HSCC/SJH/Med.Eqpt./2016 Date: 21.12.2016

Amendment-VI

Ref.: Tender No. HSCC/SJH/Med.Eqpt./2016/23 dt. 25.10.2016.

Sub.: Procurement of Medical Equipment for New Emergency Block & Super-Specialty Block at Safderjung Hospital, New Delhi.

It is informed that amendments have been received from Safdarjung Hospital (Copy Enclosed) in view of the pre –bid meeting queries submitted by the prospective bidders. These are for item no. 1,2,4,5,6,7,8 and amendment to be uploaded on the website are as mentioned below. The bid submission date for item no. 1,2,3,4,5,6,7,8,9,&10 is extended from 21.12.2016 to 28.12.2016 .

Technical Amendment:

Item No. 1

Specification for Operation table for CTVS Surgeries

1. It should be a latest electro hydraulic operating table with five sections table top with thoracic/kidney elevation and having specialized accessories.
2. Column with stainless steel pedestal base should be with four swivel castors and having special attachment with a fifth motorized wheel battery drive 360 deg. rotatable through hand controls.
3. Radioulucent table top should have 5 sections and motorized sections for Kidney bridge, back/leg enabling preferably different pre-programmed positions.
4. Specific table top reconfiguration should be quick and uncomplicated. Should have head rest with gas spring.
5. It should have all powered motorized movements including Trendelenburg, Anti – Trendelenburg, Lateral tilt, Leg section, Back section, Slide, all must happen with electro hydraulic drives.
6. The table top should be made up of scratch-less X-Ray/ C arm translucent material and should provide full access for C- arm permitting high quality images and should allow easy x ray with cassette holder bracket.
7. Table and radiolucent table top and extensions should be made of stainless steel / aluminum and carbon and table top should be scratch resistant.
8. Should have removable and interchangeable head and leg sections with an auto locking mechanism to suit different functions and orientation identifiable.
9. Should have latest cordless / corded remote hand control for all movements. The LED/LCD screen of the remote should be backlit and to provide pictorial display of memory programmed table and patient positions for quick adjustments.
10. Should achieve zero level position by pressing single button from the handset.
11. The table should be equipped with both electronic override standby control panel on the column body offering most motorized controls as in the hand controller with manual foot operated backup.
12. The system should have electrical and functional impact collision prevention safety with microprocessor sensors with interlock light & sound indicator to avoid collisions between the motorized sections and the table or the floor.
13. Mattress polyurethane foam must be moulded, antistatic with no seams and easy to fix Velcro/Pins system to stop slippage.
14. Should have maintenance free batteries which can be charged via a separate charging cable that also serves for direct mains operation, if needed. Should have battery discharge status on handset.
15. Should have safe patient weight lead capacity of at least 270kg or more in all positions. The stationary patient weight capacity. Should be 450 kg or more. The literature should support both types of weight capacities for table.

16. The table should have additional foot operated control unit for Trendelenburg/ anti-trendelenburg tilt and height.
17. It should have polished stainless steel base with fully accessible bellows, easily cleanable for disinfections to improve hygiene and working conditions in the O.T.
18. Technical Specification:-+/-5% deviation is allowed
    Trendelenburg / anti – trendelenburg_> +/- 30 deg.
    Lateral tilt : +/- 20 deg.
    Standard leg section up/down : +10 deg. To -90 deg.
    Motorized back: +80 deg./ -40 deg.
    Motorized longitudinal slide 250-400mm on both side leg and head of the patient weight support up to 350 kg.
    Length: 2100-2200mm
    Width across side bars: 520-580mm
    Minimum height: 620-670 mm
    Maximum height: 1100-1150mm
    Head section tilt adjustment: +/-45deg. And slide feature on double articulated.
    Flex/reflex: 220deg./120deg.
    Thoracic /kidney elevator or table break with elevation of minimum 3 inches.
    Power input to be 220-240VAC,50Hz. Fitted with Indian plug.
19. <u>SET of accessories from same source as table:</u>

