GOVERNMENT MEDICAL COLLEGE & HOSPITAL, CHANDIGARH

(Hospital Building), Sector 32-B, Chandigarh-160030 (Ph 0172-2605253-59, Fax: 0172-2608488)

(ESTABLISHMENT BRANCH-IV)

Endst. No.: GMCH/EIV/EA3(24/1)2016/ 22215-16 Dated, Chandigarh the, 23 JUN 2016

A copy of letter No. NHM-UT-2016/2130-31 dated 19.05.2016 alongwith enclosures received from the Mission Director, National Rural Health Mission, Chandigarh Administration, is forwarded to the followings for information & necessary compliance:

1. The System Analyst, IT Centre, GMCH with a request to e-circulate/email the same to all the HODs/Branch Incharges of GMCH Chandigarh.
2. The Store Officer, GMCH, Chandigarh.

23/6/16

Superintendent (Estt.-IV)
GMCH, Chandigarh.

From

The Mission Director,
National Rural Health Mission,
Chandigarh Administration,
Chandigarh

To

1) The Head(Purchase Section)
GMCH-32, Chandigarh.

2) The Assistant Controller (F & A),
GMSH-16, Chandigarh.

Memo No. NHM-UT/2016/ 2130-31
Dated, Chandigarh the 19/5/16

Subject: Regarding Technical Specification of Medical Devices

Please find enclosed herewith the letter received from Sh.Manoj Jhalani, IAS, Joint Secretary, GOI, MOHFW, Nirman Bhavan, New Delhi wherein the technical specifications for commonly procurement of the medical devices has been annexed to facilitate the procurement of Medical devices by the State/UT. The specification are available at http:// nhsrcindia.org/ recruitment/Technical % 20 Specification%20of%20Medical%20Devices%20ofor%20Laboratory%20Radiology.pdf

-sd-
Nodal Officer
For Mission Director
National Rural Health Mission
Chandigarh Administration
Chandigarh

Endst No. NHM/UT/2016/ 2132-34 Dated , Chandigarh the 19/5/16

A copy is forwarded to the following for information and necessary action:-

1. The Medical Superintendent,GMSH-16,Chandigarh.
2. PA to Director Principal ,GMCH-32,Chandigarh.
3. The Medical Superintendent,GMCH-32, Chandigarh.

Nodal Officer
For Mission Director
National Rural Health Mission
Chandigarh Administration
Chandigarh

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

D.O. No.7(74)/2016-NRHM-I
Dated the 29th April , 2016

Dear Mission Director,

Rapidly changing technologies, complexities and varying costs associated with procurements of medical equipment pose a challenge in selection of appropriate and cost effective equipment. I may inform you that the Ministry of Health & Family Welfare has developed technical specifications of commonly procured medical devices to facilitate procurement by state UT Governments. The technical specifications have been so designed to generate healthy competition among the vendors and reduce cost of procurement. These specifications are available at http://nhsrcindia.org/recruitment/Technical%20Specifications%20of%20Medical%20Devices%20for%20Laboratory%20and%20Radiology.pdf.

2. May I suggest that States/UTs use the same in their procurement process. If the States/UTs have any suggestions to further improve upon the specifications they are most welcome to share them. For any technical assistance you may contact Dr. Jitendar Sharma, Senior Consultant, NHSRC at jitendra.sharma@nhsrcindia.org.

With regards,

Yours Sincerely,

(Manoj Jhalani)

To,
Mission Directors, NHM – All States/UTs

Copy to: ED, NHSRC

Ministry of Health & Family Welfare
Government of India

Ministry of Health & Family Welfare
Government of India

Technical Specifications of Medical Devices for Laboratory and Radiology

Secretary

Dated: 29th April, 2015

MESSAGE

Ministry of Health and Family Welfare in its endeavour to [illegible] 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 [illegible] consultations 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 specifications suitable. The specifications are suggestive and we have tried to keep them generic. However we would seek your suggestions for further improvement in these specifications.

(B.P. Sharma)

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110011
Tele: (O) 011-230-1565, Fax: 011-2306[illegible] E-mail: secyhfw@gmail.com

C.K. Mishra, IAS
Additional Secretary &
Mission Director, NHM
Telefax : 2306 [illegible]
E-mail : [illegible]

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 NIHSRC 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 NIHSRC, 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

Manoj Jhalani, IAS
Joint Secretary
Telefax : 2306 3187
E-mail : manoj.jhalani@nic.in

31st April 2015

MESSAGE

National Health System Resource Centre which is also 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, users, engineers & 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 healthcare 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 cost. It also provides stability in user training and smooth maintenance of equipment. In order to address the variations 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 programare 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, NIHSR being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Amjad, Anuraq, Swati Barwale, Prabhat Arora, Savita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications conforming to adequate standards of safety and accuracy shall be immensely useful to the state in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NCMRC

GMDN name	Automated 3-part Differential Heamotology Analyzer
GMDN code(s)	NA

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 (neutrophils).
1.2	Used by clinical department/ ward	Clinical and Analytical Laboratories

2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	1. 18 parameters (WBC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW-SD/RDW-CV, PLT, MPV, PCT, PDW, PLCR optional), with 3-part WBC differential 2. Maximum sample volume required 50 µl 3. Screen Color touch screen 4. Printer Built in printer and external printer option 5. Memory for 1000 results and 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. Automate 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, RS 232

3.1	Dimensions (meter)	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. Calibrator - 1.

6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS

6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1) Operational 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 CDSCO approved product 2. Manufacturer and supplier should have ISO 13485/US(FDA)/EU(CE) certificate 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 standard.
7.2	Local and/or international	Manufacturer/supplier should have ISO certificate for quality standard.

