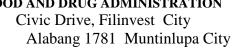


# Department of Health FOOD AND DRUG ADMINISTRATION

Republic of the Philippines





# **TECHNICAL SPECIFICATIONS FOR** CT SIMULATOR UNIT (at least 16 MULTISLICE)

### **Scope**

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

#### Application/Use

Radiotherapy patient simulation and treatment planning.

### **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
- External positioning lasers
- CT Simulation software
- Power Requirements
- Other Requirements
- Other Terms and Conditions

## **Technical Specifications**

Τ _		
Scanner aperture	80 cm or bigger	
Tilt	-30° to +30° or greater	
Laser positioning	Transaxial, sagittal, coronal with position accuracy of ± 1mm	
lights – planes	or better	
Controls	Located on either or both sides of the gantry	
Digital read-out	Couch and gantry positions/settings	
Generator type	High frequency	
Anode heat capacity	2 MHU or higher	
	☐If higher, please specify MHU	
Maximum tube	400 latter ber	
voltage	130 kV or higher	
Maximum tube current	□ 200 mA	
	☐ If higher, please specify mA	
	With AEC system	
Focal spot	Dual (high speed rotating anode)	
Detector type	Solid state array	
20.00.0. 1,70	·	
Material	Carbon fiber	
Dimension	Minimum of 235 cm by 40 cm	
Couch top movement	Motor driven and manual	
System		
Horizontal travel	Range: 170 cm or longer	
	Speed: Variable with maximum speed of at least 10 mm/s	
	Laser positioning lights – planes Controls Digital read-out Generator type Anode heat capacity  Maximum tube voltage  Maximum tube current  Focal spot Detector type  Material Dimension Couch top movement System	

		Connoble range: At least 150 cm or more		
		Scannable range: At least 150 cm or more		
	Montical travel	Reproducibility of movement: Better than ±0.25 mm		
	Vertical travel	Range: 55-95 cm when outside the gantry		
		Moving range within the gantry: 20 cm		
		Minimum height outside the gantry: 52 cm ±1cm		
	Maximum weight allowed on couch	180 kg or heavier		
	Table top	Flat with patient positioning index		
	Location of table top	Table side, control console and hand pendant		
	controls			
Operator	Input devices	Keyboard with integrated function keys and mouse		
Console	put uottioo	- Remote control of couch movement and gantry tilt		
		- Displays all scan parameters and CTDI and DLP values		
		for each procedure		
	Operating panel /	- With programmable adult and pediatric scan protocols		
	Control desk	- 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	At least 1 unit medical grade LCD/LED-type monitors		
Image display	workstation	Diagonal dimension of image screen, 21" or bigger		
device	Review workstation	At least 3 megapixel LCD/LED-type monitors		
device	(Optional)	Diagonal dimension of image screen, 21" or bigger		
	Image reconstruction	Diagonal differision of image screen, 21 of bigger		
	time	Less than 1.5 s for any mode		
	Scan region	Whole body, including head		
	Scan fields of view	At least 50 cm or more		
Scan	Extended field of	At least 50 cm of more		
parameters	view	Minimum of 70 cm		
purumoro. c	VIEW	Axial, spiral/helical, dynamic, volumetric, and other scanning		
	Scan modes	modes (please specify)		
	Minimum rotation	\(\frac{1}{2}\)		
	time in spiral/helical	≤ 0.5 s		
	mode			
	Slice thickness	User selectable, starting with 1mm or less		
Image	Reconstruction matrix	≥ 512 x 512		
Collection and	Image display	Display matrix: 1024 x 1024		
Processing		Window width: continuously variable		
		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		
	Image processing	Scanned projection radiography processing:		
		Anatomical scale		
		Slice position setting		
		Chec position detailing		
		Slice position display		
		<ul><li>Slice position display</li><li>Zoom out / zoom in</li></ul>		
		Slice position display     Zoom out / zoom in  CT image analysis:		
		Slice position display     Zoom out / zoom in  CT image analysis:     ROI setting and processing		
		Slice position display     Zoom out / zoom in  CT image analysis:     ROI setting and processing     Measurement of distance and angle between two		
		Slice position display     Zoom out / zoom in  CT image analysis:     ROI setting and processing     Measurement of distance and angle between two positions		
		Slice position display     Zoom out / zoom in  CT image analysis:     ROI setting and processing     Measurement of distance and angle between two positions     Histogram		
		<ul> <li>Slice position display</li> <li>Zoom out / zoom in</li> <li>CT image analysis:         <ul> <li>ROI setting and processing</li> <li>Measurement of distance and angle between two positions</li> <li>Histogram</li> <li>CT number display</li> </ul> </li> </ul>		
		Slice position display     Zoom out / zoom in  CT image analysis:     ROI setting and processing     Measurement of distance and angle between two positions     Histogram		

