



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	
Introd	uction	
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

LIST OF CONTRIBUTORS

S.NO	EXPERTS	DESIGNATION	ORGANIZATION	
1	Dr.Ankit Jain	Asst Prof Cardiology	VMMC & Safdarjang Hospital, New Delhi	
2	Dr Bijay Kumar Dhal	M.O (Equipment)	OSMCL, Odisha	
3	Er.Prakash Mallick	Biomedical Engineer-State Drug Management Unit	DHS, Odisha	
INDUS	STRY ASSOCIATION E	XPERTS		
1	Representatives from HI	LL- HITES		
2	Representatives from IP	С		
3	Representatives from FI	CCI Association.		
4	Representatives from MTAI Association.			
5	Representatives from AIMED Association.			
INTER	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.

Al	AUDIOMETER			
Version no. :		Draft_1		
Date:		15/02/2018		
Done b	y : (name.institution)	HCT/NHSRC		
		NAME, CATEGORY AND CODING		
UMDN	IS name	10228		
UMDN	VS code(s)	Audiometers		
		GENERAL		
		1. USE		
	Clinical purpose	Instruments designed to measure and characterize hearing loss by determining the lowest audible level		
11		of a patient for pure test tones, signals or both. These devices include tone generators, amplifiers, and		
1.1		sound-level monitors. Audiometers are intended for conducting diagnostic tests for hearing disorders		
1.0	Llood her aligical damageneration	and assisting in other otologic disorders diagnosis.		
1.2	Used by clinical department/ward			
	The sharing light and straight as	2. TECHNICAL CHARACTERISTICS		
	(spacific to this type of device)	Should be Completely Digital.		
	(specific to this type of device)	Tone Continous Tone, Dulse Tone, Warble Tone		
		Frequency Range:- Air conduction 125 – 8000Hz and Bone Conduction 250 – 80000Hz		
		Auto threshold, Bekesy test, DLI, DLF, loudness balancing, difference 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.		
2.1		Automatic calculation of Speech Scoring		
2.1		With suitable Computer & Printer.		
		Accuracy of frequency: better than 1%.		
		11.PC interface for online communication.		
		12. Data Storage facilities.		
		15.Maximum Hearing Level: - AIT: -10 dB to 120 dBHL, Bone: -10 dB to +80dBHL, Speech: 10dB to		
		Antional:		
		Should be upgradable to High Frequency Audiometry		
		Should be upgradable to Free Field Audiometry		
2.2	User's interface	Manual		
	Software and/ or standard of	In built		
2.3	communication(where ever required			
		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. EN	ERGY 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 \pm 30% of local rated		
4.4	Power consumption	-		
4.5	Other energy supplies	Mains cable to be at least 3m length.		
		5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

	Accessories, (mandatory, standard,	Insert masking phone,	
	optional);	Monitor earphone,	
5.1	Spare parts (main ones);	Patient's response switch.	
	Consumables/reagents (open, closed		
	system)		
	BIDDIN	IG/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. EN	IVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and	
6.1	conditioning, humidity, dust)	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%	
	User's care, Cleaning, Disinfection &	Disinfection: Parts of the Device that are designed to come into contact with the patient or the	
6.2	Sterility issues	operator should either be capable of easy disinfection or be protected by a single use/disposable cover.	
•		2. Sterilization not required.	
	Certificates (new monket conits -)	/. STANDAKUS AND SAFETT	
	Certificates (pre-market, sanitary,);	1. Snould be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be	
	(appricate the device type). Level	applicable only when the indian standrads like BIS/AEKB/CDSCO is not available).	
7.1	(specific to the device type), Local	Electrical sofety conforms to the standards for clostrical sofety IEC 60601.1 Conoral requirements (or	
		equivalent BIS Standard)	
		4. IEC 60645-1,IEC 60645-2,IEC60645-4 / ANSI S,3.6	
		8. TRAINING AND INSTALLATION	
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.	
0.1	nature, values, quality, tolerance		
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.	
	The initial of the ff (model in all	Local clinical start to affirm completion of installation.	
8.3	naramedical technicians)	Advanced maintenance tasks required shall be documented	
	Parametrical, comincians) Auvanceu maintenance tasks requireu shan be documenteu.		
0.1	Warranty	3 years including all sparse and caliberation	
9.1	warranty		
	Operating manuals, get manuals, other	IV. DOCUMENTATION	
	operating manuals, set manuals, other	Should provide 2 sets(hard copy and soft copy) of:	
	manuais	user, technical and maintenance manuals should be supplied in english/Hindi language along with	
10.1		I ist of equipment and procedures required for local calibration and routine maintenance:	
10.1		Service and operation manuals (original and Conv) to be provided:	
		Advanced maintenance tasks documptation:	
		Certificate of calibration and inspection.	
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;	
		11. Notes	
	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided;	
11.1	(Hierarchy Wise; including a toll	Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.	
11.0	tree/landline number)	A second	
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.	

