

# PaX-i Insight<sub>(Model: PCH-30CS)</sub>

## Product Data

(Detector: Xmaru1404CF-Plus (PANO) / Xmaru2602CF (CEPH))

Version: v1.0

### 1. General Information

#### 1.1. Equipment Overview

##### 1.1.1. Indications for Use

PaX-i Insight (Model: PCH-30CS) is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians

##### 1.1.2. Main Features

PaX-i Insight is an advanced 2-in-1 digital X-ray imaging system that incorporates PANO, CEPH (Optional) capabilities into a single system and its main features are as follows.

- Multi-imaging solution for accurate Diagnostics
- Conventional 2D (PANO and CEPH (Optional)) image acquisition in high quality
  - PANO: Insight PAN
    - . Multi-image acquisition option that reconstructs the panoramic image into multiple focal images in depth regions. Its main purpose is to diagnose depth regions, which cannot be confirmed with ordinary panoramic images.
  - CEPH: Minimized motion artifact through short scan time
- DICOM (Digital Imaging Communication in Medicine) format supported

#### 1.2 Available Modes

Equipment	Available Modes
PaX-i Insight	PANO, CEPH (Optional)

## 2. Functional Specifications

### 2.1. PANO Mode

#### 2.1.1. Overview

PANO imaging software is classified into four levels as below.

Pano Option	Detail Examination	Remark	
		Domestic	Overseas
Normal	Pano examination	○	○
	Special examination	○	○
Auto Focusing	Pano examination		○ (Optional)
Magic PAN	Pano examination	○	
Insight PAN	Pano examination	○	○
	Special examination	○	○

Also, Image Option consists of four levels as below

Image Option	Detail Examination	Remark	
		Domestic	Overseas
Pano examination	UHD		○ (Optional)
	HD	○	○
	NORMAL		○
	FAST	○	
Special examination	HD	○	○

## 2.1.2. Scan Time / Exposure Time

- PANO Examination (UHD/HD)

Arch Type	Examination Mode	Image Option (UHD/HD)			
		UHD		HD	
		Scan Time(s)	Exposure Time(s)	Scan Time(s)	Exposure Time(s)
Narrow	Standard	21.0	20.2	14.0	13.5
	Right	21.0	10.1	14.0	6.7
	Front	21.0	16.7	14.0	11.2
	Left	21.0	10.1	14.0	6.7
Normal	Standard	21.0	20.2	14.0	13.5
	Right	21.0	10.1	14.0	6.7
	Front	21.0	16.7	14.0	11.2
	Left	21.0	10.1	14.0	6.7
Wide	Standard	21.0	20.2	14.0	13.5
	Right	21.0	10.1	14.0	6.7
	Front	21.0	16.7	14.0	11.2
	Left	21.0	10.1	14.0	6.7
Child	Standard	18.1	17.2	12.1	11.5
	Right	18.1	8.6	12.1	5.7
	Front	18.1	13.8	12.1	9.2
	Left	18.1	8.6	12.1	5.7
Orthogonal	Standard	21.0	20.2	14.0	13.5
	Right	21.0	10.1	14.0	6.7
	Front	21.0	16.7	14.0	11.2
	Left	21.0	10.1	14.0	6.7
	Bitewing	21.0	14.5	14.0	9.7
	Bitewing Incisor (Optional)	21.0	3.7	14.0	2.5
	Bitewing Right	21.0	7.3	14.0	4.8
	Bitewing Left	21.0	7.3	14.0	4.8

- *Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.*
- *Exposure Time: The actual time that the patient is exposed to the X-ray emission.*

