### Amendment III

### HSCC/SJH/Med. Eqpt/2016

#### Date: 17.03.2017

Ref.: Tender No. HSCC/SJH/Med.Eqpt. /2016/28 dt. 15.02.2017

Sub.: Procurement of Medical Equipment for New Emergency Block & Super-Specialty Block at Safdarjung Hospital, New Delhi.

Technical Amendment have been received in view of the pre bid meeting queries submitted by the prospective bidders. The bid submission date extended from 17.03.2017 to 24.03.2017, for item No.1,2,4,5 amended specification are given below: -

### Item No.1

### Transcranial Doppler with Intraoperative Facility.(Amended Specification)

- 1. Two Channel Transcranial Doppler capable of Intracranial, Extracranial and intraoperative use.
- 2. Should be supplied with 2 MHz PW probes (2 Nos.) for bilateral Intracranial Monitoring
- 3. Should be supplied with 4 MHz (1 No) CW & PW for extracranial monitoring
- 4. Should be supplied with 16 MHz(1 No) PW probe for intraoperative monitoring.
- 5. Frequency range: pulsed wave: 2-24 KHz for 2 MHz probe; continuous wave : 2-32KHz
- 6. Should have color M mode feature with able to re-adjust the 64 gates digitally per probe for all the probes with max. 320 Gates.
- 7. Should have multi-frequency operation.
- 8. Should have automatic emboli detection with real time histogram of HITS Energy distribution, displaying the energy levels detected bilaterally.
- 9. Should have user-definable defaults for individual blood vessels
- 10. Should have summary screen which displays all studies performed on a patient on a single screen, enabling immediate comparison between the right and left sides of the brain.
- 11. Should have long term monitoring with trending of selected parameters
- 12. Should be supplied with probe holder made of Medical grade plastic for long term monitoring or monitoring, can be utilized in X-ray, angiographic and stenting procedures.
- 13. Probe Holder should have fixation device enabling pressure regulation of the probe to the skull after the probe is locked.
- 14. Should detect flow velicty at the contra-lateral side of the brain with its high doppler sensitivity.
- 15. Should have 8 Analog inputs and 8 Analog output to interface analog signal from ETCO2 or any other analog device to and from this system.
- 16. Should display 8 different doppler spectrum windows in 8 different depths simultaneously.
- 17. Should have manual control of gain
- 18. Should have Vasomotor Reactivity Test.
- 19. Should have FFT size adjustable from 64 points to 256 points.
- 20. Should have ability to change spectrum display size from 2.5 sec to 1 min.
- 21. Should be able to display Pulsed wave parameters like Peak Velocity, Mean Velocity, Diastolic Velocity, Pulsatalility index, Resistivity index, Standard deviation, Heart rate.

- 22. There should be provision of 2 vertical and 2 horizontal cursors for measuring the values manually.
- 23. The system should measure beat to beat pulse.
- 24. Should have 16 colour spectrum display and able to display up to 8 spectrums with Color M mode feature.
- 25. Should be able to generate report, with option of transferring all waveforms into report.
- 26. Should have facility of storing the waveforms of complete spectrum with audio digitally and replaying with audio the complete study as recorded.
- 27. Should have availability of remote control alongwith the main unit.
- Should be supplied with inbuilt PC of Pentium processor, 1 GB RAM,15" inbuilt LCD touch panel monitor, 500 GB Hard disk drive, 3 USB Port, Genuine Windows 7 operating system (with DVD and License key), Mini Keyboard, Optical Mouse.
- 29. Should be Portable System. It should be single unit and not separate laptop or computer.
- 30. Should be supplied with External DVD writer.
- 31. The data can be exported of any display in either Excel, PDF, Word or RTF format.
- 32. Should be supplied with Wireless Color Laser Printer.
- 33. Should be supplied with UPS of suitable rating and Metallic trolley with castor.
- 34. Should have an option of upgrading to 3D Imaging Doppler for Carotid studies with carotid Doppler probe.
- 35. Bidder should have atleast 5 installation in India as reference site.
- 36. Should be provided with DICOM facility, ready to use.
- 37. Should be US FDA Approved. Certificate should be attached.
- 38. Should be of US or European Origin.

