



User Manual

Portable Dental X-ray System



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










This manual contains installation, operation and maintenance instructions for the handheld, portable dental X-ray system, **Xray2Go MINI**. 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: **Xray2Go MINI** 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 **Digital Doc LLC**, 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.

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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 handling 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 XRAY2GO MINI IEC 60601-2-65: 2012

[CAUTION]

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

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1 Introduction



This X-ray unit may be dangerous to patient and operator unless the safe exposure factors and operating instructions are observed. The operator must follow all federal, state, and local laws regarding hand held x-ray use.

1.1 Product Description

The portable X-ray system, *Xray2Go MINI* is an advanced high frequency dental X-ray apparatus with fixed 70kVDC and 2mA tube current which is designed to produce diagnostic high quality X-ray for film, phosphor plates, and digital sensors.

1.2 Intended Use

The *Xray2Go MINI* 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

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

1.4 Register Device

This device must be registered with the FDA, your State, and some local city Health Depts. as an X-Ray Device by each dental office/practice. Complete FDA Form 2579 and submit to FDA and your State Health Dept. Certain States allow dealers/vendors to complete this submission, please verify that your state accepts this before allowing dealer/vendor to complete this registration for you. A fee may be charged for your State Registration. Please check your State and local Health Depts. for rules, rates and deadlines. *Failure to comply with your States regulations may result in penalties/fines and Xray2Go MINI is sold with the understanding that the user assumes sole responsibility for any non-compliance with state regulations.*

Note: The Xray2Go MINI device is a portable x-ray unit that may only be used as a handheld device in states permitting handheld x-ray units. If your state does not allow this function, use this device in

accordance with your states rules and regulations. Some states offer and accept “letters of exemption” to current laws.

1.5 Annual Certification

Certain states require annual inspection and certification of x-ray generators. Contact Digital Doc Technical Support Department to request this service.

2 Important Safety Precautions

2.1 Online Training Material

A video overview of the system, safe use and positioning is available on [YouTube](#).

2.2 Device Package Check

Unwrap individual components from the protective aluminum 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.



2.3 Labels on Device

Exclusively Distributed in the USA By:



**4789 Golden Foothill Parkway
El Dorado Hills, Ca 95762
(800) 518-1102 www.digi-doc.com**



Digimed Co., Ltd. 309-311, 318-ho, 145, Gasan digital 1-ro, geumcheon-gu, Seoul, Korea

Caution: Federal law restricts this device to sale by or on the order of a physician.



Read and follow the instructions in the user manual.

DO NOT attempt to disassemble the device – this will void the warranty. Technical service will be provided by authorized personnel.

Portable Dental X-ray system Xray2Go (Model MiniX-V) **FDA cleared device K152859**

Tube Voltage: 70kV fixed / Tube Current: 2mA fixed

Total Filtration: 2.0mmAl / Inherent Filtration: 1.0mmAl

Power Input: 100-240V / 50-60 Hz, 1.0A Output: 25 2V –0.75A

Lithium Polymer Battery: 22.2V

Non-continuous Operation: 1:60



SN _____



0434

IPX 0



Please be careful not to destroy or detach the labels.

The labels are necessary for the warranty service and by the governing law.

2.4 Radiation Safety



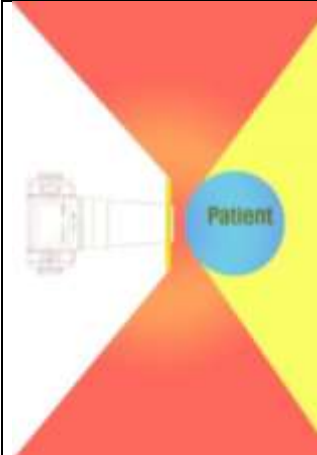


- This x-ray device may be dangerous to operator, patient and bystander unless safe exposure factors, operating instructions and maintenance schedules are observed.
- Do not operate if the backscatter shield or collimator cone are broken!

- 1) Ensure proper registration and compliance with any such 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 outer end of the collimator cone,
 - the backscatter shield is parallel to the operator,
 - the backscatter shield is close to the patient,
 - the patient tilts their head when needed to accommodate exposures, and
 - the operator remains within the Significant Zone of Occupancy immediately behind the device shield.



