PRE BID CLARIFICATION/CORRIGENDUM No. 1

Dated: 17.10.2013

With reference to NIT published for Tender No. : AIIMS Bhopal/Stores/HC/RC-Anaesthesia 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: Anaesthesia Workstation (3 Nos.)

1. Revised Technical Specifications:
   1. Should be completely integrated system, with all components like Anesthesia machine, Ventilator, Circle absorber, Vaporiser and Monitor should be from a single manufacturer.
   2. Should have provision for delivery of oxygen, nitrous oxide and medical air with pressure gauges.
   3. Should have independent attachments for connecting central gas supply and pin indexed cylinders.
   4. Should have analog display of cylinder and pipeline gas pressures
   5. Should have provision to attach one cylinders for Oxygen and one for Nitrous Oxide.
   6. Digital depiction of O2, N2O and Air Flow
   7. Oxygen and Nitrous oxide should be linked to ensure a minimum of 25% oxygen delivery at all times to avoid delivery of hypoxic mixture. Lever based anti hypoxic device is not acceptable.
   8. Should have back bar with ISO pin type to attach vaporiser easily.
   9. Should have top shelf and a table top to keep drugs and equipments.
   10. The machine should possess battery back up for ventilator.
   11. Castor wheel should be durable and moisture resistant.
   12. Unlockable oxygen flush to deliver oxygen flow of approximately 40L/min.
   13. Should have two deep drawers.
   14. Should have Anesthetic Gas Scavenging System (AGSS)

2. Standard Circle Absorber System
   1. Should have adjustable pressure limiting valve, breathing circuit pressure measuring device.
   2. Should have bag / vent selecting valve integrated onto the absorber and should automatically turn on the ventilator when positioned to vent mode.
   3. Should be suitable to use low flow techniques.
   4. Should have facility to attach oxygen sensor.
   5. Should have fully autoclavable Co2 absorbent canisters and bellows.

3. Vaporiser
   1. Temperature, pressure and flow compensated.
   2. Should provide keyed filler based Isoflurane and Sevoflurane vaporisers.
   3. Should be easy to mount and dismount form the back bar.
   4. Should have ISO pin type (Selectatec)/quick mount type back bar mount.

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5. Vaporiser should be maintenance free for ten years.

4. Ventilator
   1. Should be integrated with the anesthesia system, with bag in bottle ascending type bellows or electric driven.
   2. Should have tidal volume range from 20ml to 1500 ml±10%.
   3. Should be able to set TV, RR and I:E ratio.
   4. Should have large display with touch screen(optional) and wheel based adjustments.
   5. Shall have the following modes: VCV, PCV, SIMV + Pressure Support
   6. Ventilator should monitor and display integrated Oxygen monitoring, Inspired and expired volumes, PAW, Pressure waveform, Flow waveform
   7. Ventilator should have Inspiratory pause, Patient trigger 5 - 15pm.
   8. Ventilator should have a max flow of 100 litres per minute in PCV mode.
   9. Ventilator should provide all user alarms.
   10. Ventilator should provide Fresh gas compensation and Compliance compensation.
   11. Ventilator shall have an active proportional exhalation valve to prevent the potential of over delivery during pressure modes of ventilation.
   12. The breathing system should have a inbuilt heater/ warmer for ensuring humidified gas to the patient and also to avoid condensation in breathing circuit and sticking of ascending bellows during low flow anaesthesia.
   13. On switching on, the ventilator system check can be bypassed in the case of an emergency.
   14. Flow sensors measurement at the patient end of the circuit is preferred.
   15. Should be supplied with necessary reusable and disposable breathing circuits.

5. Integrated monitoring system
   1. Patient monitor system should be of modular type and capable of monitoring adult, pediatric and neonatal patients. Should be from the same manufacturer as the anesthesia system.
   2. Monitor should have minimum17”-19” independent color flat panel display.
   3. Should have the latest Touch screen user interface.
   4. Module rack / housing should be independent and shall be able to be placed near to the patient.
   5. Should be capable of 12-16 traces display.
   6. Facility to monitor: ECG, NIBP, SpO2, Respiration, 4 X Invasive pressures, Temperatures (2), AGM, Bispectral index.
   7. Should have Cardiac output port enabled for thermodilution method.
   8. ECG should have capability for 3, 5 and / or 10 lead monitoring and should have built in arrhythmia monitoring on all 12 leads.
   9. Separate price for EEG module to be offered.