## Item No. 2.

## <u>Automatic Hematology Analyzer5 Part Differential Cell Counter</u> (Amended Specification)

## SPECIFICATIONS OF 5 PART DIFFERENTIAL HAEMATOLOGY ANALYSER

- 1. The instrument should be fully automated impedence flow cytometry and hydrodynamic focusing technology for five part differential with automatic start up-shut down and sample analysis.
- 2. The instrument should have random access discrete analysis modes for CBC, CBC+DIFFERENTIAL CBC+RET, CBC+DIFF+ RET.
- The instrument should have 32 PARAMETERS reported. WBC, RBC, HCT, MCV, MCH, MCHC, RDW-SD, RDW-CV, PLT, NEUT%, LYMPH%, MONO%, EOS%, BASO%, NEUT#, LYMPH#, MONO#, EOS#, BASO#, PDW, MPV, PCT, P-LCR, RET%, RET#, LFR, MFR, HFR, IRF, PLT=O, IPF. TWO HISTOGRAMS – RBC, PLT and ONE SCATTERGRAM(WBC).
- 4. The instrument should have throughput of at least more than 75 samples per hour in CBC+DIFF MODE.
- 5. The sample aspiration volume for the complete differential blood count should not be more than 150-300µl.
- 6. The instrument should have the following analysis mode, Manual- open, capillary mode and sampler mode.
- 7. The instrument should have Hydrodeynamic focusing/ impedence method for RBC/PLT channel.
- 8. The instrument should have cyanide free sis-hb/colorimetric method for the haemoglobin measurement.
- 9. Instrument should be equipped with automatic rerun/reflex modes.
- 10. Instrument should have facility for upgradation.
- 11. Instrument should have options for auto sampler and integrated barcode reader.
- 12. The instrument should have COMPREHENSIVE INFORMATION PROCESSING SYSTEM WITH: User-friendly Windows XP/7 based software.
  100000 sample data with histogram and scattergrams storage.
  99 QC files each with 300 points for QC can be stored.
- 13. The instrument should have minimum maintenance with semiconductor laser has lower power consumption, higher stability and longer life thus cutting down on maintenance cost.
- 14. The instrument should be EXTENSIVE QC FEATURE.
- Min one file for X bar M. Delta checks available for cumulative review. Option for online QC available.
- 15. It should have extensive linearity preferably as WBC-0.0-400X10<sup>3</sup>/  $\mu$ l RBC-0.0-8.0X10<sup>6</sup>/  $\mu$ l PLT-0.0-3000X10<sup>3</sup>/  $\mu$ l Hb-0.0-25.0G/dL. RECTIC 0.0-24.5% HCT-10-70%
- 16. Equipment, reagents and reportable parameters should be US-FDA/EU-CE approved.
- 17. QC must include all reportable parameters for all QC levels and the price should be quoted separately in the price bid.
- 18. The company supplying the instrument should have a good track, record and excellent service and distributor network all over India.
- 19. Warranty for 2 years and 5 year CMC.
- 20. User/Technical/Maintenance manuals to be supplied in English.

- 21. List of equipments available for providing calibration and routine maintenance support as per manufacturer's documentation in service/technical manual.
- 22. List of important spare parts and accessories with their part number and costing.
- 23. Equipments should be complete in all aspect to start working from day one.
- 24. Technical support to be provided by supplier on regular daily basis.
- 25. Demonstration of equipment before finalization of technical specifications.
- 26. Start up kit for 5000 tests and 02 packs of control (Higher, Low, Normal) along with equipment at the time of installation.