IM	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	
1.1	1 1	and middle ear via tympanometry.	
1.2	Used by clinical department/ward	ENT Department	
		TECHNICAL	
	2	. TECHNICAL CHARACTERISTICS	
	Technical characteristics (specific to this	Probe tone: 220 and 1000Hz (For Pediatric testing also)	
	type of device)	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	
2.1		Tests required	
2.1		a. Compensated tympanometry (car canat volume and tympanometric peak pressure)	
		6. Ipstactal and contractal acoustic reflexes	
		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	
	XX I C	M 1	
2.2	User's interface	Manual La lucita	
2.3	Software and/ or standard of	in ouix	
	communication(where ever required		
3.1	Dimensions(metric)	NA	
3.1	Weight (lbs kg)	NA	
3.2	Noise (in dBA)	Also an	
5.5	Heat dissipation	Hast Dissiniation: Should maitain nominal Tamp and the heat should be	
3.4		disbursed through a exhaust cooling fan.	
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.	
	4. ENERGY SO	JRCE (electricity, UPS, solar, gas, water, CO2)	
4.1	Power requirements	220 to 240V, 50 Hz	
4.2	Battery operated	Should have in built rechargeable battery. Recharge should be possible with	
4.2		direct mains supply	
4.3	Protection	Voltage corrector/stabilizer to allow operation at \pm 30% of local rated	
4.4	Derver consumption	voltage.	
4.4	Other energy symplics		
4.5	Other energy supplies	Mains cabe to be at least on length.	
	J. ACCE	SSURIES, SFARE PARTS, CONSUMABLES	
	Accessories, (mandatory, standard, optionar);	insert maxing prone, Monitor carpitone, Patient's	
5.1	(open closed	response switch.	
	system)		
	BIDDING/PROCU	JREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONM	ENTAL AND DEPARTMENTAL CONSIDERATIONS	
	Atmosphere/Ambience (air conditioning,	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to	
6.1	humidity, dust)	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%	
-	User's care, Cleaning, Disinfection & Sterility	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be	
6.2	issues	capable of easy disinfection or be protected by a single use/disposable cover.	
0.2		2. Sterilization not required.	
		7. STANDARDS AND SAFETY	
	Certificates (pre-market, sanitary,);	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the	
	Performance and safety standards (specific to	Indian standrads like BIS/AERB/CDSCO is not available).	
7.1	the device type); Local and/or international	Manufacturer and Supplier should have ISO 13485 certification for quality standards.	
		4. IEC 60645-1,IEC 60645-2,IEC60645-4 / ANSI S,3.6	
	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 maintenanc shall be provided. Advanced maintenance tasks required shall be documented.
	, ,	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.

Op	Operating Microscope (ENT)			
Version no. :		Draft_1		
Date:		15/02/2018		
Done by	y : (name.institution)	HCT/NHSRC		
		NAME, CATEGORY AND CODING		
UMDN	S name	Microscopes, Light, Operating, Otorhinolaryngology		
UMDN	S 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 90 degree binocular with converging optics. 10. 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 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. ENERO	GY 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 \pm 30% of local rated voltage.		
4.4	Power consumption			
	5	. ACCESSURIES, SPARE PARTS, CONSUMABLES		

