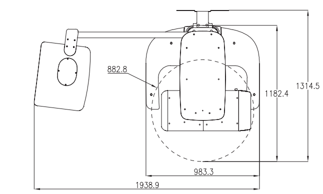
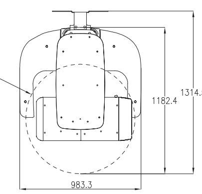
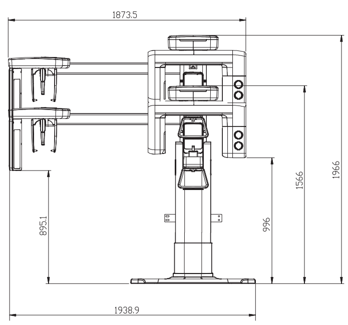
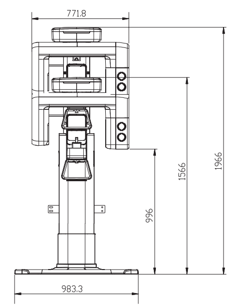
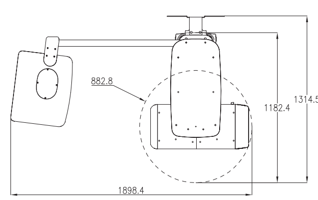
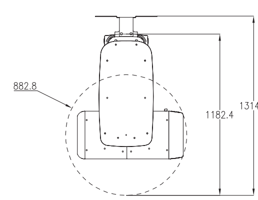
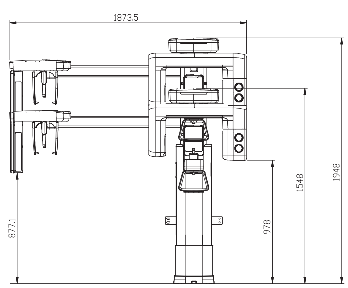
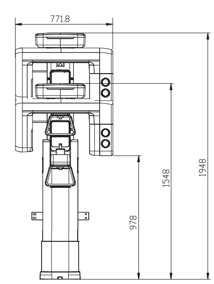
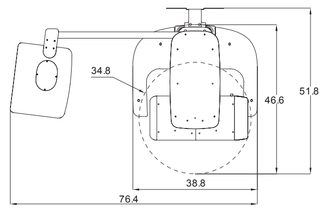
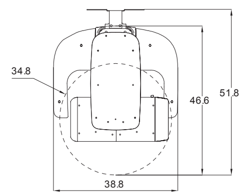
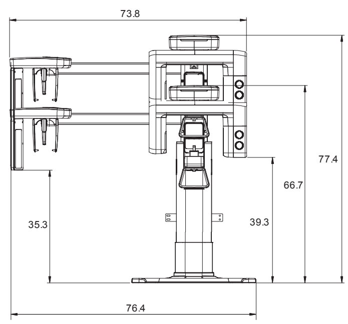
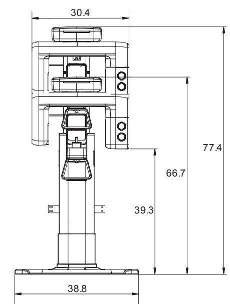
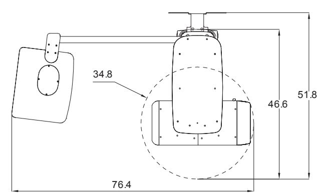
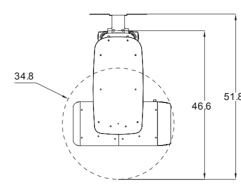
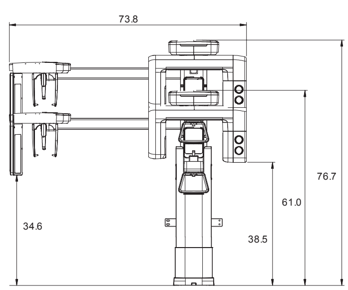
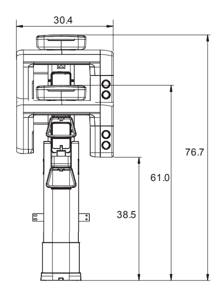
14. Technical Specifications

14.1 Mechanical Specifications

14.1.1 Dimensions

unit = mm	**With CEPH**	**Without CEPH**
Top view (with Base)		
Front View (with Base)		
Top view (without Base)		
Front View (without Base)		

unit = inch	With CEPH	Without CEPH
Top view (with Base)		
Front View (with Base)		
Top view (without Base)		
Front View (without Base)		

Item		Description
Weight	Without CEPH unit	108.3 kg (238.76 lbs. - without Base)
		160.5 kg (353.84 lbs. – with Base)
	With CEPH unit	134.3 kg (296.08 lbs. - without Base)
		186.5 kg (411.16 lbs. - with Base)
Total Height	Without Base	Max. 1948 mm (76.7”)
	With Base	Max. 1966 mm (77.4”)
Dimensions during operation (Length x Width x Height)	Without CEPH unit	without Base: 882.8 (L) x 1314.5 (W) x 1948.0 (H) (mm) 34.8 (L) x 51.8 (W) x 76.7 (H) (inch)
		with Base: 983.3 (L) x 1314.5 (W) x 1966.0 (H) (mm) 38.8 (L) x 51.8 (W) x 77.4 (H) (inch)
	With CEPH unit	without Base: 1898.4 (L) x 1314.5 (W) x 1948.0 (H) (mm) 76.4 (L) x 51.8 (W) x 76.7 (H) (inch)
		with Base: 1938.9 (L) x 1314.5 (W) x 1966.0 (H) (mm) 76.4 (L) x 51.8 (W) x 77.4 (H) (inch)
Installation type		Base Stand/Wall Mount (Default: Wall Mount type)
Packing Box Organization		Main Box, CEPH Box (Optional), Base Box (Optional)

English

14.1.2 Image Magnification

Mode	FDD (mm)	FOD (mm)	ODD (mm)	Magnification
PANO	584.6	425.6	159	1.374
CBCT	584.6	353.6	231	1.653
CEPH	1745	1524	221	1.145

- **FDD**: Focal Spot to Detector Distance
- **FOD**: Focal Spot to Object Distance
- **ODD**: Object to Detector Distance (ODD = FDD - FOD)
- **Magnification** = FDD/FOD

14.2 Technical Specifications

14.2.1 X-ray Generator Specifications

Specifications

Item			Description
Generator	Model		DG-07F23T4
	Rated output power		1.0 kW
	Inverter model name		INV-23
	Type		Inverter
	Normal/ Pulse	kVp	60 kV ~ 99 kV (1 kV increment)
		mA	4 mA ~ 12 mA (for 60 kV ~ 80 kV) 4 mA ~ 10 mA (for 60 kV ~ 99 kV) (0.1 mA increment for CBCT, 1 mA increment for PANO and CEPH)
	Cooling		Thermal protect (fan cooling ≥ 35 ℃ (95 °F))
	Total filtration		Min. 2.5 mmAl
	Default filtration		1.0 mm Al
	Added filtration		1.5 mm Al (Fixed)/PANO and CEPH mode 1.5 mm Al (Fixed) + 3.0 mm Al (Automatically added)/CBCT mode
Tube	Manufacturer		Canon Electron Tubes & Devices
	Model		D-054SB (Stationary Anode type)
	Focal spot size		0.5 mm
	Target Angle		5 degree
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	X-ray Coverage		75 mm x 380 mm at SID 550 mm
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time: Interval time)

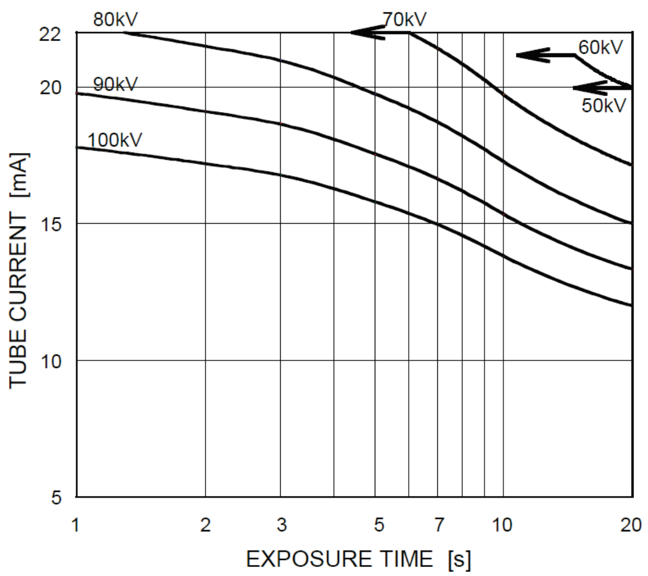
Test Condition

Mode	Tube Voltage (kVp)	Tube Current (mA)	Exposure Time (s)
PANO	60~80	4~12	2.7
	60~80	4~12	4.4
	60~80	4~12	5.7
	60~80	4~12	6.4
	60~80	4~12	6.7
	60~80	4~12	8.5
	60~80	4~12	8.8
	60~80	4~12	9.2
	60~80	4~12	9.4
	60~80	4~12	11.2
	60~80	4~12	11.4
	60~80	4~12	13.5
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
CBCT	60~99	4~10	15.5

