Owandy RADIOLOGY

EN • USER MANUAL
OWANDY-RX PORTABLE
NOXPEN010A • March 2023

OWANDY-RX PORTABLE

LESS WEIGHT FOR BETTER IMAGES

PORTABLE DENTAL X-RAY SYSTEM

Revision history Manual code NOXPEN010A

Rev.	Date	Page/s	Modification description
0	20.03.2023	-	Document approval

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Contents

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The following advisory symbols are used throughout this manual.
Their application and meaning are described below.

WARNING

Warning symbol used to indicate a potential hazard lead operators, service personnel to serious injury, death or radiation exposure.

CAUTION

Caution symbol used to indicate a potential hazard lead operators, service personnel to injury or damage of equipment.

NOTE

Note symbol used to indicate important information need to proper use and right operation of equipment.

NOTE

KEEP THIS OPERATOR'S MANUAL WITH THE EQUIPMENT AT ALL TIMES, AND REVIEW THE IMPORTANT INFORMATION WHENEVER REQUIRED.
THE STATISTICS AND SPECIFICATIONS OF THIS UNIT AND MANUAL CAN BE MODIFIED WITH OR WITHOUT NOTIFICATION FOR THE IMPROVEMENT OF PERFORMANCE AND SAFETY.

1. INTRODUCTION

The OWANDY-RX PORTABLE, a portable dental X-ray system, operates main powered by a rechargeable Li-ion polymer battery pack. The OWANDY-RX PORTABLE is an X-ray generating device which is mainly designed for dental examination (on teeth, etc.). The OWANDY-RX PORTABLE is composed of X-ray generator with an X-ray tube including device controller, power controller, user interface, beam limiting part, backscatter shielding glass, and optional remote exposure switch. The OWANDY-RX PORTABLE is designed to diagnose teeth and jaw through X-ray irradiation using intra-oral image receptor.

Indications for use / Intended purpose

The OWANDY-RX PORTABLE is a portable dental X-ray system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use OWANDY-RX PORTABLE to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

Side effects

In general, Portable Dental X-ray System is very safe and unlikely to produce side effects. The amount of radiation used is very small, so the risks are minimal. But, young children and a developing fetus carried by a pregnant woman are more sensitive to X-rays and are at greater risk for tissue damage.

Contraindications

- Do not keep the equipment liquids (coffee, beverages, flowers, etc.) or humid place.
- In case of taking X-rays of infants, pregnant women and a pacemaker recipient genital protective gear should be used on the genitalia.
- The distance from the focus to skin should be kept at least 8inch (20cm).

Available the patient population for use

- Gender: no gender restrictions
- Age: no age restrictions
- The patient population for use
    - Adults
    - Pediatric patients

NOTE

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF PHYSICIAN OR WITH THE DESCRIPTIVE DESIGNATION OF ANY OTHER PRACTITIONER LICENSED BY THE LAW OF THE STATE IN WHICH HE PRACTICES TO USE OF ORDER THE USE OF THE DEVICE.

1.1 Components

(1) Component Part
- OWANDY-RX PORTABLE (Main Body)
- Battery Charger
- Cradle
- Wrist Strap
- User Manual

(2) Option
- Remote Exposure Switch
- Backscatter Shield
- Rectangular Cover (FOV 2x3)
- Rectangular Cover (FOV 3x4)

NOTE

THIS MANUAL CONTAINS IMPORTANT SAFETY INFORMATION. AN UNDERSTANDING OF THIS INFORMATION IS CRITICAL TO THE SAFE OPERATION OF YOUR EQUIPMENT. PLEASE ENSURE THAT YOU READ THE WARNING NOTICES BEFORE USING THE EQUIPMENT

NOTE

ASSEMBLY INFORMATION: NO ASSEMBLY IS REQUIRED

2. NOTICE OF GENERAL SAFETY AND SAFE OPERATION

This user's guide is designed to ensure correct use and operation of OWANDY-RX PORTABLE. Please read all the lines thoroughly before you use this equipment.
Incorrect use and operation exceeding described conditions in this manual may occur damage of the machine and shorten its life. Particular attention must be paid to all the warnings, cautions and notes incorporated herein.
This equipment should be used only by the legally qualified persons and practitioners.
OWANDY-RX PORTABLE is designed with the due consideration for users' safety and product reliability. It, however, is advisable to follow under mentioned rules to keep your additional safety and health.

- This product should be operated only by or under the supervision of legally qualified persons.
- OWANDY-RX PORTABLE is designed for the radiographic uses and not for fluoroscopy or other associated applications.
- OWANDY-RX PORTABLE should be used for the diagnosis, not for the therapy.
- Do not modify the equipment at your discretion and in case any modification is required unavoidably, ask the help of OWANDY RADIOLOGY or its authorized dealer for the service.
- This system has been calibrated for optimal operations.

WARNING

NO PROTECTION AGAINST THE INGRESS OF THE LIQUIDS

WARNING

THE OWANDY-RX PORTABLE SHOULD BE CHARGED USING TO SUPPLY THE BATTERY CHARGER FROM OWANDY RADIOLOGY.

WARNING

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO SUPPLY MAINS WITH PROTECTIVE EARTH.

WARNING

THE EQUIPMENT MUST BE INSTALLED, MAINTAINED, AND SERVICED BY QUALIFIED SERVICE PERSONNEL ACCORDING TO THE PROCEDURES AND PREVENTIVE MAINTENANCE SCHEDULES. ONLY BATTERY REPLACEMENT CAN BE PERFORMED BY USERS.

WARNING

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.

WARNING

PROPER USE AND SAFE OPERATING PRACTICES WITH RESPECT TO X-RAY SYSTEMS ARE THE RESPONSIBILITY OF THE USERS OF SUCH X-RAY SYSTEMS.
OWANDY RADIOLOGY PROVIEDS INFORMATION ON ITS PRODUCTS AND ASSOCIATED HAZARDS, BUT ASSUMES NO RESPONSIBILITIES FOR AFTER-SALE POERATING AND SAFETY PRACTICES.
OWANDY RADIOLOGY ACCEPTS NO RESPONSIBILITY FOR ANY GENERATOR NOT MAINTAINED OR SERVICED ACCORDING TO THE SERVICE MANUAL OR ANY X-RAY SYSTEM THAT HAS BEEN MODIFIED IN ANY WAY.
OWANDY RADIOLOGY ALSO ASSUMES NO RESPONSIBILITY FOR X-RAY RADIATION OVEREXPOSURE OF PATIENTS OR PERSONNEL RESULTING FROM POOR OPERATING TECHNIQUES OR PROCEDURS.

WARNING

DO NOT ALLOW OPERATION OF THIS APPARATUS BY ANY PERSON OTHER THAN QUALIFIED PERSONNEL (PHYSICIANS, RADIOTHERAPY ENGINEERS AND CLINICAL XRAY ENGINEERS) OR UNDER OBSERVATION BY THEM.

CAUTION

INCORRECT CONNECTIONS OR USE OF UNAPPROVED EQUIPMENT MAY RESULT IN INJURY OR EQUIPMENT DAMAGE.

CAUTION

DO NOT EXCEED THE TUBE MAXIMUM OPERATING LIMITS SHOWN IN THE X-RAY TUBE DATA SECTION AT THE END OF THE OPERATOR'S MANUAL.
INTENDED LIFE AND RELIABILITY WILL NOT BE OBTAINED UNLESS X-RAY SYSTEMS ARE POERATED WITHIN PUBLISHED SPECIFICATION.

CAUTION

DO NOT CONNECT ANY OTHER ELECTRICAL DEVICE EXCEPT FOLLOWING ELECTRICAL DEVICES.
MEDICAL ELECTRICAL DEVICES WHICH CONFORM TO IEC60601-1
NON-MEDICAL ELECTRICAL DEVICES WHICH CONFORM TO RELATED IEC SAFETY STANDARDS
NON-MEDICAL ELECTRICAL DEVICES WHICH HAVE SAFETY EQUAL TO DEVICES CONFORM TO IEC SAFETY STANDARDS

WARNING

ENSURE THAT THE ON/OFF SWITCH IS SET TO OFF WHEN THE EQUIPMENT IS NOT IN USE.

WARNING

THE BACKSCATTER SHIELD PROTECTS USERS FROM BACKSCATTER RADIATION THAT THEY MIGHT BE EXPOSED DURING X-RAY EXPOSURE. OPERATING THE EQUIPMENT WITH THE BACKSCATTER SHIELD ALLOWS THE USERS TO BE EXPOSED TO LESS RADIATION COMPARED TO WHEN OPERATING WITHOUT.

3. NOTICE OF SAFE BATTERY USE

- Make sure to charge the battery in the external environment from the patient.
- Make sure to use the battery only provided or approved by OWANDY RADIOLOGY. If non-standard or damaged batteries are used, there is a risk of fire and explosion.
- Make sure to use the battery charger only provided or approved by OWANDY RADIOLOGY. Using an unauthorized charger may result in battery damage.
- DO NOT expose batteries to heat or fire. Avoid storage in direct sunlight.
- DO NOT short-circuit, crush, puncture, mutilate, or disassemble the battery.
- DO NOT store batteries haphazardly in a box or drawer where they may short-circuit each other or be shortcircuited by other metal objects.
- Observe the plus (+) and minus (-) marks on the battery and equipment and ensure correct use.
- DO NOT subject batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If the contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- Keep the battery away from children and pets.
- DO NOT make the battery wet or let it be in the water. Keep batteries clean and dry.
- Seek medical advice immediately if a battery has been swallowed.
- Make sure to turn off the device before replacing the battery.

CAUTION

DO NOT REMOVE A BATTERY FROM ITS ORIGINAL PACKAGING UNTIL REQUIRED FOR USE.
DO NOT DISPOSE OF BATTERIES WITH ORDINARY TRASH. TURN IN DISCHARGED BATTERIES TO LOCAL SUPPLY OR DISCARD OR RECYCLE BATTERIES ACCORDING TO YOUR LOCAL GOVERNMENT REGULATIONS.

NOTE

DO NOT LEAVE A BATTERY ON PROLONGED CHARGE WHEN NOT IN USE.
IF THE EQUIPMENT HAS NOT BEEN USED FOR LONG PERIODS OF TIME, IT IS RECOMMENDED TO CHARGE THE BATTERY BEFORE USE.
AFTER EXTENDED PERIODS OF STORAGE, IT MAY BE NECESSARY TO CHARGE AND DISCHARGE THE CELLS OR BATTERIES SEVERAL TIMES TO OBTAIN MAXIMUM PERFORMANCE.

NOTE

IF THE EQUIPMENT NOT IN USE HAS BEEN TURNED ON FOR LONG PERIODS OF TIME, THE BATTERY MAY BE FULLY DISCHARGED.
DEPENDING UPON THE BATTERY DISCHARGE STATUS, IT TAKES ABOUT 1 DAY FOR CHARGING THE BATTERY. IF THE DEVICE IS NOT TURNED ON AFTER CHARGING THE BATTERY FOR ABOUT 1 DAY, IT INDICATES THAT THE BATTERY HAS BEEN FULLY DISCHARGED. CONTACT YOUR SERVICE REPRESENTATIVE FOR BATTERY REPLACEMENT.
DO NOT CHARGE A FULLY DISCHARGED BATTERY, AS THIS MAY CAUSE FIRE OR EXPLOSION. BE SURE TO REPLACE THE BATTERY (PROVIDED BY OWANDY RADIOLOGY).

NOTE

BATTERIES CAN BE REPLACED BY USERS.
WHEN CHARGING THE BATTERY, THE EXPOSURE FUNCTION IS LOCKED.
BE SURE TO TURN OFF THE EQUIPMENT WHEN NOT IN USE. THIS HELPS TO ENSURE THE LIFE OF THE BATTERY.

4. RADIATION SAFETY

- Users and operators should wear appropriate protecting devices and clothes.
- Stay distance from the radiant sources and all the possible secondary radiation zones.
- Eliminate all unnecessary objects near the exposure zones.
- The distance from the focus to skin should be kept at least 8 inch (20cm).
- For the experimental uses, apply the lowest possible values of kV and exposure time (sec).
- Be careful not to exceed the limited radiograms in the exposure area.
- The contraindications for pregnant patient or children to avoid unnecessary ionizing radiation exposure.

