

PORT-X III

(Portable X-ray System)
USER'S MANUAL

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Document Version 1.1



Genoray Co., Ltd.

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I. CERTIFICATE OF WARRANTY

1.1 Range and terms for warranty

Genoray Co., Ltd. guarantee this product without any expense for the malfunction or disorders occurred under standard transportation and operation within 1year from installation.

1.2 Requirements on After service call

When the malfunction or disorder appeared, stop operating and check again the related article of this "User's Manual".

Before your calling, please put off this equipment and check for the model name, serial No. and purchasing date.

Genoray Co., Ltd. Is not responsible for indirect harm.

Genoray Co., Ltd. cannot warrant for defect or harm after warranty period.

1.3 Development Policy

Genoray Co., Ltd. pursues a policy of continual product development. Although every effort is made to produce up-to-date product documentation this manual should not be regarded as an infallible guide to current specifications. We reserve the right to make changes without prior notice.

Genoray Co., Ltd



II. GETTING STARTED

2.1 Intended Use

The PORT-X III Portable X-Ray system is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and child subjects

2.2 Compliance

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.

2.3 Cleaning

Ensure the adaptor is unplugged before attempting to clean. To make sure that power is off for PORT-X III while cleaning. Use a non-alcohol based disinfectant only - wipes or a cloth dampened with liquid or spray. PORT-X III and the accompanying adaptor are not designed to be subjected to any kind of sterilization procedure. PORT-X III is not designed to be used to sterilize anything else.

Getting Started

2.4 Symbols

Symbols used in this publication and used to mark the equipment have the following meanings.

Symbols	Description
	X-Ray Source Assembly, Emitting
	Attention, Consult Accompanying Documents
	Type B Applied Part
	Electrical Shock Hazard
	WEEE Mark

WARNING

Warning is given in situations and circumstances in which a serious hazard for the patient or user can be happened.

CAUTION

Cautions are given in situations or circumstances in which the equipment can possibly be damaged, or a threat of minor personal injury can be happened.

NOTE

Notes are given in situations requiring special attention to operate this equipment.

III. SAFETY OF PORT-X III

3.1 Electrical Safety

⚠ WARNING !

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.

Observe the following safety procedures to avoid electric shock or serious injury to operators and patients and to avoid system malfunction.

- Under no circumstance should the safety interlocks in the system be bypassed, jumped, or otherwise disabled.
- Under no circumstance should the system or assembly covers be removed by anyone other than a Genoray Co., Ltd. Trained service representative.
- Do not place food or beverage containers on any part of the equipment. They can trip over and introduce conductive substances into the electrical circuitry.

⚠ WARNING !

This system 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.

3.2 Electrical Fire

The user should develop an emergency procedure for the area in which the system is used that includes the following safety measures:

- Turn the system off and unplug the main power cable from the outlet.
- Evacuate everyone from the area.
- Call for help.
- Use only a fire extinguisher of a type approved for electrical fires.

CAUTION!

The use of the wrong type of fire extinguisher presents electrical shock and burn hazards. To avoid these hazards, a fire extinguisher which has been approved by the appropriate local, state, and federal codes must be available in the room where the equipment is being used.

3.3 Electromagnetic Compatibility Statement

This generating equipment, used and related to radio frequency energy, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in particular installation. If this equipment does cause harmful interference to other device, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by on or more of the following measures.

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

Consult the manufacturer or field service technician for help.

3.4 Radiation Safety

3.4.1 General

⚠ WARNING !

This x-ray unit may be dangerous to patient and operator unless safe exposure values are used and correct operating procedures are observed.

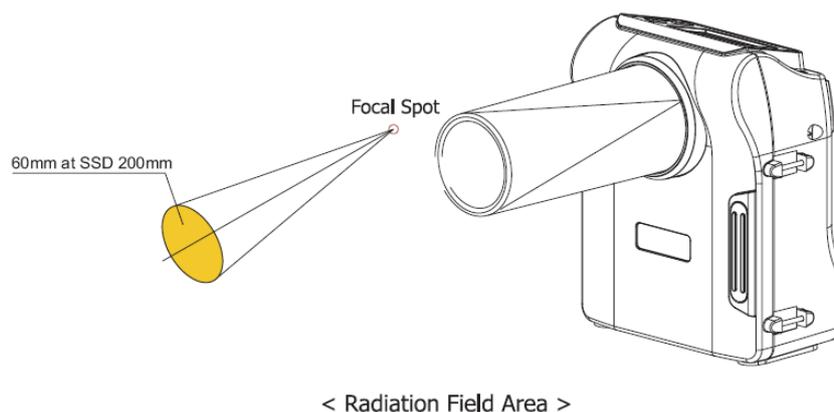
This X-Ray tube assembly produces ionizing radiation when energized. Hence, when, used, it can be better that the authorized operators wear X-ray Protective devices like X-Ray protective apron, glove or thyroid cover, etc.

