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## **Corrigendum-II**

Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) had invited E-Bids from the interested parties for the procurement, rate contract and the supply of LDR/Delivery Bed & CPAP for different Govt. Institutions of Bihar vide Notice Inviting Tender No.- BMSICL/2021-22/ME-270. During and after Pre-bid meeting various suggestions were received from different prospective bidders regarding amendment in technical specification of equipment which were discussed and deliberated on by the experts, who after due deliberation recommended certain amendments in the technical specification of the equipment, which are annexed as Annexure-I of this corrigendum. In order to facilitate maximum participation of bidders the tender schedule is being revised as follows:

Tender Reference No.	BMSICL/2021-22/ME-270
Date and time for downloading of bid document	Up to 20 <sup>th</sup> April 2022 till 17:00 Hrs.
Last date and time of submission of online bids	21st April 2022 till 17:00 Hrs.
Last date and time of submission of original documents of EMD, Tender Fee and Document	-
Date, Time and Place of opening of Technical Bid	22 <sup>nd</sup> April 2022 (at 15:00 Hrs.) on the website of www.eproc.bihar.gov.in in the office of BMSICL
Date and time of opening of financial Bids	To be announced later on www.eproc.bihar.gov.in

Note:- Bidders are advised to refer to the Annexure-I of this corrigendum before submission of bid.

Annexed:- as above

Sd/-GM (Procurement) BMSICL

		Annexure-I		
	Name of Equipment:- CPAP Machine			
SI. No	Technical Specification as per tender		Amendment Proposed	
1. TE	CHNICAL CHARACTERI	STICS		
1.1		1) Devices should able to deliver CPAP of 1 to 10 cm H2O increments of 1 cm, using a under water bubble system.	1) Devices should able to deliver CPAP up to 10 cm H2O in increments of 1 cm, using a under water bubble system.	
		2) The devices should have a heated wire a in-built air oxygen blender to deliver Fio2 21% to 100% (+/-2%) with an adjustable flow in the range of 0-15 l/min(+-0.5 l/min);	NO Change	
	Technical characteristics (specific to this type of device)	3) Should have a heated wire servo controlled humidifier with display temp. near patient end of the circuit.; to be supplied with 2 reusable infant water chamber;	NO Change	
		4) Should be supplied with 2 reusable heated wire silicone tubing circuit for infant/New-born;	NO Change	
		5) Should be able to deliver CPAP using available patient interfaces nasal prongs/nasopharyngeal prongs;	NO Change	
		6) For devices based on underwater bubble systems the water chamber should be reusable; to be supplied with 2 reusable water chamber;	NO Change	
		7) Should be provided pressure release valve at 15cmH2O to 17cmH2O;	NO Change	
1.2	User's interface	For a flow driving system a pressure display is required Audio visual alarm for low pressure, high pressure, power failure, low O2,	For a flow driving system a pressure display is required Audio/visual alarm for low pressure, high pressure, power failure(in case of power operated), low O2,	
1.3	Software and/or standard of communication (where ever required)	NA	NO Change	
2. PH	YSICAL CHARACTERIS	TICS		
2.1	Dimensions (metric)	NA	NO Change	
2.2	Weight (Ibs, kg)	<8kgs	NO Change	
2.3	Configuration	NA	NO Change	
2.4	Noise (in dBA)	<60dB; Alarm>65dB	NO Change	
2.5	Heat dissipation	Yes	NO Change	

