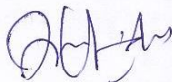


ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

1. Items/type/model No. Required along with Maintenance specification - **3D ISOCENTRIC MOBILE IMAGING SYSTEM WITH FLAT PANEL DETECTOR FOR NEUROSURGERY AND SPINE PROCEDURES**
2. Is the item a spare part attachment Or accessory for an existing equipment- **An accessory**
3. Name of the manufactures/supplier Of the item proposed by the indenter- **M/S ZIEHM**
4. Are they sole manufactures/Sole distributors of the items- **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 : **Yes, but the item will not be compatible with the existing microscope as told by the vendor (certificate enclosed)**
6. What were the efforts made to locate alternative. Source of supply or use other substitutes: **Searched on internet, spoke to the vendor**
7. Why open/limited tender can't be resorted to, For locating alternative source- **The item may be put on the AIIMS website as per AIIMS rules. If there is more than 1 bid, then an open tender may be resorted to. Please note that all items should be provided by a single vendor**
8. Are the proprietary certify that the rates are. Reasonable or not: **Certificate of reasonability may taken from the principle. Also previous purchase orders may be also looked into. The rules may be followed as suggested by AIIMS**
9. Any other justification for procuring item for single - **No**



Officer In-Charge
Neurosurgery Store
DR. P. S. CHANDRA
Professor
Department of Neurosurgery
All India Institute of Medical Sciences, New Delhi-110029

I certify that the items at Sr. No. Above is required to be procured on single tender basis as the source of supply is definitely know/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)



Counter signed
DR. P. S. CHANDRA
(HOD, Neurosurgery)
Professor
Department of Neurosurgery
All India Institute of Medical Sciences, New Delhi-110029



DR. P. S. CHANDRA
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PROPERIETARY ITEM

TECHNICAL SPECIFICATIONS FOR 3D & 2D ISOCENTRIC MOBILE IMAGING SYSTEM WITH FLAT PANEL DETECTOR FOR NEUROSURGICAL & SPINE PROCEDURES

UNITS REQUIRED: 1

COST: 300 lakhs

(as per the suggestions by the external committee experts as per the meeting held on 14/09/2015)

Grammatical corrections ONLY made by Internal faculty, copy of the original specifications signed by external experts enclosed)

State-of-the-Art, Compact, Easily Transportable, Digital Mobile C-Arm X Ray Unit with Flat Panel Detector with 3D & 2D imaging facility for Neuro, Spine, Trauma & Surgical Procedures.

The system should have the following essential features

1. Objectives:

- a. Primarily required for performing complex spine surgeries for screw and implant placement especially for the dorsal spine where visualization is sub-optimal with conventional C-arm
- b. Trans-sphenoidal surgeries, Trigeminal neuralgias (for anesthesia)

2. Generator and X-ray Tube:

- a. Generator should be microprocessor controlled with the following modes
- b. 2D Normal Fluoroscopy, Pulsed Fluoroscopy.
- c. 3D Imaging (MPR, MIP)
- d. Digital Radiography mode (Snapshot).
- e. X-ray Generator should be minimum 20 KW or more.
- f. The range of KV should be 40-120 KV for each mode.
- g. Tube Current should be upto 200mA or more.

3. Pulse width and pulse rate:

- a. The Generator should be capable of providing, Pulse Fluoroscopy with Pulse rates up to 20 Pulses/sec or more.
- b. X-ray tube Housing Heat Capacity should be minimum of 5 MHU or more for prolonged procedures.
- c. X-ray tube should have a
 - i. Dual Focal spot of minimum 0.3 / 0.6 mm or better (for Fluoroscopy and Radiography)
 - ii. Nominal X-ray tube voltage 100 KV or more
 - iii. Inherent filtration should be available
 - iv. Automatic Dose Control
 - v. Collimator unit: Shutters / Diaphragm for symmetric radiation free collimation (Virtual Collimator) should be available.

d. C- Arm:

- i. The C-Arm depth should be 65 cm or deeper and Free space should be 80 cm or more to provide a large imaging space and C-Arm clearance around the patient and the imaging table.
- ii. The C-Arm should have a Orbital rotation of 160° or more to allow the imaging chain to accomplish angled projection
- iii. The C-Arm should provide side to side (wig-wag) and horizontal travel movements to allow panning during an imaging.
- iv. The C-arm should be motorized in orbital, Angular, Horizontal and vertical movement

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 New Delhi



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 तंत्रिका विज्ञान केंद्र / Neuro sciences Centre
 ज.मा.आ.सं. नई दिल्ली / AIIMS, New Delhi-29

Dr. B. SHARMA
 Neuros. Prof. & Head
 Deptt. of Neurosurgery
 All India Institute of Medical Sciences
 New Delhi-110029

- v. The motorized C-arm should be controlled by Control panel (touch screen or joystick control)
- vi. The C-arm should have memory to storage of positions (orbital & angulations) of minimum 3 or more
- vii. Motorized Home Position should be available.
- viii. Collision Protection for patient safety should be available
- ix. The motorized movement has to stop immediately before touching the patient or object and should be available.