CAUTION

THE IONIZING RADIATION COULD BE DANGEROUS FOR PATIENTS AND OPERATORS UNLESS FOLLOWING SAFETY REGULATIONS ARE STRICTLY OBSERVED.

WARNING

THIS EQUIPMENT MUST BE OPERATED ONLY BY PROPERLY TRAINED, FULLY QUALIFIED PERSONNEL IN A CONTROLLED ENVIRONMENT.

NOTE

WHEN SELECTING A POSITION INDICATING DEVICE, IT SHOULD BE CONSIDERED IF THE PID CAN BE USED WITH THE BACKSCATTER SHIELD ATTACHED AT THE OUTER END OF THE CONE FOR MOST OPERATOR PROTECTION.
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.

5. SAFETY AND SPECIFICATIONS

5.1 Safety and warning symbols

MARK / SYMBOL	DESCRIPTION	LOCATION
	High voltage symbol	X-ray Generator Label
	Radiation hazard	X-ray Generator Label
	Refer to the accompanying documentation for details.	Main Label
	Alternate current	Cradle Label
	Direct current	Main Label, Cradle Label
	Model Name	Main Label, Cradle Label, X-ray Generator Label
	Manufacturer's name and address	Main Label, Cradle Label, X-ray Generator Label
	Date of manufacture	Main Label, Cradle Label, X-ray Generator Label
EC REP	Authorized European Representative address	Main Label
CE 0123	Portable Dental X-ray System (OWANDY-RX PORTABLE) is classified as class IIb according to the Regulation (EU) 2017/745 Annex VIII Rule 10.	Main Label
	Refer to user manual	Main Label
	This symbol indicates that electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.	Main Label
	IEC60601-1 Degree of Protection from Electric Shock TYPE B Equipment	Main Label
SN	Serial number	Cradle Label, X-ray Generator Label

X-ray radiation exposure may be damaging to health, with some effects being cumulative and extending over period of many months or even years. ***X-ray operators should avoid any exposure to the primary beam*** and take protective measures to safeguard against scatter radiation. Scatter radiation is caused by any object in the path of the primary beam and may be of equal or less intensity than the primary beam that exposes the film.
No practical design can incorporate complete protection for operators or service personnel who do not take adequate safety precautions. ***Service and operating personnel only authorized and properly trained by OWANDY RADIOLOGY should be allowed to work with this X-ray system equipment.*** The appropriate personnel must be made aware of the inherent dangers associated with the servicing of high voltage equipment and the danger of excessive exposure to X-ray radiation during system operation.

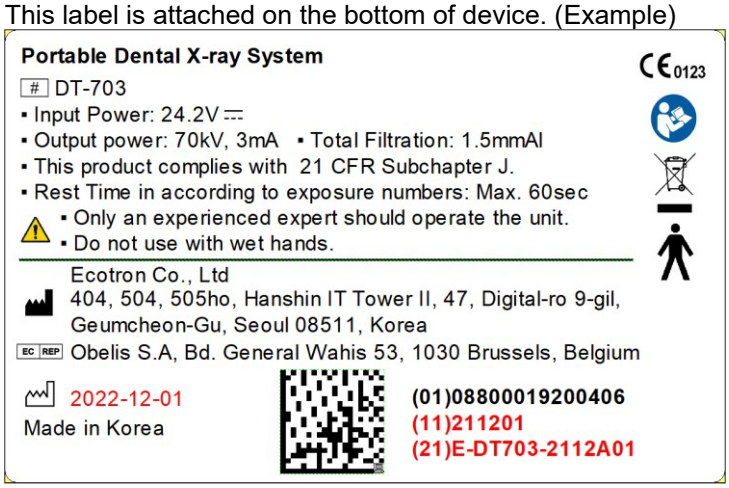
- Wear protective clothing. Protective aprons and gloves with an equivalent of a minimum of 1/64" (0.35mm) of lead are recommended.
- To protect the patient against radiation, always use radiation protection accessories in addition to devices which are fitted to the X-ray system.
- Keep as large a distance as possible away from the object being exposed and the X-ray tube assembly.
- Never operate this X-ray system in areas where there is a risk of explosion. Detergents and disinfectants, including those used on patients, may create explosive mixtures of gases. Please observe the relevant regulations.
- Do not keep the equipment liquids (coffee, beverages, flowers, etc.) or humid place.
- Do not operate the x-ray system in direct sunlight or near any heat sources.
- Do not operate the x-ray system near strong magnetic fields (microwave ovens, speakers, etc.), and avoid routing the x-ray system near these devices.
- The x-ray system must be operated in locations that are clean (free of excess dust, dirt, debris, etc.), stable (free of vibration).
- Only trained maintenance staff may remove the covers of the x-ray system.
- Contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

5.2 Composition label

5.2.1 Label locations

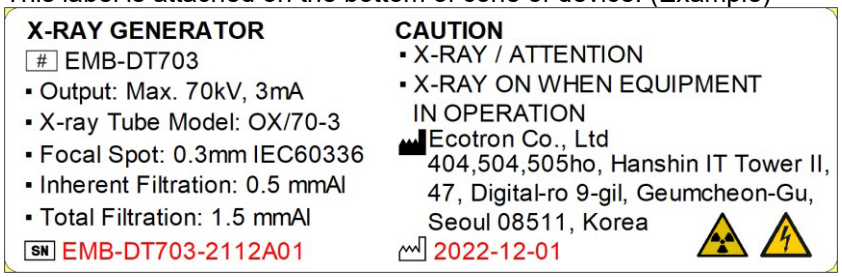
MAIN LABEL

This label is attached on the bottom of device. (Example)



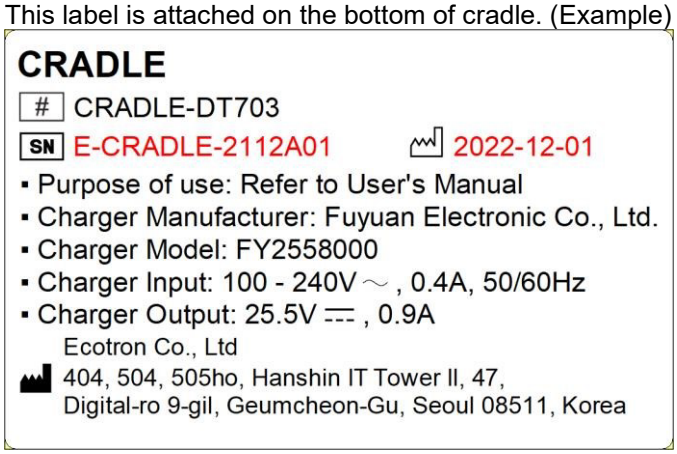
X-RAY GENERATOR LABEL

This label is attached on the bottom of cone of device. (Example)

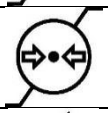


CRADLE LABEL

This label is attached on the bottom of cradle. (Example)



5.2.2 Symbols on the packing of portable dental x-ray system

SYMBOL	DESCRIPTION
	Temperature limitation
	Humidity iimitation
	Atmospheric pressure limitation
	Keep dry
	Fragile, handle with care
	This side up
	Recycle

5.3 Applicable standards and regulation

The OWANDY-RX PORTABLE complies with the regulatory requirements and design standards in this section as follows:
This product complies with 21 CFR Subchapter J.

1) SAFETY
- IEC/EN 60601-1
- IEC/EN 60601-1-3
- IEC/EN 60601-1-6
- IEC/EN 60601-2-65

2) EMC
- IEC/EN60601-1-2:2014

3) OTHERS

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021))
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
MEDDEV 2.7.1/Rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
MEDDEV 2.12.1/Rev.8	Medical Devices Vigilance System
MEDDEV 2.12.2/Rev.2	Post Market Clinical Follow-up studies
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-7	Guidance on PMCF Plan Template
MDCG 2020-8	Guidance on PMCF Evaluation Report Template

5.4 Specification

5.4.1 Classification of the device

CLASSIFICATION – EN 60601-1
- Type of protection against short circuit: Internally powered ME equipment
- Degree of protection against direct and indirect contact: TYPE B
- Degree of protection against ingress of water and particulate matter: IPX0
- Use conditions: continuous working with intermittent load
- The products have not been evaluated for use in the presence of flammable anaesthetic mixture with air or nitrous oxide

CLASSIFICATION – Regulation (EU) 2017/745
- In according with Annex VIII Rule 10: CLASS IIb

5.4.2 Technical specification

5.4.2.1 Portable Dental X-ray System (OWANDY-RX PORTABLE) Specification

Tube Voltage [kV]		70 kV (fixed)
Tube Current [mA]		3 mA (fixed)
Exposure Time [sec]		0.02 – 0.5 sec
Max. kV Deviation		-5 %
Max. mA Deviation		±5 %
X-ray Tube	Model Name	OX/70-3 (C.E.I)
	Focal Spot	0.3 mm
	Target Angle	13°
	Anode Heat Storage	7 kJ
	Inherent Filtration	0.5 mm Al
	X-ray Coverage	SID 200 mm
Total Filtration		1.5 mm Al
Weight		1.6 kg

Cooling Time Chart
Cooling time in according to exposure numbers: Max. 60 sec

5.4.2.2 Power Specification

Power	Battery Type	Li-polymer		
	Battery Voltage [Vdc]	24.2 V (Normal)	25.2 V (Max)	22.2 V[Min]
	Battery Current [A]	20 A (max)		
	Charging Method	Using cradle (with battery charger)		
	Charger Max. Voltage [Vdc]	25.4 V		
	Charger Current [A]	0.9 A		

NOTE

THE BATTERY IS CONSUMABLE, SO PERIODIC REPLACEMENT (EVER 6 MONTHS) IS RECOMMENDED. (BATTERY WARRANTY PERIOD: 6 MONTHS)

WARNING

MAKE SURE TO USE THE BATTERY ONLY PROVIDED OR APPROVED BY OWANDY RADIOLOGY. USING AN UNAUTHORIZED BATTERY MAY RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE. FOR DETAILS ON USING THE BATTERY, SEE '3. **NOTICE OF SAFE BATTERY USE'** ***ON PAGE 12***

5.4.2.3 Battery Charger Specification

Rating	Input: 100 – 240 V~, 50/60 Hz, 0.4 A
	Output: 25.4Vdc, 0.9A
Frequency	50 – 60 Hz
Standard	IEC 60950-1 (UL)

WARNING

MAKE SURE TO USE THE BATTERY CHARGER ONLY PROVIDED OR APPROVED BY OWANDY RADIOLOGY. USING AN UNAUTHORIZED BATTERY MAY RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE. FOR DETAILS ON USING THE BATTERY, SEE '3. NOTICE OF SAFE BATTERY USE' ON PAGE 12.

NOTE

POWER SUPPLY IS SPECIFIED AS A PART OF ME EQUIPMENT.
POWER PLUGS MAY HAVE VARIOUS SPECIFICATIONS FOR EACH COUNTRY

5.4.2.4 Environment Specification

Operation Environment

Temperature range	10°C - 40 °C (50 °F - 104 °F)
Relative Humidity Range	30% - 75%
Relative Atmospheric Pressure	860 – 1060 hPa

Storage and Transportation Environment

Temperature range	-10°C - 60 °C (14 °F - 140 °F)
Relative Humidity Range	10% - 75% (non-condensing)
Relative Atmospheric Pressure	500 – 1100 hPa

WARNING

FAILURE TO FOLLOW THE SPECIFICATIONS ABOVE CAN RESULT IN SERIOUS INJURY AND EQUIPMENT DAMAGE.

5.4.3 Dosimetry data

The X-ray dose data is extracted from the X-ray Dose Test Report for the OWANDY-RX PORTABLE. The X-ray dose of the DT703 in the test report were measured in accordance with the IEC collateral standards. The OWANDY-RX PORTABLE was designed in accordance with IEC 60601-1-3.

