AIIMS RISHIKESH

INDENT FOR PURCHASE OF STORES
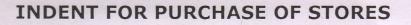
(FORM P-2)

1.   Please fill a separate form for each item

2.   Please fill completely in triplicate. Incomplete forms and those with illegible writing may not be accepted.

Name and technical specifications	quantity	Unit cost approx.	Total cost

Technical Specification: Digital OR : Advanced Intra-operative CT based Cranial & Spinal Navigaion
 	
1. **Intraoperative mobile CT:**
   a) The system should be a 32 Slice mobile CT scanner for Cranial, Spine & Trauma application. The imaging should be thin section and of high quality
   b) The System should have an Image reconstruction matrix of at least 512 x 512
   c) The system should have:
      i. X-ray Tube Voltage : up to Min 120 kV
      ii. X-ray Tube Current: up to 250 mA or more
      iii. Focal Spot: 1mm X 1mm or more
   d) The system should be able to run on standard single phase 220 V AC.
   e) The system should have a bore size of 107 cm or more for versatile patient positioning for Spine, Cranial and Trauma cases
   f) The X-Ray detector system should have solid state detector with 2.0 mm detector width to generate multi slice CT images of soft tissue and bone for Cranial and Spine
   g) The system should have air cooling ducts at the bottom side of gantry to minimize interference with OR sterility.
   h) The system should have the capability for both Axial & Helical Scans
   i) The system should allow motorized transportation with a front view camera for easy movement of the system between different Operating Rooms thus adding to its higher utilization
   j) The System should seamlessly integrate with the surgical navigation system in a way that it allows for a seamless intra-operative automatic image registration workflow which allows the surgeon to automatically register the patient by taking either a pre-operative scan for initial automatic registration or an intra-operative scan to compensate for the intra-operative anatomical changes. The automatic registration should work in a way that the acquired images should be available immediately for navigation
	One unit	18 crores	18 crores

without requiring any manual registration or intervention for both Cranial and Spinal procedures

k) The system should have built–in battery and it should have adequate cables for recharging as and when required.

l) The system should have a minimum scan range of one meter which allows to image the entire spine in one scan.

m) The system should be supplied with respective calibration devices to check the CT parameters and Quality control

n) The system should have a very small footprint for easy transportation through standard doors and lifts; the maximum dimension during transport mode should be L x W x H: 230x60x197 cm and weight should not be more than 1000 kg in transport mode

o) System should be operable with a hand held touch control panel for imaging, transport, service and calibration hence does not need a separate console cart

p) The mobile CT image reconstruction speed should be minimum 48 images per second

q) The system should support DICOM for connectivity and should have the capability to transfer the scans to navigation system or PACS

r) The system should come with a fully Integrated patient table column which helps in precise scan movement of gantry on the rails (not on floor) relative to integrated patient table thereby ensuring reproducible scan results. The Integrated radiolucent patient scanning table to be supplied as per following specification:

    i. The table should be provided with a shuttle system for the movement of the patient on the OR table top.

    ii. The table should be radiolucent with a flat carbon table top for taking CT scan without artifacts.

    iii. All positions by a wireless remote

    iv. It should have an adjustable column height range of 490mm or less to 1040 mm or more

    v. It should have a Trendelenburg ± 65° electrically motorized

    vi. Lateral tilt : +/- 30 degree

    vii. Column rotation: 0-360 degree

    viii. Table should allow patient weight of 180 KG or more.

    ix. All required table attachments/accessories should be supplied for cranial and spine imaging

s) The system should be AERB approved

2. High-end Image Guidance System

a) The system should be wireless based on Passive Marker Technology.

b) The Navigation platform should have 2 integrated touch screen monitor of minimum 27 inch each

c) It should have a brilliant display quality with full HD resolutions (1920x1080 pixels per display).

