



TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR Radio Imaging Department



Ministry of Health and Family Welfare Government of India





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Ministry of Health and Family Welfare Government of India

DISCLAIMER

Please note the following points before using these technical specifications:

The specifications are suggestive in nature. State may adopt/adapt them as per context specific needs. These specifications may be tailored appropriately by users according to the specific situation, especially:

- Local standards and legislation; local regulations and conditions; languages; installation conditions, technological levels, electrical range, capacities, utility environment, clinical procedures, personnel (users) experience and other local specific conditions.
- ii. The number of accessories, consumables, spare parts and other components indicates usual and/ or ideal number and is not a mandatory quantity. The user can determine this quantity according to a product's characteristics and frequency of use in the hospital.
- iii. The mention of specific companies or of certain manufacturer's products does not imply that they are endorsed or recommended by NHM / NHSRC in preference to others of a similar nature that are not mentioned.
- iv. All reasonable precautions have been taken by NHM / NHSRC to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the NHM / NHSRC be liable for damages arising from its use.

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भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग स्वास्थ्य एवं परिवार कल्याण मन्नालय Government of India Department of Health and Family Welfare Ministry of Health and Family Welfare

Date: 30.09.2019



MESSAGE

Various pioneering and innovative initiatives are being taken up by Government of India through National Health Mission (NHM) to provide affordable and effective healthcare to Indian Citizens. Substantial investments in the NHM have been made to strengthen Public Health System in the country.

Identifying vital medical devices is a critical part of strengthening health infrastructure. However rapidly changing technologies, complexity associated with medical devices, ensuring quality, safety performance and high costs of procurement - all these make selection of appropriate and cost effective devices a challenging task.

To address this need, the Ministry of Health and Family welfare, Government of India under the aegis of NHM formulated technical specifications of various medical devices as per Indian Public Health Standards. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am delighted to note that these have been effectively considered by NHSRC under MoHFW while preparing the specifications.

Effort has been made to make the specifications as generic as possible and this has been the corner stone of this technical exercise. State may make appropriate modifications to suit their context specific requirements.

(Preeti Sudan)







भारत सरकार स्वास्थ्य एवं परिवार कल्याण मंत्रालय निर्माण भवन, नई दिल्ली - 110011 GOVERNMENT OF INDIA MINISTRY OF HEALTH & FAMILY WELFARE NIRMAN BHAVAN, NEW DELHI - 110011



MESSAGE

National Health Mission is unique in such programmatic intervention envisioned at enrich largely on health with distinctive attention in vitalizing rural health infrastructure and services. Providing vital medical devices is a critical component of strengthening the health infrastructure.

Technical specifications play an important role in identification and procurement of appropriate cost effective medical devices. Factors to be considered include the type of health facility where the devices are to be used, the health work force available and the burden of disease experienced in the specific catchment area.

I am happy to note that, National Health System Resource Centre has filled an important technical gap by providing these specifications. The experts consulted for specification formulation exercises include experts from prestigious institutions such as AllMS, PGIMER - Chandigarh, Ram Manohar Lohia Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, JIPMER, Hindustan Life Care Limited, Representatives from various state medical corporations to name a few. The specifications were also reviewed by Directorate General Health Services, Govt of india.

I am anticipating that using them as reference specifications while undertaking procurement will diminish costs of procurement, ensure the quality, standards, optimal performance of medical devices and reduce the procurement lead time. I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

(Manoj Jhalani)

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INTRODUCTION

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufacturer industry associations / government organizations.

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with experts has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. In the consultative meeting experts has mentioned the following activities needs to be considered wisely while procuring medical devices.

- (1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation,
 - (a) Proper grounding at electrical sockets,
 - (b) Wherever generator or UPS or solar power is used as back up energy source, should ensure the stabilizer/surge protector to prevent malfunction of medical devices. The same may be undertaken at facilities having voltage/energy fluctuations.
- (2) Procurer may form rate contract on reagents/consumables anticipating yearly demand, on Medical devices which require periodic supply of reagents/consumables for its day to day operation.
- (3) Appropriate filtering mechanism to be housed at public facility to ensure maximum longevity on Medical devices which operates efficiently depending on quality of pneumatics/water supply source.
- (4) Ensure compliance for Medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution Control Board, PC PNDT, PESO etc.
- (5) Procurer/public health facility must ensure scheduling calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in Medical device manufactures operational/service manual.
- (6) Wherever necessary warning/safety information required, has to be placed at public health facilities.
- (7) User/In-house service training to be procured along with Medical devices for effective utilization.
- (8) Public health facility may actively engage with MoHFW initiative, Post market surveillance / Materiovigilance program of India.
- (9) Public health facility have to rely on manpower availability or utilization or IPD/OPD load factor to decide on quantity of medical devices to be procured and not just on number of bed at each level.

60 mA X-RAY (MOBILE)

Versio	n no :	Ver_1
Date:	11110	1/29/2019
	by : (name. Institution)	HCT/NHSRC
Done	•	ME, CATEGORY AND CODING
UMDN	IS name	Radiographic Units
	IS code(s)	13267
OWIDIN	15 coac(3)	GENERAL
		1. USE
1.1	Clinical purpose	Units that include an x-ray source to irradiate the portion of the
		patient to be examined, and an image receptor that converts in some
		form of latent image the array of x-rays that were differentially
		attenuated within the patient. This latent image is converted, usually
		in another device (e.g., a film image processor), into a visible image
		(i.e., a radiograph) reflecting the internal structure of the irradiated
		patient region. The interpretation of these images by a physician
		contributes to a clinically useful diagnosis.
1.2	Used by clinical department/ward	Intensive Care Units (ICUs) and Radiology Department
		TECHNICAL
	2	TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	X-ray Generator:
	(specific to this type of device)	 High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided. Power rating, 3 kW @ 100 kVp Maximum output, 100 kVp mAs 1-50 range mA range (rad.): 20 mA to 60 mA.
		Control:
		 A very compact, Soft touch Control panel having following functions & indications should be provided. The panel can be upplied in floor or wall mount with spill proof design following features should be on the control panel. Machine ON/OFF switch, Digital display of KV & mAs, KV&mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators. Bucky selection switch. Self diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload. X-Ray Tube:
		 Tube should have one number stationary anode and thermally protected. Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built

	3. P	HYSICAL CHARACTERISTICS
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
		disbursed through a cooling mechanism
3.5	Mobility, portability	Mobile
		(electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	Power Supply:
		230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider.
= 4		PRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	Machine should be provided with following accessories:
	standard, optional); Spare parts	1) Two numbers of BARC approved whole body lead aprons with all
	(main ones); Consumables/	attachments.
	reagents (open, closed system)	2) One pair of 8 meter HV Cable
		EMENT TERMS/DONATION REQUIREMENTS
<i>c</i> 1		AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	1. Operating Condition: Capable of operating continuously in
	conditioning, humidity, dust	ambient temperture of 5 to 50 deg C and relative humidity of 15
)	to 80% in ideal circumstances.
		2. Storage condition: Capable of being stored continuosly in
		ambient temperature of 0 to 50 deg C and relative humidity of
6.2	User's care, Cleaning,	15 to 90%
0.2	Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be
	Distillection & Sternity Issues	capable of easy disinfection or be protected by a single use/
		disposable cover.
		Sterilization not required.
	7	STANDARDS AND SAFETY
7.1	Certificates (pre-market,	Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE)
'.1	sanitary,); Performance and	requirements will be applicable only when the Indian standards
	safety standards (specific to the	like BIS/CDSCO are not available.)
	device type); Local and/or	2. Manufacturer and Supplier should have ISO 13485 certification
	international	for quality standards.
		3. Electrical safety conforms to the standards for electrical safety
		IEC 60601-1-General requirements(or equivalent BIS Standard).
		4. Shall meet internationally recognised standard for Electromagnetic
		Compatability(EMI/EMC). for electromedical equipment:
		IEC 60601-1-2
		5. Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54
		6. AERB type approved.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
		standard.

	8. TI	RAINING AND INSTALLATION
8.1	Pre- installation requirements: nature, values, quality, tolerance	Three phase stable power supply
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
	9. WA	RRANTY AND MAINTENANCE
9.1	Warranty	3 years, including all spares and calibration.
		10. DOCUMENTATION
10.1	Operating manuals,	Should provide 2 sets (hard copy and soft copy) of:
	set manuals, other manuals	1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams;
		List of equipment and procedures required for local calibration
		and routine maintenance;
		3. Service and operation manuals (original and Copy) to be provided;
		4. Advanced maintenance tasks documentation;
		5. Certificate of calibration and inspection,
		6. Satisfactory certificate for any existing installation from
		government hospital.
10.2	Other accompanying	List of essential spares and accessories, with their part number and
	documents	cost;
		11. NOTES
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be
		provided; Any Contract (AMC/CMC/add-hoc) to be declared by the
		manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

100 mA X-RAY

Versio	n no :	Ver_1
Date:		15/02/2018
	by : (name. Institution)	HCT/NHSRC
Done	•	ME, CATEGORY AND CODING
UMDN	IS name	Radiographic Units
	IS code(s)	13267
		GENERAL
		1. USE
1.1	Clinical purpose	Units that include an x-ray source to irradiate the portion of the patient to be examined, and an image receptor that converts in some form of latent image the array of x-rays that were differentially attenuated within the patient. This latent image is converted, usually in another device (e.g., a film image processor), into a visible image
		(i.e., a radiograph) reflecting the internal structure of the irradiated patient region. The interpretation of these images by a physician contributes to a clinically useful diagnosis.
1.2	Used by clinical department/ward	Radiology Department
		TECHNICAL
	2.	TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	X-ray Generator:
	(specific to this type of device)	 High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided. Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 100 mA or more. Control: A very compact, Soft touch Control panel having following
		 functions & indications should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel. Machine ON/OFF switch, Digital display of KV & mAs, KV&mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators. Bucky selection switch. Self diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload.
		X-Ray Tube:
		 Tube should have one number stationary anode and thermally protected. Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area. Coloumn Stand:
		It should have floor to ceiling stand with vertical counter balanced travel.

vertical bucky stand with machine. 3. Five position tilt table having bucky grid ratio of 8:1 with 85 lines per inches should be provided. The bucky tray should accept cassette of 8"x10",10"x12" and 14"x17" size. 2.2 User's interface Manual 2.3 Software and/ or standard of communication(where ever required 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions(metric) NA 3.2 Weight (lbs, kg) NA 3.3 Noise (in dBA) Noise-free system 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Stationary installation 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Power Supply:			2. 16.14. 141. 120.14. 142. 141. 141.
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3.3 Noise (in dBA) 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Stationary installation 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Power Supply: 230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohr 4.2 Battery operated NO 4.3 Protection Stabliser of appropriate capacity to be installed. 7 Des specified by the service provider. S. ACCESSORIES, SPARE PARTS, CONSUMABLES Machine should be provided with following accessories: (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come	3.1		NA
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disbursed through a cooling mechanism 3.5 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Power Supply: 230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohr 4.2 Battery operated NO 4.3 Protection Stabliser of appropriate capacity to be installed. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come	3.3	Noise (in dBA)	Noise-free system
3.5 Mobility, portability 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Power Supply: 230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohr 4.2 Battery operated NO 4.3 Protection Stabliser of appropriate capacity to be installed. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come	3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
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230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohr 4.2 Battery operated NO 4.3 Protection Stabliser of appropriate capacity to be installed. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come		4. ENERGY SOURCE	(electricity, UPS, solar, gas, water, CO2)
 4.2 Battery operated 4.3 Protection 4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.1 Atmosphere/Ambience (air ambient temperture of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come 	4.1		•
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4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come	4.2	Battery operated	NO
4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity 15 to 90% 6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come	 4.3	Protection	Stabliser of appropriate capacity to be installed.
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6.2 User's care, Cleaning, 1. Disinfection: Parts of the Device that are designed to come			·
	 6.2	User's care, Cleaning.	
	0. _	_	_
		Distinction a stermity issues	capable of easy disinfection or be protected by a single use/
disposable cover.			
2. Sterilization not required.			•
7. STANDARDS AND SAFETY		7	·
7.3 Certificates (pre-market, 1. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE	7 1		
	7.1	- I	requirements will be applicable only when the Indian standards
		1	• • • • • • • • • • • • • • • • • • • •
		1	•
			• •
international for quality standards.		international	• •
3. Electrical safety conforms to the standards for electrical safe			
			IEC 60601-1-General requirements (or equivalent BIS Standard).