8. TRAINING AND INSTALLATION

8.1	Pre-installation requirements (power, cables, quality, tolerance)	1) Available at the time of unpacking. 2) Safety checks to be carried out 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 for user on operation and basic maintenance. 2) All safety/maintenance tasks required shall be documented.

9. WARRANTY AND MAINTENANCE

9.1	Warranty	1 year comprehensive warranty and annual calibration.

10. DOCUMENTATION

10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1) User technical and maintenance manuals to be supplied in english/hindi language along with circuit 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 which would be adequately displayed;

Technical Specification
LABORATORY

Version no.		1
Date		5/12/2014
Done by : (name/institution)		[illegible]
GMDN name		Automated 5-part differential hematology analyzer
GMDN code(s)		NA

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.

2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	1) Five-part differential 2) [illegible] parameters, all different WBC's should be measured directly. 3) Advanced integrated self-cleaning system, 4) [illegible] patient results trending 5) Stores [illegible] test results with histograms and scattergrams. 6) Integrates [illegible] practice management systems. 7) [illegible] 100 µl sample size permits whole blood analysis from [illegible] 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) [illegible] Within [illegible] 12) System must have throughput of atleast 60 samples per hour in all [illegible] modes. 13) Manual mode. 14) Stat mode. 15) Pre-diluted mode and whole blood mode.
2.2	User's interface	[illegible] 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 not obtain normal temp and the heat should be disbursed the [illegible]
3.6	Mobility, portability	Stationary lab [illegible]
	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 hi level control 3. Closed System cartridges for one level for all test 4. Online UPS system with 30 minutes back up.
	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/IS approved product. 2. Manufacturer and Supplier should have ISO-13485/AIS(FDA)/EU(CE) certificate for quality standards. 3. Shall meet all the mandatory requirements for Electromagnetic Compatibility (EMC) for electrical 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 [illegible] 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 basic application and basic maintenance; 2) Advanced maintenance tasks required shall be documented;

Technical Specification
LABORATORY

		9. WARRANTY AND MAINTENANCE
9.1	Warranty	3 years, including all spares and calibration
		10. DOCUMENTATION
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy 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.

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NHSRC
GMDN name	Binocular Microscope
GMDN code(s)	NA

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	Clinical labs.

2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	1. Body-Single mould sturdy stand, inclined Binocular body 30 °, 360° 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-[illegible] LED light source with white light with intensity control and LED life of more than 10, 000 Hrs. 8. Finish-[illegible] acid resistant finish. 9. Battrey backup-[illegible] 1 Hour. 10. Nose piece-Backward tilted revolving nose piece suitable to acomodate four objectives with click stop and rubber grip. 11. Focussing-[illegible] coarse and fine focussing knob, capable of smooth, fine focussing movement sensitivity; minimum: 300 micron; focussing stop for slide safety.
2.2	User's interface	Manual

Technical Specification
LABORATORY

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.
	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

	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

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NHSRC

GMDN name	Capillary Bilirubinometer
GMDN code	NA

1. USE

1.1	Clinical purpose	The capillary bilirubinometer is used for a quick check of bilirubin levels to promptly act with appropriate therapy. It is used to analyse the bilirubin in centrifuged whole blood drawn in a micro capillary tube. Sample is analysed through a double beam photometric system.
1.2	Used by clinical department/ ward	Analytical laboratories

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 håematocrit 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 TERM/DEVIATION REQUIREMENT	
	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.
	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

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NHSRC
GMDN name	Colorimeter
GMDN code(s)	NA

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

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 AN

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NHSRC
1. 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
TECHNIC	
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.
	SHIPPING/PROCUREMENT TERMS/DEMONSTRATION 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

Technical specification
LABORATORY

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**

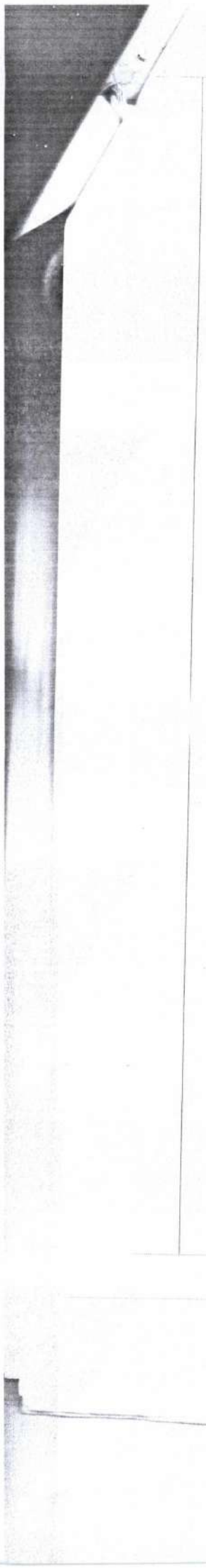
a) Micro Box :100 insertions

b) Macro Box :100 insertions

Technical Specification
LABORATORY

		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.

