

EPX-SERIES

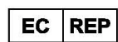
Diagnostic X-ray System

Operator's Manual



Ecotron Co., Ltd
Made by Korea

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REVSON HISTORY

Revision Number	Date	Description
A	SEP 11, 2013	First Edition
B	SEP 30, 2014	European Authorized Representative Change
C	JAN 12, 2015	Manual Update
D	Mar 23, 2015	Manual Update
E	JUN 11, 2015	Manual Update
F	SEP 01, 2015	Manual Update
G	JUN 21, 2016	Manual Update
H	SEP 22, 2016	Manual Update for UDI Label
I	AUG 23, 2018	Manual Update
J	MAR 24, 2020	Manual Update

ADVISORY SYMBOLS

The following advisory symbols are used throughout this manual. Their application and meaning are described below.



Warning symbol used to indicate a potential hazard lead operators, service personnel to serious injury, death or radiation exposure.



Caution symbol used to indicate a potential hazard lead operators, service personnel to injury or damage of equipment.



Note symbol used to indicate important information need to proper use and right operation of equipment.



KEEP THIS OPERATOR'S MANUAL WITH THE EQUIPMENT AT ALL TIMES, AND REVIEW THE IMPORTANT INFORMATION WHENEVER REQUIRED.

THE STATISTICS AND SPECIFICATIONS OF THIS UNIT AND MANUAL CAN BE MODIFIED WITH OR WITHOUT NOTIFICATION FOR THE IMPROVEMENT OF PERFORMANCE AND SAFETY.

1. INTRODUCTION

The EPX-SERIES Innovation diagnostic X-ray system features excellent x-ray Image, quality, accuracy, reproducibility and long-term stability. Fast kV rising time minimize unnecessary patient dose and supply superior Image quality, fast Image response.

The operator control console is designed to be simple and user-friendly and one can select or change x-ray parameters easily using a large soft membrane switch.

Indications for use / Intended use

This product, diagnostic X-ray system, is radiation medical equipment used by a qualified / trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

This product is used on hand (wrist), foot (ankle), shoulder, elbow, knee, and other body parts.

Available the patient population for use

- Gender: no gender restrictions
- Age: no age restrictions
- The patient population for use
 - Adults
 - Pediatric patients

NOTE

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF PHYSICIAN OR WITH THE DESCRIPTIVE DESIGNATION OF ANY OTHER PRACTITIONER LICENSED BY THE LAW OF THE STATE IN WHICH HE PRACTICES TO USE OF ORDER THE USE OF THE DEVICE.

1.1 COMPOSITION

This product is composed of the X-ray component part, accessories part. Detail information of each component follows below.

(1) X-ray component part

- Main Power board
- SMPS
- Mono block X-ray tank
- OP control board
- FET drive board
- Collimator

(2) Accessories

- Hand switch
- Foot switch(Optional)
- Operator's Manual
- Mobile Stand

NOTE

THIS MANUAL CONTAINS IMPORTANT SAFETY INFORMATION. AN UNDERSTANDING OF THIS INFORMATION IS CRITICAL TO THE SAFE OPERATION OF YOUR EQUIPMENT.

PLEASE ENSURE THAT YOU READ THE WARNING NOTICES BEFORE USING THE EQUIPMENT

NOTE

- ***ASSEMBLY INFORMATION: NO ASSEMBLY IS REQUIRED.***

2. NOTICE OF THE SAFE OPERATION

This user's guide is designed to ensure correct use and operation of EPX-SERIES. Please read all the lines thoroughly before you use this equipment.

Incorrect use and operation exceeding described conditions in this manual may occur damage of the machine and shorten its life. Particular attention must be paid to all the warnings, cautions and notes incorporated herein.

This equipment should be used only by the legally qualified persons and practitioners.

EPX-SERIES is designed with the due consideration for users' safety and product reliability. It, however, is advisable to follow under mentioned rules to keep your additional safety and health.

1. This product should be operated only by or under the supervision of legally qualified persons.
2. EPX-SERIES is designed for the radiographic uses and not for fluoroscopy or other associated applications.
3. EPX-SERIES should be used for the diagnosis, not for the therapy.
4. Do not modify the equipment at your discretion and in case any modification is required unavoidably, ask the help of Ecotron or its authorized dealer for the service.
5. This system has been calibrated for optimal operations.
6. The outside temperature of the device is not as high as burns, but there watch out for a low-temperature burns if the operator contacts with a certain part(control panel, collimator knob, metal enclosure etc.) for a long time.

EPX-SERIES should be used to plug the power cord into the wall socket.

CAUTION

NO PROTECTION AGAINST THE INGRESS OF THE LIQUIDS

WARNING

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

WARNING

DO NOT CONNECT ADDITIONAL EXTENSION CORD TO EQUIPMENT.

WARNING

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.

WARNING

PROPER USE AND SAFE OPERATING PRACTICES WITH RESPECT TO X-RAY SYSTEMS ARE THE RESPONSIBILITY OF THE USERS OF SUCH X-RAY SYSTEMS.

ECOTRON Co., Ltd PROVIDES INFORMATION ON ITS PRODUCTS AND ASSOCIATED HAZARDS, BUT ASSUMES NO RESPONSIBILITIES FOR AFTER-SALE OPERATING AND SAFETY PRACTICES.

ECOTRON Co., Ltd ACCEPTS NO RESPONSIBILITY FOR ANY GENERATOR NOT MAINTAINED OR SERVICED ACCORDING TO THE SERVICE MANUAL OR ANY X-RAY SYSTEM THAT HAS BEEN MODIFIED IN ANY WAY.

ECOTRON Co., Ltd ALSO ASSUMES NO RESPONSIBILITY FOR X-RAY RADIATION OVEREXPOSURE OF PATIENTS OR PERSONNEL RESULTING FROM POOR OPERATING TECHNIQUES OR PROCEDURES.

WARNING

DO NOT ALLOW OPERATION OF THIS APPARATUS BY ANY PERSON OTHER THAN QUALIFIED PERSONNEL (PHYSICIANS, RADIOTHERAPY ENGINEERS AND CLINICAL X-RAY ENGINEERS) OR UNDER OBSERVATION BY THEM.

CAUTION

INCORRECT CONNECTIONS OR USE OF UNAPPROVED EQUIPMENT MAY RESULT IN INJURY OR EQUIPMENT DAMAGE.

CAUTION

DO NOT EXCEED THE TUBE MAXIMUM OPERATING LIMITS SHOWN IN THE X-RAY TUBE DATA SECTION AT THE END OF THE OPERATOR'S MANUAL.

INTENDED LIFE AND RELIABILITY WILL NOT BE OBTAINED UNLESS X-RAY SYSTEMS ARE OPERATED WITHIN PUBLISHED SPECIFICATION.

CAUTION

DO NOT CONNECT ANY OTHER ELECTRICAL DEVICE EXCEPT FOLLOWING ELECTRICAL DEVICES.

- ***MEDICAL ELECTRICAL DEVICES WHICH CONFORM TO IEC60601-1***
- ***NON-MEDICAL ELECTRICAL DEVICES WHICH CONFORM TO RELATED IEC SAFETY STANDARDS***
- ***NON-MEDICAL ELECTRICAL DEVICES WHICH HAVE SAFETY EQUAL TO DEVICES CONFORM TO IEC SAFETY STANDARDS***

3. RADIATION SAFETY


1. Users and operators should wear appropriate protecting devices and clothes.
2. Stay distance from the radiant sources and all the possible secondary radiation zones.
3. Eliminate all unnecessary objects near the exposure zones.
4. The distance from the focus to skin should be kept at least 8 inch (20cm).
5. For the experimental uses, apply the lowest possible values of kV, mAs and exposure time.
6. Be careful not to exceed the limited radiograms in the exposure area.
7. The contraindications for pregnant patient or children to avoid unnecessary ionizing radiation exposure.

CAUTION

THE IONIZING RADIATION COULD BE DANGEROUS FOR PATIENTS AND OPERATORS UNLESS FOLLOWING SAFETY REGULATIONS ARE STRICTLY OBSERVED.

4. SAFETY AND SPECIFICATIONS

4.1 SAFETY AND WARNING SYMBOLS

 X-RAY EQUIPMENT IS DANGEROUS TO BOTH PATIENT AND OPERATOR
UNLESS MEASURES OF PROTECTION ARE STRICTLY OBSERVED

Never allow unqualified personnel to operate the X-ray system.



High voltage symbol used to indicate the presence of high voltage.



Warning symbol used to indicate a potential hazard to operators, service personnel or to the equipment.. It indicates a requirement to refer to the accompanying documentation for details.



Radiation symbol used to indicate the presence of radiation.



Laser radiation symbol used to indicate the presence of laser beam.

HV 3 MINUTES WARNING LABEL

⚠ WARNING



HAZARDOUS VOLTAGE ARE PRESENT INSIDE THE CABINET FOR A PERIOD THREE(3) MINUTES AFTER DE-ENERGIZING THIS EQUIPMENT

This label is attached on the main power board. The DC link capacitor (approximately 325 VDC with line voltage at 230VAC) will remain charged for up to 3 minutes after the AC mains is disconnected or the AC switch is switched off.

DANGER HIGH VOLTAGE LABEL



⚠ DANGER

Caution
High Voltage

This label attached to the main fuse cover, main noise filter cover and FET driver board. Main voltage is present inside the x-ray system whenever the main disconnect is switched on. Additionally, the DC link capacitors will remain charged for up to 3 minutes after the AC mains is disconnected or the AC switch is switched off.

LASER STARE CAUTION LABEL



This label attached to side of the collimator case. Laser pointer is present inside the collimator part of X-ray system. When X-ray system shoot a laser beam, there do not stare into beam because the eyes may be damaged from laser beam.

SAFE USE WARNING LABEL

⚠ WARNING

This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

This label attached to a control panel. This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.



Protection earth symbol

L

Live line among the single phase line powers.

N

Neutral line among the single phase line powers.

L1

First phase line power among the three phase line powers.

L2

Second phase line power among the three phase line powers.

L3

Third phase line power among the three phase line powers.

V~

Single phase AC line voltage.

X-ray radiation exposure may be damaging to health, with some effects being cumulative and extending over periods of many months or even years. ***X-ray operators should avoid any exposure to the primary beam*** and take protective measures to safeguard against scatter radiation. Scatter radiation is caused by any object in the path of the primary beam and may be of equal or less intensity than the primary beam that exposes the film.

No practical design can incorporate complete protection for operators or service personnel who do not take adequate safety precautions. ***Service and operating personnel only authorized and properly trained by ECOTRON should be allowed to work with this X-ray system equipment.*** The appropriate personnel must be made aware of the inherent dangers associated with the servicing of high voltage equipment and the danger of excessive exposure to X-ray radiation during system operation.

- Wear protective clothing. Protective aprons and gloves with an equivalent of a minimum of 1/64”(0.35mm) of lead are recommended.
- To protect the patient against radiation, always use radiation protection accessories in addition to devices which are fitted to the X-ray system
- Keep as large a distance as possible away from the object being exposed and the X-ray tube assembly.
- Never operate this X-ray system in areas where there is a risk of explosion. Detergents and disinfectants, including those used on patients, may create explosive mixtures of gases. Please observe the relevant regulations.
- The operator console or anything electrically connected to it, must never be used within 6ft(1.8m) of the patient environment.
- Do not place liquids(coffee, beverages, flowers, etc) on the X-ray system.
- Do not operate the x-ray system in direct sunlight or near any heat sources.
- Do not operate the x-ray system near strong magnetic fields(microwave ovens, speakers, etc), and avoid routing the x-ray system near these devices.
- The x-ray system must be operated in locations that are clean (free of excess dust, dirt, debris, etc), stable (free of vibration).
- Only trained maintenance staff may remove the covers of the x-ray system.
- Contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.


