ANNEXURE – B

TECHNICAL SPECIFICATIONS

01. BLOOD GAS ANALYZER

01. It should measure Blood Gas (full parameters – ph, pO2, pCO2).
02. In addition it should measure electrolytes like Na+, K+, Cl- and Haematocrit
03. Calculated parameters: TCO2, HCO3, Base Excess A-aDO2, Buffer Base etc.
04. Should display all results in print out.
05. Should have input parameters of patient Temperature, Hemoglobin FIO2, patient ID Etc.
06. Should have a sample temperature control of 37 degree centigrade.
07. It should have inbuilt printer.
08. Analysis time should not be more than 90 seconds.
09. Sample volume should be approximate 100 µ l for all parameters.
10. System should be based on liquid / gas calibration technology.
11. System should not be a cartridge based system i.e. electrodes should not be in the cartridge system.
12. Should work on whole blood and should have syringe and capillary sampling.
13. Should be with numeric keypad, graphic / LCD display, and inbuilt printer.
14. Analyzer with memory of storing patient data/result minimum 250 or more.
15. System should be supplied complete with all standard accessories, electrodes & start up kits. Onboard life of reagents should not be less than one month.
16. Power input: 220 VAC + 10%, 50 Hz and a suitable one hr. back up UPS should be supplied along with analyzer. There should be storage facility of data in case of power failure. Maintenance free electrode.
17. System should be ISI /CE marked or US FDA approved.
18. Any other parts except reagents to be replaced free of cost during warranty period.

02. NEONATAL VENTILATOR

1. Essential components
   - Ventilator
   - Air Compressor
   - Reusable Circuit with online bacterial filter
   - Humidifier
   - Stand for circuit
2. Type of ventilator: Continuous flow, time cycled, pressure control

3. Modes available: CPAP, IMV, SIMV, Assist/Control, PSV, VG, BiPAP

4. Range of set parameters
   - Peak inspiratory pressure: 0-50 cms
   - Positive end expiratory pressure: 0-20 cms
   - Fraction of inspired oxygen: 21-100%
   - Inspiratory time: 0.1- 3 secs
   - Rate: 0-150 bpm
   - Gas flow: 5-15 Lpm
5. Display: Both digital and analog
   - Measured parameters
   - Derived parameters
   - Pressure & flow waveforms and loops
   - Alarm message
   - Calibration
   - Silenced alarm

- Trends and events of last 24 hours

6. Alarms Both audio & visual
7. Humidifier :
   - Temperature control + 2°C
   - Digital display of temperature- range of display 5-80°C
   - Water level indicator
   - Warm up time less than 15 minutes
   - Alarms
   - Heater wire on:
   - Airway temp: Tracking + 2°C from set temp
   - Chamber temp: If chamber temp varies 4°C from set temp for 15 to 20 minutes or alarm immediately if set chamber is exceeded by 10°C
   - Should be compatible with both reusable & disposable chambers and reusable & disposable circuits
8. Power 220-240 V, 50-60 Hz

Uninterrupted power supply for at least half hour
EQUIPMENT SHOULD BE FDA APPROVED.

9. Spares with each ventilator

03. CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

1. Should be light weight, easily portable, reliable and sturdy

2. CPAP generator:
   Option of pressure setting from 3 to 12 cm H2O
   Should have a detachable overflow container
   Should deliver the intended pressure constantly and accurately
   Easy to clean/sterilize
   The gradations (on the sliding rod) should be easily visible from distance of 6 feet.

3. Air Oxygen Blender
   Fi0 2 concentration should be adjustable (21-100%)and accurate

4. Humidifier
   Should automatically regulate the required temperature
   Should be a closed system for filling up water
   Should have ports for heater wire as well as temperature probe
   Should display the chamber temperature and temperature at the patient end.

5. Patient circuits
   Should have the option of using both disposal and reusable circuits
   Disposal circuits should be readily available and reasonably priced.
   Should be able to accommodate a heater wire : heat loss should be minimal along its length.

6. Battery back up
   Should have a battery back up for at least 45-60 min.

7. Safety Features
   Limiting the delivered pressure in the event of an occlusion

8. Device is produced by ISO 9001 certified manufacturer

9. Device is safety certified according CE93/42 FDA 510k or equivalent

Supplied with :-

5 reusable / disposal to be included. Soft, Pliable nasal prongs- in at least 3 sizes (15 each)

04. TRANSCUTANEOUS BILIRUBINOMETER

1. It should give accurate result
2. Instant and safe test
3. LCD display for convenient observation
4. Long battery life
5. Low energy consumption
6. Storage and memory function
7. Browse and delete function
8. Convenient and self calibration