- **PANO Examination (Normal/Fast)**

Arch Type	Examination Mode	Image Option (Normal/Fast)			
		Normal		Fast	
		Scan Time(s)	Exposure Time(s)	Scan Time(s)	Exposure Time(s)
Narrow	Standard	10.4	10.1	7.5	7.2
	Right	10.4	5.0	7.5	3.6
	Front	10.4	8.4	7.5	6.0
	Left	10.4	5.0	7.5	3.6
Normal	Standard	10.4	10.1	7.5	7.2
	Right	10.4	5.0	7.5	3.6
	Front	10.4	8.4	7.5	6.0
	Left	10.4	5.0	7.5	3.6
Wide	Standard	10.4	10.1	7.5	7.2
	Right	10.4	5.0	7.5	3.6
	Front	10.4	8.4	7.5	6.0
	Left	10.4	5.0	7.5	3.6
Child	Standard	8.9	8.6	6.4	6.1
	Right	8.9	4.3	6.4	3.1
	Front	8.9	6.8	6.4	4.9
	Left	8.9	4.3	6.4	3.1
Orthogonal	Standard	10.4	10.1	7.5	7.2
	Right	10.4	5.0	7.5	3.6
	Front	10.4	8.4	7.5	6.0
	Left	10.4	5.0	7.5	3.6
	Bitewing	10.4	7.3	7.5	5.2
	Bitewing Incisor	10.4	1.8	7.5	1.3
	Bitewing Right	10.4	3.6	7.5	2.6
	Bitewing Left	10.4	3.6	7.5	2.6

- *Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.*
- *Exposure Time: The actual time that the patient is exposed to the X-ray emission.*

- **Special Examination**

<b>Examination Mode</b>	<b>Scan Time (s)</b>	<b>Exposure Time (s)</b>
TMJ LAT Open / TMJ LAT Close	14.0	6.2
TMJ PA Open (Optional) / TMJ PA Close (Optional)	13.0	10.1
Sinus LAT (Optional)	6.5	5.9
Sinus PA	10.9	10.3

- Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages
- Exposure Time: The actual time that the patient is exposed to the X-ray emission

### 2.1.3. Exposure Condition

- PANO Option - Normal

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	UHD, HD, Fast	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9
	Normal	Man	Hard	74	7
			Normal	73	7
			Soft	72	7
		Woman	Hard	73	7
			Normal	72	7
			Soft	71	7
Child		Hard	68	7	
		Normal	67	7	
		Soft	66	7	
SPECIAL Examination	-	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9

- **PANO Option > Auto Focusing & Magic PAN**

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	UHD, HD, Fast	Man	Hard	74	9
			Normal	73	9
			Soft	72	9
		Woman	Hard	73	9
			Normal	72	9
			Soft	71	9
		Child	Hard	68	9
			Normal	67	9
			Soft	66	9
	Normal	Man	Hard	74	7
			Normal	73	7
			Soft	72	7
		Woman	Hard	73	7
			Normal	72	7
			Soft	71	7
Child		Hard	68	7	
		Normal	67	7	
		Soft	66	7	

- **PANO Option > Insight PAN**

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination /Special Examination	N/A	Man	Hard	71	5
			Normal	70	5
			Soft	69	5
		Woman	Hard	71	5
			Normal	70	5
			Soft	69	5
		Child	Hard	68	5
			Normal	67	5
			Soft	66	5

- *Recommended exposure condition can be different from the values applied to the equipment.*


#### 2.1.4. Reconstruction Time

Pano Option	Reconstruction time
Insight PAN	Approximately 1 minute


- The above data is obtained from a computer system which is based on HP Workstation Z440 and Geforce GTX1060 6GB
- Image reconstruction time varies depending on computer specifications and/or working conditions.

### 2.1.5. Sample Images

#### PANO Option: Normal

Item	Images
PANO Examination	 <p style="text-align: center;">&lt; HD 모드 / Standard &gt;</p>

#### PANO Option: InsightPAN

Item	Images
PANO Examination	 <p style="text-align: center;">&lt; InsightPAN 모드 / Standard &gt;</p>



## 2.2. CEPH Mode

### 2.2.1. Scan Time / Exposure Time

Examination Mode	Normal		Fast	
	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Lateral	3.9	3.9	1.9	1.9
Full Lateral	5.4	5.4	3.9	3.9
PA	4.9	4.9	2.4	2.4
SMV	4.9	4.9	2.4	2.4
Waters' view	4.9	4.9	2.4	2.4
Carpus	4.9	4.9	2.4	2.4

- *Scan Time: The actual time that the equipment shoots the patient except for the initial acceleration and late deceleration stages.*
- *Exposure Time: The actual time that the patient is exposed to the X-ray emission.*