4.2 COMPOSITION LABEL

4.2.1 EPX-F1600

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System




REF EPX-F1600 (S/W: Ver 1.03) **SN** E-F1600-1607D01

Input Power: 100-120V ~, 50/60Hz, 3.1kVA, Standby 150VA
 Output power: 1.6kW @ 50kV, 30mA
 KVP range: 40-90kVp, mA range: 12-30mA, mAs Range: 0.4-32mAs


- Total Filtration: 3.3mmAl
 (Tube: 0.8mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
- Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube


- Focal Spot: 1.2mm x 1.2mm, Inherent Filtration: At least 0.8mmAl
 Target Angle: 16 degrees, Anode Heat Storage: 50kHU
- Certification Statement(Déclaration de certification)
 • This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)
- CAUTION (MISE EN GARDE)**
 • Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
 • Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)



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4.2.2 EPX-F2400

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System




REF EPX-F2400 (S/W: Ver 1.03) **SN** E-F2400-1607D01

Input Power: 100-120V ~, 50/60Hz, 4.8kVA, Standby 150VA
 Output power: 2.4kW @ 60kV, 40mA
 KVP range: 40-100kVp, mA range: 16-40mA, mAs Range: 0.4-100mAs


- Total Filtration: 3.3mmAl
 (Tube: 0.8mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
- Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube


- Focal Spot: 1.2mm x 1.2mm, Inherent Filtration: At least 0.8mmAl
 Target Angle: 16 degrees, Anode Heat Storage: 50kHU
- Certification Statement(Déclaration de certification)
 • This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)
- CAUTION (MISE EN GARDE)**
 • Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
 • Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)



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4.2.3 EPX-F2800

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System

REF EPX-F2800 (S/W: Ver 1.03) **SN** E-F2800-1607D01

Input Power: 100-120V ~, 50/60Hz, 5.7kVA, Standby 150VA
 Output power: 2.7kW @ 90kV, 30mA
 KVP range: 40-100kVp, mA range: 23-30mA, mAs Range: 0.4-100mAs

- Total Filtration: 3.3mmAl
 (Tube: 0.8mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
- Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube

- Focal Spot: 1.2mm x 1.2mm, Inherent Filtration: At least 0.8mmAl
 Target Angle: 16 degrees, Anode Heat Storage: 50kHU

Certification Statement(Déclaration de certification)

- This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)

CAUTION (MISE EN GARDE)

- Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
- Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)

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4.2.4 EPX-F3200

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System

REF EPX-F3200 (S/W: Ver 1.03) **SN** E-F3200-1607D01

Input Power: 100-120V ~, 50/60Hz, 6.5kVA, Standby 150VA
 Output power: 3.2kW @ 80kV, 40mA
 KVP range: 40-100kVp, mA range: 25-40mA, mAs Range: 0.4-100mAs

- Total Filtration: 3.3mmAl
 (Tube: 0.8mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
- Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube

- Focal Spot: 2.0mm x 2.0mm, Inherent Filtration: At least 0.8mmAl
 Target Angle: 20 degrees, Anode Heat Storage: 40kHU

Certification Statement(Déclaration de certification)

- This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)

CAUTION (MISE EN GARDE)

- Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
- Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)

Ecotron Co., Ltd
Made by Korea **2016.07.26**

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4.2.5 EPX-F4000

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System CE 0123

REF EPX-F4000 (S/W: Ver 1.03) **SN** E-F4000-1607D01

Input Power: 200-240V ~, 50/60Hz, 8.8kVA, Standby 150VA
 Output power: 4.0kW @ 50kV, 80mA
 KVP range: 50-110kVp, mA range: 20-80mA, mAs Range: 0.4-100mAs
 • Total Filtration: 3.0mmAl
 (Tube: 0.5mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
 • Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube

• Focal Spot: 1.8mm x 1.8mm, Inherent Filtration: At least 0.5mmAl
 Target Angle: 15 degrees, Anode Heat Storage: 42kHU
Certification Statement(Déclaration de certification)
 • This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)
CAUTION (MISE EN GARDE)
 • Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
 • Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)

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4.2.6 EPX-F5000

REPRESENTATIVE IDENTIFICATION LABEL X-RAY SYSTEM

This label is attached to rear cover of the diagnostic x-ray system. (Example)

Diagnostic X-ray System CE 0123

REF EPX-F5000 (S/W: Ver 1.03) **SN** E-F5000-1607D01

Input Power: 200-240V ~, 50/60Hz, 11kVA, Standby 150VA
 Output power: 5.0kW @ 50kV, 100mA
 KVP range: 50-110kVp, mA range: 20-100mA, mAs Range: 0.4-100mAs
 • Total Filtration: 3.0mmAl
 (Tube: 0.5mmAl, Fixed Added Filter: 2.0mmAl, Collimator: 0.5mmAl)
 • Time interval between Max kV and Max mAs exposure: rest time 5min

Inserted X-ray Tube

• Focal Spot: 1.8mm x 1.8mm, Inherent Filtration: At least 0.5mmAl
 Target Angle: 15 degrees, Anode Heat Storage: 42kHU
Certification Statement(Déclaration de certification)
 • This product complies with 21 CFR Subchapter J.
 (Ce produit est conforme à la norme 21 CFR sous-chapitre J.)
CAUTION (MISE EN GARDE)
 • Only an experienced expert should operate the unit.
 (Seul un expert expérimenté devrait fonctionner l'appareil.)
 • Do not use with wet hands.
 (Ne pas utiliser avec les mains mouillées.)

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4.2.7 EPX-SERIES COLLIMATOR

COMMON LABEL TO ALL MODELS - COLLIMATOR

This is label is attached on side of the collimator of the diagnostic x-ray system. (Example)

Beam Limiting Device(Collimator)

REF EPX-Collimator

SN

- Input Power: 3V(LED) / 5V(Laser)
- Min. X-ray field size: 0cm x 0cm at 100cm SID
Max. X-ray field size: 43cm x 43cm at 100cm SID
- Inherent Filtration: 0.5mmAl

Certification Statement









- This product complies with 21 CFR 1020.30 – 1020.31
- This product complies with 21 CFR Subchapter J.






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4.2.8 SYMBOL ON THE PRODUCT LABEL OF X-RAY SYSTEM

SYMBOL	Description
	Catalogue number
	Serial number
	Caution
	Consult instructions for use
	WEEE Symbol
	Manufacturer
	Date of manufactured
	Authorized representative in the European Community

4.2.9 SYMBOLS ON THE PACKING OF X-RAY SYSTEM

SYMBOL	Description
	KEEP DRY: This symbol means keep away from rain
	Fragile: This symbol means do not drop of product
	UP: This symbol means “This way up”

4.3 EPX-SERIES DUTY CYCLE LIMIT

NOTE

THE FOLLOWING SECTION CONTAINS IMPORTANT INFORMATION. PLEASE READ AND UNDERSTAND THIS MATERIAL BEFORE CONTINUING.

Internal X-ray system components will heat up during normal use of the x-ray system. This is similar to X-ray tube heating during normal x-ray system operation. The amount of heat produced is proportional to the product of kV,mA and time.

CAUTION

THIS X-RAY SYSTEM HAS TEMPERATURE MONITORING OF FET-DRIVE BOARD TO PROTECT THE EXCESSIVE HEAT BUILD-UP.

IF THE X-RAY SYSTEM DETECTS THE OVER-HEAT OF FET-DRIVE, AN ERROR CODE "E04" OR "E05" WILL BE DISPLAYED. EXPOSURE WILL BE INHIBITED WHEN THIS MESSAGE IS DISPLAYED, AND IT SHOULD BE UNDERSTOOD THAT CONTINUING TO MAKE EXPOSURES MIGHT CAUSE X-RAY SYSTEM DAMAGE DUE TO OVERHEATING. THE GENERATOR SHOULD BE ALLOWED TO COOL SUFFICIENTLY SUCH THAT THIS MESSAGE IS NO LONGER DISPLAYED.

4.4 DAILY X-RAY TUBE WARM-UP PROCEDURE

NOTE

THE FOLLOWING PROCEDURE PRODUCES X-RAYS. OBSERVE ALL SAFETY PRECAUTIONS TO PROTECT PERSONNEL.

Use the procedure when the generator has not been used for several days. This procedure provides for exposures at medium power before the tube is used at maximum mA or kV values. This will reduce the possibility of damaging the X-ray tube and high voltage components. No test setup is required.

For maximum stability and reliability, use the following techniques at start up:

Select the following:

- **60 kV / 5 mAs**
- **Make three to five exposures at 5 minute intervals.**

4.5 APPLICABLE STANDARDS

The EPX-SERIES comply with the regulatory requirements and design standards in this section as follows:

This product complies with DHHS requirements of 21 CFR Subchapter J.

1) SAFETY

- EN 60601-1:2006/A1:2013
- EN60601-1-3:2008
- EN60601-1-6:2010
- EN62366:2008
- EN60601-2-28:2010
- EN60601-2-54:2009

2) EMC

- EN60601-1-2:2007

The EPX-SERIES X-ray system with CE marking comply with the European Council Directive concerning Medical Devices. One of the harmonized standards of this Directive defines the permitted levels of electromagnetic emission from this equipment and its required immunity from the electromagnetic emission of other device.

It is not possible, however to exclude with absolute certainty the possibility that other high frequency electronic equipment, which is fully compliant to the EMC regulations, will not adverse effect the operation of this x-ray system. If the other equipment has a comparatively high level of transmission power and is in close proximity to the generator, these EMC concerns (the risk of interference) may as mobile telephones, cordless microphones and other similar mobile radio equipment be restricted from the vicinity of this X-ray system.

3) OTHERS

- EN ISO 13485:2012 /AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- EN980:2008 Symbols for use in the labeling of medical devices
- EN1041:2008 Information supplied by the manufacturer of medical devices
- EN62304:2006 Medical device software - Software life-cycle processes IEC 62304:2006
- MEDDEV 2.12.1/Rev.8 Medical Devices Vigilance System
- MEDDEV 2.12.2/Rev.2 Post Market Clinical Follow-up studies

4) CLINICAL EVALUATION

- MEDDEV 2.7.1/Rev.4 Clinical evaluation: Guide for manufacturers and notified bodies

4.6 SPECIFICATION

4.6.1 CLASSIFICATION OF THE DEVICE

CLASSIFICATION – EN 60601-1

- Type of protection against short circuit: CLASS I
- Degree of protection against direct and indirect contact: TYPE B
- Degree of protection against ingress of water and particulate matter: IPX0
- Use conditions: CONTINUOUS WORKING WITH INTERMITTENT LOAD
- The products have not been evaluated for use in the presence of flammable anaesthetic mixture with air or nitrous oxide

CLASSIFICATION – 93/42/EEC DIRECTIVE

- In according with Annex IX: CLASS II b

VERIFICATION – IEC 60580

- The EPX-SERIES measures data in accordance with the reference tube voltage and mAs values using DAP certified according to the requirements of IEC60580, and displays output doses by calculating the measured reference data.

4.6.2 SPECIFICATION TABLE

4.6.2.1 EPX-F1600

Max Output Power		1.6 kW		
Input Power	Voltage	100-120V / 200V-240V		
	Phase & Frequency	Single / 50/60 Hz		
Radiography kV Range in 1kV steps (40KV ~ 90KV)		Tube voltage	Current	mAs
		40KV ~ 50KV	30mA	0.4 ~ 20
		40KV ~ 50KV	25mA	25~32
		51KV ~ 60KV	25mA	0.4 ~ 20
		51KV ~ 60KV	20mA	25~32
		61KV ~ 70KV	20mA	0.4 ~ 20
		61KV ~ 70KV	15mA	25~32
		71KV ~ 80KV	18 mA	0.4 ~ 20
		71KV ~ 80KV	14 mA	25~32
		81KV ~ 90KV	16 mA	0.4 ~ 20
		81KV ~ 90KV	12 mA	25~32
MAs Range		0.4mAs – 32mAs, 20steps		
Max. kV Deviation		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.01		
Display		KV /mAs: 7-segment LED		
X-ray Tube	Model Name	D-125 (Toshiba)		
	Focal Spot	1.2mm x 1.2mm		
	Target Angle	16 degree		
	Anode Heat Storage	50 KHU		
Total Filtration		Tube:0.8mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.3 mm Al eq. @ 75kV		
Collimator with Laser Pointer	Type	Double slit type, manual operation		
	Min. X-ray Field Size	0cm x 0cm @100cm SID		
	Max X-ray Field Size	43cm x 43cm @ 100cm SID		
	Laser Pointer	Class II		
	Timer	Push button illuminator with 30 sec timer		
	Lamp	LED 3.0V, 3A, 10W		
Weight		13 Kg		

4.6.2.2 EPX-F2400

Max Output Power		2.4 KW		
Input Power	Voltage	100-120V / 200V-240V		
	Phase & Frequency	Single, 50/60 Hz		
Radiography KV Range in 1KV steps (40KV ~ 100KV)		Tube voltage	Current	mAs
		40KV ~ 60KV	40mA	0.4 ~ 64
		40KV ~ 60KV	35mA	80 ~ 100
		61KV ~ 70KV	30mA	0.4 ~ 100
		71KV ~ 80KV	30mA	0.4 ~ 32
		71KV ~ 80KV	25mA	40 ~80
		81KV ~ 90KV	25mA	0.4 ~ 40
		81KV ~ 90KV	20mA	50 ~ 80
		91KV ~ 100KV	20mA	0.4 ~ 80
mAs Range		0.4mAs – 100mAs, 25steps		
Max. KV accuracy		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.01		
Display		KV / mAs: 7-segment LED		
X-ray Tube	Model Name	D-125 (Toshiba)		
	Focal Spot	1.2mm x 1.2mm		
	Target Angle	16 degree		
	Anode Heat Storage	50 KHU		
Total Filtration		Tube:0.8mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.3 mm Al eq. @ 75kV		
Collimator with Laser Pointer	Type	Double slit type, manual operation		
	Min. X-ray Field Size	0cm x 0cm @100cm SID		
	Max X-ray Field Size	43cm x 43cm @ 100cm SID		
	Laser Pointer	Class II		
	Timer	Push button illuminator with 30 sec timer		
	Lamp	LED 3.0V, 3A, 10W		
Weight		13 Kg		

