सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Government of India

Technical Specifications of Medical Devices for **Laboratory and Radiology**

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Government of India

Technical Specifications of Medical Devices for **Laboratory and Radiology**

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन
भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

सत्यमेव जयते

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

Dated : 29th April, 2015

MESSAGE

Ministry of Health and Family Welfare in its endeavor to achieve highest standards of health for the people has undertaken several programmatic and institutional strengthening measures. National Health Mission is one such programmatic intervention aimed at improved overall health with special focus in energizing rural health infrastructure and services. Providing essential medical equipment is a critical component of strengthening health infrastructure. However, rapidly changing technologies, complexity associated with medical equipment and high costs of procurement - all these make selection of appropriate and cost effective equipment a challenging task. I am happy to note that National Health Systems Resource Centre (NHSRC) under the guidance of experts and with active participation of stakeholders have developed technical specifications of commonly procured medical devices to facilitate procurements by State / UT Governments. I am sure that you will find these very helpful. The specifications are suggestive and we have tried to keep them generic. However, we would welcome any suggestions for further improvement in these specifications.

(B.P. Sharma)

कमरा नं 156, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011
Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@gmail.com

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax : 23061066, 23063809
E-mail : asmd-mohfw@nic.in

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

Under National Health Mission, support is being provided to all States/UTs for improving quality of health services and improving necessary infrastructure including medical equipment. Providing for adequate, safe and appropriate medical equipment at all levels of public health facilities remains a focus for the Government. Given the challenges of procurement it is necessary to have generic specifications for medical equipment. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am pleased to note that these have been adequately considered by NHSRC while preparing the specifications. Keeping them as reference specifications while undertaking procurement will reduce costs of procurement, maintenance problems and procurement lead time. I am happy to note that NHSRC, has filled in an important technical gap by providing these specifications and I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

We would be happy to have your valuable suggestion on improving these.

(C.K. Mishra)

New Delhi
29th April, 2015

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Manoj Jhalani, IAS
Joint Secretary
Telefax : 23063687
E-mail : manoj.jhalani@nic.in

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

31st April 2015

MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association 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. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement.extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. 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. We would welcome suggestions from the States.

(Manoj Jhalani)

Acknowledgement

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 manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameel, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

AUTOMATED 3-PART DIFFERENTIAL HEAMOTOLOGY ANALYZER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Automated 3-part Differential Heamotology Analyzer**
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Automated differential blood count: Automated hematology instruments using multiple parameters and methods (such as impedance) are used to count and identify the 3 major white blood cell types in blood (so-called 3-part differential count):, lymphocytes, monocytes/mixed population and granulocytes/neutrophiles.
1.2	**Used by clinical department/ ward**	Clinical and Analytical Laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. 18 parameters (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW-SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional), with 3-part WBC differential. 2. Maximum sample volume required 50 µl. 3. Screen Colour touch screen. 4. Printer Built-in printer and external printer option. 5. Memory for 1000 results incl. histograms. 6. Program Built-in QC program for. 7. 3 levels/control 8. Barcode reader and external option. 9. External keyboard. 10. Automatic sample dilution. 11. Automated start up and shutdown. 12. Auto probe wipe and external option. 13. System must have throughput of atleast 60 samples per hour. 14. Linearity of 18 parameters (Hematocrit, platelet, WBC, RBC, Hb) min.
2.2	**User's interface**	Touch screen.
2.3	**Software and/or standard of communication(where ever required)**	USB printer interface, HL7.

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	N/A
3.2	**Weight (lbs, kg)**	N/A
3.4	**Noise (in dBA)**	N/A
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Stationary laboratory Installation.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	230/110 VAC, 50/60 HZ, 60 VA, +-10%
4.2	**Battery operated**	No
4.7	**Protection**	N/A
4.8	**Power consumption**	Less than 100 VA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. 2D-Barcode Scanner . 2. Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control. 3. Closed System rate to be declared for cost/test. 4. Online UPS for 30 minutes back up. 5. Caliberater - 1.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, 61010-2-101 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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 annual caliberation.

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed;

AUTOMATED 5-PART DIFFERENTIAL HEMATOLOGY ANALYZER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Automated 5-part differential hematology analyzer
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Automated differential blood count: Automated hematology instruments using multiple parameters and methods (such as fluorescence, flow cytometry and impedance) are used to count and identify the 5 major white blood cell types in blood (so-called 5-part differential count): neutrophils, lymphocytes, monocytes, eosinophils and basophils.
1.2	**Used by clinical department/ ward**	Analytical laboratories.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Five-part differential. 2) 24 parameters, all different WBC's should be measured directly. 3) Advanced, integrated self-cleaning system. 4) On-screen patient results trending. 5) Stores 5, 000 test results with histograms and scattergrams. 6) Integrates with common practice management systems. 7) maximum sample required 100 µL sample size permits whole blood analysis from venous collections. 8) Parameters Total Leukocytes (White Blood Cells) and Differential (in absolute numbers and %) for: Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils. 9) Sample Material Capillary or venous (EDTA) whole blood. 10) Linearity of all parameters. 11) Measuring Time Within 60 Sec. 12) System must have throughput of atleast 60 samples per hour in all discrete modes. 13) Manual mode. 14) Stat mode. 15) Pre-diluted mode and whole blood mode.
2.2	**User's interface**	Printer, keyboard, barcode reader, PC, optional.
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
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	Recharging unit: Input voltage- single/3-phase.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	±10%
4.4	**Pressure gauge**	NA
4.5	**Operating temperature**	Analyzer: 4-50 °C (39-122 °F). Capillary samples from finger stick:18-25 °C (67-77 °F).
4.6	**Protection**	N/A
4.7	**Power consumption**	upto 500VA.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. 2D-Barcode Scanner. 2. Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control. 3. Closed System rates to be closed for all test. 4. Online UPS System for 30 minutes back up.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, 61010-2-101 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed.

BINOCULAR MICROSCOPE

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Binocular Microscope**
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Binocular microscope is simply a microscope that lets the viewer use both eyes. The microscope has 2 eye lenses. The development of the double eye piece microscope was adapted to reduce the eyestrain and muscular strain that typically results from traditional microscopes.
1.2	Used by clinical department/ ward	Cinical labs.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Body-Single mould sturdy stand, inclined Binocular body 30 °, 360º rotatable head. 2. Eyepieces-Highest quality 10 X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces. 3. Objectives-Parfocal, antifungus coated 4x, 10x, 40x and 100x (oil immersion) with semi planner achromatic correction. Objective should be well centred even if their position on turret is changed. 4. Optical system-Infinity corrected. 5. Stage - Double plate rackless horizontal mechanical stage preferably 100 x 140 mm with fine vernier graduations designed with convenient coaxial adjustment for slide manipulation preferably through 30 x 70 mm double slide holder. 6. Sub stage-Abbe condenser focusable, continuously variable iris diaphragm 7. Illuminator-Built-in LED light source with white light with intensity control and LED life of more than 10, 000 Hrs. 8. Finish-A durable textured acid resistant finish. 9. Battrey backup : minimum 1 Hour. 10. Nose piece: Backward tilted revolving nose piece suitable to acomodate four objectives with click stop and rubber grip. 11. Focussing: Coaxial coarse and fine focussing knob, capable of smooth, fine focussing movement senstivity; minimum: 300 micron; focussing stop for slide safety.
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	**Capacity**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	NA
3.6	**Mobility, portability**	Portable
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Input voltage- single/3-phase.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Pressure gauge**	NA
4.5	**Operating pressure**	NA
4.6	**Sterilizing pressure**	NA
4.7	**Protection**	Should have over-charging cut-off with visual symbol.
4.8	**Power consumption**	Less than 2 W.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	Should provide with wooden storage box, dust cover, immersion oil.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard) 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO certificate for quality standard.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

CAPILLARY BILIRUBINOMETER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Capillary Bilirubinometer**
GMDN code		NA
GENERAL		
1. USE		
1.1	Clinical purpose	The capillary bilirubinometer is used for a quick check of bilirubin, as to promptly act with appropriate therapy. It is used to analyse the bilirubin, on centrifuged whole blood drawn in a micro capillary tube. Sample is analyzed through a double beam photometric system.
1.2	**Used by clinical department/ ward**	Analytical laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Sample centrifuged whole blood. 2) Sample volume less than 70µl. 3) Reading cuvette haeparinized haematocrit capillary. 4) Unit of measure mg/dl. 5) Measurement range 0/30 mg/dl. 6) Measure system Photometric double beam. 7) Reading time approx. 5s even with samples with high interference value. 8) Reading inaccuracy < 7%. 9) Bichromatic as per standard filters. 10) Programming by built-in keypad. 11) Results on LCD/LED display and printer.
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)**	upto 3 kg.
3.4	**Noise (in dBA)**	<65dB
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz
4.2	**Battery operated**	Yes
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Should have over-charging cut-off with visual symbol.
4.5	**Power consumption**	Less than 100 W.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	1. Lancettes. 2. Sealing plasticine. 3. Glass capillaries (100mm). 4. Thermal paper.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, IEC 61010-101 for safety.
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**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed.

