SUPPLY AND COMMISSIONING OF DIGITAL MAMMOGRAPHY
EU FUNDED PROJECT
MAURITIUS FAMILY PLANNING AND WELFARE ASSOCIATION

QUANTITITY : 1 UNIT

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. *In case the specifications are not found in the brochure/ technical specifications, authentic documentations, signed by the manufacturer, must be submitted by the bidder to provide evidence of compliance and/or details of non-compliance and degree of deviations from specifications.*

1. **I Digital Mammography Machine (Direct Type)**
   (a) Bidder shall provide a complete package consisting of:
   - Digital Mammography system with X-Ray Generator and X-Ray tube
   - Acquisition workstation
   - Digital detector
   - Image processing and workstation
   - Dedicated mammography software
   - Uninterruptible Power Supply (UPS) for digital mammography system, detector, acquisition workstation and image processing and diagnostic workstation

   (b) The high-end digital mammography machine should be:
   1. Software upgradable to do Tomosynthesis using the existing hardware
   (Bidder to provide evidence of compliance in brochure/technical specifications)

   11. Software upgradable to do contrast Enhanced Mammography

   (Bidder to provide evidence of compliance in brochure/technical; specifications)

   (c) Bidder to specify make, model of equipment and release date of model proposed.
   (d) The equipment, as well as, the biopsy facility and the printer should have US FDA approval and European CE mark Certification. Original certificates of compliance to be submitted with manufacturer's name and model of equipment for the: (1) Digital mammography machine, (ii) Printer. For CE , Dcelaration of Conformity should also be submitted.
   (e) The digital mammography machine should have undergone the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF) Type Testing – Test certificate to be supplied by the supplier for evaluation purposes
   (f) Original manufacturer certified brochure including full technical specifications to be submitted. The original brochures and technical specifications must bear the seal of the manufacturer. In case the catalogue is a copy of the original, the bidder must certify the copy by writing *'Certified to be a true copy of the original seen by me' on each page of the*

(g) *document, signing it, dating it, printing their name under the signature and adding their occupation, address and telephone number*.

(h) Equipment should appear as a current product on manufacturer's website. Bidder to submit at least 10 major health centres as reference sites in Europe and USA where the digital mammography system proposed is used. An obsolete system will not be accepted.

(i) Bidder to state life expectancy of equipment which should be at least 12 years or better

2. Electrical Requirements

a) Power Supply: Single Phase AC 230 V ± 6% or Three Phase AC 400V±6%; 50Hz ± 1.5%

b) Should include a Distribution Board and all electrical protective switchgear including an isolation transformer

c) Bidder to supply and install:

(j) One on-line UPS with an autonomy of at least 30 minutes for the whole digital mammography system and for the acquisition workstation, and

(ii) One on-line UPS with an autonomy of at least 30 minutes for the image processing workstation

3. X-ray Generator

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical provide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications

a) Power ≥ 5.0 kW.
b) Tube voltage range (minimum): 22-35kVp.
c) Tube load range: 5 – 500 mAs or better.
d) Exposure time range: At least 30ms -2s
e) Automatic Exposure Control (AEC)
f) Manual and automatic selection of kVp, mAs, filter

4. X-ray Tube

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentation, signed by the manufacturer, must be submitted by the bidder

to provide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications.

a) Dedicated X-ray mammography tube with dual (2) focal spots
b) Focal spot sizes of approximately 0.1mm and 0.3 mm.
c) Anode material: Bidder to state the material of anode and its advantages
d) At least three (3) filters. Filter material: Bidder to state material(s) used in filters
Note: the materials used for the anode and filters shall be such that they allow for low dose/high penetration spectra, even for thick and dense breasts.
e) Anode heat capacity › 200,000 HU
5. Detector technology

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentations, signed by a manufacturer, must be submitted by the bidder to provide evidence of compliance and degree of deviation from the specifications

a) Detector type: direct conversion flat panel detector (a-Se)
b) Detector field size should be at least equivalent to 24cm x 29 cm.
c) Matrix about 2.0 K x 3.0 K.
d) Pixel size < 100 µm
e) Image depth should be at least 12 bit
f) DQE charts to be submitted

6. Gantry

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentations, signed by the manufacturer, must be submitted by the bidder to provide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications.

a) Collimators: Fully automated adjustment for different paddles, sizes and magnification
b) Movements: Motorised vertical and rotating movements suitable for all mammography clinical procedures.
c) Control buttons for vertical and rotational movements on both sides of the gantry
d) Source to image distance (SID) > 65 cm
e) Motor driven compression

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f) Manual and automated breast compression
g) Maximum compression force for automated compression: ≥ 150N and ≤ 200 N.
h) Automatic decompression after exposure
i) Automatic decompression in case of power failure
j) Automatic decompression in case emergency stop which is pressed.
k) Emergency stop switches on console an gantry
l) Two foot switch control
m) Anti-scatter grid or equivalent technology for scatter rejection
n) Display of Skin Entrance Dose and Average Glandular Dose
o) Paddles: small breast, spot and magnification paddles to be included.

