(Rev. 3.7.1-v1) 1903

User Manual

Hand-held Dental X-ray System

XTG Model: MINIX-S

Digital DOC®

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS MANUAL.

This manual contains installation, operation and maintenance instructions for the portable dental X-ray system, ***XTG***. Operation should be performed only by dentists, radiologists, dental hygienists, or maintenance service technicians who are experienced in installing and servicing dental X-ray systems.

DISCLAIMER: ***XTG*** is sold with the understanding that the user assumes sole responsibility for radiation safety (as well as any state, provincial, or local regulatory compliance) and that **DIGIMED Co., Ltd.**, its agents or representatives, do not accept responsibility for:

a) injury or danger to personnel from X-ray exposure,
b) image over/under exposure due to poor operating techniques or procedures,
c) equipment not properly serviced or maintained in accordance with instructions contained in this publication, and
d) equipment which has been damaged, modified, or tampered with in any way.

The symbols used in this publication or used to mark the equipment have the following meanings:

		Attention, consult accompanying documents
		Ionizing radiation
		Type B equipment (providing a degree of protection against electric shock, pertaining particularly to allowable leakage currents)
		Instructions for handing product at end of life
		Manufacturer of the device
		Date of device manufacture
		Unique serial number for the device
		Electrical shock hazard

[STATEMENT OF COMPLIANCE]

X-RAY EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY XTG IEC 60601-2-65:2012

[CAUTION]

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE OR ON THE ORDER OF A PHYSICIAN.

Table of contents

1. Introduction

This X-ray unit may be dangerous to patient and operator unless the safe exposure factors and operating instructions are observed. To protect patient and operator from ionizing radiation during X-ray generation, the device should be used with a lead apron (patient). In the EU, the device is recommended for use with a tripod, remote hand-switch, or a mountable arm fixture for radiation safety. Applicable US state safety requirements for radiation safety, safety equipment, and use of hand held X-ray devices should be followed as appropriate.

1.1. Product Description

The portable X-ray system, XTG is an advanced high frequency dental X-ray apparatus with fixed 60kVDC and 2mA tube current which is designed to produce diagnostic high quality X-ray for both film and digital sensors. When X-rays are taken, the devices can be handheld or mounted on an optional stand.

1.2. Intended Use

The XTG X-ray system is intended to be used by trained dentists, radiologists, dental hygienists or dental technicians as an extra-oral X-ray source for diagnostic X-ray images using intra-oral image receptors. Its use is intended for both adult and pediatric subjects.

1.3. Main Features

- ❖ Light Weight & Compact Size
- ❖ High Frequency X-ray
- ❖ Micro-computer and specialized circuit for precise exposure technique factors
- ❖ Self-diagnostic control panel
- ❖ Simple and Easy Setting for X-ray Exposure
- ❖ Preprogrammed exposure time for fast and easy operation
- ❖ Internal protection shield to protect operator and patient from dispersed radiation
- ❖ Constant Emission Power Technology
  (At least 30% radiation dosage reduction compared to conventional x-rays)

1.4. Definitions

1) Lifting operation
A movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.

2) Guided load
A load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.

3) Working coefficient
The arithmetic ratio between the load guaranteed by the manufacturer or his authorized representative up to which a component is able to hold it and the maximum working load marked on the component.

4) Test coefficient
The arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.

5) Static test
The test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.

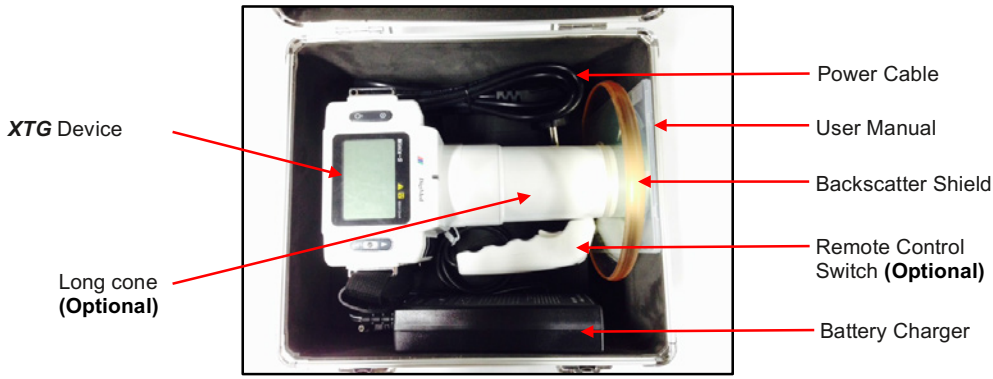
6) Dynamic test
The test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behavior of the lifting machinery in order to check that it functions properly.

7) Carrier
A part of the machinery on or in which persons and/or goods are supported in order to be lifted.

2. Important Safety Precautions

2.1. Device Package Check

Unwrap individual components from the protective case and check for any noticeable signs of damage. The standard package system includes the following items:

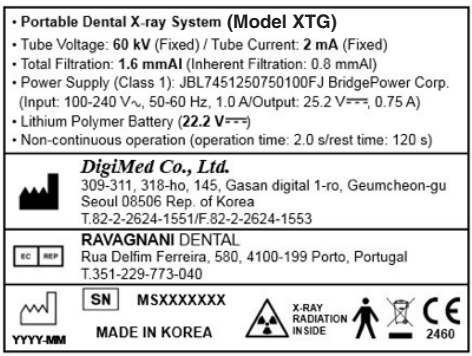


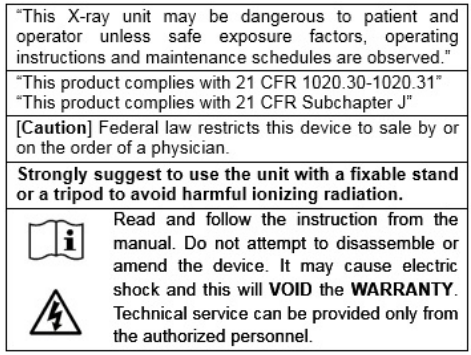
- Preliminary Checks

ITEM	CHECK
Device Label	Serialized Device Label is in place (Back side of unit)
Collimator Cone and Backscatter Shield	These two items provide operator protection and should be inspected for shipping damage.
Exposure Switch	Should freely move in and out when depressed and released.
Device Housing	Should have no cracks or fractures.

Do not open the housing (enclosure). Do not undertake disassembly of the main apparatus, or the warranty shall be invalidated. Repairs can be undertaken only by trained service personnel at an authorized distributor office. Direct all questions to an authorized distributor.

- Device Label



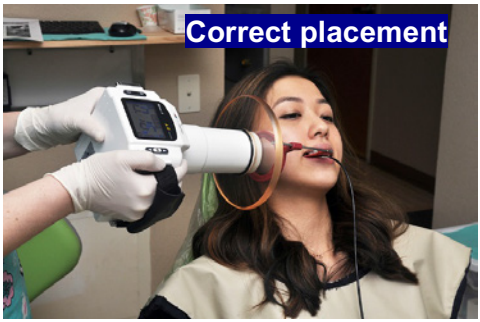


Please be careful not to destroy or detach the labels.
The labels are necessary for the warranty service and by the governing law.

2.2. Radiation Safety

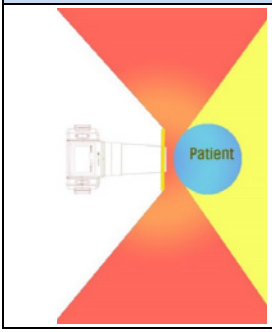
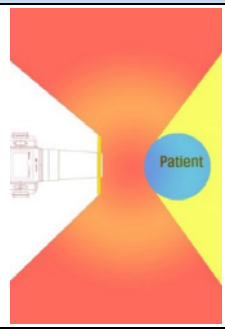
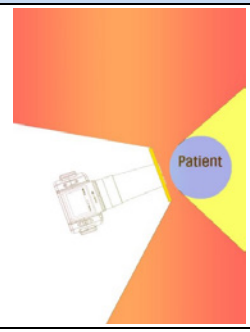
- This x-ray device may be dangerous to operator, patient and bystander unless safe exposure factors, operating instructions and maintenance schedules are observed.
- Do not operate if the backscatter shield or collimator cone are broken!