It is imperative that the owner designates areas suitable for safe operation and service of the system and operator ensure that it is used only in these designated areas.

It is the responsibility of the owner to ensure that all personnel wear protective clothing and radiation monitoring devices while using this system.

⚠ NOTE !

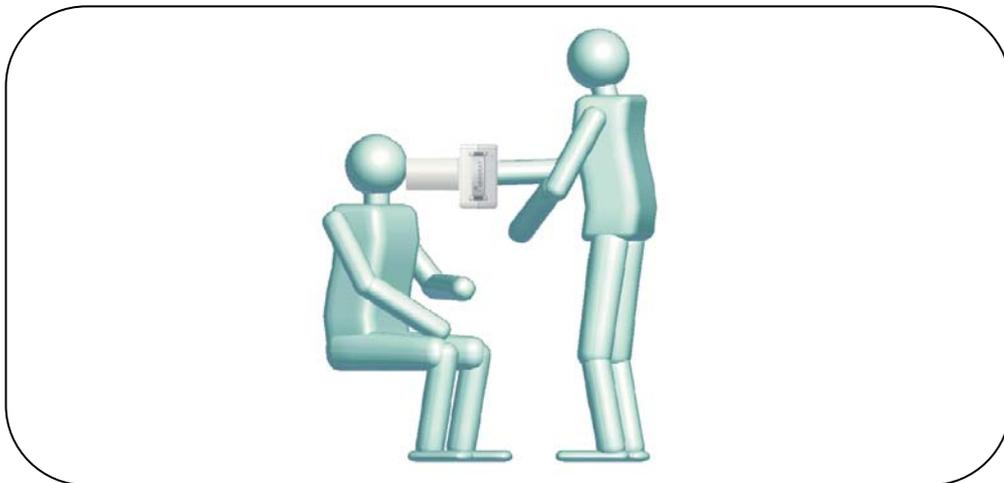
The beam limiting device(exit long cone) is lined with Pb because of leakage radiation.



Safety of PORT-XIII

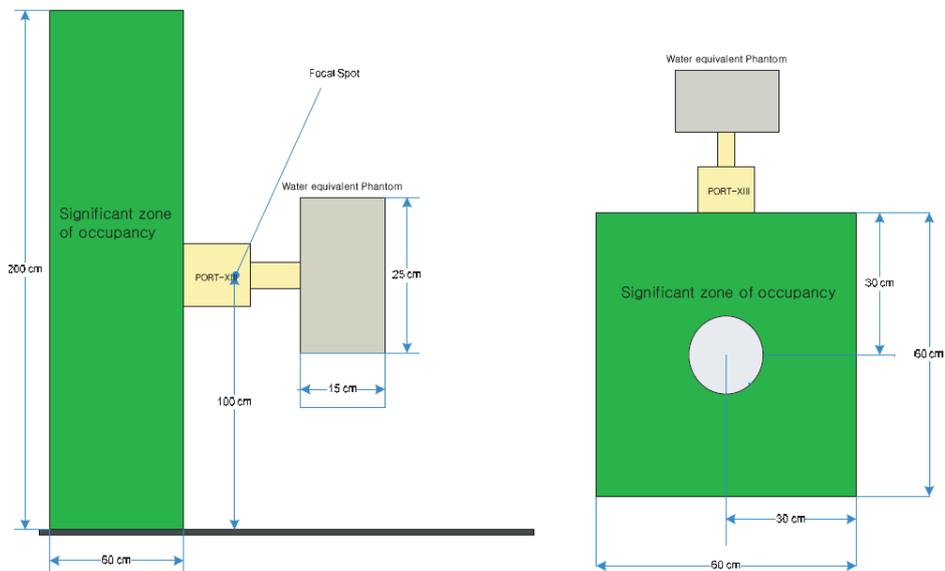
3.4.2 Handheld

PORT-X III can be used handheld equipment, it is convenient for use anytime anywhere.



3.4.3 Significant zones of occupancy

Please establish significant zone of occupancy as following and puts individual defense tool such as apron in this area and face in radiography.



3.5 Storage and Transportation Environment

Avoid the following environments for storage or transportation;

- Where the equipment is exposed to water vapor.
- Where the equipment is exposed to direct sunlight.
- Where the equipment is exposed to dust.
- Where the equipment is exposed to high humidity.
- Where there is a ventilation problem.
- Where the equipment is exposed to a salty atmosphere.
- Where the equipment is exposed to chemicals or gas.

For normal operation, you must keep away from the place with a Strong vibration and maintain the following range of temperature and humidity.

