

HSCC I Ltd

Amendment -I

Dated 13.04.2018

Tender Enquiry No: HSCC/SJH/Medical Equipment/41 Dated 14.03.2018

Amendments have been received for Item No. 2, 5 & Reply of pre bid queries for Item No. 3 and 4 are still awaited. It is therefore bid submission date may be extended from 14.04.2018 to 23.04.2018 are as mentioned in below table No. 1

Table: I

Sr.No.	Description	Detail of Items	Previous Date & Time	Revised Date & Time
i.	Sale Date of the tender	Item No.1, Holter Monitoring System	14.04.2018, 2.30 PM	23.04.2018, 2.30 PM
ii.	Closing Date & Time for receipt of Bids		14.04.2018, 2.30 PM	23.04.2018, 2.30 PM
iii.	Time and date of Opening of Tender	Item No. 2 Operating Microscope Item No. 3 EBUS Item No. 4 Portable Sleep Lab Item No. 5 Digital EEG System	14.04.2018 , 3.00 PM	23. 04.2018 , 3.00 PM

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

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

Amendments for Item No. 1, 2, 5 are as follows:

Item No.1 Holter Monitoring System

Technical Specifications are remain unchanged.

Item No. 2 Operating Microscope

1.Surgical operation microscope for Neurosurgery

Existing As

Should have Motorized zoom magnification system with apochromatic optics, zoom magnification factors to be around the range of 0.4x to 2.4x. All activation should be by handgrip, Stand mounted LCD control panel and foot control panel, with manual override. Total magnification range 2X- 18X or higher. Internal motorized fine focusing system. All activation should be by handgrip, Stand Mounted LCD control panel and foot control panel, and with manual override. These should be continuously adjustable with working distance from about 200 mm to 500 mm without exchange of objective lens. There should be integrated continuously variable illumination field from 60mm – 15mm or less. Beam Splitter should preferably be integrated in the microscope body, without any external attachment with face to face attachment with rotatable dovetail mount for fatigue free surgeries.

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2.BINOCULAR TUBE : 0-180 degree range tiltable binocular tube with focal length =170 mm or higher. Should Graduated knob for continuous adjustment of interpupillary distance from 55 mm to 75 mm

3.Auto balance and Auto Drape Existing As: – System should be capable of auto-balancing the microscope intraoperatively. Autobalance should be fully computerized and should not involve any manual rotation of knobs (automatic self balancing).

3.Auto balance and Auto Drape –Deleted

4.EYEPIECES : Pair of high eyepoint widefield push-in eyepieces 10x magnification with magnetic locks, with diopter setting range from -8D to +5D for spectacles wearers. The lenses should have rubberized cuffs for comfort and should preferably have antifogging coating.

Face to face attachment for spinal surgery. Stereo Co Observation attachment with two joints with side changer. Optics and eyepiece similar to main surgeon unit.

ILLUMINATION SYSTEM: Existing As : Coaxial xenon illumination of about 300 w with back up similar rating xenon with quick action lamp changer in case of failure of main lamp should be integrated with in the microscope stand. In case of electronic failure the light should continueto work with manual overdrive for optics adjustment. Should have automated illumination Brightness control linked to working distance and magnification. Should have automatic zoom-synchronized illumination field diameter, with manual override and reset feature

5. ILLUMINATION SYSTEM: Amended As : Coaxial xenon illumination of 300 watt Xenon Bulb back up with similar xenon with illumination system. Independent Motorized control for Focus, Zoom and light control. Should have automatic zoom-synchronized illumination field diameter, with manual override and reset feature.

6. HANDGRIPS : Easily maneuverable handgrips with adjustable keys for zoom and focus, Illumination & Magnetic brakes. Programming for magnetic brake for control of stand & Microscope body brakes. Camera controls for video and still images should be programmable on handgrips.

7. FLOOR STAND : Rollable floor stand on base with lockable castors, carrier and swivel arms with large reach of 1.30m or higher, Weight caring capacity at least 18 Kg. Should have free float magnetic system with Multiple magnetic brakes for Microscope body & Stand with, release of magnetic brakes by handgrips with contrives stand. Touch screen Liquid crystal display (LCD) with user prompts, quick set up of different parameters and their activation at press of a button such as automatic speed adjustment or automatic brightness setting depending on magnification.

System may preferably have overhead LCD display for showing important parameters to operating surgeon. INTEGRATED DIGITAL VIDEO CAMERA SYSTEM : Advanced digital 3CCD HD Video camera should be attached to supply output to the stand mounted colour LCD screen. In addition there should be ports for connection to PC via USB/FireWire ports, 15 pin VGA port for color monitor, HDMI port +/- DVI port and preferably LAN connectivity.

