



TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR CARDIO PULMONARY DEPARTMENT



Ministry of Health and Family Welfare Government of India

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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.

EC	CG Machine -Sin	gle Channel
Versio	n no. :	Draft_1
Date:		15/02/2018
Done b	by : (name.institution)	HCT/NHSRC
	#ERROF	R!
UMDN	NS name	Electrocardiographs, Single channel
UMDN	VS code(s)	11413
	GENERA	Ĺ
1. USE	Ξ	
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
	TECHNIC	AL
2. TEC	CHNICAL CHARACTERISTICS	
	Technical characteristics	Should have a digital display of single channel ECG.
	(specific to this type of device)	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
2.1		accuracy better than \pm 5 bpm.
2.1		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 \pm 5 bpm.
2.2	User's interface	Manual
	Settings	Audiovisual alarms required: high and low heart rate (operator variable
2.3	Seconds	settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
	Software and/ or standard of	In built
2.4	communication(where ever required	
2 DU		
	YSICAL CHARACTERISTICS	NTA .
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. ENI	ERGY SOURCE (electricity, UPS, solar	
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 \pm 30% of local rated
4.4	Power consumption	222222
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. AC	CESSORIES, SPARE PARTS, CONSU	MABLES
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)
	DING/PROCUREMENT TERMS/D	
	VIRONMENTAL AND DEPARTMEN	
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
	ANDARDS AND SAFETY	1.2 Ioniteedon. I alto of the Device that are designed to come into contact with the patient of the
		1 Should be EDA/Europen CE/DIS approved medicat
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.
	AINING 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.
	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.
8.3	_	
	RRANTY AND MAINTENANCE	
		3 years, including all spares and caliberation.

10. DC	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. No	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.	

EC	CG Machine -3 C	hannel
Version	n no. :	Draft_1
Date:		15/02/2018
Done b	y : (name.institution)	HCT/NHSRC
	#ERROF	<u>R!</u>
UMDN	IS name	Electrocardiographs, Multichannel
UMDN	IS code(s)	11411
	GENERA	Ĺ
1. USE	3	
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
	TECHNIC	AL
2. TEC	CHNICAL CHARACTERISTICS	
	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)
2.1		. 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. PHY	SICAL 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.
	ERGY SOURCE (electricity, UPS, solar	
4.1	Power requirements	220 to 240V, 50 Hz
4.1	Battery operated	Battery powered, silenceable alarm for power failure.
4.2	Protection	Voltage corrector/stabilizer to allow operation at \pm 30% of local rated
	Power consumption	
4.4	Other energy supplies	Mains cable to be at least 3m length.
4.5		
	CESSORIES, SPARE PARTS, CONSU	
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)
BIDD	ING/PROCUREMENT TERMS/D	ONATION REQUIREMENTS
6. ENV	VIRONMENTAL AND DEPARTMEN	TAL 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. STA	NDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.
	AINING 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. WA	RRANTY AND MAINTENANCE	

9.1	Warranty	3 years, including all spares and caliberation.	
10. DC	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. No	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.	

EC	ECG Machine -6 Channel		
Version n	10. :	Draft_1	
Date:		15/02/2018	
	: (name.institution)	HCT/NHSRC	
Boneby		RROR!	
UMDNS		Electrocardiographs, Multichannel	
UMDNS		11411	
UMDNS			
LUCE	GE	NERAL	
1. USE	Faux e la		
1.1	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram	
1.2	Lload has alinical deportment (mond	(ECG) through leads and sensors attached to the patient. ALL	
1.2	Used by clinical department/ward		
		HNICAL	
2. TECH	INICAL CHARACTERISTICS		
	Technical characteristics (specific to this	Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition	
	type of device)	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 $30 \text{ to } 250 \text{ bpm}$, with accuracy better than $\pm 5 \text{ bpm}$.	
		Heart rate trend display of at least previous 24 hours.	
2.1		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 \pm 5 bpm.	
2.2	User's interface	Manual	
2.3	Settings	Audiovisual alarms required: high and low heart rate (operator variable	
2.5		settings), cardiac arrhythmia, sensor/wire disconnected, low battery.	
	Software and/ or standard of	In built	
2.4	communication(where ever required		
	SICAL 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.	
	GY SOURCE (electricity, UPS, solar, gas, wate		
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 \pm 30% of local rated	
4.4	Power consumption	???????	
4.5	Other energy supplies	Mains cable to be at least 3m length.	
5. ACCE	SSORIES, 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)	
5.2 5.3	Consumables/reagents(open,closed	5 tubes electrode gel (if required)	
	- · · · ·		
	NG/PROCUREMENT TERMS/DONATION		
6. ENVI	RONMENTAL AND DEPARTMENTAL CONSI		
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. STAN	IDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.	
	NING AND INSTALLATION		
		Analability of 5 Ame/15 Ame Electrical Contrat	
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. WAR	RANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.	
	CUMENTATION		
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. Note			
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.	

