User Manual

Portable Dental X-ray System

(Model: **DHX-70H**)

Wellness of Your Life!

DIGIMED

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, **DHX-70H**. Operation should be performed only by veterinarians, veterinary technicians, **trained staff**, or maintenance service technicians who are experienced in installing and servicing dental X-ray systems.

DISCLAIMER: The product 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:

	Manufacturer of the device		Date of device manufacture
	Authorized representative in the European Community		Unique serial number for the device
	General Warning		Ionizing radiation
	Caution		Electrical shock hazard
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		Refer to instruction manual/booklet
	Recycling instructions		WEEE wheeled bin Must follow specific disposal or recycling instruction for this product
IPX0	No protection of equipment against ingress of water with harmful side effects (non-protected)		European Conformity mark
	Type B equipment (Providing a degree of protection against electric shock, pertaining particularly to allowable leakage currents)		

[STATEMENT OF COMPLIANCE]

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

[CAUTION]

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

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 operated with backscatter shield, collimator cone, neck strap, and lead apron.

1.1. Product Description

The portable X-ray system, **DHX-70H** 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 both film and digital sensors. When x-rays are taken, the device can be mounted on an optional stand.

1.2. Intended Use

The device is intended to be used by trained dentists and dental technicians as a portable and a mobile, extra-oral x-ray source. This can help produce diagnostic x-ray images by using with various intra-oral image detectors. This x-ray image can be used for dental examination (diagnosis) before or after treatment. Its use is intended for veterinary dentistry.

1.3. Main Features

- ◈ High-frequency x-ray
- ◈ Micro-computer and specialized circuit for precise exposure technique factors
- ◈ Self-diagnostic control panel
- ◈ Simple and easy x-ray exposure setting
- ◈ Custom-setting 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

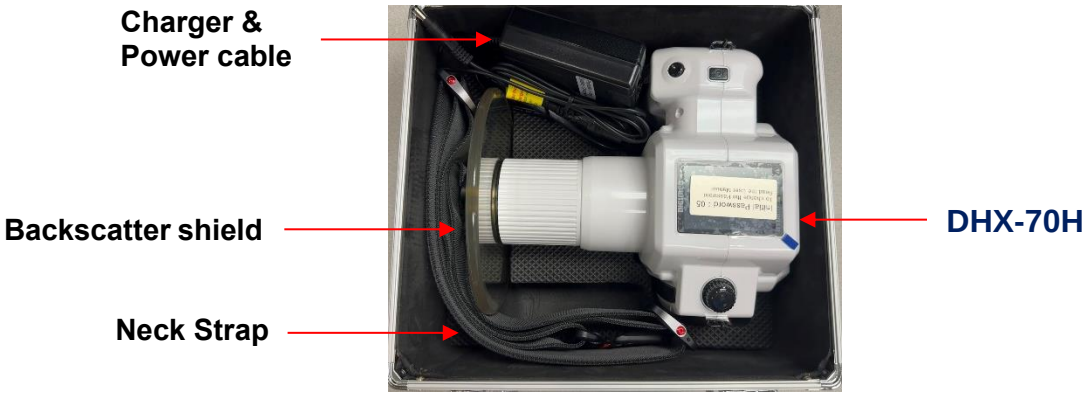
1) Lifting operation
   A movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.
2) Guided load
   A load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.
3) Working coefficient
   The arithmetic ratio between the load guaranteed by the manufacturer or their 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.

** Directive 2006/42/EC of the European Parliament and of the council (17 May 2006)

2. Device Package and Labels

2.1. Device Package

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

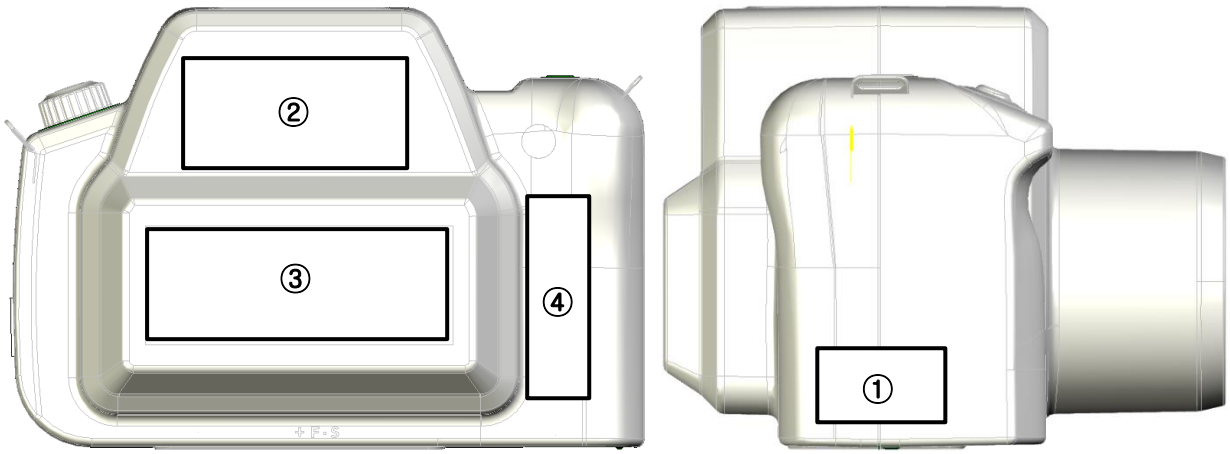


- Preliminary Checks

ITEM	CHECK
Device Label	Serialized Device Label is in place (Rear side of the device)
Collimator Cone and Backscatter Shield	These two items provide the operator protection and should be inspected for shipping damage.
Device Housing	Should have no cracks or fractures.

2.2. Labels on device

The Portable X-ray System, **DHX-70H** has its identification labels on the outside of the device. Since each label has device information and important markings as below, the labels need to be kept clean and legible.



① **Caution:** Federal law restricts this device to sale by or on the order of a physician.

Read and follow the instruction from the manual. Do not attempt to disassemble or amend the device.
It may cause electric shock and this will VOID the WARRANTY.
Technical service can be provided only from the authorized personnel

② **CAUTION!**

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

X-ray radiation. Authorized personnel only. This product complies with CFR 1020.30-1020.31. FDA Registered.

