CLAROX plus

with fully digital X-ray source based on CNT nano technology

VX-100 User Manual

Ultra light

High speed driving

Wide usable

100 kV, 1 mA, 2.5 kg

CE 2195

Value Service Innovation VSI

Check the following before use;

*Troubleshooting

In instances of abnormal operation, error messages will be displayed on the Control Panel.
If a problem persists, please request assistance from the customer support information services.

E ? : An error occurred. Turn the power off, and then turn it back on. If the error persists, contact your Service Representative.

Error Code	Check Parameter	Description
E1	X-ray Generator	In the "E1", "E2" and "E9" states where power is maintained, the errors related to X-ray exposure cannot expose the X-ray. If the equipment is turned off and on after an error related to X-ray exposure occurs, X-ray exposure is performed normally.
E2		
E9		
BATT	Battery	Appears when the battery voltage is lower than the reference value during X-ray exposure. Charge the battery.
CHG		Appears when foreign matter or temporary phenomenon in the charging hole of the equipment. Check for foreign substances and connect and disconnect the charger. If it continues to connect and disconnect the charger more than 5 times, it will be performed normally. If the error code continues to occur, contact your service representative. Appears when the battery is charging. After disconnecting the battery charger from the system, start the system.
BATT		Appears when the battery level is lower than the reference value during X-ray exposure.

A problem occurred. Turn the power off, and then turn it back on. If the problem persists, contact your Service Representative.

Problem	Cause	Solution
Equipment is not turned on.	The power switch is not turned on properly.	Turn the equipment power switch off and then on again.
	Battery discharge	Charge the battery with the charger and check again.
	Battery cable is not connected properly.	Please contact your service representative.
	Battery defect	Please contact your service representative.
Control Panel is not turned on.	Defective Control Panel board	Please contact your service representative.
	Internal cable disconnection	Please contact your service representative.

No X-ray emission	Exposure Switch	Please contact your service representative.
	Internal cable disconnection	Please contact your service representative.
	Defective generator	Please contact your service representative.
X-ray emission works, but exposure is too light or completely white.	The device is positioned incorrectly.	Adjust the position of the equipment.
	The exposure time is too long.	Reduce the setup time.
	Receptor direction problem	Adjust the direction of receptor.
X-ray emission works, but exposure is too dark.	The exposure time is too short.	Increase the setting time.

* Checking for battery

1. Environment requirements for battery

(1) Storage Temperature

* Under 1 month : -10 - +45 ℃
* Under 3 month : -10 - +30 ℃
* 1 year : 25 ± 3℃
* Best Temperature : 23 ± 3℃

(2) Operating Temperature

* Charging : +10 - +45℃
* Discharging : -10 - +50℃

(3) Humidity : < 75% RH

2. Checking period for battery(Battery is a consumable component.)

-Recharge the battery every 3 months with checking the battery recharging condition.
-Recharging capacity shall be about 80%(3 level on the battery recharging indicator of control panel) for storage.
-Recharge the battery with provided adapter within 30 mins for 80%(3 level on the battery recharging indicator of control panel) recharging.
-Do not use the battery with liquid spillage or soaked.
-Dispose the battery according to a national law.

Table of Contents

1. About User Manual

This User Manual is provided to the user along with the VX-100.
This User Manual only pertains to the VX-100 and does not serve for any other products of the company. In the event of loss of or damage to this User Manual, please contact to service center of VSI Co., Ltd.
This User Manual describes the precautions and possible risks that the user should be aware of and give attention to prior to use the VX-100. Please read carefully all the precautions before you start using the device.
Please refer to the Table of Contents to easily find the information that you need.
If you have any inquiries or need more detail information on the product, please refer to the contact information or call our customer service center.

1.1 Cautions

This document contains proprietary information that is protected by copyright.
Under copyright law, this document cannot be reproduced, modified or otherwise amended without prior approval.

1.2 Quality Assurance

The contents of this document may be revised without notification.
The company will not be responsible for any consequential problems, loss or damage arising from the use of any performance specification or information that differs from the information contained in this User Manual.

1.3 Revision History

The part numbers and revision number indicated in this document represent the current version.
The revision number will not be changed even if any sub-documents are revised.
The revision number may be changed when there is a major change in part numbers or technical information in the document.

1.4 Symbols

Symbols are indicated on the exterior, packaging of the product and in this User Manual.
The symbols represent important cautions and advice to the user. Please read the following symbols carefully and be well informed of them for the use and storage of the product.

⚠	**WARNING**	This symbol represents “WARNING.” It is associated with possible matters that may harm or cause irreversible damage to the product or the patient.
⚠	**CAUTION**	This symbol represents “CAUTION.” It is associated with possible matters that may damage the product or harm the patient.

* This User Manual may differ from the actual product in terms of functionality.
* If deemed necessary, the company may make any improvement to the product to enhance its performance, without prior notification, and the company has no obligation to apply the same specification change to the products already sold.

2. Precautions

2.1 General Cautions

CAUTIONS	
1	This product is intended for use by a radiologist having received appropriate license.
2	Please read and understand the instructions carefully and then use your device.
3	Do not touch product, charger, and power plug with wet hands, otherwise, there is danger of getting electrical shocks.
4	During cleaning process of product, do not use wet wiping clothes, or spray. Also, please only do cleaning after separating batteries from device.

2.2 General Prohibitions

PROHIBITIONS	
1	Do not use with unspecified AC/DC adapter.
2	Do not use it out of intended use.
3	Do not use without mounting the cone.
4	Do not disassemble the device.
5	Do not use the device outside of the significant zone of occupancy.
6	Do not use on patients who known to be or possibly pregnant.

2.3 General warnings

WARNINGS	
1	Electrical circuits inside the equipment use voltages which are capable of causing serious injury or death from electric shock. To avoid this hazard, operators should never remove any of the cabinet covers.
2	This X-ray device is not waterproof. Water, soap, or other liquids, if allowed to drip into the equipment, can cause electrical short circuits leading to electric shock and fire hazards. If liquids should accidentally spill into the system electronics, do not connect the power cord to a supply connection or turn the system on until the liquids have dried or evaporated completely.
3	This x-ray device may be dangerous to patient and operator unless safe exposure values are used and correct operating procedures are observed.
4	The other equipment may malfunction due to the electromagnetic waves generated by this device. This device may malfunction due to electromagnetic interference generated by other equipment. Do not use it adjacent to other equipment or load other equipment do.
5	Only use the AC/DC adapter specified by the manufacturer to charge. There is a risk of fire or explosion if unspecified AC/DC adapters are used. And, it should be placed out of the patient's reach (outside the patient environment) during charging using the AC/DC adapter.
6	Do not connect the power cord to supply mains with wet hands.
7	Do not use this device if the cone or main unit is broken or damaged. Using damaged main unit or damaged cone may be exposed to unwanted X-ray.
8	Always use the cone when using the device. If used without a cone, it may be exposed to unwanted X-radiation.
9	This device must be used by the intended user. Patients and users may be at risk from a variety of hazards when using the device by someone other than the intended user.
10	If intentionally ignore the cautions, warnings, and safety signs specified in this manual, patient and user may be at risk from various hazards.

11	To prevent the device from falling down, it is necessary to hold the device with both hands. Using a damaged device due to falling may expose the patient or user to unwanted X-ray radiation.
12	No modification of this equipment is allowed. If the product is modified or used for any purpose other than those specified in this User Manual, VSI will not be responsible for the safe operation of the VX-100.
13	Please ensure not to exceed X-ray exposure dose required for image diagnosis.
14	When using this device, if any abnormalities are found with the patients, please stop using the device, and ensure the safety of patients.
15	While using, if you suspect of breakdowns such as oil leakage, please turn off power immediately, and contact the closest customer support center.
16	When patients with a pacemaker are in radiograph successively, could result in malfunction of the pacemaker.
17	Battery replacement must only be carried out by an authorized person.
18	When using the device, care must be taken to ensure that the cone does not come into contact with the patient's skin.
19	This device should only be used within an X-ray shielding environment.
20	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.
21	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.
22	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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
23	Refer to Section 7 for EMISSIONS class and group and IMMUNITY TEST LEVEL.