EC	ECG Machine -12 Channel		
Version 1 Date:	10. :	Draft_1 15/02/2018	
	: (name.institution)	HCT/NHSRC	
Done by		RROR!	
UMDNS		Electrocardiographs, Multichannel	
UMDNS		11411	
CIVIDINS		NERAL	
1. USE			
	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram	
1.1	enniem puipose	(ECG) through leads and sensors attached to the patient.	
1.2	Used by clinical department/ward	ALL	
	TEC	HNICAL	
2. TECH	INICAL CHARACTERISTICS		
	Technical characteristics (specific to this	Simultaneous 12 Channel ECG recording with 12 lead simultaneous acquisition	
	type of device)	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 \pm 5 bpm.	
		Heart rate trend display of at least previous 24 hours.	
2.1		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 \pm 5 bpm.	
		reatrate neasurement range to be at least 50 to 250 bpm, with accuracy better than ± 5 bpm.	
2.2	User's interface	Manual	
	Settings	Audiovisual alarms required: high and low heart rate (operator variable	
2.3	Settings	Audiovisual atamis required, ingli atuli tow near tate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.	
	Software and/ or standard of	In built	
2.4	communication(where ever required		
	SICAL 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. ENEF	RGY SOURCE (electricity, UPS, solar, gas, wate		
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. ACCE	ESSORIES, 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)	
BIDDI	NG/PROCUREMENT TERMS/DONATION	REQUIREMENTS	
	RONMENTAL AND DEPARTMENTAL CONSI		
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	
	VDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.	
	NING AND INSTALLATION	and the second	
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.	
	RANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.	
	CUMENTATION		
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. Note			
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.	

FC	G Machine -12 Chai	nnel with tread mill
Version 1	10. :	Draft_1
Date:		15/02/2018
Done by	: (name.institution)	HCT/NHSRC
UMDNS		ERROR! Electrocardiographs, Multichannel
UMDNS		11411
UNIDINS		ENERAL
1. USE	0	ENERAL
I. USE	Clinical purpose	In this system, the patient exercises on a treadmill according to a standardized protocol and the cardiac
1.1		abnormalities can be studied under stress conditions
		which we may miss under resting.
1.2	Used by clinical department/ward	ALL
		CHNICAL
2. TECH	INICAL CHARACTERISTICS	
	Technical characteristics (specific to this	Should acquire and analyze 12/15 simultaneous ECG Leads
	type of device)	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
0.1		Should have facility for 12 lead resting electro cardio gram with full interpretation
2.1		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
		Dispray should have facinity to ampirity a normal gain along with a sample
2.2	User's interface	Manual
	Settings	Audiovisual alarms required: high and low heart rate (operator variable
2.3	Settings	settings), cardiac arthythmia, sensor/wire disconnected, low battery.
	Software and/ or standard of	In built
2.4	communication(where ever required	
3 DUVO	SICAL CHARACTERISTICS	
3. PHYS 3.1	Dimensions(metric)	NA
3.1 3.2	Weight (lbs, kg)	INA less than 5 kgs
3.2 3.3	Configuration	Case is to be hard and splashproof.
3.3 3.4	Noise (in dBA)	<50 dB
3.4 3.5	Heat dissipation	So dB 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.
	RGY SOURCE (electricity, UPS, solar, gas, wa	
	· · · · · · · · · · · · · · · · · · ·	220 to 240V, 50 Hz
4.1	Power requirements Battery operated	220 10 270 1, 50 IL
4.2	•	Values somester/stabilizer to allow expertise at + 200% of level or
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated
4.4	Power consumption	2929222
4.5	Other energy supplies	Mains cable to be at least 3m length.
	SSORIES, 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)
	NG/PROCUREMENT TERMS/DONATIO	•
	RONMENTAL AND DEPARTMENTAL CONS	
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. STAN	NDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.
8. TRAI	NING 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. WAR	RANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.	
10. DOC	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. Note	1. 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.	

