File No.GEM/TP/Bone Mineral Densitometer/2019 (Version 3.0)	Date:	17-Jan-19
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		
Level 4 Category: Bone Mineral Densitometer		

Name, Coding and Purpose		
1	**UMDNS Name**	**Code**
	Bone Ultrasonometers	18-382
	Densitometers, Bone, X-Ray, Dual-Energy Absorptiometry	17-747
2	**Other Names**	Absorptiometers, bone densitometers, bone sonometers, bone ultrasonometers, ultrasonic bone sonometers, ultrasonometers.
3	**Scope**	This device is used to screen patients who are at risk of osteoporosis, evaluate skeletal fragility as a prediction of future fracture risk, and to diagnose osteoporosis. They have also been used to monitor a patient's response to osteoporosis drug therapy over extended periods of time.
4	**Clinical Application**	Osteoporosis, literally "porous bone," is characterized by a loss of bone mineral (calcium hydroxyapatite) and collagen matrix. Bone mineral loss occurs in both trabecular bone and cortical bone. The strength of a bone, and thus its resistance to fracture, depends on the amount of mineral mass in the bone. A decrease in BMD and BMC causes a subsequent decrease in bone strength and an increase in fracture risk. Osteoporotic patients have low BMD and BMC levels; therefore, the risk of a fracture increases. The World Health Organization defines osteoporosis as BMD or BMC levels more than 2.5 standard deviations below the mean BMD or BMC of young, healthy patients. Measurements of BMC and BMD are used by care givers to diagnose osteoporosis and determine fracture risk for osteoporotic patients. Ultrasound methods, such as BUA and SOS, measure other parameters of bone integrity, such as stiffness, elasticity, and bone microarchitecture, which can also be used to predict fracture potential. Screening for osteoporosis is recommended for postmenopausal women and the elderly—the groups at highest risk—as well as for patients of any age who failed to build sufficient bone mass early in life (e.g., those with a milk allergy) or those who exhibit high bone-loss rates.
Confirmity to Standards		
1	**Confirmity to Certification**	US FDA/Eu CE (Notified Body)/BIS and AERB type approval for quoted model, NOC not accepeted
2	**Confirmity to Manufactures Certification**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485
3	**Confirmity to Safety Standards**	IEC 60601-2-28 or equivalent BIS
Technical Specifications		
1	**PRECISION DOSE % CV/mrem(µSv)**	
	AP Spine	<1%
	Lateral Spine	<1%
	Forearm	<1%
	Hip	<1%
	Whole body	<1%
	others	<1%
2	**Active Scan Area, (cm)**	195×65
3	**Scan Time, Sec at 1% CV**	
	AP Spine	< 65
	Lateral Spine	< 110
	Forearm	< 30
	Hip	< 65
	Whole body	< 500
4	**Scan Time, Fastest Possiable (Sec)**	
	AP Spine	≤ 10 Sec
	Lateral Spine	≤ 100 Sec
	Forearm	≤ 20 Sec
	Hip	≤ 10 Sec
	Whole body	≤ 200 Sec
5	**Data Analysis and Reporting**	Automatic
6	**Prior Scan Data**	Requried
7	**Reference Data**	Clinically accepted references requried
8	**Fat and Lean Tissue Mass**	Preferred
9	**Data Corrections and Quality Assurance**	Automatic
10	**Connectivity**	DICOM output Requried
11	**Results and Analysis**	Requried
12	**Computer and Printer**	Requried
13	**Patient Weight Limit**	≥160 Kgs
14	**Power Requriments**	Single phase 220-240 Volt, 50 Hz (AC Supply)-16Amps Scoket
PreInstallation and Installation		
1	**PreInstallation Requriments**	Need to be give at the Tender
2	**Installation**	In scope of Supplier
Purchase Information		
1	**Warranty**	3 years from the date of Installation
2	**CMC**	≤ 5% of the device cost and 2% escalation on every year (Taxes at Actuals)
3	**AMC**	≤ 3% of the device cost and 2% ecalation on every year (Taxes at Actuals)
4	**QA, QC and other tests**	6 months/ 1 year as per NABH/JCI
5	**Training & Manual**	Pre and Post installation trainning as an requried under warrantry, All user manuals with Quick referance guides and service manuals, digital manuals.
6	**eLORA**	In scope of Supplier to be registred in eLORA of quoted Model for Buyer
7	**Price Range**	N/A