3. Appearance and Specifications

This device is a portable X-ray imaging device used to diagnose by generating and controlling X-rays. It is structured to be easily moved to other places.
This device is composed of operation panel, high voltage generator (including X-ray tube), battery, etc. It does not include Detector, A/D Convert, image software, and computer for image output.

No.	Item	Qty	Note
1	Main unit	1	-
2	Cone(For receptor)	1	Attached to main unit
3	Adaptor	1	-
4	User manual	1	-
5	Cradle	1	-

3.1 Intended Use

VX-100 General purpose Portable X-ray equipment is intended to be used by trained radiologist technicians as an radiography x-ray source for producing diagnostic x-ray images using image receptors. Its use is intended for chest X-ray imaging.
The VX-100 should be used with an X-ray detector, and this detector has a digital type and a film type. But the X-ray detector is not included in the VX-100 package.

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

Ensure the adapter is unplugged before attempting to clean. To make sure that power is off for VX-100 while cleaning. Use a non-alcohol based disinfectant only - wipes or a cloth dampened with liquid or spray. Do not use acetate or acetone cleaning solutions to prevent a damage of plastic enclosures.
VX-100 and the accompanying adaptor are not designed to be subjected to any kind of sterilization procedure. VX-100 is not designed to be used to sterilize anything else.

3.2 Specification

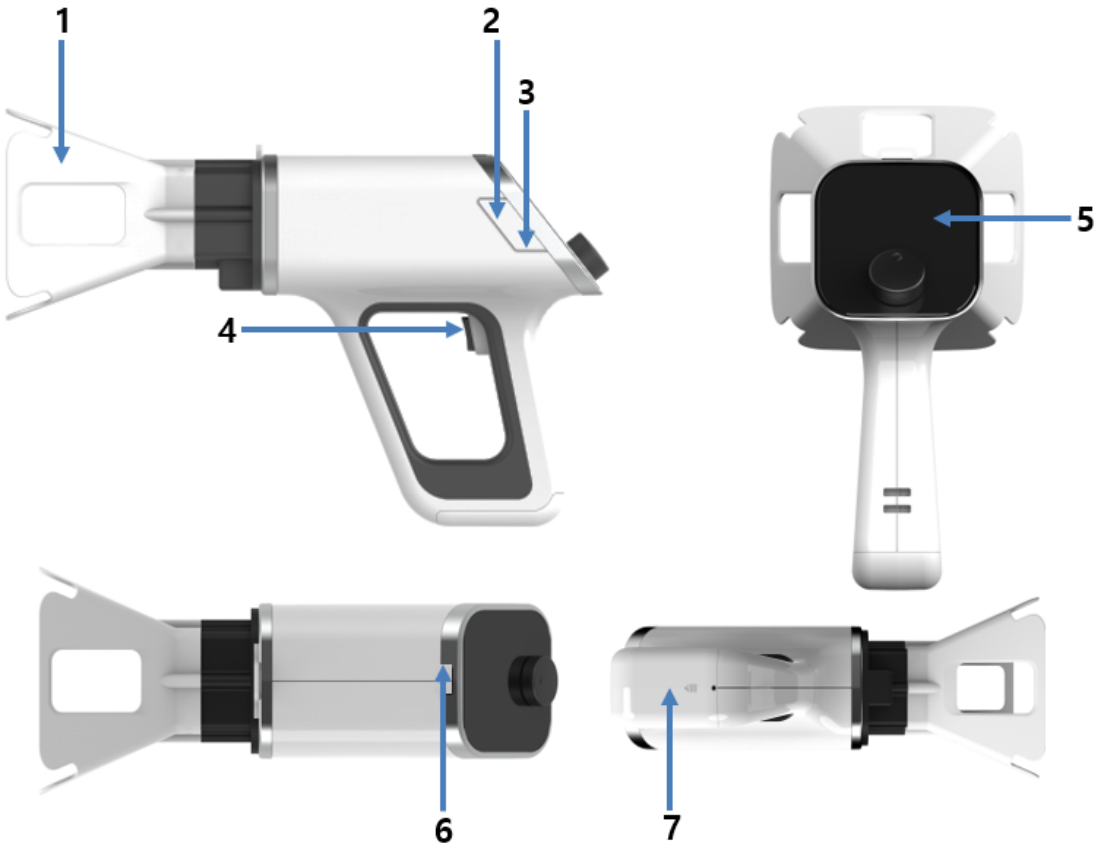
<table>
<tr><td>Classification</td><td>Class IIb (Annex IX, Rule 10, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)</td></tr>
<tr><td>Model</td><td>VX-100</td></tr>
<tr><td>Protection type from electrical shock</td><td>- Class Ⅱ equipment (Charging mode)
- Internal power source equipment (Exposure mode)</td></tr>
<tr><td>Rated power of AC/DC adapter</td><td>- Input: 100-240 Vac, 50/60 Hz, 0.4 A
- Output: 25.5 Vdc, 0.9 A</td></tr>
<tr><td>Rated power of re-chargeable battery</td><td>22.2 Vdc, 1,460 mAh</td></tr>
<tr><td>Power input</td><td>0.4 A (At charging mode)</td></tr>
<tr><td>Tube voltage</td><td>70 kV – 100 kV
(5 kV step)
*Loading condition
Min. 70 kV, 0.1s
Max. 100 kV, 1.0s</td></tr>
<tr><td>Tube current</td><td>1.0 mA (Fixed)</td></tr>
<tr><td>Exposure time range</td><td>0.10 s - 1.0 s</td></tr>
<tr><td>Focal spot size</td><td>0.6 mm (complied with IEC 60336)</td></tr>
<tr><td>Permanent filtration</td><td>3.5 mmAl 70kV / HVL 2.5 mmAl</td></tr>
<tr><td>Anode angle</td><td>0°</td></tr>
<tr><td>Thermal Characteristics</td><td>1.2 kJ</td></tr>
<tr><td>Maximum Anode Heat Dissipation Rate</td><td>100 W</td></tr>
<tr><td>Mode of operation</td><td>Continuous operation(Depend on duty rate)</td></tr>
<tr><td>Expected service life</td><td>5 years</td></tr>
<tr><td>Essential performance</td><td>*Accuracy of loading factors
-Tube voltage accuracy: not greater than 10 %
-Tube current accuracy: not greater than 20 %
-Exposure time accuracy: ± (10 % + 1 ms)
-Reproducibility of the radiation output: The coefficient of variation of measured values of air kerma: less than 0.05</td></tr>
<tr><td>Dosimetric indications</td><td>
<table>
<tr><th>Tube voltage</th><th>Tube current</th><th>Exposure time</th><th>Air Kerma (± 20 %)</th></tr>
<tr><td rowspan="2">70 kV</td><td rowspan="2">1 mA</td><td>0.1 s</td><td>0.002 mGy</td></tr>
<tr><td>1.0 s</td><td>0.021 mGy</td></tr>
<tr><td rowspan="2">100 kV</td><td rowspan="2">1 mA</td><td>0.1 s</td><td>0.005 mGy</td></tr>
<tr><td>1.0 s</td><td>0.054 mGy</td></tr>
</table>
</td></tr>
<tr><td>Radiation dose delivered to the T</td><td>
<table>
<tr><td>Tube voltage</td><td colspan="2">100 kV</td></tr>
<tr><td>Tube current</td><td colspan="2">1 mA</td></tr>
<tr><td>Exposure time</td><td>0.1 s(Min.)</td><td>1.0 s(Max.)</td></tr>
<tr><td>Radiation dose</td><td>0.0051 mGy</td><td>0.054 mGy</td></tr>
</table>
</td></tr>
</table>

3.3 Safety Standards

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012 EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3:2008+A1:2013 EN 60601-1-3:2010	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010+A1:2013 EN 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard : usability
IEC 60601-2-28:2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54:2009+A1:2015	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 62304:2008 EN 62304:2006+AC:2008	Medical device – Software life cycle
IEC 62366:2007+A1:2014 EN 62366:2008	Medical devices - Application of usability engineering to medical devices

3.4 Appearance

3.4.1 Main unit



No.	Name	Description
1	Cone	When irradiating X-rays, limit the exposure range of the beam.
2	Maintenance port	Port used to download firmware by only authorized engineer (⚠Use only with IEC 60950-1 certified PC.)
3	Adapter connection port	Port for connecting the charging adapter
4	X-ray exposure button	Button to exposure X-ray
5	Control Panel	Set exposure conditions and display battery charge and operation status
6	Power button	Power ON / OFF button
7	Battery cover	Cover to open when replacing the battery

3.4.2 Cradle

Name	Description
Cradle	Used to mount the device when not in use.

