cocoon

USER MANUAL

Model: DX-7020

Manual Version: 1820.8

DEXCOWIN®

More Safe
More Convenient
More Durable

Table of Contents

1 General Information

1.1 Notice

The **DX-7020** is a portable, handheld dental X-ray device.

This is a diagnostic device that can be used on pediatric and adult patients. It's designed for taking diagnostic intraoral dental X-rays using conventional film (F-speed or greater film), PSP (Phosphor plates), or digital sensors. This device is indicated for use by only trained and qualified dentists or dental technicians.

This manual contains instructions, procedures, technical drawings and descriptions for the DX-7020. Do not operate this device until you have read and reviewed this accompanying user manual completely.

DX-7020 complies with the MDD 93/42/EEC as amended by 2007/47/EC. Refer to the Certificate of Conformance accompanying your device for verification.

DX-7020 is a trademark registered by Dexcowin Co., Ltd in Korea and other countries.

For further information not covered in this manual and any incidents concerning the device, please report it to the manufacturer at:

DEXCOWIN CO., LTD.

Email: info@dexcowin.com

Phone: (+82) 2 2027 2880

Fax: (+82) 2 2027 2884

Version: 1820.8

Model: DX-7020

Country: EU (EN)

Initial Date: 03-10-2017

Rev. Date: 11-03-2022

1.2 Manufacturer & User Obligations

1.2.1 Manufacturer's Liability

The manufacturer of this device assumes responsibility for the safe and regular operation of this device when:

- Approved replacement parts are used.
- Maintenance and repairs are performed by an authorized distributor/ manufacturer.
- This equipment is used correctly according to the user manual.
- Equipment damage or malfunction is not the result of an error on the part of the user.

RADIATION HAZARD

This X-ray unit could be dangerous to patients and operators unless safe exposure factors, operating instructions, and maintenance schedules are observed

1.2.2 User Obligations

The user must perform periodic tests at regular intervals to ensure safety. These tests must be performed and follow country and local X-ray safety regulations.

The user must perform regular inspection and maintenance of the mechanical and electrical components of this equipment to ensure safe and consistent operation (IEC 60601-1).

The owner of this equipment must follow the safety precautions and troubleshooting outlined in this manual.

CAUTION

Please do not operate this device before reading the manual and its related materials.

1.3 Symbols

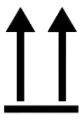
The following symbols are used throughout this manual. The symbols descriptions, as well as other necessary information, are listed below.

NOTE: Make sure to observe all safety and warning information based on their assigned symbols.

Symbols Used in this Manual

	**RADIATION HAZARD**	Indicates a possible danger to users due to exposure to radiation.
	**WARNING**	Indicates details of possible user damage or physical damage.
	**CAUTION**	Indicates that injury may occur if the product is used incorrectly.
	**CHECK**	Indicates the necessary items that users should follow during product installation, operation, and maintenance.

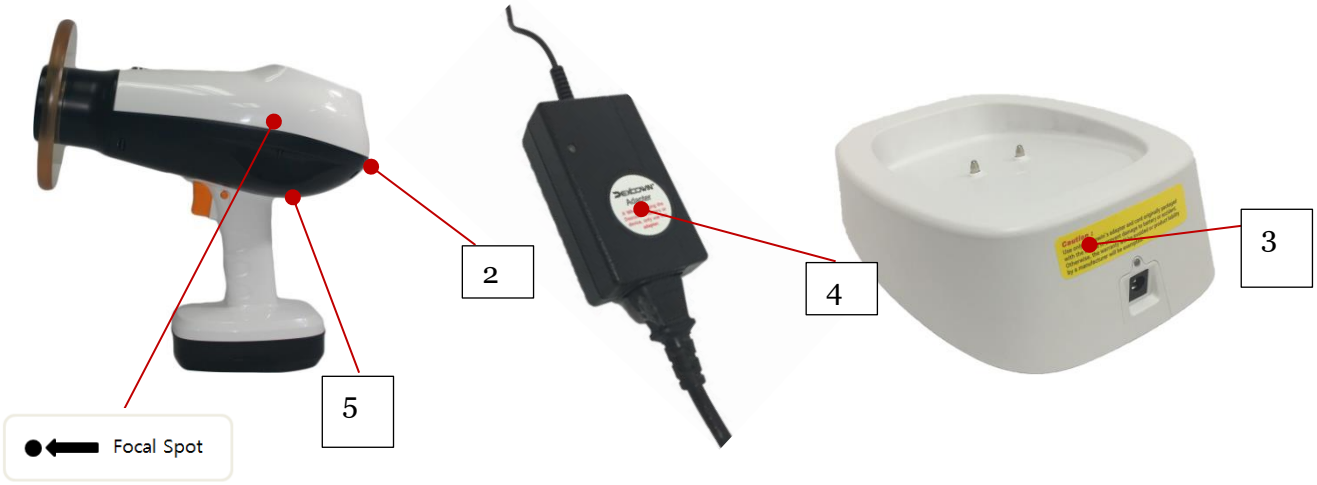
Symbols Used on DX-7020's Packaging

	**KEEP DRY**	Indicates that the transported package should be kept away from rain or damp areas.
	**FRAGILE**	Indicates that the contents of the transported package can be damaged and should be handled with care.
	**THIS SIDE UP**	Indicates which side of the transported package should face upward.

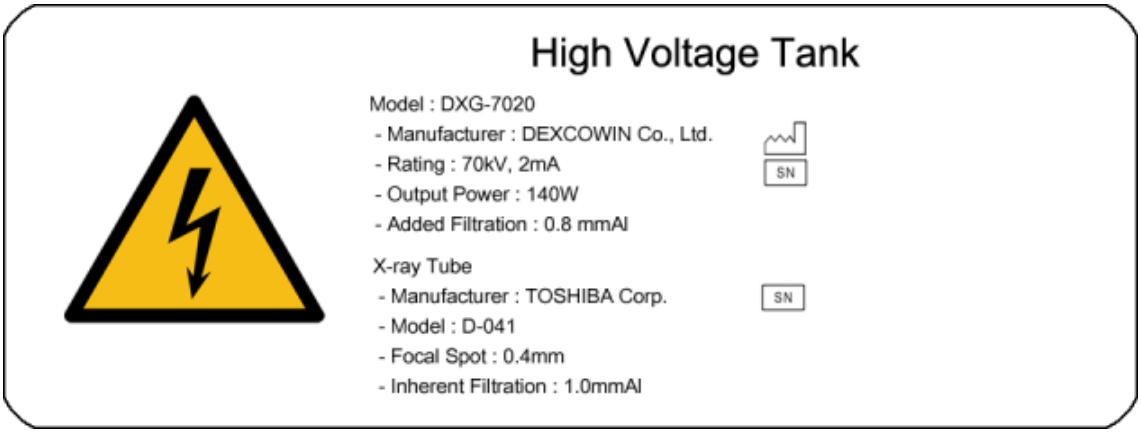
Symbols used on the device

	**ELECTRICAL PROTECTION**	Indicates Insulated patient application (Type B).
	**RADIATION HAZARD**	Indicates a radiation hazard.
	**CAUTION**	Indicates a hazard.
	**REFER TO DOCUMENTS**	Refer to the user manual and other accompanying documents.
	**MANUFACTURER'S INFORMATION**	Indicates the name and address of the manufacturer.
	**DATE OF MANUFACTURE**	Indicates the device's manufacture date in the form MM-YYYY.
	**SERIAL NUMBER**	This symbol houses the device's serial number.
	**REPRESENTATIVE ADDRESS**	This symbol represents the manufacturer's EU representative's information.
	**WASTE ELECTRICAL & ELECTRONIC EQUIPEMENT(WEEE)**	This symbol Indicates the need for a separate collection of electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. This symbol indicates that electrical and electronic equipment wastes must not be disposed as unsorted municipal waste and must be collected separately. Please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations
	**CE CERTIFICATION**	This symbol indicates the CE notified Body.

