DT-703

Portable Dental X-ray System

Operator's Manual

D/N: ECO-UM-DT703-001 Rev. J

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CONTENTS

REVISION HISTORY

Revision Number	Date	Description
A	NOV 22, 2021	First Edition
B	NOV 18, 2022	User Manual translation correction
C	DEC 05, 2022	User Manual update for safety use
D	DEC 28, 2022	User Manual update
E	MAY 25, 2023	User Manual update
F	JUN 01, 2023	Change Device Lock Setting Method
G	JUL 05, 2023	User Manual update
H	OCT 11, 2023	User Manual update
I	NOV 17, 2023	User Manual update
J	JAN 22, 2024	User Manual update

ADVISORY SYMBOLS

The following advisory symbols are used throughout this manual.

Their application and meaning are described below.

WARNING

Warning symbol indicates a potential hazard that may expose operators, service personnel and patients to serious injury, or radiation exposure.

CAUTION

Caution symbol indicates a potential hazard that may cause injury to operators, service personnel and patients or damage to equipment.

NOTE

Note symbol indicates important information for proper usage and operation of equipment.

NOTE

KEEP THIS OPERATOR'S MANUAL WITH THE EQUIPMENT AT ALL TIMES, AND REVIEW AS NEEDED.

THE CONTENTS OF THIS MANUAL ARE SUBJECT TO CHANGE AND USERS MAY OR MAY NOT BE NOTIFIED OF SUCH CHANGES.

1. INTRODUCTION

The DT-703 is a portable dental X-ray designed to diagnose teeth and jaw through X-ray irradiation using an intra-oral image receptor.

Indications for use / Intended purpose

The DT-703 is a portable dental X-ray system that captures radiographic images for dental diagnosis using intra-oral imaging sensors. Only a trained and qualified dental practitioner or radiologist shall use DT-703 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

Radiation Safety Precautions

DT-703 Portable Dental X-ray System is safe and unlikely to result in any side effects when used properly. The amount of radiation is very low, However, young children and pregnant women are more susceptible to the effects of ionizing radiation. In these cases, exposures should only be taken when the benefit of the diagnostic exam outweighs the risk of radiation exposure.

Contraindications

- Do not keep or operate the equipment near liquids or in areas with high humidity.
- The source to skin distance should be kept at least 8inch (20cm).

NOTE

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF DENTIST LICENSED BY THE LAW OF THE STATE IN WHICH THE DENTIST PRACTICES TO USE OR ORDER THE USE OF THE DEVICE.

1.1 COMPONENTS

(1) Component Part

- DT-703 (Main Body)
- Battery Charger
- Backscatter Shield (0.5 mm Pb)
- Cradle
- Wrist Strap
- User Manual

(2) Option

- Remote Exposure Switch
- Rectangular Beam Limiting Cover (FOV 2x3)
- Rectangular Beam Limiting Cover (FOV 3x4)

NOTE

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

PLEASE ENSURE TO READ THE WARNING NOTICES BEFORE USING THE EQUIPMENT.

NOTE

ASSEMBLY INFORMATION: NO ASSEMBLY IS REQUIRED.

2. NOTICE OF GENERAL SAFETY AND SAFE OPERATION

This operating manual is designed to ensure proper use and operation of DT-703. The operator must read this operating manual thoroughly before using the equipment.

Improper operation of the equipment may cause injury to the user and patient and may cause damage to the equipment. Pay particular attention to all the warnings, cautions and notes incorporated herein.

This equipment should be used by a licensed dentist, hygienist, or dental radiologic technologist licensed by the law of the state in which the practitioner practices to use or order the use of the device.

DT-703 is designed with the due consideration for user safety and product reliability. However, adhering to the following rules is advisable for additional user safety and a healthy operating environment.

- This product should be operated only by a licensed dentist, hygienist, or a dental radiologic technologist.
- DT-703 shall only be used for intra-oral dental radiography or forensic dentistry.
- Do not modify the equipment. Contact ECOTRON or its authorized dealer for the service and repair.
- The manufacturer has calibrated this system for optimal operations.
- The portable x-ray unit should be kept in a locked location (i.e., room, closet, cabinet, etc.) when not in use to prevent unauthorized use.

WARNING

THE DEVICE IS NOT WATER PROOF.

WARNING

CHARGE THE DT-703 USING THE CRADLE AND CHARGER PROVIDED BY ECOTRON.

WARNING

POWER THIS EQUIPMENT WITH THE MAIN POWER SUPPLY CONNECTED TO EARTH GROUND TO AVOID POTENTIAL LEAKAGE CURRENT AND ELECTRIC SHOCK.

WARNING

THE EQUIPMENT MUST BE INSTALLED, MAINTAINED, AND SERVICED BY QUALIFIED SERVICE PERSONNEL ACCORDING TO THE PROCEDURES AND PREVENTIVE MAINTENANCE SCHEDULES. USERS MAY REPLACE THE BATTERY.

WARNING

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

WARNING

IT IS THE USER'S RESPONSIBILITY FOR PROPER USE AND SAFE OPERATING PRACTICES OF THIS X-RAY SYSTEM.

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

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 ANY UNATHORIZED MODIFICATION IN ANY WAY.

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

WARNING

DO NOT ALLOW OPERATION OF THIS APPARATUS BY ANY PERSON OTHER THAN QUALIFIED PERSONNEL (A LICENSED DENTIST, HYGIENIST OR DENTAL RADIOLOGIC TECHNOLOSIST).

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 BE MAINTAINED ONLY IF X-RAY SYSTEMS OPERATE WITHIN PUBLISHED SPECIFICATIONS.

CAUTION

DO NOT SHARE POWER OUTLET WITH OTHER ELECTRICAL DEVICES EXCEPT THE FOLLOWING:

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

WARNING

ENSURE THAT THE ON/OFF SWITCH IS SET TO OFF WHEN THE EQUIPMENT IS NOT IN USE.

WARNING

THE BACKSCATTER SHIELD IS PERMANENTLY ATTACHED TO THE X-RAY UNIT TO PROTECT USERS FROM BACKSCATTER RADIATION THAT THEY MIGHT OTHERWISE BE EXPOSED DURING IRRADIATION OF THE X-RAY SYSTEM.

3. NOTICE OF SAFE BATTERY USE

- Charge the battery fully before first use.
- Use the battery only provided or approved by ECOTRON. Non-standard or damaged batteries may present the risk of fire and explosion.
- Make sure to use the battery charger only provided or approved by ECOTRON. Using an unauthorized charger may result in battery damage.
- DO NOT expose batteries to heat or fire. Avoid storage in direct sunlight.
- DO NOT short-circuit, crush, puncture, mutilate, or disassemble the battery.
- DO NOT place batteries in a box or drawer where they may be short-circuited by other metal objects or with each other.
- Observe the plus (+) and minus (-) marks on the battery and equipment for correct use.
- DO NOT subject batteries to external shock.
- If a cell leaks, do not let the liquid come in contact with the skin or eyes. When contacted, wash the affected area with copious amounts of water and seek medical attention.
- Keep the battery away from children and pets.
- DO NOT make the battery wet. Keep batteries clean and dry.
- Seek medical attention immediately if a battery has been swallowed.
- Make sure to turn off the device before replacing the battery.

CAUTION

KEEP THE BATTERY FROM IN ITS ORIGINAL PACKAGING UNTIL REQUIRED FOR USE.

DO NOT DISPOSE A BATTERY WITH OTHER TRASH. DISCARD BATTERIES ACCORDING TO THE LOCAL GOVERNMENT REGULATIONS FOR PROPER DISPOSAL OR RECYCLING.

NOTE

DO NOT LEAVE THE BATTERY CONNECTED TO THE CHARGER FOR A DAY OR TWO AFTER BEING FULLY CHARGED.

IF THE EQUIPMENT HAS BEEN SITTING IDLE FOR MORE THAN TWO WEEKS, CHARGE THE BATTERY BEFORE USE.

NOTE

IF THE POWER OF THE EQUIPMENT HAS BEEN ON FOR MORE THAN 10 DAYS WITHOUT BEING USED, THE BATTERY MAY HAVE DISCHARGED COMPLETELY.

• DEPENDING UPON THE BATTERY DISCHARGE STATUS, IT MAY TAKE ABOUT 1 DAY OR 24 HOURS TO CHARGE THE BATTERY FULLY. IF THE DEVICE DOES NOT TURN ON AFTER CHARGING THE BATTERY FOR 24 HOURS, IT INDICATES THE BATTERY HAS DISCHARGED COMPLETELY. CONTACT SERVICE REPRESENTATIVE FOR BATTERY REPLACEMENT.

NOTE

USERS MAY REPLACE THE BATTERY.

WHEN CHARGING THE BATTERY, THE X-RAY EXPOSURE FUNCTION IS LOCKED.

POWER OFF THE EQUIPMENT WHEN NOT IN USE TO MAINTAIN THE BATTERY'S LIFE.

CHARGE THE BATTERY FREQUENTLY TO MAINTAIN THE LIFE OF THE BATTERY.

4. RADIATION SAFETY

- Users and operators of the X-ray system should wear appropriate personal protective equipment as required by local or State regulations.
- Keep the time of radiation exposure to a minimum
- Eliminate all unnecessary objects near the exposure zones.
- The X-ray source-to-skin distance should be at least 8 inches (20cm).
- Pregnant women or children should consult a doctor to avoid unnecessary ionizing radiation exposure.

CAUTION

THE IONIZING RADIATION MAY BE HAZARDOUS TO PATIENTS AND OPERATORS IF SAFETY STANDARD AND REGULATIONS ARE NOT PROPERLY FOLLOWED.

WARNING

THIS EQUIPMENT MUST BE OPERATED ONLY BY PROPERLY TRAINED, FULLY QUALIFIED PERSONNEL IN A CONTROLLED ENVIRONMENT.

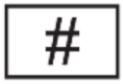
NOTE

WHEN USING A POSITION-INDICATING DEVICE (PID), PLACE THE PID AT THE END OF THE CONE WHERE THE BACKSCATTER SHIELD IS ATTACHED PERMANENTLY.

OPERATE THIS EQUIPMENT IN THE AREA THAT IS MORE THAN 6 FEET AWAY FROM OTHER PERSONNEL, SUCH AS ASSISTANTS OR OTHER PATIENTS. ANYONE WHO STAYS CLOSER THAN 6 FEET SHOULD WEAR A LEAD APRON, THYROID COLLAR OR STAY BEHIND A LEAD SHIELD AS REQUIRED BY LOCAL OR STATE REGULATIONS.