d) System should have Mobile camera cart with telescopic stand and motorized joints for

remote-controlled camera alignment. The Infrared camera should be extremely flexible in terms of providing for various adjustments to allow for various positions with camera height (67-254 cm) to allow flexible patient positioning & registration

e) System should have connection panel for plug & play connectivity e.g. with surgical microscopes, fluoroscopes, endoscopes, ultrasound etc. via state-of-the-art digital and analog video inputs supporting up to full HD resolution: 2xHD/SD-SDI up to 1080i/29.97fps, 2xComposite (CVBS, NTSC/PAL),1xS-video (NTSC/PAL)

f) System should also include 1x video output port with up to 3840 x 2160 px to connect an independent additional display as well as 1x DVI out for analog / digital video output

g) Direct patient data transfer from/to 5xUSB (3 USB-2.0 & 2 USB-3.0) and CD/DVD±RW.

h) System should have fast simultaneous access to e.g. PACS/hospital network and integration with e.g. C-Arms via 2x high-speed network connection (up to 1 Gbit/s each)

i) System should have high-performance computer (Intel Xeon E5-1620 v2 3.7 GHz Central Processor Unit, 8 GB RAM memory and 512 GB SSD)

j) The navigation system should use passive markers without batteries. No disposal of hazardous materials is required after the use of the system

k) All requisite applications should be on the Navigation System and can be controlled with touch and/or with mouse and should not require any additional computer

l) Navigation system should have a smart home button to ensure interchangeability between multiple windows at any given point of time as per surgeon discretion. Any changes made on attached window gets automatically updated into navigation window

m) It should have Live Streaming of OR procedure capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free such as -
  - Live streaming should be possible using the Navigation touchscreen which can be viewed using the hospital network or web browser from anywhere
  - It should be possible to live stream video signal from the available HD camera (Room & OT camera), Endoscope, Microscope, Ultrasound etc. whichever is being used intra-operatively

n) It should have Digital Recording capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free such as -
  a. It should be able to locally record the procedure in digital HD quality of any display content (e.g. navigation software, microscope or endoscope video).
  b. The system should allow storing of all recording to the USD, DVD or Hard disk once the procedure is finished

c. It should also allow taking screenshot of the live procedures on the display using the touchscreen. All screenshots taken of the live streaming/ videos during the procedures should also be stored on the navigation system which can later be transferred to USD, DVD or Hard disk once the procedure is finished

d. It should also have the provision of configuring to save of recordings, screenshots etc. on the hospital network

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

p) The system should also include display of Surgical checklist for improved patient safety -

    a. The Electronic checklist should be based on WHO principles

    b. 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.

    c. The Checklist should be available in English language

    d. 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

3. Spinal Navigation Specification

a) Spine Software should have the feature of automatic receipt and registration of image data from intraoperative mobile CT. Intraoperative images should be available for navigation immediately after the scanning process for optimized surgical workflows and should eliminates the need for manual registration in Spinal procedures.

b) The system should be implant independent and pedicle screw implant from any implant vendor can be used

c) Real-time tracking and 2D/3D visualization of a pointer and of up to 4 instruments simultaneously in various views

d) Simultaneous navigation of two fused / co-registered datasets, including visualization of pre-planned objects and screws

e) System should capable of Intraoperative screw planning

f) The probe should have the capability to show images at 0mm - 180mm in front of it (Tool Tip Extension). The system should also have option for full and partial virtual screw display