Maximum Rating Charts

Constant Potential High-voltage Generator

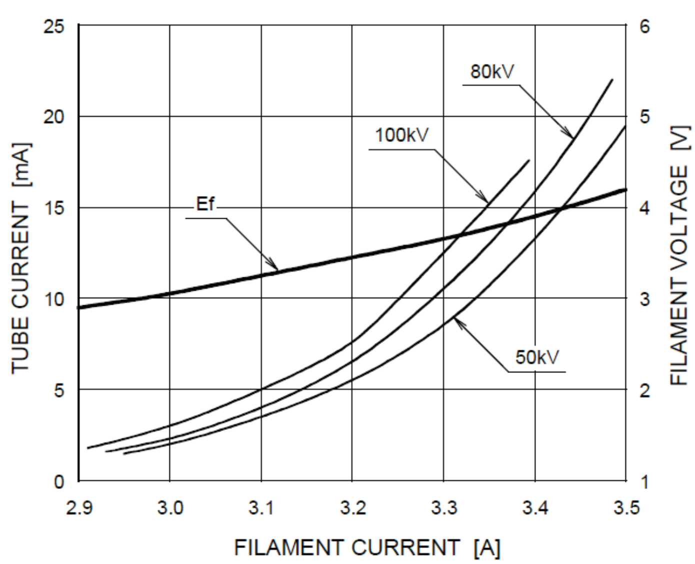
Nominal Focal Spot Value: 0.5



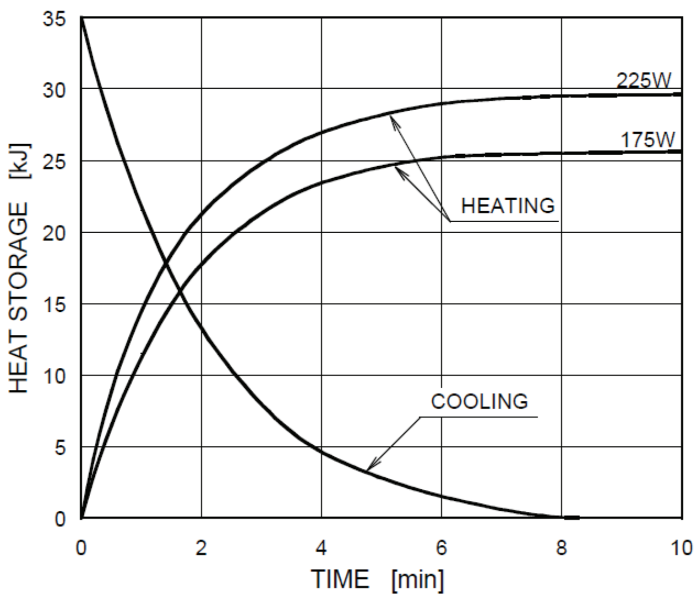
Emission & Filament Characteristics

Constant Potential High-voltage Generator

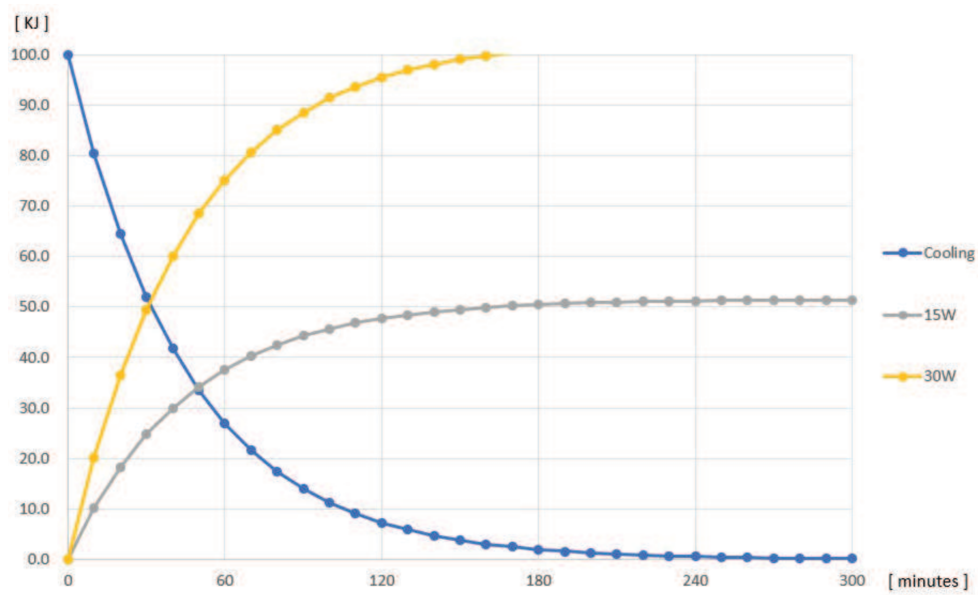
Nominal Focal Spot Value: 0.5



Anode Thermal Characteristics



X-ray Housing Assembly Tube Characteristics



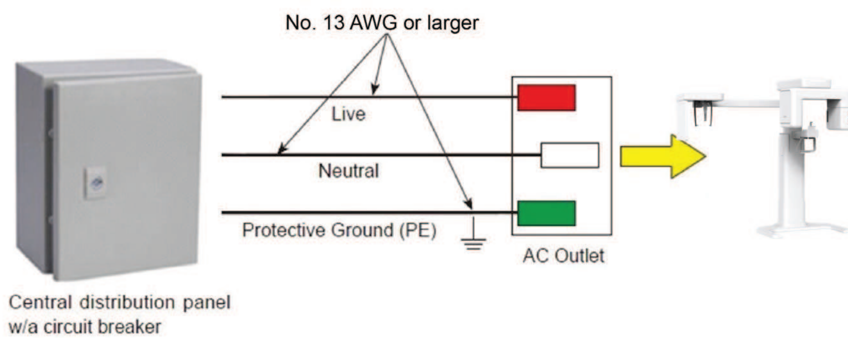
14.2.2 Detector Specifications

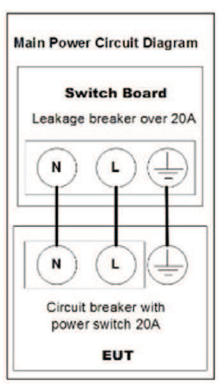
Item	Description	
	PANO & CBCT	CEPH
Model	Xmaru1404CF-Plus	Xmaru2602CF
Detector Type	CMOS photodiode array	
Pixel size	198 µm @ 4x4 binning	200 µm @ 2x2 binning
Active area	135.8 x 36.4 (mm)	259.2 x 15.6 (mm)
Frame Rate	~ 308 fps @ 4x4 binning	~330 fps @ 2x2 Binning
Analogue-Digital Conversion	14 bits	
Operating condition	10~35 ℃ (Temperature) 10~75 % (Humidity)	
Storage condition	-10~60 ℃ (Temperature) 10~75 % (Humidity)	
Sensor size	160(L) x 230(W) x 26(H) (mm)	110(L) x 279(W) x 20(H) (mm)
Sensor weight	1.5 kg	Less than 1.3 kg
Converter	CsI : Ti	
Energy Range	50~120 kVp	
Readout	Charge amplifier array	
Video Output	Optic	
MTF	> 45 % @ 1 lp/mm	> 8 % @ 2.5 lp/mm
DQE	> 60 % @~0 lp/mm	> 70 % @~0 lp/mm
Dynamic Range	> 80 dB	> 70 dB

14.3 Electrical Specifications

Item	Description
Power supply voltage	100-240 V~
Frequency	50/60 Hz
Power rating	1.7 kVA
Accuracy	Tube Voltage (kVp) ± 10 %, Tube Current (mA) ± 20 %, Exposure Time (s) ± (5 % + 50 ms)

- The input line voltage depends on the local electrical distribution system.
- Allowable input voltage fluctuation requirement: ±10 %.
- Mode of operation: Continuous operation with intermittent loading - Needs waiting time (at least 60 times the exposure time) before the next exposure begins.





NOTICE

- To assure line voltage quality, a separate 3-core grounded power cable connected directly to the central distribution panel with an over-current circuit breaker rated for 20A must be used.
- Maximally allowed deviation of the tube voltage/tube current/exposure time:

  Tube Voltage (kVp) ± 10 %/Tube Current (mA) ± 20 %/Exposure Time (s) ± (5 % + 50 ms) according to IEC 60601-2-63.
- The mains resistance should not exceed 0.045 ohms at 100 V and 0.19 ohm at 240 V.

