Admn/Prop/59/2019-AIIMS.JDH Dated: 28th November 2019

Subject: Purchase of Closed Loop Anesthesia Workstation for the department of Anesthesiology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Closed Loop Anesthesia Workstation for the department of Anesthesiology at AIIMS, Jodhpur from M/s Draegerwerk AG & Co., KGaA, Moisilinger Alee 53-55, 23558, Lubeck, Germany on proprietary basis. The proposal submitted by M/s Draegerwerk AG & Co, Germany 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/59/2019-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 20th December 2019 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.

Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference
Zeus IE Proprietary Certificate
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May 3, 2019

Reference: Proprietary Certificate - Dräger Zeus® Infinity® Empowered

This is to inform you that the Dräger Zeus® Infinity® Empowered, specifically designed for the use in clinical routine, is manufactured at Dräger Medical GmbH located at 23542 Lübeck, Germany.

The Dräger Zeus® Infinity® Empowered incorporates some of the following features:

1. Patented turbovent2 ventilator technology that can generate peak inspiratory flow up to 180 L/min.
2. Target Control Anaesthesia (TCA) -The only system available to date that can work on completely closed breathing system and with automatic control of target (TCA) parameters like inspiratory Oxygen concentration (FiO2) and end tidal concentration of anaesthetic agent (Et- agent%).
3. Smart Ventilation Control (SVC) – the new ventilation option of Zeus® Infinity® Empowered Ensures smooth and individualised transition from controlled ventilation to complete spontaneous breathing based on user defined ventilation goal.
4. Integrated Smart Pilot view is a visual support for the anaesthesiologist throughout the entire anaesthesia process using advanced mathematical modelling algorithms, it shows prospective calculated drug concentrations for any given dosage, taking into account known interactions.

These features are unique to Zeus® Infinity® Empowered devices and offered only by Dräger.
This product is presently being imported to India by Draeger India Pvt. Ltd.

Kind regards,

John Barrett
Operating Room Segment Manager – Anaesthesia Product Manager
Asia, Africa, Australia

Specifications for Closed Loop Anesthesia Workstation

General

1 The requirement is of a top of the line Anaesthesia Delivery Platform with integrated closed loop ventilation system, hemodynamic & anesthesia monitoring with patient trend data in the system.

2 The system should conform to IEC 60601 -2- 13 and the electronic & electrical modules should be European CE approved

3 It should be ergonomically designed with integrated drawers, extractable writing table, large table top and doors for media input/output

II Gas Delivery Module

1 It should have pin index yokes for Oxygen and Nitrous Oxide in addition to Central supply connections for Oxygen, Nitrous Oxide and air with clear display of the pressures.

2 It should have a digitally controlled Hypoxic guard system to ensure a minimum of 25% Oxygen in fresh gas flows of > 1 lpm and 250 ml at lesser flows. It should have automatic leak compensation by fresh gas flow adaptation.

3 Should be able to perform Target Controlled anaesthesia by target setting of FiO2 and Et AA. It should have Auto controlled mode with closed loop system that automatically calculate the desired oxygen, carrier gas and volatile agent based on patient's requirement.

4 It should have an independent Oxygen flush @ 35 lpm bypassing all the vaporisers.

5 It should also have an electronically switched external fresh gas outlet for semi open breathing systems. There should also be an auxillary Oxygen flowmeter for flow upto 16 lpm

6 The machine should have following alarm and safety features:

- i. Manual ventilation should be possible if power supply and/or battery failure
- ii. If O2 failure then it should automatically change to closed operation with Air (minimal gas consumption) and also nitrous oxide and anesthetic agent locking with corresponding alarm condition
- iii. If CS failure of (O2, N2O, Air) then there should be automatic alarm condition and change to Air cylinder with electronic monitoring
- iv. It should have uninterruptable power supply for all system components for at least 30 min with continuous battery monitoring
- v. Alarm condition if battery capacity low

III Ventilation Module

1 It should be an electronically controlled and electrically driven ventilator and should not require a driving gas.

2 It should be suitable for all age groups (infant to adult) and should provide for automatic parameter setting

3 It should be open for spontaneous breaths in all mode setting and should have inspiratory peak flow ~ 180 lpm

4 Following Ventilation Modes should be available.

a. Pressure Control/Volume Control Ventilation

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b. SIMV with pressure Control/ Volume Control
c. SIMV with Pressure Support
d. Spontaneous with pressure support with CPAP/PEEP
e. Volume guaranteed Auto flow ventilation
f. Manual/Spontaneous with CPAP/PEEP
g. Apnoea/Ventilation in Pressure Support Mode.
h. Should have Assistant system for target value oriented ventilation (SVC mode) -the target ranges for tidal volume and end-tidal carbon dioxide (etCO2) are defined, and it ensures that ventilation stays within these ranges.