4.6.2.3 EPX-F2800

Max Output Power		2.7 kW		
Input Power	Voltage	100-120V / 200V-240V		
	Phase & Frequency	Single / 50/60 Hz		
Radiography kV Range in 1kV steps (40KV ~ 120KV)		Tube voltage	Current	mAs
		40KV ~ 50KV	30mA	0.4 ~ 100
		51KV ~ 60KV	30mA	0.4 ~ 100
		61KV ~ 70KV	30mA	0.4 ~ 100
		71KV ~ 80KV	30mA	0.4 ~ 64
		71KV ~ 80KV	27mA	80 ~ 100
		81KV ~ 90KV	30mA	0.4 ~ 40
		81KV ~ 90KV	25mA	50 ~ 80
		91KV ~ 100KV	25mA	0.4 ~ 40
		91KV ~ 100KV	23mA	50 ~ 80
MAs Range		0.4mAs – 100mAs, 25steps		
Max. kV Deviation		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.01		
Display		KV /mAs: 7-segment LED		
X-ray Tube	Model Name	D-125 (Toshiba)		
	Focal Spot	1.2mm x 1.2mm		
	Target Angle	16 degree		
	Anode Heat Storage	50 KHU		
Total Filtration		Tube:0.8mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.3 mm Al eq. @ 75kV		
Collimator with Laser Pointer	Type	Double slit type, manual operation		
	Min. X-ray Field Size	0cm x 0cm @100cm SID		
	Max X-ray Field Size	43cm x 43cm @ 100cm SID		
	Laser Pointer	Class II		
	Timer	Push button illuminator with 30 sec timer		
	Lamp	LED 3.0V, 3A, 10W		
Weight		13 Kg		

4.6.2.4 EPX-F3200

Max Output Power		3.2 KW		
Input Power	Voltage	100-120V / 200V-240V		
	Phase & Frequency	Single / 50/60 Hz		
Radiography kV Range in 1KV steps (40KV ~ 100KV)		Tube voltage	Current	mAs
		40KV ~ 50KV	40mA	0.4 ~ 100
		51KV ~ 60KV	40mA	0.4 ~ 80
		61KV ~ 70KV	40mA	0.4 ~ 100
		71KV ~ 80KV	40mA	0.4 ~ 32
		71KV ~ 80KV	35mA	40 ~ 80
		81KV ~ 90KV	30mA	0.4 ~ 40
		81KV ~ 90KV	25	50 ~ 80
		91KV ~ 100KV	30mA	0.4 ~ 50
		91KV ~ 100KV	25mA	64 ~ 80
MAs Range		0.4mAs – 100mAs, 25steps		
Max. kV Deviation		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.015		
Display		KV / mAs: 7-segment LED		
X-ray Tube	Model Name	D-205B (Toshiba)		
	Focal Spot	2.0mmx2.0 mm		
	Target Angle	20 degree		
	Anode Heat Storage	40 kHU		
Total Filtration		Tube:0.8mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.3 mm Al eq. @ 75kV		
Collimator with Laser Pointer	Type	Double slit type, manual operation		
	Min. X-ray Field Size	0cm x 0cm @100cm SID		
	Max X-ray Field Size	43cm x 43cm @ 100cm SID		
	Laser Pointer	Class II		
	Timer	Push button illuminator with 30 sec timer		
	Lamp	LED 3.0V, 3A, 10W		
Weight		13 Kg		

4.6.2.5 EPX-F4000

Max Output Power		4.0 KW		
Input Power	Voltage	200V-240V		
	Phase & Frequency	Single / 50/60 Hz		
Radiography kV Range in 1KV steps (50KV ~ 110KV)		Tube voltage	Current	mAs
		50KV	80mA	0.4~16mAs
		50KV	70mA	20~32mAs
		50KV	60mA	40~100mAs
		51KV ~ 60KV	60mA	0.4~32mAs
		51KV ~ 60KV	50mA	40~100mAs
		61KV ~ 70KV	50mA	0.4~32mAs
		61KV ~ 70KV	40mA	40~100mAs
		71KV ~ 80KV	45mA	0.4~10mAs
		71KV ~ 80KV	40mA	13~80mAs
		81KV ~ 90KV	35mA	0.4~32mAs
		81KV ~ 90KV	30mA	40~80mAs
		91KV ~ 100KV	30mA	0.4~32mAs
		91KV ~ 100KV	25mA	40~80mAs
101kV ~ 110KV	25mA	0.4~32mAs		
101kV ~ 110KV	20mA	40~80mAs		
MAs Range		0.4mAs – 100mAs		
Max. kV Deviation		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.02		
Display		KV /mAs: 7-segment LED		
X-ray Tube	Model Name	OX/110-15 (C.E.I.)		
	Focal Spot	1.8mmx1.8mm		
	Target Angle	15 degree		
	Anode Heat Storage	42kHU		
Total Filtration		Tube:0.5mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.0 mm Al eq. @ 75kV		
Collimator with Laser Pointer	Type	Double slit type, manual operation		
	Min. X-ray Field Size	0cm x 0cm @100cm SID		
	Max X-ray Field Size	43cm x 43cm @ 100cm SID		
	Laser Pointer	Class II		
	Timer	Push button illuminator with 30 sec timer		
	Lamp	LED 3.0V, 3A, 10W		
Weight		13 Kg		

4.6.2.6 EPX-F5000

Max Output Power		5.0 KW		
Input Power	Voltage	200V-240V		
	Phase & Frequency	Single / 50/60 Hz		
Radiography kV Range in 1KV steps (50KV ~ 110KV)		Tube voltage	Current	mAs
		50KV	100mA	0.4~10mAs
		50KV	80mA	13~32mAs
		50KV	70mA	40~100mAs
		51KV ~ 60KV	80mA	0.4~10mAs
		51KV ~ 60KV	70mA	13~32mAs
		51KV ~ 60KV	60mA	40~100mAs
		61KV ~ 70KV	70mA	0.4~10mAs
		61KV ~ 70KV	60mA	13~32mAs
		61KV ~ 70KV	50mA	40~100mAs
		71KV ~ 80KV	60mA	0.4~10mAs
		71KV ~ 80KV	50mA	13~32mAs
		71KV ~ 80KV	40mA	40~100mAs
		81KV ~ 90KV	50mA	0.4~10mAs
		81KV ~ 90KV	40mA	13~32mAs
		81KV ~ 90KV	30mA	40~100mAs
		91KV ~ 100KV	45mA	0.4~10mAs
		91KV ~ 100KV	40mA	13~32mAs
		91KV ~ 100KV	30mA	40~100mAs
		101kV ~ 110KV	40mA	0.4~10mAs
101kV ~ 110KV	30mA	13~32mAs		
101kV ~ 110KV	20mA	40~100mAs		
MAs Range		0.4mAs – 100mAs		
Max. kV Deviation		±3 %		
Max. mAs Deviation		±5 %		
Max. Reproducibility of the RADIATION output		Coefficient of variation < 0.02		
Display		KV /mAs: 7-segment LED		
X-ray Tube	Model Name	OX/110-15 (C.E.I.)		
	Focal Spot	1.8mmx1.8mm		
	Target Angle	15 degree		
	Anode Heat Storage	42kHU		

Total Filtration		Tube:0.5mmAl / collimator: 0.5mmAl / filter:2.0mmAl 3.0 mm Al eq. @ 75kV
Collimator with Laser Pointer	Type	Double slit type, Manually operation
	Min. X-ray Field Size	0cm x 0cm @100cm SID
	Max X-ray Field Size	43cm x 43cm @ 100cm SID
	Laser Pointer	Class II
	Timer	Push button illuminator with 30 sec timer
	Lamp	LED 3.0V, 3A, 10W
Weight		13 Kg

4.6.2.7 HAND SWITCH

Two step X-ray exposure hand switch			
Type	Two stepping(ready and exposure)		
Working Voltage(AC/DC)	125V/30V		
Working Current(AC/DC)	1A/2A		
Wires and coil cord	3cores, 2.2m		
Cores	White	Red	Green
	Ready	Common	Exposure
Shell Material	White, Engineering plastics		
Useful time	1.2 million times		

4.6.2.8 MOBILE STAND

Mobile Stand for EPX-SERIES	
Available products	EPX-SERIES only
Arm angle	0° ~ 150°
Max arm vertical	1.4 m
Wt. Load	30 kg
Wheel size	50Ø, 24mm
Weight(Mobile Stand)	11.6 kg

4.6.3 kV, mAs, mA TABLE

4.6.3.1 EPX-F1600

mAs TABLE

KV	40KV ~ 50KV																			
mA	30																		25	
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32
Sec	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	1.000	1.280
	51KV ~ 60KV																			
	25																		20	
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32
	0.016	0.020	0.024	0.032	0.040	0.052	0.064	0.080	0.100	0.128	0.160	0.200	0.256	0.320	0.400	0.520	0.640	0.800	1.250	1.600
	61KV ~ 70KV																			
	23										20							15		
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32
	0.017	0.022	0.026	0.035	0.043	0.057	0.070	0.087	0.109	0.139	0.174	0.217	0.320	0.400	0.500	0.650	0.800	1.000	1.667	2.133
	71KV ~ 80KV																			
	18																		14	
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32
	0.022	0.028	0.033	0.044	0.056	0.072	0.089	0.111	0.139	0.178	0.222	0.278	0.356	0.444	0.556	0.722	0.889	1.111	1.786	2.286
	81KV ~ 90KV																			
	16																		13	
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32
	0.025	0.031	0.038	0.050	0.063	0.081	0.100	0.125	0.156	0.200	0.250	0.313	0.400	0.500	0.625	0.813	1.000	1.250	1.923	2.462

4.6.3.2 EPX-F2400

mAs TABLE

KV	40KV ~ 60KV																								
mA	40																						35		
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.000	1.250	1.600	2.286	2.857
	61KV ~ 70KV																								
	30																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.133	2.667	3.333
	71KV ~ 80KV																								
	30																				25				
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.600	2.000	2.560	3.200	
	81KV ~ 90KV																								
	25																				20				
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.016	0.020	0.024	0.032	0.040	0.052	0.064	0.080	0.100	0.128	0.160	0.200	0.256	0.320	0.400	0.520	0.640	0.800	1.000	1.280	1.600	2.500	3.200	4.000	
	91KV ~ 100KV																								
	20																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.020	0.025	0.030	0.040	0.050	0.065	0.080	0.100	0.125	0.160	0.200	0.250	0.320	0.400	0.500	0.650	0.800	1.000	1.250	1.600	2.000	2.500	3.200	4.000	

4.6.3.3 EPX-F2800

mAs TABLE

KV	40KV ~ 50KV																								
mA	30																								
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.133	2.667	3.333
	51KV ~ 60KV																								
	30																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.133	2.667	3.333
	61KV ~ 70KV																								
	30																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.133	2.667	3.333
	71KV ~ 80KV																								
	30																							27	
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.133	2.963	3.704
	81KV ~ 90KV																								
	30																					25			
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	2.000	2.560	3.200	
	91KV ~ 100KV																								
	25																					23			
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.016	0.020	0.024	0.032	0.040	0.052	0.064	0.080	0.100	0.128	0.160	0.200	0.256	0.320	0.400	0.520	0.640	0.800	1.000	1.280	1.600	2.174	2.783	3.478	

4.6.3.4 EPX-F3200

mAs TABLE

KV	40KV ~ 50KV																								
mA	40																								
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.000	1.250	1.600	2.000	2.500
	51KV ~ 60KV																								
	40																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.000	1.250	1.600	2.000	
	61KV ~ 70KV																								
	40																								
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.000	1.250	1.600	2.000	2.500
	71KV ~ 80KV																								
	40																				35				
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.143	1.429	1.829	2.286	
	81KV ~ 90KV																								
	30																				25				
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	2.000	2.560	3.200	
	91KV ~ 100KV																								
	30																				25				
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	1.333	1.667	2.560	3.200	

