NANORAY

Portable Dental X-ray

USER MANUAL

Doc. UM-02F-01
(Rev.2, 2020.11.05)

CE
0068

Notice

The **NP-350E,** is a portable dental X-ray.

This manual contains descriptions, operational instructions, imaging procedures for the **NP-350E** dental X-ray. It is recommended that you thoroughly familiarize yourself with this manual in order to make the most effective use of this equipment.
Observe all cautions, safety messages and warnings that appear in this manual.

Keep this manual with the equipment at all times, and review the operation procedures and safety instructions if needed.

The illustrations/photos of the equipment in this manual are only for illustration purposes. Actual equipment may differ.

The safety and operating instructions should be retained for future reference.

All instructions should be followed.

This appliance should not be used near water

This appliance should be situated away from heat sources such as radiators, heat registers, stoves, or other appliances (including amplifiers) that produce heat.

This appliance should be connected to a power supply only of the type described in the operating instructions or as marked on the appliance. If you are not sure of the type of power supply to your home, consult your appliance dealer or local power company.

If the appliance is equipped with a polarized alternating-current line plug, this plug will fit into the power outlet only one way.

Due to continuous technological improvements, the manual may not contain the most updated information. For further information not covered in this manual, please contact us at:

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This document is originally written in English.
The NP-350E is referred to as Equipment in this manual.

Manual Name: The Ray (Model: NP-350E) User Manual Version: Rev.2
Publication Date: 2020-11-05

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

Table of Contents

1. General and Regulatory Information

1.1 Manufacturer's Liability

The manufacturers and/or retailers of this equipment assume responsibility for the safe and normal operation of this product only when:

- Genuine NANORAY approved equipment and components have been used at all times.
- All maintenance and repairs have been performed by NANORAY authorized agent.
- The equipment has been used normally in accordance with the user's manual.
- The equipment damage or malfunction is not the result of an error on the part of the owner or operator.

1.2 Owner and Operator's Obligations

- The owner of this equipment shall perform constancy tests at regular intervals in order to ensure patient and operator safety. These tests must be performed in accordance with local X-ray safety regulations.
- The owner of this equipment shall perform regular inspection and maintenance of the mechanical and electrical components in this equipment to ensure safe and consistent operation (IEC 60601-1).
- The owner of this equipment shall ensure inspection and cleaning work is performed in accordance with the maintenance schedule outlined in **Chapter**5 **Maintenance.**

1.3 Conventions Used in this Manual

The following symbols are used throughout this manual. Make sure that you fully understand each symbol and follow the instructions which accompany it.

To prevent personal injury and/or damage to the equipment, please observe all warnings and safety information included in this document.

	**WARNING**	Indicates that a specific hazard is known to exist which through inappropriate conditions or actions may cause: • Severe personal injury (to the operator and/or patient) • Substantial property damage.
	**CAUTION**	Indicates that a potential hazard may exist which through inappropriate conditions or actions will or can cause: • Minor injury • Property damage.
	**IMPORTANT**	Indicates that a potential problem may exist which through inappropriate conditions or actions can cause: • Property damage.
	**NOTE**	Indicates precautions or recommendations that should be used in the operation of the system, specifically: • Using this Manual • Notes to emphasize or clarify a point.

1.4 Marks and Symbols

1.4.1 The following table describes the purpose and location of safety symbols and other important information provided on the equipment.

1) Device symbol

Mark/Symbol	Description	Location
	Alternate current	Battery Charger Label
	ISO 15223 Manufacturer	Main Label
	ISO 15223 Date of manufacture	Main Label
	ISO 15223 Serial number	Main Label
	ISO 15223 Catalogue number	Main Label
	IEC60417-5031 Direct current	Main Label
	ISO 7000 Small focal spot	Main Label
	ISO15223 Temperature limit	Main Label
	ISO15223 Humidity limitation	Main Label
	ISO 7010 High voltage hazard	Main Label
	ISO 7010 Radiation hazard	Main Label Generator Label
 0068	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Main Label
	ISO15223 Caution	Main Label
	European Community Directive 2012/19/EU Waste Electrical and Electronic Equipment Directive.	Main Label

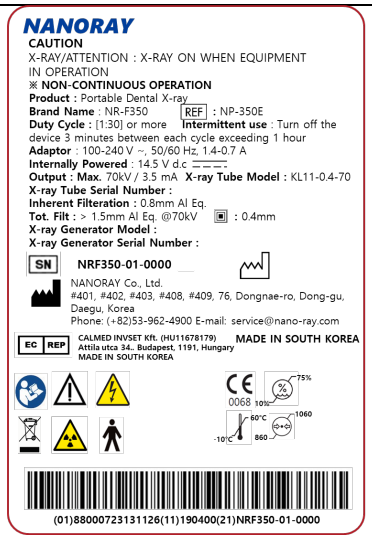
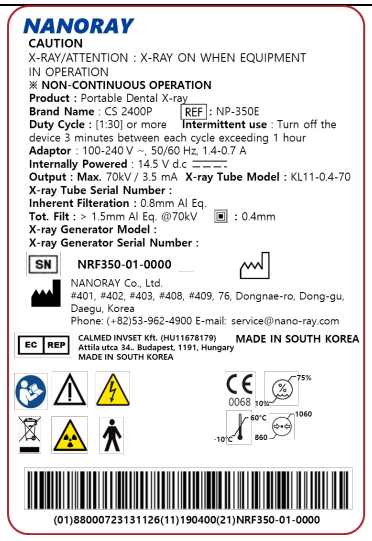
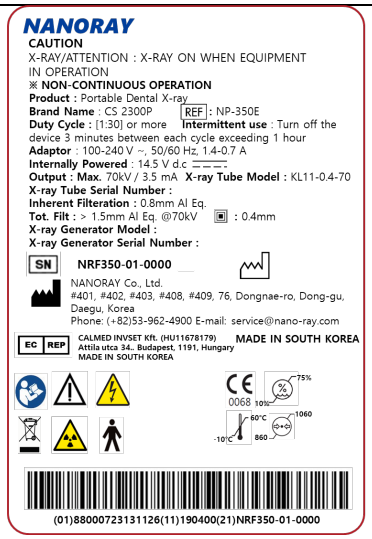
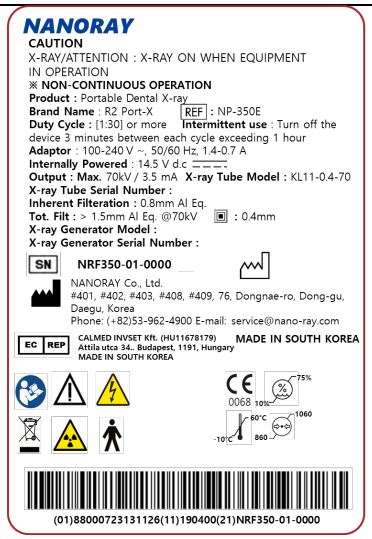
	IEC60601 Applied part : Type B	Main Label
	ISO 7010 Refer to instruction manual/booklet.	Main Label
	ISO15223 Authorized representative in the European Community	Main Label

2) Shipping Box symbol

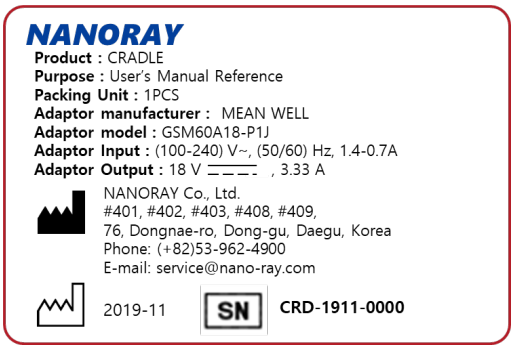
Mark/Symbol	Description	Location
	ISO15223 Keep dry	Box Label
	ISO7000 This side up	Box Label
	ISO7000 Do not use if package is damaged	Box Label
	ISO15223 Fragile, handle with care	Box Label
	ISO15223 Temperature limit	Box Label
	ISO15223 Humidity limitation	Box Label
	ISO15223 Atmospheric pressure limitation	Box Label
	ISO 780 Stacking limit by number	Box Label
	The CE symbol indicates that this product complies with the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.	Box Label

1.4.2 Label

1) Device Label (55 X 80mm)

<table>
<tr><th>NR-F350</th><th>CS 2400P</th></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><th>CS 2300P</th><th>R2 Port-X</th></tr>
<tr><td> 
</td><td> 
</td></tr>
</table>

2) Cradle Label (45 X 30mm)



3) External exposure switch Label (45 X 30mm)

4) Adaptor Label (38 X 90mm)

5) Warning Label (50 X 20mm)

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

ATTENTION : Cet appareil à rayons X peut être dangereux pour le patient et l'opérateur à moins que ne soient respectés les règles en vigueur, le mode d'emploi et les programmes de maintenance.

6) Caution Label (60 X 20mm)

CAUTION (PRUDENCE)

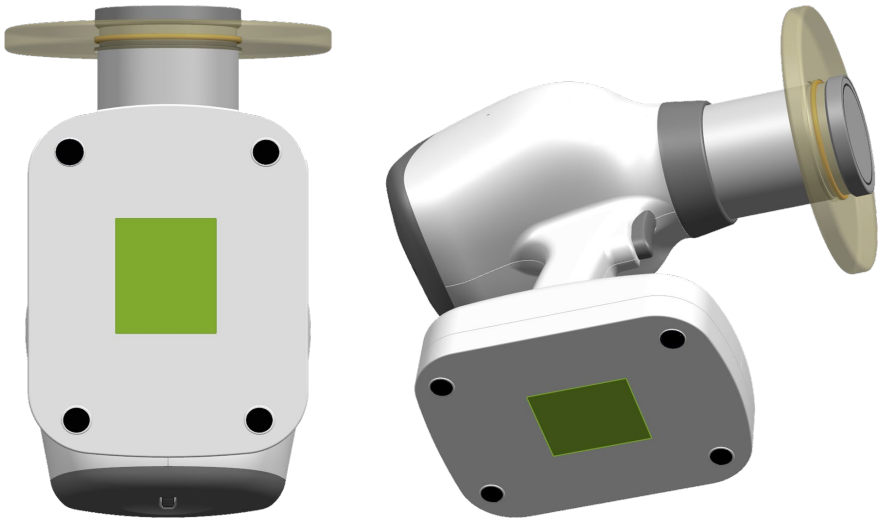
X-RAY / ATTENTION (X-RAY / ATTENUATION) :
X-RAY ON WHEN EQUIPMENT IN OPERATIOM
(X-RAY ON LORSQUE L'ÉQUIPEMENT DE FONCTIONNEMENT)

CAUTION

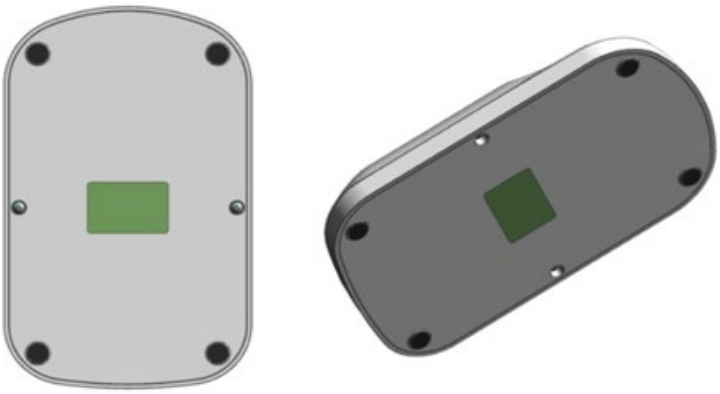
BEFORE SHOOTING X-RAY, PLEASE CEHCK WHETHER THE PATIENT IS A CHILD OR NOT.
Use special care when imaging patients outside the typical adult size range.

