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 Target Angle: 5° Heat Capacity: 35kJ	
	High-Voltage Generator	Tube Voltage: 60~100kV(±10%) Tube Current: 4~17mA(±20%) Power Input: 2.185kW Power Output: 1.7kW (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 : 100kV/17mA Max. mA when kV : 17mA/100kV	

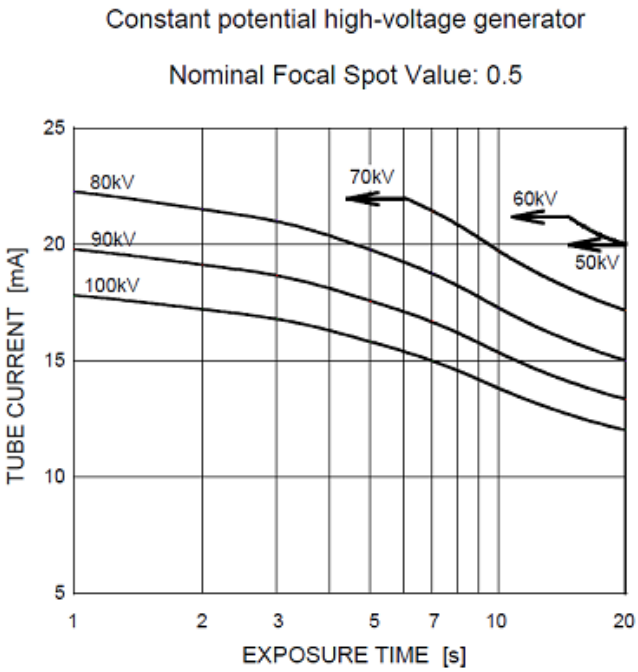
X-ray Detector	For Panoramic Use	Pixel Size: 100um Pixel Matrix: 60x1512 Pixel Area: 6.0mm(W)x151.2mm(H)	
	For Panoramic Use	Pixel Size: 119um Pixel Matrix: 1256x1256 Pixel Area: 149.5mmW)x149.5mm(H)	
	For CEPH Use (One Shot S Type)	Pixel Size: 139um Pixel Matrix: 2176x1792 Pixel Area: 302mm(W)x249mm(H)	Option
	For CEPH Use (One Shot L Type)	Pixel Size: 139um Pixel Matrix: 3072x2560 Pixel Area: 427mm(W)x356mm(H)	Option
	For CEPH Use (One Shot L Type)	Pixel Size: 127um Pixel Matrix: 3328x3328 Pixel Area: 422.7mm(W)x422.7mm(H)	
	For CEPH Use (Scan Type)	Pixel Size: 100um Pixel Matrix: 48x2400 Pixel Area: 4.8mm(W)x240mm(H)	Option
	For CT Use	Pixel Size: 200um Pixel Matrix: 624x624 Pixel Area: 124.8mm(W)x124.8mm(H) Pixel resolution: above 1lp/mm	Option
	For CT Use	Pixel Size: 119um Pixel Matrix: 1256x1256 Pixel Area: 149.5mm(W)x149.5mm(H) Pixel resolution: above 1lp/mm	Option
SID		CT: 677mm Pano: 677mm Ceph(Scan): 1650mm Ceph(Oneshot-S): 1660mm Ceph(Oneshot-L): 1507mm	
Tube Voltage	CT	Child: 60~100kV, Adult: 60~100kV	
	Pano	Child: 60~100kV, Adult: 60~100kV	
	Ceph	Child: 60~100kV, Adult: 60~100kV	

Tube Current	CT	Child : 4~17mA, Adult : 4~17mA	
	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 : ~20s, Adult : ~20s	
	Ceph(Oneshot)	Child : ~0.8s, Adult : ~0.8s	
Magnification		CT : 1.44 PANO : 1.3 Scan Ceph : 1.11 Oneshot Ceph(S): 1.12 Oneshot Ceph(L): 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)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	150kg±10%	
	One Shot S Type CEPH Inclusive	176kg±10%	
	One Shot L Type CEPH Inclusive	176kg±10%	
	Scan Ceph Inclusive	177.5kg±10%	
Quantity per pack		1 SET	
Lift Column Height Control	Stroke	670mm	

