



# VERIMA VIEWER MR (MIXED REALITY)

Version 6.0

## User Manual

**Revision 1.4** | June 2022

Verima is a product developed by **Witapp SRL**  
[www.witapp.it](http://www.witapp.it) - [info@witapp.it](mailto:info@witapp.it)



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# 1 GENERAL INFORMATION

## 1.1 Contacts

### Manufacturer

Verima Viewer MR is a product designed and developed by **Witapp S.r.l.**, a software house established in 2016 and specialized in medical software. Since 2018, the company has adopted an organizational and management model in accordance with Legislative Decree 231 and a code of ethics.

In 2021 it enriched its compliance by adopting a quality standard on the basis of **UNI ISO 13485:2016**, which is a quality management system for organizations operating in the medical device sector, and a **UNI ISO 37001:2016** standard, which is the management system for the prevention of corruption.

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### Technical Support

For any kind of information related to the individual product in the manual or its interaction with Verima Suite, contact our technical support:

Headquarters	Phone	E-mail
Via Benedetto Dei 2/A 50127 - Florence (FI)   Italy	+39 055 019 7553 Mon/Fri from 9:30 am - 5:30 pm	<a href="mailto:assistenza@witapp.it">assistenza@witapp.it</a>

Technical support period is tied to the validity period of the purchased license and the particular product with which it is bundled.

Unless otherwise agreed, Witapp is not obliged to provide technical support in any case different from the one listed above.

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### Commercial Support

For any commercial request, about the purchase or extension of a license, or to receive a subsequent commercial offer related to the purchase of a new product, please contact our sales support:

<b>Phone</b>	<b>E-mail</b>
+39 055 019 7553 Mon/Fri from 9:30 am - 5:30 pm	<a href="mailto:assistenzacommerciale@witapp.it">assistenzacommerciale@witapp.it</a>

# 1.2 Legal Information

## Patent certificate for industrial invention

Verima software holds industrial invention patent No. 102019000003809, issued by the Ministry of Economic Development - General Directorate for the Protection of Industrial Property, Italian Patent and Trademark Office.

Owner: Witapp S.r.l.

Title: System and method, implemented by computer, of 3D processing of tomographic examination.

Classification: G16H

Date of filing: 03/15/2019

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## Trademarks not owned by or related to Verima

- Magic Leap®
  - Windows®
  - Android™
  - iOS®
  - Unity®
  - Lumin®
  - Visual Studio®
  - Azure®
  - Cmake®
  - ClickOnce®
  - QLM
- 

## Integrated software from third-party manufacturers

Verima uses the following open-source third-party libraries:

- VTK (<https://github.com/Kitware/VTK/blob/master/Copyright.txt>)
- gdcM (<https://github.com/malaterre/GDCM/blob/master/Copyright.txt>)

- MRTK (<https://github.com/microsoft/MixedRealityToolkit-Unity/blob/main/LICENSE.md>)
  - MRTKExtensionForMagicLeap (<https://github.com/HoloLabInc/MRTKExtensionForMagicLeap/blob/master/License.txt>)
  - JsonDotNet (<https://github.com/JamesNK/Newtonsoft.Json>)
  - Zxing (<https://github.com/zxing/zxing>)
  - Lumin SDK (<https://github.com/magicleap/MagicLeapUnitySDK>)
  - NLog (<https://github.com/NLog/NLog>)
  - Fo-DICOM (<https://github.com/fo-dicom/fo-dicom>)
  - Anubis (<https://github.com/hesham-akmal/AnubisInputField>)
  - Unity Mobile Input (<https://github.com/mopsicus/UnityMobileInput>)
- 

## CE Mark

Verima is a device that complies with Directive 93/42/EEC requirements and is therefore placed on the market with CE mark in accordance with Article 17 of Directives 93/42/CEE and 2007/47/EEC.

Verima is a class I medical device, registered under number 1947525/R in the database of the Ministry of Health.



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## Reporting of related incidents

You are required to report to Witapp any serious incident that could be related to this product or the entire Verima Suite.

In case the incident occurs within the European Union, also contact the relevant national medical device authority.



## 1.3 System Use

### Brief product description

Verima is a software that enables interactive hologram visualization allowing medical staff an accurate clinical case study and a more immersive consultation.

Verima Viewer MR (Mixed Reality) is a Mixed Reality viewer application that allows the reception and visualization of the case 3D model, either already existing or directly created through Verima Desk, in the form of a hologram, which is interactive in a simple and intuitive way. Through the MR Viewer, it is possible to rotate, zoom and move the case hologram to enhance visualization. In addition, it is possible to share the 3D model between two or more users through the Internet connection.

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### Product's intended purpose

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

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### Known contraindications

There are currently no known complications or side effects from the instrument.

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### Target patient population

There is no limitation regarding the existing patient population.

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## **Profile of target users**

The device is generally used by medical professionals, such as physicians and their assistants or nursing staff, who need to view medical images (DICOM) and other health-related data for non-diagnostic purposes.