1.3.1 Label Locations



1. Generator Label (located inside)

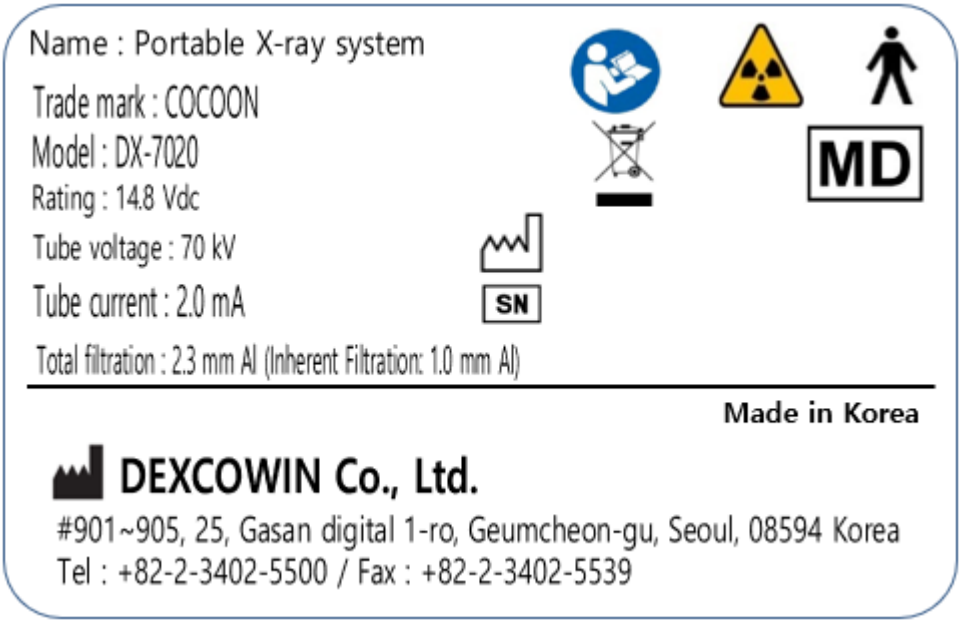


2. Charging Cradle Label

Caution :
Use only Dexcowin's adapter and cord originally packaged with the device to prevent damage to battery or accident. Otherwise, the warranty will be voided or product liability by the manufacturer will be exempted.

3. Adapter Label

4. Main Label



1.4 Standards & Classifications

DX-7020 is designed and manufactured to meet the following standards:

- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (EN ISO 13485:2016)
- ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- EN 60601-1:2006 Medical electrical equipment – General requirements for basic safety and essential performance (IEC 60601-1:2005/AMD1: 2012)
- IEC 60601-1:2012, Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests **[Rev1]**
- EN 60601-1-3:2008/A11:2016, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X- ray equipment
- IEC 60601-1-6:2010/AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 60601-2-28:2010
- IEC 60601-2-65:2012+AMD1:2017, Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.
- IEC 62366-1:2015 Medical devices-part1: Application of usability engineering to medical devices.
- IEC62304: 2015 Medical device software – software life cycle processes.
- ISO 14155-1:2010 Clinical investigation of medical devices for human subjects
- EN ISO 15223-1:2016, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN1041:2008 Information supplied by the manufacturer of medical devices
- ISO 10993-1:2009 Biological evaluation of medical devices- Part1 : Evaluation and within a risk management process
- ISO 17050-1:2010 Conformity assessment-supplier's declaration of conformity – part 1: General requirements.

Classifications

CE 1370

The CE symbol grants this equipment complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.

Protection against the ingress of water: Ordinary Equipment (IPX0)

Protection against electric shock: Class II equipment, Type B 

REFERENCES

Patent No.

Korea - 1023431200000, 1007993140000, 1009411250000, 1014040040000

United States of America – 11185300

2 Safety Precautions

2.1 Radiation Safety

 **RADIATION HAZARD**	➢ This X-ray unit could be dangerous to patients and operators unless safe exposure factors, operating instructions, and maintenance schedules are observed. ➢ A pregnant, or soon-to-be pregnant woman, and children must be advised before they are exposed to radiation. ➢ X-ray operators must pay attention to the status of patients in case of emergency. ➢ X-ray operators must stop operating the device if a problem is detected.

Diagnostic Reference Level

CHECK

Procedure	Approx. effective radiation dose	Comparable to natural background radiation for:	Additional lifetime risk of cancer from examination
DENTAL			
Dental X-ray	0.005mSv	1day	Negligible

Reference site
http://www.radiologyinfo.org/en/safety/index.cfm?pg=sfty_xray

➢ Diagnostic Reference Levels in Pediatrics, for standard five-year-old patients, expressed in entrance surface dose per image, for single views

Diagnostic Reference Level in Pediatrics

CHECK

Radiograph	Standard dose for each 5year old patient [Unit: mSv]
Dental: Orthopantomogram	0.014
Dental: Intraoral	0.008

Reference sites:
https://www.westmetrokidsdental.com/digital-dental-x-rays-and-your-child/
http://www.imagegently.org/Procedures/Digital-Radiography
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm

2.2 Cleaning Safety

 **CAUTION**	➢ Power off or remove the power supply from the base before cleaning. ➢ Do not clean the battery charger while it is plugged into an outlet. ➢ This device is not waterproof (IPX0). ➢ Do not use any liquid, wet cloth, or spray to clean this device. ➢ The warranty will be void, and Dexcowin will be exempt from any product liability in the case the device is exposed to any liquids.
 **WARNING**	This device is not a waterproof device (IPXO). Do not use any liquid-based products to clean this device. The warranty will be void and Dexcowin will be exempt from any liability in the case a liquid-based product is used to clean this device. 

2.3 Storage & Transportation

 **WARNING**	➢ To prevent unauthorized use, DX-7020 must be stored securely when not in use.
 **CAUTION**	➢ The device must be stored in a safe place with access by qualified persons only. ➢ The X-ray section that is in direct contact with the patient should be cleaned with surface disinfectant frequently. ➢ Do not use the device close to heaters and heating devices. ➢ Do not disassemble. If the seal attached to the product is damaged or removed, repair services may not be covered under warranty. ➢ Regular testing and repairs should be performed by designated repair service centers only. ➢ Avoid the following conditions when storing and using the device. - Locations with lots of moisture - Locations with direct sunlight - Locations with lots of dust - Locations with high humidity - Locations with no ventilation - Locations with excessive salt - Locations with explosive chemical substances or gases
 **CHECK**	➢ Avoid locations with high humidity or direct sunlight when storing the device. ➢ Avoid locations with lots of dust, slope, and dirt when storing the device. ➢ Transportation and storage conditions: -Transportation and storage temperature: -25 ~ 40 ℃ (-13 ~ 104°F) -Transportation and storage humidity: 10 ~ 95 % -Transportation and storage atmosphere pressure: 500 ~ 1060hPa

2.4 General Warnings/Checks/Cautions

WARNING

- Do not modify the device without authorization from the manufacturer.
- When using the device, if radiation exposure safety regulations and operation-related guidelines are not followed, both patients and operators can be at risk.
- Only an authorized skilled technician or person can operate this device.
- Please use this device only for its designated purposes.
- When using this device, if any problems are detected, please stop using the device to ensure the safety of the patient.
- Please do not modify or alter the device during operation.
- Make sure a fire extinguisher is on-site in case a fire-related emergency occurs.
- Patients with pacemakers may have their pacemakers malfunction when being exposed to radiation.
- To avoid electrical shock, do not let liquids near the device, power supply, or plug.
- If any serious accident occurs while operating the device, please contact the manufacturer (Dexcowin CO., LTD) by fax, e-mail, or contact the local authorities.

CAUTION

- The device must be stored in a protective case. Critical damage to the device may occur if placed in an unsafe area.
- Do not place the device on a high shelf or any narrow, unsafe place. If the device falls, it may harm the user or damage the device.
- Do not store the device in a vehicle or any place where it could be easily stolen or improperly used. If the device must be stored in those locations, take precautions to ensure it is stored safely.
- Please be sure not to exceed the required exposure time for image diagnosis.
- Handle the device with care; do not use sharp objects or severely damage the device. Follow the instructions carefully and use the device for recommended applications only.
- Use the device only in the environments recommended, which take into account temperature, humidity, and pressure.

- Do not let the device get wet or be exposed to liquids.
- Do not store the product in places with frequent temperature changes or direct sunlight for extended periods. In extreme temperatures, the high voltage generator's cooling and insulating oil can shrink, swell, freeze, or overheat, causing critical damage to the device and its ability to function.
- If the device fails to operate properly, label each part properly and inform the designated personnel at the repair service center of the issue(s) at hand.
- Patients should not touch the device. If they do so, it will be at their own risk.
- After the device has been dropped, do not attempt to turn it on. Detach the power supply and inform the service center.
- When discarding the device, since the device is an electrical and electronic product, it must be collected separately and be discarded in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. This symbol indicates that electrical and electronic equipment wastes must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations.

CHECK

- Read the user manual before operating the device for proper usage.
- Double-check parts of the device that comes in direct contact with patients.
- Use the device with a designated sequence with minimum exposure to get quality diagnostic images.
- Use the device at a clean location with good ventilation.
- Clean the device with a dry cloth. Do not expose the device to any liquids.
- Regularly inspect the device to see if it is operating properly.

3 Getting Started

3.1 Intended Use/ Prohibited Use

DX-7020 is intended for use only by trained or qualified dentists and dental technicians for adult and pediatric patients. The device is designed for taking diagnostic intraoral dental X-rays using conventional film or digital sensors. It's intended for use in a hospital/ clinical environment.

