



GENERIC SPECIFICATION

Cart-based Digital Echocardiogram System

1. SCOPE

- 1.1. This specification describes the requirements for a Cart-based Digital Echocardiogram System (hereinafter referred to as the “System”). The System will be used for cardiac imaging. It shall include 1) curvilinear probe and 2) linear probe designed to serve a wide range of cardiac applications with imaging for radiology and vascular applications.
- 1.2. The system shall be installed and used at the Institut des Radio-Isotopes (IRI), in Niamey, Niger (hereinafter referred as “the End-User”). The System is required in support of the Counterpart under the IAEA Technical Cooperation (TC) programme.

2. DEFINITIONS, ACRONYMS, AND ABBREVIATIONS

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

- (a) B-mode ultrasound = Brightness-mode
- (b) dB = Decibels
- (c) PW = Pulsed wave
- (d) M-mode = Motion mode
- (e) US = Ultrasound
- (f) 2D = Two dimensional
- (g) HD = high definition
- (h) SCW = Steerable Continuous Wave
- (i) DICOM = Digital Imaging and Communications in Medicine
- (j) HDMI = High-Definition Multimedia Interface
- (k) USB = Universal Serial Bus
- (l) MHz = Megahertz
- (m) GB = gigabytes
- (n) ISO = International Organisation for Standardization
- (o) PC = Personal Computer
- (p) DVD+RW = Digital Versatile Disk Rewritable
- (q) Wi-Fi = Wireless network
- (r) Site = the hospital department at the End-User
- (s) Counterpart = the organisation assigned by the receiving government to act on their behalf for this project. Counterpart and End-User may be the same organisation, or different (such as, Ministry of Health and Hospital)

3. REQUIREMENTS

- 3.1. The System shall meet the following functional requirements:
 - 3.1.1. System designed and built to perform shared service ultrasound machine system for general imaging.
- 3.2. The System shall meet the following performance requirements:
 - 3.2.1. Provide adequate image quality support for several applications.
 - 3.2.2. Provide adequate 2D & doppler image quality.



- 3.2.3. Allow and have the capabilities for precision fine needle guidance. Therefore, it shall have needle recognition.
- 3.2.4. Provide the following imaging modes general applications/exams including:
 - (a) Echocardiogram
 - (b) Vascular scanning
 - (c) Interventional Radiology including biopsy system
- 3.2.5. Capable of 2D, 3D and doppler imaging;
- 3.2.6. Provide excellent ergonomics and workflow;
- 3.2.7. Capable of providing the following imaging modes or equivalent:
 - (a) 2D, M mode
 - (b) M-colour Flow Mode
 - (c) Anatomical M-mode
 - (d) Trapezoidal Mode
 - (e) Colour doppler
 - (f) Power angio doppler
 - (g) Pulse Wave Doppler
 - (h) Bi-directional power (HD FLOW)
 - (i) SCW doppler
 - (j) Freehand 3D
 - (k) Spatial-Temporal Image Correlation
 - (l) Panoramic Imaging

3.3. Technical Requirements

The System shall meet the following technical requirements:

- 3.3.1. Monitor minimum of 21.5" with image resolution of minimum full HD resolution 1024 x 768 pixels with touch screen and tilt/rotate capabilities.
- 3.3.2. Minimum of four (4) active transducer ports: (1) DICOM, (1) Ethernet port, (1) HDMI port and (1) USB port.
- 3.3.3. Minimum of two (2) probes to provide support for cardiac imaging:
 - 3.3.3.1. Curvilinear probe for cardiology use, ranging from minimum 2.0 – 5.0 MHz;
 - 3.3.3.2. Linear probe with biopsy, ranging from minimum 4.0 – 12.0 MHz.
 - 3.3.3.3. Additional transducer types can be provided as options.
- 3.3.4. Quantification set and related software for processing images from depth of 1 cm to 30 cm.
- 3.3.5. Distributed multi-core processing architecture.
- 3.3.6. Exam Pre-sets: Shall be able to store at least user specific Image pre-sets.
- 3.3.7. PC – based operating principles. Minimum 500 GB storage capacity;
- 3.3.8. DVD+RW drive.
- 3.3.9. Wi-Fi DICOM enabled.



3.3.10. Voltage: 100V-240V, Frequency 50/60 Hz.

4. MARKING

The System shall have all safety markings in English language.

5. PACKING

The System, for the shipment by air to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

6. QUALITY REQUIREMENTS

6.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.

6.2. The Contractor shall document the compliance with this quality assurance system.

7. TESTING AND ACCEPTANCE

7.1. The System, prior to shipment, may be tested at the request of the IAEA by designated agents for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.

7.2. The System, after installation, shall be tested by the Contractor together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-User.

7.3. The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the End-User.

8. INSTALLATION AND TRAINING

8.1. The Contractor shall install the System at the End-User's facility.

8.2. The Contractor shall provide onsite a three (3)-day applications training for up to five (5) staff of the End-User in the operation and maintenance of the System as well as in the safe operation procedures at the End-User's location immediately after the installation of the System. At the end of the training, the Contractor shall issue a personal training certificate with the description of the topics covered to each trained staff. A pre-recorded video training course shall also be included in the package.

9. DELIVERABLE DATA ITEMS

The Contractor shall provide four (4) complete sets of operation and servicing manuals, safe operating guidelines, and technical drawings in the English or French language.

10. MAINTENANCE AND SPARE PARTS

10.1. Maintenance

The Supplier shall also provide full maintenance services for one (1) year during the warranty period, for the proper functioning of the System. Full maintenance services during the warranty period shall include:



- 10.1.1. preventive maintenance;
- 10.1.2. on-call interventions;
- 10.1.3. any safety, software and hardware update and upgrade for the System that will become available;
- 10.1.4. all necessary replacement and spare parts;

10.2. Support Plan

- 10.2.1. As part of the on-site acceptance, the Supplier shall provide to the hospital medical physicist a plan for preventive maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.
- 10.2.2. During the warranty period, the Supplier shall ensure that a suitable qualified person shall be onsite within forty-eight (48) hours following an unexpected breakdown and shall solve the problem within the next twenty-four (24) hours.

11. Warranty

- 11.1. The System shall be covered by one (1) year warranty including parts and labour, starting as of the date of successful on-site acceptance, as per Testing and Acceptance above.
 - 11.2. Warranty shall include all necessary spare parts, shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades, and updates).
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