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No. F-8( ) RMSC/EPM/M-1/NIB-637/2021-22/ 16

Dated: 08/04/2022

**CLARIFICATION/CORRIGENDUM/ADDENDUM**

**Subject: Amendment in technical specification and bid schedule of bid document of item (1) C-Arm Machine with DSA (2) C-Arm Machine without DSA (3) C-Arm Machine with Flat Panel Detector, under No. F-8( ) RMSC/EPM/M-1/NIB-637/2021-22/1490 date: 23.12.2021**

In reference to subject cited above NIB-637, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

**1 SPECIFICATIONS OF C-ARM Machine With DSA**

Microprocessor controlled C-arm machine should provides the excellent image quality at low radiation, ideally suited for general surgeries in many application fields and special application such as orthopedics, urology, Gastroenterology, pain management, Spine fixation, Neurology & angiography procedures.

**A) IMAGE INTENSIFIER:**

- Image Intensifying Tube: 9 Inches, Triple Field.
- Camera: High Resolution 1K X 1K camera.
- Monitors: Two nos. 19" foldable Medical display monitors mounted on modular trolley (With in Build feather touch Keyboard and mouse).

**B) C-ARM MOVEMENTS:**

1. Rotation:  $\pm 180$  Degrees.
2. Motorized Up/down: 400mm or more
3. Horizontal Travel: 200 mm or more
4. Arc Orbital Movement: 120 Degrees.
5. Wig Wag:  $\pm 12.5$  Degrees.
6. Source to Image distance should be more than 900mm.
7. Depth of "C" should be at least 600mm

**C) X-RAY GENERATOR:**

1. High Frequency 40 KHz or more
2. Output power should be 5 KW or more
3. Fluoro & Rad. Kv 40 to 110 KV or more
4. Radiographic mA: 100mA or more.
5. Pulse Fluoroscopic mA(Average):-
  - up to 5mA or more (Normal Mode)
  - up to 10mA or more (HD/Boost Flouro mode)

**D) X-RAY TUBE & COLLIMATOR:**

- Monoblock tube head having dual focus rotating anode X-Ray tube of focal spot 0.3mm

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(small focus) & 0.6mm (large focus) should be provided.

- Anode Heat Storage capacity should be 200kHU or more.
- Iris with preview Collimator and Full Parallel shutter collimator should be provided.
- Laser CENTRING Cross hair laser centering device should be provided.

**E) CONTROL: Control should have the following:**

A very compact, soft touch control panel (APR) with L.C.D display on which KV, fluoro mA, radiography mAs, fluoro time, I.I Zoom, error interlocks for KV, filament and thermal overload are displayed. Console panel has following functions and indications.

- Machine ON/OFF switch.
- I.I magnification (I.I field) selection switch.
- Fluoro and Radio mode selection.
- Fluoroscopy timer (Five minute cumulative timer with buzzer that activates after the completion of 300 seconds of exposure to reinitiate the exposure *reset* switch is provided).
- ABS (Automatic brightness stabilization) selection for hand free operation- also known as ADR
- KV and mAs increase and decrease switches.
- X-Ray ON switch with indicator.
- Switches for up/down movement of "C" on both side of panel.
- Radio and Fluoro Exposure ON Switches on Panel
- Emergency OFF switch on the control panel.
- Image rotation & Flip from control Panel

**F) MEMORY SYSTEM should include the following: -**

Standard features detail

- Image processing software with real time image capturing, storage, and display in 1K x 1K format.
- Pulse fluoroscopy facility with frames rate up to 30 FPS for Fluoro and Cine modes.
- Cine loop storage up to 150 frames (Multiple cine loop storage)

Operating Modes

- Fluoroscopy
- Boost Fluoro/ Cine

DSA:

- Up to 6 FPS image acquisition for DSA
- R-Mask
- Land marking (%age based)
- Pixel Shift
- Facility to view Subtracted and Unsubtracted image Display at same time.

Image Processing:

- Real time noise with reduction with Averaging up-to 16.
- Recursive filter for image smoothing, Contrast, Brightness, Sharpness.
- Interactive Zoom and Pan.
- Dynamic Zoom up to 400%
- Pre-programming for image setting for different operating Modes
- Image Inversion.
- WW/WL level adjustments.
- Image Flipping and Image Rotation Clockwise or Anti-clockwise.
- Live to Reference image View.
- Cine Loop Play (Auto and Frame wise)
- Real time Image Rotation & Flip (Horizontal/Vertical)

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- Real time Inversion.
- Metal Compensation.
- Collimator:
- Ultra fast Preview collimator adjustment without radiation.

**DAP Module:**

- DAP dose integrated in software and total summary for Fluoro/Cine Save and display.

