



## SPECIFICATION

### Micro SPECT-CT Preclinical Imaging Modular System

#### 1. Scope

This Specification describes the requirements for a micro-CT & micro-SPECT imaging modular systems for molecular preclinical imaging of small animals such as mice. These scanners can work both as stand-alone and/or modular combinations allowing the obtaining of preclinical images in vivo.

#### 2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

2.1 IEC 61010-2-091

#### 3. Definitions, Acronyms, and Abbreviations

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

- 3.1 AC: Alternating Current.
- 3.2 CMOS: Complementary Metal Oxide Semiconductor.
- 3.3 CT: Computed Tomography.
- 3.4 D: Depth.
- 3.5 DICOM: Digital Imaging and Communication in Medicine.
- 3.6 ECG: Electrocardiogram.
- 3.7 FDK: Feldkamp-Davis-Kress algorithm.
- 3.8 FOV: Field of View.
- 3.9 GPU: Graphics Processing Unit.
- 3.10 H: Height.
- 3.11 HVAC: Heating, Ventilation, and Air Conditioning.
- 3.12 MLEM: Maximum-likelihood expectation-maximization.
- 3.13 OSEM: Ordered Subsets – expectation maximization.
- 3.14 SiPM: Silicon Photomultiplier.
- 3.15 SPECT: Single-photon Emission Computed Tomography; and
- 3.16 W: Width.

#### 4. Requirements

##### 4.1. Functional and Performance Requirements

The micro-CT shall meet the following functional and performance requirements:

- 4.1.1. Scanner bore of 86 mm.
- 4.1.2. Axial FOV of 37 mm.
- 4.1.3. Transaxial FOV of 65 mm.



- 4.1.4. Axial (travel) range of 225 mm.
- 4.1.5. Image resolution of 50  $\mu\text{m}$ .
- 4.1.6. Scan mode circular or helicoidal.
- 4.1.7. Minimum dose <4 mGy.
- 4.1.8. Average dose of 35 mGy.
- 4.1.9. Contrast resolution of 0.8 mm.
- 4.1.10. Flat-panel CMOS + CsI detector type.
- 4.1.11. Detector has an 864 by 1536 pixels array with a pixelsize of 75  $\mu\text{m}$ .
- 4.1.12. CsI scintillator cristal.
- 4.1.13. Operates at a magnification of 1.75.
- 4.1.14. Infinite rotation range.
- 4.1.15. GPU & FDK based iterative reconstruction type.
- 4.1.16. DICOM export; and
- 4.1.17. Monitoring capabilities such as ECG and respiratory monitoring.

The micro-SPECT shall meet the following functional and performance requirements:

- 4.1.18. Scanner bore of 115 mm.
- 4.1.19. Axial FOV up to 240 mm.
- 4.1.20. Transaxial FOV up to 60 mm.
- 4.1.21. Image resolution < 500  $\mu\text{m}$ .
- 4.1.22. Peak sensitivity of 0.12%.
- 4.1.23. 7 SiPM type detectors.
- 4.1.24. Monolithic pixels.
- 4.1.25. NaI(Tl) scintillator crystal;
- 4.1.26. Detectable Energy Range of 20-365 keV.
- 4.1.27. Energy resolution <11 %.
- 4.1.28. Pinhole collimators.
- 4.1.29. 3D MLEM (GPU based) reconstruction type.
- 4.1.30. DICOM export; and
- 4.1.31. Monitoring capabilities such as ECG and respiratory monitoring.

#### 4.2. Technical Requirements

The System shall meet the following technical requirements:

- 4.2.1. Power requirements such as 100-240 V AC, circuit breaker min 16 A and 50-60 Hz.
- 4.2.2. Internet connection.
- 4.2.3. HVAC of 18-22°C and <70% humidity at 25°C.

#### 4.3. Ancillary equipment

To ensure the proper operation of the system, the following additaments are required:

- 4.3.1. Workstation: A preconfigured workstation that allows seamless operation of the modules (SPECT & CT) in a multimodal manner,



supporting imaging workflow, and facilitating the display and analysis of large image volumes.

