

LOT -1: OPERATION TABLE ELECTRO-HYDRAULIC(ELECTRICAL WITH MANUAL OVERSIDE)

Version no. :		1		
Date:		5-12-2014		
Done by : (name / institution)		HCT/NHSRC		
NAME AND CODING				
GMDN name		Electro- hydraulic table		
GMDN code		NA		
GENERAL			COMPLIANCE	
			YES	NO
1.1	Clinical purpose	An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation. This surgical equipment is usually found inside the surgery room of a hospital.		
1.2	Used by clinical department/ward	Operation theatre		
2 TECHNICAL CHARACTERISTICS			COMPLIANCE	
			YES	NO
2.1	Technical characteristics (specific to this type of device)	1) Should be manually controlled operating table, working range from floor level: 700 -1000 or more $\pm 10\%$ 2) Should be adjustable to all essential positions. 3) Should be equipped with movement controls at side of the table. 4) Should have frame and bottom made of 304 grade Stainless Steel material. 5) Should have reinforced five section stainless steel top. 6) Height should be adjustable by oil pump, foot step control. 7) Should have detachable head rest which can be easily adjustable to any desired position, above or below the table top. 8) Table top can be rotated 360° through base. 9) Head section raised from the Horizontal: 20° - 30° 10) Durable and leak-proof hydraulic pump. 11) Head section lowered from horizontal: 28° - 30° 12) Back section raised from the horizontal: 60° - 70° 13) Trendelenburg: 25-30° 14) Reverse Trendelenburg: $\geq 30^\circ$ 15) Leg section lowered from the Horizontal: 40° - 50° 16) Kidney-position should be achievable by breaking the table. 17) Table-top should be radio-lucent. 18) Should have handset for position selection by in-built stand-by control.		
2.2	User's interface	Manual		
2.3	Software and/ or standard of communication (where ever required)	NA		
3 PHYSICAL CHARACTERISTICS			COMPLIANCE	
			YES	NO
3.1	Dimensions (metric)	1910 x 530 mm		
3.2	Weight (lbs, kg)	Should be able to bear patient weight		
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	Not portable		
4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2)			COMPLIANCE	
			YES	NO
4.1	Power Requirements	Recharging unit: Input voltage- 220V-240V AC, 50Hz		
4.2	Battery operated	Yes		
4.3	Tolerance (to variations, shutdowns)	NA		
4.4	Protection	Should have over-charging cut-off with visual symbol.		
4.5	Power consumption	NA		
5 ACCESSORIES, SPARE PARTS, CONSUMABLES			COMPLIANCE	
			YES	NO
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	1) S.S Arm Rest: 2 no. 2) Anaesthetic Screen: 1 no. 3) Lithotomy Leg Holders with Stirr-Ups: 1 set 4) Leather Wristlets: 1 set 5) Padded Leg Rest (Gutter type) 6) Anti static mattress 7) Side rails		
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS			COMPLIANCE	
			YES	NO
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS			COMPLIANCE	
			YES	NO
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg 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 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			COMPLIANCE	
			YES	NO
7.1	Certificates (pre- market, sanitary, . .); Performance and safety standards (specific to the device type); Local and/or international	1. Should have FDA/CE/BIS approved product. 2. All mechanical tests. 2. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements (or equivalent BIS standard) and IEC 60601-2-46 for usability. 3. Certified to be compliant with IEC 60601-2-2 Medical Electrical Equipment Part 2-2 :Particular requirements for the safety of High frequency Surgical Equipment if applicable or equivalent		

7.2	Local and/or international	Manufacturer / supplier should have ISO 13485 certificate for quality standard.		
8 TRAINING AND INSTALLATION			YES	NO
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 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 maintenance; 2) Advanced maintenance tasks required shall be documented		
9 WARRANTY AND MAINTENANCE			YES	NO
9.1	Warranty	3 years		
9.2	Maintenance tasks	1) Maintenance manual detailing; 2) Complete maintenance schedule;		
9.3	Service contract 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			YES	NO
10.1	Operating manuals, 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 maintenance; 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			YES	NO
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 displayed		