TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR ANESTHESIA DEPARTMENT

Ministry of Health and Family Welfare
Government of India

INDEX

LIST OF CONTRIBUTORS

S.NO	EXPERTS	DESIGNATION	ORGANIZATION
1	Dr.Anjolie Chhabla	Professor - Anesthesiology	AIIMS, New Delhi
2	Dr. Rajiv Gandhi	Professor - Anesthesiology	VMMC & Safdarjang Hospital, New Delhi
3	Dr. Mohandeep Kaul	Consultant and HOD – Anesthesiology	Dr. Ram Manohar Lohia Hospital, New Delhi
4	Dr Bijay Kumar Dhal	M.O (Equipment)	OSMCL, Odisha
5	Er.Prakash Mallick	Biomedical Engineer-State Drug Management Unit	DHS, Odisha
INDUSTRY ASSOCIATION EXPERTS			
1	Representatives from HLL- HITES		
2	Representatives from IPC		
3	Representatives from FICCI Association.		
4	Representatives from MTAI Association.		
5	Representatives from AIMED Association.		
INTERNAL EXPERTS			
1	Dr. S.B.Sinha	Ex- Advisor - Healthcare Technologies	NHSRC, New Delhi
2	Er. Mohammed Ameel	Senior Consultant- Healthcare Technologies	NHSRC, New Delhi
3	Er. Anjaney	Consultant- Healthcare Technologies	NHSRC, New Delhi
4	Er. Ajai Basil	Consultant- Healthcare Technologies	NHSRC, New Delhi
5	Er. P.S.Vigneshwaran	Consultant- Healthcare Technologies	NHSRC, New Delhi
6	Er.Bharat Bhushan	Consultant- Healthcare Technologies	NHSRC, New Delhi
7	Er. Pawan Kumar	Fellow- Healthcare Technologies	NHSRC, New Delhi
8	Er. Purnima Dhamija	Fellow- Healthcare Technologies	NHSRC, New Delhi

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.

BOYLE'S APPARATUS ANESTHESIA MACHINE BASIC PERFORMANCE (2 GAS SYSTEM)

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name. Institution)	HCT/NHSRC

NAME, CATEGORY AND CODING

UMDNS name	Anesthesia Units
UMDNS code(s)	10134

GENERAL

1. USE

1.1	**Clinical purpose**	Anesthesia machine is used for delivering anesthesia agents to the patients during surgery.
1.2	**Used by clinical department/ward**	Operation Theatre

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	**Technical characteristics (specific to this type of device)**	Anesthesia apparatus with circle absorber and Sevoflurane Tec vaporizer (with provision for Selecta Tec Back bar) Must have antistatic castor wheel Should have provision for spares Cylinder with Pressure gauge Must have color coded yoke and ports Must have pin index system Must have touch coded valves Must have link 25 mechanisms Must have pop off valve Must have Oxygen failure alarm Must have vaporizer for Sevo/halothane and isoflurane Calibrated vaporizer Pressure compensated Flow compensated Must have provision for Anesthesia ventilator Must have circle absorber Must have antistatic corrugated tubing Table top for arranging drugs and syringes Should have provision for two inlets for two oxygen cylinders- A type and two inlets for two Nitrous oxide cylinders with pin index system- A type High pressure relief valve in the Back bar system Diaphragm in the pressure regulator- Teflon or Steel with 3 years warranty Breathing circuit with inflation pressure manometer 5 meters of high pressure tubing, color coded for Oxygen and Nitrous oxide with valve attachment and pin index at the machine end. Provision for two 60 psi Oxygen source built in the machine Should have audible alarm for O2 failure

		The soda lime canister should be double chambered single piece with metal bar on top with provision for APL valve. Gas inlet and outlet change over knob to isolate the canister Should have visible inspiratory and expiratory valve Should have adjustable pressure relief valve Should have single switch change over from spontaneous to bag ventilation A two gas (oxygen/nitrous oxide) anesthetic machine with pipe line inlets for oxygen, nitrous oxide and provision to mount two O2 & N2O pin indexed cylinder with cylinder pressure & working pressure gauges with 2 stage regulators for each gas. 4. Table top for keeping the monitor and Anesthesia ventilator.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (where ever required**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		
4.1	**Power requirements**	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	**Battery operated**	Yes, at least 30 minutes back up.
4.3	**Protection**	Stabilizer to be provided for protection.
4.4	**Power consumption**	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Cylinders/ Pipeline. Circle absorber – 01 No. Adult and Pediatric autoclavable silicone breathing circuits – 2 each. Humidifiers – 1 No Vaporizer for Sevoflurane – 1 no Temperature Probe Skin reusable – 02. Temperature core reusable -04 (02-Adults, 02-paediatrics) Standard accessories to make all parameters working -01 set. Disposable adult and pediatric circuit – 50 each. HME Filters – 1000 nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust ...)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%

