System Specifications

9

9 SYSTEM SPECIFICATIONS

9.1 Technical Specifications

Classification		Specification	Remark
Rated Voltage		100-240V~, 50/60Hz	
Power Consumption		2.5kVA Max	
Operation Mode		Continuous operation with intermittent loading.	
Max.permissible apparent impedance of supply mains		0.8Ω(100V)	
Overcurrent Circuit		30A	
Form and Degree of Electric Shock		Class 1, Type B	
Total Filtration		2.8mmAl/90IEC60522	
X-ray	X-ray Tube	Tube Voltage: 50~100kV Tube Current: Max 22mA Focal Point Size: 0.5mm (IEC60366) Target Angle: 5° Heat Capacity: 35kJ	
	Mono Tank	Tube Voltage: 60~90kV(±10%) Tube Current: 4~17mA(±20%) Power Input: 2.185kW Power Output: 1.530kW (less than 3s exposure) Inherent Filtration: 1.8mmAl (Tube+insulating oil+case) Added Filtration: 1.0mmAl	
	Cooling Time	Temperature is monitored and displayed on the screen with a color code. Green indicates that another scan can be performed immediately. Yellow or Red indicates that the user must wait either 3 or 5 minutes respectively.	
	Loading Factor	Max. kV when mA : 90kV/17mA Max. mA when kV : 17mA/90kV	

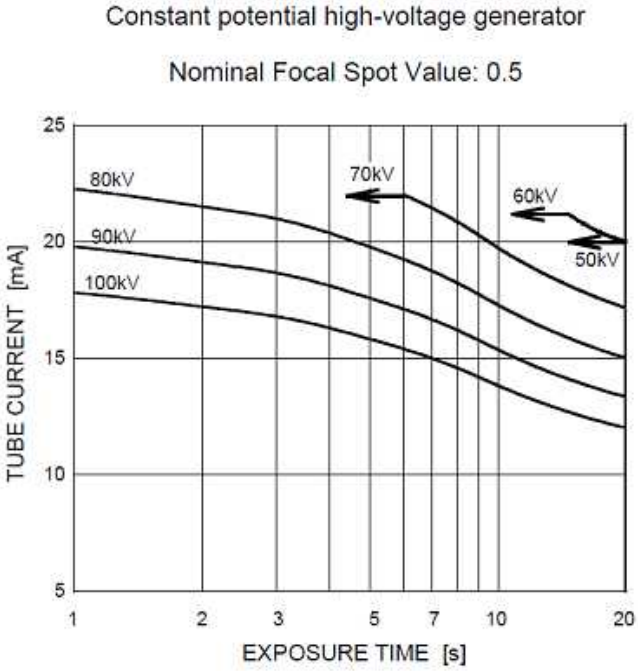
X-ray Detector	For CT Use	Pixel Size: 124um Pixel Matrix: 2560x2048 Pixel Area: 316mm(W)x253mm(H)	
	For Pano Use	Pixel Size: 124um Pixel Matrix: 2560x2048 Pixel Area: 316mm(W)x253mm(H)	
	For CEPH Use (One Shot S Type)	Pixel Size: 139um Pixel Matrix: 2176x1792 Pixel Area: 302mm(W)x249mm(H)	Option
	For CEPH Use (One Shot L Type)	Pixel Size: 127um Pixel Matrix: 3328x3328 Pixel Area: 422.7mm(W)x422.7mm(H)	Option
	For CEPH Use (Scan Type)	Pixel Size: 100um Pixel Matrix: 48x2400 Pixel Area: 4.8mm(W)x240mm(H)	Option
SID		CT: 677mm Pano: 677mm Ceph(Scan): 1650mm Ceph(Oneshot-S): 1660mm Ceph(Oneshot-L): 1507mm	
Tube Voltage	CT	Child: 85~90kV, Adult: 85~90kV	
	Pano	Child: 60~90kV, Adult: 60~90kV	
	Ceph	Child: 60~90kV, Adult: 60~90kV	
Tube Current	CT	Child: 4~12mA, Adult: 4~12mA	
	Pano	Child: 4~17mA, Adult: 4~17mA	
	Ceph	Child: 4~17mA, Adult: 4~17mA	
Exposure Time	CT	Child: ~14s, Adult: ~14s	
	Pano	Child: ~14s, Adult: ~14s	
	Ceph(Scan)	Child: ~19s, Adult: ~19s	
	Ceph(Oneshot)	Child: ~0.8s, Adult: ~0.8s	

