

AMENDMENT-XXVII

Ref.: IFB No. HSCC/SJH/Medical Equipment/2016/26 Dated 04.01.2017

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

The technical specification further amended by Neurosurgery Department Safdarjung Hospital on 10.08.2017 has been received for item no. 1, Brain Suit MRI. It is extended the bid submission date from 10.08.2017 to 22.08.2017

Due to inadequate response of Item No. 2 Flat Panel DSA Lab. It is extended the bid submission date from 10.08.2017 to 22.08.2017. No further extension will be given for item no.2 .

Amended Specification are as under: -

Item No. 1

BRAINSUITE INTRAOPERATIVE MRI 1.5T - AMENDED SPECIFICATION

Existing As :

MRI manufacturer will be the main vendor and he will be responsible for coordinating with other companies to hand over it in the functional state. This will be executed on the turnkey basis.

Competitive bids (Technical and price separately) are invited for a state of the art neuro –surgical operating room complex with fully integrated high resolution actively shielded 1.5T MR imaging system with intra operative neuronavigation with automatic image registration facility. MR compatible head fixation with parallel imaging. Functional imaging, imaging for Gamma Knife planning required for the New Super Speciality Block in Safdarjung Hospital. New Delhi, Only manufacturers of 1.5 Tesla MRI machine who are represented directly in India and who can integrate with the other vendors to provide the complete integrated solutions satisfying all the tender requirements can participate in the bid. The bidding company will be solely responsible for the supply and maintenance of the system and all the components of the bid. The system should also include floor mounted operating microscope & microscope based neuro-navigation, anaesthesia work station. Monitors and additional anaesthesia related equipment, electrophysiological monitoring. OR Lighting , ceiling, suspended high resolution image display and with all accessories. It should be possible to perform real time MR guided brain biopsy/catheter placement & deep brain stimulation. All components should be MR compatible & integrated to ensure smooth work flow. The system should permit intra –operative imaging control as well as routine MR imaging and should be designed & executed on turnkey basis in the designated area of the New Super Speciality Block in Safdarjung Hospital. New Delhi. The area construction involves modification of the existing structure with an extension on side as designated by the authorities of New Super Speciality Block in Safdarjung Hospital. New Delhi. On site inspection by the potential bidders before submission of the technical /financial bid is encouraged. The setup should offer all surgical procedure to be performed with standard surgical instruments immediately outside

of the 5 gauss field line of the MR Scanner or in the regular OT away from MR.

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1. 1.5 Tesla MRI for Intraoperative Imaging including installation and RF shielding
2. Ceiling Mounted Intraoperative neuro Image guidance system with automatic patient registration
3. Fully integrated digital OT with data management system and integration with intra-operative data Management for gamma knife surgery.
4. Ceiling mounted OR lights with integrated light camera & OR room camera.
5. Compatible Microscope
6. Compatible OR equipment
7. OT Table
8. Anesthesia Workstation
9. Installation and training

It should have the following features:

Definition (Schematic Drawing attached):

- DR : Diagnostic Intraoperative Room
- OR : Intraoperative Neurosurgical Room

1.5 Tesla MRI for Intraoperative Imaging (DR):

Stable ultra-short length (150cm or less) whole body superconductive magnet strength of 1.5 Tesla magnets with active shielding.

Existing As : High Performance gradient system with minimum gradient strength of 33mT/M or better with slew rate 120 Mt/m/ms.

Amended as : High Performance gradient system with minimum gradient strength of 40mT/M or better with slew rate 200 Mt/m/ms.

Existing As :

Patient table should be able to take at least 300 kg patient load. OT table should be usable as the operating table & should easily slide out for to operating room. It should be incorporated with operating MR compatible head holder so as to allow imaging during surgery in supine, prone and lateral position.

Amended as :

C. Patient table should be able to take at least 225 or more kg patient load. OT table should be usable as the operating table & should easily slide out for to operating room. It should be incorporated with operating MR compatible head holder so as to allow imaging during surgery in supine, prone and lateral position.

D. It should include a tried and tested effective patient transfer / transportation system to shift the patient from the OR to the MRI scanner for intra-operative scanning and back to the OR in a safe and practical manner. A MRI compatible trolley for shifting to MRI room to be provided.

E. Magnet bore to be sufficiently wide (70cm or more) after positioning of gradient shim and RF antennae to allow positioning the patient during surgery with head frame / head holder for imaging. Separate MRI table should be provided.

