MINISTRY OF HEALTH
STATE DEPARTMENT FOR MEDICAL SERVICES
SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING, TESTING AND TRAINING, ON USE AND MAINTENANCE OF BIOMEDICAL EQUIPMENT

TENDER N0. MOH/EAKIP/ICB/001/2023-2024

TENDER CLARIFICATIONS

Clarification 1

Need to give clarity on specifications whether a fluoroscopy with radiography system or a digital radiography system is required. As it is, the tender has not provided specifications for fluoroscopy.

Response: Specifications for fluoroscopy

<table>
<thead>
<tr>
<th>DIGITAL FLUOROSCOPY SYSTEM</th>
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<td>Should be a digital Radiography system with flat panel detector and fluoroscopy system, Capable of taking digital images in horizontal, vertical positions of all skeletal body including spine and chest and should be capable for various fluoroscopic applications.</td>
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**Generator**

1. Generator should be of high-frequency inverter technology for constant output.
2. Should have at least 80KW power or better
3. The KV range from 40 to 150 KV or better
4. Should have 1000mA at 80 KV or better.
5. Should have an automatic exposure control device
6. Should have anatomical programming for radiography
7. Should have an load protection feature
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<td>8.</td>
<td>Should have a digital display for KV and mAs</td>
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<td>9.</td>
<td>Should have pulsed fluoroscopy</td>
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<td>10.</td>
<td>Should have a minimum exposure time of at least 1ms or better.</td>
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**X-Ray tube and collimator:**

1. Should be a high-speed rotating anode dual-focus tube compatible with the generator
2. Focal spot sizes shall be as per OEM
3. Should have a multi-leaf collimator a light source with auto shut provision for the light, auto collimation and remote control.
4. Should have overload protection.
5. Should have an anode heat capacity of 800 KHU or more -
6. It should be a carbon fibre/equivalent motorized / hydraulic movement floating table having a weight-carrying capacity of 200kgs or more.
7. It should have automatic exposure control with at least 3 fields
8. Vertical tilt +90 -90 / equivalent or better
9. At least 6-way movements shall be available either in the table or in combination with the imaging system
10. Should have integrated bucky unit for flat panel general radiography and fluoroscopy
11. Variable SID as per recommended by OEM according to different scan type.
12. Possibility to control the table movement from inside the control room.
13. Compression cone: 80 N or more
14. Head-side hand grips shall be available

**Digital detector**

1. The detector should be a flat panel detector of latest direct digital technology / Amorphous silicon with Cesium Iodide Scintillator.
2. The size of the detector should be 43x43cm or more
3. Should have spatial resolution of 3.4 lines pair / millimeter or better
4. Detector Quantum Efficiency (DQE) should be 60% or more.
5. The active matrix size should be 2.8k x2.8k or more
6. Pixel Size: 150 um or better
7. 14 bits and 16 bits, both modes shall be available

**Display and other features**

1. One System monitor: 21” or more
2. Display: 1600 × 1200 pixels or more
3. (color/monochrome Playback images, processed images, multi-images, etc.)
4. 2 Nos. of Live monitors: 19” or more
5. Display: 1280 × 1024 pixels or more, monochrome Digital fluoroscopic images, fluorographic images, playback images, etc.
Image processing/equivalent processing

1. Recursive filter with motion detection
2. Last image hold
3. Image flipping
4. Spatial filter (edge enhancement, smoothing)
5. DCF

Recording
Fluoroscopic image and last-image-hold image can be stored to hard disk.

Fluoroscopic image acquisition
- Frame rate: 0.5 to 15 fps

Pulsed fluoroscopy
- Pulse rate: 1, 2.14, 3.75, 7.5, 15 fps

Fluorographic function
- Images should be recorded to hard disk and displayed on the monitor. Real-time image processing: DCF (Digital Compensation Filter)

Digital One-Shot
- Fluorography: 1024 × 1024, 16 bits
  1536 × 1536, 16 bits
  2048 × 2048, 16 bits
  2560 × 2560, 16 bits
  3072 × 3072, 16 bits

Digital serial fluorography
- Preset Sequence parameters: 1024 × 1024, 16 bits, max. 15 fps
  1536 × 1536, 16 bits, max. 10 fps
  2048 × 2048, 16 bits, max. 3.75 fps
- Real-time image processing: DCF (Digital Compensation Filter).

