सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR
Radio Imaging Department

Ministry of Health and Family Welfare
Government of India

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TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR
RADIO IMAGING DEPARTMENT

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:

i. 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.

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This document has been prepared and published on behalf of the National Health Mission (NHM) by its technical support institution National Health Systems Resource Centre (NHSRC), NIHFW Campus, Baba Gangnath Marg, New Delhi – 110 067.

We gratefully acknowledge the contributions made by consultants and officers in the NHM division of the MoHFW.

प्रीति सूदन
सचिव
PREETI SUDAN
Secretary

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
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)

मनोज झालानी
Manoj Jhalani
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Additional Secretary & Mission Director (NHM)

सत्यमेव जयते

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 AIIMS, 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)

Version no. :		Ver_1
Date:		1/29/2019
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units
UMDNS 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	Intensive Care Units (ICUs) and Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**X-ray Generator:** 1. High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided. 2. 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:** 1. Tube should have one number stationary anode and thermally 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 communication(where ever required	In built

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	Mobile
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 ohms.
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Machine should be provided with following accessories: 1) Two numbers of BARC approved whole body lead aprons with all attachments. 2) One pair of 8 meter HV Cable
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 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	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. 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	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 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. 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)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units
UMDNS 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 (specific to this type of device)	**X-ray Generator:** 1. High frequency X-Ray generator having frequency of 20 KHz or 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:** 1. 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 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. **Coloumn Stand:** 1. It should have floor to ceiling stand with vertical counter balanced travel.

		2. It should have 360 deg. rotation. It should be provided one 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	In built
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: 230V, AC, 50 Hz, 15 Amps, three phase, Line resistance < 0.4 ohms.
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)	Machine should be provided with following accessories: 1. Two numbers of BARC approved whole body lead aprons with all attachments. 2. One pair of 8 meter HV Cable
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 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	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. 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	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 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. 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)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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 adequaetly displayed.

100 mA X-RAY - MOBILE

Version no. :		Ver._1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units, Mobile
UMDNS code(s)		13272
GENERAL		
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 critical care units or operating and emergency rooms.
1.2	Used by clinical department/ward	Intensive Care Unit and Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**X-ray Generator:** 1. High frequency X-Ray generator having frequency of 20 KHz or 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:** 1. 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

		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 communication(where ever required	In built
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	Mobile
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 ohms.
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Machine should be provided with following accessories: 1. Two numbers of BARC approved whole body lead aprons with all attachments. 2. One pair of 8 meter HV Cable
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 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	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. 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	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 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. 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)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units
UMDNS code(s)		13267
GENERAL		
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 musculoskeletal degeneration.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**Gantry** 1. Should incorporate low Voltage Slip Rings 2. Minimum scan time for a 360º 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** 1. 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** 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 automated patient instruction system (API) should be provided.
2.3	Software and/ or standard of communication(where ever required	**Workstations:** A client server architecture based solution (Intellispace Portal 6 / 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.

		• 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. 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	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. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make: Integrated with main console and workstation 2. Color Laser Printer (High Resolution) for color coaded images 3. UPS with half hour 'back-up' to run entire CT 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/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 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, Disinfection & Sterility issues	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. 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	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 equipment: IEC 60601-1-2 5. Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS 6. AERB type approved.
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	Lead glass, door shields
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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 adequaetly displayed.

CT SCAN - 128 SLICE

Version no. :		Ver._1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Radiographic Units
UMDNS code(s)		13267
GENERAL		
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 musculoskeletal degeneration.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**Gantry** 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 2. Should be high frequency having at least 100 kW output or more 3. 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 automated patient instruction system (API) should be provided.
2.3	Software and/ or standard of communication (where ever required	**Workstations:** A client server architecture based solution (Intellispace Portal 6/ 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.

		• 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. 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	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.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make : Integrated with main console and workstation 2. Color Laser Printer (High Resolution) for color coaded images 3. UPS with half hour 'back-up' to run entire CT 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/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 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, Disinfection & Sterility issues	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. 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	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 equipment: IEC 60601-1-2 5. Certified to be complaint with IEC 60601-1-3, IEC 61010-2-44 or equivalent BIS standard 6. AERB type approved.
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	Lead Glass, Door Sheild
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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 adequaetly displayed.

