# **ANNEX II + III:** TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

# LOT 1: DIGITAL MAMMOGRAPHY UNITS

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Columns 1-2 are completed by the Contracting Authority Columns 3-4 to be completed by the tenderer Column 5 is reserved for the evaluation committee

Annex III - the Tenderers technical offer

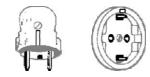
The tenderers are requested to complete the template on the next following pages:

- Column 2 is completed by the Contracting Authority and shows the specifications of the goods required (any modification applied by the tenderer may lead to the disqualification of the Lot so modified).
- Column 3 to be filled in by the tenderer and must detail what exactly is offered and name of manufacturer (for example the words "compliant" or "yes" are not sufficient).
- Column 4 allows the tenderer to make comments on his proposed goods and also to make reference to his documentation

The tenderers are required to demonstrate that specifications of the items that they offer are responsive to the requirement set out in the tender dossier and to identify model and manufacturer of each individual item in their technical offer and to provide necessary documentation such as catalogues, brochures, booklets that inform of details of technical specifications that sufficiently define the equipments being offered, and thus should enable the contracting authority to check the information provided in the technical offer. Offers that do not permit to identify precisely the models and the specifications quoted may be rejected during evaluation.

# **MANDATORY REQUIREMENTS FOR LOT 1**

Main supplies Electricity 220-230 Volt single phase, 380 Volt three phase, Frequency 50 Hertz. All equipment connected to an electrical outlet shall be provided with a solid "Schuko" Plug.



Ambient temprature: 35°C -40°C (hot zone) Humidity: 70-80% Altitude: Sea level

All equipment shall be delivered complete with all accessories, cables, plugs and sockets, required for operation including any software driver and manuals.

### WARRANTY:

All items supplied in this Lot shall include full **manufacturer warranty** granted for a minimum of two (2) years. The warranty provided shall be described in detail in the tender.

#### **STANDARDS:**

All equipment should be from a branded source with a certified quality assurance system and have the following certifications:

- International Standard Organization (ISO);
- CE marking

Tenderers shall ensure conformity of the equipment with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations. All equipment shall fully comply with international safety measures and regulations.

### MAINTAINANCE DURING WARRANTY PERIOD:

The tenderer must have a local maintenance and technical support office or a company entrusted to solve any problem on site. The response time must not be more than 24 hours. The name of the company, address, telephone- and fax numbers, e-mail address must be mentioned in the bid

## **AFTER SALES SERVICE:**

Tenderers shall submit together with their offer a proposal (description and price) for 2 years after sales service contract (after final acceptance) including regular preventive maintenance, quality check, repair. Guaranteeing the availability in supplying and replacing all needed spare parts and consumables (bulbs, X-ray tubes, CRTs, boards, sensors, etc). Such offer will not be taken into consideration within the evaluation.

## **TRAINING:**

The tenderer has to organize appropriate user training in Serbian language for effective and problem-free use of the equipment included in this LOT in each of the location mentioned in the distribution list below.

A training proposal for the operation of the equipment will be submitted by the tenderer in the tender.

This proposal shall include at least:

- Schedule and duration
- Description of training materials

#### MARKING AND LABELING

All equipment shall be marked with labels in English bearing the EU logo as per EU visibility Guidelines. See special conditions for additional details.

#### **SPARE PARTS AND / OR SUPPLIES:**

The tenderer shall confirm the availability of spare parts for a period of 5 years beyond the warranty period. A list of the manufacturer's recommended spare parts and consumables shall be submitted together with the tender.

# **DOCUMENTS:**

The following documents shall be delivered for all equipment:

- Service and operation manuals in English and Serbian language.
- Execution guidance / installation drawings.
- Certificates of compliance to safety norms and standards and/or trial test results at the manufacturer's facility.

# **TECHNICAL SPECIFICATIONS:**

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
1.1	Digital mammography units			
	Quantity: 5 (five)			
	X-ray Generator:			
	High frequency			
	Power: min. 4kW			
	kV range: 25 to 35 in 1kV steps			
	mAs range: 5 to 500			
	Displayed parameters: kV, mAS, target, filter, density selection			
	X-ray Tube:			
	X-ray Tube target material: Molybdenium or Molybdenium and Rhodium or Molybdenium and Tungsten			
	X-ray tube: single or dual track			
	Focal spots: at least 2 (two) small 0,1mm, large 0.3mm			
	Rotating anode			
	Rotation speed: min. 8500 rpm			
	Anode heat storage capacity min. 150 kHU			
	Beam filters: Mo and Rh		Focal spots: <mark>at</mark> least 2 (two),	

