



Republic of the Philippines
 Department of Health
FOOD AND DRUG ADMINISTRATION
 Civic Drive, Filinvest City
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TECHNICAL SPECIFICATIONS FOR MOBILE RADIOGRAPHIC X-RAY MACHINE

Scope

This includes the supply, delivery, installation and commissioning of mobile x-ray machine.

Application/Use

General radiography

Standard Composition

- General Specifications
- High Tension Generator
- X-ray Tube Assembly
- Control Unit
- Accessories
- Other Requirements
- Other Terms and Conditions

Technical Specifications

General Specifications of the Unit	Maneuverable	
	Complete with handrails and positive foot or hand operated breaks	
	Electrically grounded	
	<input type="checkbox"/> Motorized and manually driven <input type="checkbox"/> Manually driven	
	Maximum height of 2 meters at transport position	
	Ground to focus distance	At least 2 meters
High Tension Generator	Generator	High frequency
	Generator settings	Kilovoltage Setting: Minimum Setting: 40 kV Maximum Setting: ≥ 125 kV
		Maximum tube current: <input type="checkbox"/> 100 mA <input type="checkbox"/> If higher please specify: _____ mA
X-ray Tube Assembly	Anode	Rotating
	Nominal focal spot size	Small focus: ≤ 0.8 mm Large focus: > 0.8 but ≤ 1.5 mm
	Total filtration	≥ 2.5 mm Al equivalent
	Collimation system	Multi-leaf
		Manually controlled

		With field lamp and cross-hair centering Rotation: minimum of $\pm 45^\circ$
	Tube head rotation	Lateral axis: <input type="checkbox"/> 0 - 90° <input type="checkbox"/> Not applicable (for units with swiveling out tube support assembly) Longitudinal axis: minimum of $\pm 90^\circ$
	Tube arm movement	<input type="checkbox"/> Lateral <input type="checkbox"/> Horizontal <input type="checkbox"/> Vertical
	Locking mechanism	Electromagnetic/manual
Control Unit	Overload protection indicator	Visual/audible
	Technique selector	<input type="checkbox"/> Kilovoltage (kV) <input type="checkbox"/> Milliampere (mA) <input type="checkbox"/> Time (sec or msec and/or pulse) / milliampere second (mAs)
	Display	<input type="checkbox"/> Kilovoltage (kV) <input type="checkbox"/> Milliampere (mA) <input type="checkbox"/> Time (sec or msec and/or pulse) / milliampere second (mAs)
	Exposure switch	Dead-man type hand switch with cable (at least 2 m) and push button
	Ready and x-ray exposure indicator	Audible and/or visible
	Indicators for motor driven units	Unit is fully charged Unit is being charged Unit needs to be charged
	Shielded storage compartment	At least five (5) 14" x 17" cassettes with exposed and unexposed films divider
Accessories	Radiation Protection Device	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 <ul style="list-style-type: none"> • contact shields for male adult, female adult, infant male and infant female 		
Others	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 , 220 VAC, 60Hz as applicable to the power supply of the end-user	
Other Requirements	Grounding system	dedicated grounding system for the machine shall be provided by the bidder
	Documents	Two sets of the following: <ul style="list-style-type: none"> • 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 bid. 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 mobile x-ray machine. This constitutes revisions done by CDRRHR technical working group which was approved on June 16, 2014.