③

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Seoul 08506 Rep. of Korea
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- **Portable Dental X-ray System** (Model: **DHX-70H**) **IPX0**
- Tube Voltage: **70 kV** (Fixed) / Tube Current: **2 mA** (Fixed)
- Total Filtration: Over 1.5 mmAl (Inherent Filtration: 1.0 mmAl)
- Charger: BPL910S16N01, BridgePower Corp.
  Input 100-240 V~, 50-60 Hz, 0.5 A/Output 16.8 V⎓, 1.0 A
- Lithium Polymer Battery 14.8 V⎓
- Non-continuous operation (Operation time: 1.0 s/Rest time: 60 s)

YYYY-MM-DD SN DHXXAXXXX TYPE B EQUIPMENT

MADE IN KOREA

④ **UDI** Direct Marking

(01)08800021800021
(11)220101
(21)DH22A0001

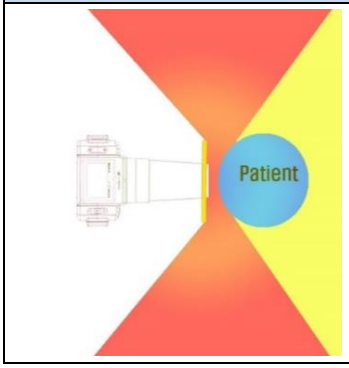
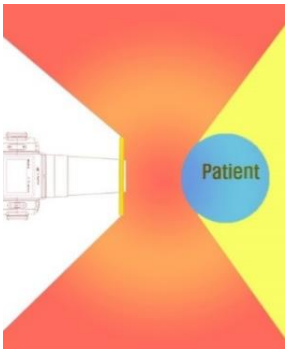
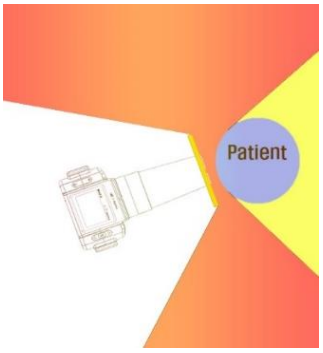
DO NOT detach or destroy the labels. The labels shall be kept safe by the governing law and has essential information for the warranty service.

3. Important Safety Precautions

3.1. 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!
- The **DHX-70H** dental unit is intended to be used only in a radiation-controlled environment. **DO NOT** take the device outside the radiology room.

1) Please 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 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 the device until the 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.
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.
9) An exposure can be terminated for any reason by abruptly releasing the depressed trigger (for more information, see Section **7.3. *X-ray Exposure***).
10) As shown in the table below, maximum protection (white area) from backscatter radiation (red area) exists when the device 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
		

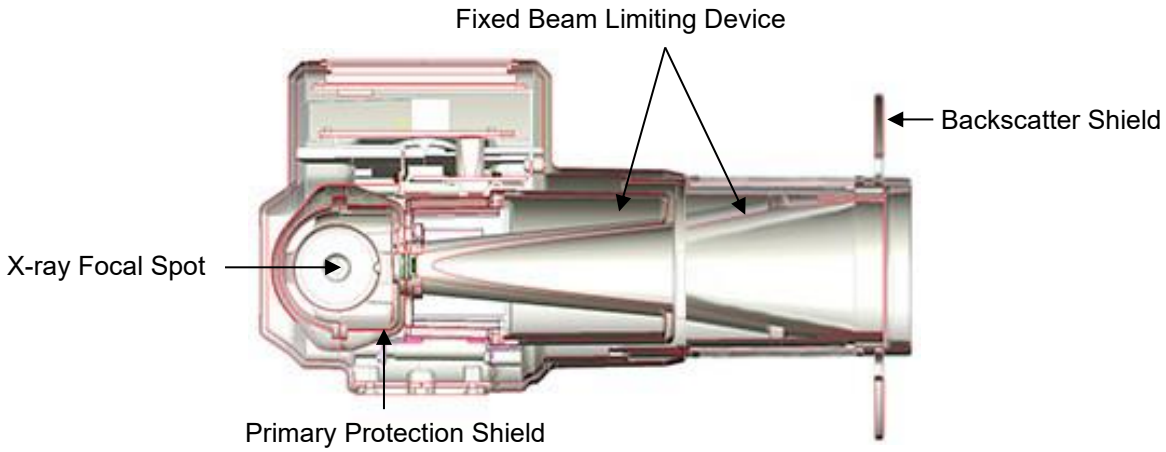
11) Operation outside the protection zone (or with a diminished protective zone) requires proper precautions such as the use of lead aprons.
12) **DO NOT** use low class image detectors.
(**Film**: higher than E class, **Sensor**: higher than 10 lp/mm, **Phosphor plate**: higher than 10 lp/mm)

3.2. Data on Radiation dose to the Patient & Operator

For the safety of the patient and operator from leakage radiation and scattered radiation, DIGIMED designed the HYBRID model with protective materials to be aligned with international regulatory requirements. Following information and data shows the radiation safety of **DHX-70H**.

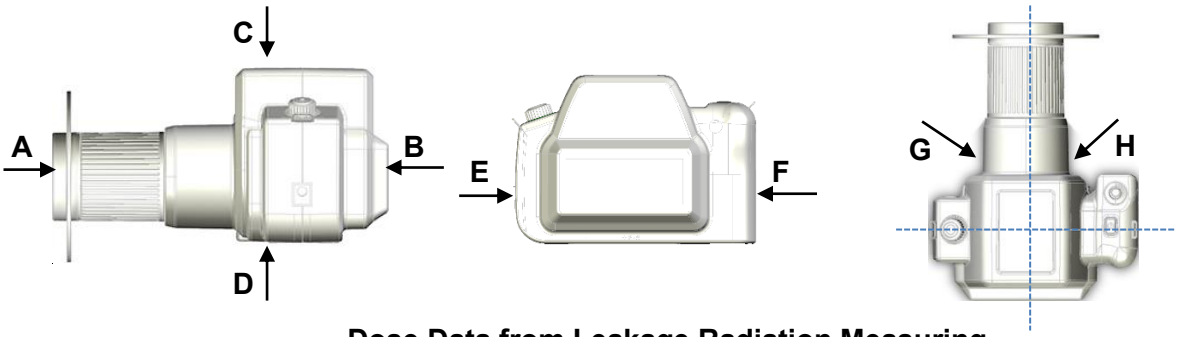
1) **Protection from leakage radiation**

The X-ray generating part of the device is positioned and covered with a specially designed internal shield. The primary protection shield of each part inside practically eliminates leakage radiation during X-ray exposures. As the given information of the device below, the X-ray tube and the X-ray generating part are encased with a protection shield.