	T	
		4. Shall meet internationally recognised standard for
		Electromagnetic Compatability (EMI/EMC). for electromedical
		equipment: IEC 60601-1-2
		5. Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54
		6. AERB type approved.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
		standard.
	8. TI	RAINING AND INSTALLATION
8.1	Pre- installation requirements:	Three phase stable power supply
	nature, values, quality,	
	tolerance	
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
	9. WA	RRANTY AND MAINTENANCE
9.1	Warranty	3 years, including all spares and calibration.
		10. DOCUMENTATION
10.1	Operating manuals,	Should provide 2 sets (hard copy and soft copy) of:
	set manuals, other manuals	1. User, technical and maintenance manuals should be supplied in
		English/Hindi language along with machine diagrams;
		2. List of equipment and procedures required for local calibration and routine maintenance;
		3. Service and operation manuals(original and Copy) to be provided;
		4. Advanced maintenance tasks documentation;
		5. Certificate of calibration and inspection,
		6. Satisfactory certificate for any existing installation from
		government hospital.
10.2	Other accompanying	List of essential spares and accessories, with their part number and
	documents	cost;
	accaments	11. NOTES
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to
		be provided; Any Contract (AMC/CMC/add-hoc) to be declared by
		the manufacturer.
11.2	Recommendations or	Any warning sign would be adequaetly displayed.
	warnings	,
1	1	

100 mA X-RAY - MOBILE

V		Van 4
Version no.:		Ver1
Date:		15/02/2018
Done b	y : (name. Institution)	HCT/NHSRC
LIMBNI		ME, CATEGORY AND CODING
	S name	Radiographic Units, Mobile
UMDN	S code(s)	13272
		GENERAL
	leu i	1. USE
1.1	Clinical purpose	Radiographic units consisting of a manually driven or motor-driven
		wheeled cart that transports an x- ray generator, an x-ray tube and
		tube stand, collimators, and a film cassette or flat-panel detector
		storage drawer (for film and digital units respectively). There are three
		different types of mobile radiographic units, which are categorized
		according to the generator: line-powered transformers, capacitor-
		discharge generators, and battery-powered transformers. Most
		mobile radiographic units utilize one of several types of digital
		imaging; advantages of digital imaging over film include greater
		dynamic range, reduced patient radiation exposure, and the ability to
		integrate with digital picture archiving and communication systems
		(PACS). Mobile radiographic units are used for imaging patients who
		cannot be moved to the radiology department or when patient
		transport is contraindicated, such as for patients in intensive care and
1.2		critical care units or operating and emergency rooms.
1.2	Used by clinical department/ward	Intensive Care Unit and Radiology Department TECHNICAL
	, ·	TECHNICAL TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	X-ray Generator:
	(specific to this type of device)	1. High frequency X-Ray generator having frequency of 20 KHz or
	(0) 00 00 00 00 00 00 00 00 00 00 00 00 0	more suitable for radiography should be provided.
		2. Power output of generator should be 20 KW Radiography KV
		range should be 40-120 KV or more. mA range (rad.): 100 mA or
		more.
		Control:
		A very compact, Soft touch Control panel having following
		functions & indications should be provided. The panel can be
		supplied in floor or wall mount with spill proof design following
		features should be on the control panel.
		Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs
		increase and decrease switches. Tube focal spot selection switch,
		Ready and x-ray on switch with indicators.
		Bucky selection switch.
		Self diagnostic programme with indicators for earth fault error,
		KV error, filament error & Tube's thermal overload.
		X-Ray Tube:
		1. Tube should have one number stationary anode and thermally
	I	and the state of t

		protected.
		2. Anode heat storage capacity of tube should be more
		, , ,
		than 140 KHU. One number manual collimator with aluminium
		filter & for adjustment of exposure area.
2.2	User's interface	Manual
2.3	Software and/ or standard of	In built
	communication(where ever	
	required	
		PHYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
		disbursed through a cooling mechanism
3.5	Mobility, portability	Mobile
	4. ENERGY SOURCI	E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	Power Supply:
		230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider.
	5. ACCESSO	ORIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	Machine should be provided with following accessories:
	standard, optional); Spare parts	1. Two numbers of BARC approved whole body lead aprons with all
	(main ones); Consumables/	attachments.
	reagents (open, closed system)	2. One pair of 8 meter HV Cable
	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	1. Operating Condition: Capable of operating continuously in
	conditioning, humidity, dust	ambient temperture of 5 to 50 deg C and relative humidity of 15
)	to 80% in ideal circumstances.
		2. Storage condition: Capable of being stored continuosly in
		ambient temperature of 0 to 50 deg C and relative humidity of
		15 to 90%
6.2	User's care, Cleaning,	1. Disinfection: Parts of the Device that are designed to come into
	Disinfection & Sterility issues	contact with the patient or the operator should either be
		capable of easy disinfection or be protected by a single use/
		disposable cover.
		2. Sterilization not required.
	7.	STANDARDS AND SAFETY
7.1	Certificates (pre-market,	1. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE
	sanitary,); Performance and	requirements will be applicable only when the Indian standards
	safety standards (specific to the	like BIS/CDSCO are not available).
	device type); Local and/or	2. Manufacturer and Supplier should have ISO 13485 certification
	international	for quality standards.
		3. Electrical safety conforms to the standards for electrical safety
		· · · · · · · · · · · · · · · · · · ·
		IEC 60601-1-General requirements (or equivalent BIS Standard).
		4. Shall meet internationally recognised standard for

		Electromagnetic Compatability(EMI/EMC). for electromedical equipment: 60601-1-2 5. Certified to be complaint with IEC 60601-1-3, IEC 60601-2-54
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
	 	standard.
8.1	Pre- installation requirements:	RAINING AND INSTALLATION Three phase stable power supply
0.1	nature, values, quality,	Trifee priase stable power supply
	tolerance	
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
	9. WA	RRANTY AND MAINTENANCE
9.1	Warranty	3 years, including all spares and calibration.
		10. DOCUMENTATION
10.1	Operating manuals,	Should provide 2 sets(hard copy and soft copy) of:
	set manuals, other manuals	1. User, technical and maintenance manuals should be supplied in
		english/Hindi language along with machine diagrams;
		2. List of equipment and procedures required for local calibration and routine maintenance;
		3. Service and operation manuals (original and Copy) to be provided;
		4. Advanced maintenance tasks documentation;
		5. Certificate of calibration and inspection,
10.2	Other accompanying	List of essential spares and accessories, with their part number and
	documents	cost;
		11. NOTES
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to
		be provided; Any Contract(AMC/CMC/add-hoc) to be declared by
		the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

CT SCAN - 64 SLICE

\/- u=:-		Mari 1
Version no.:		Ver_1
Date:		15/02/2018
Done	by: (name. Institution)	HCT/NHSRC
LIMDI		ME, CATEGORY AND CODING
	NS name	Radiographic Units
UMDI	NS code(s)	13267 GENERAL
1.1	Clinical purpose	1. USE
1.1	Clinical purpose	Computed Tomography scanners are used for a wide variety of
		diagnostic procedures, including spine and head injuries, lesions, and
		abdominal and pelvic malignancies; to examine the cerebral
		ventricles, the chest wall, and the large blood vessels; and to assess
1.2	Head by divided downston out / your	musculoskeletal degeneration.
1.2	Used by clinical department/ward	Radiology Department TECHNICAL
	٠.	
2.1	Technical characteristics	TECHNICAL CHARACTERISTICS Gantry
2.1	(specific to this type of device)	1. Should incorporate low Voltage Slip Rings
	(specific to this type of device)	2. Minimum scan time for a 360° rotation should be less than or
		equal to 0.35 sec. (350 mili sec.)
		3. Should have minimum tilt of 30 degrees on either side and
		remote tilt should be available as standard
		4. Gantry should be provided with remote/user control panels on
		either side for positioning of the patient
		5. The sub millimeter slice @0.63 mm or less in 64 row 64 slice
		acquisitions should be available. The system should be in
		position to perform 64 slices / rotation for general, cardiac and
		vascular applications
		6. Should have 3D positioning laser lights
		7. The scan FOV in acquisition mode be at least 50 cm with
		intermediate steps for scanning different anatomies
		8. Gantry aperture should be at least 70 cm. in diameter
		9. Integrated Display Panel - Gantry front showing current scan
		parameters such as kV, mA, ECG trace etc. for easy set up for ECG
		gated studies.
		X-Ray Generator
		Should be compact and in-built in the gantry
		2. Should be high frequency having at least 70 kW output or more
		3. The mA range available should be between 20 to 600 or more,
		with increment steps of not more than 10 mA.
		4. Tube Voltage: 80-140 kV
		X-Ray Tube
		1. The X-ray tube should be dual focus with heat storage capacity
		of 6 MHU or more, with effective storage of at least 15 MHU.
		2. Peak heat dissipation rate of anode should be at least 750 KHU/min

- 3. X-ray tube cooler unit should be inside the gantry
- 4. Focal spots, and type of X-ray tube should be specified as per IEC Recommendations.
- 5. Filter and beam limiting devices should be quoted as standard.

Detectors

- 1. These should be of solid state type
- 2. 64 Slice acquisition per rotation should be possible with the detectors, in 0.63 mm mode.
- 3. The system should have at least 64 'physical rows' of the detectors. Number of elements in each row should be specified
- 4. The Z-axis coverage of at least 38 mm / rotation should be possible for standard and cardiac scans
- 5. Fan-angle of X-rays and the geometry should be specified
- 6. Detectors should not require frequent calibration

Patient Table

- 1. Should have minimum weight bearing capacity of 200 kilograms
- 2. The minimum table top height should not be more than 35 cms from floor level for easy transport of trauma patients
- 3. Table top width to be at least 42 cms
- 4. The range of metal free scannable range should be at least 150 cm.
- 5. The vertical range (max. Ht. min. Ht.) 55 cm
- 6. Remote controlled UP / DOWN and FWD / BWD movement.
- 7. Pitch to be freely selectable in automatic / manual mode: 0.15 1.5
- 8. Reproducing accuracy of the Table: 1mm

Spiral CT capabilities

- 1. Minimum slice thickness should be 0.63 mm or less and maximum 10 mm or more.
- 2. Pitch factor (volume pitch): Variable between 0.5 to 1.5 or more and should be user selectable.
- 3. Spiral length: 150cm or more.
- 4. Single continuous 'spiral-on time' should be minimum 100 seconds or more.
- 5. Bolus triggered spiral acquisition should be possible.
- 6. True isotropic volume acquisition and sub-millimeter resolution of at-least 0.4 mm for all body applications.

Topogram

- 1. Length and width: specify range.
- 2. Scan times: specify range
- 3. Should be possible to interrupt acquisition manually once the desired anatomy is obtained.

Data acquisition system

- 1. System should have minimum 64 rows of detector capable of generating 64 slices through latest flying focal spot technology or equivalent.
- 2. Mention minimum acquired slice thickness in Axial & Helical mode after reconstruction.
- 3. Acquisition of cardiac images with ECG gating (prospective & retrospective) should be possible

		4. Step and shoot technique during cardiac scanning for dose
		reduction, or a similar alternative technology should be available.
		Image Evaluation Tools
		Parallel evaluation of multiple ROI in circle, irregular and
		polygonal forms.
		2. Statistical evaluation for area/volume, S.D., Mean, Min/Max and
		histogram.
		3. Distance and angle measurement, freely selectable positioning
		of co-ordinate system, grid and image annotation.
		Latest Iterative Reconstruction Technique
		1. ASIR-V/ iDose4 Premium / SAFIRE or latest available with the
		manufacturer to be quoted as standard.
		2. Model-based Iterative reconstruction technology VEO/ IMR/
		ADMIRE or equivalent for all imaging protocols including
		hardware and software.
		3. Low dose protocols for pediatric and infant scanning.
		Image Reconstruction
		1. Real time reconstruction speed: 20 images per second or more at
		512 x 512 matrix.
		2. Display matrix: 1024 x 1024 or more.
		3. Reconstructed slice thickness range should be less than
		one mm (<1) to 10mm.
		4. Patient's radiation Dose must be displayed on monitior and
		Imaging Films.
		Image Quality
		1. The high contrast resolution be more than 20 lp/mm in all
		routine scans, including spiral and axial mode
		2. The low contrast resolution should not be more than 3 mm at 0.5%
2.2	User's interface	Patient Communication System: An integrated intercom and
	oser's interrace	automated patient instruction system (API) should be provided.
2.3	Software and/ or standard of	Workstations:
2.3	communication(where ever	A client server architecture based solution (Intellispace Portal 6 /
	required	Dexus - AW server 2 / Syngo Via 30A or equivalent) with minimum
	required	concurrent 24,000 slices rendering capacity, with storage of minimum
		1TB having following client hardware specifications - Workstation:
		Z820 or equivalent CPU, dual quad core processor, 16 GB RAM, 1TB
		hard drive, DVD Writing with clinical grade monitor of minimum 2 MP.
		A reputed Anti-Virus Solution for Server should be in place.
		The Server should be with minimum three user (Three Hardware's)
		facility Fully DICOM 3.0 Compliant and PACS Interface ready.
		The workstation should have following processing tools/software's
		Available as standard:
		Multi planar reconstruction(MPR),
		Minimum and Maximum intensity projection
		3D Volume rendering,
		3D SSD (Shaded Surface Display)
		Advance Vessel Analysis with plaque visualization,
		Auto Bone Removal.
-		

		Volume measurement,
		Lung Nodule analysis.
		Liver lesion analysis.
		Colonography.
		Perfusion CT.
		Image Fusion of CT, MR & PET Data
		Neuro DSA.
		Coronary tree analysis: Automated 3D processing of coronary
		arteries, calcium scoring, stent analysis, LV analysis
		Multi-modality automatic tumour tracking & Automatic
		measurements in RECIST, WHO, Volume & Choi criteria
		calculation.
	3. F	PHYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
		disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary installation
	4. ENERGY SOURC	E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	3 phase power supply
4.2	Battery operated	NO
4.3	Protection	Stablizer of appropriate capacity to be installed.
4.4	Power consumption	To be specified by the service provider.
	5. ACCESSO	DRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	1. Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make:
	standard, optional);	Integrated with main console and workstation
	Spare parts (main ones);	2. Color Laser Printer (High Resolution) for color coaded images
	Consumables/reagents (open,	3. UPS with half hour 'back-up' to run entire CT system,
	closed system)	Workstations and Laser Imager
		4. Dual – Head Pressure injector of reputed make (100 syringes)
		5. 160 KVA Silent DG Set with AMF panel
		6. Two LED based view boxes with adjustable illumination to view
		3 films of 14" x 17" in each view box.
		7. Thyroid Collars - 2 No.
		8. Gonadal Shields - 2 each for male and female(Total 4)
		9. Lead Apron Hanger with 2 light weight Lead Aprons
		10. Lead glass
	BIDDING/PROCUR	REMENT TERMS/DONATION REQUIREMENTS
	6. ENVIRONMENT	AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	1. Operating Condition: Capable of operating continuously in
	conditioning, humidity, dust)	ambient temperture of 18 to 30 deg C and relative humidity of
		20 to 75% in ideal circumstances.
		2. Storage condition: Capable of being stored continuosly in
		ambient temperature of 18 to 30 deg C and relative humidity of
		20 to 75%
6.2	User's care, Cleaning,	1. Disinfection: Parts of the Device that are designed to come into
	Disinfection & Sterility issues	contact with the patient or the operator should either be

