

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION Civia Driva Filippost City



Civic Drive, Filinvest City Alabang 1781 Muntinlupa City

TECHNICAL SPECIFICATIONS FOR STATIONARY RADIOGRAPHIC X-RAY SYSTEM

Scope

This includes the supply, delivery, installation and commissioning of general radiography x-ray system.

Application/Use

Radiographic procedures

Standard Composition

- X-ray Generator and Tube
- X-ray Tube Support Assembly
- X-ray Table
- Vertical Image Receptor Stand
- Control Console
- Automatic Exposure Control (AEC) Device (Optional)
- Image Receptor
- Image Display Device
- Accessories
- Power Requirements
- Other Requirements
- Other Terms and Conditions

Technical Specifications

X-ray Generator and Tube	Generator	High frequency inverter system
	Generator settings	Kilovoltage: Minimum Setting: 40 kV Maximum Setting: ≥ 125 kV Maximum tube current: □ 100 mA □ If higher please specify: mA
	Anode	Rotating
	Nominal focal spot	Small focus: ≤ 0.8 mm
	size	Large focus: > 0.8 but ≤ 1.5 mm
	Total filtration	≥ 2.5 mm Al equivalent
	Permanent filtration	≥ 1.5 mm Al equivalent
	Collimation system	□ Automatically controlled collimator
		□ Manually controlled collimator
		With field lamp and automatic shut-off timer
		With crosshair centering and pre-indication of field sizes at certain source to image distance

	I	= Floor
	Mounting	□ Floor
		□ Ceiling
		□ X-ray table
		□ Floor to Ceiling
X-ray Tube		□ Floor to Wall
Support	Locking mechanism	Electromagnetic/manual
Assembly	Tube arm movement	□ Lateral
		□ Horizontal
		□ Vertical
	Swiveling out tube	At least ± 90°
	assembly (Optional)	
	Tube angulations	At least ± 90°
	Stationary	□ Basic
		□ 4 or 6-way floating
	Grid	Reciprocating
		Ratio:
		□ 12:1
		□ 10:1
X-ray Table		□ 8:1
		Grid frequency: At least 70 lines/inch (27 lines/cm)
		Focal distance: At least 35 inches (90 cm)
		□ Image receptor holder for cross-table exposure
	Accessories	Immobilizing devices:
	(Optional)	□ Head clamp
		□ Abdominal/head straps
	Grid	Reciprocating
		□ Parallel
		□ Focused
		Focal distance: At least 40 inches (100 cm)
Vertical Image		Ratio:
Receptor Stand		□ 12:1
riocopior Giarra		□ 10:1
		□ 8:1
		Grid frequency: At least 70 lines/inch (27 lines/cm)
	Movement	□ Vertical
		□ Tilting
	Overload protection	Visual/audible
	indicator	177 16 (1) 0
	Technique selector	□ Kilovoltage (kV)
		□ Milliamperage (mA)
		☐ Time (sec or msec and/or pulse) / milliampere
		second (mAs)
Comtral		□ Anatomical programming function
Control	Display	□ Kilovoltage (kV)
Console		□ Milliamperage (mA)
		☐ Time (sec or msec and/or pulse) / milliampere
		second (mAs)
		□ Anatomical programming function
	Exposure switch	Dead-man type hand switch with cable (at least 2 m)
		and/or console push button
	Ready and x-ray	Audible and/or visible
Automotic	exposure indicator	_ Toble
Automatic	Location	□ Table
Exposure		□ Vertical Image Receptor Stand

Control (AEC)		
Control (AEC) Device (Optional)	Exposure steps	At least 5 exposure steps
Image Receptor	Туре	 □ Film- Screen □ Photostimulable Phosphor (for Computed Radiography System) □ Direct Digital Radiography □ Flat panel detector □ Charge-coupled device (CCD)
Image Display Device	Туре	□ Film viewer □ Monitor
	Film viewer	Number of banks: Size: 14" x 17" each bank Luminance: 1500 cd/m ² With film clips
	Monitor	At least 1 unit medical grade LCD/LED type monitors
Accessories	Radiation protection device Viewing window Others	1 lead rubber apron of at least 0.25 mm Pb equivalence 1 lead rubber thyroid shield of at least 0.25 mm Pb equivalence 1 pair of lead rubber gloves of at least 0.25 mm Pb equivalence 1 set of lead rubber gonadal shields with minimum of 0.5 mm Pb equivalence • contact shields for male adult, female adult, infant male and infant female • upright gonadal shield for chest x-ray examinations At least 21 cm x 26 cm (8" x 10") with 1.5 mm Pb equivalence 1 pc measuring caliper, sliding, double sided, scaled in cm, with blunt edges and parallel arm Hanger/s for lead apron/s
Power Requirements	1 phase/3 phase, 220-240VAC, 60Hz as applicable to the power supply of the end-user Supplier to provide appropriate transformer when applicable	
Other Requirements	Air-conditioning units	At least 2.0 hp, 220 VAC, 60 Hz 1 unit, appropriate with the power rating of the x-ray machine and with a voltage regulation range of 150-300 V
	Grounding system	dedicated grounding system for the machine shall be provided by the bidder
	Documents	Two sets of the following:

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 stationary radiographic x-ray system. This constitutes revisions done by CDRRHR technical working group which was approved on June 16, 2014.