

**CARDIO THORACIC & NEURO SCIENCES CENTRE  
ALL INDIA INSTITUTE OF MEDICAL SCIENCES**

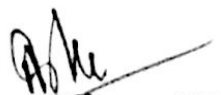
Dated: 07.3.2014

**Subject: Purchase of Multidimensional Neuro Spinal Surgical Imaging System with Integrating Image guidance System (MNIGS) on proprietary basis for the department of Neurosurgery.**

The specification of above mentioned items received from Department of Neurosurgery duly signed by the technical specification committee. The committee recommended to purchase above mentioned item as proprietary item of M/s Meditronic. The specification submitted by the department of Neurosurgery & PAC certificate provided by the department are attached & uploaded on website.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within 15 days from the date of issue/uploading of the notification. The comments should be sent to Asstt. Stores Officer, C.N. Centre at AIIMS on or before **23.03.2014 up to 4:30 P.M.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully



(Asstt. Stores Officer, CNC)

**Encl: Related documents enclosed.**

- 1. PAC Certificated enclosed.**
- 2. Specification of equipment.**


# ITEMS FOR MULTI DIMENSIONAL NEURO SPINAL SURGICAL IMAGING SYSTEM WITH INTEGRATED IMAGE GUIDED SYSTEM AND ITS RELATED EQUIPMENT FOR SEAMLESS INTEGRATION FOR PATIENT APPLICATION


**Tender #1:** Specifications for Multidimensional Neuro spinal surgical Imaging System with integrated image guidance system (MNIGS) for neurosurgery. – No. Required 1 unit


**Tender #2:** Supporting equipment for MNIGS- No. Required 1 unit

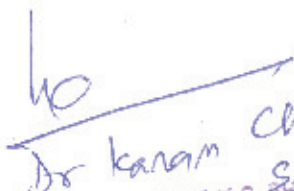
Please note:

1. There are 2 separate tenders, which will be advertised separately at the same time.
2. Equipment of Tender 1 is self-sufficient and equipment of Tender 2 enhance the capability of equipment for advanced patient applications.


  
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### Contents:

1. Tender #1
2. Tender#2
3. Manpower requirement: 2 technicians
  - a. Background
  - b. Operative load
  - c. Justification

**1.Tender #1: BASIC SYSTEM (Multidimensional Neuro spinal Imaging system with integrated image guidance system (MNIGS) for Neurosurgery): Cost: 4.95 crores approximately (subject to further negotiation)**

### **PART 1A: COMPONENTS OF THE MNIGS ONLY**

1. It should have a 360° scan and should be motorized with at least two levels of 3D slice thickness (0.4-0.8 mm thickness).
2. It should have a telescopic door section (breakable gantry) to allow lateral patient access.
3. The imaging system should have iso-wag movement with 6 degrees of robotic positioning freedom.
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. It should have a high-resolution fluoroscopy (> 40 lines/inch. in low dose mode).
7. It should have high-resolution 2-D and 3-D (Axial, Coronal, Sagittal) fluoroscopy.
8. It should have 20 kW to 32 kW X-ray generator for imaging dense anatomy.
9. It should have LCD display [minimum 29" (diagonal)] with minimum of 3-megapixel resolution.
10. It should have the Ability to go 'full-screen' on any image.
11. It should allow image manipulation & viewing wirelessly from the sterile field.
12. It should have the Ability to position x-ray tube on either side of patient for decreased radiation exposure to operating surgeon.

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13. It should have a facility of storage of pre-set imaging positions to avoid the need for re-scouting.
14. It should have Storage of pre-set position for easy access to patient while imaging is not required.
15. It should have a Power drive for easy handling of imaging system.
16. Cranial software & hardware should be included in the imaging system
17. The 3-D image should be displayed in less than 55 seconds from initiation of acquisition.
18. The imaging system should offer different levels of operation allowing optimal slice thickness/reconstruction time selection based on the clinical application.
19. The Bore diameter of the imaging system should be at least 75 cm
20. The imaging system should offer 15 X 20 cm volume cube or more anatomical coverage.
21. The imaging system should have a provision for selecting region of interest for automatic brightness and window/level control.
22. 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.
23. The imaging system should have on-board hard drive (with about 1TB capacity) for data archival and retrieval on USB pen drive/USB portable hard disk drive/ DVD R/W.
24. There has to be various outputs like Ethernet, USB, Composite video and S- video.
25. The Multidimensional Surgical Imaging System should be supplied with compatible/ integrated Surgical Navigation system. The Navigation system should be loaded with all spine and cranial applications.

