Notice Inviting e-Tender

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Supply and Commissioning of Medical equipment for setting up of Pediatric Cardiac Evaluation and Cardiac Surgery Unit under Rashtrya Bal Swasthya Karyakram (RBSK) Group – A

Bid Reference No.: **WBMSCL/NIT-103/2022** Dated-**21.03.2022**

Amendment-I

REVISED TECHNICAL SPECIFICATION

Item No. 1

Active Clotting Time Analyzer

1. Light weight, portable main (AC Power 110-240 V) Operated ACT Machine
2. Automatic identification of the tube run, with test performance.
3. Easier identification of tube type prevents error.
4. Reliable performance and safety.
5. Optional Port available enable to interface with Hospital and Laboratory date system.
6. Backlit LCD Display.
7. Fully compatible (Tubes and Instruments) with Hemochron system (optional)
8. Easy availability of tube (at least 500 tubes supplied)
9. Platelet analyser (optional)
10. Should have US FDA / European CE (4 digit notified body).

Item No. 2

Defibrillators with internal paddles

1. Biphasic, Manual and AED with voice prompt, compact and light weight
2. Energy selection 2J to 200J or more in steps
3. Momentary energy selection access on frontal panel
4. Should have adult and pediatric paddles integrated on same handle
5. Momentary charge key on front panel and on the apex hand
6. Monitor 5" or more should display selected energy.
7. Should have disarm facility
8. Energy should be delivered within (30-60) ms after the detected R wave in synchronization mode
9. Charging time maximum up-to 6 sec for 200J
10. Should have battery backup (3 to 4 hrs) for minimum 50 discharges of 200J
11. Should have ECG inputs through paddles or 3 lead cables
12. Should have display for selected ECG input source (I, II, III paddles)
13. Lead off message should appear with alert tone
14. Amplitude gain of ECG waveform should be adjustable
15. Should have display for heart rate
16. Should have alarm for high and low HR
17. Should have an inbuilt thermal recorder-paper size 50/60 mm, paper speed 25 mm/sec
18. Should have enable / disable option for printer
19. Should supply 2 bottle of jelly, 12 roll of thermal paper
20. Should supply 3 (three) pairs of AED pads
21. Should operate on mains 230 V, 50 Hz
22. External pacing facility with 6 (six) pairs of lead
23. Environmental Factors:
    - 23.1. The unit shall be capable of being stored continuously in ambient temperature of 10 – 40^0C & Relative Humidity of 15 – 90%

23.2. Shall meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility

23.3. Shall be capable of operating continuously in ambient temperature of 10 – 40^{0}C and Relative Humidity of 15 – 90%

24. Power Back-up:

24.1. Power input: 220 – 240V / 50Hz Single phase or 380 – 400V AC 50 Hz three phase fitted with appropriated Indian plugs and sockets

Standards and Safety:

i). It should be US FDA or CE ("Conformite Europeene") from European Union notified body having 4 digit identification number approved or BIS (Certificate to be submitted).

ii). Electrical safety conforms to standards for electrical safety IEC – 60601 / IS – 13450

iii). Manufacturer should have ISO certification for quality standards

iv). It should **have onsite service facility.** The service provider should have necessary equipments recommended by the manufacturer to carryout preventive maintenance test as per guidelines provided in the service/ maintenance manual.

v). Warranty for 2 years and 5 years CMC after warranty.

25. Internal paddle – for infant – 1 Set

26. Internal paddle – for paediatric – 1 set

Item No. 3

Echocariography machine with Pediatric and infant and neonatal probes (with TEE Probes - Children and neonates)

Specifications	Specification name	Bid Requirement (Allowed Values)
Scan Modes and Performance Parameters	Cardiac 3-D freehand Option	Yes,No
	Cardiac 3-D/4-D ayutomatic Option	Yes
	Contrast harmonic /Agent Imaging with angio Mode	Yes
	Provision for higher sensitivity for low frequency doppler in all probes	Yes
	Color Doppler 3-D/4-D option	Yes,No
	Power Doppler 3-D/4-D option	Yes