g) System should integrate the existing instruments based on diameter, length and vector for tracking.
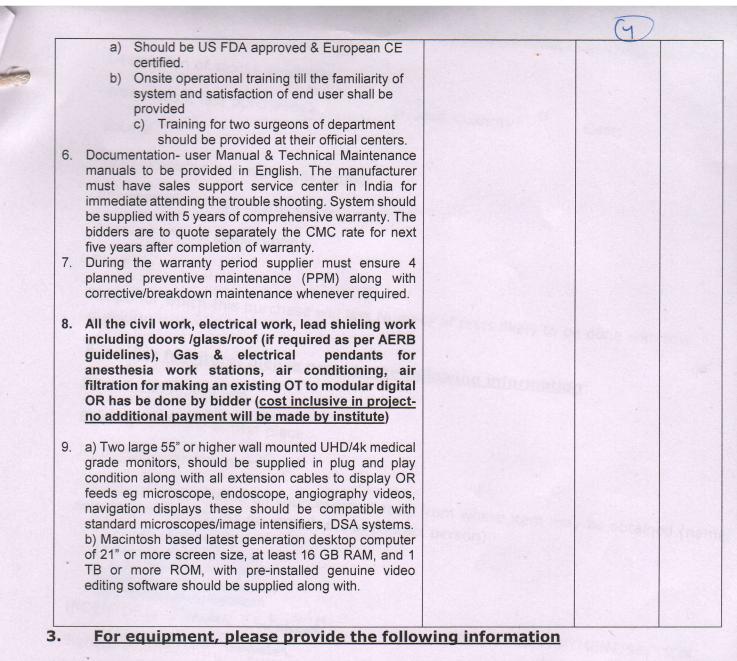
h) The system should allow the use of available rigid surgical instruments in OT like Surgical Awl and probe as navigated instruments after calibration Navigation instruments should also have Radiolucent Spine Reference Clamp to reduce artifacts in intra-operative navigated surgeries

4. **Cranial navigation specification**

   a) Cranial Software should have feature of automatic receipt and registration of image data from intraoperative mobile CT. Intraoperative images should be available for navigation immediately after the scanning process for optimized surgical workflows and should eliminates the need for manual registration in cranial procedures.

      i. The system should allow DICOM images in Axial, Sagittal or Coronal planes should be reconstructed as 3D images and advanced cranial planning can be done on any plane and should be adapted to all planes automatically

      ii. Should have the following features: 3D volume rendering of CT, MR, PET, SPECT datasets, with presets for visualization of skin, bone, vessel, DRR and MIP

      iii. Superimposition of 3D dataset visualization and surgical planning data (volume objects, trajectories and labeled points)3D multi-planar reconstructions in multiple planes (axial, coronal, sagittal, oblique)

      iv. Concurrent display of multiple medical image series Image annotations and measurement functions for distance, angles and circles Selection of region of interest to cut and zoom onto the relevant anatomical volume Crop functionality to cut viewing plane into 3D visualization along any freely definable direction

   b) 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 so that it becomes quick & time saving to outline the object during pre-operative & intra-operative planning.

   c) The cranial planning can be done on Navigation system itself and should allow fusion of multiple DICOM data (CT, MRI, DTI, BOLD etc.)

   d) The probe should have capability to show images at 0mm - 180mm in front of it (Tool Tip Extension).

   e) System should have Auto Pilot view for guided instrument to a trajectory

   f) System should have dynamic visualization of distance to target point or intra-operative landmarks for approach optimization

   g) System should integrate the existing instruments based on diameter, length and vector for tracking.

   h) Software should offer Automatic segmentation of anatomical cranial organs for the fast delineation of the anatomical structures. It should allow automatic contouring of anatomical objects such as Brainstem, Cerebrum,

Cerebellum, CSF, Gray matter, Hippocampus, Hypothalamus, Putamen, Ventricles, Thalamus, Vessels, White matter, Eyes, Optic apparatus etc.

i) Software for Frameless Biopsy system should be provided

j) System should have fine-adjustment for navigated frameless biopsies, shunt placements & endoscopic examination guided by the navigation system; It should allow precise online tracking according to the pre-planned trajectory; Should adapt to fit cylindrical instruments of 1.8mm - 8.0mm and up to 300g; Should hold instruments with a length of up to 35 cm and should have the adapter for connecting it to the head holder

k) Sterile Radiolucent Skull Pins should be provided that are designed for the fixation of a compatible head-holder unit to the patient's skull. This allows the fixation of the head and neck during craniotomy and subsequent neurosurgical procedures. This should reduce the incidence of artifacts in images acquired intra-operatively

l) Cranial Reference Unit should be such that it is optimized for navigation with intraoperative imaging. It should allow a rigid and accurate attachment of the reference array to compatible skull clamps without compromising the sterile field. The unit should consist of two pairs of radiolucent interconnectors and reference arrays with 4 marker spheres for sterile (navigation) and non-sterile(registration) use