5. SAFETY AND SPECIFICATIONS

5.1 SAFETY AND WARNING SYMBOLS

MARK / SYMBOL	DESCRIPTION	LOCATION
	High voltage symbol	X-ray Generator Label
	Radiation hazard	X-ray Generator Label
	Refer to the user manual for more details.	Main Label
	Alternate current	Cradle Label
	Direct current	Main Label, Cradle Label
	Model Name	Main Label, Cradle Label, X-ray Generator Label
	Manufacturer's name and address	Main Label, Cradle Label, X-ray Generator Label
	Date of manufacture	Main Label, Cradle Label, X-ray Generator Label
	Authorized European Representative address	Main Label
	Portable Dental X-ray System (DT-703) is classified as class IIb according to the Regulation (EU) 2017/745 Annex VIII Rule 10.	Main Label
	Refer to user manual	Main Label
	This symbol indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Main Label
	IEC60601-1 Degree of Protection from Electric Shock TYPE B Equipment	Main Label
	Serial number	Cradle Label, X-ray Generator Label

Rx Only	Federal law prohibits prescription-free preparation.	Main Label

X-ray radiation exposure may be damaging to health, with some effects being cumulative and extending over many months or even years. ***X-ray operators should avoid unnecessary exposure to the primary beam*** and take protective measures to safeguard against scatter radiation. Any object in the path of the primary beam may cause scatter radiation 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 trained adequately by ECOTRON should be allowed to work with this X-ray equipment.*** The appropriate personnel must be made aware of the inherent dangers associated with the servicing high-voltage equipment and the danger of excessive exposure to X-ray radiation.

- Operators should wear protective apparel as required by local or State regulations. Protective aprons and gloves with an equivalent of a minimum of 1/64Ⅱ (0.35mm) of lead are recommended.
- To protect the patient against radiation, always use radiation protection accessories such as a lead apron and thyroid collar in addition to devices that are fitted to the X-ray System.
- Do not place or operate the equipment near liquids or in areas with high humidity.
- Do not operate the x-ray system in direct sunlight or near heat sources.
- Do not operate the x-ray system near strong magnetic fields (microwave ovens, speakers, etc.), and avoid operating the x-ray system near other medical devices.
- Operate the X-ray system in clean locations (free of excess dust, dirt, debris, etc.) and stable (free of vibration).
- Only a trained service technician may remove the cover of the x-ray system.

5.2 COMPOSITION LABEL

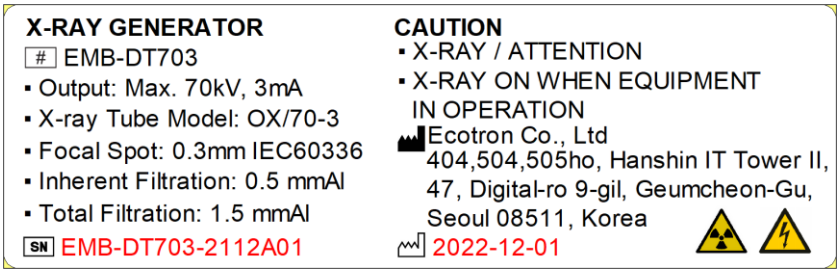
5.2.1 LABEL LOCATIONS

MAIN LABEL

This main label is on the bottom of the device. (Example)

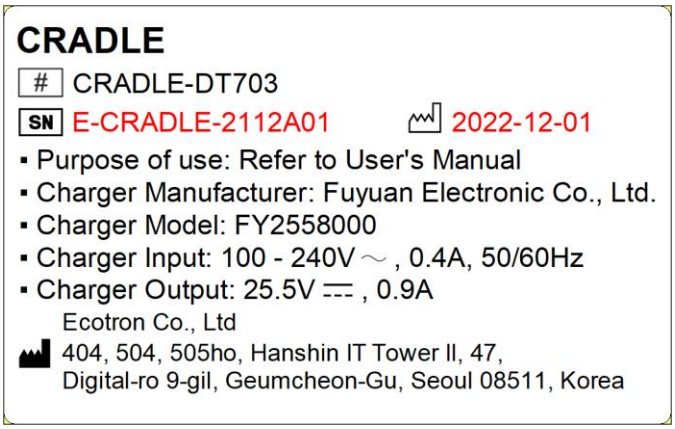
X-RAY GENERATOR LABEL

This label is on the bottom of the cone for the device. (Example)

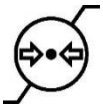


CRADLE LABEL

This label is on the bottom of the cradle. (Example)



5.2.2 SYMBOLS ON THE PACKING OF PORTABLE DENTAL X-RAY SYSTEM

SYMBOL	DESCRIPTION
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep dry
	Fragile, handle with care
	This side up
	Recycle

5.3 APPLICABLE STANDARDS AND REGULATION

The DT-703 complies with the regulatory requirements and design standards as follows:

1) SAFETY

- IEC/EN 60601-1
- IEC/EN 60601-1-3
- IEC/EN 60601-1-6
- IEC/EN 60601-2-65
- 21 CFR Subchapter J

2) EMC

- IEC/EN60601-1-2:2014

3) OTHERS

● EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
● EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
● EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021))
● EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
● EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
● EN62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
● MEDDEV 2.7.1/Rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
● MEDDEV 2.12.1/Rev.8	Medical Devices Vigilance System
● MEDDEV 2.12.2/Rev.2	Post Market Clinical Follow-up studies
● MDCG 2020-5	Guidance on clinical evaluation – Equivalence
● MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
● MDCG 2020-7	Guidance on PMCF Plan Template
● MDCG 2020-8	Guidance on PMCF Evaluation Report Template

5.4 SPECIFICATION

5.4.1 CLASSIFICATION OF THE DEVICE

CLASSIFICATION – EN 60601-1

● Type of protection against short circuit: Internally powered medical electrical equipment

● 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

CLASSIFICATION – Regulation (EU) 2017/745

● In according with Annex VIII Rule 10: CLASS IIb

5.4.2 TECHNICAL SPECIFICATION

(1) Portable Dental X-ray System (DT-703) Specification

Tube Voltage [kV]		70 kV (fixed)
Tube Current [mA]		3 mA (fixed)
Exposure Time [sec]		0.02 – 0.5 sec
Max. kV Deviation		-5 % (IEC 60601-1-65 standard limits the tube voltage of a dental X-ray system to 70 kV or lower)
Max. mA Deviation		±5 %
Max. sec Deviation		±5 %
Reproducibility		Coefficient of Reproducibility < 0.01
X-ray Tube	Model Name	OX/70-3 (C.E.I)
	Focal Spot	0.3 mm
	Target Angle	13°
	Anode Heat Storage	7 kJ
	Inherent Filtration	0.5 mm Al
	X-ray Coverage	SID 200 mm
Total Filtration		1.5 mm Al
Weight		1.6 kg (±5 %)

- **Cooling Time Chart**

Cooling time between each exposure: Max. 60 sec

(2) Power Specification

Power	Battery Type	Li-polymer		
	Battery Voltage [Vdc]	24.2 V (Normal)	25.2 V (Max)	22.2 V[Min]
	Battery Current [A]	20 A (max)		
	Charging Method	Using cradle (with battery charger)		
	Charger Max. Voltage [Vdc]	25.5 V		
	Charger Current [A]	0.9 A		

WARNING

USE THE BATTERY PROVIDED OR APPROVED BY ECOTRON ONLY. USING AN UNAUTHORIZED BATTERY MAY RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE. FOR DETAILS ON USING THE BATTERY, SEE '3.* NOTICE OF SAFE BATTERY USE*' ON PAGE 12.

NOTE

A PERIODIC REPLACEMENT (EVERY 6 MONTHS) IS RECOMMENDED.
(BATTERY WARRANTY PERIOD: 6 MONTHS)

(3) Battery Charger Specification

Rating	Input: 100 – 240 V~, 50/60 Hz, 1.5A
	Output: 29.4Vdc, 2.0A
Frequency	50 – 60 Hz
Standard	IEC 60950-1 (UL)

WARNING

USE THE BATTERY CHARGER PROVIDED OR APPROVED BY ECOTRON ONLY. USING AN UNAUTHORIZED BATTERY MAY RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE. FOR DETAILS ON USING THE BATTERY, SEE '3.* NOTICE OF SAFE BATTERY USE*' ON PAGE 12.

NOTE

- ***POWER SUPPLY IS SPECIFIED AS A PART OF MEDICAL ELECTRICAL EQUIPMENT.***
- ***POWER PLUGS MAY HAVE VARIOUS SPECIFICATIONS FOR EACH COUNTRY.***

(4) Environment Specification

- **Operating Environment**

Temperature range	10℃ - 40 ℃ (50 °F - 104 °F)
Relative Humidity Range	30% - 75%
Relative Atmospheric Pressure	860 – 1060 hPa

- **Storage and Transportation Environment**

Temperature range	-10℃ - 60 ℃ (14 °F - 140 °F)
Relative Humidity Range	10% - 75% (non-condensing)
Relative Atmospheric Pressure	500 – 1100 hPa

WARNING

FAILURE TO FOLLOW THE SPECIFICATIONS ABOVE CAN RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE.

5.4.3 DOSIMETRY DATA

The X-ray dose data is extracted from the X-ray Dose Test Report for the DT-703. The X-ray doses of the DT-703 in the test report were measured in accordance with the IEC collateral standards. The DT-703 was designed in accordance with IEC 60601-1-3.

5.4.3.1 X-RAY DOSE TABLE

TEST CONDITION	
Model Name	DT-703
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Dose Meter)	Piranha R/F 557 (CB2-21030636)

DOSE TABLE (70 kV, 3 mA, 0.5 sec, FOV: Ø 60 mm, SSD 200 mm)	
Exposure Time	Dose (μGy)
0.02	53.09
0.05	141.55
0.1	289.46
0.15	437.20
0.2	584.61
0.25	732.48
0.3	879.63
0.4	1176.71
0.5	1471.88

5.4.3.2 LEAKAGE DOSE

SCOPE

① IEC 60601-2-65 203.12.4:2021

② Michigan State Requlation

REQUIREMENTS

① IEC 60601-2-65:2021 clause 203.12.4

In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, at any point on the outer suface of the equipment, when operated at the NOMINAL X-RAY TUBE VOLTAGE under conditions of LOADING corresponding to the reference LOADING conditions, shall not exceed **0.05 mGy in one hour.**

② Michigan State Requlation

The x-ray tube housing for tubes designed to be hand-held must be constructed so that the leakage radiation measured in air at a distance 5 centimeters from a point on the external surface does not exceed **0.02 mGy (2 milliroentgens) in 1 hour** when operated under conditions of maximum radiation output permitted by the design or operating characteristics of the radiation machine.

