

Raa-Ungoofaaru, Republic of Maldives

Annex1: Requirement and specifications

Requirement:

Category 1

Item no	Requirement	Quantity
1.	CPR machine	1
2.	Defibrillator with AED	2
3.	Portable ventilator	2
4.	BiPAP Machine	2

Category 2

5.	Infusion pump	20
6.	Syringe pump	20

Category 3

7.	Cardiac monitor with capnography (wall mounted)	5
8.	Cardiac monitor (wall mounted)	6
9.	Cardiac monitor with rolling stand	3
10.	ECG machine with trolley	2
11.	Handheld pulse oximeter	2

Specifications

Note: Shown pictures are only for equipment identification

Item 1: CPR machine: Used to provide automated chest compressions to sudden cardiac arrest (SCA) victims.



- Should be easy to position easy to operate
- Should have a buckle system so that a single person can easily attach the device
- Should support Continuous and 30:2 cycles operation
- Compression rate should be adjustable in continuous mode
- Should support Adjustable depth (In the clinically relevant range) and be fixed during operation
- Should have Audible CPR timer
- Should have automatic and manual positioning of the start point

Accessories:

• All the accessories needed for the operation and storage of the device should be supplied

Power supply:

- Power input to be 220-240 VAC, 50Hz fitted with 13A plug.
- Should have a DC Input connection
- Should have battery backup with which the machine can be ran for at least 1 Hrs
- Extra battery and external battery charger should be supplied

Standards, warranty and Training

• Should be FDA/CE approved product

- The unit and the accessories must be supplied with one year warranty starting from the date of installation.
- The bidder should be responsible for conducting the installation and application training for the clinical staffs
- Technical training should be provided for the Biomedical engineering team of URH
- **Documentation**
- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.
- Contact details of both local supplier and manufacture for service and maintenance and must be provided

Item 2: Defibrillator with AED: Defibrillator is required for reviving the heart functions by providing selected quantum of electrical shocks with facility for monitoring vital parameters.



Operational Requirements:

- Should be compact, Lightweight, easy to use, Bi-Phasic Defibrillator with Manual and AED.
- Should monitor ECG and display them.
- Should be able to print the ECG on thermal papers.
- Should be capable of doing synchronized cardio version.
- Can be operated from mains as well as battery.

Technical Specifications:

- Should be a Low Energy Biphasic Defibrillator monitor with recorder, having capability to deliver shocks from 2 Joules to 200 Joules or better.
- Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles.
- Should compensate for body impedance for a range of 25 to 150 ohms.
- Should have a built in 50 mm strip printer.
- Should have charging time of less than 5 seconds for maximum energy.
- Should have High resolution more than 8-inch Color display for viewing monitoring.
- Parameters like ECG and SpO2 with 3 waveform capability of 4 seconds.
- Both Adult and pediatric paddles should be available.
- Should have event summary facility for recording and printing at least 55 events.
- Should have a battery capable of usage for at least 5 hours of monitoring.
- Should be capable of printing Reports on Event summary, configuration, self-test, battery capacity etc.
- Should have facility for self-test/check before usage and set up function.

System configuration accessories, spares and consumables:

- Defibrillator with AED and External Pacemaker 01
- Built in Adult + pediatric External Paddles 01
- ECG Cable 01
- Paper Rolls 50
- Adult SpO2 reusable Sensor 01
- AED Multifunction Pads for Adults 5 pairs with Each unit
- AED Multifunction Pads for pediatrics- 5 pairs with Each unit
- •

Power Supply:

- A 220-240AC, 50Hz single-phase electrical source with a 13amp, plug type G.
- Should have a battery, capable of usage for at least three hours.

Standards/Cortication and Safety:

• Should be a CE / FDA Approved product and should have ISO standards.

Trainings and Warranty:

- The unit and the accessories must be supplied with one year warranty.
- End users should be trained by the company application personnel.

