सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR CARDIO PULMONARY DEPARTMENT

Ministry of Health and Family Welfare
Government of India

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DISCLAIMER

Please note the following points before using these technical specifications:

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

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प्रीति सूदन
सचिव
PREETI SUDAN
Secretary

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

Date : 30.09.2019

MESSAGE

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

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

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

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

(Preeti Sudan)

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Manoj Jhalani
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Additional Secretary & Mission Director (NHM)

सत्यमेव जयते

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

MESSAGE

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

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

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

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

(Manoj Jhalani)

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INTRODUCTION

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

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

In the consultative meeting experts has mentioned the following activities needs to be considered wisely while procuring medical devices.

(1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation;

   (a) Proper grounding at electrical sockets.

   (b) Wherever generator or UPS or solar power is used as back up energy source, should ensure the stabilizer/surge protector to prevent malfunction of medical devices. The same may be undertaken at facilities having voltage/energy fluctuations.

(2) Procurer may form rate contract on reagents/consumables anticipating yearly demand, on Medical devices which require periodic supply of reagents/consumables for its day to day operation.

(3) Appropriate filtering mechanism to be housed at public facility to ensure maximum longevity on Medical devices which operates efficiently depending on quality of pneumatics/water supply source.

(4) Ensure compliance for Medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution control Board, PC PNDT, PESO etc.

(5) Procurer/public health facility must ensure scheduling calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in Medical device manufactures operational/service manual.

(6) Wherever necessary warning/safety information required, has to be placed at public health facilities.

(7) User/ In-house service training to be procured along with Medical devices for effective utilization.

(8) Public health facility may actively engage with MoHFW initiative, Post market surveillance / Materiovigilance program of India.

(9) Public health facility have to rely on manpower availability or utilization or IPD/OPD load factor to decide on quantity of medical devices to be procured and not just on number of bed at each level.

ECG Machine – Single Channel

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Electrocardiographs, Single channel
UMDNS code(s)		11413
GENERAL		
1. USE		
1.1	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have a digital display of single channel ECG. 2. Should be a single channel. 3. Should have two modes (Automatic and Manual mode). 4. Heart rate measurement range to beat least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 5. Heart rate trend display of at least previous 24 hours. 6. Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.2	User's interface	Manual, English Menu
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
2.4	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Less than 5 kgs
3.3	Configuration	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Supplied in protective case for clean storage and safe transport.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	To be specified by vendor.
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Single lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
5.2	Spare parts(main ones)	Two sets of spare fuses (if non-resettable fuses used)
5.3	Consumables/reagents (open, closed system)	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 90% in ideal circumstances.
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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.

8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals.	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

ECG Machine – 3 Channel

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Electrocardiographs, Multichannel
UMDNS code(s)		11411
GENERAL		
1. USE		
1.1	Clinical purpose	Continuously detect, measure and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Simultaneous 3 Channel ECG recording with 12 lead simultaneous acquisition. 2. Should have a digital display of 3 channel ECG and should have three modes (Automatic, Manual and rhythm). 3. Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ±5bpm. 4. Heart rate trend display of at least previous 24hours. 5. Arrhythmia detection facility required; minimum gradation of 1bpm.
2.2	User's interface	Manual, English Menu
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
2.4	Software and/ or standard of communication (where ever required)	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	Less than 5 kgs
3.3	Configuration	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Supplied in protective case for clean storage and safe transport.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	To be specified by vendor
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	3 lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
5.2	Spare parts (main ones)	Two sets of spare fuses (if non-resettable fuses used)
5.3	Consumables/reagents (open,closed systems)	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 90% in ideal circumstances.
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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.