7. Acquisition Workstation

*Each of the following requirements must be shown and highlighted in the brochure/technical specifications, by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentations, signed by the manufacturer, must be submitted by the bidder to p*rovide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications

a) Bidder must supply a workstation to allow for X-ray exposures, image acquisition, image display, registration of patient demographic data and quick review.
b) Operator controls: Detector and generator controls must be integrated in the same console.
c) Both manual and automatic exposure paramaters settings should be possible
d) Storage capacity ≥ 5000 images
e) Time between sequential acquisitions < 30s.
f) Time between actual acquisition and preview < 20s.
g) Monitor: Minimum 3MP 19" High Contrast Flat Panel TFT LCD display
h) Keyboard and mouse/trackball
i) Facility for Annotations: Left/Right Marking/Text additions/Line/rectangles
j) Facility for Measurements: Distance/Density
k) Facility to view dose delivered after each exposure.
l) Digital Magnification
m) DICOM 3.0Compatibility (DICOM Send/retrieve/Print/Worklist)
n) The acquisition workstation should be fitted with an X-Ray lead glass protective system so as to meet the requirements of the Radiation Protection Authority (RPA). The size of the lead glass should be of at least 60cm (L) x 60 cm(W) on a metal frame with lead lining, attaining a minimum height of at least 2m.
o) The whole acquisition workstation area should be designed and built to meet the requirements of the RPA.

8. Image processing and Diagnosis Workstation

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentations, signed by the manufacturer, must be submitted by the bidder to provide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications.

a) Display Monitors

1. One diagnostic mammography approved monitors of at least 5 MP21" Hi-Res Flat Panel LCD TFT display as workstation for radiologists reporting and processing software.
2. With automated self-calibration.
3. High-end, high definition medical grade display graphic card.

b) Storage capacity at least 2TB.
c) Keyboard, mouse or trackball as required
d) To receive images directly from acquisition console and display.
e) Should also have multi-modality imaging facility (ultrasound, X-ray, mammo).
f) Dedicated breast imaging software tools with the following functions:

- Magnification
- Zoom
- Panning
- Windowing
- Brightness Adjustment
- Contrast adjustment
- Distance Measurement

g) Should have complete Computer Aided Detection(CAD) facility
h) Should allow for archiving of images on DVD
i) Should be fully DICOM 3.0 Compliant (Send, receive, Worklists, Query/Retrieve and Print) and PACS ready
j) On-line UPS with an autonomy of at least 30 minutes

9. Mammography Room and Acquisition

a) The bidder must request and effect a site visit in the examination room to ensure that the proposed equipment will fit inside the room before submitting the bid
b) The bidder must propose an on-site layout for the equipment and submit a detailed drawing of the equipment layout in the room including the proposed modifications.

c) The bidder must ensure that the radiation-shielding of the existing examination room meets the requirements of the RPA
d) Any additional shielding, i.e. lead-lining of the control rooms, the walls and doors in the examination room, must be supplied and installed by the bidder so as to meet the requirements of the RPA
e) All associated electrical works needed are to be carried out by the bidder for the successful completion of the project – this includes electrical cabling, floor and ceiling duct systems, and making good any damages caused during the installation phase with regard to the walls, ceiling and floor of the examination and console rooms.

10. **Dedicated Mammoviewer/Film Light Box**: Slim type to accommodate at least 6 films of size 25 x 30 cm, with fluorescent tubes and shutters, magnification device and variable luminescence.

11. **Quality Assurance Tools**: A complete digital mammography QC test kit including an American College of Radiology (ACR) approved phantom to perform image quality verification and calibration, and an approved dosimeter for the system to perform Skin Entrance Dose tests and average Glandular Dose tests shall be provided.

12. Testing and Acceptance

a) Factory Acceptance Test

The system, prior to shipment, must be tested for conformance with the manufacturer's performance specifications and the minimum requirement specified herein. The results of the testing of the system must be submitted by the manufacturer in a Certified Factory Acceptance Test Report to be provided by the supplier/bidder to the Mauritius Family Planning and Welfare Association, **prior to shipment to the end-user location.**

The system, after installation, must be tested by the bidder/supplier together with the hospital physicist to demonstrate that the equipment meets the manufacturer's performance specifications and the minimum requirements specified herein. The results of the testing of the sytem shall be documented by the bidder/supplier in an Acceptance Protocol that shall be signed by the hospital physicist, the biomedical engineer and the bidder/supplier's representative.

