

File No.GEM/TP/CT Scanners 64 Slice/2019 (Version 3.0)		Date:	16/1/2019
Level 1 Category : Medical Devices and In Vitro Diagnostic (IVD) Medical Devices		Creator:	KIHT
Level 2 Category: Radiology Devices		Approver	GeM
Level 3 Category: Diagnostic Devices			
Level 4 Category: CT Scanners 64 Slice			
<b>A</b>	<b>Name, Coding and Purpose</b>		
<b>1</b>	UMDNS Name	Code	
	Scanning Systems, Computed Tomography	13-469	
	Scanning Systems, Computed Tomography, Axial, Full-Body	15-956	
	Scanning Systems, Computed Tomography, Axial, Head	15-955	
	Scanning Systems, Computed Tomography, Spiral	18-443	
<b>2</b>	<b>Other Names</b>	axial CT scanners, CAT scanners, cine CT scanners, computed tomography systems, EBT scanners, helical CT scanners, multislice CT scanners, spiral CT scanners, ultrafast CT scanners, volume CT scanners.	
<b>3</b>	<b>Scope</b>	This Product covers computed tomography (CT) scanners used to obtain cross-sectional images without restriction to a particular anatomic region.	
<b>4</b>	<b>Clinical Application</b>	<p>CT scanners produce thin cross-sectional images of the human body for a wide variety of diagnostic procedures. CT is a noninvasive radiographic technique that involves the reconstruction of a tomographic plane of the body (a slice) from a large number of collected x-ray absorption measurements taken during a scan around the body's periphery. The result of a CT study is usually a set of transaxial slices, which can be mathematically manipulated to produce sagittal or coronal image slices. With isotropic imaging, an image can be reconstructed in any arbitrary plane.</p> <p>CT is clinically useful in a wide variety of imaging exams, including spine and head, gastrointestinal, and vascular.</p>	
<b>B</b>	<b>Conformity to Standards and Safety</b>		
<b>1</b>	<b>Conformity to Regulatory</b>	FDA/CE and AERB type approval for quoted model, NOC not accepted	
<b>2</b>	<b>Conformity to Manufactures Certification</b>	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
<b>3</b>	<b>Conformity to Safety Standards</b>	IEC 60601-2-44 or equivalent BIS	
<b>C</b>	<b>Technical Specifications</b>		
<b>1</b>	<b>TYPE</b>	Multislice	
	Number of slices acquired simultaneously	≤64	
	Number of channels	64	
<b>2</b>	<b>DETECTOR ASSEMBLY</b>		
	Field of view (standard), cm	≥50 cm	
	Field of view (extended), cm	optional	
	Total detector width, z-axis, mm	≥38 mm	
	Reconstructed slice width options, mm	0.4 - 10 mm	
	Minimum slice width, mm	≤0.75 mm	
	Minimum Gantry Rotation Time ( 360 Deg )	< =350 msec	
<b>3</b>	<b>DETECTOR PERFORMANCE</b>		
	High-contrast spatial resolution	≥22 lp/cm	
	MTF kernel	High Resolution	
	MTF 0 (@ 120 kV , 200 mA , Slice Width > 2mm ) in lp/cm	18 lp/cm	
	MTF 10 (@ 120 kV , 200 mA , Slice Width > 2mm ) in lp/cm	12 lp/cm	
	MTF 50 (@ 120 kV , 200 mA , Slice Width > 2mm ) in lp/cm	10 lp/cm	
	Low-contrast resolution, rod size in mm at %0.3 at ≤20 mGy (2 rads)	≤3 mm	
	Noise, % at ≤25 mGy (2.5 rads)	≤0.4% at 25 mGy (2.5 rads)	
	Noise kernel	Standard	
<b>4</b>	<b>ADVANCED IMAGE ACQUISITION</b>		
	Cardiac	Preferred	
	Perfusion imaging	Preferred	
	Extended coverage for 4-D imaging	Max coverage with 1, 1.5 and 3 sec sampling resolution, cm	
	Dual-energy acquisition	Preferred	
<b>5</b>	<b>GANTRY</b>		
	Gantry tilt, °	±30	
	Gantry aperture, cm	≥70	
	Scan localizer	Laser	
<b>6</b>	<b>X-RAY TUBE</b>		
	Anode Heat storage, MHU	> 7 MHU	
	Anode Heat dissipation rate, kHU/min	> 1500 kHU/min	
	Tube cooling	Oil or water	
	Tube focal spots, mm	Small ≤= 0.7 X 0.7 mm , large < =1.4 x 1.4 mm	
	Expected tube life, scan sec (and calendar)	2,50,000	
	Max mA	≥500 mA	
	Max scan time at max mA, sec	10 sec	
<b>7</b>	<b>X-RAY GENERATOR</b>		