The profile of Verima Viewer MR users is independent of the specific clinical use cases.

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## **Intended use environment**

The software is intended to be used anywhere a computer connected to the Internet can be used.

When using Magic Leap as an additional display for mixed reality, please consider the limitations related to the device's usage environment:

- Magic Leap One is certified as a computer equipment according to ANSI/UL60950 (E492841).
  - Magic Leap One is not an electromedical device according to IEC 60601-1.
  - Magic Leap One should not be used in a surgical setting in close proximity to the patient.
- 

## **Clinical benefit**

Verima Viewer MR makes it easy to view three-dimensional models of clinical cases and share them with other specialists.

# 1.4 Compatibility with medical software and devices

## Compatible third-party manufacturer devices

Verima Viewer MR is compatible with the following device:

Device	Manufacturer
Magic Leap One	Magic Leap, Inc. 7500 West Sunrise Blvd. Plantation, FL 33322 USA

Magic Leap One is certified as computer equipment according to ANSI/UL60950 (E492841).

It does not meet the requirements for electromedical equipment according to IEC 60601-1:2012 and should not be used in the patient's environment during surgical procedures.

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## Devices from other manufacturers

The combined use of the Verima software and application with other tools not authorized by Witapp may compromise the safety and/or effectiveness of the devices or the accuracy of 3D reproduction.

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## Software Installation

Installation of Verima Viewer for MR devices can be performed via the World app store on the visor Magic Leap One™. Such an operation does not necessarily involve the presence of Witapp personnel. Nevertheless, in case issues occur, Witapp customer support can be reached through the methods specified in the Technical Support section of this Manual.

# 1.5 Working Environment and Information Security

## Patient data storage

The system is not intended for storing patient data and/or personally identifiable information. Its only functionality is to visualize three-dimensional models that do not contain any reference to patients or any sensitive data.

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## Login and profile management information

Do not share your information or login credentials with unauthorized personnel. It is an end-user's responsibility to manage this information. In case one or more credentials are compromised, please contact the facility administrator or Witapp customer support.

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## Information security vulnerabilities

In case an episode of cyber vulnerability of the device or the entire facility hosting the Verima application occurs, please contact Witapp customer support.

After analyzing the situation, our trained staff will report the most accurate procedures to protect or restore the Verima system.

# 1.6 Technical Documentation

## Responsibility

This tool provides support to the clinician only and does not in any way replace the clinician, nor replaces its expertise and/or responsibility while using the application.

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## User manuals reading

This manual describes complex medical software or devices that should therefore be used with caution. For this reason, it is important that all Verima application's users:

- Read the user manuals carefully before using the equipment connected to the application or software;
  - Always have access to the user manual.
- 

## Available manuals

**CAUTION:** Manuals availability changes as the Verima product evolves. If you have downloaded this manual from our site, be careful that the listed version is the same one installed on your device and make sure that the document's revision is the most recent.

Type of User Manual
Verima Desk
Verima Viewer MR
Verima Viewer AR

# 1.7 Technical Requirements for Verima Viewer MR

## Hardware Requirements for MR Viewer for 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.
- 

## Warnings on used device

Magic Leap can be used in the operating room for non-diagnostic and non-therapeutic examination of medical data.

Magic Leap should not be used near the patient either in the operating room or during treatment. Magic Leap is not an electromedical device according to IEC 60601-1, and therefore the limitations regarding the environment of use of Magic Leap.

# 2 INTRODUCTION TO THE SOFTWARE AND ITS FUNCTIONALITY

## 2.1 Introduction

### Verima Suite

Verima is a solution that enables the visualization of interactive three-dimensional holograms, which allow clinical staff accurate analysis during the clinical case study phase and in the medical consultation phase.

The main objective is to support health care providers, who remain ultimately responsible for the therapeutic choices made, by providing a three-dimensional representation of the data available as output from computed tomography (CT) examinations.

Verima is a class I medical device, registered under number 1947525/R in the Ministry of Health database.

The Verima Suite product offering consists of a series of software integrated with each other:

#### Verima Desk

Web platform for managing and creating 3D clinical cases, starting from DICOM and STL files. Cases of interest are uploaded to the portal, where they are processed and cataloged in a personal library. Users can manage their profile, access their cases and share them with other applications in the suite directly from their web browser.

#### Verima Viewer MR

Application for Mixed Reality viewers that allows reception and visualization of 3D models, in STL format, created through Verima Desk.

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 viewing. It is also possible through Verima Viewer MR to share a case with another user, using Room Sharing mode.

### **Verima Viewer AR**

Application for Android or iOS smartphones and tablets that, thanks to augmented reality, allows the visualization of 3D models created through Verima Desk directly within the space where the user is located. The user can zoom in, rotate, move or turn off certain details for better visualization. It is also possible through Verima Viewer AR to share a case with other users, using Room Sharing mode.

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### **Verima Viewer MR**

#### **MAIN FEATURES:**

- Visualization in the form of a hologram of the 3D model on the Verima Desk platform.
  
