

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: 50~110kV Tube Current: Max 22mA Focal Point Size: 0.5mm Target Angle: 5° Heat Capacity: 35kJ	
	High-Voltage Generator	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 Panoramic Use	Pixel Size: 100um Pixel Matrix: 60x1512 Pixel Area: 6.0mm(W)x151.2mm(H)	Option
	For Panoramic Use	Pixel Size: 150um Pixel Matrix: 960x786 Pixel Area: 144.0mm(W)x117.9mm(H)	Option
	For Panoramic Use	Pixel Size: 100um Pixel Matrix: 48x1500 Pixel Area: 4.8mm(W)x150mm(H)	Option
	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: 139um Pixel Matrix: 3072x2560 Pixel Area: 427mm(W)x356mm(H)	Option
	For CEPH Use (Scan Type)	Pixel Size: 100um Pixel Matrix: 48x2400 Pixel Area: 4.8mm(W)x240mm(H)	Option
	For CT Use	Pixel Size: 150um Pixel Matrix: 960x786 Pixel Area: 144.0mm(W)x117.9mm(H) Pixel resolution: above 1 lp/mm	
SID		CT: 661mm Pano: 657mm Ceph(Scan): 1663mm Ceph(Oneshot-S): 1663mm Ceph(Oneshot-L): 1504mm	
Tube Voltage	CT	Child: 60~90kV Adult: 60~90kV	
	Pano	Child: 69~90kV Adult: 60~90kV	
	Ceph	Child: 60~90kV Adult: 90~90kV	
Tube Current	CT	Child: 4~17mA Adult: 4~17mA	

	Pano	Child: 4~12mA 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: 1.39 Pano: 1.31 Scan Ceph: 1.11 Oneshot Ceph: 1.13	
Alignment Beam	IEC60825-1 Safety Ratings	Class I	
	Wavelength	650nm±20nm	
	Output power	<1mW	
Apparatus Specifications	Size	1,118mm(W)×1,481mm(D)×2,296mm(H)	
	One Shot S Type CEPH Inclusive	1,831mm(W)×1,481mm(D)×2,296mm(H)	
	One Shot L Type CEPH Inclusive	1,672mm(W)×1,481mm(D)×2,296mm(H)	
	Scan Ceph Inclusive	1,831mm(W)×1,481mm(D)×2,296mm(H)	
	Weight	185kg±10%	
	One Shot S Type CEPH Inclusive	211kg±10%	
	One Shot L	211kg±10%	

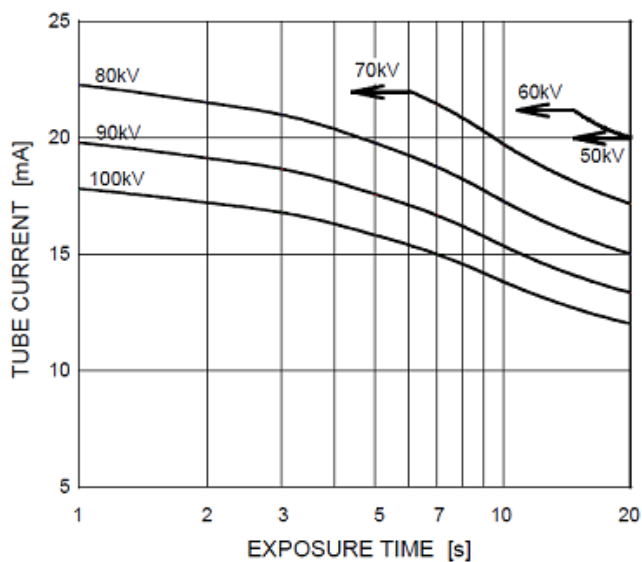
	Type CEPH Inclusive		
	Scan Ceph Inclusive	212.5kg±10%	
Quantity per pack		1 SET	
Lift Column Height Control	Stroke	670mm	
Software		RayScan ver. 2.1 or higher	
Workstation	OS	Windows 7, 64Bit	Use products with certificate from National or Accredited Organization.
	CPU	Intel Dual Core or higher	
	RAM	8GB or higher	
	HDD	1TB or higher	
	Network	Gigabit Ethernet	
Operating Environment	Ambient Temperature Range	15°C ~ 25°C	
	Relative Humidity	20%~ 60%	
	Atmospheric Pressure Range	700hPa ~1060hPa	
Transport & Storage Environment	Temperature Range	-10°C ~ 50°C	
	Relative Humidity	10%~ 90%	
	Atmospheric Pressure Range	700hPa ~1060hPa	