a. L-frame for screen for CTVS surgeries.
b. Arm positioning support with radiolucent pad and clamps- one pair
c. Shoulder supports with clamps – one pair
d. Anesthesia traction type clamps- one pair
e. Infusion pole – 1 no
f. Body strap with locking clamps – 2 nos. (one large and one extra large)
g. Raised arm support - one
h. Lateral support type: articulate both vertically and laterally – one pair
i. Leg/thigh support pads with vertical post ball socket type: 1 pair with gel pad pressure management.
j. HEAD Gel pad rings: 2 nos (one each for adult and paediatric use)
k. Set of Gel 3 D pads for supporting – Sacral pad, heels pad (pair) and lateral body positioned gel pad- 1 each

20. Table base should be small compatible with Da Vinci Robotic System.
21. Terms:
    1. The quoted equipment should be having USFDA approval, European CE certification and should confirm to CE & IEC Standards for such category of equipment meeting safely standards as per 93/42 EEC. Should meet IEC 601-2-46 (EN 60601-2-46) safety regulations applicable only to surgical tables.
    2. Original catalogue and literature to be enclosed.

Item No. 2

Equipment Specifications for IABP (Intra Aortic Balloon Pump) – High End

1.Description of Function

Intra-aortic balloon pump (IABP) is a mechanical device that is used to decrease
Myocardial oxygen demand while at the same time increasing cardiac output. By increasing cardiac output it also increases coronary blood flow and therefore myocardial oxygen delivery.

2.Operational Requirements

2.1 Microprocessor/microcontroller based system. System should be complete with Display Control system and pneumatic drive unit.

3. **Technical Specifications**

3.1 Pneumatics:
Drive System: Stepper motor driven bellows/ Compressor

Drive gas-helium (available with disposable canister or refillable cylinder.

Pumping Volume: 0.5cc-50cc Counter pulsation rate: 40-200 pulsations per minute

3.2 In Automatic Mode: System should be capable of automatically selecting appropriate trigger i.e. ECG or Pressure and also accurately select the inflation and deflation points, in automatic mode. In automatic mode of operation user should be in control of the deflation point. In Automatic mode Advance software should automatically adapt the timings for various rhythms and rate variations, without any user intervention. In Automatic mode it should automatically identify Arrhythmias and adopt R wave deflation mode for better patient support, without any user intervention In Manual mode the system allows user control of most of the pump functions.
3.3 Should be able to trigger on 7 mm Hg of Pulse pressure when used in Pressure Trigger mode
3.4 Single key start-up to make it fast, user friendly and easy to use
3.5 Should be able to display at least 3 wave forms as ECG, Invasive Pressure and Balloon Pressure wave form & Pace maker spikes if paced.
3.6 Large display for brighter and very good visibility from a distance in lighting conditions
3.7 On screen indication for Helium level in the cylinder and battery level for timely intervention and correction.
3.8 ECG inflation marker to indicate inflation period on ECG which can be useful when arterial pressure form is not available.
3.9 On screen indication of standby time and should give alarm after 15-30 minutes, to draw users attention on the system being on standby
3.10 IABP to function without any disturbance, when cautery is used on patient; when on ECG trigger mode.
3.11 Optical Blood leak detect for early indication of blood coming into the balloon lumen due to IABP leak

3.12 Should have extensive Help Text available during startup to make the system easy to use even for new users.
3.13 Should give extensive Help messages to correct the alarm conditions that are specific to the alarm condition. This should help the user to overcome the alarm problems immediately and with ease.
3.14 Should be capable of removing condensation automatically without user intervention and should be maintenance free.
3.15 Should have Peripheral Vascular Doppler for detecting limb ischemia, which is attached to the main equipment
3.16 Should have automatic Altitude correction to make it safer for the use during Air Transport
3.17 Should have software which allows the user to monitor the IABP from any remote location via a modem
3.18 In-built Comprehensive Service Diagnostics to help the technician to locate the fault immediately
3.19 Should have capability to connect on the Hospital network
3.20 Integrated Printer OR Chart recorder to print the reports