5.4.3.1 X-ray dose table

TEST CONDITION	
Model Name	OWANDY-RX PORTABLE
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Dose Meter)	Piranha R/F 557 (CB2-21030636)

DOSE TABLE (70 kV, 3 mA, 0.5 sec, FOV: Ø 60 mm, SSD 200 mm)	
Exposure Time	Dose (µGy)
0.02	53.09
0.05	141.55
0.1	289.46
0.15	437.20
0.2	584.61
0.25	732.48
0.3	879.63
0.4	1176.71
0.5	1471.88

5.4.3.2 Leakage dose

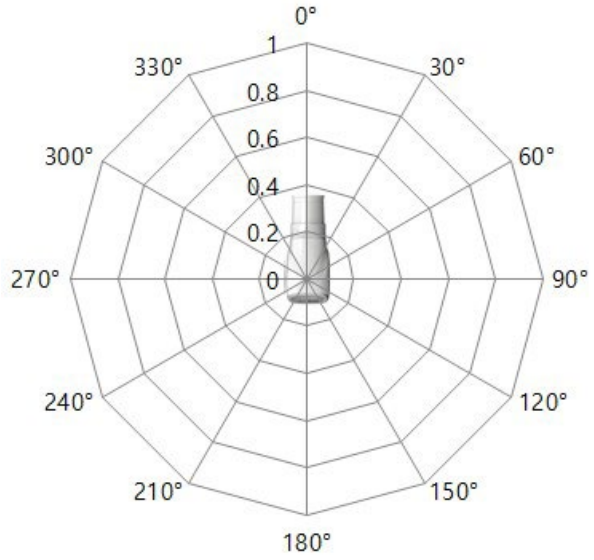
SCOPE
IEC 60601-1-65 203.12.4

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 an 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.

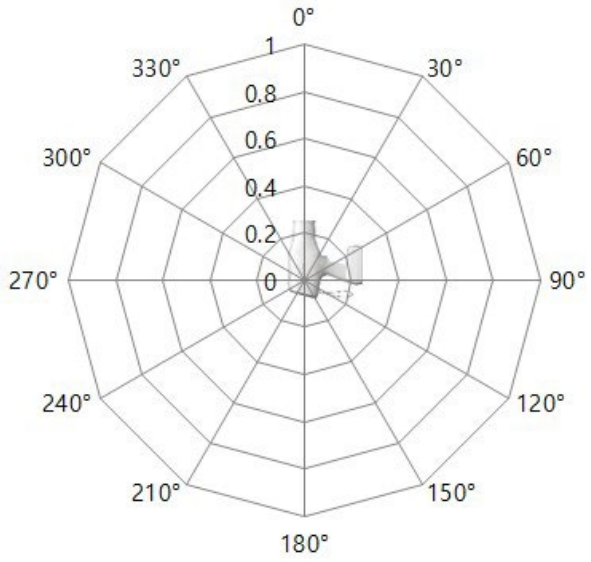
LEAKAGE DOSE	PERMISSIVE RANAGE
70 kV, 3 mA, 0.5sec (Max. Exposure Condition) At Focal Spot to Distance 1m 1 : 30 Duty Cycle	< 0.25 mGy/h

TEST CONDITION	
Model Name	OWANDY-RX PORTABLE
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Radiation Dosimeter)	RTI Scatter Probe (SP1-2111015)

RESULTS
The following exposure timetables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inches) respectively. When the leakage doses have been measured with each cover type (default, rectangular 2x3, and rectangular 3x4). The raw data about the results are shown in the table below.

THE RESULT (HORIZONTAL PLANE)


Direction	Default type	Rectangular (2x3)	Rectangular (3x4)
	mGy/h	mGy/h	mGy/h
0°	0.000472	0.000462	0.000466
30°	0.004485	0.004476	0.004477
60°	0.00177	0.00174	0.00175
90°	0.002007	0.002	0.002002
120°	0.001888	0.001881	0.001884
150°	0.001062	0.00106	0.001061
180°	0.001062	0.00106	0.001061
210°	0.001062	0.001061	0.001062
240°	0.000708	0.000701	0.000703
270°	0.000826	0.000823	0.000824
300°	0.000944	0.000939	0.000942
330°	0.007554	0.00755	0.007553

THE RESULT (VERTICAL PLANE)


Direction	Default type	Rectangular (2x3)	Rectangular (3x4)
	mGy/h	mGy/h	mGy/h
0°	0.000828	0.000822	0.000824
30°	0.000946	0.000943	0.000944
60°	0.00071	0.000695	0.0007
90°	0.00071	0.000695	0.000699
120°	0.000355	0.000351	0.000354
150°	0.000592	0.00059	0.000591
180°	0.001065	0.001059	0.001062
210°	0.001893	0.001891	0.001892
240°	0.001183	0.00189	0.001892
270°	0.001301	0.0013	0.001301
300°	0.001538	0.001533	0.001534
330°	0.014314	0.014305	0.014309

5.4.3.3 Scattered dose

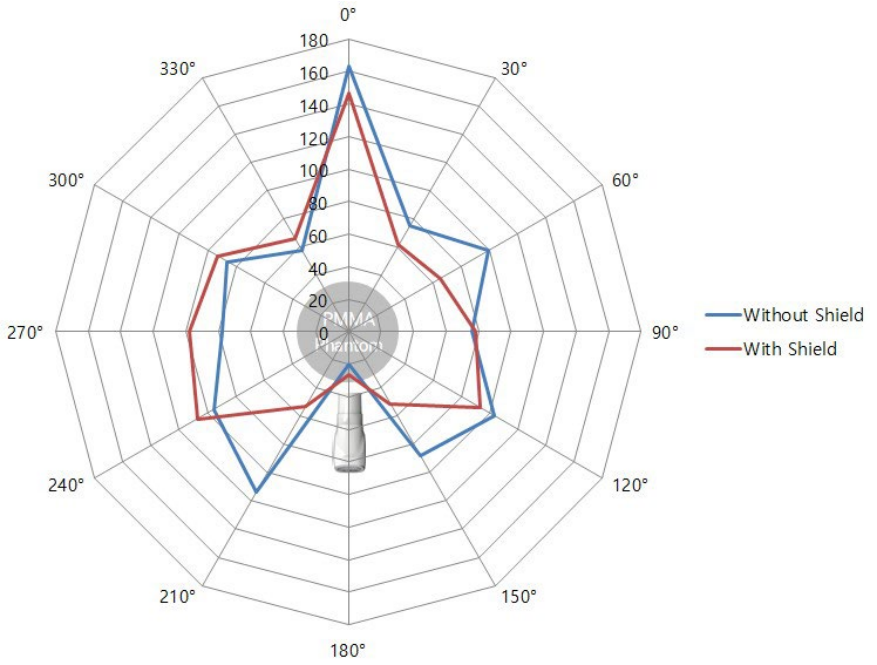
SCOPE
IEC 60601-1-65 203.13

REQUIREMENTS
ME EQUIPMENT shall be provided with means to optionally allow actuation of the EXPOSURE from a PROTECTED AREA after installation.
Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

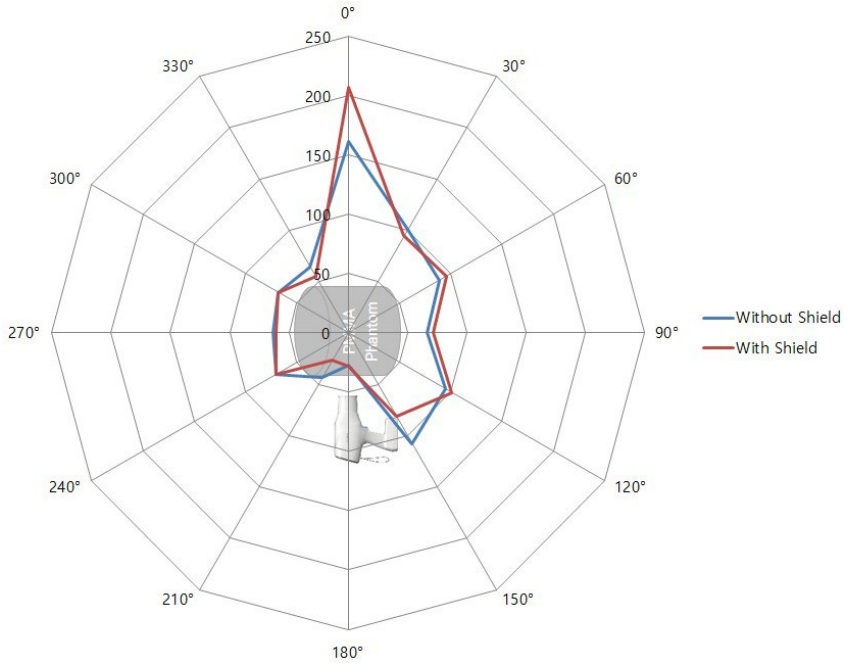
SCOPE
The following exposure timetables were established with a unit equipped with a cone that corresponds to a focus-to-skin distance of 200 mm (8 inches) respectively.

TEST CONDITION	
Model Name	OWANDY-RX PORTABLE
X-Ray Generator Model Name	EMB-DT703 (X-ray Tube: OX/70-3)
Loading Factor	70 kV, 3 mA, 0.5sec
Measuring Equipment (Radiation Dosimeter)	RTI Scatter Probe (SP1-2111015)
Phantom	PMMA Phantom

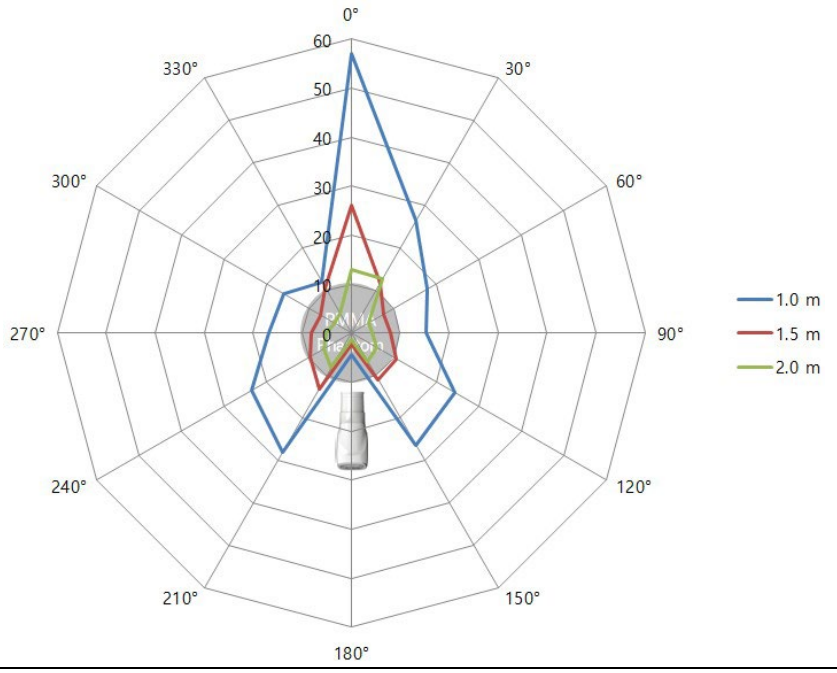
MEASURED METHOD 1		
PMMA Phantom aligned to 280 mm away from Focal Spot Max. Exposure Condition Measure point: 500 mm from PMMA Phantom		
DIRCTION	**RESULT (HORIZONTAL PLANE) [µR]**	
	WITHOUT SHIELD	**WITH SHIELD**
0°	163.4	146.5
30°	75.53	61.5
60°	99.61	65.51
90°	75.99	77.93
120°	103.9	93.56
150°	88.31	51.46
180°	19.74	26.81
210°	114.1	53.28
240°	95.5	107.0
270°	77.82	97.44
300°	86.15	93.11
330°	57.39	66.41



