सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR PHYSICAL MEDICINE AND REHABILITATION 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.
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This document has been prepared and published on behalf of the National Health Mission (NHM) by its technical support institution National Health Systems Resource Centre (NHSRC), NIHFW Campus, Baba Gangnath Marg, New Delhi – 110 067.

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

प्रीति सूदन
सचिव
PREETI SUDAN
Secretary

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

Date : 30.09.2019

MESSAGE

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

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

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

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

(Preeti Sudan)

मनोज झालानी
Manoj Jhalani
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सत्यमेव जयते

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MINISTRY OF HEALTH & FAMILY WELFARE
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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 centre for priority medical devices & health technology policy; in consultation with experts has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise.

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

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

   (a) Proper grounding at electrical sockets,

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

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

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

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

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

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

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

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

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

TRACTION UNIT

Version no. :		1
Date:		15/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Traction Units
UMDNS code(s)		14105
GENERAL		
1. USE		
1.1	Clinical purpose	Devices designed relieve pressure on compressed nerves, help muscles relax and reduce muscle spasms. Traction increases the space between vertebrae - reducing pressure on inter vertebral discs and nerve root.
1.2	Used by clinical department/ward	PMR Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Specification	1. Should able to deliver decompression therapy; 2. Should have a touch screen interactive display for easy treatment set-ups and easy angle selection and must come with treatment protocol manual; 3. Must provide along with the package Angle reference chart; 4. Should able to automatically calculate and digitally display the rope pull angle for decompression and traction as per the treatment protocol; 5. Should provide protocol manual for light therapy and lumbar and cervical protocol manual Must be a build in computerized software package and protection against accidental setting of force-must have a safety switch for emergency shut off. 6. Hold time: 20, 40, 60 and 80 seconds 7. Rest time: 1, 5, 10 and 20 seconds 8. Traction Force: 4-45 Kg (With Doubler 90 Kg) 9. Cervical: 4-15 Kg (Each 1 kg step) 10. Lumbar 23 to 45 Kg (Each 2 kg Steps) 11. Safety Switch
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should operate from 200 to 240V-AC, 50 HZ input Supply
4.2	Battery operated	
4.3	Protection	NA
4.4	Power consumption	To be specified by the Supplier
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)	1. Should come with Flexion stool, Knee bolsters, Cervical pillow, Ankle bolsters, and decompression belts thoracic and pelvic. 2. Should provide with a 4 section motorized table hi/low with clamps, frame attachments for connecting the traction unit. 3. Comfortable, durable, skin friendly and good quality cervical/ lumbar belt with standing force of upto 90 kg.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	NA
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are 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).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares.

10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/land line 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.

INTERFERENTIAL THERAPY UNIT

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Interferential Therapy Unit
UMDNS code(s)		11248
GENERAL		
1. USE		
1.1	Clinical purpose	Therapeutic ultrasound units convert electrical energy to high-frequency (i.e., 1 or 3 megahertz [MHz]) sound waves that penetrate tissues to produce pain relief and facilitate tissue healing through thermal and non thermal physiologic reactions.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Dual output Channels and isolated between channels 2. Should have 0-30 operation programs 3. Symmetrical Balanced Sine Wave 4. Output Current:0-100 mA 5. Interference Frequency 2-160 Hz 6. Output Frequency 4000Hz (with ±1% tolerance) fixed on Channel 1 7. Modulating Frequency 4002 – 4160Hz (with ±1% tolerance) adjustable on Channel 2 8. Treatment Timer Continuous, 15, 30, 45 or 60 minutes 9. 2pole/4pole multi vector mode 10. Patient safety fuse/Auto cut-out.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V-AC, 50 HZ input Supply
4.2	Battery operated	Size of battery to be specified
4.3	Protection	NA
4.4	Power consumption	To be specified by the Supplier

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system	1. One set Patient wire IFT 2. Two set Fixation straps 3. One gel bottle 4. One Power cable 5. One operating manual 6. Big and Small rubber electrode
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 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 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are 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).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;

11. Notes		
11.1	Service Support Contact details (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.

SHORT WAVE DIATHERMY

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Shortwave Diathermy
UMDNS code(s)		11246
GENERAL		
1. USE		
1.1	Clinical purpose	Diathermy applies high-frequency electromagnetic energy to generate heat in body tissues. These devices produce localized moderate heating which causes a 2° to 3° C change in tissue temperature below the skin surface
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The unit should offer minimum 20 preset therapeutic protocols with electrode placement images to make operation of the simple and convenient. 2. Should have an output of up to 500 W in continuous mode. 3. 800 to 1100 w in pulse mode. 4. Pulse repetition frequency of 20 to 200 Hz adjustable in 10 steps 5. LCD Screen display of parameter Treatment timer with all standard. 6. 30 minutes treatment timer & tuner control 7. Auto switch off as per set timings.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should operate from 200 to 240V-AC, 50 HZ input Supply
4.2	Battery operated	NA
4.3	Protection	UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up
4.4	Power consumption	To be specified by vendor.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Condenser pad with cable 2. Disc electrodes with arms and cables. 3. Patient safety switch
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 40 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 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are 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).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 15 Amp. Electrical Socket.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (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.