- Visualization available on Mixed Reality viewers (e.g., Magic Leap), via the device's see-through lenses.  
The hologram is rendered in the surrounding context, and the user has the ability to interact with it without losing contact with the real environment.
  
- Ability to move and rotate the hologram in the surrounding environment, regardless of the type of device on which it is displayed.
  
- Ability to show or hide the individual layers of which the hologram is composed.
  
- Ability to scale up and down the hologram.
  
- Remotely sharing the hologram with a user via the Internet by creating a virtual room. See section 2.3 (Sharing menu) for further details.



## 2.2 Installation

### Hardware requirements for the MR Viewer

- 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, available for application at least 5GB).
  - Connectivity: Bluetooth 4.2, WiFi 802.11ac/b/g/n, USB-C.
- 

### Hardware power-up

To turn on Magic Leap One viewer, the center button on the battery pack must be held down ("Fig. 1").



Figure 1 - Magic Leap battery pack.

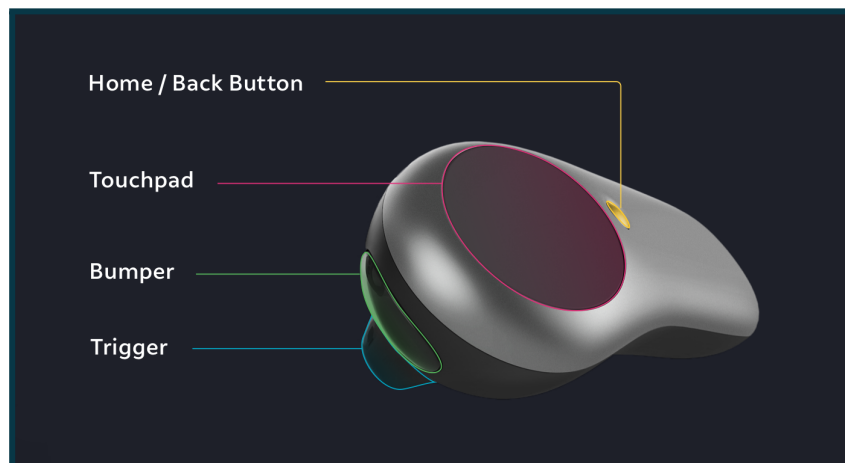
In order to turn on the Bluetooth controller, it is necessary to press and hold the *Home* button located under the touchpad ("Fig. 2").



Figure 2 - Magic Leap Controller

The controller consists of 4 components:

- **Home / Back Button** is a small circular button placed at the top.
- The **Touchpad** is the smooth circular surface located at the top.
- The **Bumper** is the long, narrow button located at the front of the controller.
- The **Trigger** is the button that resembles the shape of a trigger, located at the bottom of the controller.



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## Launching Verima Viewer MR

When you first start up, you need to install Verima Viewer MR on the Magic Leap viewer. From the main menu, select the *World app for Magic Leap* ("Fig. 3") and search the store interface for the Verima Viewer MR app.



Figure 3 - World application for Magic Leap

In order to proceed with the download, select the "Download" button on the application detail screen ("Fig. 4"). Installation is automatic and starts after the download is complete.



Figure 4 - Download Verima Viewer MR

## 2.3 Verima Viewer MR

### Software startup

To start Verima Viewer MR from the operating system home, press on the App icon ("Fig. 5" and "Fig. 6").