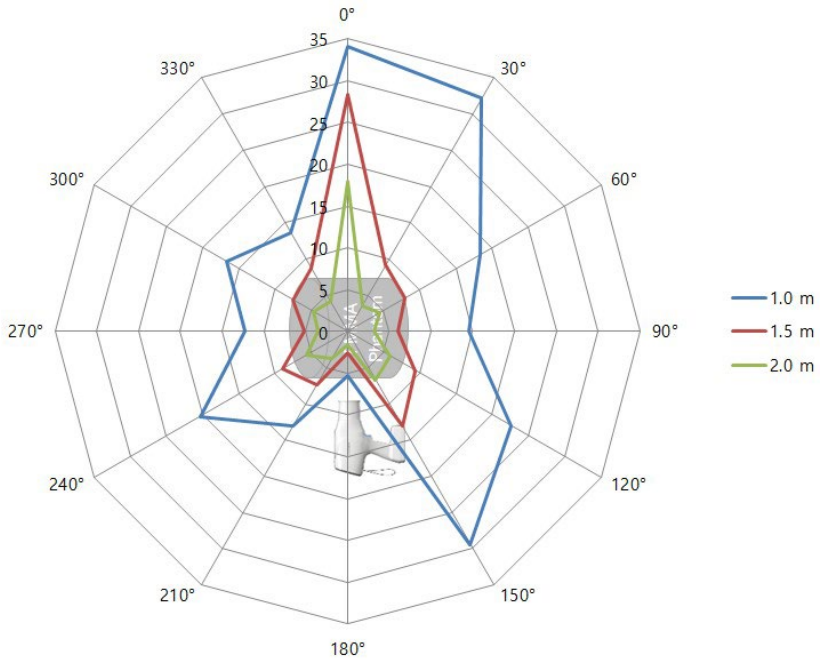
MEASURED METHOD 1		
PMMA Phantom aligned to 280 mm away from Focal Spot Max. Exposure Condition Measure point: 500 mm from PMMA Phantom		
DIRCTION	**RESULT (VERTICAL PLANE) [µR]**	
	WITHOUT SHIELD	**WITH SHIELD**
0°	161.7	207.0
30°	100.5	94.36
60°	89.23	95.62
90°	66.63	71.88
120°	94.47	101.2
150°	107.7	81.47
180°	27.16	27.73
210°	43.36	26.93
240°	70.4	70.51
270°	63.21	60.7
300°	68.23	68.12
330°	64.35	54.54



MEASURED METHOD 2			
PMMA Phantom aligned to 280 mm away from Focal Spot Max. Exposure Condition Measure point: 1.0, 1.5, 2.0 m from PMMA Phantom			
DIRCTION	**RESULT (HORIZONTAL PLANE) [µR]**		
	1.0 m	**1.5 m**	**2.0 m**
0°	57.05	26.13	12.89
30°	26.47	11.64	12.78
60°	17.80	7.759	4.222
90°	15.40	8.101	4.222
120°	24.42	10.61	6.047
150°	26.36	10.95	6.618
180°	4.45	2.282	1.369
210°	28.07	13.12	8.101
240°	23.39	9.584	6.275
270°	16.89	8.215	5.02
300°	15.86	7.302	4.108
330°	11.98	10.61	4.564

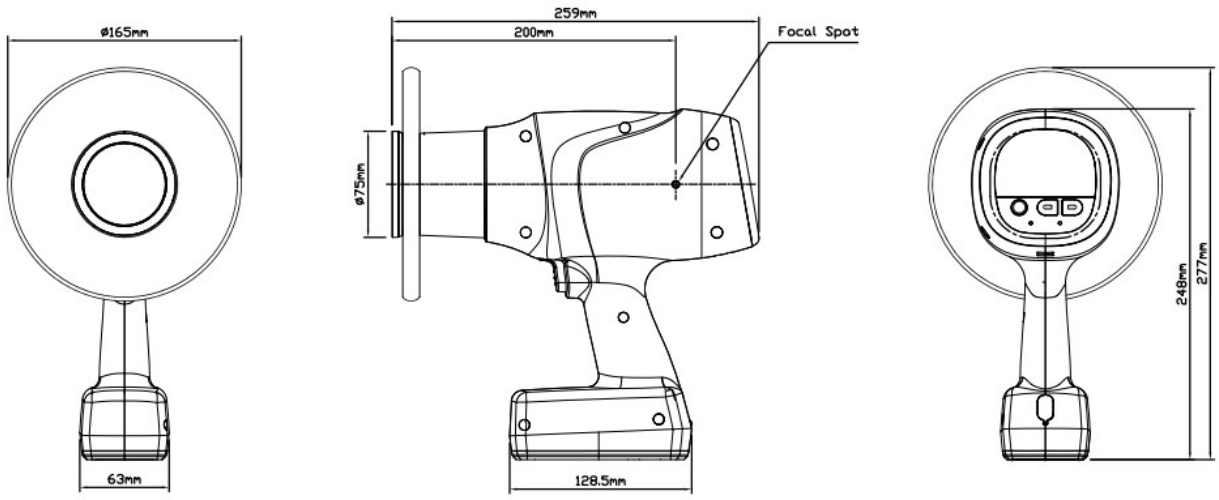


MEASURED METHOD 2			
PMMA Phantom aligned to 280 mm away from Focal Spot Max. Exposure Condition Measure point: 1.0, 1.5, 2.0 m from PMMA Phantom			
DIRCTION	**RESULT (VERTICAL PLANE) [µR]**		
	1.0 m	**1.5 m**	**2.0 m**
0°	34.12	28.3	17.91
30°	32.18	9.128	3.537
60°	18.37	7.987	4.450
90°	14.49	6.047	3.195
120°	22.59	9.356	5.933
150°	29.44	13.12	6.732
180°	5.249	2.624	1.597
210°	13.12	7.302	3.765
240°	20.31	9.014	5.59
270°	12.32	5.134	3.537
300°	16.66	7.531	4.678
330°	13.58	8.672	4.108



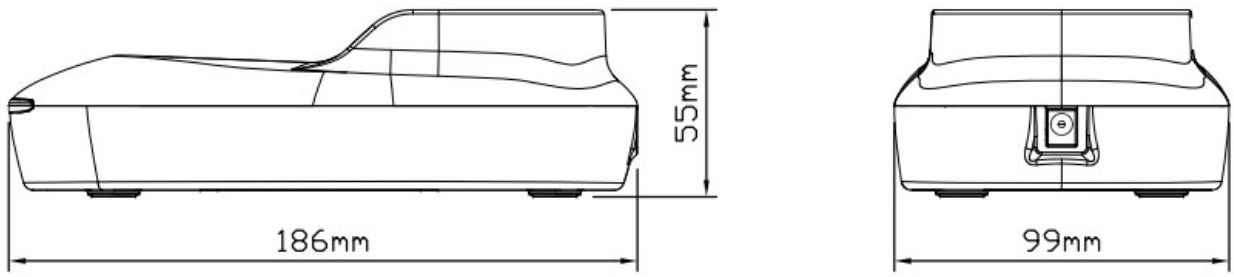
Mechanical specification

OWANDY-RX PORTABLE Dimension (unit: mm)



ITEM			DESCRIPTION
Main Body	Dimension [mm]		259 (L) x 277 (H) x Ø 165
	Weight [kg]		1.6 kg
X-ray Beam Limiting Device	X-ray Beam Area [mm]	Round Type	FOV: Ø 60
		Rectangular Type	FOV: 20 x 30, 40, 30
	SSD (Source to Skin Distance) [mm]		200

Cradle Dimension (unit: mm)



6. SYSTEM FEATURES

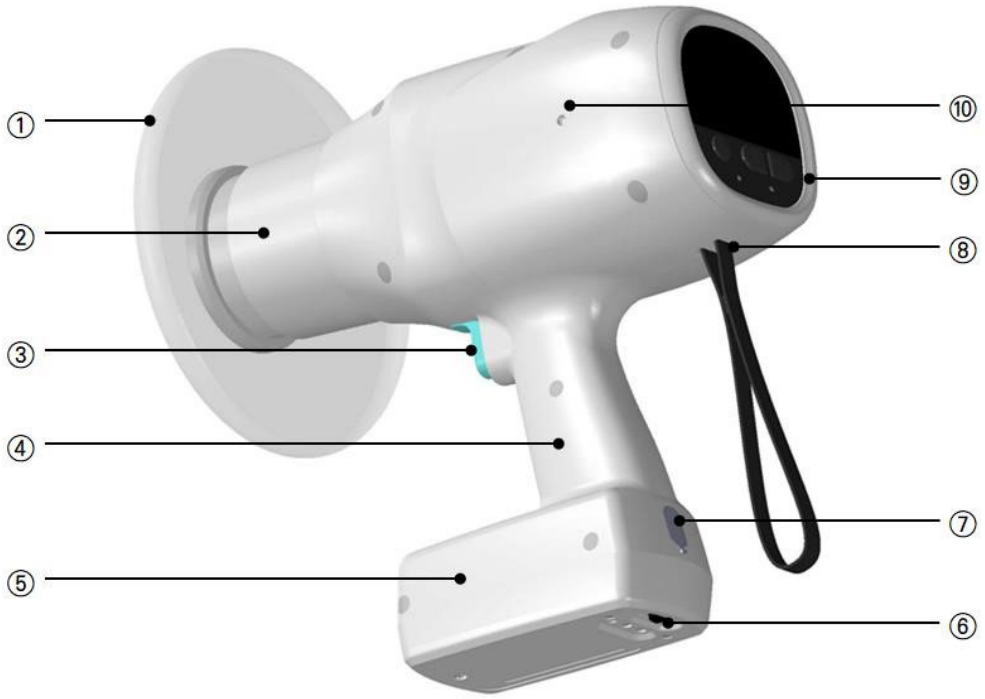
Portable Dental X-ray System (OWANDY-RX PORTABLE) is a radiological device for professional radiologist uses. It should be applied for the radiographic diagnosis and operated by qualified practitioners. Users have to comply with safety and health regulations concerning the ionizing radiation protection and the electrical and mechanical safety of the medical devices.

The OWANDY-RX PORTABLE is an intra-oral portable X-ray system that offers safety, reliability, and greater functionality:

- Lightweight and ergonomic design
- Convenience of cordless design by using battery pack
- Micro-computer and a specialized circuit that FND LCD and precisely regulates the exposure technique factors (kV, mA, and exposure time)
- Pre-programmed exposure time makes the operation fast and easy
- Failure prevention of equipment by applying cooling time technology
- Best-in-class X-ray irradiation number

6.1 General view of equipment

6.1.1 Main body



No.	ITEM	DESCRIPTION
1	Backscatter Shield	Shields from the backscattering radiation
2	X-ray Beam Limiting Device	Limits the X-ray exposure area. (FOV: Ø 60 mm)
3	X-ray Exposure Button	Press the button for X-ray exposure
4	Device Handle	Grip the handle securely when using the system
5	Battery	Rechargeable Li-polymer battery
6	Power Switch	Power On / Off switch
7	Remote X-ray Exposure Switch Port	Connect the X-ray exposure switch cable. (and can be used as a service port)
8	Strap Loop	Connect the strap
9	Control Panel	Display for the X-ray exposure settings and operation conditions
10	X-ray Generator	Includes the Mono Block (X-ray tube + high-voltage generator)

6.1.2 Control panel

No.	ITEM	DESCRIPTION
1	Sensor Mode Selection	Select the Sensor mode: DR, CR, Film
2	Battery Charging & Level	Indicates battery charging & battery remaining level
3	X-ray ready Indicator	Indicates X-ray irradiation ready status
4	X-ray Exposure Indicator	Indicates during X-ray irradiation status
5	X-ray Exposure Time	• Display the X-ray exposure time • Display an error & warning code, cooling time, low battery etc.
6	Patient Type Selection	Select adult (Big), adult (normal) or Child
7	Tooth Type Selection	Select the tooth type (incisor, canine, molar/premolar or bitewing)
8	Enter Button	Enter
9	L & R Adjustment and Movement	Move left or right for menu (or mode) selection
10	Exposure Button Rock Indicator	Indicates the X-ray irradiation button is locked
11	User Option Setting Indicator	Indicates that user have entered the user option settings menu.

6.1.3 Cradle

No.	ITEM	DESCRIPTION
1	Charging Indicator	Blue: Charging Green: Charging full or wait
2	Battery Charger Port	Connect the battery charger

6.2 Operation

6.2.1 Power ON/OFF

① Turn on the system referring to the following figure.

② The following displays and indicators light up:
- Sensor mode display
- Battery charging & level display
- X-ray exposure time display
- Patient type display
- Tooth type display

③ Make sure that at least one battery indicator light before operation.