Magnification		CT: 1.44 Pano: 1.3 Ceph(Scan): 1.11 Ceph(Oneshot-S): 1.12 Ceph(Oneshot-L): 1.13	
Alignment Beam	IEC60825-1 Safety Ratings	Class I	
	Wavelength	650nm±20nm	
	Output power	<1mW	
Apparatus Specifications	Size	1,118mmW)×1,481mm(D)×2,296mm(H)	
	One Shot S Type CEPH Inclusive	1,831mm(W)x1,481mm(D)x2,296mm(H)	
	One Shot L Type CEPH Inclusive	1,672mm(W)×1,481mm(D)×2,296mm(H)	
	Scan Ceph Inclusive	1,831mm(W)x1,481mm(D)x2,296mm(H)	
	Weight	189kg±10%	
	One Shot S Type CEPH Inclusive	219kg±10%	
	One Shot L Type CEPH Inclusive	212kg±10%	
	Scan Ceph Inclusive	217kg±10%	
Quantity per pack		1 SET	
Lift Column Height Control	Stroke	670mm	
Software		RayScan ver. 1.0 or higher	

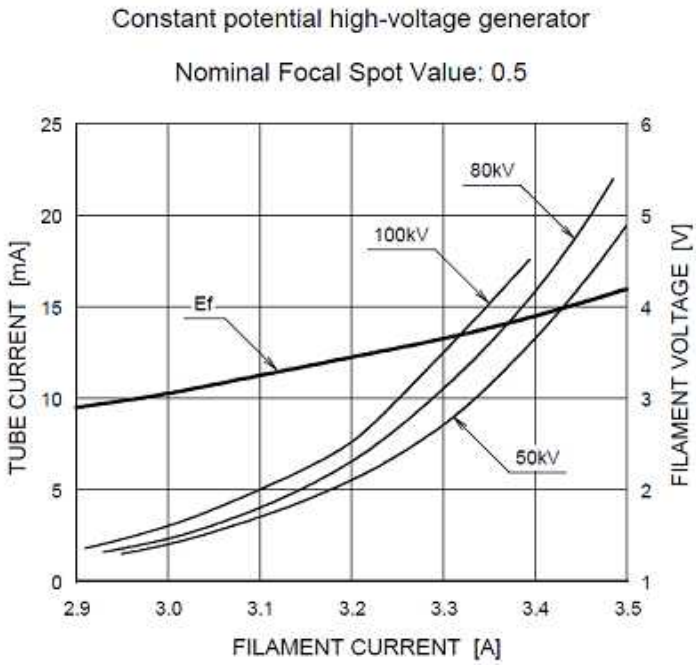
Workstation	OS	Windows 10, 64Bit	Use products with certificate from National or Accredited Organization.
	CPU	Intel Dual Core or higher	
	RAM	8GB or higher	
	HDD	1TB or higher	
	Network	Gigabit Ethernet	
Operating Environment	Ambient Temperature Range	15℃ ~ 25℃	
	Relative Humidity	20%~ 60%	
	Atmospheric Pressure Range	700hPa ~1060hPa	
Transport & Storage Environment	Temperature Range	-10℃ ~ 50℃	
	Relative Humidity	10%~ 90%	
	Atmospheric Pressure Range	700hPa ~1060hPa	