File No.GEM/TP/Digital Radiography with X-Ray Unit/2019 (Version 3.0)		Date:	18-Jan-19
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			
Level 4 Category: Digital Radiography with X-Ray Unit			
Name, Coding and Purpose			
1	**UMDNS Name**	**Code**	
	Radiographic System, Digital	18-430	
	Radiographic System, Film	17-174	
	Tables, Imaging, Radiographic	16-544	
2	**Other Names**	Digital Radiographic Room, DR X-Ray Unit, Digital Radiographic System	
3	**Scope**	Digital radiography (DR) is different from traditional film-based radiography only from the point at which the x-rays reach the detector—the production of x-rays in DR is identical to the method used in traditional radiography. Once the x-rays have interacted with the patient, they can be captured by a number of digital detector technologies, including phosphor plates (commonly called computed radiography [CR]) and DR detectors (also called flat panels).	
4	**Clinical Application**	There are two types of digital detectors: indirect DR and direct DR systems. In the former, x-rays are captured by a scintillator (fluorescent screen) and converted to visible light. The light is transformed by a photodiode array and read out by a charge-coupled device (CCD) or thin-film transistor (TFT) into an electronic signal that is digitized. Indirect DR detectors include a scintillator layer (e.g., of cesium iodide [CsI]) along with a photodiode layer (e.g., an array of amorphous silicon). Direct DR detectors include an x-ray detector layer and a read-out layer. One of the most common structures in these detectors is a layer of amorphous selenium along with a TFT panel. Amorphous selenium detects x-rays through photoelectric interactions, in which electron-hole pairs are produced on exposure. These electron-hole pairs are attracted to electrodes and form a latent image that is read out from a TFT array, creating a digital signal. This process is called direct DR because no intermediate steps are required to convert x-ray photons to digital signals. Direct DR reduces the scatter that occurs while light is traversing the phosphor detectors in indirect DR, film radiography, and CR; the clinical implications of better images, however, have not been confirmed. CR technology is also available in a DR configuration. In this configuration, the CR cassette is read out right after the exposure. This allows better workflow and improved image quality compared to normal CR systems. DR technology is available in a wireless (also called portable). In this configuration, the DR detector is read out right after the exposure and the image data is wirelessly sent to an image processing station to display and further process. The wireless capability means the awkwardness of a tether is eliminated and allows easier positioning; portable detectors can be positioned like cassettes, permitting views that were impossible with conventional radiography with the added benefit of immediate image previews. Purchasing a wireless detector can be the least expensive way to attain DR benefits with film-based or CR equipment; most vendors offer digital upgrades or retrofits to their older, film-based systems. Wireless detectors can be integrated with their respective vendor's systems and occasionally with other vendors' systems. Numerous models fit into a standard cassette holder and therefore can be used with any standard radiographic table.	
Confirmity to Standards			
1	**Confirmity to Certification**	US FDA/Eu CE (Notified Body)/BIS and AERB type approval for quoted model, NOC not accepeted	
2	**Confirmity to Manufactures Certification**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	**Confirmity to Safety Standards**	IEC 60601-2-54 or equivalent BIS	
Technical Specifications			
1	**RADIOGRAPHY MODES**		
	Film or Digital	Film/Digital (Digital Preferred)	
	Number of detectors included	≥ 1	
2	**TABLE & TABLE TOP**		