Battery Level I

NOTE

WHEN THE BATTERY INDICATOR HAS FLICKERING LIGHTNING SIGN AND DISPLAYS "LBT", CHARGE THE BATTERY IMMEDIATELY BY USING THE BATTERY CHARGER.

6.2.2 Operation mode

6.2.2.1 Sensor selection

Press the Enter Button to get into the sensor mode and you can see the sensor mode area flickers. Use the Left & Right Key to select the desired sensor mode and press the Enter Key.

No.	SENSOR MODE	ICON
1	DR (Digital Radiography)	DR
2	CR (Computed Radiography)	CR
3	FM (Film)	FM

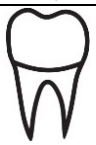
6.2.2.2 Patient type

Press the Enter Button to get into the patient type and you can see the patient type area flickers. Use the Left & Right Key to select the desired patient type and press the Enter Key.

No.	SENSOR MODE	ICON
1	Adult (Big)	
2	Adult (Normal)	
3	Child	

6.2.2.3 Tooth type

Press the Enter Button to get into the tooth type and you can see the tooth type area flickers.
Use the Left & Right Key to select the desired tooth type and press the Enter Key.

No.	SENSOR MODE	ICON
1	Incisor	
2	Canine	
3	Molar / Premolar	
4	Bitewing	

6.2.2.4 X-ray exposure time

Press the Enter Button to get into the X-ray exposure time and you can see the X-ray exposure time area flickers. Use the Left & Right Key to adjust the desired the X-ray exposure time and press the Enter Key.

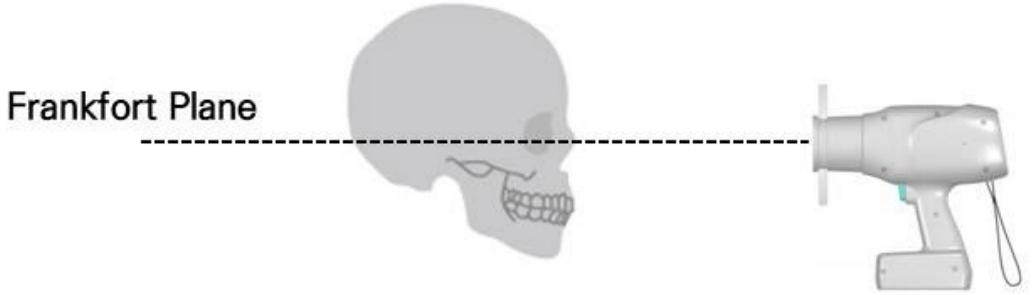
The X-ray exposure time can be set in the range of 0.02 to 0.5 sec and adjustment by 0.01 sec step.

6.2.3 Positioning the patient

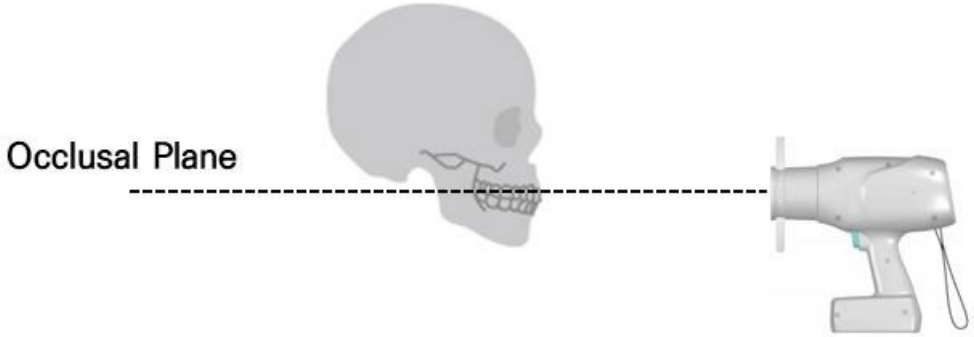
In order to obtain a high-quality intra-oral radiography image, aligning positioning the patient, the portable dental X-ray system and the intra-oral sensor shall be done exactly as directed in the entire exposure process.

① To recommend that the patient wears the lead apron for protecting from residual radiation.
② Seat the patient in a chair and make the sagittal plane of his or her head perpendicular to the X-ray exposure.

- For maxillary radiography, it shall be level with the frankfort plane.



- For mandibular radiography, it shall be level with the occlusal plane.



③ Place the cone of the portable dental x-ray system head in the area want to take an image. When holding the device, it is recommended to grip the handle by one hand and place the other on the underside of the Exposure Button and the cone as shown in the following figure.

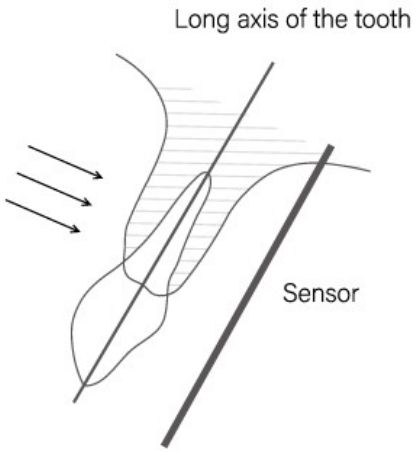
NOTE

DEPENDING ON THE IMAGING ANGLES, EXPOSURE TIMES VARY. SINCE IT IS NECESSARY TO KEEP THE PATIENT WITH LOW X-RAY DOSES AND THE USER IN THE PROTECTED AREA, HAVE THE PATIENT'S HEAD SLIGHTLY TILTED, AND RAISE OR LOWER THE CHIN IF NEEDED. PLEASE REFER TO '2. NOTICE OF GENERAL SAFETY AND SAFE OPERATION', '3. NOTICE OF SAFE BATTERY USE' AND '4. RADIATION SAFETY'.

6.2.4 Positioning instructions

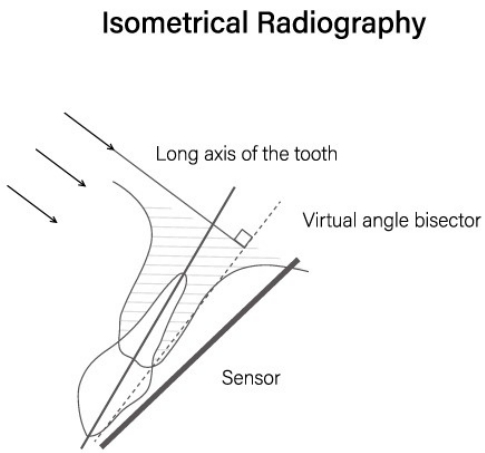
6.2.4.1 Parallel radiography

The sensor is placed parallel to the long axis of the tooth using a support.



6.2.4.2 Isometrical radiography

The patient supports the sensor with his or her finger, and then it vertically irradiates a central ray to a virtual angle bisector, a line that divides the angle between the long axis of the tooth and the sensor in half.



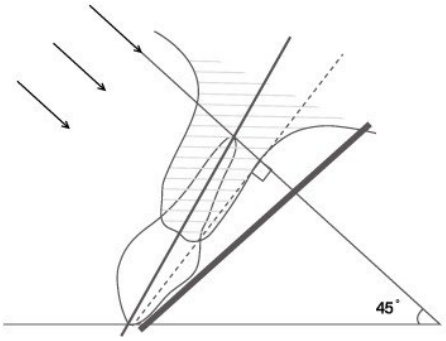
The following explains how to orient the angle to obtain the best-possible image from a particular tooth (in an isometrical radiography for instance).

CAUTION

WHEN PLACING THE SENSOR IN THE ORAL CAVITY, BE CAREFUL NOT TO DAMAGE THE SOFT TISSUES SUCH AS GUMS IN THE PATIENT'S MOUTH.

6.2.4.3 Maxillary incisor

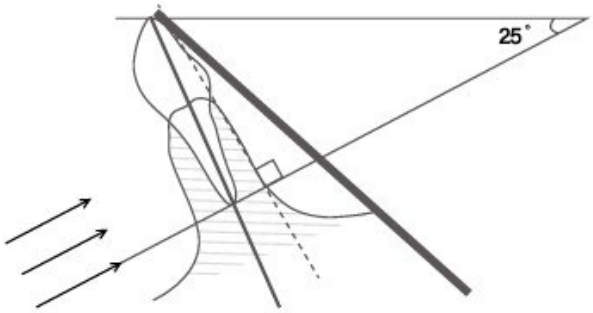
The x-ray beam is directed downward at 45°.



TEETH		ANGLE OF INCLINATION
Incisor	Maxilla	+45°

6.2.4.4 Mandibular incisor

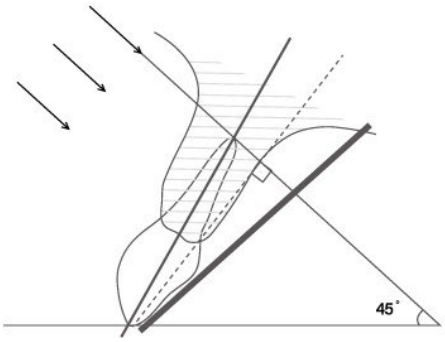
The x-ray beam is directed upward at 25°.



TEETH		ANGLE OF INCLINATION
Incisor	Mandible	-25°

6.2.4.5 Maxillary canine

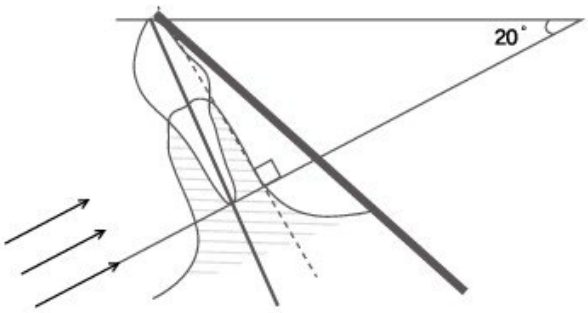
The x-ray beam is directed downward at 45°.



TEETH		ANGLE OF INCLINATION
Canine	Maxilla	+45°

6.2.4.6 Mandibular canine

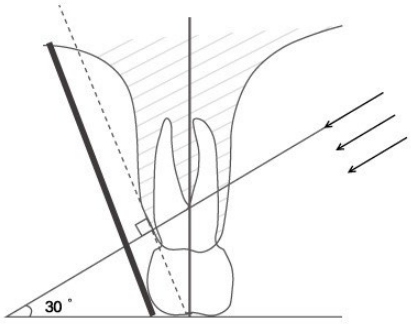
The x-ray beam is directed upward at 20°.



TEETH		ANGLE OF INCLINATION
Canine	Mandible	-20°

6.2.4.7 Maxillary molar and premolar

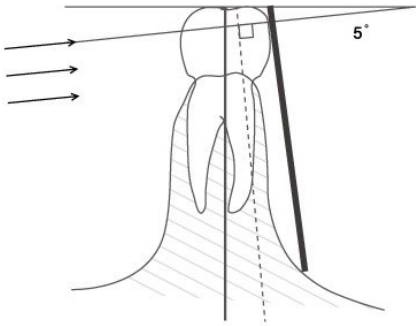
The x-ray beam is directed downward at 30°.



TEETH		ANGLE OF INCLINATION
Molar and Premolar	Maxilla	+30°

6.2.4.8 mandibular molar and premolar

The x-ray beam is directed upward at 5°.



TEETH		ANGLE OF INCLINATION
Molar and Premolar	Mandible	-5°

6.2.4.9 Bitewings

For a bitewing exposure, the patient closes their teeth during exposure on the sensor holder. The x-ray beam is directed downward at +5° - +8°.

TEETH	ANGLE OF INCLINATION
Bitewing exposure	+5° - +8°

6.2.4.10 Positioning the imaging sensor

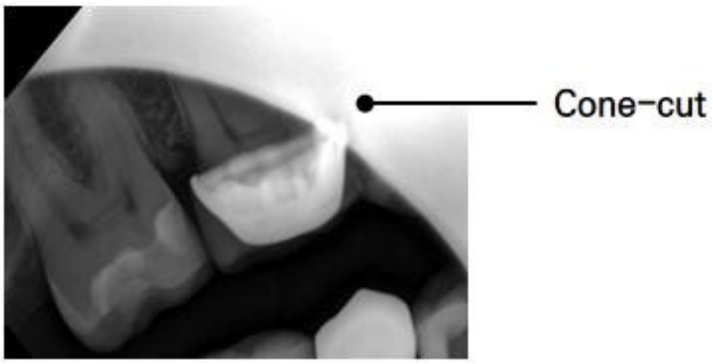
To ensure image quality, the digital imaging sensor must be positioned properly (for information about the proper placement of the imaging sensor, please refer to '6.2.4 Positioning Instructions' on page 38.