4. **System Configuration Accessories, spares and consumables**

4.1 System as specified-

4.2 System should be supplied with the following:

ECG cable with Refillable Helium cylinder Compatible with the IABP system

Qty:3 Nos

4.3 Intra Aortic Balloon Catheter for Adults, Size: 30cc Qty:2 Nos
Intra Aortic Balloon Catheter for Adults, Size: 34cc Qty:2 Nos

Reusable Invasive Blood pressure transducer system with pressure flush device system. Qty:2 Nos

5 **Environmental factors**

5.1 Shall meet IEC-606001-1-2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC;EMC directive.

5.2 The unit shall be capable of being stored continuously in ambient temperature of 0-40 deg C and relative humidity

5.3 The unit shall be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity of 1-90%

6. Power Supply
6.1.1 Power input to be 170-270 V AC,50Hz fitted with Indian plug
6.2 On line UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up

7. Standards, Safety and Training
7.1 Should be FDAand CE/UL or BIS approved product
7.2 Manufacturer/Supplier should have ISO certification for quality standards.

8. Documentation

8.1 User/Technical/Maintenance manuals to be supplied in English

8.2 Certificate of calibration and inspection

8.3 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.

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

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

9.Should have 5 years guarantee + 5 years comprehensive warranty.

Model should have be latest generation
Should have local service facility.

10 Company should make sure that after getting the complaint that instrument is non functional/malfunctional (telephonically or else) instrument must be functional within 24 hours and this period should be deducted from the warranty period or the company will provide the replacement of same or higher configuration equipment.

11 Demonstration is a must.

Item No. 4

Syringe Infusion Pump

1) The syringe pump should be programmable, user friendly, safe to use and should have battery backup and comprehensive alarm system.
2) Must Work on commonly available standard 5ml/10ml/20ml/50ml/60 ml Syringes with accuracy of minimum of +/- 2% or better, with automatic syringe size recognition.
3) US-FDA approved product.
4) Flow rate programmable from 0.1 to 1000 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.
5) Bolus rate should be programmable to 40 to 1000 ml/hr or more with infused volume display and one key press bolus. Reminder audio after every 1 ml delivered.
6) Display of Drug directory of more than 50 drugs, customized and adjustable.
7) Key board locking system for patient safety.
8) Keep Vein Open (KVO) must be available at 0.1 ml or set rate.
9) Selectable Occlusion pressure trigger levels selectable from 300/500/900 mmHg./ atleast 3 selectable levels.
10) 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.
11) Manual pusher with plunger protection guard.
12) Anti bolus system to reduce pressure on sudden release of occlusion.
13) Should have comprehensive ALARM package including: Occlusion limit exceed alarm. Near end of infusion alarm, volume limit pre-alarm & alarm, KVO rate flow, Low battery alarm, AC power failure and Drive disengaged alarm.
14) Rechargeable Battery having at least 1 hours backup for about 5ml/hr flow rate with 50ml syringes. Larger battery life and indication of residual life will be preferred.
15) Mounting device / Docking Station for at least four pumps as per requirement so as to enable to power up to 4 pumps with one power cord when mounted on IV pole.
16) The unit shall be capable of stored and operating continuously in ambient temperature of 10 – 50deg C and relative humidity of 15-90%
17) Power input to be 220-240VAC, 50Hz.
18) 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.
19) User Manual and service manual in English.
20) Should have local service facility. The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
21) List of important spare parts and accessories with their part number and costing.
22) Bidder has to give demonstration of the quoted model.

