AMENDMENT No – IV dated 14.08.2014

Date: 14/8/2014

Subject: Amendment to the tender Enquiry Document

Ref:Tender Enquiry No.: HSCC/PUR/AIIA/Medical Equipment/2014 dated 16/6/2014

Section – I
Notice Inviting Tender (NIT)

1) **For:-**

Item.No.	Name of Equipment	Department	Quantity	EMD Amount (INR)
54	Ultrasonic cutting & Coagulating Device	Obs & Gyn	1	14,000
55	Operating Microscope with coaxial Illumination and foot control	Opthmalogy	1	30,000
89	Hormonic Scalpel	OT	1	40,000

Read As:

S.No.	Name of Equipment	Department	Quantity	EMD Amount (INR)
54	**Deleted**			
55	**Deleted**			
89	Hormonic Scalpel	OT	**2**	**80,000**

Section – VIII
Technical Specifications

ITEM NO 1: Ventilator portable

Point No.	Existing tender Specification	Amended/Read As
Point No. 7.2	Product should be US FDA **&** European CE. **(As per Amendment –II)**	Product should be US FDA **or** European CE

ITEM NO 2: Paediatric Ventilator

Point No.	Existing Tender Specification	Amended/Read As
Point No. 3 Page no. 56	Certified to be compliant with ISO-7767 for Oxygen monitoring	Certified to be compliant with National/International standard for Oxygen monitoring with documentary evidence.
Point 7.2	Should be US FDA **&** CE approved product(As per Amendment II)	Should be US FDA **or** CE approved product

ITEM NO 3: ICU Ventilator

Point No.	Existing Tender Specification	Amended/Read As
Point 7.2	Should be US FDA **&** CE approved product(As per Amendment II)	Should be US FDA **or** CE approved product
Point No. 7.3 Page no. 60	Certified to be compliant with ISO-7767 for Oxygen monitoring	Certified to be compliant with National/International standard for Oxygen monitoring with documentary evidence.

ITEM NO 4: COMPLETE MONITORING SYSTEM FOR ICU

Point No.	Existing Tender Specification	Amended/Read As
Point 4.4 Page No. 63	IBP: Include four nos. per monitor of reusable pressure transducer with bracket, holder and 100 nos. disposable domes per monitor.	Completes IBP kits (100nos.) consisting of each pressure transducer, Transducer domes & tubing per monitor.
Point Bo. 5.4 Page No.63	The supplier shall provide environment friendly furnitures and wall fittings for the entire system. Cabling has to be provided by the supplier.	The supplier shall provide wall fittings for the entire system. Cabling has to be provided by the supplier.

For: **ITEM NO 54:** Cutting & Coagulation device

Amended/Read As: **Deleted**

For: **ITEM NO 55:** SURGICAL OPERATING MICROSCOPE

Amended/Read As: **Deleted**

ITEM NO 63: Bed side multifunction monitors

Point No.	Existing Tender Specification	Amended/Read As
Point No. 7.1	US- FDA & European CE approved (As per Amendment 2)	Monitor should be US FDA **or** European CE approved.

ITEM NO 66: NEONATAL OPEN CARE SYSTEM

Point No.	Existing Tender Specification	Amended/Read As
Point No. 7.1	Product should be US FDA **and** European CE approved."	Product should be US FDA **or** European CE approved."

ITEM NO 67: PHOTOTHERAPY UNIT (NEONATAL PHOTOTHERAPY UNIT-LED)

Point No.	Existing Tender Specification	Amended/Read As
Point No. 7.1	Should be US FDA **&** European CE approved product	Should be US FDA **or** European CE approved product.

ITEM NO 69: Radiant Warmer with Baby Bassinet

Point No.	Existing Tender Specification	Amended/Read As
Point No. 7.1	Product should be US FDA and European CE approved."	Product should be US FDA **or** European CE approved

ITEM NO 70: TRANSPORT INCUBATOR

Point No.	Existing Tender Specification	Amended/Read As
Point No. 7.1	Product should be US FDA and European CE approved."	Product should be US FDA or European CE approved."