1		RASONIC
Versior	1 no. :	Draft_1 15/02/2018
Date:	v · (nome institution)	HCT/NHSRC
Jone D	y : (name.institution) #E	RROR!
IMDN	S name	Aerosol Generators
	S code(s)	10046
	.,	NERAL
. 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 liqui mist appropriate for delivery to the patient's airways and/or
1.2	Used by aliginal deportment/word	for lung deposition.
1.2	Used by clinical department/ward	HNICAL
TEC		HNICAL
. IEC	CHNICAL CHARACTERISTICS Technical characteristics (specific to	1 Should be light weight, portable, Compact and easy to use 2 Frequency of
2.1	this type of device)	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
2.2	Software and/ or standard of	In built
2.3	communication(where ever required	
	SICAL 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.
	ERGY SOURCE (electricity, UPS, solar, gas	220 to 240V, 50 Hz
4.1	Power requirements	Should have in built rechargeable battery. Recharge should be possible with
4.2	Battery operated Protection	NA
4.3		NA
4.4	Power consumption Other energy supplies	NA
4.5	00 11	
	ESSORIES, SPARE PARTS, CONSUMABL	
5.1	Accessories, (mandatory, standard,	Should be provided with a complete nebulisation kit of 10 Nos. including adult
	ING/PROCUREMENT TERMS/DONA	
	TRONMENTAL AND DEPARTMENTAL C	
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
	NDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.
	INING 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.
	RRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.
0. DC	CUMENTATION	
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;
1. No	tes	
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.

/ersion	BULIZER - PNE	Draft_1
Date:	110	15/02/2018
	y : (name.institution)	HCT/NHSRC
one by		RROR!
MDN	S name	Aerosol Generators
	S code(s)	10046
		INERAL
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 liqui 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 ar 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 particle aerosol.
1.2	Used by clinical department/ward	
		HNICAL
TEC	HNICAL CHARACTERISTICS Technical characteristics (specific to	1 Charlithe Number of the base of the Comment of th
2.1	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
. PHY	SICAL 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.
. ENE	RGY SOURCE (electricity, UPS, solar, ga	s, 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
ACC	ESSORIES, SPARE PARTS, CONSUMABI	JES
5.1	Accessories, (mandatory, standard,	Should be provided with a complete nebulisation kit of 10 Nos. including adult
	NG/PROCUREMENT TERMS/DONA	
	IRONMENTAL AND DEPARTMENTAL (
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
	NDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.
	INING 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.
	RRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.
0. DO	CUMENTATION	
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;
1. No	tes	
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided;
	Recommendations or warnings	Any warning sign would be adequaetly displayed.