Item 3: Portable ventilator



- Ventilator should be compact, light in weight and easy to carry.
- The ventilator must have integrated handle for lifting and carrying by hands as well as quick latching to all common rail and pole profiles.
- Accessories: Minimum of 2 sets of reusable Breathing sets for Adult, Pediatric and neonatal each. (including reusable/autoclavable flow sensor if it is to be attached in the tubing)
- Accessories: Oxygen Regulator compatible with the Ventilator hose connection.
- Ventilation facilities available: Adjustable Tidal volume (starting from neonatal range), Breathing rate, Airway pressure, Oxygen (21 to 100) %.
- Modes Available: CMV, SIMV, C-PAP, BiPAP, IPPV
- Manual breath function should be available

- Built-in air source such as turbine
- Expected ranges of parameter settings:
 - o 21-100 %Fio2
 - Insp. Flow Rate:10 to 130 LPM
 - Insp. Flow waveform: User selectable. Square 7 decelerating.
 - Resp.Rate.2 to 70 BPM
 - Inspiratory time:0.3 to 7 sec
 - Insp.Pause time;0.1-2 sec
 - I: E Ratio: 1:4-4:1
 - Insp. Tidal Volume :20-2000 ml
- Pressure limit (Pop off):20-120 cm H2o
 - o PEEP:0-35 cm H2O
 - Pressure Support: 0-60 cm H2O
 - Pressure Control :0-80cm H2O
 - Flow cycle for PSV &PC:0,5to 30 %
 - Apnea Time:10 to60 sec
 - Apnea Back Rate :12 BPM onwards
 - Flow Trigger:1-15 LPM
- Unit must work with low flow oxygen input connections as well.
- Inbuilt Measured & monitored parameters & trends on Display:
 - Driving gas supply pressure (air/oxygen)
 - o Fio2
 - Resp. rate: Ventilator & patient
 - o I:E ratio
 - Inspired tidal volume: Ventilator & patient
 - Expired tidal volume: Ventilator & patient
 - o minute volume: Ventilator & patient
 - h. Airway pressures: P-max, Mean & P plateau
- PEEP
- Auto PEEP
- Apnea

- Both audible and visual alarms for Supply Pressure Low, Airway Pressure High and Airway Pressure Low.
- The device should be supplied with the ambulance/airplane mount complying to the same standard as the ventilator if necessary.
- Documents validating the airplane compatibility from the manufacturer and the local airlines must be supplied.

Circuits and accessories:

- Test lungs from neonatal- adult range must be provided
- Two reusable circuits and other accessories in 2 sets.
 - O Disposable circuits to be supplied Test lungs from neonatal- adult range must be provided
- All other Standard accessories to start the service of the equipment must be provided.

Power Supply

• Battery Back UP for more than 4 hours, DC connectivity. AC charger of 220V 50Hz to be included

Standards, Safety and Training

- Should be FDA approved/ CE marked
- Application training must be provided to the Nursing staff
- Manufacturer standard biomedical technical must be given to URH Biomedical Engineers within one month of installation.

Documentation

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.
- Warranty:
- 12 months from date of installation and commissioning.

Item 4: BiPAP machine



- Should be a handy and portable, light weight device for providing NIV for patients
- Should essentially have the following modes BIPAP(ST), Auto CPAP & CPAP (Spontaneous)
- Should incorporate latest algorithms for leak compensation and synchronization.
- Should have a display for real time monitoring of tidal volume, respiratory rate, I: E ratio, Delivered IPAP and EPAP.
- Should include user adjustable alarms and essential nonadjustable fixed alarms for patient safety.
- Should include alarms for leak, apnea, patient circuit disconnection, low internal battery etc. 7. Should be able to provide adequate pressure ranges for IPAP, EPAP for patients (kindly mention the pressure ranges for IPAP, EPAP that can be delivered by the machine)
- Should have provision for inspiratory and expiratory trigger sensitivity adjustment
- Should have provision for inspiratory and expiratory slope adjustments
- Shall have built in internal battery for 8 hrs. of back up at a minimum 10 mbar pressure
- Accessories to be supplied:
- Patient Circuit & Mask Reusable: 1 set each (Adult & Pediatric)
- Patient Circuit & Mask Disposable: 10 Set each (Adult & Pediatric)
- Should have humidification facility. If an external humidifier is supplied, suitable tubing also need to be provided
- Power Supply
- Power input to be 220-240VAC, 50Hz fitted 13Amp plug.
- Standards, warranty and Training
- Should be FDA approved/ CE certified
- Manufacturer should have ISO certification for quality standards.