I	canable of easy disinfection or be protected by a single use/
	capable of easy disinfection or be protected by a single use/ disposable cover.
	·
7	2. Sterilization not required. STANDARDS AND SAFETY
Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment: IEC 60601-1-2 Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS
	6. AERB type approved.
Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
	standard.
8. TF	RAINING AND INSTALLATION
Pre- installation requirements: nature, values, quality, tolerance	Lead glass, door shields
Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
Training of staff (medical,	1. Training of users on operation and basic maintenance;
paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
9. WA	RRANTY AND MAINTENANCE
Warranty	3 years, including all spares and calibration.
	10. DOCUMENTATION
Operating manuals,	Should provide 2 sets (hard copy and soft copy) of:
set manuals, other manuals	 User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
Other accompanying	List of essential spares and accessories, with their part number and
documents	cost;
	11. NOTES
Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be
Recommendations or	provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer. Any warning sign would be adequaetly displayed.
	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. The pre- installation requirements: nature, values, quality, tolerance Requirements for sign-off Training of staff (medical, paramedical, technicians) 9. WA Warranty Operating manuals, set manuals, other manuals Other accompanying documents

CT SCAN - 128 SLICE

Vorsis		Vor. 1
Version no. : Date:		Ver1 15/02/2018
Done by : (name. Institution)		
Done	•	HCT/NHSRC
ПМО	NAI NS name	ME, CATEGORY AND CODING Radiographic Units
	NS code(s)	13267
וטואוטו	va code(s)	GENERAL
		1. USE
1.1	Clinical purpose	Computed Tomography scanners are used for a wide variety of
'-'	Cirrical purpose	diagnostic procedures, including spine and head injuries, lesions, and
		abdominal and pelvic malignancies; to examine the cerebral
		ventricles, the chest wall, and the large blood vessels; and to assess
		musculoskeletal degeneration.
1.2	Used by clinical department/ward	Radiology Department
1.2	osed by clinical department, ward	TECHNICAL
	? .	TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	Gantry
	(specific to this type of device)	1. Should incorporate low Voltage Slip Rings
		2. Minimum scan time for a 360° rotation should be less than or
		equal to 0.35 sec. (350 mili sec.)
		3. Should have minimum tilt of 30 degrees on either side and
		remote tilt should be available as standard
		4. Gantry should be provided with remote control/user control
		panels on either side for positioning of the patient
		5. The sub millimeter slice @0.63 mm or less in 64 row 128 slice
		acquisitions should be available. The system should be in
		position to perform 256 slices / rotation for general, cardiac and
		vascular applications
		6. Should have 3D positioning laser lights
		7. The scan FOV in acquisition mode be at least 200 mm to 500 mm
		with intermediate steps for scanning different anatomies
		8. Gantry aperture should be at least 70 cm. in diameter
		9. Integrated Display Panel - Gantry front showing current scan
		parameters such as kV, mA, ECG trace etc. for easy set up for ECG
		gated studies.
		X-Ray Generator
		1
		 Should be compact and in-built in the gantry Should be high frequency having at least 100 kW output or more
		2. Should be high frequency having at least 100 kW output or more3. The mA range available should be between 20 to 800 or more,
		with increment steps of not more than 10 mA.
		·
		4. Tube Voltage: 80-140 kV
		X-Ray Tube
		1. The X-ray tube should be dual focus with heat storage capacity
		of 8 MHU or more, with effective storage of at least 25 MHU.
		2. Peak heat dissipation rate of anode should be at least 1600 KHU/min

- 3. X-ray tube cooler unit should be inside the gantry
- 4. Focal spots, and type of X-ray tube should be specified as per IEC Recommendations.
- 5. Filter and beam limiting devices should be quoted as standard.

Detectors

- 1. These should be of solid state type
- 2. 128 Slice acquisition per rotation should be possible with the detectors, in 0.63 mm mode.
- 3. The system should have at least 64 'physical rows' of the detectors. Number of elements in each row should be specified
- 4. The Z-axis coverage of at least 40 mm / rotation should be possible for standard and cardiac scans
- 5. Fan-angle of X-rays and the geometry should be specified
- 6. Detectors should not require frequent calibration

Patient Table

- 1. Should have minimum weight bearing capacity of 200 kilograms
- 2. The minimum table top height should not be more than 35 cms from floor level for easy transport of trauma patients
- 3. Table top width to be at least 42 cms
- 4. The range of metal free scannable range should be at least 160 cm.
- 5. The vertical range (max. Ht. min. Ht.) 55 cm
- 6. Remote controlled UP / DOWN and FWD / BWD movement.
- 7. Pitch to be freely selectable in automatic / manual mode: 0.15 1.5
- 8. Reproducing accuracy of the Table: 1mm

Spiral CT capabilities

- 1. Minimum slice thickness should be 0.63 mm or less and maximum 10 mm or more.
- 2. Pitch factor (volume pitch): Variable between 0.5 to 1.5 or more and should be user selectable.
- 3. Spiral length: 150cm or more.
- 4. Single continuous 'spiral-on time' should be minimum 100 seconds or more.
- 5. Bolus triggered spiral acquisition should be possible.
- 6. True isotropic volume acquisition and sub-millimeter resolution of at-least 0.4 mm for all body applications.

Topogram

- 1. Length and width: specify range.
- 2. Scan times: specify range
- 3. Should be possible to interrupt acquisition manually once the desired anatomy is obtained.

Data acquisition system

- 1. System should have minimum 64 rows of detector capable of generating 128 slices through latest flying focal spot technology or equivalent.
- 2. Mention minimum acquired slice thickness in Axial & Helical mode after reconstruction.
- 3. Acquisition of cardiac images with ECG gating (prospective & retrospective) should be possible

		4. Step and shoot technique during cardiac scanning for dose
		reduction, or a similar alternative technology should be available.
		Image Evaluation Tools
		1. Parallel evaluation of multiple ROI in circle, irregular and
		polygonal forms.
		2. Statistical evaluation for area/volume, S.D., Mean, Min/Max and
		histogram.
		3. Distance and angle measurement, freely selectable positioning
		of co-ordinate system, grid and image annotation.
		Latest Iterative Reconstruction Technique
		1. ASIR-V/ iDose4 Premium / SAFIRE or latest available with the
		manufacturer to be quoted as standard.
		2. Model-based Iterative reconstruction technology VEO/ IMR/
		ADMIRE or equivalent for all imaging protocols including
		hardware and software.
		3. Low dose protocols for pediatric and infant scanning.
		Image Reconstruction
		1. Real time reconstruction speed: 20 images per second or more at
		512 x 512 matrix.
		2. Display matrix: 1024 x 1024 or more.
		3. Reconstructed slice thickness range should be less than
		one mm (<1) to 10mm.
		4. Patient's radiation Dose must be displayed on monitior and
		Imaging Films.
		Image Quality:
		1. The high contrast resolution be more than 20 lp/mm in all
		routine scans, including spiral and axial mode
		2. The low contrast resolution should not be more than 3 mm at 0.5%
2.2	User's interface	Patient Communication System: An integrated intercom and
2.2		automated patient instruction system (API) should be provided.
2.3	Software and/ or standard of	Workstations:
	communication (where ever	A client server architecture based solution (Intellispace Portal 6/
	required	Dexus- AW server 2 / Syngo Via 30A or equivalent) with minimum
		concurrent 24,000 slices rendering capacity, with storage of minimum
		1TB having following client hardware specifications-
		Workstation: Z820 or equivalent CPU, dual quad core processor, 16 GB
		RAM, 1TB hard drive, DVD Writing with clinical grade monitor of
		minimum 2 MP.A reputed Anti-Virus Solution for Server should be in
		place. The Server should be with minimum three user (Three
		Hardware's) facility Fully DICOM 3.0 Compliant and PACS Interface ready. The workstation should have following processing tools/
		software's Available as standard:
		Multi planar reconstruction(MPR) ,
		Minimum and Maximum intensity projection
		3D Volume rendering,
		3D SSD (Shaded Surface Display).
		 Advance Vessel Analysis with plaque visualization,
		Auto Bone Removal.
	<u> </u>	

		Volume measurement, Volume measurement,
		Lung Nodule analysis.
		Liver lesion analysis.
		• Colonography.
		• Perfusion CT.
		Image Fusion of CT, MR & PET Data
		Neuro DSA.
		Coronary tree analysis: automated 3D processing of coronary
		arteries, calcium scoring, stent analysis, LV analysis
		Multi-modality automatic tumour tracking & Automatic
		measurements in RECIST, WHO, Volume & Choi criteria
		calculation.
2.4		HYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
	AA 1 19.	disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary installation (COS)
4.1		(electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	Three phase stable power supply
4.2	Battery operated	NO
4.3	Protection	Stabliser of appropriate capacity to be installed.
4.4	Power consumption	To be specified by the service provider.
F 1		PRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	1. Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make:
	standard, optional);	Integrated with main console and workstation
	Spare parts (main ones);	2. Color Laser Printer (High Resolution) for color coaded images
	Consumables/reagents (open,	3. UPS with half hour 'back-up' to run entire CT system,
	closed system)	Workstations and Laser Imager
		4. Dual – Head Pressure injector of reputed make (100 syringes)
		5. 160 KVA Silent DG Set with AMF panel
		6. Two LED based view boxes with adjustable illumination to view
		3 films of 14" x 17" in each view box.
		7. Thyroid Collars -2 No.
		8. Gonadal Shields- 2 each for male and female(Total 4)
		9. Lead Apron Hanger with 2 light weight Lead Aprons
		10. Lead glass
		EMENT TERMS/DONATION REQUIREMENTS
C 1		AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	1. Operating Condition: Capable of operating continuously in
	conditioning, humidity, dust)	,
		20 to 75% in ideal circumstances.
		2. Storage condition: Capable of being stored continuosly in
		ambient temperature of 18 to 30 deg C and relative humidity of
	Handa and Charain	20 to 75%
6.2	User's care, Cleaning,	1. Disinfection: Parts of the Device that are designed to come into
1	Disinfection & Sterility issues	contact with the patient or the operator should either be

		capable of easy disinfection or be protected by a single use/
		disposable cover.
		2. Sterilization not required.
	7.	STANDARDS AND SAFETY
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment: IEC 60601-1-2 Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS standard
7.2	Local and/or international	6. AERB type approved. Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
		RAINING AND INSTALLATION
8.1	Pre- installation requirements: nature, values, quality,	Lead Glass, Door Sheild
	tolerance	
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
		RRANTY AND MAINTENANCE
9.1	Warranty	3 years, including all spares and calibration.
		10. DOCUMENTATION
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
		11. NOTES
11.1	Service Support Contact details	
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