	Contrast -enhanced ultrasound (CEUS) option.	Yes
	Tisue synchronization ,tissue velocity	Yes
	provision for higher sensitivity for lower fresquency Doppler in all Probes	Yes
	Latest generation Electronic Phased/sector array Colour Doppler system.	50000 or more (if channels are being designated as digital channels)
	System should be capable of generating real time live 3-D image.	Yes with MV No analysis
Image display processing	DICOM THREE POINT ZERO COMPLIANTY	yes
	Automated B-Mode (2-D) image	yes
	Automated CDI Image optimization	No
	Automated PW Doppler image optimization	yes
	TOUCH SCREEN	yes
	Monitor display size , cm (in)	21 inch or more
	Split Screen	Twin view and Live Quad Screen
	Single/dual monitors	Dual (image display and touch panel)
	speckle-tracking strain and strain rate	yes
	Stress echo	yes
	Analysis and calculation packages	2-D wall motion tracking ,3-D wall motion tracking ,cardiac ,Mitral valve analysis ,user programmable calculations
	DVD/CD Writer	yes
	Type of printer provided with the echo cardio machine	LASER PRINTER
	Provision of PC with echocardiogram machine	yes
	Type of processor	1.7 OR LATEST
	RAM capacity of PC in GB (Hint : in case PC Not provided Put zero)	>=4
Types of Probes & Features	Conformity to Manufacturer's Certifications	ISO 9001 AND ISO 13845
	Cardiac and Vascular Probes Configuration	
	TTE Probe Type	Pediatric, Infant & Neonate
	List of probe:	
	Pediatric TEE -1 – 2D	3-10MHz
	Pediatric Phased array -1 – 2D	2.5-8 MHz
	Neonatal TEE -1 – 2D	3.3-10 MHz

	Neonatal phased array -1 – 2D	4-12 MHz
	Micro Convex probe -1 – 2D	3-10 MHz
	Linear array probe -1 –2D	5-18 MHz
	TEE Pediatric, Infant & Neonate Probe Supplied	yes
	Linear Probe for Linear /vascular applications	yes
	Pediatric, Infant & Neonate Linear Probe fresquency in MHz	5-14 MHz (t2) , 5-10 MHz (± 1) , Not Applicable
	No of Pediatric, Infant & Neonate TTE probe supplied	1 each
	No of Pediatric, Infant & Neonate TEE Probes supplied	1 each
	No of Pediatric, Infant & Neonate Linear Probe supplied and foetal echo probe	1 each
	Dedicated 3D/4D Volumn Imaging for cardiology TTE ad TTE	yes
	Live 3D imaging in color Droppler System	yes
	Color Droppler system, with all application packages ,Quad loop for serial studies with high frame rate revies ,harmonic imaging capability in all modes an dintegrated stress echo package digital storage and retrieval	yes
	Provision of Tissue Colorization (B-Colour) for Improved Contrast resolution	yes
	Application Software	Pediatric, Infant & Neonate,Vascular
		and Transesophagal applications
	Cine loop Feachers	yes
	Frame grabber facility for post analysis	Yes
	facility of various maps for pre and post porocessing	yers
	ECG Trigger facility	yes
	"Dedicated integrated dynamic stress echo package for flexible user defined protocols with stacked sub loops facility and contrast stress protocol usable for stress echocardiograaphy"	yes
	Number of transducer/probe ports	4
	Processor speed in Ghz	>=3
	Frame Grabber incorporated	Yes

	Connectivity between echo Cardiogram and PC	Through IMS/EQUIVALENT SOFTWARE
	PC with all software inclusive interfaced with echocardiograph machine	Yes
	Laser Color Printer provided with computer for reporting	yes
	Inkjet printer provided with compuetr for reporting	No
	CD/DVD produced should be playable on any system	NO CD/DVD Writer provided
	Glossy Colour Print Paper supplied	Not provided
	ECG Cable	2
	Echo cardiography system to be DICOM Ready	yes
	Dicom interfacability Dicom to PACS	yes
	Interfacability Dicom to RIS	yes
Power Requirements	Resettable over current breaker shall be fitted for protection	yes
	Power Backup	UPS
	Backup time in minutes	30
Miscellaneous Parameters	Warrenty (option of comprehensive warrenty is available through bidding only, which if opted will supersede normal warrenty in the catalogue	3
	Number of Installation of the echo cardiogram machines in central/State/PSU Govt. Hospitals (Note : Seller should supply as performance certificate of the device to the buyer if demanded after placement of order)	MORE THAN 3