9.1.1 X-ray Tube

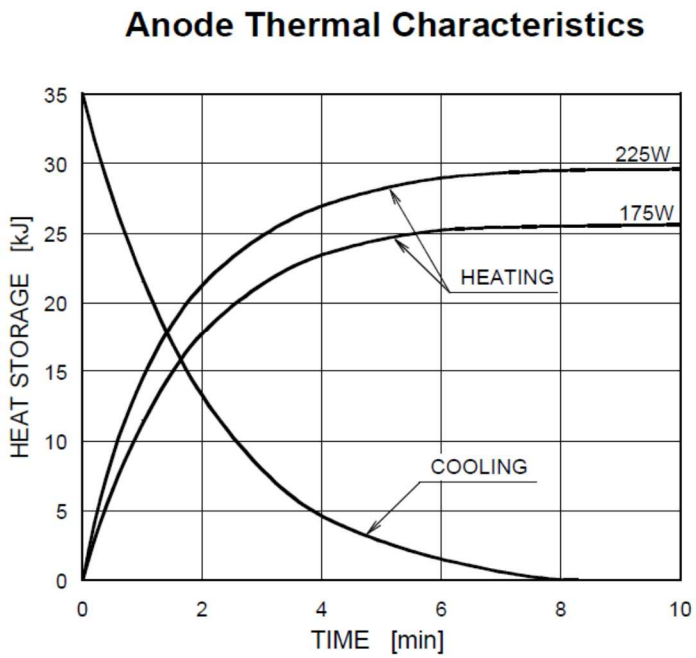
9.1.1.1 Maximum Rating Charts



9.1.1.2 Emission & Filament Characteristics

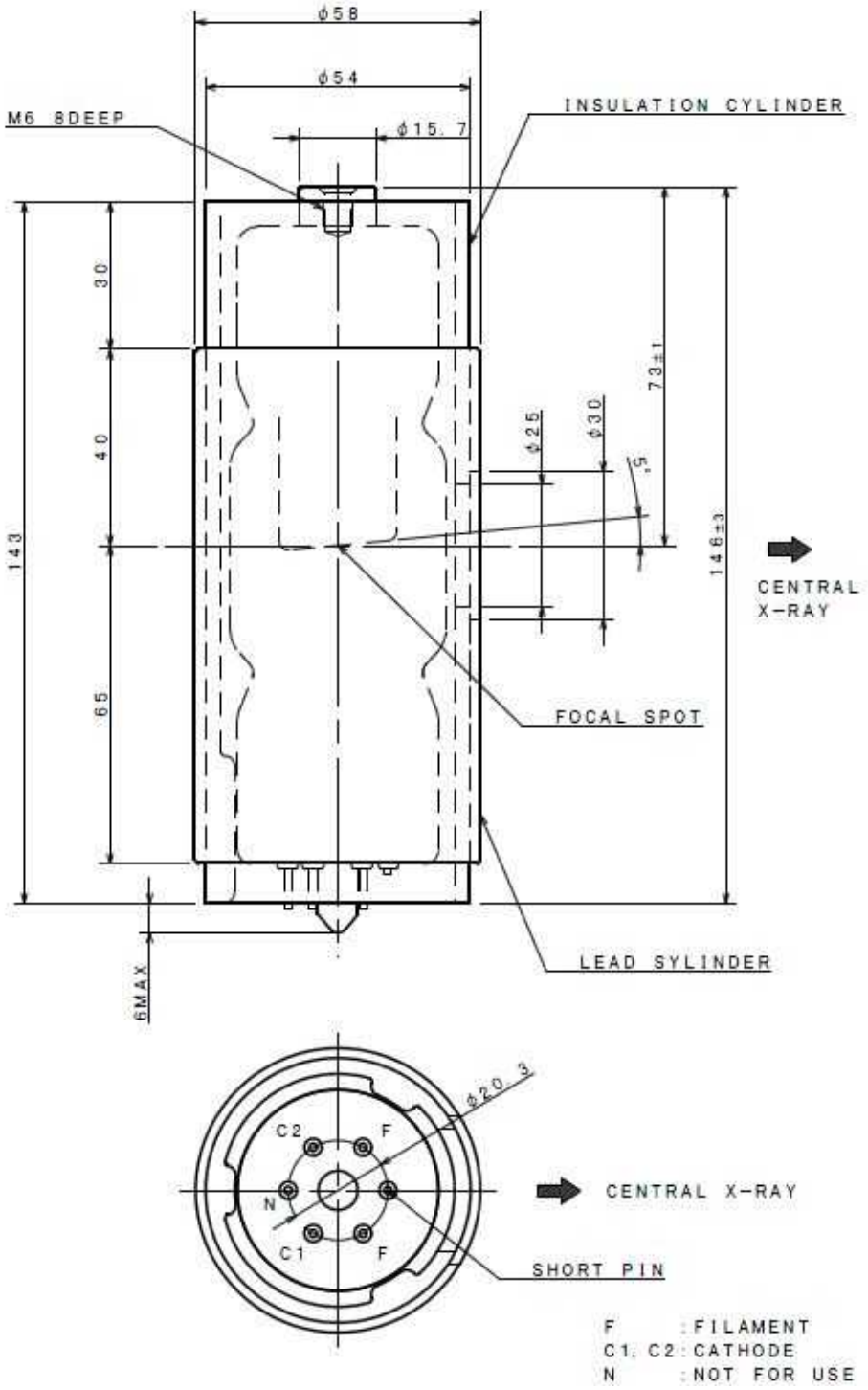


9.1.1.3 Anode Thermal Characteristics



9.1.1.4 Dimensional Outline

Unit: mm



9.2 Dose Information

9.2.1 Patient Population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.

There is no restriction for ethnic group, Gender, weight, health, or condition.