CENTRIFUGE

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Centrifuge
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used in Biochemical and Analytical labs for Hematocrit, blood Corpusule percentage, Serum Analysis, Precipitate Seperartion and Blood Group matching.
1.2	**Used by clinical department/ ward**	Analytical Laboratories.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Speed: Maximum Range 4000 to 6000 RPM. 2. Receprocating Centrifugal force (RCF): 3000 to 3500. 3. Minimum Capacity: 240 ml. 4. Digital Timer range: 0 to 59 minutes. 5. Auto Lid interlock to prevent opening while running centrifuge with emergency lidlock release. 6. Motor imbalance detector feature - desirable. 7. Microprocessor with digital display. 8. Dynamic break for quick deacleration. 9. Stainless steel Chamber easy to clean. 10. Hinges to prevent door falling. 11. Rotor Sizes: 16 x 15ml. 12. Rotors should be autoclavable.
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	**Capacity**	120 ml or above
3.4	**Noise (in dBA)**	NA

3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Portable
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	Power Requirements	220-240 V/50Hz.
4.2	Battery operated	No
4.3	Protection	NA
4.4	Power consumption	400 to 500 Watts
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Rubber adapter should be provider for the use of vacutainer for 3ml and 5ml.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard). 5. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety.
7.2	Local and/or international	Manufacturer/supplier should have ISO certificate for quality standard.
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	Requirements for sign-off	Certificate of calibration and inspection 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
9.2	Maintenance tasks	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	Service contract clauses, including prices	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

COLORIMETER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Colorimeter**
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	It is used to determine the concentration of colored compounds in solution. A colorimeter is a device used to test the concentration of a solution by measuring its absorbance of a specific wavelength of light.
1.2	**Used by clinical department/ ward**	Clinical Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Should have 5 no of filters for standard wave length from 400 nm to 700 nm. 2. Should have upto 3 decimal calibrated directly in optical density. 3. Detector should be encased spill proof photocell. 4. Should have facilities for concentration, calculation, percentage transmission and optical density. 5. Should have DetectorSilicone photo-diode. 6. Filter : Optical filter(420nm, 460nm, 510nm, 540nm, 600nm). 7. Light source : Bright Intensity LED/Halogen. 8. Display : LCD/LED display. 9. 3 Red LEDs for selected function(T%/ABS/CONC). 10. Photometric Range0-2.0. 11. Maximum reaction volume required 1 ml.
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)**	Less than 3 kg.
3.3	**Capacity**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Fixed Lab installation.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	Power Requirements	230V, 50Hz AC
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**Power consumption**	
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1) Filter case : 1 pc 2) Filter (420nm, 460nm, 510nm, 540, 600nm) : 5 pcs; Lamp/Light source 3) Square cuvette : 4 pcs (glass) 4) Round cuvette : 4 pcs (glass) 5) Cuvette adaptor : 1 pc 6) Analog output cable : 1 pc 7) Open System
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility (EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, IEC 61010-101 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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
9.2	**Maintenance tasks**	
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

FULLY AUTOMATED BIOCHEMISTRY ANALYZER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Fully automated biochemistry analyzer**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	The Fully-automated Biochemistry Analyzer measures biochemical indexes by analyzing blood and other body fluid, then combines with other clinical information, to help diagnose disease, evaluate organs function, identify disease gene and determine the norm for future therapy.
1.2	**Used by clinical department/ ward**	Diagnostic laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Fully automated, random access chemistry analyzer;The equipment should be capable all Routine STAT and special Biochemical tests including specific protein, threrapeutic grugs, drugs of abuse and user defined applications. 2. Throughput: 400 tests/hour, up to 200t/hour with ISE. 3. Must have dxirect ISE Unit for Na, K and Cl Measurement. 4. ISE Electrode should last for 6 month. 5. Must be open Ended system with bare code reading (optional). 6. System should have 12 Wavelenths 340 to 700 nm. 7. System should be supplied with PC, windows based interface and Bi-directional Connection. 8. Minimumreaction volume of 150 µl built in/stand alone. 9. Must have built inCooled reagent Compartment with minimum 350 ml with sample volume 2- 70 ml. 10 Auto diagnosis of machine errors with message and correction steps. 11. Must have on board capacity for permanent and numbered cuvettes. 12. Seperate reagent probe for R1 and R2 and sample. 13. Laundry System with minimum 5 step washing. 14. Sample dead volume maximum100 µl in sample cup and maximum 50 µl in peadiatric cups. 15. Should have external and internal probe cleaning facility. 16. calibration should be Linear factor, 2 point/point to point/multi point and Exponential with maximum 8 calibrators per test. 17. Sample type should include Serum, plasma, Urine, CSF, body fluids and Supernatant with atleast 70 sample positions for routine and STAT Test.

		18. Should have Light Source with minimum 1000 hrs life cycle with bar code facility with option for bar code on/off. 19. Should have 10, 000 Patient Result Storage 20. Online QC Tracking with Levy and Jennings Chart for upto 30 diffrent points. 21. The Equipment should be FDA/European CE/BIS certified.
2.2	**User's interface**	Built - in/Automatic
2.3	**Software and/or standard of communication(where ever required)**	Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for caliberation, control, patient sample results on daily basis.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	±10%
4.4	**Protection**	Should have over-charging cut-off with visual symbol.
4.5	**Power consumption**	
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. Suitable Water plant/Purification System on RO or any latest technology. 2. External printer. 3. UPS on line pure sine wave for back up of system with PC and IT peripherals for half hour. 4. Open System. 5. One light source.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and supplier should have ISO 13485/US (FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility (EMC) for electromedical equipment: 61326-1 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281

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**	1) Availability of 5 amp socket; 2) Safety and operation check before handover. 3) AC to be provided
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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
9.2	**Maintenance tasks**	NA
9.3	**Service contract clauses, including prices**	NA
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

PORTABLE COMPACT MOBILE LAB WITH ACCU KINE

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Portable Compact Mobile Lab with Accu Kine
GMDN code(s)		
GENERAL		
1. USE		
1.1	**Clinical purpose**	It measures biochemical indexes by analyzing blood and other body fluid, then combines with other clinical information, to help diagnose disease, evaluate organs function.
1.2	**Used by clinical department/ ward**	Bochemistry & Diagnostic.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	PORTABLE COMPACT MOBILE LAB WITH BATTERY and SOLAR POWER BACK UP: LABORATORY IN SUITCASE ENCLOSING following items considered as 1 unit. ACCU-KIN - Blood Analyzer Parameters (37 investigations - LFT, KFT, Lipid, Electrolytes, Glucose, Hematology): Egfr, Glucose, Hb, Urea, Uric acid, SGOT, SGPT, Creatinine, Cholesterol, Total Bilirubin, Direc Bilirubin, Tota Protein, Calcium, Chloride, Sodium, Potassium, LDL, HDL, ALP, Albumin, Triglyceride, Magnesium, Phosphorus, BUN UREA/RATIO, BUN, LDL Calculative, VLDL, HDL/LDL Ratio, Indirect Bilirubin, Globulin, Albumin/Globulin Ratio, RBC, PCV, MCV, MCH, MCHC, CK-MB. a) Wave Length Range: 340 - 650 nm. b) Calibration: Multi Point Calibration. c) Measuring Modes: %Transmission, Absorbance. d) Photometric Accurac: Up to 3 decimal places. e) Optical System (Photo Detector) : Silicon Photodiode. f) Display: Bright Green LCD display. g) Keyboard : Soft push-membrane type. h) Have measurement range from 0.001 to 2.300 Abs. i) Light Source : Patented Solid State Chip based LED which has long life, no Lamps are used thus reduced running expenses and maintenance. Very low power consumption. requires less calibration Light source is much more stable against the lamp because fluctuation in voltage will not effect performance of the equipment. j) Filters :No Filters are used.