- 6) Do not enable *Xray2Go MINI* until patient and operator are positioned and ready for the exposure, reducing 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.
- 8) When selecting and using Position Indicating Devices (PIDs), preference should be given to models that allow the backscatter shield to remain at the outer end of the collimator cone for maximum operator protection. For example, a Rinn-style positioner with a *shortened rod* is one solution.
- 9) An exposure can be terminated for any reason by abruptly releasing the depressed trigger (for more information, see Section 6.5. *X-ray Exposure*).
- 10) As shown in the table below, maximum protection (white area) from backscatter radiation (red area) exists when the *Xray2Go MINI* 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	Reduced 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 <i>Xray2Go MINI</i> with D-Speed Film ⁴	0.25 mSv
Average Exposure Using <i>Xray2Go MINI</i> with F-Speed Film or Digital Sensor ⁴	0.10 mSv

1) Standards for Protection Against Radiation, 10 CFR 20 (US Federal Standards), 1994

(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

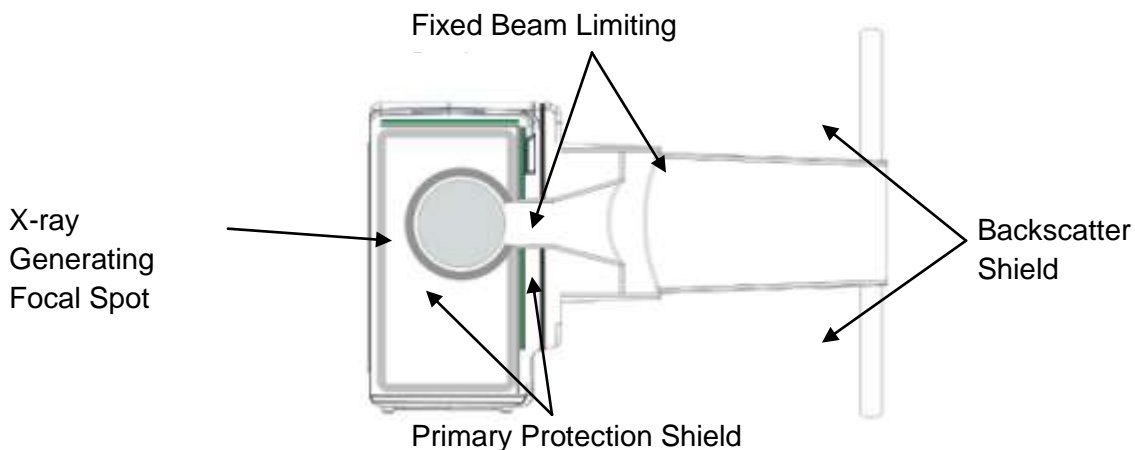
4) Normalized average assumes 7,200 exposures per year, and the average length of exposure for **E-speed Film** = 0.20 seconds, **digital sensor** = 0.10 seconds

***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 Xray2Go MINI with D-Speed Film ²	0.40 mSv
Average Exposure Using Xray2Go MINI with F-Speed Film or Digital Sensor ²	0.20 mSv

1) Standards for Protection against Radiation, 10 CFR 20 (US Federal Standards), 1994 (see also *NCRP Report No. 116*)

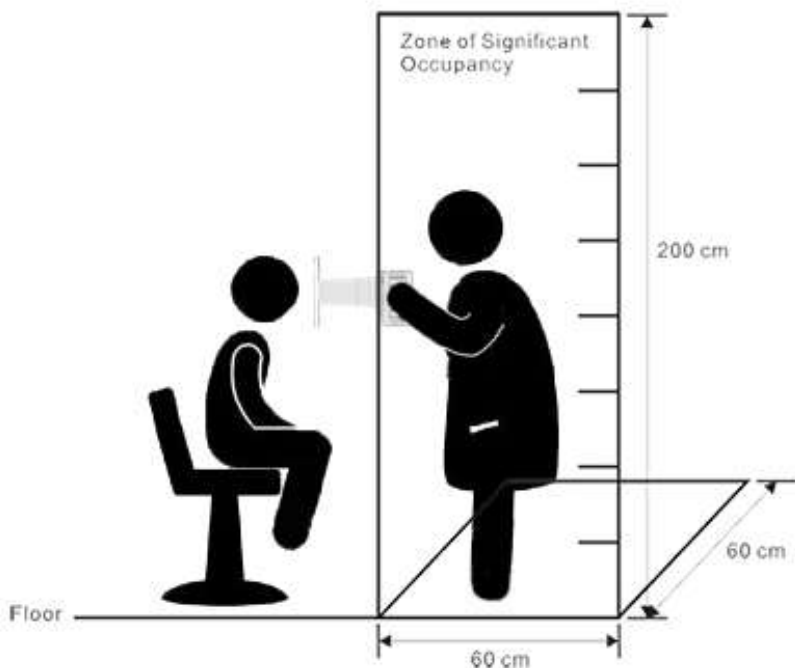
2) Normalized average (includes leakage and backscatter radiation) assumes 7,200 exposures per year, and the average length of exposure for **E-speed Film** = 0.20 seconds, **digital sensor** = 0.10 seconds



***Zone of Significant Occupancy**

Xray2Go *MINI* requires the presence of an operator, with at least one significant zone of occupancy with a floor not smaller than 60 x 60 cm wide, and not shorter than 200 cm height, including the logical information as follow.

