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सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Government of India

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

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Ministry of Health & Family Welfare
Government of India, New Delhi

NATIONAL HEALTH MISSION
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National Health Mission
Free Diagnostics Service Initiative

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

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भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

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

Dated : 29th April, 2015

MESSAGE

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

(B.P. Sharma)

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI-110011

MESSAGE

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

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

(C.K. Mishra)

New Delhi
29th April, 2015

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

31st April 2015

MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement.extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. We would welcome suggestions from the States.

(Manoj Jhalani)

Acknowledgement

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameel, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

Dr. Sanjiv Kumar
Executive Director

PORTABLE COMPACT MOBILE LAB WITH ACCU KINE

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

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

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

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		9. Cuvette Holder:4pcs. 10. Micropippette (5-50uL):1pc. 11. Micropippette (100-000uL):1pc. 12. Microtips: 1500pcs 13. Micro tip Holder:2pcs. 14. Patient Management Software :1. 15. USB port for data connectivity, data cable, charging cable :1. 16. Reagents Pack consisting of the following : a) KFT (Kidney Function Test) includes Urea/Uric Acid/Creatinine:1. b) LFT (Liver Function Test) includes Albumin/Total Bilirubin :1. c) Lipid Profile includes Cholesterol, HDL/Triglyceride :1. d) Diabetes includes Glucose: 1. e) Anaemia includes Haemoglobin :1. 17. Mini Laptop/Data Recorder loaded with PMS Version II window based: 1. 18. Solar Panel:1.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	1) Operating condition: Capable of operating continuously in ambient temperature of4 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2) Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	ISO - 9001, ISO -13485:2003 CE Marked USFDA Registered.
7.2	**Local and/or international**	Manufacturer should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	**Requirements for sign-off**	Certificate of calibration and inspection from the manufacturer.
8.3	**Training of staff (medical, paramedical, technicians)**	1) Training of users on operation and basic maintenance; 2) Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	As per DGS&D standard clause.
9.2	**Maintenance tasks**	
9.3	**Service contract clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

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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

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