Pre-Bid Clarification/Corrigendum No. 1
Dated: 17.10.2013

With reference to NIT published for Tender No. : AIIMS Bhopal/Stores/HC/RC-Emergency Medicine Department Equipment/2013-14/01 Dated 09.09.2013 for Notice Inviting Tender for Supply of Anaesthesia Department Equipment to AIIMS BHOPAL.

Subsequent to the Pre bid queries sough for clarification, received through in person dated: 14.10.2013, 15.00 Hrs. the following Clarification/Corrigendum No. 1 to Pre Bid Queries raised are circulated for the wider information to the prospective tenderers and requested them to download Pre Bid Clarification/Corrigendum No.1 and submit the same along with their “Technical Bid” Envelope.

Item No. 1: ICU Ventilator (7 Nos.)

Revised Technical Specifications:

The ventilator should be microprocessor based and work with hospital external high pressure line/external compressor to be used in ICU for Adult, Paediatric and infant patients. It should be easy to use having a color inbuilt touch screen at least 12 inch or more in size with screen lock, intuitive menu structure, Mode preset capability, Pressure bar graph/breath indicator and prioritized alarms along with the following settings/features:

1. Ventilation Mode
   - Volume Controlled ventilation (Assisted/Control) VCV
   - Pressure Controlled ventilation (Assisted/Control) PCV
   - Synchronized intermittent mandatory Ventilation V-SIMV AND P-SIMV
   - Pressure support ventilation (Spont, CPAP, PEEP) PSV
   - Non invasive ventilation VCV, PCV, SIMV, PSV
   - Volume assured pressure support VAPS
   - Mandatory rate ventilation MRV
   - Airway pressure release ventilation APRV/BI-PHASIC VENTILATION
   - Pressure regulated volume control PRVC
   - Continuous positive airway pressure CPAP

2. Ventilation Settings & Ranges
   - Tidal Volume 20 ml to 2000 ml or more
   - Inspiratory Peak Flow 0 to 200 LPM (Compensated) [preferred]
Maximum Inspiratory Peak Flow: > 200 l/min (depending on gas supply pressure)
Respiratory Rate: up to 100 BPM
SIMV Respiratory Rate: 1 to 60 BPM
Inspiratory plateau: 0 to 60% of IT
FiO2: 21% to 100%

Insp. pause, Exp. Pause, sustained exhalation, programmable sigh

**Inspiratory Trigger** (pressure and flow trigger)

Should have apnoea back up of at least 20 seconds.

3. **Monitored Parameters**
   Respiratory Phase & Type, Respiratory Rate, Exhaled Tidal Volume, Exhaled Min. Volume Total, I : E Ratio, Peak Inspiratory Pressure, Average Pressure, Plateau Pressure, End Expiratory Pressure, % Oxygen Delivered, f/Vt (RSBI), etCO2 (End tidal CO2)

4. **Respiratory Mechanics Maneuvers**
   Static Compliance and Resistance,

   Low Inflation flow (LIP) and upper inflection point (UIP),

   **Some form of alveolar recruitment monitoring to be present to determine the right level of PEEP.**

5. **Displayed Trends Values for 72 hours at least**
6. **Graphics Module with Scalars**
   Flow vs. Time
   Pressure vs. Time
   Adjustable Time Scale.

   **Loops**
   Flow / Volume
   Pressure / Volume

   **Facility for Freeze Screen**
   Individual Analysis of Each Curve
   Loop Save and Overlay Function
   Individual Analysis of Each Loop

   **Calculated Values**
   Inspiratory pause, Expiratory Pause

7. **Should have audio-visual alarms along with appropriate message for**
   Inspiratory pressure (High), circuit, FiO2 (High/Low), Resp Rate, Tidal volume, minute ventilation

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8. The ventilator should have built-in programmable nebulizer

9. **AC Power & Battery Indicators**
   - Loss of AC Power (visual)
   - Charging, In Use, Low
   - Main Battery in Use
   - Should have at least one hour back-up

10. **Self Test / Self Diagnosis**
    - Quick Self Test and Extended Self Test

11. **Interface Port**
    - RS-232 Output and Remote Communication

12. Ventilator should be EUROPEAN CE and USFDA APPROVED

13. **Scope of supply**
    - **Ventilator**
      - 1 No
    - **Air supply unit**
      - 1 No (OPTIONAL)
    - **Patient Tubing (adult)**
      - 2 Nos/unit
    - **Patient Tubing (paed)**
      - 2 Nos/unit
    - **Nebuliser Kit**
      - 50 Nos/ Ventilator
    - **NIV Mask with harness (Reusable)**
      - 2 Nos in each category/ Ventilator
    - **Humidifier (F&P 810) with chamber**
      - 1 No/ Ventilator
    - **Bacteriological filters**
      - 10 Nos/ Ventilator
    - **Reusable mask( adult and pediatric)**
      - 2 each

14. **OPTIONAL ITEM**
    1. Air compressor (from the same manufacturer)

15. The quote should quote with Five years comprehensive warranty (including labour and spares) and five years CMC (including labour and spares).

