OXYGEN CONCENTRATOR – HOME BASED

(PH NO.918105)

1. Should have BIS/Competent CE/US FDA certification and copy of certificate should be enclosed with the offer.
2. Oxygen concentrator should have provision of extraction of oxygen from ambient air.
3. Oxygen concentration measured at the flow meter by oxygen sensing device (OSD)
4. Sound level should be <55 dBA
5. Oxygen purity should be 90% or higher
6. Oxygen output 0.5-5 litres/mt or higher
7. Oxygen tube of minimum 2 M length must be provided.
8. Provision of in built nebulizer
9. Unit should function with 200-240Vac, 50/60 Hz input power supply.
10. Operating temperature range 12^0 C + 32^0 C or wider
11. Operating humidity 75% or higher
12. Provision of safety alarms including low oxygen concentration, power failure, compressor failure & pressure cycle failure.
13. The equipment shall be supplied with the following:
    - i) One additional set of tubing with nasal cannula
    - ii) One additional set of internal and external filters (bacterial)
    - iii) One additional set of fuses
    - iv) User manual and technical manual

N 95 DIPSOABLE MASK WITHOUT EXPIRATORY VALVE

(PH NO.526024)

- Shape that will not collapse easily
- High filtration efficiency
- Good Breathability
- Quality complaint with standards for medical N95 respiratory (a) NIOSH N95, EN 149 FFP2, or equivalent
- Fluid resistance: minimum 80 mmHg pressure based on ASTMF 1862, ISO 22609 or equivalent
- Quality compliant with standards for particulate respirator that can be worn with Full face shield

PERSONAL PROTECTIVE EQUIPMENT KIT-I (PPE KIT-I)

(PH NO.526095)

Detailed list of components and their specifications are –

1.1 **GLOVES**

- Nitrile
- Non-sterile
- Powder free
- Outer gloves preferably reach mid-forearm (minimum 280 mm total length)
- Different sizes (6.5 & 7)
- Quality compliant with the below standards, or equivalent.
  (a) EU standard directive 93/42/EEC Class I, EN 455
  (b) EU standard directive 89/686/EEC Category III, EN 374
  (c) ANSI/SEA 105-2011
  (d) ASTM D6319-10

1.2 Coverall (medium and large)

- Impermeable to blood and body fluids
- Single use
- Avoid culturally unacceptable colors e.g. black
- Light colors are preferable to better detect possible contamination
- Thumb/finger loops to anchor sleeves in place
- Quality complaint with following standard
  a. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

1.3 **N-95 Masks without expiratory valve**

- Shape that will not collapse easily
- High filtration efficiency
- Good breathability
- High filtration efficiency
- Quality compliant with standards for medical N95 respirator:

a. NIOSH N95, EN 149 FFP2, or equivalent
- Fluid resistance : minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent
- Quality compliant with standards for particulate respirator that can be worn with full face shield

1.4 **Shoe Covers**
- Made up of the same fabric as of coverall
- Should cover the entire shoe and reach above ankles

1.5 **Face Shield**
- Made of clear plastic and provides good visibility to both the wearer and the patient
- Adjustable band to attach firmly around the head and fit snggly against the forehead
- Fog resistant (preferable)
- Completely covers the sides and length of the face
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality complaint with the below standards, or equivalent:
  a. EU standard directive 86/686/EEC, EN 166/2002
  b. ANSI/SEA Z87.1-2010

All items to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards

HIGH FLOW NASAL OXYGEN MACHINE WITH CANNULA

(PH NO.901065)

1. It should have US FDA/CE/BIS certification and a copy of the certificate should be enclosed with the offer.
2. It should be compliant for use on patients in ICU, Emergency wards and home oxygen therapy.
3. It should be single system for treating infants, paediatric and adult patients.
4. Should have provision of inbuilt flow generator capable of delivering oxygen flows in range of 2-25 litres or wider in paediatric mode and 10-60 litres or wider in adult mode.
5. Should have provision of inbuilt Air/O2 blending and Fio2 monitoring, with facility to deliver oxygen concentration (Fio2) in range of 21-100% or wider.
6. Should have provision of inbuilt Air source without need for external compressor.
7. Should have provision of integrated heated humidifier.
8. Provision of colour monitor to display humidity setting, flow, Fio2, faults, etc.
9. Provision of Visual and audible alarms for tube disconnect leaks, tube blockages, water out, hardware fault etc. and audible alarm in case of power failure.
10. Provision of disinfection mode with heated disinfection tube for sterilization of the device after patients use and should be supplied with heated wire, patient breathing tube and nasal cannual of different sizes.
11. The paediatric nasal cannual should be made of kink proof material and should have adhesive wriggle pads to stick on skin to facilitate kangaroo care.
12. It should be compatible for use on tracheostomy patients.
13. Equipment should be provided with a mounting tray and pole with castor wheels and IV Hook.