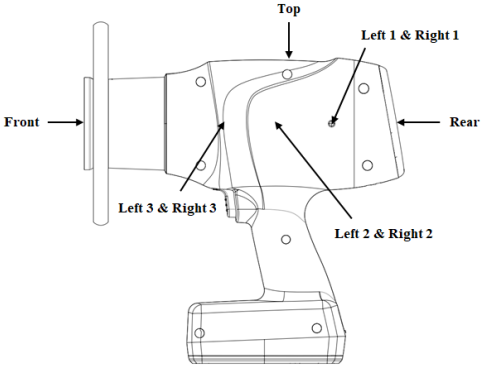
	LEAKAGE DOSE	PERMISSIVE RANGE
IEC 60601-2-65:2021 clause 203.12.4	70 kV, 3 mA, 0.5sec (Max. Exposure Condition) at any point on the outer suface of the equipment 1 : 60 Duty Cycle	< 0.05 mGy/h
Michigan State Requlation	70 kV, 3 mA, 0.5sec (Max. Exposure Condition) Air at a distance 5 centimeters from a point on the external surface 1 : 60 Duty Cycle	< 0.02 mGy/h

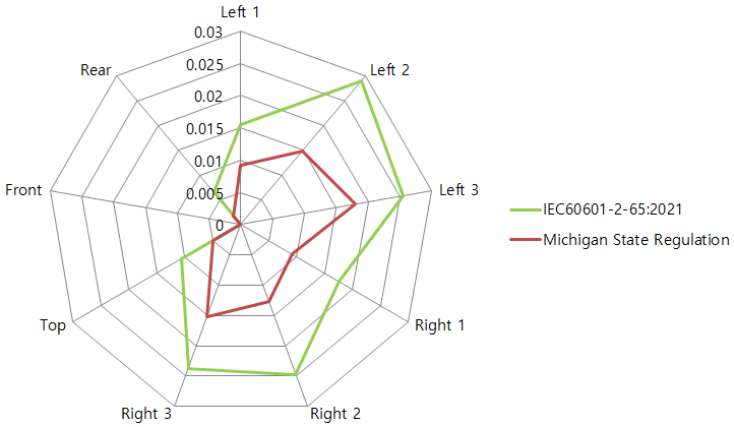
TEST CONDITION	
Model Name	DT-703
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Collimator Type	Φ 60 (Default type)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Radiation Dosimeter)	Raysafe X2 Survey Sensor

RESULTS

The following exposure timetables show the test raw data results by testing a unit equipped with a cone corresponding to a focus-to-skin distance of 200 mm (8 inches) with the default collimator type (Φ 60).

THE RESULT





Measured point	IEC60601-2-65:2021	Michigan State Regulation
	< 0.05 mGy/h	**< 0.02 mGy/h**
Left 1	0.01548	0.00924
Left 2	0.02904	0.01488
Left 3	0.02556	0.018
Right 1	0.01764	0.00912
Right 2	0.02478	0.01272
Right 3	0.02376	0.01524
Top	0.01068	0.00492
Front	0.00012	0.00006
Rear	0.00654	0.00174

5.4.3.3 SCATTERED DOSE

SCOPE

IEC 60601-1-65 203.13

REQUIREMENTS

MEDICAL ELECTRICAL EQUIPMENT shall be provided with means to optionally allow actuation of the EXPOSURE from a PROTECTED AREA after installation.

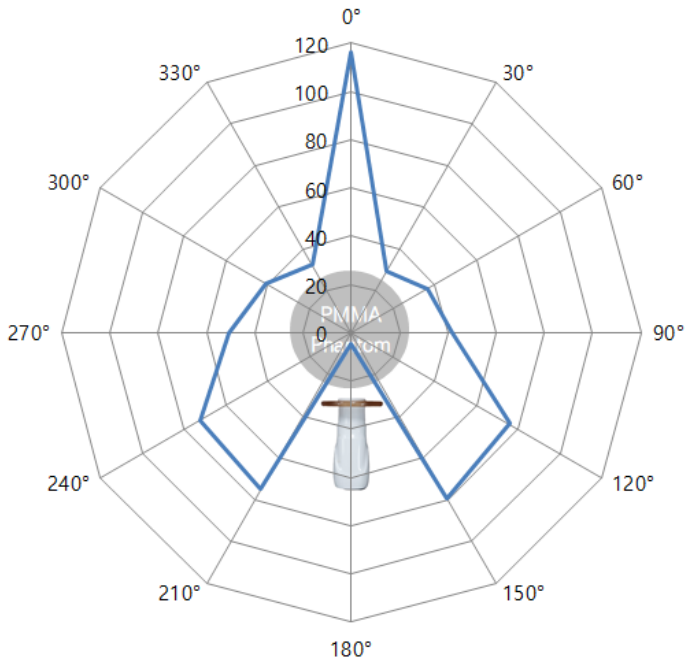
Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

SCOPE

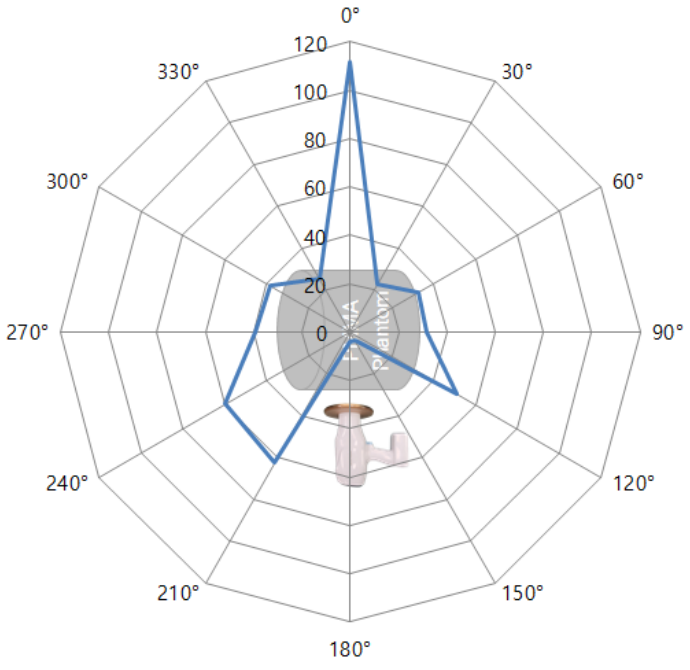
The following exposure timetables were established with a unit equipped with a cone corresponding to a focus-to-skin distance of 200 mm (8 inches) respectively.

TEST CONDITION	
Model Name	DT-703
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Collimator Type	Φ 60 (Default type)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Radiation Dosimeter)	Raysafe X2 Survey Sensor
Phantom	PMMA Phantom

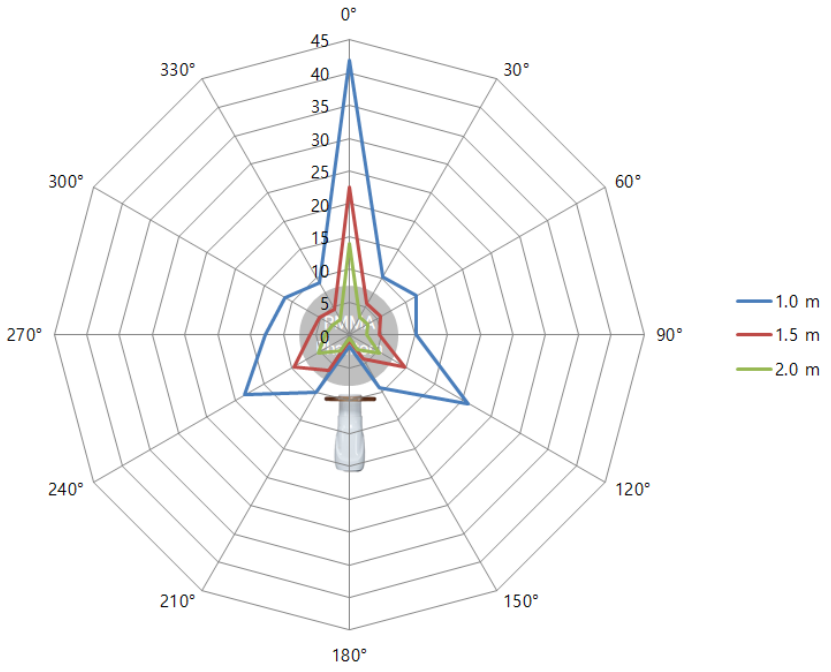
MEASURED METHOD 1	
PMMA Phantom aligned to 280 mm away from Focal Spot **Max. Exposure Condition** **Measure point: 500 mm from PMMA Phantom**	
DIRCTION	**RESULT (HORIZONTAL PLANE) [μR]**
	WITH SHIELD
0°	116.2
30°	29.5
60°	36.6
90°	41.8
120°	75.6
150°	79.2
180°	4.9
210°	74.8
240°	72.4
270°	50.4
300°	40.8
330°	32.4



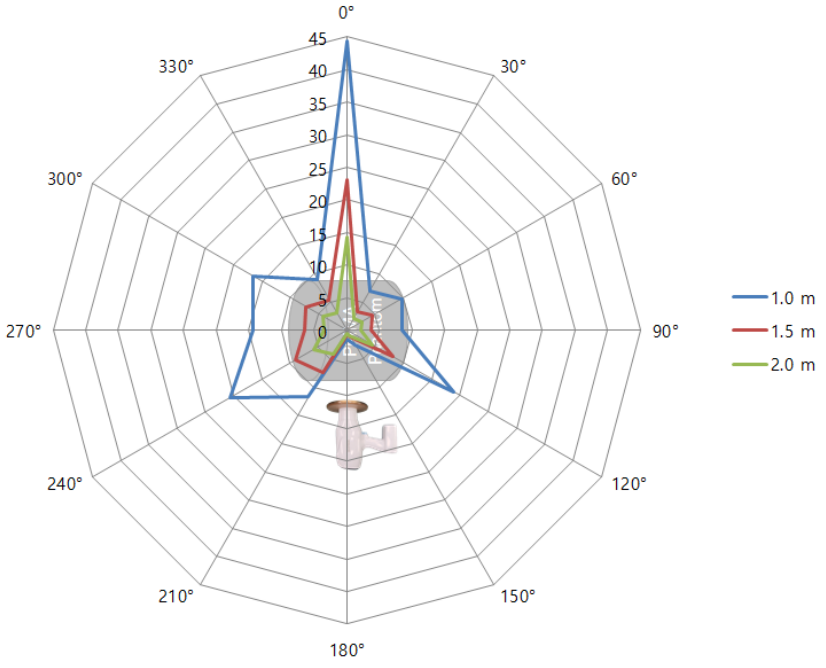
MEASURED METHOD 1	
PMMA Phantom aligned to 280 mm away from Focal Spot **Max. Exposure Condition** **Measure point: 500 mm from PMMA Phantom**	
DIRCTION	**RESULT (VERTICAL PLANE) [μR]**
	WITH SHIELD
0°	112
30°	22.6
60°	32.3
90°	31.6
120°	51.1
150°	4.3
180°	3.8
210°	62.6
240°	59.6
270°	39.2
300°	38.2
330°	25.5



MEASURED METHOD 2			
PMMA Phantom aligned to 280 mm away from Focal Spot **Max. Exposure Condition** **Measure point: 1.0, 1.5, 2.0 m from PMMA Phantom**			
DIRCTION	**RESULT (HORIZONTAL PLANE) [μR]**		
	1.0 m	**1.5 m**	**2.0 m**
0°	41.9	22.5	13.9
30°	10.3	5.5	3.2
60°	11.9	5.6	3.3
90°	10.3	4.7	2.7
120°	21	9.8	5.4
150°	9.2	4.2	2.5
180°	1.7	0.8	0.5
210°	10	6.3	2.8
240°	18.3	9.6	5.5
270°	12.7	6	3.7
300°	11.2	5.3	3
330°	9.1	4.6	2.6