Should be capable of doing video speed focus for independent focusing apart from microscopic focus. All imaging to be DICOM compatible.

8. USER PROGRAMMING: Programming for starting illumination, magnification working distance, Zoom speed & Focus speed for at least 8-9 different users.

9. VIDEO/IMAGE DATA MANAGEMENT SYSTEM: should have attached video recording system & still photo in the microscope stand with internal HDD of at least 1 TB, and high speed DVD writer. Latest generation macintosh based desktop computer system with video editing software for image processing and editing (video handling – atleast 2 GB hardware) and auto duplex printing laser multifunction printer to be provided separately. Original display adapters for 15 pin VGA and HDMI output also to be provided with the desktop along with a 1 KVA UPS.

10. VIDEO MONITOR: Existing As: medical grade 19" Touch screen Colour LCD display should be mounted on Microscope stand. Fluorescence and ICG – system should be upgradeable to Intraoperative Fluorescence as well as ICG. Systems without this upgradability will not be considered.

10. VIDEO MONITOR: Amended As: medical grade 19" Touch screen Colour LCD display should be mounted on Microscope stand.

11. Image guidance –Microscope should be fully ready for image guidance system integration.

Item No. 5 Revised Specification for Digital EEG Machine

High end digital EEG system is required along with complete set of consumables and accessories, with following specification

Hardware

1. Number of EEG channels should be 128 with additional 4 bipolar channels.
2. The computer should be supplied with the system, after passing the strict in-house quality checks by the manufacturer to comply with medical equipment standard.
3. System should have option of adding 10 or more DC channels
4. Impedance measurement both from amplifier and on screen.
5. Should have programmable Automatic Photic Stimulator.
6. Should have modules for acquiring SPo2 & Heart Rate.
7. Should have following minimum technical feature
 - a. System should have 24-bit simultaneous sampling of all input channels
 - b. Sampling frequency of 10 KHz or better
 - c. ADC resolution less than 97 nano volts.
 - d. Input impedance: 200 M ohms or better
 - e. Sensitivity 1 to 200 micro volt per mm
 - f. Noise < 1.5 micro volt Peak to peak
 - g. Built in manual / automatic sine / square wave calibration
 - h. CMRR: above 110 dB
 - i. Low filter settings: 0.08 Hz to 159 Hz
 - j. High filter settings: 15 Hz to 3000 Hz
 - k. EEG data output in ASCII format.
 - l. Display modes: Overwrite and Page-by-page
 - m. Waveforms freeze facility with simultaneous background recording

Software

1. System should have option of changing individual channel settings.

2. System should have option for password locked templates for user specific protocols.
3. Should have option for designing multiple protocols with user specific setting.
4. System must have option of comparing any segment of EEG with the current EEG by copying.
5. DC Offset of at least ± 5 mv.
6. Should have 8 channel DSA for FFT trend analysis and 3D brain mapping
7. Should have 6 channel CSD/Voltage mapping
8. Should have heart rate monitoring.
9. Should have trend analysis for physiological parameters for easy analysis.
10. EEG numerical analysis by zooming specific segment of EEG.
11. It should have facility for acquisition and review mode by split screen
12. Facility to review at least 4 EEG review simultaneously.
13. System should be able to display 120 traces on the screen with a maximum of 5 minutes per screen.
14. Facility for Prune/Trim down Video EEG data to specified events along with user defined time.
15. System should have option of selective video recording.
16. Facility for Zoom/Magnify EEG trace, copy & paste of EEG Trends to reports and presentations.
17. Facility to search EEG.
18. Facility for Automatic generation of reports without the need of MS Office.
19. Facility for viewing several recordings in tiled or cascading windows.
20. Facility to Review the data recorded from this system on a CD/DVD; any PC without the need of loading additional REVIEW software.
21. Should have facility for remote monitoring the data.
- 22.

Patient Administration Software

1. Network supported patient and test management software for patient administration, exam scheduling network connectivity, launch of data acquisition, review.
2. Should have option of programming the recording time
3. Should support multiple user support with individualized settings.
4. Should be HIS/HL7 compliant
5. Should have function for audit trail.

Computer (Acquisition)

1. The PC system should strictly be supplied by the manufacturer along with the system, after passing the strict in-house quality checks by the manufacturer to comply with medical equipment standard. Should have following or better specifications (Locally supplied PC system will not be accepted):-
 - a) Intel i7
 - b) 8GB RAM
 - c) 1 TB HDD
 - d) DVD writer
 - e) 32" monitor
2. In built speakers and mike
3. Good quality Laser printer
4. Good quality original trolley from manufacturer with provision for mounted monitor for height adjustment.
5. Should be supplied with Spo2 Module with probes.