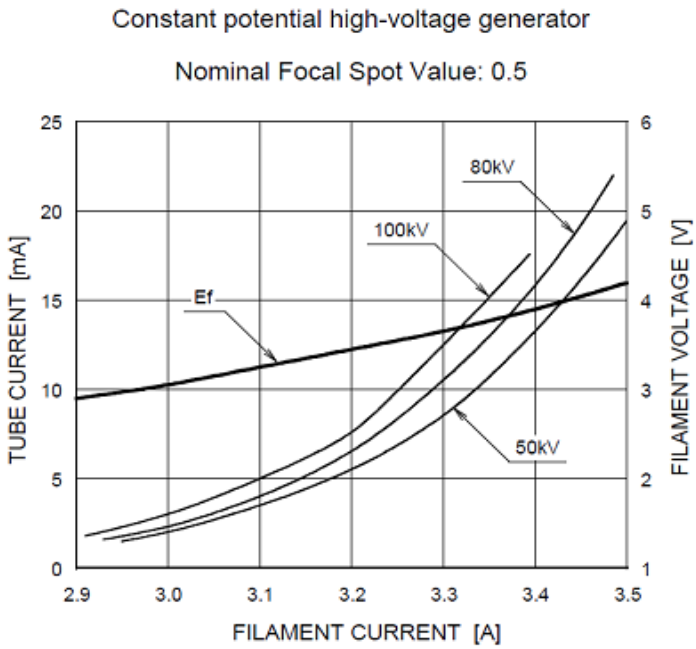
Software		RayScan ver. 2.0 or higher	
Workstation	OS	Windows 10, 64Bit	Use products with certificate from National or Accredited Organization.
	CPU	Intel Dual Core or higher	
	RAM	8GB or higher	
	HDD	1TB or higher	
	Network	Gigabit Ethernet	
Operating Environment	Ambient Temperature Range	15℃ ~ 25℃	
	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