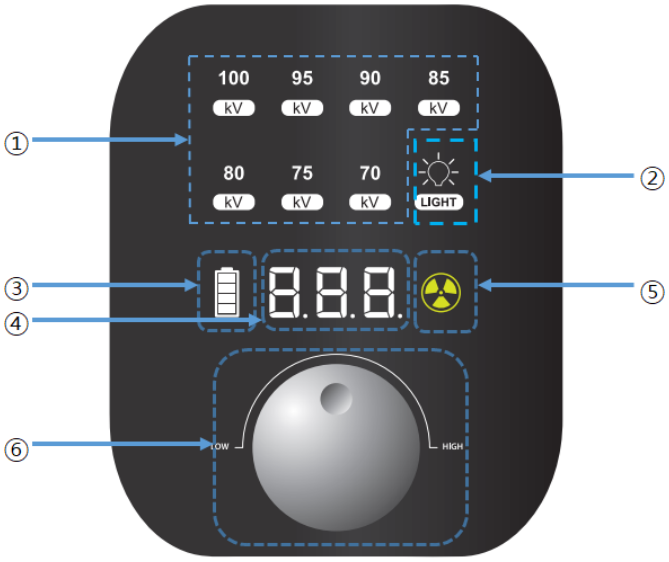
3.4.3 Wrist strap

Name	Description
Wrist strap	When using the device, it is used by hanging the strap on the wrist, and it prevents the device falling.

3.4.4 AC/DC adaptor

Name	Description
AC/DC adapter	It is used to charge the device, and the device cannot be operated when charging.

3.4.5 Control panel

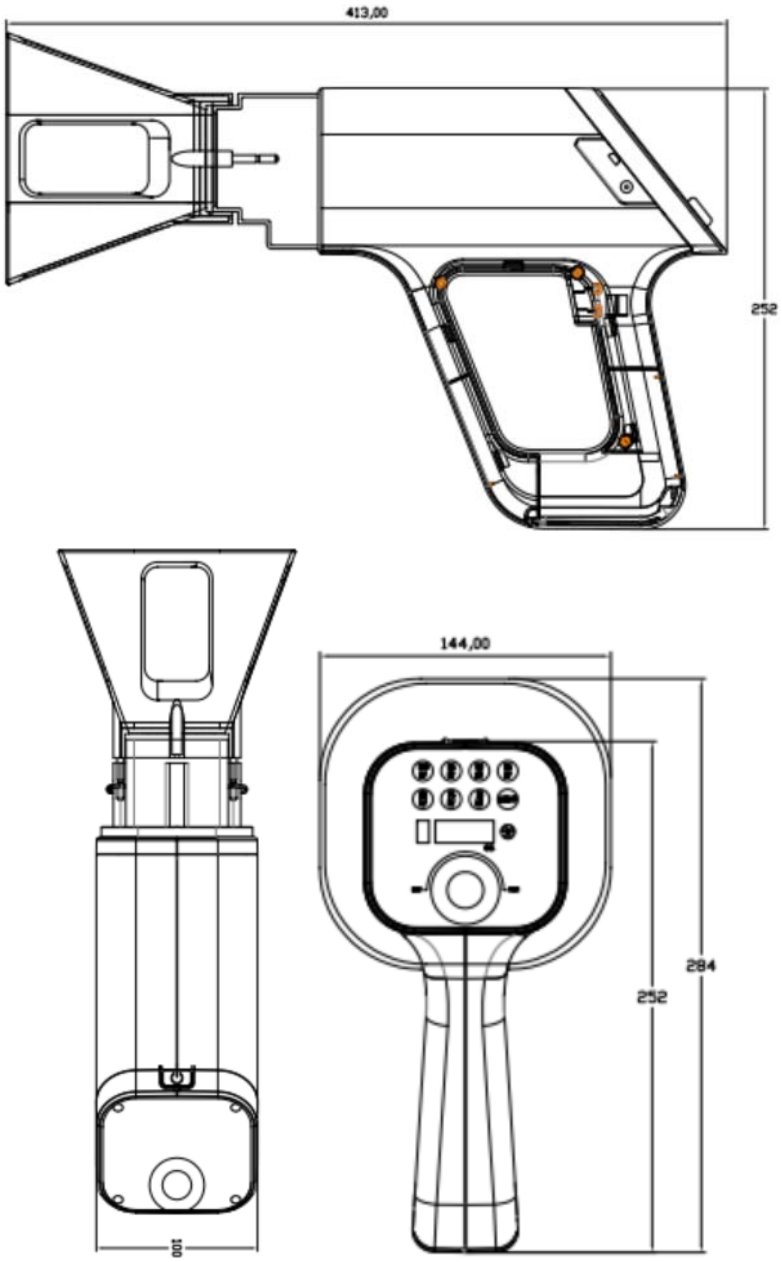


No.	Name	Description
1	Tube voltage indicator	Display the sett tube voltage.
2	Light field indicator	The user can turn the X-ray field lamp ON/OFF and display the ON/OFF status.
3	Battery level indicator	The remaining battery charge is displayed in 4 stages, and in the 1st stage, it blinks and X-rays are not irradiated.
4	Exposure time indicator	The time is set according to turn the jog dial.
5	X-ray exposure indicator	It is displayed in green when it is ready, and in yellow when X-rays are irradiated.
6	Jog dial	Used to turn or press the dial used to set the exposure conditions.

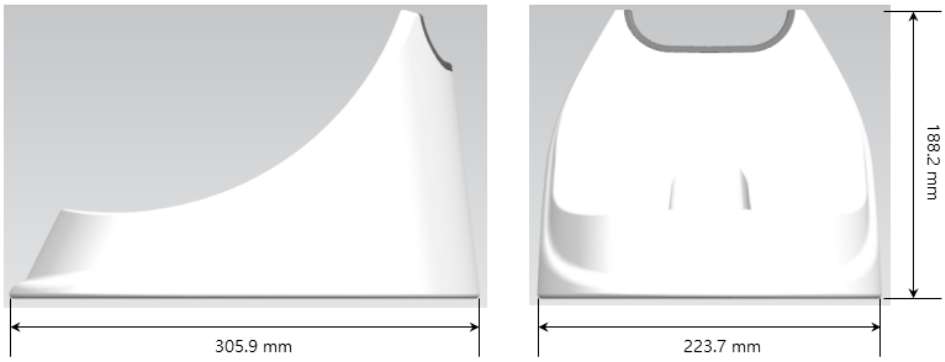
⚠	Cone should not be placed in a direction other than patient body.