4. Flat panel Detector System

- a. The system should have a Flat Panel Detector of 1.5k x 1.5k resolution and minimum noise
- b. The size of the detector should be minimum 30 x 30 cm or more
- c. The pixel size should be 200 micron or less.

5. **Monitor Cart:** The system should be equipped with two high resolution 18" LCD/TFT monitors with Image matrix at least 1024 X 1024.

6. Digital System & Image Management

- a. Must be Fully Digital Continuous Imaging Chain for Acquisition, Processing, Storage, Archiving & Documentation.
- b. The system should be capable of entering the patient data and for image annotation etc.
- c. The system should have multi patient data base for handling large quantities of images including Dose Management Report.
- d. The system should Automatically select proper imaging parameters, kVp and mA during imaging, but also provide the user to over-ride these settings manually
- e. Should provide anatomical mode for different anatomical parts
- f. Real time and Automatic Brightness and Contrast should be provided to optimize displayed images
- g. Digital image processing up to 30 bit or more should be provided
- h. Annotation, measurement of angles and distance should be possible
- i. Video output should be available in HD mode
- j. There should be no interference from terrestrial magnetic field
- k. Disk storage of minimum of 60,000 2D images in at least 1K X 1K matrix should be provided
- l. OT table side(Side rail mounted) Third touch or joy stick screen control panel should be available .
- m. Multi Functional foot switch with additional functionality should be available
- n. Laser Positioning device should be available in Flat Panel detector for dose reduction.

7. 3D Workstation

- a. should provide 3D Workstation with necessary hardware & software
- b. Anatomical program for different anatomy parts should be available.
- c. 3D Visualization with multiplayer reconstruction(MPR) & Volume Rendering should be available.
- d. Slice planes: Axial, Coronal, Saggital should be available
- e. 3D volume should be minimum of 15cm cubic or 15cm cylindrical volume.
- f. 3D volume resolution should at least 256 voxels or more.
- g. 2D Cine loop of 3D acquisition should be available.
- h. 3D acquisition time should not be more than 50 seconds.

8. Image Processing:

- a. The following options should be available for Live and Post Image Processing.
- b. The system should provide a Last Image Hold Capability that the last image is displayed on the active monitor after the termination of an exposure.

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 MS (PCL)
 Consultant
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 तंत्रिका विज्ञान केंद्र / Neuro sciences Centre
 आर्य समाज संस्थान / ARISS, New Delhi-29


- c. The system shall allow the user to change the Image Orientation on the display screen during live exposure or using the last image hold. Those functions include image rotation, left to right and top to bottom image reversals.
- d. Recursive filters, Edge Enhancement, Windowing Level adjustment, Grayscale inversion, Digital Collimators, Zoom 3 Level, should be available

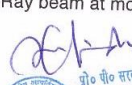
9. Image Documentation

- a. The unit should have advanced DICOM capability
- b. Should be possible to archive images on USB port (Format: DICOM & JPEG, Multimedia.)
- c. A CD/DVD/blue ray writer should be available

10. Essential Accessories

- a. Online UPS of 10 KVA or more with at least 30 minutes back up for the complete C-arm
- b. **Lead free Aprons (light weight) with thyroid shields and gonad shields along with eye radiation protective spectacles:** 4 numbers each
 - i. Lead free/ lead reduce surgical aprons for X-Ray protection (Latest) including glasses (to be fitted over the spectacles), thyroid collars and protection for body (front protection).
 - ii. Aprons and Thyroid Shield must be lead free and completely eco-friendly should be provided
 - iii. The aprons and Thyroid Shield should be very light weight- must be at least 40% lighter than standard lead aprons.
 - iv. Aprons should have optional advantage of intra-op removal without removing sterile gown
 - v. Should have Minimum 99.8% attenuation at 60kVp, 98.1 attenuation at 80kVp, 95.6% attenuation at 100kVp and 93.7% attenuation at 120kVp direct beam ASTM testing.
 - vi. The aprons should have stuffed shoulder pads to offer the maximum comfort during the procedure.
 - vii. The manufacturer must offer 5-year guarantee on core material against any manufacturing defect.
 - viii. The aprons and Thyroid shield must have international quality standards including CE/US/European FDA & ASTM/D/N guidelines
 - ix. The Aprons and Thyroid shield must have the attenuation report tested under independent LAB for each batch of aprons.
 - x. Thyroid Collars must be available without binding.
 - xi. Different size will be selected as per requirements and the different sizes should be quoted separately
 - xii. The aprons should have 0.35mm lead equivalency
- c. **Mobile leaded barrier with 24 inch window (1 No.)**
 - i. The X-Ray barrier should be of international standard and should have the all the quality standards US-FDA and CE-Europe.
 - ii. Greater than 1.0.0mm lead equivalent optically clear lead glass encased in super strong, shatter resistant acrylic plastic 1mm PB should be available
 - iii. Powder coated steel frames, precision TIG welded for years of trouble-free service hospital/Industrial grade casters, two with locking brakes for ease of movement and stability should be available
 - iv. Greater than 1.5 mm lead equivalent opaque panels attenuate 100% of the direct X-Ray beam at more than 120xVp direct beam should be available


