

Subject: -

Proposal for procurement of 3D & 2D Isocentric mobile imaging system with flat panel detector for neurosurgical & spine procedures on proprietary basis from through their authorized distributor M/s Bet Medical for the Department of Neurosurgery.

Store section is in the receipt of proprietary article certificate duly signed by officer In-Charge, Neurosurgery Store and countersigned by HOD, Neurosurgery, specification & authorization of 3D & 2D Isocentric mobile imaging system with flat panel detector for neurosurgical & spine procedures from the Department of Neurosurgery, with the request to purchase on proprietary basis form M/s. Bet Medical The competent authority has approved the uploading of proposal for 3D & 2D Isocentric mobile imaging system with flat panel detector for neurosurgical & spine procedures, for a period of 15 days for an open information to all. The PAC submitted by the department of Neurosurgery as well as by the principal M/s Ziehm Imaging.

The above documents are being uploaded for open information to all and to submit their objection, comments, if any, from any manufacturer regarding proprietary nature of the equipment/items 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 31 [10] 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.

Asst. Stores Officer, CNC

Encl: Related documents enclosed

- 1. PAC Certificated enclosed.
- 2. Specifications
- 3. Authorization

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 heigh 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 suboptimal 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.
- X-ray tube Housing Heat Capacity should be minimum of 5 MHU or more for prolonged procedures.

c. X-ray tube should have a

- 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

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.
- The C-Arm should have a Orbital rotation of 160° or more to allow the imaging chain to accomplish angled projection
- The C-Arm should provide side to side (wig-wag) and horizontal travel movements to allow panning during an imaging.
- The C-arm should be motorized in orbital, Angular, Horizontal and vertical movement
- The motorized C-arm should be controlled by Control panel (touch screen or joystick control)
- 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.
- 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

- 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
- 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
- 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
- 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 Visulalization 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.
- 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

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a. The unit should have advanced DICOM capability

- 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

- Online UPS of 10 KVA or more with at least 30 minutes back up for the complete Carm
- Lead free Aprons (light weight) with thyroid shields and gonad shields along with eye radiation protective spectacles: 4 numbers each
  - 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.
  - 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.
  - 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.)

- The X-Ray barrier should be of international standard and should have the all the quality standards US-FDA and CE-Europe.
- Greater than 1.0.0mm lead equivalent optically clear lead glass encased in super strong, shatter resistant acrylic plastic 1mm PB should be available
- 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
- 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.
- 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
- 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 FD/ approval standards.

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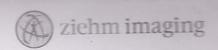
and 1.5 feet

d. Sterile covers (300

The vendor should to cover for future use.

11. Height & Weight: The s

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25 August 2015

# TO WHOM IT MAY CONCERN

#### PROPRIETARY CERTIFCATE

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.

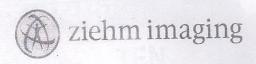
No other Company manufactures a Mobile Imaging system for Interventional and surgical applications, with the same specifications like incorporating FLAT PANEL and 3D Reconstruction facility. Mainly the first two items are the patents incorporated in our model and the third is an iterative algorithm design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

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

Yours sincerely, Ziehm Imaging Singapore Pte Ltd

Colin T. L. Loo Business Manager Asia Pacific

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# **Letter of Authorization**

We hereby certify that BET MEDICAL (P) LTD., Door No: B-1 & B-2, 1<sup>st</sup> 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,

Colin T. L. Loy

Business Manager Asia Pacific

Ziehm Imaging GmbH

14 January 2013

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