Annexure

Technical Specifications

Equipment Name: Ventilator ICU

- I. Ventilation modes
 - 1. Paediatric mode.
 - 2. Controlled mode.
 - 3. Asst. Controlled mode.
 - 4. Pressure Controlled Ventilation.
 - 5. SIMV/V and SIMV/P.
 - 6. Bipressure Ventilation.
 - 7. CPAP and PEEP.
 - 8. Facility for Non-Invasive ventilation
 - 9. Plateau Facility
- II. Ventilation parameters: -
 - 1. Tidal volume 200 2000 ML (Adult patient).
 - a. 50 to 300 ML (Paediatric PC mode).
 - 2. Respiratory rate -5 100 BPH.
 - 3. Pressure -0 100 cm H2O.
 - 4. Inspiratory Peak Flow 4 100 1/min.
 - 5. Minute volume -1-30 1/min.
 - 6. Oxygen Concentration 21 -100 %
 - 7. Inspiratory pause -0.1-5.5 sec.
 - 8. PEEP/CPAP 30 cm H2O.
- III. Standard Accessories (with each machine): -
 - 1. Patient circuit(Adult reusable) 2 complete set.
 - 2. Patient circuit (Paediatric reusable) 1 complete set.
 - 3. Nebulizer Ultrasonic one Complete set.
 - 4. Humidifier

- 1 No.
- 5. O2 Pressure Regulator with hose 1 No.
- 6. 5 meters (conversion kit)
- 7. Hose for O2 connection with connector 5 mts.
- 8. Hose for compressed air with connector 5 mts.
- 9. Test lung 1 No.

IV. Features: -

- 1. Back up mode for apnea.
- 2. Full alarm system for all ventilator settings and monitored values.
- 3. Monitor with LCD/TFT (10" or higher size) graphical display for real time simultaneous display of two waveforms. Should display minimum 3 graphs and 2 loops and may not simultaneously

- 4. Monitoring of both patient data and set values should be possible with trend facility.
- 5. Direct access to vital settings
- 6. Transducer should be sterilizable and reusable.
- 7. PEEP valve should be built in.
- 8. Patient circuit should have a separate inspiratory and expiratory limb.
- Should have safety certificate from a competent authority CE / FDA (US) / STQC CB certificate / STQC S certificate or valid detailed electrical and functional safety test report from ERTL.

V. Pneumatic Gas Sources:

- 1. Gas delivery system by sound less in built compressor / external integrated compressor with the unit.
- 2. In case of compressor failure it should also be operable with compressed air / oxygen supply of 45 to 60 psi..
- VI. Power Source: -

220/240 V Ac 50 Hz supply.

Internal battery (maintenance free) with 1 hour minimum operating time for the ventilator

Vii. Mounting

Trolley/Cast mounting for easy transportation

LARYNGOSCOPE-VIDEO

TECHNICAL SPECIFICATIONS

- 1. Should be a video laryngoscope convenient for tracheal intubation.
- 2. Should have a camera for live Image capturing
- 3. Should have LED light illumination
- 4. Should have color Image display facility LCD/TFT display
- 5. Should have provision to insert all sizes of endotracheal tube
- 6. Should have a provision to introduce all sizes of suction catheters
- 7. Should have water proof protection
- 8. Should be supplied with rechargeable battery and provision for re-charge.
- 9. Should have a battery backup facility of minimum 1 hr.
- 10. Should have all blade sizes/adjustable for adult and paediatric laryngoscopy. If the blades are disposable, should supply 50nos. of blades compatible for both adult and paediatric along with each unit.
- 11. Should have safety certificate from a competent authority CE / FDA (US) / STQC CB certificate / STQC S certificate or valid detailed electrical and functional safety test report from ERTL. Copy of the certificate / test report shall be produced along with the technical bid.

SPECIFICATION FOR PORTABLE VENTILATOR(ONE)

- Basic machine should be light weight, compact, suitable for adult and pediatric ventilation.
- The system should be able to monitor following parameters.
 Peak pressure, frequency, I/E ratio, Inspired Tv, Expired Tv, Airway Pressure
 Gauge
 - Inspiratory flow, Expiratory flow, Minute volume, Fi O2, Battery status.
- Ventilator should operate from AC and from internal battery as well. The internal battery should take over the ventilator at least up to 8 hrs. During power failure.
- It should have a combination mode of pressure and volume to guarantee a minimum tidal volume while ensuring the Pressure Ventilation within safe limits.
- It should also have inverse ratio ventilation is pressure control or assist pressure control ventilation.
- Ventilator should also have inbuilt Fi O2 monitor.
- Should have reusable Flow Sensor.
- The system should be quoted with reusable patient circuit.
- The Unit should have Alarms for following
 Mains Failure, Battery depleted, High/Low Pressure
 Leaks, High/Low Exp Volume, High/Low Fi O2
 Sensor Pressure, High Temperature and proximal Pressure.