3.5 Dimension

3.5.1 Main unit
- size: 413 mm(W) x 144 mm(D) x 284 mm(H)
- weight: 2.5 kg

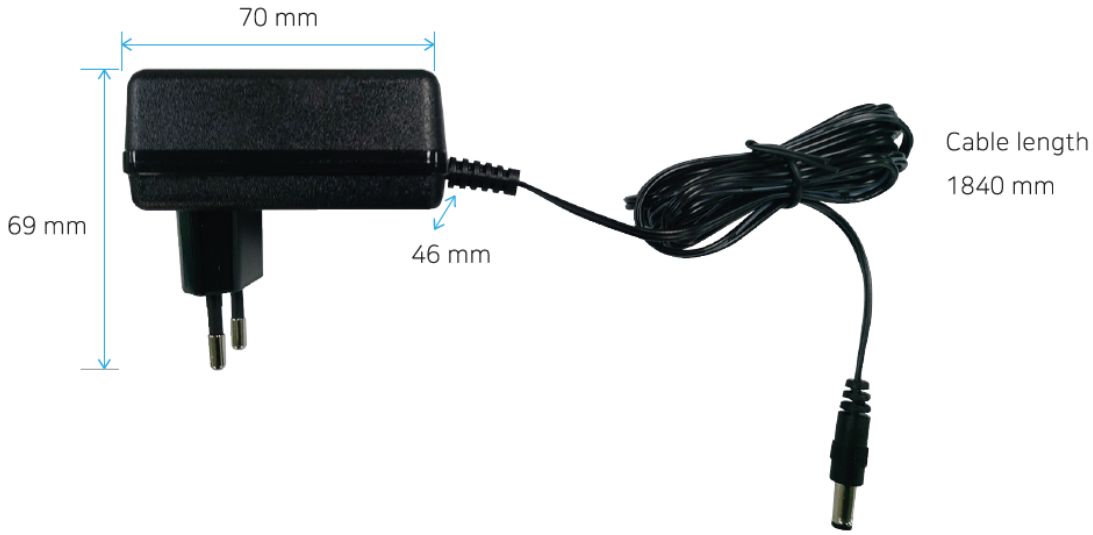


3.5.2 Cradle
- size: 305.9 mm(W) x 223.7 mm(D) x 188.2 mm(H)
- weight: 2.3 kg



3.5.3 Wrist strap
- size: 200 mm(L) X 10 mm(W)

3.5.4 AC/DC adaptor
- size: 46 mm(W) x 69 mm(D) x 70 mm(H), code length: 1840 mm



3.6 Operating condition

- Temperature: +10 ℃ - +40 ℃
- Related Humidity: 30 %R.H. - 90 %R.H. (Non-condensing)
- Atmospheric pressure: 80 kPa - 106 kPa
- Altitude: Less than 2,000 m

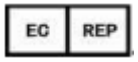
3.7 Storage and transportation condition

- Temperature: -40 ℃ - +70 ℃
- Related Humidity: 5 %R.H. - 95 %R.H. (Non-condensing)
- Atmospheric pressure: 76 kPa - 106 kPa

3.8 Symbols

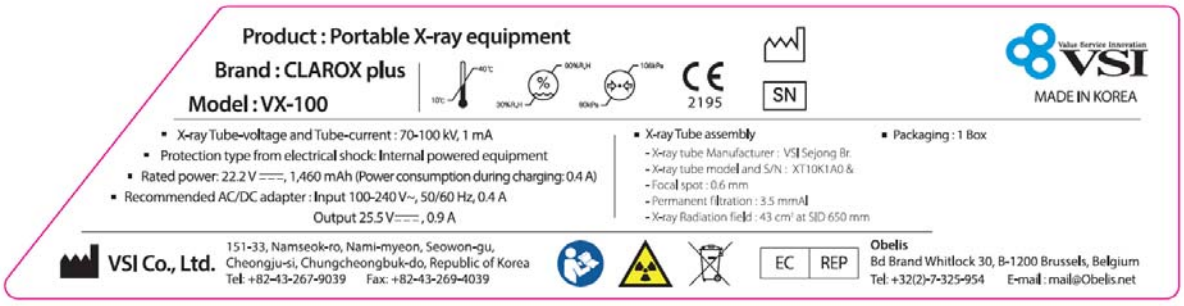
The following are descriptions of the symbols located on the outside and packaging of the product. Please read carefully before using the product.

No	Symbol	Description	Location
1		Serial Number	Product Label
2		Date of manufacture	Product Label
3		Follow instructions for use	Product Label
4		Note	User manual
5		General Caution, Warning (safety sign)	User manual
6		Warning: Electrical	Inside of equipment
7		General Prohibition (safety sign)	User manual
8		Alternating current	Product Label
9		Direct current	Product Label
10		Keep dry	Package
11		Keep away from sunlight	Package

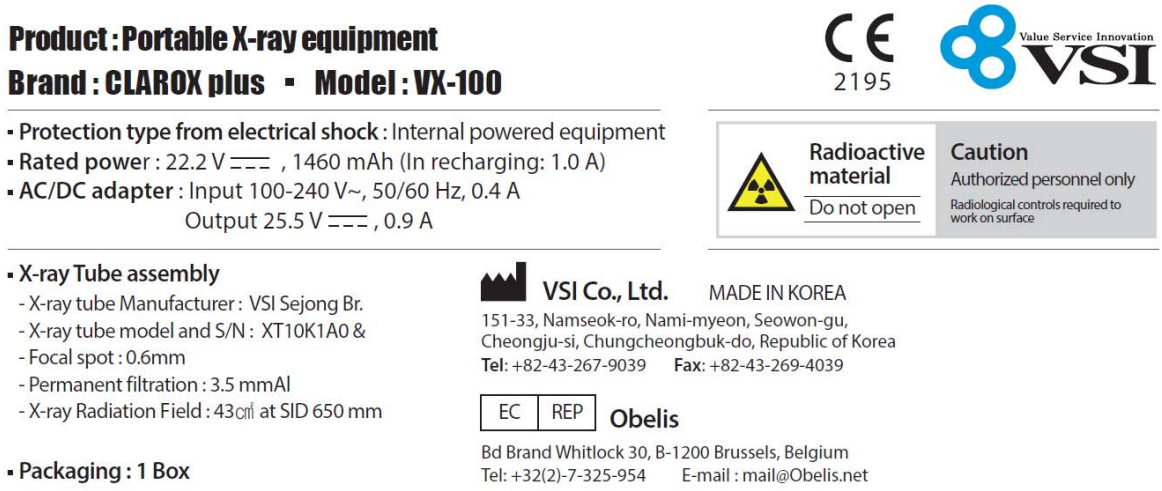
12		EC representative	Package Product Label
13		Manufacturer	Package Product Label
14		Storage temperature range	Package Product Label
15		Storage humidity range	Package Product Label
16		Storage Atmospheric pressure range	Package Product Label
17		CE marking, Complies with European medical devices directive	Package Product Label
18		WEEE Mark	Package Product Label
19		Warning: Hight voltage	Inside the device
20		Radiation hazard	Product Label Product enclosure

3.9 Labels of Main unit and packaging

1) Main unit
Label location: On the Bottom of equipment

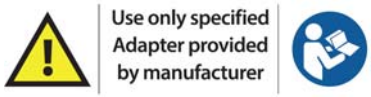


2) Packaging
Label location: On the surface of the packaging box



3.10 Label of AC/DC adapter connector

Label location: Near the AC/DC adaptor connector



3.11 Label of Radiation hazard (Physiological effects)

Label location: On the bottom right of front of the device and the surface of package

3.12 Label of re-chargeable battery

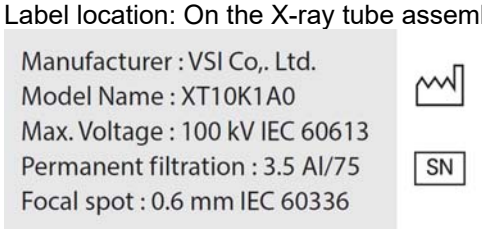
Label location: On the battery pack

3.13 High voltage tank

Label location: On the high voltage tank house(Inside the device)

3.14 X-ray tube assembly

Label location: On the X-ray tube assembly(Inside the device)