1) Ensure proper registration and compliance with any applicable regulation.
2) In implementing a radiation protection program, please consult any state, provincial, and local regulations governing radiation protection and the use of x-ray equipment.
3) Operator must follow all applicable regulatory guidelines and in-house radiation protection program in regard to patients and operators who are pregnant or expect to become pregnant.
4) Operators must be fully acquainted with industry safety recommendations and established maximum permissible doses.
5) Optimal operator radiation backscatter protection exists when:
   - the backscatter shield is positioned at the correct angle to the operator
   - the backscatter shield is close to the patient,
   - the patient tilts their head when needed to accommodate exposures
   - the operator remains within the Significant Zone of Occupancy immediately behind the permanently attached backscatter shield



6) Do not enable XTG until patient and operator are positioned and ready for the exposure, diminishing the likelihood of interruption and preventing inadvertent exposure of anyone to x-rays.
7) Do not attempt an exposure if anyone else is positioned immediately behind the patient (in line with the direction of x-ray emission). If others are assisting, then they should wear protective covering as defined in the site radiation safety plan.
8) When selecting and using Position Indicating Devices (PIDs), preference should be given to models that allow the operator to position the unit at the correct angle for maximum operator protection.

9) An exposure can be terminated for any reason by abruptly releasing the depressed trigger (for more information, see Section 7.4. X-ray Exposure).
10) As shown in the table below, maximum protection (white area) from backscatter radiation (red area) exists when the XTG is positioned near the patient, is perpendicular to the operator (with the patient's head tilted if needed), and the backscatter shield is fully extended toward the patient and parallel to the operator.

Maximum Protection	Minimized Protection	
Proper positioning	Device held back	Non-perpendicular
		

11) Operation outside the protection zone (or with a diminished protective zone) requires proper precautions such as the use of lead aprons.
12) Do not use low class image detectors.
(**Film:** higher than E class, **Sensor:** higher than 10 lp/mm, **Phosphor plate:** higher than 10 lp/mm)

***Comparative Data for Whole Body Exposure (Total Annual Operator Exposures)**

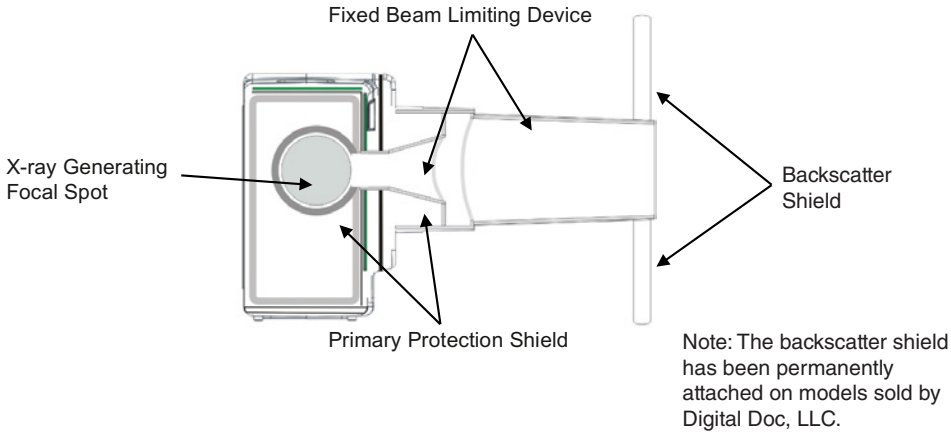
Occupational Dose Limit[1]	50 mSv
Occupational Dose Limit Required Dosimetry[1]	5 mSv
Average Natural Background Radiation[2]	3.65 mSv
Average Occupational Radiation Exposure for Flight Crews[3]	2.19 mSv
General Public Dose Limit[1]	1.00 mSv
Range of Exposure for Dental Personnel Using Conventional X-rays[2]	0.20~0.70 mSv
Average Exposure Using ***XTG*** with E-Speed Film[4]	0.22 mSv
Average Exposure Using ***XTG*** with Digital Sensor[4]	0.08 mSv

1) Standards for Protection Against Radiation, 10 CFR 20 (US Federal Standards), 1994 Most recent publication is 1-1-08 (see also NCRP Report No. 116)
2) NCRP Report No. 145 (National Council on Radiation Protection and Measurements), p7-9
3) "Estimated Cosmic Radiation Doses for Flight Personnel", Feng YJ et al, Space Medicine and Medical Engineering, 15(4) 2002, p265-9
4) Normalized average assumes 7,200 exposures per year, and the average length of exposure for **E-speed Film** = 0.20 seconds, **digital sensor** = 0.10 seconds

***Comparative Data for Hand and Extremity Exposure (Total Annual Operator Exposures)**

Occupational Dose Limit[1]	500 mSv
Occupational Dose Limit Required Dosimetry[1]	50 mSv
Average Exposure Using ***XTG*** with E-Speed Film[2]	0.35 mSv
Average Exposure Using ***XTG*** with Digital Sensor[2]	0.17 mSv

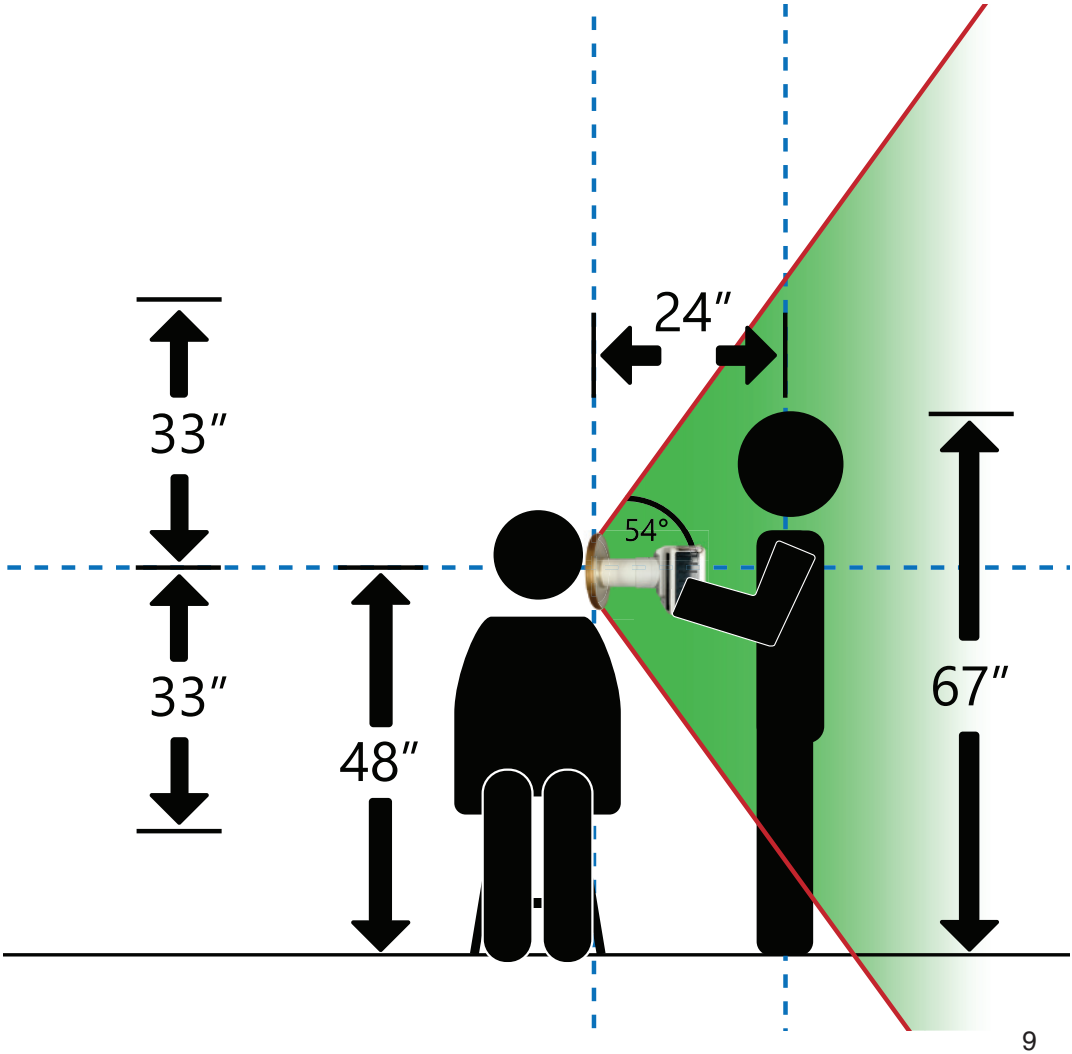
1) Standards for Protection against Radiation, 10 CFR 20 (US Federal Standards), 1994 (see also *NCRP Report No. 116*)
2) Normalized average (includes leakage and backscatter radiation) assumes 7,200 exposures per year, and the average length of exposure for **E-speed Film** = 0.20 seconds, **digital sensor** = 0.10 seconds



***Zone of Significant Occupancy**

XTG Model: MINIX-S requires the presence of an operator, with at least one significant zone of occupancy with a floor not smaller than 24 inch × 24 inches wide, and not shorter than 79 inches height, including the logical information as follows.

