MEDICAL DEVICE SPECIFICATION - Tender Refreance No.- 29 MCH Eqiupments list-1 Item No.-43

ULTRASOUND MACHINE

Version no. :	
Date	
Done by : (name/institution)	

NAME AND CODING

GMDN name	Ultrasound system
GMDN code	NA

GENERAL

1. USE

1.1	**Clinical purpose**	Diagnostic sonogrphy (ultrasonography) is an ultrasound-based diagnostic imaging technique use for visualizing internal body structures including tendons, muscles] joints, vessels and internal organs for possible pathology orlesions. The practice of examining pregnant women using ultrasound is called obstetric sonography, and is widley used.
1.2	**Used by clinical department /ward**	Radiology laboratories

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1		Ultrasound scanner with in egrated trolley with probe, soft touch alphanumeric key board with track ball: 1. With panel switches & control's easily operable. 2. Integrated hingh resolution Monitor (17''). 3. Probes & Gel holder-conviniently placed (2 each). Following transducer are to be supplied: 1. A-2.0-5.0 MHz Multi frequency Convex Transducer-One. 2. B-5.0-12.0 MHz Multi frequency Linear transducer-One. 3.C-5.0-8.0 MHz or more Endo Cavitory probe-One. (+/- 1 MHz to be allowed for each): a. All probes should be electronic transducers and multi-freuency preferably three frequencies and should give aperture & depths of scanning. b. Controls for Depth, gaing compensation, body markers with transducers poition. c. Real-time continuous dynamic focus. d. Auto annotation facility anywhere on image. e. Image disply in B, B/M&M Model (2B&2D). f. Zoom facility minimum five times or more. g. Shades of grey 256 h. Inbuilt cine memory.

		h. Unite should be capable of measuring BPD, CRL, FL & AC and other GA parameters. i. Facility for image magnification, inversion, changing, scan, direction, freeze facility. j. 8 step STC/GTC should be available. k. Frame rate minimum 50 FPS, hard disk capacity of 200 GB or more. l. Caliper with trackball for the measurement of distances circumfrences, area volume etc. should be possible to make different measurement on single image. m. Alphanumeric key board, p.Panel Swithches & Foot Controls. n. Patient reports for Cbs/Gynae including fetal growth trend, including Histogram facility for Tissue texture & Trend graph for IUGR cases, Uroloty and orthopedics. o. Give the gain adjustable/Range & its steps. p. Calculations needed, Velocity, Heart rate, Volume addl. modes. q. Dicom 3.0 compatible. r. Review of stored images is desirable. s. Channels: 100 or more. t. Depth: 25 to 30 cm. u. Dynamic range: 170dB & above. v. Cine loop preivew for minimum 60 secs or more. w. Minimum 2 active porst should be there.
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)**	Max: 400mm (L) x 300mm (w) 160mm (H)
3.2	**Weight (lbs, kg)**	Max:17 lbs
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipat on**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooligg mechanism.
3.6	**Mobility proeability**	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)		
4.1	**Power Requi ements**	Rechrging unit:Input voltage-220V-240V AC, 50Hz.
4.2	**Battery operated**	No
4.3	**Tolerance (to variations, shutdowns)**	NA
4.4	**Protection**	Should have over charging cut-off with visual symbol.
4.5	**Power consumption**	
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	The system should be supplied with the following accessories: 1. B & W thermal printer with 50 rolls. 2. Tow KVA online suitable UPS.

BIDDING/PROCUREMENT TERMS/DONATION REQUIRMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere/Ambiance (air conditionin, humidity, dust ....)**	1. Opreating condition: Capable of operating continuously in ambient temperature of 10 to 50 deg C and relative humidity of 15 90% in ideal circumstances. 2. Storage condition: Capable of being stored cotinuously 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**	1. Disinfection : Parts to 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 use/diposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	**Certification (pre-market, sanitary, ...) Performance and safety standards (specific to the device type); Local and/or international**	1. Should be FDA/CE/DIS approved product. 2. Manufacture/supplier should have ISO 13485 certificate for qulity standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601- General requirements (or equivalent BIS Standard). 4. Shall meet internationally recognised for Electromagnetic Compatibility (EMI/EMC) for electromedical equipment: 61326-1. 5. Cerfified to be compliant with IEC 61010-1, IEC 6101-2-40 for safety.
7.2	**Local and/or international**	Manufacturer/supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	1. Availability of 5 amp scoket. 2. Safety and operation check before hand over. 3. Machine to be installed only when PNDT registration is obtained by health care facility.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection from the manufacturer
8.3	**Training of staff (medical paramedical, technicians)**	1. Training of users on operation and basic manitenance atleast for two weeks. 2. Advanced maintenance task required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years
9.2	**Maintenance tasks**	CMC 5 years 2 PM Visits Annually. All Breakdown calls to be attended within 24 hrs of registartion.
9.3	**Service conteact clauses, including prices**	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;
10 DOCUMENTATION		
10.1	**Operating manuals, service mnuals, other manuals**	Should provide 2 sets (hardcopy and soft-copy) of: 1. User] technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine manitenance; 3. Service and operation manuals (original and copy) to be provided; 4. Advanced maintenance task documentation;

		5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hopital.
10.2	**Other accompanying document**	List of impotant spares and accessories, with their part numbers and cost.
		11. NOTES
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline numbe)**	Contact detalis of manufacturer, supplier and local service agent to be provided; Any Contract (AMC/CMC/add-hoc) to be declared by the manufaturer;
11.2	**Recommendation or warnings**	Any warning signs would be adequately displyed.