5 Following parameter ranges should be available
a. Tidal Volume : 20 ml to 1500ml
b. Rate - 3 to 80/min
c. Inspiratory Time - 0.2 to 10.0 sec
d. PEEP - 0 to 35 hPa
e. Pmax – 8 - 50 hPa
f. Pressure Support - Upto 50 hPa
g. Flow Trigger - 0.3 to 15 lpm

IV **Breathing System**

1 It should be a compact, light weight, latex free breathing system for closed and semi closed anaesthesia system.
2 There should be intrinsic fresh gas decoupling and compliance correction.
3 There should be an APL valve with pop off function settable to 0 to 70 hPa and completely open in spontaneous position
4 Patient triggered inspiration should be separately sensed.

V **Vaporisers**

1 The machine should have two receptacles/ports selectable through the system
2 It should be suitable for electronically controlled delivery of volatile agents (Injection principle). Setting should be possible for concentration in fresh gas or expired gas (target setting)
3 There should be 3 removable delivery modules (one each for Isoflurane, Desflurane & Sevoflurane) with electronic identification and interlock,
4 Should have volume of anesthetic agent reservoir tank of 315 mL fluid and filling should be possible during the operation and should be protected by AGSS
Delivery range: Fresh-gas control ISO: 0 – 5 kPa; SEV: 0 – 8 kPA; DES: 0 – 18 kPa
Delivery range: Auto control ISO: 0 – 2.5 kPa; SEV: 0 – 5 kPA; DES: 0 – 12 kPa
5 Should have alarm condition for "empty tank"

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VI **Monitoring Systems & Display**

1. Display should consist of single 20" colour touch screen to display upto 8 waveform.
2. There should be automatic actuation of ventilation and gas monitoring when anaesthesia ventilation is started. It should display Oxygen, Nitrous Oxide and anaesthetic agent intake, leak and uptake (including trend of oxygen uptake)
3. The ventilation monitoring & display should include- Tidal Volume, Mechanical/Ventilator Minute Volume, Leak Flow, Peak/Mean/Plateau/PEEP Pressures, Real Time Pressure/Flow/Volume Waveforms, FV/PV Loops and online measurement of lung Compliance & Resistance with R-C trend
4. Breathing Gas monitoring & display should include - Inspired & Expired concentration of Oxygen, Carbon dioxide, Nitrous Oxide and Anaesthesia Agent through side stream technology (waveforms for oxygen & Carbon di Oxide as well)
5. Should be able to use on adults, children and infants with automatic parameter settings according to Radford possible
6. Should display Integrated Metabolic Monitoring and Consumption Calculation
   - Display of current oxygen, nitrous oxide and anesthetic agent uptake, including leakage
   - Display of gas uptake according to STPD standards (Standard Temperature Pressure Dry)
   - Display of anesthetic agent and gas consumption per OR case
   - Cost and amount calculation of anesthetic agent and gas consumption per OR case
   - Possibility to input prices for anesthetic agent
   - Continuous and resettable display of anesthetic agent and gas consumption
   - Trend display of oxygen uptake

VII **Alarms & Safety**

1. There should be a completely automatic system test on switching on Power On Self Test
2. There should be an intelligent alarm management system with audio and video classification of the alarms - Warning, Caution, Advisory
3. There should be central alarm setting on one screen with direct access to the exceeded alarm limit.
4. There should be a central alarm silence
5. Ventilation Alarm - Disconnection, Stenosis, Patient leak, Systems Leak, Hi Inspiratory Resistance, Violation of set parameter upper & Lower limits & Gas Failure
6. Vaporiser low level advisory and empty alarm.
7. Breathing Gas - Blocked sample line, Filled water trap and hi/lo for agent FiO2 & EtCo2
8. It Should be possible to ventilate manually if power & battery fail.
9. It should switch off Nitrous Oxide and volatile agent if Oxygen fails and should switch over to Air. The Central Supply Failure alarm should be displayed on the screen
10. There should be an integrated UPS of ~ 30 minutes for all the system components

VIII **AGSS**

There should be a valveless anaesthetic gas scavenging system with integrated buffer volume. Complete set with attachment and accessories to be provided with the system.

