

# **TECHNICAL SPECIFICATION OF MEDICAL EQUIPMENT REQUIRED FOR NEW TYPE OF CORONAVIRUS INFECTIONS (COVID-19)**

**2021.06.07**

## **GENERAL REQUIREMENT FOR ALL ITEMS**

### **Quality Management and regulatory**

- ISO 13485:2016 Medical devices – Quality management systems -- Requirements for regulatory purposes
- At least one of: CE marking or approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g., Japan or Australia or Canada)

### **Training and installation requirements**

- The staff who use the equipment need to be trained, including any on-site service personnel. Training including on-the-job user and maintenance training, technical training and specialized training, and clinical training in specified fields.
- Operational as well as general troubleshooting/ User level maintenance should be given to the user during supply & as when required by the user.
- The successful bidder must be done the necessary work for the purpose of satisfactory assembly and operation.
- Should be provided related accessories needed for full installation, assembling and operation.

### **Documentation, Calibration & Standard Operating Protocol (for successful bidders):**

- User (Operation) manual in English, if necessary will ask Mongolian translation partly.
- Service (Technical / Maintenance) manual in English, if necessary will ask Mongolian translation partly.
- Certificate of calibration and inspection from the factory.
- Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of hospital technician and company service engineer should be clearly spelt out.
- Calibration of any specific part/parameter or the whole system as per manufacturer standard/ recommendation must be done by the supplier free of cost twice in a year or as when required during the warranty and AMC / CMC period and submit necessary calibration report.
- Separate list of recommended periodic calibrations of any specific part/parameter or the whole system to ensure accuracy & safety of the equipment should be submitted during supply.
- Separate list of cleaning and disinfection procedures along with material or reagents recommended by the manufacturer should be submitted during supply.

### **Warranty and Maintenance specific requirements**

- 12 months from the date of satisfactory installation. The warranty shall cover all the accessories.
- Submit the list of items, part numbers, and quantities of spare parts required to quick replacement and accessories likely to be required during the initial period of operation.
- Submit each unit price list of the above items. The total cost of these items shall not be added to the Bid Price and submitted separately from bid price.

<b>№</b>	<b>Name of equipment</b>	<b>Pieces</b>
<b>1</b>	<b>PATIENT MONITOR</b>	<b>100</b>
Required technical specifications		
<ul style="list-style-type: none"> <li>- Suitable for Adult/ Pediatric/ Patients monitoring</li> <li>- TFT LCD colorful screen with 12.1 inches</li> <li>- Parameters: ECG (HR), RESP (Breaths), NIBP (SYS, DIA, MAP), SpO2 (Pulse rate, Saturation), Dual Temperature, IBP</li> <li>- With thermal printer</li> <li>- Adjustable audible and visual alarms</li> </ul>		
<b>RESPIRATION</b>		
<ul style="list-style-type: none"> <li>- Measurement range: Approx. 0-200 breath/min</li> <li>- Speed: Approx. 3, 6.25, 12.5, 25, 50mm/sec</li> </ul>		
<b>TEMPERATURE</b>		
<ul style="list-style-type: none"> <li>- Measurement range: Approx. 15-50°C</li> <li>- Accuracy: <math>\pm 0.1</math> to <math>\pm 0.2^\circ\text{C}</math></li> </ul>		
<b>ECG:</b>		
<ul style="list-style-type: none"> <li>- Input: 5 leads ECG electrodes</li> </ul>		
<b>HEART RATE RANGE</b>		
<ul style="list-style-type: none"> <li>- for adults Approx. 15-300 bpm</li> <li>- for ped/neonate Approx. 15-350 bpm</li> <li>- Accuracy: <math>\pm 1</math> bpm</li> </ul>		
<b>SpO2</b>		
<ul style="list-style-type: none"> <li>- Range: 0-100%</li> <li>- Accuracy: <math>\pm 3\%</math></li> </ul>		
<b>NIBP</b>		
<ul style="list-style-type: none"> <li>- NIBP range at least 10 to 300 mmHg, minimum gradation 1 mmHg</li> <li>- Manual, automate and STAT modes</li> <li>- Measurement range: Auto mode</li> <li>- Memory: more than 500 patient's information</li> </ul>		
<b>ACCESORIES AND CONSUMABLES</b>		
<ul style="list-style-type: none"> <li>- Adult and child B.P. Cuff – 2 pcs</li> <li>- SpO2 probe /adult and child/ – 2 pcs</li> <li>- Temperature probe – 2 pcs</li> <li>- ECG cable ( 5 leads) – 2 pcs</li> <li>- Disposable electrode – 50 pcs</li> <li>- Cardio gel: 100g – 5 pcs</li> <li>- Recording paper – 10 pcs</li> <li>- ECG trunk cable – 1 pc</li> <li>- supply cable – 1 pc</li> <li>- IBP cable – 2 pcs</li> </ul>		
<b>INTERFACES</b>		
<ul style="list-style-type: none"> <li>- Able to connect to central nurse station</li> <li>- Internal Wireless Adapter</li> <li>- Internal SRR Interface</li> <li>- Measurement Link (MSL): ODU out (Proprietary)</li> </ul>		
<b>POWER SUPPLY</b>		
<ul style="list-style-type: none"> <li>- AC 220V, 50Hz</li> </ul>		
Internal rechargeable battery: operating time: > 4 h, charging time >2, type		
<b>2</b>	<b>CPAP MACHINE</b>	<b>10</b>
Required technical specifications		
<ul style="list-style-type: none"> <li>• Patient: Adult and Pediatric</li> <li>• Ventilators modes: non-invasive CPAP</li> </ul>		