ELECTROSURGICAL UNIT

NAME AND CODING

	GMDN name	Electrosurgical Unit
	GMDN code	NA

GENERAL

1. USE

1.1	**Clinical purpose**	Diathermy uses an electric current to produce heat deep inside a targeted tissue. It can reach areas as deep as tow inches from the skin's surface. The diathermy machine does not apply heat directly to the body. Instead, the current from the machine allows the body to generate heat from within the targeted tissue.
1.2	**Used by clinical department/ward**	Operation theatre

TECHNICAL

2. TECHNICAL CHARATERISTICS

2.1	**Technical characteristics (specific to this type of device)**	1) Facility for Monopolar, Bipolar and underwater cutting. 2) Monopolar cutting and coagulation 3) Micro-processor based technology 4) Monopolar cut in minimum 3 modes 5) Bipolar-coagulation in 3 or more (forced coagulation, spray coagulation and soft coagulation) 6) Blending of cutting and coagulation in minimum 2 levels 7) Automatic cut-off technology with self check on every start. 8) Foot and hand switch 9) Automonitoring and display of set parameters 10) Touch-controlled interface to set parameters 11) 4 or more programmable memory 12) Simultaneous use of Monopolar and Bipolar Coagulation. 13) output Power of 300 Watt (Minimum) 14) Monopolar Cutting and Coagulation power adjustable from 0-300 Watt 15) Bipolar Coagulation power adjustable from 0-50 W, Micro Power Range-0.1 to 9.9 Watt increment of 0.1 Watt, Macro Power range from 1-50 Watt increment of 1 Watt 16) Audio-Visual Alarm for disconnection of Neutral Plate
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
26	**Technical Specification of Medical Devices for OPERATIONAL THEATRES**	
3.2	**Weight (lbs, kg)**	Max : 10kg
3.3	**Configuration**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism
3.6	**Mobility, portability**	Portable
	4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2.....)	
4.1	**Power Requirements**	Recharging unit: Input voltage- 220V-240V AC, 50Hz
4.2	**Battery operated**	NO
4.3	**Tolerance (to variation, shutdowns)**	Plus/Minus 10%
4.4	**Protection**	Should have over-chatging cut-off with visual symbol.
4.5	**Power consumption**	60W
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional) ; Spare parts (main ones); Consumables/reagents (open, closed system)	1. Power cord : 1pc 2. Electode lever:1 pc 3. Electrode;2sets 4. Collective electric bulb: 2pcs switch 5. Trolley; Foot switch 6. Reusable electrode handle with cutting/coagulation switch 7. Disposable REM plate 8. Cable for electrode handle 9. Neutral plate for adults and pediatric
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATION	
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40deg C and relative humidity of 15 to 90 % in ideal circumstances. 2) Storage condition: Capable of being stored continuously 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	1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operation 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 (premarket, sanitary, ..); Performance and safety standards (spefific to the device type); Local and/or international	1. Shall meet internationally recognised IES 60601-1-1 standard (General Requirements) 2. Shall meety internationally recognised IEC 60601-2-2 standard (Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories) 3. Shall meet inernationally recognised IEC 60601-1-6 standard (MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD:USABILITY) 4. Shall meet inernationally recognised IEC 60601-1-8 standard (MEDICAL ELECTRICAL EQUIPMENT - PART 1-:GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD:GENERALREQUIREMENTS, TESTS AND GUIDANCE FOR ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS) 5. Shall meet inernationally recognised IEC 60601-1-2 standard (MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS) 6. Shall meet inernationally recognised IEC 62304 standard (Medical device sofware - Software life cycle processes)

7.2	Local and/or international	Manufacturer / supplier should have ISO 13485 certificate for quality standard.
		8. TRAINING AND INSTALLATION
8.1	Pre-installation requirements: nature, values, quality, tolerance	1) Availability of 5 amp socket; 2) Safety and operation check before handover;
8.2	Requirements for signoff	Certificate of calibration and inspection from the manufacturer

8.3	Training of staff (medical, paramedical, technicians)	1) Training of users on operation and basic maintenance; 2) Advanced maintenance tasks required shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	3 years
9.2	Maintenance tasks	1) Maintenance manual detailing; 2) Complete maintenance schedule;
9.3	Service contract clauese, including price	The spare price list of all spares and accessories (including mionr) required for maintenance and repairs in future after guarantee / warranty period should be attached;
	10. DOCUMENTATION	
10.1	Operating manuls, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of :- 1) User, technical and maintenance manuals to be supplied in english / hindi language along with machine diagrams; 2) List of equipment and procedures required for local calibration and routine manitenance; 3) Service and operation manuals (original and copy) to be provided; 4) Advanced maintenance tasks documentation; 5) Certificate of calibration and inspection
10.2	Other accompanying documents	List of important spares and accessories, with their part numbers 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 signs would be adequately displyed