SPECIFICATION FOR BI-PAP MACHINE – HOSPITAL BASED

(PH NO.753018)

1. It should have US FDA/CE/BIS certification and a copy of the certificate should be enclosed with the offer.
2. Ventilation modes CPAP, S, S/T, PC, T AVAPS-AE
3. AVAPS rate 0.5 to 5 cms H_20/min or wider.
4. IPAP 4 to 40 cms H_2O or wider.
5. EPAP 4 to 25 cms H_2O or wider.
6. Target tidal volume (when AVAPS and AVAPS AE enabled) 200 to 1500 ml or higher.
7. Breath rate 0-40 bpm or more and 4-40 per min in triggered mode.
8. Inspiratory time 0.5 to 3 seconds or wider.
9. Triggering and cycling Auto tack sensing and auto flow triggering should be available.
10. Rise time 100 msec to 600 msec or wider.
11. Noise level <30db.
12. Alarms for Patient disconnect, apnoea, low minute ventilation, low tidal volume with AVAPS/AVAPS-AE) and high respiratory rate alarm should be present.
13. Monitoring facility for Pressure tidal volume, minute ventilation, respiratory rate, leak, VE ratio.
14. Detachable battery backup module for minimum of 5 hours.
15. Accessories supplied per unit should include reusable tubing 5 numbers; heated humidifier 1 number; Full face mask with exhalation port with supplement oxygen port-3 numbers.

TECHNICAL SPECIFICATION FOR SEAMLESS STEEL OXYGEN CYLINDER 'D' TYPE – (PH No.109060)

* Material should be made of Seamless Steel.
* Water capacity ---47 L
* Hydrostatic test pressure --- 250 Bars
* Maximum Working pressure – 150 Bar
* Outer Diameter (approx) --- 232 mm
* Minimum wall thickness --- 5.2 mm
* Tare weight (approx) --- 50 Kg, Length (approx) --- 1370 mm
* Neck Ring, Bull nose valve & PESO filling permission should be present.

MULTI PARA MONITOR (PH NO.932057)

TECHNICAL SPECIFICATIONS

1. It should have US FDA/CE/BIS certification and a copy of the certificate should be enclosed with the offer.

2. Should have provision to measure minimum of five parameters viz., Pulse/ Non invasive Blood Pressure/ ECG/ Temperature/ Respiratory rate.

3. Should have ECG display for minimum of 3 leads, namely L1, L2 & L3 with option for 5-lead display.

4. Minimum ECG waveform/ sweep speed of 12.5/25/50 mm/ sec.

5. Should have facility for Heart rate measurement in the range of 15-300 bpm or wider.

6. Respiratory rate measurement shall be by thoracic impedance method with measurement range of 0-150/mt or higher.

7. Provision of Non invasive Blood Pressure monitoring with adult and paediatric cuffs by Automatic Oscillometry Method.

8. Measuring NiBP with range 10-270 mm/Hg or wider at pulse rates ranging from 40-240 beats/mt or wider with minimum of 10 estimations in 8 hour period.

9. Provision of SpO2 measurement in the range of 1-100%.

10. Temperature measurement range of 0-50 degree Celsius or higher with an accuracy of $\pm$0.1 degree Celsius.

11. Battery backup for a minimum of two hours with lithium ion battery.

12. Ability to perform at ambient temperatures of 5-40 degree Celsius or wider.

GENERAL SPECIFICATIONS FOR MULTI PARA MONITOR

1. Details of previous supplies to various hospitals of repute in Telangana, India, other Railway Hospitals, other Government

Hospitals with year of sale and contact person should be enclosed. Performance report from these Institutions should be enclosed, which can be verified after tender opening.