05. PHOTOTHERAPY UNIT DOUBLE SURFACE

1. Phototherapy based on advanced CFL tube/LED technology
2. Minimum 8 nos. of medical grade Blue CFL lamps on source modules. For LED technology the irradiance should cover the entire treatment area
3. Height adjustable mechanism, treatment distance to the range of 25 to 45 cms
4. Wave length of CFL lamps should be in the range of 420 – 470 nm and irradiance level should be higher than normal blue tube lights
5. The unit should provide a minimum of irradiance 10Watts/m2.
6. The irradiance should be measured and reported to the user institution at the time of installation and thereafter during every subsequent warranty/CMC/AMC
7. Visit and all breakdown visits.
8. Lamp source should be continuous tiltable to ±90 degree angle to cover the entire treatment area.
9. System should be height adjustable with built-in non resettable timer
10. Baby bed should be transparent with up / down tiltable facility
11. Should work with input 200 to 240Vac 50 Hz supply.
12. 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. Test report from ETDC. Copy of the certificate / test report shall be produced along with the technical bid
13. The measurement of irradiance should be demonstrated to the technical committee during product demonstration.

06. PAEDIATRIC OTOSCOPE

1. Should be a convenient pocket type otoscope.
2. Should be provided with a halogen light source.

3. Should be able to detach the otoscope head.
4. Should provide no reflections and obstructions.
5. Should provide detachable accessories of various sizes.
6. Should have in built rechargeable battery.
7. Recharge should be possible with direct mains supply

07. **NEBULIZER**

01. Should be compact, light-weight, low noise
02. Should have durable long life compressor. Suitable for heavy duty/institutional (hospital) use, should be able to run uninterruptedly for one hour, Max Press= 2.0-2.5 bars.
03. Should produce particle of size 1-5 micron.
04. Should have piston-type electric aspirator that offer high performance and great durability.
05. Should have protective thermal cut out relay
06. Air delivery rate app. 15 L/min
07. 24 hours continuous work for hospital use.
08. Shall meet IEC-60601-1-2:2001(or Equivalent BIS) General Requirements of safety for Electromagnetic Compatibility or should comply with 89/366/EEC;
09. EMC-directive.
10. The unit shall be capable of being stored continuously in ambient temperature of 0-50˚C and relative humidity of 15-90%
11. The unit shall be capable of operating continuously in ambient temperature of 20-40˚C and relative humidity of 15-90%
12. Power input to be 220-240V AC, 50 Hz fitted with Indian plug.
13. UPS of suitable rating with voltage regulation, spike protection and maintenance free batteries for 60 minutes back up should be provided.
14. Should be FDA,CE, UL or BIS approved product
15. Manufacturer should have ISO certification for quality standards.
16. Comprehensive warranty for 2 years and 5 years CMC after warranty including UPS.
17. User/Technical/Maintenance manuals to be supplied in English
18. List of important spare parts and accessories with their part number and costing.
19. List of Equipments available for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in Service/technical manual.
20. Logbook with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.

08. Pulse oxymeter Specification

1. Display: digital LED display
2. Parameters –SpO2,PulseRate,Pulse Bar,Plethysmogram
3. Should be in both analog & digital format
4. Should need the light indications of battery charging, Low battery.
5. Battery: Inbuilt rechargeable battery with battery backup of 24 hours.
6. Alarm : both visual & audiable ,error code
7. storage: patient IDs: 100 patients
   Data records : upto 70 hrs

09. Syringe Pump:

- Should be easy to use and nurse friendly.
- Should automatic syringe size and model detection
- Should have large format LCD/TFT display.

- Should have a minimum flow rate range from 0.1 – 1200 ml/hr for 50ml syringe, 100 ml/hr for 20ml syringe and 0.1 – 60 ml/hr for 10ml syringe.
- Syringe range from 20-50/60 ml.
- Should have a flow rate accuracy of ±2%

- Should have a bolus rate up to 1000ml/hr for 50 ml syringe.
- Should have automatic and manual bolus.
- Should have at least 3 levels of programmable occlusion pressure.
- Should have automatic bolus reduction system to avoid accidental bolus delivery afterocclusion incident.
- Should have a rechargeable battery with back up time of minimum 3 hours.
- Pump must triger following alarms with visual indication:-
- Occlusion Pressure Alarm
- KVO or 3 min pre- alarm
- Syringe empty and volume infused alarm
- Internal malfunction and Battery Charge Low Alarm
- Syringe disengaged and incorrectly placed alarm
- Alarm loudness control.
- No mains
- Line disconnected (rapid pressure drop).
- Should work with input 200 to 240Vac 50 Hz supply.
- Should have safety certificate from a competent authority CE / FDA (US) / STQC CBcertificate / 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