1.4.3 Positioning Label

1) Device Label



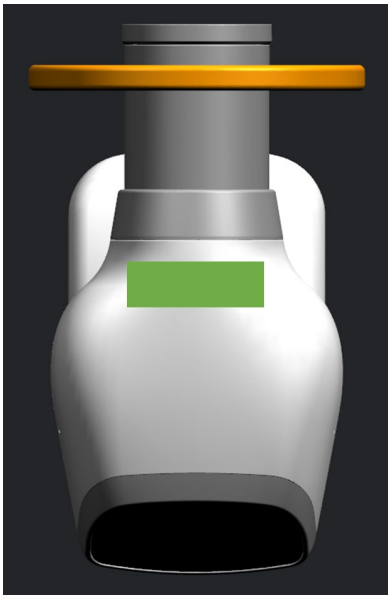
2) Cradle Label



3) External exposure Label

4) Warning Label

5) Caution Label



1.5 Standards and Regulations

Standards:

The NP-350E is designed and manufactured to meet the following standards:

- IEC/EN 60601-1, IEC/EN 60601-1-2, IEC/EN 60601-1-3, IEC/EN 60601-2-65
- IEC 60601-2-65:2012 Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
- ISO 13485

Classifications (IEC60601-1 6.1):

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

Protection against electric shock: Class I equipment, Type B Applied Parts: Cone head

1.6 Recommendation for an efficient operation

1) Please try to keep in 'Recharging' after using as the below table.

No	Exposing Value(Sec.)	Exposing Times
1	0.06	Max. 16 times
2	0.10	Max. 12 times
3	0.16	Max. 10 times
4	0.19	Max. 8 times
5	0.24	Max. 6 times
6	0.29	Max. 5 times
7	0.50	Max. 2 times
8	1.00	Max. 1 times

2. Safety Instructions

2.1 General Safety Guidelines

1) General Safety Guidelines

- This product requires a longer break time than the exposure time after an X-ray exposure. The minimum duty cycle rating (the relationship between duration and frequency of exposures) is 1:30.

Duration	0.06s	0.32s	0.56s	1s
Cycle	Every 1.8s	Every 9.6s	Every 16.8s	Every 30s

- This product is designed and manufactured in order to ensure the maximum safety. Operation and Maintenance must be in accordance with the instructions contained in this manual.
- This product must only be operated by legally qualified.(Dentist or Dental hygienist)
- Observe all the local fire regulations keep a fire extinguisher near the product at all times.
- Maintenance and services for the product should be taken by qualified service personnel according to procedures and preventive maintenance schedules.
- Always turn off the product before cleaning.
- The device uses beam limiting device(rectangular cover) for protection against stray radiation

2.2 Warnings and Safety Instructions

	This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. It is important to read this user manual carefully and strictly abide by all warnings and cautions stated within it.
	To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.
	Since rules and regulations concerning radiation safety differ between countries, it is the responsibility of the owner and/or operator of this equipment to comply with all applicable rules and regulations concerning radiation safety and protection in their area.
	Avoid touching the patient with equipment during X-ray exposure

- Exposing the product to water or moisture may cause an electrical shock or damage the product. Keep it away from water and moisture.
- Do not place any flammable materials near the product.
- Do not open or remove the cover of the product.
- For electronic medical devices, special attentions regarding electromagnetic waves are required.
- Modifying the product may damage it beyond repair and damage users and patients, thus modifying and remodeling the product (including cables) is prohibited.
- Patients should be provided lead aprons for radiation protection
- Patients (children and pregnant women particularly) must wear lead aprons during their X-ray imaging.
- Children and pregnant women must consult with their doctors before X-ray examinations.
- When users or responsible agencies take particular examinations or treatments, there might be serious hazard (e.g. noises) from the product itself.
- As the charger must be located and used at place, where users can easily connect and disconnect it to the power supply. Keep the charger in place to use at the easily accessible place.
- Users and patients are advised to use the hand-held x-ray equipment in accordance with the method of use guided by Ionizing Radiations Regulations 1999(IRR99). Especially for pregnant women, it is recommended to use personal dosimetry and a lead apron
- 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.
- The Backscatter Shield : In addition to the radiation shielded cone, the back scatter shield provides additional protection to the operator.
- DO NOT attempt to remove the backscatter shield. Attempting to do so will result in damage to your device.

- The equipment can be used at an altitude of less than 3,000 meters.

Radiation Safety

When using the equipment, it is recommended that all users comply with the following radiation safety guidance for the safety of the users and the patients.

- This equipment should be operated by a trained and qualified Dentist or a Dental hygienist in a controlled environment.
- All users and patients should wear protective equipment, such as a lead apron which is covered until collar.
- This equipment should be operated in the area that is more than 6 feet away from other personnel, such as assistants or other patients. If they should stay closer than 6 feet, it is recommended that they wear a lead apron, thyroid collar, or stay behind a lead shield.
- Pregnant women should not be exposed to X-rays unless it is strictly necessary.
- All users should comply with the Radiation Protection Policies established by the government.

2.3 Using Super Capacitor

- Make sure to charge the super capacitor in the external environment from the patient.
- Make sure to use the super capacitor only provided or approved by NANORAY. If non- standard or damaged super capacitors are used, there is risk of fire and explosion.
- Make sure to use the cradle only provided or approved by NANORAY. Using an unauthorized cradle may result in super capacitor damage.
- DO NOT expose super capacitor to heat or fire. Avoid storage in direct sunlight.
- DO NOT short-circuit, crush, puncture, mutilate, or disassemble the super capacitor.
- DO NOT store super capacitor haphazardly in a box or drawer where they may short- circuit each other or be short-circuited by other metal objects.
- DO NOT remove the super capacitor from its original packaging until required for use.
- DO NOT subject super capacitor to mechanical shock.
- DO NOT make the super capacitor wet or let it be in water. Keep super capacitor clean and dry.
- Keep the super capacitor away from children and pets.
- Seek medical advice immediately if the super capacitor has been swallowed.
- DO NOT dispose of super capacitor with ordinary trash. Turn in discharged super capacitor to local supply or discard or recycle super capacitor according to your local government regulations.
- The super capacitor cannot be replaced by users.
- When charging the super capacitor, the exposure function is locked.
- DO NOT leave a super capacitor on prolonged charge when not in use.
- If the equipment has not been used for long periods of time more than 2 hours, it is recommended to charge the super capacitor before use.
- Be sure to turn off the equipment when not in use. This helps to ensure the life of the super capacitor.
- If the equipment not in use has been turned on for long periods of time, the super capacitor may be fully discharged.

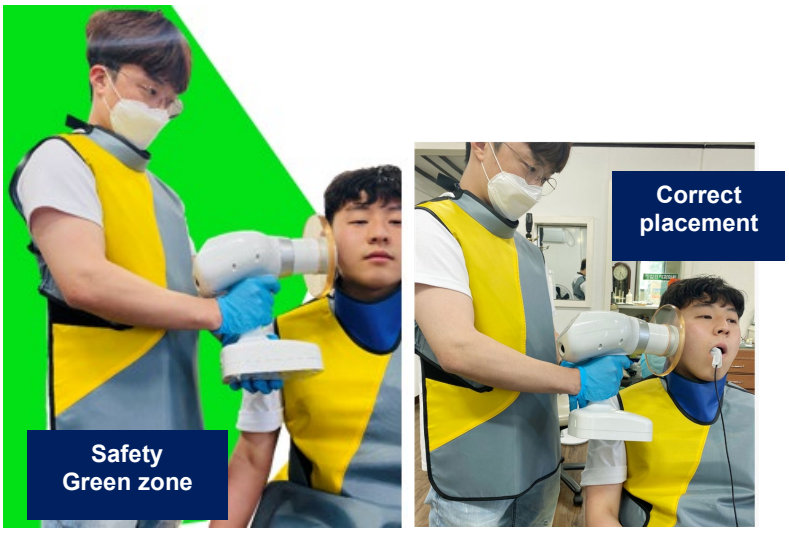
2.4 Contraindication

- patients (children and pregnant women particularly) must wear lead aprons during their X-ray imaging.

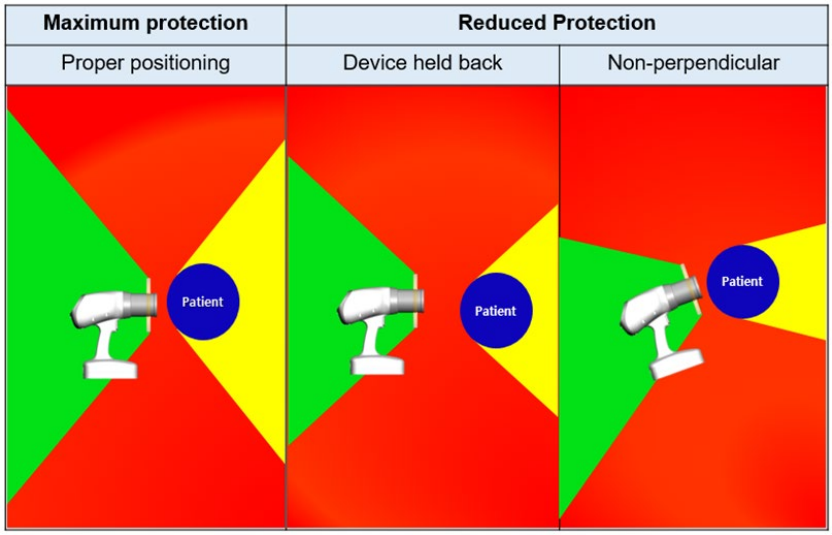
2.5 Radiation Safety

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

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



6) Do not enable The Portable Dental X-ray (Model: NP-350E) until patient and operator are positioned and ready for the exposure, reducing the likelihood of interruption and preventing inadvertent exposure of anyone to X-rays.
7) Do not attempt an exposure if anyone else is positioned immediately behind the patient (in line with the direction of X-ray emission). If others are assisting, then they should wear protective covering.
8) An exposure can be terminated for any reason by abruptly releasing the depressed trigger
9) As shown in the table below, maximum protection (green area) from backscatter radiation (red area) exists when The Portable Dental X-ray (Model: NP-350E) 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.