Page 2 of 3



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 reqtired)	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 following 1. 1. Acculine 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.

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

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. Micropipettes(5 Nos) - 2 variable(5-50, 100-1000) 5. Tips 500 - small and 500- big.

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

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.

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

		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 ITEM (DOCUMENT TO BE UPLOADED)	
	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.

		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.

Version no. :	1
Date:	5/12/2014
Done by : (name/institution)	HCT/NHSRC
NAME AND CODE	
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.

		6) Satisfactory certificate for any existing [illegible] 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.

Version no.:	1
Date:	23/12/2014
Done by : (name / institution)	HCT/NHSRC
GMDN name	500 mA X-Ray Machine(HF)
GMDN code	NA

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

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

3.4	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 (user ones); Consumables / reagents (open, closed system)	Machine should be supplied with following transducers:- 1. 2 No. BARC Approved whole body lead aprons with all attachements.
	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 real 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

Version no. :	1
Date:	23/12/2014
Done by: (name / institution)	HCT/NHSRC
GMDN name	C-ARM System(HF)
GMDN code	NA

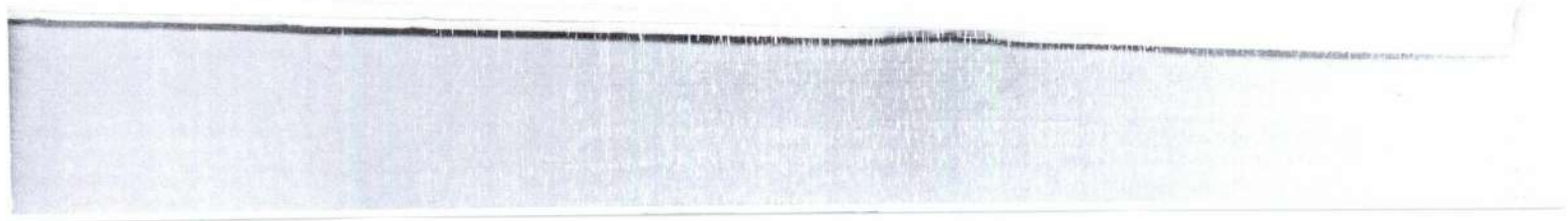
1. USE

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

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.

	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 (mandatory); Consumables / reagents (open, closed system)	Machine should be supplied with following transducers:- 1. 5 No. BARC Approved whole body lead apporns with all attachements.
	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

Technical Specifications
Radiotherapy

Version no:	1
Date:	23/12/2014
Done by: (name / institution)	HCT/NHSRC
GMDN name	CR System
GMDN code	NA

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

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 (no 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"X17"-2 No. 11"X14"/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

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 closed 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%
	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	Test documents 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

Version no:	1
Date:	23/12/2014
Done by: (name / institution)	HCT/NHSRC
GMDN name	Digital Radiography System(HF)
GMDN code	NA

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

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) 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', care, Cleaning, Disinfection & Sterility issues	1) Disinfection: Parts of the Device that are designed to come into co 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: name, 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.
9.3	Service contract clauses, including prices	All Breakdown calls to be attended within 24 hrs of registartion. 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 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	Local 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 Contract (AMC/CMC/add-hoc) to be declared by the manufacturer; Any warning signs would be adequately displayed

Version no. :	1
Date:	23/12/2014
Done by : (name / institution)	HCT/NHSRC
NAME ANNEXING	
GMDN name	Mobile X-ray machine(HF)
GMDN code	NA

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

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.

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, brownouts)	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 (replaceables); Consumables / reagents (open, closed system)	Machine should be supplied with following transducers:- 1. 2 No. BARC Approved whole body lead aprons with all attachements
	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%.

	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

Technical Specification
RADIOLOGY

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.

2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	1. Body-Single mould sturdy stand, inclined Binocular body 0 - 360° 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

		– Breast Compression: Automatic compression with digital display compression force should be provided. (Provision should be given release of compression paddle on power failure) the Switch for activ & release. Adjustable compression force should be available. Automat 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.

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.
	Certificate for international	Manufacturer/supplier should have ISO 13485 certificate for quality standard.

8. TRAINING AND INSTALLATION

8.1	Site installation requirements: electric, 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	Operation 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.