

### T.No.105/TC/CPP/Anesthesia/2024-25/St.

<u>Subject</u>: Revised specifications (after pre-bid meeting & evaluation of representations) for purchase of Digital Anesthesia Machine with Digital Vaporizer with Integrated Charting System-07Nos. for Anesthesiology & CC, JPNATC, AIIMS.

Dated: 27.08.2025

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# The updated technical specifications are as follows:

- 1. Anesthesia workstation should be advanced, reliable, compact, powder coated and mobile with integrated ventilator, circle absorber, vaporizers, patient monitor and anesthesia gas monitor from the same manufacturer.
- 2. It should have illuminated workspace with the storage space for keeping accessories. Should have central brake to lock the machine.
- 3. It should be suitable for low and minimal flow anesthesia for adults, pediatrics and neonatal patients.

### Display screen:

- 4. It should have display screen of atleast 15" with touch screen facility.
- 5. It should have a battery backup of approximately 1 hour.
- 6. It should have facility to enter patient's demographic data such as age, weight and height for ideal body weight calculation.
- 7. It should have simultaneous display of 3 waveforms and a loop for fast analysis in change in lung mechanics.
- 8. The machine should enable users to obtain a quantitative assessment of anesthetic agent absorption/uptake and consumption, as well as gas usage, both during and post-surgery.
- 9. It should be possible to view P/V and F/V loops. It should also allow user to freeze the loops and set the reference to view the change in lung mechanics.
- 10. It should have RS232 port to interface monitor to transfer the expired parameters on monitor and in-built data output port.

# Fresh gas mixer:

- 11. It should have electronic fresh gas mixer for Oxygen, Nitrous oxide and Air and onscreen virtual flow meter for each gas as per usage should be seen.
- 12. It should have integrated safety feature like electronic hypoxic guard, N2O will be cut off in case of O2 low pressure or failure condition with appropriate alarm on screen.
- 13. In case of electricity and battery failure, manual ventilation using 100 % oxygen and simultaneous delivery of volatile anesthetic agent should be possible.

## Gases and delivery system:

- 14. It should have a facility to connect to the central supply and Gas specific pin index for oxygen and nitrous oxide, one for each gas, with stainless steel clamping bar.
- 15. Non interchangeable threaded gas specific pipeline hose inlets for connection to pipelines for medical oxygen, nitrous oxide, and medical air.
- 16. It should have digital display of pressure gauges on screen for central and cylinder gas supply.
- 17. It should have adjustable pressure relief valve (APL).
- 18. It should have independent fresh gas outlet for connection to Bain's or Magill circuit. It shall be a coaxial 22 mm male/15 mm female connector.
- 19. It should have auxiliary oxygen flow meter integrated in the system.
- 20. Hypoxic Guard to ensure minimum 25 percent oxygen in gas mixture always.
- 21. Oxygen flush with flow of 30 70 LPM.
- 22. It should have integrated anesthesia gas monitor.

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- 23. Machine should prevent gas volume deficiencies for Patient safety during low-flow anesthesia by incorporating an integrated AGM gas recirculation pathway within the machine.
- 24. Should display of inspiratory and expiratory concentration of O<sub>2</sub>, CO<sub>2</sub>, N<sub>2</sub>O, anesthetic agent. Age specific MAC values should be given.
- 25. Automatic detection of anesthetic agent.
- 26. Should have advance total flow predicting tool for optimization of total flow during Low flow anesthesia practice.
- 27. Should have tool to determine precise settings of fresh gas flow during low, minimum and metabolic flow anesthesia.
- 28. Should have real time oxygen uptake measurement tool to titrate etO2 during low flow anesthesia.

#### Vaporizers:

- 29. It should have facility to mount two electronically monitored vaporizers at a time.
- 30. It should have agent specific vaporizer temperature compensated, flow compensated, and back pressure compensated.
- 31. Sevoflurane and Isoflurane from the same manufacturer as anesthesia workstation.

### It should have following features

- 32. Clinically useful range of concentrations.
- 33. Screw cap filler.
- 34. Selectatac / Auto Exclusion mounting
- 35. Latest version (Latest model) only should be quoted, demonstrated along with the brochure.
- 36. It should have transport lock to provide hermetic sealing of agent chamber during transport and storage.
- 37. Should not require any calibration for lifetime.
- 38. Should electronically monitored vaporizer have et-concentration predicting tool for better titration of vaporizer during wash-in and wash-out phase.