2. After sales service required at the place of delivery. Details of after-sales service facilities like address, telephone no., fax no., email etc; number of technicians, engineers with their qualification, inventory for repair and number of equipment serviced by centre should be enclosed.

3. Downtime in case of breakdown should be 72 hours or less failing which standby facilities should be provided during the period of warranty. Any delay after 72 hours without providing standby facilities shall attract a penalty of Rs.1000/- per day or part thereof.

4. Offer should include 3 year Comprehensive Warranty. The successful tenderer should submit a Bank Guarantee (10% of PO Value) for the warranty period.

5. Tenderers, who are OEM, must give undertaking for supply of spare parts for a period of expected life of the machine/ equipment. Other tenderers must submit undertaking from OEM for supply of spare parts for a period of expected life of the machine/equipment.

6. Original technical brochure should be enclosed.

7. The firm shall specifically provide Technical Compliance & Deviation statement for all Technical & General Specifications listed above along with supporting data sheet/Original Technical Brochure.

8. Inter-Se position of offers would be determined based on the sum of cost of equipment charges, if any, towards spares, peripherals etc. offered in the tender.

The above specifications are the minimum standards required by us and anything better would be acceptable.

SPECIFICATIONS FOR OXYGEN CONCENTRATOR – HOSPITAL USE (PH NO.918106)

* Should have BIS/CE from notified bodies/US FDA certification and copy of certificate should be enclosed with the offer.

* Oxygen concentrator should have provision of extraction of oxygen from ambient air by means of PSA technology.

* Provision of Oxygen concentration measurement of flow meter by oxygen sensing device (OSD).

* Sound level should be <60 dB.

* Oxygen purity should be 87% or higher.

* Oxygen outlet pressure should be 60kPa or higher.

* Oxygen output 10 litres/mt or higher.

* Provision of Oxygen tube of minimum 2 M length.

* Provision of in built nebulizer.

* Unit should function with 220-240Vac, 50-60 Hz input power supply.

* Operating temperature range 10^0 C to 35^0 C or wider.

* Operating humidity 75% or higher.

* Provision of safety alarms including low oxygen concentration, power failure, compressor failure, pressure cycle failure.

* The equipments shall be supplied with the following.

  i. One additional set of tubing with nasal cannula.

  ii. One additional set of internal and external filters (bacterial)

  iii. One additional set of fuses.

  iv. User manual and Technical manual

* Should be supplied with minimum of One year warranty.

SPECIFICATIONS FOR ICU VENTILATOR (PH NO.901045)

TECHNICAL SPECIFICATIONS

1. Should have BIS/USFDA certification and copy of the certificate should be enclosed with the offer.
2. Should be based on the principle of turbine technology with facility for invasive and non-invasive ventilation.
3. Operation by way of Micro processor Control and suitable for Pediatric and adult ventilation.
4. Should have touch screen colour TFT display with a minimum of 10" size.
5. Provision of measuring and display of
   a) Status indicator for ventilator mode
   b) Battery indication
   c) Wave forms for Pressure vs Time/ Volume vs Time/ Flow vs Time
   d) Alarm settings
6. Automatic compliance and leakage compensation for circuit and ET Tube.
7. Provision of log book for events and alarms with date and time.
8. Provision of setting for the following minimum parameters:
   a) Tidal volume (50-2000 ml or wider range)
   b) Inspiratory Pressure (upto 80 cm of H_2O)
   c) Respiratory rate 1 to 80 per minute or higher
   d) Apnoea backup rate
   e) CPAP/PEEP
   f) FiO2
   h) Pause Time
   i) Inspiratory flow 120 Litre/mt or higher
9. Monitoring and display of following parameters along with user selectable alarms
   a) Airway Pressure (peak & mean)
   b) Tidal volume (inspired & expired)
   c) FiO2
   d) Spontaneous minute volume
   e) Total frequency
   f) Intrinsic PEEP

g) Plateau pressure
h) Minute volume (inspired and expired)
i) Pressure flow & volume curves