1) The XTG complies with International safety standards for Dental X-ray Systems which control the level of backscatter radiation to which the operator is exposed.
2) The Zone of Significant Occupancy is defined as the area within which the operator can be standing while operating the XTG.
3) Location of the significant zone of occupancy includes knowledge of the position of its boundaries, and is relative to the clearly recognizable features of the XTG. This zone is significant because of the assumed need for the operator to occupy it during an X-ray exposure.
4) Identify necessary removable protective devices required for use with the X-ray equipment and any necessary information on their application and use.
5) The figure below shows the geometrical definition of the zone of significant occupancy (minimum) required for safe operation of this device.



2.3. Usage and Duty Cycle

XTG is designed to avoid any damage from overheating. The maximum duty cycle rating (the relationship between duration and frequency of exposures) is 1:60. Operator can refer to below example chart for optimal use.

<Example of optimal use>

Duration	0.1 sec	0.25 sec	0.46 sec	0.5 sec	1 sec
Cycle	Every 6 sec	Every 15 sec	Every 28 sec	Every 30 sec	Every 60 sec

- The device should be used with a tripod or a mountable arm fixture for radiation safety by the EU requirements.
- ***XTG*** should not be used in environments where flammable cleaning agents are present
- Locate the battery charger away from the normal patient environment
- Do not operate the ***XTG*** when the voltage level is low (one bar). The proper battery voltage level for the ***XTG*** battery is ABOVE 22.2VDC
- When the battery Charging Icon Bars show (1) one bar the battery is Below recommended voltage and it should be recharged before use.

2.4. Cleaning

1) Ensure the battery charger is unplugged before attempting to clean, and ensure the power is turned off while cleaning.
2) Cleaning can be done with a non-alcohol based disinfectant wipes, a cloth with a disinfectant liquid, or spray. (Operators must be careful not to dampen the device with any liquid, alcohol, or spray. The ***XTG*** device is not designed to be waterproof.)
3) ***XTG*** and the accompanying battery charger are not designed to be subjected by any kind of sterilization procedure. ***XTG*** is not designed to be sterilized.

The system is rated for **IPX 0**; do not operate the system or use battery charger if either was immersed liquid or subjected to undue amount moisture.

2.5. Storage and Transportation

- Store the unit in a place which is not affected by air pressure, temperature (cool), humidity (dry), ventilation, sunlight, dust, salt, sulfur, etc. for long term storage.
- Please be careful not to drop or hit the device during storage or transportation.
- If your state requires storage of battery separate from the X-ray see section 13.0.

1) Temperature conditions

Condition	Storage	Transportation	Use
Temperature	-20 ~ 60°C	-20 ~ 60°C	10-35°C

2) Humidity conditions

Condition	Storage	Transportation	Use
Percentage	5-90 %RH	5-90 %RH	10-85 %RH

3) Atmospheric pressure

Condition	Storage	Transportation	Use
Pressure	800-1060 hPa	500-1060 hPa	800-1060 hPa

2.6. Periodic Maintenance

It is recommended to make annual maintenance checks by a qualified technician for performance and safety, as well as assurance of accurate X-ray exposure levels.

- Medical electrical equipment requires special precautions regarding EMC, and must be installed and put in to service according to the EMC information provided in the user manual.
- Portable and mobile RF communication equipment can effect medical electrical equipment.
- The use of accessories other than those specified in the user manual may result in increased emissions and void the warranty.

2.7. Guidance and manufacturer's declaration

The system of ***XTG*** is tested and found to comply with the limits of electromagnetic compatibility standards for medical device (IEC 60601-1-2: 2007), which provide reasonable protection against harmful interference in a typical medical/dental setting. ***XTG*** may generate and radiate radio frequency energy that causes interference to other devices in the vicinity, if not used in accordance with the instructions (though there is no guarantee that interference will not occur in a particular instance). If interference occurs, the user is encouraged to try the following corrective measures: reorient or relocate the receiving device; increase the separation between the equipment; consult the device manufacturer or field service technician for help.

1) Electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The ***XTG*** is intended for use in the electromagnetic environment specified below. The user of the ***XTG*** should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	**Group 1 Class A**	The ***XTG*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Group 1 Class A**	The ***XTG*** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	**Complied**	

2) Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity					
The ***XTG*** is intended for use in the electromagnetic environment specified below. The user of the ***XTG*** should assure that it is used in such an environment.					
Immunity Test	IEC 60601 Test Level		**Compliance Level**		Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Direct Application	Contact: ±2, ±4, ±6 (kV) Air: ±2, ±4, ±8 (kV)	Direct Application	Contact: ±2, ±4, ±6 (kV) Air: ±2, ±4, ±8 (kV)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Indirect Application	Contact: ±2, ±4, ±6 (kV)	Indirect Application	Contact: ±2, ±4, ±6 (kV)	
Radiated Immunity IEC 61000-4-3	1) Frequency: 80 ~ 2,500 MHz 2) Position: Front, Rear, Left, Right 3) Polarity: Horizontal, Vertical 4) Field Strength: 3 V/m 5) Modulation: 80%AM (1 kHz) 6) Frequency Step: 1 % 7) Dwell Time: 3 s		1) Frequency: 80 ~ 2,500 MHz 2) Position: Front, Rear, Left, Right 3) Polarity: Horizontal, Vertical 4) Field Strength: 3 V/m 5) Modulation: 80%AM (1 kHz) 6) Frequency Step: 1 % 7) Dwell Time: 3 s		
Magnetic Field Immunity IEC 61000-4-8	1) Frequency: 50, 60 Hz 2) Axis of Orientation: X, Y, Z 3) Test Level: 3 A/m		1) Frequency: 50, 60 Hz 2) Axis of Orientation: X, Y, Z 3) Test Level: 3 A/m		
Fast transients/ Burst IEC 61000-4-4	1) 2.0 kV on AC IN 2) 1.0 kV on Signal		1) 2.0 kV on AC IN 2) 1.0 kV on Signal		Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	1) 0.5, 1.0 kV on L1-L2 2) 0.5, 1.0, 2.0 kV on L1-PE 3) 0.5, 1.0, 2.0 kV on L2-PE		1) 0.5, 1.0 kV on L1-L2 2) 0.5, 1.0, 2.0 kV on L1-PE 3) 0.5, 1.0, 2.0 kV on L2-PE		
Conducted Immunity IEC 61000-4-6	1) Frequency: 0.15 ~ 80 MHz 2) Test Point: AC IN, Signal 3) Coupling: CDN, Clamp 4) Voltage Level: 3 V 5) Modulation: 80 % AM (1kHz) 6) Frequency Step: 1 % 7) Dwell Time: 3 s		1) Frequency: 0.15 ~ 80 MHz 2) Test Point: AC IN, Signal 3) Coupling: CDN, Clamp 4) Voltage Level: 3 V 5) Modulation: 80 % AM (1kHz) 6) Frequency Step: 1 % 7) Dwell Time: 3 s		
Voltage dips and interruptions IEC 61000-4-11	1) Test Level: 0, 70, 40 % U_T 2) Voltage Dip/Int: > 95, 30, 60 % U_T 3) Duration ms/Cycle: 0,5 cycle, 5s, 25 cycle, 5 cycle		1) Test Level: 0, 70, 40 % U_T 2) Voltage Dip/Int: > 95, 30, 60 % U_T 3) Duration ms/Cycle: 0,5 cycle, 5s, 25 cycle, 5 cycle		
Variation of power frequency IEC 60601-1	1) Nominal Voltage: 230 V, 100 V, 120 V 2) Nominal Frequency: 50 Hz, 50/60 Hz, 60 Hz 3) Deviation: ≤1 Hz		1) Nominal Voltage: 230 V, 100 V, 120 V 2) Nominal Frequency: 50 Hz, 50/60 Hz, 60 Hz 3) Deviation: ≤1 Hz		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.					

