Neusoft Medical Systems

STATEMENT OF COMPLIANCE

Project Name:	"Procurement of Computers Tomography , according to the requirements of IMPS from Republic of Moldova"					
Purchaser:	Public Institution The Office for the Management of External Assistance Programs (OMEAP)					
Identification number:	ocds-b3wdp1-MD-1667232545265/ 21066478					
CT 6 units, model NeuViz Prime						
Description	**Computer Tomograph is used to perform multisection X-ray diagnosis in hospitals.**					
Purpose of use	**Clinical purpose**	Computed tomography technology is the basis in patient care algorithms for various clinical indications. The applications of a multifunctional unit range from complex imaging of the manifestations of infections such as COVID-19 and tuberculosis to cardiovascular diseases, chronic lung diseases, trauma, complications of diabetes, the most common types of cancer and other pathologies.				
	Level of use (if relevant)	CT systems are mainly used in the imaging departments of district general hospitals and specialized hospitals.				
	Overview of functional requirements	The CT scanning system is used as a complete stand-alone solution for acquisition, review, display, storage (CT console and workstation) and image transfer in resource-constrained settings. It consists of: an X-ray system, a patient table, a gantry and a PC control. A high-voltage X-ray generator supplies power to the X-ray tube, which has a rotating anode and is able to withstand the high thermal loads generated during multi-detector acquisition. The gantry includes the x-ray generator, detector system, x-ray tube, collimators and rotating frame.				

Parameters		Minimum specification required	The proposed specifications	The reference document / brochure / page where the information provided can be verified by the evaluation committee
Multi-section feature	Number of slices generated/reconstructed	⩾128	128	file pdf „Data Sheet" p.2
	Physical number of rows per detector (slices)	⩾64	64	file pdf „Data Sheet" p.2
Detector	FOV - Field of view (standard), cm	⩾50	50	file pdf „Data Sheet" p.5
	Total detector width, z-axis, mm	⩾38	40	file pdf „Data Sheet" p.4
	Reconstructed image section with values in the range:	at least 0.625 mm up to 10 mm	0.3125 up to 10 cm	file pdf „Data Sheet" p.5 (*Slice Thickness)
	Standard rotation time, dry, 360 °, seconds	⩽ 0.4	0.259s(option included), 0.32s, 0.374s, 0.4s, 0.5s, 0.6s, 0.8s, 1.0s, 1.5s, 2.0s	file pdf „Data Sheet" p.2
Spatial resolution [mm] MTF (Modulated Transfer Functions)	0% MTF, lp / cm	⩾18	30 lp/cm@0% MTF	file pdf „Data Sheet" p.5 file pdf „Brochure" p.2
	50% MTF, lp / cm	⩾8	15 lp/cm@50% MTF	file pdf „Data Sheet" p.5
Contrast resolution	Contrast resolution indices	5 mm or less, (0.3)% CTDI⩽ 20 mGy.	4 mm 0.3% CTDI⩽ 20 mGy	file pdf „Data Sheet" p.6
	Inclination, °	± 30 (± 5)	±30	file pdf „Data Sheet" p.2
	Diameter, cm	⩾70	72	file pdf „Data Sheet" p.2

Gantry	Scan location		Laser	5 laser light localizers The accuracy of the external laser light localizer is ± 2mm. The accuracy of the internal laser light localizer is ± 2mm.	file pdf „Data Sheet" p.2
X-ray tube	Heat storage, MHU		⩾7	Unlimited (Effective anode heat content 30MHU)	file pdf „Data Sheet" p.3
	Thermal dissipation, kHU / min		⩾1000	1696	file pdf „Data Sheet" p.3
	Estimated tube life		⩾200,000 rotations or at least 18 months	24 month	
X-ray generator	kW output		⩾70	100	file pdf „Data Sheet" p.3
	kVp range		80 (±10) to 140 (±10)	60-140	file pdf „Data Sheet" p.3
	mA range		20 (±10) to 600 (±50)	10 to 833	file pdf „Data Sheet" p.3
	Range of motion	Vertical, cm	44 (±5) – 90 (±5)	43-97	file pdf „Data Sheet" p.3
		Longitudinal, cm	⩾170	177	file pdf „Data Sheet" p.3
	Scanning radius, cm		⩾170	175	file pdf „Data Sheet" p.5