Existing As:

F. Digital RF Transmit and Receive System with 16 independent RF channels to permit PAT factors up to 4 (one direction) or more to help increase speed acquisitions.

Amended As :

F. Digital RF Transmit and Receive System with 32 or more independent RF channels to permit PA T factors up to 4 (one direction) or more to help increase speed acquisitions.

Existing As :

G. Head Coil with frame should be minimum 8 Channels and should have minimum 3 fixation points, can be used for image acquisition and intra-operative applications in Prone, spine & lateral positions.

Amended As:

G. Head Coil with frame should be minimum 6 Channels and should have minimum 3 fixation points, can be used for image acquisition and intra-operative applications in Prone, spine & lateral positions. Should be adequate for comprehensive examinations.

I. It should have Image acquisition for T1, T2, Flair, DTI, BOLD, SWI, DW, PW, PR & volumetric 3D sequences.

Existing As:

J. Should have all the necessary coils & supports systems for imaging brain, spine & rest of body.

Amended As:

J. Should have the imaging coil i.e Head / neck coil (20 Channel or more), spine coil (32 Channel), Body coil (18 Channel or more) 2 flex coil for supports systems for imaging brain, spine & rest of body.

K. The MRI Vendor should be responsible for the end to end installation of the MRI machine including interior finish of the MRI room and the OR, RF shielding and any required turnkey work to be done.

2. Ceiling mounted Intraoperative neuro image guidance system with automatic patient registration.

Hardware

i. The system should be wireless with passive marker technology.

ii. It should have a Zero OR footprint concept provided through ceiling-mounted camera and touch display.

iii. The system should be fully integrated with the Intra-operative MRI and both preoperative & Intraoperative patient data should be automatically registered without any manual registration steps required.

iv. The system should allow automatic patient registration in any patient position i.e separate lateral & prone position etc.

v. Pre-operative patient registration allowing patient to be registered automatically immediately as the scan is done using the MRI.

vi. It should again automatically recognize and automatically register the patient during intra-operative scan compensating for craniotomy and brain shift by deformity correction and provide an exact visualization for the 'Brainshift'.

vii. All necessary hardware should as registration matrix along with the sterilization tray and specialized MR compatible Cranial reference unit should be included.

viii. It should also included option of manual pre-operative patient registration with skin sensitive touch device for maximum accuracy in prone position & Laser guided registration device for marker less/touch free & fast registration while performing manual patient registration.

ix. It should have flexible positioning of cameras and monitor with multi articulated arms allowing adjustment to virtually any position.

x. It should have a Ceiling mounted touch screen monitor (min 26") with brilliant display quality & resolutions beyond full HD (1920x1200pixels per display). Image quality entirely preserved no visualization limitations from the touch interface (surface acoustic wave technology).

xi. Interface Box for connectivity i.e. with surgical microscopes, fluoroscopes, endoscopes, ultrasound etc. via state-of-the-art digital and analog video inputs supporting up to full HD resolution. HD/SD-SDI up to 1080i/29.9fps, composite (CVBS, NTSC/PAL), S-video (NTSC/PAL), 1x SDI HD (In), 1x S- Video (In), 1x Composite (In), 1x Microscope Connector (with: 1x USB 2.0, 1x RS232, 1x SXGA, 1x SDI HD (In), 1x Composite (In).

xii. System should be operable without keyboard & mouse.

xiii. It should have high-end Infrared camera with Optical, laser guided and advanced wireless passive marker tracking technology.

XIV. The system should display a predefined trajectory pathway, inline and probe eye views.

XV. The probe should have capability to show images at 0mm – 180mm in from of it (Tool Tip Extension). The virtual tip should be also having the accuracy verification/ predication system in-built in the system.

XVI. The system should have sub-millimetric patient accuracy ideal for deep seated cranial biopsies, at the same time the system should also have the accuracy verification / prediction system in-built in the system.

XVII. The system should have screenshot storage function for documentation purpose.

XVIII. Fine-adjustment for navigated frameless biopsies, shunt placements & endoscopic examination guided by the navigation system. Allows precise online tracking according to the pre-planned trajectory; Adapts to fit cylindrical instruments of 1.8mm -8.0mm and up to 300g, Holds instruments with length of up to 35 cm and should have the adapter for connecting it to the MRI compatible head holder.

Software

- i.** The Advance Cranial applicable software should have a separate workstation with TFT monitor for advanced cranial surgery planning enabled with transfer of preoperative data from CT, MRI, DTI, BOLD, SPECT, PET etc in DICOM format from any sources.