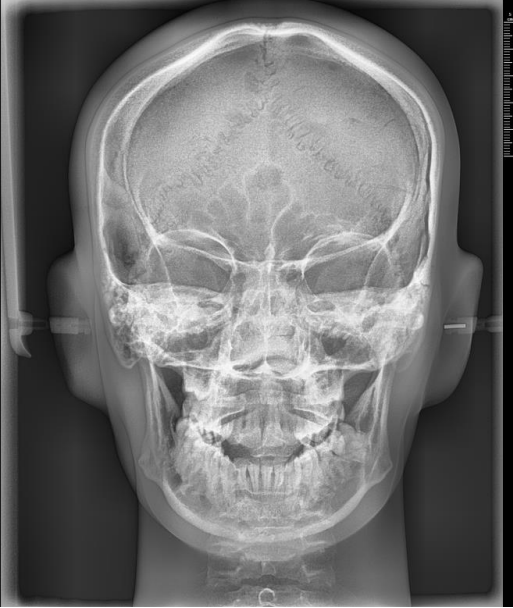
### 2.2.2. Exposure Condition

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
Lateral PA SMV Waters' view Full Lateral	Normal	Man	Hard	92	10.0
			Normal	90	10.0
			Soft	88	10.0
		Woman	Hard	90	10.0
			Normal	88	10.0
			Soft	86	10.0
		Child	Hard	88	10.0
			Normal	86	10.0
			Soft	84	10.0
	Fast	Man	Hard	92	10.0
			Normal	90	10.0
			Soft	88	10.0
Woman		Hard	90	10.0	
		Normal	88	10.0	
		Soft	86	10.0	
Child		Hard	88	10.0	
		Normal	86	10.0	
		Soft	84	10.0	
Carpus	Normal	Man	Hard	90	6.0
			Normal	88	6.0

Examination Program	Image Option	Gender / Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)	
		Woman	Soft	86	6.0	
			Hard	88	6.0	
			Normal	86	6.0	
		Child	Soft	84	6.0	
			Hard	86	6.0	
			Normal	84	6.0	
		Fast	Man	Soft	82	6.0
				Hard	90	6.0
				Normal	88	6.0
	Woman		Soft	86	6.0	
			Hard	88	6.0	
			Normal	86	6.0	
	Child	Soft	84	6.0		
		Hard	86	6.0		
		Normal	84	6.0		
		Child	Soft	82	6.0	

- *Recommended exposure condition can be different from the values applied to the equipment.*

### 2.2.3. Sample Images

Item	Images
Lateral	 A lateral cephalometric radiograph showing the side profile of a human skull. The image displays the cranial base, maxilla, mandible, and cervical spine. A vertical scale bar is visible on the right side of the image.
PA	 A posterior-anterior (PA) cephalometric radiograph showing the frontal view of a human skull. The image displays the frontal sinuses, orbits, nasal cavity, maxilla, and mandible. A vertical scale bar is visible on the right side of the image.

### 3. PC Specification (Recommended)

Item	Specifications
CPU	E5-1607v4 4C 3.1GHz 2133 10MB or Higher
RAM	2X8GB DDR4-2400 Registered RAM
Hard disk drive	1TB SATA 7200 rpm 6Gb/s 3.5" HDD
Graphic board	GALAXY Geforce GTX1060 6GB
Ethernet interface	Integrated Intel I218LM PCIe GbE Controller Intel Ethernet I210-T1 PCIe NIC(Optional)
Serial Port (RS232)	HP Serial Port Adapter Kit
Power supply	≥ 700 Watts (90% efficient)
Slots	2 PCI Express Gen3 x16 slot 1 PCI Express Gen3 x 8 Slot 1 PCI Express Gen2 x 4 Slot 1 PCI Express Gen2 x 1 Slot
	1 PCI 32bit/33MHz
CD/DVD drive	HP SuperMulti DVD Writer 5.25
Monitor Resolution	1280 x 1024 screen resolution
Operating system	Windows7 / Window10 Professional 64-Bit OS
Bios	2.14
Recommended system	HP Z440