Usable range of temperature and Relative humidity

- Temperature : 2°C ~ 50°C
- Humidity : 5% ~ 80% RH

For storage and transportation condition, you must maintain the following range of temperature and humidity and atmosphere.

- Temperature : -40°C ~ 70°C
- Humidity : 5% ~ 95% RH
- Atmosphere : 500 ~ 1100hPa

IV. PRECAUTION

⚠ NOTE !

The PORT-X III should be used only by personnel possessing relevant qualifications, including adequate training in radiation protection.

⚠ NOTE !

Read carefully the following this manual.

4.1 Caution when user starts to set PORT-X III

1. Before operating, Read carefully the User's Manual and follow direction while setting the PORT-X III.
2. Before operation, check accessories.
3. Before turning Power no, check whether battery should be fully charged.

4.2 Checking Before Operating

1. Whether the power supply line is suitable with that of the system.
(Do this before turning power on)
2. Whether it is completely grounded.
3. Whether all the connectors are in proper position.
4. Check the electricity of battery. If not sufficient, recharge through the recharge unit. If any problem occurred or battery should be changed, consult it with qualified person or manufacturer.

⚠ CAUTION !

Do not use other recharge unit in order to prevent malfunction.

4.3 Caution while Operating

1. Observe carefully on the whole system and the patient.
2. When there is problem with the system or the patient, keep the patient in safety, stop operating the system and make relevant disposition.

4.4 System Malfunction

In case of malfunction, do not attempt to operate the system until it has been checked out by a qualified service technician.

4.5 Inspection

1. Make inspection for system and part periodically.
2. In case it is used after quite a long time of recess, confirm its status from an expert of this equipment or manufacturer.
3. Wash periodically with neutral detergent very carefully.
4. Do not use erosive detergent of fluid.

V. COMPOSITION OF PORT-X III

5.1 Composition

This system is composed of main body and accessories as follows.

<p>Main Body</p> <ul style="list-style-type: none">- X-ray tube assembly- Beam limiting Device- Battery	
<p>Accessories</p> <ul style="list-style-type: none">- Adaptor	
<ul style="list-style-type: none">- Staying Necklace	

5.2 AC/DC Adaptor for recharging

- Model Name : MES30A-7P1J
- Manufacturer : Mean Well Enterprises Co., Ltd.
- Rated Input : 100~240Vac, 50~60Hz, 0.8A
- Rated output : 28Vdc/1.07A

⚠ WARNING !

Recharge with the recharge unit supplied by Genoray Co., Ltd.
Use it only for the PORT-X III, otherwise it may occur malfunction or disorder.

⚠ NOTE !

- Fuse Changing -
If fuse of adaptor is broken, please contact Genoray Co., Ltd



Explanation of Each Part

5.3 Battery

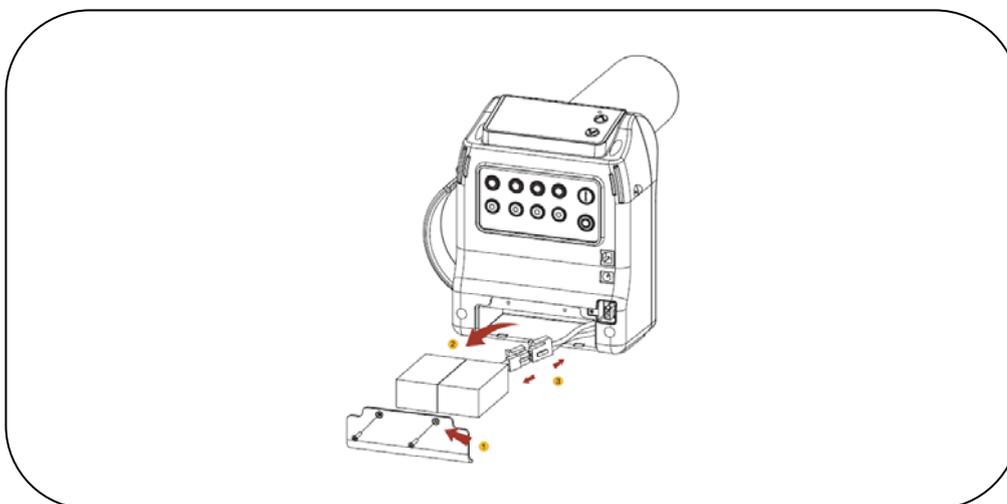
⚠ WARNING !

Use the battery supplied by Genoray Co., Ltd.

The user is responsible for any malfunction from usage with another battery.