FULL BODY MRI SYSTEM - 1.5 TESLA

Ver. 1				
Done by: (name. Institution) HCT/NHSRC NAME, CATEGORY AND CODING	n no.:		Ver1	
UMDNS name Magnetic Resonance Imaging (MRI) Units UMDNS code(s) 16260 GENERAL 1. USE 1.1 Clinical purpose MRI is primarily used to identify diseases of the central system, brain, and spine and to detect musculoskeletal discolated view cartilage, tendons, and ligaments. MRI cased used to view cartilage, tendons, and ligaments. MRI cased to image the eyes and the sinuses. MRI can be used diagnose infectious diseases; to detect metastatic liver of display heart-wall structure; to stage prostate, bladder, and canner. MRI can also be used as a functional imaging tool. 1.2 Used by clinical department/ward Radiology Department TECHNICAL 2. TECHNICAL 2. TECHNICAL CHARACTERISTICS MAGNET 1. Whole Body 1.5Tesla Magnetic Resonance Imaging Systoptimized for higher performance in Whole Body and vexaminations with superconducting magnet, high perfogradients and digital Radio Frequency System. 2. 1.5T active shielded super conductive magnet should be and non-claustrophobic. 3. It should have a least 70 cm patient bore with flared of Magnet length should be less than 200cm. 5. Homogeneity of magnet should be less than 3.5 ppm over DSV 6. The magnet should be well ventilated and illuminated in 2 way intercom for communication with patient. 7. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/ hour. 8. Emergency Rundown Control at both operator console and Gantary Room is a must. 9. Fringe Field 0.5 Gauss line radius is essential. 10. Front Panel of gantry should display table and patient in SHIM SYSTEM 1. High performance, highly stable shim system with glot localized automated shimming for high homogeneity in collection and consumption of the programment of the pro				
UMDNS name UMDNS code(s) 16260 GENERAL 1. USE 1.1 Clinical purpose MRI is primarily used to identify diseases of the central system, brain, and spine and to detect musculoskeletal diseals oused to view cartilage, tendons, and ligaments. MRI cused to image the eyes and the sinuses. MRI can be used diagnose infectious diseases; to detect metastatic liver of display heart-wall structure; to stage prostate, bladder, and cancer. MRI can also be used as a functional imaging tool. 1.2 Used by clinical department/ward Radiology Department TECHNICAL 2. TECHNICAL 2. TECHNICAL 2. TECHNICAL 3. Whole Body 1.5Tesla Magnetic Resonance Imaging Systoptimized for higher performance in Whole Body and Vexaminations with superconducting magnet, high performation with superconducting magnet, high performation with superconductive magnet should be and non-claustrophobic. 3. It should have at least 70 cm patient bore with flared of 4. Magnet length should be less than 200cm. 5. Homogeneity of magnet should be less than 200cm. 5. Homogeneity of magnet should be less than 3.5 ppm ove DSV 6. The magnet should be well ventilated and illuminated in 2 way intercom for communication with patient. 7. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/ hour. 8. Emergency Rundown Control at both operator console and Gantary Room is a must. 9. Fringe Field 0.5 Gauss line radius is essential. 10. Front Panel of gantry should display table and patient paths of the performance, highly stable shim system with glot localized automated shimming for high homogeneity in the paths of the performance	by : (name. Institution			
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Clinical purpose		-	naging (MRI) Units	
1. USE 1.1 Clinical purpose MRI is primarily used to identify diseases of the central system, brain, and spine and to detect musculoskeletal diseals oused to view cartilage, tendons, and ligaments. MRI can be used to image the eyes and the sinuses. MRI can be used display heart-wall structure; to stage prostate, bladder, and cancer. MRI can also be used as a functional imaging tool. 1.2 Used by clinical department/ward Radiology Department TECHNICAL 2. TECHNICAL CHARACTERISTICS MAGNET 1. Whole Body 1.5Tesla Magnetic Resonance Imaging Systoptimized for higher performance in Whole Body and Vexaminations with superconducting magnet, high perfogradients and digital Radio Frequency System. 2. 1.5Tactive shielded super conductive magnet should be and non-claustrophobic. 3. It should have at least 70 cm patient bore with flared of 4. Magnet length should be less than 200cm. 5. Homogeneity of magnet should be less than 200cm. 5. Homogeneity of magnet should be less than 3.5 ppm ove DSV 6. The magnet should be well ventilated and illuminated in 2 way intercom for communication with patient. 7. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/ hour. 8. Emergency Rundown Control at both operator console and Gantary Room is a must. 9. Fringe Field 0.5 Gauss line radius is essential. 10. Front Panel of gantry should display table and patient SHIM SYSTEM 1. High performance, highly stable shim system with glob localized automated shimming for high homogeneity of the process of the central display table and patient ship performance, highly stable shim system with glob localized automated shimming for high homogeneity of the process of the central display table and patient ship performance, highly stable shim system with glob localized automated shimming for high homogeneity in the patient system with glob localized automated shimming for high homogeneity in the patient system with glob localized automated shimming for high homogeneity in the patient system with glob	NS code(s)			
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2. Auto shim should be available to shim the magnet with in position. GRADIENT SYSTEM	(specific to this type)	optimized for high examinations with gradients and digit 2. 1.5T active shielder and non- claustrop 3. It should have at le 4. Magnet length should in 2 way intercom for 2 way intercom for 1. It should have a burconsumption does 8. Emergency Rundom and Gantary Room 9. Fringe Field 0.5 Gar 10. Front Panel of gant SHIM SYSTEM 1. High performance, localized automate field for imaging an 2. Auto shim should be in position.	er performance in Whole Body and Vascular superconducting magnet, high performance cal Radio Frequency System. Id super conductive magnet should be short shobic. It is ast 70 cm patient bore with flared opening. It is pulled be less than 200cm. It is genet should be less than 3.5 ppm over 45cm. If it is cryo-cooler such that helium not exceed 0.01 lit/ hour. It is a must. It is a must. It is a must. It is ry should display table and patient position. It is highly stable shim system with global and end spectroscopy.	

- 2. The gradient should be actively shielded with each axis having independently a slew rate of at least 200 T/m/s and a peak amplitude of 33mT/m.
- 3. The system should have efficient and adequate Eddy current compensation
- 4. Effective cooling system for gradient coil and power supply
- 5. Duty Cycle- 100% the gradient power amplifier.
- 6. Usable over 45 cm of FOV in all directions.

RF SYSTEM

- 1. A fully digital RF system capable of transmitting power of at least 15kw.
- 2. It should also have at least 32 independent RF receiver channels with each having bandwidth of 1 MHz or more along with necessary hardware to support quadrature ICP array/Matrix coils. The highest receiver channels available with the vendor should be quoted.
- 3. It should support Parallel acquisition techniques with a factor of up to 4 in 2D.
- 4. Should allow remote selection of coils and / or coil elements.

PATIENT TABLE

- 1. The table should be fully motorized, computer controlled table movements in vertical and horizontal directions.
- A CCTV system with colour LCD display to observe the patient should be provided:
 Moving table angiography should be possible.
- 3. There should be a hand held alarm for patients
- 4. Light Localizer for patient positioning.
- 5. Physiological signals display like ECG, Pulse and SPO2
- 6. Patient load bearing capacity, minimum 200 Kg.

MEASUREMENT SYSTEM

- 1. Largest Field of View should be at least 45 cm in all axis.
- 2. The measurement matrix should be from 128x128 to 1024x1024.
- 3. Minimum 2D slice thickness mm should be equal to or less than 0.5
- 4. Minimum 3D slice thickness mm should be equal to or less than 0.1

COIL SYSTEM

- 1. The main body coil integrated to the magnet must be Quadrature/ CP. In addition to this following coils should be provided:
 - i. Multichannel Head coils with at least 12 channel for high resolution brain imaging.
 - ii. Neuro-vascular Coil with 16 or more channels or Head / Neck Coil combined, capable of high resolution neuro-vascular imaging
 - iii. 18 Channel Spine Array/Matrix Coils for thoracic and lumbar spine imaging.
 - iv. Body Array/Matrix coil with at least 40 cm z axis coverage for imaging of abdomen, angiograms and heart with 32 channel.
 - v. Suitable Cardiac Coil
 - vi. Dedicated 8 channel extremity coil.
 - vii. Bilateral Breast Coil with at least 4 channel with fully functional spectroscopy.

- vi. Dedicated 8 channel extremity coil.
- vii. Bilateral Breast Coil with at least 4 channel with fully functional spectroscopy.
- viii. Dedicated Shoulder Coil with atleast 8 channels
- ix. Dedicated Knee Coil with atleast 8 channels
- x. General purpose flexible coil with small and large size
- 2. Coil Storage Cart from manufacturer.
- 3. The system should continuously monitor the RF coils used during scanning to detect failure modes. RF coils should not require either set up time or coil tuning; Multi coil connection for up to 2 or more coils simultaneous scanning without patient repositioning.

APPLICATION SEQUENCES

- The system should have basic sequences package with Spin Echo, InversionRecovery, Turbo Spin Echo with high turbo factor of 256 or more, Gradient Echo with ETL of 255 or more, FLAIR.
- Single slice, multiple single slice, multiple slice, multiple stacks, radial stacks and 3D acquisitions for all applications.
- 3. Single and Multi shot EPI imaging techniques with ETL factor of 255 or more
- 4. Fat suppression for high quality images both STIR and SPIR.
- 5. The system should acquire motion artifact free images in T2 studies of brain in restless patients
- Dynamic study for pre and post contrast scans and time intensity studies
- 7. MR angio Imaging: Should have 20/30 TOF, 20/30 PC, MTS and TONE, ceMRA, Facilities for Accelerated time resolved vascular imaging with applications like Treats/Tracks/Tricks sequences.
- 8. Fat and water excitation package. Diffusion Weighted Imaging, with at least b value of 5000 or more.
- 9. Bolus chasing with automatic and manual triggering from fluro mode to 3D acquisition mode with moving table facility.
- 10. Non contrast enhanced peripheral angiography for arterial flow with Native/Trance/Inhance sequences
- 11. Whole body screening imaging studies for metastasis
- 12. High resolution Abdominal and Liver imaging in breathold and free breathing modes with respirator triggered volume acquisitions
- 13. The system should have basic and advanced MRCP packages including free breathing and 3D techniques.
- 14. The system should have facility for flow quantification of CSF, vessel flow and hepatobiliary system.
- 15. The system should have the Hydrogen, Single Voxel spectroscopy, Multivoxel, Multislice & Multiangle 2D, 3D Spectroscopy and Chemical shift imaging in 2D/3D. The complete processing/post-processing software including color metabolite maps should be available on main console. Complete prostate spectroscopy hardware and applications should be provided.
- 16. Advanced Cardiac Applications:

			VCG gating, Morphology/wall motion; Cine perfusion imaging;
			Myocardial viability imaging; Arrhythmia rejection techniques,
			Advanced Cardiac Ventricular Measurement Analysis; Cine
			Cardiac Tagging Techniques; Coronary artery techniques; real
			time interactive imaging, 20/30 fast field echo/balanced/steady
			state techniques and evaluation package on workstation
		17	Advanced Breast imaging Package.
			Perfusion imaging of brain (including PASL and CASL)
			Susceptibility weighted imaging with phase information.
			Multi Direction DWI and DTI with minimum of 32 directions
		20.	(Complete package including quantification and tractography
			software). Prospective motion correction enabled software preferred.
		21	High resolution imaging for inner ear
			FETY FEATURES
		3A	
		1.	The magnet system should include an Emergency Ramp Down
			unit (ERDU) for fast reduction of the magnetic field with Ramp
		_	Down time below 3 minutes
		2.	The magnet should have .quench bands that contain the fringe
			fields to a specified value in the event of a magnet quench
		3.	Real time SAR calculation should be performed by software to
			ensure that RF power levels comply with regulatory guidelines
			and are displayed on each image
		4.	The system shall have manual override of the motor drive for
			quick removal of the patients from the magnet bore
		5.	Temperature sensor (built in) for magnet refrigeration efficiency
			must be provided
2.2	User's interface	1.	The main Host computer should have a 19 inches or more high
			resolution LCD TFT color monitor with 1024 x 1024 matrix display
		2.	The system should have image storage capacity of 100 GB for at
			least 2,00,000 images in 256x256 matrix.
		3.	The reconstruction speed should be at least 1300 or more for full
			FOV 256 matrix.
		4.	The main console should have facility for music system for
			patient in the magnet room. The system should have DVD / CD /
			flash drive archiving facility. The system should be provided with
			auto DVD writer.
		5.	Two way intercom system for patient communication.
		6.	MRI System should be DICOM ready in all parameters with no
			additional requirement of licence for connectivity to any PACS/
			HIS and Radiotherapy treatment planning system.
2.3	Software and/ or standard of	1.	A workstation with same user interface as of main console is
	communication (where ever		required with the availability of all necessary software including:
	required		i. Basic post-processing software including MIP, MPR, surface
			reconstruction and volume rendering technique.
			ii. Advanced post-processing offered applications perfusion
			quantification, advanced diffusion and DTI, processing of 2D/
			3D CSI data, with color metabolite mapping, quantification of
			CSF flow data, vascular analysis package.
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3.1 3.2 3.3 3.4	3. P Dimensions(metric) Weight (lbs, kg) Noise (in dBA) Heat dissipation Mobility, portability	 It should have at least 19 inch color monitor, with hard disk of at least 120 GB for at least 250,000 image storage in 256 matrix, and 4 GB RAM capacity or more, with self playing DVD/CD archiving facility. Seperate viewing station should be provided. HYSICAL CHARACTERISTICS NA NA Maximum 120 dBA Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism with less than 1° c change during scan Stationary installation
3.3		(electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	3 phase power supply
4.2	Battery operated	-
4.3	Protection	Stabilizer of appropriate capacity to be installed.
4.4	Power consumption	To be specified by the service provider.
		RIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	 Dual Head MRI Compatible Pressure Injector with 100 sets of syringes. Water Chiller for Cold Head I Gradients 2 Non-ferromagnetic patient transfer trolley should be provided. Fire Fighting System, Detectors and 6 Fire Extinguishers - MR compatible / MR safe Hand held metal detectors and two metal detector doors to be installed at the entrance point as will be intimated. Closed circuit CCD camera Phantoms for image quality audits. MRI compatible Anaesthesia machine (for paediatric and adult use) with dual vaporisers Suction and O2 pipeline and manifold to be provided inside the RF enclosure. Suitable RF Enclosure UPS for entire system for backup of 30 minutes. DG set
		EMENT TERMS/DONATION REQUIREMENTS
6 1	<u> </u>	AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 Operating Condition: Capable of operating continuously in ambient temperture of 18 to 30 deg C and relative humidity of 20 to 75% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 18 to 30 deg C and relative humidity of 20 to 75%
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required.

