

**FUNDACIÓ INSTITUT D'INVESTIGACIÓ EN CIÈNCIES DE LA SALUT GERMANS TRIAS
I PUJOL**

**TECHNICAL SPECIFICATIONS FOR THE SUPPLY, INSTALLATION, MAINTENANCE,
AND TECHNICAL SUPPORT OF THE US2.AI™ SOFTWARE FOR THE GERMANS TRIAS
I PUJOL RESEARCH INSTITUTE – ORCHESTRA Research Protocol**

STANDARD PROCEDURE - NEGOTIATED TENDER FOR EXCLUSIVITY REASONS

Non-harmonized Procurement

File No.: 09/2026

1. INTRODUCTION

This document defines the technical requirements and services needed for the deployment of the proprietary **US2.aiTM software** to support the ORCHESTRA research protocol, focused on AI-assisted echocardiographic analysis for the detection of cardiac amyloidosis in patients with left ventricular hypertrophy.

The purpose of this contract is to ensure that the software solution is fully operational, securely deployed within the institutional infrastructure, properly integrated with existing imaging systems, and technically supported throughout the duration of the study, enabling the research team to conduct clinical and scientific activities in compliance with regulatory and ethical standards.

2. PROJECT OBJECTIVE

The ORCHESTRA project addresses a critical clinical challenge: the early identification of cardiac amyloidosis, a frequently underdiagnosed condition for which effective treatments are available when detected at early stages.

The project is a large-scale retrospective analysis of echocardiographic studies, CE-marked AI solution capable of standardized and reproducible echocardiographic assessment.

3. SERVICE SCOPE AND OPERATIONAL CONDITIONS

The contract covers the deployment and operation of the US2.aiTM on-premise solution for the ORCHESTRA research protocol.

The total contract duration shall be up to 6 months from the date of delivery.

The project is structured in:

- **Part A:** Retrospective Analysis (up to 28,000 echocardiographic studies)

Implementation Timeline

- Hardware delivery: within one (1) week from contract signature.
- On-site installation and configuration: one (1) full working day by US2.aiTM engineer.
- System validation and go-live: completed at the end of the on-site installation visit.

Hardware Provision (Temporary Loan)

US2.aiTM shall provide a dedicated server unit under a temporary loan arrangement for the duration of the project.

- Ownership remains with US2.aiTM.
- Installation and configuration performed by US2.aiTM.
- Full hardware maintenance covered by US2.aiTM during the contract period.
- Removal of equipment upon project completion.

Estimated specifications:

- ASUS NUC 12 Extreme (or equivalent capacity)

- Ubuntu 24.04
- 16–32 core processor
- 64 GB RAM
- RTX 4070 GPU
- 4 TB SSD storage

The hardware constitutes an accessory element necessary for service provision and does not represent a separate supply contract.

Phase A – Retrospective Analysis

- Integration with PACS for batch transfer of historical echocardiographic studies.
- Remote user training (up to two sessions of maximum four hours each).
- Ongoing remote application support.
- Estimated duration: up to four (4) months from hardware delivery, provided the dataset is curated and prepared by the site.

Training

Training shall include:

- Retrospective phase: up to two (2) remote sessions, maximum four (4) hours each.

Technical Support and SLA

Premium Support shall apply.

Standard coverage:

- Monday to Friday, 09:00–17:00 (local time)

Extended coverage:

- 24×7 support for Critical (P1) incidents.

Incident response times:

P1 – Critical:

- First response ≤ 4 hours (Business Hours)
- First response ≤ 8 hours (Outside Business Hours)
- Resolution/workaround ≤ 24 hours

P2 – High:

- First response ≤ 8 hours
- Resolution/workaround ≤ 72 hours

P3 – Medium:

- First response ≤ 1 Business Day
- Resolution ≤ 7 days

P4 – Low:

- First response ≤ 2 Business Days
- Resolution on best-effort basis

4. FUNCTIONAL REQUIREMENTS

The US2.ai™ software to be deployed under the ORCHESTRA research protocol must comply with the following technical, clinical, and regulatory functional requirements:

Clinical and Analytical Functionality

- Automated analysis of transthoracic echocardiographic studies.
- AI-based algorithms specifically trained for the detection of cardiac amyloidosis.
- Automated extraction of quantitative echocardiographic parameters.
- Standardized and reproducible measurements to reduce inter-operator variability.
- Identification of echocardiographic markers (“red flags”) associated with left ventricular hypertrophy and suspected cardiac amyloidosis.
- Structured output suitable for clinical review and research analysis.

Retrospective Processing Capabilities

- Capability to process large volumes of historical echocardiographic studies (batch processing).
- Scalable performance suitable for the analysis of up to 28,000 retrospective studies.
- Secure ingestion of DICOM studies from PACS.
- Export of structured results for research database integration.

Deployment and Architecture

- On-premise deployment within the hospital's secure IT infrastructure.
- Operation on dedicated hardware provided by US2.ai™ for the duration of the contract.
- Compatibility with Ubuntu-based server environment.
- GPU-enabled processing to support AI computational requirements.

Regulatory and Compliance Requirements

- Valid CE Mark certification for clinical use in adult patients.
- Compliance with applicable European regulatory requirements.
- Compliance with General Data Protection Regulation (GDPR).
- Capability for pseudonymized data processing.
- Role-based access control.
- Secure storage and controlled access to processed data.

Reliability and Performance

- Stable operation suitable for continuous use during the 2-year prospective phase.
- Scalable performance aligned with projected study volumes.
- System architecture ensuring continuity of operation in accordance with the agreed SLA.

5. FINAL CONSIDERATIONS

The above-described technical and service requirements are essential to ensure scientific validity, regulatory compliance, data security, and operational continuity of the ORCHESTRA research protocol.

The integrated provision of licensed software, temporary hardware infrastructure, installation, training, maintenance, and premium technical support constitutes a unified and indivisible solution necessary for the correct execution of the project.