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

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

Occupational Dose limit[1]	50 mSv
Occupational Dose limit Required Dosimetry[1]	5 mSv
Average Natural Background Radiation[2]	2.4 mSv
Average Occupational Radiation Exposure for Flight Crews[3]	2.19 mSv
General Public Dose Limit[1]	1.00 mSv
Range of Exposure for Dental Personnel Using Conventional X-rays[2]	0.20~0.70 mSv
Average Exposure Using The Portable Dental X-ray (Model: NP-350E) with D-Speed Film[4]	0.03 mSv
Average Exposure Using The Portable Dental X-ray (Model: NP-350E) with F-Speed Film or Digital Sensor[4]	0.05 mSv

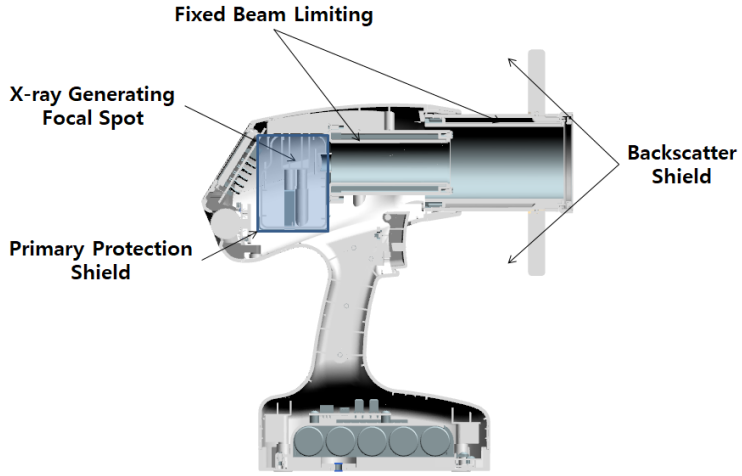
1) Standards for Protection Against Radiation, 10 CFR 20 (US Federal Standards), 1994
2) NCRP Report No. 145 (National Council on Radiation Protection and Measurements)
3) "Estimated Cosmic Radiation Doses for Flight Personnel", Feng YJ et al, Space Medicine and Medical Engineering, 15(4) 2002,
4) “Radiation Exposure with the Portable Dental X-ray(Model : NP-350E),”Goren AD et al, Dentomaxillofacial Radiology, 37(2008), S.109-12; Normalized average assumes 7,200 exposures per year, and the average length of exposure for D-speed Film = 0.40 sec, digital sensor = 0.15 sec.

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

Occupational Dose limit[1]	500 mSv
Occupational Dose limit Required Dosimetry[1]	50 mSv

Average Exposure Using The Portable Dental X-ray (Model: NP-350E) with D-Speed Film[2]	0.32 mSv
Average Exposure Using The Portable Dental X-ray (Model: NP-350E) with F-Speed Film or Digital Sensor[3]	0.05 mSv

1) Standards for Protection against Radiation, 10 CFR 20 (US Federal Standards), 1994
2) Normalized average (includes leakage and backscatter radiation) assumes 7,200 exposures per year, and the average length of exposure for D-speed Film = 0.40 sec, Digital sensor = 0.15 sec.



3. System Overview

The NP-350E is a portable dental X-ray for producing intra-oral image and operates on 14.5V DC supplied by a super capacitor.
The NP-350E is composed of high voltage module including x-ray tubes and electric circuits, main control unit, user interface and x-ray iris (collimator).
NP-350E can be used with an intra-oral imaging sensor.
The NP-350E is used for dental diagnosis in adult and pediatric patients and is available only to trained and qualified dentist or dental technician.

3.1 Indications for Use

The Portable Dental X-Ray (Model: NP-350E) is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

3.2 Principles of Operation

NP-350E is an X-ray device capable of diagnosing anatomical oral structures.
The free electrons generated from the cathode in the X-ray tube are caused to generate a high voltage between the cathode and the anode in the X-ray tube by using a high-voltage generator, and the generated X-rays are irradiated to the teeth of the human body

3.3 Intended User Profile

Considerations	Requirement Description
Education	Licensed dentist or dental hygiene, radiologist and graduates of relevant bachelor's degree (national qualifications)
Knowledge	The operator must have understood: • treatment and diagnosis of dental disease • terms and guidance of diagnostic medical radiation devices • device connection, installation and operating conditions.
Language understanding	The operator must have understood: • the English or Korean manuals (or other languages provided).
Experience	The operator must have understood: • objectives and effects of treatment and diagnosis of dental disease using diagnostic medical radiation devices • normal operation of diagnostic medical radiation devices • the contents of the user manual.

3.4 Patient population and name of disease

No	Contents	Description
1	Indications	for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.
2	Age	Not limited
3	Weight	Not limited
4	Health	No limit but patients must wear lead aprons during their X-ray imaging.
5	Nationality	Not limited
6	Condition	Not limited

3.5 Components

No.	Item	Standard	Option	Qty.
1	NP-350E Main Body	●		1
2	User Manual	●		1
3	Cradle(power cord included)	●		1
4	Rectangular Cover (2x3)		●	1

5	Rectangular Cover (4x3)		●	1
6	Back scatter shield (Ring)		●	1
7	External exposure switch		●	1

3.6 Features

The NP-350E is an intra-oral portable X-ray that offers safety, reliability, and greater functionality:

- Lightweight and ergonomic design
- Convenience of cordless design by using Super Capacitor
- Micro-computer and specialized circuit that monitors and precisely regulates the exposure technique factors (kV, mA, and exposure time)
- Pre-programmed exposure time makes the operation fast and easy.

3.7 General view of the equipment

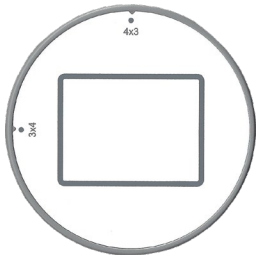
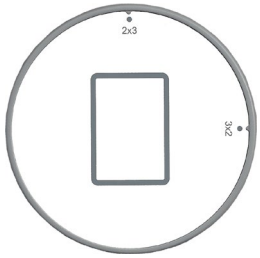
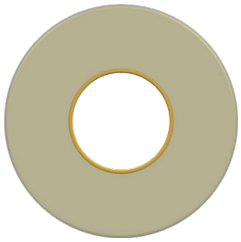
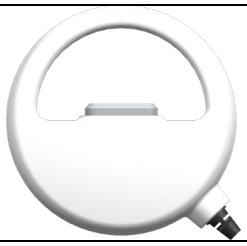
3.7.1 Components and Accessories

1) Components

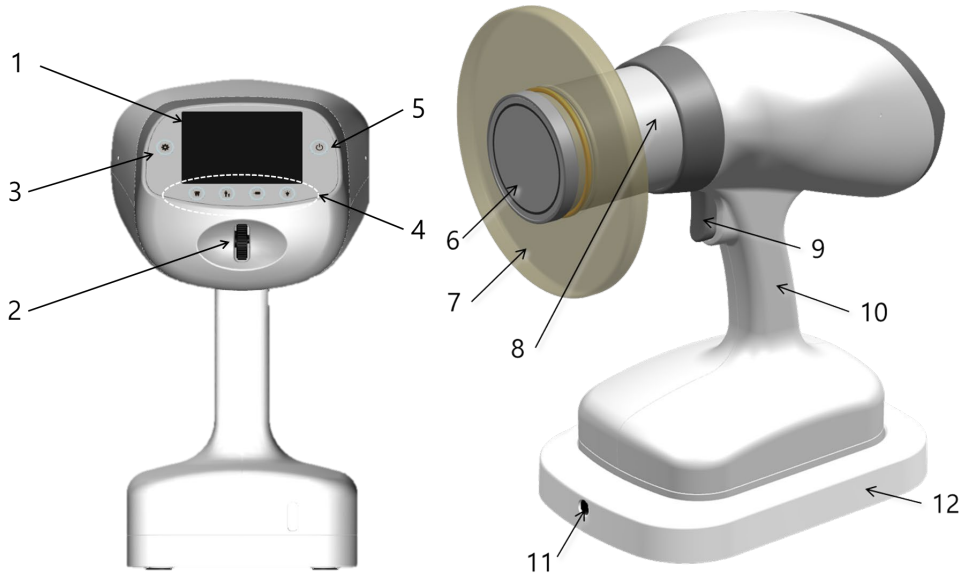
No.	Figure	Name	Specifications
1		Main Body	1) Model: NP-350E 2) Rated Input power: DC 14.5V 3.33A 3) Rated output power: 245W 4) Display: LCD Panel Display (3.5 Inch, BTN LCD, 1/4Duty, 1/3BIAS) 5) X-ray Tube: (1) Model: KL11 -0.4-70 (Kailong) (2) Inherent Filtration: Min. 0.8mm AL Eq @ 75kV
2		AC220V to DC 18V Adaptor	Input Voltage : AC 100 ~ 240V, 50~ 60Hz 1.4-0.7A Output Voltage : 18V Output Current : 3.3A Maximum Power : 60W Approved by IEC 60601-1
3		Power cord set	**Plug** Type: HG/TR Model: NEMA 5-15 (HOSPITALGRADE) Rated current and voltage: 15 A, 125 V AC **Cord** Type: SJT3X16AWG Dielectric strength: 2kVac,1min Insulation resistance: >2,5 MOhm / 1000feet Approvals: UL, CSA **Connector** Type: C13M Rated current and voltage: 13 A, 250 V AC (USA, Canada)
4		Charging cradle	Input Voltage : 18 V Output Voltage : 18V

2) Accessories

No.	Figure	Name	Specifications

1		Rectangular Cover (RC-0001)	4cm x 3cm
2		Rectangular Cover (RC-0002)	2cm x 3cm
3		Back scatter shield (BSS-0001)	16.5 cm x 1.25 cm (diameter x thickness)
4		External exposure switch (ESW-0001)	9.49 cm x 3.5 cm (diameter x thickness)

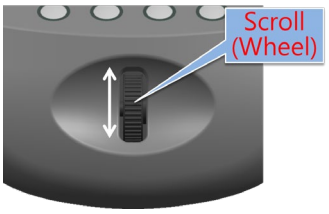
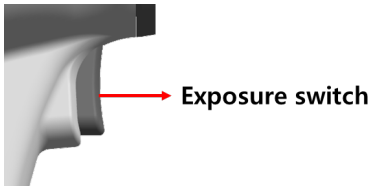
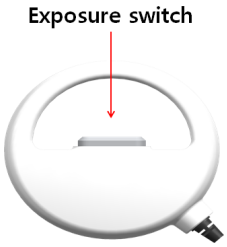
3.7.2 Name of each parts



No.	Item	Description
1	LCD	Indicates status of the product
2	wheel	Changes the X-ray exposure time
3	Enter button	Select a setup mode
4	Mode-changing buttons	Changes the X-ray exposure mode
5	Power on/off button	Turns the product on/off
6	Cone cover	Can replaced with rectangular cover
7	Back scatter shield	Shield scattered X-ray from patient
8	X-ray collimator (Cone)	Limits X-ray exposure area
9	Exposure button	Used for X-ray exposure
10	Handle	Used to hold the product
11	Adapter connection hole	Hole for adapter connection
12	Cradle	Used to charge for battery

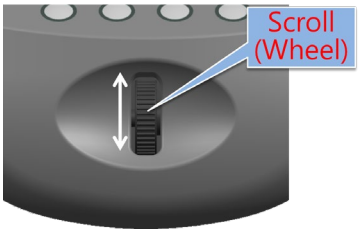
4. Instructions for Use

4.1 The frequently used functions

Scroll the wheel button to select the number.	
Press the button to turn on/off the system.	Press the power button at least one second to turn on. Press the power button at least four seconds to turn off
Press the button to turn Lock/unlock the system.	Press the lock/unlock button at least one second to lock on. Press the lock/unlock button at least four seconds to lock off.
Press the button to turn mode the system.	Press the Enter button at least six second to setting mode on/off.
Press the , , button to select the mode.	Press the ~ button one by one for selecting the mode.
Press the exposure switch to exposure	Press the exposure switch for X-ray irradiation. 
Press the external exposure switch to exposure	Press the external exposure switch for X-ray irradiation. 