Additional Specifications Parameters -Echo Cardiography Scanning Machine	
Specification Parameter Name	**Bid requirement (Allowed values)**
4D Probe	Should be latest in technology of the bidding company
Frame Rate for 2D Echo	More than 6000 frames/sec
Fusion with other Imaging modelities	yes
AI Based tools for 2D.3D/4D	yes
Certification	Should have US FDA / European CE (4 digit notified body) /BIS

Item No. 4

Flexible fibreoptic bronchoscope (Neonates & Children)

A. Optical system should include :
   1. Field of view at least 90-120 degree
   2. Depth of field 2-50 mm
   3. Insertion tube outer diameter 3.1 mm or less.
   4. Bronchoscope should easily go through an ET tube of 3-3.5 mm or more
   5. Working length up to 600 mm
   6. Instrument channel inner diameter of 1.2 mm
   7. Bending section angulation range at least 140 degree or more up and 130 degree down
   8. Insertion tube should have rotation function to left and right. (optional)
   9. Optional feature: real time chromo endoscopy for better diagnosis
   10. Flexible fibreoptic should have the provision to view through the eye-piece.

B. Video processor :
   1. Compact light weight
   2. Equipped with high resolution HD TV imaging capacity and HDTV signal output
   3. Automatic or manual brightness control
   4. Facility for colour correction and basic image enhancement
   5. Should be fully digital system (combination of digital signal processing , high definition CCD/CMOS chips and latest digital video processor
   6. Electronic magnification on scope switch/ key board button to enlarge structure 1.5 times or more (optional)
   7. Automatic IRIS control (optional)
   8. Optional :
      - storage capacity of at least 35 patient data
      - USB connection port
      - Should have pre- freeze function to select clear still image automatically

C. Light source :
   1. High intensity 300 watt Xenon short arc or LED
   2. Automatic light adjustment
   3. Emergency halogen light system

D. Monitor:
   1. Screen size shuld be 18 -27 inch , medical grade , full HD panel
   2. Resolution 1920 X1080
   3. Aspect ratio 16:9 or 16:10
   4. Viewing angle 170 degree or more(optional)
   5. Multiple inputs like : HD/SDI, Y/C, RGB, HD 15 , DVI

E. Endoscopy trolley : should have following features
   1. Trolley from same manufacturer or similar
   2. Power coated MS trolley with 4 cluster wheels
   3. Scope hanger
   4. Provision to keep video processor and monitor
   5. Attached power button , power socket and power cord
   6. 2-5 KVA UPS with 15 min- 1 hour battery back up

F. Endoscopic software should include
   1. Latest soft ware version to transfer data from video processor to other computer

2. Patient reporting software for HD quality recording and capture of still images
3. Foot switch/hand switch image capture dongle
4. DICOM facility should be available

G. Accessories:
1. Bronchoscopy brush – 3 number
2. Bronchoscopy forceps – 2 number

H. Desktop computer to transfer and store the images and videos
1. Should have at least 8 GB RAM
2. Should have 2 TB internal hard disk

I. Warranty , installation and service
1. Should give technical demonstration of the unit offered in tender within the department
2. Price of main unit and accessories to be quoted separately
3. Should provide with warranty of minimum 3 years
4. Company should have an established registered service center with address and phone number at Kolkata
5. The bidder should give an undertaking that a loaner scope will be provided as and when the scope requires any service during the break down period
6. The installation should include training of all the relevant medical personnel in the department about using the equipment . the installation report will be accepted by the department only after satisfactory training is completed.