# <u>Item No. 4</u> <u>Digital EEG-Machine with 64-channels(Amended Specification)</u>

64 Channels Amplifier(64) including 9 active/references and eight additional channels for polysomnography (ECG, EMG, Breath, oral nasal flow, respiratory belt etc) also any two channels can be configured as Bipolar, AC or DC through software wired(Ethernet 100 baseT, IP

addressable, DHCP capable)

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- 2. The system should have facility to do proper polysomnography with synchronisied CPAP titration.
- 3. Impedance Measurement: both amplifier and Monitor Screen.
- 4. Acquires SpO2 and Plethysmography from integrated (module)
- System should have modules for SpO2, and Heart Rate Monitoring
   System must be supplied with manufacturer supplied video capturing hardware for high
   quality video
- 7. Common mode Input Impedance> 100 MΩ Differential Input Impedance> 40 MΩ
- 8. Bandwidth 0.048-5333 Hz(maximum)
- 9. Analog/Digital Converter Resoltution:24 bits ADC Resolution Voltage 0.153µV
- 10. DC Offset of at least ± 1200mV Hz
- 11. Amended as Sampling Rate:8 KHz and higher
- 12. Input Noise:< 1.5μvpk-pk @ 0.1 to 100 Hz. CMRR>110 dB
- 13. Acquisition Sensitivity:  $1 \mu v$  to 500  $\mu v/mm$  for individual channel.
- 14. Low Filter: Adjustable between 0.01 to 10 Hz.
- 15. High Filter: Adjustable between 15 to 2000 Hz RF Patient Protection is must.
- 16. Water proof pouch with belts etc for easy carrying & safety to the amplifier.
- 17. 2 Waterproof cover for system for use during washing hours.

## Acquisition Software

- 18. Individual Channel Control, easy customization of Montages, along with re-montage capabilities through m, toolbar-acceleration buttons.
- 19. Combine all users defined settings into templates or protocol, for use in different applications and the protocols should be available for user by a menu selection.
   Arrange montages into sets for different patient groups & should display a graphical view of
- 20. the current montage during the EEG recording.

- 21. Define new Sensors should be included as standard viz assign to amplifiers inputs, define traces in montage, define calculated channels (Average, Source/Laplacian), or define Trends.
- 22. Facility to click any point to display corresponding traces & Slide Pointer to change displayed duration of
- Sort able list of all events placed in the recording, both automatically and manually placed such that Review and add events to recorded traces in Review Pane while still displaying live traces in
   Live Pane.
- 25. Automatic detection of bradycardia and tachycardia based on EKG or Pulse Sensor. Facility to display the current numerical value of selected traces such as vital signs, or to
- 26. indicate appearances of events like seizures.
   Amplitude Integrated EEG(aEEG)- both bipareital and cross cerebral method. EEG EEG
- 27. Amplitude- Trend and Number
- 28. Spectral Edge Frequency-Trend and Number
- 29. EEG Power Spectrum
- 30. Comparison of signals from both hemispheres.
- 31. Brain Mapping through software.
- 32. Latest Spike and seizure detection & Polyomnography automatic scoring software to be available with the system.
- 33. Enhance artifact and noise removal software for artifact.
- 34. Should be able to give EEG data output in ASCII format.
- 35. Waveform freeze facility with simultaneously background recording/split screen.
- 36. Review Software( 1 No for main system, 1 for additional review station which will be install in Neurology
- 37. Point Added HV and Photic Stimulator (1nos) HV AND PHV : Automatic time counters and events
- 38. Photic stimulator : white LED Photic stimulator must be on the adjustable stand for better arrangement