13. Direct Digital Image Guided Stereotactic Biopsy Facility

a) Should have US FDA approval and European CE mark certification. Original certificates of compliance to be submitted with manufacturer's name and model of equipment. For CE, Declaration of Conformity should also be submitted.

14. Heavy Duty dry Laser Printer

Each of the following requirements must be shown and highlighted in the brochure/technical specifications by the bidder. In case the information required is not found in the brochure/technical specifications, authentic documentations, signed by the manufacturer, must be submitted by the bidder to provide evidence of compliance and/or details of non-compliance and degree of deviation from the specifications.

a) Power Supply Single Phase AC 230V± 6%, 50 Hz ± 1.5%
b) Should have US FDA approval and European CE mark Certification, Original certificates of compliance to be submitted with manufacturer's name and model of equipment. For CE, Declaration of Conformity should also be submitted.
c) Daylight film loading
d) Floor-mounted on wheels and brakes
e) Film size selection 25 x 30 cm and 35 x 43cm films
f) Minimum 100 films per hour throughout for 35 x 43 cm.
g) Automatic self-testing, density and adjustment and calibration
h) 50 µ printing resolution
i) 14 bit contrast resolution
j) DICOM 3 compatibility (send/receive, query/retrieve, print)

15. Training

a) Radilogist training
At least 10 working days application training, per site. The application training must be conducted by an expert radiologist with case demonstrations (8 dyas) at the site of the installation of the equipment.

b) Radiographer Training
At least 10 working days application training by a qualified application specialist
c) Biomedical Engineer Training

Full factory training at the manufacturer's training centre for Biomedical Engineering staff

d) Physicist Training

Commissioning should include doing a series of QC tests on the machine by a qualified expert in mammography. QC to be performed using phantoms and Quality Assurance test kit provided. Full training to be provided to the physicist on how to do QC tests on the machine.

16. General Requirements

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a) It is the responsibility of the bidder to visit the room where the equipment will be installed and ensure that the whole system will fit in.

b) At least two-year full warranty on whole digital mammography system including X-ray tube and detector as from date of commissioning.
c) Lifetime validity for all software licenses – system, application, service diagnostic and calibration
d) System should come with the latest software and free software upgrade for a minimum of two years
e) Bidder to propose a 5 year maintenance contract (labour only) in the post-warranty period. A complete servicing and Quality Assurance, including dose measurement, must be performed by an overseas expert from factory once every year.
f) Bidder to submit a preventive servicing/maintenance schedule as per the manufacturer's recommendations.
g) Bidder to submit an updated price list of spare parts annually
h) Bidder shall be responsible for supplying the spare parts within a maximum of 10 working days
i) Full user manual (2 hard copies and 1 soft copy)
j) Full service and technical manuals with assembly diagrams, including spare parts list (2 hard copies and 1 soft copy). Errors and malfunction codes should be fully documented in the service manuals.
k) Full supply spare parts to maintain the equipment as and when required during its life expectancy
l) Acceptance tests should include all required dosimeter measurements
m) Full set of special tools to service the mammography
n) Bidder to submit the DICOM conformance statement at time of commissioning
o) Commissioning will be effected only after all acceptance tests are completed and the image quality and the functionality of the equipment are deemed acceptable
p) Original certificates from manufacturer specifying date of manufacture (signed and stamped by manufacturer), make, model, serial number, software version, release date of the model, place of manufacture or assembly, and acceptance test certificate. These documents should be submitted at time of commissioning.

17. Participation

17.1 Participation is open to all natural persons who are nationals of and legal persons (participating either individually or in a grouping – consortium – of tenderers) which are effectively established in a Member State of the European Union or in a eligible country or territory as defined under the Regulation (EU) No 236/2014 establishing common rules and procedures for the implementation of the

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Union's instruments for external action (CIR) for the applicable instrument under which the contract is financed (see also heading 22 of the contract notice). Participation is also open to international organisations. All supplies under this contract must originate in one or more of these countries. However, they may originate from any country when the amount of the supplies to be purchased (as a whole or, if divided into lots, per lot) is below EUR 100 000.

18. Origin

18.1 Unless otherwise provided in the contract or below, all goods purchased under the contract must originate in a Member State of the European Union or in a country or territory of the regions covered and/or authorised by the specific instruments applicable to the programme specified in clause 3.1 above. For these purposes, 'origin' means the place where the goods are mined, grown, produced or manufactured and/or from which services are provided. The origin of the goods must be determined according to the relevant international agreements (notably WTO agreements), which are reflected in EU legislation on rules of origin for customs purposes: the Customs Code (Council Regulation (EEC) No 2913/92) in particular its Articles 22 to 246 thereof, and the Code's implementing provisions (Commission Regulation (EEC) No 2454/93.