26. **General System Specifications for navigation system:**

26.1.1. The System should be easy to set up, user friendly, intuitive and should work under Linux operating system environment.

26.1.2. The system should have facility of keeping optical camera and viewing system together or separately to allow optimal use of O.T space, The System should have two monitors, one for the surgeon and the other for the OT/Technical staff.

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26.1.3. The Surgeon Monitor should be high resolution, touchscreen (1920 x 1200 dpi, 60 Hz) with a viewable size of 24" widescreen or higher.

26.1.4. It should have Extended Pyramid high volume hybrid tracking system with active and passive instrumentation.

26.1.5. The navigation system must have dynamic referencing.

26.1.6. The system must have USFDA and CE-Europe approval.

26.1.7. **General system specifications for various neuro spinal applications:**

26.1.7.1. **Cranial Application:**

26.1.7.1.1. Should have user-friendly cranial application software.

26.1.7.1.2. Should have facility for marker less registration.

26.1.7.1.3. The navigation system should have point as well as surface registration with accuracy prediction system.

26.1.7.1.4. It should have universal instrument adapter tracking system with active & passive option.

26.1.7.1.5. The system should include a frameless biopsy system with needles.

26.1.7.1.6. The navigation system should have 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 Leksell frames.

26.1.7.1.7. The system should have 3D graphics capability and software to merge CT, MRI and ANGIO images.

26.1.7.1.8. Look ahead view capability to show the images at 1mm to 80mm (increments of 1mm) in front of the probe.

26.1.7.1.9. The navigation software should be able to correlate with pre-operative MR/CT images. These images should have view side-by-side or overlaid.

26.1.8. **Spine Application:**

26.1.8.1. The Spine Application should be a unified Spine Application, which should comprise of 3D Spine (Spine Navigation with Spine CT Data) and Virtual Fluoroscopy Navigation for Spine.

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- 26.1.8.2. Software should have the automatic registration during Fluoroscopic Procedure from 360 Degree 3D Imaging System.
- 26.1.8.3. The Application should be able to memorize multiple surgeon preferences for each procedure.
- 26.1.8.4. It should be able to do a customized setup and automated functionality check.
- 26.1.8.5. It should have universal instrument adapter tracking system.
- 26.1.8.6. The system should have image guided spinal instruments like short drill guide, Awl/Probe/Tap system with straight or T-handles option.
- 26.1.8.7. System should have O Arm Integration with Automatic Image Registration.
- 26.1.8.8. Transfer of spine exams to the navigation system should be possible with USB stick.
- 26.1.8.9. System should be supplied with auto calibrated navigated instrumentation for Upper spine procedures.
- 26.1.8.10. System should have navigable instrumentation for Thoracic Lumbar procedure.
- 26.1.8.11. The System should interface with Nerve Integrated Monitor available at Neurosurgery Department while accessing pedicle with pedicle access needle.

#### **PART 1B: MISCELLANEOUS**

The following are to be provided free of cost along with PART 1A

27. Allen Flex frame for spinal operative procedures: 1 no.
28. LED 46" thin client monitor: 1 no.
29. Lead free/lead reduce aprons (Surgical) with thyroid shields and protective over spectacle use goggles: 8 no.
- 29.1. Should be light weight at least 40% lighter than the usual aprons
- 29.2. Minimum 99.8% attenuation at 60 kVp, 98.1 attenuation at 80 kVp, 95.6%
- 29.3. Stuffed shoulder pads
- 29.4. Surgical aprons with option of being released while wearing the sterile gown
- 29.5. 0.35 lead equivalency