3. Specifications of Device

1) Grade ..... Class II b

2) Classification ..... Type B applied part

3) X-ray Generator

- Tube Voltage ..... 60 kV (Fixed)
- Tube Current ..... 2 mA (Fixed)
- High Voltage Generating Circuit ..... High Frequency Inverter Method
- X-ray Control Method ..... Controlled by Micro Processor
- Time Setting Range ..... 0.01~1.0 second (0.01 sec. step)

4) **X-ray Tube**

- Type ..... Stationary Anode X-ray Tube
- X-ray Tube Model ..... D-081B (Toshiba)
- X-ray Tube Focal Size ..... 0.8 mm
- Target Angle ..... 20°
- Total Filtration ..... 1.6 mm Al
  (Inherent Filtration: 0.8 mm Al, Fixed Added Filtration: 1.0 mm Al)

5) Display Method ..... LCD display

6) Source to Skin Distance (SSD) ..... 200 mm

7) X-ray Field ..... 53 mm (Round style)

8) Weight ..... 1.77 kg

9) Size of Main Body ..... 123 (W) ×220 (D) ×134 (H) mm

10) **Voltage to Use**

- Battery ..... Lithium-ion polymer battery (DC 22.2 V)
- Charge ..... (Input: 100~240VAC, 50~60Hz 1.0A / Output: DC25.2V 0.75A)

4. Components of Product

The standard package has the following components.

XTG Device

Remote Control Switch

Battery Charger

Mobile Stand Arm

Wall Mount Arm

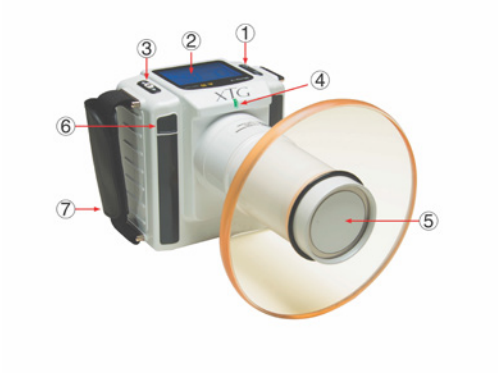
Portable Stand Arm

- Remote control switch, and Mounting arms are optional parts.
- Please check your specific state and country regulations and the specified optional equipment components appropriate to your location.

5. Description of Device

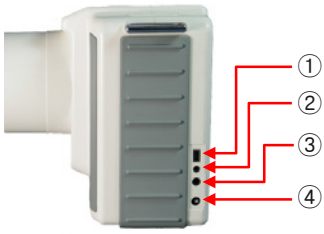
5.1. Name of each part

Front View



① Power button (ON/OFF)
② LCD control screen
③ Control buttons
④ X-ray exposure indicating LED
⑤ X-ray emission cone
⑥ X-ray exposure button
⑦ Hand strap

Side View

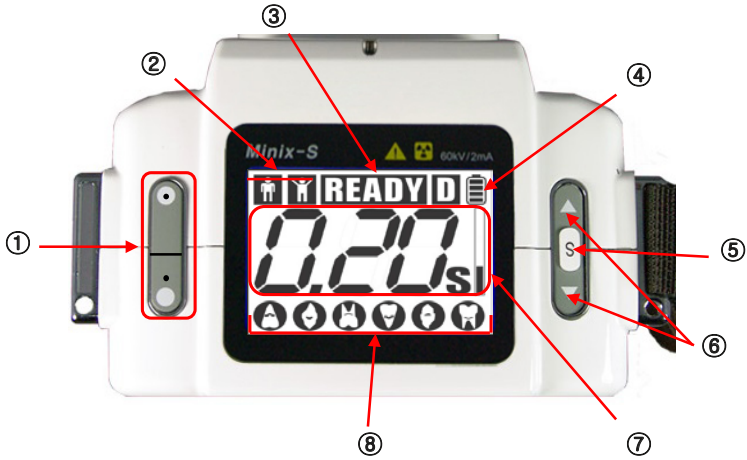


① Backup port
② mA measuring port
③ Hand Switch connection port
④ Charger connection port

Bottom View

① Connection plate for arm mounting

5.2. Description of the Control Panel and LCD functions



Control Panel

No.	Function	Description
1	Power ON/OFF button	Press  for 1 second to power on. To turn off, press  down for 2 seconds. When power is on, power off button  functions as a mode select button.
2	Adult and child display	Exposure time setting differs by the patient size
3	Equipment operating condition display	LCD displays ***READY*** when the unit is ready to expose X-ray
4	Battery charge indicator	Remaining battery power information
5	Mode control button (S button)	Press ***S*** button to begin mode control
6	Up/down control button	Exposure time change by pressing up and down
7	Exposure time display	X-ray exposure time
	Error display	**E01 ~ E06** (Refer to the **Chapter 8.** *Error List*)
8	Tooth display	Incisor, canine and molar of the upper and lower jaw (Maxilla and Mandible) display

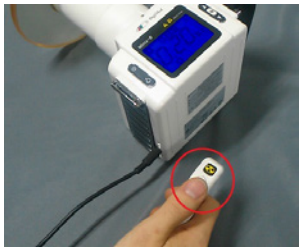
6. Setup and Power Check

6.1. Backscatter Shield

To protect the operator from scattered radiation during operation, the Backscatter Shield (More than 0.25 mm lead equivalent and 6 inches in diameter) is permanently attached and cannot be removed or repositioned. This backscatter shield is positioned at the outer edge of the x-ray emitting cone.

6.2. Remote Control Switch

To activate the Remote Control Switch, connect the hand switch jack to the connection port. The jack head should be inserted completely to the tip of the port. Press and hold the X-ray exposure button to check the function (beeping sound & X-ray exposure) from the device. X-ray exposure button should be pressed and held until the beeping sound stops. Only the exposure button on top of the switch functions at the moment (The trigger has no function).



6.3. Checking for Power

Press power on button and check the battery power indicator icon in the upper right corner of LCD control panel. If the indicator has four bars, the battery is full charged. When the indicator shows just single bar, the device should be recharged with the battery charger. If a battery does not have enough power to expose X-ray, LCD shows below error code (E01).

Full charged

Low battery power

Low battery error

4 bars indicates battery voltage above 23.9V

3 bars indicates battery voltage 23.0V - 23.8V

2 bars indicates battery voltage 22.1V-22.9V

1 bar indicates battery below 22 V

If 1 bar is indicated on the battery charge display charge unit prior to use.

7.0 Operation

7.1 Starting and Ending the Session

1) Power on Press power ON button on the left side of LCD screen and wait until blue light turns on. LCD displays below image during loading.

2) Interlock To defeat the interlock depress the X-ray button for one second to release the lock. The device is now ready to shoot an X-ray.

3) Timeout The X-ray function will timeout after 5 seconds with no exposure. If the device times out the interlock process must be repeated prior to the device being ready.

4) Power off To turn off the power, press power OFF button for 2 seconds. And the system turns off the LCD screen.

7.2. Indicators on LCD screen

Image	Function
	Exposure mode: Adult
	Exposure mode: Child
READY	X-ray exposure is available
	Full charged battery indicator
0.00s	Exposure time setting
	3 bars: Film use
	2 bars: Phosphor plate use
	1 bar: Digital sensor use

Image	Function
	Incisor (Upper jaw)
	Canine (Upper jaw)
	Premolar, Molar (Upper jaw)
	Incisor (Lower jaw)
	Canine (Lower jaw)
	Premolar, Molar (Lower jaw)
D	Dual kV Mode

7.3. X-ray Exposure Mode Setting

* See **Section 5.2.**, ***Description of the Control Panel and LCD functions*** before setting.