ITEM NO 79: Ultrasound Machine

Point No.	Existing Tender Specification	Amended/Read As
	System should be US FDA **and** European CE approved.	System should be US FDA **or** European CE approved.

ITEM NO 80: Portable Ultrasound with Color Doppler System

Point No.	Existing Tender Specification	Amended/Read As
	System should be US FDA **and** European CE approved.	System should be US FDA **or** European CE approved.

Item No. 83
BONE DENSITOMETRY

Revised Specification:

BONE MINERAL DENSITY DETERMINATION USING DUAL ENERGY X-RAY SOURCE

1. Scanning
Method-Fan Beam & Narrow Angle Fan Beam
2. X-ray Source: Constant Potential Source/ Switched Pulse Dual Energy
3. Detector System : Multi Element / Direct Digital Detectors –
4. BMD Precision : Better Than 1%
5. Scan Time: A/P Spine </ = 30 Secs; Femur </ = 30 Secs
6. Calibration: Automatic calibration Technique for test Programme & quality Control
7. Patient Position : Cross Hair Laser Light
8. Scan region -190cmx60cms or more for total body
9. Patient Weight Limits: more than 155kg Reference data: >11,000 USA/Northern European Subjects, as well as NHANES, and Numerous regional
10. Databases.
11. Table Height: 25"
12. Magnifications: None
13. Sample Size (mm): 0.60x1.05 or less for AP Sine & Femur
14. Software for the following:
a) AP Spine
b) Dual Femur
c) Total Body with Body Composition
d) Vertebral Assessment (AP & Lateral Views)
e) Lateral spine BMD
f) Fore Arm

g) Comparison to previous Scan 1
h) Composer (reporting software).
I) Pediatric software (Spine, femur & Total Body for age group 5-19)
j) Orthopedic Hip Analysis
k)DICOM
l) Visceral fat software (must).

15. Standard Information required from Vendor
Pre -installation requirements -Please Specify Including Room Size & Site Plan
No of Installations in India
No of Trained Service Engineers

16. Computer System:
a) Workable with most Advanced configuration
b) Hard Disk Minimum - 60GB
c) RAM : Minimum 1 GB
d) CD ROM (write/ read) drive
e) Monitor: At least 17" Color monitor
f) Printers: Laser/ inkjet
17. Online UPS: 2KVA with 30 mins Backup
18. AERB Type approval: Type approval must be provided for the model quoted
19. FDA & CE certification must

ITEM NO 84: OPERATION TABLE: HYDRAULIC (Imported)

Point No.	Existing Tender Specification	**Amended/Read As**
	OPERATION TABLE: HYDRAULIC (Imported)	OPERATION TABLE (Electro- HYDRAULIC)
	Point to be Added: The OT table should be imported.	**Deleted**

ITEM NO 85: Anaesthesia Work Station

Point No.	**Existing Tender Specification**	**Amended/Read As**
Point No. 6	reusable transducers with cable (4 in No.)	reusable transducers with cable (**8** in No.)

ITEM NO 87: DEFIBRILLATOR WITH MONITOR

Point No.	Existing Tender Specification	Amended/Read As

Point No. 7.1	USFDA Only	USFDA **or** European CE approved

ITEM NO 88: Diathermy

Point No.	Existing Tender Specification	**Amended/Read As:**
Point No. 4.2(d)	reusable and single use neutral electrode for adults and children along with cable for neutral electrode and fixation device wherever required,	reusable (2 Nos. each for Adult and Children) and single use (100 Nos. each for Adult and Children) neutral electrode for adults and Children along with cable for neutral electrode and fixation device wherever required
Point No. 4(e)	sterilizable and disposable electrode handle with and without finger switch with cable for electrode handle,	Reusable & sterilizable (5 Nos.) and disposable electrode handle with finger swiitch
Point No. 4(f)	set of electrodes (long and short) with electrode container with holder,	Set of electrodes (flat tip short, flat tip long & pin point- 5Nos. each) with electrode container with holder.
Point No. 4(j)	dedicated instruments for open and laparoscopic monopolar and bipolar use.	Dedicated instruments for open and laparoscopic monopolar and bipolar use (**5 Nos each**).
Point No. 7.1	US FDA as it a critical equipment	Product should be USFDA or European CE.