	Type of table (MIN)	Elevating , 4-way floating tabletop, Optional mobile
	Power assist	Manual/Motorized
	Longitudinal	100cm
	Lateral	25cm
	Length × Width	210cm×70cm (min)
	X-ray density	**<1 mm Al**
	Minimum and Maximum table heights	50-80 cms (min)
	Table Weight Capacity	≥ 200 Kgs
3	**TABLE BUCKY SYSTEM**	
	Type	Motorized/Fixed/Wireless/Stationary
	Size	17in×17in or 14in×17in-wireless
	AEC	3-field or Higher
	Grid ratios	10:1 or Higher
	Lines/mm (lines/in)	4(100) or Higher
	Cassette sizes	All Standard
	Longitudinal travel	Manual/Electronic
4	**UPRIGHT BUCKY**	
	Type	Manual vertical Bucky Stand/Wall stand/motorized/Moveable bucky stand
	Size	17in×17in or 14in×17in-wireless
	AEC	3-field or Higher
	Grid ratios	10:1 or Higher
	Lines/mm (lines/in)	4(100) or Higher
	Cassette sizes	All Standard
	Longitudinal travel	Manual/Electronic
5	**DIGITAL DETECTOR**	
	Detector material	Cesium Iodide (Csi) or Higher
	Detector size	17in×17in or 14in×17in-wireless
	Tethered	Optional
	Wireless	Optional
	Matrix size	Deponds on type of detector
	Pixel size	≥ 150 µm
	Image preview wait	< 6 sec
	Diagnostic image wait	< 10 sec
	Control Panel	Preffered
	Automatic parameter selection	Preffered

	Anatomic specific post processing	Preffered
	Dual-energy subtraction	Optional
	Orthopedic Planning	Preffered
	Digital tomosynthesis	Optional
6	**X-RAY GENERATORS & TUBES**	
	Preffered generator units	80 KW, high frequency
	maximum mA at 100kVp	> 800
	Focal spot size, mm	0.6 and 1.2
	Heat capacity, KHU	300-600
	Cooling rate, HU/min	Deponds on tube
	Control Panel on X-ray tube	yes
	Automatic tube positioning	yes
7	**TUBE SUSPENSION**	
	Tube-mounted x-ray control	Preffered
	Model, Suspension	Ceiling/floor mounted
	Model, Collimator	Manual/Automatic
8	**ACCESSORIES**	
	Compression bands	yes
	Handgrips	yes
	Others (Optional)	Footswitch for reverse side of table, cassette holder, portable/alternative grids, patient support stand
	Integration	DICOM 3.0 storage SOP classes
9	**Power Requriments**	220-240 Volt, 50 Hz (AC Supply)-16Amps Scoket
PreInstallation and Installation		
1	**PreInstallation Requriments**	Need to be give at the Tender
2	**Installation**	In scope of Supplier
Purchase Information		
1	**Warranty**	3 years from the date of Installation
2	**CMC**	≤ 5% of the device cost and 2% escalation on every year (Taxes at Actuals)
3	**AMC**	≤ 3% of the device cost and 2% ecalation on every year (Taxes at Actuals)
4	**QA, QC and other tests**	6 months/ 1 year as per NABH/JCI
5	**Training & Manual**	Pre and Post installation trainning as an requried under warrantry, All user manuals with Quick referance guides and service manuals, digital manuals.
6	**eLORA**	In scope of Supplier to be registred in eLORA of quoted Model for Buyer
7	**Price Range**	N/A

File No.GEM/TP/Digital Radiography X-Ray Films/2019 (Version 3.0)		Date:	8-Jan-19
Level 1 Category : Medical Devices and In Vitro Diagnostic (IVD) Medical Devices		Creator:	KIHT
Level 2 Category: Radiology Devices		Approver:	GeM
Level 3 Category: Miscellaneous			
Level 4 Category: Digital Radiography X-Ray Films			
Name, Coding and Purpose			
1	UMDNS Name	Code	
2	Other Names	Digital X-ray Films, X-ray Films.	
3	Scope	X-ray films are used for dignostic and surgical purpose, to treat the patient with approaite medicine.	
4	Clinical Application	X-ray films are used for dignostic and surgical purpose, to treat the patient with approaite medicine.	
Confirmity to Standards			
1	Confirmity to Certification	US FDA/Eu CE (Notified Body)/BIS	
2	Confirmity to Manufactures Certification	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	Confirmity to Standards	ISO 9236-1 or Equivalent BIS	
Technical Specifications			
1	Clear base film Sizes	8×10 Inch (or) 20×25 cm	
		10×12 Inch (or) 25×30 cm	
		10×14 Inch (or) 25×35 cm	
		14×14 Inch (or) 35×35 cm	
		14×17 Inch (or) 35×43 cm	
2	Blue base film Sizes	8×10 Inch (or) 20×25 cm	
		10×12 Inch (or) 25×30 cm	
		10×14 Inch (or) 25×35 cm	
		14×14 Inch (or) 35×35 cm	
		14×17 Inch (or) 35×43 cm	
PreInstallation and Installation			
1	PreInstallation Requriments	N/A	
2	Installation	N/A	
Purchase Information			
1	Warranty	N/A	
2	Training	N/A	
3	Price Range	N/A	