14.4 Environmental Specifications

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

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15. Appendices

15.1 Recommended X-ray Exposure Tables

15.1.1 PANO Mode

Exposure Condition

Mode	Image Option	Gender/Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PANO Examination	High Resolution	Man	Hard	75	12
			Normal	74	12
			Soft	73	12
		Woman	Hard	74	12
			Normal	73	12
			Soft	72	12
		Child	Hard	68	10
			Normal	67	10
			Soft	66	10
SPECIAL Examination	N/A	Man	Hard	75	12
			Normal	74	12
			Soft	73	12
		Woman	Hard	74	12
			Normal	73	12
			Soft	72	12
		Child	Hard	68	10
			Normal	67	10
			Soft	66	10

English

Scan Time/Exposure Time

Examination Mode	Arch Type	Examination Mode	High Resolution	
			Scan Time (s)	Exposure Time (s)
PANO Examination	Narrow	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Normal	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Wide	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
	Child	Standard	11.9	11.4
		Right	11.9	5.7
		Front	11.9	9.2
		Left	11.9	5.7
	Orthogonal	Standard	14.1	13.5
		Right	14.1	6.7
		Front	14.1	11.2
		Left	14.1	6.7
		Bitewing	14.1	8.8
		Bitewing Incisor (Optional)	14.1	2.7
		Bitewing Right	14.1	4.4
		Bitewing Left	14.1	4.4
SPECIAL Examination	-	TMJ LAT Open	14.1	6.4
		TMJ LAT Close		
		TMJ PA Open (Optional)	13.6	9.4
		TMJ PA Close (Optional)		
		Sinus LAT (Optional)	6.2	5.6
		Sinus PA	9.6	8.5

- 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.

15.1.2 CEPH Mode

Exposure Condition

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
Lateral	High Resolution	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
	Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
Full Lateral (Optional)	High Resolution/ Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10

Examination Program	Image Option	Gender/ Age group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
PA SMV Waters' view	High Resolution	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
	Green	Man	Hard	92	10
			Normal	90	10
			Soft	88	10
		Woman	Hard	90	10
			Normal	88	10
			Soft	86	10
		Child	Hard	88	10
			Normal	86	10
			Soft	84	10
Carpus	High Resolution / Green	Man	Hard	90	6
			Normal	88	6
			Soft	86	6
		Woman	Hard	88	6
			Normal	86	6
			Soft	84	6
		Child	Hard	86	6
			Normal	84	6
			Soft	82	6

Scan Time/Exposure Time

Examination Program	High Resolution		Green	
	Scan Time (s)	Exposure Time (s)	Scan Time (s)	Exposure Time (s)
Lateral	3.9	3.9	1.9	1.9
Full Lateral (Optional)	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.

English

15.1.3 CBCT Mode

Exposure Area

FOV (cm)	Vertical Position	Horizontal Position		
		Right	Center	Left
8x8	Occlusion	X	O	X

Exposure Condition

FOV (cm)	Image Option	Gender/ Age Group	X-ray Intensity	Tube Voltage (kVp)	Tube Current (mA)
8x8	High Resolution	Man	Hard	95	7.0
			Normal	94	7.0
			Soft	93	7.0
		Woman	Hard	95	6.7
			Normal	94	6.7
			Soft	93	6.7
		Child	Hard	95	6.4
			Normal	94	6.4
			Soft	93	6.4
	Green	Man	Hard	81	6.1
			Normal	80	6.1
			Soft	79	6.1
		Woman	Hard	81	5.8
			Normal	80	5.8
			Soft	79	5.8
		Child	Hard	81	5.5
			Normal	80	5.5
			Soft	79	5.5

Scan Time/Exposure Time

FOV (cm)	Scan Time (s) (High Resolution/Green)	Exposure Time (s) (High Resolution/Green)
8x8	18.0	15.5

- 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.

Reconstruction Time/File Size (Measured Object: Skull)

FOV (cm)	Voxel Size (mm)	Reconstruction Time (s)	File Size (MB)
8x8	0.2	110	154.0
	0.3	88	45.6

- The above data is obtained from a computer system which is based on Intel E5-1607 v3@3.10GHz (16GB of RAM) and NVIDIA GeForce GTX1060 6GB.
- Image reconstruction time varies depending on computer specifications and working conditions.

15.2 X-ray Dose Data

15.2.1 DAP (Dose Area Product)

The X-ray dose data is extracted from the X-ray Dose Test Report for **vatech A9 (PHT-30CSS)**.

X-ray Dose Test Report for the **vatech A9 (PHT-30CSS)** maintains dosimetric evaluation that the **VATECH** dental diagnostic system meets all requirements specified in the IEC Collateral Standard. To limit unnecessary exposure to the patient, operator, or other staff, **vatech A9 (PHT-30CSS)** is designed to comply with IEC 60601-1-3 Part 1 General Requirements for Safety.

Test Hardware	
Brand Name (Model)	**vatech A9 (PHT-30CSS)**
Sensor Type	PANO & CBCT: Xmaru1404CF-Plus CEPH: Xmaru2602CF
X-ray Generator	DG-07F23T4
Tube	D-054SB

DAP (Dose Area Product) is a quantity used in assessing the radiation risk from diagnostic X-ray examination procedures. It is defined as the absorbed dose multiplied by the area irradiated, expressed in gray square centimeters (mGy·cm^2). Despite the limitation, DAP is the best way to predict effective dose value and currently the most convenient method for patient doses monitoring.

DAP (Dose Area Product) Calculation

DAP[mGy · cm²]=Dose[mGy] x Exposed Area[cm²]

NOTICE

When you need more information on DAP measurement procedures or test results for the equipment, please contact **VATECH** service center or your local **VATECH** representative and get assistance from **VATECH**-authorized technicians

Measurement Overview

Results

Mode	Exposure Condition	DAP [mGy·cm²]
PANO Adult Man Normal (High Resolution)	74 kVp/12.0 mA/13.5 s	133
PANO Child Normal (High Resolution)	67 kVp/10.0 mA/11.4 s	82
CEPH Adult Man LAT (High Resolution)	90 kVp/10.0 mA/3.9 s	24
CEPH Child LAT (High Resolution)	86 kVp/10.0 mA/3.9 s	22
CEPH Adult Man LAT (Green)	90 kVp/10.0 mA/1.9 s	13
CEPH Child LAT (Green)	86 kVp/10.0 mA/1.9 s	12
CBCT 8x8 Adult Man (High Resolution)	94 kVp/7.0 mA/15.5 s	676
CBCT 8x8 Adult Man (Green)	80 kVp/6.1 mA/15.5 s	414

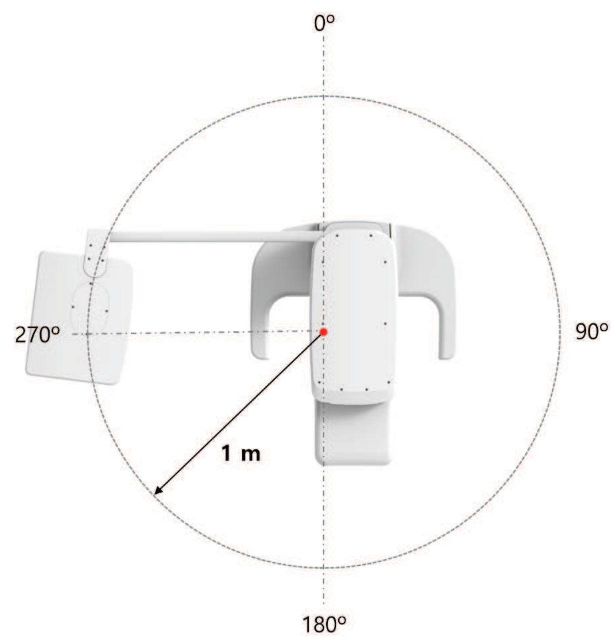
15.2.2 Leakage Dose

X-ray Leakage Dose Test Report for PHT-30CSS maintains dosemetric evaluation of the Vatech dental diagnostic system to meet requirements in IEC Collateral Standard. To limit unnecessary exposure to the patient, the operator, and other staff, PHT-30CSS is designed to fulfill IEC 60601-1 (IEC 60601-1-3, IEC 60601-2-63) and this document provides leakage test report with the evaluation condition and procedure.