- Failure to position the imaging sensor properly can result in errors on the radiograph, such as distorted teeth and roots, elongation, magnification, and overlapping contacts.

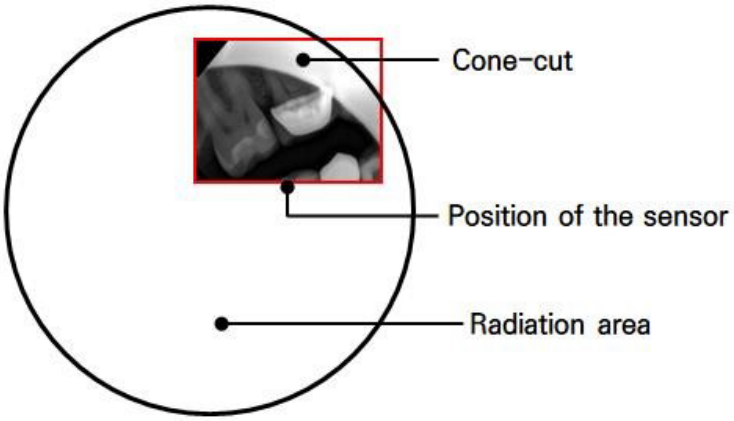
NOTE

THE PARALLELING TECHNIQUE GENERALLY REDUCES THE RISK OF SUCH ERRORS, BUT IF POSITION THE SENSOR IMPROPERLY, ANGULATION ERRORS MAY OCCUR (ANGULATION OF THE SENSOR TO THE TOOTH ITSELF).

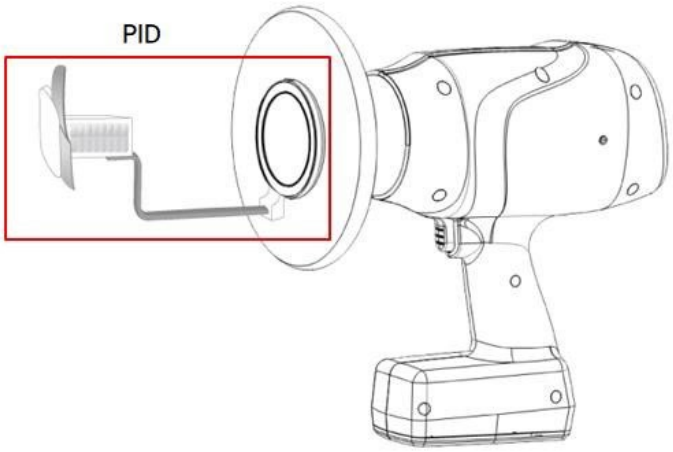
- Failure to align the imaging sensor with the exit pattern of the X-ray beam can result in cone-cuts on the radiograph. The cone-cuts are clear areas that are shown on the radiograph when part of the radiograph is not exposed to radiation. Please refer to the following figure as an example of cone-cuts.



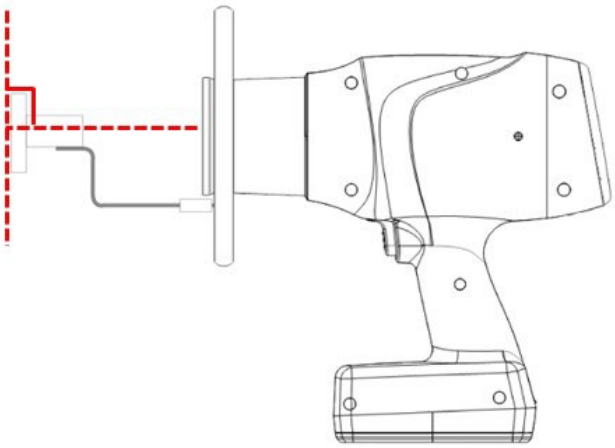
The following figure indicates how the cone-cut occurred by showing the position of the imaging sensor and the radiation area.



To ensure proper alignment between the imaging sensor and the X-ray beam, it is recommended to use a PID (Position Indicating Device) as shown in the following figure.



When using the PID, the exit pattern of the X-ray device should be aligned perpendicular to the target receptor as shown in the following figure.



NOTE

ONCE THE PID IS PROPERLY ALIGNED, INSTRUCT THE PATIENT NOT TO MOVE

6.2.5 X-ray exposure

NOTE

THE OPERATOR MUST INSTRUCT THE PATIENT TO REFRAIN FROM MOVING DURING THE ENTIRE EXPOSURE.

① Instruct the patient not to move.
② Press the exposure button for X-ray irradiation.

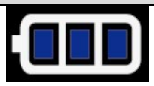
③ During the X-ray irradiation, the exposure status is displayed as follow:

- The X-ray exposure indicator lights up and audible buzzer sound is occurred.
- Keep pressing until the X-ray exposure indicator light out and the audible buzzer sound is stopped.

ICON	STATUS
	Green: Ready
	Yellow: X-ray On

6.2.6 Using battery

The battery level indicator is on the control panel. If low battery displays (Lbt sign and lightning sign blinking), X-ray irradiation is not possible, please charge the battery immediately for use.

Level 3	Level 2	Level 1	Low battery
			

ITEM		SYSTEM STATUS	
		BATTERY LEVEL 3, 2, 1	LOW BATTERY
When operating the system	Operating	Normal	Not operated
	Battery Level Indicator	Normal	Display low battery image
	Battery Charging Indicator	Not display	'Lbt' and lightning sign blinking
	Control Panel Brightness	Normal	Normal

CAUTION

A BLINKING BATTERY CHARGE INDICATOR MEANS IT NEEDS TO BE CHARGED. THE BATTERY MAY BE DISCHARGED IF LEFT (NOT USED) FOR A LONG TIME.

6.2.6.1 Charging the battery

① Connect the battery charger to the cradle

② Place OWANDY-RX PORTABLE on the cradle as following image.

③ When the battery charge is completed, the cradle LED turns on the green.

CHARGING	CHARGING FULL
	

The battery is a consumable part, and degrades over time requiring frequent charging. If the battery life after a full charge is cut in half, compared to when it was first purchased, contact the customer service center to purchase a new battery.

NOTE

X-RAY EXPOSURE IS NOT POSSIBLE DURING THE BATTERY CHRGING.

6.2.6.2 Battery replacement

① Use a screw driver, unscrew the battery bay access cover.

② Open the cover and remove the battery from the battery bay and disconnect the battery cable form the device connector.

③ Install the new battery in the reverse order of removal.

CAUTION

DO NOT PULL EXCESSIVELY ON THE BATTERY CABLE.
WORK WITH THE POWER SWITCH TURNED OFF.

NOTE

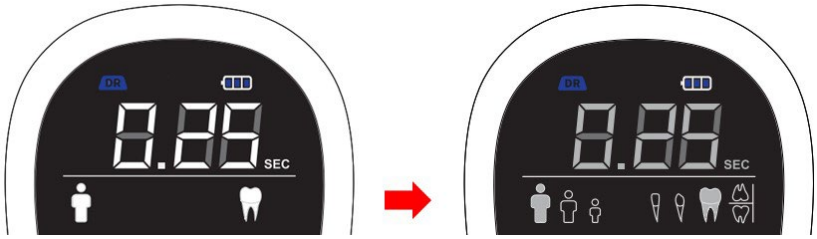
BATTERY CAN BE REPLACED BY USERS. IF YOU NEED TO REPLACE THE BATTERY, CONTACT THE SERVICE CENTER OR MANUFACTURER.

6.2.7 Dimming, sleep and power save mode

For save the battery, OWANDY-RX PORTABLE has dimming, sleep and power saving mode.

6.2.7.1 dimming mode

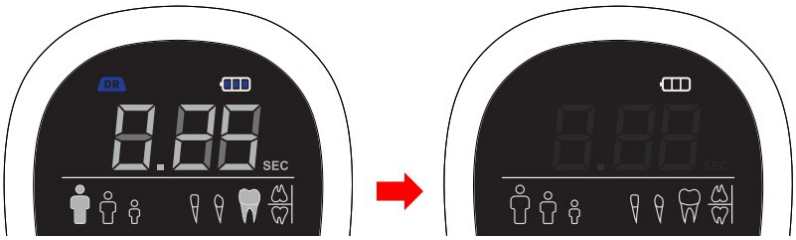
① To save the battery, the dimming mode is activated when the device is not used for more than 10 minutes. When the dimming mode is started, the control panel becomes dark as shown the right figure below.



② To return to normal operation, press any key or the X-ray exposure button.

6.2.7.2 sleep mode

① To save the battery, the sleep mode is activated when the device is not used for more than 20 minutes. When the sleep mode is started, the control panel turns off as shown the right figure below.



6.2.7.3 power save mode

① To save the battery, the power save mode is activated when the device is not used for more than 8 hours.
② To return to normal operation from the power save mode, turn off the power switch and turn it on.

7. USER SETTING OPTIONS

7.1 >How to enter user option settings

The method to enter the user option setting mode is as follows.
① Power switch on
② Press the enter key and the right key at the same time for more than 1 seconds.


③ Enter the user option setting mode.

7.1.1 Buzzer sound setting

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key M after moving to 'S.01' menu using the left and right key. ② Select the buzzer sound level (Lv.0 to Lv.3) using the left and right key and press the enter key. ③ Press the enter key and the right key to exit the user option setting mode. ※ Default: 'Lv.2'

7.1.2 Brightness setting

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key M after moving to 'S.02' menu using the left and right key. ② Select the brightness level (Lv.1 to Lv.3) using the left and right key and press the enter key. ③ Press the enter key and the right key to exit the user option setting mode. ※ Default: 'Lv.1'

7.1.3 Device lock setting

DISPLAY	DISCRIPTION
	① In the user option setting mode, press the enter key (M) after moving to 'S.03' menu using the left and right key. ② Select the lock (U.L1) or unlock (U.L0) option using the left and right key and press the enter key. ③ Press the enter key and the right key to exit the user option setting mode. ※ Default: unlock (U.L0) □ U.L1: X-ray exposure is possible at the lock status. Firstly press the X-ray exposure button at short time, secondly press the X-ray exposure button. You should hold the X-ray exposure button until the X-ray irradiation is complete.

8. TROUBLESHOOTING

These are the information about indicating a system malfunction to do not appear in the message window. If the device occurs a problem to except on the below troubleshooting table, consult manufacture or the agent. The troubleshooting table does not put it for all problems.

8.1 Error and warning messages

ERROR CODES		CHECK POINTS AND ACTION
E01	In standby state, kV feedback value is high (>10%)	Turn the power off and turn it on again
E02	In standby state, mA feedback value is high (>10%)	
E03	Tube anode heat temperature is high (>50℃)	
E04	kV feedback is low (< 90%)	
E05	kV feedback is high (> 110%)	
E06	mA feedback is low (< 90%)	
E07	mA feedback is high (> 110%)	
E09	Battery feedback value is high (overcharge battery)	Check the battery or replace the battery
E10	Preheat feedback is low (<90%)	Turn the power off and turn it on again
E11	Preheat feedback is high (>110%)	
E12	X-ray exposure button is pressed over 10 sec after booting	Check the X-ray exposure button status
E13	Remote exposure switch is pressed over 10 sec after booting	Check the remote exposure switch status
E99	No configuration data	Contact your Service Representative
WARNING CODES		
U01	Mono Block temperature warning over 43℃	Wait until the tank temperature drops to the usable temperature (36℃). It takes about 30 minutes, please work after the warning code disappears.
U20	When the enter key, left key or right key are pressed over 10 sec	Check the enter key, left key or right key status
U21	Bad connect status with temperature sensor cable	Contact your Service Representative

8.2 Troubleshooting

	PROBLEM ITEM	CAUSE	ACTION
1	Equipment is not turned on.	Power switch is not turned on properly	Turn the device power switch off and turn it back on
		Battery discharged	Recheck after charging the battery with the cradle
		Battery charger and cradle is not properly connected	Contact your Service Representative
		Defective battery	Contact your Service Representative
2	Control Panel is not turned on.	Defective main board	Contact your Service Representative
		Internal cable disconnected	Contact your Service Representative
3	No X-ray emission	Generator is cooling	Wait for the cooling time
		Defective Remote Exposure Switch	Contact your Service Representative
		Internal cable disconnected	Contact your Service Representative
		Defective generator	Contact your Service Representative
		Tube lifecycle termination	Contact your Service Representative
4	X-ray emission works, but exposure is too light or completely white	Device has been positioned incorrectly	Adjust the position of the equipment
		Exposure time is too long	Decrease the exposure time
		The I/O sensor is facing the wrong way	Reposition the I/O sensor
5	X-ray emission works, but exposure is too dark	Exposure time is too short	Increase the exposure time

9. MAINTENANCE PROCEDURE

9.1 General caution

It is recommended to follow the maintenance procedure described below, for the reliable operation. The routine inspection should be committed by a trained expert.

