

Amendment No. 1**Date: 29/08/2016****Sub: Amendment No.01 to the Tender Enquiry Document****Ref: NIT No.: HLL/PCD/PMSSY-II/11/16-17 dated: 22.08.2016.**

The following changes have been incorporated in the referred NIT.

SECTION I**NOTICE INVITING GLOBAL e-TENDERS (NIT)****(1)****For:**

Sch no	Event Number	Name of Item	Qty	EMD(Rs.)
10	3000001473	Non-invasive ventilator	2	8,000
14	3000001477	Upper GI Endoscope	1	16,000

Read as:

Sch no	Event Number	Name of Item	Qty	EMD(Rs.)
10	3000001473	Non-invasive ventilator	3	12,000
14	3000001477	Upper GI Endoscope	2	32,000

(2) Added Items:

Sch no	Event Number	Name of Item	Qty	EMD(Rs.)
30	3000001510	HPLC System With Chromatographic Workstation	3	78,000
31	3000001511	Vacuum Assisted Tissue Processor	4	80,000
32	3000001512	IABP (Intra Aortic Balloon Pump) - High End	2	1,20,000

SECTION - VI
LIST OF REQUIREMENTS

(3)

For:

Sch no	Event Number	Name of Item	Department	Qty	Consignee	Warranty in years	CMC in years
10	3000001473	Non-invasive ventilator	Anesthesia	2	Pt. BDS PGIMS Rohtak	5	5
14	3000001477	Upper GI Endoscope	General Surgery (Low end)	1	Pt. BDS PGIMS Rohtak	5	5

Read as:

Sch no	Event Number	Name of Item	Department	Qty	Consignee	Warranty in years	CMC in years
10	3000001473	Non-invasive ventilator	Anesthesia	2	Pt. BDS PGIMS Rohtak	5	5
			T.B & Chest	1	BJMC, Ahmedabad	5	5
14	3000001477	Upper GI Endoscope	General Surgery (Low end)	2	Pt. BDS PGIMS Rohtak	5	5
			Medicine	1	BJMC, Ahmedabad	5	5

(4)

Added Para:

Sch no	Event Number	Name of Item	Department	Qty	Consignee	Warranty in years	CMC in years
30	3000001510	HPLC System With Chromatographic Workstation	Research Lab	1	BJMC, Ahmedabad	5	5
			Pharmacology	1		5	5
			Biochemistry	1		5	5
31	3000001511	Vacuum Assisted Tissue Processor	Pathology	4	GMC, Mumbai	5	5
32	3000001512	IABP (Intra Aortic Balloon Pump) - High End	CTVS	2	GMC, Mumbai	5	5

Section – VII
Technical Specifications

Schedule: 30

<u>HPLC SYSTEM WITH CHROMATOGRAPHIC WORKSTATION</u>
Reciprocating pump with a parallel connection of double plungers and an intelligent control of a microprocessor has higher operating pressure, smaller pulsation, stable performance, convenient operation and some other features, etc. Through alternating the double plungers to perfuse, the service life of the piston rod and that of the leather packing collar are twice longer than those of common pumps with connection in series
Specification:
Flow rate Range: 0.001-9.999 mL/min
RSD< 0.06%
Peak Operating Pressure: 40MPa(0.001-9.999mL/min)
Pressure Pulsation<0.1 MPa
UV Detector
With its pioneering digital switch system, the detector directly outputs digital signal to the workstation, which avoids the signal distortion and interference that common UV detectors may bring about during their multiple analog-to-digital conversion of chromatograph signal
Specification:
Wavelength Range: 190-600nm
Baseline Noise: $\pm 0.5-1.0 \times 10^{-5}$
Baseline Drift: 0.4×10^{-4} AU
Minimum Detection: 1×10^{-8} g/ML(Naphthalene/methyl alcohol)
Wavelength Repeatability: less than 0.2nm
Injection Port:
C18 Column
Chromatography Workstation
Chromatogram workstation software should be a full automated integration of UV detector and high-pressure constant flow pump, and has powerful control function and simple, convenient and swift operation.
Six kinds of quantitative algorithmic methods: normalization, revised normalization, revised normalization with factor of proportionality, internal standard method, and external standard method and index calculation.
Injection System: Auto Sampler
2. Suitable compatible PC, Laser Printer & UPS to be offered with the system.
Should be FDA or CE or BIS approved product

Schedule: 31

SI NO.	<u>Vacuum Assisted Tissue Processor</u>
1	The equipment should be carousel type with 12 stations of 1.8 litre each ; 10 reagent stations, 2 wax baths.
2	The System should have inbuilt vacuum with fume control.
3	Audible alarms, error message and warning codes should be available.
4	Ergonomic control panel with full protected keyboard and LCD should be available.
5	Easy editing and changing of programs, even during a processing run should be an available feature.
6	7 Delayed start function up to 4 days should be possible. Auto-restart function should also be available.
7	Infiltration time separately programmable for each station should be available.
8	The equipment should have nine freely selectable programmes.
9	Drain time should not exceed 60 sec.
10	Possibility of interrupting an automatic process for reloading or removing cassettes for special applications before the end of a run should be available.
11	Baskets should automatically immerse in a station during the power failure.
12	Suitable online UPS support with minimum one hour backup should be available
13	The equipment should be USA- FDA/European- CE approved
14	There should be provision for display of level indicators.

Schedule: 32**IABP (Intra Aortic Balloon Pump) - High End****1 Description of Function**

- 1.1 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 Drive gas- Helium (Available with disposable canister or refillable cylinder. Pumping Volume: 0.5 cc-50 cc 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 forms
- 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 user's attention on the system being on standby
- 3.10 Optical Blood leak detect for early indication of blood coming into the balloon lumen due to IABC leak
- 3.11 Should have extensive Help Text available during start-up to make the system easy to use even for new users.
- 3.12 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.
- 3.13 Should be capable of removing condensation automatically without user intervention and should be maintenance free.
- 3.14 Should have Peripheral Vascular Doppler for detecting limb ischemia, which is attached to the main equipment
- 3.15 Should have automatic Altitude correction to make it safer for the use during Air Transport
- 3.16 Should have software which allows the user to monitor the IABP from any remote location via a modem
- 3.17 In-built Comprehensive Service Diagnostics to help the technician to locate the fault immediately
- 3.18 Should have capability to connect on the Hospital network
- 3.19 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: 34cc - Qty: 4 Nos, Size: 40cc - Qty: 6 Nos. Reusable Invasive Blood pressure transducer system with pressure flush device system. Qty: 2 Nos.

5 Environmental factors

- 5.1 Shall meet IEC-60601-1-2:2001(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 -50deg 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 15-90%

6 Power Supply

- 6.1 Power input to be 220 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 US-FDA/ European CE approved product (Copy has to be enclosed)
- 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.

Section – XXI Consignee List

Added Consignee list.

Consignee Code	Medical Institutions	Contact Address.	AirPort	Sea Port / Dry Port
BJMC	Civil Hospital / BJ Medical College	The Medical Superintendent, Civil Hospital / BJ Medical College, Ahmedabad-380016 Gujarat Ph: 079-22681024 079-22680074	Ahmedabad	Kandla
GMC	Grant Medical College & Sir J.J. Group of Hospitals	The Dean, Grant Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai 400 008 Ph: 022 23731144	Mumbai	Mumbai

All other contents of the tender enquiry including terms & conditions remain unaltered.