

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

Version no. :	1		
Date:	5-12-2014		
Done by : (name / institution)	HCT/NHSRC		
<b>NAME AND CODING</b>			
GMDN name	Electro- hydraulic table		
GMDN code	NA		
<b>GENERAL</b>		<b>COMPLIANCE</b>	
		<b>1 USE</b>	<b>YES</b> <b>NO</b>
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	
<b>TECHNICAL</b>		<b>COMPLIANCE</b>	
<b>2 TECHNICAL CHARACTERISTICS</b>		<b>YES</b>	<b>NO</b>
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> <li>1) Should be manually controlled operating table, working range from floor level: 700 -1000 or more <math>\pm 10\%</math>.</li> <li>2) Should be adjustable to all essential positions.</li> <li>3) Should be equipped with movement controls at side of the table.</li> <li>4) Should have frame and bottom made of 304 grade Stainless Steel material.</li> <li>5) Should have reinforced five section stainless steel top.</li> <li>6) Height should be adjustable by oil pump, foot step control.</li> <li>7) Should have detachable head rest which can be easily adjustable to any desired position, above or below the table top.</li> <li>8) Table top can be rotated 360° through base.</li> <li>9) Head section raised from the Horizontal: 20° - 30°</li> <li>10) Durable and leak-proof hydraulic pump.</li> <li>11) Head section lowered from horizontal: 28° - 30°</li> <li>12) Back section raised from the horizontal: 60° - 70°</li> <li>13) Trendelenburg: 25-30°</li> <li>14) Reverse Trendelenburg: <math>\geq 30^\circ</math></li> <li>15) Leg section lowered from the Horizontal: 40° - 50°</li> <li>16) Kidney-position should be achievable by breaking the table.</li> <li>17) Table-top should be radio-lucent.</li> <li>18) Should have handset for position selection by in-built stand-by control.</li> </ol>	
2.2	User's interface	Manual	
2.3	Software and/ or standard of communication (where ever required)	NA	
<b>3 PHYSICAL CHARACTERISTICS</b>		<b>YES</b>	<b>NO</b>
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	
<b>4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 )</b>		<b>YES</b>	<b>NO</b>
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	
<b>5 ACCESSORIES, SPARE PARTS, CONSUMABLES</b>		<b>YES</b>	<b>NO</b>
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	<ol style="list-style-type: none"> <li>1) S.S Arm Rest: 2 no.</li> <li>2) Anaesthetic Screen: 1 no.</li> <li>3) Lithotomy Leg Holders with Stirr-Ups: 1 set</li> <li>4) Leather Wristlets: 1 set</li> <li>5) Padded Leg Rest (Gutter type)</li> <li>6) Anti static mattress</li> <li>7) Side rails</li> </ol>	
<b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>			
<b>6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>		<b>YES</b>	<b>NO</b>
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	<ol style="list-style-type: none"> <li>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.</li> <li>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.</li> </ol>	
6.2	User's care, Cleaning, Disinfection & Sterility issues	<ol style="list-style-type: none"> <li>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.</li> <li>2) Sterilization not required.</li> </ol>	
<b>7 STANDARDS AND SAFETY</b>		<b>YES</b>	<b>NO</b>
7.1	Certificates (pre- market, sanitary, .); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> <li>1. Should have FDA/CE/BIS approved product.</li> <li>2. All mechanical tests.</li> <li>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.</li> <li>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</li> </ol>	

7.2	Local and/or international	Manufacturer / supplier should have ISO 13485 certificate for quality standard.		
<b>8 TRAINING AND INSTALLATION</b>			<b>YES</b>	<b>NO</b>
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		
<b>9 WARRANTY AND MAINTENANCE</b>			<b>YES</b>	<b>NO</b>
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;		
<b>10 DOCUMENTATION</b>			<b>YES</b>	<b>NO</b>
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;		
<b>11 NOTES</b>			<b>YES</b>	<b>NO</b>
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		