Technical data (TOF

Safety

Compliant with European directive CEE 93/42 Compliant with standards EN 60601-1 Jan. 2007 and EN 60601-2-10 EC marking (CE0499 SNCH 2014-10-02) for Class 2a device EMC Class A Material sensor clamp (part in contact with the patient) THERMOLAST® M TM4MED (free Latex)

Stimulations

TOF (Train Of Four), T1/T4 and Tref/T4 calculations AUTO TOF (Tof programmed from 15s to 15min) TET (Tetanus 50 Hz) DBS* (Double Burst Stimulation) modes 3.3, 3.2 and 2.3 PTC* (Post Tetanic Count) TWITCH (Single Twitch) 0.1 Hz and 1 Hz

Acceleration detector

Three-dimensional accelerometer (±8 G at 10 bits, Fq: 200 Hz, Resolution 0.016 G)

Electrical stimulation

Constant output current of 0 to 60 mA (accuracy ±10 %) (on an actual load of 4 Kohms) Monophasic, duration of impulse 200 μs, frequency 50 Hz 18

Power supply

2,000 mAh Lithium-Ion baftery (comes with thermal protection and protection against short-circuits) Battery power for about one month with normal use (10 TOF measurements a day) Charger/External power supply (continuous 5V 1,000 mA)

Dimensions/Weight

Monitor alone Monitor with accelerator battery and cables and electrode 60 x 150 x 55 mm (2.36 x 5.9 x 2.16 in) 320 g (0.7 lb) (approximately) excluding cable 190 g (0.41 lb)

Sperificelians: 40	stable fallent Controller analysis
Device type /	Syringe pump with motor driven linear layer actuator, pulsed motion (60 pulses per mm)
Basal rate	0.1 to 650ml/h
Bolus rate range .	0 – 1000ml/h
Actuator stroke	c.107mm available
Syringe sizes	2ml to 60ml (pump configured to most commonly used syringes including BD Plastipak, Monoject, Braun, Terumo and Codan syringes but can also be programmed to other brands)
Pump accuracy	+/- 2%
Occlusion pressure	100 to 1500mmHg. Max actuator force 50N (5Kgf)
Battery	Rechargeable Li-Polymer 7.4 volt, 1800mAh
Battery operation	100 full deliveries depending on infusion and set up parameters
Battery charging	Automatic when connected to an AC power source
Indicators	Graphic LCD display (128 x 64 pixels with backlight), dual colour operation LED to denote infusion and alarm status and keypad
Alarms	When a problem is detected, the TCPA displays the following alarm messages, sounds an audible alarm & the red LED lights - occlusion, syringe empty, near end, end battery, locking cover open, low battery, pump paused too long, syringe displaced, syringe error
TPCA dimensions	38 x 55 x 190mm (L x W x H)
Classification	Type CF Equipment, degree of protection against electrical shock Class II equipment, IPX3 protection against ingress of water
Housing	Polycarbonate ABS (fire retardant)
Weight	400g with battery

Electrical safety IEC 60601-2-24 (Infusion pumps and controllers), IEC 60601-1-4 (Programmable Electrical Medical System), UL 60601-1 and CAN/CSA C22.2 No 601.1 Standards Manufactured in accordance to ISO 9001 and ISO 13485. CE marked (in accordance with the Medical Devices Directive 93/42/EEC) **EMC** IEC 60601-1-2 (EMC) Environmental specifications Non operating conditions (transportation and storage) Temperature -25° to +50°C (-13°F to +122°F) Humidity 5% to 100% R.H, non-condensing Air pressure 48kPa to 110kPa The system may not meet all performance **Operating Conditions** specifications if operated outside of the following conditions Temperature +15°C to +45°C (+59°F to +113°F) Humidity 20% to 85% R.H at +40°C, noncondensing Air pressure 70kPa to 110kPa