File No.GEM/TP/Film Printer (Laser/Thermal)/2019 (Version 3.0)		Date:	23-Jan-19
Level 1 Category : Medical Devices and In Vitro Diagnostic (IVD) Medical Devices		Creator:	KIHT
Level 2 Category: Radiology Devices		Approver:	GeM
Level 3 Category: Miscellaneous			
Level 4 Category: Film Printer (Laser/Thermal)			
Name, Coding and Purpose			
1	**UMDNS Name**	**Code**	
	Printer-Thermal	18859	
2	**Other Names**	Film Camera, Digital X-ray Printer.	
3	**Scope**	This device is used to print the the High quality gray scale image.	
4	**Clinical Application**	X-ray films are used for dignostic and surgical purpose, to treat the patient with approaite medicine.	
Confirmity to Standards			
1	**Confirmity to Certification**	US FDA/Eu CE (Notified Body)/BIS	
2	**Confirmity to Manufactures Certification**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	**Confirmity to Safety Standards**	IEC 60601-1 or equivalent BIS	
Technical Specifications			
	Thermal Processing	Direct thermal/Dry laser	
	Modalities	Any grayscale radiographic image source in all modalities	
	Throughput	100 films/hr or <50 seconds/print	
	Multiple Orginals	50	
	Formats, images/print	1 to 16	
	Film/paper sizes, in	8×10 to 14×17/Rest all Sizes Optional	
	Standard inputs	Digital/DICOM	
	Maximum Pixel Resolution	4000×6000	
	Spatial Resolution, pixels/mm	12.2	
	Spatial Resolution, dots/in (dpi)	600	
	Gradations, bits	12	
	Interal Hard Disk	>70 GB	
	Interface Option	Direct DICOM, video and digital through Paxport	
	Keypad Functions	Preferred	
	Remote Diagnostics	Preferred	
	DICOM Compatible	Preferred	
	Calibration Method	Automatic or Manual	
	Power Requriments	Single phase 220-240 Volt, 50 Hz (AC Supply)-16Amps Scoket	
PreInstallation and Installation			
1	**PreInstallation Requriments**	Need to be give at the Tender	

2	**Installation**	In scope of Supplier
Purchase Information		
1	**Warranty**	3 years from the date of Installation
2	**CMC**	≤ 5% of the device cost and 2% escalation on every year (Taxes at Actuals)
3	**AMC**	≤ 3% of the device cost and 2% ecalation on every year (Taxes at Actuals)
4	**QA, QC and other tests**	6 months/ 1 year as per NABH/JCI
5	**Training & Manual**	Pre and Post installation trainning as an requried under warrantry, All user manuals with Quick referance guides and service manuals, digital manuals.
6	**Price Range**	N/A