	7.	STANDARDS AND SAFETY
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). Shall meet internationally recognised standard for Electromagnetic Compatability(EMI/EMC). for electromedical equipment: IEC 60601-1-2 Certified to be complaint with IEC 61010-2-33
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
		standard.
	8. TI	RAINING AND INSTALLATION
8.1	Pre- installation requirements: nature, values, quality, tolerance	Turnkey Project only space to be provided.
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
		RRANTY AND MAINTENANCE
9.1	Warranty	5 years, including all spares and calibration.
10.1		10. DOCUMENTATION
10.1	operating manuals, set manuals, other manuals	 Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals (original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying	List of essential spares and accessories, with their part number and
	documents	cost;
11.1	Service Support Contact details	11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

FULL BODY MRI SYSTEM - 3 TESLA

Version no. :	Ver1
Date:	15/02/2018
Done by : (name. Institution)	HCT/NHSRC
	ME, CATEGORY AND CODING
UMDNS name	Magnetic Resonance Imaging (MRI) Units
UMDNS code(s)	16260
	GENERAL
	1. USE
1.1 Clinical purpose	MRI is primarily used to identify diseases of the central nervous system, brain, and spine and to detect musculoskeletal disorders. It is also used to view cartilage, tendons, and ligaments. MRI can also be used to image the eyes and the sinuses. MRI can be used to help diagnose infectious diseases; to detect metastatic liver disease; to display heart-wall structure; to stage prostate, bladder, and uterine cancer. MRI can also be used as a functional imaging tool.
1.2 Used by clinical department/ward	Radiology Department
	TECHNICAL
2.1	TECHNICAL CHARACTERISTICS
2.1 Technical characteristics	MAGNET
(specific to this type of device)	 Whole Body 3 Tesla Magnetic Resonance Imaging System optimized for higher performance in Whole Body and Vascular examinations with superconducting magnet, high performance gradients and digital Radio Frequency System. 3T active shielded super conductive magnet should be short and non- claustrophobic. It should have at least 70 cm patient bore with flared opening. Magnet length should be less than 200cm. Homogeneity of magnet should be better than 1.5 ppm over 40 cm DSV The magnet should be well ventilated and illuminated with built in 2 way intercom for communication with patient. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/ hour. Emergency Rundown Control at both operator console room and Gantary Room is a must. Fringe Field 0.5 Gauss line radius is essential. Front Panel of gantry should display table and patient position. SHIM SYSTEM High performance, highly stable shim system with global and localized automated shimming for high homogeneity magnetic field for imaging and spectroscopy. Auto shim should be available to shim the magnet with patient

- 2. The gradient should be actively shielded with each axis having independently a slew rate of at least 200 T/m/s and a peak amplitude of 40mT/m.
- 3. The system should have efficient and adequate Eddy current compensation
- 4. Effective cooling system for gradient coil and power supply
- 5. Duty Cycle- 100% the gradient power amplifier.
- 6. Usable over 45 cm of FOV in all directions.

RF SYSTEM

- 1. A fully digital RF system capable of transmitting power of at least 15kw.
- 2. It should also have at least 32 independent RF receiver channels with each having bandwidth of 1 MHz or more along with necessary hardware to support quadrature ICP array/Matrix coils. The highest receiver channels available with the vendor should be quoted.
- 3. It should support Parallel acquisition techniques with a factor of up to 4 in 2D.
- 4. Should allow remote selection of coils and / or coil elements.

PATIENT TABLE

- 1. The table should be fully motorized, computer controlled table movements in vertical and horizontal directions.
- A CCTV system with colour LCD display to observe the patient should be provided:
 Moving table angiography should be possible.
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- 5. Physiological signals display like ECG, Pulse and SPO2
- 6. Patient load bearing capacity, minimum 200 Kg.

MEASUREMENT SYSTEM

- 1. Largest Field of View should be at least 45 cm in all axis.
- 2. The measurement matrix should be from 128x128 to 1024x1024.
- 3. Minimum 2D slice thickness mm should be equal to or less than 0.5
- 4. Minimum 3D slice thickness mm should be equal to or less than 0.3

COIL SYSTEM

- The main body coil integrated to the magnet must be Quadrature /
 CP. In addition to this following coils should be provided:
- 2. Multichannel Head coils with at least 12 channel for high resolution brain imaging.
- 3. Neuro-vascular Coil with 16 or more channels or Head / Neck Coil combined, capable of high resolution neuro-vascular imaging
- 4. 18 Channel Spine Array/Matrix Coils for thoracic and lumbar spine imaging.
- 5. Body Array/Matrix coil with at least 40 cm z axis coverage for imaging of abdomen, angiograms and heart with 32 channel.
- 6. Suitable Cardiac Coil
- 7. Dedicated 8 channel extremity coil.
- 8. Bilateral Breast Coil with at least 4 channel with fully functional spectroscopy.
- 9. Dedicated Shoulder Coil with atleast 8 channels

- 10. Dedicated Knee Coil with atleast 8 channels
- 11. General purpose flexible coil with small and large size
- 12. Coil Storage Cart from manufacturer.
- 13. The system should continuously monitor the RF coils used during scanning to detect failure modes. RF coils should not require either set up time or coil tuning; Multi coil connection for up to 2 or more coils simultaneous scanning without patient repositioning.

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- 3. Single and Multi shot EPI imaging techniques with ETL factor of 255 or more
- 4. Fat suppression for high quality images both STIR and SPIR.
- 5. The system should acquire motion artifact free images in T2 studies of brain in restless patients
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- MR angio Imaging: Should have 20/30 TOF, 20/30 PC, MTS and TONE, ceMRA, Facilities for Accelerated time resolved vascular imaging with applications like Treats/Tracks/Tricks sequences.
- Fat and water excitation package. Diffusion Weighted Imaging, with at least b value of 5000 or more.
- 9. Bolus chasing with automatic and manual triggering from fluro mode to 3D acquisition mode with moving table facility.
- 10. Non contrast enhanced peripheral angiography for arterial flow with Native/Trance/Inhance sequences
- 11. Whole body screening imaging studies for metastasis
- 12. High resolution Abdominal and Liver imaging in breathold and free breathing modes with respirator triggered volume acquisitions
- 13. The system should have basic and advanced MRCP packages including free breathing and 3D techniques.
- 14. The system should have facility for flow quantification of CSF, vessel flow and hepatobiliary system.
- 15. The system should have the Hydrogen, Single Voxel spectroscopy, Multivoxel, Multislice & Multiangle 2D, 3D Spectroscopy and Chemical shift imaging in 2D/3D. The complete processing/post-processing software including color metabolite maps should be available on main console. Complete prostate spectroscopy hardware and applications should be provided.
- 16. Advanced Cardiac Applications: VCG gating, Morphology/wall motion; Cine perfusion imaging; Myocardial viability imaging; Arrhythmia rejection techniques, Advanced Cardiac Ventricular Measurement Analysis; Cine Cardiac Tagging Techniques; Coronary artery techniques; real time interactive imaging, 20/30 fast field echo/balanced/steady

			state techniques and evaluation package on workstation
		17.	Advanced Breast imaging Package.
			Perfusion imaging of brain (including PASL and CASL)
			Susceptibility weighted imaging with phase information.
			Multi Direction DWI and DTI with minimum of 32 directions
			(Complete package including quantification and tractography
			software). Prospective motion correction enabled software preferred.
		21	High resolution imaging for inner ear
			FETY FEATURES
		1.	The magnet system should include an Emergency Ramp Down
		'	unit (ERDU) for fast reduction of the magnetic field with Ramp
			Down time below 3 minutes
		2.	The magnet should have .quench bands that contain the fringe
		۷٠	fields to a specified value in the event of a magnet quench
		2	Real time SAR calculation should be performed by software to
		3.	•
			ensure that RF power levels comply with regulatory guidelines
		1	and are displayed on each image
		4.	The system shall have manual override of the motor drive for
		_	quick removal of the patients from the magnet bore
		5.	Temperature sensor (built in) for magnet refrigeration efficiency
2.2	User's interface	1	must be provided The main blast computer should have a 10 in sheet or more high
2.2	Oser's interface	1.	The main Host computer should have a 19 inches or more high
		٦	resolution LCD TFT color monitor with 1024 x 1024 matrix display
		2.	The system should have image storage capacity of 100 GB for at
		2	least 2,00,000 images in 256x256 matrix.
		3.	The reconstruction speed should be at least 1300 or more for full FOV 256 matrix.
		4.	The main console should have facility for music system for
		'	patient in the magnet room. The system should have DVD / CD /
			flash drive archiving facility. The system should be provided with
			auto DVD writer.
		5.	Two way intercom system for patient communication.
		6.	MRI System should be DICOM ready in all parameters with no
		.	additional requirement of licence for connectivity to any PACS/
			HIS and Radiotherapy treatment planning system.
2.3	Software and/ or standard of	1.	A workstation with same user interface as of main console is
	communication (where ever		required with the availability of all necessary software including:
	required		i. Basic post-processing software including MIP, MPR, surface
			reconstruction and volume rendering technique.
			ii. Advanced post-processing offered applications perfusion
			quantification, advanced diffusion and DTI, processing of 2D/
			3D CSI data, with color metabolite mapping, quantification of
			CSF flow data, vascular analysis package.
		2.	It should have at least 19 inch color monitor, with hard disk of at
		2.	least 120 GB for at least 250,000 image storage in 256 matrix,
			and 4 GB RAM capacity or more, with self playing DVD/CD
			archiving facility.
		3.	Seperate viewing station should be provided.
	1	٦.	seperate viewing station should be provided.

	3. P	HYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Maximum 120 dBA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed
		through a cooling mechanism with less than 1° c change during scan
3.5	Mobility, portability	Stationary installation
		(electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	3 phase power supply
4.2	Battery operated	-
4.3	Protection	Stabilizer of appropriate capacity to be installed.
4.4	Power consumption	To be specified by the service provider.
= 4		RIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	1. Dual Head MRI Compatible Pressure Injector with 100 sets of
	standard, optional);	syringes.
	Spare parts (main ones);	2. Water Chiller for Cold Head I Gradients.
	Consumables/reagents (open, closed system)	3. 2 Non-ferromagnetic patient transfer trolley of international make should be provided
	closed system,	4. Fire Fighting System, Detectors and 6 Fire Extinguishers
		5. Hand held metal detectors and two metal detector doors to be
		installed at the entrance point as will be intimated.
		6. Closed circuit CCD camera
		7. Phantoms for image quality audits.
		8. MRI compatible Anaesthesia machine (for paediatric and adult
		use) with dual vaporisers
		9. Suction and O2 pipeline and manifold to be provided inside the
		RF enclosure.
		10. Suitable RF Enclosure
		11. UPS for entire system for backup of 30 minutes.
		12. DG set
	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS
		AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	Operating Condition: Capable of operating continuously in
	conditioning, humidity, dust)	ambient temperture of 18 to 30 deg C and relative humidity of
		20 to 75% in ideal circumstances.
		2. Storage condition: Capable of being stored continuosly in
		ambient temperature of 18 to 30 deg C and relative humidity of
		20 to 75%
6.2	User's care, Cleaning,	1. Disinfection: Parts of the Device that are designed to come into
	Disinfection & Sterility issues	contact with the patient or the operator should either be
		capable of easy disinfection or be protected by a single use/
		disposable cover.
		2. Sterilization not required.
	7.	STANDARDS AND SAFETY
7.1	Certificates (pre-market,	1. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE
	sanitary,); Performance and	requirements will be applicable only when the Indian standards
	safety standards (specific to the	like BIS/CDSCO are not available).
L_	device type); Local and/or	2. Manufacturer and Supplier should have ISO 13485 certification
	•	·

	international	for quality standards.		
		3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard).		
		4. Shall meet internationally recognised standard for		
		Electromagnetic Compatability(EMI/EMC). for electromedical		
		equipment: IEC 60601-1-2		
		5. Certified to be complaint with IEC 61010-2-33		
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality		
		standard.		
	8. TI	RAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Turnkey Project only space to be provided.		
	nature, values, quality,			
	tolerance			
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer		
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;		
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;		
	9. WARRANTY AND MAINTENANCE			
9.1	Warranty	3 years, including all spares and calibration.		
		10. DOCUMENTATION		
10.1	Operating manuals,	Should provide 2 sets (hard copy and soft copy) of:		
	set manuals, other manuals	1. User, technical and maintenance manuals should be supplied in		
		English/Hindi language along with machine diagrams;		
		2. List of equipment and procedures required for local calibration and routine maintenance;		
		3. Service and operation manuals (original and Copy) to be provided;		
		4. Advanced maintenance tasks documentation;		
		5. Certificate of calibration and inspection,		
		6. Satisfactory certificate for any existing installation from		
		government hospital.		
10.2	Other accompanying	List of essential spares and accessories, with their part number and		
	documents	cost;		
		11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be		
		provided; Any Contract (AMC/CMC/add-hoc) to be declared by the		
		manufacturer.		
11.2	Recommendations or	Any warning sign would be adequaetly displayed.		