9.1.1 X-ray Tube

9.1.1.1 Maximum Rating Charts

Constant potential high-voltage generator

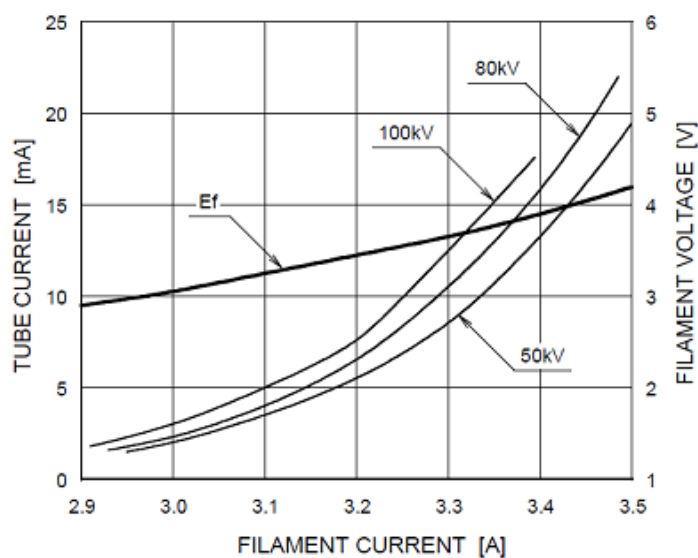
Nominal Focal Spot Value: 0.5



9.1.1.2 Emission & Filament Characteristics

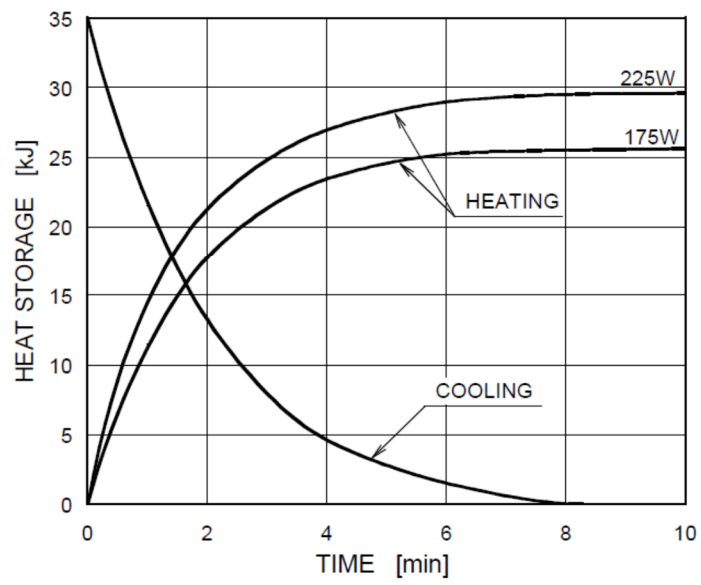
Constant potential high-voltage generator

