

HSCC I Ltd.

AMENDMENT – V

Dated: - 16.03.2017

Subject: Amendment to the tender Enquiry Document.

Tender Ref: HSCC/KCGMC/Medical Equipment/2015-06/12 dated 03.02.17

KCGMC has revised the specification of Item No.1 Dental Chair Unit as per the following:

Item No.1: Dental Chair Unit

Sr. No.	Name of equipment	Revised specifications
1 (a)	Dental chair	<ul style="list-style-type: none">• Medium Dental Chair with all attachments• Anti crushing seamless upholstery (laminated for optimal hygiene) of good material and soothing color• Fully adjustable backrest and headrest• Electrically operated <u>autowater</u> control for basin/bowl which is ceramic• Body of the chair and unit is painted and non-rustable and non painted parts should be electroplated of good quality. High density stable steel base with minimum 15 mm thickness protected by an anti-slip rubberized sleeve to avoid electrical hazards to patient & the doctors. With German/Japanese/European/USA up-down and backrest motors.• Sensor controlled lights. White & cool 3 LED Dental light with minimum intensity of <u>35000</u> Lux.• Autoclavable steel tray• <u>High & Low vacuum</u> motorized suction with <u>continuous non-stop function</u>, auto drain and auto flush system with minimum 0.5 hp motor• Ergonomic pneumatic doctor's stool <u>and assistant's stool</u> with adjustable backrest tilt and foot rest• <u>Latest overhead delivery system with attachment of one high speed Air Rotor terminal with water control on coupling supplied with original CE 380000 rpm handpiece, one high speed fiber-optic air-rotor terminal supplied with handpiece, one brushless</u>

		<p><u>micromotor (40000 rpm) terminal having straight and contra angle handpieces, LED light cure unit on unit sides, in-built Piezon ultrasonic scaler</u></p> <ul style="list-style-type: none">• <u>3 way syringes (tip autoclavable, with 4 spare tips) one on unit side and other on the assistant side. Positioning control on both operator and assistant's side as well as foot control</u>• With ultrasonic scaler and endo-unit with <u>both perio and endotypesscaler tips</u> (minimum 7), autoclavablehandpiece, with no heat generation 30,000 oscillations per sec, ISI ISO certified Piezo electronic technology. <u>FDA or CE approved.</u>• Mounted dental X-ray box (Dental LED X-ray viewer) with provision for mounting of LCD monitor• Water control for air rotor <p>Delivery system with Light cure unit with following specifications</p> <ul style="list-style-type: none">• <u>Minimum intensity 800 mW/cm²</u>, 60 deg Angle probe or light guide with 1 pistol grip handpiece, eye protection shield, power source of 230v-115v, wave length: 450-500 nm, a short beep sound set at 10 sec or 5 sec, internal voltage regulation, minimum one year warranty, <u>FDA or CE approved.</u>• Memory programming for chair positions as well as zero position. <p>System Configuration Accessories, spares and consumables</p> <ul style="list-style-type: none">• All consumables required for installation and standardization of system to be given free of cost.• Complete installation of the system including water input and drainage system has to be installed. <p>Power Supply</p> <ul style="list-style-type: none">• Power input to be 220-240VAC, 50Hz• Five KV Servo Voltage stabilizer of appropriate ratings meeting ISI Specifications.(Input 160-260 V and output 220-240 V and 50 Hz)
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		<p>Standards, Safety and Training</p> <ul style="list-style-type: none">• Should be USFDA/ European CE approved product• Manufacturer/Supplier should have ISO certification for quality standards.• Electrical safety conforms to standards for electrical safety IEC- 60601 / IS-13450. <p>Documentation</p> <ul style="list-style-type: none">• User/Technical/Maintenance manuals to be supplied in English. Certificate of calibration and inspection.• List of important spare parts, handpieces, and accessories with their part number and costing• 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.
1(b)	Autoclave	Table front loading with International standards, Fully automatic Micro-processor based control Temperature- 121°C, 134° C Wet & Dry Cycle Capacity 20 L With Accessories, ISI, ISO Certified Capacity -22 litre, ISI, ISO Certified, FDA, CE, UL or BIS Approved.
1(c)	Compressor	Oil free compressor, 1 HP with silicon filter and dryer (Medical Grade)
1(d)	Glass bead sterilizer	Digital ISI, ISO Certified, FDA, CE, UL or BIS Approved

