Amendment No.28

Date: 05.03.2015

Subject: Amendment no.28 to the Tender Enquiry Document.

Ref: (i) Tender Enquiry No.: HLL/PCD/PMSSY/AIIMS-II/11/13-14 dated 19.12.2013 and subsequent amendments published thereafter.

The following changes are incorporated to the referred tender document/ subsequent amendments published thereafter:

<u>SECTION –I</u> Notice Inviting Tenders(NIT)

(1) Added items:

S.No.	Name of Equipment	Department	Quantity per AIIMS	Total Quantity for 6 AIIMS	EMD
1	Platelet Agitator	Medical Oncology	2	12	4,32,000
11	Defibrillator	Medical Oncology	2	12	72,000

(2) For

Sl. No.	Description	Schedule	
i.	Dates of sale of tender enquiry documents	19.12.2013 to 26.02.2015, 1000 hrs to	
	for Schedule 06, 10,12(a),12(b) and 12(c)	1600 hrs IST	
vi.	Closing date & time for receipt of Tender	17.03.2015, 1600 hrs IST	
	for Schedule 06, 10,12(a),12(b) and 12(c)	17.03.2013, 1000 HIS IS I	
vii	Time and date of opening of Techno –		
	Commercial tenders for Schedule 06, 10	17.03.2015, 1630 hrs IST	
	12(a),12(b) and 12(c)		

Read as:-

Sl. No.	Description	Schedule
i.	Dates of sale of tender enquiry documents for Schedule 01, 06, 10, 11, 12(a),12(b) and 12(c)	19.12.2013 to 16.03.2015 , 1000 hrs to 1600 hrs IST
vi.	Closing date & time for receipt of Tender for Schedule 01, 06, 10, 11, 12(a),12(b) and 12(c)	17.03.2015, 1600 hrs IST
vii	Time and date of opening of Techno – Commercial tenders for Schedule 01, 06, 10, 11, 12(a),12(b) and 12(c)	17.03.2015 , 1630 hrs IST

Note: If EMD is submitted in the form of BG, then the validity of the BG should be at least 165 days from the date of tender opening, i.e, up to 29.08.2015.

SECTION VI LIST OF REQUIREMENTS

Added List:

S.No.	Name of Equipment	Department	Quantity per AIIMS	Total Quantity for 6 AIIMS	Warranty Required	CMC required
1	Platelet Agitator	Medical Oncology	2	12	5 Years	Yes
11	Defibrillator	Medical Oncology	2	12	5 Years	Yes

Section VII Technical Specifiations

Schedule No.01 Platelet Agitator

- It should have provision to store about 96 platelet bags or 36 Apheresis bags or bags of different sizes.
- It should have a clear view single pane glass roll out door which should roll inside the chamber for opening of the incubator.
- Agitator should stop automatically once the door is opened.
- It should have micro-processed controlled LCD display, temperature graph display and graphical display of agitation speed
- It should have stainless steel rtd sensor probes
- It should have provision for 4"day mkless chart recorder with battery backup foi continues operation during power failure
- It should be able to maintain a temperature of 22 degrees.
- it should have gentle side to side motion (1 V% "38 mm) with 65 ± 5 strokes per minute
- It should have drawers with holes for complete air circulation across both surfaces of platelet bags

Schedule No.11 Defibrillator with ECG Monitor

1 Description of Function

1.1 Defibrillator is required for reviving the heart functions by providing selected quantum of electrical shocks with facility for monitoring vital parameters.

2 Operational Requirements

- 2.1 Defibrillator should be Bi- Phasic, light weight and latest model
- 2.2 Should monitor vital parameters and display them

- 2.3 Should print the ECG on thermal recorders.
- 2.4 Should work on both Manual and Automated external defibrillation (AED) mode up to $200\,\mathrm{J}$ or more.
- 2.5 Should be capable of doing synchronized & asynchronized cardioversion
- 2.6 Can be operated from mains as well as battery
- 2.7 Should have defibrillator testing facility
- 2.8 Demonstration of the equipment is a must.

3 Technical Specifications

- 3.1 Should be a Low Energy Biphasic defibrillator monitor with Recorder, having capability to arrest all arrhythmia within a maximum energy of 200 Joules.
- 3.2 Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles. Should have Automatic or Manual Lead switching to see patient ECG through paddles or leads
- 3.3 Should measure and compensate for chest impedance for a range of 25 to 125 ohms
- 3.4 Should have a built in 50mm strip printer/ thermal recorder
- 3.5 Should have charging time of less than 6 seconds for maximum energy. Charging indicator should be there.
- $3.6\ Should\ have\ bright\ LCD\ /\ TFT\ display\ for\ viewing\ messages\ and\ ECG\ waveform\ of\ 4\ seconds$
- 3.7 Single Adult and pediatric paddles should be available. Internal paddles should also be available and price to be quoted separately.
- 3.8 Should have event summary facility for recording and printing at least 250 events and 50 waveforms. Patient data storage 90 mins of ECG and events.
- 3.9 Should have a battery capable of usage for at least 90minutes or 30 discharges.
- 3.10 Should be capable of printing Reports on Event summary, configuration, self-test, battery capacity etc
- 3.11 Should have facility for self-test/check before usage and set up function
- 3.12 Should have SPO2 and EtCO2 integrated facility.
- 3.13 Should be capable of delivering energy in increments of 1-2 joules up to 30J and increments of maximum 50J thereafter.
- 3.14 Should have user friendly 1,2,3 color coded operation.
- 3.15 Voice prompts on AED mode
- 3.16 Printing reports of events summary configuration/set test/ battery capacity
- 3.17 Optional noninvasive pacing/ transcutaneous pacing

4 System Configuration Accessories, spares and consumables

- 4.1 Defibrillator -01
- 4.2 Paddles Adult/Paediatric (pair) -01
- 4.3 Paddles –Internal (pair) -01
- 4.4 Patient cable -02
- 4.5 ECG Rolls -50
- 4.6 Disposable pads-10 nos.
- 4.7 "Reusable SPO2 Finger Probe-Adult -02, Reusable SPO2 Paediatric Finger Probe 02"

4.8 Complete set of ECG Leads- 02

5 Environmental factors

- 5.1 The unit shall be capable of operating continuously in ambient temperature of 10 -400 C and relative humidity of 15-90%
- 5.2 The unit shall be capable of being stored continuously in ambient temperature of 0-500 C and relative humidity of 15-90%
- 5.3 Shall meet IEC-60601-1-2: 2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.
- 6 Power Supply
- 6.1 Power input to be 220-240VAC, 50Hz
- 6.2 Resettable overcurrent breaker shall be fitted for Protection

7 Standards, Safety and Training

- 7.1 Should be **USFDA or European CE** approved product
- 7.2 Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms. (OR EQUIVALENT BIS Standard)
- 7.4 Should conform to international test protocols on exposure to shock forces and to vibration forces. The standard should be documented.
- 7.6 Should meet IEC 529 Level 3 (IP3X)(spraying water) for enclosure protection, water ingress.
- 7.7 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.

8 Documentation

- 8.1 User Manual in English
- 8.2 Service manual in English
- 8.3 List of important spare parts and accessories with their part number and costing
- 8.4 Certificate of calibration and inspection from factory.
- 8.5 Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.
- 8.6 List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
- 8.7 Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/Para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
- 8.8 Must submit user list and performance report within last 5 years from major hospitals

All other terms and conditions and specifications of the tender enquiry remain unaltered.