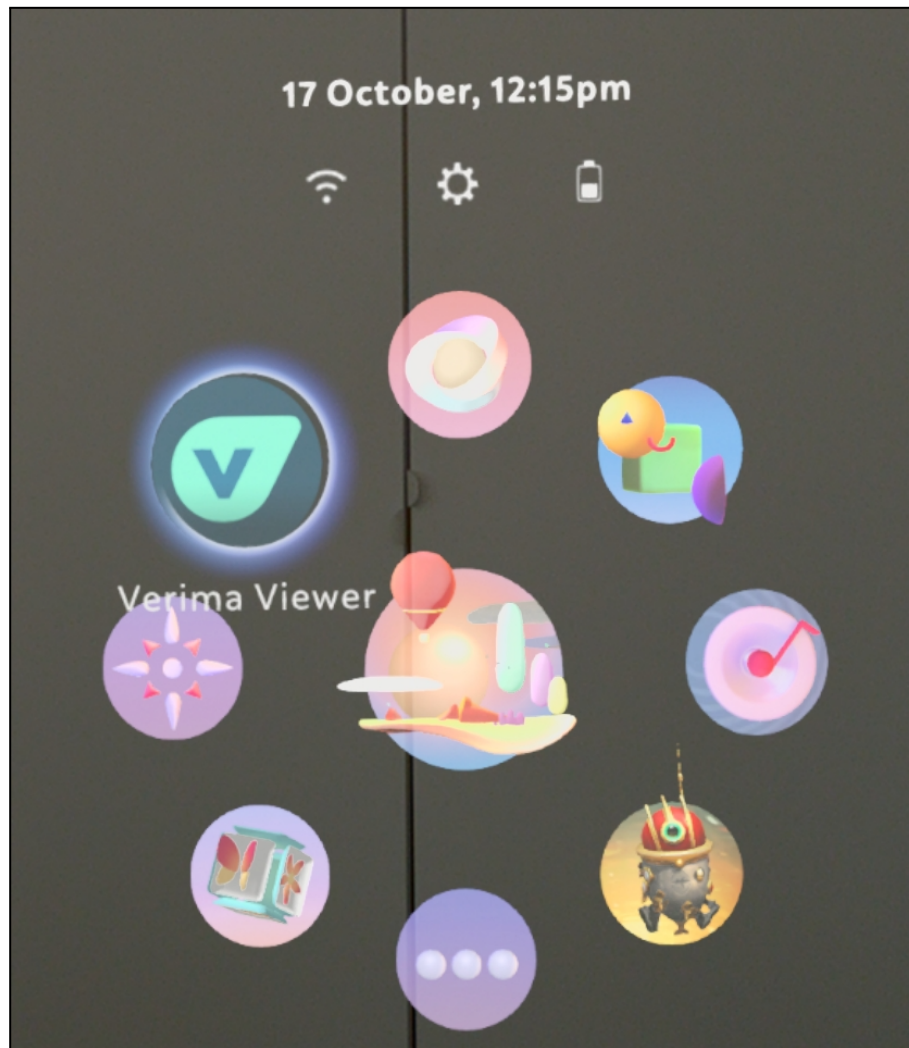


Figure 5 - Verima Viewer MR App Icon

If the app has been used recently it will be easily visible when the Magic Leap viewer starts, otherwise it can always be searched through the "All Apps" viewer section.

It may take a few seconds for the application to start.

In case your application does not start correctly, please contact our technical support.

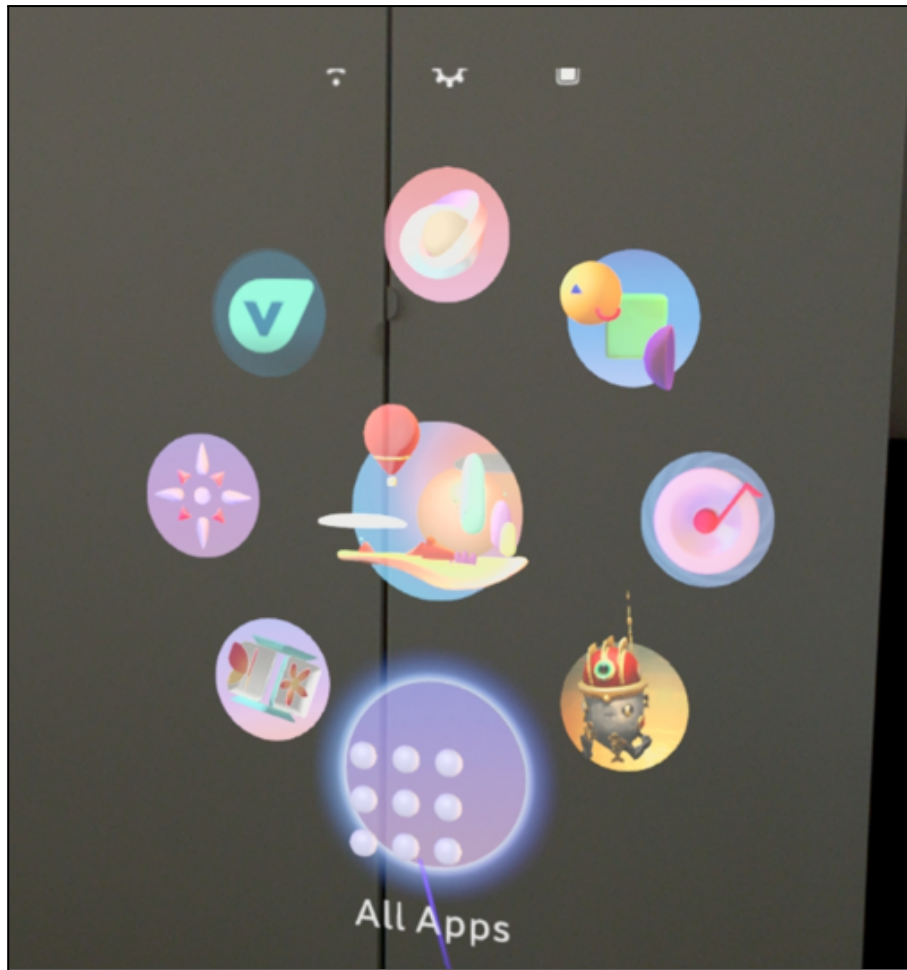


Figure 6 - All Apps icon.

## Menu interface

The first screen that will appear after the application is loaded is the login screen. The case archive on MR Viewer is synchronized with all the cases associated with Verima Desk platform user. To access these cases, simply log in from Viewer ("Fig. 7").

