

TECHNICAL DATA SHEET

VERIMA VIEWER



INDEX

Introduction: Verima	2
Classification	2
Verima Viewer	3
Verima Viewer for smartphones and tablets	3
Product characteristics	3
The needs it addresses	3
Verima Viewer for mixed reality viewers	4
The characteristics of the product	4
The needs it addresses	4
Architecture	4
Components used for development	4
Operating system required	4
Hardware requirements for the viewer	5
Magic Leap One™	5
User information	5

Introduction: Verima

Verima is a solution developed to facilitate clinical decision-making and simultaneously assist the physician's work and relationship with the patient.

Verima consists of four applications that are integrated with each other: **Verima Desk**, a web platform that enables the generation and management of 3D cases from CT and MRI; **Verima Tool**, a standalone PC software that enables analysis and segmentation of the output file generated by diagnostic imaging; and **Verima Viewer**, an application for *Mixed Reality* viewer and camera-equipped mobile devices.

Verima's main purpose and goal is to assist in training the health care professionals to whom remains the ultimate responsibility for the therapeutic choices made by offering a three-dimensional representation of the data available from imaging, particularly computed tomography (CT) examinations.

Verima is a class I medical device, registered under no. **1947525/R** in the Ministry of Health database.

Classification

1. Class of medical device	Classification in Class I: Given Annex IX of Directive 93/42/EEC concerning medical devices, in Section I point 1.4, which considers stand-alone software to be an active medical device, given, in Section III, the non-applicability of Rules 9 (point 3.1), 10 and 11 (point 3.2), and given Rule 12 (point 3.3), the Verima software falls into Class I.
2. Intended Purpose	Facilitated communication between physician and patient.
3. Target Context	Designed to be used in healthcare field
4. Actual use	The actual use of the software is characterized by providing the surgeon with a qualitatively better visualization of the region of interest by providing the latter in the form of a hologram, that is, a realistic three-dimensional representation with depth perception and observable from different perspectives.
5. Context of use	Use as support in the consultation phase with the doctor/patient and in understanding the anatomy of the case under examination.
6. Possible health and/or safety effects	The main objective of the software is to support healthcare providers to whom remains the ultimate responsibility for the therapeutic choices made. Its main feature is to provide visualization of a realistic three-dimensional representation of the images from the tomographic examination,

	which are not modified or manipulated in any way, but segmented to reconstruct the holographic model, reporting what can already be visualized from the CT radiology report. The use of the hologram is mediated by the interpretation of the surgeon, that is, the product user.
--	---

Verima Viewer

Verima Viewer for smartphones and tablets

Verima Viewer is Verima's app available for camera-equipped mobile devices (smartphones and tablets). The app is synchronized with the user's associated library on Verima Desk and, thanks to augmented reality, allows visualization of and interaction with 3D models associated with clinical cases, directly within the space where the user is located. Such cases can also be shared with other Verima users for consultation in real time or in non-real time via the Sharing Room.

Product characteristics

- Visualization in the form of an augmented reality hologram of the 3D model associated with the clinical case.
- Ability to move and rotate the hologram in the environment, regardless of the type of device on which it is displayed (smartphone or tablet).
- Ability to show or hide the individual layers of which the hologram is composed and change their name, color and transparency.
- Ability to scale up and down the hologram.
- Sharing the hologram in synchronous mode by creating a virtual room (Sharing Room) that up to 16 users can access simultaneously.
- Sharing the hologram asynchronously by sending the case to other Verima users.
- Ability to turn augmented reality visualization on and off.

The needs it addresses

- Management and cataloging of clinical cases associated with the healthcare professional.
- Intuitive understanding of the clinical case and interaction with it via 3D model visualization.
- Improved anatomical depth perception of the clinical case by taking advantage of visualization via augmented reality hologram.
- Improved visualization of clinical case anatomical tissues by enabling/disabling layers, their color and transparency.
- Case sharing with colleagues/patients, both for real-time and non-real time consultation.

Verima Viewer for mixed reality viewers

Verima Viewer is the Mixed Reality viewer application that allows users, via credentials, to access their library of cases recorded on Verima Desk in order to view their 3D models via holographic vision.

Cases are displayed as interactive three-dimensional holograms, giving full freedom to the user to be able to zoom in, rotate, move or turn off certain details for better visualization. Through Verima Viewer it is also possible to share a case with other users, using Room Sharing mode: the user creates a virtual room for a real-time viewing of the clinical case with other Verima users.

The characteristics of the product

- Visualization in the form of a mixed reality hologram of the 3D model associated with the clinical case.
- Ability to move and rotate the hologram in the environment.
- Ability to show or hide the individual layers of which the hologram is composed and change their name, color and transparency.
- Ability to scale up and down the hologram.
- Sharing the hologram in synchronous mode by creating a virtual room (Sharing Room) that up to 16 users can access simultaneously.

The needs it addresses

- Management and cataloging of clinical cases associated with the health care professional.
- Intuitive understanding of the clinical case and interaction with it via 3D model visualization.
- Improved perception of the anatomical depth of the clinical case by taking advantage of visualization by hologram in mixed reality.
- Improved visualization of clinical case anatomical tissues by enabling/disabling layers, their color and transparency.
- Case sharing with colleagues/patients for real-time consultation.

Architecture

Components used for development

- Unity: 3D engine.
- C#: Main programming language
- MRTK Mixed Reality Toolkit: open source library for developing experiences in Virtual Reality and Augmented Reality. - Reference website: <https://github.com/microsoft/MixedRealityToolkit-Unity>

Operating system required

The Verima Viewer app can be used on camera-equipped smartphones and tablets that have the following operating systems installed:

- Google Android 7.0 or later versions.
- Apple iOS 12 or later versions.

When used by visor, the app will require the following operating system:

- Lumin OS 0.93 or later versions.

Hardware requirements for the viewer

Magic Leap One™

- NVIDIA Parker SOC CPU: 2 Denver 2.0 64-bit cores + 4 ARM Cortex A57 64-bit cores
GPU: NVIDIA Pascal™ , 256 CUDA cores Graphic APIs: OpenGL 4.5, Vulkan, OpenGL ES 3.3+.
- RAM: 8GB (4GB of memory available for the application).
- Storage: 128GB (approximately 95GB, needed for application 5GB available).
- Connectivity: Bluetooth 4.2, WiFi 802.11ac/b/g/n, USB-C.

User information

A user manual is included with the software to guide the user in installing and using the product.