## Circle system:

- 39. It should have transparent, autoclavable soda lime canister, vertical during operation and approximately 1 to 1.5 L of total capacity.
- 40. Pre-operative self-test should be fully automatic with measurement of leakage and compliance to be visualized and system should be able to compensate for leakage and compliance to deliver set volumes and pressures.
- 41. should prioritize patient safety by integrating a system that shouldn't increase pressure and volume levels even when adjustments are made to the fresh gas settings during High to Low Flow titration.
- 42. It should have tool free dismantling of breathing system for cleaning, and disinfection process.
- 43. It should have active AGSS (Anesthesia Gas Scavenging System).
- 44. It should be possible to autoclave compact breathing system.
- 45. It should have calibrated APL valve with clear marking showing the level of pressure set. Setting up to 70 cmH2O.
- 46. Facility to change over from open circuits to closed circuit and vice versa.

#### Anesthesia ventilator:

- 47. It should be integrated, electronically controlled and pneumatically/electrically driven.
- 48. Should prioritize patient safety by ensuring uninterrupted ventilation, even in the event of a flow sensor failure during a case.
- 49. The same bellows for adult and pediatric patients.
- 50. Tidal Volume: 20 ml to 1500 ml
- 51. Rate: 3-100 bpm
- 52. It should be possible to limit P maximum.
- 53. It should facility of PEEP of at least up to 20 cmH₂O
- 54. It should display minute volume, peak pressure, PEEP, plateau pressure, mean airway pressure, alarm limits, alarms and alarm messages.
- 55. It should provide the following modes of ventilation:
- 56. Manual /Spontaneous (Man/Spon)
- 57. Volume-controlled ventilation (VC-CMV)
- 58. Pressure-controlled ventilation (PC-CMV)

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- 59. Volume-controlled SIMV + pressure support (VC-SIMV/ PS)
- 60. CPAP/ PS
- 61. It should have trigger threshold from 0.2 to 10 L/min.
- 62. Should have peak flow of 120 L/min or above.
- 63. Safety standard
- 64. It should have European CE from 4 digit notified body or USFDA with 510K number (Country of origin certificate required)/ BIS.
- 65. ISO-13485- "Medical devices -- Quality management systems -- Requirements for regulatory purposes. ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.
- 66. ISO 80601-2-13:2011: Medical electrical equipment -- Part 2-13: Requirements for basic safety and essential performance of an anesthetic workstation.
- 67. The system must meet the requirements about medical electrical equipment in accordance to IEC/EN 60601-1
- 68. Demonstration at the time of technical evaluation with all certificates is compulsory.
- 69. Demonstration with full gas cylinders.
- 70. Scope of supply
- 71. Main unit with integrated ventilator, trolley and drawer
- 72. Anesthesia Mask 1 each for all 5 sizes
- 73. Flow Sensors 10 sets
- 74. Sample line 20 nos
- 75. Water Trap: 20 nos
- 76. Reusable Breathing Circuit Adult/ Pediatric: 1 no
- 77. Reusable Breathing Circuit Neonatal: 1 no

## Specification for IT enabled Patient Monitor for OT

- 1. Should be suitable for adult, pediatric neonatal patients monitoring in fixed environment.
- 2. Should have 19" and above touchscreen display with large fonts and provide access to minimum 10 or more waveforms with ergonomic representation of multi-functionality.
- 3. Monitor should be IT enabled for single point access to web-based applications (like HIS, PACS, PDMS, LIS and more) without requiring extra server, hardware and software
- 4. Should give direct access to Web-based applications, without requiring extra servers or licenses (such as Microsoft® clients, Citrix)
- 5. Should have minimum ECG, NIBP, SpO2, 2 temperature and 2 Invasive pressure as standard and all other parameters should be through upgrades as pods/modules and software.
- 6. Should have basic arrhythmia detection for life-threatening alarms that include asystole, ventricular fibrillation, ventricular tachycardia, and bradycardia and more.
- 7. Should have non-volatile graphic and tabular trending of all monitored parameters as standard for minimum 72 hrs.
- 8. Should have manual as well as automatic setting of screen format with selectable parameter priority & color selection for parameter on screen.
- 9. Should have excellent cable management with as minimum as possible cables at monitor & patient end for maximum comfort to patient as well as user.