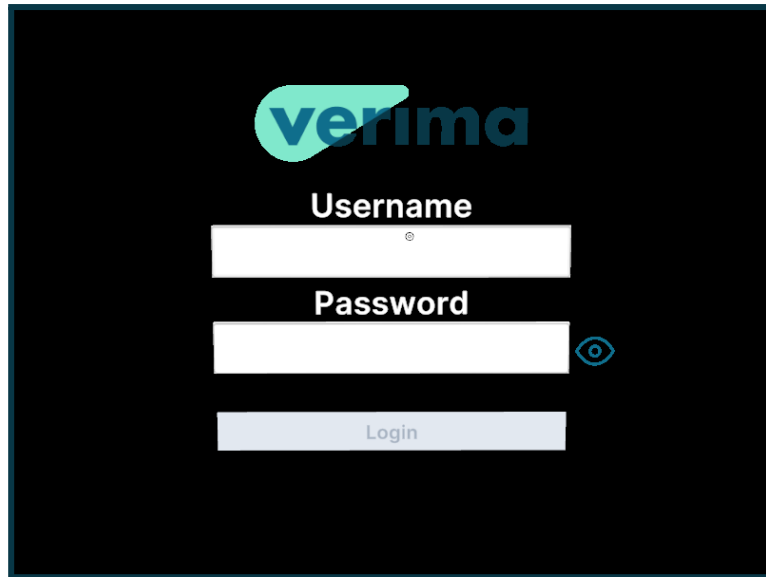


Figure 7 - Login screen

Once logged in, the Main Menu will appear, essentially Verima Viewer MR homepage. Here the various cases loaded on the viewer will be shown in the form of a list ("Fig. 8").

In this same screen, it is possible to find in the upper right corner the button dedicated to entering a Room Sharing. This feature allows users to enter inside a virtual room where other users are viewing a three-dimensional model.

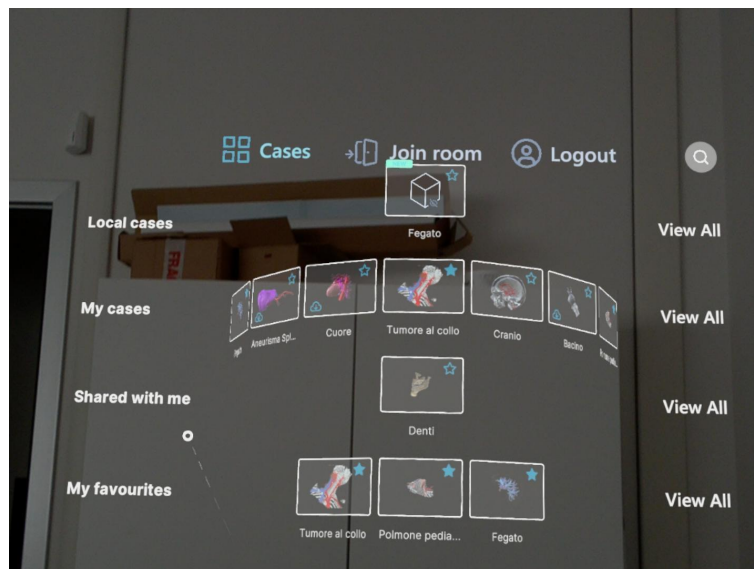


Figure 8 - Main menu

## Loading a 3D model



The operation of uploading a case to the viewer occurs after the case itself has been processed and stored on the Verima Desk platform. Please refer to the Verima Desk User's Guide for instructions on uploading the case to the platform.

The case archive on the MR Viewer is synchronized with the cases associated with the Verima Desk platform user. To access these cases, simply log in from Viewer.

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### Elimination of a case

If you want to delete a case, you must use the Verima Desk web platform or Verima Viewer AR app. Verima Viewer MR does not allow the case deletion.

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### 3D model Visualization

To display a case, it is necessary to indicate through the controller the name of the file we want to open and then press the trigger ("Fig. 9").

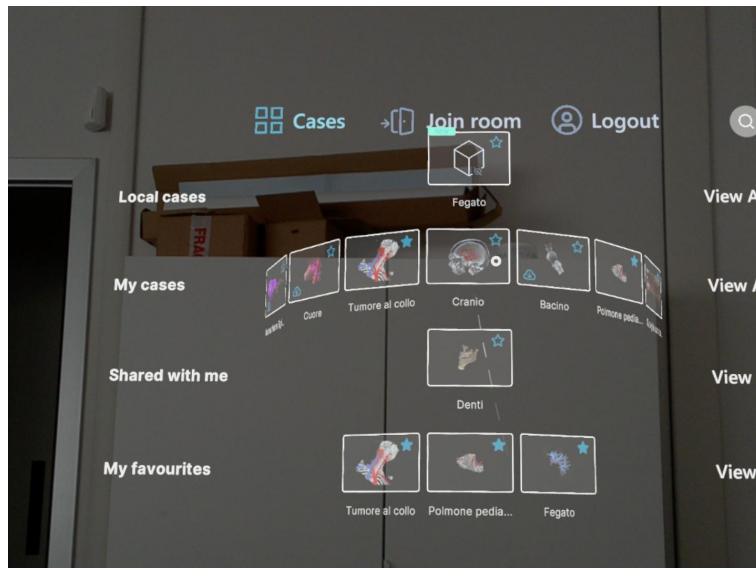


Figure 9 - Selection of a case

After a few seconds of loading, the three-dimensional model will automatically appear to the right of the menu containing the name and layers that make up the case ("Fig. 10").