15.2.2.1 Standard

National Deviation	Terminology	Permissive Range
International Standard IEC 60601-1-3	Leakage	limits leakage at 1m from the source to 100 mR in 1hr

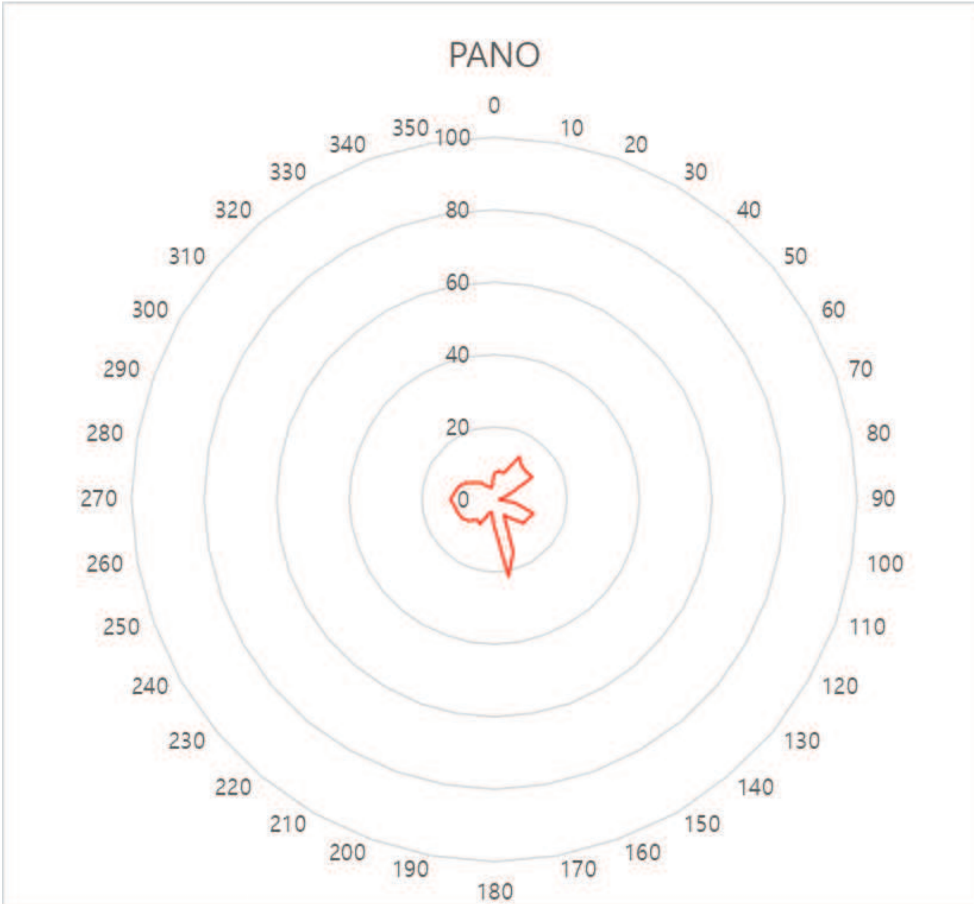
15.2.2.2 Measurement Overview



15.2.2.3 PANO Mode Results

Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	80
Applied Tube Current [mA]	12

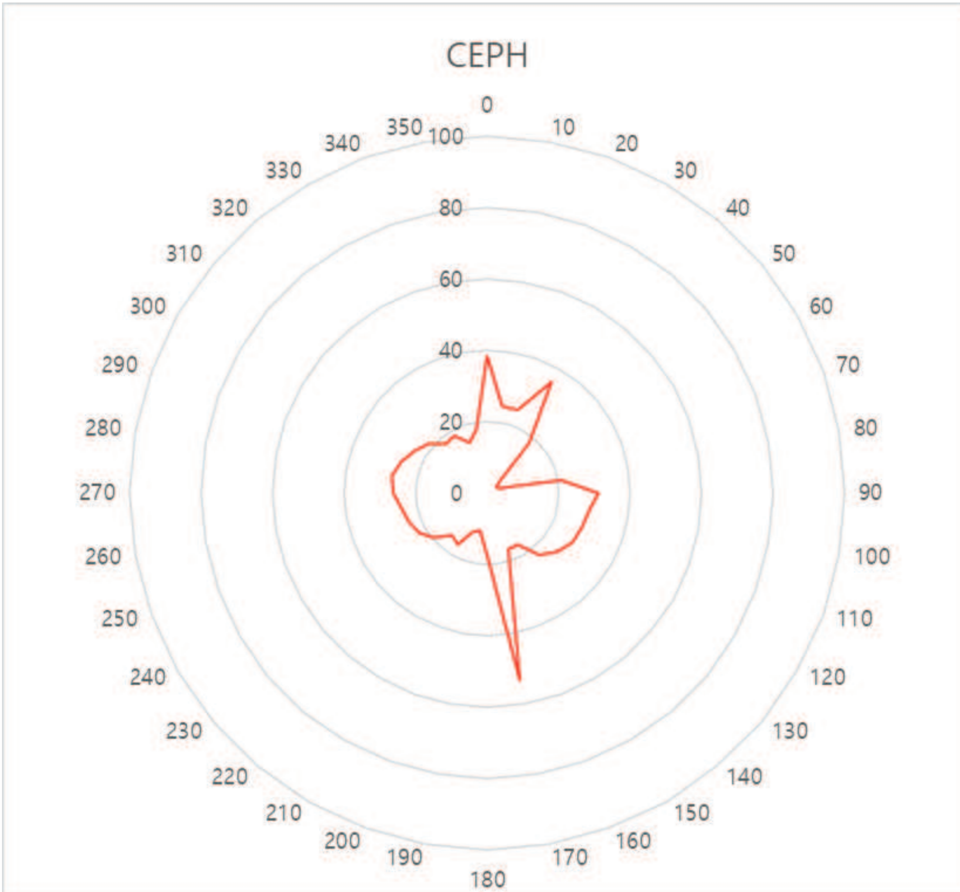
Mode / Direction [°]	PANO	
	[mR/hr]	[mGy/hr]
0	7	0.062
10	8	0.069
20	8	0.068
30	13	0.117
40	12	0.103
50	11	0.100
60	12	0.107
70	5	0.046
80	2	0.020
90	1	0.011
100	6	0.051
110	11	0.101
120	11	0.094
130	10	0.091
140	7	0.062
150	5	0.043
160	15	0.136
170	22	0.190
180	8	0.066
190	4	0.034
200	4	0.035
210	8	0.070
220	7	0.065
230	9	0.081
240	10	0.091
250	11	0.096
260	11	0.098
270	12	0.108
280	11	0.098
290	11	0.093
300	9	0.079
310	7	0.061
320	6	0.050
330	4	0.037
340	3	0.029
350	3	0.029



15.2.2.4 CEPH Mode Results

Test Condition	
Tested Mode	CEPH
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10

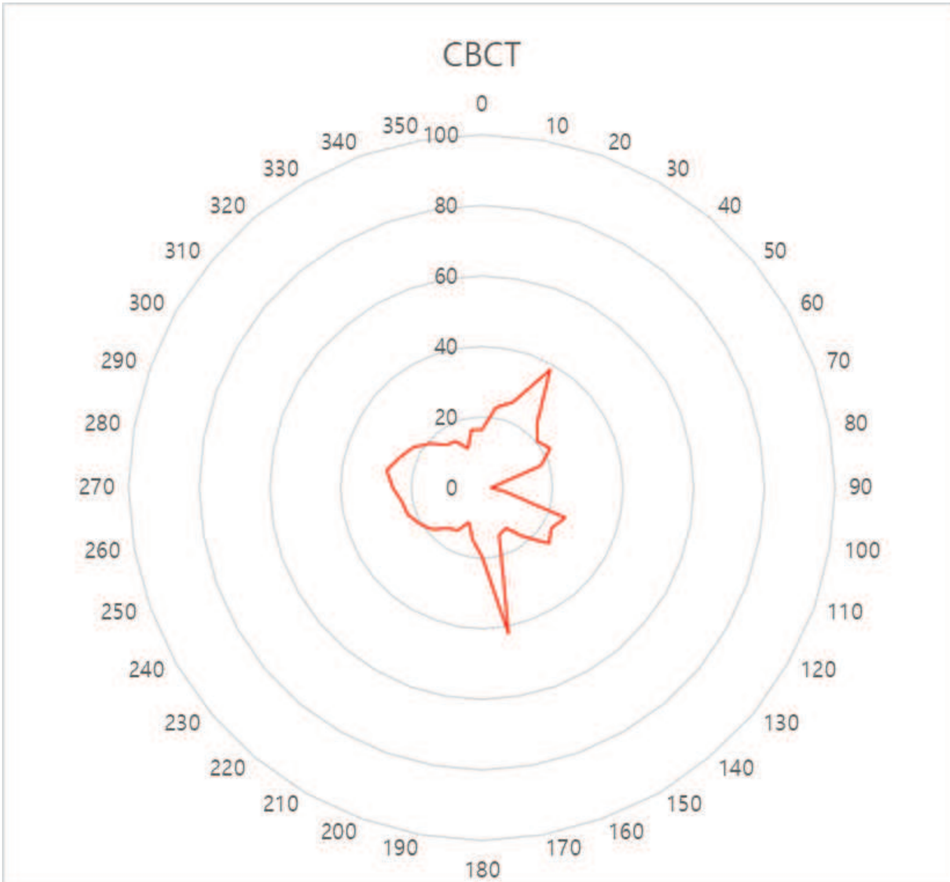
Direction [°] \ Mode	CEPH	
	[mR/hr]	[mGy/hr]
0	38	0.337
10	25	0.216
20	25	0.218
30	36	0.316
40	18	0.161
50	4	0.037
60	3	0.027
70	3	0.030
80	21	0.185
90	31	0.274
100	29	0.254
110	28	0.246
120	28	0.242
130	26	0.225
140	23	0.199
150	17	0.146
160	17	0.148
170	53	0.467
180	17	0.153
190	11	0.095
200	11	0.101
210	17	0.147
220	16	0.137
230	19	0.171
240	22	0.195
250	24	0.207
260	24	0.215
270	26	0.231
280	27	0.238
290	25	0.224
300	23	0.206
310	22	0.189
320	18	0.157
330	18	0.162
340	15	0.130
350	18	0.160



