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No. F-8 (27) RMSC/EPM/M-5/2016-17/NIB-177/ 4064

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CLARIFICATION/CORRIGENDUM/ADDENDUM

<u>Subject</u>:- <u>Amended technical Specifications and other terms and conditions of Bid document for Orthopaedic Equipments under NIB No. F-8 (27) RMSC/EPM/M-5/16-17/NIB-177/3534 Dated 05.08.2016.</u>

In Reference to above cited subject and NIB-177, the technical specification of items are here by amended as below:-

Revised Technical Specifications for Orthopaedic Equipments

1. Revised Technical Specifications of C-Arm Machine

1. IMAGE INSTENSIFIER

- a) Image Intensifying Tube: 9 Inches, Normal = 9", Zoom facility.
- b) Nominal Entrance Field Size: 200 mm or more
- c) Output Image diameter: 25 mm or more
- d) CCD/CMOS Camera: High resolution compact CCD/CMOS camera ½" size. Pixel: 1024x 1024.
- e) Monitors and Trolley: 2 Nos. 17" / single 24" or more medical grade monitors. Monitors should be along with modular trolley.
- f) Image Intensifier head safety lock. : To be provides.

2. C-ARM MOBILE STAND:

- a) Rotation: = 180 Degrees.
- b) Up/Down movement with Actuator/Motorized: 400 mm or more
- c) Horizontal Travel: 200 mm or more
- d) Arc Orbital Movement: 120 Degrees ± 5 Degree.
- e) Wig Wag: +/- 12.5 Degrees
- f) Tube Head: 15 KHz or more stationary anode dual focal tube.
- g) Min. Voltage: 100 KV
- h) Fluoroscopic mA: 0.5 3 mA or better (Normal Mode)
- i) Pulse Fluoroscopy mA: 0.1-3mA or better.
- j) Radiographic mAs: 200mAs or more

3. INVERTOR

- a) Mains Voltage: AC/DC converter for H.F. X-Ray Generator (suitable for X-Ray Tube).
- b) Max. Output power: 1.5 KW or more
- c) Display for: display for KV, mAs, mA.
- d) Radiography: Manual & Auto.
- e) Technique Selection: Fluoro and radio mode selection.
- f) Radiographic Timer: An inbuilt radio timer enables to select upto 200 mAs
- g) Fluoroscopic Timer: Five minutes cumulative timer with buzzer.
- h) Fluoro mA: Continuously variable
- i) Should support USB for image storage
- j) Collimation-radiation free, IRIS Collimation / fix collimation
- k) The C- Arm machine should be AERB Approved if applicable. Related documents should be submitted along with technical bid.
- l) Auto Brightness
- m) The equipment should be supplied with 06 numbers good quality, light weight lead aprons.

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- n) Onsite QA as per AERB Guidelines is must during guarantee period of three years.
- 4. Guarantee: 03 year from the date of successful installation.
- **5. CMC :** CMC will be given @ 4 % (of net rate-inclusive of Excise Duty & exclusive of VAT/CST etc.) plus service tax (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC will be awarded for five years on yearly basis after Guarantee period of three years.
- 6. The Company should be US FDA and European CE certified.
- 7. Consumable: NIL

2. Revised Technical Specification of OT Table (Electric)

Measurements (Approx): without mattress

Height: 700-1000mm ±50mm (without mattress)

Width: 500 mm or more Length: 2000 mm or more

Maximum patient weight capacity 150 kg or more Cranial and caudal traversing 200 mm or better

Side tilt: +/-20 degrees,

Back section adjustment: -40 degrees to 80 degrees, Foot section adjustment: -90 to degree, detachable,

Trendelenburg: 20 degree ±5 degree, Anti trendelenburg: 20 degree ±5 degree

Head section adjustment: ±45 degree, detachable

The maximum distance from perineal post to foot attachment should be more than 1200mm

The operation table should have the following features:-

Four/Five section table top with divided foot section, Table top should permit X-Ray penetration and fluoroscopy. The frame should be designed in such a way for minimum obstruction for C-Arm imaging. Mattress should be radiolucent and suitable for fluoroscopy.

Should have a handset for various functions. There should be inbuilt standby control enabling full use of table in case of handset failure. All table positioning, i.e., height, back section, lateral tilt, trendelenburg, and anti-trenelenburg, should be operated electrically through handset and standby control. The table top can be moved cranially and caudally on its base.

Electric actuators should be good quality European/Japan make.

