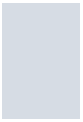


File No.GEM/TP/CT Scanners 16 Slice/2019 (Version 3.0)		Date:	16/1/2019
Level 1 Category : Medical Devices and In Vitro Diagnostic (IVD) Medical Devices		Creator:	KIHT
Level 2 Category: Radiology Devices		Approver	GeM
Level 3 Category: Diagnostic Devices			
Level 4 Category: CT Scanners 16Slice			
A	Name, Coding and Purpose		
1	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
2	Other Names	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.	
3	Scope	This Product covers computed tomography (CT) scanners used to obtain cross-sectional images without restriction to a particular anatomic region.	
4	Clinical Application	<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	Conformity to Standards and Safety		
1	Conformity to Regulatory	FDA/CE and AERB type approval for quoted model, NOC not accepted	
2	Conformity to Manufactures Certification	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	Conformity to Safety Standards	IEC 60601-2-44 or equivalent BIS	
C	Technical Specifications		
1	TYPE	Multislice	
	Number of slices acquired simultaneously	≤16	
	Number of channels	16	
2	DETECTOR ASSEMBLY		
	Field of view (standard), cm	≥50 cm	
	Total detector width, z-axis, mm	≥20 mm	
	Reconstructed slice width options, mm	0.5 - 10 mm	
	Optional minimum slice width, mm	≤1 mm	
	Standard rotation times, sec, 360°	≤1 sec	
3	DETECTOR PERFORMANCE		
	High-contrast spatial resolution (lp/cm)	> =15 lp/cm	
	MTF kernel	High Resolution	
	MTF 0 (@ 120 kV , 200 mA , Slice Width > 2mm) in lp/cm	> =15	
	MTF 10 (@ 120 kV , 200 mA , Slice Width > 2mm) in lp/cm	> =10	
	MTF 50 (@ 120 kV , 200 mA , Slice Width > 2mm) in lp/cm	> =8	
	Low-contrast resolution, rod size in mm at %0.3 at ≤20 mGy (2 rads)	≤5 mm	
	Noise, % at ≤25 mGy (2.5 rads)	≤0.5% at 25 mGy (2.5 rads)	
	Noise kernel	Standard	
4	ADVANCED IMAGE ACQUISITION		
	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	
5	GANTRY		
	Gantry tilt, °	±30	
	Gantry aperture, cm	70	
	Scan localizer	Laser	
6	X-RAY TUBE		
	Anode Heat storage, MHU	≥ 3 MHU	
	Anode Heat dissipation rate, kHU/min	≥800 kHU/min	
	Tube cooling	Oil or water	
	Tube focal spots, mm	Small < 0.7 x 0.9mm ,large<1.5 x 1.6 mm	
	Expected tube life, scan sec (and calendar)	2,50,000	
	Max mA	≥ 350 mA	
	Max scan time at max mA, sec	10 sec	
7	X-RAY GENERATOR		
	kW output	≥ 50 kW	
	kVp range	80-140	
	mA range	10-500	
8	PATIENT TABLE		
	Table top material	Carbon Fiber	
	Range of movement - Vertical, cm	30- 90 cm	
	Range of movement - Longitudinal, cm	> 160 cm	
	Scannable range, cm	140 cm	
	Max load capacity without restrictions, kg (accuracy, mm)	200 kg (0.25)	
9	RADIATION DOSE		
	Dose-modulation technique	Required	
	Pediatric-specific dose control	Preferred	
	Prospective ECG gating	Preferred	

	Retrospective ECG editing	Preferred
	Iterative image reconstruction	Preferred
	Sliding collimation (overbeaming reduction)	Preferred
	Low-dose cardiac (axial acquisition)	Preferred
	Max heart rate, bpm	NA
	Arrhythmia correction	Preferred
10	CLINICAL APPLICATIONS AND FUNCTIONALITY	
	Coronary artery calcification scoring	Preferred
	Auto vessel mapping	Required
	Quantification	Preferred
	Ventricular output	Preferred
	Myocardial evaluation	Preferred
	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	NA
	Nonsegmented reconstruction, msec	NA
	Other	
12	IMAGE RECONSTRUCTION	
	Reconstruction FOVs, cm	upto 50 cm
	Reconstruction matrices	512 x 512
	Max reconstruction rate, (512 x 512), in/sec	10
	Per slice, sec	0.5 sec
	Real-time partial image reconstruction	Required
13	SYSTEM INTEGRATION	
	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, Pdfi, CT
14	IMAGE PROCESSING	
	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
D	PLANNING AND INSTALLATION	
1	Pre-installation requirements	Required
2	RECOMMENDED ROOM SIZE, m ²	25 m ²
3	POWER REQUIREMENTS	220/240/380 V nominal, 3-phase
4	Operating temp range, °C (°F)	18-28 (64.4-82.4)
5	Humidity, %	30-75
6	SHIELDING REQUIREMENTS	as per AERB
7	UPS	YES, Chiller and Airconditioning requirement as per equipment needs
E	PURCHASE INFORMATION	
1	Price Range	
2	X-ray tube warranty	250,000 scan sec or 2 year (whichever is longest) not prorated
3	Remote service/diagnostics	Yes
4	Warranty	3 Years
5	CMC	≤5% of the Device cost and 2% escalation on every year (taxes at actuals)
6	AMC	≤3% of the Device cost and 2% escalation on every year (taxes at actuals)
7	QA and QC and other tests	Every 6 months / 1 year as per the NABH/JCI.
8	Service Support	Shall Support within 24 hrs of breakdown call
9	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.
10	eLORA	In scope of Supplier to be registered in eLORA of quoted Model for Buyer



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