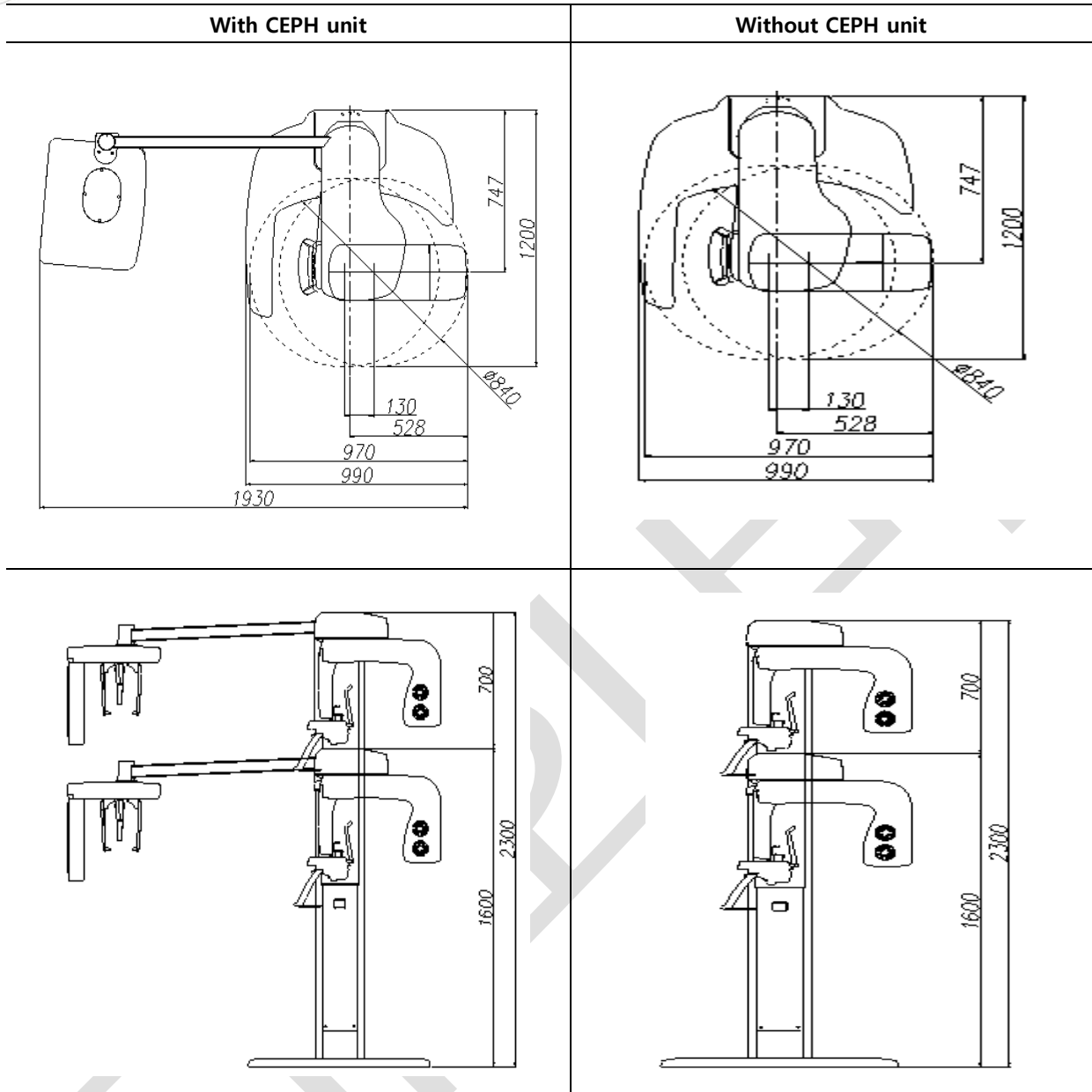
- *Recommended PC specification can be changed without prior notice.*

## 4. Mechanical Specification

### 4.1. Equipment Dimension

Item		Description
Weight	Without CEPH unit	95 kg (209.4 lbs. – without Base)
		135 kg (297.6 lbs. – with Base)
	With CEPH unit	120 kg (264.5 lbs. - without Base)
		160 kg (352.7 lbs. - with Base)
Total Height	Without base	Max. 2272 mm
	With base	Max. 2300 mm
Dimensions during operation (Length x Width x Height)	Without CEPH unit	990 mm (L) x 1200 mm (W) x 2272 mm (H) (without Base)
		990 mm (L) x 1200 mm (W) x 2300 mm (H) (with Base)
	With CEPH unit	1930 mm (L) x 1200 mm (W) x 2272 mm (H) (without Base)
		1930 mm (L) x 1200 mm (W) x 2300 mm (H) (with Base)
Rotating Unit Vertical Movement		Max. 700mm
Installation type		Base Stand / Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