4. How to use (Start-up and Shutdown procedure)

4.1 Frequently used functions

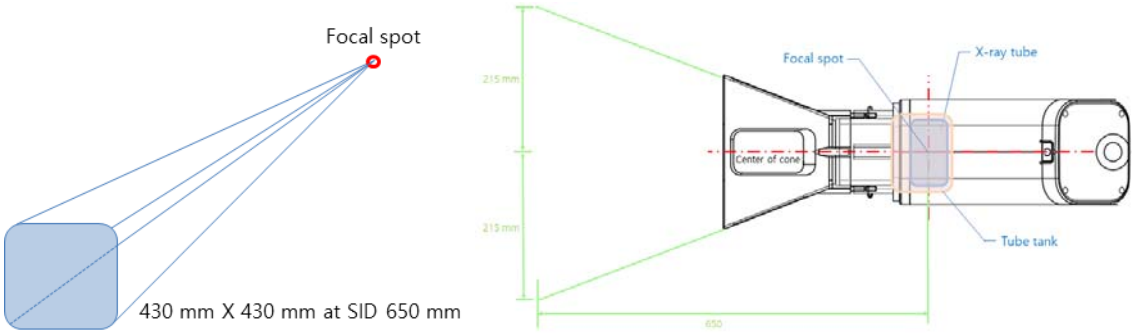
- Connecting “Charging cable”
- Checking “Charging condition”
- Mounting “Cone”
- Pushing “ON/OFF button”
- Setting “Exposure time”
- Setting “Tube voltage”
- Checking “Display LCD”
- Pushing “X-ray exposure button”

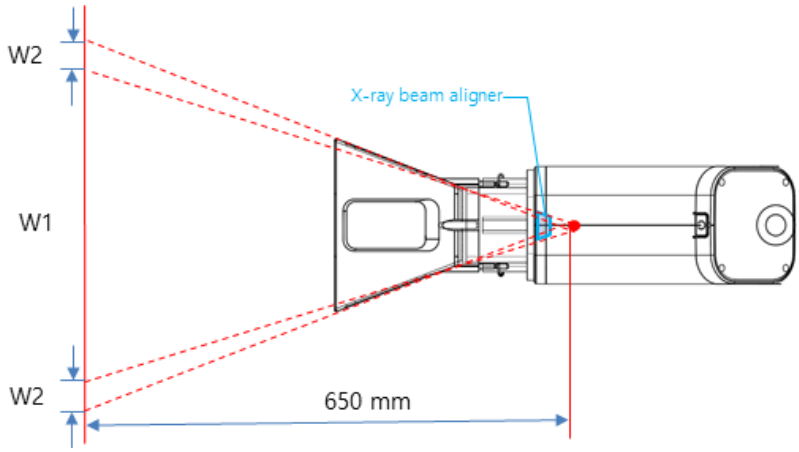
4.2 Pre-procedure

1) The operator of VX-100 must be a radiologist having received appropriate license.
2) Understand warnings, cautions and user manual.
3) Check the Charging condition of battery before use. If the battery is not charged enough, charge the battery using AC/DC adapter provided by the manufacturer. (While charging mode, VX-100 could not be used.)

⚠	Only the adapter provided by the manufacturer can be used. The plug of adapter is used as the isolation means. Do not position the device so that it is difficult to operate the disconnection device. Disconnecting the plug of the AC/DC adapter from the wall power supply disconnects the device from the mains. The plug of the AC/DC adapter should not be installed in a place where it is difficult to disadvantage the wall power. Charging the device should be done outside of the patient environment.

4) Establish significant zone of occupancy as following and puts individual defense tool such as apron in this area and diagnostic area in radiography.
5) When the power button is pressed for 2 seconds, check if the control panel is activated at the same time as the beep sounds 3 times.
-The initial display value indicates the last set value.
-If there is no Jog dial and X-ray exposure button operation for 10 minutes, the power is automatically turned off to save battery power.
6) Check that there is no error message on the exposure time display section.



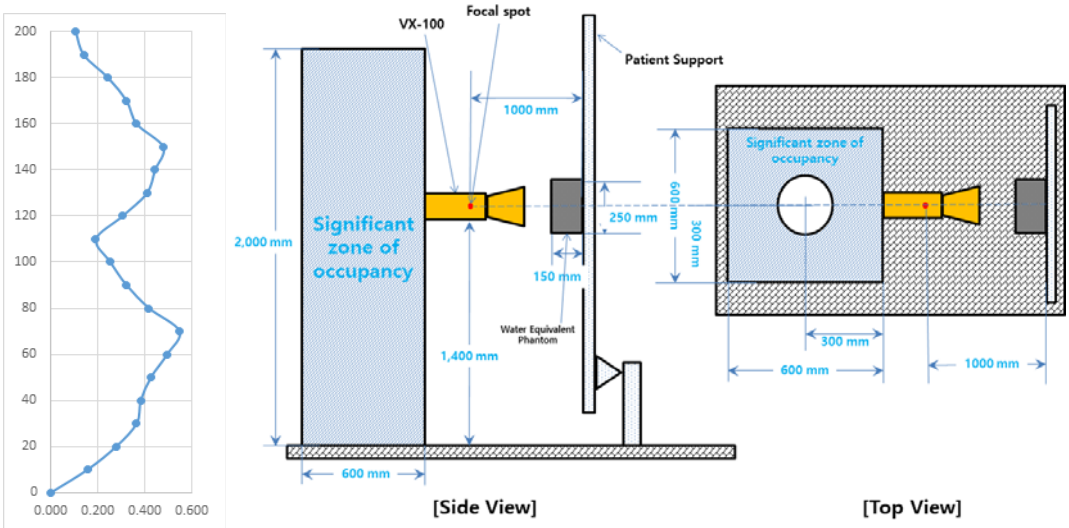


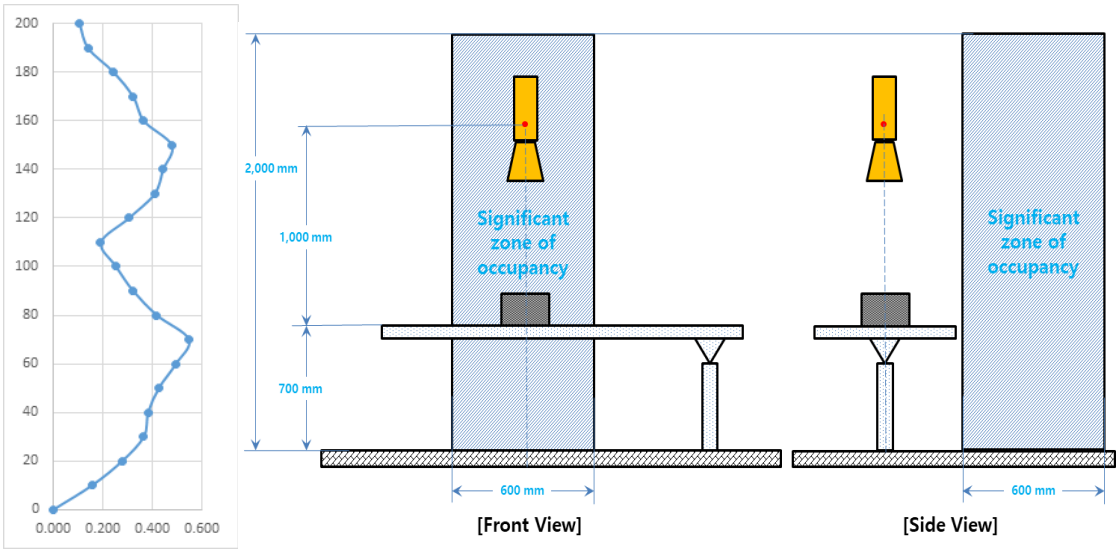
$$\tan\theta_1 = \frac{w_{1/2}}{H} \qquad w1/2 = \tan\theta_1 * H$$

$$\tan\theta_2 = \frac{w_1/2 + w_2 + F/2}{H} \qquad w_2 = H(\tan\theta_2 - \tan\theta_1) - F/2$$

F= Focal spot (0.6 mm)

[Extra-focal radiation area: The geometry of the X-ray beam aligner in front of the tube tank is designed so that the end of the cone edge from the X-ray focus is aligned in almost straight line to reduce extra-focal radiation. Therefore, the area of extra focal radiation over the X-ray field(W2), occurring at a distance of 650 mm from the focal spot, is 2 mm.]