Radio frequency ablation machine

Impedance unit

Measuring range 30 Ω - 2k Ω

Resolution: 1Ω 30Ω -1 $k\Omega$

100 1k Ω - 2k Ω

Direct nerve stimulation-motor /sensor

Stimulation frequency 1 Hz- 200 Hz resolution: 1 Hz

Pulse duration 50 μS -3 ms resolution: 50 μs

Constant voltage 50 mv -10 v resolution: 50 mv

Constant current 50μA -8 Ma resolution: 50 μA

Auto ramp rising Edge adjustable resolution: 50 μA in 0.5s/1s/2s

Waveform unipolar Square wave

Continuous RF Unit

Temperature accuracy: ± 2°C

Temperature monitor range: 20°C -105°C

RF frequency: 488 KHz sine wave

Load impedance range: $50\Omega - 2 k\Omega$

RF rated power: 50 w resolution: 1 w

Output RF voltage limitation: 100 vms

Output RF current limitation: 800 mA

Stagger time: 0 - 120 s

Thermal RF controlled mode: Temperature, Power, preset temperature- profile

Thermal RF temperature 30°C – 95°C Resolution 1 °C

Thermal RF time: 0-10 min resolution: 10 SEC

Power mode preset 0.1 w -10 w resolution 0.1 w

10 w -50 w resolution 1 w

Pulse RF

Pulse RF controlled mode temperature, voltage, RF duration

Pulse RF Temperature 30°C -95°C resolution 1°C

Pulse RF Voltage 50 mv -10 V resolution

Pulse RF Duration 3ms -40 ms resolution 1ms

Pulse RF Time 30 s -30 min resolution 30 s

Pulse RF Time per second 1Hz – 10Hz resolution 1 Hz

CE Certification required.

Technical specification for Anaesthesia Workstation

A. Basic Unit:

- The unit should completely integrated with anesthesia delivery, Gas and anaesthetic agent monitoring, in buit closed breathing circuit, inbuilt microprocessor controlled ventilator and inbuilt active low vacuum, high flow AGSS system with Modular anaesthesia Monitor.
- Should be capable of providing low-flow techniques to minimize gas and anaesthetic agent consumption. It should give gas and agent consumption data at end of each surgical case.
- 3. Should have minimum 15 inch colour touchscreen TFT display on swivel mount for ease of viewing at least 2 nos select tec type vaporizers manifold. All these components should be of the same manufacturer or brand with their label on each component.
- 4. <u>Gas delivery system</u> with digital virtual display of the flowmeters for O2, N2O and Air. Also must have Total flowmeter glass tube for measurement and monitoring of total Fresh gas.
- 5. It should be equipped with self-test routines and automatic calibration of all sensors to calculate the leak and compliance. Should also check for leak of inline vaporizer/s.

B. Breathing system (Close circuit system):

- 1. Should have canister capacity of at least 1.0 Kg in Single/double chamber design along with Co2 By-pass facility for easy removal & re-fitting during the operation. Co2 bypass message must display in screen during such activity.
- C. Vaporisers: should provide Two Selectatec mount vaporizers i.e Iso/des- and Sevo. Vaporiser should Pressure, flow and temperature compensated.

D. Integrated Anesthesia Ventilator: In built Anesthesia Ventilator:

- 1. Should be Microprocessor Controlled & Pneumatically Driven Ventilator with bellows. Should not require change of bellows in between adult and pediatric patient.
- 2. Continual fresh gas flow with fresh gas flow compensation during mechanical ventilation.
- 3. Modes of Ventilation: Must have modern advance modes like :-
 - 1) PCV-VG,
 - 2) SIMV (PCV-VG),
 - 3) PSV with apnea (Pressure support with Apnea Backup with auto reset when patient resumes breathing),

- 4) CPAP + PSV modes other than standard modes like VCV,PCV, SIMV VCV & PCV
- 4. Should display complete Patient spirometry with all the 3 loops and save loop feature. Should have pressure, flow and volume airway waveform display facility.
- 5. Parameter :- Tidal Volume: Tidal volume delivery 20 to 1500ml. PCV modes :- 5 to 1500ml, breath rate up to 100 bpm with variable flow with peak flow of more than 100 L/min
- 6. Compliance Measurement and Trending: Measures and displays the patient's compliance to offer a view of the patient's lung condition. Should simultaneously display chosen Spirometry loop and lung mechanic data with at least 3 waveform with ability to save loops for reference and visual trending of lung mechanics.

E. Integrated Anesthesia agaent measurement and monitoring:

- Gas and agent Monitioring: The In-built Anesthesia Gas Monitoring Facility should base
 on side-stream technology, using Infra-Red Photometry Principal & also it should offer
 Automatic Anesthetic Agent Identification. It should be by a plug and play module and the
 Module should compact and should be swappable between Machine and the Anaesthesia
 Monitor.
- 2. It should provide age specific MAC value
- 3. Should measure and display: Inspired and expired value Co2, N20, O2 and agent. Facility to display capnograpm, oxygram and waveform for anaesthetic agent
- 4. Oxygen measurement by paramagnetic oxygen sensor.