16. **DEMONSTRATION IS MUST AS AND WHEN REQUIRED.**

**Item No. 2: DEFIBRILLATOR WITH MONITOR (3 Nos.)**

**Revised Specifications**

1. **Description of Function**

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

2. **Operational Requirements**

2.1 Defibrillator should be Bi-Phasic, light weight (< 8kg) and latest model
2.2 Should monitor vital parameters and display them
2.3 Should print the ECG on thermal recorders.
2.4 Should work on Manual and Automated external defibrillation (AED) mode. Manual selection as well as maximum upto 360 J.
2.5 Should be capable of doing synchronised & asynchronised cardioversion
2.6 Can be operated from mains as well as battery
2.7 Should have defibrillator testing facility
2.8 Demonstration of the equipment is essential.

3. Technical Specifications

3.1 Should be a Low Energy Biphasic defibrillator monitor with Recorder, having capability to arrest all arrhythmias within a maximum energy of 360 Joules
3.2 Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles. Should have Automatic Lead switching to see patient ECG through paddles or leads
3.3 Should measure and compensate for chest impedance for a range of 25 to 125 ohms
3.4 Should have a built in 50mm strip printer/ thermal recorder
3.5 Should have charging time of less than 3-5 seconds for maximum energy. Charging indicator should be there.
3.6 Should have Display- TFT coloured LCD at least 8” diagonal for viewing messages and ECG waveform of 4 seconds
3.7 Should have external paddles with paddles contact indicator – for good paddle contact. Both Adult and pediatric paddles should be available.
3.8 Should have event summary facility for recording and printing at least 250 events and 50 waveforms. Patient data storage 90 mins. Of ECG and events.
3.9 Should have a battery capable of usage for at least 90-120 minutes and/or 25-30 discharges

3.10 Should be capable of printing Reports on Event summary, configuration, self test, battery capacity etc
3.11 Should have facility for self test/check before usage and set up function
3.12 Should have SPO2 , NIBP (optional) and Etco2 (optional).
3.13 Should be capable of delivering energy in increments of 1-2 joules up to 10J and increments 5-10 J till 50 and up to a maximum of 50J thereafter.
3.14 Should have user friendly 1,2,3 color coded operation.
3.15 Should have voice prompt on AED mode

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3.16 Should have printing report of events, summary configuration/ set test/ battery capacity
3.17 optional noninvasive pacing / transcutaneous pacing.

4. System Configuration Accessories, spares and consumables
4.1 Defibrillator - 01
4.2 Paddles Adult (pair) - 01
4.3 Paddles –Paediatrics(pair) - 01
4.4 Patient cable - 02
4.5 ECG Rolls -50
4.6 Disposable pads-10 nos.
4.7 NIBP Cuff Adult - 02 (optional)
    NIBP Cuff Paediatrics- 02 (optional)
    NIBP Cuff Infants- 02 (optional)
4.8 SPO2 Finger Probe-Adult -02
    SPO2 Ear Probe - -02
4.9 Complete set of ECG Leads- 02

5. Environmental factors
5.1 The unit shall be capable of operating continuously in ambient temperature of 0 – 50 °C and relative humidity of 15-90%
5.2 The unit shall be capable of being stored continuously in ambient temperature of -20 – 60 °C and relative humidity of 15-90%
5.3 Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

6. Power Supply
6.1 Power input to be 220-240VAC, 50Hz
6.2 Resettable overcurrent breaker shall be fitted for protection

7. Standards, Safety and Training
7.1 Should be FDA and CE( European) approved product
7.2 Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms (OR EQUIVALENT BIS Standard)
7.3 Drop Test-Withstands 1 meter drop to any edge, corner or surface.
7.4 Should conform to international test protocols on exposure to shock forces and to vibration forces. The standard should be documented.
7.5 Should meet IEC 529 Level-2 (IP2X) for enclosure protection solid foreign object ingress.