Item No.5

INTUBATING VIDEO BRONCHOSCOPE (combination of Adult and paediatric)

Technical Specification

1. Flexible Video Endoscope with CMOS/CCD chip on tip for digitally transferring the image to the screen. Intubation Endoscope to display Full Frame 4:3 Imaging. The video processor should be provided with suitable cable(s) to display the image directly on 19" size video monitor. Product certification: USFDA & EUROPEAN CE
2. The price of the medical grade video monitor, video processor, and adult / pediatric video bronchoscope should be quoted separately also.
3. It should have a video processor to process CMOS/CCD video on screen; the video processor should send signal to Video Bronchoscope to internal LED/Xenon of suitable wattage light for producing / enhancing / adjusting light to display the area. Product certification: USFDA & EUROPEAN CE
4. Automatic / manual white balance facility should be available.
5. Documentation of Video & still images should be possible through software on computer. It should be possible to record images on data card or USB drive in JPEG and MPEG4 format, which can be easily transferred to the computer/laptop. Documented videos & still images should be easily recalled on the monitor. It should have internal memory card (SD) to store data and should be able to provide back up on USB hard drive. USB HDD 1 Nos. minimum 4GB should be provided.
6. The system should be provided with battery back-up / UPS of suitable rating (operating time – 90 minutes or more)
7. Flexible Video Endoscope should be light weight & portable high resolution.
8. 10 or more Airway Guide (cum Bite block; all sizes) for oral intubation should be provided with the set.
9. TUBE HOLDER should be a part of standard accessory.
10. It should be supplied with mobile trolley with mounting stand for 19" monitor from OEM.
11. The mobile trolley should have basket for keeping accessories.
12. The Video scope should be supplied with tray system for disinfection and storage from OEM, for both pediatric and adult.
13. Set should include – Suction Valves, Leakage tester, Tube holder irrigation adaptor, Cleaning brush as standard accessories.
14. **Technical details of 'PEDIATRIC'** Flexible video Bronchoscope: Tip deflection UP/DOWN: $140^0/130^0$ or more, Angle of view 100^0 or more, Working Length: at least 60 cm or more, Total length: at least 85 cm or more, working Channel inner diameter: at least 1.2 mm or more, Distal Tip Outer Deameter: between 3.7-4.2 mm; Product certification: USFDA & EUROPEAN CE
15. **Technical details of 'ADULT'** Flexible Video bronchoscope : Tip deflection UP/DOWN : $140^0/130^0$ or more, Angle of view 100^0or more, Working Length: at least 60 cm, Total length: at least 85 cm or more, Working Channel inner diameter: at least 2.0 mm or more, Distal Tip Outer Diameter: between 5.0-5.5 mm. Product certification: USFDA & EUROPEAN CE.

Item No. 6

Neonatal intubation fiberscope

Fibrescope containing separate light bundle for light and image to be used for intubation with OD 2.2 - 2.8 mm.

- Deflection of tip should 130-180^0 up and 110-140^0 down, with integrated fibreoptic light transmission
- Working length should be 550mm or more.
- Should be waterproof and fully immersible for cleaning and disinfection.
- Angle of view should be 85 degree or more and direction 0 degree.
- Should be US FDA & European CE Approved.

Combined / Compact Camera, LED light Source & Monitor Module

- The system should be compact and portable suitable for a variety of endoscopic procedures in operating rooms and intensive care.
- Should be all-in-one unit should consist of everything needed for endoscopic imaging, Video recording, and viewing of saved Videos, the monitor, camera, and light source

Display Special Features: Should give a crystal clear display with:

- At least 15" LED display
- LED backlight display technology for extended service life, enhanced image brightness and reduced power consumption
- Image rotation
- 24 bit color depth for lifelike color display
- DVI video output for brilliant transmission quality

LED Light source

- High-performance LED light source: Light output similar 55 Watts or more
- Color temperature of 6000 K – similar to daylight – guarantees color fidelity
- Long lamp life with an average lamp life of 30,000 hours