J. Video processor and flexible fibre optics should be from the same manufacturer

K. Should have US FDA / European CE (4 digit notified body)/BIS.

Item No. 5

Ventilator (HFO)

1. A neonatal ventilator must have all these components below:

- Ventilator.
- Display monitor and user interface
- Same reusable circuits for both conventional ventilation and high frequency oscillatory ventilation (HFOV) and compatible with NO system
- Servo humidifier
- Nebulizer (standalone)/built-in.
- Proximal flow sensor
- Stand for circuits
- Internal battery backup (for ventilator, monitor)
- Operator manual
- Service manual

2. Type of ventilator

- Advanced microprocessor based continuous flow, time cycled, pressure limited ventilator capable of ventilating newborn infants and compatible to deliver **inhaled Nitric Oxide (iNO)**.
- It should have capability of Mechanical ventilation of a range of patients from 300 gm to at least 20 kg body weight**.**
- It should have capacity to deliver targeted tidal volume along with primary modes.
- It should have active inspiration and expiration in HFOV
- It should have in built trigger sensitivity parameter for synchronized modes.

3. Modes

- Nasal **CPAP** with facility for single and dual limb, Non- invasive mode of ventilation including NIPPV, nasal HFOV,High Flow O2 therapy with facility of leak compensation
- Invasive modes ventilation like CMV, SIMV, pressure supported ventilation (with back up ventilation), integrated volume ventilation with Volume targeted ventilation high frequency oscillatory ventilation (HFOV) and various hybrid mode (like HFOV+CMV+, Simv+PSV).

4. Range of set parameters

Parameters	**Desirable**	**Essential**
Non-invasive modes		
• NCPAP pressure/ PEEP	0-20	3-10
• Apnes alarm while on Ncpap		Must
• PIP (NIV) – cm of H_2O	0-65	10-50
• Ti (NIV) – cm of H_2O	0.10-5.0	0.15-2.0
• FIO_2 (%)	21-100	21-100
• Rate (NIV)	1-150	20-120
• Flow rate (for High flow O_2 therapy) L/min	2-30	2-10

Parameters	**Desirable**	**Essential**
Invasive modes		
• Peak inspiratory pressure (cm of H_2O)	1-65	10-50

• Positive end expiratory pressure (cm of H_2O)	0-30	3-10
• Fraction of inspired oxygen (%)	21-100	21-100
• Inspiratory time (sec)	0.10-5.0	0.10-2.0
• Rate (per min)	1-150	20-120
• Expiratory Tidal volume (Volume targeted mode) ml	2-200	2-200
• Pressure support (cm of H_2O)	1-65	10-50
• Additional parameters	Rise time and termination sensitivity (% peak inspiratory flow)	Rise time and termination sensitivity (% peak inspiratory flow)
Parameters	**Desirable**	**Essential**
HFOV mode		
• Frequency/rate Hz	5-20	3-10
• MAP (cm of H_2O)	5-50	0-40
• Fraction of inspired oxygen (%)	21-100	21-100
• ΔP (cm of H_2O)	4-180	10-100
• Sigh P	0-45	1-25
• I:E ratio	1:1-1:3	1:1-1:3

5. Display unit/User Interface

- LED/LCD – TFT monitor with 10" or higher digital display, preferably with touch screen operation
- Simple and user friendly
- Trend of measured parameters with memory for at least 24 hours
- Display of following set parameters:
  - Airway pressures (PIP, PEEP)
  - FIO2
  - Rate
  - Ti, Te, I:E ratio
  - Tidal volume
  - Minute volume

- Status indicator for ventilator mode

- Display of following measured parameters
  - Airway pressures (PIP, PEEP, MAP, Delta P)
  - FIO2
  - Rate
  - Ti, Te, I:E ratio
  - Leak percentage
  - Tidal volume (Vte)
  - Minute volume
  - Compliance
  - Resistance
  - Alarm message
  - Calibration
  - Battery life
- Graphics - Scalars (pressure, volume flow)/Loop (pressure-volume, flow- volume)
  - 3 waves - Pressure, volume and flow with time
  - 2 loops - P-V, F-V with facility of saving of 1loop for reference