1) Tooth Icon Setting

- Press **S** button on right side of control panel and hold for 2 seconds. Then the tooth icon in the LCD window flickers and READY icon disappears. (X-ray exposure button is not working under setting mode.)
- Each press of **S** button will change the tooth icon to the right side. (There are 6 icons and each press will move the flickering cursor to next icon.)
- Exposure time setting on each tooth icon can be controlled with Up/Down control button.
- When exit the setting mode after the tooth icon setting, press **S** button for 2 seconds.

2) Exposure Subject Setting (Adult/Child)

- Press **S** button and hold 2 seconds.
- Press the power off button once.

  Then adult icon ( ) or child icon ( ) flickers.
- Select exposure subject with **S** button.
- When exit the setting after the exposure subject setting, press **S** button for 2 seconds.

3) Exposure Mode Change by Image Receptor

- Press **S** button and hold 2 seconds.
- Press the power off button twice. Then exposure amount gauge bar flickers
- Each press of **S** button will add up the bar
  - 1 bar: Digital Sensor use
  - 2 bars: Phosphor plate use
  - 3 bars: Analog Film use

4) Dual kV setting Note: Only applies to 70kV model (not distributed by Digital Doc, LLC)

1. Press Power-off and **S** button at the same time shortly.
2. Dual kV icon (**D**) shows on the LCD.
3. At this state, press **S** button for 2 seconds. (until tooth icon blinks)
4. Press Power-off button 3 times shortly.
5. LCD shows the first kV level as "***110s***" (Check the image)
   - Operator can divide 100% of kV power into 2 levels up to 9 levels with Up/Down control buttons.
   - If the first kV level is set with 90%, next level is set with 10 % automatically.
5. Set the kV amount for each level (1-9), and press Power-off button to finish the setting. (Or press **S** button for 2 seconds.)
6. LCD shows READY.

5) Reset Defaults (Back to factory setting)

- Press and hold Power OFF button, and then press Power ON button.
- The power turns on and all the time setting will return to the original factory setting.

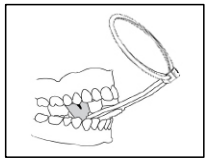
7.4. X-ray Exposure

1) Ready the Device

• Set X-ray exposure mode as necessary as explained in **Section 7.3.**

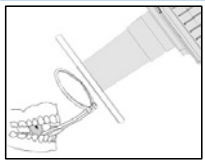
2) Detector Positioning

• Place analog film or digital sensor in patient's mouth and fix it behind the tooth for image capture.



3) X-ray Device Positioning

• Place the edge of the X-ray emission cone at least 2 inches away from patient skin, and focus the cone onto analog film or digital sensor in the patient's mouth.
(Be careful not to touch the patients' skin)



4) Initiating an X-ray Exposure (Disabling the Interlock)

• Press the exposure button once, and then immediately press and HOLD the exposure button a second time.
(Once the X-ray exposure is started, the unit LED flashes red and makes a beeping sound at the same time.)

5) Completing an X-ray Exposure

• The user must press and hold the exposure button until the exposure beeping sound stops. If the button is released too soon (during the X-ray exposure), the X-ray irradiation stops and LCD shows the error code (E04: shot time error).

• If x-ray exposure process is finished correctly, the beeping sound stops and the LED turns to green.

6) Auto-Recovery after duty cycle

• The LCD will show "READY" icon when it is ready to make next X-ray exposure.

7.5. X-ray Exposure Techniques

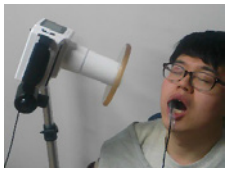
The portable X-ray system, ***XTG*** is easy to position for intraoral dental X-ray diagnosis. Since it is not fixed to other devices*, the exposure degree is high. So operators can make exposures while the patient is sitting upright, reclined, or lying on their back. Ensure the patient is protected by a radiation shield (Lead apron).

*The device is originally designed to be portable and handheld. ***XTG*** can be used with optional stands (See Chapter 4. Components of Product)

1) Handheld Use

- The portable X-ray system, ***XTG*** is mainly designed to be used handheld. Operators can hold the device by both hands on its hand grip. (Operators should be careful not to grab or hold the collimator cone during X-ray exposure.)

2) Operation with Stands



- Operators can operate ***XTG*** with optional stands or tripod. (See **Chapter 4**. *Components of Product*)

3) Device Positioning

- ***XTG*** should be positioned appropriately on the opposite side (90°) of imaging system (intraoral digital sensor) or X-ray detecting film (Phosphor plate) in patient's mouth. Operators may use detector positioner for correct X-ray exposure angle. The detectors may not make good quality images (cone-cutting image) if the collimator cone end is not positioned correctly.
- Exposure time may vary when X-ray exposure angle is away from 90° of image detectors (film or sensor). To have best operator protection and low patient X-ray dose, tilt patient head (target teeth) by the position of ***XTG*** as needed. Operators can wear or use radiation shields (as radiation protection goggle, gloves, and lead apron) if needed.
- To avoid any cross contamination, ensure not to touch the patient with the cone or backscatter shield. Disposable plastic cover can be used for protection.

4) X-ray Exposure Time

- Optimal exposure time setting can be determined by results of each type of imaging systems or detectors. See **Chapter 8.** *Chart Table for Exposure Time* to check the recommended time setting by each tooth, image detector and patient size.

8. Recommended Exposure Time Setting

X-ray exposure time settings in below chart are intended as a reference only. Read all description at **Section 7.4.** *X-ray Exposure* and **7.5.** *X-ray Exposure Techniques* and follow for a correct operation. Each result from X-ray imaging system (digital sensor, film or phosphor plate) may vary because of many factors as image density preferences, the various digital sensors or films by speeds and brands, patient size, tooth density, operator techniques and preferences.

Recommended Exposure Time Setting Chart (60 kV, 2 mA Fixed)			 Incisor	 Canine	 Premolar, Molar
Digital Sensor		Adult	0.05 ~ 0.09	0.07 ~ 0.12	0.10 ~ 0.15
		Child	0.03 ~ 0.07	0.05 ~ 0.09	0.05 ~ 0.12
Film		Adult	0.20 ~ 0.25	0.23 ~ 0.27	0.25 ~ 0.30
		Child	0.17 ~ 0.20	0.18 ~ 0.23	0.22 ~ 0.25
Phosphor Plate		Adult	0.07 ~ 0.10	0.09 ~ 0.12	0.12 ~ 0.17
		Child	0.05 ~ 0.08	0.07 ~ 0.10	0.09 ~ 0.15

X-ray exposure time settings can be adjusted by the operator. Follow below steps for change.

1) Press ***S*** button. (The tooth icon starts to blink.)
2) Press up/down control buttons to increase or decrease the exposure time.
3) Press ***S*** button to save the adjustment and move to next tooth icon.
4) Press power off button to change the exposure mode (adult/child, image receptor setting)
   Check **Section 7.3.** *X-ray Exposure Mode Setting* for more information.
5) Once the settings are all saved, the change will be maintained in memory until new adjustment or until factory defaults are restored through the Reset Defaults. (Check **Section 7.3. 5)** *Reset Defaults*.)

X-ray exposure time settings in this section are intended as a reference only.
Each result from X-ray imaging system may vary because of many factors.