Post processing
- Grayscale: Adjustment of contrast and brightness
- Automatic adjustment of gray scale
- Spatial Filter: Edge enhancement and smoothing
- Neg. / Positive
- Zoom and pan
- ROI Zoom
- Rotation: 0°/ 90°/ 180°/ 270°
• Image inversion / reversal: Top-bottom and / or left-right reversal
• Multiple Display: not less than 64 images
• Electric shutter: to hide un necessary parts of an image
• Annotation: Text, Arrow, ROI
• Scale
• Measurement function: Length/angle
• Filming:
• Laser imager interface: DICOM Print connection
• Print preview

**Network connectivity**
DICOM Storage DVD Ram Kit.
DICOM MWM DICOM MPPS
Media Storage (CD-R. DVD-R) DICOM 3.0 fully active
DAP interface: to add dose data to be added to DICOM data to be transmitted to the server

**Basic Angiography Package**
with the following functions should be available to the image processor to support angiography.
  i.  Real-time subtraction
  ii.  Fluoroscopy roadmap
  iii.  Pixel shift
  iv.  Real-time edge enhancement
  v.  Reference image display function

**Last Fluoro Hold**
LFH function with not less than 512 frames recording in the memory

**Accessories**
1. An Online UPS to support the entire system.
2. Lead glass of size 80cms x 120cms or more
3. Light weight Radiation protection Apron of 0.5 mm lead equivalence, – 5 No.
4. Four 2 ton split AC for X-Ray and work station room
5. Thyroid shield – 5 No.

**Ray Table Accessories**
• Mattress (Secured) with extra set mattress set
• Grip Bar
• Side Rail
• Hand Grip
• Footstep
Software

Full set of software to enable the system fully operate to achieve both fluoroscopy and radiography procedure including but not limited to:
- DSA Software optional
- Stitching Software
- Long Bone stitching
- Statistical tool software
- Protocol analysis
- Repeat/Reject Analysis software.
- Dose reduction software

Consumables

All necessary consumables and disposables for starting-up.
Test equipment for QC & performance verification

Integration Requirements:
Recommended that all the medical devices, should support HL7 standard especially. Query, retrieve and Archive should be possible

Approvals

- The equipment should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.
- The system should be IAEA and KeNRA type approved.
- Regular QA according to KeNRA norms will be responsibility of bidder during warranty and CMC period.

Power supply:

- Suitable Power input to be 220-240VAC, 50Hz OR 3 PHASE of appropriate rating Standards and safety and training.
- Electrical safety conforms to standards for electrical safety
- Safety aspects of Radiation dosage leakage should be spelt out
- Certificate for calibration should be provided

Documentation

- The supplier must provide User manual/Technical Manuals in English both in soft and hard copies.
- Attach original manufacturer’s product catalogue and specification sheet.

Warranty

- Minimum 2 years warranty and 5 years CMC
Clarification 2
Comprehensive maintenance - please expound on comprehensive maintenance for three years and what entails.

Response:
Comprehensive maintenance entails the supplier taking full responsibility for the equipment, thus both preventive and curative, to ensure that the equipment is readily available as and when required by the users.

Clarification 3
Currency - we are kindly requesting that we offer our prices in US dollars due to the constant change of dollar rate against the Kenyan shilling.

Response:
The Tenderers are allowed to quote in US Dollars.

Clarification 4
CT Scan specifications – 800 images per second is not achievable, so kindly clarify whether it was typing error.

Response
Reference is made to the reconstruction time of the spiral scan. Please respond as per the tender.

Clarification 5
Does the tender attract Taxes and Levies

Response:
The tender is exempt from all taxes. The bidder should quote prices exclusive of all Taxes and Levies.

Clarification 6
Most tenders have considered the immediate last three years for submission. Would it be the case for this tender? Are certified audited financial statements for the last 3 years (2022, 2021 and 2020) permitted?

Response:
Provide Audited Accounts for the last Three (3) years (2022, 2021 and 2020) and not 2018, 2019 and 2020 as earlier indicated.

Clarification 7
Proposed delivery timelines <= 3 months is not realistic for most of the deliveries. Will the procuring entity be open to delivery timelines greater than 6 months?

Response
Kindly respond as per the tender requirements.

Clarification 8
What is the lead equivalent for the 4 lead aprons with hangers to be quoted together with item number LOT1-8 digital X-ray system with Fluoroscopy?

Response:
The Lead Equivalent is provided in the Specifications for the system above.

Clarification 9
In this case, we request for a tender extension of fourteen (14) days to liaise with our principals.

Response:
Liaising with your principals is an internal matter; the tender will, therefore, NOT BE extended.

Further Clarifications on Imaging equipment

The MRI system should include: -
1. 1 No. Metal detectors for MRI (Both walk through and Handheld)
2. 1 No. MRI Compatible laryngoscope and batteries
3. 1 No. MRI Compatible Emergency Trolley
4. 4 No. MRI Compliant sandbags/Positioners

The CT-Scanner should include: -
1. 2 Pairs Head and footrests for the CT
2. 2 No. Paediatric Immobilization for CT
3. 2 No. Paediatric Immobilization for X-Ray