7.6 Should meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.

7.7 Should have local service facility. The service provider should have the necessary equipment's recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

7.8 Comprehensive warranty for 5 years and provision of CMC for next 5 years.

8. Documentation

8.1 User Manual in English

8.2 Service manual in English

8.3 List of important spare parts and accessories with their part number and costing

8.4 Certificate of calibration and inspection from factory.

8.5 Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.

The job description of the hospital technician and company service engineer should be clearly spelt out.

8.6 List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.

8.7 Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.

8.8 Must submit user list and performance report within last 5 years from major hospitals.

Terms & Conditions

- Preventive machine maintenance four times in a year.
- Response time for acknowledgment of complaint 30 minutes.
- Response time for physical presence within one working day.
- Uptime 355 days in a year.
- Downtime 48 hours with a penalty of Rs. 1000/- every day after downtime.
- Demonstration of equipment is compulsory.

Item No. 3: AUTOMATED EXTERNAL DEFIBRILLATOR (5 Nos.)

Revised Specifications

AUTOMATED EXTERNAL DEFIBRILLATOR

1. Description of Function

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

1) Defibrillator should be Bi-Phasic, light weight and latest model
2) Should monitor vital parameters and display them
3) Should print the ECG on thermal recorders.
4) Should work on Manual and Automated external defibrillation (AED) mode. Manual selection and AED energy selection up to 360 J.
5) Should be capable of doing synchronized & asynchronous cardioversion
6) Can be operated from mains as well as battery
7) Should have defibrillator testing facility
8) Demonstration of the equipment is a must.

3. Technical Specifications

1) Should be a Low Energy Biphasic defibrillator monitor with Recorder, having capability to arrest all arrhythmia within a maximum energy of 360 Joules

2) Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles.

3) Should have Automatic Lead switching to see patient ECG through paddles or leads

4) Should measure and compensate for chest impedance for a range of 25 to 150 ohms

5) Should have a built-in 50mm strip printer/thermal recorder

6) Should have charging time of less than 3-5 seconds for maximum energy. Charging indicator should be there.

7) Should have bright electroluminescent display for viewing messages and ECG waveform of 4 seconds

8) Should have external & internal paddles with paddles contact indicator – for good paddle contact. Single

9) Adult and pediatric paddles should be available.

10) Should have event summary facility for recording and printing at least 250 events and 50 waveforms.

11) Should be capable of printing Reports on Event summary, configuration, self-test, battery capacity etc.

12) Should have facility for self-test check before usage and set up function

13) Should be capable of delivering energy in increments of 1-2 joules up to 30J and increments of maximum 50J thereafter.

14) Should have user friendly color coded operation

4. System Configuration, Accessories, spares and consumables

1) Defibrillator -01
2) Paddles Adult/Pediatric (pair) -01

3) Patient cable -02

4) ECG Rolls -50

5) Disposable pads-10 nos.

5. Environmental factors

1) The unit shall be capable of operating continuously in ambient temperature of 10 -400 °C and relative humidity of 15-90%

2) The unit shall be capable of being stored continuously in ambient temperature of 0 -500 °C and relative humidity of 15-90%. Shall meet IEC-60601-1-2: 2001 (Or Equivalent BIS), general Requirements of Safety for Electromagnetic Compatibility.

6. Power Supply

1) Power input to be 220-240VAC, 50Hz. Power cable should be fitted with Indian plug and adapter.

2) Resettable overcurrent breaker shall be fitted for protection

3) Should have a Rechargeable Battery capable of usage for at least 90 minutes or 30 discharges.

7. Standards, Safety and Training

1) Should be FDA and CE (European) approved product

2) Manufacturer should have ISO certification for quality standards


4) Drop Test-Withstands 1 meter drop to any edge, corner or surface.

5) Should conform to international test protocols on exposure to shock forces and to vibration forces. The standard should be documented.

6) Should meet IEC 529 Level-2 (IP2X) for enclosure protection solid foreign object ingress.

7) Should meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.

8) Should have local service facility. The service provider should have the necessary equipment’s recommended by the manufacturer to carry out preventive maintenance

9) Test as per guidelines provided in the service/maintenance manual.

10) Comprehensive warranty for 5 years and provision of AMC for next 5 years.

8. Documentation

1) User Manual in English

2) Service manual in English

3) List of important spare parts and accessories included in the warranty with their part number and costing

4) List of important spare parts and accessories not included in the warranty with their part number and costing

5) Certificate of calibration and inspection from factory.

7) The job description of the hospital technician and company service engineer should be clearly spelt out
8) List of Equipment's available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual.

Compliance Report to be submitted in a tabulated and pointwise manner clearly mentioning the page/Para number of original catalogue/datasheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.

Must submit user list and performance report within last 5 years from major hospitals

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