4.6.3.5 EPX-F4000

mAs TABLE

KV	50KV																								
mA	80																70			60					
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.005	0.006	0.008	0.010	0.013	0.016	0.020	0.025	0.031	0.040	0.050	0.063	0.080	0.100	0.125	0.163	0.200	0.286	0.357	0.457	0.667	0.833	1.067	1.333	1.667
51KV ~ 60KV																									
mA	60																		50						
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.007	0.008	0.010	0.013	0.017	0.022	0.027	0.033	0.042	0.053	0.067	0.083	0.107	0.133	0.167	0.217	0.267	0.333	0.417	0.533	0.800	1.000	1.280	1.600	2.000
61KV ~ 70KV																									
mA	50																		40						
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.008	0.010	0.012	0.016	0.020	0.026	0.032	0.040	0.050	0.064	0.080	0.100	0.128	0.160	0.200	0.260	0.320	0.400	0.500	0.640	1.000	1.250	1.600	2.000	2.500
71KV ~ 80KV																									
mA	50													40											
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
Sec	0.008	0.010	0.012	0.016	0.020	0.026	0.032	0.040	0.050	0.064	0.080	0.100	0.128	0.160	0.200	0.325	0.400	0.500	0.625	0.800	1.000	1.250	1.600	2.000	
81KV ~ 90KV																									
mA	40																30								
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
Sec	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.325	0.400	0.500	0.625	0.800	1.333	1.667	2.133	2.667	
91KV ~ 100KV																									
mA	35																		25						
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
Sec	0.011	0.014	0.017	0.023	0.029	0.037	0.046	0.057	0.071	0.091	0.114	0.143	0.183	0.229	0.286	0.371	0.457	0.571	0.714	0.914	1.600	2.000	2.560	3.200	
101KV ~ 110KV																									
mA	30																		20						
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	
Sec	0.013	0.017	0.020	0.027	0.033	0.043	0.053	0.067	0.083	0.107	0.133	0.167	0.213	0.267	0.333	0.433	0.533	0.667	0.833	1.067	2.000	2.500	3.200	4.000	

4.6.3.6 EPX-F5000

mAs TABLE

KV	40KV ~ 50KV																								
mA	100										80					70									
mAs	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
Sec	0.004	0.005	0.006	0.008	0.010	0.013	0.016	0.020	0.025	0.032	0.040	0.050	0.064	0.080	0.100	0.163	0.200	0.250	0.313	0.400	0.571	0.714	0.914	1.143	1.429
	51KV ~ 60KV																								
	80										70					60									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.005	0.006	0.008	0.010	0.013	0.016	0.020	0.025	0.031	0.040	0.050	0.063	0.080	0.100	0.125	0.186	0.229	0.286	0.357	0.457	0.667	0.833	1.067	1.333	1.667
	61KV ~ 70KV																								
	70										60					50									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.006	0.007	0.009	0.011	0.014	0.019	0.023	0.029	0.036	0.046	0.057	0.071	0.091	0.114	0.143	0.217	0.267	0.333	0.417	0.533	0.800	1.000	1.280	1.600	2.000
	71KV ~ 80KV																								
	60										50					40									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.007	0.008	0.010	0.013	0.017	0.022	0.027	0.033	0.042	0.053	0.067	0.083	0.107	0.133	0.167	0.260	0.320	0.400	0.500	0.640	1.000	1.250	1.600	2.000	2.500
	81KV ~ 90KV																								
	50										40					30									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.008	0.010	0.012	0.016	0.020	0.026	0.032	0.040	0.050	0.064	0.080	0.100	0.128	0.160	0.200	0.325	0.400	0.500	0.625	0.800	1.333	1.667	2.133	2.667	3.333
	91KV ~ 100KV																								
	45										40					30									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.009	0.011	0.013	0.018	0.022	0.029	0.036	0.044	0.056	0.071	0.089	0.111	0.142	0.178	0.222	0.325	0.400	0.500	0.625	0.800	1.333	1.667	2.133	2.667	3.333
	101KV ~ 110KV																								
	40										30					20									
	0.4	0.5	0.6	0.8	1.0	1.3	1.6	2.0	2.5	3.2	4.0	5.0	6.4	8.0	10	13	16	20	25	32	40	50	64	80	100
	0.010	0.013	0.015	0.020	0.025	0.033	0.040	0.050	0.063	0.080	0.100	0.125	0.160	0.200	0.250	0.433	0.533	0.667	0.833	1.067	2.000	2.500	3.200	4.000	5.000

4.6.4 DOSIMETRY DATA TABLE

4.6.4.1 EPX-F1600

Unit: $\mu\text{Gy}\cdot\text{m}^2$

kV \ mAs	40	50	60	70	80	90
0.4	0.9	1.9	2.8	3.6	4.6	5.4
5	11.1	21.8	34.1	47.2	60.7	75.4
32	70.7	139	218.2	302.8	392.4	489

4.6.4.2 EPX-F2400

Unit: $\mu\text{Gy}\cdot\text{m}^2$

kV \ mAs	40	50	60	70	80	90	100
0.4	0.9	1.9	2.8	3.6	4.6	5.4	6.4
5	11.1	21.8	34.1	47.2	60.7	75.4	90.8
32	70.7	139	218.2	302.8	392.4	489	590.1
50							
64							
80					986	1231.2	1489.9
100	221.3	433.8	681.3	949.3			

4.6.4.3 EPX-F2800

kV \ mAs	40	50	60	70	80	90	100
0.4	0.9	1.9	2.8	3.6	4.6	5.4	6.4
5	11.1	21.8	34.1	47.2	60.7	75.4	90.8
32	70.7	139	218.2	302.8	392.4	489	590.1
50							
64							
80					986	1231.2	1489.9
100	221.3	433.8	681.3	949.3			

4.6.4.4 EPX-F3200

Unit: $\mu\text{Gy}\cdot\text{m}^2$

kV \ mAs	40	50	60	70	80	90	100
0.4	0.8	1.7	2.8	4	5.3	6.3	7.5
5	12.6	25.4	40.1	56.5	74.2	93	112.8
32	81.9	165.8	259.1	363.7	479.6	601.9	731.1
80			650.1		1198.9	1508.3	1843.9
100	261.7	522.7		1138.7			

4.6.4.5 EPX-F4000

Unit: $\mu\text{Gy}\cdot\text{m}^2$

kV \ mAs	50	60	70	80	90	100	110
0.4	0.9	1.9	2.5	3.2	4.3	4.4	5.4
5	19.4	32.2	46.7	61.4	77.5	92.8	110
32	132.5	217.8	310	406.6	513.9	615	737.8
80				1028.2	1307.3	1573.5	1914.7
100	429.9	693.6	974.4				

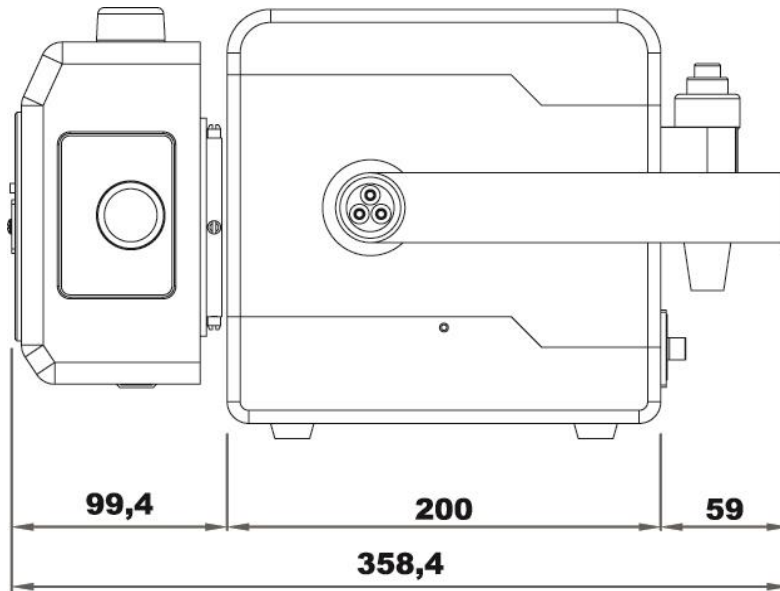
4.6.4.6 EPX-F5000

Unit: $\mu\text{Gy}\cdot\text{m}^2$

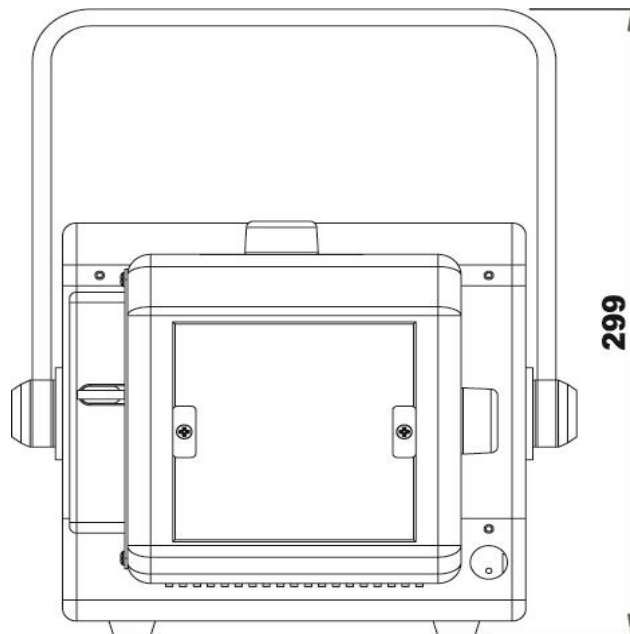
kV \ mAs	50	60	70	80	90	100	110
0.4	0.9	1.9	2.5	3.2	4.3	4.4	5.4
5	19.4	32.2	46.7	61.4	77.5	92.8	110
32	132.5	217.8	310	406.6	513.9	615	737.8
100	429.9	693.6	974.4	1287.3	1637.7	1973	2405.2

4.6.5 MECHANICAL SPECIFICATION

EPX-F1600/F2400/F2800/F3200/F4000/F5000 Dimension (unit: mm)

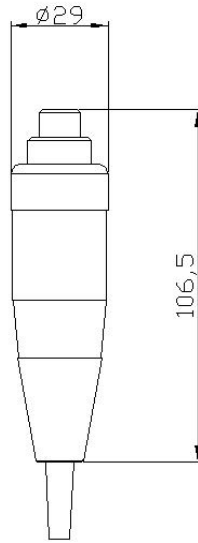


< Side View >

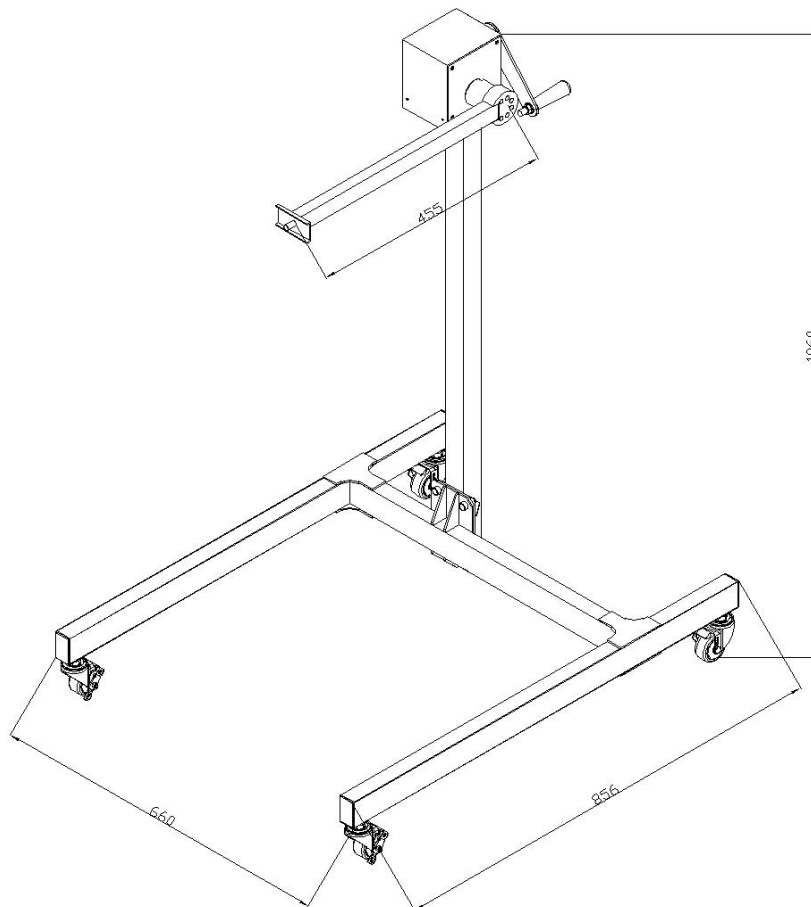


< Front View >

Hand Switch Dimension (unit: mm)



Mobile Stand Dimension (unit: mm)



4.7 WORKING ENVIRONMENT

Avoid the following places for the normal operation and safe storage:

- a. where the equipment is exposed to water vapor.
- b. where the equipment is exposed to direct sunlight.
- c. where the equipment is exposed to dust.
- d. where the equipment is exposed to high humidity.
- e. where there is a ventilation problem.
- f. where the equipment is exposed to salty atmosphere.
- g. where the equipment is exposed to chemicals or gas.