4.2 Change exposure time by manipulating the wheel

- Scroll through the wheel to manipulate exposure time from 0.06s ~ 1.00s.
- Scroll: Rolling the wheel up and down.



4.3 Power ON/OFF

- Press the button at least one second to turn on.
- Press the button at least four second to turn off..

4.4 Lock/Unlock the X-ray

- The X-ray lock and unlock functionality can be activated to prevent unauthorized use when the device is idle
- This functionality may also be used for training purposes.
- To lock the X-ray, press the button at least one second.
- To unlock the X-ray, press the button at least four seconds

4.5 Select teeth

- Press the button to select teeth.
- : bitewing
- : mandibular molar
- : maxillary molar
- : canine
- : incisor

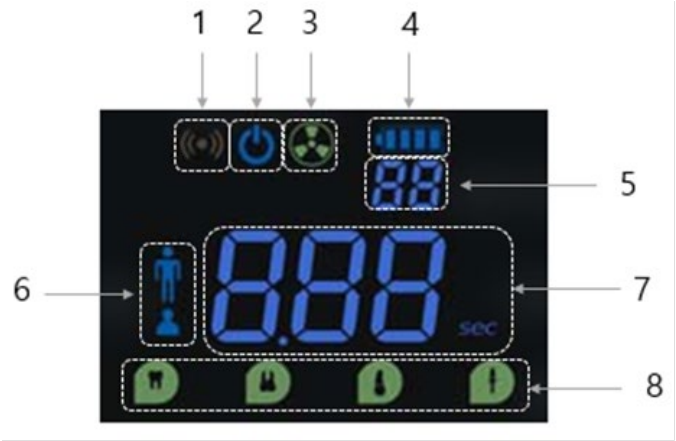
4.6 Select Adult or child

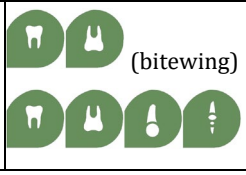
- Press the button to select Adult or child.

4.7 Select film

- Press the button to select DR, CR, Film.

4.8 LCD(Liquid Crystal Display) panel



No.	ICON	Description
1		Requires the user to pay attention such as charging or waiting.
2		Being charged.
3		X-ray is being exposed.
4		Super capacitor indicator.
5		Waiting time for retaking an X-ray
6		Adult or child
7		Exposure time and charging status Chr : being charged, rdy : fully charged Lob : Need charge , Loc : Lock mode
8	 (bitewing)	Selected teeth (press button) Bitewing → Mandible molar → Maxillary molar → Canine → Incisor in sequence

4.9 Checking the remaining in Super Capacitor

-Make sure that at least one battery indicator light comes on.

	0-25% remaining
	25-50% remaining
	50-75% remaining
	75-100% remaining

4.10 Charging the Super Capacitor & Lock display

	Needs to be charged
	Being charged
	Fully charged.
	Lock mode

4.11 Interfaces between the software system and other systems

User Interface	Function	Interface specification
Button	- Program start, end - Teeth selection - Select the exposure object - Select the type of exposure - Initialize exposure time - Administrator mode entry and exit - Change administrator mode - Select the Lock/unlock mode	6ea button (Beside LCD display)
Wheel	- Select the exposure time - Change administrator mode setting value	1ea wheel
Exposure Switch	- Exposure	1ea Exposure Switch
LCD display	- Display the start status of the system - Display the current status of the system (charge, exposure, battery level, exposure object selection mode, exposure time and Charge state, tooth selection)	3.5 inch (Out size dimension : 64 X 46mm) (Viewing Area Dimension : 60X 41mm)
Cradle	- Charge - Charging status LED indication	1 Cradle
Buzzer	- Alarm sound output	1 Buzzer
External exposure switch	- Exposure	1ea External exposure Switch

4.12 Main functional elements and functionality

No.	Contents	Function
1	System On/Off function	1) Display the start status of the system 2) Display the shutdown status of the system
2	Information of System status and Progress message	Display of the current status of the system (charging, exposure, battery level, exposure object selection, exposure time and charge status, tooth selection, etc.)
3	Teeth selection mode	1) Bitewing mode 2) Mandible molar mode 3) Maxillary molar mode 4) Canine mode 5) Incisor mode
4	Exposure object selection mode	1) Adult mode 2) Child mode

No.	Contents	Function
5	Exposure type selection mode	1) DR mode 2) CR mode 3) Film mode
6	Exposure time mode	Display exposure time (0.06 ~ 1.00 sec) Selecting the Exposure time within the settable range of each mode
7	Exposure time limit mode	Limit setting range of each exposure time(Adult :DR, CR, Film mode, Child: DR, CR, Film mode)
8	Exposure time initialization	Initialize by Administrator mode
9	Exposure	Display x-ray exposure status
10	Exposure limit	When performing other functions, it should not be exposed even though the exposure switch is pressed.
11	Charging mode	1) Display charging status 2) Display charging completion status 3) indicate charging status on cradle
12	Display battery charge	Display battery level step by step
13	Save setting value	When the power is turned off, the last setting value is saved. When the power is turned on again, it is automatically loaded, set and displayed
14	Administrator mode	1) HF mode 2) Hu mode 3) dF mode 4) du mode
15	Alarm	1) System start (long sound) 2) System status change(single sound) 3) Exposure: double sound(single and long)

4.13 Positioning

To obtain high-quality intra-oral radiography with maximum details, take extra care in all steps of the radiography process: positioning the patient and the X-ray imaging system; exposing the intra-oral sensor.

- The table below show recommended specification of intra-oral sensor.

Specifications	CR	DR
Resolution	9 ~ 21 lp/mm	10 ~ 30 lp/mm
Pixel size	30~70 ㎛	10~50 ㎛

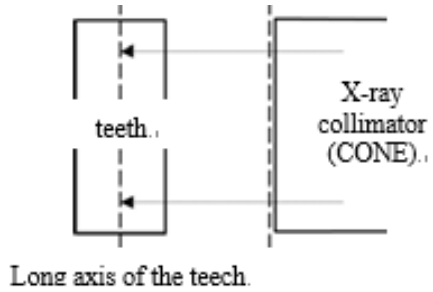
- The table below show recommended detectors.

Manufacture	CR/DR	Model
Carestream	CR	CS7200, CS7600
3DISC	CR	FireCR Dental Reader
Vatech	DR	EzSensor Soft

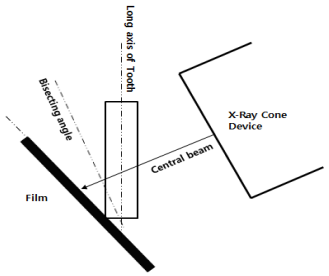
- The table below shows recommended angles of inclination (bisecting angle radiography) exposure times based on DR mode.

Teeth	Angle for inclination		Exposure Time(sec) Adult / Child
	Upper	Lower	
Incisor	45º	-25º	0.15 / 0.10
Canine	45º	-20º	0.18 / 0.12
Molar	30º	-5º	0.21~0.24 / 0.14~0.15
Bitewing	5~8º		0.30 / 0.19

- Paralleling radiography: A technique to radiograph by maintaining the x-ray collimator (CONE) in parallel with the axis of the teeth using the support.



- Bisecting radiography: A technique to radiograph while the examinee (patient) holds the intraoral sensor (or film) in place with his/her finger. The X-ray beam is directed perpendicularly towards an imaginary line, which bisects the angle between plane and the long axis of the teeth.



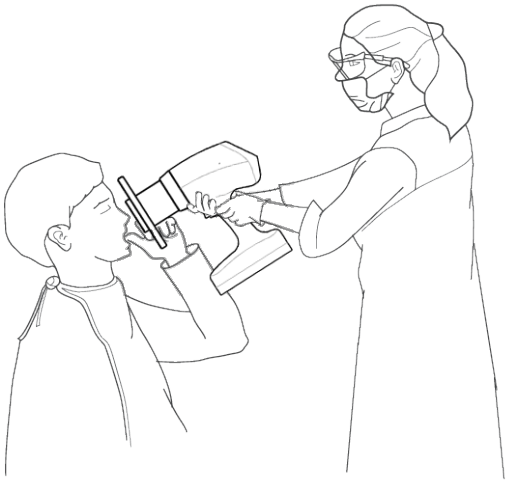
Here are the specific angulations and directions for the tube head in order to take the best images of a particular tooth (i.e. **Bisected angle technique**).

CAUTION	Position the receptor carefully not to damage the soft tissue of the patient's intra-oral area.

CAUTION	When using the device, the device should never touch the patient

- **Maxillary Incisor**

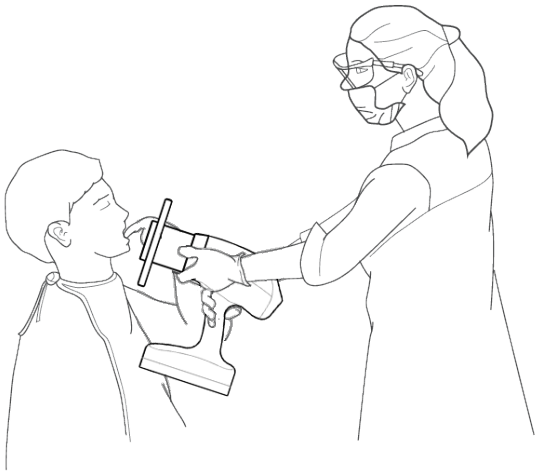
  X-ray beam is directed downward at 45°.



Tooth		Angle of inclination
Incisor	Maxilla	+45°

- **Mandibular Incisor**

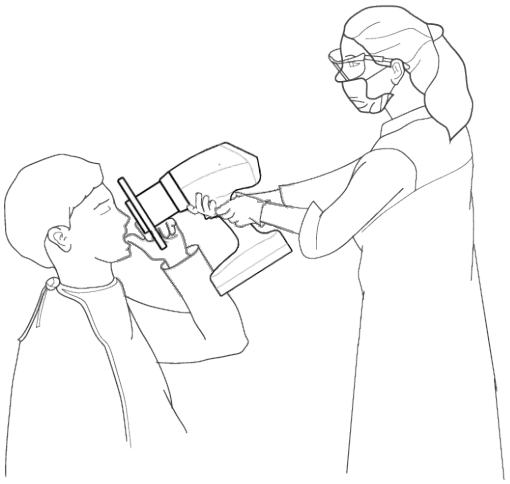
  X-ray beam is directed downward at 25°.