15.2.2.5 CBCT Mode Results

Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10

Mode / Direction [°]	CBCT	
	[mR/hr]	[mGy/hr]
0	16	0.143
10	23	0.200
20	26	0.226
30	39	0.338
40	24	0.212
50	20	0.179
60	22	0.196
70	18	0.157
80	5	0.043
90	3	0.023
100	6	0.055
110	25	0.221
120	23	0.200
130	25	0.218
140	18	0.157
150	13	0.118
160	14	0.126
170	42	0.369
180	19	0.171
190	15	0.133
200	10	0.092
210	14	0.125
220	15	0.133
230	18	0.162
240	21	0.180
250	22	0.196
260	23	0.203
270	25	0.223
280	27	0.239
290	25	0.219
300	23	0.198
310	19	0.168
320	16	0.137
330	15	0.132
340	12	0.103
350	17	0.146

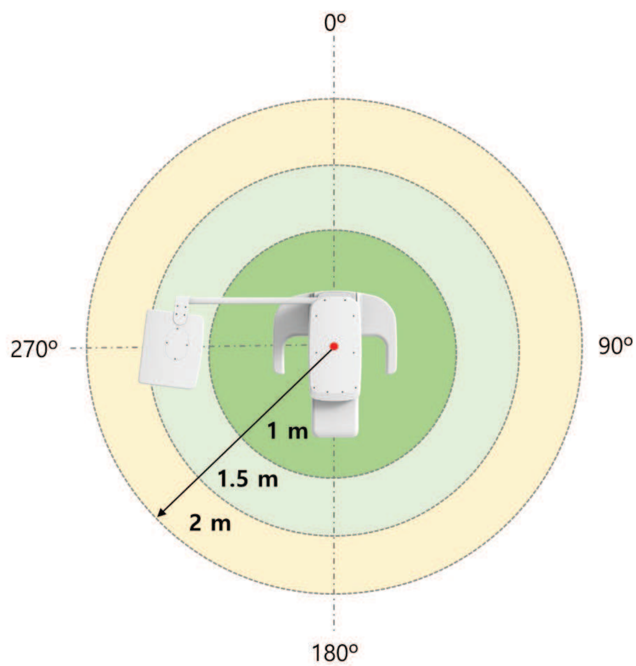

CBCT
0
10
20
30
40
50
60
70
80
90
100
110
120
130
140
150
160
170
180
190
200
210
220
230
240
250
260
270
280
290
300
310
320
330
340
350
100
80
60
40
20
0

15.2.3 Scattered Dose

X-ray Scattered Dose data concerning different angle and distance is examined for recommendations about appropriate radiation level insignificant zones of occupancy and the effectiveness of protective shielding facility around the patient's position. This information states the identity and intended position of the tested phantom and scattered dosimetric evaluation under the defined scope and test circumstances to ensure the magnitude of risks to the operator and staff, during both accident situations and routine work.

For Dental diagnosis equipment PHT-30CSS, controlled area is suggested to be a satisfied adequate condition that high level of scattered radiation within the room during exposures to restrict the exposure of the operator and staffs.

15.2.3.1 Measurement Overview

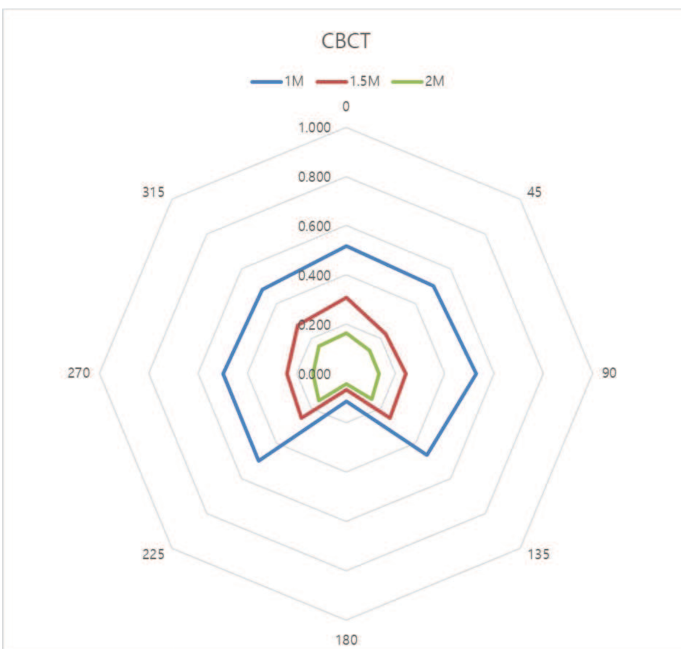


English

15.2.3.2 CBCT Mode Results

Test Condition	
Tested Mode	CBCT
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	12
Applied Exposure time [sec]	15.5

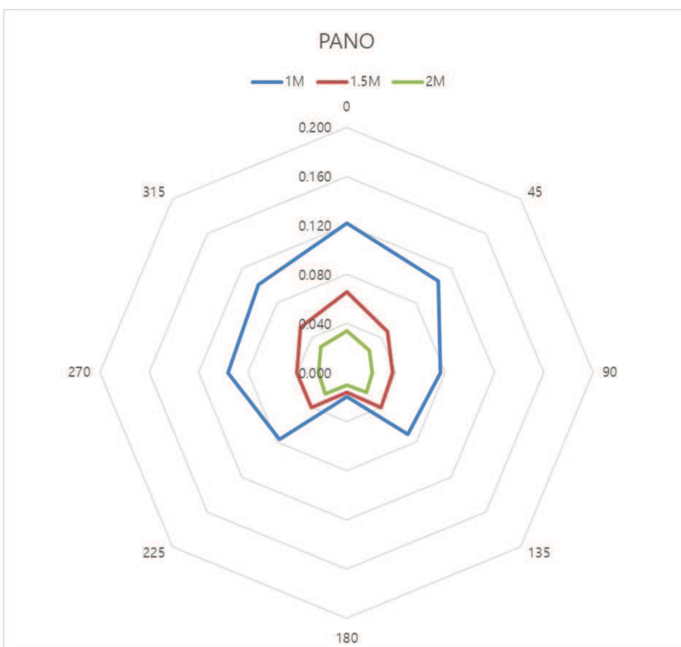
Direction [°] \ Mode		CBCT FOV 8x8 [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Occiput	0.517	0.307	0.166
45		0.502	0.229	0.133
90	Left ear	0.527	0.242	0.134
135		0.466	0.253	0.147
180	Nose	0.113	0.066	0.042
225		0.502	0.254	0.154
270	Right ear	0.500	0.239	0.135
315		0.483	0.276	0.158



15.2.3.3 PANO Mode Results

Test Condition	
Tested Mode	PANO
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	80
Applied Tube Current [mA]	12
Applied Exposure time [sec]	13.5

Direction [°]	Mode	PANO Adult Normal [mR]		
		1 m *(3.3 ft)*	**1.5 m** *(4.9 ft)*	**2 m** *(6.6 ft)*
0	Occiput	0.122	0.066	0.034
45		0.105	0.047	0.026
90	Left ear	0.077	0.038	0.021
135		0.071	0.040	0.023
180	Nose	0.019	0.016	0.010
225		0.077	0.040	0.024
270	Right ear	0.096	0.041	0.023
315		0.101	0.053	0.030



