SPECIFICATION

1. Scope

   This specification describes the requirement for a Portable Ultrasound Machine (USm) (hereinafter referred to as the “System”), to be installed at the Nuclear Medicine Department of the Clinical Centre of Serbia in Belgrade, Serbia (hereinafter referred to as the “End-User”).

   The System shall be used for routine clinical activities in the Nuclear Medicine department, imaging mainly small organs such as the thyroid gland.

2. Definitions, Acronyms, and Abbreviations

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

   USm: Ultrasound machine.

3. Requirements

   3.1. Functional and Performance Requirements

   The System shall meet the following functional and performance requirements:

   3.1.1. Be portable and simple to use;
   3.1.2. Allow to be used for standard imaging of different body parts such the neck (thyroid gland imaging), abdomen (to image the gallbladder) and patients’ back/flank to image the kidneys;
   3.1.3. Have adequate transducers for proper imaging of these areas;
   3.1.4. Allow and have the capabilities for precision fine needle guidance to small organs such as the thyroid gland. Therefore, shall have needle recognition.
   3.1.5. Have excellent connectivity facilitate the transfer of images to different media such as paper, or the PACS system currently available at the hosting institute;
   3.1.6. Have colour.

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. Factory Acceptance Test (FAT)

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.

7.2. Site Acceptance Test (SAT)

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.

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

The Contractor shall install the System at the at the End-User location.

The Contractor shall provide two (2) days training for up to three (3) staff of the End-User in the operation and maintenance of the System at the End-User's location immediately after the installation of the System.

9. Deliverable Data Items

The Contractor shall provide two (2) complete sets of operation and servicing manuals and technical drawings in the English language (and if possible in Serbian language).

10. Guarantee.

At the End-User request, the Contractor shall provide up to five (5) additional years of different plans for extension of the guarantee, following the initial one (1) year full warranty. The End-User shall be responsible for the costs associated with such additional years of guarantee services.