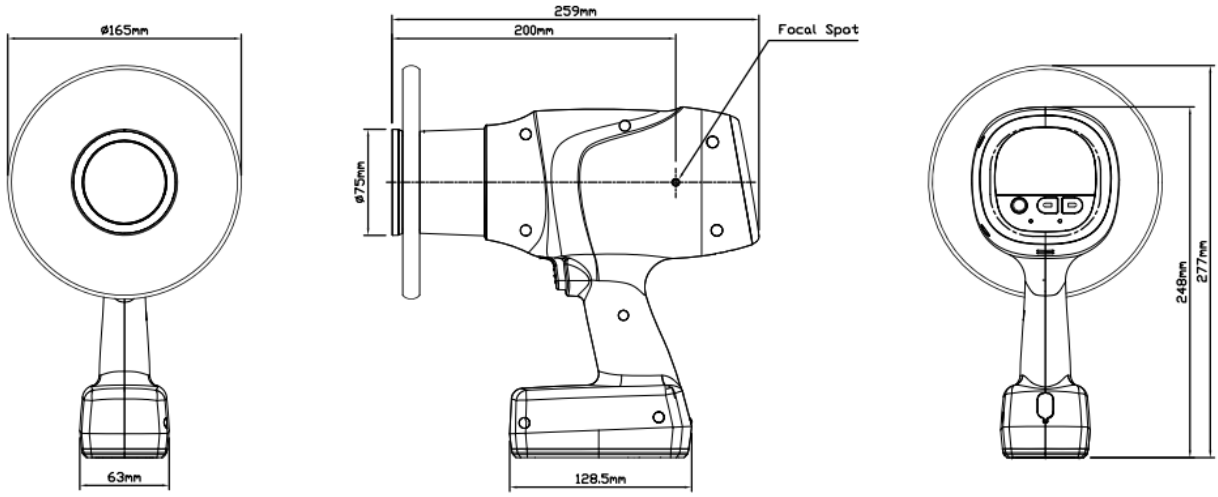


MEASURED METHOD 2			
PMMA Phantom aligned to 280 mm away from Focal Spot **Max. Exposure Condition** **Measure point: 1.0, 1.5, 2.0 m from PMMA Phantom**			
DIRCTION	**RESULT (VERTICAL PLANE) [μR]**		
	1.0 m	**1.5 m**	**2.0 m**
0°	44.4	23.1	14.2
30°	7	3.4	2.1
60°	9.7	4.5	2.6
90°	8.4	3.7	2.1
120°	18.9	8.1	4.5
150°	2.6	1.2	0.9
180°	1.4	0.7	0.4
210°	11.7	7.4	4.2
240°	20.7	9	5.8
270°	14.3	6.5	3.5
300°	16.6	7.3	4.2
330°	8.9	5.4	3.2



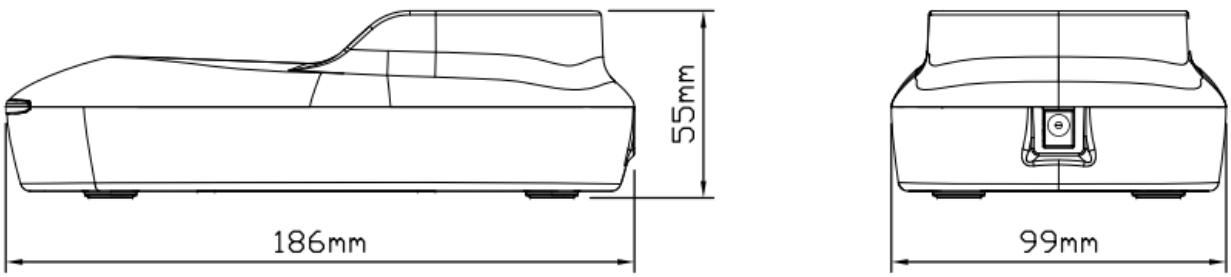
5.4.4 MECHANICAL SPECIFICATION

DT-703 Dimension (unit: mm)



ITEM			DESCRIPTION
Main Body	Dimension [mm]		259 (L) x 277 (H) x Ø 165
	Weight [kg]		1.6 kg
X-ray Beam Limiting Device	X-ray Beam Area [mm]	Round Type	FOV: Ø 60
		Rectangular Type	FOV: 20 x 30, 30 x 40
	SSD (Source to Skin Distance) [mm]		200

Cradle Dimension (unit: mm)



5.5 CUSTOMER SUPPORT

Address any questions regarding Portable Dental X-ray system operation to:

ECOTRON Co., Ltd.

404, 504, 505Ho, 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: export@ecotron.co.kr

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

In USA

ECOTRON America Inc.

12325 SW 6th PL, Newberry, Florida, 32669, USA

TEL: +1-352-363-3132

E-mail: jun1117@ecotron.co.kr

EC REP 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

6. SYSTEM FEATURES

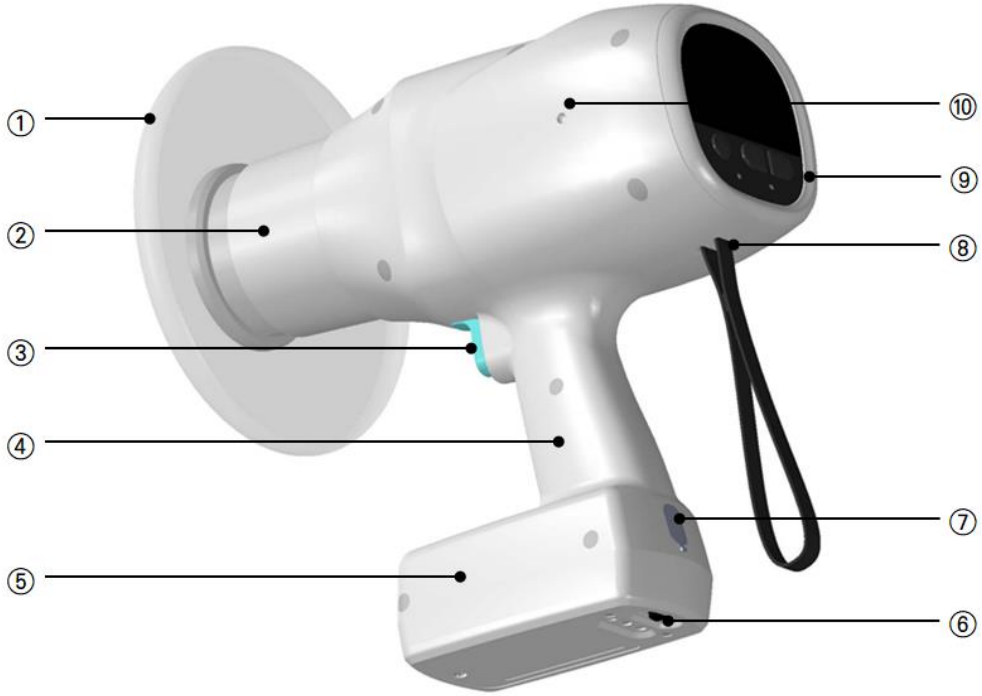
Portable Dental X-ray System (DT-703) is a radiologic device for dental radiographic diagnoses. It should be applied for the radiographic diagnosis and operated by a licensed dentist, hygienist or a dental radiologic technologist by the law of the state. Users have to comply with safety and health regulations concerning the ionizing radiation protection and the electrical and mechanical safety of the medical devices.

The DT-703 is an intra-oral portable X-ray system that offers safety, reliability, and greater functionality:

- Lightweight and ergonomic design
- Convenience of cordless design by using battery pack
- Micro-computer and a specialized circuit that Flexible Numerical Display (FND) LCD and precisely regulates the exposure time (kVp and mA are fixed).
- Pre-programmed exposure time makes the operation fast and easy
- Automatic cooling time function prevents equipment failure due to excessive heating from overuse.

6.1 GENERAL VIEW OF EQUIPMENT

MAIN BODY



No.	ITEM	DESCRIPTION
1	Backscatter Shield	Shields from the backscattering radiation
2	X-ray Beam Limiting Device	Limits the X-ray exposure area. (FOV: Ø 60 mm)
3	X-ray Exposure Button	Press the button for X-ray exposure
4	Device Handle	Grip the handle securely when using the system
5	Battery	Rechargeable Li-polymer battery
6	Power Switch	Power On / Off switch
7	Remote X-ray Exposure Switch Port	Connect the X-ray exposure switch cable. (and can be used as a service port)
8	Strap Loop	Connect the strap
9	Control Panel	Display for the X-ray exposure settings and operation conditions
10	X-ray Generator	Includes the Mono Block (X-ray tube + high-voltage generator)

CONTROL PANEL

No.	ITEM	DESCRIPTION
1	Sensor Mode Selection	Select the Sensor mode: DR, CR, F-speed Film (Do not use D-speed film)
2	Battery Charging & Level	Indicates battery charging & battery remaining level
3	X-ray ready Indicator	Indicates X-ray irradiation ready status
4	X-ray Exposure Indicator	Indicates during X-ray irradiation status
5	X-ray Exposure Time	• Display the X-ray exposure time • Display an error & warning code, cooling time, low battery etc.
6	Patient Type Selection	Select adult (Big), adult (normal) or Child
7	Tooth Type Selection	Select the tooth type (incisor, canine, molar/premolar or bitewing)
8	Enter Button	Enter
9	L & R Adjustment and Movement	Move left or right for menu (or mode) selection
10	Exposure Button Lock Indicator	Indicates the X-ray irradiation button is locked
11	User Option Setting Indicator	Indicates that user has entered the user option settings menu.

CRADLE

No.	ITEM	DESCRIPTION
1	Charging Indicator	Blue: Battery charging in progress Green: Battery fully charged and stand by
2	Battery Charger Port	Connect the battery charger

6.2 OPERATION

6.2.1 POWER ON / OFF

① Power on the system referring to the following figure.

② The following displays and indicators light up:

- Sensor mode display
- Battery charging & level display
- X-ray exposure time display
- Patient type display
- Tooth type display

③ Confirm that at least one battery indicator light is on before operation.

Battery Level I

NOTE

WHEN THE BATTERY INDICATOR HAS A FLICKERING LIGHTNING SIGN AND DISPLAYS "LBT", CHARGE THE BATTERY IMMEDIATELY BY USING THE BATTERY CHARGER.

6.2.2 OPERATION MODE

SENSOR SELECTION

Press the Enter Button to get into the sensor mode and see the sensor mode area flickers. Select the desired sensor mode and press the Enter Key using the Left and Right Key.

No.	SENSOR MODE	ICON
1	DR (Digital Radiography)	DR
2	CR (Computed Radiography)	CR
3	FM (Film)	FM

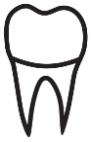
PATIENT TYPE

Press the Enter Button for the patient type setting. When the patient type area flickers, use the Left & Right Key to select the desired patient type and press the Enter Key.

No.	SENSOR MODE	ICON
1	Adult (Big)	
2	Adult (Normal)	
3	Child	

TOOTH TYPE

Press the Enter Button for the tooth type setting. When the tooth type area flickers, use the Left & Right Key to select the desired tooth type and press the Enter Key.