WARNING

THERE MAY CAUSE SERIOUS INJURY BY CONDUCTING UNAUTHORIZED SERVICE OR CHANGING THE INSTRUMENT AND MANUFACTURER SHALL NOT BE RESPONSIBLE FOR THE RESULTING COMPENSATION.

CAUTION

IF ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE, PLEASE REPORT TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE

If operator has any questions about the equipment, please let manufacture or the agent know the model name and serial number (S/N) indicated on the device, can provide a rapid service.

9.2 Maintenance

OWANDY RADIOLOGY requires periodic constancy tests to ensure image quality and the safety of the patient and operator.
Only OWANDY RADIOLOGY authorized technicians can perform inspection and service of this equipment. For the technical assistance, contact OWANDY RADIOLOGY service center or your local OWANDY RADIOLOGY representative.

CAUTION

DO NOT KEEP THE EQUIPMENT LIQUIDS OR HUMID PLACE .
DO NOT PLACE THE DEVICE NEAR TO CHMICAL OR GAS STORAGE FACILITIES.

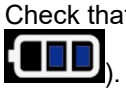
NOTE

WHEN THE EQUIPMENT IS NOT IN USE FOR A LONG TIME, FULLY CHARGE THE BATTERY AND REMOVE IT FROM THE DEVICE BEFORE STORAGE.
IT IS RECOMMENDED THAT CHARGE THE BATTERY EVERY SIX MONTHS DURING STORAGE.

9.2.1 Maintenance checklist

WARNING

ALWAYS TURN OFF THE DEVICE BEFORE PERFORMING ANY MAINTENANCE.

	CHECK ITEM	PERIOD
1	Before using the device, ensure that the device is clean and ready for use.	Daily
2	After using the device, make sure to turn off the power.	Daily
3	Wipe surfaces smoothly with soft fabric or gauze. CAUTION Do not use detergents or solvents to clean the surfaces of the device.	Daily
4	Check that the beep sound is audible and the X-ray exposure indicator is visible when making an X-ray exposure.	Daily
5	Check that the X-ray exposure indicator (yellow) light turns on when the X-ray exposure button is pressed.	Daily
6	Check that the battery charging indicator is lit while being charged.	Daily
7	Check that the battery level indicator displays at least two levels (). For more detail information on the battery levels, refer to clause '4.2.6 USING BATTERY'.	Daily
8	Check that all visible labels are intact and legible.	Monthly

CAUTION

IF ANY DEFECTS ARE FOUND, DO NOT OPERATE THE DEVICE SINCE IT HAS TO BE HANDLED BY A QUALIFIED PERSON. CONTACT YOUR SERVICE REPRESENTATIVE.

9.3 Cleaning

WARNING

BEFORE CLEANING THE DEVICE, MAKE SURE TO TURN OFF THE DEVICE.

- Clean the device surfaces with a soft cloth moistened with an alcohol-based non-corrosive solution.
- If necessary, wipe off surfaces with disinfectant.
- The soft cloth should be damp, but not dripping wet.
- The cloths or wipes cannot be re-used.

CAUTION

TO CLEAN THE MAIN-BODY AND CRADLE, TURN OFF THE DEVICE AND PULL THE PLUG OUT THE BATTERY CHARGER FROM CRADLE.
DO NOT EXPOSE THE DEVICE TO ANY LIQUIDS.
DO NOT USE SPRAY CLEANER OR DISINFECTANT DIRECTLY INTO THE DEVICE AS THIS COULD CAUSE A FIRE.

10. DISPOSAL OF WASTE

In order to reduce environmental contamination, this equipment is designed to be as safe as possible to use and dispose of.
If the device has completed its useful service life, local environmental regulations must be complied with in regard to disposal of possible hazardous materials used in the construction of the device.
In order to assist with this determination, the noteworthy materials used in the construction of this device are itemized below:

PART	MATERIAL	RECYCLABLE	WASTE DISPOSAL SITE	HAZARDOUS MATERIALS
Body case	Plastics	•		
PCB Board		•		
Cable	Copper	•		
Transformer	Copper	•		
Packing	Paper	•		
	PE	•		
	Cardboard	•		
X-ray Tube				•
Battery				•
Other parts			•	

NOTE

OBSERVE ALL REGULATIONS RELEVANT TO THE DISPOSAL OF WASTE IN YOUR COUNTRY.

11. QUALITY WARRANTY

11.1 Scope & duration of warranty

Portable Dental X-ray System (OWANDY-RX PORTABLE) manufactured by OWANDY RADIOLOGY Co., Ltd. is warranted to be free from defects for a period of two years after purchase date (X-ray tube is one year and battery is six months). If during the warranty period the product you purchased is found to be defective, it will be repaired free of charge.

In the case of one of the following, however, a certain amount of service fees will be charged.

- Defect or damage found after the warranty period.
- Defect or damage in appearance which is not related to main function of the system.
- Damage caused by a natural disaster; such as fire, earthquake, or lightning strikes.
- Damage resulting from either improper movement or inattention to the precautions.
- Damage resulting from repair or modification by someone other than OWANDY RADIOLOGY or the authenticated by OWANDY RADIOLOGY Co., Ltd.
- Incidental or indirect loss caused during system manipulation.

Any or all defect or damages in appearance, which do not affect the main functions of the product are not covered by this free of charge warranty.

11.2 Prerequisites for repair request

- When a defect is found, stop the using immediately. It is strongly recommended to refer to related material on the user manual.
- Before a service request, must power off the entire system and check the model number, serial number, and the purchase date. Then contact an authorized service office.
- Any product with a defect in appearance only shall not be returned to nor replaced by OWANDY RADIOLOGY Co., Ltd. OWANDY RADIOLOGY Co., Ltd. shall not be liable any incidental or consequential damages arising out of or relating to the use of the product.
- OWANDY RADIOLOGY Co., Ltd. shall not be liable for any damages or losses occurring after the warranty period.
- This Quality Warranty prevails over the detailed Warranty for fitness or all other warranties in relation to the product.

12. INTENDED OPERATOR AND SERVICE PERSONAL PROFILE

12.1 Operator profile

CONSIDERATIONS		REQUIREMENT DESCRIPTION
Education	Minimum	- At least graduate of medical college
	Maximum	- No maximum
Knowledge	Minimum	- Read and understand 'westernized Arabic' numerals when written in Arial font - Can distinguish of human body - Understands hygiene
	Maximum	- No maximum
Language understanding	Minimum	- Local language
	Maximum	- Understanding of manual that is writing in English
Experience	Minimum	- Have license of radiologist or have to meet local regulation
	Maximum	- No maximum
Permissible impairments	Minimum	- Mild reading vision impairment or vision corrected to log MAR 0.2 - Average degree of aging-related short term memory impairment - Impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz

12.2 Service personal profile

Considerations		Requirement description
Education	Minimum	- At least graduate of high school
	Maximum	- No maximum
Knowledge	Minimum	- Read and understand 'westernized Arabic' numerals when written in Arial font - Can distinguish of human body - Understands hygiene
	Maximum	- No maximum
Language understanding	Minimum	- Local language
	Maximum	- Understanding of manual that is writing in English
Experience	Minimum	- Only authorized and properly trained by OWANDY RADIOLOGY
	Maximum	- No maximum
Permissible impairments	Minimum	- Mild reading vision impairment or vision corrected to log MAR 0.2 - Average degree of aging-related short term memory impairment - Impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz

12.2.1 Appendix A technical chart

[Unit: sec]

DR	Adult (Big)	Adult (Normal)	Child
Incisor	0.12	0.11	0.1
Canine	0.16	0.14	0.13
Molar / Premolar	0.2	0.18	0.16
Bitewing	0.2	0.18	0.16

CR	Adult (Big)	Adult (Normal)	Child
Incisor	0.16	0.14	0.13
Canine	0.21	0.19	0.17
Molar / Premolar	0.26	0.23	0.21
Bitewing	0.26	0.23	0.21

Film	Adult (Big)	Adult (Normal)	Child
Incisor	0.25	0.22	0.2
Canine	0.3	0.27	0.24
Molar / Premolar	0.35	0.31	0.28
Bitewing	0.35	0.31	0.28

12.2.2 Appendix B EMC declaration

Guidelines and manufacturers: electromagnetic emission		
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.		
Emission test	**Compliance**	**Electromagnetic setting: guidelines**
RF emission CISPR 11	Group 1	Since the OWANDY-RX PORTABLE only uses RF energy for internal functions, it has very low RF emissions and normally causes no interference to neighboring electronic devices.
RF emission CISPR 11	Class A	The OWANDY-RX PORTABLE is suitable not only in non-household facilities but can also be used by directly connecting to the common lowpower network in a building.
Harmonic wave emission CISPR 11	Class A	
Voltage changes/flicker emission CISPR 11	Compliance	

Full compliance to the IEC 60601-1-2:2004 and the System's tolerance to EM waves			
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.			
Tolerance test	**IEC 60601 test level**	**Suitability level**	**Electromagnetic setting: guidelines**
Static electricity discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV in the air	+/- 6kV contact +/- 8kV in the air	The floor should be in wood, concrete or ceramic tiles. If the floor is in a synthetic material, the relative humidity should be at least 30%.

Suitability in electric oversprays IEC 61000-4-4	+/- 2kV power supply unit line +/- 1kV input/output line	+/- 2kV power supply unit line +/- 1kV input/output line	The main power's quality should be equal to the those of general commercial or hospital settings.
Surge IEC 61000-4-5	+/- 1kV line-line +/- 2kV line-earth	+/- 1kV line-line +/- 2kV line-earth	The main power's quality should be equal to the those of general commercial or hospital settings.
Voltage loss in the power supply, short intermittence and voltage changes IEC 61000-4-11	<5% UT(<95%Dip at the UT), 0.5 cycles 40% UT(60% Dip at the UT), 5 cycles 70% UT(30% Dip at the UT), 25 cycles <5% UT(>95% Dip at the UT), 5 seconds	<5% UT(<95%Dip at the UT), 0.5 cycles 40% UT(60% Dip at the UT), 5 cycles 70% UT(30% Dip at the UT), 25 cycles <5% UT(>95% Dip at the UT), 5 seconds	The main power's quality should be equal to the those of general commercial or hospital settings. Note : Most components in the Diagnostic Xray System have their power supplied from the uninterrupted power supply. The IEC61000-4-11 only applies to the Diagnostic X-ray System Power Box.
Magnetic field in the source frequency (50/60Hz) IEC 61000-4-8	3A/m	3A/m	The magnetic field in the source frequency should be equivalent to the those of general commercial or hospital settings.

Note: The UT is the main AC voltage before the test standards have been applied.

