

<b>1. BAG MASK DEVICE BAG - SILICON (AMBU/SELF INFLATING BAG)</b>
Material
i. Bag and mask Silicone rubber
ii. Valves and membranes-Silicone rubber
iii. Reservoir - Poly Vinyl Chloride
Ventilator bag volume - 250ml-1No, 500ml-1No,750 ml-1No & 1000ml-1No
Reservoir bag volume - 100ml, 500ml, 1300ml ,1600ml
Deliverable volume -200ml, 450ml,650ml,950ml;
Mask number 3 to be supplied for each bag
Relief valve can be present to prevent back end flow of CO2 in to the bag
i. The spring should be of stainless steel
Oxygen connector tubing
All enclosed in a bag
Mask number- 00, 0 &1, 2&3,4&5 to be supplied
Provision for PEEP valve connection
25-30 times minimum autoclave cycle with test reports.
Necessary for quality durability per NHM guidelines
USFDA or CE certified.

<b>2. Bag mask Device Bag Child – Silicon</b>
<b>Child bag:</b>
Material
o Bag and mask - Silicone rubber
o Valves and membranes - Silicone rubber
o Connectors and housing - Polysulfone
o Reservoir - Poly Vinyl Chloride
Ventilator bag volume - 500 ml
Reservoir bag volume - 600 ml
Deliverable volume - 320 ml
Mask 0A-1 number and 0B-1 number to be supplied
Relief valve should be present
Spring should be of stainless steel
Oxygen connector tubing
Above 4 to be enclosed in a bag

<b>3 &amp; 4. Oxygen Regulator with humidifier bottle for cylinder</b>
Regulator should construct of brass and finished in chrome.
Regulator should be with flow meter.
Regulator should have Cylinder pressure indicator.

Flow rate should be 1-15 L/Min.
Metal filter between gas source and seat.
Should provide with spanner for opening of cylinder.
Manufacture should have ISO 9001/13485 certificate.
2 years warranty for any Manufacturing defects.
Should be CE/BIS/US FDA approved.

### **5. Oxygen Headbox**

- Round shape or have no joins or corners, and easy to clean
- 3 x size small, approx: height 22 cm, diam 25 cm
- 3 x size medium, approx: height 18 cm, diam 20 cm
- Made of autoclavable polycarbonate
- Trauma free silicone neck
- Fitted with oxygen connector
- An adjustable porthole on top for feeding and suctioning

### **6. Infantometer**

- Portable infant length-height measuring system
- Measures laying length of neonates and babies
- No need for calibration as all parts have prefixed position
- Reads in centimetres
- Minimum graduation: 1 mm
- Long-lasting hard-wearing ruler/graduation is fully integrated with device
- Measuring slide/wedge glides smoothly and close via ruler, avoiding reading parallax
- Measuring slide/wedge wobbles max 2 mm, over full length
- No sharp edges or corners
- Low stable board, width: 30 cm
- Length, measurement range, approx: 100 cm
- Head/footplate, board and slide/wedge made of quality laminated wood or plastic
- Wood parts should be treated and finished/protected with varnish to prevent chipping of edges and allow easy cleaning
- All connections should be screwed/nailed plus glued

### **C PAP Machine**

- Nasal CPAP apparatus, which must be pneumatically powered and electronically controlled.
- The CPAP apparatus offered must have the following independent controls and operational characteristics:
  - o Integrated air / O<sub>2</sub> blender must provide an O<sub>2</sub> concentration of 21% to 100%.
  - o Air / O<sub>2</sub> flow must provide 0 to 15 LPM.
- The CPAP apparatus offered must be capable of monitoring the following parameters:
  - o Mean airway pressure.
- The CPAP apparatus offered must have audible and visible alarm parameters for the following:
  - o Low mean airway pressure.
  - o High mean airway pressure.
- The CPAP apparatus offered must be supplied with silicone nasal prongs / masks in three sizes as well as with three neonatal circuits.
- The CPAP apparatus offered must come complete with colour coded air and O<sub>2</sub> hoses 3 metres long and fitted with Heyer type keys.
- The CPAP apparatus offered must include and be mounted on a height adjustable, stable, mobile stand manufactured from corrosion proof material with at least two of the casters fitted with brakes.
- The CPAP apparatus offered must include and be fitted with a humidifier, which includes all the necessary accessories, equivalent to the Fisher and Paykel MR 850.