- ii. Both the Planning and navigation software should have the functionality of doing advanced 3D Visualization allowing display to bone-vessel, skin overlay. Maximum-intensity-Projection, Digital Radiography (DRR etc) views options with flexibility to superimpose 3D data images on the surgical plan and cut and crop functionality to adjust 3D images.
- iii. Software should offer Automatic segmentation of anatomical cranial organs for the fat delineation of the anatomical structures. All anatomical objects such as Brainstem, Cerebrum, Cerebellum, CSF, Edema, gray matter, Hippocampus, Hypothalamus, Putamen, resection cavity, ventricles, thalamus, vessels, white matter, whole brain, eyes, optic apparatus etc should be automatically contoured by the system.
- iv. Software should offer automatic Image fusion of the CT, MR, DTI, BOLD, PET & SPECT images.
- v. The software should have the capability to paint the targets and adapt to the complex 3D structure of the lesion/ object /landmark using the HU value set that it becomes quick & time saving to outline the object during pre-operative & intra-operative planning.
- vi. Software should offer Conversion of fiber tracts to 3D structures for visualization & interactive selection of Fiber tracks. It should provide automatic Fibretracking base on point to-point, point-to-location/region, and also drawn contoured object showing different color code for the direction of hydrogen atom in Fibre tracking (display of fibers in original red-green-blue color code for detailed functional information.
- vii. Software should allow anatomical images to be merged with functional maps to visualize perceptual, motoric & cognitive areas of the brain using the Blood Oxygen level dependent (BOLD) mapping & localization of functional areas. It should include Pre-processing of data including motion correction, since time correction and smoothing, flexible definition of different functional paradigms and should support of block-designed paradigms for motoric and speech areas with automatic detection of functional activations in the time series view for verification of signal to paradigm correlation. It should include Interactive selection and display of functional areas and regions of interest with possibility to Convert into 3D objects for use in navigation.
- vii. Software for Frameless Biopsy system
- viii. Microscope interface software should have advanced image guided microscope: Tracking of spatial orientation, viewing, direction, and associated focal point of the microscope, Superposition of 3D projections and reformatted contours of pre-planned anatomical structures, targets, and trajectories Injection of such 3D information (contours, trajectories, targets) into the optical pathway of the microscope Injection of non-correlated video images (e.g. endoscope) or diagnostic images (reformatted 2D/3D images) into optical pathway Continuous “smart” auto focus to the instrument or pointer tip.
- ix. The System should provide additional navigation information like “distance to target”, “tumor extension” and “target/trajectory” information.

xi. The microscope integration should deliver Heads up display and image injection module into the microscope eyepiece provided the microscope itself has those features.

xii. The system should have the entire kit for microscope integration.

3. Fully Integrated Digital OT with Data Management System & Integration with follow-up Radio surgery /Radiotherapy.

It should include IP based Digital OR with seamless integration with Intra-operative MRI & the Navigation platform:

i. Minimum 42" wide Full HD (1920x1080 pixel) ON-wall (2 units required in the OT). Both units should seamlessly integrate with each other and pair with each other. Control unit of video signals and routing from 24" or touch screen located inside the sterile area for surgeon.

ii. In-built high performance workstation (min. 8GB RAM & 2 TB storage) allowing connection with up to 12 video signals and routing contents with pre-designed expandable capabilities/ connection point on the surgical pendant for future addition of Intra-operative devices.

iii. In-built communication controls such as video conferencing, Recording and Live Streaming should be possible using the touch screen.

iv Full integration with the Hospital Network and should be able to configure the IP series as provided by the hospital.

v Full DICOM Import of patient data from Hospital Network / PACS.

vi Analog/ Digital import of any modalities such as MRI, CT, X-Ray, PET, SPECT, Ultrasound etc.

vii Transfer of DATA using USB, CD or DVD.

viii In-built patient data privacy & HIPPA compliant with user log-in and auto log-off.

ix Possibility to route images, patient data, Intra-operative video sources through touchscreen without the use of keyboard or mouse.

x The system should include all transfer lines/ cables connection within the OR

xi It should include Intra-operative Device management & Integration including.

xii Video inputs with Full HD with SDI (OT light camera & OT Room Camera) should be integrated.

xiii Different input formats such as S-video (Ultrasound), Composite (C-arm), DVI (Endoscope/ Microscope) & also standard RGB/VGA should be supported for integration.