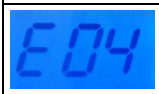
9. Battery Handling, Charging and Maintenance

1) Do not impart any physical force onto the unit or the battery. If the unit or the battery is affected by any physical force and modified from its original shape, the unit and its lithium ion polymer battery may not function normally.
2) The high efficiency lithium ion polymer battery makes more than 200 X-ray exposures after a full recharging.
3) If the battery charge is too low, LCD will show error code E01. (Chapter 6.3) indicating the need to recharge the unit with its battery charger.
4) Full battery charge takes about 3 hours. Monitor the unit during battery recharge, and be careful not to overcharge.
5) During recharge, battery charging status is displayed on the left top of LCD Screen by icon. (Battery icon blinks)
6) If the equipment is not in use for a long period of time, it is necessary to charge the battery every 3 months. (After full charge, at least 1 exposure has to be made to keep the battery functioning at its best.)
7) Only use the authorized charger which is provided from the manufacturer or an authorized distributor.
8) Battery is a consumable part and the battery use time will degrade over time and/or with continued use, shortening the usable battery life. For the best function of the unit and safety, battery pack should be replaced when its life is decreased noticeably, or after 2 years of use. Replace the battery if duration decreases by half when compared new.
9) Do not place the unit in contact with heat generating devices. The battery is vulnerable to heat. Place the unit in a cool shaded spot out of direct sunlight.
10) Best temperature for storage and recharging is between 10°C to 25°C. Operation in colder temperatures may cause fast discharge, and recharging may take longer. Battery level may indicate lower than normal readings.
11) Be careful with the device and do not get it wet. If any foreign substances and moisture come into the unit or the battery pack, it may cause malfunction.
12) There is a potential danger for an electric shock when connecting or removing the power plug to an outlet. Do not touch the outlet with wet hands or make physical contact with any conducting part of the outlet.

- Once battery recharging is completed (charging indicator LED changes from red to green), disconnect the DC output connector from the charger and pull out the power connector for storage.
- For battery replacement, consult with the manufacturer or an authorized distributor.
- Risk of fire or explosion exists if the battery pack inside the device is replaced by unauthorized service personnel.
- Properly dispose of spent or damaged battery packs.
- Return to the manufacturer or an authorized distributor for recycling.
- Do not place in municipal waste stream.

10. Error List

If any error occurs from the unit, following error messages will help identifying the problem or status.

Error code	Error name	Cause and Handling
	**Low battery** error	This error code indicates the battery needs recharging. Please recharge the battery.
	**kV** error	This error code indicates the kV value has exceeded the tolerance range (54kV ~ 66kV). Please contact the authoriized distributor or manufacturer.
	**mA** error	This error code indicates the mA value has exceeded the tolerance range (1.8mA to 2.20mA). Please contact the authorized distributor or manufacturer.
	**Shot time** error	This error code indicates the exposure button is released too soon. Please wait and re-operate when READY icon shows.
	**Back up time** error	This error code indicates the X-ray is exposed longer than 2.2 sec. Please contact the authorized distributor or manufacturer.
	**H.V tank overheat** error	This error code indicates temperature of H.V Tank is higher than tolerance range. Turn off the unit and cool down for 30 minutes.

- Temporary exit from each code are Press UP, DOWN or S button.
- Do not attempt to disassemble or amend the device if the control panel continues to show an error code.
- Contact the manufacturer or an authorized distributor immediately especially with E02, E03 or E06 errors.

11. Instruction for Quick Start

Function	Description
Power up	Press the power on button for 3 seconds (until blue light turns on).
Exposure time setting	Set exposure time with up and down control buttons (△/▽).
Exposure	Expose X-ray by pressing exposure button on front or by remote activator.
Power down	Press the power off button for 2 seconds.

This instruction is just for operators' convenience only, to aid with understanding before actual use. The ***XTG*** should not be used until after reading the manual completely.

12. Technical Description

12.1. Basic Technical Specification

1) Environmental

- **Operation**
  Temperature: 10°C to 35°C
  Relative humidity: 10% to 85% RH
- **Storage and transportation**
  Temperature: -20°C to 60°C
  Relative humidity: 5% to 90% RH

2) Classification/Specification Compliance

- MDD 93/42/EEC amended by Council Directive 2007/47/EC, Annex IX: Class II b
- IPX specification: IPX 0 (Do not operate under wet conditions.)
- Type of protection against electric shock: Internal powered device
- Degree of protection against electric shock: Type B applied part [ ]

3) Electrical

- Rechargeable lithium polymer battery: DC **22.2** V
- Maximum battery charge: DC 25.2 V
- Battery current at 2 mA, 60 kV output: 15 A
- Power supply:
  - Input: AC100-240 V, 50-60 HZ 1.0 A
  - Output: DC 25.2 V, 0.75 A
  - Cable length of DC output: 1000 mm
  - Cable length of AC input: 1700 mm
- Cable length of remote controller: 3000 mm

4) X-ray Control and Generator

- Exposure time range: **0.01 ~ 1.0** sec.
- Maximum duty cycle: 1 : 60
- Maximum inherent filtration: **1.6** mm Al
- Maximum output power: 120 W nominal at 60 kV, 2 mA
- Generator rating: 2 mA at 60 kV ±5%
- Leakage technique factors: 60 kV, 2 mA, 2.0 sec.

5) Measurement Criteria of Technique Factors

- **kV Measurement**
  The kV is measured during pre-install testing using a calibrated high voltage divider with ±1% accuracy (Calibration report guaranteed). Final performance measurements are checked using a *VICTOREEN NERO mAx 8000* X-ray meter from *FLUKE*.
- **Tube Current Measurement**
  The tube current is measured across a series connected resistor with an accuracy of ±1% and measured using a digital multi-meter, prior to encapsulation; ***XTG*** has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure, referenced to 75% rise/fall, using the *VICTOREEN NERO mAx 8000* X-ray meter from *FLUKE*.

6) Collimator Cone

- Minimum source to skin distance: 200 mm
- X-ray field size and configuration: **53** mm diameter circle
- Radiation shielding: lead lined

* For IRRADIATION TIMES shorter than 0.08 s in ONE-PEAK HIGH-VOLTAGE GENERATORS and TWO-PEAK HIGH-VOLTAGE GENERATORS where, because of the dependence on the pulsed nature of SUPPLY MAINS, it is not possible to provide all values belonging to the geometrical series within the range, missing values and consequently different geometrical intervals between the values provided shall be recognisable on the scale.

12.2. X-ray Tube Specifications and Characteristics

1) Stationary Anode X-ray Tube

- Specially designed for the ***XTG***
- Provided with an insulation cylinder (***D-081B***)
- The tube has a 0.8 mm focus, with a maximum tube voltage of 65 kV
- Installed with a high tension transformer

2) General Data

The X-ray tube is especially designed for dental X-ray unit. The tube has below specification

- ELECTRICAL

- Nominal X-ray Tube Voltage (IEC60613: 2010) ---------- 65 kV
- Nominal Focal Spot Value ---------- 0.8
- Nominal Anode Input Power (at 1.0s) ---------- 600 W
- Exposure Duty Cycle ---------- 1:60 or more (Exposure time : Interval time)

- MECHANICAL

- Overall length ---------- 69 mm
- Max. Diameter ---------- 31 mm
- Target angle ---------- 20˚
- Inherent filtration ---------- At least 0.8 mm Al equivalent at 50 kV
- X-ray coverage ---------- 354×354 mm at SID 490 mm
- Weight ---------- 96 g
- Cooling method ---------- Oil immersed (60˚C Max.) and convection oil cooling
- Tube holding ---------- Holding the glass envelop of the anode end and cathode end, or the screw of the anode shank

- MAXIMUM AND MINIMUM RATING

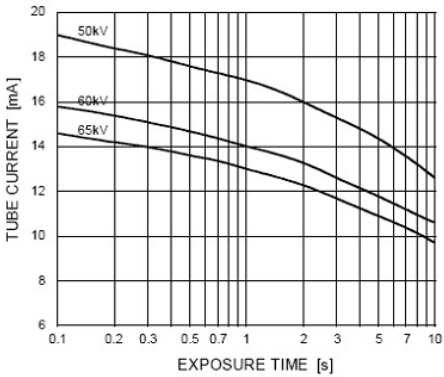
(At any time, these values must not be exceeded)

- Max. Tube voltage ---------- 65 kV
- Min. Tube voltage ---------- 50 kV
- Max. Tube current ---------- 19 mA
- Max. Filament current ---------- 2 A
- Filament voltage: At max. filament current ---------- 2.9 to 4.0 V
- Thermal characteristics:
  Anode heat storage capacity ---------- 6.0 kJ (8.5 kHU)
  Max. Anode heat dissipation rate ---------- 128 W (180 HU/s)