File No.GEM/TP/Mammography/2019 (Version 3.0)		Date:	21-Jan-19
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			
Level 4 Category: Mammography			
Name, Coding and Purpose			
1	**UMDNS Name**	**Code**	
	Radiographic System, Digital, Mammographic	18-432	
	Radiographic Units, Mammography	12-425	
	Stereotactic Systems, Image-Guided, Biopsy, Mammographic	17-833	
2	**Other Names**	Breast lesion localization systems, Full-Field Digital Mammography (FFDM) Systems.	
3	**Scope**	Mammographic units use x-rays to produce images of the breast—a mammogram—that provide information about breast morphology, normal anatomy, and gross pathology. Mammography is used primarily to detect and diagnose breast cancer and to evaluate palpable masses and nonpalpable breast lesions.	
4	**Clinical Application**	The breasts, which are modified sweat glands, overlie the pectoral muscles and are attached to them by fasciae. Each breast is composed of 15 to 20 lobes of glandular tissue connected by fibrous connective tissue, and each lobe consists of lobules—clusters of secretory cells called alveoli—that open into the lactiferous ducts. Adipose tissue up to 1 cm thick underlies the outer layer of skin; fatty tissue interspersed between the lobes gives the breast its shape and size. Following menopause, the glandular tissue gradually atrophies and is replaced by fat from the base of the breast toward the nipple. Breast cancers usually begin in the upper outer quadrant of the breast, and malignant tumors may attach to the fascia of the chest wall and/or extend to the skin, causing dimpling. Breast cancer eventually spreads, often to the nodes along the internal mammary artery or through the blood stream to form secondary tumors. Many breast lesions, both benign and malignant, are discovered by palpation of the breast; however, by the time a solitary, painless, malignant mass is detected by palpation, it may have already spread to the lymph nodes. Thus, early detection of breast cancer is a critical factor in successful treatment. Radiologic examination of the breast currently provides the most practical means of detecting cancer in large numbers of asymptomatic individuals, thereby increasing their chances for survival. Mammography units are mechanically and electronically designed to meet the stringent radiographic and positioning requirements of breast imaging. They differ from conventional radiographic equipment in the use of low-energy radiation to distinguish between normal and pathologic soft tissue, to produce high-resolution images, and to visualize the subtle signs of early breast cancer with a low radiation dose to the patient.	
Confirmity to Standards			
1	**Confirmity to Certification**	US FDA/Eu CE (Notified Body)/BIS and AERB type approval for quoted model, NOC not accepeted	
2	**Confirmity to Manufactures Certification**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	**Confirmity to Standards**	IEC 60601-2-45 or equivalent BIS	
Technical Specifications			
1	**X-RAY GENERATOR**		
	Type	Single-phase, high frequency	

	kV Range	22-35, increments of 1kV
	mAs Range	4-600
	Time range, sec	0.02-8
	Power Requirements	Single phase 220-240 Volt, 50 Hz (AC Supply)-16Amps Scoket
	AEC Detector	Requried
	Parameters controlled	kV, mAs, anode/filter
2	**X-RAY TUBE**	
	Anode type	Rotating
	Heat capacity, HU	≥ 3,00,000
	Heat dissipation rate	60,000
	Traget/filter combinations	Mo/Mo, Mo/Rh
	Focal spot size, mm	0.1 and 0.3
3	**ASSEMBLY POSITIONING AND MOVEMENT**	
	Collimation for both sizes	Requried
	Movement locks	Electromachanical/Electromagnetic
	Rotation	-135° to +150°
	Vertical, cm	100
	SID, cm	≥ 65
	Scale guide	Distance and pressure
	Hand Switch	Optional
4	**Radiation output-mR/sec @28kVp**	> 800
5	**Radiation Shield**	Requried
6	**Radiation Shield Thickness**	Minimum 0.25 mm Pb equivalent
7	**Compression System**	Manual, Automatic, Fine adjustments
8	**Force, N**	200
9	**Screen-film systems**	Requried
10	**Grid Ratio**	5:01
11	**Bucky**	For both film sizes(18×24 cms and 24×30 cms)
12	**Magnification Device**	1.5x , 1.8x (variable)
13	**Stereotactic Devices**	Optional
14	**Film ID System**	Optional
15	**Other Specifications**	Quick Switch cassette release and dose calculation; OPCOMP selects optimum compression pressure; OPDOSE for selection of kV, track, and filter. Meets requirements of CSA, HHS, IEC 60601-1 standards, MPG, and UL 187.
16	**Optional Accessories**	Opdima digital spot imaging system, compatible with Mammotome vacuum stereotactic biopsy device
14	**Power Requriments**	Single phase 220-240 Volt, 50 Hz (AC Supply)
PreInstallation and Installation		