As followed by the requirement from IEC 60601-2-65, Clause 203.12, leakage radiation in the loading state shall not exceed 0.25 mGy/hr at 1 meter distance. In response to the regulation, DIGIMED will only manufacture product that tests below 0.25 mGy/hr at 1 meter distance for leakage radiation safety. In order to verify compliance with this requirement, **DHX-70H** is tested with a calibrated survey meter at 8 points on the device housing, as showing in the following diagram.

Test Points for Product Final Inspection



Dose Data from Leakage Radiation Measuring

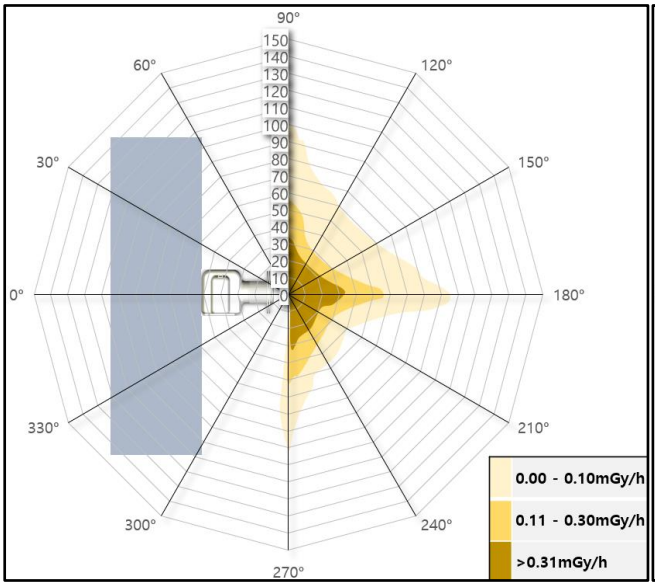
	Dose Amount by Distance (mGy/h)	
Measuring point	50 cm	1 meter
A (Front)	0.005	0.003
B (Rear)	0.006	0.002
C (Top)	0.005	0.001
D (Bottom)	0.023	0.020
E (Left)	0.015	0.006
F (Right)	0.028	0.019
G (Front left)	0.021	0.015
H (Front right)	0.029	0.023

1) Measuring Equipment
Fluke-481 (S/N: 3784) Ion Chamber from Fluke Biomedical
2) Loading Factor
70 kV, 2 mA, 1 sec exposure time (5 times at each point)

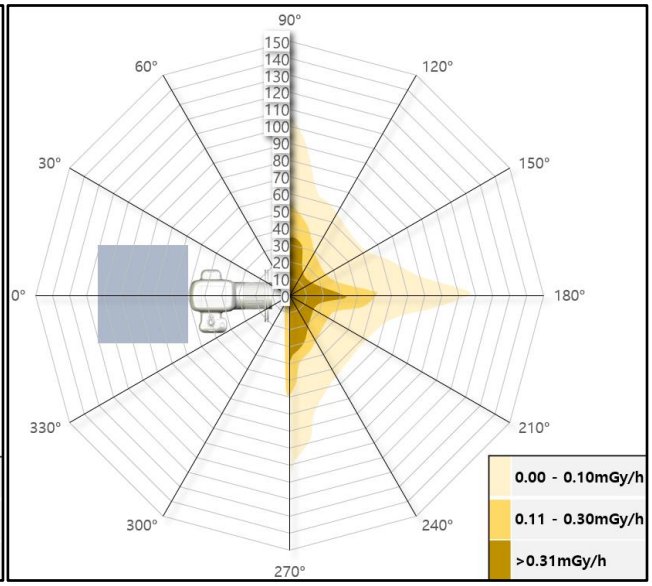
2) **Scattered Radiation**

When the Backscatter shield is properly mounted on the **DHX-70H** collimator, it acts as a barrier against backscatter radiation and makes the operator safe to stay behind the device when loading.
A **DHX-70H** was remotely fired into a water phantom repeatedly, with an ion chamber recording radiation readings at 72 points around the device, to establish the vertical significant zone of occupancy and then to establish the horizontal significant zone of occupancy for each unit located 100 cm above the floor. Each exposure was taken at 1.00 seconds in order to simulate “worst case scenario” results. The vertical significant zone of occupancy measures 60 cm X 200 cm, while the horizontal significant zone of occupancy is 60 cm X 60 cm. A calibrated survey dosemeter is used in order to record scattered radiation as in the following diagrams.

Vertical Measurement



Horizontal Measurement



* Measuring Equipment
Fluke-481 (S/N: 3784) Ion Chamber from Fluke Biomedical

3.3. Radiation Dose to Patient

A **HYBRID-S70** device was fired into a water phantom to measure the estimated Radiation Dose to patient on each exposure. The water phantom was placed 20 cm away from the focal spot of the device, and the Radiation Dose measuring device was placed close (≦5cm) to the **DHX-70H** device. The measured Radiation Dose value at each frequently-usable time setting is described on below table. The Radiation Dose value is increased as the exposure time is added. On the contrary, when the exposure time is decreased, the Radiation Dose value becomes lower.

Exposure Time [Sec]	**0.10**	**0.18**	**0.25**	**0.30**	**0.40**	**0.70**	**1.00**
Air Kerma [mGy]	0.04	0.08	0.11	0.14	0.19	0.41	0.57

3.4 Dose Area Product (DAP) Measurement

Exposure time [Sec] at 70kV, 2mA	**Air Kerma [mGy]**	**Dose Area Product [mGy*cm²]**	
		Circular collimator	**Rectangular collimator**
0.10	0.17	3.74	2.04
0.18	0.30	6.61	3.60
0.25	0.46	10.1	5.52
0.30	0.54	11.9	6.48
0.40	0.73	16.0	8.76
0.70	1.24	27.3	14.8
1.00	1.82	40.1	21.8

Air Kerma at other distance from the focal spot can be determined by the following formula;

DAP = Dose (at 20cm from focal spot) x Exit Field Size

Operator is able to check the DAP value with the above formula, and the Exit Field Size of each collimator is described on table below.

[X-ray Exit Field Size]

Circular Collimator
Exit Field Size of Circular Collimator is $(5.3\ cm/2)^2$ x 3.14 (π) = **22.05 cm^2**

3.5. Duty Cycle

To avoid any damage from overheating, follow the duty cycle period below. The maximum duty cycle rating* is 1:60.