No.	SENSOR MODE	ICON
1	Incisor	
2	Canine	
3	Molar / Premolar	
4	Bitewing	

X-RAY EXPOSURE TIME

Press the Enter Button for the X-ray exposure time setting. When the X-ray exposure time area flickers, use the Left & Right Key to adjust the desired the X-ray exposure time and press the Enter Key.

The X-ray exposure time can be set between 0.02 to 0.5 sec and adjustment by 0.01 sec increment.

6.2.3 POSITIONING

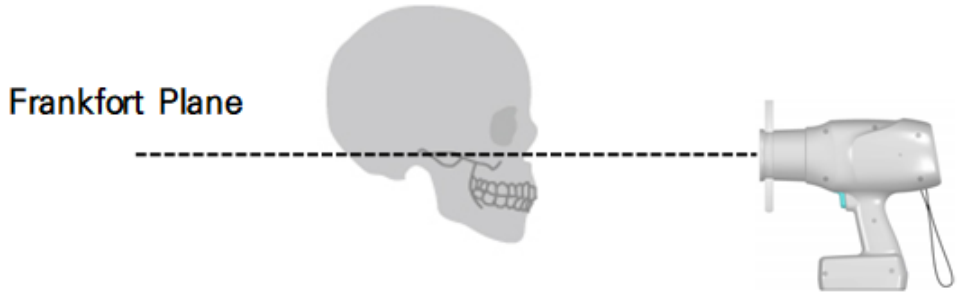
POSTIONING THE PATIENT

In order to obtain a high-quality intra-oral radiography image, align the patient positioning, the portable dental X-ray system, and the intra-oral image receptor as directed in the entire exposure process.

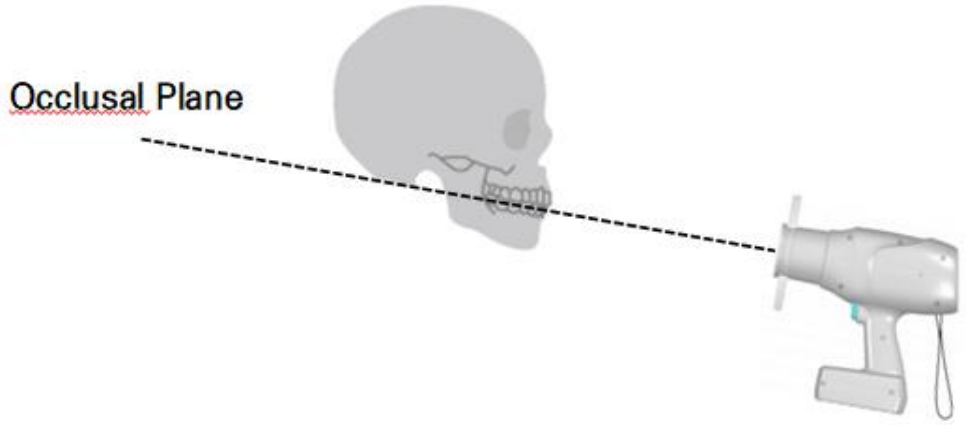
① Direct the patient to wear the lead apron to protect from scatter radiation.

② Position the sagittal plane of the patient's head perpendicular to the X-ray exposure.

- For maxillary radiography, it shall be level with the Frankfort plane.



- For mandibular radiography, it shall be level with the occlusal plane.



③ Place the cone of the portable dental x-ray system in the targeted area for imaging. When holding the device, it is recommended to grip the handle by one hand and place the other on the underside of the cone of the X-ray system as shown in the following picture.

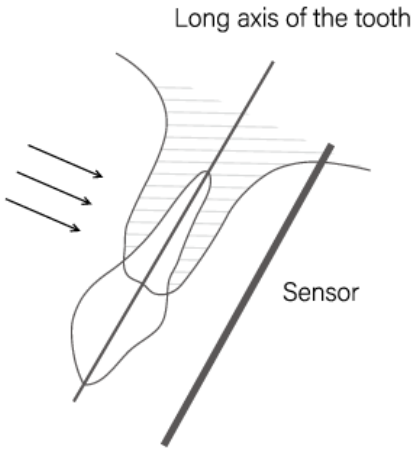
NOTE

DEPENDING ON THE IMAGING ANGLES, EXPOSURE TIMES MAY VARY. SINCE IT IS NECESSARY TO KEEP THE PATIENT WITH LOW X-RAY DOSES AND THE USER IN THE PROTECTED AREA, HAVE THE PATIENT'S HEAD SLIGHTLY TILTED, AND RAISE OR LOWER THE CHIN IF NEEDED. PLEASE REFER TO '2. NOTICE OF GENERAL SAFETY AND SAFE OPERATION', '3. NOTICE OF SAFE BATTERY USE' AND '4. RADIATION SAFETY'.

6.2.4 POSITIONING INSTRUCTIONS

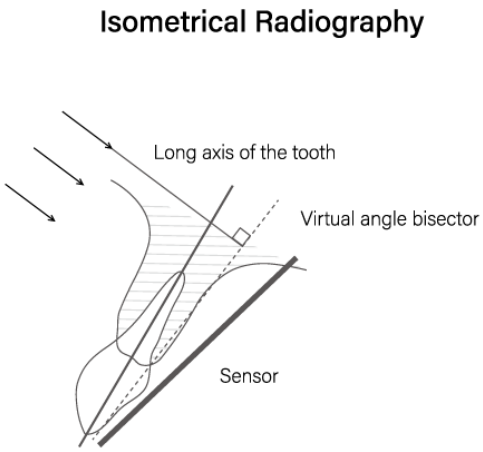
PARALLEL RADIOGRAPHY

Position the sensor parallel to the long axis of the tooth using the position indicating device (PID).



ISOMETRICAL RADIOGRAPHY

Position the position indicating device (PID) perpendicularly to a virtual angle bisector, a line that divides the angle between the long axis of the tooth and the sensor.



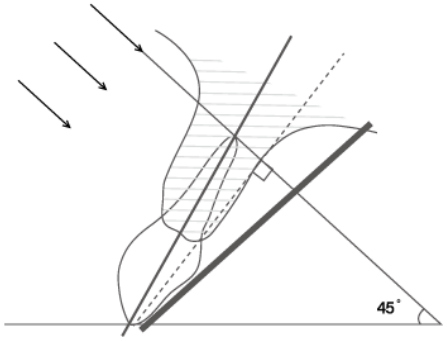
The following explains how to orient the angle of the position indicating device (PID) to obtain the best possible image from a particular tooth (in an isometrical radiography, for instance).

CAUTION

WHEN PLACING THE IMAGE RECEPTOR IN THE ORAL CAVITY, AVOID DAMAGING THE SOFT GUM TISSUES IN THE PATIENT'S MOUTH.

MAXILLARY INCISOR

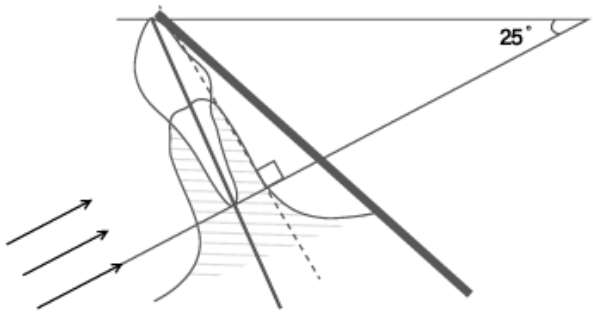
The x-ray beam is directed downward at 45°.



TEETH		ANGLE OF INCLINATION
Incisor	Maxilla	+45°

MANDIBULAR INCISOR

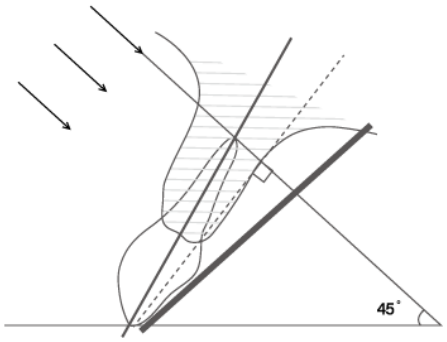
The x-ray beam is directed upward at 25°.



TEETH		ANGLE OF INCLINATION
Incisor	Mandible	-25°

MAXILLARY CANINE

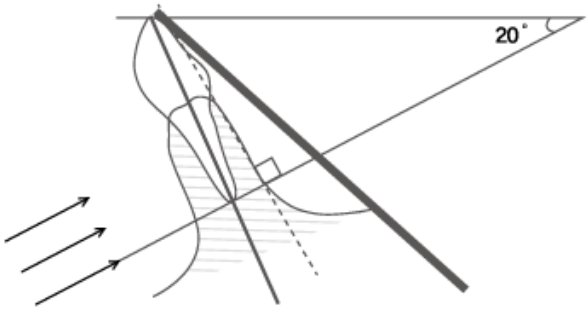
The x-ray beam is directed downward at 45°.



TEETH		ANGLE OF INCLINATION
Canine	Maxilla	+45°

MANDIBULAR CANINE

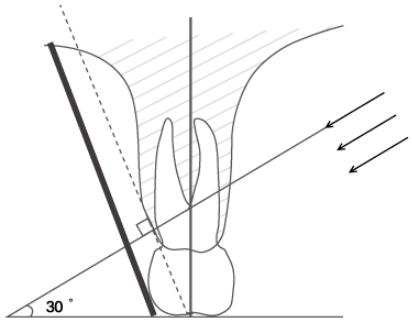
The x-ray beam is directed upward at 20°.



TEETH		ANGLE OF INCLINATION
Canine	Mandible	-20°

MAXILLARY MOLAR AND PREMOLAR

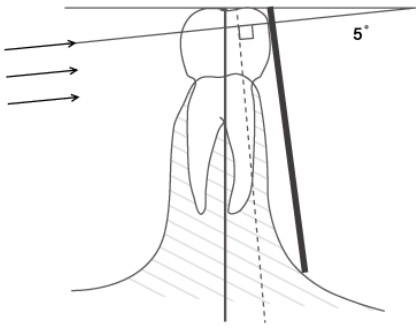
The x-ray beam is directed downward at 30°.



TEETH		ANGLE OF INCLINATION
Molar and Premolar	Maxilla	+30°

MANDIBULAR MOLAR AND PREMOLAR

The x-ray beam is directed upward at 5°.



TEETH		ANGLE OF INCLINATION
Molar and Premolar	Mandible	-5°

BITEWINGS

For a bitewing exposure, the patient closes their teeth during exposure on the image receptor holder.

The x-ray beam is directed downward at +5° - +8°.

