

2. 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 : SONIALVISION G4 (Shimadzu/Japan)

- 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 SONIALVISION G4 (Shimadzu/Japonia)
1.General characteristics		
X-ray tube above the table	yes	Yes
Remote operation, remote control table	yes	Yes
Control panel in control room	yes	Yes
Control panel in examination room	optional	Yes, optional, on request
Intercom device: Patient-doctor communication (control room)	yes	Yes
2.Technical characteristics of table:		

Functional capabilities of X-ray table:	yes	Yes
- inclination	yes	Yes
- lateral movement of tabletop	yes	Yes, 25 cm, pag.4 Product Data
- longitudinal movement of tower	yes	Yes, 160.5 cm (Imaging range: Max. 202.5cm), pag.4 Product Data
Table inclination angles	-90 ° to +90 °	Yes, +90° to -90°, , pag.4 Product Data
Maximum patient weight, including tilt	≥200 kg	Yes, 205 kg, , pag.4 Product Data
Automatic horizontal table stop function	yes	Yes, soft stop (Pag.4 Product Data Brochure)
Tabletop dimensions	≥220x70 cm	Yes, 76.5 × 235 cm, pag. 4 Product Data
Maximum patient weight	≥200 kg	Yes, 318 kg (patient is stationary and lying horizontal.), pag.4 Product Data
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, 47 – 110 cm from floor, pag. 4 Product Data
Lateral movement of tabletop	≥25 cm	Yes, 25 cm. pag. 4 Product Data
Longitudinal movement of tower	X-ray patient coverage area ≥160 cm	Yes, 160.5 cm (Imaging range: Max. 202.5cm), pag.4 Product Data
Position indicators	yes, on the control panel and /or at the table in the examination room	Yes, Pag. 2-4 User Manual Sonialvision G4
Ensuring motorized movement	yes	Yes, pag. 4 Product Data
3. Technical characteristics of X-ray generator:		
Type of X-ray generator	high frequency	Yes, D150BC-40S, pag. 8 Product Data
Power of X-ray generator	≥80 kW	Yes, 80 kW, pag. 8 Product Data
Scope of kV regime, X-ray	≥40-150kV	Yes, 40-150 kV, pag. 8 Product Data
X-ray range	≥0.5-800mAs	Yes, 0,5-800 mAs, pag. 8 Product Data
Scope of kV regime, Fluoroscopy	≥50-120kV	Yes, 50-125 kV, pag. 8 Product Data
Maximum X-ray output current	≥800mA	Yes, 1000 mA (Pag. 8 ProductData Brochure)
Maximum fluoroscopy output current	≥20mA	Yes, 20 mA (Pag. 8 ProductData Brochure)
Serial radiography working regime	≥15 fps	Yes, 15 fps (Pag. 5 ProductData Brochure)

Working regime pulsed fluoroscopy	≥ 30 fps	Yes, 30 fps (Pag. 5 ProductData Brochure)
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Equipped with an ionization chamber for automatic exposure control (AEC)	min 3 fields	Yes, 4 fields- AEC (Automatic exposure control): 4 fields Photaimer(AEC), (ProductData,pag.2,pag.9/G4 Instruction Manual
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4. Technical characteristics of X-ray tube:

Thermal storage capacity of the assembly	≥ 700 kHU	Yes, 750 kHU, 0.7/1.2JG326D-265, pag. 2 Product Data
Focal spot	Min. 2	Yes, , 2 (Pag. 10, OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
Small focal spot	Size max. 0.7mm	Yes, 0,7 Pag. 10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
Big focal spot	Size min. 1mm	Yes, 1,2 Pag.10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
Small focal spot power	Max. 60kW	Yes, 55 kW Pag.10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
Big focal spot power	Min. 80kW	Yes, 105 kW Pag.10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
kV max X-ray	Min. 150kV	Yes, 150 Pag.10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265
kV max fluoroscopy	Min. 125kV	Yes, 125 Pag.10 OPERATION MANUAL X-RAY TUBE ASSEMBLY 0.7/1.2JG326D-265

5. Technical characteristics of tower:		
X-ray outside the table	yes	Yes, Stretcher applications; The tube head can rotate 90 degrees at vertical position for the stretcher (pag. 3 ProductData)
Detachable grid	yes	Yes, Scatter removal grid (Pag. 4 Product Data)
SID (source image distance) max.	≥ 125 cm	Yes, 150 (Pag. 4 Product Data)
SID (source image distance) min.	90-110cm	Yes, 110 cm (Pag. 4 Product Data)
Complete control panel, including table and generator control in control room	yes	Yes (Pag. 2 Product Data)