3.1   Power Requirements   220VAC, 50 Hz   NO Change	2.6	Mobility, portabilty	Portable	NO Change
3.3 Tolerance (to variations, shutdowns)  3.4 Protection  ACCESSORIES, SPARE PARTS, CONSUMABLES  Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closes system)  5. ENVIRONMENTAL AND DEPARETMENTAL CONSIDERATIONS  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% in ideal circumstances.  1) 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.  1) D'E(EU) and BIS/ISO 13485:2003;  1) USEPACE(EU) BIS/ISO 13485:2015 from NABCB accredited Body  1) E(Certificates (premarket, sanitary,): Performance and safety standards (specific to the device type); Local and/or international  1) E(EU) and BIS/ISO 13485:2003;  1) E(EU) and BIS/ISO 13485:2003;  1) IUSEPACE(EU) BIS/ISO 13485:2015 from NABCB accredited Body  NO Change  1) TRAINING AND INSTALLATION  1) Pre-installation requirements: nature, values, quality, successions and requirements: nature, values, quality.		V . 1	220VAC, 50 Hz	
3.4   Protection   OVP, earth leakage protection   NO Change	3.2	Battery operated	with at-least 6 hours battery backup	NO Change
4. ACCESSORIES, SPARE PARTS, CONSUMABLES  Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closes system)  5. ENVIRONMENTAL AND DEPARETMENTAL CONSIDERATONS  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%  1) 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.  1) CE(EU) and BIS/ISO 13485:2003;  1) CE(EU) and Cleaning, 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.  1) CE(EU) and BIS/ISO 13485:2003;  2) IEC-60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 15001-2010 (acsthetic & respiratory equipment-compatibility with oxygen)  7. TRANNING AND INSTALLATION  Pre-installation requirements: nature, values, quality, values quality, val	3.3		± 10% of input	NO Change
Accessories (mandatory, standard, optional); Spare parts; (main continual); Spare parts; (main continual); Spare parts; (open, closes system)  2) Air and O2 hose of 3m length each along with the appropriate socket;  5. ENVIRONMENTAL AND DEPARETMENTAL CONSIDERATONS  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%  3) 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.  6. STANDARDS AND SAFETY  1) CE(EU) and BIS/ISO 13485:2003;  2) IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC de01-1-8-2006; IEC de01-1-8	3.4	Protection	OVP, earth leakage protection	NO Change
(mandatory, standard, optional). Spare parts (main ones); Consumables/reagents (open, closes system)  2) Air and O2 hose of 3m length each along with the appropriate socket;  5. ENVIRONMENTAL AND DEPARETMENTAL CONSIDERATONS  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%  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.  1) DESIDENCE (EU)/BIS/ISO 13485:2003;  1) DESIDENCE (EU)/BIS/ISO 13485:2003;  1) DESIDENCE (EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) DESIDENCE (EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) CE(EU) and BIS/ISO 13485:2003;  1) CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) Tatalning And Installation requirements: nature, values, quality, values, values, quality, values, values, values, quality, values, quality, values, values, quality, values, values, quality, values, values, quality, values, val	4. AC	CESSORIES, SPARE PAR	TS, CONSUMABLES	
5. ENVIRONMENTAL AND DEPARETMENTAL CONSIDERATONS  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%  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.  6. STANDARDS AND SAFETY  1) CE(EU) and BIS/ISO 13485:2003;  1) USEPDA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) CE(EU) and BIS/ISO 13485:2003;  1) DISPA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) CE(EU) and BIS/ISO 13485:2003;  1) DISPA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) DISPA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  2) IEC-60601-1-8-2000; IEC 60601-1-8-2006; IEC 6	4.1	(mandatory, standard, optional); Spare parts (main ones);	prongs (At least three sizes suitable for neonates weighing < 1000grms, 1000-1500grms &>1500grms)	NO Change
Atmosphere/Ambiance (air conditioning, humidity, dust)  2) Storage 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%  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.  6. STANDARDS AND SAFETY  1) CE(EU) and BIS/ISO 13485:2003;  1) USFDA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  1) CE(EU) and BIS/ISO 13485:2013;  1) USFDA/CE(EU)/BIS/ISO 13485:2015 from NABCB accredited Body  2) IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-8ER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 15001-2010 (aesthetic & respiratory equipment- compatibility with oxygen)  7. TRAINING AND INSTALLATION  Pre-installation requirements: nature, values, quality, and in the properties of the device type; and interpretature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.  NO Change		(open, closes system)		NO Change
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%  2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  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.  1) DEFECTION OF THE CETTING OF THE CONTINUOUS OF THE	5. EN	VIRONMENTAL AND DE	EPARETMENTAL CONSIDERATONS	
humidity, dust)  2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%  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.  6. STANDARDS AND SAFETY  1) CE(EU) and BIS/ISO 13485:2003;  1) CE(EU) and BIS/ISO 13485:2003;  1) CE(EU) and BIS/ISO 13485:2003;  1) CE(EU) and BIS/ISO 13485:2015 from NABCB accredited Body  1) CE(EU) and BIS/ISO 13485:2015 from NABCB accredited Body  2) IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-8 Ed-4.0-2010; ISO 15001-2010 (aesthetic & respiratory equipment- compatibility with oxygen)  7. TRAINING AND INSTALLATION  7. TRAINING AND INSTALLATION  Pre-installation requirements: nature, values, quality, electrical sockets; Oxygen supply	5.1	(air conditioning,	continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal	NO Change
5.2 User's care, Cleaning, Disinfection & Sterility issues  6. STANDARDS AND SAFETY  Certificates (premarket, sanitary,): Performance and safety standards (specific to the device type); Local and/or international  7. TRAINING AND INSTALLATION  Pre-installation requirements: nature, values, quality, selecting issues  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.  NO Change  NO Change  NO Change  1) CE(EU) and BIS/ISO 13485:2003;	3.1		continuously in ambient temperature of 0 to 50 deg C	NO Change
Certificates (premarket, sanitary,): Performance and safety standards (specific to the device type); Local and/or international  7. TRAINING AND INSTALLATION  1) CE(EU) and BIS/ISO 13485:2003;  10 CE(EU) and BIS/ISO 13485:	5.2	Disinfection & Sterility	to come into contact with the patient or the operator should either be capable of easy disinfection or be	NO Change
Certificates (premarket, sanitary,): Performance and safety standards (specific to the device type); Local and/or international  7. TRAINING AND INSTALLATION  Pre-installation requirements: nature, values, quality,  Pierormance and safety standards (specific to the device type); Local and/or international  Occupant BIS/ISO 13485:2015 from NABCB accredited Body  In CE(EU) and BIS/ISO 13485:2015 from NABCB accredited Body  Signature (pre-market, sanitary, color internation)  1) CE(EU) and BIS/ISO 13485:2015 from NABCB accredited Body  NO Change	6. STA	ANDARDS AND SAFETY		
Performance and safety standards (specific to the device type); Local and/or international equipment- compatibility with oxygen)  7. TRAINING AND INSTALLATION  Pre-installation requirements: nature, values, quality, electrical sockets; Oxygen supply  Performance and safety standards (specific to the device type); Local 60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601		market, sanitary,): Performance and safety standards (specific to the device type); Local	1) CE(EU) and BIS/ISO 13485:2003;	BIS/ISO 13485:2015 from NABCB
7.1 Pre-installation requirements: nature, values, quality, electrical sockets; Oxygen supply NO Change	6.1		60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 15001-2010 (aesthetic & respiratory	NO Change
7.1 requirements: nature, values, quality, electrical sockets; Oxygen supply NO Change	7. TRAINING AND INSTALLATION			
	7.1	requirements: nature, values, quality,	electrical sockets; Oxygen supply	NO Change
7.2 Requirements for sign-off Supplier to perform installation, safety and operation checks before handover NO Change	7.2			NO Change