DI	BP APARATUS - DIGITAL		
D		DS-DIONAL	
Version	no. :	Draft_1	
Date:		15/02/2018	
Done by	: (name.institution)	HCT/NHSRC	
		RROR!	
UMDNS			
UMDNS	s code(s)		
	GEI	NERAL	
1. USE			
	Clinical purpose		
1.2	Used by clinical department/ward	ALL	
	TEC	HNICAL	
	HNICAL CHARACTERISTICS		
	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. 	
	User's interface Software and/ or standard of communication(where ever required	Manual NA	
2 DUV	SICAL CHARACTERISTICS		
	Dimensions(metric)	NA	
	Weight (lbs, kg)	NA	
	Noise (in dBA)	NA	
	Heat dissipation	NA	
	•		
	Mobility, portability	Supplied in protective case for clean storage and safe transport.	
	RGY SOURCE (electricity, UPS, solar, gas	s, water, CO2)	
-	Power requirements	NA	
-	Power requirements Battery operated	NA NA	
4.2			
4.2 4.3	Battery operated	NA	
4.2 4.3 4.4 4.5	Battery operated Protection Power consumption Other energy supplies	NA NA NA NA	
4.2 4.3 4.4 4.5	Battery operated Protection Power consumption	NA NA NA NA	
4.2 4.3 4.4 4.5 5. ACCE	Battery operated Protection Power consumption Other energy supplies	NA NA NA NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL	NA NA NA NA ES Pediatric blood pressure cuffs (compatible with quoted digital blood	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT	NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood TION REQUIREMENTS	
4.2 4.3 4.4 5. ACCE 5.1 BIDDIN 6. ENVI	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard,	NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood TION REQUIREMENTS	
4.2 4.3 4.4 5. ACCE 5.1 BIDDIN 6. ENVI 6.1	Battery operated Protection Power consumption Other energy supplies SSSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS I .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection &	NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood TON REQUIREMENTS ONSIDERATIONS	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2 7. STAN	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL C Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS I .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and I.Disinfection: Parts of the Device that are designed to come into contact with the patient or the	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2 7. STAN 7.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,);	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS I .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2 7. STAN 7.1 8. TRAI	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL C Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); INING AND INSTALLATION	NA NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product.	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2 7. STAN 7.1 8. TRAI 8.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); INING AND INSTALLATION Pre- installation requirements:	NA NA NA NA NA NA ES Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the I. Should be FDA/Europen CE/BIS approved product. NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); INING AND INSTALLATION Pre- installation requirements: Requirements for sign-off	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the I. Should be FDA/Europen CE/BIS approved product. NA NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical,	NA NA NA NA NA NA ES Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the I. Should be FDA/Europen CE/BIS approved product. NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); INING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty	NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDERATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the I. Should be FDA/Europen CE/BIS approved product. NA NA	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1 10. DOO	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty CUMENTATION	NA NA NA NA NA NA NA ES Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 . Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA Sapara (Sapara) I approved product.	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1 10. DOO 10.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty CUMENTATION Operating manuals, set manuals,	NA NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA Should be routers in operation and basic maintenanc shall be provided. 3 years, including all spares and caliberation. Should provide 2 sets(hard copy and soft copy) of:	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1 10. DOO 10.1	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty CUMENTATION	NA NA NA NA NA NA NA ES Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 . Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA Sapara (Sapara) I approved product.	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1 10. DOO 10.1 10.2 11. Note	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty CUMENTATION Operating manuals, set manuals, Other accompanying documents es	NA NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA Should be routers in operation and basic maintenanc shall be provided. 3 years, including all spares and caliberation. Should provide 2 sets(hard copy and soft copy) of:	
4.2 4.3 4.4 4.5 5. ACCE 5.1 BIDDIN 6. ENVI 6.1 6.1 6.2 7. STAN 7.1 8. TRAI 8.1 8.2 8.3 9. WAR 9.1 10. DOO 10.1 10.2 11. Note	Battery operated Protection Power consumption Other energy supplies SSORIES, SPARE PARTS, CONSUMABL Accessories, (mandatory, standard, NG/PROCUREMENT TERMS/DONAT RONMENTAL AND DEPARTMENTAL CO Atmosphere/Ambience (air User's care, Cleaning, Disinfection & NDARDS AND SAFETY Certificates (pre-market, sanitary,); NING AND INSTALLATION Pre- installation requirements: Requirements for sign-off Training of staff (medical, RANTY AND MAINTENANCE Warranty CUMENTATION Operating manuals, set manuals, Other accompanying documents	NA NA NA NA NA NA Pediatric blood pressure cuffs (compatible with quoted digital blood ION REQUIREMENTS ONSIDER ATIONS 1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and 1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the 1. Should be FDA/Europen CE/BIS approved product. NA NA NA NA Should be routers in operation and basic maintenanc shall be provided. 3 years, including all spares and caliberation. Should provide 2 sets(hard copy and soft copy) of:	

BP APARATUS - ANEROID

Version	ersion no. : Draft_1				
Date:		15/02/2018			
Done by	one by : (name.institution) HCT/NHSRC				
	#ERROR!				
UMDNS					
UMDNS	S code(s)				
	GEN	ERAL			
1. USE					
1.1	Clinical purpose				
1.2	Used by clinical department/ward	ALL			
		NICAL			
2. TEC	HNICAL CHARACTERISTICS				
	Technical characteristics (specific to	Should be able to measure blood pressure in adult as well as pediatric patients.			
	this type of device)	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			
2.1		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			
	Software and/ or standard of	NA			
2.3	communication(where ever required				
2 DUV					
3.1	SICAL CHARACTERISTICS 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.			
	RGY SOURCE (electricity, UPS, solar, gas,				
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			
	ESSORIES, SPARE PARTS, CONSUMABLE				
5.1	Accessories, (mandatory, standard,	Pediatric blood pressure cuffs (compatible with quoted digital blood			
	NG/PROCUREMENT TERMS/DONATI				
	RONMENTAL AND DEPARTMENTAL CO				
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			
	NDARDS AND SAFETY				
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.			
	INING 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.			
	RRANTY AND MAINTENANCE				
9.1	Warranty	3 years, including all spares and caliberation.			
	CUMENTATION				
10. DO	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:			
10.1	Other accompanying documents	List of essential spares and accessories, with their part number and cost;			
10.2 11. Not		and or opportunit spartes and accessories, with their part number and cost,			
11. Not 11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided;			
11.1	Recommendations or warnings	Any warning sign would be adequaetly displayed.			
11.2	warmings	m) maning sign source acquired asphaled.			