xiv Special provision of additional input signals on the surgical pendant.

b. **Interactive DICOM viewer capabilities should include:**

- i. Capability on Interactive DICOM capabilities including Zoom-in/out, panning, scrolling, add/subtract slices, flipping, Rotating, Adjusting contrast/ brightness.
 - ii. Capability of Measurement functionalities for distance, angles and circles should be possible on the modalities.
 - iii. The system should allow instantaneous 3D visualization for analysis.
 - iv. 3D volume rendering of CT, MR, PET, SPECT datasets with presets for visualization of skin, bone, vessel, DRR and MIP should be included.
 - v. Superimposition of 3D dataset visualization and surgical planning data such as 3D contours, trajectories and annotation should be visualized instantaneously.
 - vi. It should allow crop functionality to cut through the planes in 3D along any direction and should allow to manipulate the threshold of the relevant anatomy.
 - vii. The system should allow quick and easy volumetric outlining of pathologies and anatomical structures with instant volumetric contouring and calculation of outlined structure in just two orthogonal slices.
 - vii. It should allow automatic creation of volumetric report defining the geometrical measurements like volume, PECIST & Macdonald criteria.
 - ix. It should allow automatic fusion of multiple data CT, MRI, MRA, PET, SPECT, DTI & BOLD
 - ix. The system should also allow planning for multiple trajectories for different Neurosurgical workflow with interactive touch screen control for target and entry point definition.
 - x. Option for flexible scaling of trajectory diameter should be included in the system.
- C. It should include Live Streaming of OR procedure capabilities as-**
- i. Live streaming should be possible using the touch screen which can be viewed using the hospital network or web browser from anywhere.
 - ii. It should be possible to live stream video signal from HD camera (Room & OT camera), endoscope, Microscope, Ultrasound etc whichever is being used intra-operatively.

D. Digital Recording capabilities as :-

- i. It should be able to locally record the procedure in digital HD quality on the in-built computer on the wall itself using the touch screen.
- ii. The system should allow storing of all recording to the USD or Hard disk once the procedure is finished.
- iii. It should also allow taking screenshot of the live procedures on the display using the touch screen. All screenshots taken on the live streaming /videos during the procedures should also be stored on the in-built computer platform on the wall which can later be transferred to USD/Hard disk once the procedure is finished.
- iv. It should also have the provision of configuring to save of recordings, screenshots etc on the hospital network.

E. Audio-Video conferencing capabilities should include-

- i. Web-based/VOiP based audio video conferencing should be provided
- ii. The system should have built-in camera and microphone for conferencing
- iii. It should also have the capabilities to configure Bluetooth microphone for conferencing in sterile environment.
- iv. It should also allow network based remote consulting, viewing and communication from Surgeon's office, Doctor's lounge, Seminar room/ hall, Auditorium room through the network.

F. The system should allow integration with the existing Hospital HIS platform HL7, DICOM3, IHE standard.

G. The system should also include display of Surgical checklist for improved patient safety-

- i. The Electronic checklist should be based on WHO principles.
- ii. Checklist should guide through different questions to make sure that e.g. the correct patient is operated at the correct site, the OR team prepares for risk of high blood loss, the OR team will avoid inducing an allergic drug reaction for which the patient is known to be at risk, etc.\
- iii. The Checklist should be available in English language.
- iv. It should have Full integration of checklist in Hospital Information System (HIS). It should create document providing evidence that all steps in the checklist were completed and is sent to HIS and embedded in the electronic medical record of the patient.

H. Intra-operative simulation of follow-up SRS/SRT planning:

- i. It should allow automated analysis of follow-up Stereotactic Radiosurgery/Radiotherapy simulation plant for residual benign brain tumours during surgery.
- ii. SRS/SRT plan feasibility should allow reducing surgery time and decreasing morbidity by providing criteria for concluding subtotal resection.
- iii. It should have automatic intra-operative plan simulation of follow-up SRS/SRT based on initial or updated tumour volume.
- iv. It should include Automatic simulation and intuitive side-by-side comparison of single fractionated, hypo-fractionated, and conventional fractionated treatment plans
- v. It should have comprehensive visualization of the simulated plan results like dose volume histogram, including dose conformity and constraints and visualization of the dose distribution.

4. Compatible ceiling mounted OR lights :

Existing As :

A .Operating Room should have high-end surgical OR lights with 2-arm system with single /multi bulb technology with High illumination intensity at least 130000 lux. For attachment to roof Part should be provided.