- The unit and the accessories must be supplied with one year of warranty starting from the date of installation
- System should be supplied with all reusable accessories
- Application training must be provided to the users.

• Documentation

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.

Contact details of both local supplier and manufacture for service and maintenance and must be provided

Item 5: Infusion pump: Used to deliver controlled volume of fluids to patients



Specifications

- Should have LCD/LED Display
- Clearly visible visual alarms
- Air bubble detector with single and cumulative functions
- Line clamping device should be available
- Adjustable occlusion sensitivity
- Audible and visual alarms in following conditions
 - 1. Power failure
 - 2. Low battery
 - 3. Air in line
 - 4. Occlusion
 - 5. End of infusion
 - 6. Door opened

- 7. Infusion errors or equipment malfunction
- Infusion flow rate : 0.1 to 999 ml/Hr
- Flow rate accuracy tolerance not higher than +/- 5%
- KVO Rate: 0.1 5ml/hr
- RS232/USB Interface for data transmission
- Machine should be spill proof and easy to clean
- Drug library should be available and the bidder should load the same
- Application training should be provided for nurses

Power Supply

- Power input to be 220-240VAC, 50Hz fitted 13Amp plug.
- Should have battery backup which can run for at least 4 Hrs.
- Alarm protection in following situations
 - Power failure
 - Battery low

Standards, Safety and warranty

- Should be FDA/CE approved product
- The unit must be supplied with one year of warranty starting from the date of installation.

Documentation

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.

Contact details of both local supplier and manufacture for service and maintenance and must be provided.

Item 6: Syringe pump: helps deliver an accurate number of fluids, whether nutrients or medications, into the patient's body in a controlled manner



- 1. Microprocessor controlled with digital LCD alphanumeric display of parameters and Alarms
- 2. Variable rate ranging from 0.1 to 500 mL/hr. or better, with 0.1 mL/hr. increments
- 3.3% accuracy or better
- 4. Variable volume-to-be-infused from 1 to 1,000 mL or similar
- 5. Digitally displayed parameters to include:
 - 5.1. Infusion rate
 - 5.2. Battery / AC operation
 - 5.3. Running indicator
 - 5.4. Alarming condition when active, with indication of alarm type or code
 - 5.5. Back pressure monitor / indicator

6. Capability to accept different syringe types and sizes with automatic syringe detection and identification

7. Syringe compatibility and auto detection shall include but not be limited to all sizes of the following (1 to 60 mL):

- 7.1. BD
- 7.2. Terumo
- 7.3. Monojet
- 7.4. Braun
- 7.5. Fresenius
- 8. Variable bolus rate
 - 8.1. Specify maximum flow rate
 - 8.2. Bolus infused volume indicator during bolus activation
 - 8.3. Protected access
- 9. Audiovisual alarms shall include but not be limited to the following:
 - 9.1. Syringe installation and integrity (detection)
 - 9.2. Line disconnection (sudden drop in back pressure)
 - 1.3. Occlusion pressure pre-alarm
 - 9.4. Occlusion pressure

