

# LOT 3: OPERATION TABLE HYDRAULIC MAJOR

|  |  |   |                   |           |
|--|--|---|-------------------|-----------|
| Version no. :  |  | 1   |                   |           |
| Date:  |  | 5-12-2014   |                   |           |
| Done by : (name / institution)                                     |  | HCT/NHSRC   |                   |           |
| <b>NAME AND CODING</b>   |  |   |                   |           |
| GMDN name  |  | Operation Table Hydraulic Major   |                   |           |
| GMDN code(s)   |  | NA  |                   |           |
| <b>GENERAL</b>   |  |   | <b>COMPLIANCE</b> |           |
| <b>1 USE</b>   |  |   | <b>YES</b>        | <b>NO</b> |
| 1.1  | <b>Clinical purpose</b>  | 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  | <b>Used by clinical department/ward</b>  | Operation theatre   |                   |           |
| <b>TECHNICAL</b>   |  |   | <b>COMPLIANCE</b> |           |
| <b>2 TECHNICAL CHARACTERISTICS</b>                                 |  |   | <b>YES</b>        | <b>NO</b> |
| 2.1  | <b>Technical characteristics (specific to this type of device)</b>   | 1) Should be a manually controlled operating table, working range from floor level: 800-1040mm.<br>2) Should be adjustable to all essential positions.<br>3) Should be equipped with movement controls at side of the table.<br>4) Should have Frame and bottom made of Stainless Steel 304 material.<br>5) Should have reinforced three section stainless steel top.<br>6) Height should be adjustable by oil pump, foot step control.<br>7) Should have detachable head rest which can be easily adjustable to any desired position, above or below table top.<br>8) Table top can be rotated 360° through base.<br>9) Trendelenburg: ≥25°-30°<br>10) Reversed Trendelenburg: ≥30°<br>11) Head Section Raised from the Horizontal: ≥20°-30°<br>12) Head Section Lowered from the Horizontal: ≥28°-30°<br>13) Back Section Raised from the Horizontal: ≥60°-70°<br>14) Leg Section Lowered from the Horizontal: ≥40°-50°<br>15) Kidney Position should be achievable by breaking the table.<br>16) Table-top should be radio-lucent. |                   |           |
| 2.2  | <b>User's interface</b>  | Manual  |                   |           |
| 2.3  | <b>Software and/ or standard of communication(where ever required)</b>   | NA  |                   |           |
| <b>3 PHYSICAL CHARACTERISTICS</b>                                  |  |   | <b>YES</b>        | <b>NO</b> |
| 3.1  | Dimensions (metric)  | Table top dimension (1900 mm x 525 mm) ± 15% Table elevation: (700mm -1000 mm) ± 10%  |                   |           |
| 3.2  | Weight (lbs, kg)   | Should be able to bear patient having weight upto 160 kg  |                   |           |
| 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, 50 Hz  |                   |           |
| 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) | 1) S. S. Arm Rest 1 No<br>2) Anaesthetic Screen 1 No.<br>3) Lithotomy Leg Holders with Stirr-Ups 1 Set<br>4) Leather Wristlets 1 Set<br>5) Padded Leg Rest (Gutter Type)-2 nos<br>6) Anti static mattress-2 nos<br>7) Side rails-2 nos  |                   |           |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>         |  |   | <b>COMPLIANCE</b> |           |
| <b>6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>              |  |   | <b>YES</b>        | <b>NO</b> |

|                                    |   |   |            |           |
|------------------------------------|---|---|------------|-----------|
| 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.<br>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.<br>2) Sterilization not required.  |            |           |
| <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 | 1. Should be FDA/CE/BIS approved product.<br>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.<br>3. Shall meet internationally recognised IEC 60601-1-2 for Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI)   |            |           |
| 7.2                                | Local and/or international  | Manufacturer / supplier should have ISO 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;<br>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;<br>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;<br>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:-<br>1) User, technical and maintenance manuals to be supplied in english/ hindi language along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>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   |            |           |

## 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)  | 1) Should be manually controlled operating table, working range from floor level: 700 -1000 or more $\pm 10\%$<br>2) Should be adjustable to all essential positions.<br>3) Should be equipped with movement controls at side of the table.<br>4) Should have frame and bottom made of 304 grade Stainless Steel material.<br>5) Should have reinforced five section stainless steel top.<br>6) Height should be adjustable by oil pump, foot step control.<br>7) Should have detachable head rest which can be easily adjustable to any desired position, above or below the table top.<br>8) Table top can be rotated 360° through base.<br>9) Head section raised from the Horizontal: 20° -30°<br>10) Durable and leak-proof hydraulic pump.<br>11) Head section lowered from horizontal: 28° -30°<br>12) Back section raised from the horizontal: 60° -70°<br>13) Trendelenburg: 25-30°<br>14) Reverse Trendelenburg: $\geq 30^\circ$<br>15) Leg section lowered from the Horizontal: 40° -50°<br>16) Kidney-position should be achievable by breaking the table.<br>17) Table-top should be radio-lucent.<br>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  |                   |           |
| <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) | 1) S.S Arm Rest: 2 no.<br>2) Anaesthetic Screen: 1 no.<br>3) Lithotomy Leg Holders with Stirr-Ups: 1 set<br>4) Leather Wristlets: 1 set<br>5) Padded Leg Rest (Gutter type)<br>6) Anti static mattress<br>7) Side rails   |                   |           |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>         |  |   | <b>COMPLIANCE</b> |           |
| <b>6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>             |  |   | <b>YES</b>        | <b>NO</b> |
| 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.<br>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.<br>2) Sterilization not required.  |                   |           |
| <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 | 1. Should have FDA/CE/BIS approved product.<br>2. All mechanical tests.<br>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.<br>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.  |            |           |
| <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;<br>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;<br>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;<br>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:-<br>1) User, technical and maintenance manuals to be supplied in english/ hindi language along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>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;<br>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;  |            |           |
| 11.2                               | Recommendations or warnings   | Any warning signs would be adequately displayed  |            |           |