10. Ventilation modes should include
    a) Assist/control
    b) Volume control
    c) Pressure control
    d) Pressure support
    e) SIMV with pressure support (pressure and volume control)
    f) PEEP
    g) Inverse ratio ventilation
    h) Non invasive ventilation – BIPAP & CPAP
    i) Apnea ventilation
11. Should have built in safety alarms for parameters including Airway pressure (high & low), Minute volume (high & low), power failure, low oxygen, high respiratory rate.
12. Should have inbuilt exhalation filter.
13. Should be compatible with existing central pipe line.
14. Servo technology controlled heated respiratory Humidifer with autoclavable humidifier jar.
15. Data storage facility for minimum of 24 hours.
16. Internal rechargeable battery with minimum back up for 30 minutes.
17. The equipment should be supplied with the following minimum standard accessories, free of cost:
    a) Reusable silicone breathing circuit, Adult & Pediatric each 5 Numbers
    b) HME filter – 10 Numbers
    c) Disposable flow sensors – 30 numbers

<u>GENERAL SPECIFICATIONS</u>

1. The firm shall provide details of previous supplies to various hospitals of repute in Hyderabad, Telangana, India, other Railway Hospitals, other Government Hospitals with year of sale and contact person. Performance report from these Institutions should be enclosed, which can be verified after tender opening.

2. After sales service is required at the place of delivery. Details after-sales service facilities like address, telephone no., fax no, e-mail, etc; number of technicians, engineers with their qualification, inventory for repair and number of equipments serviced by center should be enclosed.
3. Downtime in case of breakdown during the period of warranty should be 72 hours or less failing which standby facilities should be provided. Any delay 72 hours without providing standby facilities during the period of warranty shall attract a penalty of 0.5% of the total cost of equipment per week or part thereof. During the period of cAMC, the penalty shall be 1% of the cost of cAMC per week or part thereof which will be deducted from the cAMC charges.
4. Offer should include 3 years comprehensive Warranty. The successful tenderer should submit a Bank Guarantee (10% of PO value) for the warranty period.
5. The firm shall quote separately for 4 years Comprehensive Annual maintenance Contract (cAMC) after the warranty period. These charges shall include all costs of personnel and spares. Any exception of inclusion like consumables shall be specifically mentioned in the offer, with their current cost. The cAMC shall necessarily include minimum of 4 preventive visits and any number of breakdown calls.
6. Tenderers who is OEM, must give undertaking for supply of spare parts for a period of expected life of the equipment. Other tenderers must submit undertaking from OEM for supply of spare parts for a period of expected life of the equipment.
7. Original Technical Brochure should be enclosed, which shall indicate compliance of the technical specifications as required by us.
8. The firm shall specifically provide Technical compliance & deviation statement for all Technical & General specifications listed above along with supporting data sheet/ Original Technical Brochure.
9. Inter-Se position of offers would be determined based on the sum of cost of the equipment, the cost towards comprehensive annual maintenance contract for 4 years following free

comprehensive warranty for 3 years and charges, if any, towards spares, peripherals, etc. offered in the tender.

The above specifications are the minimum standards required by us and anything better would be acceptable.

TECHNICAL SPECIFICATIONS FOR C-PAP MACHINE - HOME BASED THERAPY (PH NO.763010)

C-Pap Machine – Home Based Therapy should have the following specifications:

1. Should have US FDA/CE/BIS certificate and a copy of the relevant certificate to be included with the offer.

2. The pressure range for both IPAP (Inspiratory Positive Airway Pressure) should be between 4-20 cmH_20 or wider.

3. Should have ramp facility.

4. Should have automatic altitude or climate compensation.

5. Should be provided with an integrated heated humidifier.

6. Should have facility to store compliance data on external memory card.

7. Should be provided with either 1 Reusable nasal mask or 1 Reusable full-face mask.

8. Should be provided with minimum of 2 numbers of hose pipes.

9. Should be provided with a carry bag.

10. Should have leak compensation and be able to compensate for variable resistance related to deferent mask like Nasal/ Minimal contact mask etc.

11. Should be able to detect and respond to apnea, Hypopnea, Central Apnea, Snoring

12. Should have low sound level of less than 30 db

13. Manufacturer should have a wide national network and office with complete service, repair and application backup capability for the quoted equipment.

