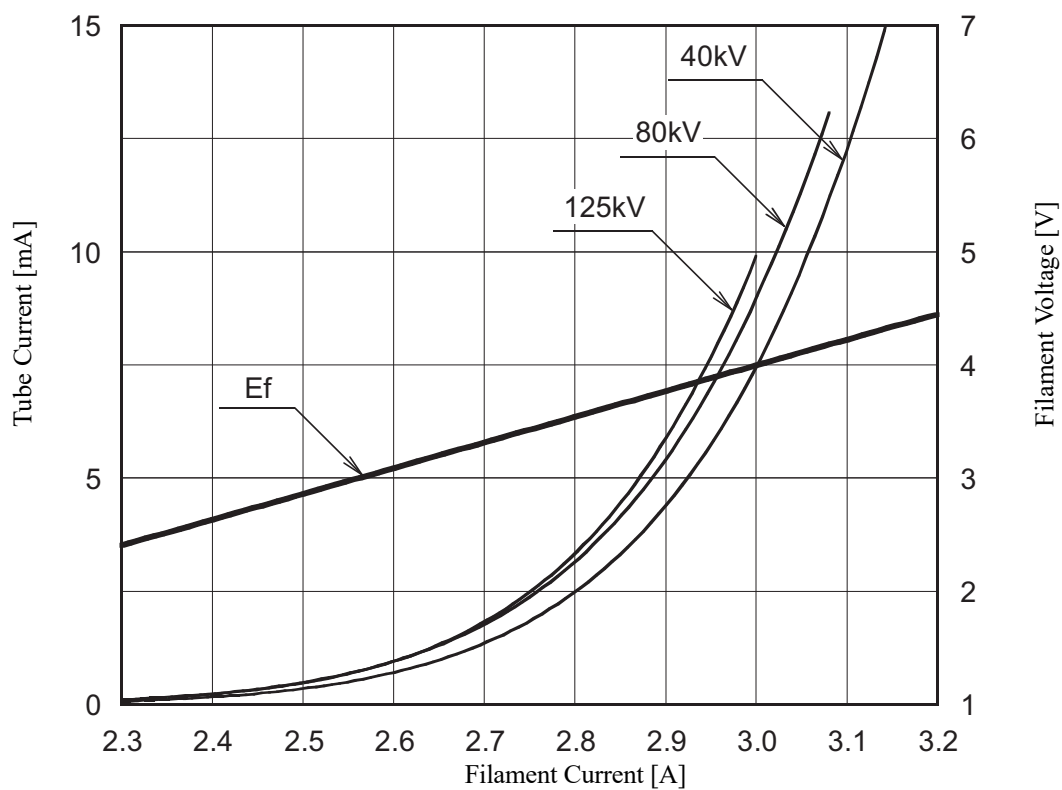
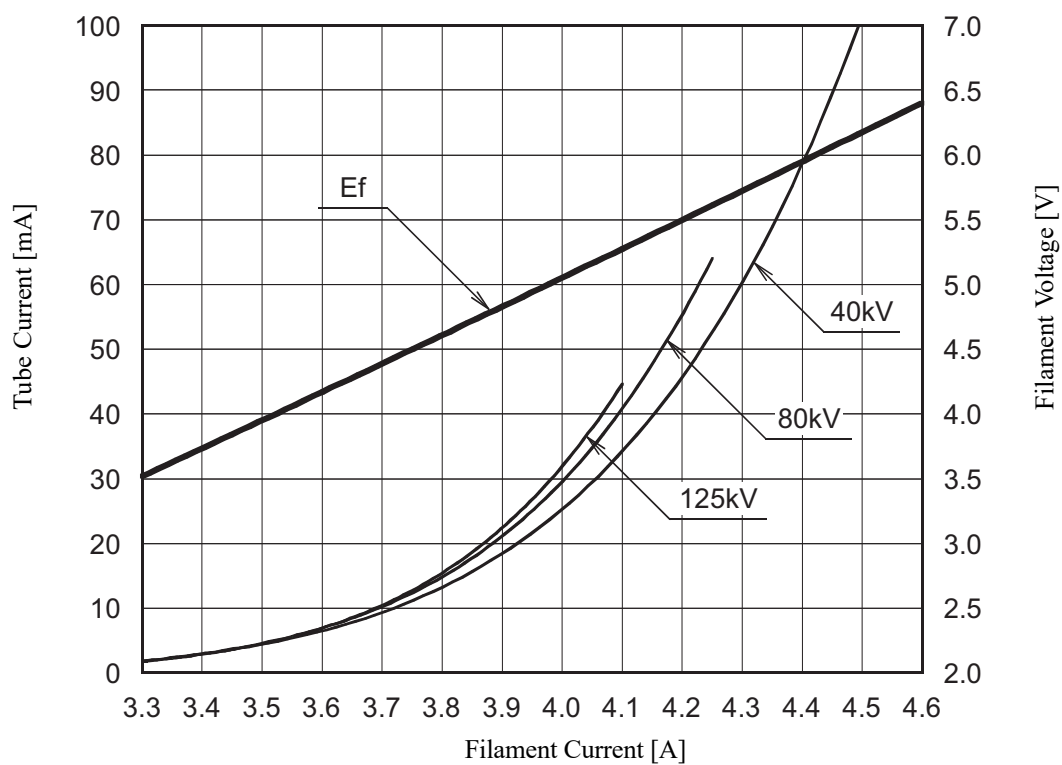