10. Infusion Pump specification:

1. Should be operated on drip rate Peristaltic finger pump method.

2. Should compatible with most of the IV set (macro/micro drip sets).

3. Should have the following flow rates.

4. IV Set ml/hr drops/min

- 15 drops/ml 3~450ml/hr 1~100drops/min
- 20drops/ml 3~450ml/hr 1~100drops/min
- 60drops/ml 1~100ml/hr 1~100drops/min

5. Should have a flow rate accuracy of ±10% and drip rate accuracy of ±2%.

6. Should have a volume infused display from 0 to 999.9ml.

7. Should have a purge and KVO facility.

9. Should have an audible and visual alarm for occlusion pressure, air alarm, door open, empty, low battery.

10. Should have a LCD display with backlight and graphical display of infusion Should have a minimum 2hr battery back up at highest delivery rate.

11. Should work with input 200 to 240Vac 50 Hz supply.

12. Should have safety certificate from a competent authority CE/FDA(US)/STQC CBcertificate / STQC S certificate or valid detailed electrical and functional safety test reportfrom ERTL. Copy of the certificate / test report shall be produced along with the technical bids

11. Reusable Fiber Optic MacIntosh Laryngoscope Blades

- fiber optic core to provide user with bright white illumination for tracheal intubation
- the xenon handle to distal tip of blade
- Fiber bundle is sealed within the blade, no crevices to trap dirt or body fluids, allows blade to be easily decontaminated and cleaned, without the need for any disassembly
- For use with green striped laryngoscope handle
- Reusable
- Removable
- repolishable light pipes
- With 3 blades
- Blades should be in stainless steel

12. SPECIFICATIONS FOR ASEPTIC SCRUB STATION

- Scrub station should have Two Water posts and one soap dispenser for use in O.T.
- Basin should be made up of polyester/steel and should be deep to avoid splashes.
- It should incorporate a bacteriological water treatment system using ultra violet radiations in the band of 2537^0A.
- The water and soap supply System should be activated by means of proximity detectors with adjustable detection field for soap & water.
- It should have an additional pipe asepticization system to counter the problem of bacterial residue caused by water stagnation by periodically injecting disinfectant into the water circulating system
- It should have 1 micron prefiltration for removal of physical impurities.
- Each water tap should be fitted with (0.2 μ) end filtration cartridge.
- It should have an elapsed time counter to monitor the operating time of the U.V. Source, The normal useful life time of U.V. Source should be atleast 3000 hours.
- It should have an electronic descaler and thermostatic mixer.
- Upper & Lower part of basin should be tilt-able/ open-able for easy maintenance.
- The Firm should provide Free Installation of the System at site.
- Should meet international quality directives such as CE, ISO 9001 & ISO 14001.

13. FLEXIBLE INTUBATION VIDEO ENDOSCOPE

- Set 5.5 * 65,
- CMOS Technology
- With Suction valve
- For use with C-MAC Monitor 8402 ZX and C-HUB 20290101 Deflection up/down:140 degree /140 degree of view: 0 degree angle of view 120 degree working length 65cm total length 93 cm working channel inner diameter 2.3 mm distal tip outer diameter 5.5 mm consisting of: 11301 BMX Flexible intubation video endoscope 5.5*65 27677 FV Case 11025 E Pressure compensation Cap 13242 XL Leakage tester 11301 CFX Tube Holder 27651 B Cleaning Brush 11301 CD1 irrigation adaptor 11301 CE1 suction valve 10309 E Bronchoscope insertion Tube,
- size 4 29100 plug,

- black package of 10 8401 YZ protection cap for use with C MAC Monitor 8402 ZX and C-HUB 20290101

14. Ultrasonic Cleaner specification

- 23 Gal. tank Heated Tank.
- Adjustable LED digitally controlled thermostat.
- Stainless steel tank and housing construction.3
- Adjustable LED digital countdown timer.
- Thermostat range 32 degree- 176 degree F
- Timer range 0-60 minutes
- Should need steel lid ,steel mesh basket ,power cord and manual

15. SPECIFICATIONS FOR STERILE STORAGE CABINET

Sterile Storage Cabinet should have the following Essential Specifications

- A unit suitable for storage of Sterile Products
- Should be suitable for storage of sterile instrument and product used in operating theatre.
- It should have glazed door
- It should have four ultra violet generators emitting radiations in germicidal band of 2537 A for Sterilization.
- It should be equipped with tangential flow turbine ventilation system to create vertical and horizontal air circulation over Ultra Violet Sources.
- The sterilization cycle should start automatically, each time the doors are opened and it should have a timer switch to select the sterilization time from 1-6 hrs.
- Should have a safety switch to automatically turn off the system when door of cabinet are opened.
- It should have an elapsed time counter to monitor the operating time of the UV Sources.
- It should be usable in the presence of personnel and equipped with an external indicator lamp to show the functioning of cabinet
- Power Consumption of UV Sources – 30 W.
- Should meet international quality directives such as CE, ISO 9001 & ISO 14001.

