TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR ENT DEPARTMENT

Ministry of Health and Family Welfare
Government of India

INDEX

S.No	DETAILS	Page No
List of contributors		
Introduction		
1	AUDIOMETER	3
2	IMPEDENCE AUDIOMETER	5
3	Operating Microscope (ENT)	7
4	OAE Analyser	9
5	HEAD LIGHT-ENT	11
6	EAR SURGERY INSTRUMENTS SET	13
7	ENT NASAL SET	15
8	Oesophagoscope	17
9	Tuning Fork	19
10	Sound Proof Room	21
11	OTOSCOPE	23
12	Tracheostomy SET	25
13	Bronchoscopes	27

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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.

AUDIOMETER

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		10228
UMDNS code(s)		Audiometers
GENERAL		
1. USE		
1.1	Clinical purpose	Instruments designed to measure and characterize hearing loss by determining the lowest audible level of a patient for pure test tones, signals or both. These devices include tone generators, amplifiers, and sound-level monitors. Audiometers are intended for conducting diagnostic tests for hearing disorders and assisting in other otologic disorders diagnosis.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should be Completely Digital. Two Channel digital audiometer with ANSI specified standard Tone Continous Tone, Pulse Tone, WarbleTone Frequency Range:- Air conduction 125 – 8000Hz and Bone Conduction 250 – 80000Hz. Auto threshold, Bekesy test,DLI,DLF,loudness balancing, diference masked & unmasked MLB , SISI.stenger,Lombard test,ABLB SISI with increment 1-2-3-4-5 dB, DECAY Test. Should have facility for AC, BC and Speech Audiometery. External Inputs: Live, Tape recorder, CD Player or Microphone. Automatic calculation of Speech Scoring With suitable Computer &Printer.). Accuracy of frequency: better than 1%. 11.PC interface for online communication. 12. Data Storage facilities. 13.Maximum Hearing Level:- Air: -10 dB to 120 dBHL, Bone: -10 dB to +80dBHL, Speech: 10dB to +100dBHL, Masking: -10dB to + 100dBHL. Optional: Should be upgradable to High Frequency Audiometry Should be upgradable to Free Field Audiometry
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<150 dB
3.4	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	-
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Insert masking phone, Monitor earphone, Patient's response switch.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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) 4. IEC 60645-l,IEC 60645-2,IEC60645-4 / ANSI S,3.6
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

IMPEDENCE AUDIOMETER

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		10228
UMDNS code(s)		Audiometers
GENERAL		
1. USE		
1.1	Clinical purpose	The primary purpose of impedance audiometry is to determine the status of the tympanic membrane and middle ear via tympanometry.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Probe tone: 220 and 1000Hz (For Pediatric testing also) Probe assembly with contralateral test facility (with supra aural earphones: TDH 39/TDH39A/TDH49/TDH49A/TDH 50 with MX 41 AR ear cushions or insert earphones (ER Tone 3A) Test cavities (0.5, 2, 5cc) Probe tips - assorted Shall have Printer Tests required a. Compensated tympanometry (ear canal volume and tympanometric peak pressure) b. Ipsilateral and contralateral acoustic reflexes c. Eustachian tube function tests - intact and perforated 7. Air pressure range: + 200da Pa to – 400 da Pa 8. Stimuli for acoustic reflexes: a. Type: Pure tones; b. Frequencies: 500Hz, 1000Hz, 2000Hz and 4000Hz c. ntensity : up to 120 dB HL 10. Shall have Self-calibration
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<150 dB
3.4	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	--
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Insert masking phone, Monitor earphone, Patient's response switch.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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) 4. lEC 60645-l,IEC 60645-2,IEC60645-4 / ANSI S,3.6
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.
	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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

Operating Microscope (ENT)