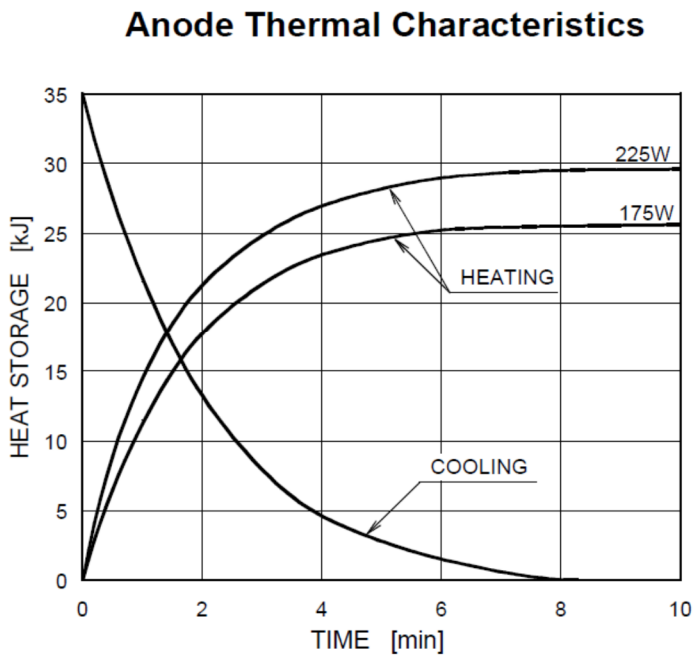
9.1.1.1 Maximum Rating Charts



9.1.1.2 Emission & Filament Characteristics

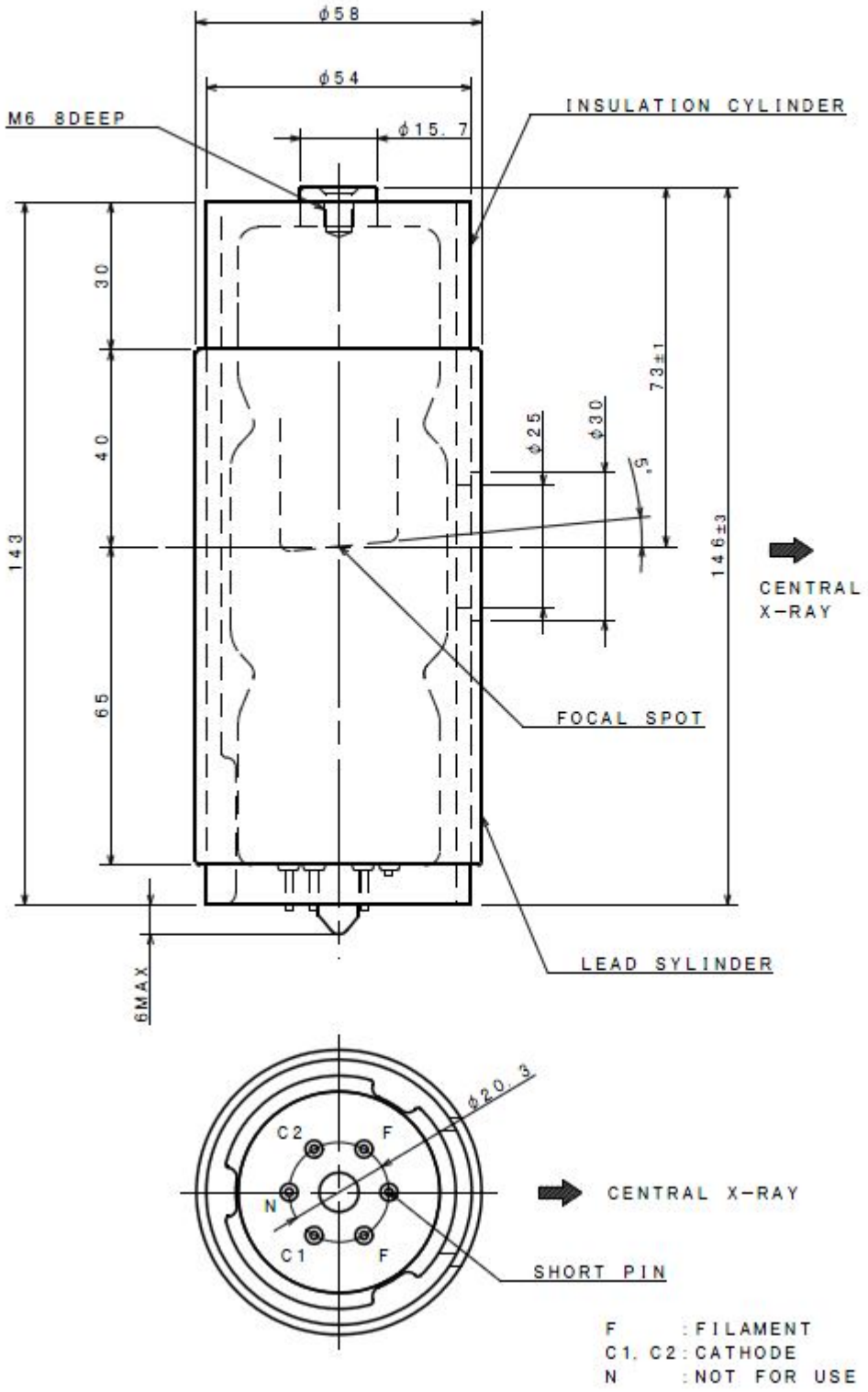


9.1.1.3 Anode Thermal Characteristics



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

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

9.2.3 Procedures Performed

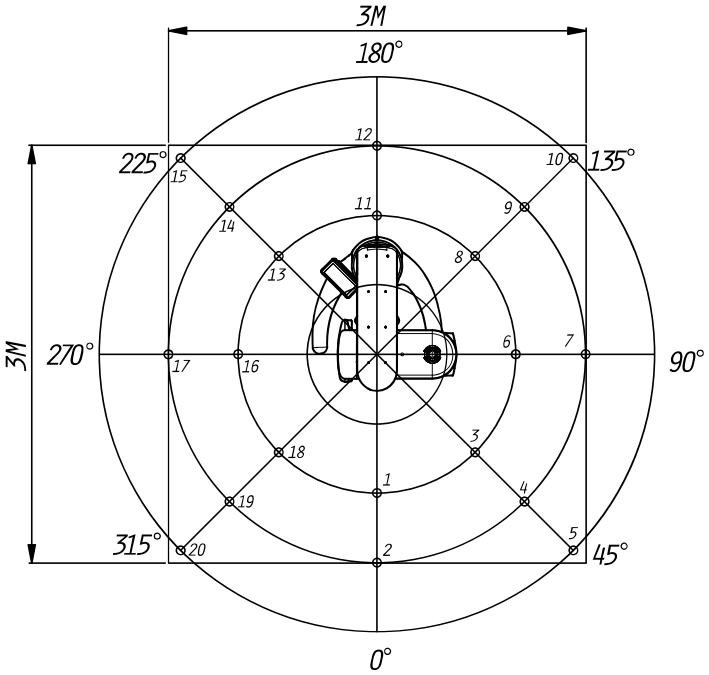
9.2.3.1 Panoramic/CEPH

- 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 Stray Radiation



Angle (º)	Measuring Point	Distance (m)	uGy/mAs
0	1	1	2.53E-02
	2	1.5	7.27E-03
45	3	1	2.53E-02
	4	1.5	1.68E-02
	5	2	6.23E-03
90	6	1	3.41E-02
	7	1.5	2.14E-02
135	8	1	6.71E-02
	9	1.5	1.92E-02
	10	2	8.90E-03
180	11	1	6.19E-05
	12	1.5	2.53E-05
225	13	1	8.91E-02
	14	1.5	2.29E-02
	15	2	1.12E-02
270	16	1	7.32E-02