6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details**	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

ANAESTHESIA MACHINE – 3 GAS SUPPLY SYSTEM

Version no. :		Ver_1
Date:		12/07/2018
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Anesthesia Units
UMDNS code(s)		10134
GENERAL		
1. USE		
1.1	**Clinical purpose**	Anesthesia machine is used for delivering anesthesia agents to the patients during surgery.
1.2	**Used by clinical department/ward**	Operation Theatre
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	Should be portable stainless steel, with large antistatic sturdy castor wheels fitted with brakes. Anesthesia machine should be with 3 gas supply system (O_2, N_2O and Air) with pipeline connections and reserve cylinder yokes All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. System should permit connection of at least two yokes, one dedicated to O_2 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. All the vaporizers should be maintenance free. It should have following Ventilation modes Manual/spontaneous, VCV. Tidal volume: A control adjusts the volume of individual breaths within range of 50-1,200 cc. Minute volume: A control adjusts the total inspiratory volume-per-minute delivery from the bellows shall be >20 L/min. The respiratory frequency can be set within range of 5-60 breaths per minute. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-120 L/min. Pressure limit shall be adjustable and <70 preferred cm H_2O. Unit should have PEEP of 0-20 cm H_2O. Unit can able perform to ensure proper functioning of Pre-use vent, gas supply, ongoing system. It should have active or passive scavenging system. It should provide facility to monitor of Airway pressure along with

		High-pressure alarm, Sub atmospheric pressure alarm, continuing pressure alarm and Low pressure/apnea. System should also provide facility to monitor of expiratory volume/flow along with Apnea alarm. It should have 3 (caution, advisory, alarm) prioritized alarms for ventilator failure, low oxygen supply pressure, inadequate volume delivery, disconnecting alarm and power supply failure. Should have dual cascade type flow meter for O2, N2O and Air calibrated in multiple scale. Should have adjustable pressure limiting valve, breathing circuit pressure measuring device. Should have a bag/ ventilator select valve integrated on to absorber. Should be able to use low flow anesthesia technique and facility to attach oxygen sensor. Should have CO2 absorbent chamber canister. Integrated physiological monitoring is preferred.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (where ever required**	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise pressure level: ≤60 dbA.
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	**Battery operated**	Yes, at least 30 minutes back up.
4.3	**Protection**	Stabilizer to be provided for protection.
4.4	**Power consumption**	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should have a provision for mount monitors on top of the machine. The table top made up of stainless steel/ chemical resistant fiber Standard bains circuit : 2 nos. with each unit Humidifier – 1 no Vaporizer Halothene – 01 No. Vaporizer Desflurane – 01 No. Vaporizer isoflurane – 01 No. Vaporizer sevoflurane – 01 No. Reservoir bag (2liters): 3 nos. with each machine Connectors for bains circuit: 5 nos with each machine. AMBU bag: 1 no. with each machine. Pressure regulated valve with 5 meter hose and connector (conversion kit) for oxygen should be provided with each machine. Should be supplied with driver gas

		hoses with necessary attachments (color coded).
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust ...)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. 1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements:**	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		

11.1	**Service Support Contact details**	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

ANAESTHESIA WORKSTATION

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name. Institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Anesthesia Units
UMDNS code(s)	10134
GENERAL	
1. USE	
1.1 Clinical purpose	Devices that continuously or intermittently administer a mixture of gases (e.g., oxygen, nitrous oxide, the vapor of a volatile liquid such as halogenated hydrocarbon), varying the proportion of gases in order to control an individual's level of consciousness. These devices are also designed to facilitate spontaneous, controlled, or assisted ventilation with these gas mixtures. An anesthesia unit is typically comprised of four basic subunits: a gas supply and control circuit, breathing and ventilation circuit, a scavenging system to help prevent the escape of exhaled gases, and a set of function and breathing circuit monitors (e.g., inspired oxygen concentration, breathing circuit integrity).
1.2 Used by clinical department/ward	Operation Theatre
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 Technical characteristics (specific to this type of device)	Flow Management: Should be compact, ergonomic and easy to use. Machine should provide electronic gas mixing. Multi color TFT display of at least 15" size, with virtual meters for O2, N2O or Air. Dual flow sensing capability at inhalation and exhalation ports. Should have backup O2 control which provides an independent fresh gas source and flow meter control in case of electronic failure. Gas regulators (flow control valves) shall be of modular design/graphic display. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. System should permit connection of at least two yokes, one dedicated to O2 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases.