- The case thickness of water equivalent phantom is less than 10 mm, the material of it is PMMA. The size of it is 250 × 250 × 150 mm^3.
- In this area, the all performance of VX-100 can be used.
- Operator Max. Dose rate of the significant zone of occupancy: 0.548 mGy/h

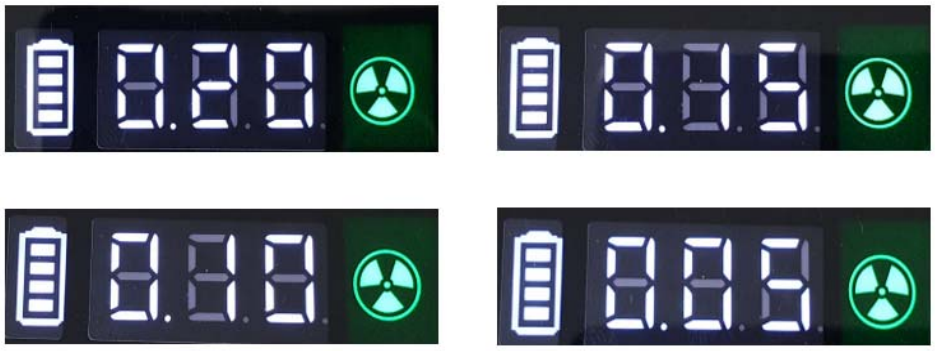
4.3 Operation procedure

⚠	Always use the device with the cone attached. The cone is fixed to the main unit.

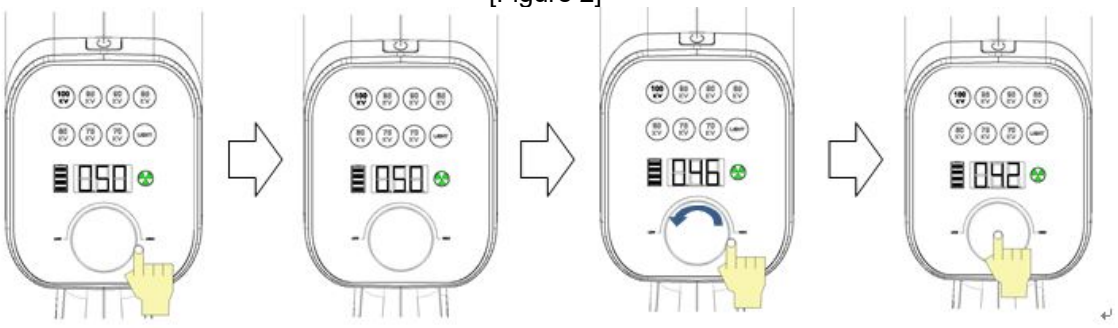
1) If the Jog dial is pressed while the Control Panel is activated, the beep sounds once and the currently set tube voltage and exposure time is displayed. See the below [Figure 1].

[Figure 1]

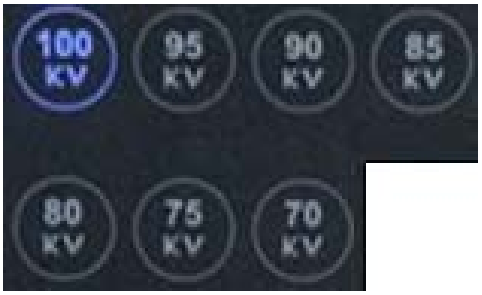
2) Turn the jog dial to determine the exposure time[Figure 2]. And Turn the jog dial to determine the tube voltage. [Figure 3]. When you adjust the exposure time with jog dial, the time on the control panel is blinked. After setting the desirable exposure time, press the jog dial once to irradiate X-ray with the desired exposure time. Completely set exposure time is not blinked on the control panel.



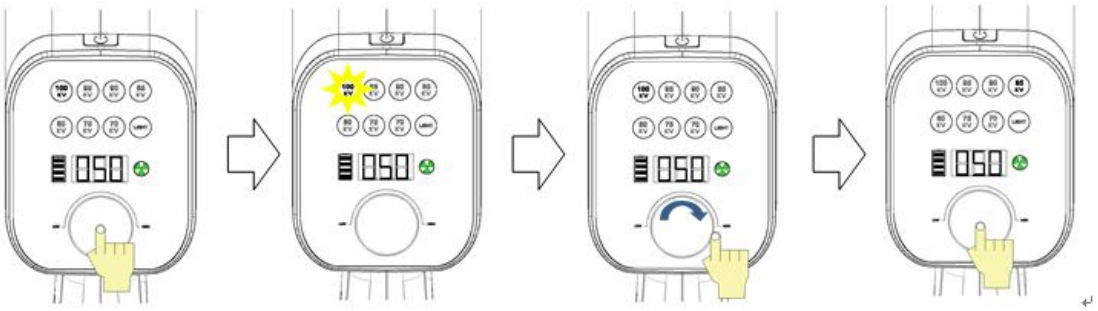
[Figure 2]



[Figure 2]

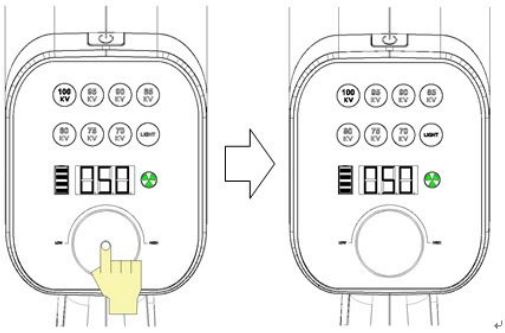


[Figure 3]



[Figure 3]

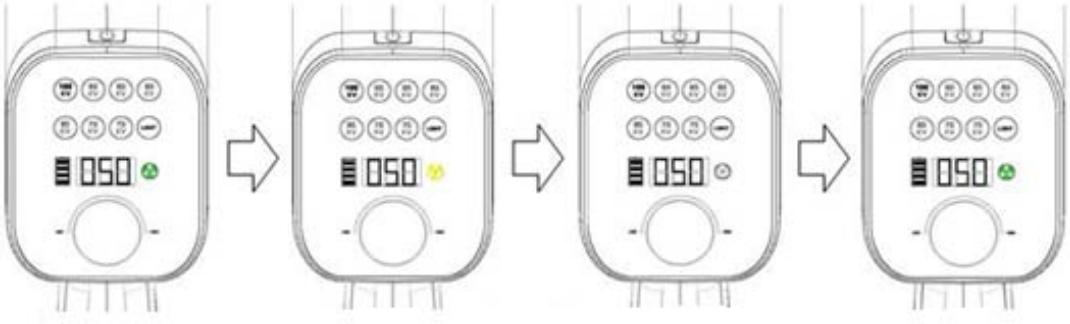
3) How to turn on/off the light field indicator
- Power is ON, and if you press JOG DIAL once, the field is turned on.
- “LIGHT” turns on the control panel. When 3 seconds elapse from the ON state, it will automatically turn off.
- Press JOG DIAL once to turn off the light field indicator while the it is on.



4) After all the settings are completed, the device's target area is accurately positioned and the X-ray film or detector is placed in the patient’s body part.

5) Set the location intended to exposure X-ray. The focal spot is aligned in the center of this beam area. The plane of the intended location should be perpendicular to the cone. And the image receptor is positioned in the patient’s body part.