Prospective User Requirements

Education: A licensed dentist or dental assistant, radiologist, and graduates with a relevant bachelor's degree (national qualifications)

Knowledge: The operator must understand:

- ✧ How to treat and diagnose dental diseases
- ✧ How the device functions
- ✧ How to connect, install, and operate the device

Language: The operator must understand:

- ✧ The English manual

Experience: The operator must understand:

- ✧ How diagnostic medical radiation devices affect treatment and diagnosis of dental diseases
- ✧ How radiation emitting diagnostic devices operate
- ✧ The contents of the user manual.

3.2 Product Composition

Preliminary Checks

 **CHECK**	➢ Make sure that the serial number on the warranty matches the device and carrying case's serial number. ➢ Inspect for damage; the lead lining must cover the entire interior surface. ➢ The trigger button should freely move in when pushed and out when released. ➢ The device should be smooth and free of scratches, damages, or nicks.

3.3 Features & Specifications

The DX-7020 is a portable X-ray device to treat and diagnose dental diseases that is durable, safe, and convenient to use.

Available features for users:

- ✧ Exposure time automatically sets itself depending on the patient and tooth type
- ✧ Intuitive Graphic User Interface
- ✧ Ability to set the exposure time in intervals
- ✧ Trigger makes the DX-7020 convenient and easy to use
- ✧ Automatic power off feature
- ✧ Designed for user wrist protection

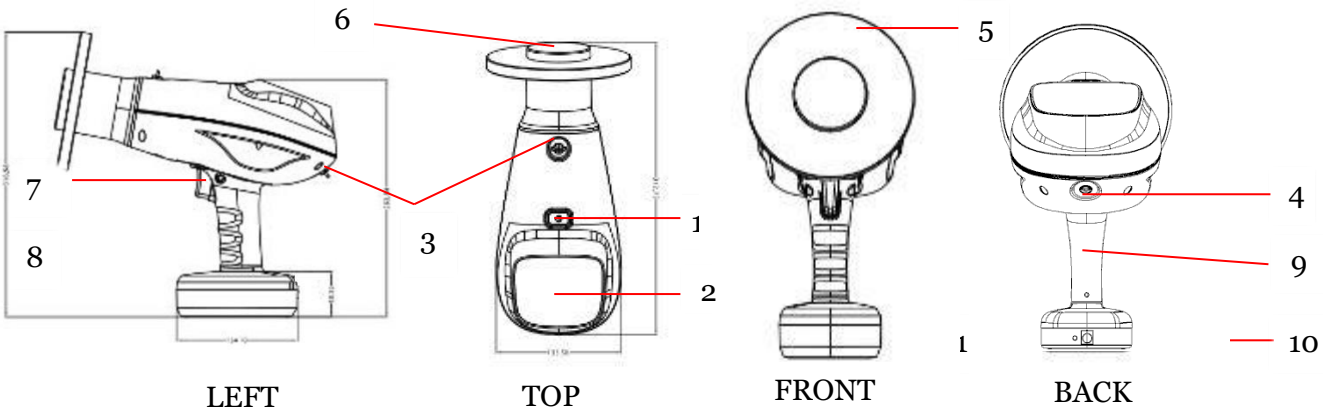
Specifications

CHARGER	Model name	BPL910S16F01
	Input	AC 100-240[V], 50/60 [Hz], 0.5 [A]
	Output voltage	DC 16.8V
	Output current	1.0A
BATTERY CHARGING CRADLE	Model name	Cradle
	Charging voltage	DC 16.8V
	Charging current	1.0A
	Discharge voltage (at the time of battery connection)	Varies depending on discharge condition
	Discharge current(at the time of battery connection)	Varies depending on discharge condition
	Size	270mm(L) x 132mm(W) x 195mm(H)

DX-7020 Main Body	Model Name	DX-7020
	X-RAY tube focal spot size	0.4 mm
	Protection type	B type
	Grade for electrical shock	
	Waterproof rating	IPX0
	Mode of operation	Discontinuous operation
	Cooling method	Oil cooling method
	Total filtration	More than 2.3mmAl (inherent filtration: 1.0 mmAl)
	Input power	DC 14.8 V
	Target angle	12.5°
	Distance to target	Distance between target and focal spot > 20 cm
	Main body weight	2.35 kg (including back scatter shield)
	Operating temperature	10 - 40℃(50 - 104℉)
	Operating humidity	30-75% RH, non-condensing
	Atmosphere pressure condition of use	700 ~ 1060 hPa
	Battery type	Embedded inside of the main body and not a removable battery type
	kV (fixed)	70kV
	mA (fixed)	2.0mA
	Power consumption	140 W
	Exposure time	0.05~1.0sec
	Exposure time setting interval	0.01 sec

3.4 Equipment Parts

Main Body

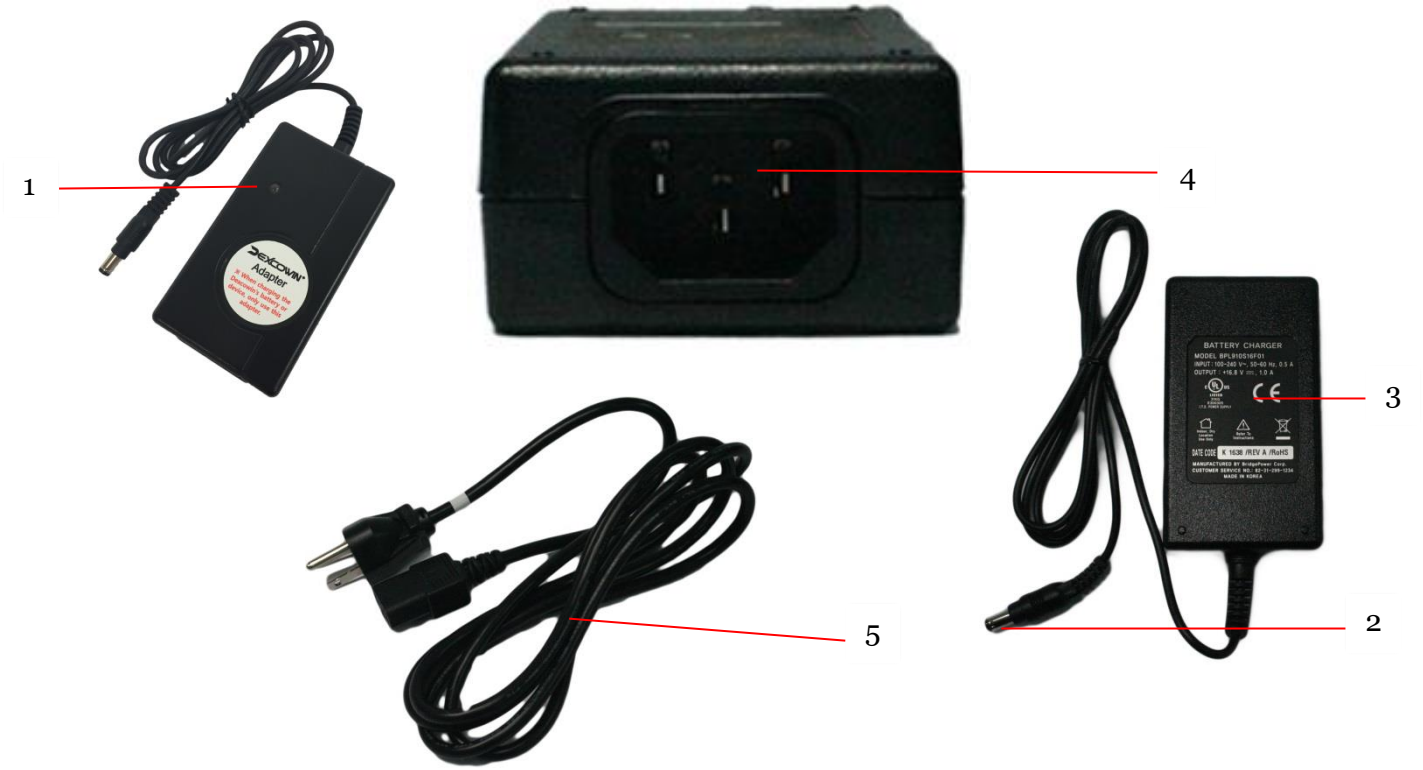


NO	Item	Description
1	Power Button	Power on/off button
2	OLED Screen	Display screen
3	Neck Strap Ring	Ring used to connect the neck strap to the device
4	External Battery Terminal Connector	Where the external battery is connected
5	Back Scatter Shield	A shield that blocks off back scattered radiation
6	Exposure Field	Limits the X-ray exposure field
7	Trigger	Button used to emit radiation
8	Safety Lock	Locks the trigger when the device is not in use
9	Handle	Helps to hold the device firmly when using the device
10	DC Input Connector	Receives power from the charging adapter
11	Input Indicator Lamp	Displays the charging status of the device

