Admn/Prop/82/2019-AIIMS.JDH Dated: 18th March 2020

Subject: Purchase of High End Anesthesia Workstation with Electronic vaporizers for the department of Anesthesiology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of High End Anesthesia Workstation with Electronic vaporizers for the department of Anesthesiology at AIIMS, Jodhpur from M/s GE Healthcare, 3030 Ohmeda Drive, Madision, WI 53718, USA on proprietary basis. The proposal submitted by M/s GE Healthcare, USA and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/82/2019-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 08th April 2020 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.

GE Healthcare

3030 Ohmeda Drive,
Madison, WI 53718
USA
Tel: 608 221 1551

20th November 2019

The Director,
AIIMS
Basni Industrial Area,
MIA 2nd Phase,
Basni, Jodhpur,
Rajasthan 342005

SUBJECT: Proprietary Certificate

This is to certify that GE Healthcare who are established and reputable manufacturers of **Anesthesia Workstation Model Aisys CS2 with Accessories** and having production facility at 3030 Ohmeda Drive, PO Box 7550, Madison, Wisconsin 53707-7550 are the sole manufacturer & proprietor of **Model Aisys CS2 with Aladin2 Cassette and Accessories** in the world and sold directly in India by: Wipro GE Healthcare Pvt. Ltd. Plot No 4; Kadugodi Industrial Area; Bangalore – 560067, Karnataka State, INDIA.

1 -Target End Tidal control for Oxygen & Anesthetic Agent;

2 -Aladdin Cassette,

Above are Proprietary feature of Aisys CS2, and unique parts of Aisys CS2.

Sincerely,

Mike Foulis
Global Product Manager
GEHC CCS – Anesthesia & Respiratory Care

High End Anesthesia Workstation with Electronic Vaporizers

Technical Specification
A. Basic unit:
1. Complete Digital Anesthesia workstation for performing and monitoring inhalation Anesthesia, suitable for Adult as well Child upto neonatal age.
2. It should be capable of providing low-flow techniques to minimize gas and Anesthesia agent consumption for economical day-to-day operation. It should give gas and agent consumption data.
3. The Anesthesia workstation should have in-built Ventilator with colored touch screen 15-inch TFT display, integrated CO2 absorber, In-built & integrated Anesthesia Gas Monitoring facility, Electronic vaporizers and Multi parameter monitor. All these components should be of the same manufacture.
4. Electronic Gas Mixing and Electronic agent mixing.
5. Should have end tidal target control for Anesthetic Agent.
6. The unit should be able to connect to Central pipeline & there should be provision of One PIN index Yoke to connect to One Emergency Gas Cylinder of O2 & N2O each. Pipeline inlet for Oxygen, Air, Nitrous Oxide.
7. The unit should have Powder Coated Steel Trolley with 4 Wheels & 2 Drawers & the front wheels should have locking device. The unit should have Rail on one side to mount other equipment.
8. Unit should have illumination facility over a writing drawer.
9. Gas delivery system with digital virtual display of the flow meters for O2 and N2O/ Air.
10. Electronic Hypoxic guard to provides a nominal minimum 25% concentration of oxygen in O2/N2O mixture.
11. The machine to have Auxiliary Oxygen Flow meter.
12. The machine should have active AGSS facility.
13. Machine should have timer.
14. Oxygen Flush: Range: 25 to 75 L/min.
15. It should be equipped with self-test routines and automatic calibration of all sensors. The machine checks out should calibrate all the sensors, calculate the leak and compliance. Preferable to do even the vaporizer leaks tests in the machine check out is needed.
16. The unit should have Common Gas Outlet for using open circuit & the unit should have easy change over from open circuit to closed circuit or vice-versa.
17. International Standards: - The unit should comply with international Standards & should have CE Marking, AAMI ES60601-1, CSA C22.2 #601.1, EN/IEC 60601-1, ISO 806001-2-13 Quality Systems-Medical Devices Certification.
B. Breathing system (close circuit system)
1. It should be integrated to the CO2 absorber of minimum 0.8 Kg & CO2 absorber should be Single/Double chamber design having easy removal & re-fitting during operation.
2. It should have fully autoclavable at 134 deg. C. It should have Pressure Graduated Metallic APL Valve, and Inspiratory Valve, Expiratory Valve and Bag to Vent switch to easily move from ventilator to manual bag ventilation
3. The machine should have patient airway pressure monitoring giving the P max, Pmean, and Peep values.
4. Machine shall provide circle mode breathing circuit-Reusable closed ckt for adult and neonate.
C. Vaporizers: it Should have provision to connect one or more Electronic vaporizers & the control should be from main screen. Should be provided with Three vaporizers Isoflurane, Sevoflurane and Desflurane (Price of Desflurane should be quoted Separately)
D. Integrated Anesthesia Ventilator: In built Anesthesia Ventilator:
1. It should integrate Microprocessor Controlled & Pneumatically Driven Ventilator with bellows and the same bellows should be useful for Pediatric & Adult Application, thus avoiding change of bellows.
2. The unit should have Fresh Gas De-coupling or Continual fresh gas flow with fresh gas flow compensation