FULL BODY MRI SYSTEM - 1.5 TESLA

Version no. :		Ver._1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, 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. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**MAGNET** 1. Whole Body 1.5Tesla 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. 2. 1.5T active shielded super conductive magnet should be short and non- claustrophobic. 3. It should have at least 70 cm patient bore with flared opening. 4. Magnet length should be less than 200cm. 5. Homogeneity of magnet should be less than 3.5 ppm over 45cm DSV 6. The magnet should be well ventilated and illuminated with built 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 room 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 position. **SHIM SYSTEM** 1. High performance, highly stable shim system with global and localized automated shimming for high homogeneity magnetic field for imaging and spectroscopy. 2. Auto shim should be available to shim the magnet with patient in position. **GRADIENT SYSTEM** 1. Actively shielded Gradient system

		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. 2. 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** 1. 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. 2. 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 6. 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. 18. Perfusion imaging of brain (including PASL and CASL) 19. Susceptibility weighted imaging with phase information. 20. 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 **SAFETY 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 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 communication (where ever required	1. A workstation with same user interface as of main console is required with the availability of all necessary software including: 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 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.
3. PHYSICAL 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
4. ENERGY SOURCE (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.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Dual Head MRI Compatible Pressure Injector with 100 sets of syringes. 2. Water Chiller for Cold Head I Gradients.. 3. 2 Non-ferromagnetic patient transfer trolley should be provided. 4. Fire Fighting System, Detectors and 6 Fire Extinguishers - MR compatible / MR safe 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/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 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, Disinfection & Sterility issues	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. 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	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 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. TRAINING 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, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	5 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: 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 documents	List of essential spares and accessories, with their part number and 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 adequaetly displayed.

FULL BODY MRI SYSTEM - 3 TESLA

Version no. :		Ver._1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, 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. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**MAGNET** 1. 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. 2. 3T active shielded super conductive magnet should be short and non- claustrophobic. 3. It should have at least 70 cm patient bore with flared opening. 4. Magnet length should be less than 200cm. 5. Homogeneity of magnet should be better than 1.5 ppm over 40 cm DSV 6. The magnet should be well ventilated and illuminated with built 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 room 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 position. **SHIM SYSTEM** 1. High performance, highly stable shim system with global and localized automated shimming for high homogeneity magnetic field for imaging and spectroscopy. 2. Auto shim should be available to shim the magnet with patient in position. **GRADIENT SYSTEM** 1. Actively shielded Gradient system

		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. 2. 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 0.3 **COIL SYSTEM** 1. 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. **APPLICATION SEQUENCES** 1. 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. 2. 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 6. 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. 18. Perfusion imaging of brain (including PASL and CASL) 19. Susceptibility weighted imaging with phase information. 20. 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 **SAFETY 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 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 communication (where ever required	1. A workstation with same user interface as of main console is required with the availability of all necessary software including: 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 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.

3. PHYSICAL 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
4. ENERGY SOURCE (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.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Dual Head MRI Compatible Pressure Injector with 100 sets of syringes. 2. Water Chiller for Cold Head I Gradients. 3. 2 Non-ferromagnetic patient transfer trolley of international make should be provided 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/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 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, Disinfection & Sterility issues	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. 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	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

	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. TRAINING 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, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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 adequaetly displayed.

PORTABLE ULTRASOUND

Version no. :		Ver._1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Scanning Systems, Ultrasonic, Cardiac, gynaological, General, Anaesthesia, vascular
UMDNS 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 (specific to this type of device)	1. A typical configuration for a cardiac ultrasound system consists 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: • A-2.0-5.0 MHz Multi frequency Convex Transducer-One. • B-5.0-12.0 MHz Multi frequency Linear transducer-One. • C-5.0-8.0 MHz or more Endo Cavitory probe-One. 4. Transesophageal Echocardiogram - TEE scanning capability 5. Penetration depth of at least 30 cm 6. Digital and caliper measurement functions required for both distance and area 7. Alphanumeric annotation to be possible 8. Measurement accuracy to be better than 2% over 10cm distance 9. Doppler display to indicate blood flow both numerically and in colour. 10. System that is DICOM compatible for communication efficiency. 3D or 2D image for cardiac studies in adults, children and infants 11. ZOOM in real time at least 4X and ZOOM for frozen image at least 20X. 12. Equipment dynamic range, at least, 180 dB.
2.2	User's interface	Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.

2.3	Software and/ or standard of communication(where ever required	The hardware and software included will allow the following application: Cardiac and stress echo; tissue differentiation to clearly show the walls of the left ventricle and regional wall motion 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		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	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 …)	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	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. 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	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 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. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Single phase stable power supply; PCPNDT Act clearance
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 documents	List of essential spares and accessories, with their part number and 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.

X-RAY DEVELOPING TANK

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		X-Ray Film Manual Processing Equipment
UMDNS code(s)		15945
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		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Manual film processing unit- with the tanks with lid shall be of 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 communication (where ever required	NA
3. 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 disbursed through a cooling mechanism
3.5	Mobility, portability	
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	-
4.2	Battery operated	-
4.3	Protection	NA
4.4	Power consumption	-

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Machine should be provided with following accessories: 1) 3 numbers of non corrosive tanks for solution 2) Hanger of 10 clips and loose clips.
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 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	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. 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	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.
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	-
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
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; 2. List of equipment and procedures required for local calibration and routine maintenance;
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	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.