Patient table	Patient weight, kg	⩾250	300 (option included)	file pdf „Data Sheet" p.3
	Hand support	optional	Yes	Included in the configuration
	Head support for coronary imaging	Yes	Yes	file pdf „Brochure" p.7
	Speed	≥ 170 mm/second	0,375-464 mm/s	file pdf „Data Sheet" p.3
	Automatic/semi-automatic patient isocentration	Yes	Yes, option Aye-positioning	Aye-positioning included in the configuration
Irradiation dose	Technical dose modulation	Yes	Yes	file pdf „Data Sheet" p.15 file pdf „Brochure" p.8
	Specific control of pediatric doses	optional	Yes, O-Dose technology	file pdf „Data Sheet" p.15
	Prospective ECG gating	Yes	Yes	file pdf „Data Sheet" p.9
	Retrospective ECG editing	Yes	Yes	file pdf „Data Sheet" p.9
	Iterative image reconstruction	Yes	Yes	file pdf „Data Sheet" p.9
Cardiac axial	Cardiac low dose (axial acquisition)	optional	Yes	file pdf „Data Sheet" p.9-10
	Arrhythmia correction	optional	Yes	file pdf „Data Sheet" p.9-10 file pdf „Brochure" p.3
Dose calculation and display	DAP	Yes	Yes	
	Display CT dose index (CTDI) – volumetric (CTDIvol) and weighted (CTDIw) – and dose-length product (DLP) and the ability to transfer this information to the exam sheet	Yes	Yes	All the Dose calculations can be transferred to the exam sheet
	Dose optimization tools should be available	Yes	Yes option O-Dose	option O-Dose is included in the configuration
Reconstruction of the image	Reconstitution of FOVs, cm	⩾ 50	50	file pdf „Data Sheet" p.5
	Image reconstruction with dimensions	512x512	512x512 768x768 1024x1024	file pdf „Data Sheet" p.5
	Maximum reconstruction rate, (512x512), frame / sec	⩾ 40	40	file pdf „Data Sheet" p.5

Software available on the operating station and on the post-processing station	Neuro CT package (digital subtraction neuro angiography [DSA] CT and neuro perfusion CT).	Yes	Yes	refers to Nerve System DSA file pdf „Data Sheet" p.10
	Vessel structure analysis package with 2-D and 3-D measurement, cerebral blood flow analysis (CT angio software).	Yes	Yes	refers to Vessel Analysis file pdf „Data Sheet" p.9
	Body infusion	Yes	Yes	refers to Body Perfusion file pdf „Data Sheet" p.11
	Cardiovascular CT package, with at least the following functions available: calculation of the density/quantity of calcium in the coronary arteries, functional/anatomical and morphological analysis of the cardiac system (coronary and left ventricle) and coronary plaque characterization software.	Yes	Yes	file pdf „Data Sheet" p.9
	The Complete Pulmonary Examination/Analysis Package.	Yes	Yes	file pdf „Data Sheet" p.12
	Virtual Bronchoscopy and Virtual Colonoscopy Packages.	Yes	Yes	file pdf „Data Sheet" p.13
	Automatic Bone Exclusion Package	Yes	Yes	file pdf „Data Sheet" p.9
	Pediatric protocols	Yes	Yes	O-dose file pdf „Data Sheet" p.15
	All software should be provided for the reporting procedure with export availability in DICOM, pdf, rtf format to allow transfer of tele-radiology images to electronic medical records, to other medical facilities or to other individuals as appropriate stipulated.	Yes	Yes	All the reports and formats are available
	It must be interconnected with existing HIS, RIS and PACS systems or be able to connect in the future at no additional cost	Yes	Yes	All the connections are available
	A two-way verbal/audio communication system must be provided between operator and patient	Yes	Yes	file pdf „Data Sheet" p.8

Integration system	Hardware	**Operating console with at least the following features:**			
		19" or larger LCD monitors	2	2 dual monitors, 24"	file pdf „Data Sheet" p.4
		with keyboard and mouse	Yes	Yes	
		Simultaneous scanning and reconstruction capability	Yes	Yes	
		Simultaneous routine scanning and analysis capability	Yes	Yes	
		Display matrix	no less than 1024 x 1024 pixels.	1920x1200 pixels	file pdf „Data Sheet" p.4
		storage	minimum 200,000 images	1 920 000 images	file pdf „Data Sheet" p.4
		RAM	> 4 Gb	144 GB	file pdf „Data Sheet" p.4
		RAW data reconstruction hardware:			
		RAM	4G or better	144 Gb	file pdf „Data Sheet" p.3
		storage	300 GB or better	7 TB	
		Dual monitor post-processing workstation with at least the following features:	Yes	yes	file pdf „Data Sheet" p.4
		LCD monitors of at least 21 inches	at least 2	2 dual monitors, 24", 1920x1200 px	file pdf „Data Sheet" p.4