- 9.5. Near end of perfusion alarm
- 9.6. End of perfusion
- 9.7. Volume limit pre-alarm
- 9.8. Volume limit
- 9.9. KVO (1 ml/hr.; if other, specify)
- 9.10. Low battery pre-alarm
- 9.11. Discharged battery
- 9.12. Internal malfunction
- 10. Drug library should be available and bidder should load the same
- 12. Safety features shall include but not be limited to:
 - 12.1. Self-test at start-up
 - 12.2. Nurse call interfacing capability
 - 12.3. Splash proof design
 - 12.4. Auto priming
 - 12.5. Adjustable alarm volume. No permanent silencing shall be possible.
 - 12.6. Keypad lock
 - 12.7. Impossibility to improperly install infusion set
 - 12.8. Free flow prevention system
 - 12.9. Last parameter setting retention

Power Supply

• Power input to be 220-240VAC, 50Hz fitted 13Amp plug, type G Should have battery backup with which machine can be ran for minimum 4 Hrs.

Standards, warranty and Training

- Should be FDA approved / CE marked
- The unit and the accessories must be supplied with one year of warranty starting from the date of installation.
- Application training must be provided to the users.

Documentation

• User/Technical/Maintenance manuals to be supplied in English.

List of important spares, accessories with their part numbers must be provided

Item 7: Cardiac monitor with capnography (wall mounted):



Specifications:

- Modular & Suitable for Adult/Pediatric/ Patients monitoring.
- Minimum 15 inches display screen.
- Eight Channel digital and waveforms/ traces display.
- Capability of storage of patient data and printing of patient reports.
- The Patient Monitor must have a provision for telemetry data transmission for central monitoring

Parameters

- Facility to monitor and display ECG, Respiration, NIBP, SpO2, EtCO2, Temp
- ECG: Monitoring, Diagnostic & OT modes of monitoring of ECG should be available

Simultaneous Multi-lead ECG monitoring of 7 ECG lead

HR range 20-350 BPM

Automatic arrhythmia detection & alarm for standard & lethal arrhythmia

 Pulse Oximetry: Nellcor or Masimo technology. Display of Plethysmograph with Pulse Strength indicator & SpO2 values & perfusion index. SpO2 Range – 1-100% PR Range – 20 to 230 BPM

- ETCO2: Should be Main Stream capnography with display of CO2 and digital Values of EtCO2, FiCO2 & RR. EtCO2 Range 0-99 mmHg FiCO2 0 to 20 mmHg.
 Flow rate 50ml/min Units mmHg, KPA/Vol%
- NIBP: Measurement and display of systolic diastolic and mean pressure values of NIBP measurement for adult, child & neonate. User selectable alarm settings, Range 20-250 mmHg.
- **Temperature:** Two channels and with two units (0c and 0F) selectable Temp. Range – 0- 50 Deg C.
- **Respiration:** RR range 1-150 bpm, Sourced through ECG cable or CO2. Apnea alarms should be provided.

Trends & alarms:

- 72 Hrs. graphical/tabular trends with zoom facility and separate dedicated trend for storing min 200 NIBP readings
- Should have multiple patient data storage facility.
- Auto-setting of alarm limits depending on present patient condition for all the parameters
- Should have Alarm recall facility for last 24 Alarm events with date, time and Message
- Should have facility to print Graphical trend, tabular trend and alarm recall.

Recorder: Inbuilt thermal printer should be available

Others: Defibrillator and cautery protection should be provided Should work on Mains as well as battery (backup for 2 Hrs

Accessories:

- Lead ECG with clips 2 sets
- NIBP Cuffs for Adult 2, Child 2 each
- EtCO2 module with all accessories.
- Esophageal/Rectal Temperature probe -2 and skin temperature probe 1 per monitor.
- Reusable SPO2 probes adult 2 and pediatric 2 per monitor
- Wall mount plates and rails

Central monitoring system (if purchased):

- Display Monitor: Color LED screen at least 21-inch size
- With licensed Operating System software
- Capable of receiving and displaying data simultaneously from at least 16 patient monitors
- Capable of trend review per patient
- Capable of alarm history review
- Capable of freezing data for further review and analysis
- Capable of graphic and tabular data trend presentation
- CPU: at least 2 processors with minimum of 4 cores and 4 threads
- RAM: at least 16GB should be extendable up to 32GB
- Video Card: at least 4GB video RAM
- Hard drive/storage: at least 2TB
- USB ports xiv. Licensed Operating System (OS)
- Input voltage: 220V, 50Hz

Accessories: Keyboard, mouse, external speaker, Automatic Voltage Regulator, laser printer

Power supply:

- Power input to be 220-240 VAC, 50Hz fitted with 13A plug.
- Should have battery backup with which the machine can be ran for at least 2 Hrs.