Flexible storage options

- SD slot for high storage capacity
- USB ports for external hard drives and USB sticks

Easy & Reliable Control

Membrane keyboard included, suitable for wipe-down disinfection

- Hot keys for rapid and direct manipulation
- Arrow buttons for intuitive control

- Connection socket for pedal control without lag time
- Stroboscopy mode can be activated via a special footswitch

Camera head-Tech specifications

- Image sensor: ¼" CCD-Chip.
- Resolution: > 450 lines (horizontal)
- Signal-to-noise ratio: > = 60 dB.
- AGC: Microprocessor controlled with integrated optical zoom lens system 25.50mm.
- Min. sensitivity: 3 Lux (f 1.4).

Trolley and light cable

Should be provided with a fibreoptic light cable dia 3.5mm and length 180cm approx or more.

Also a suitable trolley should be provided by same manufacturer.

All the above equipments should be manufactured from one company

Standard set of accessories:-

Carrying case	: 1 nos.
Owners manual	: 2 nos.
Pressure compensation cap	: 1 no.
Leak taster	: 1 no.

Terms & Conditions

Preventive machine maintenance four times in a year.

Response time for acknowledgment of complaint 30 minutes.

Response time for physical presence within one working day.

Uptime 355 days in a year.Downtime 48 hours with a penalty of R

Item No. 7

SPECIFICATION FOR PORTABLE VENTILATOR

1. Should be microprocessor based Portable Ventilator for use in Emergency Transport/ Intra Hospital Transport purpose. It can be used from infant to adult patients.
2. It should be less than 7 Kgs. It should have in built source of compressor and work with high pressure hospital pipe line/cylinders for variable Fio2.
3. It should have volume control and pressure control ventilation with following modes.
   VCV and AVCV, PCV and APCV, SIMV-(volume) with PS, SIMV-(pressure) with PS, PSV, CPAP, Bipap/Bi –phasic ventilation, Non-invasive ventilation in VCV,PCV,SIMV,CPAP,BIPAP

4. It should have the following setting parameters:

Tidal volume	50 to 2000 mL
Frequency	1 to 60 bpm
PEEP	up to 20 cmH2O or more
FiO2	40 to 100%
I: E ratio	1:4 to 4:1
Inspiratory time	0.25 to 5 s
Inspiratory flow trigger	OFF, 0.5 to 10 l/min
Inspiratory pressure	5 to 60 cmH2O
Rise time	Adjustable
Peak Flow	2 to 100 l/min in volumetric mode
	Up to 200 1/ min in spontaneous mode
Inspiratory pause	minimum 6 sec
Expiratory pause	minimum 6 sec

5. It should have the following audio and visual alarms :
High pressure, Tidal Volume (low/high), Minute volume (low/high), Frequency (low/ high), FiO2 (low/ high) disconnection, power supply failure, battery.

6. It should have user configurable Apnea /backup ventilator settings

7. It should have the following measured parameters:
Minute volume (insp & Exp), Tidal Volume (Insp & Exp)
Frequency (f)
Peak airway pressure
Positive expiratory pressure (PEEP)
Mean airways pressure
Plateau Pressure
Leak index
Ti/Ttot
I: E ratio
FiO2

8. It should have built in battery backup at least for 4 hours or more.

9. It should have built in colour touch screen not lesser than 5 inches

10. It should have graphics-pressure, flow and volume (- time) curves

11. It should have trending facility for vital parameters

12. It should be European CE and US FDA.

13. It should have drop test certificate.

14. Scope of supply per ventilator.

1. Patient tubing - 1 No. each(Adult & paediatric)
2. Trolley - 1 from OEM (orig equip manuf)
3. Mask - 1 Set (Paediatric, Adult)
4. Arm set - 1 No.
5. Connection for high pressure Oxygen pipe line/Cylinders.