For safe operation of the equipment, it should be kept away from the place with strong vibration and maintain proper environment and conditions.

Operation Environment

Temperature range	10°C ~ 40 °C (50 °F ~ 104 °F)
Relative Humidity Range	30% ~ 75% RH

Optimal Temperature and Humidity

Temperature range	16.7 °C ~ 22.8 °C (62 °F ~ 73 °F)
Relative Humidity Range	40% ~ 60% RH

For safe storage and transportation, the following range of temperature and humidity must be kept while using.

Environment for storage and transportation

Temperature range	-25 °C ~ 60 °C (-13 °F ~ 140 °F)
Relative Humidity Range	10% ~ 95% RH

4.8 CUSTOMER SUPPORT

Address any questions regarding X-ray system operation to:

ECOTRON Co.,Ltd

4F & 5F, Hanshin IT Tower II, 47, Digital-ro 9-gil,
Geumcheon-Gu, Seoul 08511, Republic of Korea

TEL:+82-2-2025-3760, FAX:+82-2-2025-3764

E-mail: ecotron@ecotron.co.kr

Web-site: <http://www.ecotron.co.kr>

In USA

Contact DRGEM USA Inc.

7018 NW 50TH Terrace, Gainesville, Florida, 32653, USA

TEL:201-370-6672, FAX: 352-337-1271

E-mail: drgemusa@gmail.com



Obelis S.A

Bd. General Wahis 53, 1030 Brussels, Belgium / E-mail:mail@obelis.net

Representative: Mr.Gideon ELKAYAM / TEL:32.2.732.59.54, FAX:32.2.732.60.03

5. SYSTEM CONFIGURATION

EPX-SERIES is a radiological device for professional radiologist uses. It should be applied for the radiographic diagnosis and operated by qualified practitioners. Users have to comply with safety and health regulations concerning the ionizing radiation protection and the electrical and mechanical safety of the veterinary medical devices.

5.1 PREPARATION FOR OPERATION

5.1.1 OPERATION PRATICES

- a. Wear a lead apron while making exposures.
- b. Stay at least 6.5feet (2m) away from the unit or extend the cord of hand switch as long as possible in order to secure enough space for your safety.
- c. Use proper field size and technical values for each procedure to minimize x-ray exposure dose and obtain the best radiographic result.
- d. When you make exposure to the patient on the bed, ask visitors to leave the room first and keep appropriate distance from the patient.
- e. Pay attention to the maintenance schedule of the device and keep up with it.
- f. Cumulative radiation dose usually does not exceed recommended maximum levels. However, if you make radiographic exposures using high kV and mAs quite often, the evaluation of the specialist is needed to check whether extra protective devices are necessary for the user or not.

5.1.2 POSITIONING OF THE PATIENT AGAINST THE COLLIMATOR

- a. Place a loaded cassette on the patient's backside.
- b. Arrange the SID (Source to Image Receptor Distance) using a tape measure (2 meter) located on the side of the collimator. When the SID is 1 meter, the device is shown the best performance.
- c. Turn on the collimator lamp and laser pointer by the pushing collimator/laser switch is on.
- d. Adjust the size of the x-ray beam in accordance with the film size using the x-ray field adjustment knobs. The collimator and laser pointer will be turned off after 30 seconds by internal timer.

CAUTION

THE OPERATION OF THE MACHINE SHOULD NOT BE STARTED UNLESS ALL VERIFICATIONS AND CONNECTIONS ARE FULLY CHECKED.

CAUTION

FOR THE FIRST TIME INSTALLATION OF THE (MACHINE) OR OPERATION AFTER LONG PERIOD OF NON-USE, IT NEEDS TO BE PREHEATED TO SECURE LONG SERVICE LIFE OF THE TUBE. FOLLOWING METHOD OF PILOT TEST WILL RELIEVE THE DAMAGE ON THE X-RAY TUBE. OPERATE THE (MACHINE) WITH LOW KV / MAS VALUES (50 KV / 5 MAS) THREE TIMES IN ROW AND EXECUTE WITH HIGHER VALUES (70KV/5MAS) THREE TIMES IN ROW AGAIN. THEN HIGH KV/MAS VALUES (90 KV / 5 MAS) WILL BE APPLIED WITHOUT TROUBLE.

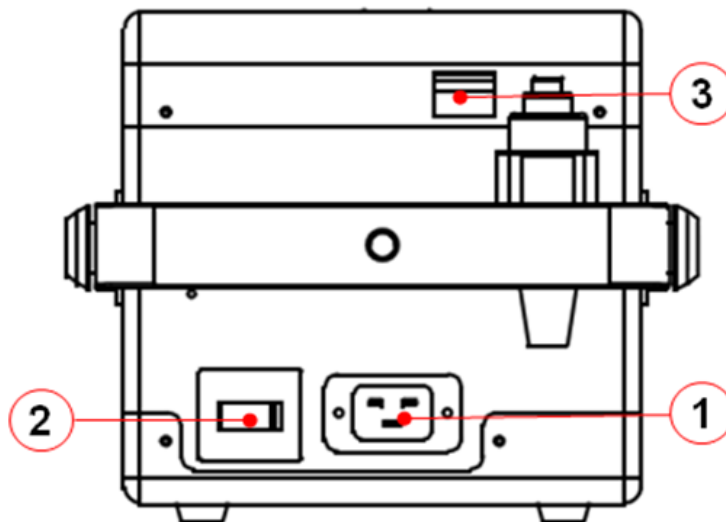
CAUTION

THIS X-RAY SYSTEM HAS TEMPERATURE MONITORING OF X-RAY TUBE TO PROTECT THE EXCESSIVE HEAT BUILD-UP. IF THE X-RAY SYSTEM DETECTS THE OVER-HEAT OF X-RAY TUBE, AN ERROR CODE "E02" WILL BE DISPLAYED.

EXPOSURE WILL BE INHIBITED WHEN THIS MESSAGE IS DISPLAYED, AND IT SHOULD BE UNDERSTOOD THAT CONTINUING TO MAKE EXPOSURES MIGHT CAUSE X-RAY SYSTEM DAMAGE DUE TO OVERHEATING. THE GENERATOR SHOULD BE ALLOWED TO COOL SUFFICIENTLY SUCH THAT THIS MESSAGE IS NO LONGER DISPLAYED.

IF THE OPERATOR USES TO CONTINUE TWO TIMES THAT IS HIGH TUBE VOLTAGE AND HIGH MAS CONDITION, IT IS RECOMMENDED TO USE AGAIN AFTER 5 MINUTE REST TIME.

5.2 CONNECTION OF POWER CODE AND HAND SWITCH



No.	Description	Function
1	Power Connector(inlet)	Connect the power cable
2	Power Switch	Power on/off switch
3	Hand Switch Connector	Connect the hand switch cable

WARNING

PLEASE CHECK WHETHER THE VOLTAGE AND FREQUENCY OF THE INPUT POWER ARE IN ACCORDANCE WITH THE FIGURES WRITTEN IN THE SYSTEM LABELS, WHICH ATTACHED ON THE BODY OF THE MACHINE. THE LEVEL OF INPUT VOLTAGE FLUCTUATION SHOULD BE WITHIN $\pm 10\%$ OF THE NOMINAL VALUES.

CAUTION

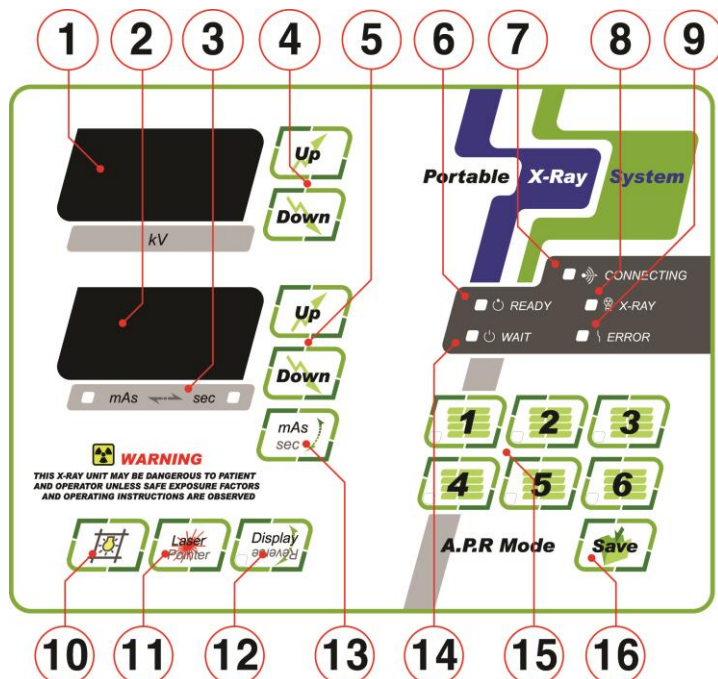
ALWAYS POWER SWITCH IS OFF BEFORE CONNECTED THE POWER CABLE.

WARNING

TO AVOID THE RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAIN WITH PROTECTIVE EARTH.

6. OPERATION MODE

6.1 EPX-F1600 / F2400 / F2800 / F3200 / F4000 / F5000



No.	Description	Function
1	KV indicator	Display KV value
2	mAs indicator	Display mAs value
3	mAs & sec indicator	Display mAs & sec indicator
4	KV up/down control switch	Select KV value by up or down buttons
5	mAs up/down control switch	Select mAs value by up or down buttons
6	Ready indicator	Lighted push the hand switch one time for preparation
7	PC interface connecting indicator	Lighted when EPX series is connected to PC
8	Exposure indicator	Alert lamp during x-ray exposure
9	Error lamp	Lighted in case of system problem
10	Collimator lamp on	Switch for operation of the lamp inside the collimator
11	Laser pointer	To adjust exposure focus
12	Display reversal switch	Help to read LED value of kV, mAs reversed
13	mAs & sec select switch	The switch select between mAs and sec
14	Wait lamp	Lighted until the second exposure started
15	APR Switch (1-6)	Memory setting is available for 6 APR data
16	Save APR Data	Save the selected APR Data

6.1.1 NORMAL MODE

- a. Connect power plug into the device.
- b. Turn on the power switch located on the back of the equipment.
- c. Select the KV values using the KV up/down switch.
- d. Select the mAs values using the mAs up/down switch.
- e. Positioning the machine at the ready condition by pushing the hand one time switch.
- f. When the "Ready LED" lighted, press the hand switch again and make exposure. During the x-ray exposure, "X-ray LED" will be lighted on.
- g. After the exposure is ended, "wait LED" sign will be lighted on for the waiting time and beep sound will be heard.

6.1.2 APR MODE

- a. Connect power plug into the device.
- b. Turn on the power switch.
- c. Select the APR memory out of 1~6.
- d. Select the kV values using the KV up/down switch.
- e. Select the mAs values using the mAs up/down switch.
- f. Save the selected KV and mAs figures with pushing the "save" button.
- g. When the "Ready LED" sign appears, press the hand switch again and make exposure. During the x-ray exposure, the "X-ray LED" will be lighted on.
- h. After the exposure is ended, "wait LED" sign will be lighted on for the waiting time and beep sound will be heard.

6.1.3 DOSIMETRY DATA DISPLAY MODE

- a. After the exposure is ended, dosimetry data will be displayed on the FND for two seconds.
- b. Push the button 1 for two seconds, there will be displayed a dosimetry data for current kV and mAs value.
- c. Push the button 2 for two seconds, there will be displayed the total exposed dose.
- d. Push the button 3 for two seconds, there will be reset to zero.

6.1.4 COOLING TIME DISPLAY MODE

EPX-series have the cooling time function for protecting the device. The cooling time function is to stop the device when operator uses the device over standard. EPX-series will start automatically the cooling time procedure when operator shoots x-ray twice in a row. If the cooling time has more than 60 seconds, the cooling time will be extended after shooting twice consecutive. But the cooling time doesn't excess more than 300 seconds.

- The Cooling time range: 15 seconds ~ 300 seconds

Cooling time (CLT) basis of each EPX models are as follows:

- EPX-F1600, EPX-F2400, EPX-F2800, EPX-F3200
 - If $300[\text{J}] < \text{Heat Value} \leq 1,000[\text{J}]$, the CLT is 15 seconds.
 - If $1,000[\text{J}] < \text{Heat Value} \leq 2,000[\text{J}]$, the CLT is 30 seconds.
 - If $2,000[\text{J}] < \text{Heat Value} \leq 4,000[\text{J}]$, the CLT is 60 seconds.
 - If $4,000[\text{J}] < \text{Heat Value} \leq 5,500[\text{J}]$, the CLT is 90 seconds.
 - If $5,500[\text{J}] < \text{Heat Value}$, the CLT is 120 seconds.
- EPX-F4000, EPX-F5000
 - If $300[\text{J}] < \text{Heat Value} \leq 1,000[\text{J}]$, the CLT is 15 seconds.
 - If $1,000[\text{J}] < \text{Heat Value} \leq 2,000[\text{J}]$, the CLT is 30 seconds.
 - If $2,000[\text{J}] < \text{Heat Value} \leq 3,200[\text{J}]$, the CLT is 60 seconds.
 - If $3,200[\text{J}] < \text{Heat Value} \leq 5,000[\text{J}]$, the CLT is 90 seconds.
 - If $5,000[\text{J}] < \text{Heat Value} \leq 6,500[\text{J}]$, the CLT is 120 seconds.
 - If $6,500[\text{J}] < \text{Heat Value}$, the CLT is 180 seconds.