		with keyboard and mouse	Yes	yes	file pdf „Data Sheet" p.4
		storage	⩾ 1 TB	1 TB	file pdf „Data Sheet" p.4
		Processor speed	>2.5GHz	3.3 GHz	file pdf „Data Sheet" p.4
		RAM	> 4GB	16 GB	file pdf „Data Sheet" p.4
	DICOM	The entire system must be compatible and connected to DICOM, including all workstations.	Yes	Yes	file pdf „Data Sheet" p.6
		Storage of SCU / SCP images	Yes	Yes	file pdf „Data Sheet" p.6
		Increased storage space CT SCU / SCP	Yes	Yes	file pdf „Data Sheet" p.6
		Worklist SCU modality	Yes	Yes	file pdf „Data Sheet" p.6
		Query/retrieve SCU and SCP	Yes	Yes	file pdf „Data Sheet" p.6
		Storage commitment SCU (Storage commitment SCU)	Yes	Yes	file pdf „Data Sheet" p.6
		Able to print, store, send/receive	Yes	Yes	file pdf „Data Sheet" p.6
Accessories and spare parts	Quality assurance phantoms, required for image quality verification and CT scanner calibration		Yes	Yes	
	Ghost support		Yes	Yes	
Electrical requirements	The power supply should be approximately 380V, 50 Hz, 90 kVA, connected to the three-phase power supply.		Yes	power 380/400VAC +- 10%; 50/60Hz+- 1Hz; 100kVA; three-phase.	Vol.1 pag 45, p. 3.1.2 file pdf „Data Sheet" p.16,
	Protection against overvoltage (overvoltage and overcurrent) under line conditions.		Yes	Yes	
Transport to the beneficiary's location			Yes	Yes	

Pre-installation requirements	Direct electrical connection of the equipment to the three-phase power supply network. The connection will be made directly to the network with a thermomagnetic switch.	Yes	Yes	
	Connect the equipment to the radiology DICOM network, when available. The contractor must review the fitting room to ensure compliance with the technical requirements before supplying the system.	Yes	Yes	
	Project sketch detailing all electrical, structural, air conditioning, data, medical gas, or any additional requirements to be performed on site by the beneficiary for the system installation.	Yes	Yes	
	Project management and communication with the user to verify the suitability of the designated area for system installation.	Yes	Yes	
	Technical visit, inspection and ensuring that all necessary conditions are met at the beneficiary's/user's site before starting any activity. Any comments or suggestions regarding room conditions should be made at least 6 weeks prior to commencement of installation activities.	Yes	Yes	
	Lead shielding of suitable or equivalent thickness for walls, doors, floors, ceilings and operator's barrier in accordance with (IAEA) ANSP and ANRANR requirements regarding radiation protection barriers	to be performed of beneficiary for system installation	Yes	
	Factory Acceptance Test (FAT): The system, prior to delivery, must be tested for compliance with the manufacturer's performance specifications and specified minimum requirements.	Yes	Yes	

Testing and acceptance	Perform: pre-commissioning installation, calibration, safety and operational checks		Yes	Yes	
	On-Site Acceptance Test (SAT): The system, after delivery, will be tested by the contractor together with the user to demonstrate that the performance meets the manufacturer's performance specifications and specified minimum requirements as determined by WHO, IAEA and users. The SAT results will be documented in a test and acceptance protocol that will be signed by the end user (after consultation with the hospital's physiotherapist (imaging doctor)) and the manufacturer.		Yes	Yes	
	The documented results of all system testing should be in an acceptance protocol.		Yes	Yes	
	Specific cleaning and disinfection instructions need to be included for IPC (Infection Prevention and Control)		Yes	Yes	
	User training for operation should include at least the following topics (a detailed training program must be provided):	Computed tomography technology;	Yes	Yes	
		Description of all settings, parameters;	Yes	Yes	
		Protocol optimization procedures on a patient-selective basis;	Yes	Yes	
		Dose considerations according to patient physiology, especially for pediatric patients;	Yes	Yes	
		Image quality and techniques to use for different clinical indications;	Yes	Yes	