OLED Main Menu Display Screen

NO.	Item	Description
1	Sensor Type	Can select the sensor type
2	Patient Type	Can select the type of patient receiving diagnosis and treatment
3	Tooth Type	Can select the type of tooth being exposed to radiation
4	Control Panel	Selects parameters and changes its settings
5	Exposure Light	Indicates whether the X-ray is ready to emit radiation or not (Ready: Green/ Emitting Radiation: Yellow)
6	Battery Status	Indicates the current battery level
7	Safety Mode	Indicates whether safety mode is on or not
8	Exposure Status Indicator	Indicates whether the X-ray is ready to emit radiation
9	Selected Setting Indicator	Indicates which setting is being modified
10	Exposure Time	Shows the X-ray exposure time

Charger

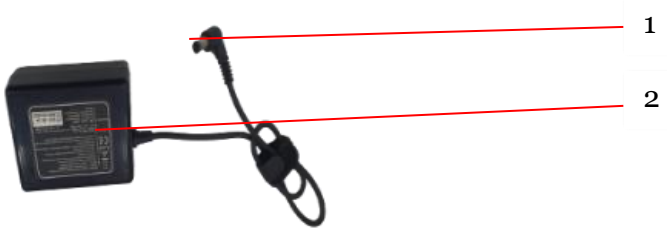


NO	Item	Description
1	Output Indicator Lamp	Displays whether the battery is fully charged or not
2	Power Charging Jack	Supplies DC output power from the adapter
3	Charger Adapter Label	Lists the model's name, input/output conditions, certification, serial number, etc.
4	AC Input Connector	Connects the AC input of the power cord
5	AC Power Cord	Connects external AC power

Battery Charging Cradle

NO	Item	Description
1	Charging Terminals	Connects the output terminal of the battery pack to the charging terminals of the charging cradle to charge the battery.
2	Charging Indicating Lamp	Status of whether COCOON is finished charging or not is indicated on the cradle using two different colors: red—charging, green—charging complete
3	DC Input Connector	Receives charging power from the charging adapter

External Battery



NO	Item	Description
1	Output Terminal Jack	Supplies DC output power from the external battery
2	Battery Label	Lists the model's name, input/output conditions, certification, serial number, etc.

4 Operation

4.1 Switching on the Device

① Turn on the device by following the steps below:

② After pressing the power button located at the top of the main body for one second, a green light should appear around the button. The device will then say, “power on.” The display screen will turn on and display the manufacturer’s logo.

③ When the logo disappears, the main (X-ray) menu screen will display:

- ✧ Sensor Type
- ✧ Patient Type
- ✧ Tooth Type
- ✧ Exposure Time Indicator
- ✧ Battery Status Indicator
- ✧ Safety Mode Indicator
- ✧ Selected Setting Indicator

CHECK

Fully charge the DX-7020 battery. Press the POWER button to check the button’s status.

4.2 Operating the Control Panel

In the main menu screen, the detector type, patient type, tooth type, and exposure time can be adjusted.

Each setting is adjustable by using the control panel.

A. To select either an adult or child patient, push the ◀ ▶ keys on the control panel to go to the setting and then the ▲ ▼ keys on the control panel to choose the type of patient.

Before selection

After selection

B. Touch the ◀ ▶ keys on the control panel to go to the 'Tooth Type' setting and touch the ▲ ▼ keys to change the type of tooth being exposed to radiation. Depending on the type of tooth selected, the exposure time will change accordingly.

C. Touch the ◀ ▶ keys to enter the exposure time setting and touch the ▲ ▼ keys to change the exposure time. When the exposure time is changed, the tooth type changes accordingly. When the device is powered off and then turned back on, the most recent settings that were set are displayed.

D. Press the ◀ ▶ keys simultaneously for three sec to activate/deactivate safety mode.

CAUTION

Radiation is emitted only when the trigger button is pressed. If the trigger button is released before the exposure buzzer sound ends, irradiation stops immediately.

CHECK

When the device is powered on, press the up and down arrow keys to check that the exposure time displayed on the OLED display changes accordingly.

4.3 Positioning

In-order to achieve a high-quality dental radiograph, follow the processes below:

Positioning the Patient

- Place the device parallel to the patient's mouth.
- Make sure the patient's head remains still.
- It is recommended to position the DX-7020 about 15~30 ° from the patient, but the degree and position can be adjusted according to the user's convenience. However, the patient should not move while being exposed to radiation.

Positioning the Intra-oral Sensor or Film

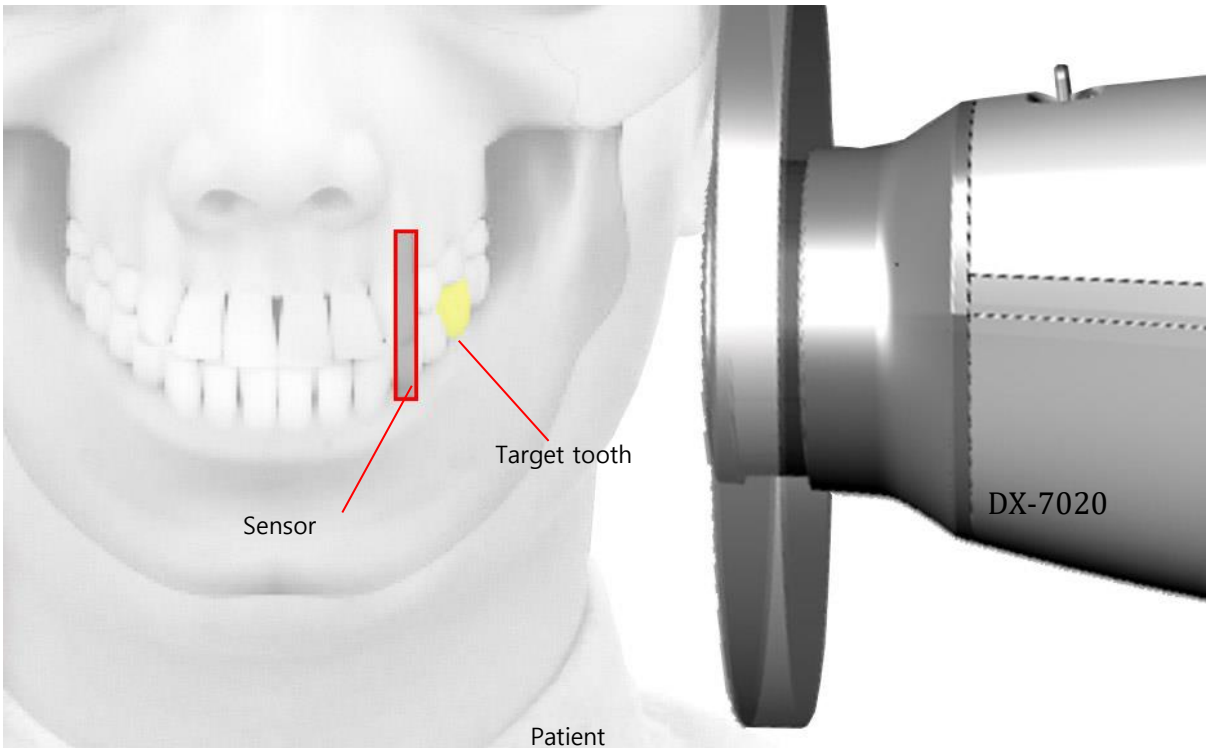
- X-rays generated by the DX-7020 can be detected by various sensors such as film, intraoral sensor (digital), and PSP (phosphor plates).
- Place film or a sensor behind the teeth and hold it with a finger or positioning device to keep the film or sensor from not moving.
- In the case of using film or PSP, make sure it's not bent or twisted to avoid distortion of the images.
- Sensors should be placed parallel to the center of the focal spot

CHECK

Before the user operates the device, the position of the film, intraoral sensor, or PSP and DX-7020 should be parallel to each other. If the position deviates, the image can come out distorted.

Positioning the DX-7020

- The distance between the end of the cone and the patient must be within at least 20cm (7 inches) from the focal spot (X-ray focus point).
- The tooth being exposed to radiation (target tooth) should be located at the center of the cone to obtain a full image of the tooth.
- Press the trigger button to emit radiation when the intraoral sensor and the center of the DX-7020's cone are placed parallel to the teeth.
- When holding the device, it is recommended to grip the handle with one hand and place the other hand on the underside of the trigger button and the cone.



4.4 Battery Usage

There are two types of batteries used for the DX-7020.

Internal Battery

This battery type is not detachable. It is embedded in the bottom part of the handle. Turn on the device to check if it is operating properly.