	Accessories, (mandatory, standard,	1. BeamSplitter with 'C' Mount		
	optional);	2. Motorised with Foot Control		
5.1	Spare parts (main ones);	3. Objective lens 250mm, 300mm & 400mm		
5.1	Consumables/reagents (open, closed	4. Monocular assistoscope		
	system)	5. Binocular Assistoscope		
		6. Battery operated light source		
	BIDDING/I	PROCUREMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIE	RONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative		
6.1	conditioning, humidity, dust)	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%		
	User's care, Cleaning, Disinfection &	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator		
62	Sterility issues	should either be capable of easy disinfection or be protected by a single use/disposable cover.		
0.2		2. Autoclavable eye pieces		
		7. STANDARDS AND SAFETY		
	Certificates (pre-market, sanitary,);	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable		
	Performance and safety standards	only when the Indian standrads like BIS/AERB/CDSCO is not available).		
7.1	(specific to the device type); Local and/or	Manufacturer and Supplier should have ISO 13485 certification for quality standards.		
	international	Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent		
		BIS Standard). 4. IEC 60645-1.IEC 60645-2-40 for safety.		
	8. TRAINING AND INSTALLATION			
Q 1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.		
0.1	nature, values, quality, tolerance			
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	paramedical technicians)	Iraining of users in operation and basic maintenanc shall be provided.		
	parametical, technicians)	Q WARRANTY AND MAINTENANCE		
0.1	Warranty	2 warrain all sparse and salibaration		
9.1	wairanty	10 DOCUMENTATION		
	operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:		
	outer manuals	User, technical and maintenance manuals should be supplied in english/rindi ranguage along with machine		
		uidgrams,		
10.1		Service and operation manuals (original and Conv) to be provided:		
		Advanced maintenance tasks documptation:		
		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		
	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided; Any		
11.1	(Hierarchy Wise; including a toll free/landline number)	Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.		
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.		

OA	OAE Analyser		
Version 1	10. :	Draft_1	
Date:		15/02/2018	
Done by	: (name.institution)	HCT/NHSRC	
		NAME, CATEGORY AND CODING	
UMDNS	name		
UMDNS	code(s)		
CIMBINS		GENERAL	
	Clinical purpose	AF testing often is used as a screening tool to determine the presence or absence of cochlear function, although analysis can be	
1.1	Chinear purpose	on the using other is used as a settemp tool to determine the presence of absence of coefficient function, annough analysis can be	
		Portonnee to: mail tagan control to group	
1.2	Used by clinical department/ward	ENT Department	
		TECHNICAL	
	2	. TECHNICAL CHARACTERISTICS	
	Technical characteristics (specific to this	TEOAE Specifications:	
	type of device)	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:	
		L 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.	
2.1		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	
		2. Subtree interoptions to pick upSOAE	
		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	
	Software and/ or standard of	In built	
2.3	communication(where ever required		
		3. PHYSICAL CHARACTERISTICS	
3.1	Dimensions(metric)	NA	
3.2	Weight (lbs, kg)	NA	
3.3	Noise (in dBA)	<150 dB	
2 /	Heat dissipation	Heat Dissipiation: Should maitain nominal Temp and the heat should be	
5.4	-	disbursed through a exhaust cooling fan.	
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.	
	4. ENERGY SO	URCE (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	
<u> </u>	Durate stire a	airect mains supply	
4.3	rotection	voltage corrector/stabilizer to allow operation at \pm 50% of local rated voltage.	
44	Power consumption	191919191	
4 5	Other energy supplies	Mains cable to be at least 3m length.	
	5_ACCF	SSORIES, SPARE PARTS, CONSUMABLES	
	Accessories, (mandatory, standard, optional).	Reusable ear tips, Rechargeble Battery.	
	Spare parts (main ones): Consumables/reagents		
5.1	(open, closed		
	system)		
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

	Atmosphere/Ambience (air conditioning,	1. Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to		
6.1	humidity, dust)	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%		
	User's care, Cleaning, Disinfection & Sterility	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be		
6.2	issues	capable of easy disinfection or be protected by a single use/disposable cover.		
		2. Sterilization not required.		
		7. STANDARDS AND SAFETY		
	Certificates (pre-market, sanitary,);	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the		
	Performance and safety standards (specific to	Indian standrads like BIS/AERB/CDSCO is not available).		
7.1	the device type); Local and/or international	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)		
		The 00010 file 00010 2, he 00010 47 m 010, 5, 0		
	8	3. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.		
0.1	nature, values, quality, tolerance			
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.		
	Training of staff (as disc) as a set of the	Local clinical start to anime completion of instantion.		
8.3	technicians)	Advanced maintenance tasks required shall be documented.		
	9.	WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and caliberation.		
	10. DOCUMENTATION			
	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;		
10.1		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;	Contact details of manufacturer, supplier and local service agent to be provided; Any		
11.1	including a toll	Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.		
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed		
11.4	recommendations of warmings	ing naming sign nour of adequatily displayed.		