- Connect oxygen inlet and oxygen cylinder
- Display easily readable in low ambient light and sunlight.
- Controls to be easy to operate, numbers and displays to be clearly visible.
- Displays information about the of oxygen, flow, and air leakage
- Expiratory relief features that reduce the pressure slightly at the end of each breath to make it easier for the patient to exhale.
- LCD colorful screen with 5 inches
- Adjusted to oxygen levels 21-100%
- Pressure support: 4-45 cm H2O
- Easy transportation
- Noise level to be less than 35 dbA at mid pressure range

**AUDIBLE AND VISUAL ALARMS:**

- High/low pressure and/or minute ventilation.
- High/low oxygen (preferable).
- Breathing circuit disconnection.
- Lack of water (preferable).
- System failure.
- Air filter to be replaced.
- Power failure (preferable).
- Low battery (preferable).

**ACCESORIES AND CONSUMABLES**

- Full face mask with tubing (for paediatric and universal fit for adult), alternative oral-nasal mask for adult and paediatric with tubing (at least 2 adult and 2 paediatric); withstands high-level disinfection and sterilization.
- Helmet for adult and
- Reusable, sterilizable masks and tubes (adult, pediatric) – 2 peices
- Air filters – 2 pieces
- Inlet bacteria filters-
- Built-in humidifier 400 to 700 ml container - 2 peices
- Five sets of nasal prongs reusable of all sizes (adult, pediatric)
- Oxygen and air connectors – 1 peices

**POWER SUPPLY:**

- AC 220V, 50Hz
- In-built rechargeable battery (preferable); if the equipment does not have an internal battery, an external battery or uninterruptible power supply should be included to provide battery back up in the case of AC power failure.
- Automatic switch from AC power electric-line mode to battery operating mode and vice versa, if applicable.

<b>3</b>	<b>PORTABLE ULTRASOUND SCANNER</b>	<b>10</b>
<ul style="list-style-type: none"> <li>• Capable of generating imaging procedures involving lungs, heart, abdomen, pelvis, blood vessels, musculoskeletal and soft tissue.</li> <li>• Console: laptop style console design, optional touchscreen combined with conventional user-control panel.</li> <li>• Total weight of the equipment 5 – 10 kg.</li> <li>• Dimensions, approximately: 35 – 45 cm (L); 35 – 45 cm (H); 5 – 10 cm (D).</li> <li>• Field of view: imaging depth at least 20 cm.</li> <li>• Image orientation: capable of lateral and vertical inversion (in B-mode).</li> <li>• Equipment with zoom functionality available.</li> <li>• Transducer ports: at least two active transducer ports permanently available; capability of electronic (preferable) or manually switch between probes.</li> </ul> <p><b>MONITOR AND DISPLAY:</b></p> <ul style="list-style-type: none"> <li>• high-definition (HD) digital black and white and colour liquid-crystal display (LCD) monitor of 15 inches</li> </ul>		

- Screen monitor protection available. Laptop monitor fold-down and lock mechanism of the screen for safe and easy transportation

**COMMUNICATION AND STORAGE:**

- 1TV memory
- DICOM 3.0 conformity.
- USB cable

**IMAGE MODES AT LEAST:**

- 2-D imaging
- M-mode
- B/M mode
- dual 2-D/colour image mode with cine loop
- pulsed wave Doppler, colour Doppler imaging (CDI), power Doppler imaging (PDI), duplex, continuous wave Doppler, triplex mode (optional).

**SOFTWARE:**

- obstetrics/gynaecological measurements and calculations, including gestational sac mean diameter, femur length, crown-rump length, biparietal diameter and abdominal circumference, enabling estimation of gestational age and foetal weight (preferable);
- small parts/soft tissues;
- lung;
- vascular/basic cardiac quantification;
- abdominal
- MSK-general
- MSK-superficial

**TRANSDUCERS:**

- Phased-array 2-5 MHz for basic cardiac and lung studies.
- Phased-array up to 8 MHz for paediatric patients.
- Broadband curvilinear at least 2-5 MHz for general abdominal, obstetrics/gynaecological and lung ultrasound applications. This should have colour, power and spectral Doppler capabilities. M-mode is desirable for obstetrics.
- Linear-array high frequency broadband at least 5 – 10 MHz, with colour, power and spectral Doppler capabilities for vascular and small parts.
- Capability to connect endocavitary transducers

**ACCESSORIES:**

- With matching trolley
- Cables and other connection accessories.
- Built-in rechargeable battery included.
- With printer
- Ultrasound gel – 5 peices
- Printer paper– 5 peices

**POWER SUPPLY:**

- Operates from AC power electric line: 100 – 240 V ~, 50/60 Hz.
- Automatic switch from AC power electric line mode to battery operating mode and vice versa.
- Power supply: power supply may vary according to country.
- Working time in battery mode and standard operations not less than 2 hours.
- Battery recharging time not more than 4 hours.