8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spare parts and accessories. (or) State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

ECG Machine – 6 Channel

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Electrocardiographs, Multichannel
UMDNS code(s)		11411
GENERAL		
1. USE		
1.1	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition. 2. Should have a digital display of 6channel ECG and should have three modes (Automatic, Manual and rhythm). 3. Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 4. Heart rate trend display of at least previous 24 hours. 5. Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.2	User's interface	Manual, English Menu
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
2.4	Software and/ or standard of communication (where ever required)	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	Less than 5 kgs
3.3	Configuration	Case is to be hard and splash proof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	To be specified by vendor.
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	6 lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
5.2	Spare parts(main ones)	Two sets of spare fuses (if non-resettable fuses used).
5.3	Consumables reagents (open, closed systems)	5 tubes electrode gel (if required).
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 90% in ideal circumstances.
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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.

8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

ECG Machine -12 Channel

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Electrocardiographs, Multichannel
UMDNS code(s)		11411
GENERAL		
1. USE		
1.1	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition. 2. Should have a digital display of 6 channel ECG and should have three modes (Automatic, Manual and rhythm). 3. Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. 4. Heart rate trend display of at least previous 24 hours. 5. Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.2	User's interface	Manual, English Menu.
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
2.4	Software and/ or standard of communication (where ever required)	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	Less than 5 kgs
3.3	Configuration	Case is to be hard and splash proof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Battery powered, silence able alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	To be specified by vendor.
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	12 lead ECG cable.
5.2	Spare parts(main ones)	Two sets of spare fuses (if non-resettable fuses used)
5.3	Consumables/reagents (open,closed systems)	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 90% in ideal circumstances.
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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.

8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

ECG Machine -12 Channel with treadmill

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Electrocardiographs, Multichannel
UMDNS code(s)		11411
GENERAL		
1. USE		
1.1	Clinical purpose	In this system, the patient exercises on a treadmill according to a standardized protocol and the cardiac abnormalities can be studied under stress conditions which we may miss under resting.
1.2	Used by clinical department/ward	Cardio Department, TMT room, etc.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should acquire and analyze 12/15 simultaneous ECG Leads. 2. Should have facility for display of all 12/15 leads real time rhythm ECG on screen. 3. Should have facility of on-line storage of patient ECG data. Storage of at least 500 patients on HDD. In addition, the storage on floppy drive or CD or USB pen driver should be possible. 4. Updated medians with elimination of artificial recopy and aberrancy in all leads. 5. Filters with facility to eliminate artifact due to respiration muscle/ noise, AC interference, baseline wandering without compromising/ distortion in ST segment changes. 6. Should have facility to do the re-analysis of stored ECG report with reanalysis of the current stress report by changing the measurement point(i.e) E,J and post J points. 7. The monitor should display auto comparison of resting versus current lead of maximum ST depression separately with color coded protocol, stage, clocks for elapsed time, total time, target HR, treadmill speed & grade, PVC counts / minute, warning messages & prompts, lead check torso. 8. The system should have user defined report generation in different formats including the ST/HR loops and ST/HR index up to 15 leads formats for close diagnosis. 9. Should have facility for 12 lead resting electro cardiac gram with full interpretation. 10. Should have provision of software driven, user programmable exercise protocols or standard protocols. Facility should be available for choice for both staged and ramp protocols. 11. System should print comprehensive final report on a minute by minute record of ST segment changes ST segment trend plot and acceleration of ST segment. 12. Display should have facility to amplify a normal gain along with a sample of resting ECG complex for close test.