		i. Hypoxic guard to ensure minimum 25% O2 across all O2-N2O mixtures and Oxygen failure warning. Breathing System: Latex free fully autoclavable/ disposable with minimal flow of 250 ml of O2. Sensor should not require daily maintenance. Bag to vent switch shall be bi stable and automatically begins mechanical ventilation in the ventilator position. Adjustable pressure limiting valve shall be flow and pressure compensated. Vaporizers: Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. All the vaporizers should be temperature, pressure and flow compensated vaporizers and maintenance free. Ventilation: The work station should have integrated anesthesia ventilator system. It should have following Ventilation modes Manual/spontaneous, VCV, PCV, SIMV or pressure support, advanced modes. Tidal volume: A control adjusts the volume of individual breaths within range of 20-1,500 cc. Minute volume: A control adjusts the total inspiratory volume- per-minute delivery from the bellows shall be >20 L/min. The respiratory frequency can be set within range of 5-60 breaths per minute. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-180 L/min. Pressure limit shall be adjustable and <70 preferred cm H2O. Unit should have PEEP of 0-20 cm H2O. The workstation should be capable of delivery of low flow anesthesia. Anesthesia Monitoring Specifications: Monitoring of vital parameters: ECG, NIBP, SPO2, and Invasive Blood Pressure. Twin temperature measurement with skin and core temperature probes –Two sets with each monitor. Automatic identification and measurement of anesthetic agents EtCO2, O2, and N2O and MAC value. FiO2 measurement. Facility to store snapshots during critical events for waveform review at a later stage. Audio visual and graded alarming system. Display of ventilator: Mode of ventilation to be displayed, Respiratory rate, flow, pressure also to be displayed.
2.2	**User's interface**	Manual

2.3	Software and/or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Cylinders/ Pipeline. Circle absorber – 01 No. Vaporizer Halothene – 01 No. Vaporizer Desflurane – 01 No. Vaporizer isoflurane – 01 No. Vaporizer sevoflurane – 01 No. Adult and Pediatric autoclavable silicone breathing circuits – 2 each. Reusable IBP cable -04. Humidifiers – 1 No Disposable transducer – 100 Temperature Probe Skin reusable – 02. Temperature core reusable -04 (02-Adults, 02-paediatrics) Depth of anesthesia sensors – 50 Accessories for neuromuscular transmission monitor -01 set. Standard accessories to make all parameters working -01 set. Disposable adult and pediatric circuit – 50 each. HME Filters – 1000 nos Vital parameter accessories (ECG Leads – 5 sets, NIBP Cuffs all sizes) -01 set. Spo2 probes both adult and pediatric 2 in no should be supplied with each machine. EtCo2 sampling line and connector should be supplied 25 no each with apparatus.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Sterilization not required.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

MULTI PARAMETER MONITOR WITH ANESTHESIA GAS MONITOR

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name. Institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Anesthesia Units
UMDNS code(s)	10134
GENERAL	
1. USE	
1.1 Clinical purpose	
1.2 Used by clinical department/ward	Operation Theatre
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 Technical characteristics (specific to this type of device)	Should have modular Multi parameter monitor with TFT/LED/LCD/touch screen display with more than 15 inches with at least 8 wave forms and upgradable up to 14 waveforms & 22 parameter numeric on single display. The waveforms should be user selectable. Monitor should have in built Lithium-ion type battery for 2 Hour continuous operation. Should have keys for quick access to main functions. Should be able to monitor ECG(3,5,12 leads), SPO2, NIBP, 2 IBP, Respiration Rate, 2 temp, ETCO2, for adult, pediatric and neonatal patients as standard and Anesthesia gas monitoring. Monitor must have facility for at least 2 IBP measurements simultaneously. Also should have SPV/PPV monitoring facility 5 Lead ECG monitoring with full range of lethal arrhythmia recognition capability and ST analysis up to 12 leads and 72hour trend facility. Respiration, Apnea alarm, Prioritized audio visual alarms and snap shot facility. Transport module with display and battery backup of at least 1 hour. Pulse Oxymeter (SPO2) with Plethysmogragh &Pulse strength indicator With Variable pitch with change in SpO2 (low perfusion motion tolerance technology). Side-stream Capnography with display of CO2 wave form & digital values (ETCO2, FiCO2, RR). Monitor should have provisions for automatic identification and measurement of anesthesia agents, CO2, O2, N2O and facility to measure at least 5 volatile agents with automatic detection. Should be upgradable to monitor cardiac output (Thermo dilution/ PICCO), BIS/DA and NMT. It should have provision for automatic identification and measurement and anesthetic agents, Co2, O2, N2O and facility to measure MAC. The display setting should have at least 10 user defined setups variable as per applications for flexible use of the monitor in various clinical

		environments as in OT, PACU, ICU, ER, NICU. 16. Monitor should have networking options with bidirectional & bed to bed communication.
2.2	User's interface	Manual
2.3	Software and/or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Should provide following accessories 20 Nos of Disposable IBP transducers with all standard accessories & 6 nos of reusable adapter cable (type as requested by the end user) Accessories for Anesthesia Gas/Co2 monitoring -25 Nos (disposable) Reusable adult 5 lead ECG cable set – 2 nos. NIBP cuffs for standard Adult(2 Nos), Obese Adult, Child and infant – all 1 each.(5 Nos) Temperature Probe(esophageal/ rectal)- 2Nos Accessories Spo2 probe adult (Reusable) – 2 Nos Spo2 probe pediatric (Reusable) – 2 Nos Fore Head Spo2 Sensor – 2 Nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