Tooth		Angle of inclination
Incisor	Mandible	-25°

- **Maxillary Canine**

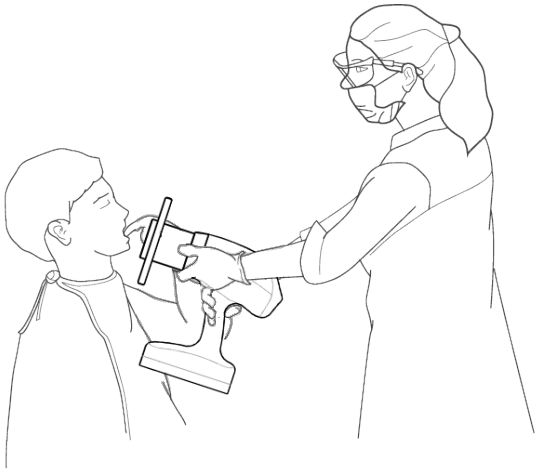
  X-ray beam is directed downward at 45°.



Tooth		Angle of inclination
Canine	Maxilla	+45°

- **Mandibular Canine**

  X-ray beam is directed downward at 20°.



Tooth		Angle of inclination
Canine	Mandible	-20°

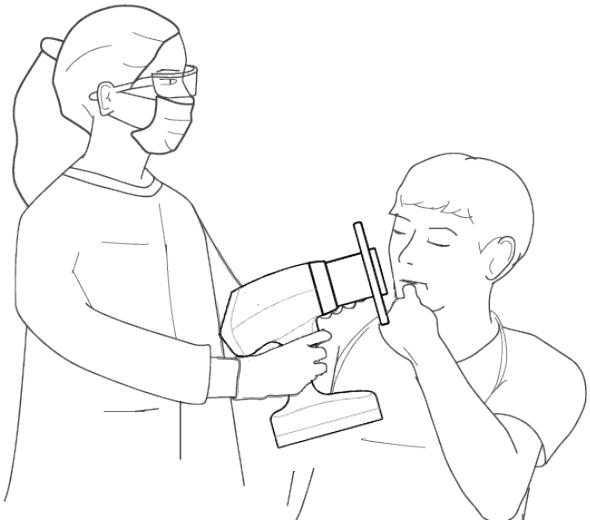
- **Maxillary Molar and premolar**

  X-ray beam is directed downward at 30°.

Tooth		Angle of inclination
Molar and premolar	Maxilla	+30°

- **Mandibular Molar and premolar**

  X-ray beam is directed downward at 5°.



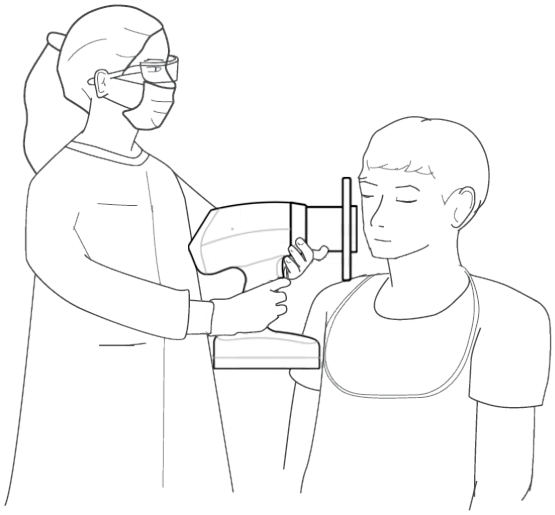
Tooth		Angle of inclination
Molar and premolar	Mandible	-5°

- **Bitewing**

  For a bitewing exposure, the patient doses their tooth during

  exposure on the sensor holder.

  X-ray beam is directed downward at 5° ~ 8°.



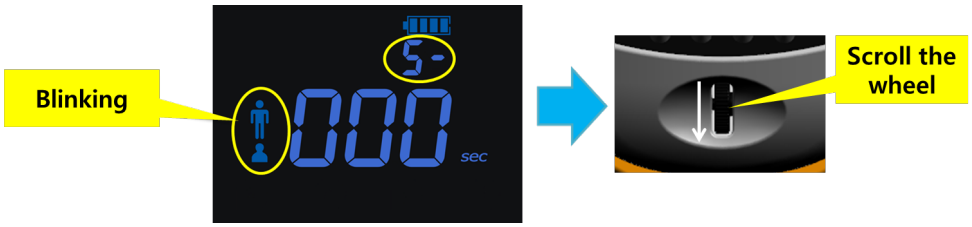
Tooth	Angle of inclination
Bitewing exposure	+5° ~ +8°

4.14 Exposure times Auto-save mode / Reset exposure time

● When initially used, exposure times will operate at the default value when power is cycled.

● When automatically saving exposure time

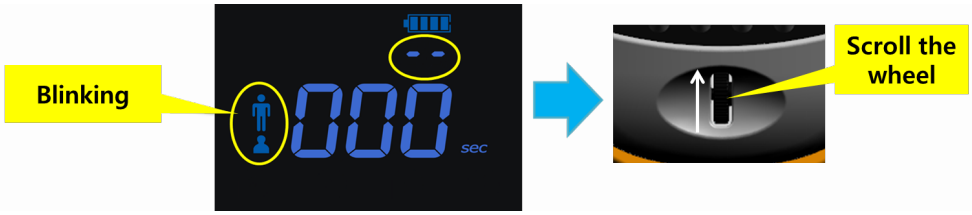
(1) When you press the button to blink an adult or a child, scroll the wheel down so that the mode indicator is " S - ".



(2) When the product is turned off, press the button to turn it on before using it.

● If you want to cancel automatically saving exposure time settings

(1) When you press the button to blink an adult or a child, scroll the wheel up so that the mode indicator is " - - ".



(2) When the product is turned off, press the wheel to turn it on before using it.

● When initialization of saved exposure time

(1) When you press the button to blink an adult or a child, press the exposure switch for five seconds.

(2) When the product is turned off, press the to turn it on, and it will be displayed as the default value.

4.15 Troubleshooting

Error Code	Potential Problem	Corrective Action
E02 (Tube current under)	If it is lower than the set tube current	NP-350E will require authorized service.
E03 (Generator High voltage cable disconnect)	Generator high voltage cable not connected	NP-350E will require authorized service.
E04 (High voltage under)	If the set tube voltage is low	NP-350E will require authorized service.
E11 (Generator filament cable disconnect)	If the generator filament cable is not connected	NP-350E will require authorized service.

4.16 Charging the Battery

1) Connect the charging cable to Cradle
2) Plug the cradle into an electrical socket via the power supply unit provided.
   If using it overseas please ensure that an appropriate adaptor for the country of visit is purchased prior to departure.
3) LED indicator lights on and turns Orange when provide an electricity.
4) Docking the equipment on the cradle properly.
5) The Super Capacitor is charged when the LED turns Blue.

	Do not turn on the equipment during charging.

	1. Do not use the charger in humid conditions. 2. Do not use the charger if it has a damaged plug. 3. Do not use the charger after it has been dropped or damaged 4. Do not open / disassemble the charger. 5. Do not use the charger in direct sunlight 6. Do not charge in the environment with patient.

5. Maintenance

5.1 Storage

Avoid placing the product, the charger and the charging cradle in places, unlikely to have any issues/damages due to temperature/humidity, direct sunlight, dust and salinity.

Keep the charger and the charging cradle disconnected from the power supply when the product is not used for a long period of time
Avoid keeping the product near chemical or gas storage facilities

5.2 Cleaning

When cleaning the product, turn off the power and disconnect the charging cradle and the charger from the power.

When cleaning the surfaces make sure that the equipment is not connected to the cradle.
The product surface can be wiped off with a soft cloth damped in noncorrosive alcohols or disinfectant.
If necessary, wipe off surfaces with disinfectant.

Do NOT allow liquids to drop into the product, the charger and the charging cradle.

Do NOT use spray cleaner or disinfectant, as this could cause a fire or hazard

The soft cloth should be damp, but not dripping wet.

The cloths or wipes cannot be re-used.

5.3 Maintenance

NANORAY requires periodic constancy tests to ensure image quality and the safety for the patient and operator.

Only **NANORAY** authorized technicians can perform inspection and service of this equipment. For the technical assistance, contact **NANORAY** service center or your local **NANORAY** representative.

Our products are fast-charging products using Super Capacitor without using a typical lithium-ion battery, so if they are not used within 2 hours after full charging, they must be charged.

Note: If the product has a failure or malfunction that requires repair, it must be repaired by the manufacturer

Cautions and Notes

DO NOT keep the equipment or its parts in a humid place or near a liquid substance.

Avoid placing the equipment near chemical storage and gas-filled storage facilities.

1) Maintenance Task Checklist

Always turn off the equipment before performing any maintenance.

Tasks	Period
Before operation, ensure that the equipment is clean and ready for use.	Daily
After using the equipment, make sure that the equipment has been turned off.	Daily
Wipe the outer covers of the equipment with a dry cloth at the end of each day's operation. **DO NOT use detergents or solvents to clean the outer covers of the equipment.**	Daily

Tasks	Period
Ensure that the signal is audible and the X-ray emission light is visible when you make an exposure.	Daily
Ensure that the yellow (exposure) indicator light turns on when the Exposure Button is pressed.	Daily
Ensure that the battery charging LED indicator comes on when charging the battery.	Daily
Ensure that all visible labels are intact and legible.	Monthly

If any defects are found, do not operate the equipment since it has to be handled by a qualified person. Contact your Service Representative.

6. Disposing of the Unit

In order to reduce environmental contamination, this equipment is designed to be as safe as possible to use and dispose of. Many components of this equipment are environment-friendly and can be recycled.

All parts and components that contain hazardous materials must be disposed of in accordance with disposal regulations. (IEC 60601-1 6.8.2 j)

Part	Material	Recyclable	Waste Disposal Site	Hazardous waste; Needs Separate Collection
Covers	Plastics	●		
Boards		●		
Cables and transformer	Copper	●		
Packing	Polystyrene	●		
	Cardboard	●		
	Paper	●		
X-ray tube				●
Battery (super capacitor)				●
Other parts			●	

Observe all regulations relevant to the disposal of waste in your country.

This symbol on the product and/or accompanying documents means that used electrical and electronic equipment (WEEE) should not be mixed with general household waste.