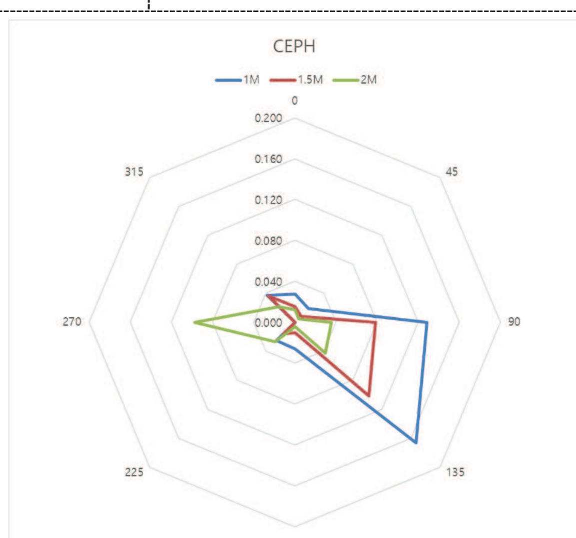
English

15.2.3.4 CEPH Mode Results

Test Condition	
Tested Mode	Ceph
Distance from focal point [m]	1~2
Applied Tube Voltage Peak [kVp]	99
Applied Tube Current [mA]	10
Applied Exposure time [sec]	5.4

Direction [°]	Mode	Ceph Full Lateral [mR]		
		1 m *(3.3 ft)*	1.5 m *(4.9 ft)*	2 m *(6.6 ft)*
0	Nose	0.027	0.015	0.012
45		0.019	0.009	0.005
90	Right ear	0.129	0.079	0.036
135		0.167	0.102	0.042
180	Occiput	0.026	0.010	0.004
225		0.025	0.016	0.027
270	Left ear	-	-	0.097
315		0.038	0.036	0.022

NOTICE Since the Ion chamber is located between the generator and the object, Data of 1 m and 1.5 m at 270 ° are not measured.



15.3 Electromagnetic Compatibility (EMC) Information

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
Mains terminal disturbance voltage	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Radiated disturbance	CISPR 11:2015	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Group1, Class A
Harmonic Current Emission	EN 61000-3-2:2014 IEC 61000-3-2:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	230 V, 50 Hz	Class A
Voltage change, Voltage fluctuations and Flicker Emission	EN 61000-3-3:2013 IEC 61000-3-3:2013	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	230 V, 50 Hz	Pst: 1 Plt: 0.65 dmax: 4% dc: 3.3%
Electrostatic Discharge Immunity	EN 61000-4-2:2009 IEC 61000-4-2:2008	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	EN 61000-4-3:2006 +A2:2010 IEC 61000-4-3:2010	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communic	EN 61000-4-3:2006 +A2:2010 IEC 61000-4-3:2010	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Table 9 in IEC 60601-1-2: 2014

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
ations Equipment					
Electrical Fast Transient/Burst Immunity	EN 61000-4-4:2012 IEC 61000-4-4:2012	IDLE mode CT mode PANO mode CEPH mode	AC Mains	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line: ± 2 kV Signal: ±1 kV 100 kHz repetition frequency
Surge Immunity	EN 61000-4-5:2014 IEC 61000-4-5:2014	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	EN 61000-4-6:2014 IEC 61000-4-6:2013 EN 61000-4-8:2010 IEC 61000-4-8:2009	IDLE mode CT mode PANO mode CEPH mode	AC Mains Hand piece cable	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	AC Line & Signal: 3 V, 0.15-80 MHz 6 V in ISM bands Between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	EN 61000-4-11:2004 IEC 61000-4-11: 2004	IDLE mode CT mode PANO mode CEPH mode	Enclosure	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 230 V, 50 Hz	30 A/m 50 Hz & 60 Hz
Voltage dips	EN 61000-4-11:2004 IEC 61000-4-11:2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°,

Phenomenon	Basic EMC standard or test method	Operating mode	Port tested	Test Voltage	Test level/requirement
				AC 240 V, 60 Hz	270° and 315°
					0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	EN 61000-4-11:2004 IEC 61000-4-11: 2004	IDLE mode CT mode PANO mode CEPH mode	AC Mains of power supply unit	AC 100 V, 50 Hz AC 100 V, 60 Hz AC 220 V, 60 Hz AC 240 V, 50 Hz AC 240 V, 60 Hz	0 % U_T; 250/300 cycle

15.4 Acquiring Images for Pediatric Dental Patients

15.4.1 Age Group: Classification Table

Ages are classified loosely into the following correspondence between FDA definition and one used in this manual.

Age Group	FDA's standard	VATECH's Standard
Infant	1 month to 2 years	N/A
Child	2 ~ 12 years of age	Child
Adolescent	12 ~16 years of age	Adult
Other	16 ~ 21 years of age	
Adult	> 21 years of age	

15.4.2 Positioning the Pediatric Dental Patients

1. Use a laser light beam guide to locate the midsagittal plane. Direct patient focusses on mirroring reflection. Affix decal to mirror to aid the patient in maintaining the correct position throughout the exposure.
2. Move the Chinrest into a position that is slightly higher than the patient's chin height before requesting that the weak place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.
3. Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the X-ray device into a position that feels as if he/she is slightly leaning backward.
4. Direct the patient to close lips around the Bite Block during the exposure.
5. Direct the patient to swallow and note the flat position of the tongue. Request that the patient sucks in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

<How to product error-free radiographic images for the pediatric patient>

(http://www.dimensionsofdentalhygiene.com/print.aspx?id=3612)

- By Evelyn M. Thomson, BSDH, MS

Panoramic radiographs are often recommended for assessing growth and development of the pediatric patient and for evaluation of developing third molars during adolescence.[1-3] While the panoramic technique seems relatively straightforward, producing a diagnostic quality image of the pediatric patient requires a mastery of technical skill.[4] Modern panoramic x-ray equipment is designed for ease of use, yet studies continue to demonstrate a high incidence of errors.[5-7] Positioning errors may occur at an even higher rate in pediatric panoramic radiographs.[7] The goal of the dental hygienist is to maximize the use of panoramic imagery in the assessment of the pediatric patient while minimizing the occurrence of retakes that result from the radiographic error.

Producing A Quality Panoramic Image

A quality panoramic radiograph should image all of the teeth, erupted and unerupted, in both the maxillary and mandibular arches from condyle to condyle in the horizontal dimension, and from the superior third of the orbit in the superior region to the inferior border of the mandible in the inferior region.[8,9] The arches should appear straight or slightly U-shaped with the occlusal plane parallel to the horizontal edges of the film **(Figure 1)**. The anterior teeth must not be magnified or diminished in size, and overlapping of adjacent posterior teeth should be kept to a minimum.

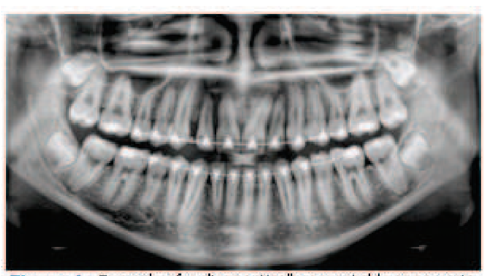


Figure 1: Example of a diagnostically acceptable panoramic radiograph of an adolescent patient undergoing orthodontic intervention. (Courtesy of Jamie Mace and Will Wright of Schick Technologies Inc.)

The most critical component in producing a diagnostically acceptable panoramic image is patient positioning. All panoramic x-ray machines have guidelines to assist with positioning the dental arches within the three dimensions of the focal trough, an area where the anatomical structures will be imaged in relative clarity. Most panoramic x-ray machines have a bite block to indicate the correct anterior-posterior position, or how far forward or back the patient should be positioned, side positioner guides for determining the correct lateral alignment, and chin rest to correctly locate the superior-inferior dimension or how far up or down the chin should be positioned.[4,10] Panoramic x-ray machines are available with a mirror and laser light beam guide that shines on the patient's face to illustrate various anatomical planes **(Figure 2)**. Incorrectly positioning the patient in any of these three dimensions will produce unique and distinct radiographic image errors **(Table 1)**.

Figure 2: Laser light beam guides that assist with determining correct patient positioning.