6.1.5 TURN OFF

- a. Set to the minimum kV and mAs value.
- b. Turn off the power switch.
- c. Unplug the power cable from the device.

6.2 TOUCH MAIN SCREEN OF OPERATION MODE (OPTION)

6.2.1 NORMAL MODE OF TOUCH MAIN SCREEN

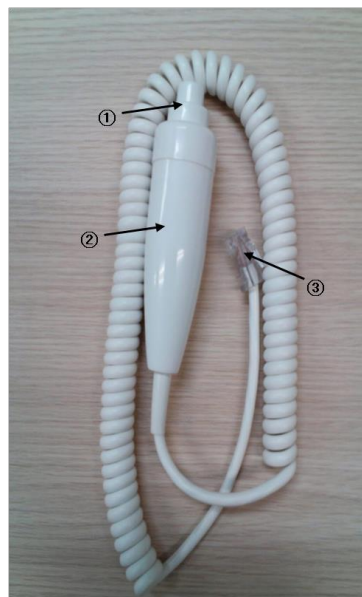
After Start-up Screen is successfully launched, the following Touch Main Screen will be displayed.



No.	Description	Function
1	kV Indicator	Display kV Value (1KV increment)
2	kV value up/down control buttons	Select kV value by tapping up (increase) or down (decrease) buttons
3	mAs Indicator	Display mAs Value
4	mAs value up/down control buttons	Select mAs value by up or down buttons
5	Sec indicator	kV, mAs set values calculate the time automatically.
6	Sec value up/down control buttons	Select sec value by tapping up/down buttons. Changing Sec value automatically change mAs accordingly.
7	mA Indicator	Filament current value determined by kV and mAs setting
8	Collimator lamp on/off button	Switch for operation of the lamp inside the collimator
9	Laser pointer on/off button	To turn on/off the dual laser to adjust exposure SID
10	Ready button	Before any X-ray exposure, press this button for 3 seconds to complete filament Pre-heating. When the preheating is completed, this item (13) Ready indicator will light up. This is the same function as half-pressing the exposure hand-switch.

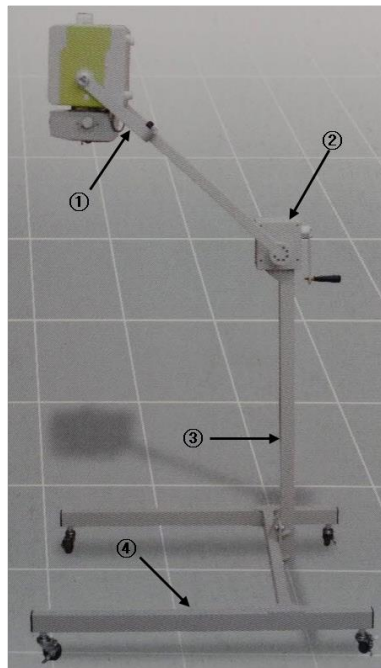
11	X-ray exposure button	X-ray exposure is done by pressing this button. During exposure, the X-ray Exposure indicator (14) will light up. This function also can be accomplished by pressing down the hand-switch completely.
12	Menu button	Reserved
13	Ready indicator	Lighted push the hand switch one time for preparation
14	X-ray exposure indicator	Alert lamp during X-ray exposure
15	Error indicator	When the system has error, this Error indicator will light up.
Ⓐ	Equipment angle indicator	Dispalys the horizontal/vertical tilting status of the equipment
↔	Scroll	Touch-and-drag the screen action (left-right or right-left direction) will display alternating screen (kV, mAs indicator vs. sec and mA display)

6.3 HAND SWITCH



No.	Name	Description
1	Hand Switch (Dead-man type)	1 st stage: The equipment gets ready when the button is half pressed with a thumb. 2 nd stage: The equipment exposes X-ray when the button is fully pressed with a thumb. It automatically turns off according to the value of mAs set by the program or when the thumb is off the switch.
2	Handle	Hand-Switch to grab with hands.
3	Connector	Connector to connect X-ray equipment and a Hand-Switch

6.3 MOBILE STAND



No.	Name	Description
1	Arm	Arm of a stand to fix X-ray equipment or change its direction
2	Height adjustment	Handle or gearbox to adjust height of the equipment
3	Gantry	Gantry to fix arm or height adjustment component
4	Rack	Rack to hold up X-ray device or stand components (wheels included for carrying the equipment)
5	Caster	Wheels for movement with the brake

CAUTION

THE OPERATOR MUST KEEP THE PRECAUTIONS WHEN USING MOBILE STAND WITH DEVICE.

Precautions for use

- Mobile stand arm should be 0° position when moving.
- Mobile stand casters should put on the brake when using.
- Do not strongly push, press and lean on the mobile stand side.
- Do not use other products except specified products.
- Do not use to exceed the maximum allowable weight.
- Do not swing to the mobile stand arm and hanging on the mobile stand arm.

7. MAINTENANCE PROCEDURE

7.1 GENERAL CAUTION

It is recommended to follow the maintenance procedure described below, for the reliable operation. The routine inspection should be committed by a trained expert.

WARNING

THERE MAY CAUSE SERIOUS INJURY BY CONDUCTING UNAUTHORIZED SERVICE OR CHANGING THE INSTRUMENT AND MANUFACTURER SHALL NOT BE RESPONSIBLE FOR THE RESULTING COMPENSATION.

If operator has any questions about the equipment, please let manufacture or the agent know the model name and serial number (S/N) indicated on the device, can provide a rapid service.

7.2 MAINTENANCE SCHEDULE

	Maintenance/control item	Period	Inspector
1	mA: (Lower than management standards of EN60601-2-54) Should be within accuracy boundary of $\pm 3\%$, with the voltage set by 40 kV and 120 kV.	1 Year	Service personnel with expertise
2	mAs: (Lower than management standards of EN60601-2-54) Should be within accuracy boundary of $\pm 5\%$, when the mAs value is between 0.4 mAs and 100 mAs.	1 Year	Service personnel with expertise
3	kV: (Lower than management standards of EN60601-2-54) Should be within accuracy boundary of $\pm 5\%$, when the kV value is between 40 kV and 120 kV.	1 Year	Service personnel with expertise
4	Optical Maintenance: When dirt appears on the image, remove dirt on Collimator window with soft brush.	1 Year	Service personnel with expertise
5	Reproducibility of the RADIATION output Maintenance: The displayed value on the FND should not exceed 40% of the actual value for areas larger than 200 cm^2 .	1 Year	Service personnel with expertise

7.3 CLEANING

- Keep the machine clean when it gets dirt.
- To clean the main-body, turn off the power and pull the plug out from the outlet.
- Scrub surfaces smoothly with soft fabric or gauze.

7.4 TROUBLESHOOTING

These are the information about indicating a system malfunction to do not appear in the message window. If the device occurs a problem to except on the below troubleshooting table, consult manufacture or the agent. The troubleshooting table does not put it for all problems.

	Problem Item	Cause	Action
1	If the X-ray does not be exposed,	1. Hand switch contact failure 2. Hand switch malfunction 3. HV mono block tank malfunction	1. Try hand switch plug out and plug in 2. Replacing the hand switch 3. Call for service
2	If the power switch down automatically,	FET Driver Board malfunction	Call for service
3	If the device dose not power on,	1. Main power board malfunction 2. SMPS malfunction	Call for service
4	If the control button does not operate,	1. Control button failure 2. Main control board malfunction	Call for service
5	If the console does not display,	1. Main power board or SMPS malfunction 2. Main control board malfunction	Call for service
6	(Option) If the touch screen does not operate incorrectly,	1. Fail to initialize touch screen 2. Touch screen malfunction	1. Please turn it off and on again 2. Call for service

7.5 THE EQUIPMENT OPERATION CHECKLIST FOR OPERATOR

	Check Item	Verdict
1	kV and mAs values display on the console when power on.	
2	kV and mAs up/down button operation.	
3	Collimator lamp on/off operation	
4	Laser pointer on/off operation	
5	Display reversal button operation	
6	Ready indicator light on when the hand switch push one time for preparation	
7	Exposure indicator light on during x-ray exposure	
8	Wait indicator light on after x-ray exposure	
9	Occur beep sound after x-ray exposure	
10	Display APR data when push APR 1~6 button	
11	Save APR data when push save button	
12	Movement of knob on the collimator	
13	Movement of handle on the equipment	
14	(Option) Check touch screen operation	

7.6 MAINTENANCE CHECKLIST

MAINTENANCE CHECKLIST

MODEL: _____

SERIAL NUMBER: _____

Measuring tool:

- Oscilloscope (EP: 1 V = 20 kV, IP: 1 V = 5.8 mA)
- Dose Area Product Meter

	Checklist	Verdict
1	Check that mA accuracy within boundary of $\pm 3\%$.	
2	Check that mAs accuracy within boundary of $\pm 5\%$.	
3	Check that kV accuracy within boundary of $\pm 5\%$.	
4	Check that reproducibility of the radiation output. The displayed value on the FND should not exceed 40% of the actual value for areas larger than 200 cm ² .	
5	Check that remove dirt on Collimator window with soft brush.	
6	Check that collimator mounting ring is tight.	
7	Check beam alignment.(SID)	
8	Check that all indicator lights are operating.	
9	Check that all hardware is tightly secured.	
10	Check all interconnect cables for broken or frayed wires.	
11	Make sure all bolts are secure.	

Service Engineer: _____

Check Date: _____

8. DISPOSAL OF WASTE



If the X-ray system has completed its useful service life, local environmental regulations must be complied with in regard to disposal of possible hazardous materials used in the construction of the generator.

In order to assist with this determination, the noteworthy materials used in the construction of this generator are itemized below:

ITEM

- Electrical insulating oil in HT tank. This is a mineral oil with trace additives (1.8 Liter)
- Solder (lead/tin).
- Epoxy fiberglass circuit board materials, tracks are soldering on copper.
- Wire, tinned copper. Insulated with PVC or silicone.
- Steel and / or aluminum (x-ray system body and console chassis).
- Plastic (console membrane).
- Electrical and electronic components: IC's, transistors, diodes, resistors, capacitors, etc.

9. QUALITY WARRANTY

■ Scope & Duration of Warranty

EPX-SERIES manufactured by Ecotron Co.,Ltd are warranted to be free from defects for a period of two years after purchase date. If during the warranty period the product you purchased is found to be defective, it will be repaired free of charge.

In the case of one of the following, however, a certain amount of service fees will be charged.

- Defect or damage found after the warranty period.
- Defect or damage in appearance which is not related to main function of the system.
- Damage caused by a natural disaster; such as fire, earthquake, or lightning strikes.
- Damage resulting from either improper movement or inattention to the precautions.
- Damage resulting from repair or modification by someone other than Ecotron or the authenticated by Ecotron Co.,Ltd.
- Damage caused by a natural disaster; such as fire, earthquake, or lightning strikes.
- Incidental or indirect loss caused during system manipulation.

Any or all defect or damages in appearance, which do not affect the main functions of the product are not covered by this free of charge warranty.

■ Prerequisites for Repair Request

- When a defect is found, stop the using immediately. It is strongly recommended to refer to related material on the Service Manual.
 - Before a service request, must power off the entire system and check the model number, serial number, and the purchase date. Then contact an authorized service office.
- Any product with a defect in appearance only shall not be returned to nor replaced by Ecotron Co.,Ltd. Ecotron Co.,Ltd. shall not be liable any incidental or consequential damages arising out of or relating to the use of the product.
- Ecotron Co.,Ltd. shall not be liable for any damages or losses occurring after the warranty period.
- This Quality Warranty prevails over the detailed Warranty for fitness or all other warranties in relation to the product.
- When a problem occurs with the product, customer should pay to the shipping cost of the product.