7.3	Training of staff (medical, paramedical, technicians)	Training of users operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented	NO Change
8. WA	RRANTY AND MAINTE	NANCE	
8.1	Warranty	3 years;	NO Change
	Maintenance tasks	1) Maintenance manual detailing:	NO Change
8.2		2) Complete maintenance schedule;	NO Change
8.3	Service contract clauses, including prices	1) 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;	NO Change
		2) warranty of three years with free servicing (min.6) during warranty;	NO Change
9. DO	CUMENTATION		
		Should provide 2 sets(hardcopy) of:-	NO Change
0.1	Operating manuals, service manuals, other manuals	1) User, technical, maintenance and service manuals to be supplied along with machine diagrams:	NO Change
9.1		2) List of equipment and procedures required for local calibration and routine maintenance;	NO Change
		3) Certificate of calibration and inspection;	NO Change
9.2	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost;	NO Change
10. NO	OTES		
10.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;	NO Change
10.2	Recommendations or warnings	Any warning signs would be adequately displayed	NO Change
10.3	Added		Air Compressor (optional)
10.4	Air Compressor Certification	Air Compressor	1)USFDA/CE(EU)/ BIS/ISO 13485:2015 from NABCB accredited Body

Note- for 10.3 1. Some locations air compressor may require and other locations may not require.