TEETH	ANGLE OF INCLINATION
Bitewing exposure	+5° - +8°

PROPER POSITIONING THE IMAGE RECEPTOR

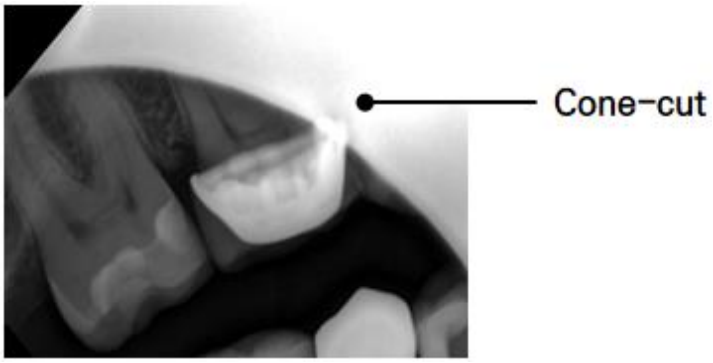
Position the image receptor properly (for information about the proper placement of the image receptor, please refer to '6.2.4 Positioning Instructions' on page 45).

- Improper position of the image receptor may result in errors on the radiograph, such as distorted teeth and roots, elongation, magnification, and overlapping contacts.

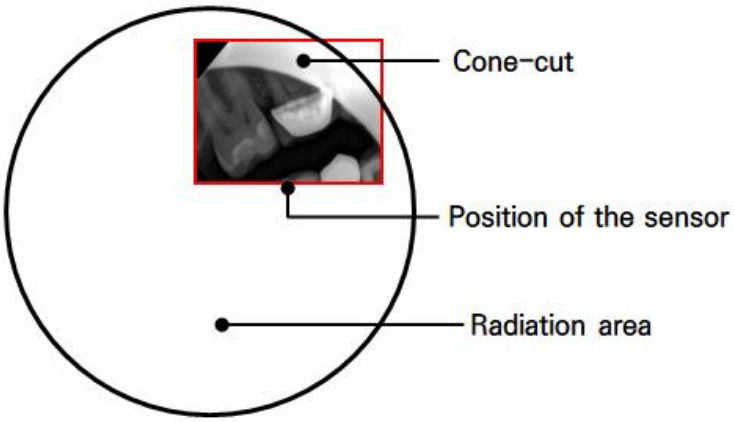
NOTE

THE PARALLELING TECHNIQUE REDUCES THE RISK OF ANGULATION ERROR, IMPROPER PLACEMENT OR ANGULATION OF THE IMAGE RECEPTOR TO THE TOOTH.

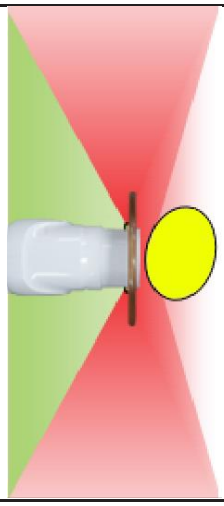
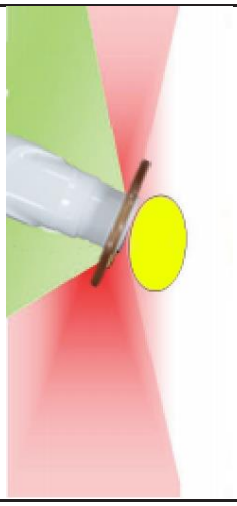
- Failure to align the image receptor with the exit pattern of the X-ray beam can result in cone-cuts on the radiograph. The cone-cuts are clear areas shown on the radiograph where the irradiation did not occur. Please refer to the following figure as an example of cone-cuts.



The following figure indicates how the cone-cut occurred by showing the position of the image receptor and the radiation area.

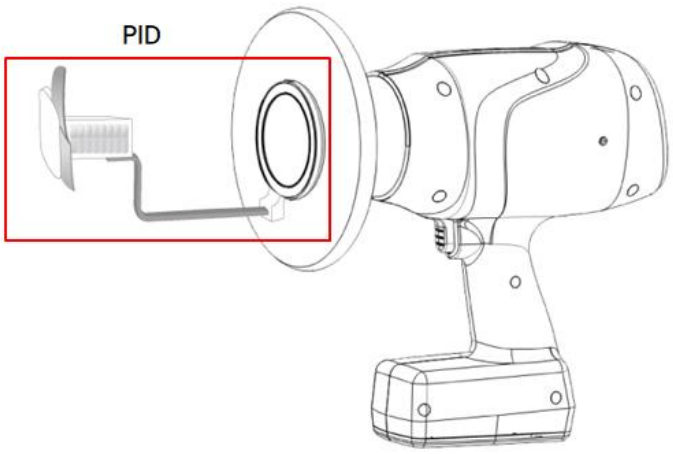


As shown in graphic representations, maximum protection (green area) from backscatter radiation (red area) exists when positioning the DT-703 near the patient is perpendicular to the operator (with the patient's head tilted if needed).

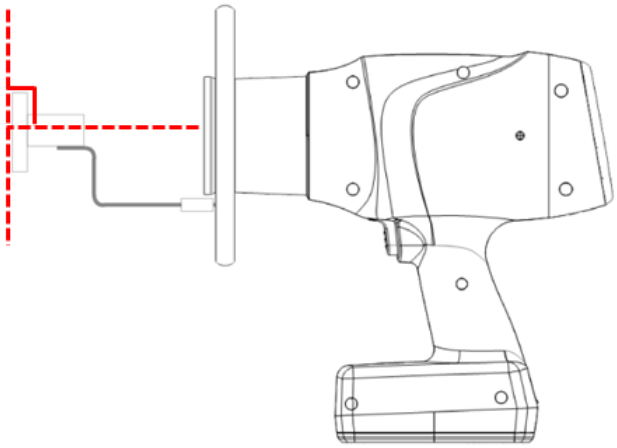
	
Positioning DT-703 perpendicular to the sensor	Non-perpendicular to the sensor may expose the operator to the back scattering X-ray

The operator and patient should wear a lead apron and thyroid collar, according to requirements of local jurisdictions.
Do not operate if the backscatter shield or collimator cone is damaged or broken.

Use a Position Indicating Device (PID) to ensure proper alignment between the imaging sensor and the X-ray beam, as shown in the following figure.



When using the PID, align the cone of the X-ray device perpendicular to the target receptor, as shown in the following figure.



NOTE

ONCE THE PID IS PROPERLY ALIGNED, INSTRUCT THE PATIENT NOT TO MOVE.

6.2.5 X-RAY EXPOSURE

NOTE

THE OPERATOR MUST INSTRUCT THE PATIENT TO REFRAIN FROM MOVING DURING THE ENTIRE EXPOSURE PROCESS.

① Instruct the patient not to move.

② Press the exposure button for X-ray irradiation.

③ During the X-ray irradiation, the exposure status is displayed as follows:

- The X-ray exposure ready indicator ( ) lights up, and audible buzzer sound occurs.
- Press until the X-ray exposure indicator light is out and the audible buzzer sound ends.

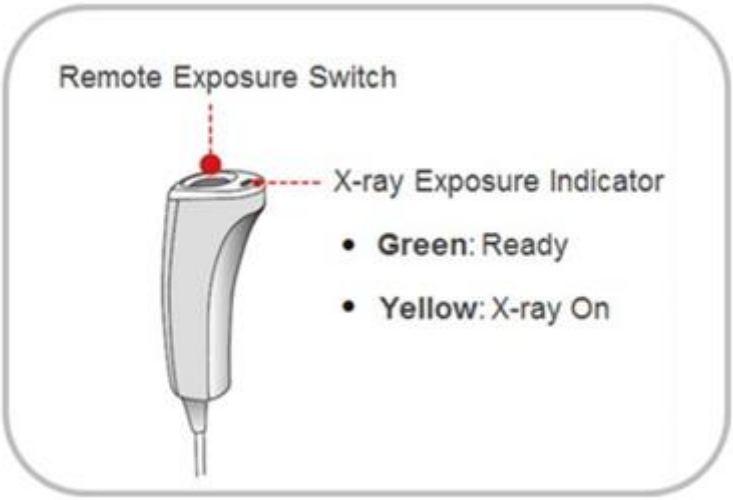
ICON	STATUS
	Green: Ready
	Yellow: X-ray On

6.2.5.1 REMOTE EXPOSURE SWITCH

The Remote Exposure Switch lets the operator control image acquisition outside the X-ray room.

Press and hold the Remote Exposure Switch until the acquisition ends. Premature release of the Remote Exposure Switch will abort image acquisition.

Pressing the Remote Exposure Switch activates the X-ray Exposure Indicator to turn yellow. The yellow color indicates that the X-ray emission occurs.



NOTE

THE REMOTE EXPOSURE SWITCH IS DETACHABLE. ENSURE THAT THE REMOTE EXPOSURE SWITCH CABLE IS NOT DETACHED FROM THE UNIT ACCIDENTALLY DURING THE X-RAY EXPOSURE OPERATION.

KEEP VOCAL/VISUAL CONTACT WITH THE PATIENT DURING EXPOSURE. IF ANY PROBLEM OCCURS DURING EXPOSURE, RELEASE THE REMOTE EXPOSURE SWITCH IMMEDIATELY.

6.2.6 USING BATTERY

The battery level indicator is on the control panel. X-ray irradiation is impossible if a low battery displays (Lbt sign and lightning sign blinking). Recharge the battery immediately for use.

Level 3	Level 2	Level 1	Low battery
			

ITEM		SYSTEM STATUS	
		BATTERY LEVEL 3, 2, 1	LOW BATTERY
When operating the system	Operating	Normal	Not operated
	Battery Level Indicator	Normal	Display low battery image
	Battery Charging Indicator	Not display	'Lbt' and lightning sign blinking
	Control Panel Brightness	Normal	Normal

CAUTION

WHEN THE BATTERY CHARGE INDICATOR IS BLINKING, CHARGE THE BATTERY. THE BATTERY DISCHARGE MAY OCCUR IF NOT CHARGED FOR A LONG TIME.

CHARGING THE BATTERY

① Connect the battery charger to the cradle

② Place DT-703 on the cradle as shown below.

③ After completing the battery charge, the cradle LED turns on green.

CHARGING	CHARGING FULL
	

The battery is a replaceable and degrades over time, requiring frequent charging. If the battery life after a full charge lasts only half the time that was first purchased, contact the customer service center to purchase a new battery.

NOTE

X-RAY EXPOSURE IS NOT POSSIBLE WHILE CHARGING THE BATTERY.

BATTERY REPLACEMENT

① Use a screwdriver to unscrew the battery bay access cover.

② Open the cover and remove the battery from the battery bay and disconnect the battery cable form the device connector.

③ Install the new battery in the reverse order of removal.

CAUTION

DO NOT PULL EXCESSIVELY ON THE BATTERY CABLE.
WORK WITH THE POWER SWITCH TURNED OFF.

NOTE

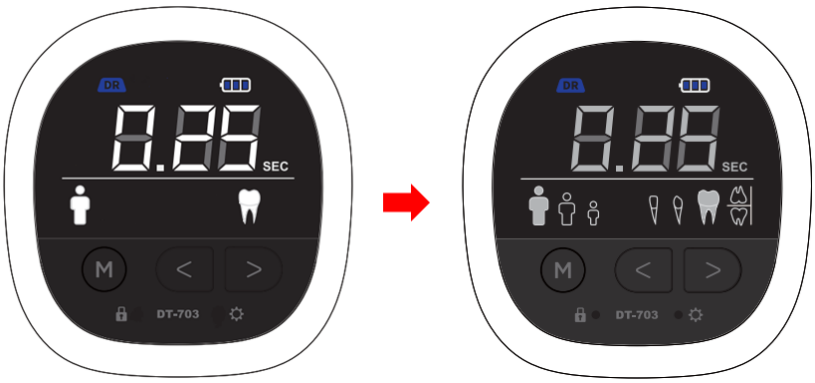
USERS CAN REPLACE THE BATTERY OR CONTACT THE SERVICE CENTER OR MANUFACTURER TO REPLACE THE BATTERY.