[단위 : mm]



#### 4.2. Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	490.3	375.5	114.6	1 : 1.3
CEPH	1745	1524	221	1 : 1.14

\* FDD : Focal Spot to Detector Distance

\* FOD : Focal Spot to Object Distance

\* ODD : Object to Detector Distance (ODD = FDD - FOD)

\* Magnification = FDD / FOD

## 5. Technical Specification

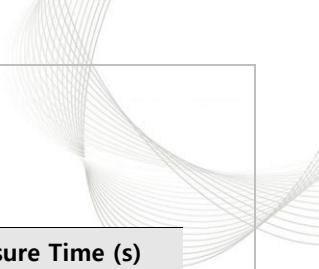
### 5.1. X-ray Generator

Item		Description	
Generator	Model	DG-07D21T2	
	Rated output power	1.0 kW	
	Inverter model name	INV-21	
	Type	Inverter	
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 10 mA (1mA increment)
	Cooling	Air Cooling / Protect $\geq 60^{\circ}\text{C}$ 1:60 or more (Exposure time : interval time)	
	Total filtration	Min. 2.5 mm Al	
Added filtration	1.5 mm Al		
Tube	Manufacturer	Toshiba	
	Model	D-052SB (Stationary Anode type)	
	Focal spot size	0.5 mm x 0.5 mm (IEC 60336)	
	Target Angle	5 degree	
	Inherent Filtration	At least 0.8mm Al equivalent at 50kV	
	X- ray Coverage	95 mm x 380 mm at SID 550 mm	
	Anode Heat Content	35 kJ	
	Duty Cycle	1:60 or more (Exposure time : Interval time)	

● Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
	60 ~ 99	4 ~ 10	20.2
	60 ~ 99	4 ~ 10	17.2
	60 ~ 99	4 ~ 10	16.7
	60 ~ 99	4 ~ 10	14.5
	60 ~ 99	4 ~ 10	13.8
	60 ~ 99	4 ~ 10	13.5
	60 ~ 99	4 ~ 10	11.5
	60 ~ 99	4 ~ 10	11.2
	60 ~ 99	4 ~ 10	11.1
	60 ~ 99	4 ~ 10	10.3
	60 ~ 99	4 ~ 10	10.1
	60 ~ 99	4 ~ 10	9.7
	60 ~ 99	4 ~ 10	9.2
	60 ~ 99	4 ~ 10	8.6
	60 ~ 99	4 ~ 10	8.4
PANO	60 ~ 99	4 ~ 10	7.3
	60 ~ 99	4 ~ 10	7.2
	60 ~ 99	4 ~ 10	6.8
	60 ~ 99	4 ~ 10	6.7
	60 ~ 99	4 ~ 10	6.2
	60 ~ 99	4 ~ 10	6.1
	60 ~ 99	4 ~ 10	6.0
	60 ~ 99	4 ~ 10	5.9
	60 ~ 99	4 ~ 10	5.7
	60 ~ 99	4 ~ 10	5.2
	60 ~ 99	4 ~ 10	5.1
	60 ~ 99	4 ~ 10	5.0
	60 ~ 99	4 ~ 10	4.9
	60 ~ 99	4 ~ 10	4.8
	60 ~ 99	4 ~ 10	4.3
	60 ~ 99	4 ~ 10	3.7





Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
	60 ~ 99	4 ~ 10	3.6
	60 ~ 99	4 ~ 10	3.1
	60 ~ 99	4 ~ 10	2.6
	60 ~ 99	4 ~ 10	2.5
	60 ~ 99	4 ~ 10	1.8
	60 ~ 99	4 ~ 10	1.3
CEPH	60 ~ 99	4 ~ 10	1.9
	60 ~ 99	4 ~ 10	2.4
	60 ~ 99	4 ~ 10	3.9
	60 ~ 99	4 ~ 10	4.9
	60 ~ 99	4 ~ 10	5.4