If any problem occurs during troubleshooting, see section 5.2

External Battery

This battery is an external back-up battery. It connects to the terminal on the main body at the rear of the machine just behind the main control panel.

Turn on the device to check if it is operating properly.

If any problem occurs during troubleshooting, see section 5.2

NOTE

- A low battery level will be indicated by a buzzer sound, a warning pop-up on the screen, change of color on the indication lamp, or a battery warning sound when the power is turned on.
- The battery level is displayed on the upper right side of the main menu screen. The figure below shows how the battery level is displayed. When the battery level is between 0 ~ 15%, please charge the battery.

- If the device is used without charging the battery, after the 'LOW' battery indicator is displayed, a warning message will pop-up on the screen for a few seconds, and the device will automatically power itself off.

Charging the Battery

NOTE

NOTE

The battery is tested and fully charged before it is shipped to the factory. However, the battery should be fully charged before initial use to prevent battery damage or being at a low level. The battery should be charged in cases when it's unused or in storage for long periods of time (e.g., three months).

Internal Battery

I. Connect the AC power cord to the charger.

II. Connect the power charging jack to the DC input connector on the cradle, and then insert the handle of the main body into the cradle.

NOTE

NOTE

Both the battery charging cradle and DC adapter's LED indicator turns red when the battery is charging. Make sure that the external back up battery is not attached when charging the internal battery.

III. When the battery is fully charged, the battery charging cradle light or the input indicator lamp and DC adapter's LED indicator will turn green.

External Battery

I. Connect the AC power cord to the DC adapter.

II. Connect the external battery to the connector gender and then to the DC output connector. When the power is connected, the DC adapter's LED indicator will turn red.

III. When the battery is fully charged, the DC adapter's LED indicator will turn green.

CAUTION
Use only Dexcowin's adapter and cord originally packaged with the device to prevent battery damage or failure.
Use of the incorrect battery adapter or power supply will void the warranty and the manufacturer will be exempt from any liability.

CHECK

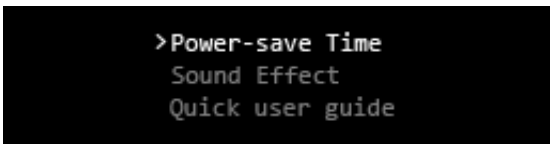
- After the battery is fully charged, press and release the power button. The OLED display should illuminate, accompanied by a single audible signal.
- Check the battery level on the upper right side of the main menu screen.
- When the battery level is low, a warning noise and a low battery indicator lamp on the OLED window will be displayed.
- If the battery level is low, it needs to be charged before use.

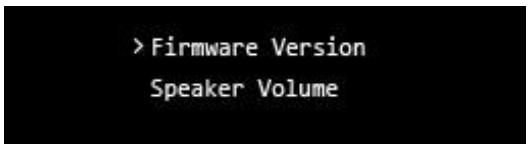
4.5 Settings Menu

Entering the Settings Menu

Press the ▲▼ keys simultaneously for three seconds to enter the settings menu.

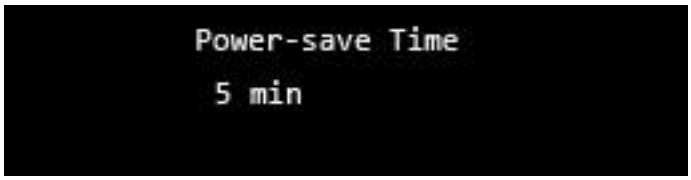
Move through the menu using the ▲ ▼ keys, and select an item by touching the ▶ key. To go back to the previous setting screen, press the ◀ key.





Power Save time

This indicates that the device turns off automatically if not used for the time set. The time can be adjusted by using the ▲ ▼ keys.

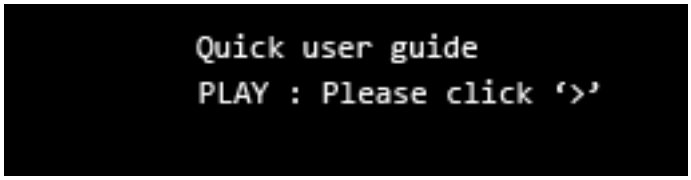


Sound Effect

This setting changes what sound the DX-7020 makes. You can choose between a buzzer or speaker sound by touching the ▲ ▼ keys and select the desired option by touching the ▶ key. [*]Sign indicates which option is selected.

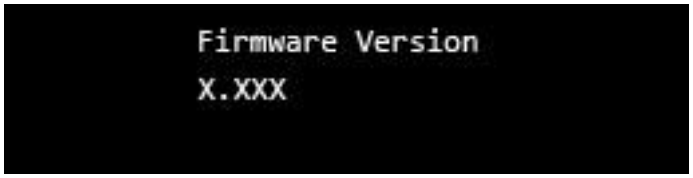
Quick User Guide

A brief description of the product is played for about three minutes after touching the ▶ key.



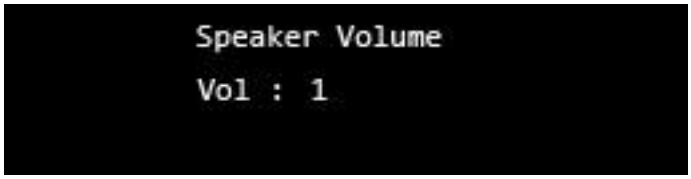
Firmware Version

This shows the current firmware version that is being used.



Speaker Volume

Adjust the speaker volume by touching the ▲▼ keys.



Powering the Device Off

To turn off DX-7020, press the POWER button for one second. (DX-7020 will turn off automatically if not used for about 5 minutes.)

4.6 Exposure

CAUTION

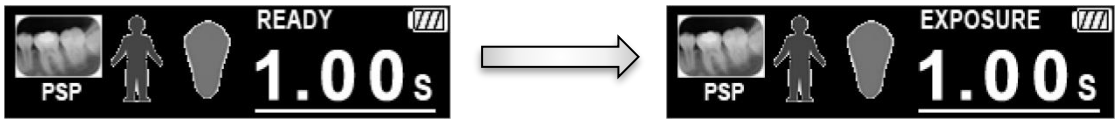
The operator must tell the patient not to move when the device is in use.

The DX-7020's radiation exposure procedure is described below. Please correctly set up the position of the user and patient before exposing the patient to radiation.

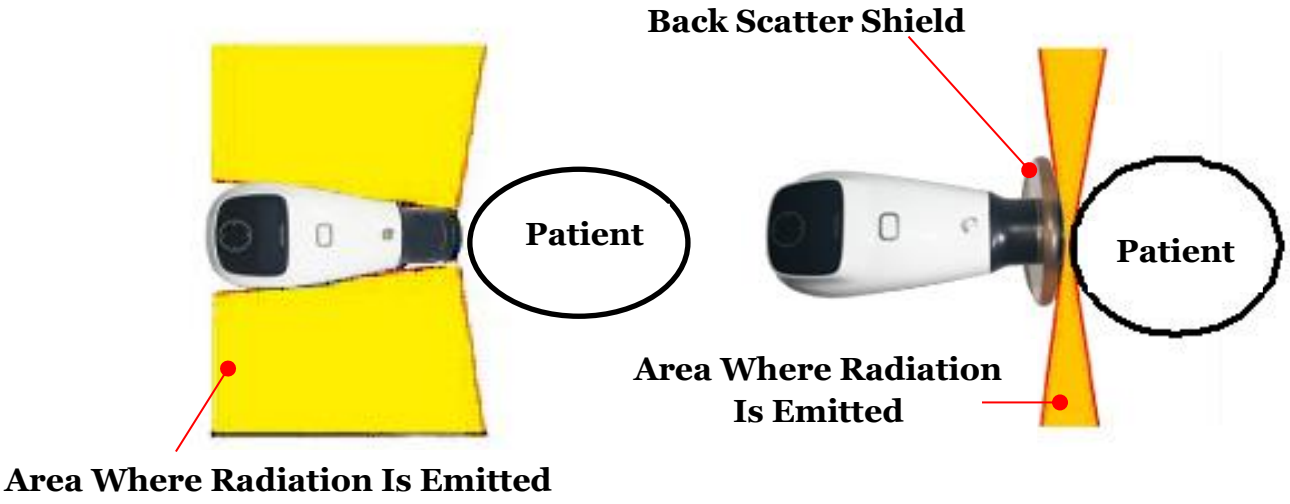
1. Set up the exposure time depending on user experience or recommended time for the tooth being exposed to radiation.
2. Place the film, digital intraoral sensor, or PSP tightly inside the target tooth.
3. Point the main body of the device toward the target tooth and make sure the main body is parallel to the film, intraoral sensor, or PSP. Then press the trigger button.