	kW output	> 70 kW	
	kVp range	80-140	
	mA range	10-700	
<b>8</b>	<b>PATIENT TABLE</b>		
	Range of movement - Vertical, cm	40-100 cm	
	Range of movement - Longitudinal, cm	150 cm	
	Scannable range, cm	150 cm	
	Max load capacity without restrictions, kg (accuracy, mm)	220 kg (0.25)	
<b>9</b>	<b>RADIATION DOSE</b>		
	Dose-modulation technique	Preferred	
	Pediatric-specific dose control	Required	
	Prospective ECG gating	Preferred	

	Retrospective ECG editing	Preferred
	Iterative image reconstruction	Required
	Sliding collimation (overbeaming reduction)	Required
	Low-dose cardiac (axial acquisition)	Required
	Max heart rate, bpm	65 bpm
	Arrhythmia correction	Required
<b>10</b>	<b>CLINICAL APPLICATIONS AND FUNCTIONALITY</b>	
	Coronary artery calcification scoring	Required
	Auto vessel mapping	Required
	Quantification	Required
	Ventricular output	Required
	Myocardial evaluation	Required
	Lung nodule assisted reading	Preferred
	Lung nodule CAD	Required
	Lung function analysis	Required
	Respiratory gating	Required
	Virtual colonoscopy assisted reading	Required
	Virtual colonoscopy CAD	Required
	Vessel analysis (noncardiac)	Required
	Brain perfusion	Preferred
	Z-axis coverage for brain perfusion	Preferred
	Auto bone removal	Yes
	Body perfusion	Yes
	Highest achievable temporal resolution	<0.1
	Nonsegmented reconstruction, msec	150 msec
	Other	
<b>12</b>	<b>IMAGE RECONSTRUCTION</b>	
	Computer CPU	
	Reconstruction FOVs, cm	50 cm
	Reconstruction matrices	512 x 512
	Max reconstruction rate, (512 x 512), in/sec	20
	Per slice, sec	0.2 sec
	Real-time partial image reconstruction	Required
<b>13</b>	<b>SYSTEM INTEGRATION</b>	
	DICOM	Required
	CT image storage SCU/SCP	Yes
	Enhanced CT storage SCU/SCP	Yes
	ECG waveform SCP/SCU	Yes
	Modality worklist SCU	Yes
	Query/retrieve SCU and SCP	Yes
	Storage commitment SCU	Yes
	Modality performed procedure step SCU	Yes
	IHE profiles supported	SW, PIR, CPOI, PGI, KIN, BS, EDM, PDI, CT
<b>14</b>	<b>IMAGE PROCESSING</b>	
	Standard or optional	Standard
	Recommended postprocessing workstation	Advantage Workstation or Server or Portal
	Remote access to raw image data	Yes
	Remote access to clinical applications	Yes
	DICOM 3-D image export	Yes
	ACCESSORIES	AW analysis and review workstations - 3No, Cardiac and respiratory gating device, variety of phantoms for quality control, patient table accessories, storage devices, Printers, Injectors
	Contrast Injection Integration with Injector	Yes
<b>D</b>	<b>PLANNING AND INSTALLATION</b>	
<b>1</b>	Pre-installation requirements	Required
<b>2</b>	RECOMMENDED ROOM SIZE, m <sup>2</sup>	25 m <sup>2</sup>
<b>3</b>	POWER REQUIREMENTS	220/240/380 V nominal, 3-phase
<b>4</b>	Operating temp range, °C (°F)	18-28 (64.4-82.4)
<b>5</b>	Humidity, %	30-75
<b>6</b>	SHIELDING REQUIREMENTS	Preferred
<b>7</b>	UPS	YES, Chiller and Airconditioning requirement as per customer need
<b>E</b>	<b>PURCHASE INFORMATION</b>	
<b>1</b>	Price Range	
<b>2</b>	X-ray tube warranty	250,000 scan sec or 2 year (whichever is longest) not prorated
<b>3</b>	Remote service/diagnostics	Yes
<b>4</b>	Warranty	3 Years
<b>5</b>	CMC	≤5% of the Device cost and 2% escalation on every year (taxes at actuals)
<b>6</b>	AMC	≤3% of the Device cost and 2% escalation on every year (taxes at actuals)
<b>7</b>	QA and QC and other tests	Every 6 months / 1 year as per the NABH/JCI.
<b>8</b>	Service Support	Shall Support within 24 hrs of breakdown call
<b>9</b>	Manuals and Training	Pre and Post installation training as an required under warranty, All User manuals with Quick reference guides and service manuals, Digital manuals.
<b>10</b>	eLORA	In scope of Supplier to be registered in eLORA of quoted Model for Buyer