For professional users in the European Union:

If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

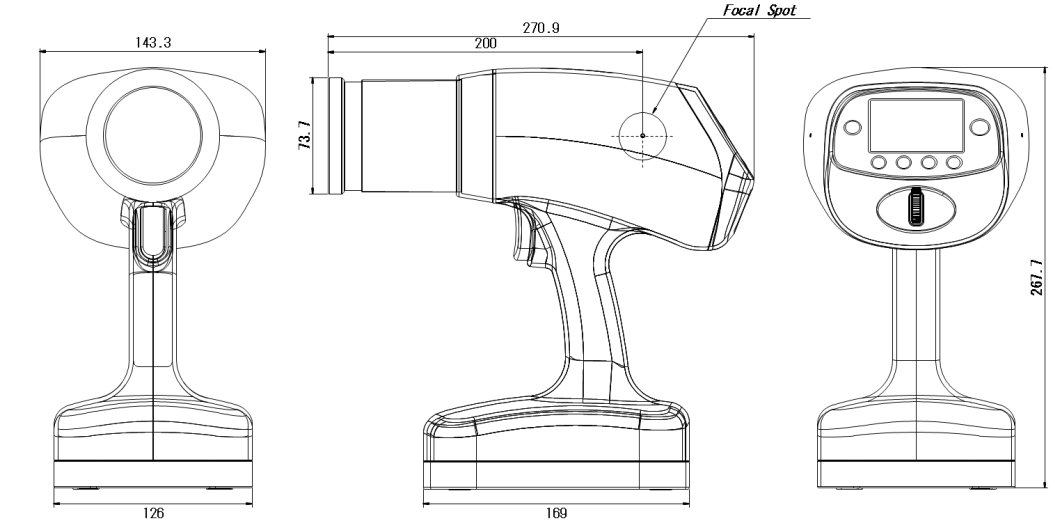
For disposal in countries outside of the European Union:

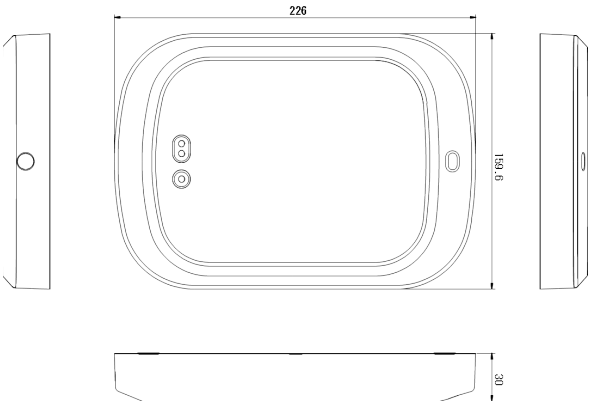
This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer and ask for the correct disposal method.

7. Product Specifications

7.1 Mechanical Specifications

Dimensions





Item			Description
Main Body	Dimension (mm)		270.9(L) x 267.7(H) x 143.3(W)
	Weight (kg)		1.95 (± 10 %)
Main Body	Dimension (mm)		226(L) x 159.6(H) x 30(W)
	Weight (kg)		0.55 (± 10 %)
X-ray	X-ray	Round Type	FOV: < ø 60

Beam Limiting Device	Beam Area (mm)	Rectangular Type	FOV: 20 x 30, 40 x 30
	SSD(Source to Skin Distance) (mm)		200

7.2 Technical Specifications

1) Portable dental X-ray

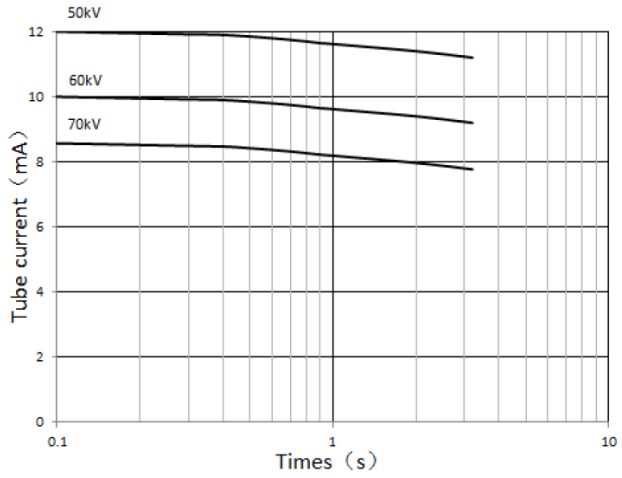
Items		Specifications
Model Name		NP-350E
Rated Input power	Device	DC 18V 3.33A
	Adaptor	100-240 VAC, 50-60Hz 1.4-0.7A
Rated output power		245W
Internal Power		14.5 VDC (Super capacitor), 10EA
kV/mA		70 kV /3.5 mA
Exposure time range [sec]		0.06 - 1.00 sec ±5%
Measuring efficiency,	kV	±10%
	sec	±5%
	mA	±20%
Display		LCD Panel Display (3.5 Inch, BTN LCD, 1/4Duty, 1/3BIAS)
X-ray Tube	Model	KL11 -0.4-70 (Kailong)
	Inherent Filtration	Min. 0.8mm Al Eq @ 75kV
	Focal spot size	0.4 mm
Total Filtration	Inherent Filtration	0.8mmAl Eq. @70kV
	Added Filtration	2.2mmAl
	Total Filtration	3.0 mm Al Eq. @ 70 kV
CONE Length (from focal spot)		200mm
Material of CONE		PB, ABS
Language		English
Weight	Main body	Total 1.95 kg(± 10%)
	Cradle	550g (± 10%)

2) X-ray Generator

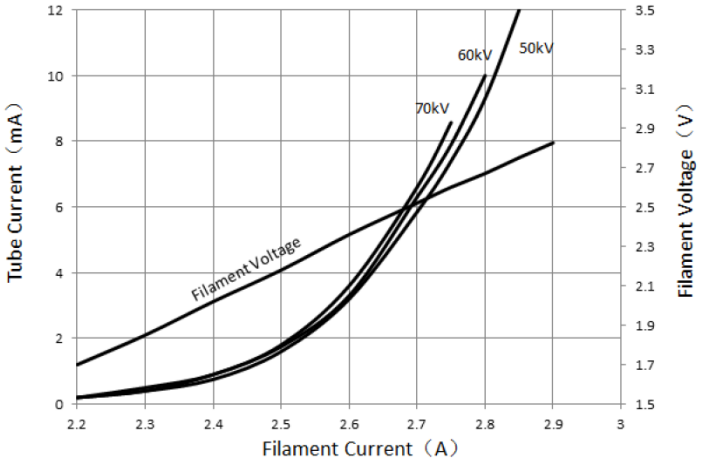
Item		Specifications
High Voltage Generator (Assembly)	Model	NRG1
	Rated output power	Max. 0.21 kW
	Duty Cycle	1:30 or more (Exposure time: Interval time)
	Cooling Protection	Thermistor ≥ 70 °C
	Type	Inverter Type
	Tube Voltage	65-75kV
	Tube Current	2.8 - 4.2 mA
X-ray Tube	Manufacturer	Hangzhou Kailong Medical Instrument Co., Ltd
	Model	KL-11-0.4-70
	Focal spot size	0.4 mm (IEC 60336)
	Anode heat contents	4.5 kJ
	Maximum Anode Heat Dissipation	110 W
	Target Material	Tungsten
	Target Angle	12°
	Inherent Filtration	Min. 0.8mm Al Eq @ 75kV
	X-ray Coverage	70 mm at SID 200 mm
	Tube Voltage	70 kV
	Tube Current	Max. 12.0 mA

3) X-ray Tube Characteristics

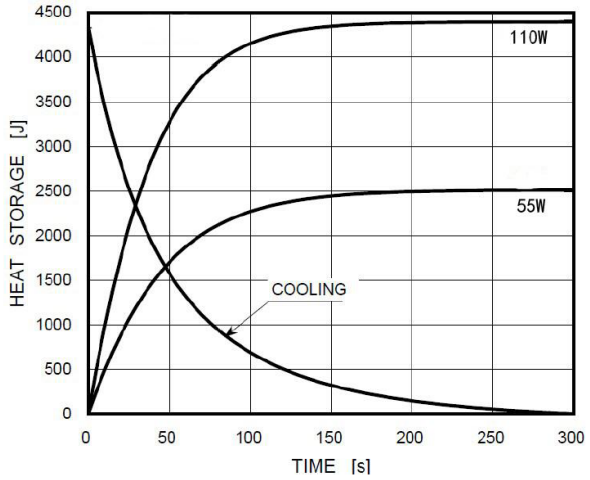
① Maximum rating chart



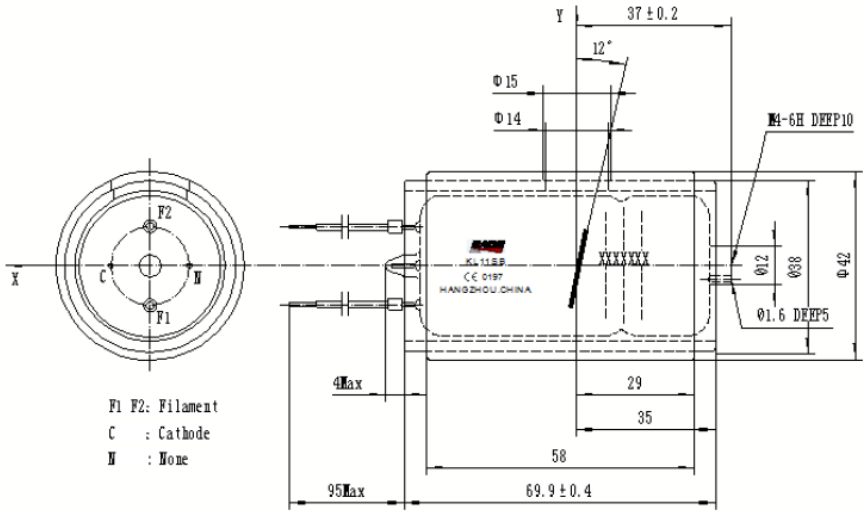
② Emission characteristics



③ Heating and cooling curves of X-ray tube



④ Tube Dimensions [mm]



F1 F2: Filament
C : Cathode
N : None

X axis :horizontal Y axis :vertical
OUTLINE DRAWING
(KL11SB-0.4-70)

4) Battery

Item	Description
Type	Super Capacitor
Nominal Capacity	100 F
Nominal Voltage	3.0 V d.c. 5 by 2
Charging Voltage	14.5 V d.c. (2.9 V d.c./Cell)

5) Adaptor & Power cord set

Adaptor

Item	Description
Model	GSM60A18
Manufacturer	MEAN WELL
Rating	Input: 100 - 240 V~, 50 - 60 Hz, 1.4-0.7A
	Output: 18 V DC., 3.33 A
Frequency	50 - 60 Hz
Standard	IEC 60601-1 (UL)
Power Cord	250 V~, 16 A

Power cord set(Plug)

Item	Description
Model	NEMA 5-15 (HOSPITALGRADE)
Type	HG/TR
Manufacturer	Feller

Rated current and voltage	15 A, 125 V AC

Power cord set(Cord)

Item	Description
Type	SJT3X16AWG
Manufacturer	Feller
Dielectric strength	2kVac,1min
Insulation resistance	>2,5 MOhm / 1000feet
Approvals	UL, CSA

Power cord set(Connector)

Item	Description
Type	C13M
Manufacturer	Feller
Rated current and voltage	13 A, 250 V AC (USA, Canada)

7.3 Electrical Specifications

Item	Description
Tube Voltage	70 kV (± 10%)
Tube Current	3.5 mA (± 20 %)
Exposure Time	0.06 - 1.0 s (±5% or ±20ms)
Rated Voltage	14.5 V d.c.