- 1) The type of radio examinations the significant zone of occupancy is only designated to be used for its main purpose.
- 2) Location of the significant zone of occupancy includes the positions of its boundaries, and is relative to the clearly recognizable features of the X-ray equipment.
- 3) Identity of the removable protective devices for use with X-ray equipment and information on their application and use.



2.5 Usage and Duty Cycle

Xray2Go MINI 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 chart below for optimal use.

<Example of optimal use>

Duration	0.1 sec	0.25 sec	0.46 sec	0.5 sec	0.99 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 according to European Union (EU) requirements.
- **Xray2Go MINI** should not be used in environments where flammable cleaning agents are present
- Locate the battery charger away from the normal patient environment.
- **Xray2Go MINI** is not operated with insufficient voltage.
The proper voltage rating for **Xray2Go MINI** battery is **22.2V**.


2.6 Cleaning

- 1) Ensure the battery charger is unplugged before attempting to clean, and make sure the power is turned off while cleaning.
- 2) Cleaning can be done with a non-alcohol based disinfectant wipes. (Operators must be careful not to dampen the device with any liquid, alcohol, or spray. Controls are not waterproof.)
- 3) **Xray2Go MINI** and the accompanying battery charger are not designed to be subjected by any kind of sterilization procedure. **Xray2Go MINI** 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.

2.7 Storage and Transportation

	<ul style="list-style-type: none"> • 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. • Device function and battery charging should be checked every 2-3 months.
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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

2.8 Periodic Maintenance

Annual maintenance is recommended by a qualified technician for performance and safety, as well as assurance of accurate X-ray exposure levels.

The battery should be tested and replaced approximately every two years. See section 10 - **Battery Removal and Replacement Procedure.**







	<ul style="list-style-type: none"> - 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.
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3 Components and Accessories

The standard package has following components.

Xray2Go MINI with BackScatter Shield



Remote Control Switch*	Battery Charger	Replacement Battery	Shoulder Strap
			
Mobile Stand Arm*	Wall Mount Arm*	Portable Stand Arm*	Pistol Grip*
			

* Remote control switch, Mounting arms, and Pistol Grip are optional accessories.

4 Description of Device

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 Backscatter Shield
- ⑦ X-ray exposure button
- ⑧ Hand strap

Side View



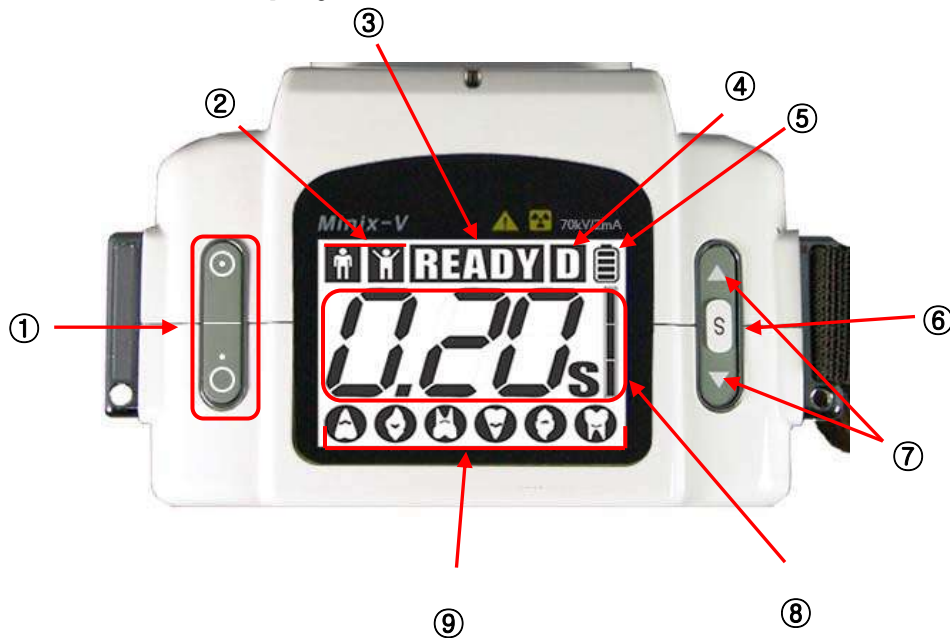
- ① Backup port
- ② mA measuring port
- ③ Hand Switch connection port
- ④ Charger connection port