…contd

GENERAL SPECIFICATIONS FOR C-PAP MACHINE – HOME BASED THERAPY (PH NO.763010)

1. The firm shall provide details of previous supplies to various Hospitals of repute in Telangana, India, other Railway Hospitals, other Government Hospitals with year of sale and contact person should be enclosed. Performance report from these Institutions should be enclosed, which can be verified after tender opening.

2. After sales service required at the place of delivery. Details of after-sales service facilities like address, telephone no., fax no., email, etc., number of technicians, engineers with their qualification, inventory for repair and number of equipment serviced by centre should be enclosed.

3. Downtime in case of breakdown during the period of warranty should be 72 hours or less failing which standby facilities should be provided. Any delay 72 hours without providing standby facilities during the period of warranty shall attract a penalty of 0.5% of the total cost of equipment per week or part thereof.

4. Offer should include 2 year Comprehensive Warranty. The successful tenderer should submit a Bank Guarantee (3% of PO Value) for the warrant period.

5. Tenderer who are OEM, must give undertaking for supply of spare parts for a period of expected life of the machine/ equipment. Other tenderers must submit undertaking from OEM for supply of spare parts for a period of expected life of the machine/equipment.

6. Original technical brochure should be enclosed, which shall indicate compliance of technical specifications as required by us.

7. The firm shall specifically provide technical compliance & deviation statement for all Technical & General specifications listed above along with supporting data sheet/Original Technical Brochure.

The above specifications are the minimum standards required by us and anything better would be acceptable.

Bi-Pap Machine - Home Based Therapy should have the following specifications (PH No.763001):-

1. Should have US FDA/CE/BIS Certificate and a copy of the relevant certificate to be included with the offer.

2. The pressure range for both IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) should be between 4-20 cmH_2O or wider.

3. Should have ramp facility.

4. Should have automatic altitude or Climate compensation.

5. Should be able to work also as Auto C-Pap.

6. Should be provided with an integrated heated humidifier.

7. Should have facility to store compliance data on external memory card.

8. Should be provided with either 1 Reusable nasal mask or 1 Reusable full-face mask.

9. Should be provided with minimum of 2 numbers of hose pipes.

10. Should be provided with a carry bag.

<u>GENERAL SPECIFICATION</u>

1. Details of previous supplies to various hospitals of repute in Hyderabad, Telangana, India, other Railway Hospitals, and other Government Hospitals with year of sale and contact person should be enclosed. Performance report from these Institutions should be enclosed, which can be verified after tender opening.

2. After sales service required at the place of delivery. Details of after-sales service facilities like Address, Telephone no., fax Number, email, etc. to be provided. Number of equipments serviced by this centre should be enclosed.

3. Downtime in case of breakdown should be 72 hrs or less failing which standby facilities should be provided. Any delay after 72 hrs without providing standby facilities shall attract a penalty of Rs.1,000/- per day or part thereof.

4. Offer should include 3 years comprehensive warranty for all the components of the Technical Specifications.

5. Tenderer who are OEM, must give undertaking for supply of spare parts for a period of expected life of the equipment. Other tenderers must submit undertaking from OEM for supply of spare parts for a period of expected life of the equipment.

6. Original Technical Brochure should be enclosed with quotation which shall indicate compliance of the technical specification as required by us.

7. The firm shall specifically provide Technical Compliance & Deviation statement for all Technical & General specifications listed above along with supporting data sheet/ Original Technical Brochure.

The above specifications are the minimum standards required by us and anything better would be acceptable.

Specifications for Finger Pulse Oxymeter (Adult) PH No.104023

- Should be able to monitor oxygen saturation by application to finger tip.
- Should have US FDA/CE/BIS certification and copy of certificate should be enclosed.
- Rated Voltage : DC 3.0 V.
- Should detect Oxygen saturation in the range of 35-100% or wider.
- Should detect Pulse rate in the range of 50-130 or wider.
- Alert sounds when the measured value goes beyond the preset alert parameter range with definable set range.
- Measurement precision and Accuracy : Oxygen saturation $\pm$ or better.
- Should provide One year's warranty.

Specification for N 95 Disposable Mask (PH No.526026)

- Shape that will not collapse easily.
- High filtration efficiency.
- Good Breathability with expiratory valve.
- Quality compliant with standards for medical N95 respirator (a) NIOSH N95, EN 149 FFP2, or equivalent.
- Fluid resistance : minimum 80 mmHg pressure based on ASTMF 1862. ISO 22609 or equivalent.
- Quality compliant with standards for particulate respirator that can be worn with full-face shield.