### **Mechanical Ventilator**

- The following components must be included
  - o Ventilator
  - o Trolley
  - o All essential accessories.
  - o Starter pack of consumables.
- The material used for the construction of both ventilator and trolley must be corrosion resistant and suitable for use in an intensive care environment.
- Ventilator must be well secured on to the trolley.
- Castors must be at least 100mm in diameter with a brake on at least two castors.
- The trolley must be stable and suitable for moving the unit within the institution.
- Patient setting must be user friendly and must include the following:
  - a. Frequency: minimum range of 0 – 100bpm.
  - b. Inspiratory time: minimum range of 0.1s – 3.0s. 8
  - c. Inspiratory Pressure: minimum range of 0 – 60cm H<sub>2</sub>O.

- d. PEEP: minimum range of 0 – 20cm H<sub>2</sub>O.
- e. Flow: minimum range of 0 – 30L/min.
- f. FiO<sub>2</sub>: 21% - 100%.
- g. Trigger Sensitivity: Flow or pressure trigger.
- h. Any additional settings available on the unit offered must be detailed by the tenderer.
  - The unit must operate off an Input voltage of 220Volt a.c. 50hz single phase allowing a variation of plus and minus 10%. The unit offered must be fused in both the live and neutral.
  - o Battery back up must be provided to operate the ventilator for a period of at least one hour
  - Pneumatic gas sources – oxygen and medical air.
  - Unit must be supplied with hoses of at least 3 metres that are colour coded to the requirements of the South African Bureau of Standards and must be terminated with the specific gas SABS Number: 1409 probe.
  - Essential Modes and features must be included as follows:
    - o Time cycled pressure limited continuous flow. SIMV/AC.
    - o Pressure support.
    - o Flow measurement: A proximal flow sensor of the hot wire anemometry type must be used and supplied at no extra cost.
    - o Continuous positive airway pressure.
    - o Manual breath.
    - Monitoring must be as follows:
      - o Peak Airway Pressure
      - o Mean Airway Pressure
      - o PEEP
      - o Expiratory / Inspiratory Tidal Volume
      - o Minute Volume
      - o Leakage in %
      - o Total frequency
      - o TI: TE o FiO<sub>2</sub>
      - o Inspiratory / Expiratory Flow
    - Display of the following waveforms must be included
      - o Pressure, flow and volume waveforms
      - o Loops
    - Additional features must include
      - o Control settings locking mechanism
      - o Nebulizer
      - o Internal blending system
      - o Diagnostic Self-test after power switch on
      - o Self - calibrating oxygen monitoring

- The following ALARMS must be provided
  - o Audible and visible with manual override for audible alarm
  - o Alarm silence must be for a maximum period of 60 seconds
  - o Audible alarm volume control must be provided
  - o High breath rate
  - o Low battery warning o Loss of Power supply 9
  - o Apnoea o Fail to cycle
  - o High and low airway pressure alarm
  - o Incompatible settings o Low PEEP
  - o Loss of gas supply o High and low FiO<sub>2</sub>
  - o Minute volume alarm

The unit must be supplied with the necessary accessories in order that it can be put into use immediately.

- One complete Neonatal circuit must be supplied at no extra cost.
- Dual servo controlled humidifier (water bath type) similar or equivalent to Fisher & Paykel-MR850) must be supplied, complete, at no extra cost so that the unit can be put into operation immediately
- Supply details of the cleaning protocols between patients as per manufacturer's recommendation.
- Specify the details and cost of any consumables that may be required. State the price in the schedule at the end of this specification.