Ste	Stethoscope				
Version no. : Draft_1					
Date:	1 110	15/02/2018			
	y : (name institution)	HCT/NHSRC			
Done o	Done by : (name.institution) HCT/NHSRC #ERROR!				
UMDN	IS name	13755			
	IS code(s)	Stethoscopes, Mechanical			
UMDI	GENER				
1. USF					
1. USE	Clinical purpose	designed for listening to sounds from the heart and lungs. It typically comprises a membrane at the listening			
1.1	Chinear purpose	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			
	TECHNIC	CAL			
2. TEC	CHNICAL 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	NA			
2 DUX	communication(where ever required				
	/SICAL CHARACTERISTICS	ht a			
3.1	Dimensions(metric)	NA NA			
3.2 3.3	Weight (lbs, kg) Noise (in dBA)	NA			
		NA			
3.4	Heat dissipation				
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.			
-	ERGY SOURCE (electricity, UPS, solar				
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. ACC	ESSORIES, SPARE PARTS, CONSUM				
5.1	Accessories, (mandatory, standard,	Spare set of earpieces			
BIDD	ING/PROCUREMENT TERMS/DO	NATION REQUIREMENTS			
6. ENV	IRONMENTAL AND DEPARTMENTA	L 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. STA	NDARDS AND SAFETY				
7.1	Certificates (pre-market, sanitary,);	1. Should be FDA/Europen CE/BIS approved product.			
	AINING AND INSTALLATION				
8.1	Pre- installation requirements:	NA			
8.2	Requirements for sign-off	NA			
8.2	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.			
	RRANTY AND MAINTENANCE				
		2 years including all sparse and caliberation			
9.1	Warranty	3 years, including all spares and caliberation.			
-	OCUMENTATION	Charles and a construction of			
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. No					
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.			

Pe	Peak flow meter				
	Version no. : Draft_1				
Date:		15/02/2018			
Done by : (name.institution)		HCT/NHSRC			
	#ERROR!				
UMDI	NS name	15965			
UMDI	NS code(s)	Flowmeters, Gas, Respiratory, Peak Expiratory Flow			
	GENERAL				
1. US	E				
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				
2 TE	TECHNICAL CHNICAL CHARACTERISTICS				
2. TE	Technical characteristics	1.Range of measurement to include 50 to 400 L/min (paediatric), 60 to 800 L/min (adult)			
2.1	(specific to this type of device)	2.Accuracy of measurement shall be better than $\pm 10\%$, 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			
	YSICAL CHARACTERISTICS				
3.1	Dimensions(metric)	NA			
3.2	Weight (lbs, kg)	NA <150 dB			
3.3	Noise (in dBA) 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.			
	ERGY SOURCE (electricity, UPS,				
	Power requirements	NA			
4.2	Battery operated	NA			
4.3	Protection	NA			
4.4	Power consumption	NA			
4.5	Other energy supplies	NA			
	CESSORIES, SPARE PARTS, CO				
5.1		Five replacement sterilizable mouthpieces (if removable type)			
BIDE	DING/PROCUREMENT TERM	IS/DONATION REQUIREMENTS			
	VIRONMENTAL AND DEPART				
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			
	ANDARDS AND SAFETY	1. Should be EDA /European CE/DIS			
7.1 <mark>8 TR</mark>	Certificates (pre-market, sanitary,); AINING AND INSTALLATION	1. Should be FDA/Europen CE/BIS approved product.			
	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.			
8.2 8.3	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.			
	ARRANTY AND MAINTENANCE				
9.1	Warranty	3 years, including all spares and caliberation.			
	OCUMENTATION				
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. N	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.	