10. INTENDED OPERATOR AND SERVICE PERSONAL PROFILE

10.1 OPERATOR PROFILE

Considerations		Requirement description
Education	Minimum	- At least graduate of medical college
	Maximum	- No maximum
Knowledge	Minimum	- Read and understand 'westernized Arabic' numerals when written in Arial font - Can distinguish of human body - Understands hygiene
	Maximum	- No maximum
Language understanding	Minimum	- Local language
	Maximum	- Understanding of manual that is writing in English
Experience	Minimum	- Have license of radiologist or have to meet local regulation
	Maximum	- No maximum
Permissible impairments	Minimum	- Mild reading vision impairment or vision corrected to log MAR 0.2 - Average degree of aging-related short term memory impairment - Impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz

10.2 SERVICE PERSONAL PROFILE


Considerations		Requirement description
Education	Minimum	- At least graduate of high school
	Maximum	- No maximum
Knowledge	Minimum	- Read and understand 'westernized Arabic' numerals when written in Arial font - Can distinguish of human body - Understands hygiene
	Maximum	- No maximum
Language understanding	Minimum	- Local language
	Maximum	- Understanding of manual that is writing in English
Experience	Minimum	- Only authorized and properly trained by ECOTRON
	Maximum	- No maximum
Permissible impairments	Minimum	- Mild reading vision impairment or vision corrected to log MAR 0.2 - Average degree of aging-related short term memory impairment - Impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz

APPENDIX A EMC DECLARATION

Guidelines and manufacturers: electromagnetic emission			
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.			
Emission test	Compliance	Electromagnetic setting: guidelines	
RF emission CISPR 11	Group 1	Since the Diagnostic X-ray System only uses RF energy for internal functions, it has very low RF emissions and normally cause no interference to neighboring electronic devices.	
RF emission CISPR 11	Class A	The Diagnostic X-ray System is suitable not only in non-household facilities but can also be used by directly connecting to the common low-power network in a building.	
Harmonic wave emission CISPR 11	Class A		
Voltage changes/flicker emission CISPR 11	Compliance		
Full compliance to the IEC 60601-1-2:2004 and the System's tolerance to EM waves			
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.			
Tolerance test	IEC 60601 test level	Suitability level	Electromagnetic setting: guidelines
Static electricity discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV in the air	+/- 6kV contact +/- 8kV in the air	The floor should be in wood, concrete or ceramic tiles. If the floor is in a synthetic material, the relative humidity should be at least 30%.
Suitability in electric oversprays IEC 61000-4-4	+/- 2kV power supply unit line +/- 1kV input/output line	+/- 2kV power supply unit line +/- 1kV input/output line	The main power's quality should be equal to the those of general commercial or hospital settings.
Surge IEC 61000-4-11	+/- 1kV line-line +/- 2kV line-earth	+/- 1kV line-line +/- 2kV line-earth	The main power's quality should be equal to the those of general commercial or hospital settings.

<p>Voltage loss in the power supply, short intermittence and voltage changes</p> <p>IEC 61000-4-11</p>	<p><5% UT(<95%Dip at the UT), 0.5 cycles 40% UT(60% Dip at the UT), 5 cycles 70% UT(30% Dip at the UT), 25 cycles</p> <p><5% UT(>95% Dip at the UT), 5 seconds</p>	<p><5% UT(<95%Dip at the UT), 0.5 cycles 40% UT(60% Dip at the UT), 5 cycles 70% UT(30% Dip at the UT), 25 cycles</p> <p><5% UT(>95% Dip at the UT), 5 seconds</p>	<p>The main power's quality should be equal to the those of general commercial or hospital settings.</p> <p>Note : Most components in the Diagnostic X-ray System have their power supplied from the uninterrupted power supply.</p> <p>The IEC61000-4-11 only applies to the Diagnostic X-ray System Power Box.</p>
<p>Magnetic field in the source frequency (50/60Hz)</p> <p>IEC 61000-4-8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>The magnetic field in the source frequency should be equivalent to the those of general commercial or hospital settings.</p>

Note: The UT is the main AC voltage before the test standards have been applied.

Guidelines and manufacturers: electromagnetic tolerance			
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.			
Tolerance test	IEC 60601 test level	Suitability level	Electromagnetic setting: guidelines
Conductive RF IEC61000-4-6	3Vrms 150kHz-80MHz	3Vrms	When using a portable or a mobile RF communication equipment, the recommended intervals, which have been calculated using the equations, should be maintained. These calculations should be made in accordance with all of the Diagnostic X-ray System's parts (including switches) and its transmitter-receiver's frequency. Recommended intervals: $d = 1.17\sqrt{p}$ $d = 1.17\sqrt{p}80\text{MHz} \sim 800\text{MHz}$ $d = 2.33\sqrt{p}800\text{MHz} \sim 2.5\text{GHz}$,
Radioactive RF IEC61000-4-3	3v/m 80MHz-2.5GHz	3v/m	where p is the transmitter-receiver's maximum power rating in watts (W) and d is the recommended interval. The magnetic field strength in the fixed RF receiver, which has been determined in the EM wave walkdown ¹ , should be lower than the compliance standards of each frequency range ² . Interference may occur around the equipment whose symbol is as follows. 
Note 1: The high-frequency range is applied at 80MHz and 800MHz.			
Note 2: This guideline does not apply in all situations. Electromagnetic waves may be affected through absorption into and reflection from structures, objects and people.			

Guidelines and manufacturers: electromagnetic tolerance

It is very difficult to accurately predict the magnetic field strength of wireless (mobile/wireless) telephones, land mobile radio base station, amateur wireless, AM, FM wireless and TV broadcasting systems. To assess electromagnetic settings using fixed RF receivers, area walkdown is needed. If the magnetic field strength measured at the point where the Diagnostic X-ray System is used exceeds the applicable RF compliance level, you should check whether the Diagnostic X-ray System is operating normally. Should any performance abnormality is observed, additional action may be needed such as changing the Diagnostic X-ray System's direction or location. At the frequency range between 150kHz and 80MHz, the magnetic field strength should be less than 3v/m.

Recommended intervals between the Diagnostic X-ray System and the portable or mobile RF communications equipment

The Diagnostic X-ray System should be used in an electromagnetic setting where RF communication interferences are controlled. Users of the Diagnostic X-ray System should maintain the minimum intervals between the System and the portable or mobile RF communications equipments to prevent electromagnetic interferences more effectively.

Maximum output power rating of the transceiver-receiver Watts	Interval depending on the transceiver-receiver's frequency meters		
	150kHz ~ 80MHz $d = 1.17\sqrt{p}$	80MHz ~ 800MHz $d = 1.17\sqrt{p}$	800MHz ~ 2.5GHz $d = 2.33\sqrt{p}$
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.7	3.7	7.36
100	11.7	11.7	23.3

For maximum power voltages of receivers not on the above list, the recommended interval, d(m), can be calculated by using the equation used for the receiver's frequency. The p is the transmitter-receiver's maximum power rating in watts (W).

Note 1 : The high-frequency range is applied at 80MHz and 800MHz.

Note 2 : This guideline does not apply in all situations. Electromagnetic waves may be affected through absorption into and reflection from structures, objects and people.

APPENDIX B TECHNICAL CHART

Film Screen: Lanex Regular Screen (400 speed) 40" SID

EXAMI-NATION	Adults					Pediatric				
	THICK-NESS	KVP	MAS	Grid	Dosimetry (μGy* m ²)	THICK-NESS	KVP	MAS	Grid	Dosimetry (μGy* m ²)
HAND	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	50	2.0	NO						
WRIST	2-4cm	52	2.0	NO	9.792	-	52	1.0	NO	4.498
	5-7cm	52	2.0	NO						
FOREARM (AP)	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	56	2.5	NO						
	8-10cm	60	2.5	NO						
FOREARM (LAT)	4-6cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	7-9cm	56	2.5	NO						
	10-12cm	60	2.5	NO						
ELBOW (AP)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ELBOW (LAT)	4-6cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	7-9cm	63	2.5	NO						
HUMEROUS	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ANKLE (AP)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ANKEL (LAT)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
KNEE	7-9cm	60	4.0	NO	17.08	-	60	2.0	NO	13.68
	10-12cm	66	5.0	NO						
FOOT (AP)	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	54	2.5	NO						
FOOT (LAT)	4-6cm	58	2.0	NO	12.716	-	58	1.0	NO	6.406
	7-9cm	64	2.5	NO						
FEMUR	6-8cm	63	3.2	NO	24.348	-	63	1.6	NO	12.172
	12-14cm	66	4.0	NO						
SHOULDER	4-6cm	60	3.2	NO	21.84	-	60	1.6	NO	10.96
	7-9cm	64	4.0	NO						
L/SPINE (AP)	21-23cm	80	20	NO	245.05	-	80	8	NO	97.57

L/SPINE (LAT)	32-34cm	100	32	YES	590.1	-	100	13	YES	238.72
PELVIS/HIP	12-14cm	73	10	YES	102.8	-	73	4	YES	40.944
	20-22cm	77	20	YES	228.25					
	26-28cm	78	32	YES	374.48					
CHEST (AP)	12-16cm	80	1.0	NO	11.92	-	80	0.6	NO	7.04
	22-24cm	80	1.6	NO	19.24					
	30-34cm	80	2.5	NO	30.22					
CHEST (LAT)	32-36cm	90	2.0	NO	29.752	-	90	1.0	NO	14.532
	36-40cm	90	2.5	NO	37.362					
ABDOMEN	8-12cm	72	10	YES	100.05	-	72	4.0	YES	39.872
	18-22cm	77	20	YES	228.25					
	28-32cm	80	32	YES	392.4					

CR System: 40" SID

EXAMINATION	Adults					Pediatric					
	THICKNESS	KVP	MAS	Grid	Dosimetry (μGy* ^m)	THICKNESS	KVP	MAS	Grid	Dosimetry (μGy* ^m)	
HAND	2-4cm	50	4.0	NO	17.488	-	50	2.0	NO	8.828	
	5-7cm	50	4.0	NO		-	50	2.0	NO		
WRIST	2-4cm	52	4.0	NO	19.432	-	52	2.0	NO	9.792	
	5-7cm	52	4.0	NO		-	52	2.0	NO		
FOREARM (AP)	2-4cm	50	4.0	NO	17.488	-	50	2.0	NO	8.828	
	5-7cm	56	5.0	NO			56	2.5	NO		14.641
	8-10cm	60	5.0	NO			60	2.5	NO		17.08
FOREARM (LAT)	4-6cm	50	4.0	NO	17.488	-	50	2.0	NO	8.828	
	7-9cm	56	5.0	NO			56	2.5	NO		14.641
	10-12cm	60	5.0	NO			60	2.5	NO		17.08
ELBOW (AP)	5-7cm	60	5.0	NO	34.1	-	60	2.5	NO	17.08	
	8-10cm	63	5.0	NO			63	2.5	NO		19.021
ELBOW (LAT)	4-6cm	60	5.0	NO	34.1	-	60	2.5	NO	17.08	
	7-9cm	63	5.0	NO			63	2.5	NO		19.021
HUMEROUS	5-7cm	60	5.0	NO	34.1	-	60	2.5	NO	17.08	
	8-10cm	63	5.0	NO			63	2.5	NO		19.021
ANKLE (AP)	5-7cm	60	5.0	NO	34.1	-	60	2.5	NO	17.08	
	8-10cm	63	5.0	NO			63	2.5	NO		19.021
ANKEL (LAT)	5-7cm	60	5.0	NO	34.1	-	60	2.5	NO	17.08	
	8-10cm	63	5.0	NO			63	2.5	NO		19.021
KNEE	7-9cm	60	8.0	NO	54.56	-	60	4.0	NO	17.08	
	10-12cm	66	10.0	NO			66	5.0	NO		41.96
FOOT (AP)	2-4cm	50	4.0	NO	17.488	-	50	2.0	NO	8.828	
	5-7cm	54	5.0	NO			54	2.5	NO		13.432
FOOT (LAT)	4-6cm	58	4.0	NO	25.336	-	58	2.0	NO	12.716	
	7-9cm	64	5.0	NO			64	2.5	NO		19.647
FEMUR	6-8cm	63	6.4	NO	48.684	-	63	3.2	NO	24.348	
	12-14cm	66	8.0	NO			66	4.0	NO		33.556
SHOULDER	4-6cm	60	6.4	NO	43.648	-	60	3.2	NO	21.84	
	7-9cm	64	8.0	NO			64	4.0	NO		31.452
L/SPINE (AP)	21-23cm	80	32	NO	392.4	-	80	16	NO	195.89	

L/SPINE (LAT)	32-34cm	100	64	YES	1190.1	-	100	32	YES	590.1
PELVIS/HIP	12-14cm	73	20	YES	205.9	-	73	10	YES	102.8
	20-22cm	77	32	YES	365.52		77	16	YES	182.49
	26-28cm	78	64	YES	749.52		78	32	YES	374.48
CHEST (AP)	12-16cm	80	2.0	NO	24.12	-	80	1.0	NO	11.92
	22-24cm	80	3.2	NO	38.76		80	1.6	NO	19.24
	30-34cm	80	5.0	NO	60.7		80	2.5	NO	30.22
CHEST (LAT)	32-36cm	90	4.0	NO	60.192	-	90	2.0	NO	29.752
	36-40cm	90	5.0	NO	75.4		90	2.5	NO	37.362
ABDOMEN	8-12cm	72	20	YES	200.35	-	72	10	YES	100.05
	18-22cm	77	32	YES	365.52		77	16	YES	182.49
	28-32cm	80	64	YES	788.24		80	32	YES	392.4