*The relationship between duration and frequency of exposures

Example of optimal use

Duration	0.10 sec	0.25 sec	0.46 sec	0.50 sec	1.00 sec
Cycle	Every 6 sec	Every 15 sec	Every 28 sec	Every 30 sec	Every 60 sec

- The device should not be used in environments where flammable agents are present.
- Locate the battery charger away from the normal patient environment.

3.6. Cleaning

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

1) Before cleaning, please make sure the battery charger is unplugged and the device is turned off.
2) The device and the accompanying parts are not designed to be subjected by any kind of sterilization procedure. It is not designed to be sterilized. Do not place them in any sterilization equipment.
3) Clean the device with non-alcohol based disinfectant wipes or wipe the device with disinfectant liquid (spray) on a soft cloth.
4) Operators must be careful not to dampen the device with any liquid, alcohol, or spray. The device is not designed to be waterproof.
5) Please wait until the device is all dried. Then, turn the power on and check the function.

3.7. Storage, Transportation and Use Condition

- 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.

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

Humidity 	5 ~ 90 %RH	5 ~ 90 %RH	10 ~ 85 %RH
Atmospheric pressure 	800 ~ 1060 hPa	500 ~ 1060 hPa	800 ~ 1060 hPa

3.8. Periodic Maintenance

To ensure safe performance, the key functions of the device should be checked regularly every year. The Portable X-ray System should be inspected in accordance with each inspection item and quality assurance method described in **section 12.6** to **12.8** and ensure that the device maintains each function within its normal range. The calibration and regular inspection should be carried out by the authorized distributor or DIGIMED.

4. Specifications of Device

1	**Model Name**	**DHX-70H**
2	**Device Classification**	**Class IIb**
3	**Device Type**	Type **B** applied part
4	**X-ray Generator**	
	Tube Voltage	70 kV (fixed)
	Tube Current	2 mA (fixed)
	High Voltage Generating circuit	High-frequency inverter method
	X-ray control	Controlled by Micro processor
	Time setting range	0.05 - 1.0 sec (0.01 sec step)
5	**X-ray Tube**	
	Model	D-045
	Type	Stationary anode X-ray tube
	Focal size	0.4 mm
	Target angle	12.5°
	Total filtration	2.6 mm Al (Inherent: 1.0 mm Al / Fixed Added: 1.6 mm Al)
6	**Display**	TFT LCD
7	**Source to Skin Distance**	200 mm
8	**X-ray field**	Round type: 53 mm
		Rectangular type: 30 x 40 mm
9	**Weight**	2.0 kg
10	**Dimension**	168 (W) ×228 (D) ×118 (H) mm
11	**Voltage to Use**	
	Battery	DC 14.8 V
	Charger	Input: 100~240VAC, 50~60Hz, 0.5A
		Output: DC16.8V, 1.0A

5. Components of Product

DHX-70H Main body


Neck Strap	Battery Charger
	

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- In accordance with the EU Radiation Safety requirements, the device should be used (mandatory) with backscatter shield.
  Follow the user instruction for Radiation Safety and regulation appliance.
- Check the Health Ministry regulation of your country, and follow the requirements. Contact DIGIMED or the authorized distributor for more information.

6. Description of Device

6.1. Name of Each Part

Front View

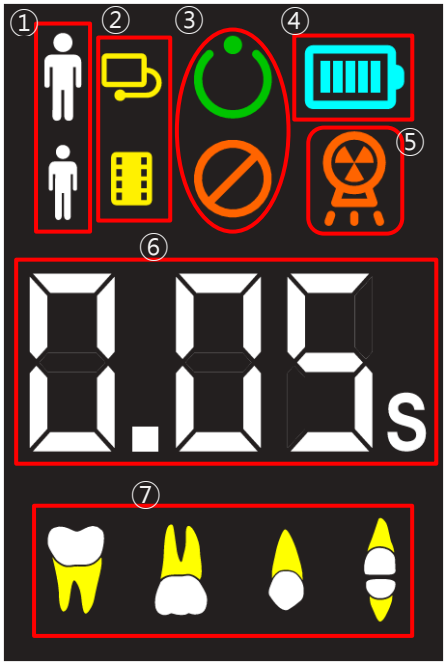
① X-ray emission area
② Backscatter Shield (Permanently attached)
③ X-ray exposure button

Top View

① Control rotary button
② Power button / Mode selecting button
③ X-ray exposure button

Charger Connection Port

6.2. Description of the User Interface



No.	Function	ICON			Description
1	Exposure subject icon	Large	Small		Display of Large or Small Exposure time is changed by the patient type.
2	Mode condition icon	IO Sensor	IO Film		Display of Analog film or Digital sensor Exposure time is changed by the detector type.
3	Operating condition display icon	READY	STOP		Once the device is ready to expose X-ray, LCD shows green icon. And, after X-ray exposure, it shows red stop icon during the duty cycle.
4	Battery power indicator	Fully charged	Low power		Remaining battery power information
5	X-ray exposure display icon				The icon appears while the X-ray exposure.
6	X-ray exposure time	0.05s			Display of X-ray exposure time
7	Anatomical tooth icon	Molar	Canine	Incisor	Display of incisor, canine, and molar of the upper and lower jaw (Maxilla and Mandible)

7. Operation

7.1. Starting and Ending the System

Power ON/OFF	Press the power button for 1 second and wait for the LCD to turn on. To turn off the power, press the power button for 3 seconds. Then, the system turns off the LCD screen and the device power.	
Input Password	As the device is turned on, turn the rotary switch and enter 2-digit password. If the input password is not correct, STOP icon is displayed. (Long beeping sound once)	
READY	LCD shows READY icon when the unit has no error and is ready to expose X-ray.	

7.2. Checking for Power

Press power on button and check the battery power indicator on the LCD control panel. If the indicator has five bars, the battery is fully charged. When the indicator shows just a 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 error code as **E-1**.

Fully charged	Low battery power	Low battery error



7.3. X-ray Exposure Mode Setting

1) Tooth Icon Setting

※While the device is turned on, the Power Button functions as a Mode selecting button.

(1) Press the power button shortly, and the READY icon turns off and the tooth icon blinks.

(2) Rotate the control rotary button to choose the tooth icon for X-ray exposure.
(3) Press the control rotary button to exit the setting mode.

2) Patient Type Setting (Large/Small)

(1) Press the power button shortly twice, and the READY icon turns off and the patient icon blinks.