6.2.7 DIMMING, SLEEP AND POWER SAVE MODE

DT-703 has dimming, sleep, and power-saving mode to save the battery.

DIMMING MODE

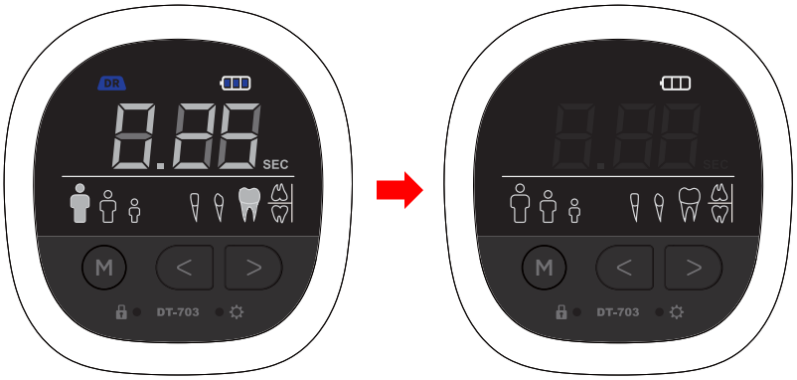
① The device's dimming mode is activated when idle for over 10 minutes. The control panel becomes dark when the dimming mode is activated, as shown below.



② Press any key or the X-ray exposure button to return to normal operation.

SLEEP MODE

① The device's sleep mode is activated when idle for over 20 minutes. The control panel turns off when the sleep mode is activated, as shown below.



POWER SAVE MODE

① The device's power save mode terminates the main power circuit when idle for over 8 hours.

② Tun off the power switch and turn it on to return to nomal operation.

7. USER SETTING OPTIONS

7.1 HOW TO ENTER USER OPTION SETTINGS

The method to enter the user option setting mode is as follows.

① Power switch on

② Press the enter key and right keys simultaneously for more than 1 seconds. (M + >)

③ Enter the user option setting mode.

BUZZER SOUND SETTING

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key (M) after moving to 'S.01' menu using the left and right keys. ② Select the buzzer sound level (Lv.0 to Lv.3) using the left and right keys and press the enter key. ③ Press the enter and right keys to exit the user option setting mode. ※ Default: 'Lv.2'

BRIGHTNESS SETTING

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key (M) after moving to 'S.02' menu using the left and right keys. ② Select the brightness level (Lv.1 to Lv.3) using the left and right keys and press the enter key. ③ Press the enter and right keys to exit the user option setting mode. ※ Default: 'Lv.1'

DEVICE LOCK SETTING

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key (M) after moving to 'S.03' menu using the left and right keys. ② Select the lock (U.L1) or unlock (U.L0) option using the left and right keys and press the enter key. ③ Press the enter and right keys to exit the user option setting mode. ※ Default: unlock (U.L0)

8. TROUBLESHOOTING

The information indicating a system malfunction is listed below. If the troubleshooting table below does not include the device problem experienced, contact the manufacturer or the local sales agent. The problems listed in the troubleshooting table may not be exhaustive.

8.1 ERROR AND WARNING MESSAGES

ERROR CODES		CHECK POINTS AND ACTION
E01	In standby, kV feedback value is high (>10%)	Turn the power off and turn it on again
E02	In standby, mA feedback value is high (>10%)	
E03	Tube anode heat temperature is high (>50℃)	
E04	kV feedback is low (< 90%)	
E05	kV feedback is high (> 110%)	
E06	mA feedback is low (< 90%)	
E07	mA feedback is high (> 110%)	
E09	Battery feedback value is high (overcharge battery)	Check the battery or replace the battery
E10	Preheat feedback is low (<90%)	Turn the power off and turn it on again
E11	Preheat feedback is high (>110%)	
E12	X-ray exposure button is pressed over 10 sec after booting	Check the X-ray exposure button status
E13	Remote exposure switch is pressed over 10 sec after booting	Check the remote exposure switch status
E99	No configuration data	Contact the Service Representative
WARNING CODES		
U01	Mono Block temperature warning over 43℃	Wait until the tank temperature drops to the usable temperature (36℃), which may takes about 30 minutes. Please work after the warning code disappears.
U20	When the enter key, left key or right key are pressed over 10 sec	Check the enter key, left or right key status
U21	Bad connect status with temperature sensor cable	Contact the Service Representative

8.2 TROUBLESHOOTING

	PROBLEM ITEM	CAUSE	ACTION
1	The equipment won't turn on.	The power switch won't turn on properly.	Turn the device power switch off and turn it back on
		Battery discharged	Recheck after charging the battery with the cradle
		The battery charger and cradle are not correctly connected.	Contact the Service Representative
		Defective battery	Contact the Service Representative
2	The Control Panel won't turn on.	Defective main board	Contact the Service Representative
		Internal cable disconnected	Contact the Service Representative
3	No X-ray emission	Generator is cooling	Wait for the cooling time
		Defective Remote Exposure Switch	Contact the Service Representative
		Internal cable disconnected	Contact the Service Representative
		Defective generator	Contact the Service Representative
		Tube lifecycle termination	Contact the Service Representative
4	X-ray emission works, but exposure is too light or completely white	The device has been positioned incorrectly.	Adjust the position of the equipment
		Exposure time is too short.	Increase the exposure time
		The intra-oral sensor is facing the wrong way.	Reposition the intra-oral sensor
5	X-ray emission works, but exposure is too dark	The exposure time is too long.	Decrease the exposure time

9. MAINTENANCE PROCEDURE

9.1 GENERAL CAUTION

Follow the maintenance procedure described below for reliable operation. A trained expert should perform the routine inspection.

WARNING

IN NO EVENT, THE MANUFACTURER SHOULD BE LIABLE FOR ANY INJURY OR EQUIPMENT DAMAGE CAUSED BY UNAUTHORIZED MODIFICATION OF THE DEVICE.

CAUTION

IF ANY SERIOUS INCIDENT HAS OCCURRED WITH THE DEVICE, PLEASE REPORT TO THE MANUFACTURER AND THE REGULATING LOCAL AUTHORITY OF THE STATE.

Please contact the manufacture or the local service agent for question about the equipment. For a rapid service, provide the model name and serial number (S/N) indicated on the device.

9.2 MAINTENANCE

ECOTRON requires periodic constancy tests every six months to ensure image quality and the safety of the patient and operator.

Only ECOTRON authorized technicians can perform inspection and service of this equipment. Contact ECOTRON service center or local ECOTRON representative for technical assistance.

CAUTION

DO NOT KEEP THE EQUIPMENT NEAR LIQUIDS OR HUMID PLACE .

NOTE

WHEN THE EQUIPMENT IS NOT IN USE FOR MORE THAN TWO WEEKS, FULLY CHARGE THE BATTERY AND REMOVE IT FROM THE MAIN BODY FOR STORAGE.

REPLACE THE BATTERY EVERY SIX MONTHS AS RECOMMENDED.

9.2.1 MAINTENANCE CHECKLIST

WARNING

ALWAYS TURN OFF THE DEVICE BEFORE PERFORMING ANY MAINTENANCE.

	CHECK ITEM	PERIOD
1	Before using the device, ensure that the device is clean and ready for use.	Daily
2	After using the device, make sure to turn off the power.	Daily
3	Wipe the surface of the device with soft fabric or gauze. CAUTION Do not use detergents or solvents to clean the surface of the device.	Daily
4	Check that the beep sound is audible and that the X-ray exposure indicator is visible when exposing X-ray.	Daily
5	Check that the X-ray exposure indicator (yellow) light turns on when pressing the X-ray exposure button.	Daily
6	Check that the battery charging indicator light is on while being charged.	Daily
7	Check that the battery level indicator displays at least two levels (). For more detail information on the battery levels, refer to clause '4.2.6 USING BATTERY'.	Daily
8	Check that all visible labels are intact and legible.	Monthly

CAUTION

FOR ANY DEFECTS, DO NOT OPERATE THE DEVICE IF IT HAS TO BE HANDLED BY A QUALIFIED PERSON. CONTACT LOCAL SERVICE REPRESENTATIVE.

9.2.2 MAINTENANCE SCHEDULE

	Maintenance / control item	Period	Inspector
1	kV: (Lower than management standards of IEC 60601-2-65) It should be within the accuracy range of -5% when the kV value is 70 kV.	1 Year	Service personnel with expertise
2	mA: (Lower than management standards of IEC 60601-2-65) It should be within the accuracy range of ±3%, with the current set by 3mA.	1 Year	Service personnel with expertise
3	sec: (Lower than management standards of IEC 60601-2-65) It should be within the accuracy range of ±5% when the sec value is between 0.02 sec and 0.5 sec.	1 Year	Service personnel with expertise
4	Optical Maintenance: When dirt appears on the image, remove dirt on Collimator with a soft brush.	1 Year	Service personnel with expertise

9.3 CLEANING

WARNING

BEFORE CLEANING THE DEVICE, MAKE SURE TO TURN OFF THE DEVICE.

- Clean the device surfaces with a soft cloth moistened with an alcohol-based non-corrosive solution.
- The soft cloth should be damp but not dripping wet.
- The cloths or wipes cannot be re-used.

CAUTION

TO CLEAN THE MAIN BODY AND CRADLE, TURN OFF THE DEVICE AND PULL THE PLUG OUT OF THE BATTERY CHARGER FROM CRADLE.

DO NOT EXPOSE THE DEVICE TO ANY LIQUIDS.

DO NOT USE SPRAY CLEANER OR DISINFECTANT DIRECTLY INTO THE DEVICE AS THIS COULD CAUSE ELECTRICAL SHORT CIRCUIT.

10. DISPOSAL OF WASTE

In order to reduce environmental contamination, this equipment is as safe as possible to use and dispose of.

For proper disposal of the device after its useful service life, observe local environmental regulations regarding the disposal of possible hazardous materials used in the device.

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

PART	MATERIAL	RECYCLABLE	WASTE DISPOSAL SITE	HAZARDOUS MATERIALS
Body Case	Plastics	●		
PCB Board		●		
Cable	Copper	●		
Transformer	Copper	●		
Packing	Paper	●		
	PE (Polyethylene)	●		
	Cardboard	●		
X-ray Tube				●
Battery				●
Other parts			●	

NOTE

OBSERVE ALL LOCAL REGULATIONS RELEVANT TO THE DISPOSAL OF WASTE IN YOUR COUNTRY.