**DICOM Features:**

- Connectivity with DICOM workstation/PACS
- DICOM Send
- DICOM Print
- DICOM Worklist

**Storage:**

- Storage capacity of >50000 frames.
- Fluoro saving as per user need
- LIH saving as per user need
- Annotation
- Text
- Line
- Ellipse
- Rectangle
- Ruler
- Angle

**Measurements:**

- Stenosis Measurement
- Length/ Distance measurement
- Area measurement
- Angle Measurement

**PACS Connectivity:**

- /Multiple Image Tagging to transfer into PACS/Workstation

**G) Power requirement:**

- The unit should be operable on Single Phase 230 V  $\pm$  10% AC, 50 Hz
- Suitable rating voltage stabilizer should be provided.

**Following Accessories should be supplied with the unit:-**

- Lead Aprons -6 Nos (light weight)
- Thyroid shields – 6 Nos
- Lead Gloves – 10 pairs
- lead goggles- 2 Nos
- Lead Aprons stand with 6 hangers – 01 No

**H) OTHER REQUIREMENTS:**

- The latest model should be quoted
- The quoted model should be European CE Certified with Notified Body /USFDA /BIS Approved
- **The manufacturer should be ISO 13485 certified.**
- The unit should have AERB type approval certificate.
- The company should have a Service center in State.

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- Bidder should provide datasheets from principal manufacturer of X-Ray tube, Image Intensifier, Camera, Monitors, Generator and Memory system if imported from other country.
- Quoted manufacturer should be principal manufacturer of minimum two out of four major components i.e. X-Ray Tube, Generator, Image Intensifier and Memory system.
- The vendor should arrange demonstration of the machine at their own cost if required.

**2 SPECIFICATIONS OF C-ARM Machine without DSA**

Microprocessor controlled C-arm machine should provides the excellent image quality at low radiation, ideally suited for entry level surgery in many application fields.

**A) IMAGE INTENSIFIER:**

- Image Intensifying Tube: 9 Inches, Triple Field.
- Camera: High Resolution CCD/CMOS 1KX1K camera.
- Monitors: Two nos. 19" High resolution LCD monitors along with trolley (With in Build feather touch Keyboard and mouse).

**B) C-ARM MOVEMENTS:**

1. Rotation:  $\pm 180$  Degrees.
2. Motorized Up/down: 400mm or more
3. Horizontal Travel: 200 mm or more
4. Arc Orbital Movement: 120 Degrees.
5. Wig Wag:  $\pm 12.5$  Degrees.
6. Source to Image distance should be more than 900mm.
7. Depth of "C" should be at least 600mm

**C) X-RAY GENERATOR:**

1. High Frequency 40 KHz or more
2. Output power should be 5 KW or more
3. Fluoro & Rad. Kv 40 to 110 KV or more
4. Radiographic mA: 100mA or more.
5. Pulse Fluoroscopic mA(Average):-
  - up to 5mA or more (Normal Mode)
  - up to 10mA or more (HD/Boost Fluoro mode)

**D) X-RAY TUBE:**

- Monoblock tube head having dual focus rotating anode X-Ray tube of focal spot 0.3mm (small focus) & 0.6mm (large focus) should be provided.
- Anode Heat Storage capacity should be 200kHU or more.
- Fix Cylindrical Collimator should be provided.

**E) CONTROL: Control should have the following:**

A very compact, soft touch control panel(APR) with L.C.D display on which KV, fluoro mA, radiography mAs, fluoro time, I.I Zoom, error interlocks for KV, filament and thermal overload are displayed. Console panel has following functions and indications.

- Machine ON/OFF switch.
- I.I magnification (I.I field) selection switch.

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- Fluoro and Radio mode selection.
- Fluoroscopy timer (Five minute cumulative timer with buzzer that activates after the completion of 300 seconds of exposure to reinitiate the exposure *reset* switch is provided).
- ABS (Automatic brightness stabilization) selection for hand free operation- also known as ADR
- KV and mAs increase and decrease switches.
- X-Ray ON switch with indicator.
- Switches for up/down movement of "C" on both side of panel.
- Radio and Fluoro Exposure ON Switches on Panel
- Emergency OFF switch on the control panel.
- Image rotation & Flip from control Panel

**F) MEMORY SYSTEM** should include the following: -

Standard features detail

- Image processing software with real time image capturing, storage, and display in 1K x 1K format.
- Pulse fluoroscopy facility with frames rate up to 30 FPS for Fluoro and Cine modes.
- Cine loop storage up to 150 frames (Multiple cine loop storage)

Operating Modes

- Fluoroscopy
- Boost Fluoro/ Cine

Image Processing:

- Real time noise with reduction with Averaging up-to 16.
- Recursive filter for image smoothing, Contrast, Brightness, Sharpness.
- Interactive Zoom and Pan.
- Dynamic Zoom up to 400%
- Pre-programming for image setting for different operating Modes
- Image Inversion.
- WW/WL level adjustments.
- Image Flipping and Image Rotation Clockwise or Anti-clockwise.
- Live to Reference image View.
- Cine Loop Play(Auto and Frame wise)
- Real time Image Rotation & Flip(Horizontal/Vertical)
- Real time Inversion.
- Metal Compensation.
- Torch Tool to enhance the contrast at particular region.