Each layer can be activated or deactivated individually, to favor the display of one or more details, more or less visible, in the original scene.

If you wish to return to the *Main menu*, on the other hand, simply select the "Menu" button in the upper left corner, through the controller.

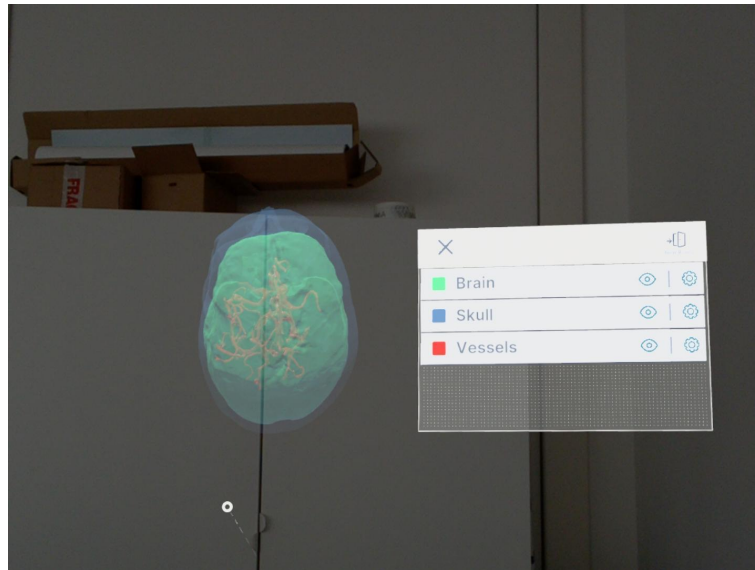


Figure 10 - The model appears next to the menu

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### 3D model manipulation

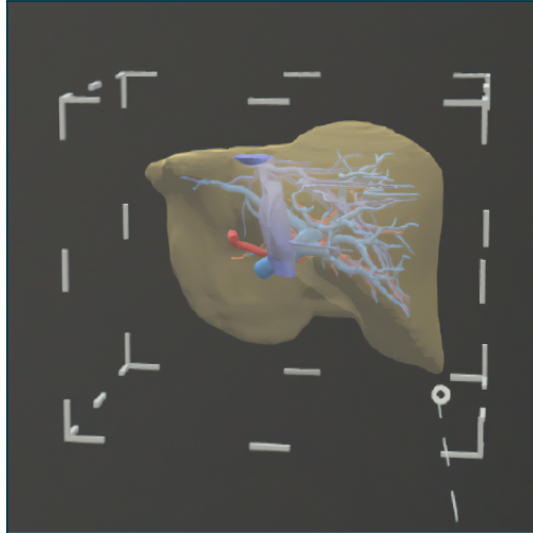
Once the 3D model appears in space, it can be manipulated and moved through the gray control box enclosing it.

The operations possible on each case are as follows:

#### Moving

By selecting the central part of the model and holding the Trigger you can drag the 3D model and move it in space. Releasing the Trigger will cause the model to remain in the position indicated by the user through the controller ("Fig. 11").

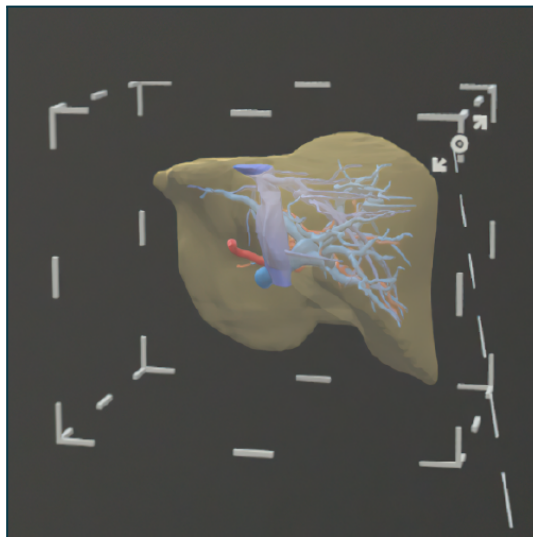




*Figure 11 - Moving a 3D model.*

### **Enlargement**

Selecting one of the vertices of the control box using the Trigger and moving the controller forward and backward in space can change the size of the model. The latter will always scale proportionally, maintaining fidelity to the original three-dimensional model ("Fig. 12").



*Figure 12 - Magnification of a 3D model.*

### **Rotation**

You can rotate the three-dimensional model to improve its visibility or to better view a detail hidden by other elements. Rotation can be done via the touchpad on the controller ("Fig. 13").



Figure 13 - Magic Leap controller touchpad.