- Model Name : AE603560P4H3R(Li-Polymer Type)
- Manufacturer : Advanced Electronics Energy Ltd.
- Voltage : 22.2Vdc
- Capacity : 930mAh

- Battery changing -

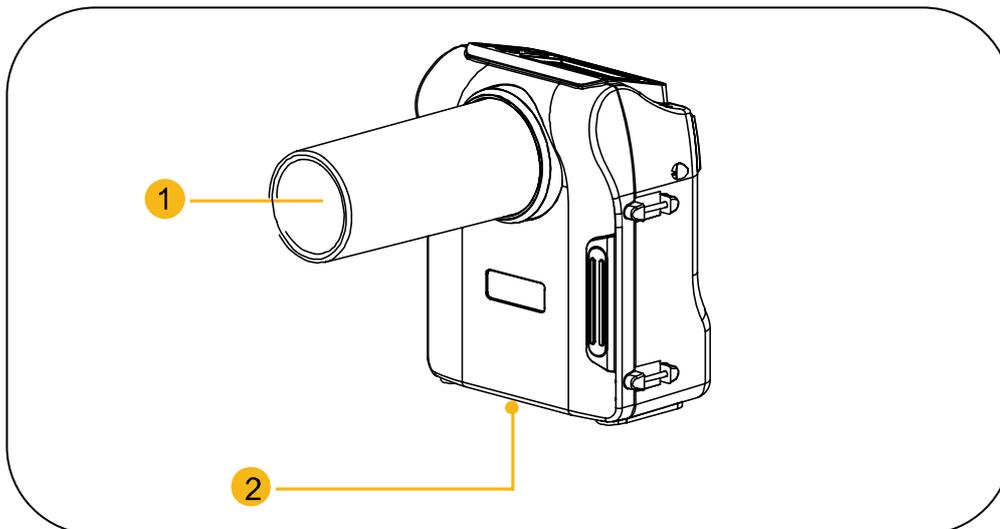


1. Unfasten bolts from the battery cover.
2. Take out the battery from main body.
3. Disconnect the battery connector and change the battery.

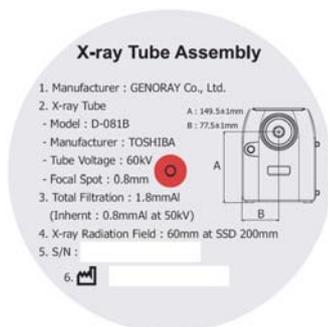
⚠ NOTE !

To remove these battery if PORT-X III is not likely to be used for some time, unless there is no risk of a safety hazard arising.

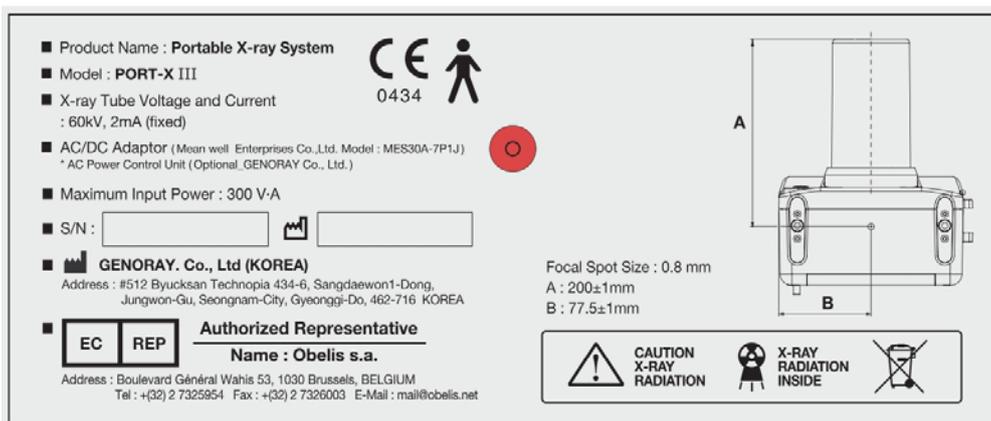
5.4 Labeling



1. X-ray tube assembly Label and Focal spot label



2. ID Label and Focal spot label



VI. EXPLANATION OF EACH PART



1. X-ray Exposure key
2. Main Display
3. Beam Limiting Device
4. Direct key for each Exposure
5. Connector for Hand Switch
6. Connector for recharging
7. Test point for management of PORT-X III
8. Ring for Necklace
9. Exposure time-set key

6.1 X-ray Exposure key



Use This in order to generate X-Ray.

When this key is pushed, x-ray generates as for the setting exposure time.

6.2 Main Display



Indicates shooting condition, operating status and storage of battery.



Waiting



Ready



Shooting



Storage of
Battery



Age of
Patient



Tooth



Exposure Time

6.3 Beam Limiting Device



Block inside with lead and attach aluminum filter, prevent inefficient x-ray to flow out

Explanation of Each Part

6.4 Direct key for each exposure condition(see section 8.3)



It controls On/Off for the equipment.
It remembers the last exposure condition for each button.