		k) It is microprocessor based and above all based on virtual filter technology which makesit more reliable and maintenance free for future. l) Sample System :10mm path length Cuvette based m) Sample Volume Required:5 µL n) Printer Output Device:In built thermal printer available o) Power Supply:12V DC ±10%, 50Hz. p) USB Port:Connectivity to Laptop q) Weight:< 1.5 kg r) Dimensions (in mm):< 280 X 130 X 100 s) No pump system required for flow cell which reduces complexity and delicacy in sample reading and sample analysis. t) ISO Certified, CE marked u) US FDA Registered v) Internal Memory of test storage: 3000 tests **1) Centrifugation Unit** a) Fixed Angle Rotors:6 x 1.5 ml b) Adapter :Adapter for 0.2 ml & 0.5 ml tubes c) Speed :6000 RPM d) Safety Provision:Lid interlocking e) Slots to keep centrifuge tubes :8+ adapter of 16 f) Operation :Quick acceleration to full speed. g) Power Supply:230V AC ±10%, 50Hz. h) Dimension (in mm) :Diameter- 131.5, Height -128 **2) Incubation Unit** a) Temperature Selection: Between 25°C (ambient temperature)to 45°C b) Heating Material:Mica. c) Heating Control :PID Controller d) Sensor Calibration:Simple at the user end. e) Power supply:230V AC ±10%, 50Hz. f) Dimensions:Diameter-155.5, Height -80 mm g) Capacity:25 samples incubation at one time **3) Cuvettes** Sample Capacity :2.5ml Quantity:100 **4) Cuvette Stand** Carrying Capacity :25 X 4 cuvettes:4, made of plastic Quantity:4 **5) Micropipettes** a) Measuring Volume Range :5-50ul b) Measuring Volume Range :100-1000ul **6) Micro Tips** Microtips (sample capacity) :5-50ul Quantity:1000 Macrotips (sample capacity) :100-1000ul Quantity:500 **7) Micro Tip Box :2** a) Micro Box :100 insertions b) Macro Box :100 insertions

		8) Reagents Containers Carrying capacity :10 Units **9) Blood Centriguge Tube** Sample capacity :1.5 ml Quantity:500 **10) Centrifuge Tubes Stand Fixed In The Platform:15**
2.2	**User's interface**	
2.3	**Software and/or standard of communication(where ever required)**	PATIENT MANAGEMENT SOFTWARE Version II - Accurate All 10.0.1 Prerequisites USB Drive:Prolific USB Driver (PL-2303 USB-to-serial) Microsoft Office: XP, 2007 or above (licensed) Database :MS-Access 2007 Java Runtime Environment :1.6 or 1.7 Dropbox For syncing purpose. Processor:IntelCore, DualCore, Core2Duo, Atom, i3, i5. Internet Connection:At the time of Installation and syncing.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	Dimensions (in mm) : 685 X 470 X 285.
3.2	**Weight (lbs, kg)**	< 20 kg
3.4	**Noise (in dBA)**	
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	portable suitcase with omni directional wheels.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power supply : 230V AC ±10%, 50Hz. Solar Panel :Photonex/Tata BP/Power Tech/Equivalent brand Suitcase backside has 3 ports for AC, external battery(12 volt DC) and Solar. panel connection Power circuit is powered by AC supply-230/110 volt, DC/ battery supply - 12 volt and Solar panel (40- 100 watt) as well. g) All the equipments (analyzer, centrifuge, incubator) working on different power sources are distinctively placed on single unbreakable platform in coordination with each other inside the suitcase.
4.2	**Battery operated**	Battery POWER BACK-UP of 4 hours provided via one inbuilt battery and one. external battery pack. External battery can be charged through any external dc power source like vehicle etc.
4.7	**Protection**	
4.8	**Power consumption**	Power to run all components : 40 - 100 watt.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Open System List of deliverables Model : PCML-KIN Particulars QTY. Accuster Mobile Lab Portable Compact Mobile Lab comprising the following1. 1. Accukine Analyzer-USB port :1. 2. Centrifuge :1. 3. Power Backup (Designed for at least 4 hrs. backup): 1. 4. Incubator :1. 5. Case/Mobile Carrying Platform: 1. 6. Cover Bag/Rucksack bag:1. 7. Cuvettes :100 pcs. 8. Centrifuge Tubes: 500pcs.

		9. Cuvette Holder:4pcs. 10. Micropippette (5-50uL):1pc. 11. Micropippette (100-000uL):1pc. 12. Microtips: 1500pcs 13. Micro tip Holder:2pcs. 14. Patient Management Software :1. 15. USB port for data connectivity, data cable, charging cable :1. 16. Reagents Pack consisting of the following : a) KFT (Kidney Function Test) includes Urea/Uric Acid/Creatinine:1. b) LFT (Liver Function Test) includes Albumin/Total Bilirubin :1. c) Lipid Profile includes Cholesterol, HDL/Triglyceride :1. d) Diabetes includes Glucose: 1. e) Anaemia includes Haemoglobin :1. 17. Mini Laptop/Data Recorder loaded with PMS Version II window based: 1. 18. Solar Panel:1.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of4 to 50 deg C and relative humidity of 15 to 90% 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**	ISO - 9001, ISO -13485:2003 CE Marked USFDA Registered.
7.2	**Local and/or international**	Manufacturer should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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**	As per DGS&D standard clause.
9.2	**Maintenance tasks**	
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

SEMI AUTOMATED BIOCHEMISTRY ANALYZER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Semi automated biochemistry analyzer**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	The Semi -automated Biochemistry Analyzer measures biochemical indexes by analyzing blood and other body fluid, then combines with other clinical information, to help diagnose disease, evaluate organs function.
1.2	**Used by clinical department/ ward**	Pathology and diagnostic laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Analyzer should use wet chemistry reagent. 2. Analyzer should have ability to use external cuvettes and intigrated flow cell. 3. Analyzer should have more than 200 programmable channels. 4. Key board should be touch/mechanical. 5. Analyzer should have 5 assay types: End point, Fixed time, Kinetic, absorbance and 1-point caliberation with option for extended keyboard. 6. Analyzer must have caliberation types: Linear factor, multi point, pint to point and Log-Logit. 7. In kinetic essay measurement interval should be 1 second. 8. 3 levels control with day to day levey jennings chart stored and displayed. 9. Flow cell mut be quartz. 10. Flow cell must have optical path of 10mm. 11. Flow cell volumeshould be less than 20 µL. 12. Measurement range should be 25, 30, 37 degree celsius with 1 degree increment. 13. Standard wavelengths in the range of 340-700. 14. Analyzr must store 1000 results. 15. Analyzer resolution must be 0.0001 absorbance unit and absorption range from 0.00-3.00 unit.
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	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.6	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	±10%
4.4	**Protection**	NA
4.5	**Power consumption**	
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. UPS for back up of system for half hour. 2. Light source/Lamp-1 no. 3. Open System 4. Micro pipettes(5 No.) - 2 variable(5-50), (100-1000) 5. Tips 500 - small and 500- big.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and supplier should have ISO 13485/US (FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility (EMC) for electromedical equipment: 61326-1 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281
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**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed

SEMI-AUTOMATED ELISA WASHER & READER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Semi-automated ELISA reader**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	The enzyme-linked immunosorbent assay (ELISA) is a test that uses antibodies and color change to identify a substance.ELISA is a popular format of "wet-lab" type analytic biochemistry assay that uses a solid-phase enzyme immunoassay (EIA) to detect the presence of a substance, usually an antigen, in a liquid sample or wet sample. ELISA evaluates either the presence of antigen or the presence of antibody in a sample, it is a useful tool for determining serum antibody concentrations.
1.2	**Used by clinical department/ ward**	Analytical Laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	**Washer:** 1. The device should be fully automated and easy to operate with 8 and 12 channel manifold. 2. It should be capable to wash flat, round and V bottom plates and strips. 3. It should have large display along with more than 40- 50 program storage facility. 4. System should have calibration facility. 5. System should have warning/alarm for waste container full; wash bottle empty. 6. Residual volume after washing should be < 2ul. 7. It should have specially designed peristaltic pump to dispense 50 - 400 ul. 8. It should be supplied with waste bottle, wash bottle and rinse bottle of capacity 2 liters with tubings. 9. It should have option of washing cycles. 10. Cross wise aspiration, over flow washing, bottom washing. Automatic manifold detection. 11. Equipment should be un-pressurized, capable of using any bottle or container for washing.It should be suitable for UV & flat bottom micro plate.
		Microplate Reader: 1. Bichromatic/Optics with six wavelenths. 2. Trichromatic Light source.

		3. Internal Printer with port for external printer. 4. Should read ELISA Plate Horizontally A to Hand and verically 1 to 12. 5. Photometric Accuracy should be ±3%. 6. Print Out of whole plate in Matrix Format. 7. Linear measurement range 0 to 4 Absorbance unit. 8. Interference, filters. 9. Filters of 405, 450, 492, 630 nm with two extra positions.
2.3	**Software and/or standard of communication(where ever required)**	Compatibilty with external Printer.
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Stationary lab Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Operable at- Input voltage- 220V-240V AC, 50Hz.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	±10%
4.4	**Protection**	
4.5	**Power consumption**	
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	1) External dot matrix printer. 2) Light/Lamp source. 3) Multichannel pipette with variable dispensing volume 50-200 ul. 4) Paper rolls for internal printer- 10 nos.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic. Compatibility(EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, IEC 61010-101, IEC 61010-2-40 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO certificate for quality standard.

8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Should be operable at 220 -240 volts (50 - 60 Hz). 2) Safety and operation check before handover.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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 documente.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

SEMI-AUTOMATED URINE STRIP ANALYSER

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Semi- Automated Urine Strip Analyser**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used in biochemical labs for identification of specific bio-chemical marker in urine like Glucose, Ketones proteins pH etc. in clinical conditions like Diabetes, Renal failure Acidosis etc.
1.2	**Used by clinical department/ ward**	Biochemistry Laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Type: reflectance photometer Throughput of min 50 strips/hour at two. levels - normal and abnormal. Memory: patient test results: 1000 and QC test results: 50. Display: touch-screen LCD Should have flagging facility Should be Able to analyse 10 Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Blood Specific: gravity, Ketones, Bilirubin, Glucose.
2.2	**User's interface**	Manual: with USB interface/Rs 232.
2.3	**Software and/or standard of communication(where ever required)**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)		
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz.
4.2	**Battery operated**	Yes
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Should have over-charging cut-off with visual symbol.
4.5	**Power consumption**	Less than 50 W

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	1) Thermal Paper 10 rolls. 2) Test Strips price to be declared and 1000 test strips to be provided. 3) Caliberation strip 2.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485/US(FDA)/EU(CE) certification for quality standards. 3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1. 4. Certified to be compliant with IEC 61010-1, IEC 61010-2-281, 61010-2-101 for safety.
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**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection 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. DOCUMENTATION		
9.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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;
9.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
10. NOTES		
10.1	**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;
10.2	**Recommendations or warnings**	Any warning signs would be adequately displayed.

300 mA HF X-RAY MACHINE

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**300 mA HF X-Ray machine**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiography of the bones and fractures and other arthropathies. X-Ray Chest for the supportive diagnosis of the Pulmonary Tuberculosis X-Ray Pelvis (KUB) for renal disorders and stones. Sinusitis, Fractures of the Skull Cardiac diseases and cardiac enlargement Silicosis and other respiratory conditions, like Pleual effusion, hydrothorax, Pneumothorax Peritonitis by X-Ray abdomen.
1.2	**Used by clinical department/ ward**	
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	High Frequency X-Ray machine suitable for general Radiography. **X-Ray Generator** • High Frequency X-Ray generator having Frequency of 40 KHz more suitable for Radiography should be provided. • Power output of generator should be 25 KW or more. • Radiography KV range should be 40 to 110 KV or more. • mA range (Rad.) : 300mA or more • Exposure time (Rad.): 1 ms to 2 sec. with maximum numbers of steps. **Control:** • A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with Spill Proof design Following features should be available on the control panel. • Machine ON/OFF switch • Digital Display of KV& mAs.• K V & mAs increase and decrease switches. • Tube focal spot selection switch.• Ready and x-ray on switch ith indicators. • Bucky Selection switch. • Self diagnostic Programme with Indicators for Earth fault error, KV error, filament error & Tube's Thermal Overload. **X-Ray Tube** • One No Dual focus Rotating Anode BEL/Toshiba/Imported X-ray tube thermally protected having focal spot: • 1mm or less small Focus, 2mm or less large Focus.

		• Anode heat storage capacity of tube should be more than 140 KHU. • One no manual collimator with aluminum filter & for adjustment of exposure area. **Column Stand:** • It should have floor to ceiling stand with vertical counter balanced travel. • It should have 360 deg. Rotation. • It should be provided one vertical bucky stand with machine. • Table. • Five position manual tilt table having buky grid ration of 8:1 with 85 lines per inches should be provided. • The bucky tray should accept cassette of 8"x10", 10"x12" and 14"x17" size.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (where ever required)**	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.6	**Mobility, portability**	Certified Room Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power unit: Input voltage- 400V-440V AC, 50Hz ;3 -phase
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Stabliser of appropriate capacity to be installled.
4.5	**Power consumption**	25 to 30 KW.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	Machine should be supplied with following transducers: I. 2 No. BARC Approved whole body lead apporns with all attachements. II. One Pair of 8 meter H. V. Cable.
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/European CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)

		4. Shall meet internationally recognised for Electromagnetic Compatibility (EMI/EMC) for electromedical equipment: 61326-1. 5. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety. 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**	1) Availability of three phase uniform power supply. 2) Safety and operation check before handover. 3) To be installed in a separate room. 4) Facility for dark room should be availlable.
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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed.

COLOR DOPPLER FLOW ULTRASOUND

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		**Color Doppler Machine**
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Doppler ultrasonography is a non-invasive diagnostic procedure that changes sound waves into an image that can be viewed on a monitor. an ultrasonic technique for detecting anatomic details by color coding of velocity shifts. In cardiography blood flowing in one direction appears red, and blood flowing in the opposite direction appears blue. The technique can also indicate the velocity of red blood corpuscles moving through the circulatory system, which makes it possible to quantify the flow, measure the pressures within the heart chambers, and calculate the stroke volume. In laparoscopy, Doppler color flow allows for rapid identification and differentiation of ducts and valves in the viscera, particularly in detection and diagnosis of pancreatic and liver tumors and colorectal liver metastases.
1.2	**Used by clinical department/ ward**	Radiology diagnostic laboratories.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	The system should be state art with full Digital Technology & should be capable of whole body sonography & other application for adult & pediatrics (Infants & Neonates) which includes abdominal, Obs/Gyn, Endovascular, Peripheral vascular, transcranial, transvaginal, transrectal & small parts. 1) The system should incorporate facility for high resolution 2D, 3D, M mode, PW color imaging, Power Doppler Angio Imaging Modes. 2) The system should have more than 20000 Digital Channels & on the site to higher number of channels (preferable). 3) The system should have 256 Grey shade or more. 4) The system should have capability of triplex display in real time with all probes. 5) The system should have a very high frame rate of 700 frames per second or more.Please specify frame rate in triplex mode. 6) The system should have Harmonic imaging for hard to image patients. The system shall support Tissue Harmonic Imaging capability on phased, linear, 3D and curved array transducers. 7) The system should have advance image processing algorithms to analyze between targets & artifacts so as to sharpen target anatomy, reduce the sparkle & artifacts to improve image quality.