  (The above specifications were downloaded from MOHFW website during the month of March-2020.

SPECIFICATION OF GLUCOMETER TO BE SUPPLIED ALONG WITH STRIPS FOR CAPILLARY BLOOD GLUCOSE ESTIMATION (PH NO.341015)

1. BIOSENSOR TECHNOLOGY FOR GLUCOSE ESTIMATION.

2. GLUCOMETER SHOUD BE ABLE TO "ASPIRATE" THE BLOOD SAMPLE TO ENSURE CORRECT VOLUME DELIVERY.

3. SAMPLE VOLUME 1uL OR LESSER.

4. TIME FOR ANALYSIS 10 SECONDS OR LESSER.

5. ESTIMATION RANGE 20-600 MG/DL OR WIDER.

6. PROVISION OF AUTO ON-OFF FACILITY.

7. SHOULD ENCLOSE THE ORIGINAL TECHNICAL BROUCHURE.

8. FIRM SHOULD SUPPLY AND MAINTAIN "FREE OF COST", THE REQUIRED GLUCOMETERS FOR EACH DIVISION. THE REQUIREMENTS OF GLUCOMETERS WILL BE AT THE RATE OF ONE GLUCOMETER FOR EVERY 10 BEDS IN THE HOSPITALS OF THE ZONE (760 BEDS) INCLUDING CH/LGD AND ALL DIVISIONS. IN CASE OF OTHER DIVISIONS, APART FROM ONE GLUCOMETER FOR EVERY 10 BEDS, TWO ADDITIONAL GLUCOMETER WILL BE REQUIRED FOR EACH HEALTH UNIT (50x2 = 100) AND 10 ADDITIONAL METERS FOR EACH DIVISION (6x10 = 60) AS A WHOLE FOR USAGE IN DIABETES SCREENING CAMPS/; LINE BOXES. TOTAL 240 NUMBERS

9. THE FIRM SHOULD PERIODICALLY (AT LEAST ONCE A MONTH) CALIBRATE THE GLUCOMETERS FOR QUALITY CONTROL PARAMETERS TO THE SATISFACTION OF HOSPITAL ADMINISTRATION

10. SHOULD HAVE BIS/US FDA APPROVAL AND CERTIFICATE TO BE ENCLOSED WITH OFFER.

Specification for ITC/CIC Hearing Aid (Product Code No.261303)

TECHNICAL AND GENERAL SPECIFICATIONS FOR IN THE CANAL(ITC) /COMPLETELY IN THE CANAL (CIC)HEARING AID

1. SHOULD HAVE BIS/CE/USFDA CERTIFICATION
2. SHOULD BE IN THE CANAL TYPE, EITHER PARTIALLY OR COMPLETELY
3. SHOULD HAVE MINIMUM OF 12 CHANNELS
4. BATTERY LIFE SHOULD BE MINIMUM 120 HOURS
5. SHOULD HAVE MINIMUM WARRANTY OF THREE YEARS
6. SHOULD HAVE TWIN MIC
7. SHOULD HAVE PROGRAMMABLE VOLUME CONTROL
8. SHOULD HAVE AUTOMATIC FEEDBACK CANCELLATION
9. SHOULD BE CONFIGURABLE BY PROGRAMMING BY A COMPUTER
10. SHOULD HAVE A FITTING RANGE FROM 30 TO 90 DECIBELS OR WIDER
11. SHOULD HAVE A MINIMUM GAIN OF 80 dB SPL
12. THE SUPPLIER SHOULD HAVE THE FACILITY FOR REPAIR AND REPLACEMENT OF THE HEARING AID DURING THE WARRANTY PERIOD.
13. THE FIRM SHOULD UNDERTAKE TO PROVIDE HEARING AID TRIAL, FITTING AND POST SALES SERVICE AT DIFFERENT LOCATIONS IN SOUTH-CENTRAL RAILWAY AS REQUIRED BY THE CONSIGNEE

Specification for Digital BTE 6 Channel Hearing Aid (PH No.261306)