Adult



Upper Incisor



Upper Canine



Upper Molar



Child



Lower Incisor



Lower Canine



Upper Incisor

6.5 Connector for Hand Switch



Connector for Hand switch
It connects to hand switch.

6.6 Connector for Recharging



Connector for recharging
It connects to adaptor.

6.7 Test Point for management of PORT-X III(see section 7.6)



This is a test point for management of PORT-X III.
Please do not touch at a normal time.

6.8 Ring for Necklace



Ring for necklace
It hooks necklace.

6.9 Exposure time-set key



User this key in order to set the exposure time
It is composed of 56steps.
The exposure time setting plus (▲) key increases
the sec value and the minus (▼) key decreases it.

VII. OPERATION OF PORT-X III

⚠ NOTE !

Before using PORT-X III, Please clean to surface contact to patient
(see section 2.3)

7.1 Power ON

Push "Power ON" key for 0.3 seconds, then electricity turns on this equipment.

While booting time, "Wait" signal is on and off and warm up for about 10 seconds if the equipment is normal condition.

In case of showing "Fail" (when memory check)

Equipment lost data stored inside. So, the setting value of timer is initializing.

Battery storage is less than required extent.

When the battery storage is less than the minimum dose, the power is put off automatically.

You should recharge it with adaptor supplied by Genoray Co., Ltd.

7.2 Adjustment of Exposure time(see section 6.9)

This equipment adopt APR(Anatomic Programmed Radiography) mode for the convenience of operator.

APR mode is programmed by the following procedure.

While booting time, "Wait" signal is on and off and warm up for about 10 seconds if the equipment is normal condition.

(1) First, push adult or child key.(User can check it on main display)

(2) Then, push one key during 6key for upper/lower, molar/canine/incisor key.
(User can check it on main display)

If the image is not satisfactory because the dose of X-Ray is excessive or deficient, adjust the exposure time pushing the key right side of main display.

7.3 Memorize the exposure time on each key

Then the last exposure time for each key is memorized automatically.

You can set 12 direct exposure time according to your patient.

7.4 Exposure

- 1) Set the exposure time
- 2) Sight the cone for the area you want to get the image
- 3) Push "X-ray Exposure key"
- 4) "Ready" signal is flickering for 2seconds on Main Display.
- 5) When X-Ray generates, "shooting" signal appears on Main Display, yellow LED turns on and buzzer rings.
- 6) Push "X-ray Exposure key" until the end of exposure period.
- 7) When "X-ray Exposure " is finished, Buzzer rings and Yellow LED turns off.
- 8) About 5 seconds of waiting time is required for next exposure.

When "waiting" signal appears in Main Display, user cannot exposure it.

IF you do not push "X-ray Exposure key" until the end of adjusted exposure time, "Not Enough" message appears on left-upper side of Main Display.

Then you will get bad image for the lack of X-Ray.

⚠ NOTE !

The most important thing for the X-ray is the distance from the source.

In order to get the best image from the equipment, please exposure the X-ray, contacting the cone to skin. Because of PORT-X III supplies the suitable distance with its cone.

7.5 Battery recharging and operation time

⚠ WARNING !

When you use ordinary adaptor, the battery can be damaged.
You should use its own adaptor supplied by Genoray Co., Ltd.

⚠ WARNING !

This battery is exclusive for PORT-X III.
You cannot use any other battery for this equipment.
When life span of battery is finished, you should change it with the same
Battery supplied by Genoray Co., Ltd.

7.5.1 Specification of Battery

This adopted Lithium-Polymer battery which is very safe.
Its specification won't be changed after long time of disuse.

7.5.2 Operation Time

The remaining extent of battery is shown on right-upper side on Main Display. If the battery is not sufficient, you cannot acquire the best image.
Keep the battery charged enough. When the remaining extent of battery is lower than the minimum, the electricity is automatically shut off in order to protect any damage for the equipment
The recharging time(from empty to full) is about 4hours.
Please recharge the battery for about 12hours when the first using of the equipment.

7.6 Periodic Check

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

VIII. HELP MESSAGE

8.1 Error Code

If there's any error happens on this equipment, it shows the following error code in order to clarify the problem.