3) Tube Rating Chart

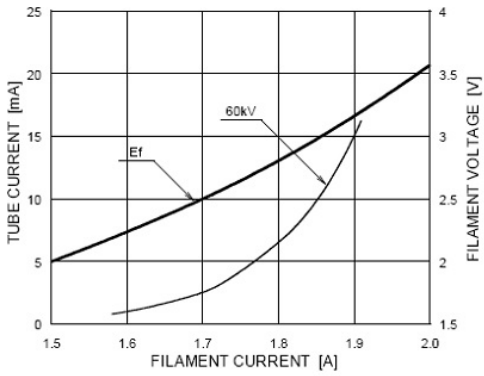
Maximum Rating Charts
(Absolute maximum rating charts)

Self-Rectified
Focal Spot : 0.8 mm

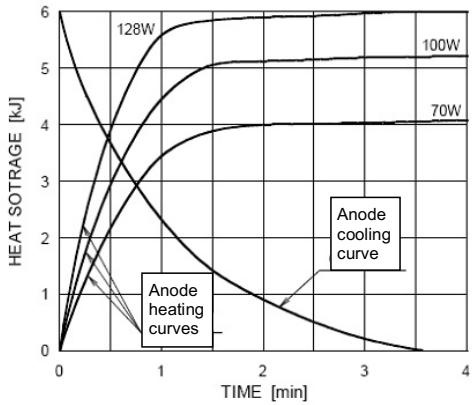


Emission & Filament Characteristics

Self-Rectified

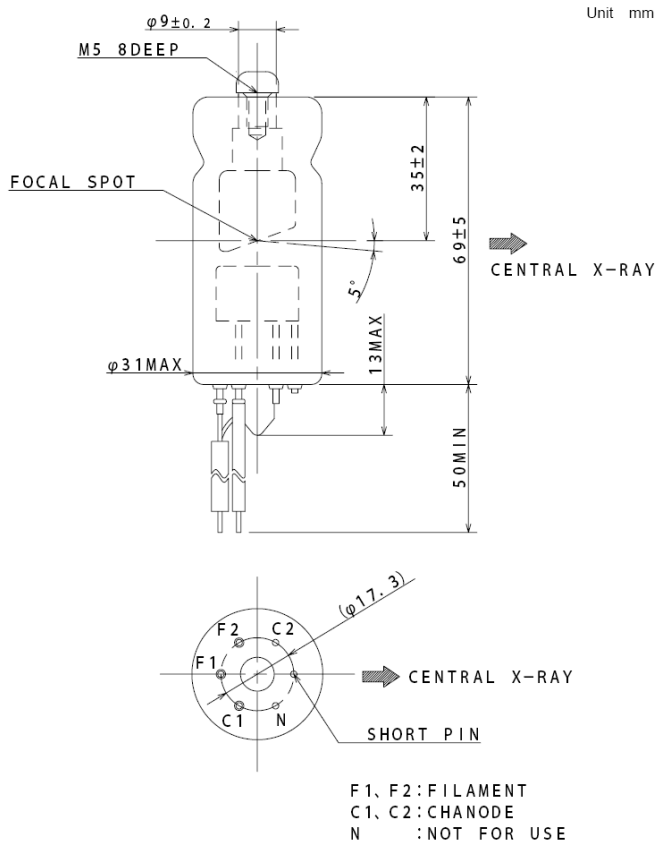


Anode Thermal Characteristics

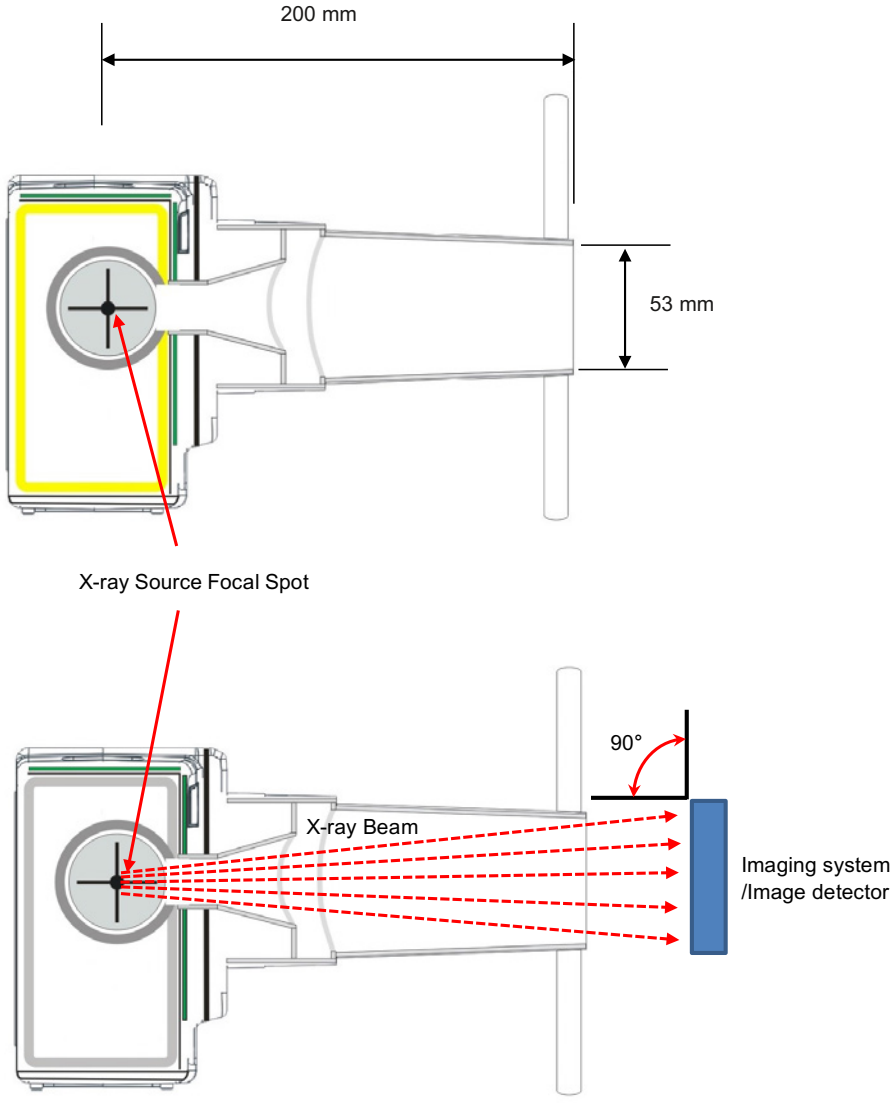


Cooling and heating curves for the anode and tube housing are equivalent to the anode heating and cooling curves shown here.

4) Dimensional Outline of D-081B



12.3. Distance from Focal Spot to Radiation Aperture and Diameter of X-ray Field



12.4. Optional Calibration Checks

The ***XTG*** is factory calibrated and tested prior to release (see the enclosed *Final Inspection Report*) and there are no adjustment options, A self-diagnostics is completed each time the device is powered up. However, the optional checks listed below may be performed by a qualified technician as desired.

Setup a calibrated Performance Meter (such as the *Victoreen NERO, mAx model 8000*) according to manufacturer's specifications to detect and report the following: X-ray Tube Voltage [kV Effective Mode], Radiation Time [ms Effective Mode], and Dose [mR Average Mode]. The filter card for the Test Detector should be in the 50-100kVp position.

Final performance measurements are made using a *NERO mAx, model 8000* X-ray meter from *Victoreen*. Tube current (mA) is sensed across a series connected resistor with an accuracy of ±1% and measured using a digital multimeter, prior to encapsulation; ***XTG*** has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure; referenced to 75% rise/fall, using the *NERO mAx 8000* X-ray meter. Accelerating voltage (kV) is measured at both peak (kVp) conditions and effective conditions (kVeff), which is the equivalent kV as if the kV were constant through the whole exposure time. Linearity is calculated per IEC 60601-2-65, 203.6.3.1.101

This X-ray unit may be dangerous to testing technician and any bystanders unless safe test exposure factors, such as placing the Test Detector in a lead lined box or the use of a protective lead apron are observed.

Enable the ***XTG*** and, with the cone perpendicular to the test detector, make exposures into the Test Detector and capture the resulting data. And compare the result with the factory release parameters (indicated in the chart below). For results outside below tolerance limits, discontinue use and contact your dealer/distributor or **DIGIMED**.