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IX **Miscellaneous**

1. The machine should be supplied with all the necessary accessories in a ready to use condition
2. There should be offer of CMC for atleast 5 years after the warranty is over. Rates for the same should be quoted separately.
3. All the components of anesthesia machine, vaporiser and monitor should of same make and manufacturer

X **Scope of supply**

1. Anaesthesia Machine (3 Gas with 20" Screen)
2. Pipeline Connections for all three gases
3. Central gas supply hoses (Colour coded)
4. Pin Index Yokes for Oxygen & Nitrous Oxide
5. Semi-closed Breathing System
6. Patient Circuit - Adult (x1) & Child (x1)
7. Vaporisers - Isoflurane, Desflurane & Sevoflurane
8. Original manufactured mountings for patient monitor
9. The scope includes supply, installation & commissioning of the machine.
10. Two compatible TCI syringe pumps along with communication cables should be provided with the system.

Specifications of Patient Monitor with Workstation

1. Should be suitable for adult, paediatric neonatal patients monitoring in fixed environment.
2. Should have 20" and above Touchscreen display with large fonts and provide access to minimum 16 and above waveforms with ergonomic representation of multi-functionality
3. Monitor should be IT enabled for single point access to web based applications (like cath Lab, X-ray, HIS 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 event recall minimum up to 150 events, graphical and tabular trends, drug dose calculations, alarm logs, OxyCRG, Oxygen/ventilation & Hemodynamic calculations as standard.
6. Should have minimum ECG, NIBP, SpO2, 4 IBPs, 2 Temperature as standard. All other parameters should be through upgrades as pods/modules and software.
7. Should have Arrhythmia detection including life threatening arrhythmias such as VTACH , ASYST, VFIB as standard feature
8. Should have non-volatile graphic and tabular trending of all monitored parameters as standard for minimum 96hrs.
9. Should have manual as well as automatic setting of screen format with selectable parameter priority & colour selection for parameter on screen.
10. 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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11	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.
12	The transport display shall automatically adjust its orientation using a gravitational sensor when it is rotated to a different view.
13	The user should be able to choose up to 8 pre-configured views, and 8 custom views (with View Editor option) including split-screen views, where at least half of the available screen real estate is dedicated to real time patient information
14	The transport monitor shall be protected against the ingress of water with a rating of IPX4, and be submersible to 30 centimeters of water for ten minutes and withstand a drop of at least one meter and still function afterwards.
15	It should be US FDA approved for monitor as well as all the parameters.
16	Monitor connected to Anethesia machine should have Synchronised OR Mode (alarms) and Cardiac Bypass Mode
17	Monitor should have detailed visualization of Lung Recruitment Therapy for easy assessment and adaptation of therapy strategy.
18	Monitor should document the procedure in form of report and can be printed whenever needed
19	Should have Defibrillator and ESU protection, ECG Sync, IABP interface (ECG and Arterial for triggering and deflation with a device delay of <20 millisec)
20	Ready for wired networking.
21	Facility to provide automatic electronic charting and data management solution with data archival facility for patient monitor and ventilator data in future. It should be single centralised server based for multiple bed's upgrade. Charts should be seen on patient monitor screen itself.
22	User can configure up to 4 profiles per patient category and can save profile by chosen name, thus adapting alarm limits and parameter settings depending on the patient, the acuity, and the environment
23	Should have manual as well as automatic setting of screen format, mini trend and should support min 10 different layout.
24	360-degree alarm bar & Rotary knob lights up when conformation for user selection is required
25	Touchscreen, Rotary knob & keyboard mouse interface.
26	SAW (Surface Acoustic Waveform) touchscreen technology enables crystal clear screen for better readability as used for display of HIS, LIS & PACS images.
27	Large fonts and provide access to upto 32 waveforms
28	Upto 96 hours of real time trend and patient information at the bedside as standard Should have following parameters
29	ECG 6 lead ECG monitoring with three leads of ECG waveform simultaneously monitoring. Should display 12 leads of ECG monitoring Range 15 to 300bpm

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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