15. Warranty 5 years with spares and next 5 years CMC.
16. Rates to be quoted for spares, consummables which are not covered under the warranty, CMC.
17. Circuits: Pediatric, Adult : (Silicon material) – 2 each
18. Test lung: Adult
19. Company should do the demo as and when required.
20. It should have integrated bed rail/trolley mounting facility

21. It is hereby certified that these specifications are general in nature and not favouring any particular company

TRANSPORT VENTILATOR

1. Ventilator should be suitable for emergency and critical care transport for use by professionals in pre-hospital and hospital settings.
2. Suitable for adults, pediatric operations.
3. Should be wall mounted, light weight (max. 7 kg), robust and user friendly.
4. Ventilator should be capable to show wave forms
5. Ventilator should have large color TFT display of minimum 5'' size, with the option to change into night mode.
6. Modes of ventilation: CPAP + PSV, PCV,IPPV, S-IPPV, SIMV, Apnea Mode, NIV. Integrated etCO2 preferable, prices to be quoted separately
7. Should have option of up gradation.
8. NIV should able to operate in all modes
9. Should have facility of leak compensation
10. Should have the measurements of P-Peak, P plat and P mean
11. Should have apnea- backup function with possible modes Bi-level or SIMV
12. Should have audiovisual color alarms on screen for: High/low inflation pressure, Tidal volume (inspired &expired), Minute volume (inspired &expired), Total frequency, spontaneous frequency, FiO2, PEEP (external & intrinsic), Plateau pressure, Dynamic R and C.
13. Settings

Tidal Volume	: 50 to 2000ml
Frequency Rate	: 0 to 60 min-1
P insp :	: 3 to 60 mbar mbar
Pressure support (ASB)	: 0 to 30 mbar
PEEP	: 0 to 20
I:E ratio	: 4:1 to 1:4
Peak inspiratory Flow	: $\geq$ 100l/min
Trigger (Flow)	: 1 to 15 l/min
FIO2	: 40 to 100%

14. Large clearly visible bright red alarm light
15. Alarm volumes should be regulated separately for adjusting limits as per requirements
16. Ventilator should have battery backup of minimum 4 hrs and should b supply one additional battery.

17. Charging time of the battery should not be more than 5 hrs for 0- 100%
18. Equipment should be complete with carry bag, patient circuit, pressure regulator for the oxygen cylinder and relief valve. (Transport Ventilator Kit)
19. The above kit should be supplied with all required brackets/ mounts to ensure mounting in ambulance and on stretcher rails without hampering patient care in an acute scenario. Should be from the same manufacturer which should be complying with crash proof test EN-1789 standard.
20. Device power supply : 12 – 24 volt DC
21. Power for external mains unit : 100-240 V AC, 50/60 Hz
22. Facility of data transfer
23. Should have simulation mode / demo for trainings and demonstration purposes
24. Product surgery 93/42/ EEC : class IIb protocol certificate
25. Degree of protection against water IPX4 protocol certificate
26. Should be European CE and US-FDA
27. Should have air worthy certification
28. Should have drop test worthy certification.
28. Scope of supply per ventilator.
    1. Patient tubing 1 No. each (Adult & paediatric)
    2. Trolley 1 from OEM (original equip. manufacture)
    4. Mask1 Set (Paediatric, Adult)
    5. Arm set 1 No.
    6. Connection for high pressure Oxygen pipe line/Cylinders.
    7. Circuits: Pediatric, Adult : (Silicon material) – 2 each
    8. Test lung: Pediatric, Adult

29. Warranty 5 years with spares and next 5 years CMC

30. Rates to be quoted for spares, consumables which are not covered under the warranty, CMC.

31. Company should do the demo as and when required.

32. This is hereby certified that the specifications are general and not favouring any particular company.

All other tender terms and conditions remain unchanged.

Amendment to be issued will be uploaded on websites www.tenderwizard.com/HSCC & www.hsccltd.com.

Medical Superintendent
Safderjung Hospital &
VMMC, New Delhi.