Review Station

1. The PC system should strictly be supplied by the manufacturer along with the system, after passing the strict in-house quality checks by the manufacturer to comply with medical equipment standard. Should have following or better specifications (Locally supplied PC system will not be accepted):-
 - a. Intel i7
 - b. 8GB RAM

- c. 1 TB HDD
- d. DVD writer
- e. 32" monitor
- f. In built speakers
2. Good quality Laser printer
3. UPS one each for Acquisition Station and review station of suitable rating with MF Batteries with one hour back up time
4. Good quality original trolley from manufacturer with provision for mounted monitor for height adjustment
5. Easy customization of montages and re-montaging to be possible, during review on acquiring system or any other networked system. Facility for viewing several recording in tiled or cascading window.
6. Facility to review and run two events simultaneously.
7. Facility to review and prune/modify/remontage the data recorded from this system on CD/DVD/Pen Drive, on any PC without the need of loading additional REVIEW Software. To provide the facility of individualized workspaces, such that individual users can select and save their interpretations, pruned portions of files, slideshows with annotations, within originally saved and pruned files.
8. Facility for Prune/ Trim down EEG or video to specified events along with user define time before or after.
9. Facility for Zoom/Magnify EEG Trace, Copy & Paste of EEG or trends to reports and presentations.
10. Facility to search EEG in a record by time.
11. All Vendors can visit the lab to evaluate the tentative installation site for acquisition and Review Stations. However these stations may be moved to other locations for which no extra charges will be given at later stage

Should be supplied with camera with following minimum specs (two Nos.)

1. Should not require any additional mixer.
2. Should have optional moving secondary camera image during review.
3. Image device 1/4-type EXview HAD CCD
4. Should provide minimum effective resolution of 640 x 480 pixels
5. Number of effective pixels Approx. 0.44 Megapixel
6. Minimum Illumination Color: 1.4lx
7. True Day/Night Mode
8. Auto-focus Zoom Lens
9. Optical zoom 36x, Digital zoom 12x, Total zoom 432x
10. Horizontal viewing angle 57.8 to 1.7 degrees
11. Minimum object distance upto 1500mm (tele)
12. Pan angle 340 degrees

Consumables

1. Gold plated discElectrodes sets - 60 Nos.
2. Conduction paste (228gms) - 25 Nos .
3. Cleaning gel (114 gms) - 25 nos.
4. DVDs -100 nos
5. 2 TB External HDD one

Environmental Factors:

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

General Specifications.

2. The system should be wall and hinge mountable with mobile arms (from Manufacturer) along with isolation power transformer and power supply should be 220-224 V AC, 50 Hz fitted with Indian Plug.

3. Resettable over current breaker shall be fitted for protection.
4. Voltage corrector/stabilizer of appropriate rating meeting ISI Specifications(Input 160-260 V & output 220-240 V & 50 Hz).
5. It is mandatory that the system should be Certified US FDA approved. Vendor to attach the
6. Certificate clearly mentioning the model, address of manufacturer and validity on the certificate.

Compliance/ Regulatory Standards

1. Designed, tested, manufactured and certified to meet the following domestic(USA), Canadian, European and International Standards.

Patient Isolation BF

1. **UL60601-1** Medical Electrical Safety Standard(USA)
2. **CAN/CSA-C22.2 no. 601.1-M90** Medical Electrical Safety Standard(Canada)
3. **EN/IEC 60601-1** Medical Electrical Safety of Medical Equipment(International and Europe)
4. **IEC 60601-2-26** Particular Safety of electroencephalographs equipments
5. **EN 60601-1-2** Collateral safety standard for EMC
6. European Community(CE Mark)
7. Medical Device Directive(MDD) product certified to comply to EC Directive 93/42/EEC USFDA Approved.

Archiving of data:

1. Price of all accessories and amplifier and screen and software to be provided and freeze for 5 years.
2. Periodic software updates to be done. Total Internet Security antivirus to be provided with system with free updates done every year till machine works.
3. Demonstration of equipment would be mandatory once technical bids are opened.
4. Comprehensive warranty for 5 years & 5 years CMC after warranty. No extra charges for warranty or CMC for above duration.

Documentation

1. User/Technical/Maintenance manuals to be supplied in English.
2. Certificate of calibration and inspection.
3. Should have local service facility & service provider should have necessary equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual.
4. Log book with instructions for daily, weekly, monthly & quarterly maintenance checklists. The job description of the hospital technician should be clearly spelt out.
5. Compliance report to be submitted in a tabulated & 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.

Medical Superintendent
Safdarjung Hospital New Delhi

