

LAIA XR

Powered by **ARSOFT**

ADVANCED VOLUMETRIC VISUALIZATION AND SURGICAL PLANNING PLATFORM

LAIA XR V1.0.0 is a comprehensive 3D surgical planning platform that combines advanced medical image processing with immersive visualization technologies, designed to optimize the preoperative workflow and enhance clinical training.

Thanks to the convergence of advanced reconstruction algorithms and **Virtual Reality (VR)** technologies, the platform shifts the cognitive load associated with anatomical reconstruction from the specialist to the software, transforming two-dimensional DICOM data into high-fidelity, interactive three-dimensional biometric models.

This solution allows for the immersive exploration and manipulation of each patient's 3D anatomical model, while also facilitating the structured definition of surgical planning sequences. Within this environment, it is possible to integrate measurements, advanced visualization settings, and multimedia resources. As a result, LAIA XR significantly contributes to improving the accuracy, efficiency, and quality of routine clinical practice.



CLINICAL CAPABILITIES AND FEATURES

Three-Dimensional Display of the Latest Generation

LAIA XR features a 3D display that includes the key functions for interactive analysis of 3D patient images.

Hybrid Display



Dual-display system, **Desktop–Virtual Reality (VR)**, which allows for quick and seamless switching between both environments. The desktop environment offers all the tools necessary for comprehensive surgical planning. Virtual Reality complements this experience by providing an immersive and advanced visualization of three-dimensional reconstructions. In this way, the user can turn to VR when it adds value to the planning process, facilitating a deeper spatial understanding of each patient's specific anatomy.

Minimum Latency



Reduced post-processing times, delivering editable 3D reconstructions within seconds of DICOM file upload.

Advanced Volumetric Visualization



Application of volumetric rendering presets to highlight specific densities (e.g., bone vs. vascular tissue), overlay of axial planes on the 3D model, and a custom rendering configuration tool.

Annotations and Immersive Manipulation



LAIA XR includes a suite of immersive 3D manipulation tools, such as oblique cuts, cubic and spherical cross-sections, and fine 3D sculpting. It also features immersive measurement and annotation tools that allow for precise and anatomically accurate measurements of distances, angles, and regions of interest.

Immersive Surgical Planning (Preoperative)

The planning module allows the surgeon to optimize the preparation of the surgical approach in an immersive visualization and interaction environment.

Definition of Surgical Steps



The surgeon interactively creates a step-by-step sequence of the procedure, with the ability to add audio annotations and descriptive text for each stage. Each of these steps will display the 3D anatomy in a fully customizable way to accompany the conceptual explanation of the stage being studied.

Real-Time Spatial Referencing



Visualization of the patient's "digital twin" for anatomical analysis.

Trajectory Simulation and Influence Ranges



Three-dimensional assessment and manipulation of access pathways and spatial relationships between different anatomical structures. LAIA XR enables immersive visualization and manipulation of the geometric relationships between elements of interest, such as tumors and vascularization.

3D Manipulation



A gesture-based interface that allows the surgeon to rotate, zoom in and out, and virtually dissect the model.

Planning Review



The surgical plan generated in LAIA XR remains available within the platform, allowing users to access, review, and update it as needed for the clinical process. Users can view it and make changes whenever they deem necessary.



WORKFLOW SPECIFICATIONS

1. Data Upload and Management

- Direct connection to hospitals' Picture Archiving and Communication Systems (PACS). LAIA XR offers native compatibility with the DICOM communication protocol, enabling direct import of each patient's radiological studies (CT, MRI, and related imaging modalities).
- Centralized management of patient profiles, linking multiple studies and time series for longitudinal follow-up.

2. Advanced Analysis Tools

- **Transfer Functions:** Adapting transfer functions to the model to highlight specific frequencies.
- **3D Manipulation:** Interactive navigation through the axial, coronal, and sagittal planes, synchronized with the 3D volume. Scaling of the 3D model.
- **Geometric Cuts and Exclusion Areas:** Cutting tools (oblique, cubic, and spherical). Freeform 3D sculpting.
- **Measurements and ROI:** Linear and angular measurement tools, as well as the definition of Regions of Interest (ROI) for targeted analysis.
- **Documentation Capture:** Generate high-resolution screenshots, record video of the planning process, and save "states" (preconfigured views) for clinical sessions or teaching purposes.

