

Technical Specifications

Note: Bidders must state in the Statement of Compliance either “*Comply*” or “*Not Comply*” against each of the individual parameters of each Specification stating the corresponding performance parameter of the equipment offered. Statements of “Comply” or “Not Comply” must be supported by evidence in a Bidders Bid and cross-referenced to that evidence. Unless otherwise categorically stated hereunder, evidence shall be in the form of manufacturer’s un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate. A statement that is not supported by evidence or is subsequently found to be contradicted by the evidence presented will render the Bid under evaluation liable for rejection. A statement either in the Bidders statement of compliance or the supporting evidence that is found to be false either during Bid evaluation, post-qualification or the execution of the Contract may be regarded as fraudulent.

A. General Specifications

No.	General Specifications	Statement of Compliance
1	Supply, Delivery, Testing and Commissioning of Brand New One (1) Unit Two (2) Dimension Echocardiology System (2D Echo)	

Detailed Technical Specifications

ITEM NO.	ITEM	SPECIFICATIONS	STATEMENT OF COMPLIANCE
1	Supply, Delivery, Testing and Commissioning of Brand New One (1) Unit Two (2) Dimension Echocardiology System (2D Echo)	1. Physical Characteristics:	
		a. At least 15 inch monitor that can be tilted up to -10 degrees and +65 degrees and can be rotated at least -90 and +90 degrees	
		b. With keyboard for easy patient data annotation and report entries	
		c. With trackball for first and easy control of equipment functions	
		d. With built-in image printer and built-in digital image archiving	
		e. With built-in DVD writer and USB port	
		f. Mounted on a cart with 4 anti-static wheels with brakes	
		2. Power Supply	
		220V, 60Hz with at least 2 KVA Uninterruptible Power Supply (UPS) that can provide back-up power of up to 30 minutes	
		3. Technical Characteristics	
		1. Display channel	
		Electrocardiogram (ECG) amplifier and display in addition to at least one other physiological amplifier display	
		2. Adequate resolution	
		a. Adult	
		Axial less than 0.5mm at all depths and less than 2mm in focal zones	
		Slice thickness of less than 8mm at all depths	
		b. Pediatric	
		Axial less than 0.3mm, lateral less than 3mm at all depths and less than 1mm in focal zone	

		Slice thickness of less than 8mm at all relevant depths	
		3. Multiple image display	
		Capable of displaying at least two images in same mode simultaneously	
		4. Multi-mode Display	
		Simultaneous display of B, M spectral, CD and power Doppler modes	
		B) Functions	
		1. Brightness (B) mode with tissue harmonic imaging	
		2. Focal level/Focal depth adjustment	
		3. Adjustment of frequency range on all transducers	
		4. Capability to select at least three transducers without physical removal and reconnection	
		5. Gain and Time Gain Compensation (TGC) control	
		6. Operator-controlled multiple and adjustable focal zones	
		7. Provision for scanning pre-sets	
		8. Measurement of linear and curved distances, areas and volumes	
		9. Look-up tables to link measurements to relevant clinical applications	
		10. Cine-loop capability	
		11. Automatic and manual calculation of waveform indices	
		12. Capability of operator application presets	
		13. Magnification using both read and write zoom	

		14. Freeze and replay capabilities	
		15. Capability of displaying at least 5 measurements simultaneously	
		16. Patient identification and entry of other relevant clinical information	
		17. Capability of displaying, Patient name, Institution Name, Transducer type, date, time, frame rate/resistance, Thermal Index (TI) and Mechanical Index (MI)	
		C) Modes	
		1. 2 Dimension (2D), Motion (M) mode	
		2. Anatomical M mode	
		3. Continuous Wave (CW) Doppler	
		4. Pulsed-Waved (PW) Doppler	
		5. Color Doppler	
		D) Spectral Doppler: Range gate accuracy of less than 1mm	
		E) Color Doppler: Adjustable thump filter	
		F) Microbubble Imaging: Suitable scanning mode capability	
		G) Adequate penetration: At least 15 cm of normal tissue	
		H) Transducers (<i>The transducers must have been steering capability</i>)	
		1. Adult Echo Transducer	
		2. Pediatric Echo Transducer	
		3. Curved array probe for fetal echocardiography	
		4. Adult trans-esophageal probe	