(2) Rotate the control rotary button to choose the patient type for X-ray exposure.
(3) Press the control rotary button to exit the setting mode.

3) Detector Type Setting (Sensor/Film)

(1) Press the power button shortly three times, and the READY icon turns off and the detector icon blinks.

(2) Rotate the control rotary button to choose the detector type for X-ray exposure.
(3) Press the control rotary button to exit the setting mode.

4) Manual Time Setting

• Rotate the control rotary button and change the time setting.
  - **Left turn**: Decrease the time
  - **Right turn**: Increase the time

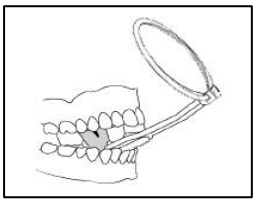
7.4. X-ray Exposure

1) Ready the Device

• Set x-ray exposure mode as necessary as explained in **Section 8.2.**

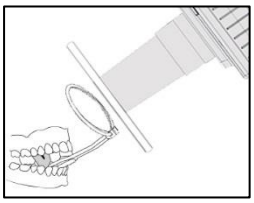
2) Detector Positioning

• Place “Intraoral dental film” or “Intraoral digital sensor” in patient’s mouth and fix it behind the tooth.



3) X-ray Device Positioning

• Place the edge of the x-ray emission cone at least 2 inch (5 cm) 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 patient’s skin)



4) Initiating an X-ray Exposure

• DOUBLE TAP the exposure button and HOLD until the beeping sound ends. READY icon disappears, and x-ray exposure icon is displayed while x-ray exposure.

* If the exposure button is tapped only once, x-ray is not generated.

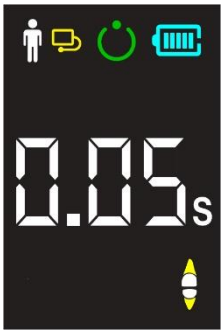
5) Completing X-ray Exposure

• The exposure button should be pressed and held until the beeping sound stops. If the x-ray exposure button is released too soon (during the x-ray exposure), the x-ray irradiation stops and the LCD shows an error code. (**E-5**: shot time error).

6) Auto-Recovery after duty cycle

• Duty cycle icon is displayed after completing the X-ray exposure.

• The LCD shows READY icon back when it is ready to make next x-ray exposure.



8. Recommended Exposure Time Setting

X-ray exposure time settings in below chart are intended as a reference only. Read all description at **Section 7.3. *X-ray Exposure*** and **7.4. *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 (70 kV, 2 mA Fixed)			 Incisor	 Canine	 Premolar, Molar
Digital Sensor 		Large	0.10	0.15	0.23
		Small	0.07	0.10	0.18
Dental Film 		Large	0.25	0.30	0.40
		Small	0.20	0.25	0.32
Phosphor Plate (Manual Setting)		Large	0.18	0.25	0.32
		Small	0.15	0.20	0.27

X-ray exposure time setting of each part (Incisor, Canine, and Molar) can be customized.
Follow the instruction below to change the setting.

1) As the device is turned on, press the **Power Button** lightly once. (The tooth icon starts to blink.)
2) Turn the Control rotary button and choose the icon for setting.
3) Press the **Power Button** lightly once. (The tooth icon stops to blink.)
4) Turn the Control rotary button and change the time as it should be customized.
5) Press the **Power Button** lightly once. (The time is set on the tooth icon.)

*The exposure time setting has four options as below.
(1) Large / Digital sensor mode
(2) Large / Dental Film mode
(3) Small / Digital sensor mode
(4) Small / Dental Film mode

Check the **Section 7.3. *X-ray Exposure Mode Setting*** for more information.

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

9. Battery Handling, Charging and Maintenance

- **DO NOT** apply any excessive physical force on the unit or the battery.
- **DO NOT** place the unit near the heat generating devices.
- **DO NOT** touch the outlet with wet hands or apply physical contact with the conducting part of the outlet.

1) If the unit or the battery is affected negatively by any physical force and modified from its original shape, the unit and the battery may not function normally.
2) The device is powered by a high efficiency lithium-ion polymer battery.
   And the full charged battery can generate more than 200 times of X-ray exposures.
3) If the battery power is too low, LCD shows the error code. (**Chapter 11. E1**)
   Recharge the battery as instructed below.
4) Full charge takes about 3 hours.
   Monitor the device and the charger while recharging, and disconnect the charger when the LED indicator turns to green from red.
5) Be careful not to overcharge the battery.
   Battery overcharge may shorten the battery life and cause malfunction.
6) While the battery is recharged, the battery indicator shows the recharging status on the LCD. (**Chapter 7.2**)
7) When the unit is stored for a long time, the battery should be recharged once every 3 months. (After fully charge, irradiate X-ray exposure once to keep the battery in best condition.)
8) Only use the authorized charger and battery which are provided from DIGIMED.
9) Battery is a consumable part and the battery use time will be shortened slowly. For best function and safety, battery pack should be replaced when its life is decreased noticeably at least 2 years later from the first use. Replace the battery if the use time decreases by half when compared new.
10) **DO NOT** place the unit near heat generating devices.
    The battery is vulnerable to heat. Place the unit where air circulation is good.
11) Temperature range for storage and recharging is between 10~25°C.
    Operation under cold temperature may cause fast discharge. And recharging may take longer. Battery level may be indicated lower than normal.
12) Be careful that device does not get wet..
    If any foreign substances and excessive moisture get 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 in and out from outlet. **DO NOT** touch the outlet with wet hands or apply physical contact with the conducting part of the outlet.

- For battery replacement, contact to **DIGIMED** or the authorized distributor.
- Risk of fire or explosion exists if the battery pack inside the device is replaced by unauthorized service personnel.
- **DO NOT** dispose of any parts of this product with industrial or domestic waste. Incorrect disposal of any of these materials may lead to serious environmental pollution.
  Please return the replaced device and the battery to DIGIMED or the authorized distributor for safe disposal and recycling. **DO NOT** place in municipal waste stream.