### **TRANSCUTANEOUS BILIRUBINOMETER**

- Measure the transcutaneous bilirubin level of the newborn with measurements up to a minimum of 40 mmol/l
- Handheld and lightweight in order to facilitate measurements to be carried out within an Infant incubator.
- Operates off a rechargeable battery / battery pack.
- The measurement probe must be built onto the unit and the measurement must be by means of a simple technique e.g
- The measured value is clearly displayed under all lighting conditions on a three digit numerical display and provides measurement values equivalent to laboratory values for serum bilirubin levels.
- The unit offered must provide an accuracy of typically +/- 5% at a reading of 0 to 529 mmol/l and an accuracy of +/- 10% at a reading of 530 – 684 mmol/l

- The unit must be provided with a known test measurement value to confirm the calibration accuracy.
- All essential accessories in order to put the unit into operation immediately must be supplied.
- A protective carry case must be supplied

### **ELECTRONIC BABY SCALE (Measuring Tape)**

- Measuring range 0 to 10 kg
- Minimum graduation: 5 g
- On switch and auto-off
- Auto-calibration with each switch-on
- Large LED display readable in low light working situations, display cover durable plastic
- Display in kg
- Reading time max 5 seconds
- Zero weighing adjustment
- Freeze reading feature
- Smooth surface, finishing allows for easy cleaning and disinfection.
- All vital parts made of rust proof materials
- Horizontal levelling with height adjustable feet
- Splash proof and shock resistant light-weight body
- Power supply connects to wall sockets and internal rechargeable battery

### **Stadimeter**

1. Measuring range in Cm 20-205cm
2. Measuring range in inch: 8-81"
3. Graduation {Measuring Rod} : 1 mm / 1/8 inch
4. Measure (WxHxD): 337x 2165 x 590mm, 13,3 x 85,2 x 23,2 inch
5. Net weight : 2,4 kg, 5,3 lbs
6. Functions: Mobile measuring and weighing

### **Bone marrow aspiration needle (sternal/ilic)**

- Stainless steel body with adjustable depth guard and twist off cap.
- Superior needle quality (Surgical grade steel).
- Sharp cutting edge.

- Available in complete/partial stainless steel body.
- Disposable/Reusable (after sterilization or autoclaving/ET)
- USFDA/ECE and/or ISO certified.
- Sample needles to be submitted to the department, to check the performance prior to making final decision

### **Mechanical Ventilator – neonatal & Child**

1. Premature Neonates patients.
2. Should have facility for Invasive and Non-Invasive ventilation
3. Microprocessor controlled system with individual selection of various ventilation parameters & PEEP.
4. 12" inch size full colour, total touch screen operation for big display to access from long distance.
5. Machine should be Compressed air (medical oil free air compressor of the same brand as ventilator).
6. Should have battery backup at least 30min.
7. It should allow the user to deliver conventional ventilation as well as HFOV.
8. Should have the following modes of ventilation:
  - Assist/ Control
  - Volume control
  - Pressure control
  - Pressure support
  - SIMV with pressure support (Pressure and volume control)
  - PEEP
  - Inverse ratio Ventilation
  - Non-invasive ventilation-BIPAP, CPAP and Nasal C PAP
  - Apnea ventilation, user selectable, volume & pressure control
  - HFOV.
9. Should have facility to measure and display of the following parameters:
  - Airway Pressure (Peak & Mean)

- Tidal volume (Inspired & Expired)
- Minute volume (Inspired & Expired)
- Respiratory mechanics
- Spontaneous Minute Volume
- Total Frequency
- FiO<sub>2</sub>
- PEEP
- Plateau Pressure
- Use selector Alarms for all measured & monitored parameters
- Occlusion Pressure
- Pressure Flow & Volume curves