Another way to perform rotation of a model in a controlled manner is by engaging the sides of the hologram control box through the indicator while holding down the Trigger of the controller. By moving the latter from right to left or vice versa, it will be possible to rotate the 3D model at will ("Fig. 14").

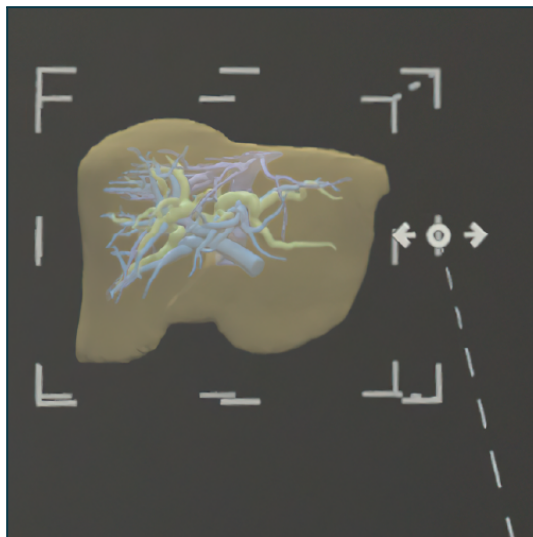


Figure 14 - Rotation of a 3D model

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## Layer options

Each layer that makes up the three-dimensional case model is editable in name and its transparency.

Selecting the gear icon, next to the name of the affected layer, it is possible to open an editing panel where the above properties will be editable ("Fig. 15").

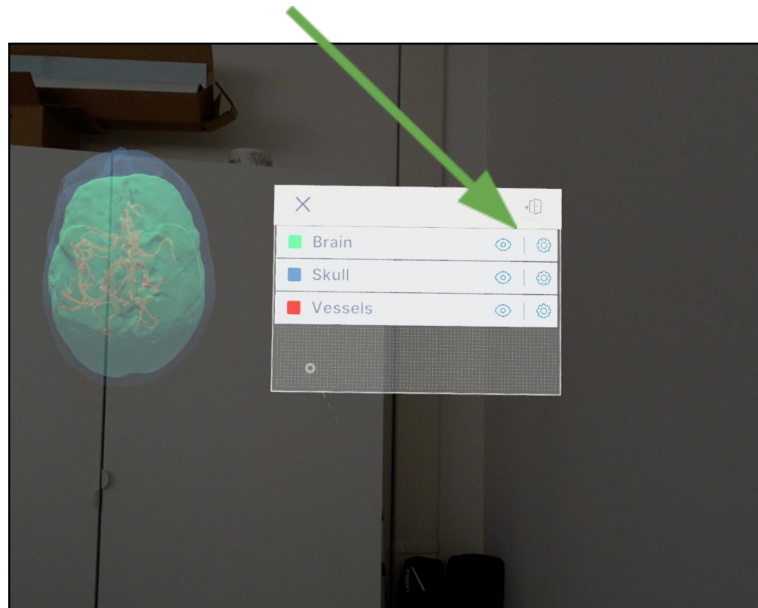


Figure 15 - Open the layer options

To edit the name you need to select the "Edit" button with the pencil icon. Once the button is activated a keyboard will appear with which you can edit and delete the layer name or even change its color, adding the desired changes.

To change the transparency, simply drag the controller from left to right to decrease the percentage of opacity present in the layer ("Fig. 16").

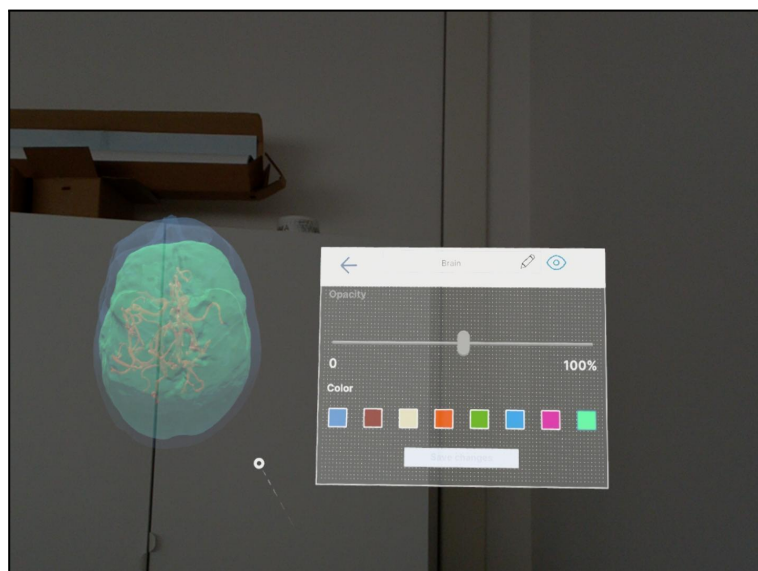


Figure 16 - Transparency Management

Any changes made will have to be confirmed and saved before leaving the layer edit panel.