- 39. Should be able to connect with any system.
- 40. Point Added Acquisition station computer (01 Nos) ; Wall mountable (Non Space Occupying)
- 41. The acquisition station computer should strictly be supplied by the manufacturer along with the system Latest Core i7 or beter available processor
- 42. 8 GB RAM or better available RAM
- 43. 1 TB OR better available HDD
- 44. Preloaded Microsoft genuine windows 8 /(Compatible windows and bit to the software)
- 45. DVD writer, key board ,optical mouse with standard accessories.24 " colored LED Display monitor
- 46. Good study mike to pick up sound (not collar wearable) in built speakers for hearing sound (not extra external speakers)
- 47. The system comes with its standard trolley and on the alter stage if we want it wall mounted it can be
- 48. Point Added : Review Station Computer (01 Nos. Neurology faculty room):
- 49. The PC should be branded and not assembled
- 50. Latest Core i7 or better available processor
- 51. 8 GB RAM or better available RAM
- 52. 1 TB OR better available HDD
- 53. Preloaded Microsoft genuine windows 7 ulimate with latest pack.
- 54. DVD writer ,key board, optical mouse with standard accessories.
- 55. 24 Colored LED Display monitor.
- 56. Easy Customization of montage and remontage to be possible during review on acquirieng system or
- 57. Facility for viewing several recordings in tiled or cascading windows . Facility to review and run two
- 58. Facility to review and prune /modify remontage the data recorded from these system on a CD/ DVD

- 59. To provide the facility of individualized workspaces, such that individual users can select and save their Facility for Prune/ Trim down EEG or video to specified events along with user define time before or after.
- 60. Facility for Zoom/Magnify EEG Trace, Copy & Paste of EEG or trends to reports and presentations.
- 61. Facilty to search EEG in a record by time.
- 62. All Vendors can visit the lab to evaluate the tentative installation site for acquisition and Review
- 63. Printer(1 Nos for Acquisition Station and 01 No. Of Review Station): Colour Laser Printer. UPS (01 Nos for Acquisition Station and 01 No of Review Station): UPS of suitable rating
- 64. with MF Batteries with 1 Hour Back Up time.
- 65. Environmental Factors:

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

- 66. General Specifications.
- I.The system should be supplied with mountable trolley of good quality based on specification and design<br/>Voltage corrector/stabilizer of appropriate rating meeting ISI Specifications(Input 160-260 V
- li &output 220-240 V & 50 Hz.

It is mandatory that the system should be Certified US FDA approved. Vendor to attach

- lii theCertificate clearly mentioning the model, address of manufacturer and validity on the certificate
- 67 Compliance/ Regulatory Standards

Designed, tested, manufactured and certified to meet the following domestic(USA), Canadian,

- European and International Standards.
- 68 Patient Isolation BF
- 69. UL60601-1 Medical Electrical Safety Standard(USA)
- 70. CAN/CSA-C22.2 no. 601.1-M90 Medical Electrical Safety Standard(Canada)
- 71. EN/IEC 60601-1 Medical Electrical Safety of Medical Equipment(International and Europe) IEC 60601-2-26
- 72. Particular Safety of electroencephalogrpahs equipments EN 60601-1-2 Collateral safety standard for Medical Device Directive(MDD) product certified to comply to EC Directive 93/42/EEC USFDA Approved

## 73. Consumables:

- Compatible EEG net caps 3 of each small, medium and large size saline applicable(total 09)
- Ii
   Gold plated EEG Disc Electrode(length-1.5m)-100 Nos. Ten 20 Paste, 228 Gms Jar-50 Nos.
- lii Nu-Prep Gel, 114 Gms tube-50 Nos. DVDs-100 Nos.
- Iv 2 TB External HDD Archiving of data:

Price of all accessories and amplifier and screen and software to be provided and freeze for 5 years.

- Vi Demonstration of equipment would be mandatory once technical bids are opened. Comprehensive warranty for 5 years & 5 years CMC after warranty. No extra charges for
- Vii warranty or
- Viii CMC for above duration.
- 74. Documentation
- I User/Technical/Maintenance manuals to be supplied in English.
- li Certificate of calibration and inspection.