4. When pressing the trigger:
   - An audible sound is produced and is followed by a buzzer sound. Radiation is only emitted when the buzzer sound emits.
   - After radiation is emitted, the “READY” sign on the main menu screen will change to 'EXPOSURE.' The X-ray indicating light on the device will change from green to yellow.

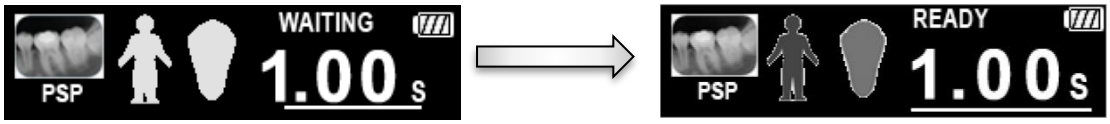
Before Exposure **During Exposure**



- During radiation exposure, the back scatter shield limits radiation exposed to the patient.



- After the X-ray emits radiation, the "EXPOSURE" sign disappears from the main menu screen, the "WAITING" sign is displayed, and the LED turns off. When the "READY" text returns, the lamp will turn green.



CAUTION

Radiation is emitted only when the buzzer sound goes off while the trigger is being pressed but will stop when the trigger is released. (DMS method - Dead Man Switch)

CAUTION

Emergency shut off - Press and hold the power button until the unit shuts off during emergencies.

CAUTION

WATCHDOG - DX-7020 is equipped with a safety device that automatically shuts down the product when a dose exceeding the maximum irradiation time of the product is detected to avoid unwanted or accidental radiation exposure to users and patients.

X-ray Exposure Time Parameter

The DX-7020's X-ray exposure strength is 70 [kV], 2.0[mA], 0.05-1.0 [s]. Its exposure time ranges anywhere from 0.05–1.0 [s].

Please refer to the table below to adjust the exposure time for each tooth type.

Classification		Tooth Types and Exposure Time				
Teeth						
Distance between cone and skin 20cm (7.87 in)	**SENSOR**	Adult	0.10 ~ 0.20	0.20 ~ 0.30	0.30 ~ 0.40	0.40 ~
		Child	0.05 ~ 0.15	0.15 ~ 0.25	0.25 ~ 0.35	0.35 ~
	PSP	Adult	0.20 ~ 0.30	0.30 ~ 0.40	0.40 ~ 0.50	0.50 ~
		Child	0.15 ~ 0.25	0.25 ~ 0.35	0.35 ~ 0.45	0.45 ~
	FILM (F-speed or greater)	Adult	0.30 ~ 0.40	0.40 ~ 0.50	0.50 ~ 0.60	0.60 ~
		Child	0.25 ~ 0.35	0.35 ~ 0.45	0.45 ~ 0.55	0.55 ~

CAUTION

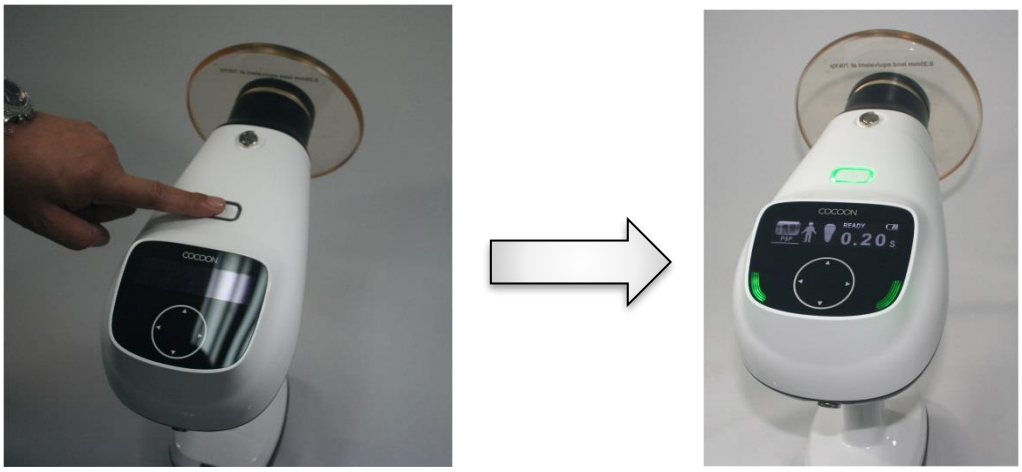
Exposure time set depending on tooth type can vary by sensor type, whether film is being used, distance to patient, and image preference. The chart is only for recommendation purposes.

CHECK

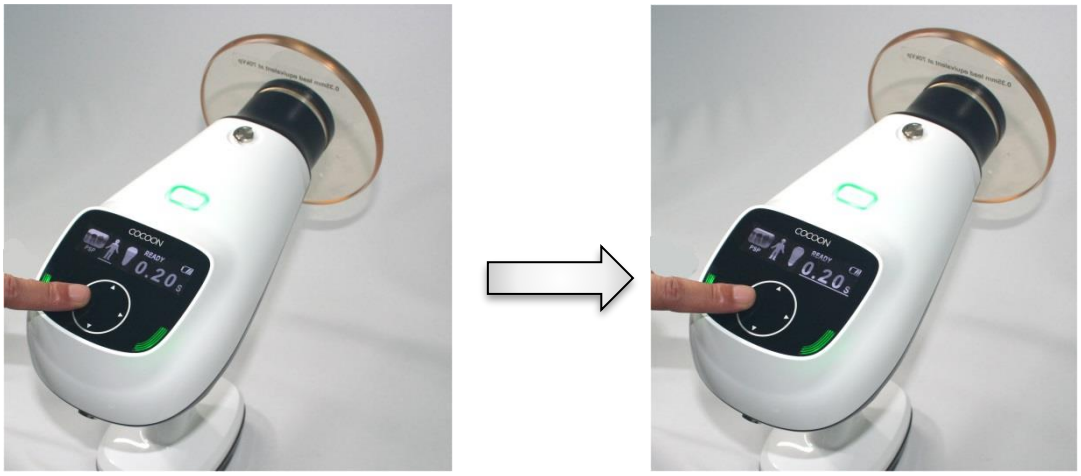
The settings that were last set will remain until new settings are implemented.

4.7 User Guide

1. Press the power button for three seconds. The OLED display should illuminate, accompanied by a “power on” sound.



2. On the main menu screen, the user can select a setting using the ◀/▶ keys on the control panel.



3. The user can change each setting’s values by using the ▲/▼ keys.

4. Check the safety lock position before operating the X-ray. Then press the trigger button.

5. Press the ◀ ▶ keys simultaneously for three seconds to activate/deactivate safety mode.

6. The position of the film, intraoral sensor, or PSP and DX-7020's cone should be parallel (as shown in section 4.3). The tooth being exposed to radiation should be located at the center of the cone. This is to get a whole image of the tooth.
7. Check the X-ray image. If the image is distorted, try operating the device again by following the guidelines above. If there are no issues with the device, press the power button for one second to turn off the device.
8. After using DX-7020, please store it in a safe place.

4.8 Handle Replacement

How to Replace the Handle of the Product

① Prepare the DX-7020
*** The product must be turned off.**

② Slide the switch to the left to remove the handle

③ Disassemble by sliding the handle upwards
*** Do not push too hard or the connector may break**

④ Separate both parts of the product

⑤ Prepare the handle for replacement

⑥ Insert the handle into the main body

⑦ Insert the handle by following the guide

⑧ Pull down the handle to finish connecting the handle to the body

⑨ Slide the lock button to the right to secure the handle.

⑩ Check if the device is operating properly

What to Look Out for After Replacing the Handle

1. Check if the power turns on

2. Check if the device can emit radiation

3. Check if the battery charges

5 Troubleshooting

5.1 Inspection Checklist

If an abnormality is found in the device, confirm the following items before requesting to repair the device.

Steps to Take If the Device Malfunctions

Symptom		Steps to Take
Power defect	After powering on the device, the OLED screen does not display the main menu screen and a sound is not emitted	➢ Check that the battery is charged.
	The device turns off automatically while in use.	➢ Check that the battery is charged.
Exposure defect	There is no exposure sound when the X-ray emits radiation.	➢ Check the status of the OLED display. It should be on. Radiation is emitted when the "exposure" message is displayed on the main menu screen.
Others	DC adapter is not working.	➢ Check that the DC adapter is connected to the AC power cord. ➢ Check that the AC power cord is connected correctly to the AC power outlet. The Correct input voltage of this device is AC 100-240V, 50/60[Hz] ➢ When the DC adapter is connected correctly to the power outlet, the LED at the upper part of the device lights up green. ➢ If the device does not operate despite being connected successfully, disconnect it from the power outlet and contact an authorized service center.