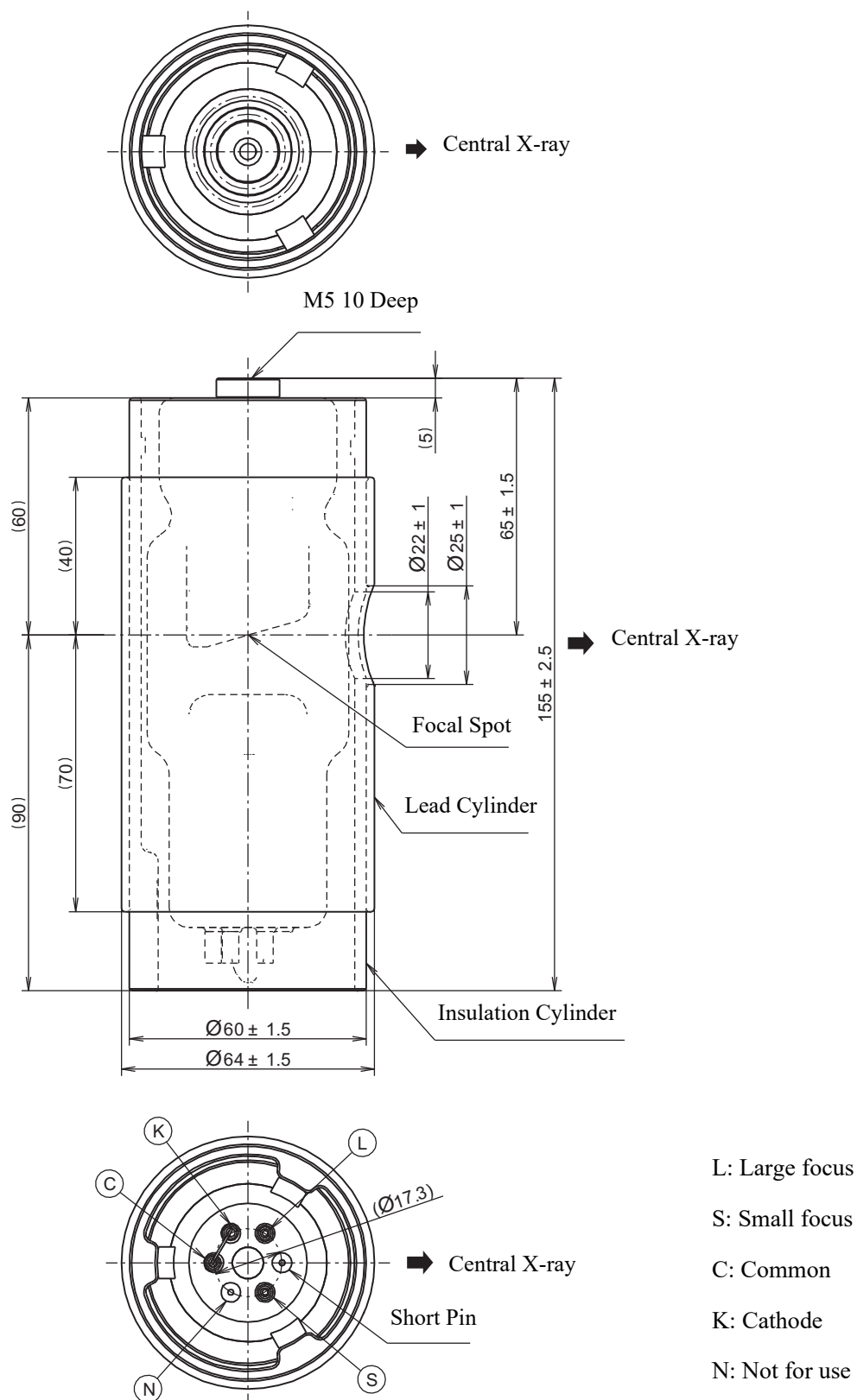