16. CAUTERY MACHINE

- Should be double padel footswitch with cable for Monopolar
- Should be surgical handle with cable
- Needle electrodes set of 5
- TUR adopter for connecting / resectoscope
- SS Patient Plate with cable
- Unit cover
- Bopolar Forceps with Cord and Jack
- Pencil switch with cord and jact

17. SPECIFICATION OF MOBILE OT LIGHT

- It should be mobile LED O.T. Light.
- It should have ergonomic handle for better positioning.
- There should not be any external paint on the Light Head.
- Light Head should be made of Polycarbonate.
- O.T. Light supplied with suitable driver.
- The Light should be easy to clean & disinfection.
- Working distance should be 70 to 150 cm.
- Dome Dia. Should not be more than 25 cm.
- It should have white light.
- The Light Intensity should be more than 50,000 Lux.
- It should have color temperature of 4300 K.
- Excellent color rendering.
- No UV or Infrared output.
- Exceptional longevity LED life of 50,000 hrs.
- Dome and No. of LEDs should be 24.
- O.T. Light should have four good quality Castors.
- Power consumption should be not more than 24 w
- CE & ISO certified.

18. Technical Specification of Boyle's apparatus

Gas supply: O2,N2O:Air 0.28-0.6Mpa
Flowmeters: O2: 0-1L/min; 1-10L/min; N2O: 0-1L/min; 1-10L/min
Gas system: O2 deficiency alarm; Hypoxic guard system ; O2 flush: 35-75L/min
Working mode: Closed, Semi-closed, Semi-open
Driven mode: Pneumatically driven and electronically controlled
Operating mode: Man. / Vent.
Safety valve: ≤8kpa
Ventilator Specification
Patient type: Adult,pediatric
Ventilation modes: IPPV, Manual
Tidal volume: 0-1500ml
Ventilation frequency: 6-60bpm
I:E ratio: 2:1-1:4
Ppeep: 0-20 cmH2O
High pressure: 21-60cmH2O
Low pressure: 0-20cmH2O
Pressure: Paw
Volumes: Vt
Breath rate
Alarm: Pressure: Paw high/low limit, Low O2 supply pressure ,Power failure
Alarm silence: ≤120s
Vaporizer
Support 1 vaporizer (Selectatec compatible)
Agent type: Halothane, Enflurane, Isoflurane , Sevoflurane available.

19. Specifications for Low temperature H2O2 Plasma Sterilizer

- Should provide simple and fast sterilization of medical devices at low temperature using Hydrogen Peroxide Plasma sterilization technology

- Should be suitable for sterilization of metal & non metal medical devices like flexible endoscopes, rigid endoscopes, metal & plastic lumen items heat & moisture sensitive instruments etc.

- Should be able to sterilize lumens of internal diameter 1mm or above steel lumens up to 50 cm length and plastic lumens upto 200cm length without use of any additional accessory/consumable like boosters/adapters

- Usable volume of chamber should be at least 125 liters.

- The chamber should be rectangular shaped enabling max. usage of chamber volume.

- Sterilization temperature should not be more than 50 deg C.

- Should have selectable pre programmed sterilization cycles for different types/ quantity of load with max. sterilization time not more than 50 min.

- Should use minimum quantity of sterilant to ensure safety of instruments

- Should detect excess moisture thus eliminating chances of contamination due to residual bio burden

- Should have touch screen LCD display for controlling & monitoring the sterilization process.
- Should have storage facility for sterilization cycle records for recall & printing.
- Should have inbuilt thermal printer for printing cycle details.

- Should be easy to install without any civil / plumbing work and should be mobile on wheels for easy movements.

- Should conform to international safety & quality standards ISO13485, FDA/CE

- Should be supplied with following
  * Instrument Tray / appliance box - 02 nos
  * Sealing Machine - 01 No.
  * Biological Indicator Incubator- 01 No.

- Should be supplied with following consumables sufficient for atleast 100 sterilization cycles as follows
  * Sterilant bottle / Cassette for 100 cycles.
  * Chemical Indicator Strips- 250 Nos.
  * Chemical Indicator Tape (40m)- 02 Rolls
  * Packing Paper for wrapping instruments (with chemical indicator) different sizes.
    75mm x 80m 1 roll
    100mm x 80m 1 roll
    150mm x 80m 1 roll
    200mm x 80m 1 roll
    300mm x 80m 1 roll
  * Biological Indicator- 30 Pcs.
  * Wrap Cloth (1.2m x 1.2m) 150 Pcs
  * Printer paper 15 rolls