		13. System should have dynamic scan facility to display automatically the worst ECG lead. 14. Signal acquisition from patient and analysis should be performed at the patient itself to eliminate the environmental noise. 15. Automatic arrhythmia detection and documentation. 16. Facility for display of processed ECG vectors after signal averaging allowing view of artifact free ECG complexes. 17. Should have beat to beat on-line storage and event review. 18. System should be able to provide the real time printing by auto or manual mode in desired formats. Writer resolution should be thermal 1000 line/sec X200 dpi for printing. 19. System should have automatic noise free programmable treadmill and FDA/CE/ISI approved / certified. 20. System should be able to be integrated with hospital information system/LAN/WLAN. 21. Should be able to transfer data through modem card (optional). 22. The treadmill should always start form 0mph and has load capacity of 450 lbs and speed range of 0-13 mph and elevation 0-25% and should have facility to run the self-calibration programme. Treadmill should have minimum 60' walking surface. 23. Treadmill should have two stop modes with digital microprocessor control, including the same should be interfaced to the main analysis system.
2.2	User's interface	Manual, English Menu.
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
2.4	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	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.3	Power consumption	To be specify by vendor
4.4	Other energy supplies	Mains cable to be at least 3m length.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	12 lead ECG cable. 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type). Stress test system : 1 No Treadmill : 1 No Interface cable : 1 No Printer : 1 No Patient cable : 2 No Body wear : 1 No Paper : 1000 A4 sheets/standard ECG paper recording. Any standard accessories required for running the system.
5.2	Spare parts (main ones)	Two sets of spare fuses (if non-resettable fuses used).
5.3	Consumables/reagents (open,closed systems)	5 tubes electrode gel (if required).
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 90% in ideal circumstances.
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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

NEBULIZER - ULTRASONIC

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Aerosol Generators
UMDNS code(s)		10046
GENERAL		
1. USE		
1.1	Clinical purpose	Devices designed to produce (i.e., generate) gaseous suspensions of extremely small particles of a liquid or solid. These generators typically include a micro-ultrasonic, or pneumatic pumping mechanism capable of creating a fine-particle liquid mist appropriate for delivery to the patient's airways and/or for lung deposition.
1.2	Used by clinical department/ward	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be light weight, portable, Compact and easy to use. 2. Frequency of ultrasonic generator should be greater than 1.5 MHz. 3. Speed nebulization rate control (minimum, medium, maximum) . 4. Should have a nebulisation capacity of 0.3 ml/min. 5. Transducer element should have life of at least 5000 hours. 6. Medication cup capacity should have capacity of maximum 8ml. 7. Should uses water as ultrasonic conduction medium, no gel is required. 8. Should provide silent operation. 9. Should have a built in timer and shuts off after 10 minutes use.
2.2	User's interface	Manual, English Menu
2.3	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz

4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply.
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Should be provided with a complete nebulisation kit of 10 Nos. including adult.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

NEBULIZER - PNEUMATIC

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Aerosol Generators
UMDNS code(s)		10046
GENERAL		
1. USE		
1.1	Clinical purpose	Devices designed to produce (i.e., generate) gaseous suspensions of extremely small particles of a liquid or solid. These generators typically include a micro-ultrasonic, or pneumatic pumping mechanism capable of creating a fine-particle liquid mist appropriate for delivery to the patient's airways and/or for lung deposition.
1.2	Used by clinical department/ward	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be Non heating, light weight, portable, Compact and easy to use. 2. Should have 3 speed nebulization rate control (minimum, medium, maximum). 3. Should have a nebulisation capacity of 0.3 ml/min. 4. Should provide silent operation. 5. Should have a built in timer and shuts off after 10 minutes use.
2.2	User's interface	Manual, English Menu
2.3	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Should be provided with a complete nebulisation kit of 10 Nos. including adult and child mask and medication cup – 5 Nos, Air Tube, 5 pcs Replacement Filters, Mouthpiece, Adult Mask, Child Mask, Carrying Bag, Instruction Manual.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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 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,..);	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