	17	1.5	2.84E-02
315	18	1	4.40E-02
	19	1.5	7.73E-03
	20	2	1.10E-03

9.4 Imaging Performance

9.4.1 Panoramic

<table>
<tr><td colspan="3">Low Pair Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Line Pair Resolution
(LP/mm)</td></tr>
<tr><td>75</td><td>13</td><td>3.1</td><td>Line Pair Resolution
≥ 2.5</td></tr>
<tr><td colspan="3">Line Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>75</td><td>13</td><td>4</td><td>Producing Low Contrast
Resolution ≥ 2 step</td></tr>
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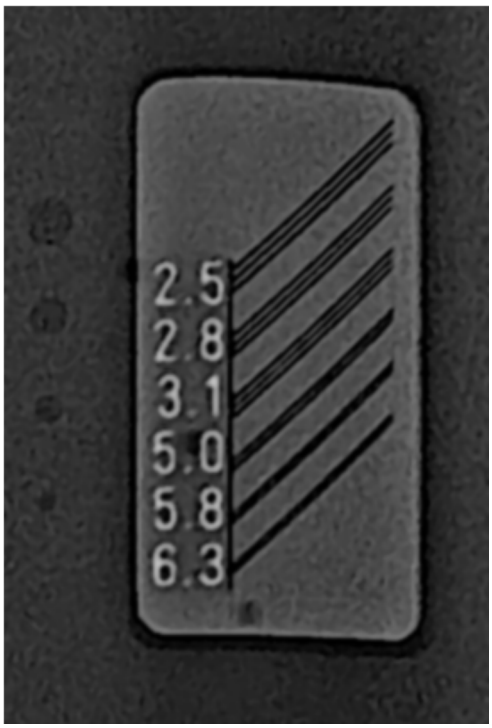
<tr><td colspan="4"> 
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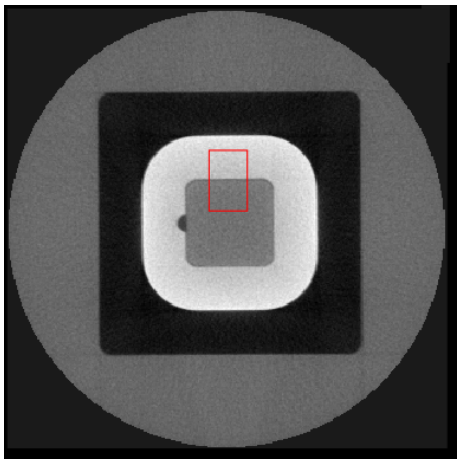
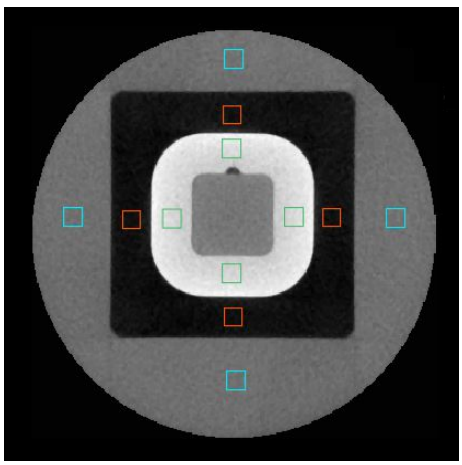
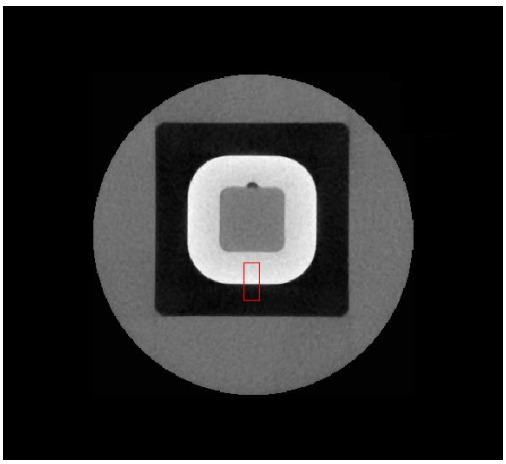
9.4.2 CT