10. Battery Replacement

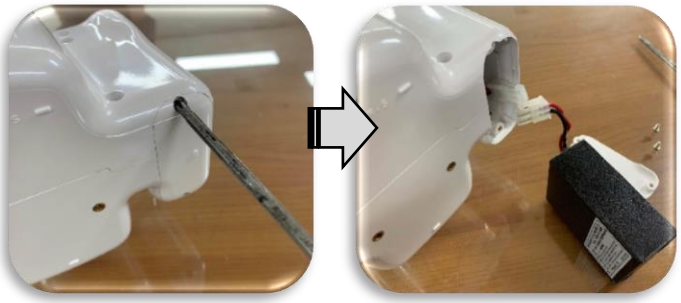
> ⚠
> • Only use **DIGIMED** manufactured battery. Otherwise, it may cause malfunction of the device or a serious harm to operator and patient.
> • **DO NOT** dispose the battery in municipal waste stream. If the battery reached the end of its service life, contact the authorized service center, authorized distributor, or **DIGIMED** for safe disposal.

1) **DHX-70H** battery may be replaced to a new one when;
- even after the battery is fully charged, the battery power indicator decreases fast.
- the LED indicator on battery charger is not turning to green after 3 hours charging or more.
- battery malfunction error is displayed continuously.
- battery is damaged physically and it is evident.
- battery is used more than 2 years.

2) Maintenance/calibration is necessary after every battery replacement.
Contact the authorized service center or **DIGIMED** for safe replacement and quality assurance.

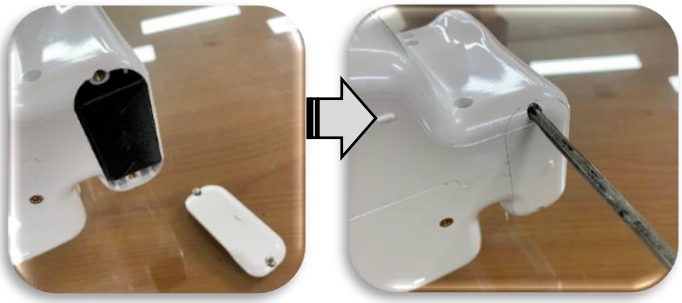
3) Battery can be replaced as instructed below.

① Loosen the screws with a screwdriver and open the battery cover.



② Take the battery pack out and disconnect the battery connector from the device.

③ Connect the new battery connector to the device and put the battery into the device. Close the battery cover and tighten the screws.



11. Error List

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

Error code	Image	Error type	Cause and Handling
E1		**Low Battery Power** error	This error code indicates the battery needs recharging. Please recharge the battery.
E2		**Battery malfunction error**	This error code indicates the battery is functioning abnormally or physically transformed inside the device. The battery needs to be replaced and calibrated from DIGIMED or the authorized service center.
E3		**mA** error	This error code indicates the mA value exceeded the tolerance range. The device needs to be repaired and calibrated from DIGIMED or the authorized service center.
E4		**kV** error	This error code indicates the kV value has exceeded the tolerance range. The device needs to be repaired and calibrated from DIGIMED or the authorized service center.
E5		**Shot time** error	This error code indicates the X-ray irradiation time exceeds the tolerance limit. Please reboot the system.
E6		**X-ray tube** error	This error code indicates the filament is broken due to the X-ray tube being old. The device needs to be repaired and calibrated from DIGIMED or the authorized service center.
E7		**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.

Contact the manufacturer or an authorized distributor immediately especially with kV, mA, X-ray tube or battery malfunction error.

Disassembling or transforming the device without permission will **VOID** the **WARRANTY**. Only personnel who have completed technical training at an authorized distributor from DIGIMED is permitted to carry out repairs.

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 14.8 V**
- Maximum battery charge: DC 16.8 V
- Battery current at 2 mA, 6 kV output: 14 A
- Battery charger:
  - Input: AC100-240 V, 50-60 HZ 0.5 A
  - Output: DC 16.8 V, 1.0 A
  - Cable length of DC output: 1000 mm
  - Cable length of AC input: 1700 mm

4) X-ray Control and Generator

- Exposure time range: **0.05 ~ 1.0 sec.**
- Maximum duty cycle: **1 : 60**
- Maximum inherent filtration: **2.6mm Al**
- Maximum output power: 12 W nominal at 70 kV, 2 mA
- Generator rating: 2 mA at 70kV ±7%
- Leakage technique factors: 60kV, 2 mA, 1.0 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 Cobia DENTAL X-ray meter from RTI Group.
- **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; It 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 Cobia DENTAL X-ray meter from RTI Group.

6) Collimator Cone

- Minimum source to skin distance: 200 mm
- X-ray field size and configuration: **53** mm diameter circle
- Radiation shielding: Barium sulfate and PP.

* 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 should be recognizable on the scale.

12.2. X-ray Tube Specifications and Characteristics

1) Stationary Anode X-ray Tube

- Model: **D-045**
- Specially designed for the **DHX-70H**
- Provided with an insulation cylinder
- 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

- ELECTRICAL

- Nominal X-ray Tube Voltage (IEC60613: 2010) ---------- 70 kV
- Nominal Focal Spot Value ---------- 0.4
- Nominal Anode Input Power (at 1.0s) ---------- 585 W
- Exposure Duty Cycle ---------- 1:60 or more (Exposure time **:** Interval time)

- MECHANICAL

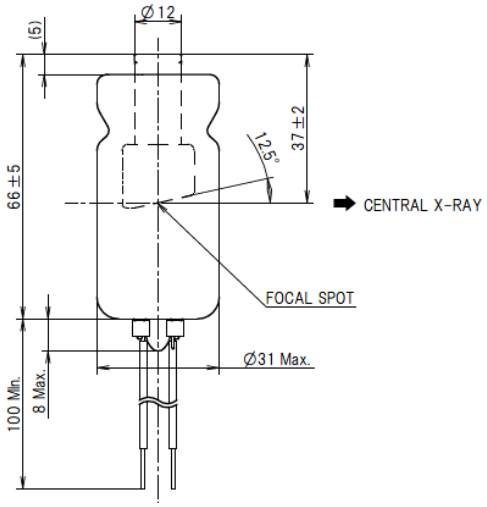
- Overall length ---------- 66±5 mm
- Max. Diameter ---------- 31 mm (Max.)
- Target angle ---------- 12.5˚
- Inherent filtration ---------- At least 1.0 mm Al
- X-ray coverage ---------- ø70 mm at SID 200 mm
- Weight ---------- Approx. 100 g
- Cooling method ---------- Oil immersed (60˚C Max.) and convection oil cooling
- Tube holding ---------- Holding the glass envelop of the anode end and cathode end, or the screw of the anode shank