Nominal Focal Spot Value: 0.5



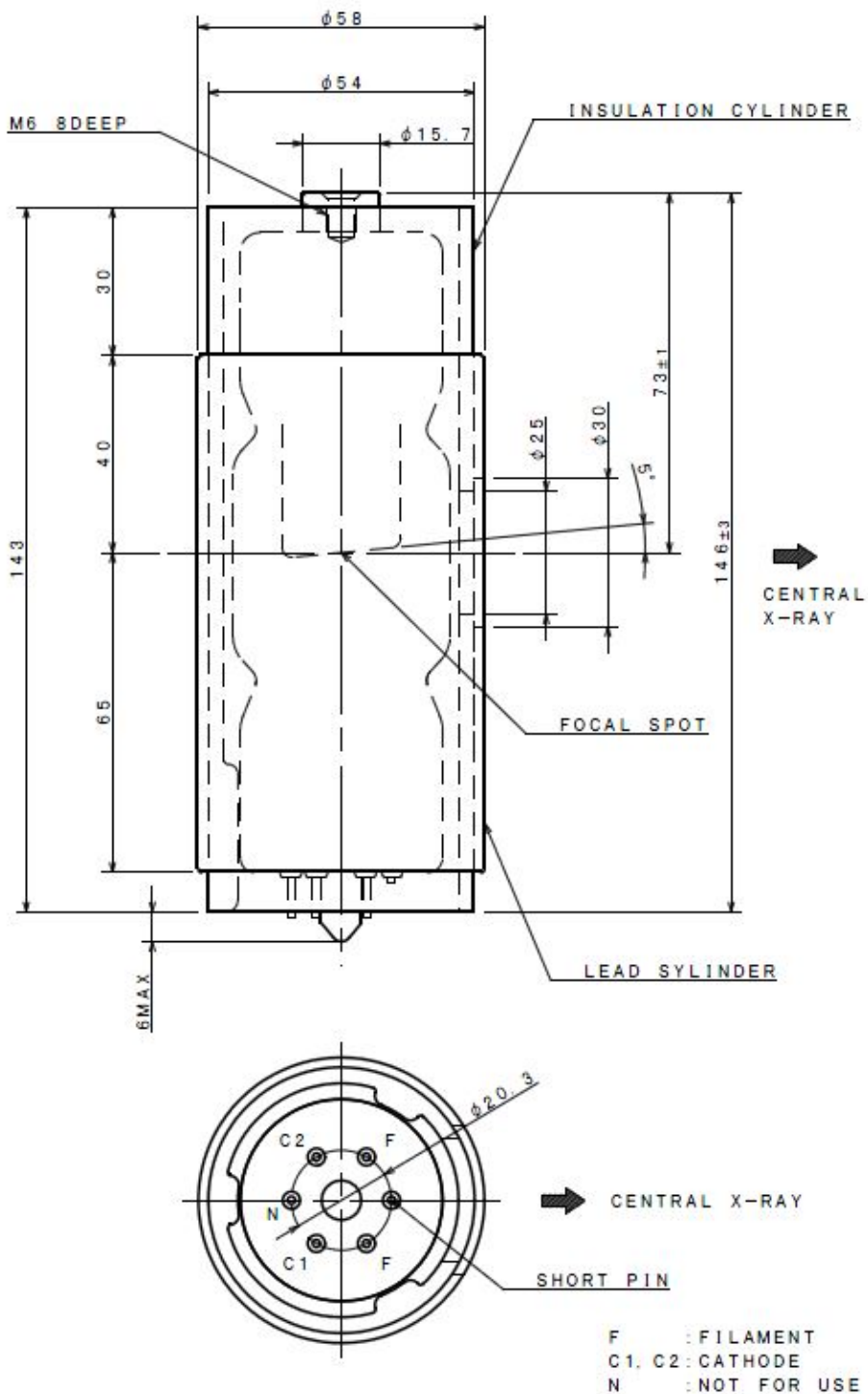
9.1.1.3 Anode Thermal Characteristics

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

Radiation exposure is a concern in both adults and children. However, children are more sensitive to radiation than adults and have a longer life expectancy. Radiation risk is higher in young patients, as they have more rapidly dividing cells than adults. The younger the patient, the more sensitive they are. Using the same exposure parameters on a child as used on an adult may result in larger doses to the child. There is no need for these larger doses to children, and X-ray settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

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

- X-ray dosage is noted as $\text{mGy}\cdot\text{cm}^2$ (dose area product) and measured in the primary collimator. The dosage has $\pm 25\%$ tolerance.

9.2.3.2 CT

- X-ray dosage is noted as CTDIvol (mGy) and has $\pm 25\%$ 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.
- $\text{CTDI}_{100} = [f \times \text{measured value}] / (\text{beam width})$, conversion factor $f=0.0087\text{mGy/mR}$
- $\text{CTDI}_w = 1/3\text{CTDI}_{100} \text{ center} + 2/3\text{CTDI}_{100}$ (mean value of 4 positions)
- CT consists of 1 revolution imaging, therefore CTDIw and CTDIvol are equivalent.
- $\text{CTDI}_{\text{vol}} \leq 20\text{mGy}$ 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	23x11	23x2	23x11
	PED	20x8	20x2	20x11
	Wide	25x11	25x2	25x11
Standard (Segment)		Selection	H 2	H 11
Bitewing		13x8	13x2	13x11
TMJ	TMJ Close	26x11	26x2	26x11
	TMJ Open	14x11	14x2	14x11
Sinus		11x11	11x2	11x11
Orthogonal		18x11	18x2	18x11