10. Automatic compliance and leakage compensation for circuit.

11. Conventional ventilation & HFO Ventilation Mode Parameters:

- BPM: 4 to 150
- Inspiratory Time: 0.1 to 3.0 sec
- CPAP Pressure: 0 to 35 mbar
- Inspiratory Pressure: 0 to 60 mbar
- FIO<sub>2</sub>: 21% to 100%
- Tidal Volume 2-300 ml with Volume Guarantee
- HFO Mode Parameters:
- HFO Frequency should be wide range with 3 to 20 Hz i. MAP-0-45M Bar
- I: E Ratio: 1:10 to 4:1, MAP-5-40m CmH<sub>2</sub>O, Delta P- 0-100 CmH<sub>2</sub>O, RR-4 to 150 bpm, Ti-0.1-5 sec, P-0-60m Bar.

12. Alarm No change a. Alarm :-

- Adjustable Alarm. - Low/high minute volume, low/high pressure, low/high tidal volume, low/high rate, apnea time, low/high oxygen
- Special alarm - O<sub>2</sub> cell Failure, flow sensor, battery, power supply, gas supply, oxygen concentration,

13. Should have inbuilt Nebulization assembly facility.

14. Ventilator, Compressor & Humidifier should be Same Trolley/cart mounting for easy transportation.

15. Humidifier

- Servo controlled heated Respiratory Humidifier. No change
- Display Should be of LED /LCD.



- Temperature control settings & Temperature range: 28-40 deg.
- Temperature should be adjustable.
- Jar should be autoclavable

16. Standard Accessories/spare & Consumable.

- Silicon breathing circuit circuit (Neonatal reusable) - 5 complete set.
- Nebulization assembly compatible circuit 5 complete set.
- Humidifier - 1 No.
- Hose for O2 connection with connector - 5 mts.
- Hose for compressed air with connector - 5 mts.
- Test lung - 1 No.
- g.HME filter – 10 no
- Inbuilt / integrated nebulizer-1 NO
- All sensors and other non-consumable items (other than reusable silicon ventilator circuits) should be free of cost during warranty and CMC.

17. Ventilator, Humidifier & Compressor Power Supply input to be 200- 240VAC, 50 Hz fitted with Indian conditions plug .

18. Suitable online UPS with commensurate capacity for all ventilators including compressor & Humidifier with maintenance free batteries for minimum Two hours back-up should be supplied.

Ventilator, Humidifier & Compressor Should be US FDA (510 K) approved Model should be offered. No change

1) Reusable consumables (other than reusable silicon ventilator circuits) should last during the warranty period. No change

2) Ventilator & Humidifier any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier. No change

3) The life expectancy of the reusable consumable is expected to be of at least one year from the date of installation of the same. The reusable consumables will be procured at the prices accepted as per the contract.

### **CPAP Machine**

1. Device should be able to deliver CPAP of 1 to 10 cmH<sub>2</sub>O increments of 1 cm, using an underwater bubble system.

2. 100% (+/- 2%) with an adjustable flow in the range of 0-15 L/min (+/- 0.5 L/min); No change
3. Should have a heated wire servo-controlled humidifier with display temp near patient end of the circuit; to be supplied with 2 reusable infant water chamber. No change
4. Should be supplied with 2 reusable heated wire silicone tubing circuit for infant/New born. No change
5. Should be able to deliver CPAP using available patient interfaces nasal prongs/nasopharyngeal prongs; No change
6. For devices based on underwater bubble systems the water chamber should be reusable; to be supplied with 2 reusable water chamber. No change
7. Should be provided pressure release valve at 15cm H<sub>2</sub>O to 17 cm H<sub>2</sub>O; No change
8. User's interface: No change
9. For a flow driving system a pressure display is required. No change
10. Audio visual alarm for low pressure, high pressure, power failure, low O<sub>2</sub>. No change
11. Physical Characteristics No change
12. Weight (lbs, Kg) : < 8 Kgs No change
13. Noise (in dBA) : 65dB No change
14. Heat dissipation : Yes No change
15. Mobility, portability : Portable No change
16. Energy Source (electricity, UPS, Solar, gas, water, CO<sub>2</sub> ...) No change
17. Power requirement : 220VAC, 50 Hz No change
18. Battery Operated : with at-least 6 hours battery backup No change
19. Tolerance (to variations, shutdowns) : ± 10% of input No change
20. Protection : OVP, earth leakage protection No change
21. Power consumption : < 140 Watt No change
22. Other energy supplies: electric/battery driven. No change