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Microscopes, Light, Operating, Otorhinolaryngology
UMDNS code(s)		12538
GENERAL		
1. USE		
1.1	Clinical purpose	Operating light microscopes designed to magnify minute structures (e.g., nerves, vessels) in the performance of delicate ear, nose, and/or throat (ENT) surgical procedures, which require high magnification and adjustable focusing. ENT operating microscopes typically consist of a stereo microscope (standard or modified) and a mobile floor stand or wall or ceiling mount. The microscope is usually held by an adjustable arm attached to the support mechanism. Most operating microscopes are equipped with motorized focusing, adjustable magnification systems (manual, zoom, or both), backup lamps, and inclined tubes that permit the surgeon to see the field from a vertical perspective while keeping his or her head erect. Dual- or multiple-observation capability and the optical integration of still, motion picture, and TV cameras are common features of otorhinolaryngoscopy microscopes.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should be mobile floor stand on four caster wheels for easy handling and absolute stability with brake. Should have apochromatic optics and should have LED Light Source with bright natural Light. Should have Manual Fine Focusing Should have Focul Distance of Objective Lens(F=200mm) Should have three step magnification : 5x,10x & 20x and Should have total magnification from at least 0.6x to 1.6x. Additional objective lens of 250mm and 300 mm and 400mm should be supplied. Eye piece should be minimum 10x or 12.5x or 15x paired super wide field with eye guards. Should have universal coupling. Should have 90 degree binocular with converging optics. 10. Should have cold light coaxial illumination by fiber light guide . Should have tools free design for stand-by bulb change over and for failed bulb replacement. 12. Should have heat absorbing and UV filters. 13. Should have in-built green and cobalt blue filters. 14. Should have counter balanced arm mechanism. 15. Should have a minimum vertical stroke of 400mm
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)	< 50 dB
3.4	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should be operated in 200-240 Vac 50/60 Hz input supply.
4.2	Battery operated	NA
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	???????
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Beam Splitter with 'C' Mount 2. Motorised with Foot Control 3. Objective lens 250mm, 300mm & 400mm 4. Monocular assistoscope 5. Binocular Assistoscope 6. Battery operated light source
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Autoclavable eye pieces
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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). 4. lEC 60645-l,IEC 60645-2-40 for safety.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospial.
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 adequaetly displayed.

OAE Analyser

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	OAE testing often is used as a screening tool to determine the presence or absence of cochlear function, although analysis can be performed for individual cochlear frequency regions
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	TEOAE Specifications: Facility of click stimulus and Tone burst stimulus Configurable stimulus intensity Band analysis from 1 KHz to 8 KHz Reproducibility in half octave bands Should have suppression facility Full cross correlation, frequency analysis with reproducibility and signal to noise data on single test or between test pairs Customized TEOAE protocol DPOAE specifications: 1. Frequency range Minimum of 500-10,000 Hz. 2. Number of test points per octave: Upto 32 points per octave 3. Intensity: f1 and f2 levels from 0 to 70 dB SPL. 4. Customizable measurement protocols. 5. Variable Ratio: f2/f1. 6. DP Definition Points: f2-f1; 2f2-f1; 2f1-f2; 3f1-2f2; 3f2-2f1; 4f1- 3f2; 4f2-3f1. 7. Contra lateral suppression facility 8. SNR assessment SOAE specification 1. Sensitive microphone to pick up SOAE 2. Multiple SOAE's 3. Actual and latent spontaneous OAE Computer Specification: 1. Minimum Core i5 Pentium processor 2. 4 GB DDR 3 RAM
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<150 dB
3.4	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 to 240V, 50 Hz
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply
4.3	Protection	Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage.
4.4	Power consumption	????????
4.5	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Reusable ear tips, Rechargeble Battery,
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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) 4. lEC 60645-l,IEC 60645-2,IEC60645-4 / ANSI S,3.6
	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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.
	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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

HEAD LIGHT-ENT

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		NA
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	It is concave and is used to produce a parallel beam of light; doctor views through the hole to focus light into the cavity under inspection during surgery.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Should be a cold headlight system suitable for ENT Operating Theater with provision to adjust light intensity. Should have head light adjustment side to side and up and down and Multiple position swivel head - 180° rotation, made of chemical resistant resin and includes adjustable comfortable elasticated light weight headstrap with lock. Should be a coaxial fiber optic light headlight with a variable light spot. Should have focusing sleeves for uniform quality illumination. Should use a halogen light source with spare lamp and should have provision to change over in the event failure of the primary bulb.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	<50 dB
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should work with input 200 to 240Vac 50 Hz supply.
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply
4.3	Protection	NA
4.4	Power consumption	???????
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Spare bulbs, 2. 5 numbers of AA size batteries.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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). 4. lEC 60645-l,IEC 60645-2-40 for safety.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