		8) The system shall offer Harmonic Imaging in Power Doppler Imaging mode for improved sensitivity and specificity in differentiating blood/ agent from tissue. 9) The system should have facility for Zoom(Real-time and Frozen-image) & manipulation of image through pre-processing and post-processing with cine loop viewing image of all modes. 10) System should have disc of atleast 500 GB or more. 11) The system should have facility of digital storage & retrieval of B/W & color image data(Both frozen & cine loops) on built in as well as ramble media(CD, DVD)USB port. 12) The system should have automatic real time quantification of Doppler parameter like velocity, frequency, time heart rate stop, flow volume, plasticity index, resistivity index, peak velocity, average value, point value, area & diameter flow volume etc. 13) The system should have high dynamic range of 170 dB with scanning depth of 30 cm or more. 14) All transducers(minimum 3) should be broadbandwidth, Frequency range 2 to 12 MHz or more with universal ports for transducer interchange. Two active ports and one parking probe is required. 15) System should have 19" HD display with tilt and swivel Facility along with alphanumeric keyboard with illuyminating keys and status functinon. 16) Dicom 3.0 compatible. 17) Review of stored images is desirable.
2.2	**User's interface**	Software, Automatic (stages to be displayed or recordable for printing).
2.3	**Software and/or standard of communication (where ever required)**	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system.
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism.
3.6	**Mobility, portability**	Certified Room Installation.
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power unit: Input voltage- 220V-240V AC, 50Hz Single-phase.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**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 supplied with following transducers: I. Broad band convex array transducer with multi-frequency range of 2 to 5 MHz or wider range-1 No. II. Broad band transvaginal/transrectal probe with multi-frequency range between 5 to 8 MHz or wider range-1 No. III. Linear probe Transducer 5 to 12 MHz or more.

		The system should have following documentation devices a) Laser color printer for color image printing b) B/W Thermal printer of latest model c) Glazed thermal paper rolls 50 no. & 5 rim of Glossy paper sheet. d) Online UPS for power back up of minimum 30 minutes e) 50 nos. of CDs to be supplied
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/European CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard) 5. Shall meet internationally recognised for Electromagnetic Compatibility (EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety.
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: ature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover; 3) To be installed in a separate room.
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 for 2 weeks; 2)Advanced maintenance tasks required shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

ULTRASOUND MACHINE

Version no. :		1
Date:		5/12/2014
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Ultrasound system
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Diagnostic sonography (ultrasonography) is an ultrasound-based diagnostic imaging technique used for visualizing internal body structures including tendons, muscles, joints, vessels and internal organs for possible pathology orlesions. The practice of examining pregnant women using ultrasound is called obstetric sonography, and is widely used.
1.2	**Used by clinical department/ ward**	Radiology laboratories
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1		**Ultrasound scanner with integrated trolley with probe, soft touch alphanumeric key board with track ball:** 1. With panel switches & control's easily operable. 2. Integrated high resolution Monitor(17"). 3. Probes & Gel holder-conviniently placed (2 each). **Following transducers are to be supplied:** 1. A-2.0-5.0 MHz Multi frequency Convex Transducer-One. 2. B-5.0-12.0 MHz Multi frequency Linear transducer-One. 3. C-5.0-8.0 MHz or more Endo Cavitory probe-One. **(+/- 1 MHz to be allowed for each):** a. All probes should be electronic transducers and multi-frequency preferably three frequencies and should give aperture & depths of scanning. b. Controls for Depth, gain compensation, body markers with transducers position. c. Real-time continuous dynamic focus. d. Auto annotation facility anywhere on image. e. Image display in B, B/M&M Model(2B&2D). f. Zoom facility minimum five times or more. g. Shades of grey 256 h.Inbuilt cine memory.

		h. Unite should be capable of measuring BPD, CRL, FL & AC and other GA parameters. i. Facility for image magnification, inversion, changing, scan, direction, freeze facility. j. 8 step STC/GTC should be available. k. Frame rate minimum 50 FPS, hard disk capacity of 200GB or more. l. Caliper with trackball for the measurement of distances circumfrences, area volume etc. should be possible to make different measurement on single image. m. Alphanumeric key board, p.Panel Switches & Foot Controls. n. Patient reports for Obs/Gynae including fetal growth trend, including Histogram facility for Tissue texture & Trend graph for IUGR cases, Urology and orthopedics. o. Give the gain adjustable/Range & its steps. p. Calculations needed, Velocity, Heart rate, Volume addl. modes. q. Dicom 3.0 compatible. r. Review of stored images is desirable. s. Channels: 1000 or more. t. Depth: 25 to 30 cm. u. Dynamic range: 170dB & above. v. Cine loop preivew for minimum 60 secs or more. w. Minimum 2 active ports should be there.
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)**	Max: 400mm (L) x 300mm (W) 160mm (H)
3.2	**Weight (lbs, kg)**	Max:17 lbs
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Portable
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Should have over-charging cut-off with visual symbol.
4.5	**Power consumption**	-
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)**	The system should be supplied with the following accessories: 1. B & W thermal printer with 50 rolls. 2. Two KVA online suitable UPS.

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 to 90% 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 FDA/CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements (or equivalent BIS Standard). 4. Shall meet internationally recognised for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 5. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety.
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**	1) Availability of 5 amp socket. 2) Safety and operation check before hand over. 3) Machine to be installed only when PNDT registration is obtained by health care facility.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection from the manufacturer
8.3	**Training of staff (medical, paramedical, technicians)**	1) Training of users on operation and basic maintenance atleast for two weeks. 2) Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: 1) User, technical and maintenance manuals to 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 important spares and accessories, with their part numbers 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 signs would be adequately displayed.

500 mA X-RAY MACHINE(HF)

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		500 mA X-Ray Machine(HF)
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiography of the bones and fractures and other arthropathies. X- Ray Chest for the supportive diagnosis of the Pulmonary Tuberculosis. X - Ray Pelvis (KUB) for renal disorders and stones. Sinusitis, Fractures of the Skull. Cardiac diseases and cardiac enlargement. Silicosis and other respiratory conditions, like Pleual effusion,, hydrothorax, Pneumothorax. Peritonitis by X-Ray abdomen.
1.2	**Used by clinical department/ ward**	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	High frequency X-Ray machine suitable for general radiography. **X-RAY GENERATOR:** - High Frequency X-Ray Generator having frequency of 50KHz or more should be provided. - Power output of generator should be 50KW. - Radiographic KV Range should be 40 to 125KV. - mA Range (Rad.): 500mA or more. - Exposure time (Rad.): 1ms to 3Sec. - mAs Range (Rad.): 1 to 200mAs. **CONTROL:** A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in Floor or Wall mount with Spill Proof design. Following features should be available 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. • Anatomical Programming Radiography (i.e. APR) should have Preprogrammed parameters of human Anatomy Up to 216 programs which helps the user to select exposure parameters based on bodypart, examination view and size of the patient.
2.1	**Technical characteristics (specific to this type of device)**	A dual action hand switch with retractable cord should be provided for Radiation Protection of Operator. There should be provision for a cordless Exposure switch also. There should be provision of auto shut off of Control if no key is pressed for 10Min. **X-RAY TUBE:** - Two Nos. Dual focus Rotating Anode X-Ray tube thermally protected - Anode heat storage capacity of tube should be more than 140KHU. - Two Pair of 8 meter H.V. Cable. - Two Nos. Collimator with auto shut off facility should be provided. **HV TANK:** A very compact H.V. Tank filled with high dielectric transformer oil should be provided. The H.V. Tank should contain H.V. transformer, Filament Transformers, H.V. Rectifiers & H.V. Cable receptacles. **TUBE STAND:** - Floor to Ceiling Stand with Counter Balanced Tube Head (Rotatable ± 180 Degree), 360 Degree Rotatable; mounted on Floor Ceiling Rails for convenient movements should be provided.
2.1	**Technical characteristics (specific to this type of device)**	TABLE: - Motorized table should have motorized bucky consisting of bucky grid of size 17 ¼" x 18 7/8" ratio 8:1, 85 lines/inch. Spot Film Device (semi automatic) capable of doing all routine spot filming (4 on 1, 2 on 1, 1 on 1) for use with 8" x 10", 10" x 12", 14" x 14" cassettes. Grid size 15" x 15", 6:1 ratio, 103 lines per inch. Compression movement of spot film device is motorized. The fluoroscopic parameters (fluoro KV, fluoro mA and fluoro time) should be digitally displayed on the SFD. Control of fluoro KV should be available on SFD. VERTICAL BUCKY STAND: • Vertical Bucky Stand with oscillating Grid of Ratio 8:1, 85 lines/inch is provided. • The Bucky moves up & down & is equipped with a stainless steel cassette tray. • The stand is floor-mounted type & can accommodate cassettes up to 14" X 17". The Bucky is tilted in 6 steps of 15 degree Angle each for various Radiographs.
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	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power supply: 230V, AC, 50Hz. 15 Amps ,three phase, Line resistance < 0.4 ohms
4.2	**Battery operated**	no
4.3	**Tolerance (to variations, shutdowns)**	line regulation of ±10%.
4.4	**Protection**	NA
4.5	**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 supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements.
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 and IEC 62304 7. 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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

