

File No.GEM/TP/3 T, Wide-Bore MRI System/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: 3 T, Wide-Bore MRI System			
Name, Coding and Purpose			
1	UMDNS Name	Code	
	Scanning Systems, Magnetic Resonance Imaging, Extremity	18-109	
	Scanning Systems, Magnetic Resonance Imaging, Full-Body	18-108	
	Scanning Systems, Magnetic Resonance Imaging, Mammographic	18-110	
	Scanning Systems, Magnetic Resonance Imaging, Neurosurgical	18-862	
2	Other Names	MRI, fMRI, Magnetic Resonance Imaging	
3	Scope	This Product covers stationary magnetic resonance imaging (MRI) units, including models capable of magnetic resonance angiography (MRA), echo planar imaging (EPI), and spectroscopy. Models for imaging the whole body, as well as models dedicated to imaging only the head, breasts, and/or extremities, are listed in the chart. Open MRI systems and dedicated intraoperative systems are included. MRI systems used exclusively for clinical research are not covered in this product comparison.	
4	Clinical Application	MRI is primarily used to identify diseases of whole body with high performance. MRI is also used in conjunction with other modalities (e.g., CT) to localize treatment areas for stereotactic radiosurgical and image-guided surgical procedures. MRA is used for imaging venous and arterial malformations, thromboses, stenoses, and other vascular abnormalities and, in particular, for evaluating the carotid artery and cerebral vasculature, etc.,	
Confirmity to Standards and Safety			
1	Confirmity to Regulatory	FDA/CE	
2	Confirmity to Manufactures Certification	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	Confirmity to Safety Standards	IEC 60601-2-33 or equivalent BIS	
Technical Specifications			
1	Magnet		
	Configuration	Wide bore	
	Strength	3 T	
	Guaranteed homogeneity, ppm, within 30 cm DSV	<0.3	
	Guaranteed homogeneity, ppm, within 45 cm DSV	<2	
	Dimensions of maximum useful FOV and homogeneity, (x, y, z), cm	50 x 50 x 45	
	Shimming, main magnet	Active	
	Cryogen refill frequency	Zero refill	
2	GANTRY		
	Bore diameter at isocenter, cm	70	
	Total bore length with covers, cm	<195	
3	TABLE		
	Load limit, kg (lb)	500 (227); to facility requirements; larger load limit preferred	
	Detachable	Detachable table or MRI-safe patient transfer cart required	
	Dockable patient stretcher	Preferred	
	Lateral movement	Preferred	
	Minimum height, cm	<70	
	Feet-first imaging studies	Required	
4	ACOUSTIC NOISE		
	Maximum sound pressure level (SPL) at peak gradient amplitude and slew rate, dB(A)	<110	
	With acoustic noise reduction	<80	
5	GRADIENT SYSTEM		
	Standard strength, z-axis, mT/m	40	
	Standard slew rate, z-axis, T/m/sec	200	
	Spin echo pulse sequences, minimum TR, msec	<12	
	Gradient echo pulse sequences, minimum TR in 2-D, msec	<2	
	Gradient echo pulse sequences, minimum TR in 3-D, msec	<2	
	Echo planar imaging, minimum echo spacing, msec	<0.4	
	Minimum slice thickness 2-D/3-D, mm	0.1	
6	RF TRANSMIT AND RECEIVE		
	Power output, kW	30	
	Receiver bandwidth, kHz	1	
	Channel options	32	
	Maximum number of simultaneously addressable coil elements	32	
	Parallel imaging	Required	
7	COILS		
	Dedicated surface or adaptable multi-element matrix coils	Adaptable required	
	Automatic or manual element selection	Automatic selection required	
	Head	Number of elements <16	
	Neck	Number of elements <16	
	Spine	90 cm superior to inferior coverage, integrated coil, Number of elements - 16	
	Torso	flexible, 50 cm superior to inferior coverage, Number of elements - 16, Maximum coils used	
	Breast	Number of elements - 16 with breast biopsy	
8	SCANNING TECHNIQUES		
	Standard pulse sequences	Required	
	Image acquisition	Patient movement compensated - head & body, Isotropic 3-D (T1), Isotropic 3-D fast spin	
	Fat-suppressed single breath-hold body imaging	Yes	
	Single-point Dixon acquisition	Water contrast, Fat contrast, Phase contrast	
	Gradient echo	Spoiled techniques, Rewound techniques, Steady state free precession	
	Inversion recovery	Yes	
	Magnetic transfer contrast	Yes	

	Magnetic susceptibility imaging	Yes
	Diffusion imaging	Yes
	Diffusion tensor imaging	Yes
	Perfusion imaging, head	Yes
	Perfusion imaging, body	Yes
	Spectroscopy, single voxel	Yes
	Functional imaging, neurological	Yes
	Breast imaging with fat suppression	Yes
	Cardiac imaging	ECG gated and Respiratory Gated
	Contrast-enhanced imaging	Yes
	Extremity contrast-enhanced imaging	Yes
	Non-contrast angiographic imaging	Time of flight, Phase contrast, SSFP
9	WORKSTATION QUANTITATIVE IMAGE ANALYSIS TOOLS	
	Perfusion imaging	Yes
	fMRI	Yes
	Diffusion imaging	Yes
	Diffusion tensor imaging	Yes
	Cardiac imaging	Yes
10	CONTROL CONSOLE	
	Workflow efficiency features	Yes
	Protocol-sharing tools	Yes
	Parameter adjustment aides	Yes
	Tools for scanning MR-conditional implants	Yes
11	SYSTEM INTEGRATION	
	DICOM	Modality worklist SCU, MR image storage SCU, Query/retrieve SCU and SCP, Storage commitment SCU, Modality performed
	IHE profiles supported	Yes
12	CONTRAST INJECTION INTEGRATION WITH INJECTOR	Yes
PLANNING AND INSTALLATION		
1	Pre-installation requirements	Required
2	Overall gantry dimensions (including table), H x W x L, m	>2m x >2m x >3m
3	Gantry weight (including cryogen and covers), kg (lb)	<9000 (19,800)
4	Minimum ceiling height, m	2.8m
5	Fringe field (0.5 mT, 5 gauss) in x, y, z directions, m	3 radially and 5 axially from isocenter
6	Minimum magnet room size, H x W x L, m	Required
7	Minimum equipment room size, H x W x L, m	Required
8	Power consumption	Scanning <18 kW, Standby <10kW, Not in Use <8kW (Sleep/power mode)
9	UPS	Chiller and Airconditioning requirement as per customer need
PURCHASE INFORMATION		
1	Price Range	
2	Warranty	3 Years
3	CMC	≤5% of the Device cost and 2% escalation on every year (taxes at actuals)
4	AMC	≤3% of the Device cost and 2% escalation on every year (taxes at actuals)
5	QA and QC and other tests	Every 6 months / 1 year as per the NABH/JCI.
6	Service Support	Shall Support within 24 hrs of breakdown call
7	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.