KCGMC has revised the specification, quantity and EMD of Item No. 3 ICU Ventilator – Neonatal as per the following:

Quantity revised to : 02

EMD revised to : Rs.80,000/-

Specification : As per the details mentioned in the next page

Specifications for neonatal ventilators

1. The ventilator should be microprocessor controlled designed for neonatal use with possibility to upgrade with additional features.
2. Continuous flow, pressure limited, time cycled ventilator design.
3. Ventilator should be **US FDA and European CE certified** and the company should submit the respective certificate of US FDA and European CE.
4. Ventilator should be provided with good quality medical air compressor (**European CE/US FDA**) marked. Also the ventilator should be operational with central compressed air supply also.
5. One Training CD/DVD to be provided with each ventilator.
6. The ventilator should be supplied with a servo controlled heated wire humidifier (autoclavable) along with a autoclavable and reusable patient circuit.
7. **Battery**- back up of minimum 30 minutes. The battery should be integrated and provide backup to both ventilator and air compressor.
8. The ventilator should have **integrated nebulizer facility** with capability to deliver fine particle size of ≤ 3 micron aerosols and to be used in on line with ventilator.
9. **Ventilator modes:**
 - IMV/IPPV
 - CPAP INCLUDING NON INVASIVE VENTILATION
 - SIMV, SIPPV/Assist control
 - Pressure support mode of ventilation
 - Apnea back up ventilation
 - High frequency oscillatory ventilation- oscillating diaphragm/jet/piston based with active expiration.
In high frequency mode, the ventilator must be able to provide high frequency ventilation successfully to entire neonatal weight range i.e. (500gm to 4 kg).
 - Volume targeted/ guarantee mode of ventilation with ability to deliver and monitor tidal volume as low as 1-2 ml. (range- 2ml to 50 ml).
10. Ventilator should have the following features in Pressure support/Volume guarantee mode:-
 - It should be possible to give leakage adapted inspiratory trigger during pressure support to spontaneously breathing patients with a set volume guarantee.
 - Volume guarantee should be regulated with lowest possible airway pressure within a set of PIP.
 - It should be possible to adjust the volume guarantee manually as per patient requirement.
11. **Should have integrated high resolution LCD screen** (minimum 10 inch color display) with touch screen facility for real time display of scalar (pressure, flow and volume against time) and loop (pressure-volume, volume-flow and pressure-flow). Graphic display of at least 3 waveforms together out of choice of flow, volume and pressure versus time with a facility