		5. Neonatal transthoracic probe	
		Note: The bidder must declare all transducer frequency ranges and applications in the bid specifications.	
		I) Software and applications for trans-esophageal and echocardiography (including Doppler) and other cardiac function analysis applications (such as lumen border measurement and analysis, mitral valve analysis, etc.) must be installed.	
		J) The equipment must be compliant with Digital Imaging and Communications in Medicine (DICOM) 3 and must be compatible with color inkjet printers.	
		K) Accessories	
		1. Thermal printer	
		2. DVD burner	
		L) Non-removable embossed DOH - EAMC letters on the visible part of the equipment.	
		Documentary Requirements	
		1. Certificate of availability of stocks and can deliver within the prescribed delivery schedule.	
		2. Product brochure or technical sheet(s) of the equipment showing the technical specifications in English language.	
		3. Valid and current Certificate of Compliance of manufacturer of the equipment with the latest version of ISO 13485: Quality Management System - Requirements for regulatory purposes in the name of the manufacturer . The Certificates must be issued by an independent Certifying Body/Agency.	
		4. Valid Marketig Authorization, Registration Approval or Free Sale certificate for the equipment issued by the Health Authority in the country of origin.	
		5. Valid Certificate of Distributorship (as first Tier Distributor) issued by the Manufacturer of the equipment authorizing the bidder to sell/distribute the offered equipment.	
		6. List and address of the equipment manufacturer's branch office, sales office and/or distributor's office in any of the following:	
		a) Western Europe;	

		b) USA or Canada and:	
		c) Japan	
		7. Proof (such as sales invoice) that the Brand of the equipment has been sold to other health facilities in the Philippines.	
		8. Notarized Certificate from the bidder:	
		a) That the brand of the equipment has been in the local and/or international market for at least ten (10) years.	
		b) That the equipment and its accessories are brand new, unused, not discontinued models and were not subjected to any product recall.	
		c) Bidder's valid and current License to Operate (LTO) as a medical device distributor issued by the Philippine Food and Drug Administration. In case of expired LTO, the following must be submitted:	
		Copy of expired LTO	
		Application for renewal	
		Official Receipt as proof of payment for the renewal of LTO	
		Requirements if awarded the Contract	
		1. Delivery and Completion Schedule: Ten (10) working days with no extension upon receipt of approved NOA and NTP. Failure to comply with the delivery schedule shall mean forfeiture of the contract.	
		2. Testing: Prior to acceptance, the COVID Task Force, End user, HBAC shall conduct a physical inspection and functionality test. The equipment must be functioning and must have no physical damage and defect.	
		3. Training: The supplier shall provide a training on the proper use and maintenance of the equipment to the end-users and to the hospital maintenance staff. The training must consist of familiarization of the equipment controls, displays, functions, settings, etc. Specialized applications training for Doppler and 2D echo and other cardiac capabilities of the ultrasound machine.	
		4. Warranty: Warranty certificate for One (1) year on PARTS and on SERVICES . The supplier shall either repair or replace any item or part in the	

		equipment that is found to be defective in material or in workmanship under normal use. The warranty period shall commence from the date of acceptance by the end-user after testing and commissioning.	
		5. Notarized undertaking that the supplier shall conduct the necessary corrective maintenance within five (5) calendar days upon notification of the equipment breakdown from the end-user. The undertaking shall include a statement that the number of days where the equipment is unusable due to defective material or workmanship, shall be added to the warranty period.	
		6. Manuals: The supplier must provide Manual in English Language (2 hard copies and 1 soft copy of Operator's/User's Manual and 2 hard copies and 1 soft copy of Service/Technical and Maintenance Manual) upon delivery	

<i>Conforme:</i>
<i>Company/Bidder's Name:</i>
<i>Name and Signature of Authorized Representative:</i>
<i>Date:</i>