PORTABLE ULTRASOUND

Versio	on no. :	Ver1
Date:		15/02/2018
Done	by : (name. Institution)	HCT/NHSRC
	NAI	ME, CATEGORY AND CODING
UMD	NS name	Scanning Systems, Ultrasonic, Cardiac, gynaological, General,
		Anaesthesia, vascular
UMD	NS code(s)	17422
		GENERAL
		1. USE
1.1	Clinical purpose	An assembly of devices designed for extracorporeal and / or intracorporeal (endosonography or endoscopic) imaging procedures involving the heart and blood vessels. Included are software packages that support a variety of static or real-time cardiac specific imaging applications used to diagnose anatomical defects of the heart, determine blood flow characteristics and functional
		anatomical problems associated with myocardial infarction.
1.2	Used by clinical department/ward	Radiology Department
		TECHNICAL
	2.	TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	1. A typical configuration for a cardiac ultrasound system consists
	(specific to this type of device)	of a scanner and software, several single- or multi frequency transducers, a TEE probe, color Doppler, M-mode, CFM, cardiac analysis software. 2. Phased array transducers required 3. Following transducers are to be supplied:
2.2	User's interface	Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.

communication(where ever required application: Cardiac and stress echo; tissue differentiation to clearly show the walls of the left ventricle and regional wall motion abnormalities software; abdominal: obstetrical and gynecological; peripheral and deep vascular; 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions(metric) NA 3.2 Weight (lbs, kg) NA 3.3 Noise (in dBA) Noise-free system 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Trolley is mobile 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional): Spare parts (main ones): Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues of easy disinfection or be protected by a single use/disposable cover. 2. Storage condition: Capable of perating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 7. Storage condition: Capable of perator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (speedific to the device type); Local and/or international 8. Foliate of the produce of the produced of the period of	2.3	Software and/ or standard of	The hardware and software included will allow the following
abnormalities. Left ventricle wall abnormalities software; abdominal; obstetrical and gynecological; peripheral and deep vascular; 3. PHYSICAL CHARACTERISTICS 3.1 Dimensions(metric) NA 3.2 Weight (lbs, kg) NA 3.3 Noise (in dBA) Noise-free system 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Trolley is mobile 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 4.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ standard, optional); Spare parts (main ones); Consumables/ standard, optional); Spare parts (main ones); Consumables/ scapents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 8.1 Operating Condition: Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 3. Sterilization not required. 4. Sherilization not required. 5. Sterilization not required. 6. Sterilization and requirements (or equivalent BIS Standard). 5. Manufacturer and Supplier should have ISO 13485 certification for equality standards. 6. Electrical safety conforms to the standards for electromedical		communication(where ever	1
3.1 Dimensions(metric) 3.2 Weight (lbs, kg) 3.2 Weight (lbs, kg) 3.3 Noise (in dBA) 3.4 Heat dissipation 3.5 Mobility, portability 3.5 Mobility, portability 3.6 Exercise (speen, closed system) 3.7 Protection 3.8 Power requirements 3.9 Recharging unit: Input voltage 220V-240V AC, 50Hz. 3.1 Power requirements 3.2 Protection 4.1 Power requirements 4.2 Battery operated 4.3 Power consumption 4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) 3. BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 5. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6. Conditioning, humidity, dust) 5. Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international 6. Manual Certification (Septiment)		required	show the walls of the left ventricle and regional wall motion
3.1 Dimensions(metric) NA 3.2 Weight (lbs, kg) NA 3.3 Noise (in dBA) Noise-free system 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Trolley is mobile 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 5. ACCESSORIES, SPARE PARTS, CONSUMBLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues Disinfection & Sterility issues Disinfection & Sterility issues To estable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 1. Disinfection or be protected by a single use/disposable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary): Performance and safety standards (specific to the device type); Local and/or international 8 (Bis/CDSCO are not available). 4. Shall meet internationally recognised standard for electrical safety internationally recognised standard for electromagnetic Compatability (EM/EMC). for electromedical			abnormalities. Left ventricle wall abnormalities software; abdominal;
3.1 Dimensions(metric) NA			obstetrical and gynecological; peripheral and deep vascular;
3.2 Weight (lbs, kg) 3.3 Noise (in dBA) 3.4 Noise (in dBA) 3.4 Noise (in dBA) 3.5 Noise (in dBA) 3.6 Noise (in dBA) 3.7 Noise (in dBA) 3.7 Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.8 Mobility, portability 3.9 Trolley is mobile 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements 4.2 Battery operated 3.3 hours 4.2 Battery operated 3.3 hours 4.3 Protection 4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) 8.1 BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Losses (and and one one one operation in the event of mains power failure. 7.4 Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international 8 Incentification and the maintain nominal temperature and the heat should be designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 9. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international 8 Incentification and provided the patient of the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 9. Sterilization not required. 9. Shall meet internationally recognised standard for electrical safety IEC 66601-1-General requirements/or equivalent BIS Standard). 9. Shall meet internationally recognised standard for Electromagnetic Compatability (EM/EMC). for electromedical		3. P	
3.3 Noise (in dBA) Noise-free system 3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Trolley is mobile 4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional): Spare parts (main ones): Consumables/ reagents (open, closed system) 8IDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 TanDards AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 6.1 And the patient of the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7.1 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Belectrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC), for electromedical	3.1	Dimensions(metric)	NA
3.4 Heat dissipation Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism 3.5 Mobility, portability Trolley is mobile 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2) 4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) 8 IDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 8 Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues of easy disinfection or be protected by a single use/disposable cover. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. Shall meet internationally recognised standard for equivalent BIS Standard). 8. Shall meet internationally recognised standard for Electrical safety incompanies and supplier should have ISO 13485 certification for quality standards. 8. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical	3.2	Weight (lbs, kg)	NA
disbursed through a cooling mechanism	3.3	Noise (in dBA)	Noise-free system
A. Nobility, portability A. Nobility, portability A. Nobility, portability A. Nobility, portability A. Nobility A. Nob	3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
4.1 Power requirements Recharging unit: Input voltage 220V-240V AC, 50Hz. 4.2 Battery operated 3 hours Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption To be specified by the service provider. 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 5. Storage condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,) Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical			disbursed through a cooling mechanism
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4.2 Battery operated 4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 8.1 Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Liectrical safety of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. Electrical safety conforms to the standards for electrical safety like BIS/CDSCO are not available). 9. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC), for electromedical		4. ENERGY SOURCI	E (electricity, UPS, solar, gas, water, CO2)
4.3 Protection Voltage corrector / stabilizer / UPS to allow operation at ± 30% of local rated voltage and one hour operation in the event of mains power failure. 4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) BIDDING/PROCURE MENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 5. Storage condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 5. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Disinfection or be protected by a single use/disposable cover. 5. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical	4.1	Power requirements	Recharging unit: Input voltage 220V-240V AC, 50Hz.
rated voltage and one hour operation in the event of mains power failure. To be specified by the service provider. To be specified by the service provider. S. ACCESSORIES, SPARE PARTS, CONSUMABLES All probes required for frequency range stated. It is recommended include the type of transducers and the minimum of transducers with harmonics. BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) Atmosphere/Ambience (air conditioning, humidity, dust) 5.1 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Linch and the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7.1 Should be US FDA/CEPIBS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromedical	4.2	Battery operated	3 hours
Failure. To be specified by the service provider.	4.3	Protection	Voltage corrector / stabilizer / UPS to allow operation at \pm 30% of local
4.4 Power consumption 5. ACCESSORIES, SPARE PARTS, CONSUMABLES 5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 8.2 Storage condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.2 User's care, Cleaning, Disinfection as Sterility issues 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. Electrical safety conforms to the standards for electrical safety lEC 60601-1-General requirements (or equivalent BIS Standard). 8. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC), for electromedical			rated voltage and one hour operation in the event of mains power
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5.1 Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS 6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Disinfection & Sterility issues 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC), for electromedical	4.4		
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Reagents (open, closed system) BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		standard, optional); Spare parts	include the type of transducers and the minimum of transducers with
6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 6.2 User's care, Cleaning, Disinfection & Sterility issues 6.3 Disinfection & Sterility issues 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 6.2 Matmosphere/Ambience (air condition); Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 9. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 1. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 8. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 9. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 1. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical		(main ones); Consumables/	harmonics.
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IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical		international	for quality standards.
4. Shall meet internationally recognised standard for Electromagnetic Compatability (EMI/EMC). for electromedical			3. Electrical safety conforms to the standards for electrical safety
Electromagnetic Compatability (EMI/EMC). for electromedical			IEC 60601-1-General requirements(or equivalent BIS Standard).
			4. Shall meet internationally recognised standard for
equipment: IEC 60601-1-2.			Electromagnetic Compatability (EMI/EMC). for electromedical

		5. Certified to be complaint with IEC 61010-2-33	
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality	
		standard.	
	8. TI	RAINING AND INSTALLATION	
8.1	Pre- installation requirements:	Single phase stable power supply; PCPNDT Act clearance	
	nature, values, quality,		
	tolerance		
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer	
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;	
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;	
	9. WA	ARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and calibration.	
	10. DOCUMENTATION		
10.1	Operating manuals,	Should provide 2 sets(hard copy and soft copy) of:	
	set manuals, other manuals	1. User, technical and maintenance manuals should be supplied in	
		english/Hindi language along with machine diagrams;	
		2. List of equipment and procedures required for local calibration	
		and routine maintenance;	
		3. Service and operation manuals (original and Copy) to be	
		provided;	
		4. Advanced maintenance tasks documentation;	
		5. Certificate of calibration and inspection,	
10.2	Other accompanying	List of essential spares and accessories, with their part number and	
	documents	cost;	
		11. NOTES	
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be	
		provided; Any Contract (AMC/CMC/add-hoc) to be declared by the	
		manufacturer.	
11.2	Recommendations or	Any warning sign would be adequately displayed.	
	warnings		

X-RAY DEVELOPING TANK

		War 1
		Ver_1
Date:		15/02/2018
Done	e by : (name. Institution)	HCT/NHSRC ME, CATEGORY AND CODING
ПМП	NS name	X-Ray Film Manual Processing Equipment
	NS code(s)	15945
OIVID	N3 Code(s)	GENERAL
		1. USE
1.1	Clinical purpose	The equipment includes appropriate tanks (or trays) for developing,
		fixing, and washing; heaters and timers to control the temperature
		and time of the procedure; safe lights (illuminators) to regulate the
		light in the darkroom permitting operator work while avoiding film
		damage; and appropriate bins to prevent fogging of stored film.
1.2	Used by clinical department/ward	Radiology Department
		TECHNICAL
		TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	1. Manual film processing unit- with the tanks with lid shall be of
	(specific to this type of device)	capacities 13.5 liters for fixing and developing tanks, 22.5 liter for
		washing tank along with hangers.
		2. Casing shall be of robust anti-corrosive material of stainless steel
		316 grade.
		3. Tanks to be made out of 23 SWG, 304 grade mirror finish, quality
		stainless steel sheet for developer, wash chemicals.
		4. Single welding joint in the body height of tank and polished to
		avoid corrosion. All welding joints are fold pressed welded to
		avoid leakage.
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	DIVERSAL CHARACTERISTICS
2 1		PHYSICAL CHARACTERISTICS
3.1	Dimensions(metric) Weight (lbs, kg)	NA NA
3.3	Noise (in dBA)	NA NA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
3. 4	neat dissipation	disbursed through a cooling mechanism
3.5	Mobility, portability	disbursed through a cooling mechanism
5.5		E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	-
'''	Tower requirements	
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	-
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	5. ACCESSORIES, SPARE PARTS, CONSUMABLES			
5.1	Accessories, (mandatory,	Machine should be provided with following accessories:		
	standard, optional); Spare parts	1) 3 numbers of non corrosive tanks for solution		
	(main ones); Consumables/	2) Hanger of 10 clips and loose clips.		
	reagents (open, closed system)			
	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	Operating Condition: Capable of operating continuously in		
	conditioning, humidity, dust	ambient temperture of 5 to 50 deg C and relative humidity of		
)	15 to 80% in ideal circumstances.		
		2. Storage condition: Capable of being stored continuously in		
		ambient temperature of 0 to 50 deg C and relative humidity of		
		15 to 90%		
6.2	User's care, Cleaning,	1. Disinfection: Parts of the Device that are designed to come into		
	Disinfection & Sterility issues	contact with the patient or the operator should either be capable		
		of easy disinfection or be protected by a single use/disposable		
		cover.		
		2. Sterilization not required.		
	7.	STANDARDS AND SAFETY		
7.1	Certificates (pre-market,	1. Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE		
	sanitary,); Performance and	requirements will be applicable only when the Indian standards		
	safety standards (specific to the	like BIS/CDSCO are not available).		
	device type); Local and/or	2. Manufacturer and Supplier should have ISO 13485 certification		
	international	for quality standards.		
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality		
		standard.		
0.4		RAINING AND INSTALLATION		
8.1	Pre- installation requirements:			
	nature, values, quality,			
0.2	tolerance			
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer		
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;		
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.		
9.1	waitanty	10. DOCUMENTATION		
10.1	Operating manuals, set	Should provide 2 sets(hard copy and soft copy) of:		
10.1	manuals, other manuals	User, technical and maintenance manuals should be supplied in		
	mariadis, other mariadis	english/Hindi language along with machine diagrams;		
		 List of equipment and procedures required for local calibration 		
		and routine maintenance;		
10.2	Other accompanying	List of essential spares and accessories, with their part number and		
10.2	documents	cost;		
		11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be		
	2 3 2 2 2 pport 20 maet details	provided; Any Contract (AMC/CMC/add-hoc) to be declared by the		
		manufacturer.		
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.		
	1	,		

CHEST STAND: FLOOR MODEL

Versio	on no. :	Ver_1
Date:		15/02/2018
Done	by : (name. Institution)	HCT/NHSRC
	NA	ME, CATEGORY AND CODING
UMDI	NS name	NA
UMDI	NS code(s)	NA
		GENERAL
		1. USE
1.1	Clinical purpose	A device that is specifically designed to ensure adequate positioning
		of chest during diagnostic imaging procedures.
1.2	Used by clinical department/ward	Radiology Department
		TECHNICAL
		TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	1. Floor model vertical stand with rigid L channel structure on a
	(specific to this type of device)	stable platform for standing patients.
		2. L channel to be made of 4 mm thick 50 mm sq. angle and approxi
		mately 180 cm height and fitted on patient platform.
		3. Cassette holder to take cassettes up to 14 x 17" to move vertically
		up and down on two SS guide rods with facility to lock cassette
		holder in any desired position for taking radiographs
		4. Cassette holder up and down movement to be approximately
		60 cm.
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	PHYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
	·	disbursed through a cooling mechanism
3.5	Mobility, portability	
	4. ENERGY SOURC	E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
		DRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	

closed system)