Control panel for basic functions in examination room	optional	Yes, optional (Pag. 2 Product Data)
Complete control panel, including monitors that duplicate the information on control room monitors	optional	Yes, optional (Pag. 2 Product Data)
6. Technical characteristics of detector:		
Detector type	Flat panel	Yes
Size, cm(in)	$\geq 43 \times 43 (17" \times 17")$	Yes, 43x43 (Pag. 5 Product Data)
Size pixels	$\leq 150 \mu\text{m}$	Yes, 139 μm (Pag. 5 Product Data)
Maximum matrix size in X-ray capture mode	$\geq 2048 \times 2048$ pixel	Yes, 3032 x 3032 (Pag. 5 Product Data)
X-ray acquisition depth	≥ 16 bit	Yes, 16 bit (Pag. 5 Product Data)
Serial X-ray, fps	≥ 10	Yes, 15 fps (Pag. 5 Product Data)

Maximum matrix size in capture mode, Fluoroscopy	$\geq 1024 \times 1024$ pixel	Yes, 1024x1024 (Pag. 5 Product Data)
Fluoroscopy acquisition depth	≥ 16 bit	Yes, 16 bit (Pag. 5 Product Data)
7. Technical characteristics of collimator:		
Working regime	automatic and manual	Yes, Pag. 2 Product Data
Light source type	LED	Yes, G4 Instruction Manual,pag.446 (anexa 13)
Collimation type	Rectangular min. symmetrical left and right; option: iris/octagonal	Yes, ProductData,pag.2,pag4
Built-in filters	≥ 3 types	Yes, 0.1/0.2/0.3 mmCu (Pag. 4 Product Data)
Filter selection	Manual and automatic	Yes, ProductData,pag.2/G4 Instruction Manual,pag233)Anexa 15
8. Image characteristics:		
Display last image	yes	Yes, 5.2.2 L.I.H. (Last Image Hold) Function manual DR-300
Virtual collimation	yes	Yes, Pag.2 Product Data Virtual collimation
9. Technical characteristics of a radiologist's workplace		
Display and Workstation (acquisition/post-processing)	yes	
Quantity min. 2 monitors in control room	yes	Yes, 2 monitors Acquisition / Reference (pag 2 Product Data)

Min. 2 monitors in examination room	optional	Yes, optional on request
Monitor sizes	≥ 18 inch	Yes, 19 inch (pag 2 Product Data)
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
10. Technical characteristics of printer:		
Printer type	compact, desktop	Yes, Horizon G2 (Codonics/USA)
Printing technology	Printing technology direct thermographic or laser printing	Yes, Direct thermal

Film formats used	$\geq 20 \times 25 - 35 \times 43$ cm.	Yes, 8" x 10", 14" x 17", 11" x 14"
Spatial resolution, pixels/mm	≥ 12	Yes, 12,6
Simultaneously available formats	≥ 2	Yes, 2
11. X-ray		
Size scope	$\geq 15 \times 15 - 42 \times 42$ cm	Yes, 42 x 42 cm, 38 x 38 cm, 30 x 30 cm, 23 x 23 cm, 15 x 15 cm (Pag.5 Product Data)
Tinted images	\geq "four in one"	Yes, Multiple-image display (2 x 2 or 4 x 4) (pag. 6 Product Data)
Serial acquisition	yes	Yes, pag. 5 Product Data
Acquisition with contrast	optional	Yes, Real-time DSA, optional , pag. 5 Product Data
12. Digital tomosynthesis		
Automatic acquisition scheme for reconstruction	yes	Yes, (DR-300 ACQ , pag.255-259)Anex 17
Acquisition rate	≥ 15 fps	Yes, 15 (ProductData, pag.7)
Pre-tested programs with possibility of manual modification for different anatomical areas	≥ 5	Yes, (Preset EU,pag.12/G4 Instruction Manual,pag.331)Anexa 18/Anexa 19
Automatic reconstruction by acquisition station	yes	Yes, (G4 Instruction Manual, pag.303-307/DR-300 ACQ Pag260-264)Anexa 20/Anexa 21

