

# Technical Specifications

## LOT 1. DIGITAL X-RAY UNIT

No.	Item	Quantity
1	Digital fluoroscopic X-ray diagnostic tomosynthesis system with dynamic flat panel detector	1

Delivery to:

**Republican TB Hospital from Bender - 1 item;**

148, Benderskogo Vosstanya str., Bender, Republic of Moldova, Transnistrian region

**Incoterms CIP**

**Minimum requirements:**

### Lot 1. DIGITAL X-RAY UNIT :

- Item: **Digital fluoroscopic X-ray diagnostic tomosynthesis system with dynamic flat panel detector**

*The Goods and Related Services shall comply with following Technical Specifications and Standards:*

Name of the medical-technical requirement	Requested	Offered
<b>1.General characteristics</b>		<b>Model: Helios DRF x-ray system</b> <b>Manufacturer: Assing SPA</b> <b>Country of origin: Italy</b>
X-ray tube above the table	yes	Yes
Remote operation, remote control table	yes	Yes
Control panel in control room	yes	Yes, with touch display and joystics
Control panel in examination room	optional	Yes, optional
Intercom device: Patient-doctor communication (control room)	yes	Yes, Patient-doctor communication (control room)

<b>2. Technical characteristics of table:</b>		
Functional capabilities of X-ray table:	yes	yes
- inclination	yes	yes
- lateral movement of tabletop	yes	yes
- longitudinal movement of tower	yes	yes
Table inclination angles	-90 ° to +90 °	Yes, table inclination -90 ° to +90 °
Maximum patient weight, including tilt	≥200 kg	Yes, 300 kg
Automatic horizontal table stop function	yes	Yes
Tabletop dimensions	≥220x70 cm	249,5 x 71,5 cm
Maximum patient weight	≥200 kg	Yes, 300 kg
Vertical movement	At least in the range 60-100 cm, in case the lower limit cannot be reached, a step (made of stainless steel) must be provided to facilitate the patient's climb onto the table	Yes, vertical movement Range minimal from the ground 45- and max 145 cm
Lateral movement of tabletop	≥25 cm	Yes, 30 cm
Longitudinal movement of tower	X-ray patient coverage area ≥160 cm	Yes, 210 cm
Position indicators	yes, on the control panel and /or at the table in the examination room	Yes, on the control panel and /or at the table in the examination room
Ensuring motorized movement	yes	Yes, motorized movement
<b>3. Technical characteristics of X-ray generator:</b>		
Type of X-ray generator	high frequency	Yes, high frequency
Power of X-ray generator	≥80 kW	Yes, 80 kW
Scope of kV regime, X-ray	≥40-150kV	Yes, 40-150kV
X-ray range	≥0.5-800mAs	Yes, 0,4-1000mAs
Scope of kV regime, Fluoroscopy	≥50-120kV	Yes, 40-150kV
Maximum X-ray output current	≥800mA	Yes 10-1000mA
Maximum fluoroscopy output current	≥20mA	Yes, 125 mA

Serial radiography working regime	≥15 fps	Yes, 15 fps
Working regime pulsed fluoroscopy	≥30 fps	Yes, 30 fps
Equipped with an ionization chamber for automatic exposure control (AEC)	min 3 fields	Yes, 3 fields
<b>4. Technical characteristics of X-ray tube: Model : RTC700HS</b>		
Thermal storage capacity of the assembly	≥700kHU	Yes, 800 kHU
Focal spot	Min. 2	Yes, 2 focal spots
Small focal spot	Size max. 0.7mm	Yes, small focus 0,6 mm
Big focal spot	Size min. 1mm	Yes, large focus 1,2 mm
Small focal spot power	Max. 60kW	Yes, small focus 40 kW
Big focal spot power	Min. 80kW	Yes, large focus 100kW
kV max X-ray	Min. 150kV	Yes, 150kV
kV max fluoroscopy	Min. 125kV	Yes, 125kV
<b>5. Technical characteristics of tower:</b>		
X-ray outside the table	yes	Yes, x-ray outside the table
Detachable grid	yes	Yes, removable grid
SID (source image distance) max.	≥125cm	Yes, SID max 180 cm
SID (source image distance) min.	90-110cm	Yes, SID min 100 cm
Complete control panel, including table and generator control in control room	yes	Yes, Complete control panel, including table and generator control in control room
Control panel for basic functions in examination room	optional	Yes, included (Installed on the X-ray tube and bucky)
Complete control panel, including monitors that duplicate the information on control room monitors	optional	Yes, optional
<b>6. Technical characteristics of detector:</b>		<b>Pixium RF 4343FL</b>
Detector type	Flat panel	Yes, flat panel
Size, cm(in)	≥43x43(17" x 17")	Yes, 43x43 cm
Size pixels	≤150µm	Yes, 148 µm
Maximum matrix size in X-ray capture mode	≥2048x2048 pixel	Yes, 2874x2840 pixel