6. **Alarms (Audio/ Visual)**
   - Power/Mains failure
   - Monitor Failure
   - O2 not connected/pressure low
   - Air not connected
   - MV low/ high
   - Leak alarm
   - Battery low
   - Flow sensor not connected
   - Flow sensor not calibrated
   - Oxygen too high
   - Oxygen too low
   - Low & High pressure
   - High/ low respiratory rate
   - Apnea alarm
   - Compressor failure
   - Tube obstructed
7. **Humidifier (US FDA approved)**

- Capable of working with both invasive and non-invasive modes
- Must conform to ISO 8185
- Should be capable of always supplying fully saturated gas at 37°C
- Flow resistance <20 cm H2O/L/sec (Ins R <12, Exp R<8)
- Temperature range: 31- 40°C
- Temperature control: ± 2°C
- Digital display of temperature: 5 - 80° C
- Capable of ambient humidity compensation
- Should be compatible with both reusable & disposable chambers and circuits
- Must have water level indicator
- Minimum warm up time (<30 min)

8. iNO compatibility (Same Manufacturer)

- Should be compatible with iNO system.
- Should be supplied with NO dual hose scavenging filter assembly.
- Should be supplied with NO delivery kit with adaptors.

9. Medical Air Compressor (Same Manufacturer)

a) Imported standalone or in-built or integrated, **USFDA / CE approved.**
b) Oil free Medical Air Compressor, not turbine generator
c) Air quality should comply with ISO 8573.1 compressed air purity class 1.4.1
d) Air Compressor should automatically be activated in the event of wall air supply loss
e) Replacement of filters should be performed without removing the compressor (in-built)
f) Low noise

10. Nebulizer (US FDA approved)

- Purpose: aerosolized drug delivery while Intubated
- Integrated or pre-installed software and required hardware for nebulization
- Reusable nebulization chamber or unit along with tubing, cable and adapter /accessories

11. Proximal flow sensor

- Type: flow sensor/ volume sensor; Flow/ volume should be measured proximally.
- Dead space: ≤1 ml
- TV: 1-200 ml
- Reusable and autoclaveable

12. FIO_2/ Oxygen sensor

- Sensors having long lives more than 5 years are preferable.
- If supplied with cells with shorter lives, cost of cells to be required for 5 years are to be included in total cost.
- Environmental factors

13. Environmental factors

- The unit should be capable of being stored continuously in an ambient temperature of 10 - 50° Cand relative humidity of 10-90%.
- The unit should be capable of operating continuously in an ambient temperature of 10 - 40°C and relative humidity of 10-90%.
- Shall meet lEC - 60601 - 1 - 2: 2001 (or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

14. Power Supply

- Power input to be 100-240VAC, 50Hz
- Resettable over current breaker shall be fitted for protection
- System should have suitable internal battery back-up for minimum one hour.

15. Standards, Safety and Training

- Should be US FDA / CE ("Conformite Europeene") from European Union notified body having 4 digit identification number approved.
- Should meet IP 21 rating for protection against water ingress
- Sound level should not be more than 50 dBA,
- Demonstration of quoted equipment model is a must
- Should have local service facility, The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual
- Warranty for 2 years and provision of CMC for next 5 years

ITEM NO-6

Multipara Monitor (Non-Invasive)

1. The monitor should have bright, highly visible minimum 10 inch LED/TFT LCD screen colour display of minimum 800 X 600 line resolution for easy viewing from a distance.
2. Integrated modules for standard measurements with ECG, Heart Rate, Respiration Rate, SpO2, Arterial pressure, Central Venus pressure, Non Invasive blood pressure & Temp. SpO2 measurement (accuracy ±2%) with NELLCORE /

MASHIMO or recognized equivalent technology. The bidder should supply original accessories from OEM.