HE	HEAD LIGHT-ENT		
Version	no. :	Draft 1	
Date:		15/02/2018	
Dono hy	· (nome institution)		
Done by	. (nanc.nistitution)		
		NAME, CATEGORT 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	
	Technical characteristics (specific to this	Should be a cold headlight system suitable for ENT Operating Theater with provision to adjust light intensity.	
	type of device)	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.	
2.1		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	
	Software and/ or standard of	In built	
2.3	communication(where ever required		
	communication(where ever required		
		PHYSICAL CHARACTERISTICS	
3.1	Dimensions(metric)	NA	
2.2	Weight (the tra)		
3.2		50 ID	
3.3	Noise (in dBA)	୍କ ସ୍ଥାନ କରିଥିଲେ । ସ୍ଥାସ ଅନ୍ୟ	
3.4	Heat dissipation	NA	
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.	
	4. ENERGY SO	JRCE (electricity, UPS, solar, gas, water, CO2)	
4.1	Power requirements	Should work with input 200 to 240Vac 50 Hz supply.	
4.0	Battery operated	Should have in built rechargeable battery. Recharge should be possible with	
4.2	5 1	direct mains supply	
4.3	Protection	NA	
4.4	Power consumption	222222	
	5 ACCE	SORIES SPARE PARTS CONSUMARIES	
	Accessories (mandatory standard optional):		
	Spare parts (main ones): Consumables/reagents	1. Spare bulls, 2. 5 numbers of AA size batteries	
5.1	(open_alosed	2. 5 Inditions of AA sizeballetics.	
5.1	system)		
	BIDDING/PROCI	REMENT TERMS/DONATION REGUREMENTS	
	6 ENVIRONME	NTAL AND DEPARTMENTAL CONDERATIONS	
	Atmosphere/Ambience (pir	1. Operating Condition: Canable of operating continuously in ambient topporture of 5 to 50 deg C and	
6.1	conditioning, humidity, dust	r coporating condition, capable of operating continuously in anotent temperture of 5 to 50 deg c and relative humidity of 15 to 90% in ideal circumstances.	
	User's care Cleaning Disinfection & Sterility	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be	
	issues	canable of assy disinfection or he protected by a single use/disposable cover	
6.2	issues	Capable of easy distinction of be protected by a single use/disposable cover.	
		7. STANDARDS AND SAFETY	
	Certificates (pre-market sanitary):	Should be USFDA/Europen CE/BIS approved product (USEDA/Europen CE requirement will be applicable only when the	
	Performance and safety standards (specific to	Indian standrads like BIS/AEBB/CDSCO is not available)	
	the device type): Local and/or international	Manufacturer and Sumplier should have ISO 13485 certification for quality standards	
7.1	the device type), Elocal and/or international	Financial estaty conforms to the standards for slowing starting leaf the C6060111 General requirements (or equivalent RIS Standard)	
		4. IEC 60645-LIEC 60645-2-40 for safety.	
		TRAINING AND INSTALLATION	
	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.	
8.1	nature, values, quality, tolerance		
	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.	
8.2		Local clinical staff to affirm completion of installation.	
0.2	Training of staff (medical,	Training of users in operation and basic maintenanc shall be provided.	
8.3	paramedical, technicians)	Advanced maintenance tasks required shall be documented.	
	9. '	WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.	
	• • • • • • • • • • • • • • • • • • •	10. DOCUMENTATION	

	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;
10.1		Service and operation manuals(original and Copy) to be provided;
		Advanced maintenance tasks documntation;
		Certificate of calibration and inspection,
10.2	Other accomponiting decomponents	List of according and according with their part number and acot
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost,
		11. Notes
	Service Support Contact details (Hierarchy Wise;	Contact details of manufacturer, supplier and local service agent to be provided; Any
11.1	including a toll	Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
	free/landline number)	
11.2	Recommendations or warnings	Any warning sign would be adequaetly displayed.

EA	R SURGERY INSTR	RUMENTS SET
Version	10. :	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 Far
OMDINS		
		UENERAL
1.1	Chnical 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
	List of instruments	1 Fisch adjustable mastoid retractor 3 x 4 pronos self retaining sharp - 16 cms 2 Wullstein self
2.1		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 450 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 Car 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 Migro Ear alligator forceps, serrated, straight jawed - 0.8x 3.5 mm Wullstein's ear raspatory blade rounded curyel 160 mm Beales ear microelevator 160 mm Wullstein's ear raspatory blade rounded curved 160 mm Rosen round knife, 4.5 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, straight - 16 cm Micro Pick 90 degree, 0.4mm Plester's sickle knife Micro car 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 0.2mm 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
33	Noise (in dBA)	NA
3.4	Heat dissipation	NA
2.4	Mobility portability	Supplied in protective SS case for clean storage and sofe transport
3.5	woonity, portability	Supplied in protective SS case for clean storage and safe transport.
	4. ENERGY SOU	UKCE (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. ACCES	SORIES SPARE PARTS CONSUMABLES