2. So separate price to be quoted for air compressor.

	Name of Equipment:- LDR/Delivery Bed		
SI. No	Technical Specification as per tender		Amendment Proposed
1. U	SE		
	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.	No Change
1		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.	No Change
		1. The LDR bed should be electro-mechanically controlled.	No Change
		2. It should have three sections and seamless joint it each part with minimal gap between section al mattresses and the seat-section should have a large perinea cut.	No Change
		3. Mattresses cover should be non-slippery, washable and waterproof.	No Change
	Technical Characteristics (Specific to this type of device)	4. The foam density of the mattresses should be of minimum 60 kg/m³ and thickness of minimum 3-4 inches.	No Change
		5. The mattress should be fixed with high grade adhesive Velcro tape for proper fixing on the bed top.	No Change
2.1		6. Removable SS (304)/ABS head and leg bows with padded panel.	No Change
		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 position should be achievable by both mechanically and electronically.	No Change
		8. Should have control device for back and height adjustments through remote control as well as manually operable.	No Change
		9. Pre-fitted SS-304 grade adjustable/collapsible side rails.	No Change
		10. Push grip handle (grab bars) with soft cushion padding on both sides of the bed.	No Change

		11 Ch14 h f t t f t - ff	No Change
		11. Should have foot support for nursing staff.	No Change
		12. Frame should be of epoxy powder coated steel.	No Change
		13. Should be easy to clean, sterilize (especially blood stains) and maintain.	No Change
		14. Should have catheter bag holder which can be attached on either side of bed.	No Change
		15. Should have infusion rods (made of SS-304 grade) which have adjustable heights, quick release and attachable to all corners of the bed.	No Change
		16. Should have retractable foot section (section can be telescoped under) so as to convert bed into table.	No Change
		17. To and fro motion of the leg section should be very smooth.	No Change
		18. Should be able to hold minimum 150 Kg of load.	No Change
		19. Caster: Should have minimum 100mm or more heave duty roller wheels with ball bearing and with central & directional locking mechanism.	No Change
		20. Should have rectangular sliding/detachable SS-301 tray at perineal part of table.	No Change
2.2	User's Interface	Electro-mechanical.	No Change
3.1	Dimensions (in mm)	Overall approximate size 1880-2160 mm (L)*550 mm to 880 mm (H) (With option of manual adjustable height of the bed)	No Change
3.3	Noise	Less than 50 db.	No Change
3.5	Mobility/Portability	Area Specified above (Labour room)	No Change
4.1	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.	No Change
		2. Should have facility to operate manually in case of power failure	No Change

		1. All consumables required for installation and	No Change
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	standardization of the system should be provided free of cost.	No Change
		2. Minimum 60 mm thick Kg/m3 high density foam matters washable and waterproof and detachable in three parts.	No Change
		3. Should be provided with extra one pair of leg rest.	No Change
		4. Should be provided with minimum four infusion rods (SS 340) with hook for hanging IV fluids.	No Change
6.ENV	VIRONMENT AL AND D	EPARTMENTAL	
	Atmosphere /Ambiance	The unit shall be capable of operating continuously in ambient temperature of 5-50 deg C and relative humidity of 30-90%	No Change
6.1	(air conditioning, humidity, dust)	The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%	No Change
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	No Change
		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).	1. Should be US FDA/ European CE/BIS approved
7.1	Certificates (premarket, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	2. Manufacturer and supplier should have ISO 13485 certification for quality standards.	Manufacturer and supplier should have ISO 13485 certification from NABCB Accredited Body.
		3. The product should confirm to the latest safety standards of IS: 13450	3. The product should confirm to the latest safety standards of IS: 13450 certification from NABCB Accredited Body.
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		Should provide 2 sets (hardcopy and soft-copy of:-	
	Operating manuals, service manuals, other manuals	1. User, technical and maintenance manuals to be supplied in English/Regional language along with machine diagrams;	No Change
8.1		List of equipment and procedures required for local calibration and routine maintenance;	No Change
		3. Service and operation manuals (original and copy) to be provided;	No Change
		4. Advanced maintenance tasks documentation;	No Change
		5. Certificate of calibration and inspection	No Change
8.2	Other accompanying documents	ISO Certification on quality of stainless steel used;	No Change
		Contact details of manufacturer, supplier and local service agent to be provided.	No Change
9.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer; Purchaser my engage third party for maintenance of equipment and vendor need to comply in all terms.	No Change
		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.	No Change