Should have local service facilit y & service provider should have necessary equipments available for

Iv Log book with instructions for daily, weekly, monthly & quarterly maintenance checklists. The job Compliance report to be submitted in a tabulated & point wise manner clearly mentioning the

### Item No. 5

### <u>Ultrasound-cum-Echo</u> Colour Doppler.

#### Amended Specification:-

- 1. The equipment must be US FDA approved and capable of operating in B Mode, Color Doppler, Color Power Doppler, PW, CW modes and should weigh less than 6 kg including battery.
- 2. It must support transducers with linear, phased array TEE and curved array probes.
- 3. The system shall have broadband architecture with an operating frequency of at least 1-15 MHz.
- 4. The system shall have the ability to enhance tissue margins and improve contrast resolution by reducing artifacts and improving visualization of texture patterns, please specify the technology.
- 5. System must have needle visualization technology by which needle can be seen clearly during nerve block at any angle.
- 6. Unit should be able to give very high image for better contrast resolution, tissue differentiation and edge detection, equivalent to high and card based system.
- 7. The system must display at a maximum depth of 3-35 cm
- 8. Controls for 2d mode: Total gain, depth, TCG, dynamic range, acoustic power output, number for\position of focus.
- 9. Controls for Colour Doppler: PRF, colour gain, position and size of ROI, steering of ROI, colour maps and colour invert.
- 10. Controls for pulsed Doppler: variable sample volume size from 1 to 5mm or more, steer, PRF, baseline, gain angle correction, spectral invert, duplex/triplex on/off.
- 11. Measurements for Doppler modes: Stenosis quantification in percentage, diameter, PSV, EDV, mean, PI, RI, floor volume, acceleration time and index. Automatic and manual measurements and display of pulsed Doppler calculations should be possible.
- 12. Sorting of data base with patient name and date should be possible.
- 13. Unit should function with 200-240 V, 50 Hz AC, 5 amp power outlet. Power requirement to be specified.
- 14. The firm must provide a user installation List of minimum 50 installations orders of the same/similar equipment users in India in major hospitals and satisfactory performance reports of these in the last 5 years order list and satisfactory performance certificates should be enclosed along with the tender.
- 15. The system shall provide the user with generic digital callipers for Measurements in 2D mode : Multiple distances, area and volume
- 16. The system must have a dedicated cardiac, vascular calculations package
- 17. The system shall provide a backlit keypad with ease of use, with facility to disinfect the keypad of system must be possible to avoid any cross contamination and nosocomial infections in OT.
- 18. The system should be able to go from the off status of active scanning in less than 30 seconds for critical and emergency situation in OT.
- 19. The system must have trolley for transport

- 20. Transducer must be sturdy, resistant to breakage & damage & fall against hard surfaces.
- 21. The system should have an LCD screen size of more than 10 inch size
- 22. The system shall have digital Video interface (DVI), S-Video, VGS, USB and audio output with provision for storage of images and transfer to external devices.
- 23. The system shall have the ability to function by AC/DC or battery power with the same degree of functionality, the battery life (run time) shall be at least 2 hours.
- 24. The system shall support the DICOM function ability storage, print and work list, also ready to connect to PACS.
- 25. Demonstration is a must

### TRANSDUCERS AND ACCESSORIES

- 1. 2-5 MHz, multi-frequency broadband curved array transducer for general purpose, abdominal, deep nerve access, sciatic nerve and abdominal applications
- 2. 6-13 MHz multi-frequency, broadband linear array transducer for vascular, small parts, musculoskeletal, nerve imaging with less than 40 mm size.
- 3. High frequency linear transducer 6-12 MHz for nerve blocks, vascular access, vascular imaging. With small foot print of 25 mm for pediatric applications
- 4. ECHO probe 2D. Phased array probe specs 1.5 4 Hz., small foot print (2.5- 1.5 cm probe, good axial resolution & large coverage
- 5. A trolley and carry bag must be available to store and / or transport the system
- 6. The manufacturer should provide a stand by machine in case of failure of the system for more than 24 hrs.
- 7. Provision of attaching three probes simultaneously multi-docking system.

The unit and transducers should be covered with comprehensive onsite warranty for 5 years commencing from the date of issue of installation certificate. The firm should also quote the rate for CMC for next 5 years after the expiry of warranty period of 5 years. The firm must quote of all consumable, spare parts/accessories

All other tender terms and conditions remain unchanged

Amendment to be issued will be uploaded on website www.Tenderwizard.com/HSCC & www.hsscltd.com

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