Radiation Tolerance Limit		
kV Accuracy	Not greater than ± 10% from 60 kV	54 ~ 66 kV
mA Accuracy	Not greater than ± 20% from 2 mA	1.6 ~ 2.4 mA
Exposure Time Accuracy	Not greater than ± 5% or ± 20 ms	1.9 ~ 2.1 sec (5%)

12.5. Dosimetric Control

The ***XTG*** is factory tested with AIR KERMA for the selected LOADING FACTORS. As followed by the requirement of IEC EN, DAP Meter (Model: *KermaX Plus TinO IDP*) is used for the test. The overall deviation of the AIR KERMA from the estimated AIR KERMA does not exceed 50 %.

12.6. Quality Assurance

We assure the accuracy and the quality of below items by the full functional test report of each device.

The manufacturing test tolerances are tighter than the intended field performance tolerances to ensure that when the device is operating in the field it will always meet its designed specification.

(Final test data is available upon request by serial number.)

No.	Test Item	Annual Requirement	
1	kV, mA, Time test	1) kV: Not greater than ± 7 % from 60 kV	
		2) mA: Not greater than ± 10 % from 2 mA	
		3) Exposure time: Not greater than ± 5% or ± 20 ms	**0.2** sec (Standard use time)
			0.7 sec (mA check time)
			1.0 sec (Maximum load)
2	Reproducibility of the radiation output	The coefficient variation of measured value of AIR KERMA is not greater than 0.05 mGy for any combination of LOADING FACTORS.	
3	X-ray load test	When maximum rating is loaded on the generator, it should not have any errors.	
4	X-ray beam limit test	The field size diameter should be at maximum 60 mm at the outer end of the cone tip.	
5	Total Filtration test for Half-Value Layer	Quality Equivalent Filtration not less than 1.5 mm Al	

13.0 Battery removal and replacement

In the event that state regulations require the battery to be removed when the unit is not in use, please follow these instructions.

Step 1: Using a phillips head screw driver remove the 2 screws shown in **Fig 1.0**

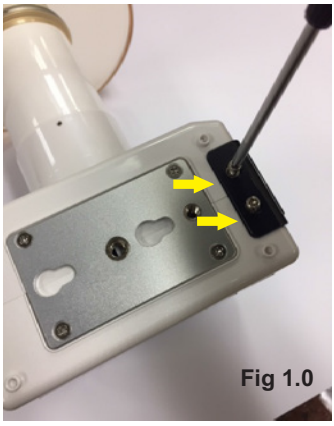


Fig 1.0

Step 2: Slide the grip panel down and remove the panel from the main body of the unit as shown in **Fig 2.0 & 2.1**

Fig 2.0

Fig 2.1

Step 3: Slide the battery out by gripping the battery tag and pulling gently as shown in **Fig 3.0**

Fig 3.0

Step 4: Disconnect the molex connector by depressing the tab and seperating as shown in **Fig 4.0**

Fig 4.0

Step 5: To reconnect and reinsert the battery repeat steps 1-4 in reverse.

14.0 Operator Training Test

Name: _____ **Date:** _____

Results: **Passed** ❑ **Failed** ❑

---

1) Parents must leave the room when x-rays are taken of their child.

a. True

b. False

2) How is the unit locked and secured when not in use?

a. Sitting on the counter in the exam room

b. Placed in a storage cabinet away from exam rooms

c. Locked in the case and place the keys in another location

3) When do you remove the backscatter shield?

a. Anytime it gets in the way

b. Never. It is permanently affixed to the end of the cone for operator safety

4) What position should the backscatter shield be to the operator?

a. Perpendicular

b. Angled

c. Parallel

5) What is the meaning of ALARA?

a. As Low As Reasonably Achievable

b. As Little As Randomly Achievable

c. As Long As Rationally Alerted

6) What type of disinfectant should you use to clean the device?

a. Non-acetone and non-alcohol disinfectant wipes

b. Xylene

c. Rubbing alcohol

7) The correct way to hold the device is by the cone.

a. True

b. False

8) How would you change the radiology settings from adult to child?

a. • Press and hold the “S” button for 2 seconds
   • Press the power off button once
   • Press the “S” button to select child
   • Press and hold the “S” button for 2 seconds

b. Press the up arrow button, the down arrow button, then press OK

c. Press the up arrow button, then press OK

9) How would you change the exposure time?

a. Press the Up or Down arrow keys

b. Choose another tooth type

c. All of the above

10) What is displayed immediately after a full exposure?

a. “XTG”

b. “READY”

c. “EXPOSURE”

11) How do you change the tooth type setting?

a. Press the up “^” button 3 times, then down ”v”, then OK

b. Press the down “v” button 3 times, then up “^”, then OK

c. Press and hold the “S” button for 2 seconds

Press the “S” button to select type

Press and hold the “S” button for 2 seconds

12) How do you resolve error codes?

a. Ask another technician for advice

b. Refer to the Error List in the User Manual

13) Required exposure times typically differ from film to sensor.

a. True

b. False

14) What will happen if a cell phone is used near XTG?

a. A beeping signal will occur

b. An error message will appear

c. Nothing. The device has been tested safe to use without interference from cell phones.

15) What is the source to skin distance in accordance with FDA regulations?

a. A limit SSD to not less than 18 centimeters

b. A limit SSD to not less than 20 centimeters

16) The pistol grip is an accessory that is approved in my state for use.

a. True

b. False

17) This device is FDA approved and therefore we can ignore our state requirements.

a. True

b. False

18) Does your state department have any restrictions for a handheld x-ray device?

a. Yes

b. No

19) How do you register the XTG with the state department?

a. Call the state department and let them know you have the XTG.

b. Send a letter to the state health department on our letterhead and state that you have the XTG.

c. Fill out an application from your state health department and send it in to them.

20) If your state department has restrictions for XTG, please list the restrictions.

NOTE: Answers to Questions 16-20 will varies from state to state. The purchaser should go over their specific state requirements with their staff/employees.

15.0 Operator Training Test Answers

1. A
2. C
3. B
4. C
5. A
6. A
7. B
8. A
9. C
10. B
11. C
12. B
13. A
14. C
15. A
16. A or B ***
17. B.
18. A or B***
19. C.

*** depends on each state's regulation

This Certifies that

HAS SUCCESSFULLY COMPLETED THE

XTG

Model MiniX-S

OPERATOR TRAINING & SAFETY PROGRAM

AND IS THEREFORE AWARDED THIS

Certificate of Training

Dated

Supervising Physician

Digital DOC®

LIMITED WARRANTY

DIGIMED Co., Ltd. (**DIGIMED** hereunder) warrants the portable X-ray system, ***XTG*** to be free from any defects in material or workmanship for a period of one (1) years from the date of purchase. (Battery: 12 months)

The liability of **DIGIMED** is limited repair or replacement of any parts that **DIGIMED** or its authorized resellers determine to be defective. Parts proving defective will be repaired or replaced free of charge, F.O.B. Seoul Korea (or the location of the authorized reseller), if defective equipment is returned to such location for inspection, freight charges prepaid. All warranty claims must be made not later than ten (10) business days following the expiration of the applicable warranty period. Equipment repaired or replaced under warranty will continue to be warranted for the balance of the original warranty term.

This warranty does not apply to equipment that is or has been abused, misused, or altered (including opening enclosure or tampering), improperly maintained, subjected to use beyond rated conditions, or damaged as a result of any carelessness or accidents. This warranty does not cover ordinary wear and tear or maintenance.

DIGIMED makes no other warranty, either express or implied, with respect to any equipment purchased from **DIGIMED**, including without limitation any implied warranties of merchantability or fitness for a particular purpose, whether or not **DIGIMED** may have been informed of the actual uses to which any of such equipment may be put. **DIGIMED** shall not under any circumstance be liable for incidental, indirect, consequential, punitive or exemplary damages, including without limitation damages for delay or lost profits, and in no event shall liability of **DIGIMED** arising from the purchase, sale or use of the equipment, or breach of any warranty made above, exceed in the aggregate the purchase price paid therefore.

◈ Product Warranty & Registration Card ◈

Product name	***Portable Dental X-ray System***	
Model name	***XTG***	
Serial number		
Purchased date		
Name of hospital or clinic		
Address of hospital		
Phone number		
Name of distributor		
Warranty period	Product	*1 years*
	Battery	*12 months*

DIGIMED Co., Ltd.

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EC REP

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XTG

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