1	**PreInstallation Requriments**	Need to be give at the Tender
2	**Installation**	In scope of Supplier
	Purchase Information	
1	**Warranty**	3 years from the date of Installation
2	**CMC**	≤ 5% of the device cost and 2% escalation on every year (Taxes at Actuals)
3	**AMC**	≤ 3% of the device cost and 2% ecalation on every year (Taxes at Actuals)
4	**QA, QC and other tests**	6 months/ 1 year as per NABH/JCI
5	**Training & Manual**	Pre and Post installation trainning as an requried under warrantry, All user manuals with Quick referance guides and service manuals, digital manuals.
6	**eLORA**	In scope of Supplier to be registred in eLORA of quoted Model for Buyer
7	**Price Range**	N/A

File No.GEM/TP/Mobile Digital Radiography Unit/2019 (Version 3.0)		Date:	18-Jan-19
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			
Level 4 Category: Mobile Digital Radiography Unit			
Name, Coding and Purpose			
1	**UMDNS Name**	**Code**	
	Radiographic Unit, Mobile	13-272	
2	**Other Names**	Portable X-Ray unit.	
3	**Scope**	Mobile radiographic units are used for radiographic imaging of patients who cannot be moved to the radiology department	
4	**Clinical Application**	Mobile radiographic units are used for radiographic imaging of patients who cannot be moved to the radiology department and who are in areas—such as intensive and critical care units or operating and emergency rooms—that lack standard, fixed radiographic equipment. Mobile units, which are manually or motor driven to the patient, are designed for use only when patient transport is contraindicated; the radiology department offers a more controlled, optimal setting for radiographic imaging. These devices are used mainly for general adult two-dimensional (2-D) radiographic studies (predominantly for chest x-rays) as well as pediatric, neonatal, and orthopedic imaging.	
Confirmity to Standards			
1	**Confirmity to Certification**	US FDA/Eu CE (Notified Body)/BIS and AERB type approval for quoted model, NOC not accepeted	
2	**Confirmity to Manufactures Certification**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485	
3	**Confirmity to Safety Standards**	IEC 60601-2-54 or equivalent BIS	
Technical Specifications			
1	**RADIOGRAPHY MODES**		
	Film or Digital	Film/Digital (Digital Preferred)	
2	**DIGITAL DETECTOR**		
	Detector material	Cesium Iodide (Csi) or Higher	
	Detector size	14in×17in Large ; 10in×12in Small	
	Wireless	Optional	
	Matrix size	Deponds on type of detector	
	Pixel size	≥ 150 µm	
	Image preview wait	< 6 sec	
	Diagnostic image Display size	>10" touch screen	
	Automatic parameter selection	Preffered	
3	**X-RAY GENERATORS & TUBES**		
	Preffered generator units	4 KW, high frequency	
	maximum output Range, kVp	40-120	
	Increments	1 kV	
	mAs Range	0.5-200	

	Increments	20%
	Focal spot size, mm	0.8
	Heat capacity, KHU	2,00,000
	Cooling rate, HU/min	above 15,000
	Aluminum Filter, mm	>2.5
	SID Range, cm(in)	100-200 (39.4-78.7)
	Model, Collimator	Manual/Automatic
4	**TUBE MOVEMENT**	
	Horizontal, cm	45
	Vertical, cm	130
	Rotation Z-axis, °	± 90
	Rotation Y-axis, °	± 90
5	**Power Requriments**	220-240 Volt, 50 Hz (AC Supply)-16Amps Scoket
6	**Battery**	Optional
PreInstallation and Installation		
1	**PreInstallation Requriments**	Need to be give at the Tender
2	**Installation**	In scope of Supplier
Purchase Information		
1	**Warranty**	3 years from the date of Installation
2	**CMC**	≤ 5% of the device cost and 2% escalation on every year (Taxes at Actuals)
3	**AMC**	≤ 3% of the device cost and 2% ecalation on every year (Taxes at Actuals)
4	**QA, QC and other tests**	6 months/ 1 year as per NABH/JCI
5	**Training & Manual**	Pre and Post installation trainning as an requried under warrantry, All user manuals with Quick referance guides and service manuals, digital manuals.
6	**eLORA**	In scope of Supplier to be registred in eLORA of quoted Model for Buyer
7	**Price Range**	N/A