3. Surgical Planning

- A structured collection of user-generated steps and resources. All data and elements created are stored in the planning module, allowing them to be viewed and edited at any time.



CLINICAL SPECIALTIES AND COLLABORATIONS



LAIA XR is a modular system based on a dual-display core (Desktop-Virtual Reality) for manipulation and interaction with 3D medical images. Building on this foundation, the system integrates clinical specialty modules that utilize artificial intelligence for advanced medical image analysis, developed in collaboration with leading hospitals.

Some of the modules currently under development include:

Modules under development

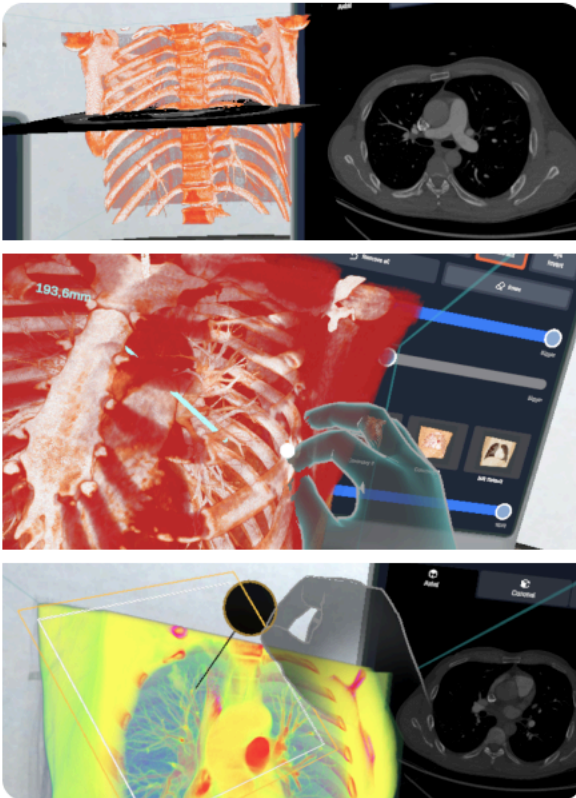
- Thoracic Surgery Module.
- General CT and MRI Segmentation Module.
- Cardiac Surgery Module.
- Hepatic Surgery Module.
- Urological Surgery Module.

SOFTWARE ARCHITECTURE AND REQUIREMENTS

The deployment of **LAIA XR** is structured as a hybrid ecosystem that combines a powerful processing station with state-of-the-art immersive display devices. The software and hardware components required for the platform to operate are detailed below.

1. Software Architecture

The LAIA XR platform consists of two synchronized software modules that cover the entire process, from data ingestion to intraoperative visualization:



LAIA XR Viewer

- **Function:** Acts as the command center for patient management, DICOM image acquisition, and surgical planning.
- **Capabilities:** Allows for the configuration of display presets (bone density, vascular, soft tissue), user management, 3D image manipulation, and surgical planning.
- **Compatibility:** Designed for integration with Hospital Medical Imaging Systems (PACS) and the DICOM medical imaging standard.
- **Educational Integration:** Compatible with learning management systems (LMS) such as Moodle for university environments.

LAIA XR Server

- **Function:** Acts as a centralized processing hub. This is where image preprocessing and automatic volumetric reconstruction take place.
- **Interface:** HTTPS connections using the TLS 1.2 secure communication protocol, with controlled security mitigations.

2. Hardware Requirements

To ensure smooth performance and rendering of high-polygon-count models, the system requires a workstation and high-performance computing equipment. LAIA XR has been validated to meet the technical specifications listed below, which ARSOFT guarantees will ensure its proper operation.

Workstation Requirements

- **OS:** Windows 11
- **CPU:** Intel i7-11700 or higher
- **GPU:** Nvidia RTX 4060 or higher
- **RAM:** 16 GB or more

Server Requirements

- **Please inquire**

- **Deployment Model:** ARSOFT offers a “turnkey” implementation that can include the supply of the necessary hardware (PCs, headsets, and a server), all preconfigured and validated.
- **Processing:** The computers running the LAIA XR Server require advanced graphics processing capabilities to support the preprocessing of volumetric 3D images.