Bottom View



- ① Connection plate for arm mounting

4.1 Control Panel and Display Functions



No.	Function	Description
1	Power ON/OFF button	Press  for 3 seconds to power on. To turn off, press  down for 3 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	kV type display	Signal " D " means "Dual kV Mode"
5	Battery charge indicator	Remaining battery power information
6	Mode control button (S button)	Press S button to begin mode control
7	Up/down control button	Exposure time change by pressing up and down
8	Exposure time display	X-ray exposure time
	Error display	E01 ~ E06 (Refer to the Chapter 8. Error List)
9	Tooth display	Incisor, canine and molar of the upper and lower jaw (Maxilla and Mandible) display

5 Setup and Power Check

5.1 Backscatter Shield

To protect the operator from scattered radiation during hand-held use, the Backscatter Shield has more than 0.25 mm lead equivalent and is 6 inches in diameter. The backscatter shield is fixed at the outer edge of the x-ray emitting cone. Do not attempt to remove the backscatter shield or the X-ray emitting cone.



5.2 Remote Control Switch

To activate the Remote Control Switch, connect the 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.).



5.3 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

6 Operation


6.1 Instructions 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 (Δ/∇).
Exposure	Expose X-ray by pressing exposure button on front or by remote activator.
Power down	Press the power off button for 2 seconds.

	<p>This instruction is just for operators' convenience only, to aid with understanding before actual use. The Xray2Go MINI should not be used until after reading the manual completely.</p>
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6.2 Starting and Stopping the System

1) **Power on**


Press power ON button  on the left side of LCD screen and wait until blue light turns on.

LCD displays [Pic.1] during loading.



[Pic.1]

2) **Power off**

To turn off the power, press power OFF button  for 3 seconds. And the system turns off the LCD screen. [Pic.2]



[Pic.2]

6.3 Indicators on LCD screen












Image	Function
	Exposure mode: Adult
	Exposure mode: Child
READY	X-ray exposure is available
	Full charged battery indicator
8.88s	Exposure time setting
	1 bar: Intraoral digital sensor
	2 bars: Phosphor plate
	3 bars: Analog dental film

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

6.4 X-ray Exposure Mode Setting

See Section 4.1 - *Control Panel and Display Functions*.



1) Tooth Type Setting

- Press **S** button on right side of control panel and hold for 2 seconds. The current tooth type icon in the LCD window will flicker and READY icon disappears. X-ray exposure button is inactive in this mode.
- Each press of **S** button will select the next tooth type icon to the right. There are 6 tooth type icons and each press will move the flickering cursor to next tooth type.
- Exposure time setting for each tooth icon can be changed with the Up/Down ("^/v") control buttons.
- To exit this mode, press the **S** button for 2 seconds.
- A 3-second timer will count down, then return to READY mode.



2) Exposure Subject Setting (Adult/Child)

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

The current adult icon () or child icon () flickers, and READY icon disappears. X-ray exposure button is inactive in this mode.

- Select adult or child with **S** button.
- Exposure time setting for each subject can be changed with the Up/Down ("^/v") control buttons.
- To exit this mode, press the **S** button for 2 seconds.
- A 3-second timer will count down, then return to READY mode.



3) Exposure Mode for Image Receptor (Sensor, PSP, or Film)

- Press **S** button and hold 2 seconds.
- Press the power off button twice. The current receptor gauge bar will flicker, and READY icon disappears. X-ray exposure button is inactive in this mode.
- Each press of **S** button will change the number of bars
 - 1 bar: Digital Sensor use
 - 2 bars: Phosphor plate use
 - 3 bars: Analog Film use
- To exit this mode, press the **S** button for 2 seconds.
- A 3-second timer will count down, then return to READY mode.



4) 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.

6.5 X-ray Exposure

1) Ready the Device

- Set X-ray exposure mode necessarily as explained in preceding section.
- The LCD will show “READY” icon and LED green when it is ready to make next X-ray exposure.

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)



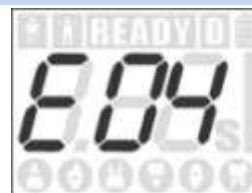
4) Initiating an X-ray Exposure

- Press the exposure button once.
- **Green LED** changes to **white**. (**Safety is unlocked**)
- Press the exposure button again and hold.
- During X-ray exposure, the “**READY**” icon will flash, and the LED changes to **red**.
(Once the X-ray exposure is started, the unit will make a beeping sound. And the sound will stop when the exposure is completed.)
- “**Safety Lock**” is effective for 5 seconds.
 - If no exposure is made in 5 seconds, **Safety Lock** will be released.



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 will stop and LCD will show below error code (E04: shot time error).