Pressure Injectors- MRI, CT				
File No.GEM/TP/Pressure Injectors /2019 (Version 3.0)			Date:	1/19/2019
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: Pressure Injectors				
A:	**Name, Coding and Purpose**			
1	**UMDNS Name**	Injectors, Contrast Media, Magnetic Resonance Imaging		
2	**UMDNS Code**	18-158		
3	**Other Names**	multiwavelength oximeters, operating room monitors, oxygen monitors, PO screening devices.		
4	**Scope**	Automatic electromechanical contrast media injectors for angiography, computed tomography (CT), and magnetic resonance imaging (MRI) procedures		
5	**Clinical Application**	Contrast media injectors introduce viscous fluids into an artery or vein through a small catheter, making vessels in an angiogram, CT scan, or MRI study contrast with their surroundings. Injectors are also used to introduce contrast media in CT and MRI procedures for routine body, vascular, cerebral, and perfusion imaging.		
B:	**Certifictions**			
1	**Confirmity to Regulatory**	CDSCO/BIS/US FDA/CE (Notified Body)		
2	**Confirmity to QMS**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485		
3	**Confirmity to Standards**	IEC 60601-1, IEC 62366-1, ISO 10993-1, ISO 11137-1 or their equivalent BIS		
C:	**Technical Specifications**			
1	**TYPE**	Dual Head for CT & MRI		
2	**DRIVE MECHANISM**	Electromechanical/motor driver/roll pump		
3	**INJECTOR HEAD MOUNTING OPTIONS**	Movable stand/ space-saving ceiling suspension		
4	**SYRINGES**			
	Disposable	Required		
	Reusable	24 hr, flexible for all contrast media containers		
	Fluid heating	Preferred		
5	**SYRINGE CAPACITY, mL**			
	Disposable	≥100, 200 preferred		
	Reusable	24 hr usage pump tube /casettes		
6	**FLOW RANGE, mL/sec**	0.1-10		
7	**DELIVERY PRESSURE**	Range, psi 0-300		
8	**SELECTABLE PRESSURE**	Required		
	Increments, psi	10		
9	**ADJUSTABLE RISE TIME**	Required		
10	**ADJUSTABLE VOLUME STOP, type**	Required		
	Increments, mL	1		
11	**SALINE FLUSH**	Required		

12	**SAFETY FEATURES**			
	Extravasation detection	Required		
	Air detection	Required		
13	**VOLTAGE, VAC**	100-240V, Battery 24-25		
D:	**PURCHASE INFORMATION**			
1	**Warranty**	3 years		
2	**CMC**	3 years		
3	**Preventive Maintenance**	Every 6 months		
4	**Training**	Required as per the request from Users		
5	**Service contract clauses**	1) All Breakdown calls to be attended within 24 hrs of registartion of the complaint. 2) Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;		
6	**Documents**	Should provide 2 sets (hardcopy and soft-copy) of: 1) List of equipment and procedures required for local calibration and routine maintenance; 2) Service and operation manuals (original and copy) to be provided; 3) Advanced maintenance tasks documentation; 4) Certificate of calibration and inspection from the manufacturer. 5) Satisfactory certificate for any existing installation from government hospital. 6) List of important spares and accessories, with their part numbers and cost. 7) Service Support Contact details (Hierarchy Wise; including a toll free/landline number)		