5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
	BIDDING/PROCL	REMENT TERMS/DONATION REOUIREMENTS
	6. ENVIRONME	NTAL 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. 1	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

EN	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		
1.1	Used by clinical department/ward	ENT Department	
1.2	esed by ennear department ward	TECHNICAL	
	2	TECHNICAL CHARACTECHNICA	
	List of instruments	Legis Tangua damagan Curiad SS Bagdiatria aira 2 Legis Tangua	
		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 SS 11 Hartmann's arr	
2.1		dressing forceps SS 12 Suction tip SS, different sizes from 1 - 4 13 Luc's forceps – Paediatric 14 Luc's forceps –	
2.1		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 Tork 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	Sumplied in protective SS case for clean storage and safe transport	
5.5	4 ENERGY SOL	Despined in protective DPS calls for each intervence of the many o	
4 1	Power requirements	NA	
4.1	Battery operated	NA	
4.2	Protection	NA	
4.5	Power consumption	NA	
4.4		SSORIES SPARE PARTS CONSUMABLES	
	Accessories (mandatory standard optional):	NA	
5.1	Spare parts (main ones); Consumables/reagents (open, closed system)		
	BIDDING/PROCL	JREMENT 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. STANDADDS AND SAFETY	
	Contractor (and a later in the later	/. 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	
Q 1	Pre- installation requirements:	NA	
0.1	nature, values, quality, tolerance		

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. V	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.

Oes	Oesophagoscope		
Version no. :		Draft_1	
Date:		15/02/2018	
Done by :	(name.institution)	HCT/NHSRC	
		NAME, CATEGORY AND CODING	
UMDNS	UMDNS name Esophagoscopes		
UMDNS of	code(s)	11603	
		GENERAL	
		1 USE	
	Clinical purpose	Endoscopes designed for direct insertion through the mouth into the unper gastrointestinal tract for visual examination, bionsy, retrieval of	
	chinem pulpose	foreign bodies, and treatment of lesions of the interior of the esophagus. Esophagoscopes usually consist of an outer sheath a lighting	
1.1		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. TEC	CHNICAL CHARACTERISTICS	
	Technical characteristics (specific to this type	1. Oval Esophagoscopes with fibreoptic light carrier distal illumination with handle.	
	of device)	2. length 30 cm OD 10 mmx14 mm length 50 cm OD8mmx12mm length 30	
		cm and OD 12 mmx16mm	
2.1		Optical pediatric and adult forceps for esophagoscopes, optical alligator forceps, optical forceps for peanmt and soft foreign bodies and	
2.1		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	
	Software and/ or standard of	NA	
2.3	communication(where ever required		
	3. PH	IYSICAL 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 SOURC	E (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. ACCESSOF	RES. SPARE PARTS. CONSUMABLES	
	Accessories. (mandatory, standard, optional):	Standard accessories set for diagnostic purpose to be provided with extra fenestrated and alligator forceps no 2 each.	
	Spare parts (main ones):		
5.1	Consumables/reagents (open, closed system)		
	BIDDING/PROCURE	MENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTA	L AND DEPARTMENTAL CONSIDERATIONS	
	Atmosphere/Ambience (air conditioning,	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	
6.1	humidity, dust)	circumstances.	
		2. Storage condition: Capable of being stored continuosly in ambient temperature of 0 to 50 deg C and relative burnidity of 15 to 90%	
	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	
	User's care, creaning, Disinfection & Sternity issues	Disinfection, r be protected by a single use/disposable cover	
6.2		2. Sterilization not required	
	7. S	TANDARDS AND SAFETY	
	Certificates (pre-market, sanitary,); Performance	Should be USFDA/Europen CE/BIS approved product (USFDA/Europen CE requirement will be applicable only when the Indian	
	and safety standards (specific to the device type);	standrads like BIS/AERB/CDSCO is not available).	
7.1	Local and/or international	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			
	Dra installation requirements:		
8.1	nature, values, quality, tolerance	00	
8.2	Requirements for sign-off	NA	
	Training of staff (medical, paramedical	Training of users in operation and basic maintenanc shall be provided.	
8.3	technicians)	Advanced maintenance tasks required shall be documented.	
	9. WAR	RANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.	
	1	0. 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.	