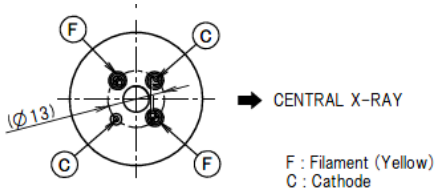
- MAXIMUM AND MINIMUM RATING

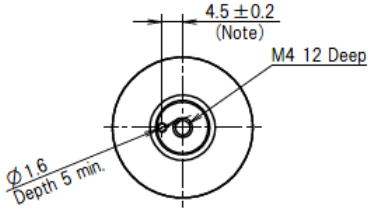
(At any time, these values must not be exceeded)

- Max. Tube voltage ---------- 70 kV
- Between Anode (or Cathode) and Ground ---------- 35 kV
- Min. Tube voltage ---------- 50 kV
- Max. Tube current ---------- 12 mA
- Max. Filament current ---------- 3.0 A
- Filament Frequency Limits ---------- DC or AC (Sine Wave) 0 ~ 20kHz
- Thermal characteristics:
  Anode Heat Content ---------- 4300J
  Max. Anode Heat Dissipation ---------- 100 W
- Max. Radiographic Exposure Time ---------- 3.2 s

3) Dimensional Outline of X-ray Tube





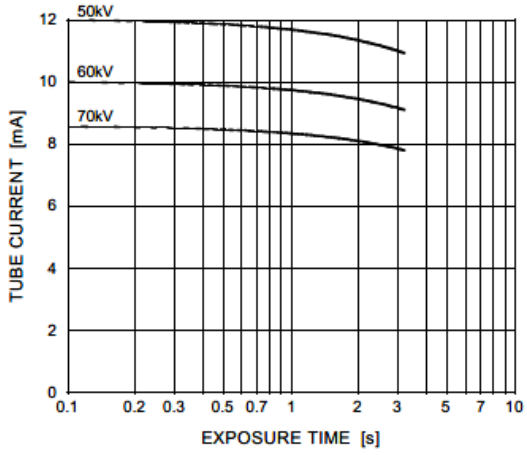


4) Tube Rating Chart

Maximum Rating Charts
(Absolute maximum rating charts)

Constant Potential High-voltage Generator

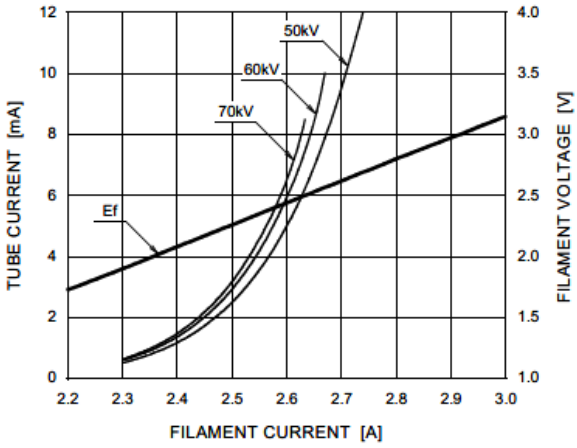
Nominal Focal Spot Value: 0.4



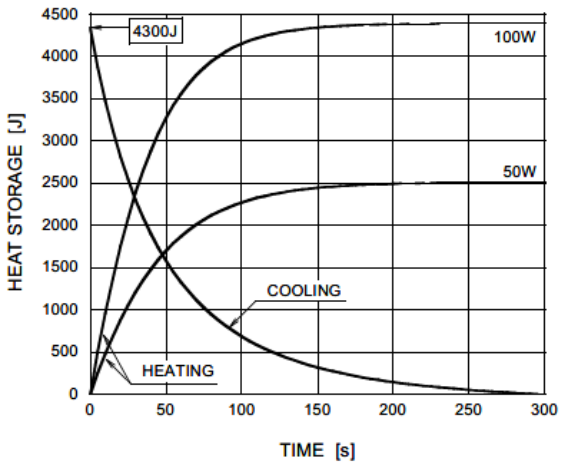
Emission & Filament Characteristics

Constant Potential High-voltage Generator

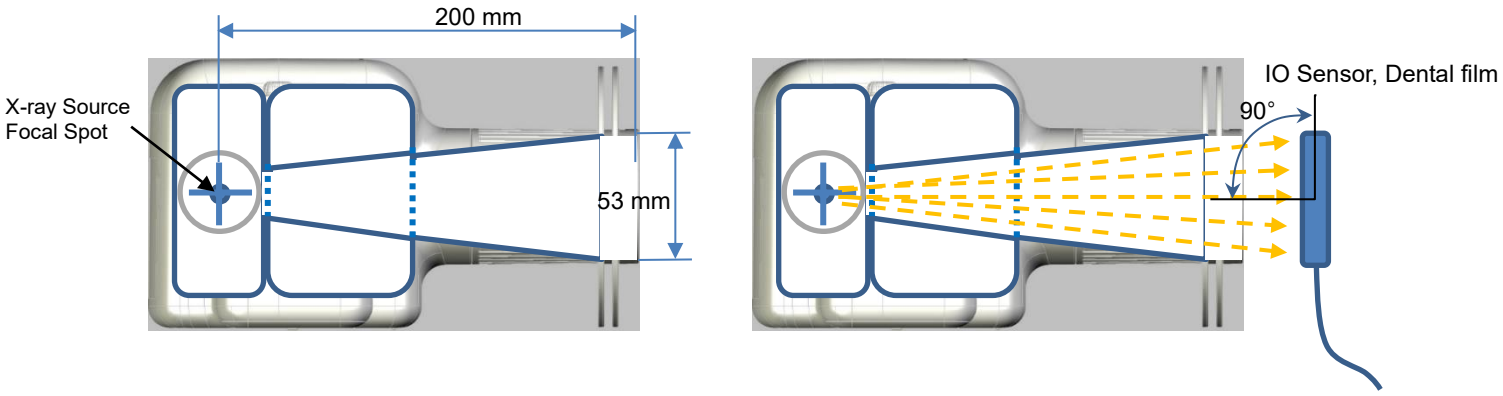
Nominal Focal Spot Value: 0.4



Anode Heating / Cooling Curve



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



12.4 Collimator Exit Field Size

Circular collimator cone

Exit field size of circular collimator cone is
$(5.3\ cm/2)^2 \times 3.14\ (\pi) = 22.05\ cm^2$

12.5. Optional Calibration Checks

Each unit from **DIGIMED** 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 Cobia DENTAL X-ray meter) 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 Cobia DENTAL X-ray meter from RTI Group. Tube current (mA) is sensed across a series connected resistor with an accuracy of ±1% and measured using a digital multimeter, prior to encapsulation; It 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 Cobia DENTAL 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 device 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 70 kV	63 ~ 77 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	0.95 ~ 1.05 sec (± 5%)

12.6. Repair

All parts of the device cannot be repaired by the user. If repairs are needed, contact DIGIMED or DIGIMED authorized service representative.

