

AMDA-Nepal

Siddhartha Children and Women Hospital

Butwal-7, Rupandehi

Technical Specification of Bedside monitors with (7 parameters).

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes/No)	Reference Page No.	Remarks
	Patients monitor with seven parameter			
	Manufacturer:			
	Brand:			
	Type / Model:			
	Country of Origin:			
1	Description of Function:			
1.1	A bedside patient monitor to monitor physiological parameters of patients in the critical care units, operating theatres, emergency room and general wards.			
2	Operational Requirements:			
2.1	It shall operate on AC power supply 100-240VAC 50-60Hz, as well as inbuilt battery and should have integrated storage space to store accessories, cables etc.			
3	System configuration:			
3.1	Patient monitor with ECG, SpO ₂ (Oxygen Saturation), NIBP (Blood Pressure), Pulse Rate, Respiration Rate, Body Temperature, and EtCO ₂ with two channel IBP).			
3.2	IBP and EtCO ₂ is compulsory.			
3.3	It should be compact multi-parameter patient monitor, used for adult, pediatric and neonatal patients.			
3.4	It should have more than 12.1 display with touch screen and rotary knob. The control should be form rotary knob and touch screen with high resolution color LED screen, color resolution not less than 1280 x 800 pixels, up to 10 waveforms display.			
3.5	Weight should not exceed 4 kg with battery.			
3.6	It should be touch screen and support gesture operations.			
3.7	It should have monitoring of ECG, Rasp, NIBP, SpO ₂ , and PR EtCO ₂ with IBP). And Temp as standard.			

4	Technical specification of monitor.			
4.1	Multi-lead ECG algorithm is implemented to analyze the ECG signals from multiple leads to ensure the measurement accuracy when one lead is interfered.			
4.2	ECG Bandwidth: multi modes I,II,III,AVR,AVL,AVF, V.			
4.3	It should support ARR analysis and 27 arrhythmia events should be detected and alarmed.			
4.4	It should support ST and QT/QTc interval monitoring, QT analysis.			
4.5	It should have smart Lead-off detection that enables the continues monitoring if the electrode is disconnected.			
4.6	Respiration measurement range: 0 to 200 rpm, RR Analysis lead: I, II, III or auto.			
4.7	Support RR from SPO2 to reduce false alarms.			
4.8	SPO2 accuracy: Accuracy: $\pm 2\%$ (70 to 100%, Adult/Pediatric :)			
4.9	$\pm 3\%$ (70 to 100%, Neonate).			
4.10	PR range: 20 to 300 bpm.			
4.11	Systolic range Adult: 25 to 290 mmHg.			
4.12	Pediatric: 25 to 240 mmHg.			
4.13	Neonate: 25 to 140 mmHg.			
4.14	The NIBP should have the following mode: Manual/Auto/Continuous.			
4.16	Measurement type systolic, Diastolic, Mean.			
4.17	Adult: SBP 25-290mmHg/DBP 10-240mmHg/MAP 20-250mmHg.			
4.18	Pediatric: SBP 25-240mmHg/DBP 10-200mmHg/MAP 15-210mmHg.			
4.19	Neonate: SBP 25-130mmHg/DBP 10-115mmHg/MAP 15-125mmHg.			
4.20	Respiration should follow the auto current drift balance system to ensure the accuracy of respiration. Should have measurement range 0-120.			
4.21	ETCo2 Main stream/ side stream.			
4.22	Measuring Parameter Etco2, Fico2, AwRR.			
4.23	EtCo2:0 mmHg to 150mmHg.			
4.24	Fico2: 0mmHg to 50mmHg.			
4.25	AwRR: 0rpm to 150rpm.			
4.26	Should have automatic barometric pressure compensation feature.			

4.27	It should have Drug, Hemodynamic, Oxygenation, Ventilation, Renal calculations and Titration table.			
4.28	It should have 24 hour summary analysis and dynamic NIBP analysis.			
4.29	It should have Clinical Assistive Applications: EWS score, GCS scoring, 24h Summary.			
4.30	It should have 3-level audible/visual alarm and adjustable alarm level.			
4.31	It should have standard 2G internal storage card review and storage of 1200 hours trend, 1000 alarm events, 1600 groups of NIBP measurements, 128 ARR alarms and 48-hour full disclosure waveforms.			
4.32	It should have external USB storage for review and storage of 2400 hours trend, 5000 alarm events, and 5000 groups of NIBP measurements.			
4.33	It should have three default configurations for adult/pediatric/neonatal patient, support customized configurations and transferring configuration via USB drive.			
4.34	It should have 4.5 hours of working time with standard Li-ion battery.			
4.35	Working temperature is 0~40°C, unaffected by extremes temperatures.			
4.36	Strong plastic housing resists aging and yellowing, with high corrosion resistance.			
4.37	It should have Clinical Assistive Applications: EWS score, GCS scoring, 24h Summary.			
5	Accessories, Spares and Consumable:			
5.1	All stander accessories, consumables and spare parts required to operate the equipment including all stander tolls and cleaning and lubrication materials, in the offer .Bidders must specify the quantity of every item including their offer.			
5.2	5 Lead ECG with cable-1 set.			
5.3	SpO2 Probe and connector-2(Neonatal and adult) set. 2			
5.4	NIBP connection hose and cuff-2(Neo and Adul) set. 2 set			
5.5	Skin Temperature probe-1 set.			
5.6	EtCO ₂ : full -1 set.			
5.7	IBP: 2 channel -1set			

5.8	Support self-training mode for basic instructions.			
5.9	Water drop –protection with IP1			
6	Standards and safety requirement			
6.1	Must submit ISO13485:2016 for Medical Devices AND			
6.2	It must have EU Quality Management System Certificate (MDR) (EU 2017/745) with USFDA approved product certificate must be submitted.			
6.3	Shall meet IEC-60601-1-2:2007/AC: 2010 General Requirements of Safety for Electromagnetic Compatibility.			
7	Installation and Commissioning & User Training			
7.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.			
7.2	During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.			
8	Warranty & Maintenance Service During Warranty Period			
8.1	Comprehensive warranty (Software, hardware/ parts maintenance labor cost etc.) for 2 years grantee after installation.			
8.2	Planned preventive maintenance (PPM) and corrective maintenance (CM) during warranty period. Supplier must commit to provide 2to 3PPM in a year.			
8.3	The Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.			
9	Authorization			
9.1	The bidder must submit a valid authorization letter from the manufacture company.			
9.2	Certificate of calibration and inspection from factory.			
10	Documentation			
10.1	User (Operating) manual in English.			

	Service (Technical/Maintenance) manual in English. List of important spare parts and accessories with their numbers and costing. Shall accomplish all the qualification criteria of the bidder mentioned in the main bid document.			
--	--	--	--	--

Note:

- I. The bidder must completely fill the technical specification form (TSF). Only Yes/ No /All complies should not be written.
- II. Commitment letter and documents must be provided in separate letter head also.
- III. Evaluations, will be done on the basis of documents submitted by the bidder. All sorts of documents, brochures, certificates , letters, manuals will be cross checked and verified in internet browsers, clarifications (if needed) .Failure in doing so may lead to rejection of bid from technical committee.