30 RESPIRATION
Through impedance pneumography/ Capnography method

31 SpO2 - Should be upgradeable to dual SpO2. Monitor should have both Masimo and Nellcor Oximax technology on offer.
Should be supplied with Nellcor technology with two sensors each for Adult & Pediatric use
Should display digital value and Plethysmograph

32 NIBP
By oscillometric principle of measurement with step wise deflation.
Suitable for adult, pediatric , neonatal patients, to be supplied with two cuffs each for adult , pediatric and infant use.
Should display Systolic, diastolic, mean pressure in large easy to read display
Should have manual/ stat mode or automatic mode with adjustable time intervals from 2 – 240 minutes and adjustable alarm limits
Monitor should have capability for continuous arterial pressure monitoring through non-invasive technique – preferred

33 IBPs - Simultaneous monitoring of 4 IBP's should be standard and should be upgradable to 8 IBPs. 2 IBP intermittent cable, 10 disposable pressure transducers to be supplied.

34 Temperature - two temperature one core and second skin simultaneous monitoring. (One core & one skin probe) - Range: -5 to 50Deg C

35 Neuro Muscular Monitoring (NMT) should be modular and feasibility to use it in any OR independently.

36 BISx Module for measuring depth of anesthesia with 10 adult BIS sensors feasibility to use it in any OR independently.

37 Monitor should be ready for interface with quoted Anaesthesia machine displaying ventilation parameters, trends, waveforms & loops.

38 Should be upgradable to – (Quote unit prices in price bid)
1 Masimo rainbow SET; SpHb, SpOC, SpCO, SpMet or PVI, at the users discretion from one sensor source.
2 Cardiac Output module for measuring the cardiac output using the thermodilution technique with four Invasive pressure channels.

39 The monitor should be capable of connecting upto two independent display which is completely configurable and does not mimic the main display

40 The monitor should be capable of showing display of decision support software for visualizing anesthetic drug effects based on pharmacology model.

41 Monitor should be capable to measure the body core temperature continuously and non-invasively on the patient's forehead.

Additionally, the closed loop anesthesia system should have the following :-

Pharmacokinetic display

Trend graph with prediction for supported volatile anesthetic agent and intravenous drugs to monitor the measured end tidal concentration and calculated effect concentration

20 min time scale for prediction; 45 min time scale for trend

Time scale is scrollable from 60 minutes before the beginning of the case until the end of the preview

Automatically, display areas that are not used will be hided

Display of the effect site concentration as numerical value

Pharmacodynamic / interactive display

Visualization of synergetic and additive drug effect on a screen in a 2D pharmacodynamic diagram including prediction

Possibility to use volatile anesthesia, intravenous anesthesia or both in combination

Monitor volatile and intravenous anesthesia on same screen

Display of pharmacodynamic reference stimuli (isobole) that represent light and deeper anesthesia

Calculation of additive pharmacodynamics of propofol and one volatile drug

Possibility to display the interaction of more than one volatile hypnotic

Possibility to display the interaction of one intravenous and one volatile hypnotic

Possibility to display the interaction of more than one opioid

Display of combined effect between hypnotics and opioids in comparison to reference stimuli as trend and numerical value

Display of Noxious Stimulus Response Index (NSRI) to show the depth of anesthesia

Supported drugs:

Calculation of effect concentration for volatile hypnotics: Sevoflurane, Desflurane, Isoflurane

Calculation of effect concentration for intravenous opioids: Propofol/Alfentanil, Fentanyl, Remifentanil, Sufentanil

Calculation of effect concentration for intravenous muscle relaxants: Pancuronium, Rocuronium

Calculation and display of up to two hypnotics (intravenous and/or volatile) and up to three opioids

Calculation and display of interaction between N2O and up to two hypnotics and up to three opioids

Possibility to show the prediction of effect concentration even during setting process

Additional functions:

Setting a manually given bolus

Possibility to enter dosing rate manually into the monitoring display

Possibility to set different event markers to document the individual patient status

Allocation of event markers for subsequent documentation

Display of calculated necessary time to reach the reference stimulus for light anesthesia

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Specifications for connections:

Application should be compatible with following pumps:
B.Braun – Perfusor Space (up to three pumps)
Fresenius Orchestra Base A (up to four pumps)
Fresenius Orchestra Base Primea (up to four pumps)
Carefusion Alaris GH, PK or TIVA with gateway
Terumo Terufusion (up to two pumps)

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