7.4 Environmental Specifications

Item		Description
During operating	Temperature	10 ~ 35 ℃
	Relative humidity	30 ~ 75 %
	Atmospheric pressure	860 ~ 1060 hPa
Transport and storage	Temperature	-10 ~ 60 ℃
	Relative humidity	10 ~ 75 % non-condensing
	Atmospheric pressure	860 ~ 1060 hPa

8. Appendix 01

8.1 Tables of Exposure Times (Default)

The following exposure time tables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inch) respectively.
We can use it with DR, CR, Film type detectors, the exposure Times according to the type are as follow table.

Patient		Teeth		Angle of inclination	SSD: 200mm(8 inch)		
					kV	mA	sec
Adult 	DR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.15
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.18
		Upper Molar		Maxilla : +30˚	70	3.5	0.24
		Lower Molar		Mandible : -5˚	70	3.5	0.21
		Bitewing		+5˚ ~ +8˚	70	3.5	0.30
	CR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.40
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.49
		Upper Molar		Maxilla : +30˚	70	3.5	0.64
		Lower Molar		Mandible : -5˚	70	3.5	0.58
		Bitewing		+5˚ ~ +8˚	70	3.5	0.81
	FL	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.51
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.59
		Upper Molar		Maxilla : +30˚	70	3.5	0.77
		Lower Molar		Mandible : -5˚	70	3.5	0.69
		Bitewing		+5˚ ~ +8˚	70	3.5	1.00

Patient		Teeth		Angle of inclination	SSD: 200mm(8 inch)		
					kV	mA	sec
Child	DR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.10
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.12
		Upper Molar		Maxilla : +30˚	70	3.5	0.15
		Lower Molar		Mandible : -5˚	70	3.5	0.14
		Bitewing		+5˚ ~ +8˚	70	3.5	0.19
	CR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.24
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.30
		Upper Molar		Maxilla : +30˚	70	3.5	0.39
		Lower Molar		Mandible : -5˚	70	3.5	0.36
		Bitewing		+5˚ ~ +8˚	70	3.5	0.50
	FL	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.33
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.39
		Upper Molar		Maxilla : +30˚	70	3.5	0.50
		Lower Molar		Mandible : -5˚	70	3.5	0.45
		Bitewing		+5˚ ~ +8˚	70	3.5	0.65

8.2 X-ray Dose Data

The X-ray dose data is extracted from the X-ray Dose Test Report for the NP-350E. The X-ray doses of the NP-350E in the test report were measured in accordance with the IEC collateral standards. The NP-350E was designed in accordance with Part 1. General Requirements for Safety, IEC 60601-1-3.

Test Condition	
Model Name	NP-350E
Tube Model Name	KL-11-0.4-70
Generator Model Name	NRG1-
Loading Factor	70 kV, 3.5 mA

1) X-ray Dose Table

Test Equipment			
Instrument	Manufacturer	Model	S/N
Dose Meter	Ray-safe	X2 Base Unit	225575

Dose Table (70 kVp, 3.5 mA, FOV: Ø 6 cm, SSD 200 mm, at Al 6 mm)	
t (s)	**Dose (µGy)**
0.06	41
0.10	68
0.14	95
0.20	134
0.34	221
0.5	320
0.6	377
0.8	487
1.0	595

2) Leakage Dose

Scope

IEC 60601-2-65 203.12.4

Requirements

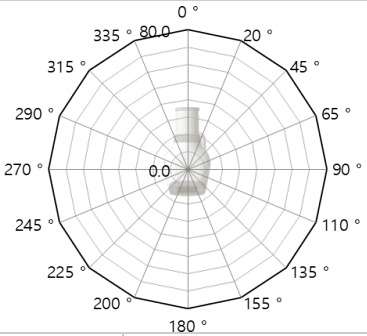
In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, 1 m from the FOCAL SPOT, average over any area of 100 cm^2 of which no principal linear dimension exceeds 20 cm, when operated at the NOMINAL X-RAY TUBE VOLTAGE under condition of LOADING corresponding to the reference LOADING conditions, shall not exceed 0.25 mGy in one hour.

Leakage Dose	Permissive Range
70 kVp, 3.5 mA, 1.0 s (Max. Exposure Condition) At Focal Spot to Distance 1 m 1 : 30 Duty Cycle	< 0.25 mGy/h

Results

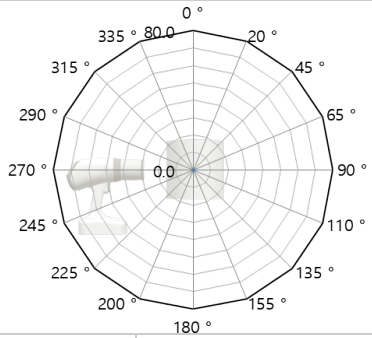
The following exposure time tables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inch) respectively. When the leakage doses have been measured with each cover type (default, rectangular 2x3, and rectangular 4x3), all the results have been ND (Not Detected).
The raw data about the results is shown in the table below. (exposure time : 160 ms)

Result (Horizontal Plane, Without Backscatter shield)



Direction	Default type [mGy/h]	Rectangular 2x3 [mGy/h]	Rectangular 4x3 [mGy/h]
0°	ND	ND	ND
90°	0.062	0.061	0.061
180°	0.058	0.059	0.059
270°	0.091	0.091	0.091

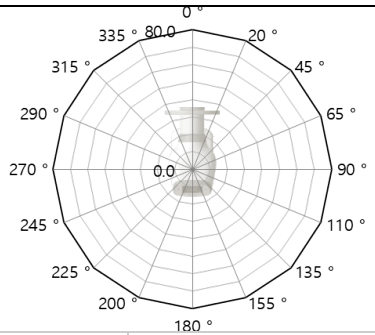
Result (Vertical Plane, Without Backscatter shield)



Direction	Default type [mGy/h]	Rectangular 2x3 [mGy/h]	Rectangular 4x3 [mGy/h]
0°	0.039	0.038	0.038
90°	ND	ND	ND
180°	0.067	0.067	0.066
270°	0.058	0.058	0.058

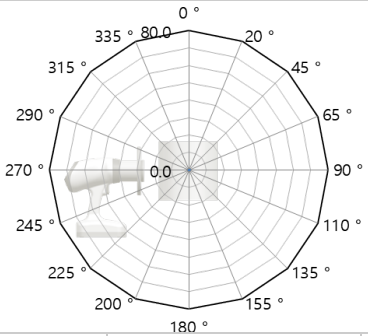
ND: Not Detected. Detection limit is 0.00001 mGy per exposure.

Result (Horizontal Plane, With Backscatter shield)



Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[mGy/h]
0°	ND	ND	ND
90°	0.060	0.060	0.060
180°	0.055	0.055	0.054
270°	0.090	0.090	0.090

Result (Vertical Plane, With Backscatter shield)



Direction	Default type	Rectangular 2x3	Rectangular 4x3
	[mGy/h]	[mGy/h]	[mGy/h]
0°	0.035	0.035	0.035
90°	ND	ND	ND
180°	0.066	0.067	0.067
270°	0.057	0.057	0.058

ND: Not Detected. Detection limit is 0.00001 mGy per exposure.

8.2.3 Scattered Dose

Scope

IEC 60601-2-65 203.12.2

Requirements

ME EQUIPMENT shall be provided with means to optionally allow actuation of the IRRADAIATION from a PROTECTED AREA after installation.

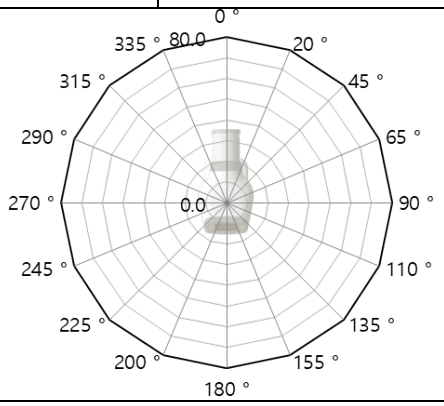
Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

Results

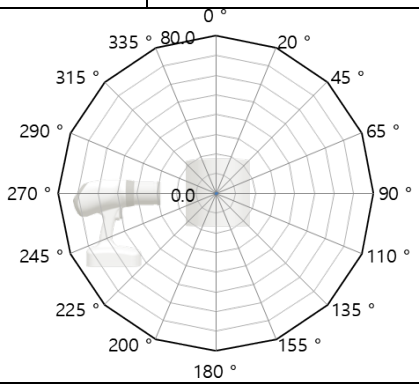
The following exposure time tables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inch) respectively.

Method
PMMA Phantom aligned to 280 mm away from Focal Spot (with Position Indicating Device) Max. Exposure Condition : 70 kVp / 3.5mA / 1 s Measure point : 500 mm from PMMA Phantom

Direction [°]	Result(Horizontal plane) [μR/s]
0 °	57.6
20 °	24.5
45 °	28.0
65 °	17.9
90 °	30.3
110 °	35.5
135 °	39.7
155 °	7.8
180 °	2.0
200 °	10.8
225 °	35.3
245 °	35.0
270 °	31.6
290 °	15.2
315 °	22.9
335 °	26.8



Direction [°]	Result(Vertical plane) [μR/s]
0 °	32.1
20 °	15.7
45 °	23.5
65 °	26.5
90 °	56.6
110 °	24.3
135 °	24.7
155 °	18.1
180 °	30.7
200 °	33.8
225 °	29.8
245 °	9.5
270 °	2.3
290 °	9.8
315 °	28.3
335 °	32.7



8.3 Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration - electromagnetic emissions

<table>
<tr><td colspan="3">The NP-350E is intended for use in the electromagnetic environment specified below. The customer or the user of the NP-350E should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF-emissions
KN 11/CISPR 11</td><td>Group 1</td><td>The NP-350E 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.</td></tr>
<tr><td>RF-emissions
KN 11/CISPR 11</td><td>Class A</td><td rowspan="3">The NP-350E 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: This NP-350E 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 NP-350E or shielding the location.</td></tr>
<tr><td>Harmonic emissions
Acc. IEC 61000-3-2</td><td>Compliance</td></tr>
<tr><td>Voltage fluctuations/
Flicker emissions
Acc. IEC 61000-3-3</td><td>Compliance</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity

<table>
<tr><td colspan="4">The NP-350E is intended for use in the electromagnetic environment specified below. The customer or the user of the NP-350E should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 Test level</th><th>Compliance level</th><th>Electromagnetic environment -guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2:2009</td><td>±8 kV Contact
±2,4,8,15 kV air</td><td>±8 kV Contact
±15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td></tr>
<tr><td>Electrical fast transient/burst
IEC 61000-4-4:2012</td><td>± 2 kV
100 kHz repetition frequency</td><td>± 2 kV
100 kHz repetition frequency</td><td>Main power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5:2014</td><td>± 0,5 kV, ± 1 kV</td><td>± 1 kV</td><td>Main power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td rowspan="2">Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td><td>0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td><td rowspan="2">Main power quality should be that of a typical commercial or hospital environment. If the user of the NP-350E image intensifier requires continued operation during power mains interruptions, it is recommended that the NP-350E image intensifier be powered from an uninterruptible power supply.</td></tr>
<tr><td>0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°</td><td>0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°</td></tr>
<tr><td>Power frequency (50/60 Hz) magnetic field
IEC 61000-4-8:2009</td><td>30 A/m</td><td>30 A/m</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td></tr>
<tr><td colspan="4">NOTE) UT is the a.c. mains voltage prior to application of the test level.</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity

The NP-350E is intended for use in the electromagnetic environment specified below. The customer or the user of the NP-350E should assure that it is used in such an electromagnetic environment.