- to freeze these waveforms. Facility for loops together with a facility to freeze the same. Should have graphical as well as tabular trend facility of data upto 24 hours.
- 12. Digital display** of FiO₂, peak pressure, MAP, CPAP/PEEP, expiratory tidal volume, expiratory minute volume, total frequency, spontaneous frequency, lung function monitoring including compliance, resistance, lung distension coefficient (C₂₀/C), lung time constant, rate volume ratio etc.
- 13.** Should have built in log book for recording events like various alarms.
- 14. Integrated monitoring:** Integrated volume and pressure monitoring i.e. monitoring of PEEP P_{max}, P_{mean} and VT, VT_{spont}, MV and MV_{leak}. The volume monitoring should have NTPD TO BTPS correction. Integrated monitoring of FiO₂.
- 15.** Monitoring of I:E, frequency and Spontaneous frequency.
- 16. Settings Range:**
- Trigger flow/volume leak adapted
 - PIP range – 8 to 60 cm H₂O.
 - PEEP/CPAP – 0 to 20 mbar.
 - I: E ratio 1:0 to 1: 10.
 - Inspiratory time 0.1 to 2 seconds.
 - Expiratory time 0.2 to 30 seconds.
 - Frequency upto 200 BPM
 - Base flow (VIVE) 1 to 30 LPM.
 - Synchronization – patient synchronization with adjustable flow trigger.
 - Higher frequency amplitude- 1 to 100%
 - Integrated blender for Oxygen- 21 to 100%.
- 17.** Monitoring of flow: at the Y piece with facility to activate or deactivate it.
- 18.** Should measure parameters in HFOV like: DCO₂, VtHF, MV_{im}, VT_{im}.
- 19. Audio-visual alarms with advisory on-screen message:** MV high/low; Apnea; Tube obstruction; Fio₂ high/low; PIP high/low; PEEP/CPAP low/high; fail to cycle, gas supply low, power failure, ventilator inoperative; alarm log book.
- 20.** The ventilator should show trends of important parameters viz: C,R,Fio₂,MAP etc. for evaluation of patient improvement.
- 21.** The ventilator should have automatic compensation for leakage and should monitor and display leakages
- 22.** Ventilator should have upgradation facility with EtCO₂. It should have facility to set up expiratory flow different than inspiratory flow to help in EtCO₂ flush.
- 23.** Oxygen sensor: The ventilator should have permanent electronic Oxygen sensor. The company should provide lifetime warranty on Oxygen sensor and replace free of cost if it becomes malfunctional. The machine should have automatic calibration for Oxygen sensor.
- 24. Scope of supply** (with each ventilator)
- Ventilator on trolley with wheels and brake facility.
 - Circuit support arm for holding the circuit.
 - Integral medical air compressor(European CE approved)

- Humidifier- servo controlled heated wire humidifier (autoclavable)-2 with each ventilator. (European CE/US FDA approved)
- 2 hose sets for conventional (autoclavable and reusable) neonatal ventilation circuit.
- 5 hose sets of disposable conventional neonatal ventilator circuit.
- 1 hose set for High frequency ventilation (autoclavable and reusable)
- Bacterial filters
- Flow sensors (2 reusable and autoclavable with each ventilator). If disposable- then minimum 30 to be supplied with each ventilator.
- Oxygen sensor.
- Oxygen connecting hose
- Air connecting hose
- Test lung (one with each ventilator)
- Heater wire (3 each)
- Temperature probe (3 each)
- Expiratory valve/expiratory cassette (2 reusable, autoclavable with each ventilator)
- Nasal interface (3 in number) with nasal mask (4 each of all sizes) and nasal prongs (4 each of all sizes) and bonnet (5 each of only preterm size) with each ventilator.
- Integral battery (back up 30 minutes)
- Instruction manual (original, not photocopy).
- Original literature and not photocopy to be supplied with quotation.
- Training cd/dvd (1 each)

25. Items covered under warranty/CMC:

- Prices of all consumables/accessories/essential spares/expanables should be quoted separately and frozen for the period including warranty and CMC.

26. The company should provide local functional service facility for after sales service and should have necessary equipments to carry out preventive maintenance tests.

27. Onsite physical demonstration and training of the equipment to all the end users with all the requested facilities is mandatory.

28. Company should certify that the model quoted is latest and not obsolete and spares and consumables are available for 6 years after warranty.

29. The ventilator should have:

- RS 232C port for data transfer and software compatible with windows.
- Provision for future software/hardware upgrades should be available.

Optional: PC software for archiving and analysis and Communication interface with laptop

All other terms and conditions of the tender enquiry document shall remain unchanged.

Prospective bidders are advised to regularly visit HSCC website/ CPPP website for corrigendum /amendments etc. if any, as these will be notified on these portals only. No separate advertisement will published in the news papers in this regard.

s/d
CGM, HSCC India Limited
For and on behalf of DGMR, Panchkula