C-ARM SYSTEM(HF)

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		C-ARM System(HF)
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	C-arm machine is a device used by a physician/surgeon to guide surgical instruments while watching the instrument being driven on a live x-ray machine
1.2	**Used by clinical department/ ward**	OT and Screening labs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	High End C-Arm with large LCD display. 1K X 1K High resolution imaging chain with progressive scan CCD camera, 9" Image Intensifier and dedicated computer based acquisition system. The movements should be smooth having very simple positioning mechanism. X-RAY GENERATOR: High Frequency 50 KHz X-Ray Generator with power output 5KW or more should be provided. Following modes should be provided: o Radiography o Fluoroscopy selection of continuous, single pulse, multi pulse should be there. o KV Range (Rad./Fluoro): 40 to 120KVP in 1KV/Step. o Radiographic mA Range: more than 100mA o Fluoroscopy mA output: Up to 5mA (Normal Fluoroscopy) o Up to 20mA (Boosted fluoroscopy) o mAs output: 0.1 - 200mAs or more X-RAY TUBE: o Dual focus Rotating Anode X-Ray Tube of focal spot 0.3mm (small) & 0.6mm (large) to be provided. o Anode heat storage capacity should be more than 250KHU. o Iris Collimator should be provided.

2.1	**Technical characteristics (specific to this type of device)**	CONTROL PANEL: A very compact, soft touch control panel(A.P.R) with 20 X 3 (column x rows) L.C.D display on which KV, mAs, fluoro time, FmA, I.I ZOOM, Error inter lock for KV, filament, thermal are displayed on wide angle LCD. Console panel has following functions & indications. o Anatomical programming for radiography of 4 body parts (up to 8 programmes). o Selection of Continuous/multi pulse/single pulse fluoroscopy. o Machine ON/OFF switch. o Collimator's position adjustment. o I.I magnification(I.I field) selection switch o "Emergency Flouro". o Flouro and Radio mode selection. o In built radio timer that enables to select mAS from 0.1 to 300 in 25steps for radiography. o Fluoroscopy timer (Five minute cumulative timer with buzzer that activates after the completion of 300seconds of exposure and to reinitiate the exposure reset switch is provided.) o ABS (Automatic brightness Stabilization) selection for hands free operation. o KV and mAs increase and decrease switches. o X-Ray on switch with indicators. o Switches for up/down movement of "C". o Emergency OFF Switch on the control panel
2.1	**Technical characteristics (specific to this type of device)**	STAND: o Up/Down movement (Noise free Actuator movement): At least 430mm o Horizontal Movement: At least 210 mm. o Arc Orbital: 90° + 30° (120°) o Wig wag: ± 12.5° (25°) o Rotation: ± 360° (with I.I. Safety lock) o Focus Screen Distance: 950mm or more o C Depth: 600mm or more o Locks: Locks for all the movements. o Foot lock: Control Stand foot lock. o Steering wheel for easy steering & movement should be available. High resolution Imaging Chain: o 9 Inches, Triple Field Image Intensifier should be provided.. o CCD Camera with a progressive scan sensor of 2/3" of 1K x1K Medical Grade o The acquisition should be made at 14 bits. MEMORY SYSTEM: PC based memory system with the following features should be provided:- o Image processing software with Real time image capturing, storage, and display in 1kX1k format o Boosted Fluoroscopy (CINE) up to 30 FPS with real time recording on Hard Disk Drive. o More than 1000 image storage capacity in 1kX1K format o Dicom 3.0 Ready o Dicom CD/DVD

2.1	**Technical characteristics (specific to this type of device)**	o Connectivity with PACS and HIS o Length and angle Measurements with Annotation o Pre Programming for Image setting for different operating Modes. o Image Flipping and Image rotation o WW/WL adjustments o Recursive Filters for image smoothening o Programmable Motion Detection facility o Gamma Curve adjustments for optimum image quality. o Image Zoom with Pan o Image Inversion MONITORS: 02Nos. Medical Grade Monochrome high brightness, High contrast 19" LCD Monitors should be provided. High-end monitor trolley with foldable monitors, actuator assisted height adjustable movement of monitors to facilitate viewing of images at most convenient eye level position, specially designed integrated keyboard having feather touch keys and touch pad should be provided instead of double unit keyboard and mouse, 5" wheels for better mobility
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	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Mobile
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power supply: 230V, AC, 50Hz. 15 Amps ,single phase, Line resistance < 0.4 ohms
4.2	**Battery operated**	no
4.3	**Tolerance (to variations, shutdowns)**	line regulation of ±10%.
4.4	**Protection**	NA
4.5	**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 supplied with following transducers:- I. 5 No. BARC Approved whole body lead apporns with all attachements.
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 and IEC 62304 7. 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**	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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

CR SYSTEM

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		CR System
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used for Digitization of the already existing Analog X-ray Systems giving advantage of image processing and increased speed Ideal for Medium workload facilities and Secondary care facilities.
1.2	**Used by clinical department/ ward**	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Digitizer (CR) system should have capacity to process more than 70 or more cassette/films per hour of 14 X 17" size. 2. Standard work station (Console) coupled with CR image storage capacity – at least 2000 images specify the numbers. It should have a resolution of 5 pixels/mm (Minimum) for standard resolution cassette & up to 20 pixels/mm or more. 3. Separate DICOM workstation in ultra modality with all processing facilities in a centralized reporting. 4. Other feature of CR system. • Image post processing. • Window leveling • Annotation • Area of interest Zoom • Magnification • Flipping & panning • Automatic exposure correction • Pre view software • Edge enhancement stepwise • Contrast/Brightness adjustment • Shuttering / ROI Finder • Application related software like Pediatric should be available – The system should have software & hardware to perform full leg/Full spine/ Long Body imaging/imaging stitching. • DICOM Print • DICOM image output to network workstation. • Grid Pattern removal software & noise compression processing. • Gray Scale reversal • Rotation • Image preview time 25 to 60 Sec. (For large image)

2.1	**Technical characteristics (specific to this type of device)**	System should be fully complaint with DICOM 3. • Automatic cassette identification through bar code reader. 5. Laser camera with at-least three film size on line 14"X 17", 11"X 14"/ 10" X 14", 10" X 12", & 8" X 10" 6. • Contrast spatial / Reading resolution 10 pixel/ mm or more constant high resolution in all sizes. True size printing should be possible from reader console. Automatic exposure correction & facility for maneuvering reading sensitivity manually. Gamma curves for multiple object intensity processing. Registration & cassette identification should b e possible to be done before & after the exposure (Pre/Post registration) 7. Specification for Laser Camera • Mention Spatial resolution higher level preferable minimum 500 DPI/PPI. • Mention Gray Scale resolution : more than 12 bits preferable • Mention Processing capacity/hour for (14" X 17") films, It should be more than 70 films /Hour 8. Acceptable film size: 14"X 17", 11"X 14"/ 10" X 14", 10" X 12", & 8" X 10". • Online film size : at least three film size • DICOM compatible
2.1	**Technical characteristics (specific to this type of device)**	9. CR workstation should have following feature • Multiple image printing with multiple format • Measurement of image, insert scale • Preloaded annotation • DICOM CD writing & reading • Image inverse, image flipping, image magnification, zooming • Reporting format • Image preview • Image cropping • Printing multiple patient on one film • CD writing for multiple patient on one CD • Should have a hard disk of 80 GB or more for storing image.
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	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power supply: 230V, AC, 50Hz.
4.2	**Battery operated**	no

4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	NA
4.5	**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 supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements. II. Please provide cassette for CR with PSP Plate (IP) 14" X 17" -2 No. 11" X 14" /10"X14"-2 No. 10"X12"-2 No. III. Suitable online pure sine wave UPs for 30 minute backup IV Closed System??? V Compatible computer System with 2 medical grade monitors
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 and IEC 62304
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
9.2	**Maintenance tasks**	CMC 5 years. 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.