10. Inbuilt ST segment analysis and arrhythmia detection for all the leads.
11. Haemodynamic and drug dose calculations should be available.
12. Respiration should be available with Cardio Vascular Artifact filter. Monitor should have a display of Spirometry loops
13. Oxy CRG should be available for monitoring neonates.
14. Alarm parameter should flash red in the presence of high priority alarms (e.g. ventricular fibrillation and asystole) and flash yellow in the presence of medium or low priority alarms (e.g. noisy signal, etc.)
15. 48 hours trend data should be displayed.
16. All monitors including central station should have similar user interface for easy usage among all clinicians.
17. Monitor shall provide capability to remote view of real time waveforms via the internet.
18. On-screen keyboard for entering this data is preferable. Should have USB ports to connect mouse, key board, bar code scanner.
19. Alarm limit status (ON/OFF) must be indicated on-screen for each parameter and actual parameter alarm settings must be displayed on-screen when alarms are on.
20. Position of the displayed waveforms must be user configurable.
21. Waveform color changing should be user configurable.
22. Monitor shall permit the optional ability to receive and display information from other patient devices such as ventilators, infusion pumps and other standalone devices.
23. All modules should be compatible with all monitors quoted.
24. Should be supplied with necessary accessories for adult, pediatric and neonatal accessories.
25. Monitor should be compatible with HIS and Should be HL7 compliant & DICOM
26. Monitor should provide remote viewing facility of real time waveforms through internet.
27. Depth of Anesthesia Monitoring module - one per monitor with 50 sensors with each monitor
28. Neuromuscular Transmission Monitoring with all accessories. One set with each monitor

6. Accessories and spares
   i. Anaesthesia Gas Delivery system -01
   ii. Circle absorber -01
   iii. Ventilator -01
   iv. Monitor -01
   v. Vaporiser Sevoflurane -01
   vi. Vaporiser Isoflurane -01
   vii. Adult and Paediatric autoclavable silicone breathing circuits -02 each
   viii. Reusable IBP Transducer -04
   ix. Disposable domes-100
   x. Temp probe Skin reusable- 02
   xi. Temp probe Rectal Reusable-02
   xii. Accessories Anesthetic gases-01 set
   xiii. Depth of Anesthesia Sensors-50
   xiv. Accessories for Cardiac Output module- 01 set
   xv. Accessories for neuromuscular transmission monitor- 01 set
   xvi. Standard accessories to make all parameters working- 01 set
   xvii. Disposable Adult & Paediatric circuits- 50 each
   xviii. HME filters - 50

7. Standards, Safety and Training
   7.1 Should be US FDA and CE (European) approved product
   7.2 Electrical safety conforms to standards for electrical safety IEC-60601 /IS-13450
   7.3 Manufacturer should be ISO certified for quality standards.
   7.4 Particular requirements for the safety of Anaesthesia Workstations Safe disposal system: Anesthetic Gas Scavenging System, should be in place
   7.5 Certified to be compliant with IEC 60601-2-13-Medical Electrical equipment part 213:
   7.6 Should have local service facility. The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
   7.7 All imported components like anaesthesia machine, monitor and ventilator should be from one manufacturer/principal.
   7.8 Back to back warranty to be taken by the supplier from the principal to supply spares for a minimum period 10 years.
   7.9 Comprehensive warranty for 3 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 the factory
   8.5 Log book 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.
8.6 List of Equipment 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

**Item No. 2: MULTIPARA MONITOR (Non Invasive Bed Side) – (20 Nos.)**

**Revised Technical Specifications:**

1. Monitor should be of latest platform with modular & multi measurement server design and should be wall mountable. The company should have supplied the similar models in any of the government institutions in last two years.

2. It should have color coded modules to avoid inserting wrong cables or leads.

3. It should have bright, highly visible minimum 12 inch- 15 inch flat Touch screen color TFT medical grade display of the parent company preferably with 1024 x 768 line resolution for easy viewing from a distance.

4. It should have the capability to be operated through either Touch screen or Trim Knob interface.

5. It should have the capability to display at least four real time waveforms along with related numerical parameters on a single screen.

6. The size of the numerics and waveforms should be adjustable to become larger for viewing from very long distance.

7. It should have continuous 12 lead ECG monitoring facility through 5 or 10 lead cable including 12 lead ST segment analysis.

8. It should have minimum 48 hours of Graphical, tabular trending facility.

9. It should have advanced multi-lead arrhythmia analysis capability

10. It should have configurable screen configurations for various monitoring settings like emergency, general monitoring, 12 lead screen etc.

11. The monitor should facility to be connectable to central nursing station and should use a single network for all kinds of networking with the central station or the other hospital systems.

12. The monitor should be facility to be upgraded for connectivity to the other diagnostic and administrative systems of the hospital like through PACS system or other systems.

13. It should have the facility to be upgraded to display images and reports from other diagnostic and administrative systems of Hospital like X-ray frames, Echo studies, Cath Lab frames. All tests conducted for a particular patient including images should be visible on the bedside monitor display itself and the user should be able to interact.