9.3.2 CT Protocol

Protocol	CT130			CT160			
	ΦxH Default (cm)	ΦxH Min. (cm)	ΦxH Max. (cm)	ΦxH Default (cm)	ΦxH Min. (cm)	ΦxH Max. (cm)	
Jaw	10x10	8x3	12x10	10x10	8x3	12x10	
Jaw-Fast	8x10	6x3	8x10	8x10	6x3	8x10	
Large-Jaw	13x10	10x8	13x10	16x10	12x8	16x10	
Tooth	5x5	4x3	6x6	5x5	4x3	6x6	
Endodontics	4x4	4x3	6x6	4x4	4x3	6x6	
TMJ	Left	8x6	8x3	12x10	8x6	8x3	12x10
	Right	8x6	8x3	12x10	8x6	8x3	12x10
	Both	-	-	-	16x6	12x3	16x10
Sinus	13x10	8x3	13x10	14x10	12x3	15x10	
Airway	12x10	8x3	12x10	12x10	12x3	15x10	

9.3.3 Cephalo (One shot S-type)

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

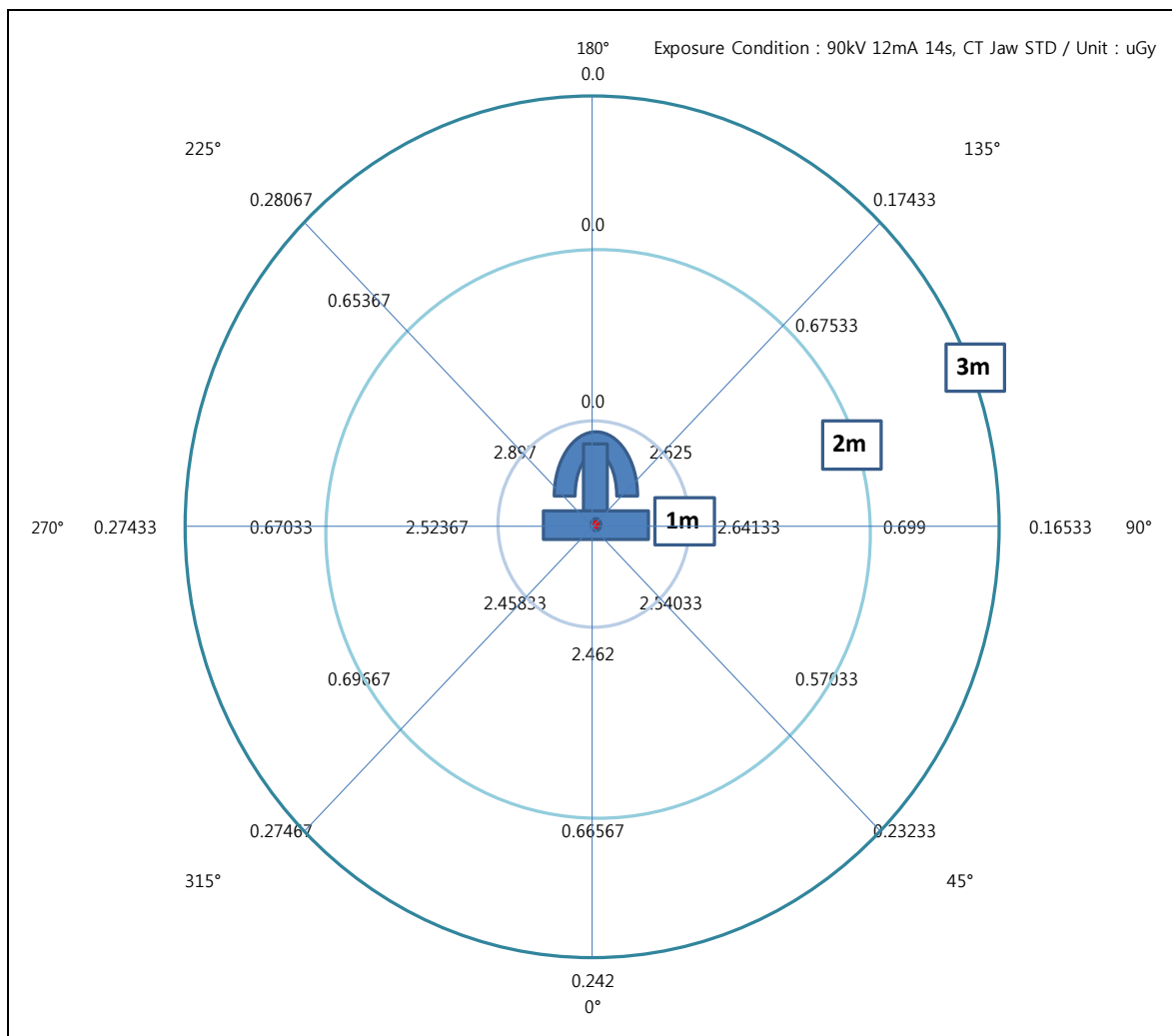
9.3.4 Cephalo (One shot L-type)