F. Alarm management:

1. Should have clear alarms and user information as text messages.

G. Specifications for Multi Parameter Patient Monitor:

- 1. Should have secure mounting on workstation with measurement and monitoring of Heart rate, SPO2, NIBP, ECG, 2x Temp, RR and 2x IBP as standard hemodynamic parameter.
- 2. Display: Should have a Display of 12 or 15 inch inch and above diagonal colour TFT display screen.
- 3. Should operate through Rotary knob & Membrane keyboard.
- 4. Fields: Should have 6 waveform fields.
- 5. ECG: Should have provisions to connect 3 or 5 Lead ECG cables

- 6. NIBP: Should have NIBP measurement by Osillometric method. Should have Manual / Automatic modes of measurement... Should have a measurement range of 20 to 250 mm Hg.
- 7. Invasive BP: -Should have 2 channel Invasive Blood pressure (IBP) measurement. Should have waveform IBP1 and IBP2.
- 8. Temperature: Should have provision for two temperatures with display of T1 and T2.
- 9. Respiration: Should have Respiration by Impedence method.
- SPO2:- It must use Low perfusion technology to measure oxygen saturation for accuracy during motion artifacts, low perfusion states like shock, bradycardia and hypothermia. Should have SPO2 measurement with plethysmograph, and SPO2 values with range 50% to 100%.
- 11. Depth of Anesthesia Monitoring- either BIS or Entropy module with 50 sensors
- 12. Alarm facility:-Should have Alarm facility for HR limits, Arrythmia, ST Segment Limit, and all other parameter limits. Should be audio visual and graded.
- 13. Graphs & Trends:-Should have 24 hr. of Graphical and Tabular Trend for NIBP, HR, Resp, SPO2, RR, IBP, IBP2, T1, T2, and ST Segment.
- 14. Facility to store snapshots during critical events for waveform review at a later stage.

H. Reguatory standard:-

The complete system must comply with International Standards:- The unit should comply with International Standards & should have CE Marking, AAMI ES60601-1, CSA C22.2 #601.1, EN/IEC 60601-1, ISO 80601-2-13 Quality Systems- Medical Devices Certification and US FDA with 510 (k) certified.

I. Communication port

Work station must have communication port like VGA Output RS-232C compatible serial interface USB Port Ethernet

Other facility and Accessories/consumables to include:-

1. AC Power inlet with additional outlets in machine

- 2. Intergrated and secure patient monitor mount
- 3. Side vertical rail
- 4. Adult resuable patient circuit (silicon) with bag and face mask -1 set.
- 5. 5 leadwire ECG with electrocautery filter and trunk cable -1 set
- 6. SPO2 probe adult -1 no
- 7. NIBP hose -1 no.
- 8. Adult cuffs size- XL, L, M, and child and infant and cuffs- 2 sets.
- 9. Sample lines (pack of 10)
- 10. Water traps (pack of 10 nos)
- 11. Skin Temerature Probe and central probe
- 12. 2X IBP cable and Disposable IBP transducer (pack of 5 nos)
- 13. All necessary items for completeness and correctness of the system.

Specification of Portable Patient Monitor.

- Lead mode: 3-lead or 5-lead
- Heart rate: Adult:15-300bpm Pediatric/Neonatal: 15-300bpm
- ECG waveform: 2 channels
- Accuracy: ± 1 bpm or ±1%
- S-T segment detection Measuring rang: 0.2mv~2.0mv
- Alarm: Yes, audible and visual alarm, alarm events review
- High resolution 12.1' color TFT display
- Lightweight, compact and portable
- ECG, APO2, NIBP, RESP, 2-TEMp, PR
- Optional: 2-IBP, ETCO2, And thermal printer
- Built-in rechargeable lithium battery
- ECG waveforms of 7-leads display on the same screen
- 72-hours graphic and tabular trends of all parameters
- 72 alarm events of all parameters recall
- 32 seconds full-disclosure waveform review
- 500NIBP measurement date can be storage and recall
- Date and waveforms color be adjustable
- Arrhythmia analysis and S-T segment analysis
- Suitable for adult, Pediatric and neonatal patient

Standard Configuration:

ECG, NIBP, SpO2, RESP, 2-Temp, PR

Peripheral Nerve Stimulator

Technical specification

- 1. Should have a current range from 0 .1 to 5mA.
- 2. Should have a resolution of 0.01mA
- 3. Should have a digital display for current.
- 4. Should have short stimulus pulse duration of 0.1ms.
- 5. Should have a frequency range from 0.1 to 99 Hz.
- 6. Should be able to monitor single twitch, Train of four, PTC and DBC.
- 7. Should have integrated electrode cable with lead.
- 8. Should be battery operated.
- 9. Should be supplied with 5 sets of insulated needles in varied length.
- 10. Should have safety certificate from a competent authority CE / FDA (US) / STQC CB certificate / STQC S certificate or valid detailed electrical and functional safety test report from ERTL. Copy of the certificate / test report shall be produced along with the technical bid.