		<ul> <li>CT image processing: <ul> <li>Continuously selectable image magnification</li> <li>Multi-frame display</li> <li>Addition/Subtraction of images</li> <li>Comment and annotation insertion</li> <li>Top/bottom, right/left, black/white reversal of image</li> <li>Image reconstruction algorithms/filtering</li> <li>Multiplanar reconstruction/reformatting</li> <li>Image stacking</li> <li>Image annotation and labeling</li> <li>Images are DICOM format ready for storage, retrieval, and compatible for teleradiology and networking system</li> </ul> </li> </ul>
Data/Image		□ Film
Storage,	Storage media	□ CD/DVD
Management	Giorago modia	□ Others, please specify:
and	Back-up storage	□ CD/DVD
Connectivity	media	
Connectivity		□ Hard drive with storage capacity of 3 TB
Accessories	<ul> <li>QC phantom(s) to test low contrast, high contrast, CT number calibration, Uniformity, Slice thickness, and Scan localization accuracy</li> <li>Electron density phantom</li> <li>Couch and laser alignment test tool</li> <li>Immobilization and positioning devices         <ul> <li>Headrests</li> <li>Positioning pads and cushions</li> <li>Straps (head, body, shoulders, knees, and legs)</li> <li>Support (head, shoulders, knees, and legs)</li> <li>Boards (Belly, Wing, Breast, etc.) (Optional)</li> </ul> </li> <li>Couch top extension/Cradle extender (Optional)</li> <li>Automatic injector for contrast media (Optional)</li> <li>2 lead rubber apron of at least 0.25 mm Pb equivalence</li> <li>at least 100 cm x 60 cm (39" x 24") lead glass of 1.5 mm Pb equivalence</li> <li>Hard copy imaging device (for film and paper storage media) (Optional)</li> <li>External laser (advantageous if supplied/installed with the CT scan unit to ensure compatibility)</li> <li>Simulation software (advantageous if supplied and installed by the authorized CT scan and TPS unit supplier to ensure compatibility)</li> </ul>	
	-	-460 VAC, 60 Hz as applicable to the power supply of the end-
Requirements	user	
Other Requirements	Air-conditioning units  Automatic voltage regulator  Grounding system  Dehumidifier  UPS  Emergency light	At least 2 units split type, 2 hp, 220 VAC, 60 Hz for the CT scan room and 1 unit split type, 1 hp, 220 VAC, 60 Hz for the control room  1 unit, appropriate with the power rating of the CT scanner and with a voltage regulation range of 150-300 V  dedicated grounding system for the machine shall be provided by the bidder  1 unit, 60 Hz, 220 VAC  1 unit for electrical ancillary equipment, with a battery run-time of ≥ 20 min  2 units for CT room and 1 unit for the control room  Two sets of the following:  • operation and instruction manuals  • service and installation manuals  • wiring and schematic diagrams
		x-ray tube data specifications     parts list

#### Additional specification/requirement for upgrading diagnostic CT scanner to CT simulator:

CT simulator external laser	1 set	
Table top	-Flat with patient positioning index - Material: carbon fiber - Dimension: Minimum of 235 cm by 40 cm	
CT Simulation software	Must be compatible with the CT Scan and Treatment Planning System	
Immobilization and positioning device	-Boards (Belly, Wing, Breast, etc.)	
QC phantom(s)	- to test low contrast, high contrast, CT number calibration, Uniformity, Slice thickness, and Scan localization accuracy (If not yet available)	
Electron density phantom		

#### **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 CT Simulator unit. This constitutes revisions done by CDRRHR technical working group which was approved on September 29, 2014.