CHEST STAND: FLOOR MODEL

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS 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		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Floor model vertical stand with rigid L channel structure on a 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 communication (where ever required	NA
3. 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 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
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 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	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. 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	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.
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	-
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Shields, X-Ray, Barrier
UMDNS code(s)		15872
GENERAL		
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 individual and a source of primary or scattered radiation.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Triple fold type- Lead Screen movable on a sturdy, rust proof wheels with 1.5 mm lead sheet sandwiched between phenol 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 communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
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
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

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 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	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. 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	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.
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	-
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	-
10. DOCUMENTATION		
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	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.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

FILM HANGER

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Film hanger clips are used to hang wet films during film developing process
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Stainless steel film hanger clip type or channel type to hang wet films. Sizes should be 8 "x 10", 10"x 12", 12"x 15" and 14"x 14", 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 communication (where ever required	NA
3. 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 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
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. The equipment should be suitable for operation in temperatures from 10° C to 45° C with a relative humidity of 100 % 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	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. 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	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.
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
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		View Boxes, X-Ray
UMDNS code(s)		14498
GENERAL		
1. USE		
1.1	Clinical purpose	An electromechanical and/or software-controlled motorized device designed to support, retrieve, and illuminate x-ray image recorded on radiographic film for direct viewing.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (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 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 communication (where ever required	NA
3. 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 disbursed through a cooling mechanism
3.5	Mobility, portability	
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	-
4.2	Battery operated	-
4.3	Protection	NA
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 …)	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 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	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. 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	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.
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	-
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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 SAFETY LIGHT

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Safelights, X-Ray, Darkroom
UMDNS code(s)		16562
GENERAL		
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 radiographic film being loaded, stored or developed.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Body to be made out of MS sheet with outside black coating and unbreakable red plastic filter for satisfactory results 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 communication (where ever required	NA
3. 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	
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	-
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	-
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

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 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	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. 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	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.
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)	1. Training of users on operation and basic maintenance; 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: 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 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)	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

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Timers, Darkroom
UMDNS code(s)		23803
GENERAL		
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., processing of x-ray sheets).
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	**DARK ROOM TIMER** 1. Electronic type in the range from 0.1 seconds 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.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. 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 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	-
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

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 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	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. 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	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.
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
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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.

X-RAY CASSETTE

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Cassettes, Radiography, X-Ray Film
UMDNS code(s)		14474
GENERAL		
1. USE		
1.1	Clinical purpose	A device used in medical imaging applications to hold and shield an 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
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. A set of cassettes having system for indicating whether or not it is 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 communication (where ever required	NA
3. 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 disbursed through a cooling mechanism
3.5	Mobility, portability	Portable
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
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 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	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. 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	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.
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
8.2	Requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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.

INTENSIFYING SCREENS

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		X-Ray Film Cassette Image Intensifying Screens
UMDNS code(s)		14486
GENERAL		
1. USE		
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 reduce motion artifact on exposed film.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. High speed in class 100 to 160 in various sizes 2. Calcium tungstate emulsion layer on polyester base 3. 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
2.3	Software and/ or standard of communication (where ever required	NA
3. 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 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
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA

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 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	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. 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	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/ISO 9001 certification for quality standards. 3. 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.
8. TRAINING 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, paramedical, technicians)	1. Training of users on operation and basic maintenance; 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: 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 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)	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.

LEAD APRON

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Shields, X-Ray, Apron
UMDNS code(s)		14491
GENERAL		
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 attached or detachable collars for neck and thyroid protection.
1.2	Used by clinical department/ward	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Coat type aprons fabricated from multiple leaded vinyl fabric having minimum 0.25mm lead equivalent for protection from scattered radiation 2. Apron to cover over shoulders through upto knees 3. Item should be light in weight and durable 4. Necessary water proof cloth lining to be stitched on vinyl fabric. 5. Apron should have approval certificate of AERB 6. Suitable wooden hanger to be provided for hanging apron to avoid damage
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. 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 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
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	NA

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 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	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. 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	1. 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. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
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8.3	Training of staff (medical, paramedical, technicians)	1. Training of users on operation and basic maintenance; 2. Advanced maintenance tasks required shall be documented;
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
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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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Acknowledgements are also expressed to Directorate General of Health Services (DGHS) who have enriched the documents with their contributions and suggestions.

NOTES

NATIONAL HEALTH MISSION

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सत्यमेव जयते

Ministry of Health and Family Welfare

Government of India