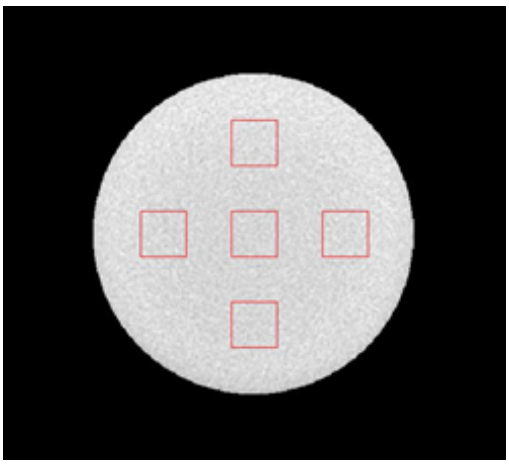
Noise			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	CT Number (HU)	
90	4	50.42	PMMA Noise ≤ 200
Image			
			

CT Number				Verdict
				P
X-ray Tube Condition		Measured Value		Criteria
Voltage (kV)	Current (mA)	CT Number (HU)		
90	4	Area	CT Number	Air(HU) = -1000 ± 100 PMMA(HU) = 0 ± 100 PVC(HU) ≥ 500
		Air	-1000.75	
		PMMA	-7.69	
		PVC	1191.42	
Image				
				

High Contrast Resolution			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	MTF 10% (lp/mm)	
90	4	1.65	MTF10% ≥ 1.0lp/mm
Image			



Uniformity			Verdict
			P
X-ray Tube Condition		Measured Value	Criteria
Voltage (kV)	Current (mA)	Homogeneity	
90	4	31.22	Homogeneity ≥ 25
Image			



9.4.3 CEPH (One Shot L Type)

<table>
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(mA)</td><td>Line Pair Resolution
(lp/mm)</td></tr>
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≥2.5</td></tr>
<tr><td colspan="3">Low Contrast Resolution</td><td>Verdict</td></tr>
<tr><td colspan="3"></td><td>P</td></tr>
<tr><td colspan="2">X-ray Tube Condition</td><td>Measured Value</td><td rowspan="2">Criteria</td></tr>
<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>15</td><td>4</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
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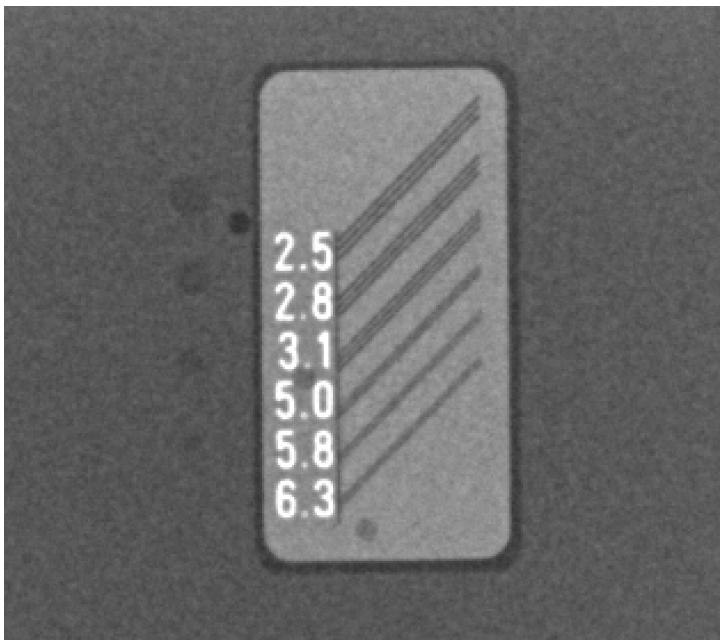
<tr><td colspan="4"> 
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9.4.4 CEPH (One Shot S Type)