5.2 Troubleshooting

Problem	Cause	Solution
Nothing lights up	The battery level is low	Connect the device to a charger.
No X-ray emission	The generator is preparing to emit radiation, so there is no display on the screen.	Wait about five seconds until the X-ray emits radiation
	Button or trigger defective.	Call a qualified service technician.
X-ray emission works, but the image is too bright or completely white	Receptor defective.	Call a qualified service technician.
	The patient is positioned incorrectly	Adjust the position of the patient according to the user manual.
	Exposure time is too short.	Increase the exposure time.
	Device defective.	Call a qualified service technician.
X-ray emission works, but the image is too dark	Receptor defective.	Change the receptor or compare it with another receptor.
	Exposure time is too long.	Decrease the exposure time.
	Device defective.	Call a qualified service technician.

5.3 Maintenance Schedule

- Periodically review Section 3.1 Intended use / Prohibition for Use and product labeling to verify instructions for DX-7020.
- Users should regularly familiarize themselves with Section 2.4 General Warnings/checks/Cautions in the instructions.
- When a malfunction occurs, please refer to section 5.1 to inspect the item. Please contact the manufacturer/distributor immediately if the product seems to have any abnormalities.

On-Going Check

- When turning on the product, confirm that the "power on" sound emits and the main menu screen is displayed.
- Exposure time settings are changed by using the control panel. Confirm if time is changed per standard.
- When radiation is emitted, confirm that a sound is emitted and that the exposure light turns yellow.
- After the device is powered on, check that the LED light is on and the device is operating properly.

Annual Check Up

Users should review the following materials yearly. Be sure to record the results in the Maintenance Log Sheets located at the bottom of this Section.

- Power button functionality verification- Press and hold the power button for one second. A "power on" sound will emit indicating that the device has powered on. While the device is on, press and hold the power button for one second to turn off the device. Please check that the device has indeed turned off.
- Confirm that the status on the main menu screen shows "Ready" and that it blinks when the control panel is tinkered with.
- Dead-man button verification: sets the exposure time to the maximum time it can be set to. Press the trigger button to start X-ray emission. Before the exposure time reaches the maximum time set, release the trigger. Check that X-ray exposure has stopped.
- Setting verification—In the settings menu, check that the appropriate settings have been saved.
- DC adapter verification-Connect the DC adapter to an AC source, and make sure that the LED light turns on.

Annual Calibration

- DX-7020 is factory calibrated and tested prior to release and there are no adjustment options. However, the optional checks listed below may be performed by a qualified technician as desired.

- Set up a calibrated Performance Meter (such as the Piranha554) according to the manufacturer's specifications to detect and report the following: X-ray tube voltage, exposure time, and dosage.
- Measurement Method: Final performance measurements are made using Piranha554. The exposure time is measured from the moment radiation is detected until radiation is no longer detected. This means a 90% cross setting is selected with no timer delays. Linearity is calculated per IEC60601-2-7, 50.102.2a.
- Enable the DX-7020 and, with the collimator perpendicular to the test detector, check exposures using the test detector. Compare results with the factory parameters indicated in the chart below.
- For results outside these parameters, discontinue use and contact DEXCOWIN.
- This device should be calibrated once a year.

Acceptable ranges for the calibration

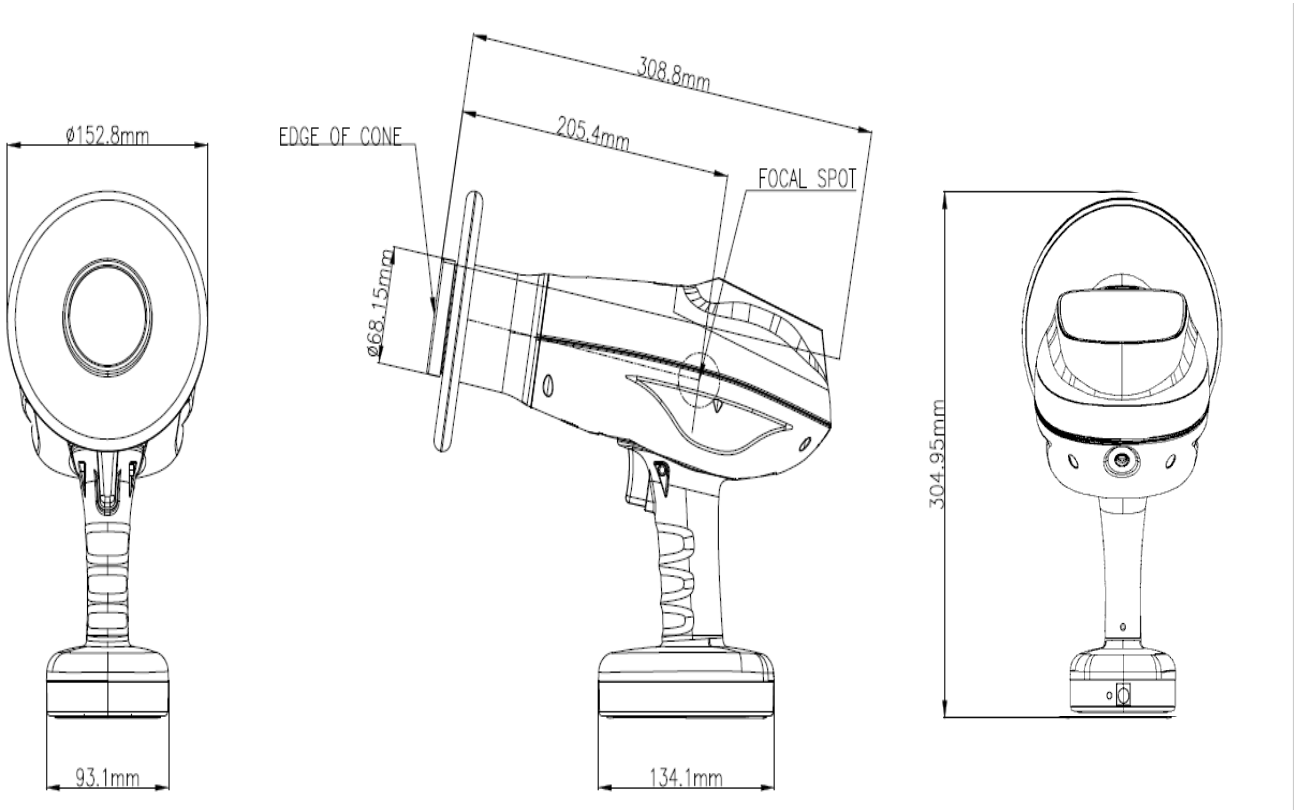
Test description	Acceptance limits	Exposure Time (ms)				
		50ms	100ms	300ms	500ms	1000ms
kVp Accuracy	70kV ±10%	64 ~ 77kV	64 ~ 77kV	64 ~ 77kV	64 ~ 77kV	64 ~ 77kV
Timer Accuracy	Set point ±10%	45 ~ 55ms	90~ 110ms	270~ 330ms	450 ~ 550ms	900 ~ 1100ms

Maintenance Log

Maintenance Test	Year 1 Date /Initial	Year 2 Date /Initial	Year 3 Date /Initial	Year 4 Date /Initial	Year 5 Date /Initial	Year 6 Date /Initial
1. Power button						
2. Exposure sequence						
3. Remote button						
4. Dead-man button						
5. Setting						
6. DC adapter						
7. Calibration						

6 Equipment Specifications

6.1 Technical Specifications



Item		Description
High Voltage Generator	Model name	DXG-7020
	Input voltage	DC 14.8V
	Max output power	140 W
	Rating	70kV, 2.0mA
X-ray Tube D-041	Focal spot	0.4 mm
	Target angle	12.5°
	Inherent filtration	At least 1.0mmAl
	Operating tube voltage	70kV

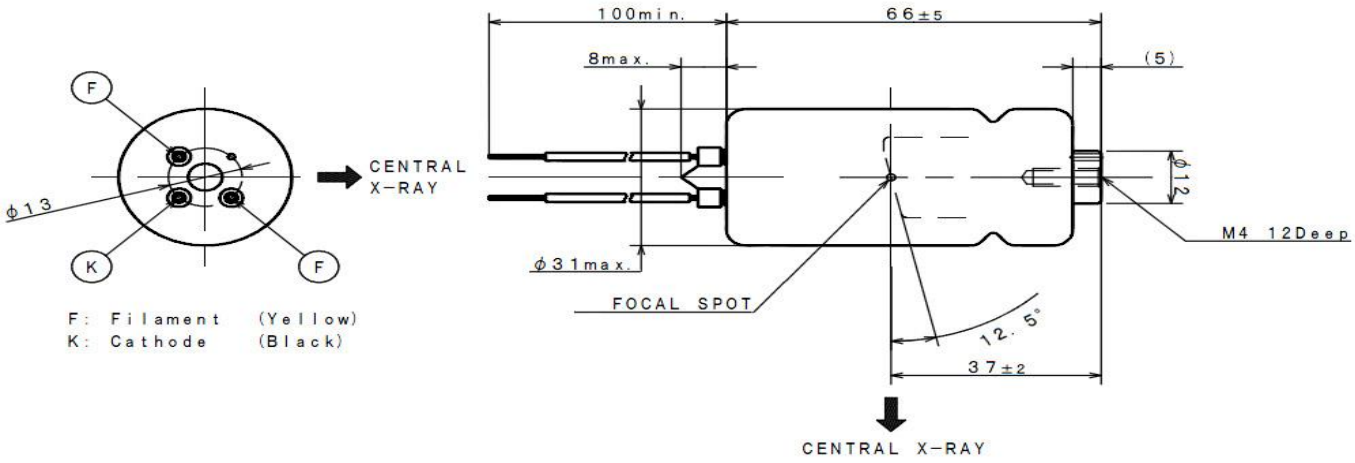
6.2 X-ray Tube Characteristics & Specifications