The casing on the frame and made of hygienic stainless steel. Table should have mobile base with lockable castors with electric/mechanical floor locking mechanism, The centre supporting column should be eccentrically placed on the base.

The table should have a battery back-up of at least 30 minutes.

The table should be provided with the following standard accessories:

- a. Anaesthesia screen double ended with clamp: 1 No.
- b. Body strap: 1no.
- c. Knee crutch with clamp: -1 pair
- d. Shoulder support 1 pair
- e. Side support 1 pair
- f. Padded arm rest with straps one pair
- g. Polyurethane mattress 50 mm thick with Volero attachment
- O.T. Table should be provided with the following orthopaedic attachments
- a. Fracture attachment (attached to base, non hanging).
- b. Perennial post with pad adult and pediatric one each.
- c. Sacral rest wedge shaped.
- d. Hip rest.
- e. Counter traction device for femur and tibia nailing.
- f. L-shaped Traction extension

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- g. Traction bow.
- h. Universal Leg holder adult and pediatric one each.
- i. Multi-purpose Arm Board with cushion and clamp.

Guarantee: 03 year from the date of successful installation.

CMC: CMC will be given @ 4 % (of net rate-inclusive of Excise Duty & exclusive of VAT/CST etc.) plus service tax (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC will be awarded for five years on yearly basis after Guarantee period of three years.

The equipment should be CE certified and ISO 13485.

Revised Technical Specification of Bone Cutting, Drilling & Reaming System

1. Driving Unit - Completely enclosed Motor with MCB, Supported on a Mobile Folding Stand (Stainless Steel tubes & M.S. square bars, with castors). Includes a Foot Control/ Hand Synchronised, (Stainless Steel Body) with step-less speed control & ON/OFF switch with fuse.

2. Cannulated Drill Pistol Grip Handpiece (Autoclavable)

- Stainless Steel Jacob's (USA) Drill Chuck (0-1/4")
- Light Weight
- Maximum speed 1200 R P M or more
- Cannulation 4 mm ot more

3. Cannulated Reaming Pistol Grip Handpiece (Autoclavable)

- Maximum Speed 400 to 800 R P M
- AO type quick coupling
- Cannulation 4 mm ot more
- Ideal for Intra Medullary Reaming
- Light Weight

4. Saggital Saw Pistol Grip Handpiece (Autoclavable)

- More than 11000 Oscillation per second.
- Ideal for TKR, THR
- Five types of blades can be set at different directions.
- Light Weight
- Set of 5 blades (hardened & tempered high quality stainless steel)
- 2 Special Blades for Total Knee Replacement (TKR) is provided.

5. Flexible Reamers (Autoclavable)

- Flexible Reamer Shaft 8mm dia. fixed Head 01 No.
- Flexible Reamer Shaft for detachable heads up to 12mm (dia. 8mm).
- Flexible Reamer Shaft for detachable heads above 12 mm (dia. 10 mm).
- Detachable Reamer Heads from 8.5 to 12mm, steps 0.5mm
- Detachable Reamer Heads from 12.5 to 15mm, steps 0.5mm
- Guide Wires (3 Nos.) standard length 100cm.
- Exchange tube 01 no.

6. Guarantee: 03 years from the date of successful installation.

- 7. CMC: CMC will be given @ 4% (of net rate- inclusive of Excise Duty & exclusive of VAT/CST etc.) plus service tax (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC will be awarded for five years on yearly basis after guarantee period of three years.
- 8. The equipment should be CE certified and ISO 13485. The bidder should be ISO 9001
- 9. Consumable: Saw blades
- 10. Additional Key (Qty-01) should be provided.



4. Revised Technical Specification - Pulse Lavage System

- 1. Company should be at least in its 5 years of operations at the date od submission of tender.
- 2. Should have electronically controlled Irrigation Pressure.
- 3. Should have autoclavable & reusable tubes.
- 4. Should have minimum three type of irrigation & suction
- 5. Should have shower for dual purpose irrigation & suction
- 6. Should have in built voltage control rectifier.
- 7. One spare set of tubing should be provided additionally

5. Revised Technical Specification - Electronic pneumatic tourniquet for orthopaedic Surgery

- Company should be at least in its 5 years of operations at the date of submission of tender.
- Should have battery backup and pressure & timer display.
- Should have five silicon autoclavable cuffs of different sizes

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Note: Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of the bid document. This corrigendum/ addendum should be signed and annexed with bid document.

All other terms and conditions of bid shall remain the same.

This bears the approval of M.D., RMSCL, Jaipur

Executive Director (EPM)
RMSCL, Jaipur