6) Auto-Recovery after duty cycle

- The LCD will show “READY” icon and LED green when it is ready to make next X-ray exposure.



6.6 X-ray Exposure Techniques

This portable X-ray system is easy to position for intraoral dental X-ray diagnosis. Operators can make exposures while the patient is sitting upright, reclined, or lying on their back. Be sure to follow state and local laws regarding operator safety, and ensure the operator and patient are protected by a radiation shield (Lead apron). The device is originally designed to be portable and handheld, or can be used with optional stands (See **Chapter 3. Components and Accessories.**)

1) Handheld Use

- **Xray2Go MINI** is mainly designed to be used held with two hands, and one hand inside the attached strap. Operators should be careful not to grab or hold the collimator cone.



2) Operation with Stands

- Operators can operate **Xray2Go MINI** with optional stands or tripod. See **Chapter 3. Components and Accessories.**



3) Device Positioning

- **Xray2Go MINI** should be positioned squarely 90° to the receptor (intraoral digital sensor, PSP, or film) in the patient's mouth. Exposure may vary when X-ray exposure angle is not squarely 90° to the receptor.
- Operators may use RINN/Flow/Clikstik-style positioners with a short bar designed for handheld X-ray use to assure correct exposure angle, and avoid cone-cutting the image if the collimator cone end is not positioned correctly. This unit is very low-dose and requires the end of the cone to be as close to the receptor (Film, Plate, or Sensor) as possible.
- For best operator protection, keep the backscatter shield parallel to the operator. Tilt patient head if necessary, but do not tilt Xray2Go MINI. Operators should use radiation shields (goggles, gloves, and lead apron) as 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


- See **Chapter 7 – Recommended Exposure Time Setting** for each type of tooth, image receptor and patient size.

7 Recommended Exposure Time Setting

X-ray exposure time settings in below chart are intended as a reference only. Each result from an 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					
			Incisor	Canine	Molar
Digital Sensor		Adult	0.07	0.09	0.12
		Child	0.05	0.07	0.10
Film		Adult	0.25	0.27	0.30
		Child	0.20	0.22	0.25
Phosphor Plate		Adult	0.10	0.12	0.15
		Child	0.08	0.09	0.12

X-ray exposure time settings can be changed by the operator as described in 6.4 **X-ray Exposure Mode Setting**. If the settings are all saved, the change will be maintained in memory until changed adjustment or until factory defaults are restored.

	<ul style="list-style-type: none"> • 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.
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- If an x-ray image is not captured, do not re-expose the patient. Check all settings of generator, receptor, and imaging software, then retest on another object and confirm test image is captured before re-exposing patient.

8 Battery Charging and Maintenance







1. The high efficiency lithium ion polymer battery will generate more than 200 X-ray exposures after full recharging, depending on exposure and recharging patterns of usage.
2. The battery is a consumable part. After several months, the battery capacity may slowly decrease. For reliable function and safety, battery pack should be replaced when its capacity is noticeably decreased. See section 9 – Battery Removal and Replacement.
3. Do not attempt to open the unit except for the battery compartment. Opening the unit will void the warranty. There are no user-serviceable parts inside except for the battery.
4. If the battery charge is too low, LCD will show error code E01. (See Section 8 – Error List) Recharge the unit with its battery charger.
5. Full battery charge takes about 3 hours. Monitor the unit during battery recharge, and be careful not to overcharge.
6. During recharge, battery charging status is displayed by an icon on the left top of LCD Screen. (Battery icon will blink)
7. If the equipment is not used for an extended time period, charge the battery once every 3 months. After full charge, at least 1 exposure has to be made to keep the battery in best function.
8. Use only the authorized charger which is provided from the manufacturer or an authorized distributor.
9. Do not use physical force on the unit. If the unit is affected by any physical force and modified from its original condition, the unit and its lithium ion polymer battery may not function normally.
10. Do not place the unit with heat generating devices. The battery is vulnerable to heat. Place the unit where air quality is good.
11. Best temperature for storage and recharging is between 10~25°. Operation under cold temperature may cause fast discharge and recharging may take longer. Battery level may be indicated lower than normal.
12. Be careful not to get the device wet. If any foreign substances or moisture come into the unit or the battery pack, it may cause malfunction.
13. There is a potential danger of 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 the conductive elements 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 them to the manufacturer or an authorized distributor for recycling. Do not place in municipal waste stream.

9 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 is exceeded the tolerance range. Please contact the authorized distributor or manufacturer.
	mA error	This error code indicates the mA value exceeded the tolerance range. 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 1 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 though the control panel still shows error code.
- Contact the manufacturer or an authorized distributor immediately especially with E02, E03 or E06 error.