	<u> </u>	
Version no. :	:	Draft_1
Date:		15/02/2018
Done by : (na	ame.institution)	HCT/NHSRC
		NAME, CATEGORY AND CODING
UMDNS nam	me	
UMDNS code	e(s)	CINIED AL
		UENERAL
Cli	linical purpose	I. USE A tuning fact, is an acoustic measurement in the form of a two prepared fact, with the proper (time) formed from a LL shand her of alastic metal
1.1	nincai puipose	(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 Us	sed by clinical department/ward	ENT Department
	0 TEC	TECHNICAL
Ta	2. IEC	HINICAL CHARACTERISTICS
2.1	connear enaracteristics (specific to this type	1.Should be in Fundamental (AT cut) Mode of Oschlaton. 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 Us	ser's interface	Manual Manual
2.3 Cor	ottware and/ or standard of ommunication(where ever required	NA
	3. PH	YSICAL CHARACTERISTICS
3.1 Dir	imensions(metric)	NA
3.2 We	/eight (lbs, kg)	NA training the second s
3.3 No	oise (in dBA)	NA Na
3.4 He	eat dissipation	NA Sumliad in protoctive once for clean storage and cofe transport
5.5 MIC	4 ENERGY SOURCE	Supplied in protective case for clean storage and safe transport.
4.1 Po	ower requirements	NA
4.2 Ba	attery operated	NA
4.3 Pro	rotection	NA
4.4 Po	ower consumption	NA
4.5 Oth	ther energy supplies	NA
	5. ACCESSOR	IES, SPARE PARTS, CONSUMABLES
5.1 Ac Spa (op sys	ccessories, (mandatory, standard, optional); pare parts (main ones); Consumables/reagents open, closed (stem)	NA
	BIDDING/PROCURE	MENT TERMS/DONATION REQUIREMENTS
	6. ENVIRONMENTAI	AND DEPARTMENTAL CONSIDERATIONS
6.1 Att	tmosphere/Ambience (air onditioning, humidity, dust)	NA
6.2 Ste	terility issues	Creaning requirements as per user manual
	7. ST	FANDARDS AND SAFETY
7.1 Cer 7.1 Log and	ertificates (pre-market, sanitary,); Performance ad safety standards (specific to the device type); ocal ad/or international	NA
	8. TRA	INING AND INSTALLATION
8.1 Prenat	re- installation requirements: ature, values, quality, tolerance	NA
δ.2 Re	requirements for sign-off	INA Training of years in gravition and basic maintenance shall be provided
8.3 tec	chnicians)	Advanced maintenance tasks required shall be documented.
	9. WAR	RANTY AND MAINTENANCE
9.1 Wa	Jarranty	3 years, including all spares and caliberation.
10.1 Op	perating 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 Otl	ther accompanying documents	List of essential spares and accessories, with their part number and cost;