We recommend patients for X-ray diagnostic radiation exposure to be over 5 years old.

9.2.2 Pediatric Subpopulation

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old according to FDA guidance “Pediatric Information for X-ray Imaging Device Premarket Notifications. (Draft Guidance)”

a. 5 year old [~21 kg, 113 cm standing height]: Child
b. 12 year old [~52 kg, 156 cm standing height]: Overlap small size adults
c. 21 year old [~80 kg, 170 cm height]: Adult
d. Adult [more than 80 kg, 180 cm standing height]: Large Adult

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lb) in weight and 150 cm (59 in) in height,measurements, which approximately correspond to that of an average 12 year old or a 5th percentile U.S. adult female.)

Exposure to ionizing radiation is of particular concern in pediatric patients because: 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients); 2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and 3) younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, you should follow the ALARA (As Low As Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically

Please refer the web pages regarding additional pediatric information.

• FDA’s Pediatric X-ray Imaging webpage:
http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging /ucm298899.htm

• The Image Gently Back to Basics campaign materials:
http://www.pedrad.org/associations/5364/ig/?page=824

9.2.3 Procedures Performed

9.2.3.1 Panoramic/CEPH/Model Scan

- X-ray dosage is noted as mGy.cm^2 (dose area product) and measured in the primary collimator. The dosage has ±25% tolerance.

9.2.3.2 CT

- X-ray dosage is noted as CTDIvol (mGy) and has ±25% tolerance.
- X-ray dosage is measured at the center of the patient position and 3, 6, 9, 12 o'clock.
- Positions in the pencil ionization chamber.
- The measured value is used to calculate CTDIw.
- CTDI100 = [f X measured value]/(beam width), conversion factor f=0.0087mGy/mR
- CTDIw = 1/3CTDI100 center + 2/3CTDI100 (mean value of 4 positions)
- CT consists of 1 revolution imaging, therefore CTDIw and CTDIvol are equivalent.
- CTDIvol ≤ 20mGy at CT condition of operation. (Tube voltage: 85kV, Tube current: 5mA, Exposure time: 14s)

9.3 FOV Variable range

9.3.1 Panorama Protocol

Protocol		WxH Default (cm)	WxH Min. (cm)	WxH Max. (cm)
Standard	Normal	22x12	22x2	22x12
	PED	20x8	20x2	20x12
	Wide	24x12	24x2	25x12
Standard (Segment)		Selection	H 2	H 12
Bitewing		13x8	13x2	13x12
TMJ	TMJ Close	26x12	26x2	26x12
	TMJ Open	14x12	14x2	14x12
Sinus		14x12	14x2	14x12
Orthogonal		18x12	18x2	18x12

9.3.2 CT Protocol

Protocol		ΦxH Default (cm)	ΦxH Min. (cm)	ΦxH Max. (cm)
Jaw		10x10	8x3	12x12
Jaw-Fast		8x10	6x3	8x12
Large-Jaw		16x10	12x8	16x12
Facial		20x20	19x19	20x20
Endodontics		4x5	4x3	5x5
TMJ	Left	12x10	10x6	12x12
	Right	12x10	10x6	12x12
	Both	16x10	12x6	16x12
Sinus		14x10	12x3	15x12
Airway		12x10	12x3	15x12

9.3.3 Cephalo (One shot S-type)

Protocol	WxH Default (cm)	WxH Min. (cm)	WxH Max. (cm)
Lateral	30x25	8x8	30x25
PA	30x25	8x8	30x25
Carpus	30x25	8x8	30x25
SMV	30x25	8x8	30x25
Waters	30x25	8x8	30x25
Reverse Towne	30x25	8x8	30x25