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during mechanical ventilation.
3. Modes of Ventilation: VCV, PCV, PCV-VG, SIMV+PSV (For VCV, PCV), PSV pro (with Apnea Backup).
4. Should have lung recruitment facility.
5. Cardiac Bypass Mode during cardiac bypass Procedure to stop the system from alarming and turns off automatically, when the ventilator is turned back on. Complete Patient spirometry with all the 3 loops and save loop feature should be available.
6. Tidal Volume: Tidal volume delivery 20 to 1500ml (volume control, PCV-VG and SIMV volume 20 to 1000ml; PCV modes 20 to 1500ml).
7. Rate: 4 to 100bpm
8. Peep: 0-30cms H2O
9. Settable I: E ratio, Pause, Trigger (0.2-10L/min), Insp Pressure from 5 upto 60cms H2O.
10. Ventilator shall be capable of 120+L/min peak flow.
11. Compliance Measurement and Trending (Preferable): Measures and displays the patient's compliance to offer an view of the patients lung condition.
12. It should have a high contrast color 15 inch TFT Touch screen Display.
13. Gas Monitoring:- The In-built Anesthesia Gas Monitoring Facility should based on side-stream technology, using InfraRed Photometry Principal & also it offer Automatic Anesthetic Agent Identification.
it should have a display of MAC (Minimum Alveolar Concentration).
14. Alarms: - It should have clear alarms and user information as text massage. It is essential that unit should prompt user for corrective action rather than giving only alarm with no diagnostic message.
E. Specifications for Multi Parameter Patient Monitor:
1. Should be capable of Monitoring Heart rate SPO2, NIBP, ECG, 2x Temp, RR and 2x IBP
2. Should have a Display of 19 inch and above diagonal colour TFT Display, Touch screen.
3. Should operate through Rotary knob & Membrane keyboard.
4. Should have 8 waveform fields.
5. ECG:- Should have provisions to connect 3 or 5 Lead ECG cables
6. NIBP:- Should have NIBP measurement by Osillometric method. Should have Manual/Automatic modes of measurement. Should have a measurement range of 20 to 250 mm Hg.
7. Invasive BP:- Should have 2 channel Invasive Blood pressure (IBP) measurement. – Should have waveform IBP1 and IBP2.
8. Temperature:- Should have provision for two temperature with display of T1 and T2.
9. Respiration:- Should have Respiration by Impedance method.
10. SPO2:- It must use Low perfusion technology to measure oxygen saturation for accuracy during motion artifacts, low perfusion states like shock, bradycardia and hypothermia. Should have SPO2 measurement with plethysmograph, and SPO2 values with range 50% to 100%.
11. Alarm facility:- Should have Alarm facility for HR limits, Arrythmia, ST Segment Limit, and all other parameter limits.
12. Graphic & Trends:- Should have 24 hr. of Graphical and Tabular Trend for NIBP, HR, SPO2, RR, IBP, IBP2, T1, T2, AWRR, ST. Segment.
13. Facility to store snapshots during critical events for waveform review at a later stage.
14. Audio Visual and graded alarming system.
15. Should have depth of Anesthesia Monitoring by means of BIS/ Entropy.
16. Should have NMT
17. Should be upgradable to Cardiac output. (Rate to be quoted)
Anesthesia Charting software Solution System should have Anesthesia Charting facility. It should be supplied with all hardware, software and