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
			small 0,1 mm, large 0.3 mm	
	Gantry assembly			
	Isocentric system			
	Motorized rotation and vertical movement			
	Rotation angle: $+180^{\circ}$ to $-135^{\circ}$			
	Distance floor to image receptor: 70 to 140 cm (approx.)			
	SID: min. 65 cm			
	Face shield			
	Compression force display			
	Pair of dual foot pedals			
	Automatic decompression after exposure			
	Magnification stand with dedicated paddles			
	Magnification: 1,5 or 1,8x			
	Compression plates: 24x30cm and 18x24cm			
	Motorized and manual compression			
	Grid/Breast support assembly			
	Motorized grid			
	Grid ratio: min. 4:1			

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
	Low attenuation carbon fiber support			
	Exposure control			
	Automatic optimization of parameters based on radiological density of the breast using virtual or discrate cells for identifica- tion (AEC)			
	Control (operated) console with integrated lead glass protection to be used in the same room where the sys- tem is installed			
	Manual selection of all parameters			
	Automatic technique selection			
	All exposure parameters displayed			
	Collimator			
	Beam filter: Mo and Rh			
	Molybdenum: min. 0.030 mm			
-	Rhodium: min. 0,025 mm			
	FOV selected automatically based on the paddle and based on magnification platform or selected by operator either manually or by equivalent feature with digital processing			
	FOV to be modified manually			
	Flat panel detector			
	Size: min. 23.9 x 30 cm			

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
	Pixel size: max 110 μm			
	Image depth: > 13 bit			
	Digital acquisition system			
	Local storage capacity: min. 3000 images (Acquisition Work- station			
	Average time to display processed image: < 30 seconds			
	Exposure to exposure time: < 30 seconds			
	LCD image monitor			
	Image annotation			
	Measurements functions			
	Mean glandular dose display for every image			
	Automatic windowing			
	Zoom and roam			
	Image invert			
	Integrated CD/DVD			
	Connectivity			
	Autosend (autopush)			
	Autoprint			
	Autodelete based on storage commitment			

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
	DICOM Storage commitment (Storage commitment user)			
	DICOM Worklist (Modality Worklist User)			
	DICOM Query / Retrieve User or DICOM connectivity for PACS/RIS			
	DICOM Print (Basic Grayscale Print User)			
	Verification service (Verification Provider)			
	DICOM CD			
	DICOM MPPS (Modality Perform Procedure Step User)			
	Diagnostic Review Workstation			
	5Mpixels LCD B/W Display, 2 units			
	1280 x1024 LCD color display, 1 unit			
	CPU: min. 2x2.3GHz			
	HDD: min. 140GB			
	Storage capacity: min. 30000 images, integrated or via external storage			
	Image processing			
	Magnifying glass			
	Flip, Rotate, Invert			
	User annotations			

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
	Distance measurement			
	Networking:			
	DICOM 3.0 Storage SCU/SCP			
	Quiery/Retrieve SCU/SCP			
	DICOM Print SCU			
	Media interchange CD-R			
	Image display:			
	After the patient selection, the folder automatically appears and images are loaded.			
	Image display chronologically, including previous images.			
	Image folder widening, when several previous images are available.			
	Image panel allowing a visual control of all mammo patient im- ages, differentiating standard examination, magnification, stereotaxis, screenshot by date, laterality.			
	Patient's collection creation possibility for next examination discussion or for presentation.			
	Multiple hanging protocols			
	Fit to screen function for all images of FFDM, CR and digitized films (the system to recognize automatically the shape of the breast in the image for display or Optimal breast image repre- sentation on the screen of acquisition workstation			

1. Item Number	2. Specifications	3. Specifications Offered	4. Notes, remarks, ref to documen- tation	5. Evaluation Committee's notes
	Automatic symmetrical alignment of the image (FFDM, CR and digitized films).			
	Local contrast enhancement at the location of mouse cursor.			
	Possibility to put marker on the image.			
	Mammography dedicated dry imager			
	Image resolution:min.500 dpi on every format			
	Film size 10"x12" and 8"x10"			
	Min.two trays to be supplied			
	Output grey level: min. 14 bits			
	100 films for dry image			
	Interface: DICOM print			
	Warranty (minimum two years)			
	Training			

# LOT 1 Delivery, installation and training list:

Items to be delivered and installed	Location	institute
1 Full-field digital mammography unit	Beograd	Bežanijska Kosa Clinical Hospital Centre
1 Full-field digital mammography unit	Beograd	Zemun Clinical Hospital Centre
1 Full-field digital mammography unit	Beograd	Dr. Dragiša Mišović Clinical Hospital Centre
1 Full-field digital mammography unit	Kragujevac	Kragujevac Clinical Centre
1 Full-field digital mammography unit	Užice	Health Centre