3. Modules should be colour coded to avoid inserting wrong cables, leads.
4. The monitor shall be able to mount on the wall with a battery backup of minimum two hrs. as well as on bed side trolley.
5. Should have the capability to display at least five (05) real-time waveforms along with related numerical parameters on a single screen.
6. The size of the numeric and waveforms should be adjustable to become larger for viewing from very long distance.
7. The monitor should have the capability to be operated through knob/touch screen or both.
8. Should have at least 5 lead ECG facilities and ST analysis.
9. Should have advanced multi – lead arrhythmia analysis capability.
10. The monitor should have configurable screen configurations for various monitoring settings like emergency, general monitoring, 5 lead screens etc.
11. Trends recording for 120 hrs with full disclose to 72 hrs.
12. The monitor should have the facility to connect to central nursing station.
13. The monitor must have audio & visual alarms for the vital parameter specifically covering the range for the neonates.
14. Should have apnea alarm.
15. Should have slave monitor facility.

Standard Accessories should be supplied as standard: (Same manufacturing unit)

- ECG/Respiration ECG lead: 02 nos.
- ECG electrodes for paediatric: 10 nos.
- ECG electrodes for Adult: 10 nos.
- NBP Disposable cuff neonates (size 1 and 2): 25 nos each
- NBP Reusable cuff infant: 02 no.
- NBP Reusable cuff paediatric: 02 no.
- NBP Reusable cuff Adult: 01 no.
- NBP Hose for reusable cuff: 01 no.
- SpO2 sensor for neonates flex wrap type: 05 nos.
- SpO2 sensor for paediatric jack type with restrain / Clip type: 05 nos
- SpO2 sensor for adults: 01 no.
- Reusable Temperature probe for neonate: 01 no. (Core & Skin)
- Reusable Temperature probe for paediatric: 01 no. (Core & Skin)
- Reusable Temperature probe for Adult: 01 no. (Core & Skin)
- Wall mount to be provided: 01 no.
- Saline pressure bag (500 ml) to maintain Arterial line: 05 nos. (other than OEM)
- Arterial pressure transducer: 05 nos.
- Central Venus pressure transducer: 05 nos.
- Pressure transducer cable: 02 nos.

- $EtCo_2$ mainstream/side stream

Standards & Safety:

i). The product should be US FDA or CE ("Conformite Europeene") from European Union notified body having 4 digit identification number approved (Certificate to be submitted) or BIS.

ii). It should have onsite service facility. The service provider should have necessary equipments recommended by the manufacturer to carryout preventive maintenance test as per guidelines provided in the service/ maintenance manual.

iii). Warranty for 2 years and 5 years CMC after warranty.

iv). HDMI or other port should be there for LAN connection to 2nd monitor
especially for OT **(HDMI/VGA splitter)**

ITEMS NO. 8

Extracorporeal Life Support System (ECMO)

General Features

A Centrifugal blood pump with fully magnetically levitated/coupling technology for extracorporeal circulatory support

It should be useable/indicated for post cardiotomy support, bridge to decision, bridge to transplant, bridge to recovery, acute cardiogenic shock, and pulmonary supply.

A Centrifugal blood pump should be used for right heart failure and also for pulmonary support (If needed)

The Pump should be able to support both adult & Pediatic patient.

The system should have a backup console, emergency drive unit (Optional)

The blood pump shouldn't have any mechanical bearing or seals with the pump / (optional)

Motor shall b magnetically levitate the impeller for achieving rotation or rotor with flow channel.

Console/system has to be transportable.

Technical Specification for System

Pump speed range between 0-5000 revolutions per minute.

Flow range of 0-10 liters per minute

AC power specifications are as follows:-

100-240 ACV at 50/60 Hz 170 VA (Version 2)

The priming volume of the pump should be less than 35 ml.

Rechargeable Li Ion internal battery (14.8 V) with a life of 150 Cycles

Battery time of approximately 80 min or more @ 3300 RPM, 5.5 LPM

System monitor should display the parameter of both right and left heart. (Optional)

In build Alarm alert volume up to 75 DB.

Console/system has to be transportable.

Weight approx.5-6 Kg.

Heater unit and other accessories including arterial and venous filter, pump head, tubing, trolley

Heamatocrit display, bubble sensor and other sensors.

Should have USFDA (4 digit notified number)/ BIS.