EAR SURGERY INSTRUMENTS SET

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		22970
UMDNS code(s)		Instruments, Surgical, Middle Ear
GENERAL		
1. USE		
1.1	Clinical purpose	Surgical instruments designed to cut middle-ear tissues during endaural procedures. These scissors are typically small handheld, manual instruments with two long metallic (e.g., stainless steel) blades with straight, angled, or curved, very fine sharp tips that slide past each other (i.e., shearing action). The blades are attached through long slender shanks to handles with the proximal end conformed as a ring to facilitate holding and operating with the fingers; both parts are joined by a swivel pin in the center. Middle-ear surgery scissors are used to cut soft tissue in several procedures of the stapes and tympanic membrane (e.g., tympanoplasty).
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1.Fisch adjustable mastoid retractor 3 x 4 prongs, self retaining, sharp - 16 cms 2.Wullstein self retaining mastoid retractor 2 x 3 prongs 3.Shea aural speculum – oblique ended, anodized black – set of five 4.(3.3 x 4mm, 4 x 5.5mm, 5 x 7.5mm, 6 x 8.5 mm, 7 x 9.5 mm) 5.Mahadevaiya's self retaining endomeatal retractor 6.Farabeuf periosteal elevator, SS - Tip 11 mm wide 7.Lempert's periosteal elevator (3 mm) - 18 cms long 8.Cell seeker 45O with ball end - 15.5 cms long 9.Lempert's Mastoid Curette 21 cm long - set of 3 of different sizes 1.8 mm, 2.4 mm, 2.8 mm Micro Ear alligator forceps, serrated, straight jawed, fine - 0.4 x 3.5 mm, 8cms working length Micro Ear alligator forceps, serrated, straight jawed - 0.8x 3.5 mm Wullstein Micro cupped forceps (round cup) - 2mm, 8cms working length Micro cup forceps up-biting, oval cup - 0.9 x 1 mm, 8cms working length Myringotomy knife adjustable (160 mm) Beales ear microelevator 160 mm Wullstein's ear raspatory blade rounded curved 160 mm Rosen round knife, 45 degree angled, cutting – 1 mm dia. - 16 cms long Rosen round knife, 45 degree angled, cutting with fenestrated blade - 3 mm diameter, 16 cms long Plester's flap knife – round cutting blade - 2.4 x 3mm, 160 mm long Wullstein's needle, sharp, straight - 16 cm Wullstein's needle, sharp, slight curved - 16 cm Micro Pick 90 degree, 0.4mm Plester's sickle knife Micro ear scissors – straight, 8cms working length - 4 mm/5 mm blade Set for stapedectomy a) Teflon piston cutting jig b) Fisch Perforator 0.2mm tip c) Fisch Perforator 0.4mm tip
2.2	User's interface	NA
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. Ear retractors must detachable for easy cleaning. All micro scissors and cup forceps must be dismountable for better cleaning. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

ENT NASAL SET

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	1 Lacks Tongue depressor - Curved SS, Peadiatric size 2 Lacks Tongue depressor - Curved SS, Adult size 3 Nasal speculum – Thudichu different sizes from 40, 55, 65, 90 mm 4 Nasal speculum – Killian / Hartman –15 cm different sizes from 40, 55, 65,90 mm 5 Jobson Horne's probe with ring curette 6 Hartman Ear speculum SS – Set of 4 7 Laryngeal mirror with handle SS, 180 mm length, different sizes from 1-5 8 Post nasal mirror Different sizes from 1 – 3 9 Tilley,s nasal dressing forceps Small SS 10 Tilley,s nasal dressing forceps Large SS 11 Hartmann's ear dressing forceps SS 12 Suction tip SS, different sizes from 1 - 4 13 Luc's forceps – Paediatric 14 Luc's forceps – Adult 15 Quinsy draining forceps 16 Henkel's aural forceps 75 mm 17 Siegle pneumatic speculam set Consisting of speculam, body with magnifying lens, Male adaptor, Female adaptor, window with optically plain glass, tubings & bellows 18 Aural Syringe(Ear Syringe) 19 Hartman Tuning fork 256 Hz 20 Hartman Tuning fork 512 Hz 21 Hartman Tuning fork 1024
2.2	User's interface	NA
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. All nasal specula must be dismountable for better cleaning 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares.
	10. DOCUMENTATION	
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