TECHNICAL AND GENERAL SPECIFICATIONS FOR DIGITAL BEHIND THE EAR (BTE) 6 CHANNEL HEARING AID

1. SHOULD HAVE BIS/CE/ USFDA CERTIFICATION
2. SHOULD HAVE MINIMUM OF 6 CHANNELS
3. BATTERY LIFE SHOULD BE MINIMUM 120 HOURS
4. SHOULD HAVE TWIN MIC
5. SHOULD HAVE MANUAL VOLUME CONTROL
6. SHOULD HAVE AUTOMATIC FEEDBACK CANCELLATION
7. SHOULD HAVE MINIMUM WARRANTY OF THREE YEARS.
8. SHOULD HAVE MINIMUM OF 6 DIGITAL PROGRAMS
9. SHOULD BE CONFIGURABLE BY PROGRAMMING BY A COMPUTER
10. SHOULD HAVE A FITTING RANGE FROM 30 TO 90 DECIBELS OR WIDER
11. SHOULD HAVE A MINIMUM GAIN OF 80 dB SPL
12. THE SUPPLIER SHOULD HAVE THE FACILITY FOR REPAIR AND REPLACEMENT OF THE HEARING AID DURING THE WARRANTY PERIOD.
13. THE FIRM SHOULD UNDERTAKE TO PROVIDE HEARING AID TRIAL, FITTING AND POST SALES SERVICE AT DIFFERENT LOCATIONS IN SOUTH CENTRAL RAILWAY AS REQUIRED BY THE CONSIGNEE.

Specification for Digital Behind the Ear Hearing Aid with High gain item for procurement under ZRC (Product Code No.261315).

TECHNICAL AND GENERAL SPECIFICATIONS FOR DIGITAL BEHIND THE EAR (BTE) HEARING AID WITH HIGH GAIN

1. SHOULD HAVE BIS/CE/USFDA CERTIFICATION
2. SHOULD HAVE MINIMUM OF 12 CHANNELS
3. BATTERY LIFE SHOULD BE MINIMUM 120 HOURS
4. SHOULD HAVE MINIMUM WARRANTY OF THREE YEARS
5. SHOULD HAVE TWIN MIC
6. SHOULD HAVE MANUAL VOLUME CONTROL
7. SHOULD HAVE AUTOMATIC FEEDBACK CANCELLATION
8. SHOULD HAVE MINIMUM OF 12 BANDS/ CHANNELS.
9. SHOULD BE CONFIGURABLE BY PROGRAMMING BY A COMPUTER.
10. SHOULD HAVE A FITTING RANGE FROM 40 TO 110 DECIBELS OR WIDER.
11. SHOULD HAVE A MINIMUM GAIN OF 80 dB SPL
12. THE SUPPLIER SHOULD HAVE THE FACILITY FOR REPAIR AND REPLACEMENT OF THE HEARING AID DURING THE WARRANTY PERIOD
13. THE FIRM SHOULD UNDERTAKE TO PROVIDE HEARING AID TRIAL, FITTING AND POST SALES SERVICE AT DIFFERENT LOCATIONS IN SOUTH-CENTRAL RAILWAY AS REQUIRED BY THE CONSIGNEE

NON REBREATHER MASK PAEDIARIC (PH NO.101562)

- Latex free odourless transparent mask and tubing
- Adjustable elastic band
- Mask designed to fit the face contours
- Mask adult and paediatric sizes
- Provision of low resistance check valve on either side of the mask to prevent the re-breathing through the mask and allow exhaled gases to escape
- A valve and a reservoir for oxygen
- 0.7 Lt Reservoir bag for Paediatric
- Provision of Tubing minimum of 7 ft length
- Non kinking connecting tube analysis after 30-45 min of oxygen therapy.

NON REBREATHER MASK ADULT (PH NO.101561)

- Latex free odourless transparent mask and tubing
- Adjustable elastic band
- Mask designed to fit the face contours
- Mask adult and paediatric sizes
- Provision of low resistance check valve on either side of the mask to prevent the re-breathing through the mask and allow exhaled gases to escape
- A valve and a reservoir for oxygen
- 1.5 Lt Reservoir bag for adults
- Provision of Tubing minimum of 7 ft length
- Non kinking connecting tube analysis after 30-45 min of oxygen therapy.