Guidelines and manufacturers: electromagnetic tolerance			
The Diagnostic X-ray System is used in the following electromagnetic settings. Users of the Diagnostic X-ray System should check whether their systems are used in these settings.			
Tolerance test	**IEC 60601 test level**	**Suitability level**	**Electromagnetic setting: guidelines**
Conductive RF IEC61000-4-6 Radioactive RF IEC61000-4-3	3Vrms 150kHz-80MHz 3v/m 80MHz-2.5GHz	3Vrms 3v/m	When using a portable or a mobile RF communication equipment, the recommended intervals, which have been calculated using the equations, should be maintained. These calculations should be made in accordance with all of the Diagnostic X-ray System's parts (including switches) and its transmitterreceiver's frequency. Recommended intervals: d = 1.17√p d = 1.17√p80MHz ~ 800MHz d = 2.33√p800MHz ~ 2.5GHz, where p is the transmitter-receiver's maximum power rating in watts (W) and d is the recommended interval. The magnetic field strength in the fixed RF receiver, which has been determined in the EM wave walkdown[1], should be lower than the compliance standards of each frequency range[2]. Interference may occur around the equipment whose symbol is as follows. 

Note 1: The high-frequency range is applied at 80MHz and 800MHz.
Note 2: This guideline does not apply in all situations. Electromagnetic waves may be affected through absorption into and reflection from structures, objects and people.

Guidelines and manufacturers: electromagnetic tolerance
It is very difficult to accurately predict the magnetic field strength of wireless (mobile/wireless) telephones, land mobile radio base station, amateur wireless, AM, FM wireless and TV broadcasting systems. To assess electromagnetic settings using fixed RF receivers, area walkdown is needed. If the magnetic field strength measured at the point where the Diagnostic X-ray System is used exceeds the applicable RF compliance level, you should check whether the Diagnostic X-ray System is operating normally. Should any performance abnormality is observed, additional action may be needed such as changing the Diagnostic X-ray System's direction or location. At the frequency range between 150kHz and 80MHz, the magnetic field strength should be less than 3v/m.

Recommended intervals between the Diagnostic X-ray System and the portable or mobile RF communications equipment

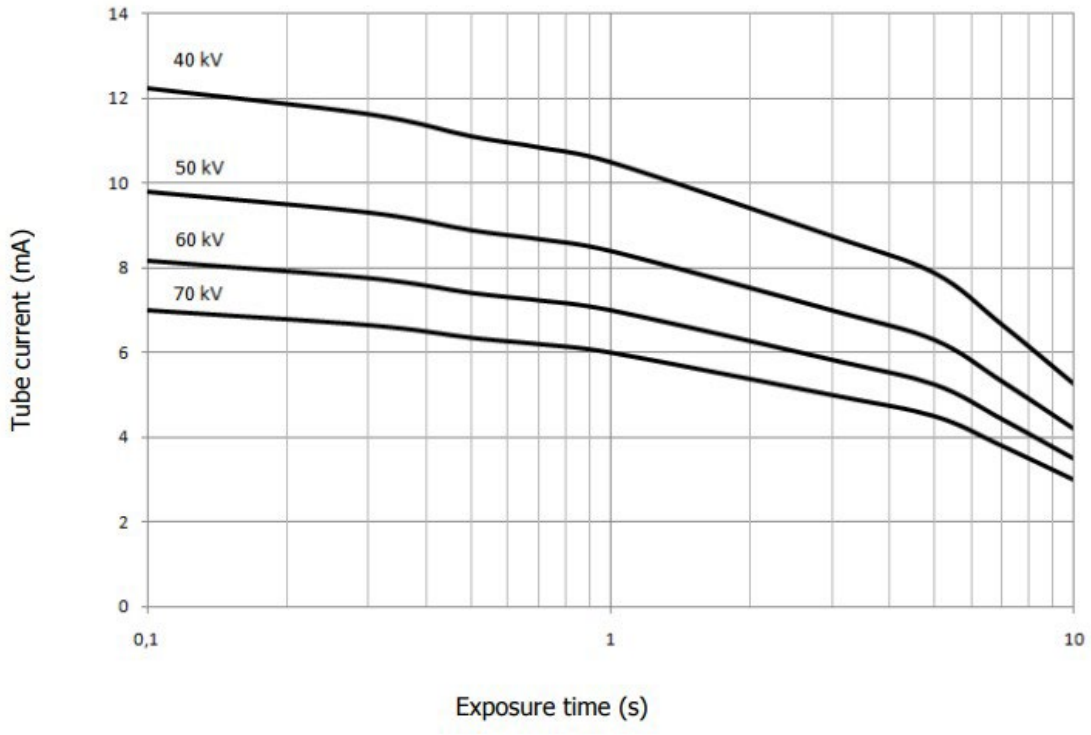
The Diagnostic X-ray System should be used in an electromagnetic setting where RF communication interferences are controlled. Users of the Diagnostic X-ray System should maintain the minimum intervals between the System and the portable or mobile RF communications equipments to prevent electromagnetic interferences more effectively.

Maximum output power rating of the transceiverreceiver Watts	Interval depending on the transceiver-receiver's frequency meters		
	150kHz ~ 80MHz d = 1.17√p	80MHz ~ 800MHz d = 1.17√p	800MHz ~ 2.5GHz d = 2.33√p
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.7	3.7	7.36
100	11.7	11.7	23.3

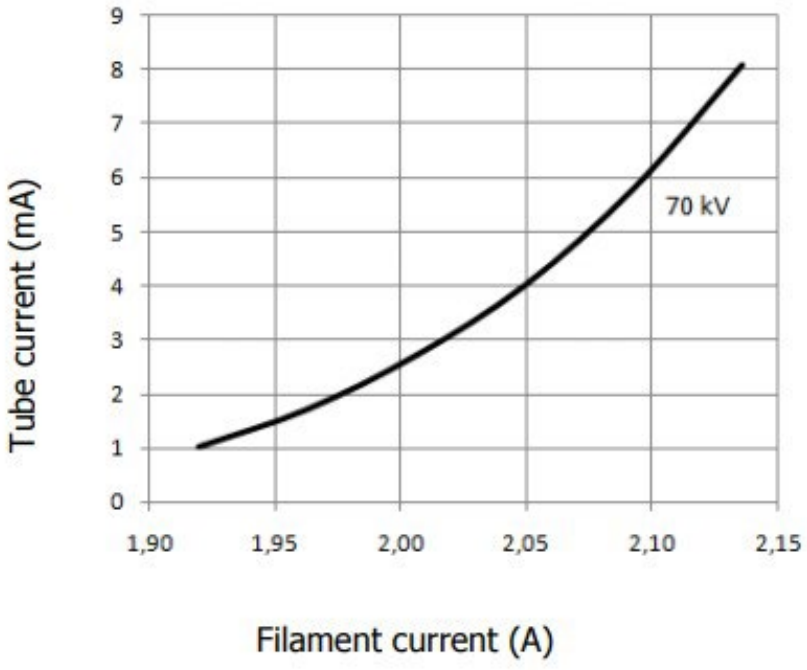
For maximum power voltages of receivers not on the above list, the recommended interval, d(m), can be calculated by using the equation used for the receiver's frequency. The p is the transmitter-receiver's maximum power rating in watts (W).
Note 1: The high-frequency range is applied at 80MHz and 800MHz.
Note 2: This guideline does not apply in all situations. Electromagnetic waves may be affected through absorption into and reflection from structures, objects and people.

12.2.3 Appendix C characteristics of x-ray tube (ox/70-3)

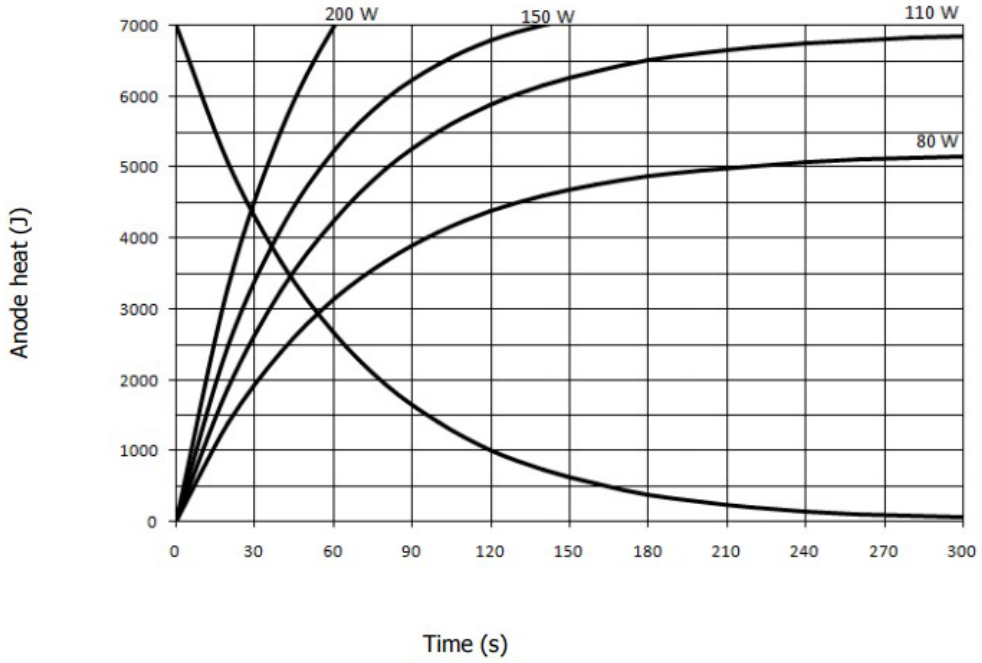
Rating Charts



Emission Characteristics



Thermal Curves



12.2.4 Appendix D backscatter shield fastening method

① Unlock the collimator by turning as the below picture.

② Remove the collimator and backscatter shield ring as the below picture.

③ Fastening backscatter shield and collimator as below picture. Lock the collimator by turning as the above ① picture.

※ Removing backscatter shield is the reverse of fastening method.

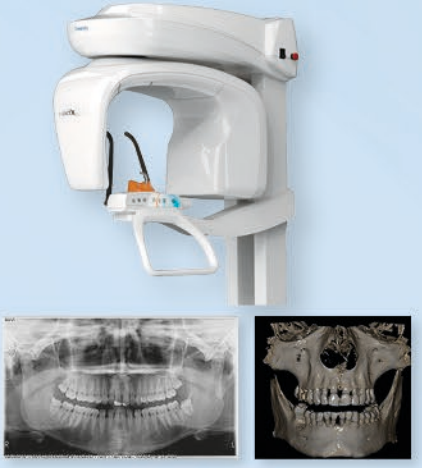
Manufacturer:

Owandy Radiology Co., Ltd
Made by Korea
404, 504, 505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-Gu,
Seoul 08511, Korea Obelis S.A

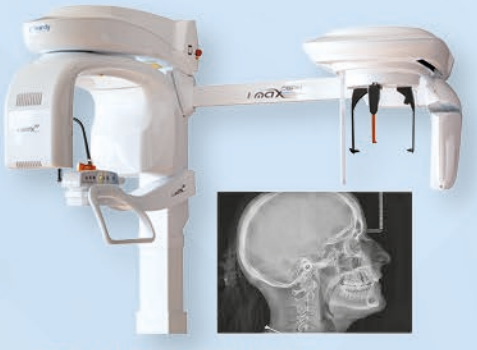
CE 0123

DIGITAL WORKFLOW OWANDY RADIOLOGY

A COMPREHENSIVE RANGE TO MEET ALL YOUR REQUIREMENTS



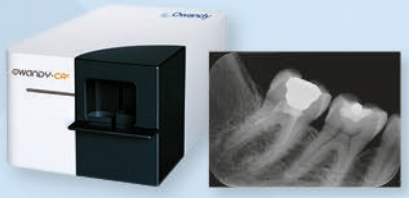
2D/3D UNITS



CEPHALOMETRIC UNITS

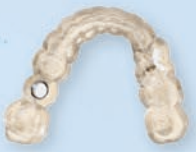
HF INTRA-ORAL GENERATOR

FACE SCAN
.PLY IMPORT



INTRAORAL
PLATE SCANNER

DENTAL IMPRESSIONS
.STL IMPORT

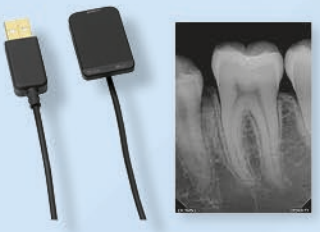


SURGICAL
GUIDE

DIGITAL USB
INTRAORAL CAMERA

EXPORT TO
3D PRINTER

DIRECT USB
SENSORS



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