3. Display Devices

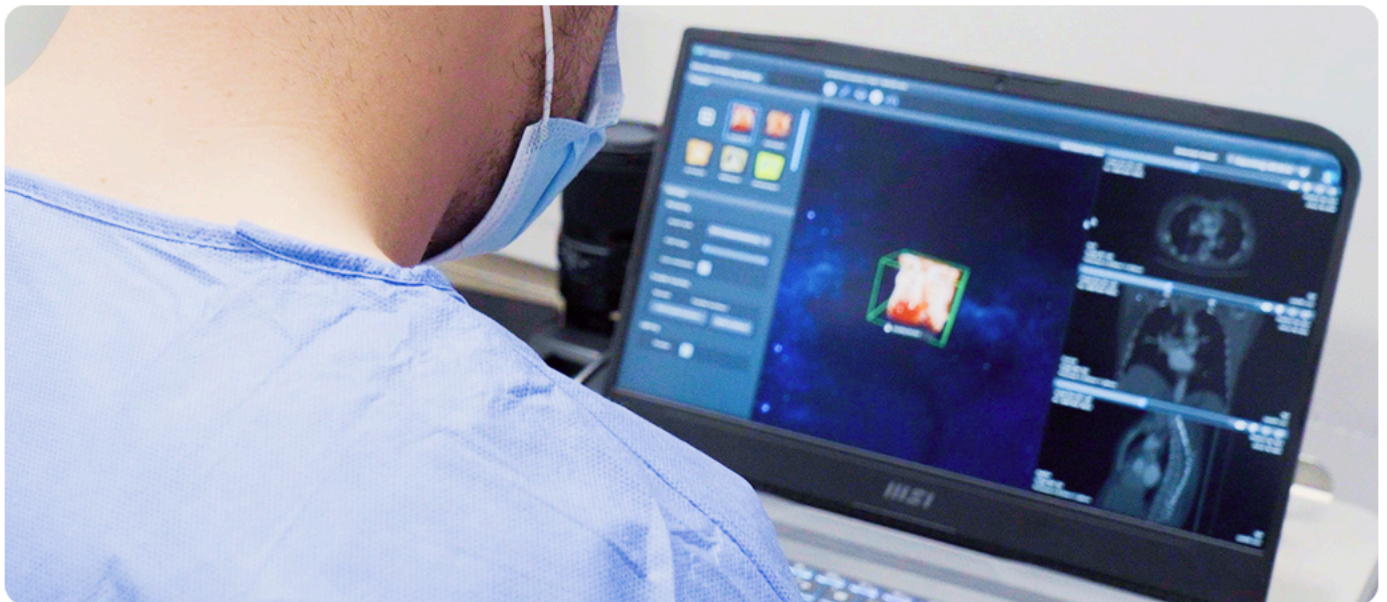
LAIA XR is hardware-agnostic and compatible with any mixed reality device that supports OpenXR standards, but it is optimized for **Extended Reality (XR)** devices in the Meta Quest lineup. These devices support high-fidelity hand tracking, eliminating the need for external controllers.

- **Virtual Reality (VR) Headset:**

The system has been validated for safety and proper operation in accordance with the intended use of the META Quest 3 Virtual Reality device. This device enables full immersion (for training and in-depth planning).

- **Natural Interaction (Hand Tracking):**

The software is calibrated to recognize precise hand gestures. The user interacts by using their own hands to grab, rotate, and scale the model (pinch gesture with the index finger and thumb) or tap virtual buttons with the index finger, simulating real tactile interaction.



4. Integration and Compliance with Standards

Ability to integrate with:

- ✓ **Compliance with the DICOM protocol and integration with Picture Archiving and Communication Systems (PACS).**
 - Standard DICOM messaging via C-GET/C-MOVE for importing images from PACS servers.
 - Compatible with radiological modalities such as CT and MRI, and their variants.
- ✓ **LMS systems (Moodle)** for academic settings and hospital databases.

LEGAL AND REGULATORY NOTICE

LAIA XR (v1.0.0) is CE Marked (0051) as a Class IIa medical device under the European Medical Device Regulation (EU MDR) and has received FDA (510(k) clearance) from the U.S. Food and Drug Administration (FDA), for the functionalities included within its certified scope.

Certain features or modules not included within the scope of current certifications may be intended for **research or evaluation use**, depending on the jurisdiction and applicable regulatory status.