Collimator:

- Ultra fast Preview collimator adjustment without radiation.

**DAP Module:**

- DAP dose integrated in software and total summary for Fluoro/Cine Save and display.

**DICOM Features:**

- Connectivity with DICOM workstation/PACS
- DICOM Send
- DICOM Print
- DICOM Worklist

**Storage:**

- Storage capacity of >50000 frames.
- Fluoro saving as per user need

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- LIH saving as per user need
- Annotation
- Text
- Line
- Ellipse
- Rectangle
- Ruler
- Angle
- Measurements:
- Stenosis Measurement
- Length/ Distance measurement
- Area measurement
- Angle Measurement

**PACS Connectivity:**

- Multiple Nodes can be configured.
- Single/Multiple Image Tagging to transfer into PACS/Workstation

**G) Power requirement:**

- The unit should be operable on Single Phase 230 V  $\pm$  10% AC, 50 Hz
- Suitable rating voltage stabilizer should be provided.

**Following Accessories should be supplied with the unit:-**

- Lead Aprons -6 Nos (light weight)
- Thyroid shields – 6 Nos
- Lead Gloves – 10 pairs
- lead goggles- 2 Nos
- Lead Aprons stand with 6 hangers – 01 No

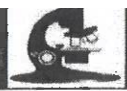
**H) OTHER REQUIREMENTS:**

- The latest model should be quoted
- The quoted model should be European CE Certified with Notified Body No./USFDA /BIS Approval
- **The manufacturer should be ISO 13485 certified.**
- The unit should have AERB type approval certificate.
- The company should have a Service center in State.
- Bidder should provide datasheets from principal manufacturer of X-Ray tube, Image Intensifier, Camera, Monitors, Generator and Memory system if imported from other country.
- Quoted manufacturer should be principally manufacturer of minimum two out of four major components i.e. X-Ray Tube, Generator, Image Intensifier and Memory system.
- The vendor should arrange demonstration of the machine at their own cost if required.
- The company should have proven track record of quoted model with same configurations in Govt. sector.

**3 SPECIFICATIONS OF C-ARM MACHINE WITH FLAT PANEL DETECTOR**

Microprocessor controlled C-arm machine with FPD should provide the excellent image quality at low radiation, ideally suited for general surgeries in many application fields and special application

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such as orthopedics, urology, Gastroenterology, pain management, Spine fixation, Neurology & angiography procedures.

**A) FLAT PANEL DETECTOR:**

- Receptor Type should be of Amorphous Silicon technology
- Conversion Screen should be of CsI
- FPD with 20 x 20cm size should be provided
- Image Matrix should be 1K x 1K or more
- Pixel pitch should be 195  $\mu$ m or less.
- ADC conversion should be 16bit or more

**B) Monitor on Trolley:-**

1 no. 32" colored monitor with split screen for live & reference image display is provided on mobile trolley

**C) Monitor on C-carriage:-**

Touch screen console mounted on C-carriage for the operator.

**D) C-ARM MOVEMENTS:** Fully counter balanced all movements

1. Rotation:  $\pm 180$  Degrees.
  2. Motorized Up/down: 420mm or more
  3. Horizontal Travel: 200 mm or more
  4. Arc Orbital Movement: 120 Degrees.
  5. Wig Wag:  $\pm 12.5$  Degrees.
  6. Source to Image distance should be 950mm or more.
  7. Depth of "C" should be at least 650mm
  8. Free space should be 750mm or more
- Steering handle with  $\pm 90$  degree movement for both side diagonal scan.

**E) X-RAY GENERATOR:**

1. High Frequency 50 KHz or more.
2. Output power should be 6KW or more.
3. Fluoro & Rad. Kv 40 to 120 KV.
4. Digital Spot: 60mA or more
5. Pulse Fluoroscopic mA(peak):-
  - up to 10mA or more (Normal Mode)
  - up to 20mA or more (boost fluoro mode)
6. Radiography mA: 120 mA or more

**F) X-RAY TUBE:**

- Monoblock tube head having dual focus Rotating anode X-Ray tube of focal spot 0.3mm (small focus) & large focus (0.6mm) should be provided.
- Anode Heat Storage capacity should be min 200kHU or more
- Lead collimator Shutters with preview-Radiation free should be provided.