9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

DIGITAL RADIOGRAPHY SYSTEM(HF)

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Digital Radiography System(HF)
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used for Radiographic Images in a digital format (DICOM) greatly reducing the time for image capture and processing. Ideal for heavy workload facilities and tertiary care facilities.
1.2	**Used by clinical department/ ward**	Radiology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Unit should be High frequency Digital Radiography system with rotating anode X-Ray tube. 3D ceiling suspended stand with Autotracking. 2 separate detectors be provided. One in table and one in the vertical bucky each. System should have following features. A. HIGH FREQUENCY GENERATOR: Generator should be of latest technology with high frequency 40KHz or more X-Ray generator. Constant Power output of 65KW. KV range should be 40 to 150KV in 1KV/step. mA output: 800 mA mAs range should be 1 to 600mAs or more. It should have solid state automatic exposure control device. B. TUBE: A Dual focus Rotating anode X-ray tube. Large Anode Heat storage capacity for high patient throughput (250KHU or more). Multi leaf collimator having halogen lamp / bright light source and auto shut provision of the light. HV Cable: 1 Pair of 12 meter HV cable. C. Fully Integrated x-ray generator console control: • System should be fully integrated. All the exposure factors should be controlled from the image acquisition computer and exposure parameters information should be attached to acquired image in DICOM format. • System should have unlimited Anatomical Programs (APR). • Anatomical Programs should be flexible and should be editable by user according to his/her convenience. • Exposure interlocks and self diagnostic messages should be available on Image acquisitions computer for easy troubleshooting of the system.

2.1	**Technical characteristics (specific to this type of device)**	D. Stand: 3D- Ceiling Suspended tube stand should be a new generation stand providing the user three-dimensional movements of the tube head covering a huge area. Noiseless and swift up/down movement of the tube head should be provided. • Stand should have Auto tracking facility with table & vertical bucky stand. • Stand should have motorized Longitudinal, Transverse and vertical movement with automatic stop. It should have Tube Head Rotation along its axis. • Movements of stand should be: – Longitudinal movement motorized: 2500mm or more – Transverse movement motorized: 1500mm or more – Vertical up/down movement motorized: 1000mm or more – Tube head Rotation (along with Vertical Column axis): ±90° – Tube head rotation along Horizontal axis - ±90° • Smart collision avoidance system should be provided. • Manual override facility for x and y axis. • Electromagnetic locks should be available for comfortable operations. Digital touch based display should be available on the X-ray tube/Collimator Assembly atleast with following features: • Display and control of Exposure parameters like KV and MAS • Display and control of Mechanical parameters like SID and tube Inclination • Display of APR and patient position guide image • Display of Acquired x-ray image
2.1	**Technical characteristics (specific to this type of device)**	The autotracking system should also be capable of doing motorized oblique tracking with Vertical Bucky Stand during special cases. E. Table: Horizontal table with floating tabletop and adjustable height should be provided. Tabletop should have three-dimensional movement, for ease of operation and use by patients. • Table should be provided with Inbuilt FPD (FLAT PANEL DETECTOR) beneath the tabletop having manual movement. It should have electromagnetic locking facility and should be unlocked by the foot switch for its movement. • Transverse and longitudinal movements of the tabletop should be locked by electromagnetic locks. • Table should have up/ down motorized movement and it should be controlled by two up & down foot switches. • Movements of table top should be: Transverse movement: 18cm or more, Longitudinal movement: 45cm or more. Height adjustment facility should be available. • Maximum weight carrying capacity for the table during up/down movement should be 150Kg or more. F. Vertical Bucky (VB) Stand: Floor mounted Motorized Vertical bucky stand should have inbuilt FPD (FLAT PANEL DETECTOR) for lung and skeleton x-ray examinations. It should have user friendly design and handling. VB stand should have provision to do chest radiography with and without grid. Motorized Tilting should be -30 degree to + 90 degree. Vertical Up Down Movement Speed should be 60mm/sec or more G. Flat panel Detector (Each for Table bucky and vertical bucky) : A complete imaging solution with cutting edge of performance integrated with X-ray systems.

2.1	**Technical characteristics (specific to this type of device)**	Specifications: The detector should be flat panel type with A-Si (amorphous silicon) and CsI for scintillation. Size of detector must be 43cm x 43cm. Active Image matrix 3K x 3K. Image depth should be 14bit. Pixel size should be less than 150um (Smaller pixel size is proffered) Detector resolution should be more than 3.3 lp/mm. DQE (Detector Quantum Efficiency) should be more than 65%. H. IMAGE ACQUISITION SOFTWARE: SOFTWARE provides complete control of all image capture functions within the examination room, enhancing the entire workflow by delivering diagnostic images instantly, and allowing users to move X-ray images electronically to remote workstations, image archives, and printers, also has the super excellent performance on image quality control such as:
2.1	**Technical characteristics (specific to this type of device)**	i. Image Acquisition and Processing: • Digital image processing technology • Preview image should be available in less than 5 seconds. • Processed image should appear in less than 8 seconds. • Exam Specific Algorithms image processing for consistent image quality of all body parts. • Automatic image optimization • Image harmonization algorithms for uniform images. • Preset image processing tools for different anatomy • Preset GAMMA correction table with manual override • Image cropping • Image mirror, rotate. • Image annotation with circle, square, rectangle, Arrow markers • Add image accept/reject comments • Rejected images archival with provision of converting them to Accepted images. • Separate log for Rejected, Accepted and Printed images. • True size for printing • User defined printing formats. • Should have high image storage capacity with 1TB HDD. ii. Dose Reduction: • Advanced noise reduction and image enhancement technology for best image quality at minimum dose.
2.1	**Technical characteristics (specific to this type of device)**	iii. Excellent Maintainability • Remote online system diagnosis • Remote online software upgrade • Image quality control tools • Easy and quick Offset and gain calibration with bad pixel removal algorithm. • Automatic programmed offset calibration for best image quality. iv. Full DICOM 3.0 Compatibility • Get DICOM work list from HIS/RIS • Store Images through PACS network system • Support user defined format DICOM image print • Support DICOM MPPS v. Image Management: • Resend/ Reprint image

		• Send/print queue management • Re-preview image • Protect patient record • Rejected image management Image Stitching: Image stitching software should be provided for long limb imaging. At least 4 images should be stitched together.
2.1	**Technical characteristics (specific to this type of device)**	H. MONITORS: 1 No. 19" High Brightness Monochrome LCD Medical grade monitor should be provided. additional Work station: Additional workstation should be provided. It should have following features: • DICOM connectivity • Image review • Image processing • Patient Reporting • Image SEND, RECEIVE, PRINT facility • Should have DIOCM connectivity for existing PACS, RIS system. • Should have large image archival capacity (at least 1TB HDD).
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	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	Power Requirements	Power supply: 230V, AC, 50Hz. 15 Amps ,three phase, Line resistance < 0.4 ohms.
4.2	Battery operated	no
4.3	Tolerance (to variations, shutdowns)	line regulation of ±10%.
4.4	Protection	NA
4.5	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 supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements.
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 and IEC 62304 7. 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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
		10. DOCUMENTATION
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