Error No.	Class of Error	Counter plan
Error 1	OCP_EPR (OCP error) Detail : HFG driver controller is turned aside	Check the temperature (10°C to 35°C) Ask Genoray
Error 2	EP_OVR_ERR (kV over error) Detail : kV feedback volume of X-ray output is input 10% higher	Ask Genoray
Error 3	EP_LOW_ERR (kV low error) Detail : kV feedback volume of X-ray output is input 10% lower	Check the temperature (10°C to 35°C) Ask Genoray
Error 4	IP_OVR_ERR (mA over error) Detail : mA feedback volume of X-ray output is input 10% higher	Ask Genoray
Error 5	IP_LOW_ERR (mA low error) Detail : mA feedback volume of X-ray output is input 10% lower	
Error 6	mAs_ERR (mAs error) Detail : mAs is measured under 10%	
Error 7	OVR_HEAT_ERR (over-heat error) Detail : Inner temperature of tank is higher than 45°C	1. Stop using machine 2. After 2 hours, check 3. If same message, ask Genoray.
Error 8	SHOT_SW_ERR (shot switch error) Detail : hand s/w or shot s/w is still pressed after X-ray irradiation	Release hand s/w or shot s/w after shooting. Ask Genoray
Error 9	EP/IP_LVL_OVR_ERR (level over error) Detail : hand s/w or shop s/w is still pressed after X-ray irradiation	Ask Genoray

When the error happens, the error No. appears,

“Call Service” message flickers every second and buzzer rings 3 times.

Help Message

8.2 Exposure Time Setting

⚠ WARNING !

The table above is only for the reference. If the image is vague or dark, adjust exposure time.

Item	Part		Exposure Time
Chemical Film	Upper	Incisor	0.7 sec ~ 0.8 sec
		Canine	0.9 sec ~ 1.0 sec
		Molar	1.1 sec ~ 1.2 sec
	Lower	Incisor	0.5 sec ~ 0.6 sec
		Canine	0.6 sec ~ 0.7 sec
		Molar	0.7 sec ~ 0.8 sec
Digital Sensor	Upper	Incisor	0.15 sec ~ 0.2 sec
		Canine	0.12 sec ~ 0.18 sec
		Molar	0.3 sec ~ 0.35 sec
	Lower	Incisor	0.07 sec ~ 0.09 sec
		Canine	0.12 sec ~ 0.18 sec
		Molar	0.15 sec ~ 0.2 sec

8.3 Initialization Value of Direct key(see section 6.4)

 Adult  Upper Incisor  Upper Canine  Upper Molar			
 Child  Lower Incisor  Lower Canine  Upper Incisor			
Adult	0.3	0.4	0.5
	0.25	0.3	0.35
Child	0.2	0.3	0.4
	0.15	0.2	0.25

IX. TECHNICAL DATA

9.1. Basic Technical Specifications

9.1.1. Classification / Spec Compliance

Electrical classification (Battery)	Internally Power Type B
Electrical classification (AC/DC Adaptor)	Class II Type B
MDD(93/42/EEC):Annex IX	Class IIb
IPX specification	IP0; do not operate under wet conditions
Mode of operation	Intermittent operation

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

9.1.2. Complied Standards

- IEC/EN 60601-1	- IEC/EN 60601-1-2
- IEC/EN 60601-1-3	- IEC/EN 60601-2-7
- IEC/EN 60601-2-28	- IEC/EN 60601-2-32

9.1.3 X-Ray Exposure Control

Exposure time range	0.01sec~2.0sec manually adjustment(56steps)
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9.1.4 X-ray Tube Assembly

kV range	60kV(fixed)
mA range	2mA(fixed)
Maximum duty cycle	1:5
Total filtration	1.8mmAl
Intended Angle	17.06°
Maximum output power	70kW
Maximum Leakage technique factors	60kV X 4mAs
Operating frequency	80kHz

9.1.5 Beam Limiting Device

Type	Round Type
Source to Skin Distance	20cm
X-ray field size	Ø60

9.1.6 Battery

Model Name	AE603560P4H3R(Li-Polymer Type)
Manufacturer	Advanced Electronics Energy Ltd.
Voltage	22.2Vdc
Capacity	930mAh

9.1.7 AC/DC Adaptor

Model Name	MES30A-7P1J
Manufacturer	Mean Well Enterprises Co., Ltd.
Rated Input	100~240Vac, 50~60Hz, 0.8A
Rated output	28Vdc/1.07A

9.1.8 Dimension(Unit : mm) and Weight

Main Body	155 X 200 X 83,	2.6kg±10%
Battery	73 X 69 X 20	0.25kg±10%
AC/DC Adaptor	108 X 67 X 36	0.5kg±10%

9.1.10 Environmental requirements

Operation

Temperature	2℃ ~ 50℃
Relative humidity	5% ~ 80%RH

Storage and transportation

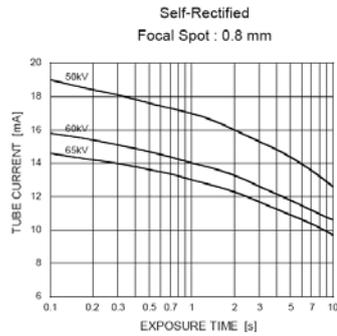
Temperature	-40℃ ~ 70℃
Relative humidity	5% ~ 95%RH
Atmosphere	500 ~ 1100hPa