Acquisition possible for any table tilt angle	yes	Yes, (ProductData,pag.7)
Reconstruction parameters:		
Layer thickness scope	$\geq 0.5\text{-}10\text{mm}$	Yes, 0.5 mm-30mm (DR-300 ACQ,pag.357Anexa 22)
Depth of acquisition in relation to patient's table	$\geq 0\text{-}20\text{cm}$	Yes, 0 – 25 cm(ProductData, pag.7)
Pre-set programs for different anatomical areas	≥ 5	Yes, 8 (Preset EU ,pag.12)Anex 23
Post reconstruction software that allows tomosynthesis reconstruction with different parameters without repeatedly irradiating the patient (including thickness and depth)	Availability	Yes, (DR-300 ACQ, pag.260-264)Anex 25
Post-processing, including image processing tools	Availability	Yes, (ProductData,pag.6/G4 Instruction Manual,pag.312)Anex 26
Reconstruction of oblique images to the vertical or horizontal axis	Availability	Yes, (T-SmartPro,ProductDat,pag.7)
13. X-ray scanning technology:		
Acquisition of slit type or longitudinal scanner	Availability	Yes, Slot radiography, ProductData,pag.7
Automatic acquisition scheme for CT radiography reconstruction	Option	Yes, Tomosynthesis

Automatic scan radiography reconstruction on acquisition station	Availability	Yes, (DR-300ACQ,pag.216/p6.2.4)Anex 27
Pre-set programs with the possibility of manual modification for different anatomical areas	≥ 3	Yes, (Preset EU, pag.68-77)Anex 28
Scanning area	$\geq 42\text{x}42\text{cm}$	Yes, 145x42 cm (ProductData,pag.7)
Scanning speed	$\geq 10\text{cm/sec}$	Yes, 12 cm/sec (ProductData,pag.7)
Acquisition rate	$\geq 3\text{fps}$	Yes, 3 fps (ProductData, pag.7)
Integrated DAP meter with display of results in patient database	yes	AK Air Kerma Rate DAP Cumulativ Referens Air Kerma Pacient Name ID (G4 Instruction Manual ,pag.242)Anex 29
14. Processing software		
Post processing	yes	Yes, pag. 6 Product Data
Zoom level control; Rotate/Reverse	yes	Yes, pag. 6 Product Data

Image annotations marker, text, lines, angle, missing	yes	Yes, pag. 6 Product Data
DICOM 3.0	yes	Yes, pag.2&6 Product Data
- DICOM Verification	yes	Yes, pag.2&6 Product Data
- DICOM Modality worklist	yes	Yes, pag.2&6 Product Data
- DICOM MPPS	yes	Yes, pag.2&6 Product Data
- DICOM Storage	yes	Yes, pag.2&6 Product Data
- DICOM Storage commitment	yes	Yes, pag.2&6 Product Data
- DICOM Grayscale print	yes	Yes, pag.2&6 Product Data
- DICOM Query / Retrieve	yes	Yes, pag.2&6 Product Data
- DICOM GSPS	yes	Yes, pag.2&6 Product Data
-Import and export of images from PACS	yes	Yes, pag.2&6 Product Data
Export of images to CD/DVD	yes	Yes, pag.6 Product Data
Export of examination results to HIS / RIS	yes	Yes
Tomosynthesis software	yes	Yes
X-ray scan software	yes	Yes
15. General conditions		
Leaded glass	minim 1x0,8 m	Yes, 1x0,8 m

Protective collar	2 sets	Yes
Protective apron	2 sets	Yes
Support on wheels for (Protective collar & apron) with at least 5 hangers	yes	Yes
User manual (s) that include technical operation & software compartment description	RO / RU	Yes, Ro/Ru included
Service manual	In English	Yes, included
All components of the system must be new (unused), year of production at least 2025	yes	Yes, 2025
License for the right to carry out activities involving use of ionizing radiation sources (provide copy of valid license)	yes	Yes, attached

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
15. For confirmation, the Participant must provide:		
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
CE Certificate of Conformity issued by a conformity assessment body included in the NANDO list - https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies	yes	Yes
EC Declaration of Conformity 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

ISO 13485/9001 - Quality Management System	yes	Yes
EN 60601-1 and/or EN 60601-2-44	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
Presence of service center on the territory of Moldova . 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

Warranty and post-warranty services must be performed by a certified engineer (provide a copy of the engineer's certificate)	yes	yes
The service warranty period must be at least 24 months 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
Related Services: Operation, maintenance and installation		
1. Installation of Digital X-ray unit 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
2. Operation and/or maintenance of Digital X-ray unit 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
3. Training of medical staff 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
4. Spare parts Equipment must be accompanied by an authorized list of accessories and spare parts.	yes	yes