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(lp/mm)</td></tr>
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<tr><td>Voltage
(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>16</td><td>3</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
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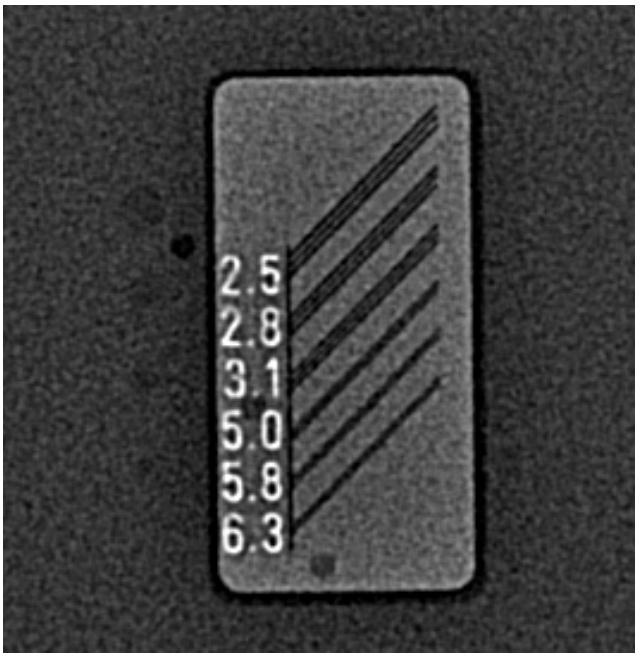
<tr><td colspan="4"> 
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9.4.5 CEPH (Scan Type)

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(lp/mm)</td></tr>
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(kV)</td><td>Current
(mA)</td><td>Low Contrast
Resolution (Step)</td></tr>
<tr><td>90</td><td>6</td><td>4</td><td>Producing Low Contrast
Resolution ≥ 1 step</td></tr>
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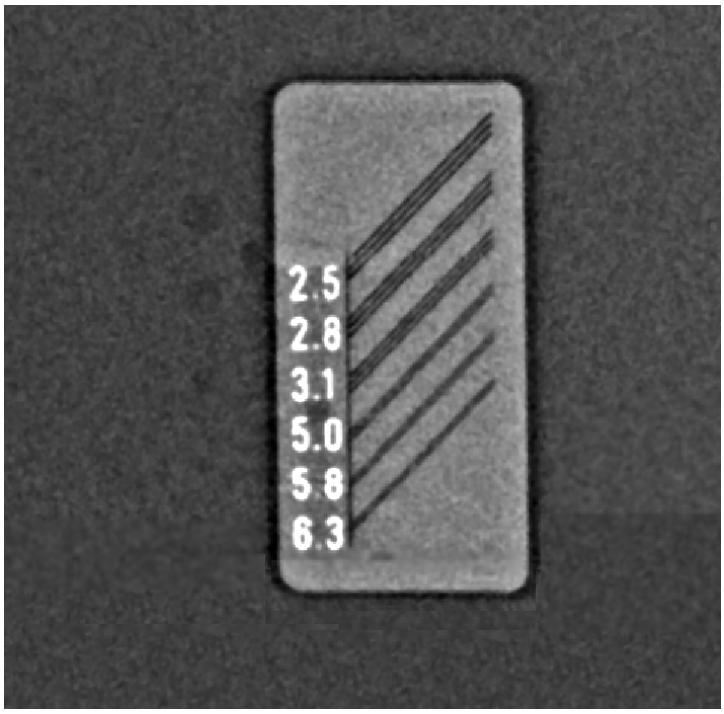
<tr><td colspan="4"> 
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