m) Navigation system should have facility to upgrade it to integrate 3D Ultrasound for combining intraoperative ultrasound images with navigated patient data

n) Intra-operative simulation of follow-up SRS/SRT planning

    e. It should allow Automated analysis of follow-up Stereotactic Radiosurgery/Radiotherapy simulation plan for residual benign brain tumors during surgery

    f. SRS/SRT-plan feasibility should allow reducing surgery time and decreasing morbidity by providing criteria for concluding subtotal resection

    g. It should be have automatic intra-operative plan simulation of follow-up SRS/SRT based on initial or updated tumor volume

    h. It should include Automatic simulation and intuitive side-by-side comparison of single fractionated, hypo-fractionated, and conventional fractionated treatment plans

    i. 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

5. Standard, safety & Training

a) Should be US FDA approved & European CE certified. b) Onsite operational training till the familiarity of system and satisfaction of end user shall be provided c) Training for two surgeons of department should be provided at their official centers. 6. Documentation- user Manual & Technical Maintenance manuals to be provided in English. The manufacturer must have sales support service center in India for immediate attending the trouble shooting. System should be supplied with 5 years of comprehensive warranty. The bidders are to quote separately the CMC rate for next five years after completion of warranty. 7. During the warranty period supplier must ensure 4 planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required. **8. All the civil work, electrical work, lead shieling work including doors /glass/roof (if required as per AERB guidelines), Gas & electrical pendants for anesthesia work stations, air conditioning, air filtration for making an existing OT to modular digital OR has be done by bidder (cost inclusive in project-no additional payment will be made by institute)** 9. a) Two large 55" or higher wall mounted UHD/4k medical grade monitors, should be supplied in plug and play condition along with all extension cables to display OR feeds eg microscope, endoscope, angiography videos, navigation displays these should be compatible with standard microscopes/image intensifiers, DSA systems. b) Macintosh based latest generation desktop computer of 21" or more screen size, at least 16 GB RAM, and 1 TB or more ROM, with pre-installed genuine video editing software should be supplied along with.			

3. For equipment, please provide the following information

Detailed description of the actual use of the equipment- **required for navigation guided precisions procedures like biopsies, functional lesioning, treatment of deep seated leisons, deformity correction as well as streaming of procedures to outside the ORs.**

Is the equipment to be used for patient care or research: **patient care**

If both, state % of time to be used for patient care: % of time to be used for research **NA**

Is this/ similar equipment already available in the department? **No**

When purchased? Cost at that time: Present functional status:
Tests/ procedures done on this equipment in last year:

Revenue generated by this equipment in last year:

If yes, what is the justification for this purchase?

Is this/similar equipment available in any other department in the Institute?

If yes, what is the justification for this purchase?

4. For Consumables, please provide following information:

Description of stocks available

When was it last purchased?   In what quantity?   Cost;

Source

Test/ procedures done in this period:

Revenue generated in this period:

Average annual consumption

Shelf life

Period for which this purchase will last Number of tests likely to be done with this quantity:

5.   For furniture, please provide the following information:

Exact location and use

Existing furniture at that place

Justification for this purchase

Possible sources (name all sources you know) from where item may be obtained (name, address, phone no, fax no, email, etc of contact person)

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HEAD OF DEPARTMENT/SECTION

Signature..........Rajnish..........

Name.Dr. Rajnish K. Arora

Designation.Associate Prof. & Head

Stamp..........................
डॉ. रजनीश कुमार अरोड़ा
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6. For use of Central Store

Details of last purchase of this item

Date/Reference	Indentor/Deptt	Quantity	Rate (per unit)	Source	Stock in hand

Store Keeper
Date

Store Technical Assistant
Date

Store Purchase Officer
Date

7. For use of Purchase Section

Method of purchase recommended:
Single tender/ limited tender/ open tender/ DI/UP-CMSD/DGS&D Rate Running
Contract/ Local Cash Purchase

JD MM
Date
Tender/ Enquiry No.   Date
Supply Order No.   Date