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

Sou	Sound Proof Room		
Version n	0. :	Draft_1	
Date:		15/02/2018	
Done by :	(name.institution)	HCT/NHSRC	
		NAME, CATEGORY AND CODING	
UMDNS 1	name		
UMDNS c	code(s)		
		GENERAL	
		1. USE	
	Clinical purpose	Soundproofing is used to reduce the sound pressure with respect to a specified sound source and receptor. There are several basic approaches	
1.1		to reducing sound: increasing the distance between source and receiver, using noise barriers to reflect or absorb the energy of the sound waves,	
1.1		using damping structures such as sound baffles, or using active antinoise sound generators	
1.2	Used by clinical department/ward	ENT Department	
		TECHNICAL	
	2. TEC	CHNICAL CHARACTERISTICS	
	Technical characteristics (specific to this type	A single chambersound treated room.	
	of device)	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: I here will be one sound treated door for the main entry which will be of /50mm	
		Chamber should have one double grass window of at least 211. A 211.	
2.1		For a mena electrical withing including required electrical points, fixing of tube and fixtures for proper mensity in fux shart be carried out	
2.1		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) or better	
		- Transmission loss 30dB(A) or better	
		- Reverberation 0.6 sec or better	
2.2	User's interface	Manual	
	Software and/ or standard of	NA	
2.3	communication(where ever required		
	2 01		
2.1	Dimensions(matric)		
2.2	Weight (be kg)	NA MA	
3.2	Noise (in dBA)	NA NA	
3.3	Host dissipation	NA MA	
2.5	Mobility portability	NA NA	
3.5	4 ENERGY SOURCE	PA E (alectricity LIDS solar gas water CO2)	
4.1	4. ENERGT SOURCE	NA	
4.1	Pottory operated	NA NA	
4.2	Protection	NA NA	
4.3	Power consumption	NA NA	
4.4	Other energy supplies	NA NA	
4.5	5 ACCESSOR	ING SPAPE PARTS CONSUMARIES	
	Accessories (mandatory standard ontional):	NA	
	Spare parts (main ones): Consumables/reagents	174	
5.1	(open, closed		
	system)		
	BIDDING/PROCURE	MENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTA	L AND DEPAKIMENTAL CONSIDERATIONS	
6.1	Atmosphere/Ambience (air	NA	
	User's care Cleaning Disinfection &	NA	
6.2	Sterility issues		
	7. S	TANDARDS AND SAFETY	
	Certificates (pre-market, sanitary,); Performance	NA	
71	and safety standards (specific to the device type);		
	Local and/or international		
8 TRAINING AND INSTALLATION			
	O. 1K/	NA	
8.1	nature, values, quality, tolerance	ри 1	
8.2	Requirements for sign-off	NA	
0.2	Training of staff (medical, paramedical,	Training of users in operation and basic maintenanc shall be provided.	
8.3	technicians)	Advanced maintenance tasks required shall be documented.	
	9. WAR	RANTY AND MAINTENANCE	
9.1	Warranty	3 years, including all spares and caliberation.	
	1	0 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.	

O	OTOSCOPE		
Version	1 no. :	Draft_1	
Date:		15/02/2018	
`		HCT/NHSRC	
		NAME, CATEGORY AND CODING	
UMDN	S name		
UMDN	(S code(s)		
CINIDI	5 couo(s)	GENERAI	
1.1	Clinical purpose	1. 05E	
1.1	Used by clinical department/ward	ENT Department	
1.2	Osed by chilical department/ward		
		2. TECHNICAL CHARACTERISTICS	
	to this type of device)	1. At least 2.5 V Aenon of Halogen light source. 2. Should be a convenient pocket type of ascone	
	to this type of device)	Swivelling viewing with at least 3x magnification	
		Should be able to detach the otoscope head	
2.1		Should be able to detach the ofoscope nead.	
		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	
	Software and/ or standard of	In built	
2.3	communication(where ever required		
2.1	Dimensions(metric)	S. FITISICAL CHARACTERISTICS	
3.1	Weisht (he les)		
3.2	weight (IDS, Kg)	NA	
3.3	Noise (in dBA)	NA	
3.4	Heat dissipation	NA 2	
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.	
	4. ENERG	GY 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	
1.2	Durata ati a u	urect mains supply	
4.3	Protection	NA	
4.4	Power consumption		
	5.	ACCESSORIES, SPARE PARTS, CONSUMABLES	
	Accessories, (mandatory, standard,	set of plastic specula, varying diameters between 2.0 and 5.0 mm 1 wo spare	
5.1	Spere ports (main anas):	DUIDS At least n 10 reveable (autoclaushie) atoggene anoule for each one of the following massure 2, 2 and 5 mm	
5.1	Consumplies/reagents (open_closed	At least ii. To reusable (autociavable) otoscope specula for each one of the following measure: 2, 5 and 5 min.	
	system)		
	BIDDING/	PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIF	RONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	Atmosphere/Ambience (air	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and	
0.1	conditioning, humidity, dust)	relative humidity of 15 to 90% in ideal circumstances.	
	User's care, Cleaning, Disinfection &	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator	
6.2	Sterility issues	should either be capable of easy disinfection or be protected by a single use/disposable cover.	
		2. Sterilization required.	
		7 STANDARDS AND SAFETY	
	Certificates (nre-market sanitary)	7. 51 AIND AIND 5 AIND	
	Derformance and safety standards	only when the Indian standrads like RIS/AFRR/CDSCO is not available)	
_	(specific to the device type): Local and/or	Manufacturer and Sumplier should have ISO 13/85 certification for quality standards	
7.1	international	Figure and supplier should have 150 13403 certification for quality statistics.	
		BIS Standard).	
	4. IEC 60645-1,IEC 60645-2-40 for safety.		
	8. TRAINING AND INSTALLATION		
Q 1	Pre- installation requirements:	Availability of 5 Amp/15 Amp. Electrical Socket.	
0.1	nature, values, quality, tolerance		