Specifications

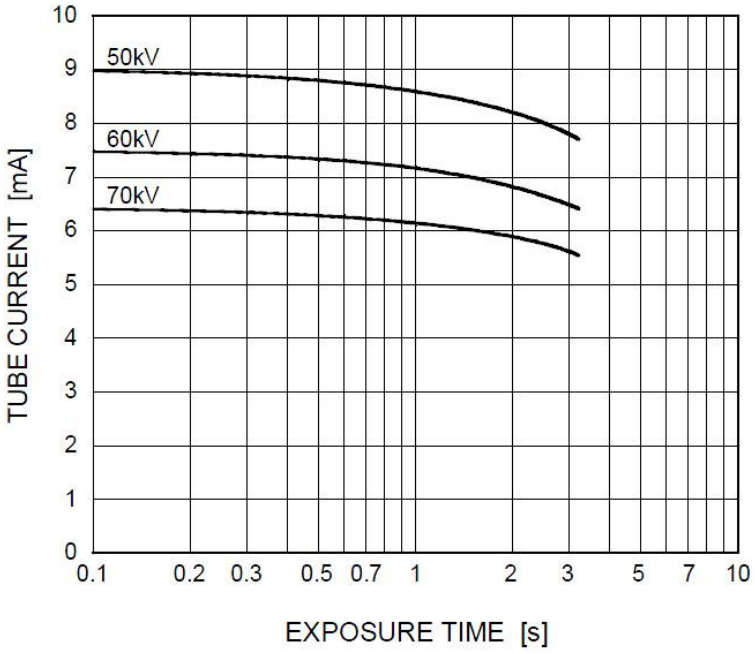
X-ray Tube model name	D-041
Manufacturer	TOSHIBA(JAPAN)
Operating Tube Voltage	70kV
X-ray Tube Focal Spot	0.4
Nominal Anode Input Power (at 1.0s)	See rating chart
Constant Potential High-Voltage Generator	430W
Anode Angle	12.5 degree
Material	Tungsten
Inherent Filtration	At least 1.0 mm AL
X-ray Coverage	φ70 mm at SSD 200 mm
Anode Heat Content	4300 J
Maximum Radiographic Exposure Time	1.2 s

Characteristics

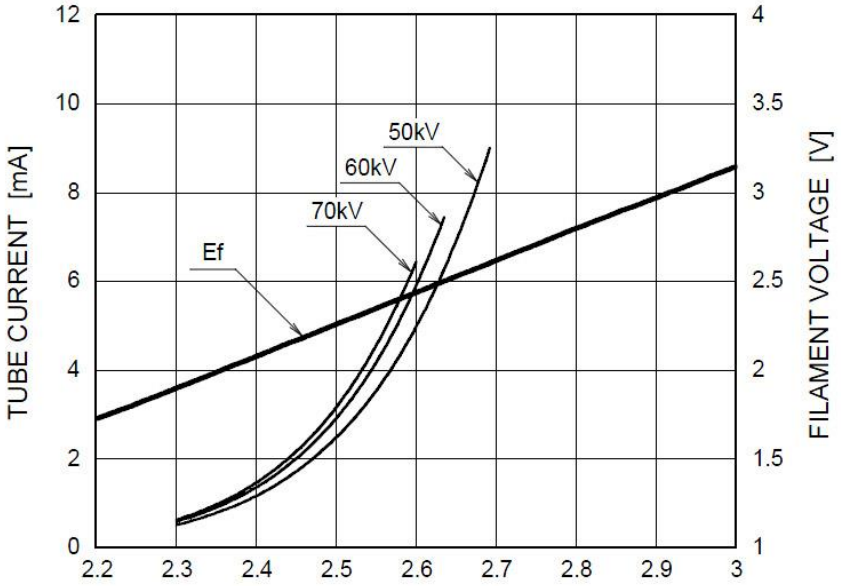
1. Tube characteristics



2. Maximum ratings chart



3. Emission & Filament characteristics



Note: This graph indicates typical characteristics.

6.3 EMC Data

WARNING

- Other cables and accessories may negatively affect EMC performance.
- Use of other accessories may result in non-compliance.
- The DX-7020 should not be used in conjunction with other devices. If it is necessary to use in conjunction with other devices, make sure it is operating properly.

- DX-7020 has been tested to comply with the limits of medical devices in IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interferences in a typical medical installation.
- Mobile RF communications equipment can affect medical devices.
- This device generates, uses, and can radiate radio frequency energy. If not installed and used by following the instructions listed in this manual, it may cause harm to other devices in its vicinity. However, there is no guarantee that interference will not occur during a particular installation. Whether this device causes harm to other devices in its vicinity is determined by powering the device on and off. The user is encouraged to try to correct the damage inflicted by following one or more of the following measures:
  - Reorient or relocate the receiving device
  - Increase the distance between the devices
  - Consult the manufacturer or a field service technician for help

Electromagnetic Emission

The DX-7020 is intended for use in the electromagnetic environment specified below. The customer or the user of the DX-7020 should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions – CISPR11	Group 1	DX-7020 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions- CISPR11	Class B	The DX-7020 is suitable for all establishments, including domestic establishments and establishments that are directly connected to the public low voltage power supply network that supplies buildings with power.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC6100-3-3	Complies	

Electromagnetic Interference

- Radiated emission (electric field): 30 ~ 1000[MHz].
- Min. limit margin: 4.9dB at 1000[MHz].

Radiated Emission Data

Test	Frequency [MHz]	Antenna pol. [h/v]	Reading level [dbuv]	Correction (af+cl) [db/m]	Emission level	Limit(10m) [dbuv/m]	Margin [dbu/v]
Value	1000	H/V-	<2.0	30.1	<32.1	37	>4.9

Electromagnetic Susceptibility

Field	Contents			
Radiation field	Frequency range	Field strength	Modulation	Frequency step
	80 ~ 2500 [MHz]	3 [V/m] 10 [V/m]	AM 80 [%] 1 [kHz] sine wave	1 [%] / 3 step
Magnetic field	Test frequency	Field level(EMF)	Duration	Axis of orientation
	50 [Hz]	3 [A/m]	60 seconds each axis	X. Y, Z axis

6.4 Product Warranty

Medical Device Name	Portable X-ray System	**Model Type**	DX-7020
Manufacturing Number		**Manufacture Date**	
Customer Name		**Contact Information**	
Customer Address			
Place of Purchase		**Warranty Period**	One year from the date of purchase
E-mail		**Purchase Date**	

- Dexcowin offers a manufacturer warranty to all products for one year from the date of purchase or installation date.
- This product is manufactured under strict quality assurance standards and inspection processes.
- If a malfunction occurs during the warranty period when operating the device normally, free repair services will be provided.
- If the device malfunctions due to incorrect usage or negligence, users will be charged for repair services even if the device malfunctions within the warranty period.
- The battery is excluded from this warranty or any extended warranty.
- We strongly recommend replacing the battery every year or at least every two years. Failure to do this will result in excessive heat or damage to the internal components of the DX-7020.
- Failure by the customer to replace the battery during the recommended time interval will exempt Dexcowin from any product liability for any accidents caused by battery failure.
- Failure to use the correct supplied battery adapter will immediately void all warranties and exempt Dexcowin from any and all liability.
- If you have other questions or product related inquiries, please contact Dexcowin's customer service center.

LOCATIONS

Korea HQ

#901~905, 25, Gasan digital 1-ro,

Geumcheon-gu, Seoul, 08594, South Korea

Tel: +82-2-3402-5500 / Fax: +82-2-3402-5539

cocoon

#901~905, 25, Gasan digital 1-ro,
Geumcheon-gu, Seoul, 08594,
Korea

Tel: +82 2 3402 5500
Fax: +82 2 3402 5539
Website: www.dexcowin.com
Email: info@dexcowin.com

DEXCOWIN