11. QUALITY WARRANTY

SCOPE & DURATION OF WARRANTY

Portable Dental X-ray System (DT-703) manufactured by ECOTRON Co., Ltd. is warranted to be free from defects for two years after the purchase date (Exception: One year for X-ray tube and Six months for the battery). If, during the warranty period, the product purchased is defective, it will be repaired free of charge, including the shipping charge. The warranty does not cover any accidental damage to the product during the shipping and delivery.

However, a certain amount of service fees will be charged in the case of one of the following.

- Defect or damage found after the warranty period has expired.
- Defect or damage in appearance which is not related to the system's primary function.
- Damage caused by a natural disaster; such as fire, earthquake, or lightning strike.
- Damage from mishandling, dropping, or improper device operation by the user.
- Damage resulting from repair or modification of the device unauthorized by ECOTRON.

Any or all defects or damages in appearance, which do not affect the product's main functions are not covered by this warranty.

PREREQUISITES FOR WARRANTY REPAIR REQUEST

- When a defect is found, stop using the system immediately. Refer to Trouble Shooting, Section 8.2 (page 62)
- For a service request, power off the entire system and be ready to provide the model number, serial number, and purchase date before contacting an authorized service office.
- ECOTRON Co., Ltd. shall not be liable for any damages or losses occurring after the expired warranty.

APPENDIX A TECHNICAL CHART

[Unit: sec]

DR	Adult (Big)	Adult (Normal)	Child
Incisor	0.12	0.11	0.1
Canine	0.16	0.14	0.13
Molar / Premolar	0.2	0.18	0.16
Bitewing	0.2	0.18	0.16

CR	Adult (Big)	Adult (Normal)	Child
Incisor	0.16	0.14	0.13
Canine	0.21	0.19	0.17
Molar / Premolar	0.26	0.23	0.21
Bitewing	0.26	0.23	0.21

Film (F-Speed)	Adult (Big)	Adult (Normal)	Child
Incisor	0.25	0.22	0.2
Canine	0.3	0.27	0.24
Molar / Premolar	0.35	0.31	0.28
Bitewing	0.35	0.31	0.28

NOTE

THE APR (ANATOMIC PROGRAMMING RADIOGRAPHY) VALUE SET IN THE EQUIPMENT IS A RECOMMENDATION ACCORDING TO THE TECHNICAL CHART, IT CAN BE ADJUSTED ACCORDING TO THE PATIENT TYPE.

APPENDIX B 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 DT-703 only uses RF energy for internal functions, it has very low RF emissions and normally causes no interference to neighboring electronic devices.
RF emission CISPR 11	Class A	The DT-703 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 61000-4-5	+/- 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.
Voltage loss in the power supply, short intermittence and voltage changes IEC 61000-4-11	<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 <5% UT(>95% Dip at the UT), 5 seconds	<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 <5% UT(>95% Dip at the UT), 5 seconds	The main power's quality should be equal to the those of general commercial or hospital settings. Note : Most components in the Diagnostic X-ray System have their power supplied from the uninterrupted power supply. The IEC61000-4-11 only applies to the Diagnostic X-ray System Power Box.

Magnetic field in the source frequency (50/60Hz) IEC 61000-4-8	3A/m	3A/m	The magnetic field in the source frequency should be equivalent to the those of general commercial or hospital settings.

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 Radioactive RF IEC61000-4-3	3Vrms 150kHz-80MHz 3v/m 80MHz-2.5GHz	3Vrms 3v/m	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: $d = 1.17\sqrt{p}$ $d = 1.17\sqrt{p}$ 80MHz ~ 800MHz $d = 2.33\sqrt{p}$ 800MHz ~ 2.5GHz, 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 be 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

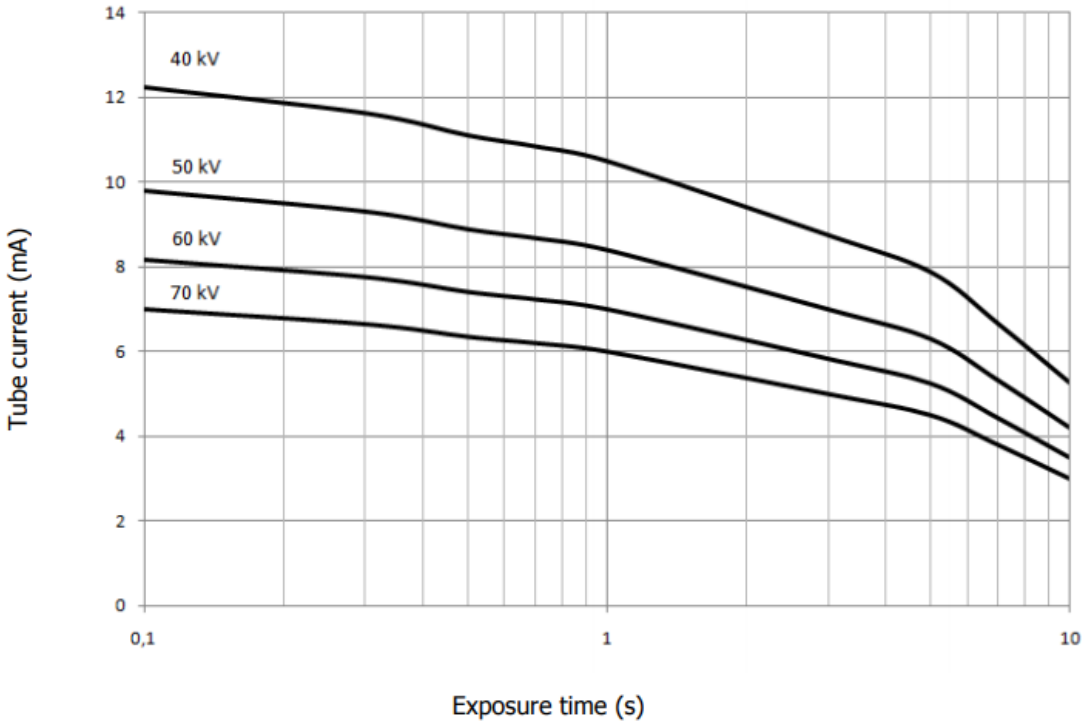
For maximum power voltages of receivers not on the above list, the recommended interval, d(m), can be calculated by using the equation used for the receiver's frequency. The p is the transmitter-receiver's maximum power rating in watts (W).

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

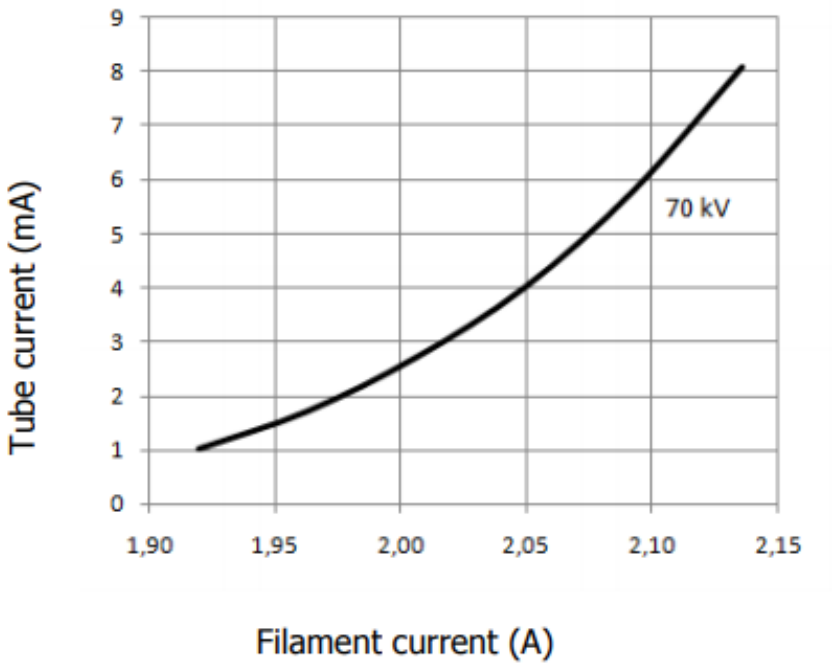
Note 2: This guideline does not apply in all situations. Electromagnetic waves may be affected through absorption into and reflection from structures, objects and people.

APPENDIX C CHARACTERISTICS OF X-RAY TUBE (OX/70-3)

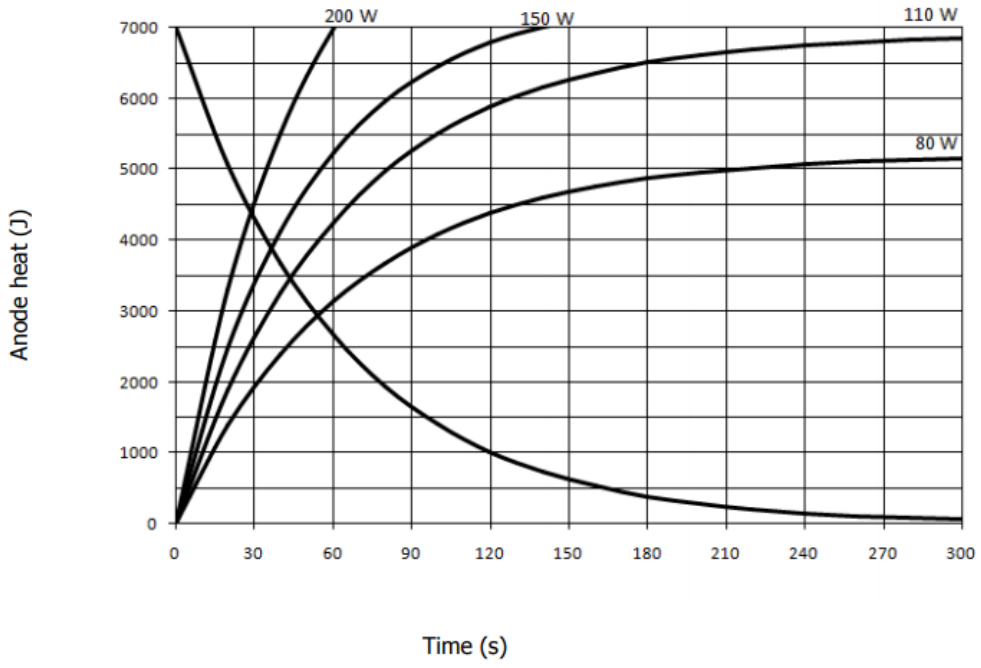
- **Rating Charts**



- **Emission Characteristics**



- **Thermal Curves**



APPENDIX D PEDIATRIC X-RAY IMAGING

To help reduce the risk of excessive radiation exposure for pediatric patients, please follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically. Exposure time (sec) can be adjusted to reduce dose significantly while maintaining diagnostic image quality. Work with a medical physicist to determine the lowest possible dose for the desired image quality.

The following links provide more information about pediatric x-ray imaging:

- US Food and Drug Administration (FDA): http://www.fda.gov/radiatio n-emittingproducts/radiationemittingproductsandprocedures/medicalima ging/ucm298899.htm
- Image Gently: www.imagegently.org
- Society of Pediatric Radiology (SPR): www.pedrad.org
- American College of Radiology (ACR): www.acr.org