Standards, warranty and Training

- Should be FDA/CE approved product
- The unit and the accessories must be supplied with one year of warranty starting from the date of installation.
- Application training should be provided within two months of installation

Documentation

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.
- Contact details of both local supplier and manufacture for service and maintenance and must be provided.

Item 8: Cardiac monitor wall mounted



- Specifications:
- Modular & Suitable for Adult/Pediatric/ Patients monitoring.
- Minimum 12 inches multi-color display screen.
- Requires the basic 5 parameters
- Capability of storage of patient data and printing of patient reports.
- Should be supplied with accessories for wall mount

• PARAMETERS

- Facility to monitor and display ECG, Respiration, NIBP, SpO2, Temp
- ECG: Monitoring, Diagnostic & OT modes of monitoring of ECG

Simultaneous Multi-lead ECG monitoring of 7 ECG lead

HR range 20-350 BPM

HR/PR Source selection facility from Automatic, Spo2 or NIBP. Automatic

arrhythmia detection & alarm for standard & lethal arrhythmia

- Pulse Oximetry: Nellcor or Masimo technology. Display of Plethysmograph with Pulse Strength indicator & SpO2 values & perfusion index. SpO2 Range – 1-100% PR Range – 20 to 230 BPM
- **NIBP:** Measurement and display of systolic diastolic and mean pressure values of NIBP measurement for adult, child & neonate. Range 20-250 mmHg.
- **Temperature:** Two channels and with two units (0c and 0F) selectable Temp. Range – 0- 50 Deg C. Option for differential temperature should be provided
- **Respiration:** RR range 1-150 BPM Sourced through ECG cable. Apnea alarms should be provided.
- Trends & alarms:
- 72 Hrs graphical/tabular trends with zoom facility and separate dedicated trend for storing min 200 NIBP readings
- Auto-setting of alarm limits depending on present patient condition for all the parameters
- Should have Alarm recall facility for last 24 Alarm events with date, time and Message
- Should have facility to print Graphical trend, tabular trend and alarm recall.
- **Recorder:** Inbuilt thermal printer should be available
- **Others** Defibrillator and cautery protection should be provided should work on Mains as well as battery (backup for 2 Hrs.) Automatic zoom in Facility in the monitor display. Should have facility to download trend data on USB and SD Card.
- Accessories:
- Lead ECG 1 sets
- NIBP Cuffs for Adult 1, Child 1 each
- Esophageal/Rectal Temperature probe 1 and skin temperature probe 1 per monitor.
- Reusable SPO2 probes adult 1 and pediatric 1 per monitor
- Wall mount plates and rails
- Power supply:
- Power input to be 220-240 VAC, 50Hz fitted with 13A plug.

- Should have battery backup with which the machine can be ran for at least 2 Hrs
- Standards, Safety and warranty
 - Should be FDA/CE approved product
 - The unit and the accessories must be supplied with one year of warranty starting from the date of installation.

• **Documentation**

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.
- Contact details of both local supplier and manufacture for service and maintenance and must be provided.