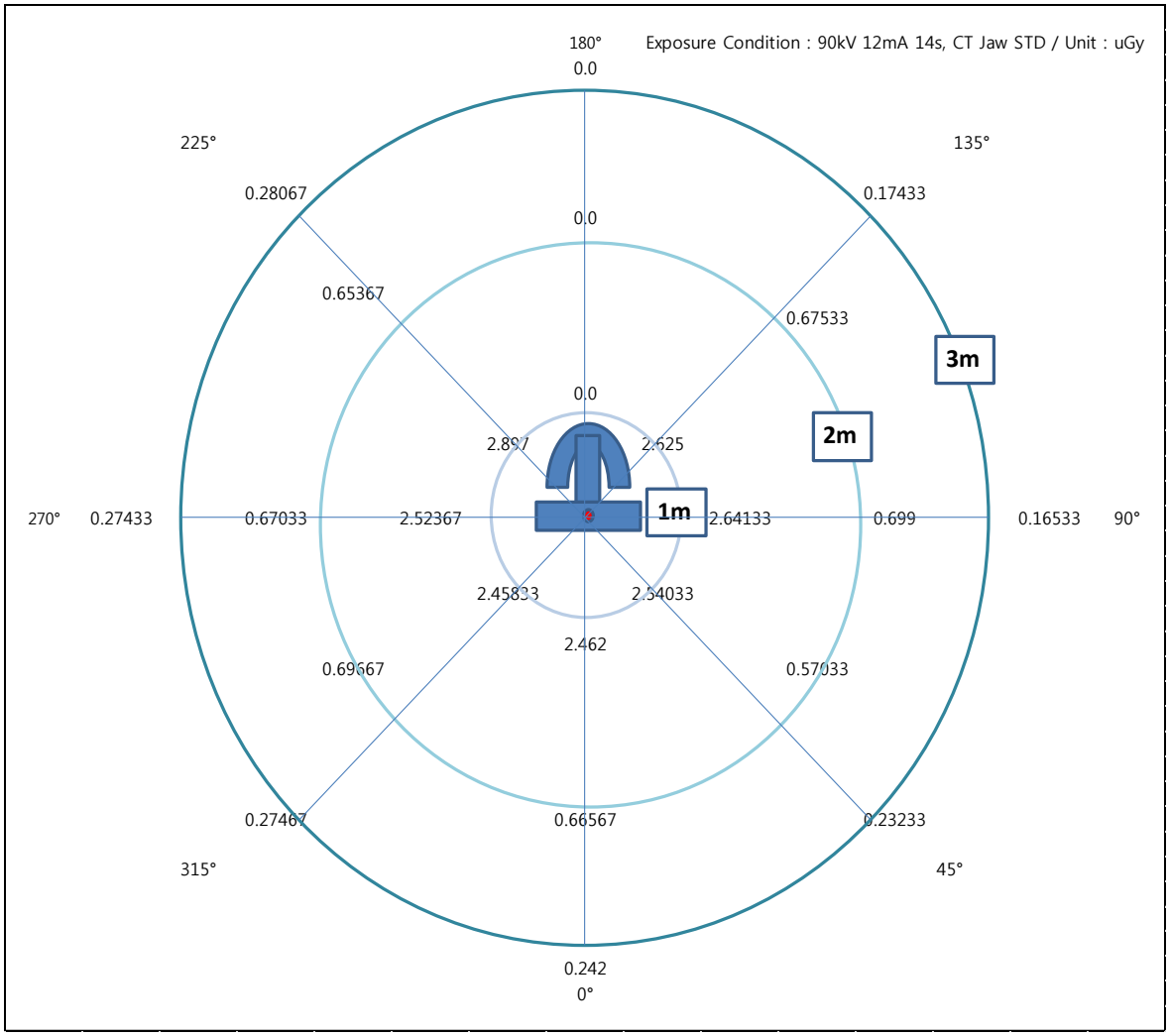
9.3.4 Cephalo (One shot L-type)

Protocol	WxH Default (cm)	WxH Min. (cm)	WxH Max. (cm)
Lateral	33x33	8x8	33x33
PA	33x33	8x8	33x33
Carpus	33x33	8x8	33x33
SMV	33x33	8x8	33x33
Waters	33x33	8x8	33x33
Reverse Towne	33x33	8x8	33x33