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with these reports The real time patient monitoring should continue unaffected at all times while retrieving these remote patient information.

14. The monitor should have facility to be operated through AC mains and rechargeable battery with backup of more than 4 hours

15. Should have facility to interchange all the modules/servers between all the monitors, so that one or more optional modules/servers can be operatable on all monitors at different point of time.

16. The monitor should have proper valid FDA approval and CE certification.

17. Standard measurements to be provided with all the monitors are ECG, Heart Rate, Respiration Rate, SpO2, Non Invasive Blood Pressure.

18. Additional optional modules required with the monitors, which should be used in any of the monitor at any time are as follows

19. Recorder Module which can be shared between all monitors- 01 no wall mount 01 with each monitor

Accessories to be offered as standard:

ECG/Respiration 5 lead cable – 01 no. with each monitor
Non-Invasive Blood Pressure cuff adult – 01 no. with each monitor
Non-Invasive Blood Pressure cuff paediatric – 01 no. with each monitor
Pulse Oximetry finger adult sensor – 01 no. with each monitor
Pulse Oximetry paediatric – 01 no. with each monitor
5 Lead cable set w/adult cup electrodes with Trunk Cable – 01 no. with each module

Item No. 3: Syringe Infusion Pump - (20 Nos.)

Revised Technical Specifications:

1. Description of Function

1.1 The Syringe Infusion Pump provides uniform flow of fluid by Precisely driving the plunger of a syringe down its barrel. It provides accurate and continuous flow rate for precise delivery of I.V. medication in critical medical care.

2. Operational Requirements

2.1 The syringe pump should be programmable, user friendly, safe to use and should have battery backup and comprehensive alarm system. This should be able to integrate in the HIS

2.2 Demonstration of the equipment is a must.

3. Technical Specifications

3.1 Flow rate programmable from 0.1 to 200 ml/hr or more in steps of 0.1 ml/hr with user selectable flow set rate option. SAVE last infusion rate even when the AC power is switched OFF.

3.2 Bolus rate should be programmable to 400 – 500 ml/hr or more with infused volume display. Reminder audio after every 0.5 ml delivered bolus. SAVE last Bolus rate even when the AC power is switched OFF.

3.3 Display of Drug Name with a provision of memorizing 10–15 names by the operator

3.4 Keep Vein Open (KVO) must be available 1.0 ml/hr or set rate if lower than 1.0 ml. User should have choice to disable KVO whenever desired.

3.5 Selectable Occlusion pressure trigger levels selectable from 300/500/900 mmHg

3.6 Must Work on commonly available ISI/CE/FDA APPROVED/CERTIFIED 20, 50/60 ml Syringes with accuracy of minimum of +/-2% or better.
Automatic detection of syringe size & proper fixing. Must provide alarm for wrong loading of syringe such as flanges out of slot; disengaged plunger, unsecured barrel etc.

Anti bolus system to reduce pressure on sudden release of occlusion

Should have comprehensive alarm package including: Occlusion limit exceed alarm, Near end of infusion pre-alarm & alarm, Volume limit pre-alarm & alarm, KVO rate flow, Low battery pre alarm and alarm, AC power failure, Drive disengaged and preventive maintenance.

Rechargeable Battery having at least 5–6 hour backup for about 5ml/hr flow rate with 50ml syringes. Larger battery life and indication of residual life will be preferred.

4. System Configuration Accessories, spares and consumables

4.1 Syringe Infusion Pump –01

4.2 Mounting device/ Docking Station for two or four pumps as per requirement so as to enable to power up to 2-4 pumps with one power cord when mounted on IV pole. – 01

5. Environmental factors

5.1 Shall meet IEC-60601-1-2: 2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

5.2 The unit shall be capable of operating continuously in ambient Temperature of 10 -40deg C and relative humidity of 15-90%

5.3 The unit shall be capable of being stored continuously in ambient temperature of 0 -500 C and relative humidity of 15-90%

Power Supply

6.1 Power input to be 220-240VAC, 50Hz

7. Standards, Safety and Training

7.1 Should be FDA or CE approved product

7.2 Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements

7.3 Manufacturer should be ISO certified for quality standards.

7.4 Certified for meeting IEC60601-2-24: Particular requirements for the safety of infusion pumps and controllers

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

7.6 Electrical Safety Classification Class I/II, Type CF and Internally powered equipment.

7.7 Certified for meeting IEC 60601-1-4 Medical electrical equipment -Part 1 - 4: General requirements for safety - Collateral Standard: Programmable electrical medical systems

8. Documentation

8.1 Certificate of calibration and inspection from factory.

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

8.3 User Manual in English

8.4 Service manual in English

8.5 Log book 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.

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

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