

Section II : Requirement List

eSourcing reference : ITB/2023/49245

A. Technical specifications for Goods – Comparative Data Table

| No | Description | Quantité |
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| 1 | Digital Mobile Radiographic X-ray Unit | 15 |
| 2 | Thermal X-ray printer Accessories for each 4 boxes/125 films for 43 x 43 cm format 2 boxes/125 films for 35 x 43 cm format 2 boxes/125 films for 28 x 35 cm format 1 box/125 films for 25 x 30 cm format 1 box/125 films for format 20 x 25 cmr | 15 |
| 3 | Radiation protection equipment (accessories) - each kit consists of: two (02) leaded aprons two (02) face shields two (20) thyroid protectors two (02) leaded goggles | 15 |

Delivery requirements -- Comparative Data Table

| N° | UNOPS minimum technical requirements | Quantity |
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| 1 | <p>Digital Mobile Radiographic X-ray Unit</p> <p>Digital mobile radiographic X-ray unit with wireless flat panel detector for radiographic examinations in the operating room, hospital room, emergency department, pediatrics, orthopedics and intensive care.</p> <p>Examinations to be performed: 2D general adult X-rays, mainly chest X-rays, pediatric and neonatal X-rays and orthopedic X-rays, among others, capable of performing at least 30 examinations per day.</p> <p>Suitable for use in harsh environments: → Ability to operate successfully in a variety of adverse conditions through features such as: dust protection, ability to operate in environments with power fluctuations, ability to operate in high humidity and temperature conditions, ability to be used on slopes and</p> | 15 |

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| | <p>difficult soil types ensuring safe transportation in demanding hospital environments (maximum floor slope requirements)</p> <ul style="list-style-type: none"> → Uncomplicated installation requirements: installation should pose no unusual problems → Training and operation: no major challenges or concerns. Easy to learn. Comprehensive user manual readily available. → Maintainability: Spare parts available and easily accessible, and no specialized tools required for service and maintenance. <p>Self-propelled unit on motorized castors with telescopic column for positioning the tube head unit With safety features to prevent collisions during transport for example: bumper-actuated collision braking, dead-man brakes, and pressure-sensitive steering.</p> <p>Number of 43x43 cm cassettes stored : At least 1</p> <p>High-voltage generator</p> <ul style="list-style-type: none"> → Electrical power kW @ 100 kVp: 32 kW minimum → Increments in: 1 kV min → Aluminum filter >2.5 <p>X-ray tube anode</p> <ul style="list-style-type: none"> • Anode heat content: at least 120,000 HU • Continuous anode heat dissipation: no less than 14,000 HU/min • Maximum exposure time: 4 sec • Maximum output, kVp • Range: 40 min-120 min kVp • Increments: 1 kV minimum <p>Tube movement</p> <ul style="list-style-type: none"> → Rotating tube movement , Horizontal, vertical → Rotation Z axis: +/- 90 minimum → Rotation in X axis: +/-90 minimum <p>Battery</p> <ul style="list-style-type: none"> → Energy capacity: At least 300 number of exposures @ 100 kV and 20 mA at full charge. → Battery type: Crystal lead, lead acid or lithium → Charging time: ≤ 8 hours → Radiographs can also be taken using only the AC main line → When the motor or battery are not working, movement and circulation of the unit must be possible. <p>Flat-panel detector</p> <ul style="list-style-type: none"> → Wireless data transfer between detector and mobile unit → CR or DR → Wireless: Yes | |
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- 43 X 43 detector and a second detector is required as backup
- IP56 minimum
- Image transfer time to show images, to be specified in seconds by the supplier.
- Flat panel sensor internal memory: minimum 1000 images
- Number of images per battery charge to be specified by the supplier if applicable.
- Image access time: less than 10 sec after exposure

Collimator

- Patient-Centering /Collimator light required: LED

Visualization System

- Image acquisition workstation fully integrated into the mobile unit
- Anatomical programs : ≥500
- Size of built-in display monitor: minimum 17" touchscreen
- Resolution: minimum 1280 x 1024
- Adjustment range: 0.5 to 400 mAs
- Display functions: Mirror image / Zoom, Annotations, Linear and angular measurements, Grayscale inversion, Image rotation, Multi-image viewing and ordering options, etc.
- Control functions: select or insert patient/examination, check and adjust radiography parameters, make exposure and acquire radiographic image, visualize, process or archive image.

Image processing

- Dispersion correction, Contrast processing, Dynamic range compression, Noise reduction, Multi-frequency processing, with or without grid pattern removal process, Automatic exposure field recognition.

Storage/archiving and connectivity

- All radiographic parameters from the acquisition are stored with the device and can be reviewed with the image
- DICOM 3.0 print, query, storage required minimum
- Image storage: 20000 images minimum
- Integrated Ethernet connectivity required.
- Storage capacity on removable media, for data transfer via various options (CD/DVD and/or USB)
- Send images via wireless network and cable