In those territories or for those functionalities where certification is not available, the use of LAIA XR will be limited to research and non-clinical purposes. In these cases, any interpretation must be validated using approved standard radiological imaging methods.

The platform has been validated in experimental settings and clinical studies (including the University Hospital of Salamanca), demonstrating its utility as a tool to support surgical planning and clinical training.



0051

FDA Cleared

K251577

CYBERSECURITY

LAIA XR is compatible with hospital infrastructure and integrates with the most advanced communication standards, including DICOM messaging and secure data transmission protocols.

The platform's architecture has been designed in accordance with the principles of security by design and privacy by design, incorporating end-to-end protection mechanisms such as encrypted communications via HTTPS and TLS 1.2, with controlled security mitigations, role-based access control, and secure identity management.

LAIA XR's cybersecurity has been validated in accordance with recommendations applicable to medical devices, including the FDA's *Cybersecurity Guidance (2023)* and the *European MDCG 2019-16 guidelines for medical devices*.

Additionally, ARSOFT holds ENS Medium Level certification (National Security Scheme) for its software solutions, ensuring a robust security framework for the development and operation of the platform.

ADVANCED FEATURES (IN DEVELOPMENT)

LAIA XR is a modular system with a dual visualization core (desktop and Virtual Reality), general-purpose manipulation, interaction and segmentation applicable to 3D medical imaging. Building on this foundation, clinical specialty modules deliver more advanced medical image analysis through Artificial Intelligence (AI)-based functionalities.

The new modules currently under development integrate Deep Learning algorithms for the automated processing of radiological studies, automatic anatomical and pathological segmentation, and advanced analysis of the results obtained.

Note: The AI functionalities are currently undergoing CE Certification under the EU/MDR Regulation and FDA 510(k) clearance, and their use is therefore limited to research and development purposes.

The following describes some of these functionalities, each specifically designed around the needs of individual medical specialties:



Semantic Segmentation

Automatic identification and isolation of critical structures relevant to the specialty module (vascular system, parenchyma, bony structures, trachea, and bronchi). Automatic segmentation in LAIA XR allows for the independent manipulation of these structures, facilitating the planning process.



Fine Segmentation of Sub-structures

LAIA XR employs advanced sub-structure segmentation technology that enables comprehensive manipulation and interaction with the target area for surgical planning (lung segments, segmental vessels and bronchi, and low-level vascular tree mapping).



Tree Structure

Automatic generation of contextual relationships within structures to facilitate interaction and the representation of anatomy (Lung -> Lobe -> Segment -> Vessels, Parenchyma, Bronchus).



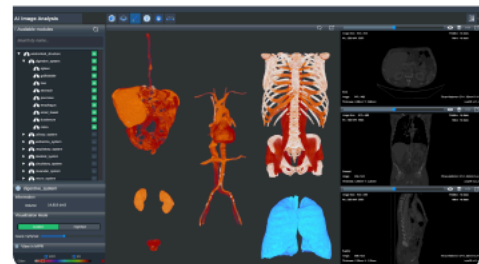
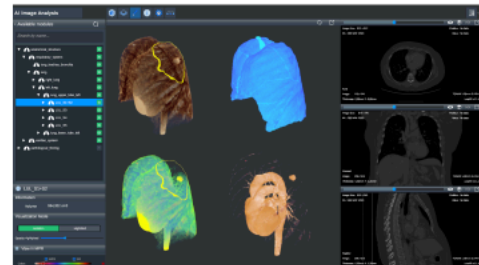
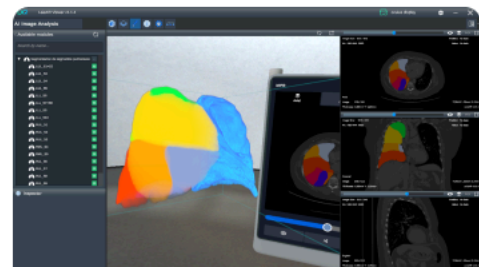
Pathology Detection and Segmentation

LAIA XR incorporates a model for detecting and classifying pathologies in medical images.



Advanced Tools for Surgical Planning

Automatic calculations of volumes, densities, diameters, and sphericity indices; automatic calculation of resection ranges; calculation of sections affected by resection and the extent of involvement in those sections.





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