

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION Civic Drive, Filinvest City



Civic Drive, Filinvest City Alabang 1781 Muntinlupa City

TECHNICAL SPECIFICATIONS FOR SPIRAL/HELICAL (____ SLICE) CT SCAN UNIT

Scope

This includes the supply, delivery, installation and commissioning of CT scan.

Application/Use

Routine head/spine and body imaging procedures including contrast studies.

Standard Composition

- Scanner Gantry
- X-ray Generator and Tube
- Detection System
- Couch
- Operator Console
- Image Display Device
- Scan Parameters
- Image Collection and Processing
- Data/Image Storage, Management and Connectivity
- Accessories
- Power Requirements
- Other Requirements
- Other Terms and Conditions

Technical Specifications

Scanner	Scanner aperture	70 cm or bigger
		-25° to +25° or greater or other means
	Tilt	suitable to the tilting movement of the
		gantry in consideration.
Gantry	Laser positioning lights – planes	Transaxial, sagittal, coronal
	Controls	Located on either or both sides of the
		gantry
	Digital read-out	Couch and gantry positions/settings
X-ray Generator and Tube	Generator type	High frequency
	Anode heat capacity	□ 2 MHU
		☐ If higher please specify: MHU
	Maximum tube voltage	130 kV or higher

		□ 200 mA
	Maximum tube current	☐ If higher please specify: mA
waximum tube current	Witaximum tube current	with AEC System
	Focal spot	Single or dual
	Minimum slice thickness	≤ 1.0 mm
Detection	William shee thekness	
System	Detector type	Solid state array
Couch	Scannable horizontal range (Standard, without extension)	120 cm or longer
	Vertical travel	54 cm or higher
	Maximum weight allowed on couch	180 kg or heavier
	Couch top movement System	Motor driven and manual
	Input devices	Keyboard with integrated function keys and mouse
Operator Console	Operating panel/ Control desk	 Remote control of couch movement and gantry tilt Displays all scan parameters and CTDI and DLP values for each procedure. With programmable adult and pediatric scan protocols Allows selection of scan parameters Allows window width and window level adjustments With image processing/evaluation functions
	Recorded instruction system options	User customizable recording
	Operator-patient communication	Two-way communication system
	system	 Microphone and speakers
	Acquisition workstation	At least 1 unit medical grade LCD/LED- type monitors Diagonal dimension of image screen, 21"
Image Display		or bigger
Device	Review workstation (Optional)	At least 3 megapixel LCD/LED-type
		monitors
		Diagonal dimension of image screen, 21"
		or bigger
	Scan region	Whole body, including head
Scan Parameters	Maximum scan fields of view	≥ 50 cm
	Scan modes	Axial, spiral/helical, dynamic, volumetric, and other scanning modes (please specify)
	Minimum rotation time in	≤ 1 s (For cardiac application
	spiral/helical mode	recommended rotation time is $\leq 0.5 \text{ s}$
Image	Reconstruction matrix	≥ 512 x 512
Collection and		Display matrix: $\geq 1024 \times 1024$
Processing Processing	Image display	Window width: continuously variable
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		Window level: continuously variable
		Multiple image display
		Three-dimensional (3D) display of images
		Image retrieval: Display images can be
		changed from patient to patient or from one
		image to another image for the same
		patient using the keyboard or on-screen
		menus
		Scanned projection radiography
		processing:
		Anatomical scale
		Slice position setting
		Slice position display
		• Zoom out / zoom in
		CT image analysis:
		ROI setting and processing
		Measurement of distance and angle
		between two positions
		Histogram
		CT number display
		Volume calculation
	Image processing	Profile
		CT image processing:
		Continuously selectable image
		magnification
		Multi-frame display
		Addition/Subtraction of images
		Comment and annotation insertion
		Top/bottom, right/left, black/white
		reversal of image
		Image reconstruction
		algorithms/filtering
		Multiplanar
		reconstruction/reformatting
		Image stacking
		Image stacking Image annotation and labeling
		Image amotation and labeling Images are DICOM format ready
		for storage, retrieval, and
		compatible for teleradiology and
		networking system
		□ Film
Data/Image Storage, Management	Storage media	
		☐ Others, please specify:
and	Back-up storage media	□ CD/DVD □ Hard drive with storage conseity of 3 TP
Connectivity		☐ Hard drive with storage capacity of 3 TB
	Magnetic hard disk	Ability to burn images to disc

