

AMENDMENT – I

Dated: - 04.2.2014

Subject: Amendment to the tender Enquiry Document.

Ref: Tender Enquiry No.: HSCC/PUR/AIIMS/RAEBARELI/TEMP OPD/2014 Dated 24.01.2014

The pre-bid meeting for the referred tender enquiry was held on 30.1.2014. The following amendments are being incorporated in the referred tender enquiry document.

(1) Revised Specification For ITEM No. 9

ELECTRO SURGICAL UNIT (ESU)

1 Description of Function

1.1 ESUs are used for surgical cutting and for controlling bleeding by causing coagulation (hemostasis) at the surgical site. They deliver high-frequency electrical current through an active electrode tip, causing desiccation, vaporization, or charring by resistive heating in the target tissue.

2 Operational Requirements

2.1 Microprocessor/Microcontroller technology

3 Technical Specifications

- 3.1 Should provide monopolar output for cut, coagulation (fulguration & spray) & blend
- 3.2 Should have bipolar cut and coagulation in multiple levels with automatic bipolar coagulation.
- 3.3 Activation by foot switch and hand switch
- 3.4 Activation of bipolar by foot switch and automatic start/stop system
- 3.5 Auto diagnosis on switching on and during working to continuously monitor all parameters
- 3.6 Automatic stoppage of output in case of malfunction with acoustic and visual signal with display of error code.
- 3.7 Output powers adjustable automatically or manually from the control panel.
- 3.8 Programmable memory for output settings
- 3.9 The Unit should have minimum of 2 monopolar output and should have simultaneous access to 2 monopolar units by more than one user.
- 3.10 Should be usable with laparoscopic monopolar and bipolar instruments, for which programmes and accessories must be available
- 3.11 System for neutral plate safety by continuous monitoring of contact quality and connection
- 3.12 System for monitoring and control of leakage current
- 3.13 Frequency leakage on the patient should be less than 10 micro Amp.
- 3.14 a. Monopolar cut : 300-400 watt
 - b. Monopolar Coagulation : 120 W min
 - c. Bipolar Coagulation : 100 W.
 - d. Bipolar Cut: 150 W or more

4 System Configuration Accessories, spares and consumables

4.1 System as specified

4.2 The accessories should include

- (a) trolley,
- (b) mains cable with power plug for standard Indian sockets,
- (c) foot switches for different outputs,
- (d) reusable(1 Nos.) and single use (15 Nos.) Neutral electrode for adults and children along with cable for neutral electrode and fixation device wherever required,
- (e) Reusable & sterilizable (2 Nos.) and disposable electrode handle with finger switch (10 Nos.) with cable.
- (f) set of electrodes(Flat tip short, flat tip long & pin point – 2 Nos. Each) with electrode container with holder,
- (g) tip cleaner – 2 (Nos)
- (h) bipolar forceps with cable (straight & bayonet) – 1 each
- (i) cable for connecting to standard mono polar and bipolar laparoscopic instruments – 1 Nos

All accessories should be same principal equipment manufacturer.

4.3 The system should be capable of accepting standard accessories of major international brands, which should be specified and for which suitable adaptor, if required, is to be quoted

4.4 The codes and rates of all possible individual accessories should be quoted separately with clear mention of period of validity of rates

5. Environmental Factors

5.1 The unit shall be capable of being stored continuously in ambient temperature of 0 - 50 deg C and relative humidity of 15-90%

5.2 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 power-plug

7 Standards & Safety

7.1 Should be US-FDA or European CE approved model.

7.2 Manufacturer and Supplier should have ISO certification for quality standards.

7.3 IEC 60101-1 Medical Electrical Equipment, General Requirements for safety

7.4 Shall meet internationally recognised standard for Electro Magnetic Compatibility (EMC) for electromedical equipment: IEC-60601-1-2 : latest edition Or Equivalent BIS) or should comply with 89/366/EEC; EMC-directive as amended

7.5 Certified to be compliant with IEC 60601-2-2 Medical Electrical Equipment Part 2-2: Particular requirements for the safety of High Frequency Surgical Equipments: latest edition

8 Training

8.1 Comprehensive training for staff of user department and support services till familiarity with the system.

9 Warranty & Service

9.1 Comprehensive Warranty & CMC as per tender document.

9.2 Percentage of uptime guarantee of the equipment during warranty and CMC period for which commitment is to be given must be specified with acceptance of Applicable penalty clauses in case of failure to do so.

9.3 After sales service must be provided in the city of installation. In situations requiring service/repair of the unit outside the city of installation, the expenditure on account of this will have to be borne by the supplier

10. Documentation

10.1 Product Literature in original along with that of accessories and indigenous components if any. Photocopies/computer generated copies are not acceptable

10.2 Statement of compliance with tender specifications with clear and unambiguous links to relevant portions of product literature/authentic document, which should be highlighted. Alternatives provided for noncompliant specifications with justification must be described in detail with supporting literature.

10.3 Certificate of compliance with standards and approvals stated above

10.4 Certificate of manufacturer/principal regarding authorisation of service facility provided by the supplier

10.5 List of Equipment available in the Service Centre for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in service/technical manual.

10.6 List of important spare parts and accessories, which are required for maintenance and repair, with their part number and costing.

10.7 Terms and conditions of warranty and CMC including schedules of visit by service personnel with check list of services to be carried out

10.8 Commitment for supply of log book with check list for daily, weekly, monthly and quarterly preventive maintenance with contact details of service personnel along with the equipment. The job description of the hospital technician and company service engineer should be clearly spelt out in the log book.

10.9 List of users of quoted model with performance certificate from major hospitals

(2) OPERATION THEATRE HYDRAULIC (Pg. No. 66, 67)

For:-

List of Installations preferable Govt. Institutions/ Medical colleges with performance certifications (Min Three Nos.)

Read As:-

DELETED

HSCC (India) Ltd

(3)

SECTION – IX QUALIFICATION CRITERIA (Pg No. 77)

(3) FOR :-

02. (a) The Manufacturer should have supplied and installed in last **Five** years from the date of Tender Opening, atleast 100% of the quoted quantity of the similar equipment meeting major specification parameters which is functioning satisfactorily, anywhere in India.

02. (b) The Tenderers quoting as authorized representative of the manufacturer meeting the above criteria 02 (a) should have supplied and installed in last **Five** years from the date of Tender Opening, atleast 100% of the quoted quantity of similar equipments which is functioning satisfactorily, anywhere in India of any manufacturer

READ AS:-

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02. (b) The Tenderers quoting as authorized representative of the manufacturer meeting the above criteria 02 (a) should have supplied and installed in last **Five** years from the date of Tender Opening, atleast 100% of the quoted quantity of similar equipments which is functioning satisfactorily, anywhere in India of any manufacturer in **Government Institutions/ Medical Colleges**.

All other terms & conditions of bid document shall remain unchanged.

Dy. Secretary (PMSSY), MOHFW