9.3.5 Cephalo (Scan type)

Protocol		WxH Default (cm)	WxH Min. (cm)	WxH Max. (cm)
Lateral	Normal	20x24	20x8	26x24
	Fast	20x24	20x8	26x24
PA		24x24	8x8	26x24
Carpus		22x24	8x8	26x24
Lateral Wide	Normal	26x24	20x8	26x24
	Fast	26x24	20x8	26x24
SMV		24x24	8x8	26x24

9.4 Stray Radiation



Angle (º)	Measuring Point	Distance (m)	uGy/mAs
0	1	1	0.015
	2	2	0.004
	3	3	0.001
45	4	1	0.015
	5	2	0.003
	6	3	0.001
90	7	1	0.016
	8	2	0.004
	9	3	0.001
135	10	1	0.016
	11	2	0.004
	12	3	0.001
180	13	1	Not measured
	14	2	Not measured
	15	3	Not measured
225	16	1	0.017
	17	2	0.004
	18	3	0.002
270	19	1	0.015
	20	2	0.004
	21	3	0.002
315	22	1	0.015
	23	2	0.004
	24	3	0.002

9.5 Imaging Performance

9.5.1 Panoramic

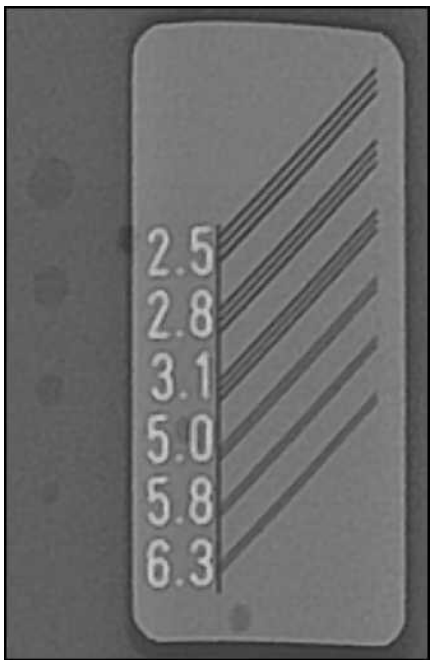
Characteristic s of Sensitivity, Dynamic range, MTF, DQE

PANORAMIC	Sensitivity	5.5 GL/nGy
	Dynamic range	16000
	MTF	60% at 1 lp/mm
	DQE	45% at 1 lp/mm

Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	
75	13	13.9	4	Producing Low Contrast Resolution ≥ 2 step

Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution(lp/mm)	
75	13	13.9	3.1	Line Pair Resolution ≥ 2.5

Image



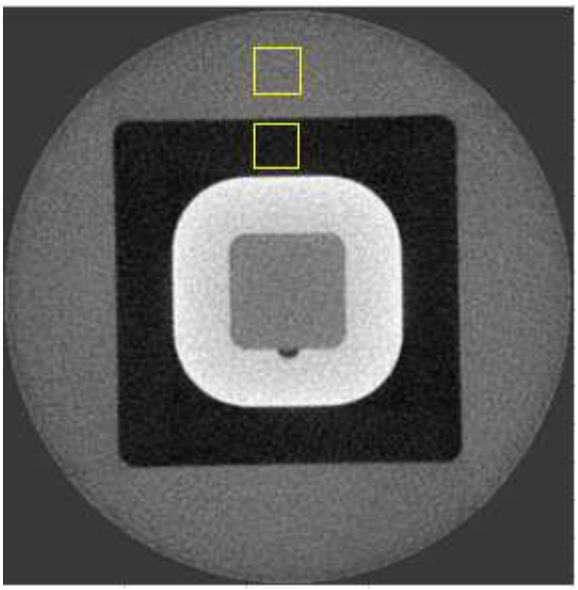
9.5.2 CT

Characteristics of Sensitivity, Dynamic range, MTF, DQE, CT Number, Uniformity and Contrast Resolution.

