

10.09.2018

TAMILNADU MEDICAL SERVICES CORPORATION LTD.,

**TENDER FOR SUPPLY AND INSTALLATION OF NEURO NAVIGATION SYSTEM
FOR CRANIAL & SPINAL APPLICATION AND COMPLETE MULTI-DIMENSIONAL
SURGICAL IMAGING SYSTEM TO DEPT. OF NEURO SURGERY, GOVT. RAJAJI
HOSPITAL, MADURAI UNDER PMSSY SCHEME**

TENDER NO.293/NNS/PMSSY-GRHM/TNMSC/ENGG/2018, DT.22.03.2018

Corrigendum

a) The following corrigendum are issued:-

Sl. No.	Tender Document Reference	Instead of	Read as
1.	Page No.54 to 59 Section VI: Technical Specification And refer corrigendum issued on 11.06.2018	Existing Text	Revised Text at Annexure - I

All other terms and conditions of the tender remain unaltered.

The above forms part of the bidding documents. The bidder shall attach the copy of this corrigendum duly signed by their authorized signatory, in their bid.

Sd/-

General Manager (E)

SECTION VI: TECHNICAL SPECIFICATION - REVISED

1. SPECIFICATIONS FOR NEURO NAVIGATION SYSTEM FOR CRANIAL AND SPINAL APPLICATION

General

1. The system must provide state of the art navigation software with detailed planning functionality
2. The system should be based on optical along with Electromagnetic Tracking or equivalent option.
3. The system is basically for Brian Tumour resection, Spine Tumour resection, Biopsy, Shunt placement, Pedicle screw fixation, ENT and skull base. It should have add options for other neurosurgery, spine and orthopaedic/pelvic surgeries.
4. The system must support DICOM data import and processing.
5. The system must be mobile to transfer easily between surgical theaters by a single person.
6. The system must come equipped with instruments for navigation
7. The system must include an integrated CD/DVD/USB/ Network Port drive for data import and data export.
8. The system must support 220V power supply.
9. The system must allow to output the navigation view at monitors in the surgical theater in HD.
10. The system must allow to connect a endoscopic or microscopic camera system and display its video signal without loss of resolution on the monitors of the navigation system
11. The navigation system must include software for pre-operative and intraoperative planning.
12. The planning software must be able to transfer data to the navigation system via USB and LAN.
13. The system must include documentation
14. True wireless system based on Active or Passive Marker Technology.
15. The system should have touch-sensitive screen or smart instruments that could be used in sterile field.

16. It should have Mobile cart with or without separated camera stand for flexible positioning within the OT
17. The navigation system should be operable without keyboard or mouse.
18. Surgeon monitor should have display size of minimum 24”.
19. System should have facility to recall registration intraoperatively in case of patient or reference movement.
20. The system should have sub-millimetric patient accuracy ideal for deep seated Cranial biopsies and should track the needle trajectory and depth and should be displayed on the screen.
21. The Frameless biopsy system should allow online tracking of biopsy needle according to pre-planned trajectory and should have ability to change the plan if required during the procedure and changed trajectory should be tracked.
22. The System must have Intraoperative Ultrasound imaging software and ultra Sound scanner detecting for brain shift compensation, tumor delineation & resection.

Navigation software:

23. The navigation software must support reading patient images from:
 - USB Storage Media
 - CD/DVD
 - PACS & LAN
24. The software must support the following modalities in DICOM format:
 - CT
 - MRI/MRA
 - CBCT
 - DTI
 - fMRI
25. The software must not limit the number of instruments to use during surgery.
26. System should have software for Cranial and Spine surgery.
27. System should have software for 3D modelling, Image merging , Deep Brain Stimulation implant surgery and Biopsy surgery
28. System should have option to merge different images up to minimum 10 data.

Instruments:

29. The offer must include the instruments for invasive/noninvasive fixation to the patient skull

30. All instruments, adapters and calibration bodies must be autoclavable or sterile.
31. System should have pre-calibrated Lumbar and Thoracic probes or system should be able to calibrate the 3-dimensional geometry of any Lumbar and Thoracic probes.
32. System should have instruments for Tumor resection, Lumbar Spine, Cervical Spine and Deformity surgery
33. It should have universal instrument adapter tracking system with passive option or active option.
34. The system should have image guided pre-calibrated and ready to navigate spinal instruments like short drill guide, Awl/Probe/Tap or it should be able to calibrate the 3-dimensional geometry of the short drill guide/AWL/Probes/ Tap.
35. It should have Specific reference frames and clamps for Cervical, thoracic, and Lumbar
36. It should have minimally invasive Spine Instruments to do spinal navigation during MIS procedures, with Navigated Dilator and Percutaneous clamps.
37. It should have Pre-calibrated Tactile Probe set for left and right Thoracic and Lumbar or it should be able to calibrate the 3-dimensional geometry of the Tactile or Lenke probes.
38. System should have facility of virtual fluoroscopic navigation for spinal applications compatible with CT 3D C-arms. Complete multi dimensional surgical imaging system/intraoperative CT/MRI, compatible with 9" and 12 " C-arm of Philips, Shimadzu, Toshiba, Siemens, GE.
39. The System must have portable high resolution Intraoperative ultrasound imaging system with autoclavable intraoperative probe for Neurosurgery and software for brain shift compensation, tumour delineation & resection. Navigation system should be supplied along with compatible intraoperative ultrasound scanner.
40. The system should capture & display live USG video images. It should do a 3D reconstruction & perform the 3D overlay on the intra-operatively acquired USG images.
41. The Ultrasound navigation software should be able to co-relate with pre-operative MR/CT images. These images should have view side by side or overlaid.