DR System: Flap Panel with CSI Screen, 40" SID

EXAMI-NATION	Adults					Pediatric				
	THICK-NESS	KVP	MAS	Grid	Dosimetry (μGy* ^m ²)	THICK-NESS	KVP	MAS	Grid	Dosimetry (μGy* ^m ²)
HAND	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	50	2.0	NO						
WRIST	2-4cm	52	2.0	NO	9.792	-	52	1.0	NO	4.498
	5-7cm	52	2.0	NO						
FOREARM (AP)	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	56	2.5	NO						
	8-10cm	60	2.5	NO						
FOREARM (LAT)	4-6cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	7-9cm	56	2.5	NO						
	10-12cm	60	2.5	NO						
ELBOW (AP)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ELBOW (LAT)	4-6cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	7-9cm	63	2.5	NO						
HUMEROUS	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ANKLE (AP)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
ANKEL (LAT)	5-7cm	60	2.5	NO	17.08	-	60	1.3	NO	8.92
	8-10cm	63	2.5	NO						
KNEE	7-9cm	60	4.0	NO	17.08	-	60	2.0	NO	13.68
	10-12cm	66	5.0	NO						
FOOT (AP)	2-4cm	50	2.0	NO	8.828	-	50	1.0	NO	4.498
	5-7cm	54	2.5	NO						
FOOT (LAT)	4-6cm	58	2.0	NO	12.716	-	58	1.0	NO	6.406
	7-9cm	64	2.5	NO						
FEMUR	6-8cm	63	3.2	NO	24.348	-	63	1.6	NO	12.172
	12-14cm	66	4.0	NO						
SHOULDER	4-6cm	60	3.2	NO	21.84	-	60	1.6	NO	10.96
	7-9cm	64	4.0	NO						
L/SPINE (AP)	21-23cm	80	20	NO	245.05	-	80	8	NO	97.57

L/SPINE (LAT)	32-34cm	100	32	YES	590.1	-	100	13	YES	238.72
PELVIS/HIP	12-14cm	73	10	YES	102.8	-	73	4	YES	40.944
	20-22cm	77	20	YES	228.25					
	26-28cm	78	32	YES	374.48					
CHEST (AP)	12-16cm	80	1.0	NO	11.92	-	80	0.6	NO	7.04
	22-24cm	80	1.6	NO	19.24					
	30-34cm	80	2.5	NO	30.22					
CHEST (LAT)	32-36cm	90	2.0	NO	29.752	-	90	1.0	NO	14.532
	36-40cm	90	2.5	NO	37.362					
ABDOMEN	8-12cm	72	10	YES	100.05	-	72	4.0	YES	39.872
	18-22cm	77	20	YES	228.25					
	28-32cm	80	32	YES	392.4					

The patient population can be divided into several subgroups which are defined according to age and approximate average height and weight measurements:

- Adult [~80kg (176lb); standing height 170cm (67.0in)]
- Pediatrics
 - 12 year old [~52 kg (115 lb); 156 cm (61.5 in) standing height]
 - 5 year old [~21 kg (46 lb); 113 cm (44.5 in) standing height]
 - 1 year old [~11 kg (24 lb); recumbent length 100 cm (39.4 in.)]

NOTE

THESE SUBGROUPS ARE LISTED AS A GENERAL GUIDE. DIFFERENT SUBGROUPS THAT STILL COVER THE BROAD SIZE RANGE EXPECTED FOR PEDIATRIC PATIENTS MAY BE APPROPRIATE. THE INSTRUCTIONS COVERING PEDIATRIC USE OF RADIOGRAPHIC IMAGING SYSTEMS WAS REFERRED TO THE FDA PEDIATRIC X-RAY IMAGING WEBSITE.

[http://www.fda.gov/Radiation-](http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm)

[EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm](http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm)

IF THE X-RAY SYSTEM IS USED FOR ELDERLY PATIENTS; PREGNANT WOMEN; CHILDREN AND PATIENTS WHO REQUIRE SUPPORT, ADDITIONAL CARE MAY BE REQUIRED FOR SAFETY SUCH AS CHANGING X-RAY SETTING BY AN EXPERT.

NOTE

THE STATISTICS AND SPECIFICATIONS OF THIS UNIT AND MANUAL CAN BE MODIFIED WITH OR WITHOUT NOTIFICATION FOR THE IMPROVEMENT OF PERFORMANCE AND SAFETY.

APPENDIX C PEDIATRICS AND SMALL PATIENTS

ECOTRON strongly suggests reducing radiation dose to As Low As Reasonably Achievable (ALARA) in all patients, especially pediatric and small patients, whenever it is determined that an x-ray is necessary.

X-ray is an extremely valuable tool for diagnosing injury and disease, but its use is not without risk. This section discusses the importance of minimizing the radiation dose in children and small adults consistent with ALARA principles. Topics covered include:

- Pediatric Use
- Optimize Pediatric Protocols for your facility
- What Do I Need to Know About?

■ Pediatric Use

Radiation exposure is a concern in both adults and children. However, children are more sensitive to radiation. Using the same exposure parameters on a child as used on an adult may result in larger doses to the child. X-ray settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

■ Optimize Pediatric Protocols for your facility

The protocols supplied with the system represent examples for procedures commonly conducted in radiography. Based on the needs of a particular practice, these protocols may be modified to optimize factors such as image quality or dose reduction. Work with your team of Radiologists, Medical Physicists and Technologists to evaluate techniques that may reduce radiation dose and provide adequate diagnostic information. In addition to the recommended protocols installed on your system and suggestions in this guide, the following websites offer excellent sources of additional information on how to optimize protocols safely and effectively:

- American College of Radiology (ACR): www.acr.org
- Society of Pediatric Radiology (SPR): www.pedrad.org
- National Cancer Institute (NCI): www.nci.nih.gov/aboutnci
- Image Gently: www.imagegently.org
- US Food and Drug Administration (FDA): <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm>

■ What Do I Need to Know About?

This section presents the concepts necessary to understand Pediatric x-ray imaging. The concepts you need to understand are:

- Radiation Exposure Sensitivity
- Suggestions for Minimizing Unnecessary Dose

- Guidelines for Adjusting Individual Exposure Parameters by patient
- Patient Dose Reporting
- Dose Index Reporting Considerations
- Protocol Database Edit

Everyone shares the responsibility of minimizing pediatrics dose. There are several steps that can be taken to reduce the amount of radiation that pediatrics and small patients receive from x-ray examinations.

■ Radiation Exposure Sensitivity

Radiation exposure is a concern in all people of all ages, however, pediatrics are more sensitive to radiation exposure. Radiation risk is higher in the young as they have more rapidly dividing cells than adults. The younger the patient, the more sensitive they are.

■ Suggestions for Minimizing Unnecessary Dose

- Image the Anatomical Region Indicated (Collimation): Collimation and anatomical coverage should be carefully considered prior to each exposure. Follow your facility imaging guidelines to determine appropriate collimation.
- Check Technical Factors Before Exposure: Review technical display carefully before making an exposure to verify selected and intended technique are the same. Pay particular attention to placement of decimal point in display of numerical values. • Use Pediatric Positioning Accessories: Approved Pediatric positioning accessories are often useful for certain patients and exams. These may be helpful in decreasing motion that may contribute to repeat exposure. Understand your facilities guidelines when implementing these devices.
- Protective Apparel/Barriers/Shielding: When applicable, utilize proper protective measures as they comply with your facility guidelines.
- Consider Patient Radiation Safety Protocols: Ensure understanding and conformance of Patient Radiation/Protection Safety and ALARA principles as required by your facility. This includes patient shielding to reduce exposure to unintended areas.

■ Guidelines for Adjusting Individual Exposure Parameters by patient

Adjust Parameters: The single most important thing you can do is to always use pediatric protocols to avoid over exposure. Protocols based on patient type; adult and pediatric patients. These protocols should be considered a baseline. ECOTRON strongly recommends that you work with your Radiologist and Physicist to determine the lowest possible dose for the desired image quality. Once patient size is selected, further adjustments to kVp, MAS, Filtration and Grid can be made to further minimize patient dose.

For questions or further information, contact your local ECOTRON representative.

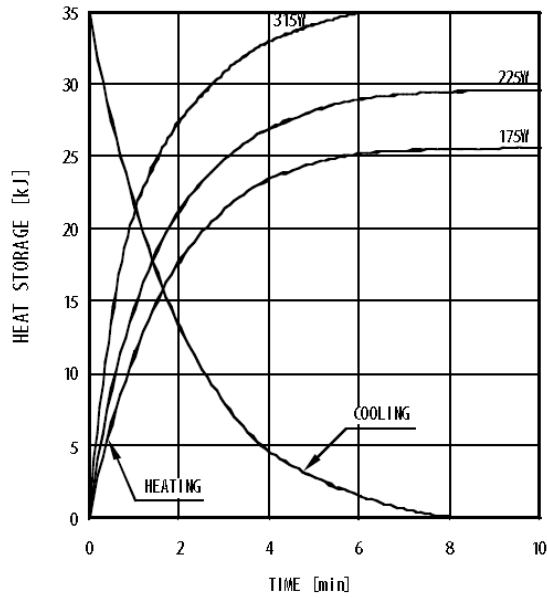
APPENDIX D ACTION TO CORRECT THE ERROR OF EPX-SERIES

Error Codes		Check points and Action
7	Ready SW ERR	a. Replace the hand switch
8	Exposure SW ERR	
10	Standby Fil FB Error	a. If error repeats at the condition of 40kV 0.4mAs EXP, replace the OP board
11	Standby EP FB Error	
12	Standby IP FB Error	
14	Run Fil FB Error	a. If error repeats at the condition of 40kV 0.4mAs EXP, check the followings by sequence. 1. Check TP in the power input of the OP board 2. Check the Reference voltage value 3. If the reference voltage is normal, replace the FET board 4. If replacing FET board does not solve the problem, the replace the HV tank.
15	Run EP FB low ERR	
16	Run IP FB High ERR	
17	Run EP FB High ERR	
18	Run IP FB low ERR	
28	Pulse by Pulse ERR	
30	KV_OVP ERR	a. If error pops up right after the unit power is turned on, then replace the OP board.
31	FIL_OC ERR FIL	b. If error repeats at the condition of 40kV 0.4mAs EXP, 1. Replace the FET board 2. If replacing FET board does not solve the problem, the replace the HV tank.
32	IP_OCP ERR	
Warning Codes		
2	Thermal ERR excess from 60°C	Wait until the temperature inside the monotank comes down to normal (Once the temperature drop to normal, the Warning Message will disappear)
29	FET-OTP FET board overheat	Wait until the temperature inside the FET board comes down to normal (Once the temperature drop to normal, the Warning Message will disappear)

APPENDIX E ANODE THERMAL CHARACTERISTICS OF X-RAY TUBE

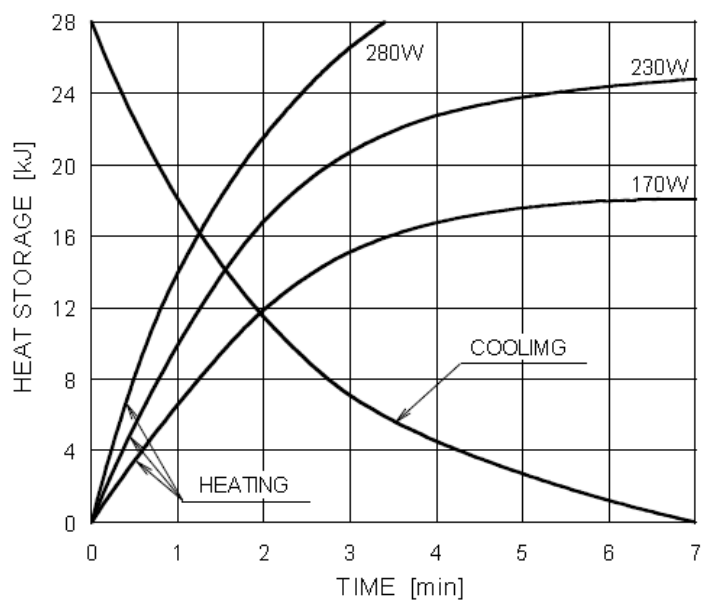
- D-125

Anode Thermal Characteristics



- D-205B

Anode Thermal Characteristics



- OX/110-15