BP APARATUS - DIGITAL

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Sphygmomanometers
UMDNS code(s)		13106
GENERAL		
1. USE		
1.1	Clinical purpose	Digital sphygmomanometers are automated, providing blood pressure reading without needing someone to operate the cuff or listen to the blood flow sounds.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be able to measure blood pressure and pulse rate in adult as well as pediatric patients. 2. Should be based on oscillometric measurement technology, using dynamic linear deflation method. 3. Should have back light LCD display with easy to view readings in dim light. 4. Pressure measurement range should be 60 to 250 mm Hg systolic, and 40 to 200mm Hg diastolic. 5. Pressure display accuracy of +/- 3 to 5 mm Hg. 6. Pulse rate measurement range of 40 to 200 per minute. 7. Pulse measurement accuracy of within 5%. 8. Should include AC adapter (input range 100-240V and output voltage DC 6V), preferably with rechargeable battery (3.6V to 4.8V, 1900 to 2400mAh). 9. Should be supplied with standard adult size cuff (22 to 32 cm size). 10. Single button operation for start and stop functions with auto-inflation of blood pressure cuff.
2.2	User's interface	Manual, English Menu.
2.3	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	YES
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Pediatric blood pressure cuffs (compatible with quoted digital blood pressure device). a) Infant with 4 cm width and 8 cm length. b) Child with 9 cm width and 18 cm length. c) Adolescent with 10 cm width and 24 cm length.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

BP APARATUS - ANEROID

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Sphygmomanometers
UMDNS code(s)		13106
GENERAL		
1. USE		
1.1	Clinical purpose	Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. The systolic and diastolic pressure is usually assessed by listening to Korotk off sounds generated by arterial blood flow using a stethoscope simultaneously.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be able to measure blood pressure in adult as well as pediatric patients. 2. Should be based on aneroid measurement technology. 3. Should have a dial type display, with a hook which can be attached to the blood pressure cuff. 4. Pressure measurement range should be 0 to 300 mm Hg systolic and 40 to 200 mm Hg diastolic. 5. Pressure measurement accuracy of +/- 3 to 5mm Hg. 6. Manual inflation of blood pressure cuff. 7. Should be supplied with standard Adult size cuff (22 to 32 cm size).
2.2	User's interface	Manual, English Menu.
2.3	Software and/ or standard of communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA

4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Pediatric blood pressure cuffs (compatible with quoted digital blood pressure device). a) Infant with 4 cm width and 8 cm length. b) Child with 9 cm width and 18 cm length. c) Adolescent with 10 cm width and 24 cm length.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 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,..);	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance.

		3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

STETHOSCOPE

Version no. :	Ver,-1
Date:	15/02/2018
Done by : (Name/Institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Stethoscopes, Mechanical
UMDNS code(s)	13755

GENERAL		
1. USE		
1.1	Clinical purpose	Designed for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening head connected by a split "Y" tube to the head gear with earolivesth at a replaced in to the users ears.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Bi-aural unit. 2. Double stent chest piece. 3. Plain spring non-folding frame. 4. Plastic ear tips. 5. Vinyl stethoscope tubing. 6. Combined bell and diaphragm sprague type. 7. Two earpieces, sprung to stay fixed in ears. 8. Dual head: Cup/bell for low frequency sounds, membrane for skin contact pickup Cup or membrane use selected by secure, easy to use mechanism.
2.2	User's interface	Manual, English Menu
2.3	Software and/ or standard of Communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Two spare membranes

BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

PEAK FLOW METER

Version no. :		Ver.-1
Date:		15/02/2018
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Flow meters, Gas, Respiratory, Peak Expiratory Flow
UMDNS code(s)		15965
GENERAL		
1. USE		
1.1	Clinical purpose	A manual, hand-held instrument designed to measure only the maximum rate of expiratory gas flow [peak expiratory flow (PEF) or peak expiratory flow rate (PEFR)] from the lungs.
1.2	Used by clinical department/ward	Respiratory and General medical wards.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Range of measurement to include 50 to 400 L/min (pediatric), 60 to 800 L/min (adult). 2. Accuracy of measurement shall be better than ±10%, as per ISO 23747:2007. 3. Resetting value for next use to be simple and easy for patients with limited dexterity. 4. Supplier should specify if EU or ATS scale is used on charts provided. Wright scale is not acceptable.
2.2	User's interface	Manual, English Menu.
2.3	Software and/or standard of Communication (where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<150 dB
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Five replacement sterilizable mouthpieces (if removable type). Chart of normal values for all ages and both genders.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. **Operating Condition:** Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 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. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares parts and accessories or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.

10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Service and operation manuals(original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided. Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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