MOBILE X-RAY MACHINE(HF)

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Mobile X-ray machine(HF)
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Used to get the radiographic images where patient mobility to stationary installation is compromised such as use of other life support equipment. Finds great utility in intensive care units.
1.2	**Used by clinical department/ ward**	Intensive care units and radiology deparment
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Mobile X-Ray machine: – High Frequency generator of 40KHz or more. – Radiographic KV: 40 to 110KV. – Rad mA: 150mA or more – Output power: 6.0 KW. – mAs range: 1 to 200mAs X-Ray tube head: – Monoblock version X-Ray Tube Head with Stationary Anode Single focus X-Ray Tube. The monoblock consists of Tube, H.V. transformer, filament transformer, H.V. Rectifiers & Capacitors, all immersed in High Grade, High dielectric oil. – One No. Manual Collimator should be provided, with auto off facility. Tube Stand: Mobile Stand with 4-wheel design, which ensures easy mobility and steering. The Spring Balance Stand should be very light in weight with tube arm. It should be very easy to maneuver & allows smooth movements of Tube Head in vertical Plane. Lead lined cassette storage box. Large wheels for easy mobility should be provided. The stand is designed for maximum maneuverability of the unit and is able to achieve tube focus to floor distance of minimum 75 inch and tube focus to tabletop distance of minimum 46 inches (Standard Radiography Table). The equipment should occupy minimum floor area & is capable to be taken through elevators with ease.
2.1	**Technical characteristics (specific to this type of device)**	Control Panel: • KV Increase & Decrease Switches. • mAs Increase & Decrease Switches • Machine ON/OFF Switch.

		• Collimator Lamp 'ON' Switch. • Stand by & Exposure Switch. • Self diagnostic Programme with indicators for:- o Earth fault Error o KV Error o Filament Error o Tube head Thermal Error • Stand by (Ready) & X-Ray On Indicator. • Incoming Voltage Indicator. There should be provision for the machine to work from 190Volts Input supply to 250V input supply. • Anatomical Programming Radiography (i.e. APR) should be provided in which KV and mAs are automatically selected depending upon the physique of the patient and part of the body to be X-Rayed. Anatomical Programming up to 200 programmers or more There should be a provision that the control should get off, if no key is pressed for 10Min. A Hand Switch with Dual action for exposure Release with Retractable Cord is provided for Radiation Protection to the Operator. There should be cordless remote for exposure along with corded exposure switch.
2.2	**User's interface**	manual
2.3	**Software and/or standard of communication(where ever required)**	
	3. PHYSICAL CHARACTERISTICS	
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	mobile
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ....)	
4.1	**Power Requirements**	Power supply: 230V, AC, 50Hz. 15 Amps ,single phase, Line resistance < 0.4 ohms
4.2	**Battery operated**	no
4.3	**Tolerance (to variations, shutdowns)**	line regulation of ±10%.
4.4	**Protection**	NA
4.5	**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 supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements.
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 7. 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**	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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

MAMOGRAPHY

Version no. :		1
Date:		23/12/2014
Done by : (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Mamography
GMDN code		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A mammography is a screening tool used to detect and diagnose breast cancer
1.2	**Used by clinical department/ ward**	Radiology/Oncology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	A) X-RAY GENERATOR – High Frequency 40KHz or more X-Ray Generator should be provided. – Power of generator should be more than 5KW. – Maximum mA output should be more than 190mA – KV Range should be 22 to 35KV in steps of increment of 0.5 KV each. – mAs Range for large filament should be from 1 mAs to 700 mAs or more. – 1 No. High Voltage Cable should be provided. B) X-RAY TUBE – Rotating Anode X-Ray Tube having dual focus, dual angle should be provided. – Focal Spots: Small Focus = 0.1 mm^2 Large Focus = 0.3 mm^2 – Anode Heat Storage Capacity 300KHU – Tube Assembly Heat capacity should be at least 1.5MHU C) CONTROL PANEL – Micro Processor controlled Feather Touch Control Panel with LCD display should be provided. – KV Range should be 22 to 35 KV in steps of increment of 0.5 KV each. – mAs Range should be from 1 mAs to 700 mAs or more. – Technique selection: Manual Two Point Technique (i.e. KV, mAs) should be possible. – Anatomic Program (APR) for small, medium & Large breasts should be provided. – more than 2 Film Screen Combinations should be provided.

2.1	**Technical characteristics (specific to this type of device)**	More than 2 Step Film Density Control should be provided – Multi chamber solid state Automatic Exposure Control (AEC) device should be provided – Automatic selection of filter as per the KV selected (Molybdenum Filter and Aluminum Filter) should be provided. – Following Digital display should be provided: • LCD Display on Control Panel • KV • mAs • Focus • AEC/APR mode • Diagnostic Interlocks of the equipment • Filter Selected • Large format LCD display on the stand • Compression force in Kg • Compressed breast thickness • Gantry angle – Following Switches and indicators should be provided: • Focal Spot Selection Switch • Machine ON/OFF Switch • Ready and X-Ray Switch. • AEC/APR selection switch • Film density and Film screen selection switch • Ready and x-ray exposure indicator. Breast Release mechanism in case of power failure:
2.1	**Technical characteristics (specific to this type of device)**	Push to OFF type emergency switches should be available on both sides of gantry to release breast in case of power failure. This mechanism should operate from a battery inside the equipment. Below Safety features should be provided: • Microcontroller based embedded platform to ensure accurate delivery of exposure parameters. • Automatic compression locking after maximum compression of compression paddle. • Earthing interlock is provided in the machine for safety of user and machine. (Without proper earthing machine would show error). • Fast Compression release mechanism in case if patient is uncomfortable with compression. • Automatic breast release after x-ray exposure is completed. D) STAND ASSEMBLY – A compact Stand having Iso-Centric movement on which C-Arm containing X-Ray Tube & Bucky Assembly is mounted should be provided. – Vertical Movement (Motor operated) should be 650mm or more. – Motorized rotation: +180degree – 165 degree – Source to image distance (SID) should be 600mm or more

		– Breast Compression: Automatic compression with digital display of compression force should be provided. (Provision should be given for the release of compression paddle on power failure) the Switch for activation & release. Adjustable compression force should be available. Automatic Compression release after Exposure completion should be available. – Compression Paddles for Normal & Magnification Mode (Spot Compression) should be provided – Magnification Device: 1.5X and 1.8 X should be provided.
2.1	**Technical characteristics (specific to this type of device)**	18 x 24 cm Bucky, Motor operated Oscillating Grid of Size 18 X 26 cm, 5:1, 30 lines/cm focal distance 60 to 70 cm should be provided. – Molybdenum Filter & Aluminum Filter Changer. – Light Beam collimator with Halogen Lamp with Auto shut off facility after 1 minute should be provided. – 18 X 24cm collimation plate should be provided. – Cone for Localization & Radiation protection should be provided. – Switches for up/down movement of gantry, placed conveniently on both sides of gantry should be provided. Separate foot control for gantry movements should also be available for hands free operation. – Hand Switch with Retractable cord for initiation of exposure should be provided.
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	**Configuration**	NA
3.4	**Noise (in dBA)**	Noise-free system
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary Installation
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO_2 ...)	
4.1	**Power Requirements**	Power supply: 230V, AC, 50Hz. 15 Amps ,single phase, Line resistance < 0.4 ohms
4.2	**Battery operated**	no
4.3	**Tolerance (to variations, shutdowns)**	line regulation of ±10%.
4.4	**Protection**	NA
4.5	**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 supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements. II. Free standing fully Transparent Lead Glass Screen for operator protection should be provided. III. - Film marking device & Alpha Numeric identification system should be provided.

BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored 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 FDA/ European CE/BIS approved product. 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) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3,IEC 61010-1-2,IEC 61010-2-54,IEC 61010-1-6 and IEC 62304 7. 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**	Earthing
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
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets(hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to 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 numbers 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 signs would be adequately displayed

NATIONAL HEALTH MISSION
Ministry of Health and Family Welfare
Government of India
website : www.nrhm.gov.in