10 Battery Removal and Replacement Procedure

If the battery will not hold a charge, follow this procedure to remove and replace it. NOTE: Damage to the Xray2Go MINI or battery as a result of mishandling will not be covered by the manufacturer's warranty against defects. Digital Doc offers this service at our office; contact Customer Service at 1-800-518-1102.

10.1 Battery removal

1. Remove 2 Phillips head screws and flat washers from bottom of black plastic side cover (see Figure 1).
2. Slide side cover towards bottom of body (see Figure 2) to release inner hooks (see Figure 3).
3. Remove side cover by pulling it away from the body
4. Slide battery out of body (see Figure 4). Note: it may be necessary to carefully use a small tool to extract the battery from the body.
5. Disconnect battery plug



Figure 1 - Bottom of body, showing 2 screws



Figure 2 - Slide side cover towards bottom



Figure 3 - Edge view of side cover, showing hooks inside cover



Figure 4 - Battery partially removed, showing correct orientation with CE mark towards bottom of body



Figure 5 - Battery plug tucked into front of body

10.2 Battery replacement

1. Connect battery plug
2. Insert battery plug toward front of case where it will not interfere with battery (see Figure 5).

3. Insert battery into body, with battery CE label towards bottom of body (see Figure 4).
4. Slide battery into body until flush with bottom of body. If it will not go completely into the body, remove battery and ensure plug is tucked into front of body.
5. Replace side cover and slide it towards top of body until retainer hooks engage.
6. Replace 2 Phillips head screws in bottom of black plastic side cover.
7. Charge new battery fully using supplied charger.

11 Technical Description

11.1 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, 70 kV output: 15 A
- Power supply:
 - Input: AC 100-240 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: **2.0 mm Al**
- Maximum output power: 120 W nominal at 70 kV, 2 mA
- Generator rating: 2 mA at 70 kV ±5%
- Leakage technique factors: 70 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 $\pm 1\%$ 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 $\pm 1\%$ and measured using a digital multi-meter, prior to encapsulation; *Xray2Go MINI* 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 recognizable on the scale.

11.2 X-ray Tube Specifications and Characteristics

1) Stationary Anode X-ray Tube

- Specially designed for the *Xray2Go MINI*
- Provided with an insulation cylinder (*D-041*)
- The tube has a 0.4 mm focus, with a maximum tube voltage of 70 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) ----- 70 kV
- Nominal Focal Spot Value ----- 0.4mm
- Nominal Anode Input Power (at 1.0s) ----- 430 W
- Nominal Radiographic Anode Input Power (IEC60613: 2010) ----- 450 W
- Exposure Duty Cycle ----- 1:60 or more (Exposure time : Interval time)

- MECHANICAL

- Overall length ----- 66 mm
- Max. Diameter ----- 31 mm
- Target angle ----- 12.5°
- Inherent filtration ----- At least 1.0 mm Al equivalent at 70 kV
- X-ray coverage ----- Ø70 mm at SID 200 mm
- Weight ----- 100 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

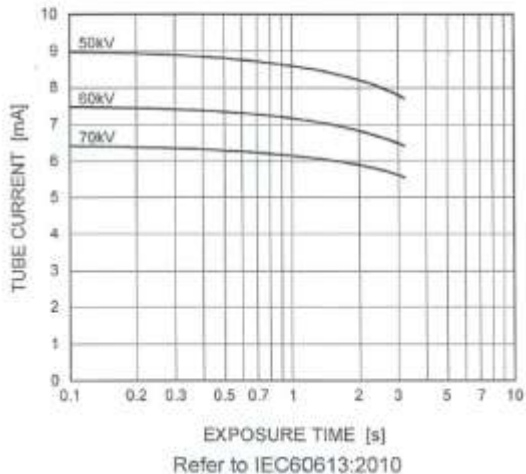
(At any time, these values must not be exceeded)

- Max. Tube voltage ----- 70 kV
- Min. Tube voltage ----- 50 kV
- Max. Tube current ----- 9 mA
- Max. Filament current ----- 3.0 A
- Filament voltage: At max. filament current ----- 3.0 to 3.7 V
- Thermal characteristics:
 - Anode heat storage capacity ----- 4300 J
 - Max. Anode heat dissipation rate ----- 100 W