Table 1. Common Panoramic Positioning Errors

Error	Cause	Corrective action	Tips for pediatric patients
Anterior teeth narrow Severe posterior overlap Vertebrae superimposed over condyles	Arches positioned too far anterior	Position anterior teeth in appropriate position on bite guide. Locate appropriate position with anterior laser light guide.	Use a cotton roll to fill in missing primary teeth or partially erupted permanent teeth. Adapt adult recommendation for direction of laser light beam guide for use with primary teeth. Observe laser light beam guide on both the right and left sides.
Anterior teeth wide, blurred out of image Condyles not imaged	Arches positioned too far posterior		
Teeth on the right side appear narrowed, severely overlapped Teeth on the left side appear broad, poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the right	Position the midsagittal plane perpendicular to the floor.	Use laser light beam guide to locate midsagittal plane. Direct patient focus to mirror reflection. Affix decal to mirror to aid patient in maintaining the correct position throughout exposure.
Teeth on the left side appear narrowed, severely overlapped Teeth on the right side appear broad and poorly defined Condyles asymmetrical in width and height	Arches tipped or tilted to the left		
Flat, downward-turned, "frown" appearance to the occlusal plane Palate appears as a widened, thick, dense radiopacity Condyles flare out off the edges of the image Anterior teeth appear wide, elongated	Arches positioned too far superior	Position the Frankfort or the canthomeatal plane parallel to the floor, or the ala-tragus line 5° down toward the floor.	Move chin rest into a position that is slightly higher than the patient's chin height before requesting that the patient place chin onto the rest. Direct the patient to assume a position that resembles the erect stance of a soldier.
Exaggerated upward curve of the occlusal plane creating a "smile" appearance Hyoid bone superimposed over the mandible Condyles tilt inward Anterior teeth appear narrowed; elongated in the maxilla and foreshortened in the mandible	Arches positioned too far inferior		
Pyramid-shaped radiopacity superimposed over the anterior teeth	Patient in slumped position	Position the back and neck straight.	Direct the patient to stick out the chest while dropping the chin down. While holding the unit handles for stability, direct the patient to take a half step in toward the vertical column of the x-ray machine into a position that feels as if he/she is slightly leaning backward.
Radiolucent shadow of the commissure superimposed over the teeth, mimicking caries	Lips not closed around bite block	Position the lips around the bite block.	Direct the patient to keep the lips closed around the bite block during the exposure.
Radiolucency superimposed over the maxillary teeth apices	Tongue not placed against palate	Position the tongue flat against the roof of the mouth.	Direct the patient to swallow and note the flat position of the tongue. Request that the patient suck in the cheeks, pushing the tongue into the correct flat position against the palate and maintain this position throughout the exposure.

Anterior-Posterior Positioning Error

When the arches are positioned incorrectly in the anterior-posterior direction, distortion or ghosting of the anterior anatomy occurs. Unerupted teeth in the anterior region may not be imaged on the radiograph if positioned outside of the focal trough. It is important to note that an error of only 3 mm to 4 mm in either direction will result in a significantly compromised image.[11] When the arches are positioned too far anterior, the anterior teeth will appear narrow and diminished in size. The vertebrae of the spinal column may be superimposed over the condyles at the edges of the film and, depending on the size of the child, may be superimposed over the rami of the mandible blocking a clear view of the posterior teeth **(Figure 3)**. When the arches are positioned too far posteriorly, the anterior teeth will appear broad or widened. If the position is excessively posterior, anterior teeth may be blurred entirely from the image, and the condyles may be cut off from the edges of the film.

Figure 3: Incorrect position too far anteriorly. Note the narrow anterior teeth and superimposition of the spinal column over the condyles. The radiolucency superior to the maxillary apices indicates that the tongue was not placed against the palate. An open lip line can also be detected.

To avoid these imaging errors, the anterior teeth must occlude edge-to-edge onto the designated area of the bite block. Achieving this position is easily compromised during exfoliation of primary teeth, making precise occlusion difficult when one tooth or multiple teeth are missing or partially erupted. A cotton roll may be attached to the bite block to fill in the space created by the missing tooth or teeth. Additionally, an adjustment may be necessary when using a laser light beam guide. The manufacturer's instructions for directing the laser light beam at a predetermined tooth or interproximal space usually apply to adult patients. These instructions may need to be modified for the pediatric patient with primary or mixed dentition.

Lateral Left-Right Positioning Error

When the arches are positioned incorrectly in the lateral left-right dimension, the posterior teeth on one side will appear broad or widened, while the teeth on the other side will appear narrowed or diminished in width and severely overlapped **(Figure 4)**. This image distortion is like that which occurs with an incorrect anterior-posterior position. When the arches are rotated or tilted, the posterior teeth on one side move out of the focal trough to a position further away (back) from the image receptor, while the opposite side simultaneously moves closer (forward) to the image receptor. Depending on the severity of rotation or tilting, the inferior border of the mandible will appear distorted, and the condyles and rami will appear asymmetrical.

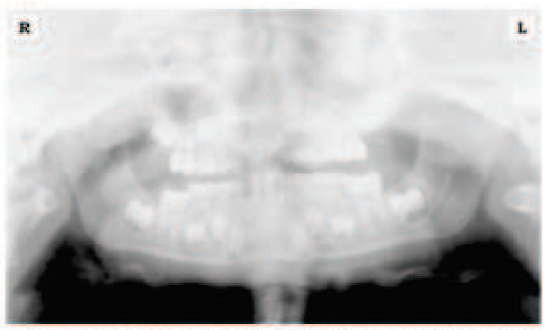


Figure 4: Incorrect lateral position tilted to the right. Note the teeth on the left are wide and poorly defined, while the teeth on the right are narrowed and severely overlapped. The inferior border of the mandible is distorted and the condyles appear asymmetrical.

To avoid imaging errors that result from incorrect lateral positioning, the midsagittal plane must be positioned perpendicular to the floor. Most panoramic x-ray machines have a head positioner and laser light beam guide, along with a mirror, to assist in determining the correct lateral head position. The pediatric patient may need additional instructions to maintain the correct position throughout the exposure.

Movement of the tube head during exposure may pique the pediatric patient's curiosity, causing the head to rotate as the eyes follow the movement of the tube head. A vertical line decal affixed to the mirror can serve as a visual aid and a focus point. An eye-catching sticker, such as those purchased from a craft store, can be adhered to the mirror in a position that aligns with the midsagittal plane. The patient can be directed to position the head so that the sticker appears at the tip of the nose and to maintain focus on this reflection throughout the exposure. Pediatric patients may find looking at themselves in the mirror entertaining and a fun way to participate in the process.[9]

Superior-Inferior (Up-Down) Positioning Error

Positioning the dental arches within the superior-inferior (up-down) dimension of the focal trough can be challenging to achieve, especially with children whose smaller size reduces the distance between the shoulders and the inferior border of the chin. When the arches are positioned incorrectly in the superior-inferior direction, the image exhibits multiple distortions, including increased overlap in the premolar regions. When the arches are positioned too far up or down, the teeth will simultaneously move into a position that is too far back or too far forward, respectively, out of the focal trough.[11]

Positioning the arches too far superiorly produces a characteristic "frown" or flat, downward- turned appearance to the occlusal plane **(Figure 5)**. The condyles flare out and off the edges of the image, and the palate appears as a widened, thick, dense radiopacity. This positioning error results in a widened appearance of the palate and obliterates the apical regions of the maxillary teeth, compromising the images of the unerupted developing dentition. As the maxillary arch tips upward, the anterior teeth tilt backward, producing the same widened appearance that results from an incorrect anterior-posterior position. Positioning the arches too far inferior produces a characteristic "smile" appearance or the upward curve of the occlusal plane, with the condyles tilting inward toward the center of the image **(Figure 6)**. Depending on the severity of the downward position, the vertebrae may also curve inward and appear superimposed over the condyles, and the hyoid bone may be superimposed over the mandible blocking a clear view of the erupted and unerupted mandibular teeth.

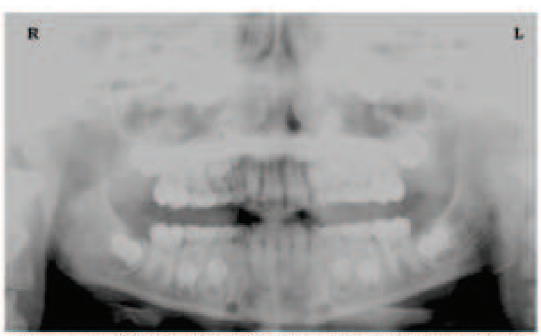


Figure 5: Chin positioned too far up. Note the characteristic "frown" or flat, downward-turned appearance to the occlusal plane. The widened palate obscures the view of the maxillary apices and the developing permanent dentition.

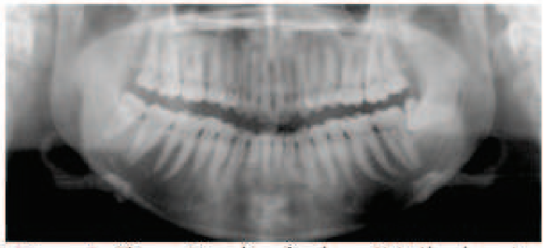


Figure 6: Chin positioned too far down. Note the characte-istic "smile" or upward curved appearance to the occlusal plane and the hyoid bone superimposed over the mandible.