23. Accessories, Spare Parts, Consumables No change
24. Each device should be provided with 30 nasal prongs (At least three sizes suitable for neonates weighing < 1000grms, 1000-1500grms &> 1500 grams). No change
25. Air and O2 hose of 3m length each along with the appropriate socket; No change
26. Environmental and Departmental Considerations No change
27. Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances. No change
28. Only US FDA ( 510 K) Approved model should be offered.

### **Transcutaneous Bilirubinometer**

1. Measuring method should measure the optical density difference at two wavelengths to determine the yellowness of the subcutaneous tissue.
2. The instrument should be suitable for non-invasive bilirubin measurement of neonates with gestational age 27 – 42 weeks and 1 month post-natal age; body weight 900 grams to 4000 grams.
3. Measurement range: 0.0mg/dL to 20mg/dL or 0  $\mu$ mol/L to 340 $\mu$ mol/L
4. Error of estimate (SEE):  $\pm$  1.5mg/dL or  $\pm$  25.5 $\mu$ mol/L
5. It should measure readings at sternum and forehead.
6. Should have alarms when measurements are greater than 20mg/dl or 340 $\mu$ mol/L
7. Can be used in all skin colors, >35 weeks gestational age, prephototherapy.
8. Light source should be Pulse xenon arc lamp
9. Light source should have life of more than 10000 measurements.
10. Light source checker should be built in to the charger base.
11. Should have detectors with Silicon photodiodes.
12. Should have Ni-MH battery as power source.
13. Protection type and level Internally-powered instrument, BF type
14. It should measure at least 400 single measurements when fully charged.

15. It should have operating temperature range from 100 C to 400 C

16. It should be light weight; less than 250 g.

17. It should be supplied with: Charger unit with a checker, AC adapter, Carrying case and wrist strap, Power cable adapter set.

### **Infantometer**

1. Portable baby/infant length-height measuring system
  2. Measures laying length of neonates and babies
  3. No need for calibration as all parts have a prefixed position
  4. Reads in centimeters and inches
  5. Minimum graduation: 1 mm
  6. Long-lasting hard-wearing ruler/graduation is fully integrated with the device
  7. Measuring slide/wedge glides smoothly and closes via ruler, avoiding reading parallax
  8. Measuring slide/wedge wobbles max 2 mm, over the full length
  9. No sharp edges or corners
  10. Low stable board, width: ca 30 cm
  11. Length, measurement range, approx: 100 cm
  12. Head/footplate, board, and slide/wedge made of quality laminated wood or plastic
  13. Wood parts should be treated and finished/protected with varnish to prevent chipping of edges and allow easy cleaning; all connections should be screwed/nailed plus glued
- Graduation {Measuring Rod} : 1 mm / 1/ 16 inch

Measure (WxHxD): 1110x115 x 333 mm, 43,7 x 4,5 x 13,1 inch

### **Stadiometer**

specifications:

- (1) A vertical board with an attached metric rule.
- (2) An easily moveable horizontal headpiece that can be brought into contact with the superior part of the head.
- (3) A wide and stable platform or firm uncarpeted floor as the base.
- (4) Easily read, stable tape or digital readout in 0.1 cm (1 mm) increments.
- (5) The stadiometer should have a height range of at least 70 cm to 205 cm so that it can be used with the majority of children and adolescents.
- (6) The stadiometer should be foldable, portable and should have vertical columns with detachable pieces.
- (7) The stadiometer should have stable platform and material of it should be hard, unbreakable, and light weighted.
- (8) The downtime of the equipment must not be more than 10 days annually and system must be made functional within 48 hours of breakdown and in case of such incident the period of breakdown will not be counted while calculating warranty or CMC period. If the downtime during any year is more than 10 days a penalty at the rate of 0.1% of the cost of the equipment will be levied for each extra day of downtime.
- (9) Operation manual with user demonstration video CD

### **Oxygen regulator with Humidifier**

- with pressure regulator, with humidifier, variable-area, plug-in type, Flow tube and humidifier body use high-strength polycarbonate plastic
- Back pressure compensated and calibrated at 50 psi
- 100% tested to ensure accuracy
- Installed can be wall or rail mounted
- OUTPUT-Max.: 15 l/min (4 us gal/min) Min.: 0 l/min (0 us gal/min)
- Should be ISO approved

### **Ambu bag and Face mask - Neonate , infant & Pediatric**

- Ambu bag must be autoclavable
- Should be adaptable to all type of face masks.

- Ambu bag should be self inflatable and should have pop up valve, attachment for oxygen tube & oxygen reservoir
- Bag should be made up of Silicon, latex free double layered rubber and should retain sensitivity and should be resistant to rough use.
- Inlet end of the bag should have separate port for Oxygen supplement.
- Outer port should be such that re-breathing valve or non return valve can be attached.
- Should be supplied with Oxygen reservoir bag and should deliver tidal volumes of 250/500/750 and 1000 mL.

### **Oxygen head-box (of each size)**

1. Should have Aerodynamic design to allow even flow of oxygen to baby and Joint free to allow optimal cleansing and disinfection.
2. Should have soft silicone flap at opening to prevent trauma to the baby.
3. Should have fully transparent design for clear view of the baby.
4. Made of medical grade material with minimal breakage /damage caused by frequent handling.
5. sizes i.e. Neonatal & Infant
6. round shape, unbreakable, transparent made up of auto clavable polycarbonate material
7. Easy to clean with trauma free auto clavable soft neck adjustment silicon flap bilateral oxygen outlet nozzle to prevent direct flow of cold oxygen on patient's head  
Zero projection parts makes it easy for cleaning & disinfection

### **Shakir's tape**

Technical Specifications:

- MUAC measuring tape is suitable for measuring child's Middle Upper Arm Circumference (MUAC) with range up to 26.5 cm.
- Graduated with 1 mm precision with thicker line at 21.0 cm.
- Accuracy:  $\pm 1$  mm of the maximum measurement (26.5 cm)

Front side:

- Colour-coded as follows:
- Red (Pantone code 1795 C): from 0 to 11.5 cm,
- Yellow (Pantone code 107 C) from 11.5 to 12.5 cm,
- Green (Pantone code 369 C) from 12.5 to 26.5 cm.

### **Bone marrow needle**

#### **Bone marrow aspiration needle**

- Stainless steel body with adjustable depth guard and twist off cap.
- Superior needle quality (Surgical grade steel).
- Sharp cutting edge.
- Available in complete/partial stainless steel body.
- Disposable/Reusable (aftersterilization or autoclaving/ET)
- USFDA/ECE and/or ISO certified.
- Sample needles to be submitted to the department,

#### **Bone marrow biopsy needle**

- Should have lightweight handle with built-in comfort knob.
- Should have bevel tip for easy coring of bone.
- Should have bevel cannula tip.
- Should have tapered distal cannula for easy recovery of sample.
- Should be US FDA Approved

### **Measuring Tape (Steel Tape Roll)**

- Minimum 5 M Steel Tape Roll

### **Lumbar Puncture (L.P.) Needles**

Specification:

#### **Pleural aspiration needle**

**Specification:**

**Vim-Silverman liver biopsy needle**

**Specification:**

**True Cut Renal biopsy needle**