3) Tube Rating Chart

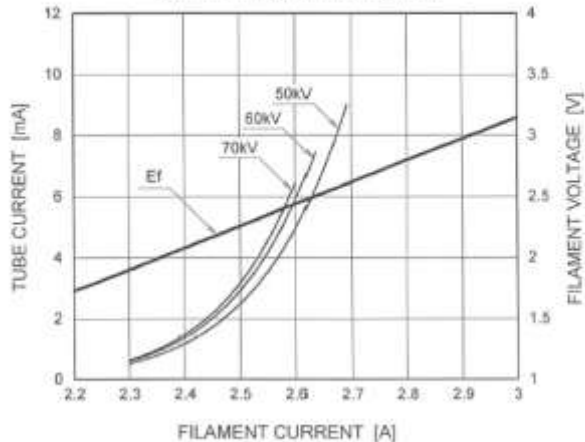
Maximum Rating Charts (Absolute maximum rating charts)

Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.4



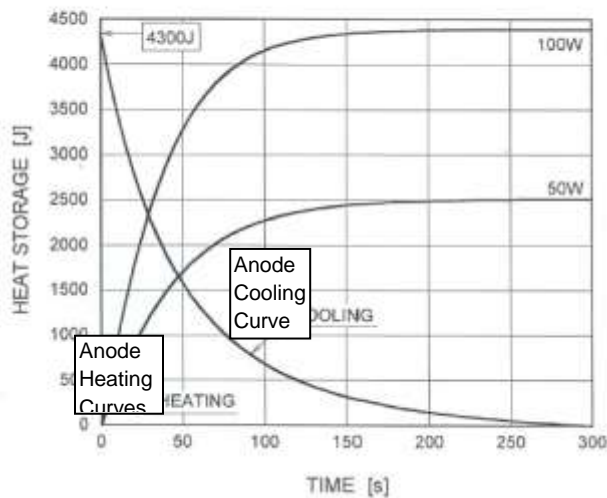
Emission & Filament Characteristics


Constant Potential High-Voltage Generator
Nominal Focal Spot Value: 0.4



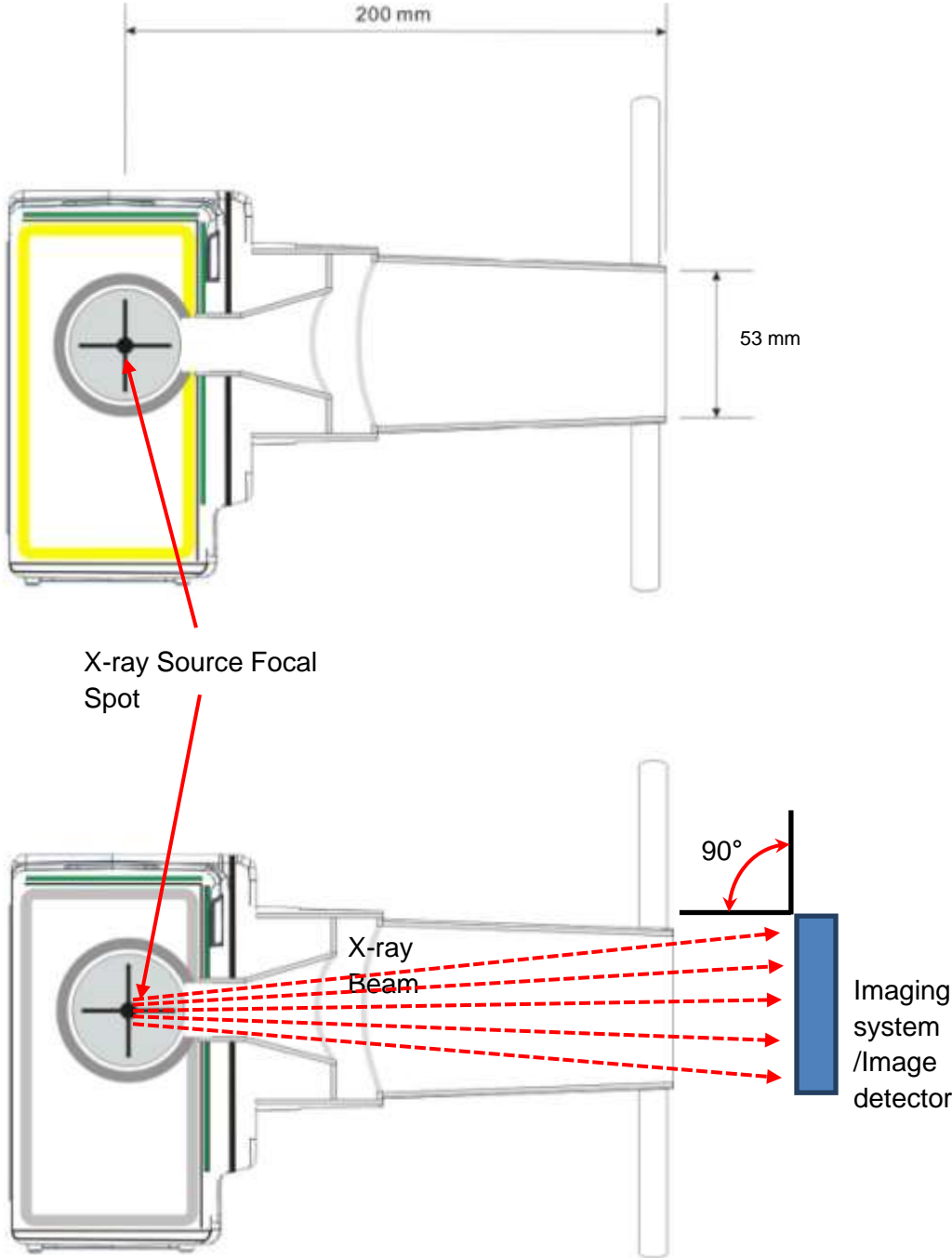
Note 1) This graph indicates typical characteristics.
Note 2) Refer to IEC60613:2010