Line voltage: 220 VAC, 1 phase

Voltage tolerance: 230 VAC ±10

Rated frequency: 50 Hz ±2 Hz

Line-voltage compensator

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| | <p>Capable of operating continuously in ambient temperatures of 10–40 °C and RH 20%-80%</p> <p>Accessories:</p> <ul style="list-style-type: none"> → An online inverter suitable for the equipment and any necessary electrical protection equipment. → At least one protective dust cover. → Equipment supplied with the quality assurance equipment i.e. phantoms to check image quality and calibration of the mobile X-ray unit. → Software and licenses <p>Standards</p> <p>Compliance with the following international standards or regional or national equivalents</p> <ul style="list-style-type: none"> → IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. → IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. → IEC 60336:2005 X-ray tube assemblies for medical diagnosis → IEC 60601-1-3:2008+AMD1:2013 Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment. → IEC 60601-2-28:2017 Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis. → IEC60601-2-54:2009+AMD1:2015+AMD2:2018 Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and fluoroscopy. | |
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| 2 | <p>Thermal X-ray printer</p> <p>Reprographer for printing X Rays from mobile X Ray Throughput: 30 large-format prints per hour minimum. Photo Thermography, DDI direct digital imaging (chemistry-free laser) or equivalent technology With 2 film trays DICOM 3.0 interface for integration Suitable for various formats 43 x 43, 35 x 43 cm, 28 x 35 cm, 25 x 30 cm and 20 x 25 cm, with two of these formats directly selectable. Wi-Fi network connection Ethernet connection Network Protocols: (TCP/IP) FTP, Telnet, HTTP, SNMP, SMTP, LPD Power supply: 220 +/- 10% VAC, 50 +/- 2 Hz</p> <p>Accessories:</p> <p>Cables and all accessories required for connection Software and licenses</p> <p>Consumables for color printer:</p> <p>4 boxes/125 films for 43 x 43 cm format 2 boxes/125 films for 35 x 43 cm format 2 boxes/125 films for 28 x 35 cm format 1 box/125 films for 25 x 30 cm format 1 box/125 films for format 20 x 25 cm</p> <p>Standards IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and testing.</p> | 15 |
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| 3 | <p>Radiation protection equipment (accessories)</p> <p>Each accessory kit will consist of:</p> <p>Two leaded aprons</p> <ul style="list-style-type: none"> → Equivalence. Pb : 0.50 mm → One size - minimum length 110 cm - width 60 cm → Material: Nylon <p>Two gonad protection</p> <ul style="list-style-type: none"> → Equivalence. Pb : 10 mm → Anti-X protection held by a belt with velcro. → Material: polyurethane <p>Two thyroid protectors</p> <ul style="list-style-type: none"> → Equivalence. Pb : 0.50 mm → Adjustable collar with Velcro closure <p>Two leaded goggles</p> <ul style="list-style-type: none"> → Pair of 0.75 mm leaded goggles, specially adapted for interventional radiology. → A pair of goggles with side vision protected by a 0.50 mm leaded lens to guarantee perfect eye protection. | 15 |
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B. Durability, standards and warranty requirements (manufacturer & product) for ALL items

| N° | UNOPS minimum technical requirements |
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| Quality standards and certificates (manufacturer & product) | <p>The bidder must provide:</p> <ul style="list-style-type: none"> → Marketing authorisation issued by Australia, Canada, Japan, the European Union and/or the United States regulatory authority (Ancient GHTF). If EU authorisation is presented, please provide the EU Declaration of Conformity with all elements. → Evidence of the manufacturer's valid and certified quality management system which includes the scope and locations and facilities where the relevant activities are performed in accordance with the latest versions of ISO 13485, issued by CABs, Notified Bodies or accredited bodies recognised by at least one regulatory authority in Australia, Canada, Japan, the European Union and/or the United States (FDA). → If the bidder is the manufacturer, it must provide a manufacturing approval/ license from the competent authority or If the tenderer is |

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| | not the manufacturer, it must provide the manufacturer's authorisation to distribute the items. |
| Warranty | <p><u>Period:</u> The minimum guarantee period is 12 months, starting from the date the equipment is brought into service.</p> <p><u>Service:</u> The warranty covers preventive maintenance services and repair/replacement of defective equipment or spare parts during the warranty period.</p> <p>The bidder must provide the contact details/profile of the partner/representative local or regional (name, focal point, legal status, services provided and experience in the field) to be contacted in case of need.</p> |
| After-sales services | <p>The tenderer must provide the contact details/profile of the partner/representative at local or regional level (country in the geographical area) (name, focal point, legal status, contact details, services provided and experience in the field) to be contacted if necessary.</p> <p>Note : In case the local representative is located in the region and not exactly in Togo, the supplier must ensure the diligence of services throughout the use of the equipment by undertaking to establish a partnership in Togo, in the event of a contract being awarded.</p> |
| Operating and/or equipment manual in French | The bidder will provide the equipment operating and/or user manual in French and the maintenance/ troubleshooting manual in French. |
| Gender promotion and diversity at work | The bidder must share its internal policy on the promotion of gender and diversity at work and/or specify the measures and actions that are in place. |
| Environmental management system or Health & safety system | The bidder must demonstrate that the manufacturer is in possession of a valid certificate confirming its good environmental management practices (ISO 14001 or ISO 45001 or equivalent). Failing this, the bidder must share its internal policy or related measures. |

Delivery requirements and data comparison tables

| UNOPS Requirements | |
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| Delivery times | The tenderer must deliver the goods within a maximum of 100 days of signing the contract. |
| Place of delivery and Incoterms | In accordance with Incoterms 2020: |

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| | <p>CPT: Port of Lomé, Togo</p> <p>The supplier must provide all the documents required for customs formalities relating to the import of goods into the country.</p> |
| Recipient details | Ministry of Health - Government of Togo |
| UNOPS right to modify requirements | <p>At the time of contract award, UNOPS reserves the right to vary the quantity of related goods and services indicated above, provided that the variation does not exceed 20% more or less than the quantities originally required, and without any change in the unit price or other terms and conditions of the offer and tender.</p> |

A. Inspections et tests

UNOPS reserves the right to carry out a pre-shipment and/or arrival inspection and if the equipment does not meet the established specifications, the supplier shall take immediate action to remedy the defects or replace the defective equipment to the satisfaction of the purchaser.