The following components are replaceable by user.

1) Battery Charger

Damaged or faulty parts of the device must be properly disposed of according to local requirements, or returned to an authorized distributor or **DIGIMED** office. Do not improperly dispose of any part of the device and accessories to protect the environment. When the device reached the end of life, return the items to **DIGIMED** for proper disposal or recycling.

If product return is required, contact **DIGIMED** for shipping instructions to return the product to DIGIMED office. You will be required to provide the serial number from the label affixed on the device.

Repair of the device shall be performed with only **DIGIMED** supplied parts. Using non-authorized parts may cause malfunction or failure of the device.

If you experience any unusual operation, non-recoverable faults, malfunction, or failures including the errors listed in the **Chapter 12**, contact DIGIMED or the authorized service center to avoid any potential hazard or danger to Operators and Patients.

DO NOT operate the device with any covers open or removed. Operating the device with open or removed covers could expose mechanical operating systems that could cause serious or fatal personal injury to the operator or the patient. Only qualified and authorized service personnel should remove covers from the device.

DO NOT dispose of any parts of this product with industrial or domestic waste. Incorrect disposal of any of these materials may lead to serious environmental pollution.
Please return the device to **DIGIMED** or an authorized distributor for replacement and recycling. **DO NOT** place in municipal waste stream.

12.7. Dosimetric Control

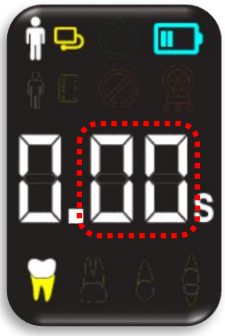
The device is factory tested with AIR KERMA for the selected LOADING FACTORS. As followed by the requirement of IEC EN, DAP Meter (Model: *KermaX Plus TinO IDP*) is used for the test. The overall deviation of the AIR KERMA from the estimated AIR KERMA does not exceed 50 %.

12.8. 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.)

<table>
<tr><th>No.</th><th>Test Item</th><th colspan="2">Annual Requirement</th></tr>
<tr><td rowspan="4">1</td><td rowspan="4">kV, mA, Time test</td><td colspan="2">1) kV: Not greater than ± 10% from 70 kV</td></tr>
<tr><td colspan="2">2) mA: Not greater than ± 20% from 2 mA</td></tr>
<tr><td rowspan="3">3) Exposure time:
Not greater than ± 5%
or ± 20 ms</td><td>0.2 sec (Standard use time)</td></tr>
<tr><td>0.7 sec (mA check time)</td></tr>
<tr><td>1.0 sec (Maximum load)</td></tr>
<tr><td>2</td><td>Reproducibility of the radiation output</td><td colspan="2">The coefficient variation of measured value of AIR KERMA is not greater than 0.05 for any combination of LOADING FACTORS.</td></tr>
<tr><td>3</td><td>X-ray load test</td><td colspan="2">When maximum rating is loaded on the generator, it should not have any errors.</td></tr>
<tr><td>4</td><td>X-ray beam limit test</td><td colspan="2">The field size diameter should be at maximum 60 mm at the outer end of the cone tip.</td></tr>
<tr><td>5</td><td>Total Filtration test for Half-Value Layer</td><td colspan="2">Quality Equivalent Filtration not less than 1.5 mm Al</td></tr>
</table>

12.9 Password Setting



Follow the process below to customize the password.

1) As the device is turned on, input default password.
2) When the READY icon shows on LCD,
   press rotary switch for 3 seconds.
3) All the icons on LCD blink.
4) Turn the rotary switch and set the 2-digit password.
5) Once the 2-digit password is set, press rotary switch once.
6) Short beeping sound is generated twice and the password setting is finished.

12.10 Password Reset

Follow the process below to reset the password.

1) As the device is turned off, press the exposure button and the power button at the same time for 3 seconds.
2) Short beeping sound is generated three times and the password is changed to the default digits.

*Please contact the local distributor or the manufacturer if the default password is lost.

*Default password is given only when the device serial number is correct.

13. Electromagnetic Compatibility

1) **Emissions Test**

The **DHX-70H** is intended for use in the electromagnetic environment specified below. The customer or the user of the **DHX-70H** should ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions (Conducted and Radiated) EN55011 CISPR 11	Group 1	The **DHX-70H** 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 (Conducted and Radiated) EN55011 CISPR 11	Class A	The **DHX-70H** is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, Provided the following warming is heeded: **WARNING**: The device is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the **DHX-70H** or shielding the location.
Harmonics current emissions IEC 61000-3-2	Compliance	
Voltage Fluctuations and Flicker emissions IEC 61000-3-3	Compliance	

2) **Immunity Test**

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 (kV) Air: ±2, ±4, ±8, ±15 (kV)	Contact: ±8 (kV) Air: ±15 (kV)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric Fast transients/ Burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 1 kV	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Main power quality should be that of a typical commercial or hospital environment. If the user of the **DHX-70H** requires continued operation during power mains interruptions, it is recommended that the **DHX-70H** be powered from an uninterruptible power supply or battery.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	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.			

The **DHX-70H** is intended for use in the electromagnetic environment specified below.
The customer or the user of the **DHX-70H** should assure that it is used in such an electromagnetic environment.

Test Method/Item	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Portable mobile RF communications equipment should be used no closer to any part of the **DHX-70H**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range. [b]Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **DHX-70H** is used exceeds the applicable RF compliance level above, the Model 005 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **DHX-70H**.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

3) **Recommended separation distances between portable and mobile RF communications equipment and the DHX-70H**

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **DHX-70H** can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **DHX-70H** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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.

LIMITED WARRANTY

DIGIMED Co., Ltd. (**DIGIMED** hereunder) warrants the Portable X-ray System to be free from any defects in material or workmanship for a period of one (1) year from the date of purchase. (Battery: 6 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.

DIGIMED Co., Ltd.

Wellness of Your Life!

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