PERSONAL PROTECTIVE EQUIPMENT KIT (PPE KIT)
(for Contact & Airborne precautions)
(PH NO.526091)

Detailed list of components and their specifications are –

1. **PPE KIT**

1.1 GLOVES

- Nitrile
- Non-sterile
- Powder free
- Outer gloves preferably reach mid-forearm (minimum 280 mm total length)
- Different sizes (6.5 & 7)
- Quality compliant with the below standards, or equivalent.
  (a) EU standard directive 93/42/EEC Class I, EN 455
  (b) EU standard directive 89/686/EEC Category III, EN 374
  (c) ANSI/SEA 105-2011
  (d) ASTM D6319-10

1.2 Coverall (medium and large)

- Impermeable to blood and body fluids
- Single use
- Avoid culturally unacceptable colors e.g. black
- Light colors are preferable to better detect possible contamination
- Thumb/finger loops to anchor sleeves in place
- Quality complaint with following standard
  b. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

1.3 Goggles

- With transparent glasses, zero power, well fitting covered from all sides with elastic band/or adjustable holder
- Good seal with the skin of the face
- Flexible frame to easily fit all face contours without too much pressure

- Covers the eyes and the surrounding areas and accommodates for prescription glasses
- Fog and scratch resistant
- Adjustable band to secure firmly so as not to become loose during clinical activity
- Indirect venting to reduce logging.
- May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable
- Quality complaint with the below standards or equivalent
  a. EU standard directive 86 686 EEC EN 166 2002
  b. ANSI SEA 787 1-2010

1.4 N-95 Masks

- Shape that will not collapse easily
- High filtration efficiency
- Good breathability with expiratory valve
- High filtration efficiency
- Quality compliant with standards for medical N95 respirator:
  b. NIOSH N95, EN 149 FFP2, or equivalent
- Fluid resistance : minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent
- Quality compliant with standards for particulate respirator that can be worn with full face shield

1.5 Shoe Covers

- Made up of the same fabric as of coverall
- Should cover the entire shoe and reach above ankles

1.6 Face Shield

- Made of clear plastic and provides good visibility to both the wearer and the patient
- Adjustable band to attach firmly around the head and fit snggly against the forehead
- Fog resistant (preferable)
- Completely covers the sides and length of the face

- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality complaint with the below standards, or equivalent:
  c. EU standard directive 86 686 EEC, EN 166/2002
  d. ANSI/SEA Z87.1-2010

3. **Triple Layer Medical Mask**

* Three layered medical mask of non-woven material with nose piece having filter efficiency of 99% for 3 micron particle size

  a. ISI specifications or equivalent

4. Gloves

* **Nitrile**
* **Non-sterile**
* **Powder free**
* **Outer gloves preferable reach mid-forearm (minimum 280 mm total length)**
* **Different sizes (6.5 & 7)**
* **Quality complaint with the below standards or equivalent**
  1. **EU standard directive 93/42/EEC Class 1.EN 455**
  2. **EU standard directive 89/686/EEC Category III, EN 374**
  3. **ANSI/SEA 105-2011**
  4. **ASTM D6319-10**

5. Body Bags – Specifications

1) Impermeable
2) Leak proof
3) Air sealed
4) Double sealed
5) Disposable
6) Opaque
7) White
8) U Shape with Zip
9) 4/6 grips
10) Size 2.2 x 1.2 Mts

11) Standards

a) ISO 16602 2007
b) ISO 16003 2004
c) ISO 16004 2004
d) ISO DIS 22611 2003

All items to be supplied need to be accompanied with certificate of analysis from national/international organizations/labs indicating conformity to standards

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Due to scarcity of coveralls, and risk versus benefit, that as an emergency temporary measure in larger public, present given circumstances, the fabric that cleared/passed "Synthetic Blood Penetration Resistance Test' (ISO 16603) and the garment that passed 'Resistance to penetration by biologically contaminated solid particles (ISO 22612.2005) may be considered as the benchmark specification to manufacture Coveralls". The Coveralls should be taped at the seams to prevent fluid/droplets/aerosol entry.

The test for these two standards (ISO 16603 and ISO 22612.2005) which can be performed in Indian Laboratories are as per WHO Disease Commodity Package (Version 4.0)