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29.6. Goggle must be fitted over spectacles

**30. Mayo trolley: 1 no.**

30.1. Durable strong, stainless steel and rust proof

30.2. Industry grade castor wheels

**31. A radiation mobile shield should be also provided for ground personnel: 1 no.**

31.1. Should have 3 panels- be of size 6' height with 3' breadth along with side panels of 1.5' X 6' size on each side. Total: 6' X 6'

31.2. They should have support of industrial grade castor wheels for easy transport

31.3. Powder coated steel frames

31.4. Should have a transparent window

31.4.1. Of size 20-24"

31.4.2. > 10 mm lead equivalent clear lead glass encased in super strong shatter resistant acrylic plastic

**32. Other terms and conditions:**

32.1. The imaging system should have DICOM ready functions and full DICOM compatibility. It will be the responsibility of the vendor to seamlessly integrate the system with the existing PACS network of N.S.C, AIIMS. Prior to bidding the vendor should assess the suitability of the same by on site inspection of the PACS system at the neurosciences center, AIIMS and should be multi vendor compatible.

32.2. Training on the Multi Dimensional Surgical Imaging System should be provided to 10 Neurosurgeons in batches available onsite.

32.3. One-year supply of all disposable should be supplied (including 300 disposable drapes for the Imaging System and 600 glions). Prices of all disposables required for the imaging system & image guidance should be quoted at the time of price bid and will be frozen for 5 years.

32.4. The Complete Multidimensional Imaging System should come with a full 5-year warranty (spares and service). Quotation for maintenance along with spares and service should be provided for another additional 5 years. Annual cost for this should be provided up front. Spares should be available for at least 10 years after installation.

32.5. There should be a 98% uptime warranty. If the downtime extends more than 2% a year, the warranty will be extended for double the downtime period.

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- 32.6. Registration of equipment and site plan approval will be the responsibility of the vendor. The institute will provide necessary documents.
- 32.7. The vendor will post a technical person for about 400 cases in the OT for the smooth functioning of the system on all working days.
- 32.8. The equipment should have AERB approval. It should be US-FDA/ CE-Europe approved

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PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1. Items/Type/Model No. required along with maintenance Specification
2. Is the item a spare part attachment or accessory for an existing equipment *O-ARM- Multidimensional surgical image system with integrated image guided system*
3. Name of the manufacturers/Supplier Of the item proposed by the indenter *Medtronic*
4. Are they sole manufacturers/ Sole distributors of the item *Yes*
5. Is there any other item with similar/equivalent Specification available in the market to meet the Job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding officer should bring out comparative Functional advantages/cost effectiveness of the recommended item from these offered by other. *-NO-*
6. What were the efforts made to locate alternative Source of supply or use other substitutes *Internet search*
7. Why open/Limited tender can't be resorted to, for locating alternative source. *Proprietary Item*
8. Are the propriety items certify that the rates Are reasonable or not *Yes*
9. Any other justification for procuring item for single Source. *Life saving equipment for accurate surgery*

*[Signature]*  
Officer In-Charge  
Neurosurgery Store

*[Signature]*  
Counter signed H.O.D.  
(Head of the Department)  
Neurosurgery  
Centre.  
AllMS

I certify that the items at Sr.No. 1 above is required to be procured on single tender basis are the source of supply is definitely known/the specified brand proposed was advantage in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose I this particular case.

(Strike out whichever is not applicable)



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3<sup>rd</sup> March, 2014

**Re: Sole Source – Proprietary Certificate**

**To whom it may concern:**

I hereby affirm, to the best of my knowledge, that Medtronic Navigation, Inc. is the sole manufacturer, seller and distributor of the O-arm® Intra-operative Imaging product covered by the US patents listed below:

6,940,941  
7,108,421  
7,001,045  
7,106,825

By signing this certificate, I am attesting to the facts listed above to the best of my knowledge.

for India Medtronic Pvt. Ltd.

Authorised Signatory

