TABLE FOR OBSTETRIC LABOUR (LDR)		
Version no.:		2
Date:		16-07-2021
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Birthing Bed/Table, Powered
GMDN Code		15732
GENERAL		
1. USE		
1.1	Clinical Purpose	Table for Obstetric labour (LDR) is specifically designed to support the mother during all stages of giving birth that includes labour, delivery and recovery. The bed should convert quickly from a practical labour bed to a delivery platform and back to a comfortable recovery bed. At any stage, it can be rapidly adjusted to any positions to cater for emergency situations.
1.2	Used by clinical department/ward	Labour Room Complex (As per Labour room standard Guideline)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics (Specific to this type of device)	1. The LDR bed should be electro-mechanically controlled. 2. It should have three sections and seamless joint in each part with minimal gap between sectional mattresses and the seat-section should have a large perineal cut. 3. Mattresses cover should be non-slippery, washable and waterproof.

		4. The foam density of the mattresses should be of minimum 60 kg/m^3 and thickness of minimum 3-4 inches. 5. The mattress should be fixed with high grade adhesive velcro tape for proper fixing on the bed top. 6. Removable SS (304)/ABS head and leg bows with padded panel. 7. The unit should have provision for trendelenburg and reverse trendelenburg positions (minimum 15 degree or more) and reclinable adjustable back rest angle of 60 degree or more. All positions should be achievable by both mechanically and electronically. 8. Should have control device for back and height adjustments through remote control as well as manually operable. 9. Pre-fitted SS-304 grade adjustable/collapsible side rails. 10. Push grip handle (grab bars) with soft cushion padding on both sides of the bed. 11. Should have foot support for nursing staff. 12. Frame should be of epoxy powder coated steel. 13. Should be easy to clean, sterilize (especially blood stains) and maintain. 14. Should have catheter bag holder which can be attached on either side of bed. 15. Should have infusion rods (made of SS-304 grade) which have adjustable heights, quick release and attachable to all corners of the bed. 16. Should have retractable foot section (section can be telescoped under) so as to convert bed into table. 17. To and fro motion of the leg section should be very smooth. 18. Should be able to hold minimum 150 Kg of load. 19. Caster: Should have minimum 100mm or more heavy duty roller wheels with ball bearing and with central & directional locking mechanism. 20. Should have rectangular sliding/detachable SS-304 tray at perineal part of table.
2.2	User's Interface	Electro-mechanical.
3. PHYSICAL CHARACTERISTICS		

3.1	Dimensions (in mm)	Overall approximate size 1880 -2160 mm (L) * 900 - 1010 mm (W) * 550 mm to 880 mm (H) (With option of manual adjustable height of the bed)
3.2	Weight	To be specified by the Manufacturer/Supplier
3.3	Noise	Less than 50 db.
3.4	Heat Dissipation	Not applicable
3.5	Mobility/Portability	Area Specified above (Labour room)
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power input	220-240V AC,50 Hz fitted with Indian plug
4.2	Power consumption	To be specified by the Manufacturer/Supplier
4.3	Battery backup	1. Battery backup of minimum 30 minutes operation time with inbuilt battery charger shall be provided. The handset shall have indications for power on and battery charge. 2. Should have facility to operate manually in case of power failure.
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. All consumables required for installation and standardization of the system should be provided free of cost. 2. Minimum 60 mm thick kg/m^3 high density foam mattress washable and waterproof and detachable in three parts. 3. Should be provided with extra one pair of leg rest. 4. Should be provided with minimum four infusion rods (SS 304) with hook for hanging IV fluids.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	The unit shall be capable of operating continuously in ambient temperature of 5-50 deg C and relative humidity of 30-90% The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15- 90%

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 be compatible with medical grade disinfectant solution
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary,..);Performance and safety standards (specific to the device type);Local and/or international	1. Should be US FDA/ European CE/ BIS approved (USFDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS are not available). 2. Manufacturer and supplier should have ISO 13485 certification for quality standards. 3. The product should confirm to the latest safety standards of IS:13450.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp electrical socket
8.2	Requirements for sign-off	Compliance with quantity checklist, Quality check of the product
8.3	Training of staff (medical, paramedical, technicians)	1. Hands on training to be provided to healthcare professional on using the equipment, day to day maintenance/cleaning. 2. Hand on training for in-house (Biomedical engineers) for preventive and Corrective maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1. 5 years comprehensive warranty including all spares parts, battery and other accessories. 2. Linkages with Biomedical Equipment Management and Maintenance Program under NHM.

9.2	Maintenance tasks	1. Maintenance manual detailing. 2. Complete maintenance schedule;
9.3	Service contract clauses, including prices	CAMC (as per warranty clause 9.1)
10. DOCUMENTATION		
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/Regional 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	ISO Certification on quality of stainless steel used;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	1. Contact details of manufacturer, supplier and local service agent to be provided. 2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer; Purchaser may engage third party for maintenance of equipment and vendor need to comply in all terms. 3. Manufacturer/ Supplier of medical services should provide price quote for spare part of medical device or supply items, against requisition/Purchase order from Biomedical engineers/technicians.

11.2	Recommendations or warnings	Appropriate warning sign/labels should be adequately displayed on the LDR Bed.