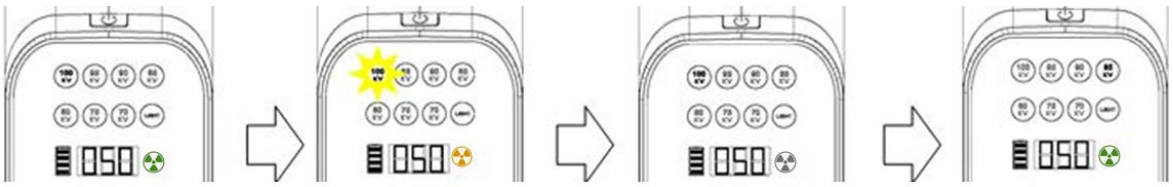
6) When the X-ray exposure display is displayed in green after shooting preparation is completed, pressing the X-ray exposure button irradiates the X-ray and the beep sounds once, and the X-ray exposure display is displayed in yellow. At this time, do not let go of the X-ray exposure button.



7) If an error message is displayed on the display, the X-ray is not irradiated even if the X-ray exposure button is pressed, and measures such as A/S and charging must be taken.

8) When the charging adapter is connected while the power is ON, the power is OFF, and when the power button is pressed, the battery charging status is displayed for 10 seconds.

9) For the next X-ray irradiation, the X-ray irradiation display part is displayed in green after the specified cooling time according to the Duty Rate, and is ready. If the X-ray exposure display is green after the preparation time, exposure is possible.



10) Battery status
- Battery charge level is displayed in 4 steps.

- Flashes when charging is required.

- If the charging adapter is connected in the power ON state, X-ray irradiation will not be performed and the power will be OFF. At this time, if you press the power button once, you can check the battery charging status, and the charging status is displayed for 10 seconds.

11) Auto power off: If there is no operation of the jog dial and irradiation button switch for 10 minutes, the power is automatically turned off.

⚠	If the image is not satisfactory because the dose of X-Ray is excessive or deficient, adjust the tube voltage and exposure time turning the Jog dial. Blurring of the X-ray image may occur due to movement of the patient or operator. To reduce the image degradation, minimize the movement of patient and operator when X-ray is irradiated. (The Max. exposure time is 1.0 s, and the max. tube voltage is 100 kV, care should be taken not to move the patient for a while, and the operator should be careful not to move.)

4.4 Storage and Cleaning after use

1) Press “ON/OFF button” to turn off VX-100. When the power button is pressed for 2 seconds, the beep sounds twice and the Control Panel is deactivated.
2) Check the charging condition of battery after use. If the battery is not charged enough, charge the battery using the AC/DC adapter provided by the manufacturer.
3) Equipment should not be disassembled for cleaning, only the exterior should be wiped.
4) Ensure the adapter is unplugged before attempting to clean. To make sure that power is off for VX-100 while cleaning. Use a non-alcohol based disinfectant only - wipes or a cloth dampened with liquid or spray. Do not use acetate or acetone cleaning solutions to prevent a damage of plastic enclosures.
6) After cleaning, store the equipment in a place isolated from dust or moisture or in a case provided.

	When you use ordinary adapter, the battery can be damaged. Only the adapter provided by the manufacturer should be used. Disconnect the adapter cable from the adapter connection port after charging fully.

	Do not use too wet cloth, and do not let water or liquid enter the unit.

7) Store the device in a designated safe place. Do not store in the places mentioned below.

	Where water comes in contact Where there is a risk of warping, vibration, or shock Where chemicals or gas are generated Outside the specified storage environment

4.5 Procedure allowing measurement of the radiation quantity

- Refer to the figure [Significant zone of occupancy]
- Place the dosimeter(μGy) on the surface of the center of the one side of the water equivalent phantom(The phantom should be filled with pure water free of bubbles.).
- Place the VX-100 on the surface of the center of the opposite side of the water equivalent phantom.
- The center should be aligned with the focal spot of VX-100.
- Setting of VX-100: 1.0 s of exposure time
- Press the exposure button and measure the dose rate of the dosimeter.
- This measured RADIATION QUANTITY is reduced by low setting of exposure time and increment of SSD. And it can reduce the patient exposure dose.

5. Technical Data

5.1 Specifications

- Electrical classification(Battery): Internally powered equipment
- Electrical classification(AC/DC Adaptor): Class II
- MDD(93/42/EEC) classification: Annex IX, rule 10, Class IIb
- Mode of operation: Continuous operating
- Radiation quantity: Max. entrance surface dose 6.319 mR at 100 kV / 1.0 mA / 1.0 s / SID 650 mm exposure condition.
- For use in environments where no flammable anesthetics and/or flammable cleaning agents are present; non-alcohol based disinfectant only-wipes or cloth dampened with liquid/spray

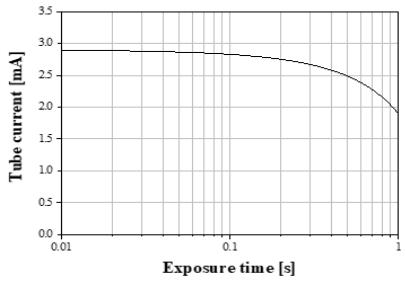
5.2 X-ray exposure control

- Tube voltage range: 70 kV - 100 kV
- Exposure time range: 0.10 s - 1.0 s

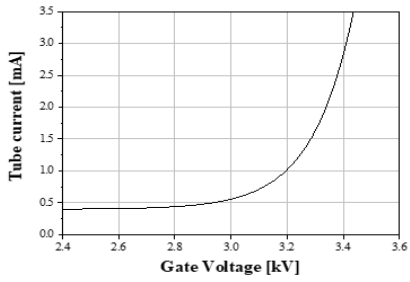
5.3 X-ray tube assembly

- X-ray target material: Tungsten
- Permanent filtration: 3.5 mmAl / 75 kV IEC 60522:2010
- Tube voltage range: Max. 110 kV
- Tube current range: Max. 1.2 mA
- Focal spot size: 0.6 mm
- Type: stationary
- Anode angle: 0°
- Anode heat storage capacity: 1.2 kJ
- Maximum Anode Heat Dissipation Rate: 100 W
- Nominal Radiographic anode input power according to IEC 60613:2010: 0.1 kW
- X-ray tube Characteristic curve (X-ray tube Single Load Rating)

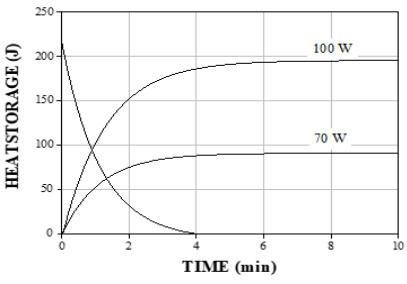
Maximum rating chart



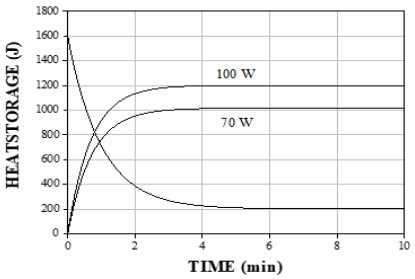
Emission characteristics



Heating and cooling curves of the X-ray tube



Heating and cooling curves of X-ray tube housing assembly



5.4 High voltage tank

- Tube voltage: 100 kV constant potential
- Tube current: 1 mA direct current

5.5 X-ray exposure area

- Type: Square
- Source to Image receptor Distance (SID): 650 mm
- X-ray field size: 430 mm X 430 mm at SID 650 mm

5.6 Re-chargeable battery

- Model name: FB703562-061PBTC
- Type: Li-ion polymer Battery
- Rating: 22.2 Vd.c (Charging voltage 25.2 Vd.c)
- Capacity: 1,460 mAh
- Size: 66(Length)×42(Height)×39(Width) mm^3

5.7 AC/DC adapter Specification

- AC/DC adapter provided by VSI is a part of VX-30.
- Model name: FY2550900
- Rated input: 100-240 Va.c., 50/60 Hz, 0.4 A
- Rated output: 25.5 Vd.c., 0.9 A

5.8 Software for VX-100

- Type: Built-in
- S/W name: ClaroxV100ControlFirmware
- S/W version: V1.0.0

5.9 Extra accessory

- Cradle
- Wrist strap

5.10 Minimum requirement for digital X-ray image receptor

- Min. resolution: more than 1000
- Min. size: more than 430 mm × 430 mm
- Max. pixel pitch: less than 300 μm

5.11 Protection against Residual Radiation

- To avoid residual radiation caused by using of VX-100, the operator should stay in the Significant zone of occupancy described in section 4.2 of this user manual and the alinement between the patient and VX-100 should be kept like [Figure 6].