		Steps on how to adapt to different noise textures;	Yes	Yes	
		CT dose amounts;	Yes	Yes	
		Diagnostic Reference Levels for Computed Tomography	Yes	Yes	
		Rebuild software and application	Yes	Yes	
	Training of specially designated technical personnel for basic maintenance (also provided in an online format, if available).		Yes	Yes	
	The training provided to the user will last no less than 40 hours. Training sessions will be organized for not less than four persons/staff. A further training stage is also required		Yes	Yes	
	Training of maintenance personnel will take no less than 30 hours. The training session will be organized for not less than four persons/staff. A further training stage is required.		Yes	Yes	
	Contact details of the manufacturer, supplier and lists of local service agents will be provided with the documentation.		Yes	Yes	
	The contractor must include full maintenance services during the warranty period (2 years). Full maintenance services during the warranty period should include:	Preventive maintenance	Yes	Yes	
		Emergency interventions in case of failure	Yes	Yes	
		Any system software updates/upgrades that become available;	Yes	Yes	
		All your spare parts needs	Yes	Yes	

Maintenance requirements	As part of the site acceptance, the contractor must provide the local engineer and medical physicist (imaging doctor) of the hospital with a preventive maintenance plan, including the name and contact details of a representative/service office for intervention in the event of a request defect rectification.		Yes	Yes	
	The intervention time must be clearly defined and must respect the time requirements regarding the operation of the device as a whole	The contractor must guarantee that the CT scanner will have an uptime of at least 95% (excluding outages for maintenance or external system causes).	Yes	Yes	
		The operating time is calculated based on 250 operating days per year (weekly working days).	Yes	Yes	
		If the downtime exceeds 2 working days cumulatively on a 6 month basis (ie totaling the hours) then the warranty and/or maintenance (as applicable) will be extended for an appropriate period.	Yes	Yes	

		The record of the tomograph downtimes will be kept by a representative of the beneficiaries/users; the contractor should have the right to request copies of these records.	Yes	Yes	
	The contractor will provide a suitably qualified person who can be on site within 48 hours of an unexpected breakdown to resolve any problem within 5 working days throughout the warranty period.		Yes	Yes	
Manufacturing details	The CT should be manufactured in 2022		Yes	Yes	
CERTIFICATION	CE certificate of conformity issued by a conformity assessment body included in the NANDO list - https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main		Yes	Yes	
	EC declaration of conformity issued on the basis of directive 93/42 EEC or Regulation 2017/745 which refers to the CE certificate of conformity by number or by the NOTIFY BODY code.		Yes	Yes	
	ISO 13485/9001 - Quality management system		Yes	Yes	
	Report from the technical documentation "ESSENTIAL REQUIREMENT"		Yes	Yes	
	EN 60601-1/ (IEC 60601-1) EN 60601-1/AC EN 60601-1/A1 (IEC 60601-1/A1)	Electronic devices. Part 1: General requirements for basic safety and essential performance	Yes	Yes	

Standards	**EN 60601-1-2 (IEC 60601-1-2)**	Electronic devices. Part 1-2: General basic security requirements and essential performance. Collateral standard: Electromagnetic disturbances. Requirements and trials	Yes	Yes	
	EN 60601-1-3/EN 60601-1-3/AC EN 60601-1-3/A11	Electronic devices. Part 1-3: General basic safety requirements and essential performance. Collateral standard: Radiation protection in X-ray diagnostic equipment (IEC 60601-1-3:2008)	Yes	Yes	
	EN 60601-1-6	Electronic devices. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Ability to use (IEC 60601-1-6:2010) This European standard does not necessarily cover the requirements introduced by 2007/47/EC.	Yes	Yes	

	EN 60601-2-44/A1	Electronic devices. Part 2-44: Particular requirements for basic safety and essential performance for X-ray machines for computed tomography (IEC 60601-2-44:2009) This European Standard does not necessarily cover the requirements introduced by 2007/47/EC.	Yes	Yes	
	EN 62304/AC	Software for medical devices. Software life cycle processes (IEC 62304:2006)	Yes	Yes	
	EN 62366	Medical devices. Applications of the use of technological engineering in medical devices (IEC 62366:2007 This European standard does not necessarily cover the	Yes	Yes	
	LABEL it is presented in the state language and in one of the languages of international circulation according to GD 702 " for the approval of the Regulation on the conditions for placing medical devices on the market" Section 7. "Information provided by the manufacturer", namely point 48.		Yes	Yes	

LABEL/USER MANUAL	**OPERATING INSTRUCTIONS/OPERATING MANUAL** - it is presented in the state language and in one of the languages of international circulation according to HG 702 "for the approval of the Regulation on the conditions for placing medical devices on the market" Section 7. "Information provided by the manufacturer", namely point 51. The bidder will present the manual/instructions for use in printed and electronic copies. The supplier must describe any materials contained in the device that are classified as hazardous according to local regulations.	Yes	Yes	

(authorized signature)