ITEM NO 89: Harmonic Scalpel (Quantity-2, EMD- 80,000Rs.)

Revised Equipment Specifications for Harmonic Scalpel

1 Description of Function

1.1 Ultrasound is the basis for an efficient surgical instrument: the HARMONIC SCALPEL cuts and coagulates by using lower temperatures than those used by electrosurgery or lasers. HARMONIC SCALPEL technology controls bleeding by coaptive coagulation at low temperatures ranging from 50°C to 100°C: vessels are coapted (tamponaded) and sealed by a protein coagulum. It Should not be combined with any other energy source.

2 Operational Requirements

2.1 The system is required for laparoscopic & open Procedures which should operate at the same frequency.

3 Technical Specifications

3.1 1.Ultrasonic generator generating ultrasound frequency in between 35-70 KHz.
2. Hand-piece with in-built transducer & silicon cable
3. Capability of being operated by hand control or foot switch.
4. Single/ Dual foot-switch attachment
5. Stand-by mode for better safety

6. System diagnostics and trouble shooting guide
7. Warning system for malfunctioning cable, probe etc (Audible/Visual).
8. It should not interfere with other electromagnetic devices.
9. It should have a horizontal/torsional vibration.
10. Should be capable of sealing vessels up to 5mm in diameter.
11. Should have different audible tone setting for different modes.

4 System Configuration Accessories, spares and consumables

4.1 ***Accessories:***1. Foot-switch with cable. 2. Cart to house the generator and accessories 3. Sterlization Box with pad for transducer and instruments

4.Open surgery Instruments:

a. Coagulation shears- 5mm dia, 18-20cm long or more
b. Dissecting grasper 5mm dia for Coagulation 18-20 cms. or more

5. Endoscopic surgery Instruments:

a. Dissector Grasper 5mm diameter 30cm-45cm long
b. Curved Shear,5mm diameter,30cm- 45cms long

6. Any Other compatible Accessories has to be offered if any.

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 -50 deg C and relative humidity of 15-90%
5.3 The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%

6 Power Supply

6.1 Power input to be 220-240VAC, 50Hz fitted with Indian plug
6.2 UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up.

7 Standards, Safety and Training

7.1 The generator must be CF isolated applied device and defibrillator protection must be available.
7.2 Should be US FDA/European CE approved product
7.3 Manufacturer should have ISO certification for quality standards.
7.4Electrical safety conforms to standards for electrical safety IEC-60601 / IS-13450
7.5 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/Technical/Maintenance manuals to be supplied in English.
8.2 Certificate of calibration and inspection.
8.3 List of Equipments available for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in service/technical manual.
8.4 List of important spare parts and accessories with their part number and costing.
8.5 Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job descriptin of the hospital technician and company service engineer should be clearly spelt out.
8.6 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.

NOTE:

Bidders are requested to visit AIIA, Sarita Vihar, New Delhi to assess the site condition of Equipment placement and installation in this Section. Bidders must take into consideration in its bid costs to be incurred for any additional work viz. Electrical cabling of suitable ratings, Electrical points of suitable ratings, water connection, water drainage, plumbing & allied requirement for the equipment etc. required for successful installation, commissioning and running of the Equipment and the "All inclusive lump sum price" should include all such costs.

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

Prospective bidders are advised to regularly visit HSCC website/ CPP as corrigendum /amendments etc. if any, will be notified on this portal only, no separate advertisement will published in the news papers.

s/d

Director (AIIA)