Correct positioning of the arches in the superior-inferior dimension requires that the patient stands with erect posture while tucking the chin in and down slightly, a direction that both adults and pediatric patients often find difficult to follow without specific guidance. The result is often a slumped position with the patient hunching the neck and shoulders over to place the chin on the chin rest. The vertebrae collapse causing attenuation of the x-ray beam that produces a triangular radiopacity superimposed over the mandible, and if severe, over the anterior maxillary regions as well.

Depending on the manufacturer, panoramic x-ray machines direct the operator to position the Frankfort or the canthomeatal plane parallel to the floor, or the ala-tragus line 5° down toward the floor. This is achieved by raising or lowering the chin rest so that the appropriate landmark lines up with indicators on the machine **(Figure 2)**. The patient should be directed to stand in front of the panoramic x-ray machine allowing the operator to place the chin rest in a position that is slightly higher than the patient's chin. The patient is then requested to move into the overhead assembly of the machine and remain standing tall. If further adjustment is needed, it is usually to a lowered chin position. Once the patient's chin is resting on the chin rest, it is easier to move to a lower position than to a higher one. To assist with placing the chin on the chin rest while maintaining an erect posture, the pediatric patient can be directed to stand like a soldier. Most children are familiar with the straight back, chest forward tucked chin position demonstrated by military persons, and can readily mimic this stance.

Further Recommendations

Before beginning the exposure, the patient should be directed to close the lips around the bite block and to place the tongue against the palate. Leaving the lips open will create a soft tissue shadow across the teeth that that can be mistaken for caries.[7] Leaving the tongue at rest during the exposure allows the radiation to easily penetrate the space of the oral cavity between the dorsal surface of the tongue and the palate, producing a radiolucent shadow that diminishes the diagnostic quality of the radiograph (Figure 3).

"Filling in" this space with the soft tissue of the tongue can increase the quality of the image by diminishing this radiolucent shadow. When directed to place the tongue on the roof of the mouth, the pediatric patient is likely to press only the tip of the tongue against the palate. While an adult patient can usually understand what is required when directed to swallow and note the position of the tongue, a child may be directed to suck in the cheeks, which results in pushing the tongue into a position flat against the palate.[7]

Conclusion

In addition to these guidelines for producing error-free radiographic images for the pediatric patient, panoramic machines should be evaluated periodically for accuracy. Changes may occur over time to the focal trough that interferes with the diagnostic quality of the machine.[6] If a decrease in image quality is noted despite following accurate patient positioning steps, the panoramic x-ray machine should be inspected, and the focal trough recalibrated. The dental hygienist who is skilled in understanding general equipment operation and pediatric patient management is more likely to produce radiographic images that result in higher diagnostic yields.

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10. Johnson ON, Thomson EM. Essentials of Dental Radiography for Dental Assistants and Hygienists. 8th ed. Upper Saddle River, NJ: Prentice-Hall 2007:388-397.

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15.4.3 Setting Exposure Values to the Age Group

For more information about this topic, refer to the Appendices **15.1 Recommended X-Ray Exposure Table**.

15.4.4 The References Pertinent to the Potential Risks for the Pediatric Patients

1) Literature

- I. ESPELID, I. MEJÀRE, K. WEERHEIJM:

  EAPD guidelines for the use of radiographs in children, P40-48. European Journal of Pediatric Dentistry 1/2003 Guidelines in dental radiology is designed to avoid unnecessary exposure to X-radiation and to identify individuals who may benefit from a radiographic examination. Every prescription of radiographs should be based on an evaluation of the individual patient benefit. Due to the relatively high frequency of caries among 5-year-old children, it is recommended to consider dental radiography for each child even without any visible caries or restorations. Furthermore, radiography should be considered at 8-9 years of age and then at 12-14, which is 1-2 years after the eruption of premolars and second molars. Additional bitewing controls should be based on an overall assessment of the caries activity/risk. The high-risk patient should be examined radiographically annually, while a 2-3 year interval should be considered when caries activity/risk is low. A routine survey by radiographs, except for caries, has not been shown to provide enough information to be justified considering the balance between cost (radiation and resources) and benefit.

- MICHAEL L. TAYLOR, B.SC. TOMAS KRON, PH.D., AND RICK D. FRANICH, PH.D.:

ASSESSMENT OF OUT-OF-FIELD DOSES IN RADIOTHERAPY OF BRAIN LESIONS IN CHILDREN, Int. J. Radiation Oncology Biol. Phys., Vol. -, No. -, pp. 1–7, 2010 To characterize the out-of-field doses in pediatric radiotherapy and to identify simple methods by which out-of-field dose might be minimized, to reduce the risk of secondary cancers Out-of-field doses to pediatric patients can be minimized by using simple treatment

- C. THEODORAKOU, K. HORNER, K. HOWARD, A. WALKER:

  Pediatric organ and effective doses in dental cone beam computed tomography Dental CBCT has been associated with higher radiation risk to the patients compared to conventional dental X-ray imaging. Several studies have investigated the radiation doses involved in dental CBCT for adults, but none has investigated pediatric doses. This study estimates the organ and effective doses to two pediatric tissue-equivalent phantoms using thermoluminescent dosimeters for three dental CBCT units and six imaging protocols. The doses to the thyroid, salivary glands and brain ranged from 0.068mSv to 1.131mSv, 0.708mSv to 2.009mSv and 0.031mSv to 1.584mSv respectively. The skin and red bone marrow have received much lower doses than the other three organs. The effective doses ranged from 0.022 mSv to 0.081 mSv. The effective doses calculated in this study were much higher than these of panoramic X-ray imaging but lower than conventional CT

- CHIYO YAMAUCHI-KAWAURA & KEISUKE FUJII & TAKAHIKO AOYAMA & SHUJI KOYAMA & MASATO YAMAUCHI:

  Radiation dose evaluation in the head and neck MDCT examinations with a 6-year-old child anthropomorphic phantom, Pediatr Radiol (2010) 40:1206–1214 DOI 10.1007/s00247-009-1495-z

  Background: CT examinations of the head and neck are the most commonly performed CT studies in children, raising concerns about radiation dose and their risks to children.

  Objective: The purpose of this study was to clarify radiation dose levels for children of 6 years of age undergoing head and neck multi-detector CT (MDCT) examinations.

  Materials and methods: Radiation doses were measured with small-sized silicon photodiode dosimeters that were implanted at various tissue and organ positions within a standard 6-year-old anthropomorphic phantom. Organ and effective doses of brain CT were evaluated for 19 protocols in nine hospitals on various (2–320 detector rows) MDCT scanners.

Results: The maximum value of the mean organ dose in brain CT was 34.3 mGy for the brain. Maximum values of mean doses for the radiosensitive lens and thyroid were 32.7 mGy for a lens in brain CT and 17.2 mGy for thyroid in neck CT. The seventy-fifth percentile of effective dose distribution in brain CT was approximately the same as the diagnostic reference level (DRL) in the 2003 UK survey.

2) Website

For additional information on pediatric X-ray imaging, please refer to the websites below.

- http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm
- http://www.imagegently.org/

15.5 Abbreviations

3D	Digital Dental Design
AC	Alternating Current
AF	Auto-Focusing
AMPT	Adaptive layer Mode Panoramic Tomography
CAN	Controlled Area Network
CBCT	Cone-Beam Computed Tomography
CEPH	Cephalogram
CMOS	Complementary Metal-Oxide -Semiconductor
CRS	Chronic rhinosinusitis
CT	Computed Tomography
DAP	Dose Area Product
DC	Direct Current
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
ESD	Electrostatic Discharge
EUT	Equipment Under Test
FDD	A focal spot to Detector Distance
FOD	A focal spot to Object Distance
FOV	Field of View
FPD	Flat Panel Detector
IEC	International Electrotechnical Commission
ISO	International Standards Organization

English

3D	Digital Dental Design
AC	Alternating Current
LCD	Liquid Crystal Display
LED	Light-Emitting Diode
MAR	Metal Artifact Reduction
MPSO	Multiple Portable Socket-Outlet
ODD	Object to Detector Distance
PA	Posterior/Anterior
PANO	Panoramic
PC	Personal computer, a general-purpose computer for individuals
RF	Radio Frequency
ROI	Region of Interest
SID	Source to Image Receptor Distance
SIP	Signal Input Part
SOP	Signal Output Part
SPCC	Steel plate cold commercial
SMV	Submento-Vertical
SSXI	Solid State X-ray Imaging Device
STL	Stereo Lithography
SW	Software
TMJ	Temporomandibular Joint
UHD	Ultra-High Definition

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