HYDRO COLLATOR

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Moist Heat Therapy Pack Conditioners
UMDNS code(s)		12565
GENERAL		
1. USE		
1.1	Clinical purpose	Devices designed to keep hot packs (also known as hydrocollator packs) warm at a consistent temperature. These devices usually consist of a stainless steel container where water is heated to a thermostatically controlled temperature (usually 165 F); hot packs are immersed in the water. Moist heat therapy pack conditioners are used to store and keep packs warm. The packs are wrapped in towels and used to provide moist heat therapy.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	The Unit should be provided with thermostat temperature control. 1. The unit should have detachable insert rack to hold and suspend packs for heating. 2. The Unit should made of stainless steel with rubber wheels for mobility. 3. Tank Capacity 30-50 Liters approx 4. Filled Weight 50 kg - 80 kg approx 5. Temperature Range upto 90° C) 6. Thermal Cut-out Temp (88° C ± 8° C) 7. Heating Up Time to (70° C) - 3 Hours 8. Cool Down Time from 160° F (70° C) - 2 Hours 9. Device should be Safety Class Type B and Safety Tests UL 544 10. Heating Indicator 11. It Should have Drainage valve
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Portable

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Includes two Oversize Hot Pacs, 2. Three Standard size Hot Pacs 3. Neck Contour Hot Pac. 4. Forceps and Tongue
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 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 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are not available 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards-(Not applicable if CDSCO approved) 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. 5. The manufacturer must have a management system certified to ISO 9001.
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	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (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.

EXERCISE TABLE

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Exercise Plinth/Couch
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Tables are designed for treatment of diseases using therapeutic exercises and massage. It may be used for all purpose related to PMR department
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Made up of solid wood, Should have 4 legs 2. Plinth Size: High and Low 3. Top 19 mm thickness ply. 4. 4 inch cushioned with rexin cover legs cross section 8 x 10 cm. L*B*H (to be specified as per the requirements)
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories,(mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Exercise plinth High and Exercise Plinth Low
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA

6.2	User's care, Cleaning, Disinfection & Sterility issues	NA
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	NA
11.2	Recommendations or warnings	NA

STATIC CYCLE

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ergometers, Bicycle
UMDNS code(s)		10383
GENERAL		
1. USE		
1.1	Clinical purpose	Aerobic cycle exercisers designed to simulate the motions of riding a bicycle; the bicycles remain stationary while the wheels move. These exercisers are usually self-powered devices; they may use friction belts or wheels, magnets, fans, or hydraulics to increase resistance. Some stationary bicycles may include a motor to regulate speed.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. LCD Display unit to measure heart rate, speed, distance, time and energy. 2. Should have digital display showing speed, time, distance and calorie used. 3. Body should be rugged and made up of SS-304 grade (Anti-Rust). 4. Should have comfortable saddle and foam fitted handle. 5. Should have adjustable design to fit all heights and weights. 6. Should be able to bear body weight upto 100 kg. 7. Comfortable latex/Rubber hand grip facility for pulse oximetry. 8. Should have Resistance system with manual control. 9. Should have large adjustable softer HR seat. 10. Should have firm, durable, broad paddle with adjustable locking strap.
2.2	User's interface	Manual
2.3	Software and or standard of communication (where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	To be specified by vendor.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are 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).
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. 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 and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.

10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (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.

MEDICINE BALL

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	A medicine ball is a weighted ball often used for rehabilitation and strength training. The medicine ball also serves an important role in the field of sports medicine.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Ideal for classic medicine ball workouts. 2. Should be single colour, inflatable, moulded, heavy duty vinyl ball can support up to 150 kgs. 3. Should be in Textured finish provides a superior grip 4. Should be available in dia 65 cm, 75 cm, 85 cm.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA

6.2	User's care, Cleaning, Disinfection & Sterility issues	NA
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	NA
11.2	Recommendations or warnings	NA

QUADRICEPS TABLE WITH WEIGHTS

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Flexibility exercisers designed to improve the range of motion around a joint by supporting and/or positioning the user, making it possible to stretch any of the major muscle groups in the body. These exercisers are usually portable devices with handlebars or stand-alone exercise workstations. They may also increase muscle strength and improve balance and stability.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be made up of stainless steel(SS-304). 2. Torque Unit – 1 set interchangeable to either side. Calibrated resistance arms to vary resistance even without changing weights. 3. Two lever arm, one to hold weights and the other with shin foam roller. 4. A degree scale to measure range of motion from either side. 5. SEAT – Foam padded seat with foam padded back rest and arm rests preferably adjustable. 6. Stabilizing straps for torso and thighs. 7. Weights: Weight plates of 1⁄2 Kg -2 numbers and 1 kg – 5 or more to suit the torque 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	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Stationery
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. One pair chromate torque unit with different weight options. 2. Two sets of ½ kg, 1 kg, 2 kg, 3 kg weights.
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 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	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	NA
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.
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided;

		4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (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.