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- 10. Should have integrated transport monitor with battery backup of 180min and one-button disconnect and without additional modules or batteries and shall allow transport with all currently monitored parameters remaining active.
- 11. The transport display shall automatically adjust its orientation using a gravitational sensor when it is rotated to a different view.
- 12. The transport monitor should have minimum 5 inches of touch screen and 3 or more waveforms
- 13. It should be US FDA WITH 501 K number / European CE from 4 digit notified body approved / BIS for monitor as well as all the parameters.
- 14. Should have Defibrillator and ESU protection, and ECG Sync
- 15. Ready for wired networking.
- 16. Facility for automatic electronic charting and data management solution with data archival facility for patient monitor and ventilator data. Charts should be seen on separate screen.
- 17. Monitoring solution shall support at least sixteen (16) different customizable configurations, and at least five (5) for the transport component.
- 18. While using another application, the monitor configuration will always allow for continuous viewing of the real-time parameter data
- 19. 360-degree alarm bar & Rotary knob lights up when conformation for user selection is required
- 20. Touchscreen, Rotary knob & keyboard.
- 21. Monitor when interfaced with Anaesthesia Machine, the monitor shall provide capabilities for display of multiparameter sets to be used in lung recruitment procedures through an analysis tool.
- 22. Monitor shall provide the option to connect a secondary display that can be configured independent display without the need for additional hardware and users the ability to configure the location, speed and color of the parameters and their associated waveforms separately to the monitoring workstation.
- 23. Monitor should able to connect to anaesthesia machine and should be able to display ventilator waveforms, parameters and loops.
- 24. Should have following parameters.

#### **ECG**

- 25. 5 lead ECG monitoring with three leads of ECG waveform simultaneously monitoring.
- 26. Should display 12 leads of ECG monitoring
- 27. Range 15 to 300bpm
- 28. Should display 12 leads of ECG by connecting 6/5 ECG lead wires (Reduced lead set algorithm) as standard feature with max. lead positions as per standard lead placement

#### RESPIRATION

- 29. Through impedance pneumography/ capnography method
- 30. Through impedance pneumography

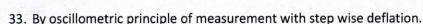
#### SpO<sub>2</sub>

- 31. Should be supplied with Masimo rainbow SET technology with respective sensors
- 32. Should display digital value and Plethysmograph

**NIBP** 

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- 34. Suitable for adult, pediatric, neonatal patients
- 35. Should display Systolic, diastolic, mean pressure in large easy to read display
- 36. Should have manual/ stat mode or automatic mode with adjustable time intervals from 2 240 minutes and adjustable alarm limits
- 37. May have the option of continuous arterial pressure monitoring through non-invasive technique
- 38. IBPs Simultaneous monitoring of 2 Invasive Pressures should be standard and upgradable to 4 Invasive Pressures
- 39. Range: -50 to 360 mmHg
- 40. **Temperature** two temperature one core and second skin simultaneous monitoring and upgradable to 4 Temperature
- 41. Range: -5 to 50Deg C
- 42. Demonstration of quoted model with all required capabilities is a must
- 43. BIS/Entropy to measure depth of anaesthesia (integrated / Stand-alone)
- 44. NMT Neuro muscular transmission (integrated / Stand-alone)

# Following upgrades should be offered - (Quote unit prices in price bid)

- 45. Cardiac Output by thermodilution technique
- 46. Masimo rainbow SET; SpHb, SpOC, SpCO, SpMet or PVI, at the user's discretion from one sensor source.

# Standard Scope of supply for patient monitor must include:

- 47. Cockpit unit with Transport monitor/module- 1no
- 48. 3 and 5 lead ECG Cable 2 no
- 49. SpO2 Masimo set finger sensor with extension cable 2 no
- 50. Skin temperature Probe 2 no
- 51. Rectal /Oesophageal temperature probe 2 no
- 52. NIBP Hose 2 no
- 53. Adult & Paediatric Cuff 4 each
- 54. IBP reusable cable for 4 IBP and 10 pcs disposable transducers
- 55. BIS Module with 10 sensors
- 56. NMT module with 5 sensors
- 57. Instruction for Use.

Note: The other terms & conditions mentioned in the tender will remain same. The bidders are advised to see the above modified specifications (after pre-bid meeting) and quoted their product, make & model accordingly.

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