Anode Heating / Cooling Curve



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

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



11.4 Optional Calibration Checks

The **Xray2Go MINI** 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 $\pm 1\%$ and measured using a digital multimeter, prior to encapsulation; **Xray2Go MINI** 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: 2012, 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 **Xray2Go MINI** 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 **Digital Doc**.

Radiation Tolerance Limit		
kV Accuracy	Not greater than $\pm 10\%$ from 70 kV	63 ~ 77 kV
mA Accuracy	Not greater than $\pm 20\%$ from 2 mA	1.6 ~ 2.4 mA
Exposure Time Accuracy	Not greater than $\pm 5\%$ or ± 20 ms	1.9 ~ 2.1 sec ($\pm 5\%$)

11.5 Dosimetric Control

The **Xray2Go MINI** 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 %.

11.6 Quality Assurance

We assure the accuracy and the quality of below items by the full functional test report of each device. (Final test report is enclosed in each device package by the serial number.)

No.	Test Item	Annual Requirement	
1	Accuracy of loading factors	1) kV : Not greater than $\pm 10\%$ from 70 kV	
		2) mA : Not greater than $\pm 20\%$ from 2 mA	
		3) Exposure time : Not greater than $\pm 5\%$ 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	Quality Equivalent Filtration not less than 1.5 mm Al	

12 Specifications of Device

- 1) **Grade** ----- Class II b
- 2) **Classification** ----- Type B applied part
- 3) **X-ray Generator**
 - Tube Voltage ----- **70 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 ----- **0.01~2.0** second (0.01 sec. step)
- 4) **X-ray Tube**
 - Type ----- Stationary Anode X-ray Tube
 - X-ray Tube Model ----- **D-041** (Toshiba)
 - X-ray Tube Focal Size ----- **0.4** mm
 - Target Angle ----- 12.5°
 - Total Filtration ----- **2.0** mm Al
(Inherent Filtration: 1.0 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** ----- 1.95 kg
- 9) **Size of Main Body** ----- 123 (W) x220 (D) x134 (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)

12.1 Guidance and manufacturer's declaration

The system of *Xray2Go MINI* 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. *Xray2Go MINI* 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		
<p>The <i>Xray2Go MINI</i> is intended for use in the electromagnetic environment specified below. The user of the <i>Xray2Go MINI</i> should assure that it is used in such an environment.</p>		
Emissions test	Compliance	Electromagnetic environment-guidance
Conducted Emission CISPR 11	Group 1 Class A	<p>The <i>Xray2Go MINI</i> 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.</p> <p>The <i>Xray2Go MINI</i> 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.</p>
Radiated Emission CISPR 11	Group 1 Class A	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complied	

2) Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity					
The Xray2Go MINI is intended for use in the electromagnetic environment specified below. The user of the Xray2Go MINI 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		
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.					

13 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 must stay 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. "Xray2Go"
 - 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 Xray2Go?**
- a. A beeping signal will occur
 - b. An error message will appear
 - c. The device may autofire.
- 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 Xray2Go with the state department?**
- a. Call the state department and let them know you have the Xray2Go.
Send a letter to the state health department on our letterhead and state that you
 - b. have the Xray2Go.
 - c. Fill out an application from your state health department and send it in to them.
- 20) **If your state department has restrictions for Xray2Go, 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.

14 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 – depends on each state's regulation
17. B.
18. A or B – depends on each state's regulation
19. C.

20. List the information.

XRAY2GO MINI OPERATOR TRAINING & SAFETY

THIS CERTIFIES THAT

has successfully completed

The Xray2Go Operator Training and Safety Program

and is therefore awarded this

CERTIFICATE

Dated this __ day of _____, ____

_____ Supervising Physician



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