WHEEL CHAIR

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Wheelchairs
UMDNS code(s)		14449
GENERAL		
1. USE		
1.1	Clinical purpose	Chairs mounted on large wheels, designed for indoor (e.g., hospital, institution, home) or outdoor transportation of patients or individuals with impaired walking ability.
1.2	Used by clinical department/ward	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Overall size: 670 mm W x 1120mm D x 920 mm H. 2. Should be made of 16 gauge SS 304 grade tube frames and 16 gauge SS 304 sheet for seat & back rest. 3. Should have a fixed arm rest. 4. Should have Reticulated and breathable cushion 5. Should have minimum 6" swivel nylon caster front wheel, 24" bicycle type rear wheel with pneumatic tyre 6. Two handles are provided with the hand grips 7. Back wheel fixing bolt shall be covered with cup type nut. 8. Should have breaking system on both side 9. All pipes & Foot rest should be made of aluminum
2.2	User's interface	NA
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	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	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 made of 16 gauge SS 304 grade tube frames and 16 gauge SS 304 sheet for seat & back rest. 2.The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
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.

PATIENT TROLLEY

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	A patient trolley is a bed on wheels for moving patients in hospital.
1.2	Used by clinical department/ward	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Overall Dimension: 1985 mm (L) x 610 mm (W) x 810 mm (H). 2. Frame Work: • Vertical member- Thickness of tube Cut size diameter of tubing pipe- 18 Gauge 31.75mm • Horizontal member - 18 Gauge 31.75mm 3. Removable stretcher made of curved CRCA Sheet 20 SWG supported on tubular frame having steel supports under the sheet. 4. Wheels: 4 Nos. swivel caster wheels are fitted in front and rear side of the wheel 150mm diameter x 38mm with plug diameter 32.5mm fitted with thrust bearing and solid rubber wheels with sleeve 21mm thick fork 10 SWG zinc plated. King pin is 14.5mm ; length of plug is 65mm inclusive of collar. 5. Handle should be made of SS-304. 6. All the steel components should be pre-treated for de-greasing, de-rusting and phosphating. After proper pre-treatment, the steel components should be epoxy powder coated and oven baked at temp. Above 200 °C to provide scratch resistance surface coating film thickness 45-50 microns.
2.2	User's interface	NA
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	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA

4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	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	The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
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.

ADL TRAINING KIT

Version no. :		1
Date:		28/02/2017
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Activities of daily living (ADL) are also called self-help or self-care activities. These activities can include everyday tasks such as dressing, self-feeding, bathing, laundry, and / or meal preparation. Sometimes adaptive equipment is needed to assist with these tasks, which can include items such as a reacher, long-handled sponge, buttonholer, rocker knife, and / or built-up spoon. ADL Training kits are used to help the patients to address these skills and work to improve as needed.
1.2	Used by clinical department/ward	Physio Therapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. This multifunctional upper extremity work station 2. Activities to be performed while sitting / standing 3. TWO, wheelchair-accessible side shelves 4. TWO, Drop-out doors converting into workspace 5. Lockable double doors for security 6. Sturdy construction with durable laminated work surfaces 7. Provides storage space for at least 12 most recognized activities i. Pinch tree ii. Pipe assembly unit in PVC iii. 25 Hole peg board iv. Hand tool test frame v. Finger dexterity board vi. Door latch board vii. Dressing board set viii. Shoulder abduction ladder ix. Bilateral shoulder ladder x. Hand exercise board (Velcro) xi. Hand gym board
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA

3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (US FDA/CE/BIS/ CDSCO requirements will be applicable only when the Indian Standards like BIS/CDSCO are not available; 2. Manufacturer should have ISO 13485 certification for quality standards 3. The manufacturer must have a management system certified to ISO 9001.
		8. TRAINING AND INSTALLATION
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	1. Training of users in operation and basic maintenance shall be provided. 2. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.

10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (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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2	Representatives from Indian Pharmacopoeia Commission (IPC)		
3	Representatives from Federation of Indian Chambers of Commerce & Industry (FICCI) Association.		
4	Representatives from Medical Technology Association of India (MTaI) Association.		
5	Representatives from Association of Indian Medical Device Industry (AIMED) Association.		
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