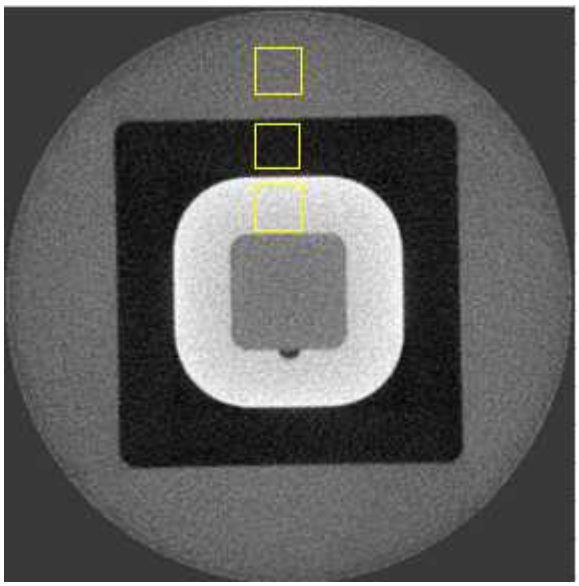
CT	Sensitivity	0.8 GL/nGy
	Dynamic range	16000
	MTF	60% at 1 lp/mm
	DQE	45% at 1 lp/mm

CT Number				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	CT number (HU)	
90	4	14	Air (HU) = -1007 PMMA (HU) = -12	Air (HU)= -1000 ± 100 PMMA (HU)= 0 ± 100

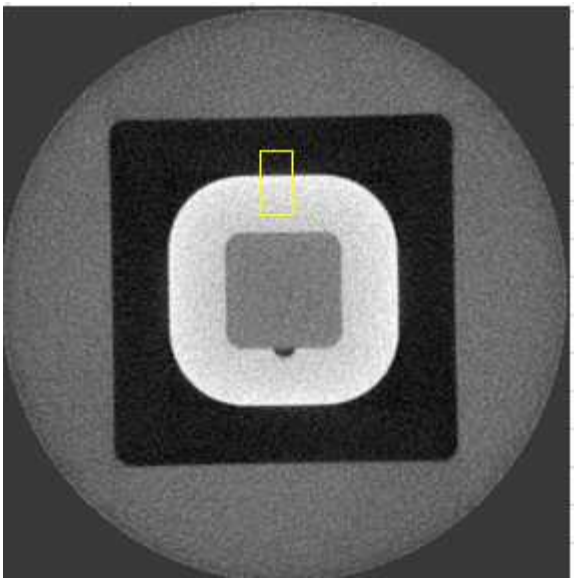
Image



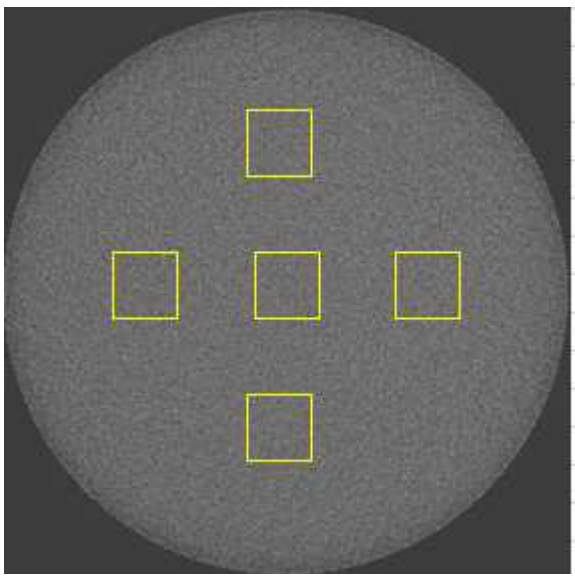
Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	CT number (HU)	
90	4	14	Air (HU) = -1007 PMMA (HU) = -12 PVC (HU) = 1284	Air (HU)= -1000 ± 100 PMMA (HU)= 0 ± 100 PVC (HU) ≥ 500
Image				



High Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	MTF 10% (lp/mm)	
90	4	14	1.65	MTF 10% ≥ 1.0LP/mm
Image				



Uniformity				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Homogeneity	
90	4	14	52	Homogeneity > 5
Image				