9.2 X-Ray Tube Specifications and Characteristics

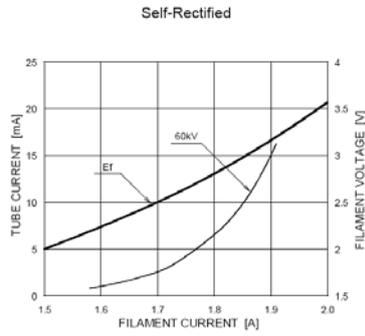
(1) Manufacturer	Toshiba(D-081B)
(2) Type	Stationary
(3) Focal Spot	0.8mm
(4) Target Angle	20°
(5) Target Material	Tungsten
(6) Inherent Filtration	0.8mmAl
(7) Cooling Method	Oil cooling
(8) Input Energy(see rating chart)	600W(at 1.0s)
(9) Maximum Tube Voltage	65kV
(10) Minimum Tube Voltage	50kV
(11) Maximum Tube Current	19mA
(12) Filament Voltage (at the maximum filament current)	2.9~4.0V
(13) Maximum Filament Current	2.0A
(14) Thermal Characteristics	
Anode Heat Storage Capacity	6.0kJ(8.5kHU)
Maximum Anode Heat Dissipation Rate	128W(180HU/s)
(15) X-Ray Tube Housing(approximate value)	
Max. Heat Storage Capacity	18.0kJ(25.2kHU)
Max Heat Dissipation Rate	40W(56HU/s)

(13) Rating chart

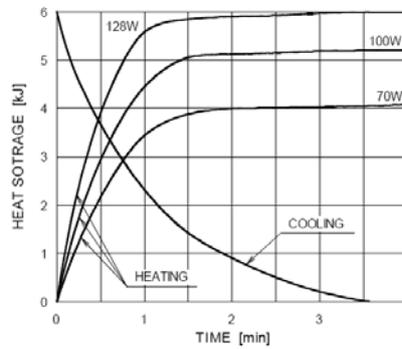
Maximum Rating Charts
(Absolute maximum rating charts)