- 4.3.2. Tablet: A preconfigured tablet designed to facilitate seamless, multimodal, and wireless operation of the modules (SPECT & CT).
- 4.3.3. Calibration Phantoms: Specifically designed for automated quality control procedures for each module of the system (SPECT & CT).
- 4.3.4. Animal Preparation Station: Compatible with the system, used to facilitate animal handling and establish a safer and increased workflow. Unit provides heating and physiological monitoring.
- 4.3.5. Animal Bed (for mice): Compatible with the system, the beds have integrated heating, anaesthesia, and animal monitoring capabilities such as ECG and respiratory monitoring.
- 4.3.6. Scavenging Package: Designed for use with the anaesthesia system and any of the modules (SPECT & CT).
- 4.3.7. Collimator GP Mouse: Compatible with the system, it incorporates Lofthole technology and features a laser-sintered collimator.
- 4.3.8. Software Suite Licence: The software platform integrates physiological monitoring, quality control, image acquisition and advanced reconstruction techniques.
- 4.3.9. Post-processing Software Licence: Software licence for viewing and making analysis enabling image post-processing using DICOM format.
- 4.3.10. Processing and Fusion Software Licence: A license of 3 years is required. This software facilitates biomedical image processing, analysis, and quantification. It enables the visualization of volumetric images and offers both basic and advanced image processing procedures. These procedures include merging static into dynamic series, averaging across time or slices, spatial filtering (such as Gaussian, median, and Deriche), morphological operations, interpolation to various pixel or field-of-view sizes, and VOI-based partial volume effect correction of PET SUV values; and
- 4.3.11. Anaesthesia Vaporizer: For small animals to provide accurate amounts of anaesthetic gas (isoflurane).
- 4.3.12. Heavy-duty lab table (min. weight 100 kg).
- 4.3.13. 4 Personal dosimeters.
- 4.3.14. Gaseous anaesthesia device; and
- 4.3.15. Calibration sources and their shielding where relevant.

## 5. Marking

The System shall have all safety markings in accordance with IEC 61010-2-091 standard in English language.

## 6. Packing

Packing must comply with international standards that are applicable for the shipment by air of this kind of equipment.



## 7. Quality Requirements

- 7.1. The System shall be manufactured, shipped, and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.
- 7.2. The Contractor shall document the compliance with this quality assurance system.
- 7.3. The System shall have automated procedures daily, monthly, and periodic quality control procedures and End-User shall be trained in implementing them.

## 8. Testing and Acceptance

- 8.1. The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein such as detector response, image uniformity, spatial resolution, contrast resolution, sensitivity, energy resolution, image resolution and image quality.
- 8.2. The System, after installation, shall be prepared and calibrated by the Contractor, in other words, Start-up of the equipment, 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.
- 8.3. Short onsite acceptance tests shall be performed for each system. Full acceptance testing of the System shall take place at Contractor's lab in advance. The results of both measurements shall then be presented during the acceptance meeting scheduled after installation.
- 8.4. Immediately after the Contractor has demonstrated that the installed equipment is performing according to Contractor's equipment specification, a duly authorized representative of the End-User shall sign the Contractor acceptance test form concluding the Start-up.

## 9. Installation and Training

- 9.1. The Contractor shall install the System at the End-User's location. The Contractor shall provide for this purpose all necessary tools and staff (including their travel, accommodation, and subsistence as necessary).
- 9.2. The Contractor shall provide a 5-day training for up to 5 staff of the End-User in the operation and application of the System at the End-User's location immediately after the installation has been completed, as well as online support as needed during the first 3 months after the acceptance of the equipment.



## 10. Maintenance

- 10.1. The Contractor shall provide onsite full maintenance services for one (1) year during the warranty period, for the proper functioning of the System.
- 10.2. Full maintenance services shall include:
  - preventative maintenance
  - on-call interventions
  - any safety, software and hardware update and upgrade for the System that will be become available.
  - all necessary replacement and spare parts.
- 10.3. As part of the On-Site acceptance, the Contractor shall provide to the local hospital medical physicist a plan for preventative maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.
- 10.4. The Contractor shall guarantee the response time (time from when the request is made to the time a technician is at site to assess the situation) on site within 35h.
- 10.5. The Contractor shall provide pricing per year for up to five (5) additional years of full maintenance services (as defined in 10.1), following the initial one (1) year full warranty. The related costs shall be borne by the End-User.

## 11. Deliverable Data Items

The Contractor shall provide a complete set of user manual in the English or Spanish language.

## 12. Warranty period

A minimum warranty period is twelve (12) months after delivery or 18 months after shipment, whichever comes first.