	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required.
		STANDARDS AND SAFETY
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
		standard.
	8. TF	RAINING AND INSTALLATION
8.1	Pre- installation requirements: nature, values, quality, tolerance	-
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and calibration.
		10. DOCUMENTATION
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection,
10.2	Other accompanying	List of essential spares and accessories, with their part number and
	documents	cost;
		11. NOTES
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

LEAD SCREEN BARRIER

-	on no.:	Ver_1
Date:		15/02/2018
Done	by : (name. Institution)	HCT/NHSRC
		ME, CATEGORY AND CODING
	NS name	Shields, X-Ray, Barrier
UMD	NS code(s)	15872
		GENERAL
1 1	Clinital manners	1. USE
1.1	Clinical purpose	It is used to shield the operators from unnecessary exposure to radiation
		used in diagnostic or therapeutic medical and dental procedures. The
		shield provides a physical radiation-attenuating barrier between an
1.2	Used by clinical department/ward	individual and a source of primary or scattered radiation.
1.2	Used by clinical department/ward	Radiology Department TECHNICAL
	.	TECHNICAL TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	Triple fold type- Lead Screen movable on a sturdy, rust proof
2.1	(specific to this type of device)	wheels with 1.5 mm lead sheet sandwiched between phenol
	(specific to this type of device)	bonded laminated sheet with teak wood finishing.
		2. Lead glass window (1.0 mm lead or equivalent) of minimum size
		7" x 7" at a convenient height to be provided.
		3. Angle iron frame work for durability of screen to be provided.
		4. Size of the screen: Central part 6 feet height x 2 feet width. Item
		to conform to IS 7620 or equivalent.
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	
	•	HYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
2.5	Malatter and a latter	
3.5	Mobility, portability	E (electricity, UPS, solar, gas, water, CO2)
4 1		NA
4.1	Power requirements Battery operated	NA
4.2	Protection	NA NA
4.4	Power consumption	NA
7.4	•	PRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	NA
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	
	closed system)	
	ciosca system,	

to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambien temperature of 0 to 50 deg C and relative humidity of 15 to 90% 1. Disinfection & Sterility issues 2. Storage condition: Capable of being stored continuously in ambien temperature of 0 to 50 deg C and relative humidity of 15 to 90% 2. Disinfection & Sterility issues 3. Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cove 2. Sterilization not required. 7. STANDARDS AND SAFETY 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 7. Local and/or international 8. TRAINING AND INSTALLATION 8.1 Pre- installation requirements: nature, values, quality, tolerance 8. TRAINING AND INSTALLATION 8.1 Pre- installation requirements: nature, values, quality, tolerance 8.2 Requirements for sign-off 8.3 Training of staff (medical, paramedical, technicians) 7. WARRANTY AND MAINTENANCE 9.1 Warranty 10.1 Operating manuals, set manuals, other manuals 10.2 Other accompanying documents 11. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 11. NOTES 11. NOTES		BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS		
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9.1 Warranty 10. DOCUMENTATION 10.1 Operating manuals, set manuals, other manuals manuals, other manuals manuals manuals, other manuals manu		1.5	•		
10.1 Operating manuals, set manuals, other manuals Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 10.2 Other accompanying documents 1. List of essential spares and accessories, with their part number and cost; 11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.		and the second s	RRANTY AND MAINTENANCE		
10.1 Operating manuals, set manuals, other manuals 10.2 Other accompanying documents 10.3 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 1. NOTES 11. NOTES	9.1	Warranty	-		
manuals, other manuals 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 10.2 Other accompanying documents 1. User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; 1. List of essential spares and accessories, with their part number and cost; 11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.					
english/Hindi language along with machine diagrams; 10.2 Other accompanying documents 11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) english/Hindi language along with machine diagrams; List of essential spares and accessories, with their part number and cost; 11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.	10.1				
10.2 Other accompanying documents List of essential spares and accessories, with their part number and cost; 11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) List of essential spares and accessories, with their part number and cost; 11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.		manuals, other manuals			
documents cost; 11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) cost; Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.					
11. NOTES 11.1 Service Support Contact details (Hierarchy Wise; including a toll free/landline number) 11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.	10.2	Other accompanying	List of essential spares and accessories, with their part number and		
11.1 Service Support Contact details Contact details of manufacturer, supplier and local service agent to be (Hierarchy Wise; including a toll free/landline number) Contact details of manufacturer, supplier and local service agent to be free/landline number.		documents	·		
(Hierarchy Wise; including a toll provided; Any Contract (AMC/CMC/add-hoc) to be declared by the free/landline number)					
free/landline number) manufacturer.	11.1		Contact details of manufacturer, supplier and local service agent to be		
			provided; Any Contract (AMC/CMC/add-hoc) to be declared by the		
11.2 Recommendations or warnings Any warning sign would be adequaetly displayed.		<u>'</u>			
	11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.		

FILM HANGER

Version	n no. :	Ver_1
Date:		15/02/2018
Done k	oy : (name. Institution)	HCT/NHSRC
		ME, CATEGORY AND CODING
	S name	NA
UMDN	S code(s)	NA
		GENERAL
1 1	Climical marganes	1. USE
1.1	Clinical purpose	Film hanger clips are used to hang wet films during film developing
1.2	Used by divisal department / yard	process Padiology Department
1.2	Used by clinical department/ward	Radiology Department TECHNICAL
	7 -	TECHNICAL TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	1. Stainless steel film hanger clip type or channel type to hang wet
2.1	(specific to this type of device)	films. Sizes should be 8 "x 10", 10" x 12", 12" x 15" and 14" x 14",
	(specific to this type of device)	14"x 17" (dimensions in inches)
		2. The equipment should be suitable for operation in temperatures
		from 10° C to 45° C with a relative humidity of 100 %
		3. Labels and markings should be clear and visible.
		4. Equipment should be simple to use, operate and maintain. It
		should be designed for easy access to serviceable parts.
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
2.3	communication (where ever	
	required	
	•	HYSICAL CHARACTERISTICS
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
		disbursed through a cooling mechanism
3.5	Mobility, portability	
	4. ENERGY SOURCE	(electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
	·	PRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	NA
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	
	closed system)	

	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 The equipment should be suitable for operation in temperatures from 10° C to 45° C with a relative humidity of 100 % Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 		
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required. 		
		STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. 		
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.		
	8. TRAINING AND INSTALLATION			
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA NA		
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer		
8.3	Training of staff (medical, paramedical, technicians)	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; 		
	9. WARRANTY AND MAINTENANCE			
9.1	Warranty	3 years, including all spares and calibration.		
101		10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, 		
10.2	Other accompanying	List of essential spares and accessories, with their part number and		
	documents	cost;		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.		
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.		

X-RAY LOBBY- SINGLE FILM

\/		Mari 1
-	n no. :	Ver_1
Date:		15/02/2018
Done	by : (name. Institution)	HCT/NHSRC
LIMADA		ME, CATEGORY AND CODING
	NS name	View Boxes, X-Ray
UMDN	NS code(s)	14498 CENERAL
		GENERAL 1. USE
1.1	Clinical purpose	An electromechanical and/or software-controlled motorized device
'-'	Cirrical purpose	designed to support, retrieve, and illuminate x-ray image recorded on
		1
1.2	Used by dinical department/ward	radiographic film for direct viewing.
1.2	Used by clinical department/ward	Radiology Department TECHNICAL
	.	
2 1	Technical characteristics	TECHNICAL CHARACTERISTICS
2.1	(specific to this type of device)	1. For viewing single X-ray film having dimensions of $15"x 5"x 25"$ (L x D x H) with 2 nos. of 20W fluorescent tubes of 2 feet length each with
	(specific to this type of device)	
		necessary fittings in MS housing of 20 SWG and is duly powder coated.
		2. View box to be fitted with white acrylic sheet to reduce glare
		and provide uniform illumination.
		3. Grip clips/ grip rollers are to be provided to hold the film.
		4. Ventilation for cooling.
		5. Drip tray for wet films
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	NIVELS AL SULADA STEDISTICS
2.4		PHYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
	100	disbursed through a cooling mechanism
3.5	Mobility, portability	
4.4		E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	-
4.2	Battery operated	- NA
4.3	Protection	NA
4.4	Power consumption	- CONCLINABLES
- A		PRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	
	closed system)	

	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 		
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required. 		
	7.	STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. 		
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.		
	8. TRAINING AND INSTALLATION			
0.1		RAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	-		
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer		
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;		
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;		
0.1	_	RRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.		
101		10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals (original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, 		
10.2	Other accompanying	List of essential spares and accessories, with their part number and		
	documents	cost;		
		11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be		
	(Hierarchy Wise; including a toll free/landline number)	provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.		
11.2	· · · · · · · · · · · · · · · · · · ·			
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.		

DARK ROOM SAFETY LIGHT

	on no. :	Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
		ME, CATEGORY AND CODING
	NS name	Safelights, X-Ray, Darkroom
UMD	NS code(s)	16562
		GENERAL
1.1		1. USE
1.1	Clinical purpose	A device that is a special light source designed to emit specific
		wavelengths of light that will provide sufficient illumination for
		darkroom workers but does not affect the x-ray film or other kinds of
1.2	Used by clinical department/ward	radiographic film being loaded, stored or developed. Radiology Department
1.2	osed by clinical department, ward	TECHNICAL
	<u> </u>	TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	Body to be made out of MS sheet with outside black coating and
2.1	(specific to this type of device)	unbreakable red plastic filter for satisfactory results
	(specific to this type of device)	2. Lamp holder to be included
		3. Size approximately 25 x 20 x 15 cm made of MS housing of 20 SWG
		epoxy powder coated
		4. Necessary electrical fittings are provided to the housing to fit a red
		colored 25W bulb along with mains cable and 3 pin plug with
		provision for switching ON/ OFF
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	
	3. F	PHYSICAL CHARACTERISTICS
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed
		through a cooling mechanism
3.5	Mobility, portability	
		E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	-
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	-
		ORIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	NA
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	
	closed system)	

	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 		
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required. 		
	7.	STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available). Manufacturer and Supplier should have ISO 13485 certification for quality standards. 		
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.		
	8. TRAINING AND INSTALLATION			
8.1	Pre- installation requirements: nature, values, quality, tolerance	Three phase stable power supply		
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer		
8.3	Training of staff (medical, paramedical, technicians)	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; 		
		RRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.		
10.1		10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, 		
10.2	Other accompanying	List of essential spares and accessories, with their part number and		
	documents	cost;		
111	Complete Cummont Contact date the	11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.		
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.		

DARK ROOM TIMER

Vorcio	n no .	Vox 1
Version Date:	11110	Ver_1 15/02/2018
	by : (name. Institution)	
Done		HCT/NHSRC
HMDN	IS name	ME, CATEGORY AND CODING Timers, Darkroom
	IS code(s)	23803
OMDIN	is code(s)	
		GENERAL
1 1	Cliniaal reverses	1. USE
1.1	Clinical purpose	Timers designed for the measurement and easy reading of time
		intervals during procedures performed in a darkroom (e.g.,
1.2	Used by clinical department/ward	processing of x-ray sheets). Radiology Department
1.2	Osed by Clinical department/ward	TECHNICAL
	<u> </u>	TECHNICAL TECHNICAL TECHNICAL CHARACTERISTICS
2.1	Technical characteristics	DARK ROOM TIMER
2.1	(specific to this type of device)	1. Electronic type in the range from 0.1 seconds
	(specific to this type of device)	2. Accuracy: ± .01 %
		3. Digital display with audio signal.
		4. Auto reset option.
		5. Power supply: 220-240 V AC, 50 Hz, Single phase.
		6. Easy to use in darkroom.
		o. Lasy to use in darkfoom.
2.2	User's interface	Manual
2.3	Software and/ or standard of	NA
	communication (where ever	
	required	
	3. F	HYSICAL CHARACTERISTICS
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be
		disbursed through a cooling mechanism
3.5	Mobility, portability	
	4. ENERGY SOURC	E (electricity, UPS, solar, gas, water, CO2)
4.1	Power requirements	NA
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	NA
	5. ACCESSO	DRIES, SPARE PARTS, CONSUMABLES
5.1	Accessories, (mandatory,	NA
	standard, optional);	
	Spare parts (main ones);	
	Consumables/reagents (open,	
	closed system)	

6.1 Atmosphere/Ambience (air conditioning, humidity, dust) 1. Operating Condition: Capable of or ambient temperture of 5 to 50 deg to 80% in ideal circumstances.			
conditioning, humidity, dust ambient temperture of 5 to 50 deg to 80% in ideal circumstances.	perating continuously in		
2. Storage condition: Capable of being temperature of 0 to 50 deg C and re	stored continuously in ambient		
 User's care, Cleaning, Disinfection & Sterility issues Sterility issues Of easy disinfection or be protected cover. Sterilization not required. 	erator should either be capable		
7. STANDARDS AND SAFETY			
 7.1 Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international 1. Should be US FDA/CE/BIS/CDSCO a requirements will be applicable onl like BIS/CDSCO are not available.) 2. Manufacturer and Supplier should for quality standards. 	ly when the Indian standards		
7.2 Local and/or international Manufacturer/Supplier should have ISO	O 13485 certificate for quality		
standard.	o 15 105 certificate 101 quality		
8. TRAINING AND INSTALLATION			
8.1 Pre- installation requirements: NA			
nature, values, quality, tolerance			
8.2 Requirements for sign-off Certificate of calibration and inspection of	of parts from the manufacturer		
8.3 Training of staff (medical, 1. Training of users on operation and	basic maintenance;		
paramedical, technicians) 2. Advanced maintenance tasks requi	ired shall be documented;		
9. WARRANTY AND MAINTENANCE	· ·		
9.1 Warranty 3 years, including all spares and calibrat	tion.		
10. DOCUMENTATION			
10.1 Operating manuals, set Should provide 2 sets(hard copy and so	oft copy) of:		
manuals, other manuals 1. User, technical and maintenance m English/Hindi language along with 2. List of equipment and procedures r and routine maintenance; 3. Service and operation manuals(orig 4. Advanced maintenance tasks docu- 5. Certificate of calibration and inspec	machine diagrams; required for local calibration ginal and Copy) to be provided; mentation; ction,		
10.2 Other accompanying List of essential spares and accessories	s, with their part number and		
documents cost;			
11. NOTES			
11.1 Service Support Contact details Contact details of manufacturer, supplied	_		
(Hierarchy Wise; including a toll provided; Any Contract (AMC/CMC/ad	ld-hoc) to be declared by the		
free/landline number) manufacturer.			
·	displayed.		