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

9.4 Stray Radiation

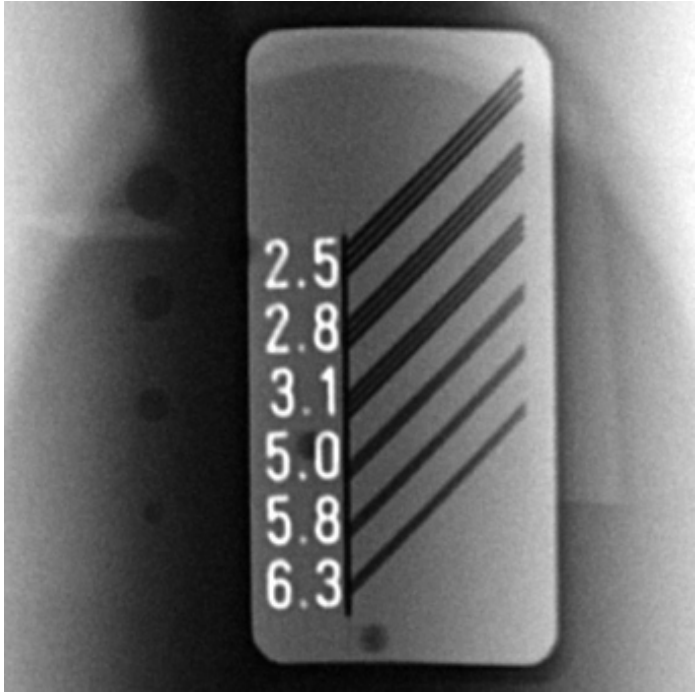


Angle (°)	Measuring Point	Distance (m)	uGy/mAs
0	1	1	0.015
	2	2	0.004
	3	3	0.001
45	4	1	0.015
	5	2	0.003
	6	3	0.001
90	7	1	0.016
	8	2	0.004
	9	3	0.001
135	10	1	0.016
	11	2	0.004
	12	3	0.001
180	13	1	Not measured
	14	2	Not measured
	15	3	Not measured
225	16	1	0.017
	17	2	0.004
	18	3	0.002
270	19	1	0.015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

Characteristics of Sensitivity, Dynamic range, MTF, DQE

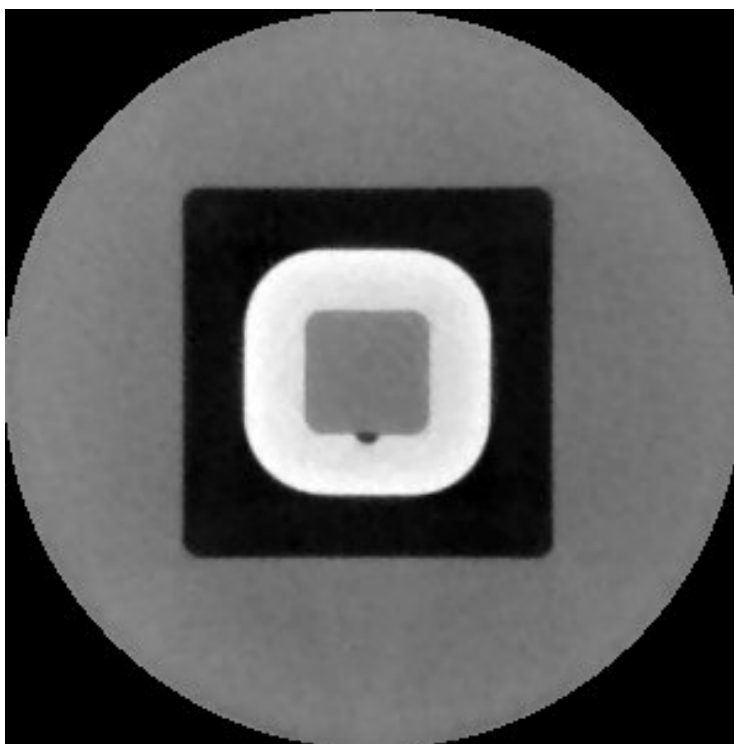
PANORAMIC			Sensitivity	5.5 GL/nGy
			Dynamic range	16000
			MTF	60% at 1 lp/mm
			DQE	45% at 1 lp/mm
Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	
78	14	13.9	4	
				Producing Low Contrast Resolution ≥ 2 step
Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution (lp/mm)	
78	14	13.9	3.1	
				Line Pair Resolution ≥ 2.5
Image				
				