Pulse Oximeter MRI Compatible

File No.GEM/TP/Pulse Oximeter/2019 (Version 3.0)			Date:	1/19/2019
Level 1 Category : Medical Devices and In Vitro Diagnostic (IVD) Medical Devices			Creator:	KIHT
Level 2 Category: GENERAL HOSPITAL AND PERSONAL USE DEVICES			Approver	GeM
Level 3 Category: Diagnostic Devices				
Level 4 Category: Pulse Oximeter MRI compatible				
A:	**Name, Coding and Purpose**			
1	**UMDNS Name**	Oximeters, Pulse		
2	**UMDNS Code**	17-148		
3	**Other Names**	multiwavelength oximeters, operating room monitors, oxygen monitors, PO screening devices.		
4	**Scope**	Pulse oximeters, both stand-alone units and modular units that interface with anesthesia units or physiologic monitoring systems.		
5	**Clinical Application**	Pulse oximeters noninvasively monitor SpO_2 (generally expressed as a percentage [e.g., 70% to 100%]) of arterial hemoglobin by measuring light-absorbance changes resulting from arterial blood flow pulsations. Their use allows continuous and instantaneous monitoring of oxygenation and pulse rate, can provide early detection of hypoxia before other signs such as cyanosis are observed, and may reduce the frequency of arterial puncture and laboratory blood gas analysis. It is considered a standard of care for monitoring arterial oxygen saturation in the operating room during procedures requiring anesthesia and in intensive care units and recovery. It is also frequently used in burn units, cardiac catheterization laboratories, and ambulances. It is also used in general medical/surgical and outpatient areas for spot-checking. Other applications include dentistry anesthesia, sleep studies, exercise testing, and home monitoring of certain patients, such as infants at risk for sudden infant death syndrome and patients requiring respiratory therapy. Battery-powered units are particularly convenient because they can also monitor the patient during transport.		
B:	**Certifictions**			
1	**Confirmity to Regulatory**	CDSCO/BIS/US FDA/CE (Notified Body)		
2	**Confirmity to QMS**	ISO 9001 & ISO 13485 / ICMED 9001 & 13485		
3	**Confirmity to Standards**	ISO 80601-2-61:2017 or equivalent BIS		
C:	**Technical Specifications**			
1	**STAND-ALONE/ MODULAR**	Stand alone/Handheld		
2	**MOUNTING OPTIONS**	Bed rail or infusion pole		
3	**DISPLAYS**	SpO2, pulse rate, pulse strength and/or signal, low battery		
	Type	LCD, LED, others		
	SpO2 RANGE, %	70-100, Accuracy, % 70-100 ±3		
	PULSE RATE, bpm	30-240, Accuracy ±5		

4	**PERFUSION INDEX AND/OR SIGNAL STRENGTH INDICATOR**	Required, continuous monitors; preferred, spot check monitors		
5	**RESPONSE TIME, sec**	Every pulse		
6	**ALARMS**			
	Audible and visual	High/low SpO2 and pulse rate, sensor off, sensor failure, low battery		
	Visual only	High/low SpO2 and pulse rate, sensor off, low battery		
7	**ALARM OVERRIDE**	Preferred		
	Reactivation method	Automatic or manual		
	Volume control	Preferred		
	SELF-TEST MODE	Preferred		
8	**PROBE TYPES**			
	Disposable	Required		
	Reusable	Required		
	Patient range	Adult, pediatric, infant, neonate		
	Cable length, m (ft)	≥ 1.5 (5)		
9	**DATA MANAGEMENT**			
	Data stored	≥10 patients data		
	External output	Wireless/Bluetooth/ analog, serial		
	PRINTER/RECORDER	optional		
10	**MRI CONDITIONAL**	Required for use in MRI environment		
11	**LINE POWER, VAC**	100-240		
12	**BATTERY TYPE (NUMBER)**	Lithium ion preferred 2		
	Life, hr	4 intrahospital, 8 interhospital		
	Rechargeable	Preferred; optional for handheld		
	Recharge time, hr	≤10		
	Low-battery notice	Preferred		
	WEIGHT inc battery, g (oz)	≤2000 gm		
D:	**PURCHASE INFORMATION**			
1	**Warranty**	3 years		
2	**CMC**	3 years		
3	**Preventive Maintenance**	Every 6 months		
4	**Training**	Required as per the request from Users		
5	**Service contract clauses**	1) All Breakdown calls to be attended within 24 hrs of registartion of the complaint. 2) Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;		

6	**Documents**	Should provide 2 sets (hardcopy and soft-copy) of: 1) List of equipment and procedures required for local calibration and routine maintenance; 2) Service and operation manuals (original and copy) to be provided; 3) Advanced maintenance tasks documentation; 4) Certificate of calibration and inspection from the manufacturer. 5) Satisfactory certificate for any existing installation from government hospital. 6) List of important spares and accessories, with their part numbers and cost. 7) Service Support Contact details (Hierarchy Wise; including a toll free/landline number)