Item 9: Cardiac monitor with rolling stand



- Specifications:
- Modular & Suitable for Adult/Pediatric/ Patients monitoring.
- Minimum 12 inches multi-color display screen.
- Requires the basic 5 parameters
- Capability of storage of patient data and printing of patient reports.
- Should be supplied with rolling stand and attaching plate

• PARAMETERS

- Facility to monitor and display ECG, Respiration, NIBP, SpO2, Temp
- ECG: Monitoring, Diagnostic & OT modes of monitoring of ECG

Simultaneous Multi-lead ECG monitoring of 7 ECG lead

HR range 20-350 BPM

HR/PR Source selection facility from Automatic, Spo2 or NIBP. Automatic arrhythmia detection & alarm for standard & lethal arrhythmia

- Pulse Oximetry: Nellcor or Masimo technology. Display of Plethysmograph with Pulse Strength indicator & SpO2 values & perfusion index. SpO2 Range – 1-100% PR Range – 20 to 230 BPM
- NIBP: Measurement and display of systolic diastolic and mean pressure values of NIBP measurement for adult, child & neonate. User selectable alarm settings. Range 20-250 mmHg.
- **Temperature:** Two channels and with two units (0c and 0F) selectable Temp. Range – 0- 50 Deg C. Option for differential temperature should be provided
- **Respiration:** RR range 1-150 BPM Sourced through ECG cable. Apnea alarms should be provided.
- Trends & alarms:
- Auto-setting of alarm limits depending on present patient condition for all the parameters
- Should have facility to print Graphical trend, tabular trend and alarm recall.
- **Recorder:** Inbuilt thermal printer should be available
- Others Defibrillator and cautery protection should be provided should work on Mains as well as battery (backup for 2 Hrs.) Should have facility to download trend data on USB and SD Card.
- Accessories:
- Lead ECG with clips 1 sets
- NIBP Cuffs for Adult 1, Child 1 each
- Esophageal/Rectal Temperature probe 1 and skin temperature probe 1 per monitor.
- Reusable SPO2 probes adult 2 and pediatric 2 per monitor
- Rolling stand
- Power supply:

- Power input to be 220-240 VAC, 50Hz fitted with 13A plug.
- Should have battery backup with which the machine can be ran for at least 2 Hrs
- Standards, Safety and Training
 - Should be FDA/CE approved product
 - The unit and the accessories must be supplied with one year of warranty starting from the date of installation.

• **Documentation**

- User/Technical/Maintenance manuals to be supplied in English.
- List of important spare parts and accessories with their part number and costing.
- Contact details of both local supplier and manufacture for service and maintenance and must be provided..

Item 10: ECG machine with trolley



- 12 lead multi-channel digital ECG machine capable of operating on dual power
- Lead standard: 12 lead ECG and simultaneous acquisition of 12 lead ECG data
- Should have complete digital filter to avoid baseline drifting and interfering from AC
- Machine should have ECG interpretation on record
- Should have acceptable storage to save at least last 20 ECGs
- LCD screen displaying settings, operation menu and ECG waveforms
- Built in high resolution thermal printer
- ON/OFF switch and power indicator should be available
- Floating input circuit protection from defibrillation and pacemaker
- Automatic and manual operating modes
- The unit should detect lead off and display.

• Mobile Cart with cord hanger has to be supplied with equipment

Power Supply:

- Line voltage 220-240AC, 50-60Hz and fitted with a 13amp plug.
- Should have battery backup which supports at least 1 hour operation without power

Standards/Cortication, Safety:

• Should be a CE / FDA Approved product and should have ISO standards

Warranty:

• 12 months from the date of handing over or installation and commissioning

Other:

• User/Technical/Maintenance manuals to be supplied in English and certificate of calibration and inspection.

Item 11: Handheld pulse oximeter: Used to measure the oxygen saturation of blood and pulse rate



- Continuous measurement
- Measuring range: 50 100%
- SpO2 accuracy: +/-2 % (80 100 % saturation) , +/-3 % (70 79 % saturation)
- PR measuring range: 30 250 bpm.
- PR accuracy: +/- 2 bpm
- Should have audible and visual alarm
- Should be working with rechargeable battery and charger should be supplied with the machine
- Standards, Safely, Training and warranty
 - 1. Should be a CE / FDA Approved product and should comply with ISO standards
 - 2. 12 months warranty from the date of handing over or installation and commissioning