9.5.2 CT

Characteristics of Sensitivity, Dynamic range, MTF, DQE, Mean CT Number, Uniformity and Spatial Resolution

CT			Sensitivity	0.8 GL/nGy
			Dynamic range	16000
			MTF	60% at 1 lp/mm
			DQE	45% at 1 lp/mm
Noise				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Contrast/Noise Ratio	Criteria
90	6	14	30.096%	CNR ≥ 20%

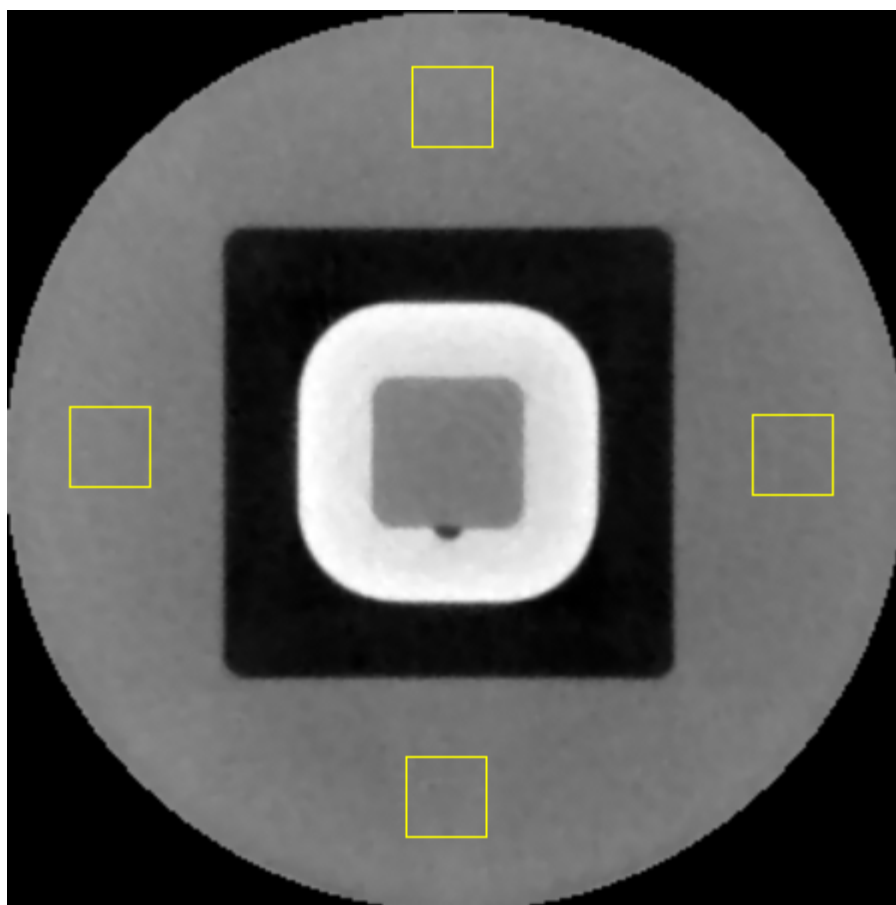
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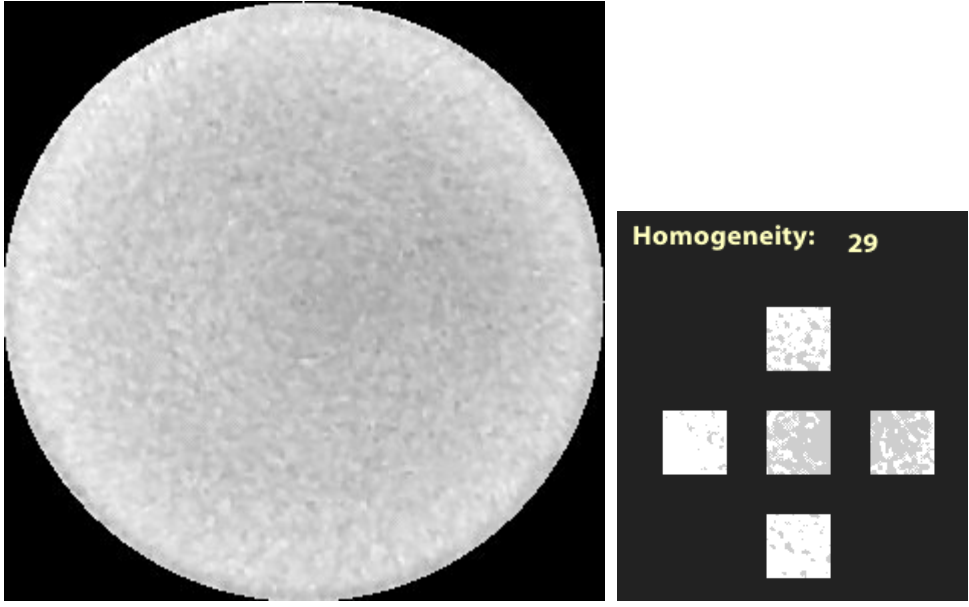