5.12 Metrics about imaging performance

- To keep the imaging performance, The following parameters should be measured once for every year and performed by an authorized person or manufacturer.

1) Tube voltage: measurement point 70-100 kV / Tolerance ± 10 %
2) Tube current: measurement point 1 mA / Tolerance ± 20 %
3) Exposure time: measurement point 0.10 s, 1.0 s / Tolerance ± (10 % + 1 ms)
4) Leakage radiation

5.13 Characteristics of the X-ray tube voltage waveform

- The rising phase: rise up to 100 kV within 20 ms, and kept it before push the exposure button.
- The falling phase: fall down to 0 kV within 5 ms after push the exposure button.
- The shape and amplitude of the X-ray tube voltage ripple: ripple is less than ± 4 % while 100 kV is maintained.

6. Maintenance

6.1 Replacement of Rechargeable battery

- Unfasten bolts(See the [Figure 8] above.) from the battery cover located on the bottom of the device.
- Take out the battery from the main unit.
- Disconnect the battery connector and change the new battery.

⚠	Use only specified battery provided by manufacturer. The replacement should be performed by authorized person only. The battery should be performed periodic checking or replaced.

6.2 Periodic inspection (Quality Control Procedure)

We recommend to check this equipment annually.

⚠	Only qualified people can check this equipment. Check items according to the Regulations of the country.

- Inspection period: 1 time / 1 year
- If the result is not satisfied the criteria, please contact to manufacturer.

Inspection item	Method	Criteria
Tube voltage	Place the voltage measuring device at (25 ± 2) cm away from the focus point, set the device to 70-100 kV, and measure the value of irradiating the X-ray.	Within 70 - 100 kV ± 10 %
Tube current Exposure time	Open the battery cover. Connect the oscilloscope to current measurement terminal. Set the device to 1 mA(= 4 V), and measure the value of irradiating the X-ray.	Within 4 V ± 20 % Within 0.10 - 1.0 s ± (10 % + 1 ms)
Battery voltage	Open the battery cover. Connect the oscilloscope to battery terminal and measure the value of battery DC voltage.	More than 20 Vdc

6.3 Disposal of the device

The device shall be disposed of in accordance with a national law. Or it must be returned to the manufacturer for disposal.
Please contact to Service Center of VSI Co., Ltd.

6.4 Circuit diagram, component part list, etc to repair certain parts of the device

The circuit diagrams, component part lists and etc. required to repair the device could be provided upon Request to only service representative authorized by VSI.
Please contact to service representative of VSI.

6.5 Assessment of the leakage and stray radiation to the operator

- The leakage and stray radiation value to the operator is described in section 4.2.
- This value is expressed as the value of “Significant zone of occupancy” because this device is hand-held type equipment and the operator should stay near the patient while X-ray exposure.

7. Statements and tables for EMC

Table 1 – Enclosure port

Phenomenon	Basic EMC standard or test method	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 fields a)	IEC 61000-4-3	3 V/m f) 80 MHz – 2,7 GHz b) 80 % AM at 1 kHz c)
RATED power frequency magnetic fields d) e)	IEC 61000-4-8	30 A/m g) 50 Hz or 60 Hz

a) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.
b) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. d) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
e) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1). f) Before modulation is applied.
g) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Table 2 – Input a.c. power PORT (VX-100 has No a.c. power Port)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
Electrical fast transients/bursts a	IEC 61000-4-4	Not applicable ± 2 kV 100 kHz repetition frequency
Surges a) b) j) o) Line-to-line	IEC 61000-4-5	Not applicable ± 0,5 kV, ± 1 kV
Surges a) b) j) k) o) Line-to-ground	IEC 61000-4-5	Not applicable ± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields c) d) o)	IEC 61000-4-6	Not applicable 3 V m) 0,15 MHz – 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)
Voltage dips f) p) r)	IEC 61000-4-11	Not applicable 0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° q)
		Not applicable 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0°
Voltage interruptions f) i) o) r)	IEC 61000-4-11	Not applicable 0 % UT; 250/300 cycle h)

a) The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.
b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.
c) Calibration for current injection clamps shall be performed in a 150 Ω system.
d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.
g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.
h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.
j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).
k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.
l) Direct coupling shall be used.

m) r.m.s., before modulation is applied.
n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.
p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.
q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.
r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range. See Table 1 Note c) for examples calculations.

Table 3 – Input d.c. power PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
Electrical fast transients/bursts a) g)	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges a) b) g) Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges a) b) g) Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields a) c) d) i)	IEC 61000-4-6	3 V m) 0,15 MHz – 80 MHz 6 V m) in ISM bands between 0,15 MHz and 80 MHz n) 80 % AM at 1 kHz e)
Electrical transient conduction along supply lines f)	ISO 7637-2	Not applicable

a) The test is applicable to all d.c. power PORTS intended to be connected permanently to cables longer than 3 m.
b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test
c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.
d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.
e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems
g) Direct coupling shall be used.
h) r.m.s., before modulation is applied.
i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
j) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Table 4– Patient coupling PORT (VX-100 has No Patient coupling Port)

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS Professional healthcare facility environment
ELECTROSTATIC DISCHARGE c)	IEC 61000-4-2	Not applicable ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields a)	IEC 61000-4-6	Not applicable 3 V b) 0,15 MHz – 80 MHz 6 V b) in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

a) The following apply:
– All PATIENT-COUPLED cables shall be tested, either individually or bundled
– PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
– No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
– Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
– Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
– If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
– The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
b) r.m.s., before modulation is applied
c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 5– SIP/SOP PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		Professional healthcare facility environment
ELECTROSTATIC DISCHARGE e)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transients / bursts b) f)	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges a) b) g) Line-to-ground	IEC 61000-4-5	± 2 kV
Conducted disturbances induced by RF fields b) d) g)	IEC 61000-4-6	3 V h) 0,15 MHz – 80 MHz 6 V h) in ISM bands between 0,15 MHz and 80 MHz i) 80 % AM at 1 kHz c)

a) This test applies only to output lines intended to connect directly to outdoor cables.
b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Calibration for current injection clamps shall be performed in a 150 Ω system.
e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
f) Capacitive coupling shall be used.
g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
h) r.m.s., before modulation is applied.
i) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

8. Product Warranty Policy

The product is manufactured under VSI Co., Ltd. thorough quality management, inspection and manufacture.

Compensation criteria regarding product repairs and exchanges correspond to the Economic Planning Board's "Consumer Injury Compensation Rule."

VSI Co., Ltd. warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness.

Handling, storage and cleaning of this product as well as factors relating to the patient, diagnosis and other matters beyond VSI Co., Ltd.'s control directly affect the product and the results obtained from its use.

VSI Co., Ltd.'s obligation under this warranty is limited to the repair or replacement of this product and VSI Co., Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product.

VSI Co., Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product. VSI Co., Ltd. assumes no liability with respect to products reused or reprocessed makes no warranties, express or implied, including but not limited to merchantability or fitness for intended use, with respect to such product.

Contact Us: You can reach us through the following contact points to get detailed information on our services and products.

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VSI Co., Ltd. homepage is available to you and provides a page where you can let us know if you have any complaints. If you have experienced any inconveniences during the use of our product or have any suggestions for improvement, except for product defects, please feel free to contact us and help us incorporate your ideas.

VSI Co., Ltd.,

Manufacturer / Customer Service Team

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