X-ray acquisition depth	$\geq 16$ bit	Yes, 16 bit
Serial X-ray, fps	$\geq 10$	Yes, 15 fps and 30 fps
Maximum matrix size in capture mode, Fluoroscopy	$\geq 1024 \times 1024$ pixel	Yes, 1024x1024 pixel
Fluoroscopy acquisition depth	$\geq 16$ bit	Yes, 16 bit
<b>7. Technical characteristics of collimator:</b>		<b>R225/ACS touch screen</b>
Working regime	automatic and manual	Yes, automatic and manual
Light source type	LED	Yes, LED
Collimation type	Rectangular min. symmetrical left and right; option: iris/octagonal	Yes, Rectangular min. symmetrical left and right;
Built-in filters	$\geq 3$ types	Yes, 3 types
Filter selection	Manual and automatic	Yes, manual & automatic
<b>8. Image characteristics:</b>		
Display last image	yes	Yes
Virtual collimation	yes	Yes
<b>9. Technical characteristics of a radiologist's workplace</b>		
Display and Workstation (acquisition/post-processing)	yes	Yes, Display and Workstation (acquisition/post-processing)
Quantity min. 2 monitors in control room	yes	Yes, 2 monitors in control room
Min. 2 monitors in examination room	optional	Yes, optional
Monitor sizes	$\geq 18$ inch	Yes, 21 inches
On-screen data display and post-processing capability	Availability	Yes
Multimodal visualisation and comparison of DICOM images	Availability	Yes
Measurement of length and angles	Availability	Yes
Printing on DICOM printers	Availability	Yes
Creation of DICOM CD with a built-in viewer	Availability	Yes
<b>10. Technical characteristics of printer: Colenta HighCapXP</b>		
Printer type	compact, desktop	Yes

Printing technology	Printing technology direct thermographic or laser printing	Yes, Laser printing
Film formats used	$\geq 20 \times 25 - 35 \times 43$ cm.	Yes (20x25 cm-35x43 cm)
Spatial resolution, pixels/mm	$\geq 12$	Yes, 12 pixels/mm
Simultaneously available formats	$\geq 2$	Yes, 2 formats
<b>11. X-ray</b>		
Size scope	$\geq 15 \times 15 - 42 \times 42$ cm	Yes 15x15 to 43x43 cm
Tinted images	$\geq$ "four in one"	Yes, 2x2, etc
Serial acquisition	yes	Yes
Acquisition with contrast	optional	Yes, optional
<b>12. Digital tomosynthesis :</b>		
Automatic acquisition scheme for reconstruction	yes	Yes
Acquisition rate	$\geq 15$ fps	Yes
Pre-tested programs with possibility of manual modification for different anatomical areas	$\geq 5$	Yes
Automatic reconstruction by acquisition station	yes	Yes
Acquisition possible for any table tilt angle	yes	Yes
Reconstruction parameters:		
Layer thickness scope	$\geq 0.5 - 10$ mm	Yes
Depth of acquisition in relation to patient's table	$\geq 0 - 20$ cm	Yes
Pre-set programs for different anatomical areas	$\geq 5$	Yes
Post reconstruction software that allows tomosynthesis reconstruction with different parameters without repeatedly irradiating the patient (including thickness and depth)	Availability	Yes
Post-processing, including image processing tools	Availability	Yes
Reconstruction of oblique images to the vertical or horizontal axis	Availability	Yes
<b>13. X-ray scanning technology:</b>		
Acquisition of slit type or longitudinal scanner	Availability	Yes, included

Automatic acquisition scheme for CT radiography reconstruction	Option	Yes, option
Automatic scan radiography reconstruction on acquisition station	Availability	Yes
Pre-set programs with the possibility of manual modification for different anatomical areas	$\geq 3$	Yes, min 20 presets
Scanning area	$\geq 42 \times 42 \text{ cm}$	Yes, $43 \times 43 \text{ cm}$
Scanning speed	$\geq 10 \text{ cm/sec}$	Yes, $10 \text{ cm/sec}$ (Adjustable)
Acquisition rate	$\geq 3 \text{ fps}$	Yes, $3 \text{ fps}$ in radiography
Integrated DAP meter with display of results in patient database	yes	Yes, Integrated DAP meter with display of results in patient database
<b>14. Processing software</b>		
Post processing	yes	Yes
Zoom level control; Rotate/Reverse	yes	Yes
Image annotations marker, text, lines, angle, missing	yes	Yes
DICOM 3.0	yes	Yes
- DICOM Verification	yes	Yes
- DICOM Modality worklist	yes	Yes
- DICOM MPPS	yes	Yes
- DICOM Storage	yes	Yes
- DICOM Storage commitment	yes	Yes
- DICOM Grayscale print	yes	Yes
- DICOM Query / Retrieve	yes	Yes
- DICOM GSPPS	yes	Yes
- Import and export of images from PACS	yes	Yes
Export of images to CD/DVD	yes	Yes
Export of examination results to HIS / RIS	yes	Yes
Tomosynthesis software	yes	Yes
X-ray scan software	yes	Yes
<b>15. General conditions</b>		

