TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR CARDIO PULMONARY DEPARTMENT

Ministry of Health and Family Welfare
Government of India

INDEX

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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.

ECG Machine -Single Channel

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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)	Should have a digital display of single channel ECG . Should be a single channel. Should have two modes (Automatic and Manual mode). Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. Heart rate trend display of at least previous 24 hours. Arrhythmia detection facility required; minimum gradation of 1 bpm. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	User's interface	Manual
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 splashproof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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, silenceable alarm for power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard,	single 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	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.

10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

ECG Machine -3 Channel

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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)	Simultaneous 3 Channel ECG recording with 12 lead simultaneous acquisition Should have a digital display of 3 channel ECG and should have three modes(Automatic, Manual and rhythm) . Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. Heart rate trend display of at least previous 24 hours. Arrhythmia detection facility required; minimum gradation of 1 bpm. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	User's interface	Manual
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 splashproof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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, silenceable alarm for power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard,	3 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	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		

9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

ECG Machine -6 Channel

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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)	Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition Should have a digital display of 6 channel ECG and should have three modes(Automatic, Manual and rhythm). . Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. Heart rate trend display of at least previous 24 hours. Arrhythmia detection facility required;minimum gradation of 1 bpm. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	User's interface	Manual
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 splashproof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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, silenceable alarm for power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard,	6 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	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

ECG Machine -12 Channel

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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)	Simultaneous 12 Channel ECG recording with 12 lead simultaneous acquisition Should have a digital display of 12 channel ECG and should have three modes(Automatic, Manual and rhythm). . Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. Heart rate trend display of at least previous 24 hours. Arrhythmia detection facility required;minimum gradation of 1 bpm. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	User's interface	Manual
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 splashproof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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, silenceable alarm for power failure.
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard,	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	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

ECG Machine -12 Channel with treadmill

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should acquire and analyze 12/15 simultaneous ECG Leads Should have facility for display of all 12/15 leads real time rhythm ECG on screen 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 Updated medians with elimination of artificial ectopy and aberrancy in all leads Filters with facility to eliminate artifact due to respiration muscle/noise, AC interference, baseline wandering without compromising / distortion in ST segment changes 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 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 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 Should have facility for 12 lead resting electro cardio gram with full interpretation 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 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 Display should have facility to amplify a normal gain along with a sample
2.2	User's interface	Manual
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 splashproof.
3.4	Noise (in dBA)	<50 dB
3.5	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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	
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard,	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	5 tubes electrode gel (if required)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

NEBULIZER - ULTRASONIC

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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	
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 Should have 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.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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
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,	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/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

NEBULIZER - PNEUMATIC

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
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. Aerosol generators are available in a variety of sizes and configurations according to the clinical procedure and/or the device used for aerosol delivery; they are usually connected through flexible hoses or tubes to face masks, ventilator breathing circuits, or aerosol tents. Some generators are an integral part of fixed and/or portable nebulizers. Aerosol generators are used mainly to produce an aerosolized mist from saline solutions and drug formulations; some dedicated devices are intended to produce a radioactive particleaerosol.
1.2	Used by clinical department/ward	
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. Should provide silent operation. Should have a built in timer and shuts off after 10 minutes use
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	7
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,	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/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

BP APARATUS - DIGITAL

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should be able to measure blood pressure and pulse rate in adult as well as pediatric patients. Should be based on oscillometric measurement technology, using dynamic linear deflation method. Should have backlight LCD display with easy to view readings in dim light. Pressure measurement range should be 60 to 250 mm Hg systolic, and 40 to 200mm Hg diastolic. Pressure display accuracy of +/- 3 to 5 mm Hg Pulse rate measurement range of 40 to 200 per minute Pulse measurement accuracy of within 5% 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) Should be supplied with standard adult size cuff (22 to 32 cm size) Single button operation for start and stop functions with auto-inflation of blood pressure cuff.
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	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,	Pediatric blood pressure cuffs (compatible with quoted digital blood
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

BP APARATUS - ANEROID

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should be able to measure blood pressure in adult as well as pediatric patients. Should be based on aneroid measurement technology Should have a dial type display, with a hook which can be attached to the blood pressure cuff. Pressure measurement range should be 0 to 300 mm Hg systolic and and 40 to 200mm diastolic Pressure measurement accuracy of +/- 3 to 5mm Hg Manual inflation of blood pressure cuff. Should be supplied with standard Adult size cuff (22 to 32 cm size)
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	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,	Pediatric blood pressure cuffs (compatible with quoted digital blood
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

Stethoscope

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
UMDNS name		13755
UMDNS code(s)		Stethoscopes, Mechanical
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 headgear with ear olives that are placed into 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)	Bi-aural unit. Double stent chest piece. Plain spring non-folding frame. Plastic ear tips. Vinyl stethoscope tubing. Combined bell and diaphragm sprague type. Two earpieces, sprung to stay fixed in ears Dual head: Cup/bell for low frequency sounds, membrane for skin contact pickup
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	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,	Spare set of earpieces
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
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 adequaetly displayed.

Peak flow meter

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
#ERROR!		
UMDNS name		15965
UMDNS code(s)		Flowmeters, Gas, Respiratory, Peak Expiratory Flow
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. It typically includes a tube for patient exhalation, an easy-to-grip handle, and a calibrated scale that shows the value of the peak flow. The device helps to discriminate the pulmonary status in routine tests performed in or outside of a clinical setting; it is also intended for periodic self-evaluation of the respiratory status of a patient, and to help in the treatment evaluation of patients suffering from chronic respiratory disorders (e.g., asthma, emphysema).
1.2	Used by clinical department/ward	
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 (paediatric), 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
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	Heat Dissipiation: Should maitain nominal Temp and the heat should be
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,	Five replacement sterilizable mouthpieces (if removable type)
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and
6.2	User's care, Cleaning, Disinfection &	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..);	1. Should be FDA/Europen CE/BIS approved product.
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,	Training of users in operation and basic maintenanc shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:

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 adequaetly displayed.