Figure 7-11 Large focus (this graph indicates typical characteristics)



7.3.6 Dimensional Outline

Figure 7-12 Dimensional outline of X-ray tube



8 EMC Guidance and Manufacturer's Declaration

The device complies with the EMC standard IEC 60601-1-2:2014+A1:2020 as well as Safety restrictions on electromagnetic radiation exposure from CE.

Intended Environments: professional healthcare facility environment (except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

WARNING

- The use of unapproved accessories may diminish device performance.
 - 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.
 - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions exposure beyond intended use 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
 - 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.
-

NOTE:

- 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.
 - Recommendations for actions that are known to affect the EMISSIONS and IMMUNITY of equipment throughout the EXPECTED SERVICE LIFE:
-

- recommendations for maintenance or service intervals;
 - service procedures to maintain effectiveness of shields and grounds;
 - precautions to take if the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas.
 - The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
 - Operation of device, in the case that the animal physiological signal is lower than the minimum amplitude or value specified in the product specifications, may cause inaccurate results.
 - Portable and mobile RF communications equipment can affect device.
- See Table 8-1, Table 8-2, Table 8-3 and Table 8-4 below.

Table 8-1

GUIDANCE AND MINDRAY ANIMAL MEDICAL DECLARATION-ELECTROMAGNETIC EMISSIONS		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not applicable	

Table 8-2

GUIDANCE AND MINDRAY ANIMAL MEDICAL DECLARATION-ELECTROMAGNETIC IMMUNITY			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT- GUIDANCE
Electrostatic Discharge(ESD) IEC 61000-4-2	±8 kV contact; ±15 kV air	±8 kV contact; ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s); ±2 kV line(s) to earth	±1 kV line(s) to line(s); ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 0% U_T ; 250/300 cycle	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 0% U_T ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:

U_T is the A.C. mains voltage prior to application of the test level.

Table 8-3

GUIDANCE AND MINDRAY ANIMAL MEDICAL DECLARATION-ELECTROMAGNETIC IMMUNITY			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz – 80 MHz	3 Vrms 0.15 MHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz	6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380–390 MHz	27 V/m	
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	
	9 V/m 704–787 MHz, 5100–5800 MHz	9 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

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

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

Table 8-4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE DEVICE			
The device is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and device as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150kHz -80MHz $d = 1.2 \sqrt{P}$	80MHz-800MHz $d = 1.2 \sqrt{P}$	800MHz-2.7GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

If device image distortion occurs, it may be necessary to position device further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

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

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

Table 8-5

GUIDANCE AND MINDRAY ANIMAL MEDICAL DECLARATION-ELECTROMAGNETIC IMMUNITY			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT - GUIDANCE
Proximity magnetic fields IEC 61000-4-39	65 A/m 134.2 kHz Pulse modulation 2.1 kHz	Not applicable	There are magnetic sensitive circuits in this device. However, due to the shielding design structure of the DR device, the nearby magnetic field interference source will not be directly close to the magnetic sensitive circuit at a distance less than 0.15 m. On the other hand, the digital radiography system is expected to be installed in the medical X-ray shielding room, and it is almost impossible for the user to close the magnetic field identification device such as the RFID card reader to the user environment. Therefore, the manufacturer considers that there are no risks affecting the basic safety and basic performance.
	7.5 A/m 13.56 MHz Pulse modulation 50 kHz	Not applicable	

Table 8-6 Cable sample

No.	Name	Cable length (m)	Shield or not	Remarks
1.	Power input cable of the whole unit (including earthing wire)	5	No	/
2.	DB9 extension cable	5	Yes	/
3.	USB cable	5	Yes	/
4.	Footswitch patch cord	3	No	/
5.	1-to-3 splitter cable	2.7	Yes	/
6.	USB2.0 extension cable	10	Yes	