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networking cabling etc.
Which includes follows:

1. Server with Minimum of Dual 3GHZ Processor 64 GB RAM and 8TB storage should be quoted.
2. Machine Mounting Arm for the Anaesthesia Model should be Quoted
3. All in One Touch enabled Medical Grade PC for each OT should be provided with following configuration:
   Intel Core i5 Processor 8GB RAM and 120 GB Internal Storage with WIFI.
   With Windows Operating system
4. Charting Software with following modules should be quoted:
   a. Medication Module,
   b. Drug Ordering Module,
   c. Intra-OP Protocols,
   d. Fluid summary charts
   e. Medication summary charts
   f. Vitals charts
   g. Labs data charts
   h. Nursing Summary,
   i. 3 Anaesthesia check with surgical safety checks (WHO check list etc.)
   j. Patient List
5. Networking for each OT with adequate Switch 24 Ports or more if required.
6. Integration cables included for the anesthesia workstation and Patient Monitor in the respective OTs. (Additional devices integration list should be submitted along with Quote for e.g. Infusion Pump, Syringe Pump, Hemofiltration device etc.)
7. HL7 Module for the HIS/LIS Integration should be quoted.
8. System should be capable of Querying the old patient data through the module.
9. System should allow to take print out in PDF format and allow to store the PDF copies of the reports generated.
10. System should be CE OR FDA Certified and should Follow the MDD directive. Certificate for the same should be submitted at the time of Quoting.
11. Customer should have implemented at least of 30 OTs Prior in Private or Government setup in India. And should submit the Install Base list for the same along with the quote.
12. All the User and Technical Manuals with respect to the product should be submitted in the English Language as a soft copy at the time of implementation.

F. System Configuration Accessories, spares and consumables:-
Should be Supplied with the following standard Accessories
1. 5 Lead ECG cable-5 Nos,
2. SPO2 finger probe for Adult-5 Nos and Pediatric application – 2 Nos.
3. SPO2 Neonatal Probe – 2
4. NIBP cuff for Large Adult – 2#, Adult – 5 #, Pediatric – 2#, Neonate – 2# Set and NIBP Hose -2Nos for Adult and one for Neonate Application.
5. 2 IBP cable with 10 Sensors
6. General Temperature Probes- 5#, Pediatric Temperature Probe – 2Nos and Skin – 2Nos.
7. Reusable Adult 3# & Paediatric circuits 2 #
8. Silicon Mask Size 1-5 – 1,2 &5 (1each), 3 & 4 (2each)
9. Reusable Bag – 0.5 Ltr, 1 Ltr & 2ltr – 2 Each
10.Gas Sample Lines – 50 Nos.
11. Water trap – 50 Nos.
9. Entropy Cable with 25 sensors

10. NMT Cable with sensor
11. Complete set of compatible AGSS system with attachment and accessories to be provided
Environmental Factors:-
The unit shall be capable of operating continuously in ambient temperature of 10 – 40 deg C and relative humidity of 15 – 90%.
The unit shall be capable of being stored continuously in ambient temperature of 0 – 50 deg C and relative humidity of 15 – 90%.
Shall meet IEC – 60601-1-2: 2001 (Or Equivalent BIS) General Requirements of safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EM directive.
Power Supply:-
Power input to be 220-240VAC, 50Hz fitted with Indian plug
Should provide Suitable Isolation Transformer with true online UPS with maintenance free Batteries for minimum one-hour back up should be supplied with the system.
Standards, Safety & Training: -
~~Should be US FDA approved product~~ USFDA OR EQUIVALENT
Shall meet the safety requirements as per IEC 60601
Requirements for the safety of electrocardiographic monitoring equipment.
Manufacture/Supplier should have ISO certification for quality standards
Should have local service facility. The service provider should have the necessary equipments recommended by the manufacture to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
Back to back warranty to be taken by the supplier from the principal to supply spares for a minimum period 10 years
Comprehensive warranty for 5 years and provision of AMC/CMC for next 5 years.
Documentation: -
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.

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Medical Superintendent
Chairperson

Dr Pradeep Bhatia
Professor and Head
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Co-Chairperson

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