9.5.3 CEPH (One Shot L Type)

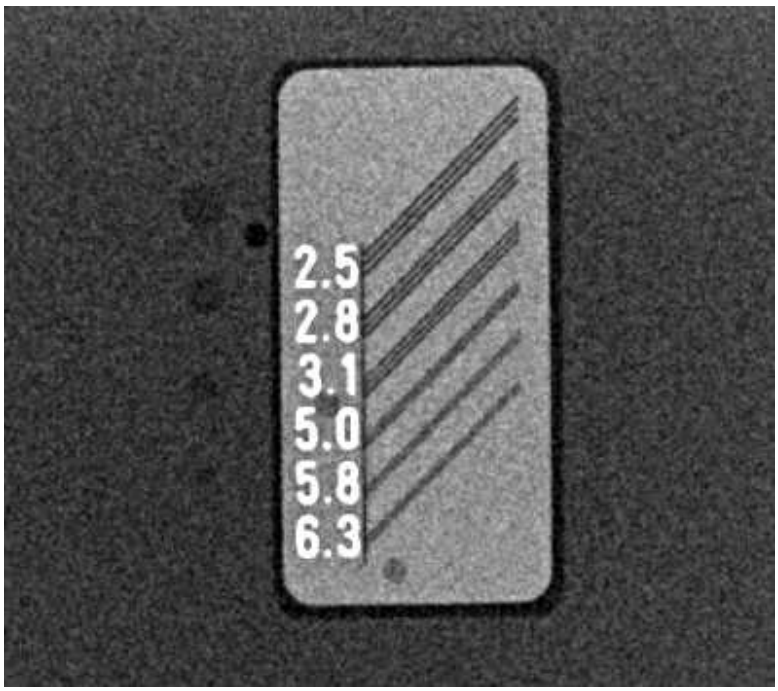
Characteristics of Sensitivity, Dynamic range, MTF, DQE

Ceph (One shot L Type)	Sensitivity	0.412 LSB/nGy
	Dynamic range	54000
	MTF	54% at 1 lp/mm
	DQE	0.2 at 1 lp/mm

Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	
90	15	0.2	4	Producing Low Contrast Resolution ≥ 1 step

Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution (lp/mm)	
90	15	0.2	3.1	Line Pair Resolution ≥ 2.5

Image



9.5.4 CEPH (One Shot S Type)

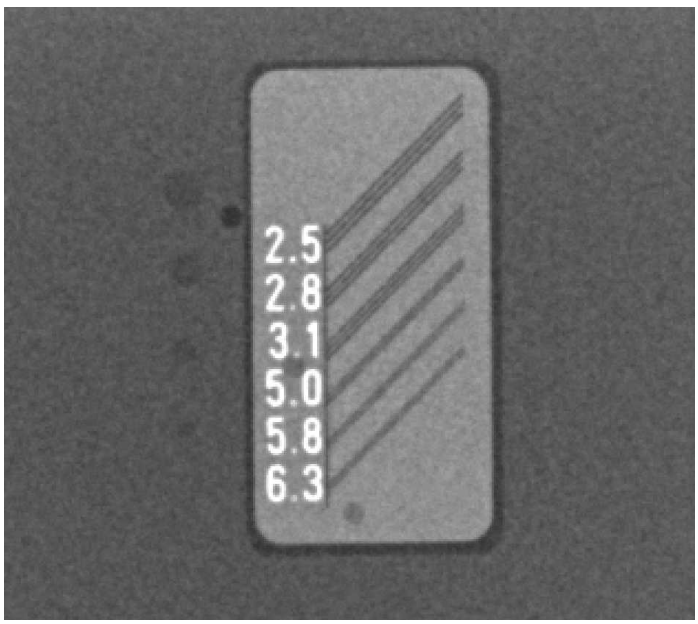
Characteristics of Sensitivity, Dynamic range, MTF, DQE

Ceph (One shot S Type)	Sensitivity	2400 ADU/uGy
	Dynamic range	15000
	MTF	54% at 1 lp/mm
	DQE	0.2 at 1 lp/mm

Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	
90	16	0.3	4	Producing Low Contrast Resolution ≥ 1 step

Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution (lp/mm)	
90	16	0.3	3.1	Line Pair Resolution ≥2.5

Image



9.5.5 CEPH (Scan Type)

Characteristics of Sensitivity, Dynamic range, MTF, DQE

Ceph (Scan type)	Sensitivity	117000 LSB / mR
	Dynamic range	≥72dB
	MTF	75% at 1 lp/mm
	DQE	0.88 at 1 lp/mm

Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	
90	6	15	3	Producing Low Contrast Resolution ≥ 1 step

Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution(lp/mm)	
90	6	15	2.5	Line Pair Resolution ≥2.5

Image