Edge between lines: 15 & 24
Noise: 27.711 (R)
Contrast: 834.000 (K)
Contrast / Noise ratio: 30.096 (K/R)

Mean CT Number						Verdict
X-ray Tube Condition			Measured Value			P
Voltage(kV)	Current (mA)	Time (sec)	CT number (HU)			Criteria
			Area	CT number	Average	
90	6	14	Upper	68.225	12.451	-100HU ≤Average≤ 100HU
			Lower	-25.583		
			Left	53.203		
			Right	-46.041		

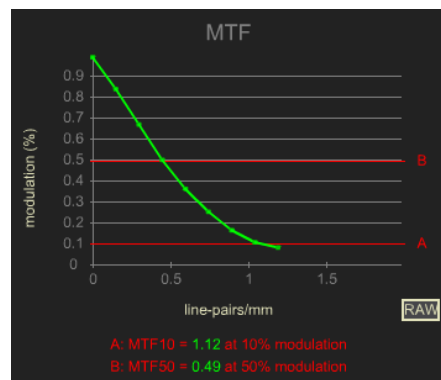
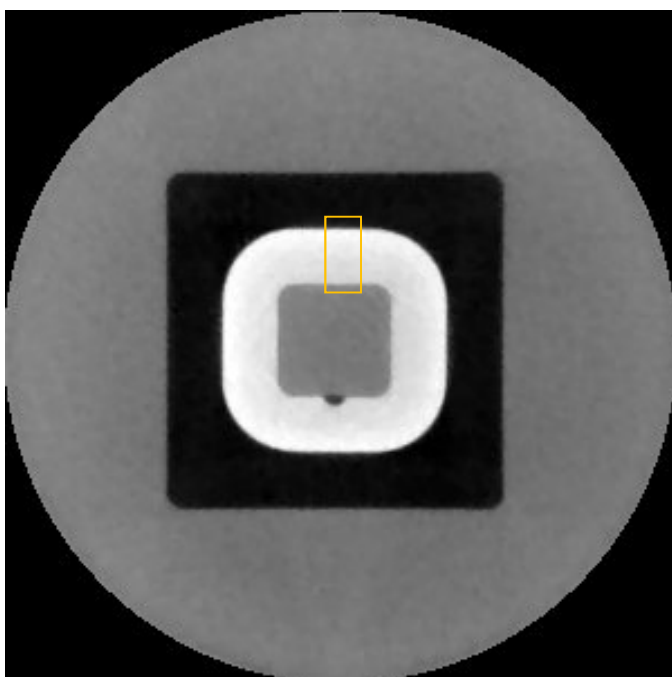
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Uniformity				Verdict
				P
X-ray Tube Condition			Measured Value	Criteria
Voltage (kV)	Current (mA)	Time (sec)	Homogeneity	
90	6	14	29	Homogeneity \geq 25
Image				
				