Oesophagoscope

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Esophagoscopes
UMDNS code(s)		11603
GENERAL		
1. USE		
1.1	Clinical purpose	Endoscopes designed for direct insertion through the mouth into the upper gastrointestinal tract for visual examination, biopsy, retrieval of foreign bodies, and treatment of lesions of the interior of the esophagus. Esophagoscopes usually consist of an outer sheath, a lighting system, and a working channel for catheters and operative devices; these endoscopes may be rigid or flexible.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Oval Esophagoscopes with fibreoptic light carrier distal illumination with handle. 2. length 30 cm OD 10 mmx14 mm length 50 cm OD8mmx12mm length 30 cm and OD 12 mmx16mm Optical pediatric and adult forceps for esophagoscopes, optical alligator forceps, optical forceps for peanmt and soft foreign bodies and optical universal forcep. Esophagoscopic forceps, alligator grasping peanut grasping, circular cup biopsy, punch biopsy, scissors straight, trituration of bone, universal biopsy and grasping forcep.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Standard accessories set for diagnostic purpose to be provided with extra fenestrated and alligator forceps no 2 each.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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)
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

Tuning Fork

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	A tuning fork is an acoustic resonator in the form of a two-pronged fork with the prongs (tines) formed from a U-shaped bar of elastic metal (usually steel). It resonates at a specific constant pitch when set vibrating by striking it against a surface or with an object, and emits a pure musical tone after waiting a moment to allow some high overtones to die out. The pitch that a particular tuning fork generates depends on the length and mass of the two prongs. It is frequently used as a standard of pitch to tune musical instruments
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1.Should be in Fundamental (XT cut) Mode of Oscillation. 2.3 drops from 75 cm onto a hard wood board; ±5 ppm maximum frequency change 3.10 to 55 Hz, 1.5 mm double amplitude, 1.5 minute sweep, 2 hrs. in each of 3 mutually perpendicular axes, 6 hrs. total; ±5 ppm maximum frequency change 4.should be Moisture Sensitivity Level MSL1 type
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning requirements as per user manual
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		

11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

Sound Proof Room

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	Soundproofing is used to reduce the sound pressure with respect to a specified sound source and receptor. There are several basic approaches to reducing sound: increasing the distance between source and receiver, using noise barriers to reflect or absorb the energy of the sound waves, using damping structures such as sound baffles, or using active antinoise sound generators
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	A single chambersound treated room. The wall of the chamber will be cavity walls filled with Sound insulation material. The inside of the cubicle will have acoustic treatment on wall and ceiling and sound absorbent flooring. Inner size of the cubicle should not be less than 8 ft. X 8 ft. Air Conditioner: Split type at least 1 ton. A.C. should be fitted inside the chamber. Door : There will be one sound treated door for the main entry which will be of 750mm Chamber should have one double glass window of at least 2ft.X 2ft. Total internal electrical wiring including required electrical points, fixing of tube and fixtures for proper intensity in lux shall be carried out. Equipment connections including patch panel and audio sockets at desired points should be provided. 10. The finished room must satisfy - Noise criteria shall be 30dB(A) orbetter - Transmission loss 30dB(A) or better - Reverberation 0.6 sec orbetter
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
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	NA
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	NA
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