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- v. The barrier should have 3 panels of heights 6 feet and width being 3 feet, and 1.5 feet (for sides panels each). The window should be 20-24" inches.
- d. Sterile covers (300 set reusable) for C-Arm, X-ray tube and Flat Panel Detector. The vendor should tie up with a local Indian company to provide inexpensive sterile cover for future use.

11. Height & Weight: The system should be minimum weight, compact size & Easy to transport.


12. Other Features:

- a. Quoted equipment should meet European CE and USA FDA approval standards.
- b. The system offered should have AERB Type approval.
- c. Company should quote Optional accessories and Consumables if any and the prices should be valid for a period of 5 years after the expiry warranty
- d. This equipment must be registered with the AERB after installation and the vendor should assist the institute in getting it registered.

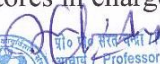
13. Terms and conditions:

- 1) The cost of all spares should be quoted upfront and should be valid for 10 years
- 2) Warranty: 5 years onsite comprehensive including spares + 5 years CMC
- 3) In no case the instrument should remain in non-working condition for more than 7 days, beyond which a penalty of 2% will be charged per day
- 4) The vendor should have a good service and application back up along with instruments to provide an effective trouble shooting and support. (response time < 24 hours)
- 5) All technical bids comparative statement to the tender specifications must be enclosed along with reference no., paragraph no. from original catalogue of the equipment.
- 6) **If the company quotes false information regarding technical specifications, the committee will then have the right to reject this company and also black list the company.**
- 7) **A 24X7 technical support should be available. These personnel should be available on a daily basis for a period for 5 years. Exclusive technical support should be employed for the same.**

Prof SS Kale



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Prof P Sarat Chandra (Stores in charge)

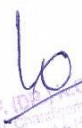

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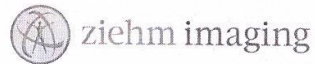
Prof A Suri




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Prof Manmohan Singh


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25 August 2015

TO WHOM IT MAY CONCERN

PROPRIETARY CERTIFICATE

This is certifying that Ziehm Imaging gmbH C-Arm System model **Ziehm Vision RFD 3D** system is the proprietary item of Ziehm Imaging GmbH., Donaustrasse 31, 90451 Nuremberg, Germany.

No other Company manufactures a Mobile Imaging system for Interventional and surgical applications, with the same specifications like incorporating FLAT PANEL and 3D Reconstruction facility. Mainly the first two items are the patents incorporated in our model and the third is an iterative algorithm design specially for this model.

- 1) SmartScan
- 2) Variable Isocentric Movement
- 3) Ziehm Iterative Reconstruction

Yours sincerely,
Ziehm Imaging Singapore Pte Ltd

A handwritten signature in blue ink, appearing to read "Colin T. L. Loo".

Colin T. L. Loo
Business Manager Asia Pacific

A handwritten signature in blue ink, appearing to read "W. N. N. N.". It is positioned below the signature of Colin T. L. Loo.



ziehm imaging

Letter of Authorization

We hereby certify that BET MEDICAL (P) LTD., Door No: B-1 & B-2, 1st Floor, Malles Manor, No: 19 (Old No: 8-A), Periyar Road, T.Nagar, Chennai – 600 017. is our authorized and sole distributor for our complete range of products in India. They are highly technically competent and they are authorized to Sell / maintain and Service our products sold by them in India, which will be completely backed by Ziehm Imaging, Germany.

We further declare that BET MEDICAL (P) LTD is authorized to participate in Public and Govt. Tenders and conclude on our behalf.

Yours faithfully,



ziehm imaging

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Colin T. L. Loy
Business Manager Asia Pacific
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14 January 2013