PFT MACHINE

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name. Institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Spirometers
UMDNS code(s)	13674
GENERAL	
1. USE	
1.1 Clinical purpose	Instruments designed to measure the volume and flow rate of air inhaled and/or exhaled from the lungs and additional variables needed for pulmonary function assessment. These instruments are typically a mechanical or electromechanical device with volume and/or flow sensors and a gauge or display; they may also include a computerized unit to process the data and a graphical recorder.
1.2 Used by clinical department/ward	Operation Theatre
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 Technical characteristics (specific to this type of device)	It must meet latest ATS/ERS standards. It should be able to measure/do the following: Spirometry & Flow Volume Parameter Maximum Ventilation Volume Pre & Post Bronchodilator comparison Lung Volumes & Sub – divisions Broncho Provcation Test. Flow meter –Bi-directional digital turbine (flow: up to 14L/s or more, accuracy: within 3%) or Pneumotach (flow: up to 14L/s or more; accuracy: within 3%). Resistance : less than 1.5 cm H2O/L/Sec. Parameters should be measured with highest accuracy & reproducibility and accuracy should be least, if at all affected with High surrounding Temperature and humidity levels. Should incorporate Electronic Barometer & temperature. Sensors, for Automatic BTPS Correction. Overlaying of previous test curves for comparison. Real Time Flow Volume and Volume – time Traces on Computer Screen. Capability to select and modify predicted equations. Facility to interface for desktop / Laptop Computer. System software should be based on Windows 7/XP OS. Should be supplied with Computer Interfacing package, Cables, Software, 3-Litre Precision Calibration Syringe, Standard accessories & Manual. Laptop / Desktop Computer: 4 GB RAM, Intel core i3/i5 processor(3rd generation),15"TFT Screen, USB Ports, DVD R/W, Hard Disc Drive 500GB, Laser Printer, UPS.

2.2	User's interface	Manual
2.3	Software and/or standard of communication(where ever required	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Pneumotach Screens (05 Nos.), Pulmonary Filters (100 Nos), Disposable Mouthpieces (500 Nos.).
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		

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

CONSUMABLES

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name. Institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	NA
UMDNS code(s)	NA
GENERAL	
1. USE	
1.1 Clinical purpose	
1.2 Used by clinical department/ward	OPERATION THEATRE
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1 Technical characteristics (specific to this type of device)	**AMBU BAG** **Ambu Bag Pediatric - 500ml** Should have silicon rubber bellow to withstand autoclave at 134 deg. C Should provide with autoclavable face mask & Oxygen connecting tube. Should be supplied with a carry pouch It should have a bag volume of 500 ml. and a variation of ± 100ml. will be accepted. Should have an expiratory resistance of 2.2cms of water Should have an inspiratory resistance of 3.3cms of water. It should have controlled flow rates and ventilation, and with reduced airway pressure. Should have a port in the bag to connect oxygen with reservoir bag **Ambu Bag Adult- 1700ml** Should have silicon rubber bellow to withstand autoclave at 134 deg. C Should provide with autoclavable face mask & Oxygen connecting tube. Should be supplied with a carry pouch. It should have a bag volume of 1700 ml. and a variation of ± 100ml. will be accepted. Should have an expiratory resistance of 2.2cms of water Should have an inspiratory resistance of 3.3cms of water. It should have controlled flow rates and ventilation,

		and with reduced airway pressure. Should have a port in the bag to connect oxygen with reservoir bag **ENDOTRACHEAL TUBE SET:** Allows for placement in either the esophagus or the trachea. Soft, pharyngeal cuff. Color-coded stems and pilot balloons make it easier to identify the esophageal and tracheal lumens. Placement ring to line up with the teeth or alveolar ridge helps to assure proper placement Single-use, sterile. **LARYNGAL MASK AIRWAY** Laryngal Mask Airway Silicon size 1, 1.5, 2 &2.5 (Peadiatrics) 3&4(Adult), Flexible and disposable(1 no each) LMA with a drainage tube for insertion of Ryles Tube(reusable 40 insertions). Introducer along with LMA Pro seal for insertion. **CONNECTOR SET OF ETT** 60 and 90-degree curves Non-sterile Compatible with all common endo tracheal tubes and Y-connectors. **MOUTH PROP** **TONGUE DEPRESSOR**
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication(where ever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	NA
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1 YEAR
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.