	Set of QC phantoms with water phantoms for adult head and body and	
	pediatric head	
	Adult and pediatric headrests and straps	
	Coronal headrests	
	Positioning pads and cushions	
	Headrest support	
	Wide and narrow body straps	
Accessories	Knee support	
	Elbow and shoulder level arm supports	
Accessories	Leg support accessory	
	Patient mat	
	Couch top extension/Cradle extender	
	Automatic injector for contrast media	
	□ single	
	□ dual (recommended for cardiac applications)	
	• 2 lead rubber aprons of at least 0.25 mm Pb equivalence	
	• At least 100 cm x 60 cm (39" x 24") lead glass of 1.5 mm Pb equivalence	
	Hard copy imaging device (for film and paper storage media)	
Power	3 phase, 220 VAC/380-460 VAC, 60 Hz as applicable to the power supply of	
	the end-user	
Requirements	Supplier to provide appropriate transformer when applicable	

		At least 2 unit split type, 2 hp, 220 VAC, 60
	Air-conditioning units	Hz for the CT scan room and 1 unit split
		type, 1 hp, 220 VAC, 60 Hz for the control
		room
	Automatic voltage	1 unit, appropriate with the power rating of
	regulator	the CT scanner and with a voltage regulation
		range of 150-300 V
	Grounding system	dedicated grounding system for the machine
		shall be provided by the bidder
		Surge protection system shall be provided by
Othor		the bidder (optional)
Other Requirements	Dehumidifier	1 unit, 60 Hz, 220 VAC
Requirements	UPS	1 unit for electrical ancillary equipment,
		with a battery run-time of ≥ 20 mins
		1 unit for the CT scan equipment (Optional)
	Emergency light	2 units for CT room and 1 unit for the
		control room
	Documents	Two sets of the following:
		 operation and instruction manuals
		 service and installation manuals
		 wiring and schematic diagrams
		 x-ray tube data specifications
		• parts list

Other Terms and Conditions

- Three (3) years warranty for parts and service after passing the acceptance testing of the Center for Device Regulation, Radiation Health, and Research (CDRRHR) of the Food and Drug Administration (FDA) Department of Health (DOH) as provided in the DOH AO No. 21, s. 1996 dated 4 June 1996.
- Must comply with the applicable requirements under the DOH Administrative Order (A.O.) No. 35, s. 1994.
- The transportation expenses and per diem of the CDRRHR-FDA Medical Physics Team shall be shouldered by the bidder.
- Bid offer is in Philippine peso to include taxes and duties; transportation to site, delivery, installation and testing expenses on site (hospital) by the bidder.
- Certification from the manufacturer
 - that the bidder has the capability for corrective and preventive maintenance of the unit.
 - that the bidder/supplier has the engineer/s trained and capable for corrective and preventive maintenance for the model bidded. Service engineer should be presently employed by the bidder/supplier or authorized by the manufacturer.
 - guaranteeing delivery of equipment and all accessories within the time period set by the Bids and Awards Committee (BAC).
 - guaranteeing the availability of all spare parts for the next ten (10) years duly authenticated by the Philippine Embassy in the country of origin.
 - that the equipment is a brand new unit and not a discontinued model.
 - that the terms and conditions stated in the contract shall be honored by the manufacturer in the event that a change of exclusive distributorship will occur during the duration of the said contract.
- Supplier's engineer shall perform preventive maintenance on the machine during the warranty period of at least quarterly.
- The bidder must provide certification type of training on the applications/operations, and basic maintenance for users and maintenance personnel of the hospital.
- Certificate of exclusive distributorship from the unit manufacturer mentioning the name of the Philippine representative.
- Certification from the bidder of 95% uptime guarantee for the equipment offered within the warranty period. Accumulated downtime in excess of 5% shall be added to the warranty period.
- The bidder must submit the original brochure with technical specifications in English language.
- The machine should conform to the International Electrotechnical Commission (IEC) standard or its equivalent national standard. The bidder must provide Certificate of Declaration of Conformity.
- Inventory of spare parts for the unit/model offered duly signed by the manufacturer.
- Certification from the Foreign Ministry of Health that the company can sell the product/model in that country of origin.
- The bidder shall specify post warranty comprehensive preventive maintenance costs including list and price of major spare parts for the next three years after warranty.

Note: This technical specifications replaces the previous technical specifications for computed tomography x-ray machine. This constitutes revisions done by CDRRHR technical working group which was approved on July 17, 2014.