**G) CONTROL: Control should have the following:**

Touch screen monitor mounted on C-arm carriage for Image & Exposure parameters control is provided with following functions and indications:-

**On GUI Screen**

- Fluoro and Radio mode selection.

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- Image rotation & Flip
- Fluoroscopy timer (Five minute cumulative timer with buzzer that activates after the completion of 300 seconds of exposure to reinitiate the exposure *reset* switch is provided).
- Metal Compensated ABS (Automatic brightness stabilization) selection for hand free operation- also known as ADR
- KV and mAs increase and decrease switches.
- X-Ray ON indicator.
- Collimator open/close switches

**Others**

- Switches for up/down movement of "C" on both side of machine frame.
- Emergency OFF switches mounted on monitor.
- Machine ON/OFF Key switch.
- Fluoro, Cine & spot switches on both side of panel.
- Laser Centering Device.
- Virtual DAP meter.
- Removable Grid should be provided.

**H) MEMORY SYSTEM should include the following: -**

**Image Acquisition:**

- Image processing software with real time image capturing, storage, and display in 1K X 1K format.
- Digital Radiography (SPOT) exposure mode is available

**User selectable view on Single monitor with 4k Resolution.**

- User selectable image display for Live & Reference view

**DSA:**

- Up to 4 FPS image acquisition for DSA
- R-Mask
- Land marking
- Pixel Shift

**Image Processing:**

- Real time noise with reduction with Averaging up-to 16
- Recursive filter for image smoothing, DRC, Contrast, Brightness, Sharpness.
- Interactive Zoom and Pan
- Dynamic Zoom up to 400%
- Pre-programming for image setting for different operating Modes
- Image Inversion
- WW/WL level adjustments
- Dynamic Noise Filtration.
- Selectable dose level operation- 03 levels.
- Image Flipping and Image Rotation Clockwise or Anti-clockwise.
- Live to Reference View on Single Monitor
- Cine Loop Play(Auto and Frame wise)
- Real time Image Flip(Horizontal/Vertical)

**Collimator:**

- Ultra fast Preview collimator

**DAP Module:**

- DAP dose integrated in software and total summary for Fluoro/Cine Saved.

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- Real Time Patient dose monitoring display with overdose warning message

**MAG:**

- Real Time Three step Digital MAG.

**Touch monitor :**

- Touch based console for frequently used parameters along with image display.

**DICOM Features**

- Connectivity with DICOM workstation/PACS
- DICOM Send/Storage Commitment
- DICOM Print
- DICOM Worklist

**Storage:**

- Upto 780 GB Hard disk for storing images
- Fluoro saving as per user need
- LIH saving as per user need

**Annotation:**

- Rectangle, Ellipse, Line, Text

**Measurement:**

- Stenosis measurement, Length Measurement

**I) Power requirement:**

- The unit should be operable on Single Phase 230 V ± 10% AC, 50 Hz
- Inbuilt electronic voltage stabilizer should be provided.
- UPS for power backup of the software should be provided.

**J) OTHER REQUIREMENTS:**

- The manufacturer should be ISO 13485 certified.
- The quoted model should be European CE Certified with Notified Body No.
- The unit should be approved by AERB.
- The company should have a Service center in State.
- The company should have proven track record in Govt. sector.

**Following Accessories should be supplied with the unit:-**

- Lead Aprons -6 Nos (light weight)
- Thyroid shields – 6 Nos
- Lead Gloves – 10 pairs
- lead goggles- 2 Nos
- Lead Aprons stand with 6 hangers – 01 No

**Revised Bid Schdeule--**

E-bids are invited as per following revised time schedule:-

Existing Dates				Extended Dates			
Last date & time for sale of bid form	Last date & time of receipt of bid form	Last date of submission of bid document fees	Date & time of opening of technical bid	Last date & time for sale of bid form	Last date & time of receipt of bid form	Last date of submission of bid document fees	Date & time of opening of technical bid
<u>12.04.2022</u> <u>11:00 a.m.</u>	<u>12.04.2022</u> <u>6:00 p.m.</u>	<u>13.04.2022</u> <u>02:00 p.m.</u>	<u>13.04.2022</u> <u>03:00 p.m.</u>	<u>26.04.2022</u> <u>11:00 a.m.</u>	<u>26.04.2022</u> <u>6:00 p.m.</u>	<u>27.04.2022</u> <u>02:00 p.m.</u>	<u>27.04.2022</u> <u>03:00 p.m.</u>

**Note:-** Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-VIII) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

**Executive Director (EPM)**  
**RMSCL, Jaipur**