

MEDICAL DEVICE SPECIFICATION		
LOT-1: MULTI PARAMETER MONITOR FOR OBS&GYNE OT		
		<b>UNOPS Minimum Technical Requirements</b>
Version no. :		Ver_1
Date:		12/07/2018
Done by: (name.institution)		HCT/NHSRC
UMDNS name		
UMDNS code(s)		12636
1.1	Clinical purpose	These systems usually include a central station monitor that receives, consolidates, and displays the information and a set of monitors that are deployed near the patient (bedside monitors) to provide the required data from each patient (ECG, respiratory rate, noninvasive blood pressure (NIBP) and invasive blood pressure (IBP) (systolic, diastolic, and mean), body temperature, (SpO2), (ETCO2).
1.2	Used by clinical department/ward	Operation Theatre
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> <li>1. Should have Multi parameter monitor with TFT/LED/ LCD / display with more than 15 inches with at least 8 wave forms</li> <li>2. The waveforms should be user selectable.</li> <li>3. Monitor should have in built Lithium-ion type battery for 2 Hour continuous operation.</li> <li>4. Should have keys for quick access to main functions.</li> <li>5. Should be able to monitor ECG( 3,5,12 leads), SPO2, NIBP, 2 IBP, Respiration Rate, 2 temp, ETCO2, for adult, pediatric and neonatal patients as standard.</li> <li>6. Monitor must have facility for at least 2 IBP measurements simultaneously. Also should have SPV/PPV monitoring facility.</li> <li>7. 5 Lead ECG monitoring with full range of lethal arrhythmia recognition capability and ST analysis up to 12 leads and 72 hour trend facility.</li> <li>8. Respiration, Apnea alarm, Prioritized audio visual alarms and snap shot facility.</li> <li>9. Transport module with display and battery backup of at least 2 hour</li> </ol>

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2.2	User's interface	Manual
2.3	Software and/or standard of communication (where ever required)	Inbuilt
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
35	Mobility, portability	Portable
4.1	Power	Plug.
4.2	Battery operated	Yes, at least 2 back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.

5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	<ol style="list-style-type: none"> <li>1. 20 Nos of Disposable IBP transducers with all standard accessories &amp; 6 nos of reusable adapter cable (type as requested by the end user)</li> <li>2. Reusable adult 5 lead ECG cable set —2 nos.</li> <li>4. NIBP cuffs for standard Adult(2 Nos), Obese Adult, Child and infant —all 1 each.(5 Nos)</li> <li>5. Temperature Probe (esophageal/ rectal)-2Nos</li> </ol> <p><b>Accessories</b></p> <ol style="list-style-type: none"> <li>1. Spo2 probe adult (Reusable) —2 Nos</li> <li>2. Spo2 probe pediatric (Reusable) —2 Nos</li> <li>3. Fore Head Spo2 Sensor —2 Nos</li> </ol>
6.1	Atmosphere/Ambience (air conditioning, humidity, dust . . .)	<ol style="list-style-type: none"> <li>1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances.</li> <li>2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%</li> </ol>
6.2	User's care, Cleaning, Disinfection & Sterility issues	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.
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. Product Should be US FDA/EU CE approved.</li> <li>2. Manufacturer should have ISO 13485 certification for quality standards.</li> <li>3. The manufacturer must have a management system certified to ISO 9001.</li> </ol>
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9.1	Warranty	3 years, including all spares and calibration.

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi/ 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, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
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 sign would be adequately displayed.







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