Amended as :

A .Operating Room should have high-end surgical OR lights with 4-arm system with si angle /multi bulb technology with High illumination intensity at least 130000 lux. For attachment to roof

Part should be provided.

5. Compatible Microscope:

High end 300 w xenon light source having contravas stand, able to incorporate images guidance. should have binocular surgeon eye pieces, binocular Assistant diploscope, high definition recording system with at least 24 " medical grade monitor to be fixed on wall panel. Recording system should have 4 GB RAM, 2 TB HDD storage memory. A side binocular tube for assistant should also be provided. The microscope should have ICG and ALA Facilities. Necessary Software & hardware should be provided.

6. Compatible equipment: MR Compatible Items

i. RF Cabin: The system should be supplied with the imported RF cabin with RF room shielding, RF Door screen, and interiors for the same should be carried out suitably.

ii. Dual/ triple Head MRI-Compatible Pressure Injector (minimum 2000 cost line) with 500 sets of syringes (Two syringes & connecting tubing per set). It should be compatible with 10, 15, 20 & 30 ml pre-filled contrast syringes and 50 ml syringes for both saline and contrast.

iii. Water Chiller for Cold Head and Gradients.

iv. Two Non-ferromagnetic MR compatible patient transfer trollies of international make should be provided. (in case of dockable table, one extra trolley to be supplied)

v. Fire Fighting System, Detectors and 6 Fire Extinguishers (MR Compatible) to be provided

vi. Hand held metal detectors - 4 Nos

vii. Closed circuit CCD camera for patient observation. Phantoms for image quality audits to be provided.

viii. Patient positioning accessories with hand held alarm & look-out mirror.

ix. MR Compatible Transport Ventilator. (1000 Gauss Line)

x. Two laptops with 1 TB storage, 4 GB RAM & Windows 10 operating system (of reputed make) with laser Printer, UPS & Dictaphone.

xi. Two Set of boom and spring arm to be installed in the OR to hold monitors, surgical and anaesthesia equipment.

Xii. MRI Compatible anaesthesia workstation having with digital display having facility for ETCO₂, bispectral index inbuilt ventilator. It should be on wheels with brakes and total machine should be transportable to MRI Room.

XIII.MRI safe I.V Pole 4 hook system – Qty. 08

Existing As: XIV. Two Multi parameter monitors MRI Compatible which should display SPO₂, Heart RATE, ECG, and NIBP. It should have 2 invasive ports for lines like intra arterial pressure and central venous pressure. One will be mounted on wall & one to be transportable.

Existing As:

xv. Drug administration system/ pump for exact medication dosage – Qty. 02

Amended as:

Amended as: MR Compatible Infusion Pump (2000 Gauss Line) 5 Nos. (3 infusions + 2 syringes)

xvi. OT Chairs– Two for Surgeons Chairs and Two assistant chair should be provided, which should have height adjustment.

7. OT Table: OT Table high end, top of which to should be MR Compatible and top should be slide on to trolley to be taken to MRI room. MR compatible 3 pin head fixation system should be supplied with 6 spare pins set and table attachments.

8. Anaesthesia workstation: MRI Compatible anaesthesia workstation having with digital display having facility for ETCO₂, bispectral index inbuilt ventilator. It should be on wheels with brakes and total machine should be transportable to MRI Room.

9. Installations & Trainings:

The main bidder shall be MRI manufacturer, who shall be comprehensively responsible for supply installation testing and commissioning of brain suite on turnkey basis as per the tender condition.

Training for 3 surgeons, 3 Radiographers, 3 Nurses & 2 Technicians should be done onsite 3 surgeon to be trained to be trained on other centres where brain suit exist by the supplier for two continuous weeks followed by repeat trainings of one weeks each at 6 months & 12 months from the day of going clinical.

All interior and finishing of the Brain suite intra-operative MRI area shall be done by supplier. Finishing should be like other modular O.T. in super specialty block of Safderjung Hospital.

Warrantee: :-5 Year warranty with 95 % up time maintenance.

At the end of Assembly of intraoperative MRI Neuro Navigation and other things needed for the Brain suit should be complete and system should be able to perform the surgery on the patient in the brain suite.

Amendment to be issued will be uploaded on websites www.tenderwizard.com/HSCC & www.hsccltd.com.

All other tender terms and conditions remain unchanged.

Medical Superintendent
VMMC & Safdarjung Hospital
New Delhi