## 5.2. Detector Specifications

Item	Description	
	PANO	CEPH
Model	Xmaru1404CF-PLUS	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198um @ Full Resolution	200um @ 2X2 Binning
Active area	135.8mm x 36.4mm	259mm x 15.6mm
Frame Rate	~308 @ 4X4 binning	~330 @ 2x2 binning
Analogue-Digital Conversion	14 bits	
Operating condition	10 ~ 35 °C (Temperature) / 10 ~ 75 % (Humidity)	
Storage condition	-10 ~ 60 °C (Temperature) / 10 ~ 75 % (Humidity)	
Sensor size	230(W) x 160(L) x 26(H) mm	279(W) x 110(L) x 20(H) mm
Sensor weight	1.5kg	1.3kg
Converter	CsI:Ti	
Energy Range	50~120 kVp	50~120 kVp
Readout	Charge amplifier array	
Video Output	Optic	
MTF	>45% @1 lp/mm >8% @ 2.5 lp/mm	>35% @1 lp/mm >5% @ 2.5 lp/mm
DQE	> 60% @ ~0lp/mm	> 60% @ ~ 0 lp/mm
Dynamic Range	≥80dB	> 70dB

## 6. Electrical Specifications

Item	Descriptions
Power supply voltage	100 - 240 V
Frequency	50/60 Hz
Power rating	1.3 kVA
Accuracy	Tube Voltage (kVp) $\pm 10 \%$ , Tube Current (mA) $\pm 20 \%$ , Exposure Time (s) $\pm (5 \% + 50 \text{ ms})$

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement :  $\pm 10\%$

## 7. Environmental Specification









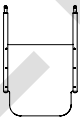



Item		Descriptions
During Operation	Temperature	10 ~ 35 °C
	Relative humidity	30 ~ 75 %
	Atmospheric pressure	860 ~ 1060 hPa
During Transport and Storage	Temperature	-10 ~ 60 °C
	Relative humidity	10 ~ 75 %
	Atmospheric pressure	860 ~ 1060 hPa

## 8. Software Information

Item	Model	Interworking	Version for Domestic Market	Version for Overseas Market
Console Program	VCaptureSW	o	1.0.0.1	1.0.0.1
2D Viewer/Patient information management program	EzDent-i	o	2.2.1	2.2.1

- SDK method has been applied for 3<sup>rd</sup> party programs.

## 9. Enclosed Components



Components	Name and Function	Materials
	Normal Bite : For PANO	PC (Polycarbonate)
	Special Bite A : For PANO TMJ and Sinus modes	PC (Polycarbonate)
	Special Bite B : For PANO edentulous patients	PC (Polycarbonate)
	Normal Chinrest : For Normal Bite	ABS (Acrylonitrile butadiene styrene) copolymer
	Special Chinrest : For Special Bite A and Special Bite B	ABS (Acrylonitrile butadiene styrene) copolymer
	Temple Supports (1 set)	PC (Polycarbonate)
	Ear Rods (1 set)	Silicone
	Nasal Positioner Cover : For CEPH	Silicone
	Carpus Plate	PC (Polycarbonate)
	Sanitary Vinyl Covers (disposable) for the Bite 	LDPE (Low-density polyethylene)
	Protractor (1 set) : For positioning the patient's body in CEPH mode.	PC (Polycarbonate)

## 10. Standards and Regulations

### 10.1. Standards

**Green Smart** is designed and developed to comply with the following international standards and regulations.

- IEC 60601-1, IEC/EN 60601-1-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-63
- CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1-3:09, CAN/CSA-C22.2 No. 60601-1-6:11, CAN/CSA-C22.2 No. 60601-2-63:15, CAN/CSA-IEC 62366:15
- ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, A2:2010 / (R)2012 (Consolidated text - edition 3.1)
- 21 CFR 1020.30, 31
- NEMA Standard publication PS 3.1-3.18, 2008

 <p>CE 0434</p>	This is Class IIb equipment and obtained CE marking in April, 2007 for regulations compliance in accordance with the revised European Union's MDD (Medical Devices Directive) 93/42 EEC.
 <p>CSA<sup>®</sup> C US 266436</p>	This equipment received the CSA certification mark in accordance with CAN/CSA C22.2 No.601.1 regulations.

### 10.2. Classifications (IEC 60601-1 6.1)

- Degree of protection against water ingress: Ordinary Equipment: IPX0
- Degree of protection against electric shock: Class 1 equipment, Type B Applied Parts: Temple Supports, Chinrests and Bites.



## 11. Additional Information

For further information for PaX-i Insight, please contact us at:

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