Spatial Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	MTF 10% (lp/mm)	
			Criteria	
90	6	14	1.12 lp/mm	
			MTF10% ≥ 1.0lp/mm	

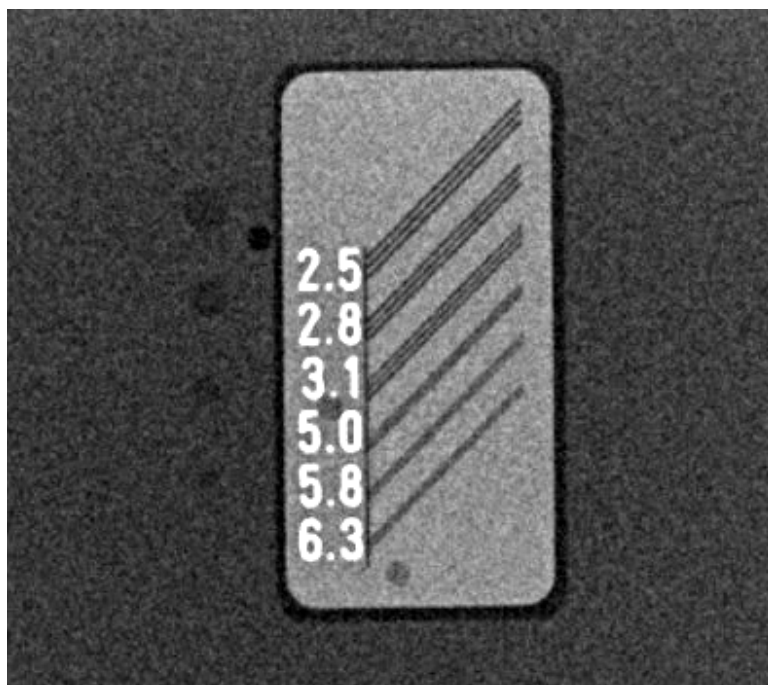
Image



9.5.3 CEPH (One Shot L Type)

Characteristics of Sensitivity, Dynamic range, MTF, DQE

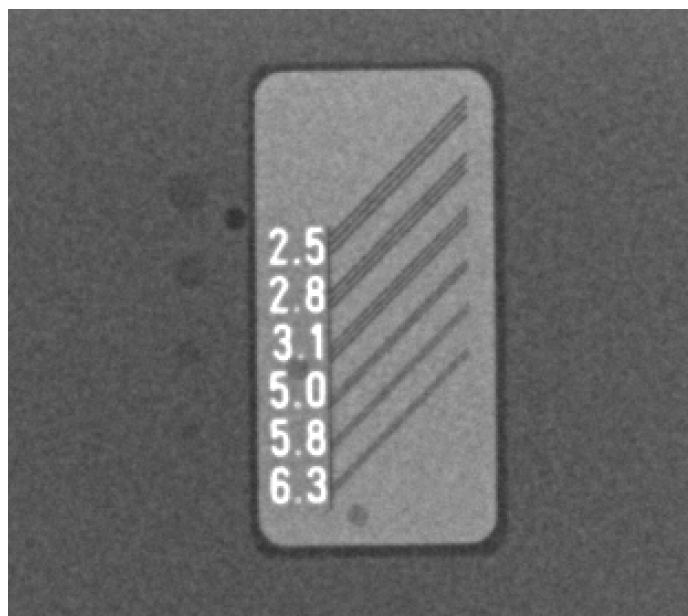
Ceph (One shot L Type)			Sensitivity	0.412 LSB/nGy
			Dynamic range	54000
			MTF	54% at 1 lp/mm
			DQE	0.2 at 1 lp/mm
Low Contrast Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	Criteria
90	16	0.3	4	Producing Low Contrast Resolution ≥ 1 step
Line Pair Resolution				Verdict
				P
X-ray Tube Condition			Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution (lp/mm)	Criteria
90	16	0.3	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	
Voltage (kV)	Current (mA)	Time (sec)	Low Contrast Resolution (Step)	Criteria	
85	10	15	4	Producing Low Contrast Resolution ≥ 1 step	
Line Pair Resolution					Verdict
					P
X-ray Tube Condition				Measured Value	
Voltage (kV)	Current (mA)	Time (sec)	Line Pair Resolution(lp/mm)	Criteria	
85	10	15	3.1	Line Pair Resolution ≥ 2.5	
Image					