X-RAY CASSETTE

Vorcio	on no ·	Vor 1			
Version no. : Date:		Ver_1 15/02/2018			
	by : (name. Institution)	HCT/NHSRC			
Done	•	ME, CATEGORY AND CODING			
UMDI	NS name	Cassettes, Radiography, X-Ray Film			
	NS code(s)	14474			
OIVIDI	GENERAL				
		1. USE			
1.1	Clinical purpose	A device used in medical imaging applications to hold and shield an			
	Cirrical parpose	attached storage phosphor screen from exposure to room light			
		during transport and insertion into a diagnostic imaging x-ray system			
		and a computed radiography scanner, in the process of producing a			
		digital image of a patient radiation pattern.			
1.2	Used by clinical department/ward	Radiology Department			
	The state of the s	TECHNICAL			
	2.	TECHNICAL CHARACTERISTICS			
2.1	Technical characteristics	1. A set of cassettes having system for indicating whether or not it is			
	(specific to this type of device)	loaded and a slot for patient identity card.			
		2. Cassettes to be compatible with the radiology equipment			
		3. Should include 14"x 17", 15"x 12", 12"x 10", 10"x 8"			
		4. Cassettes to be made of Aluminium for light weight. 4 corners to be			
		connected with non-metallic construction to give protection covers.			
		5. Soft push button locking arrangement with stainless springs			
		6. Suitable lead protection spray to be given on the inside rear flap of			
		the cassette to eliminate fog effect on X-ray film			
		7. High grade foam material to be pasted inside to give the film a			
		uniform contact with intensifying screens			
2.2	User's interface	Manual			
2.3	Software and/ or standard of	NA			
	communication (where ever				
	required				
		PHYSICAL CHARACTERISTICS			
3.1	Dimensions(metric)	NA			
3.2	Weight (lbs, kg)	NA NA			
3.3	Noise (in dBA)	NA Charald are interior and all the characteristics and the characteristics are small to the characteristics and the characteristics are characteristics.			
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be			
3.5	Mobility portability	disbursed through a cooling mechanism Portable			
٥.٥	Mobility, portability	E (electricity, UPS, solar, gas, water, CO2)			
4.1	Power requirements	NA			
4.2	Battery operated	NA NA			
4.3	Protection	NA NA			
4.4	Power consumption	NA			
	· ·	DRIES, SPARE PARTS, CONSUMABLES			
5.1					
Ľ.,					

1	standard autional). Crawa wanta	
	standard, optional); Spare parts	
	(main ones); Consumables/	
	reagents (open, closed system)	EMENT TERMS/DONATION REQUIREMENTS
		AL AND DEPARTMENTAL CONSIDERATIONS
6.1	Atmosphere/Ambience (air	Operating Condition: Capable of operating continuously in
0.1	conditioning, humidity, dust	ambient temperture of 5 to 50 deg C and relative humidity of 15
)	to 80% in ideal circumstances.
	,	 Storage condition: Capable of being stored continuosly in ambient
		temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning,	Disinfection: Parts of the Device that are designed to come into
0.2	Disinfection & Sterility issues	contact with the patient or the operator should either be capable
	Distinction & Sternity issues	of easy disinfection or be protected by a single use/disposable cover.
		 Sterilization not required.
	7.	STANDARDS AND SAFETY
7.1	Certificates (pre-market,	Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE)
' ' '	sanitary,); Performance and	requirements will be applicable only when the Indian standards
	safety standards (specific to the	like BIS/CDSCO are not available.)
	device type); Local and/or	Manufacturer and Supplier should have ISO 13485 certification
	international	for quality standards.
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality
		standard.
	8. TF	RAINING AND INSTALLATION
8.1	Pre- installation requirements:	NA
	nature, values, quality, tolerance	
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	T	· · ·
ر.نا	Training of staff (medical,	Training of users on operation and basic maintenance;
0.5	paramedical, technicians)	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented;
0.5	paramedical, technicians) 9. WA	Training of users on operation and basic maintenance;
9.1	paramedical, technicians)	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration.
9.1	paramedical, technicians) 9. WA Warranty	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION
	paramedical, technicians) 9. WA Warranty Operating manuals, set	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of:
9.1	paramedical, technicians) 9. WA Warranty	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in
9.1	paramedical, technicians) 9. WA Warranty Operating manuals, set	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;
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9.1	paramedical, technicians) 9. WA Warranty Operating manuals, set manuals, other manuals Other accompanying documents	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE 3 years, including all spares and calibration. 10. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, List of essential spares and accessories, with their part number and cost; 11. NOTES
9.1	paramedical, technicians) 9. WA Warranty Operating manuals, set manuals, other manuals Other accompanying documents Service Support Contact details	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, List of essential spares and accessories, with their part number and cost; 11. NOTES Contact details of manufacturer, supplier and local service agent to be
9.1	paramedical, technicians) 9. WA Warranty Operating manuals, set manuals, other manuals Other accompanying documents Service Support Contact details (Hierarchy Wise; including a toll	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, List of essential spares and accessories, with their part number and cost; 11. NOTES Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the
9.1	paramedical, technicians) 9. WA Warranty Operating manuals, set manuals, other manuals Other accompanying documents Service Support Contact details	 Training of users on operation and basic maintenance; Advanced maintenance tasks required shall be documented; RRANTY AND MAINTENANCE years, including all spares and calibration. DOCUMENTATION Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, List of essential spares and accessories, with their part number and cost; 11. NOTES Contact details of manufacturer, supplier and local service agent to be

INTENSIFYING SCREENS

Version Date: Done by UMDNS	y : (name. Institution)	Ver_1 15/02/2018			
Done by		15/02/2018			
UMDNS	NIA N	HCT/NHSRC			
אטואטן		ME, CATEGORY AND CODING			
UMDNS code(s)		X-Ray Film Cassette Image Intensifying Screens			
UMDNS	code(s)	14486			
		GENERAL 1. USE			
	Clinian I anno ann				
1.1	Clinical purpose	A device typically considered to be a component of an x-ray film cassette used in diagnostic x-ray applications. It is typically used in			
		pairs with double side emulsion x-ray film. It is used to reduce the			
		•			
		x-ray dose to the patient and to allow for shorter exposure times to			
1.2	Used by clinical department/ward	reduce motion artifact on exposed film. Radiology Department			
1.2	osed by clirical department, ward	TECHNICAL			
	2 1	TECHNICAL TECHNICAL CHARACTERISTICS			
2.1	Technical characteristics	High speed in class 100 to 160 in various sizes			
	(specific to this type of device)	Calcium tungstate emulsion layer on polyester base			
	(specific to this type of device)	Compatible with all X-ray films available			
		4. Sizes of screens: 14"x 17", 15"x 12", 12"10", 10"x8" (5 nos. each)			
2.2	User's interface	Manual			
	Software and/ or standard of	NA NA			
	communication (where ever				
	required				
		HYSICAL CHARACTERISTICS			
3.1	Dimensions(metric)	NA NA			
	Weight (lbs, kg)	NA			
	Noise (in dBA)	NA			
	Heat dissipation	Should maintain nominal temperature and the heat should be			
	·	disbursed through a cooling mechanism			
3.5	Mobility, portability				
		(electricity, UPS, solar, gas, water, CO2)			
4.1	Power requirements	NA			
4.2	Battery operated	NA			
4.3	Protection	NA			
4.4	Power consumption	NA			
	5. ACCESSO	RIES, SPARE PARTS, CONSUMABLES			
5.1	Accessories, (mandatory,	NA			
:	standard, optional);				
:	Spare parts (main ones);				
	Consumables/reagents (open,				
1 1	closed system)				
	•				

	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS				
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS				
6.1	Atmosphere/Ambience (air conditioning, humidity, dust)	 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 			
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required. 			
	7.	STANDARDS AND SAFETY			
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	 Should be US FDA/CE/BIS/CDSCO approved. (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO are not available.) Manufacturer and Supplier should have ISO 13485/ISO 9001 certification for quality standards. Shall complaints to IEC 61262-7: Medical electrical equipment - Characteristics of electro-optical X- ray image intensifiers - Part 7: Determination of the modulation transfer function 			
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality			
		standard.			
		RAINING AND INSTALLATION			
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA			
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer			
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;			
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;			
		RRANTY AND MAINTENANCE			
9.1	Warranty	3 years, including all spares and calibration.			
101		10. DOCUMENTATION			
10.1	Operating manuals, set manuals, other manuals	 Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, 			
10.2	Other accompanying	List of essential spares and accessories, with their part number and			
	documents	cost;			
		11. NOTES			
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number) Recommendations or warnings	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer. Any warning sign would be adequately displayed.			
	1	,			

LEAD APRON

Version no.:		Ver_1			
Date:		15/02/2018			
Done	by : (name. Institution)	HCT/NHSRC			
		ME, CATEGORY AND CODING			
	NS name	Shields, X-Ray, Apron			
IUMDI	NS code(s)	14491			
	GENERAL				
1 1	Clinian number	1. USE			
1.1	Clinical purpose	It is intended to shield portions of the body of an individual (i.e., the			
		operator, patient, or other attending person) from exposure to			
		radiation during medical or dental procedures. Some include			
1.2	Used by dinical department/ward	attached or detachable collars for neck and thyroid protection. Radiology Department			
1.2	Used by clinical department/ward	TECHNICAL			
	<u> </u>	FECHNICAL CHARACTERISTICS			
2.1	Technical characteristics	Coat type aprons fabricated from multiple leaded vinyl fabric			
2.1	(specific to this type of device)	having minimum 0.25mm lead equivalent for protection from			
	(specific to this type of device)	scattered radiation			
		Apron to cover over shoulders through upto knees			
		Item should be light in weight and durable			
		 Necessary water proof cloth lining to be stitched on vinyl fabric. Apron should have approval certificate of AERB 			
		6. Suitable wooden hanger to be provided for hanging apron to			
2.2	User's interface	avoid damage Manual			
2.3	Software and/ or standard of	NA NA			
2.3	communication (where ever	INA			
	required	HYSICAL CHARACTERISTICS			
3.1	Dimensions(metric)	NA			
3.2	Weight (lbs, kg)	NA NA			
3.3	Noise (in dBA)	NA NA			
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be			
3.4	neat dissipation	disbursed through a cooling mechanism			
3.5	Mobility, portability	dispursed through a cooling mechanism			
ر.د	1	(electricity, UPS, solar, gas, water, CO2)			
4.1	Power requirements	NA			
4.2	Battery operated	NA			
4.3	Protection	NA			
4.4	Power consumption	NA			
.,,	•	PRIES, SPARE PARTS, CONSUMABLES			
5.1	Accessories, (mandatory,	NA			
	standard, optional); Spare parts				
	(main ones); Consumables/				
	reagents (open, closed system)				
	1 - 23 (-				

	BIDDING/PROCUR	EMENT TERMS/DONATION REQUIREMENTS				
	6. ENVIRONMENTA	AL AND DEPARTMENTAL CONSIDERATIONS				
6.1	Atmosphere/Ambience (air conditioning, humidity, dust	 Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% 				
6.2	User's care, Cleaning, Disinfection & Sterility issues	 Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Sterilization not required. 				
	7.	STANDARDS AND SAFETY				
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	Manufacturer and Supplier should have ISO 13485/ISO 9001 certification for quality standards				
7.2	Local and/or international	Manufacturer/Supplier should have ISO 13485 certificate for quality				
		standard.				
	8. TF	RAINING AND INSTALLATION				
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA				
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer				
8.3	Training of staff (medical,	1. Training of users on operation and basic maintenance;				
	paramedical, technicians)	2. Advanced maintenance tasks required shall be documented;				
	9. WARRANTY AND MAINTENANCE					
9.1	Warranty	3 years, including all spares and calibration.				
		10. DOCUMENTATION				
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10.2	Other accompanying	List of essential spares and accessories, with their part number and				
	documents	cost;				
		11. NOTES				
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.				
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.				

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3	Representatives from Federation of Indian Chambers of Commerce & Industry (FICCI) Association.				
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NOTES





Ministry of Health and Family Welfare Government of India