OTOSCOPE

Version no. :		Draft_1
Date:		15/02/2018
`		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1.At least 2.5 V Xenon or Halogen light source. 2.Should be a convenient pocket type otoscope. Swivelling viewing with at least 3x magnification. Should be able to detach the otoscope head. Should provide no reflections and obstructions. Should provide detachable accessories of various sizes. Should have in built rechargeable battery. Recharge should be possible with direct mains supply
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	Should work with input 200 to 240Vac 50 Hz supply.
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with direct mains supply
4.3	Protection	NA
4.4	Power consumption	???????
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Set of plastic specula, varying diameters between 2.0 and 5.0 mm Two spare bulbs At least n. 10 reusable (autoclavable) otoscope specula for each one of the following measure: 2, 3 and 5 mm.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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). 4. lEC 60645-l,IEC 60645-2-40 for safety.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.
	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 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 documntation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospial.
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 adequaetly displayed.

Tracheostomy SET

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1. USE		
1.1	Clinical purpose	Prepackaged collections of the devices and supplies (i.e., either custom or standard kits) needed to keep a temporary or permanent opening in the trachea by inserting a tube after an incision is made through the neck (i.e., after a tracheostomy procedure). Items in these kits usually include a flexible PCV tube with inner cannula, dilators, an obturator/dilator, stick sponge applicators, gauze sponges, fenestrated drapes with tabs, povidone-iodine, needles, scalpel, plastic syringes, and lidocaine. The kits may also include a tracheal tube holder, a swivel adapter, and introducer needle, a tip guide wire, and a guiding catheter. The kits are frequently supplied in supporting trays (i.e., procedure trays) consisting of a flat- bottomed receptacle with a border around the periphery supporting all the instruments and supplies needed for the procedure; the trays are usually covered or wrapped. Tracheostomy procedure kits and trays are intended for placing a tube through the opening in the trachea to provide an artificial airway and/or to remove secretions from the lungs. They are used mainly in operating and emergency rooms.
1.2	Used by clinical department/ward	ENT Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	Needle holder, BP knife handle, Ribbon right angle retractor, Curved arteries, Straight arteries, Criocoid hook, Tracheal dilator.
2.2	User's interface	NA
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	The surgical instruments should be made using top quality medical grade hardened stainless steel with defined specifications like AISI-410, AISI-420, AISI-304, AISI-303, AISI- 440 etc. using guidelines of ASTM standard F899-94 and ISO 7153 and with a dull finish.
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares.
	10. DOCUMENTATION	
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in english/Hindi 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 documntation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospial.
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 adequaetly displayed.
11.2	Recommendations or warnings	

Bronchoscopes

Version no. :		Draft_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		10491
UMDNS code(s)		Bronchoscopes
GENERAL		
1. USE		
1.1	Clinical purpose	Respiratory tract endoscopes designed to view the interior of the respiratory tract, particularly the trachea and the bronchi of the lungs for therapeutic or diagnostic purposes. These endoscopes usually consist of an outer sheath, a lighting system, and a working channel for catheters and operative devices; these endoscopes may be flexible or rigid. Therapeutic bronchoscopes (with operating channels) may be used to perform biopsies and laser surgery, remove foreign objects, aspirate fluids, and administer diagnostic agents or therapy using devices such as lasers, electrosurgical units, or surgical instruments. These endoscopes may be flexible or rigid.
1.2	Used by clinical department/ward	ALL
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The system should be portable within the hospital. Field of view - in excess of 110degree. 2. Depth of field - from 3 mm – 50 mm. Distal end outer diameter – less than 5 mm. 3. Insertion tube outer diameter – maximum 5 mm. Working length – 600 mm. Channel inner diameter - 2.2 mm or more. Minimum visible distance from end – 5mm. Angulations achieved – up – 180 degree, down – 130 degree. Total length – 900 Compatible light source, suction pump, leak tester and trolley in which entire assembly may be
2.2	User's interface	Manual
2.3	Software and/ or standard of communication(where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
4.5	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Standard accessories set for diagnostic purpose to be provided with extra fenestrated and alligator forceps no 2 each.
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 temperture of 5 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. 2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian standrads like BIS/AERB/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)
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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.
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 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 documntation; Certificate of calibration and inspection,
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
	11. Notes	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.