Lead glass	minim 1x0,8 m	<b>Yes, 1x0,8m Lead Glass included</b>
Protective collar	2 sets	Yes, included
Protective apron	2 sets	Yes, included
Support on wheels for (Protective collar & apron) with at least 5 hangers	yes	Yes, included
User manual (s) that include technical operation & software compartment description	RO / RU	Yes, included
Service manual	In English	Yes
All components of the system must be new (unused), year of production at least 2025	yes	Yes
License for the right to carry out activities involving use of ionizing radiation sources (provide copy of valid license)	yes	Yes
Product offered by the Participant must be registered in the State Register of Medical Equipment and Medical Devices and/or put into circulation in accordance with the legislation in the field of technical regulation and conformity assessment as prescribed by law.	yes	Yes
<b>14. For confirmation, the Participant must provide:</b>		
A certified copy of declaration or copy of documents confirming the possibility of putting the medical device into circulation and/or use based on results of conformity assessment procedure in accordance with the requirements of technical regulation;	yes	Yes
<b>CE Certificate of Conformity</b> issued by a conformity assessment body included in the NANDO list - <a href="https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies">https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies</a>	yes	Yes
<b>EC Declaration of Conformity</b> issued under Directive 93/42 EEC or Regulation 2017/745 referring to the EC Certificate of Conformity by number or NOTIFY BODY code.	yes	Yes

<b>ISO 13485/9001</b> - Quality Management System	yes	Yes
<b>EN 60601-1</b> and/or <b>EN 60601-2-44</b>	yes	Yes
The Participant must have authorization from manufacturer (it is necessary to provide relevant documents from manufacturer) - a letter of guarantee from the manufacturer that the participant is able to supply the proposed equipment in the quantity and within the time specified in the tender documentation	yes	Yes
The Participant must provide confirmation that technical parameters of the equipment offered by him comply with the medical and technical requirements in the tender documentation, in the form of printed official information from the manufacturer or instructions for use with a link to relevant page in such documents. materials	yes	Yes
<b>Presence of service center</b> on the territory of <b>Moldova</b> . Suppliers are committed to provide a detailed description of their after-sale services in Moldova. The Bidder must have service facilities with qualified technical personnel at least in the capital of Moldova – Chisinau. These facilities, which shall operate directly under the authority and the responsibility of the Supplier, will be able to perform full servicing and repair of the equipment to the extent possible without return to the manufacturer, and will have at their disposal all the spare parts needed for routine repair or scheduled maintenance, or will be able to procure them within fourteen (14) days of notice of request at the latest.	yes	Yes



<b>Warranty and post-warranty services</b> must be performed by a certified engineer (provide a copy of the engineer's certificate)	yes	yes
The service warranty period must be at <b>least 24 months</b> from the date of signature of the certificate of putting into operation. During the warranty period, all preventive and corrective maintenance services recommended by the manufacturer will be performed.	yes	Yes, 24 month
<b>Related Services: Operation, maintenance and installation</b>		
<b>1. Installation of Digital X-ray unit</b> The bidder must arrange for the equipment to be installed by certified or qualified personnel. Any prerequisites for installation will be communicated to the beneficiary in advance, described in detail in written form.	yes	yes
<b>2. Operation and/or maintenance of Digital X-ray unit</b> The bidder will provide a comprehensive maintenance plan. The cost of the maintenance plan to be defined and guaranteed over the period of warranty.	yes	yes
<b>3. Training of medical staff</b> from Bender for routine maintenance operation of the equipment (all instruments under this Lot). The bidder will provide user training (including how to use and maintain the equipment).	yes	Yes
<b>4. Spare parts</b> Equipment must be accompanied by an authorized list of accessories and spare parts.	yes	Yes

Name of Bidder: **Andrei MATEI** Signature of Bidder \_\_\_\_\_ Date **11.02.2026**