42. The system should allow performing the Updation of the real time by moving the object to the current position compensating for the 'Brainshift'.
43. The system should include a frameless biopsy system with needles.
44. The navigation system should have hardware & software for stereotactic surgery including functional stereotactic procedures. The software should re-orient the scan images along the AC-PC plane. The stereotactic system should be adaptable to major frames like Leksell and CRW.

Additional Deliverables / Services:

1. Set of manuals, sterilization instructions in English
2. Training must be provided to 2 neurosurgical faculties from our institute until they are comfortable with the system.

Certifications:

1. All products offered must be medical grade and compliant with US FDA or CE.

General conditions:

1. All Equipment should be USFDA/CE (European)UL/DGCI approved for medical use.
2. Manufactures/Suppliers should have ISO certification for Quality Standards.
3. Electrical safety conforms to standards for electrical safety IEC-60601 or better-general requirements.
4. Certificate of calibration and inspection.
5. All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipments(if any).

2. SPECIFICATIONS FOR COMPLETE MULTI DIMENSIONAL SURGICAL IMAGING SYSTEM

1. It should have a minimum 270 to 360° scan and should be motorized with more than 100 images and two levels of 3D slice thickness.
2. System should be intra operative cone beam or regular CT.
3. It should have a Telescoping door section for lateral patient access
4. The Imaging components should be in enclosed housing for increased patient and staff safety.
5. It should be fully functional with no component movement in and out of sterile field.

6. System should be compatible with regular Translucent OT table.
7. System should have facility to transfer between OTs.
8. It should have a High resolution fluoroscopy (> 50 LP/in. in low dose mode)
9. It should have High resolution 3-D - Axial, Coronal, Sagittal planes.
10. It should have 20 kW to 32 kW X-ray generator for imaging dense anatomy.
11. It should have Large 30" (diagonal) display for superior viewing at a distance.
12. It should have the Ability to go 'full-screen' on any image for superior viewing at a distance.
13. System should have open Gantry for lateral access during Spine surgery.
14. It should have a Wireless, sterile mouse control of image viewing.
15. It should have a Robotic positioning system in 6 degrees of freedom.
16. It should have Storage of pre-set imaging positions for quick, accurate access to commonly viewed images, avoiding the need for re-scouting.
17. It should have Storage of pre-set 'park' position for easy access to patient while imaging is not required.
18. It should have a Power drive for easy handling of imaging system.
19. It should have minimum 40 x 30 cm digital flat panel detector, 3 megapixel (2K x 1.5K; pixel pitch of 0.192mm) for increased image quality (large field of view, square images without distortion).
20. It should complete 3-D image acquisition in ~13 seconds.
21. The 3-D image should be displayed in less than 30 seconds from initiation of acquisition.
22. The Bore diameter of the imaging system should be more than 78cms.
23. The source to image distance should be more than 39".
24. The imaging system should have a provision for selecting region of interest for automatic brightness and window/level control.
25. The imaging system should have an automatic noise reduction, edge enhancement, full screen zoom, digital image rotation, digital window/level control, left/right and top/bottom image reversal, positive/negative image inversion.
26. The imaging system should be able to store more than 10,000 2D images and more than 200 3D scans on hard disk.
27. The imaging system should have a CD R/W .
28. There has to be various outputs like Ethernet, USB, Composite video, S- video.

29. The imaging system should have DICOM functions.
30. The imaging system should offer two levels of operation allowing optimal slice thickness/reconstruction time selection based on the clinical application.
31. The imaging system should offer 12cm volume cube or more anatomical coverage.
32. The imaging system should have different types / features of rotation like Orbital, pivot, swivel, Iso-wag.
33. The Multi - Dimensional Surgical Imaging System should be compatible with Surgical Navigation system.
34. System should have facility to remember scan setting.
35. Should be US FDA or European CE approved product.
36. Vendor has to ensure proper training of at least 2 neurosurgical faculties from our institute until they are comfortable with the system.

General conditions:

1. All Equipment should be USFDA/CE (European)UL/DGCI approved for medical use.
2. Manufactures/Suppliers should have ISO certification for Quality Standards.
3. Electrical safety conforms to standards for electrical safety IEC-60601 or better-general requirements.
4. Certificate of calibration and inspection.
5. All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipments(if any)