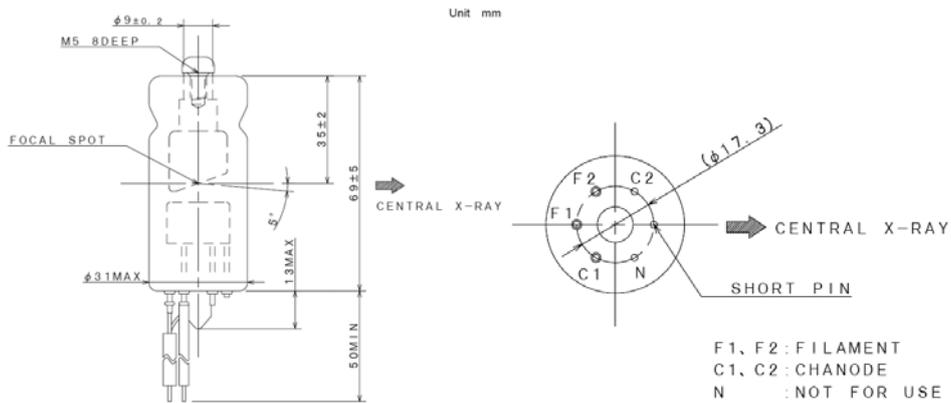
Emission & Filament Characteristics



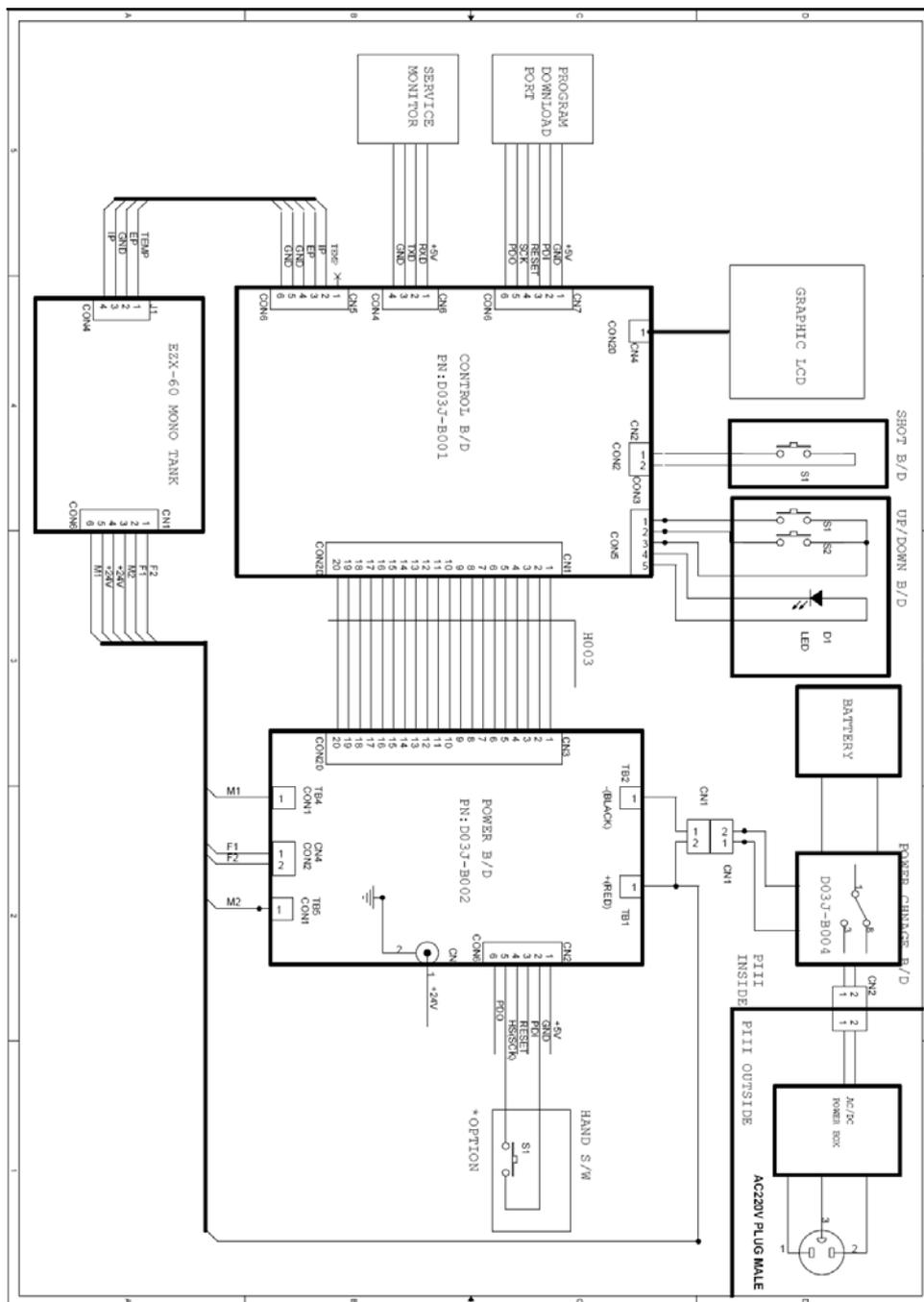
Anode Thermal Characteristics



(14) Dimensional Outline of X-ray Tube (D-081B)



9.3 Wiring Diagram





#512 Byucksan Technopia 434-6 Sangdaewon 1-Dong Jungwon-Gu Seongnam-City Gyeonggi-Do Korea

EC Declaration of Conformity

Manufacturer : GENORAY Co., Ltd.

#512 Byucksan Technopia 434-6 Sangdaewon 1-Dong
Jungwon-Gu Seongnam-City Gyeonggi-Do, 462-716, KOREA

European Authorized Representative :

Obelis s.a.
Boulevard Général Wahis 53, 1030 Brussels, BELGIUM
Tel: +(32) 2 7325954 Fax: +(32) 2 7326003

GMDN Code : 37617

Device name : Portable X-ray System

Model name : PORT-XIII

Multiple Model name : ZEN-PX3, VEGA RX-84

Complied Standards

EN 60601-1-2:2001,
EN 60601-1: 1990 + A1: 1993 + A2: 1995
EN 60601-1-3:1994, EN 60601-2-7:1998, EN 60601-2-28:1993,
EN 60601-2-32:1994

Classification : Class IIb by Rule 10 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC

Conformity Assessment Route : Annex II excl. section 4, MDD 93/42/EEC as amended by 2007/47/EC

We(Genoray) hereby declare that the PORT-X III complies with the Medical Device Directive 93/42/EEC as amended by 2007/47/EC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annex II excl. section 4 as the conformity assessment procedure via DNV(Det Norske Veritas Certification AS, Veritasveien 1, 1322 HOVIK, Norway , NB No. : 0434) as the Notified Body.

GENORAY CO., LTD.

BYUNG-UK PARK
PRESIDENT

Place, Date of issue : Seoul, Korea April, 04th 2011

Signature :

President on behalf of GENORAY Co., Ltd.

CE
0434



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