Immunity test	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 NP-350E, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ **80 MHz to 800 MHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ **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 strength 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 outside the shielded location in which the NP-350E is used exceeds the applicable RF compliance level above, the NP-350E should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NP-350E.

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

Recommended separation distances between portable and mobile RF communications equipment and the NP-350E

This is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NP-350E can help Prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NP-350E as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	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	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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.

8.4 Abbreviations

Acronym	Name
AL	Aluminum
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
FOV	Field of View
IEC	International Electro technical Commission
ISO	International Standards Organization
LED	Light-Emitting Diode
ME	Medical Electrical
PMMA	PolyMethylMethAcrylate
RF	Radio Frequency
SID	Source to Image receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SSD	Source to Skin Distance

8.5 X-ray for Pediatric patients

- **Risk of the Pediatric patients**

We all are exposed to small amounts of radiation daily from the sun, soil, rocks, buildings, air and water. People living in the mountains or flying in planes are exposed to higher amounts of radiation than those living near sea level. This type of natural radiation is called background radiation. The radiation used in x-rays has been compared to the amount of background radiation a person gets in one year. This is shown to help you compare how much radiation your child is getting during their x-ray exam.

Radiation Source	Radiation Dose estimate	Estimates of Equivalent amount of background radiation
Natural Background Radiation	3 mSv	1 year
Airline Passenger (cross-country)	0.04 mSv	4 days
Chest X-ray (single)	0.01 mSv	1 day

The FDA's Center for Devices and Radiological Health defines the age range of the pediatric population as birth through 21 years. While the risk of radiation-induced cancer depends on age, patient size (i.e., height, weight, body part thickness) is a more important factor than age for optimizing image quality and radiation dose for x-ray imaging exams.

- **Principles of Operation**

NP-350E is an X-ray device capable of diagnosing anatomical oral structures.
The free electrons generated from the cathode in the X-ray tube are caused to generate a high voltage between the cathode and the anode in the X-ray tube by using a high-voltage generator, and the generated X-rays are irradiated to the teeth of the human body

- **Intended User Profile**

Considerations	Requirement Description
Education	Licensed dentist or dental hygiene, radiologist and graduates of relevant bachelor's degree (national qualifications)
Knowledge	The operator must have understood: • treatment and diagnosis of dental disease • terms and guidance of diagnostic medical radiation devices • device connection, installation and operating conditions.
Language understanding	The operator must have understood: • the English or Korean manuals (or other languages provided).

Experience	The operator must have understood: • objectives and effects of treatment and diagnosis of dental disease using diagnostic medical radiation devices • normal operation of diagnostic medical radiation devices • the contents of the user manual.

- **Patient population and name of disease**

No	Contents	Description
1	Indications	for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.
2	Age	Not limited
3	Weight	Not limited
4	Health	No limit but patients must wear lead aprons during their X-ray imaging.
5	Nationality	Not limited
6	Condition	Not limited

- **Contraindication**

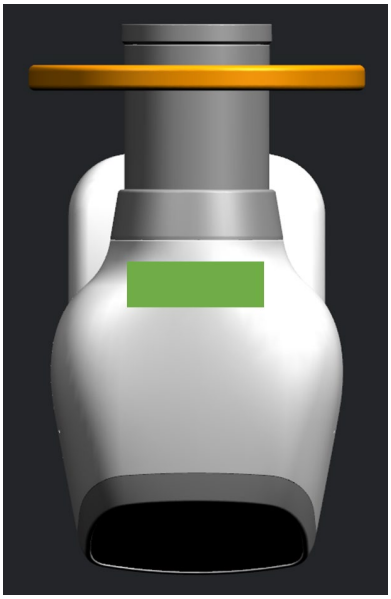
patients (children) must wear lead aprons during their X-ray imaging.

- **Warnings and Safety Instructions**

Patients (children and pregnant women particularly) must wear lead aprons during their X-ray imaging.
Children must consult with their doctors before X-ray examinations.
Before use the Portable Dental X-ray to the pediatric patients, please check this label on the device.

Before use the Portable Dental X-ray to the pediatric patients, Please press the child button on the device.
(In child mode, exposure dose of Portable Dental X-ray (NP-350E) reduced 60% compared to the adults based on the literature)

CAUTION (PRUDENCE)
X-RAY / ATTENTION (X-RAY / ATTENUATION) :
X-RAY ON WHEN EQUIPMENT IN OPERATIOM
(X-RAY ON LORSQUE L'ÉQUIPEMENT DE FONCTIONNEMENT)
CAUTION
BEFORE SHOOTING X-RAY, PLEASE CEHCK WHETHER THE PATIENT IS A CHILD OR NOT.
Use special care when imaging patients outside the typical adult size range.



Label Position

The amount of radiation from an x-ray is very small. Still, it is important to keep the radiation amount as low as possible. Doctors balance the benefit of the test and potential small risks of x-ray tests. Your doctor and the radiologist (x-ray doctor) will work together to decide which test is best for your child. Different tests are done based on your child's illness.

There are ways to make sure your child is exposed to the lowest amount of radiation possible during an x-ray test.

- Take an x-ray when there is a clear medical benefit
- Use the lowest amount of radiation based on size of the child to get pictures that may show the doctor the problem
- X-ray only the area needed
- Shield patients when possible
- Repeat images only when necessary

- **Tables of Exposure Times for children**

Patient		Teeth		Angle of inclination	SSD: 200mm(8 inch)		
					kV	mA	sec
Child	DR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.10
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.12
		Upper Molar		Maxilla : +30˚	70	3.5	0.15
		Lower Molar		Mandible : -5˚	70	3.5	0.14

Patient		Teeth		Angle of inclination	SSD: 200mm(8 inch)		
					kV	mA	sec
		Bitewing		+5˚ ~ +8˚	70	3.5	0.19
	CR	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.24
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.30
		Upper Molar		Maxilla : +30˚	70	3.5	0.39
		Lower Molar		Mandible : -5˚	70	3.5	0.36
		Bitewing		+5˚ ~ +8˚	70	3.5	0.50
	FL	Incisor		Maxilla : +45˚ Mandible : -25˚	70	3.5	0.33
		Canine		Maxilla : +45˚ Mandible : -20˚	70	3.5	0.39
		Upper Molar		Maxilla : +30˚	70	3.5	0.50
		Lower Molar		Mandible : -5˚	70	3.5	0.45
		Bitewing		+5˚ ~ +8˚	70	3.5	0.65

Use of equipment and exposure settings designed for an average-sized adult can result in excessive radiation exposure for a smaller patient, especially pediatric. Pediatric patients may be more radio-sensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients. Please use caution when configuring the Portable Dental X-ray System (NP-350E) by considering the patient's age, size, body habitus, and clinical indication when verifying exposure time settings.

For safety for the pediatric patients, In child mode, exposure dose of Portable Dental X-ray (NP-350E) reduced 60% compared to the adults based on the literature.

National DRLs have been typically set at a rounded 75th percentile of the dose distribution. The values presented in Table are proposed as new NDRLs for the UK.

X-ray type	Patient size	Proposed NDRL
Intra oral	Adult mandibular moral	1.2mGy
	Child mandibular moral	0.7mGy

And We got the data using Portable Dental X-ray System (NP-350E). These exposed dose values are more safer than requirements of NDRLs for the UK in adults and children.

Dose Table (70 kVp, 3.5 mA, FOV: Ø 6 cm, SSD 200 mm, at Al 6 mm)	
t (s)	**Dose (μGy)**
0.06	41
0.10	68

0.14	95
0.20	134
0.34	221
0.5	320
0.6	377
0.8	487
1.0	595

Table below is information about used equipment for test.

Test Equipment			
Instrument	Manufacturer	Model	S/N
Dose Meter	Ray-safe	X2 Base Unit	225575

- **Strategy of reduction of X-ray for pediatric patients**

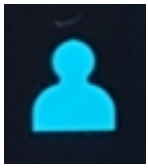
  According to the prior results the change over age and gender for Mandibular Angle Breadth is 3% at maximum. And the BMI which related to body shape have change over age and gender of 6% at maximum.

  Therefore, we simplified the maximum change over gender, age, body shape as 6% and we determined the range for exposure time.

  In case of child, according to NDRL report*, the child to adult DAP ratio at 50th percentile at mandibular molar intra-oral radiograph, panoramic radiograph, CBCT is 0.6, 0.7 and 0.6 respectively. The main purpose of our product (NP-350E) is intra-oral radiograph we choose the ratio 0.6 (60%) of adult for child. In addition, the dose of DR/CR/Film in the mandibular molar region of children was measured as 0.19/0.48/0.59mGy, respectively, and was lower than 0.42/0.48/0.6mGy, which is 60% of the adult value in the 50th percentile in Table 4 of the NDRL report.

- **Child mode**

If you press this button, you can change child mode or adult mode.



If this image appears on the display, it is child mode. In child mode, quantities of exposure dose are reduced to 60% compared to adult mode.

- **Essential Performance**

No	Essential performance	Description
1	Accuracy of LOADING FACTORS	Confirm that Accuracy of LOADING FACTORS according to EN 60601-2-65 203.6.4.3.102
2	Reproducibility of the RADIATION output	Confirm that Reproducibility of the RADIATION output according to EN 60601-2-65 203.6.3.2

- **Intended performance, including the technical performance**

No.	Item	Requirements	Standard
1	Safety	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1
		Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3
		Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	EN 60601-2-65
2	EMC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2
3	Performance	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray	EN 60601-2-65

		equipment	
4	Clinical Performance and Clinical Safety	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	MEDDEV 2.7.1 Rev 4

- **References**

- PHE-CRCE-59: Dose to patients from dental radiographic X-ray imaging procedures in the UK-2017 review, September 2020 Published by Public Health England (PHE)

- X-Rays for Children: What Parents Should Know About Radiation Protection in Medical Imaging by image gently.

- Pediatric Information for X-ray Imaging Device Premarket Notifications, Nov 28, 2017, Publicated by FDA (U.S. Food & Drug Adminiration.

Thank you very much for choosing the NANORAY as your X-ray solution.
We would like to hear your valuable comments, due to your feedback or suggestions are important to us.
If you have opinion, please contact to us on the below email or phone.

We reserve the right to make any alterations which may be required due to technical improvement. For the most current information, contact your NANORAY representative.

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	NANORAY Co., Ltd. **#401,#402,#403,#408,#409, 76, Dongnae-ro, Dong-gu, Daegu, Republic of Korea**
CE 0068	**The CE symbol grants this product compliance to the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.**
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