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
	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:
	other manuals	User, technical and maintenance manuals should be supplied in english/Hindi language along with machine
		diagrams;
10.1		List of equipment and procedures required for local calibration and routine maintenance;
1011		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
	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided; Any
11.1	(Hierarchy Wise; including a toll	Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
	free/landline number)	
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		
UMDN	S name			
UMDN	S code(s)			
		GENERAL		
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		
	The second se	TECHNICAL		
		2. TECHNICAL CHARACTERISTICS		
2.1	List of instruments	Needle holder, BP knife handle, Ribbon right angle retractor, Curved arteries, Straight arteries, Criocoid		
2.1		hook, Tracheal dilator.		
2.2	User's interface	NA		
2.3	Software and/ or standard of	NA		
210	communication(where ever required			
		3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA		
3.2	Weight (lbs, kg)	NA		
3.3	Noise (in dBA)	NA		
3.4	Heat dissipation			
3.5	Mobility, portability	Supplied in protective SS case for clean storage and safe transport.		
4.1	4. ENERG	SY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power requirements	NA NA		
4.2	Protection	NA		
4.5	Power consumption	NA		
	5.	ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed	NA		
	system) BIDDING/	PROCUREMENT TERMS/DONATION REQUIREMENTS		
	6 ENVI	RONMENTAL 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					
	Operating manuals, set manuals,	Should provide 2 sets(hard copy and soft copy) of:				
	other manuals	User, technical and maintenance manuals should be supplied in english/Hindi language along with machine				
		diagrams;				
10.1		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	Contact details of manufacturer, supplier and local service agent to be provided; Any				
	(Hierarchy Wise; including a toll free/landline number)	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 n	0. :	Draft_1			
Date:		15/02/2018			
Done by : (name.institution)		HCT/NHSRC			
		NAME, CATEGORY AND CODING			
UMDNS 1	name	10491			
UMDNS code(s)		Bronchoscopes			
		GENERAL			
		1. USE			
	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			
1.1		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. TEO	CHNICAL CHARACTERISTICS			
	Technical characteristics (specific to this type	1. The system should be portable within the hospital. Field of view - in excess of 110degree.			
	of device)	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 -			
2.1		2.2 mm or more.			
		Minimum visible ustatec from end $-$ simil. Angulations achieved $-$ up -1 so uegree, down -1 so degree. Total length -900			
		comparise right source, succion particip, reak concer and using in which charter assentisty may be			
	XX 1 2 . C				
2.2	User's interface	Manual			
2.3	Software and/ or standard of	NA			
	3 PH	I I I I I I I I I I I I I I I I I I I			
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 SOURC	c (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. ACCESSOF	RIES, SPARE PARTS, CONSUMABLES			
	Accessories, (mandatory, standard, optional);	Standard accessories set for diagnostic purpose to be provided with extra fenestrated and alligator forceps no 2 each.			
5.1	Spare parts (main ones);				
5.1	Consumables/reagents (open, closed system)				
	BIDDING/PROCURE	MENTTERMS/DONATION REQUIREMENTS			
	6. ENVIRONMENTA	AND DEPARTMENTAL CONSIDERATIONS			
	Atmosphere/Ambience (air conditioning,	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			
6.1	humidity, dust)	circumstances.			
		2. Storage condition: Capable of being stored continuosity in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%			
	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			
6.2		disinfection or be protected by a single use/disposable cover.			
		2. Sterilization not required.			
	7 \$	I TANDARDS AND SAFETY			
	Certificates (pre-market sanitary): Performance	Should be USED A furgence CF RIS approved product (USED A/Europen CF requirement will be applicable only when the Indian			
	and safety standards (specific to the device type):	standrads like BIS/AER8/CDSCO is not available).			
7.1	Local and/or international	Manufacturer and Supplier should have ISO 13485 certification for quality standards.			
7.1		Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard)			
8 TRAINING AND INSTALLATION					
0.1	Pre- installation requirements:	NA			
8.1	nature, values, quality, tolerance				
8.2	Requirements for sign-off	NA			
8.3	Training of staff (medical, paramedical,	Training of users in operation and basic maintenanc shall be provided.			
	Q WAE	RANTY AND MAINTENANCE			
9,1	Warranty	3 years, including all spares and caliberation.			
	IV, 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.		