To make a layer invisible in the scene, simply turn it off with the eye icon in the previous screen.

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## Sharing menu

Through Verima Viewer MR, it is also possible to share a case and its detailed 3D model visualization with other users. This is possible through the "Room Sharing" feature, which allows the user to create a virtual sharing room where they can share their case with other guests.

The Room Sharing functionality is accessible through the button in the upper right corner of the individual model menu called "New Room" ("Fig. 17"). On the other hand, if the user wants to join a pre-existing room, the "Join Room" button in the main menu must be selected ("Fig. 18").

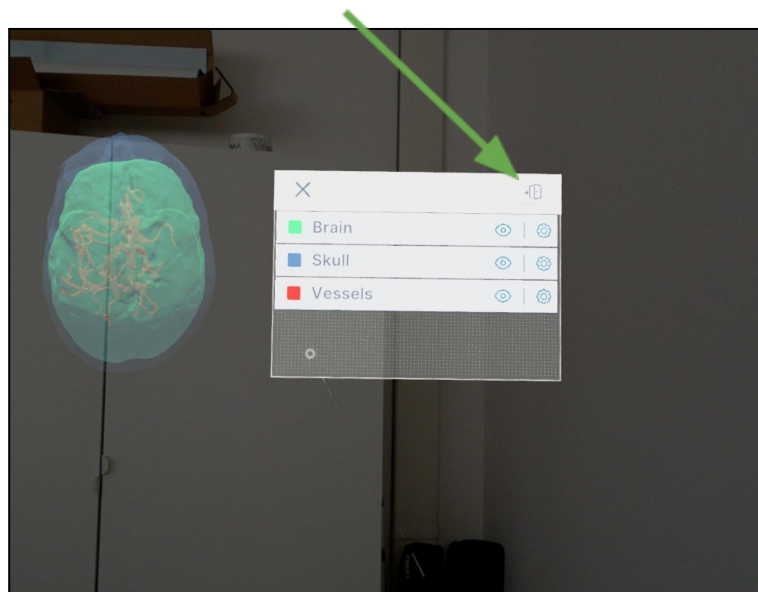


Figure 17 - Creating a room

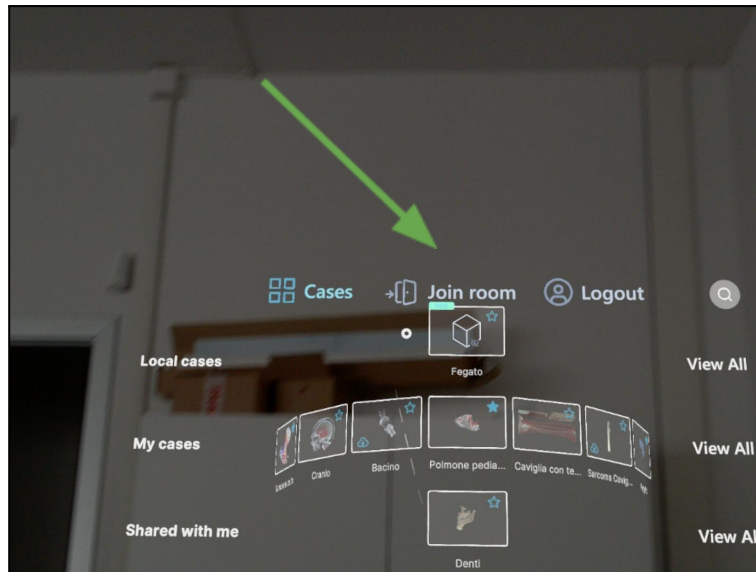


Figure 18 - Joining a room

### Create a room

By selecting the "New Room" button in the sharing menu, you can create a room to share a view of your three-dimensional model with other users.

Each time a room is created, a 4-digit identification PIN is generated and associated with it. The same digits that will be required of guest users to identify the room they want to access.

The room creator, whom we will refer to as the "Host user" from now on, possesses the ability to interact with the model and can decide whether or not to keep these capabilities active for other Host users. There are, in fact, two types of sharing called "Room Sharing Not-Aligned" and "Room Sharing Aligned."

### Room Sharing Not-Aligned

Users can share, through room creation, their case with other Verima App users of Verima Viewer MR and Verima Viewer AR. This type of sharing allows all viewers to see the same 3D model with the possibility to rotate it, move it in space, and modify it in levels, regardless of other users' choices. The individual user's changes will not, therefore, be visible to other users and vice versa.

This type of sharing is designed to take full advantage of the potential of Sharing mode even when you are not all present within the same physical room.

### Room Sharing Aligned

The user can share their case with other Verima users through the creation of a room and the recognition of a physical target. This type of sharing allows the user who creates the room (Host user), to share their case manipulation with other viewers present within the virtual

room. The latter will never have the ability to modify the 3D model as long as the alignment target is active.

Only the Host user will be able to stop this type of sharing by disabling the alignment from the appropriate function in the upper right corner and then reverting back to the sharing previously described as "Not-Aligned."

### Joining a room

It is possible to join an existing room by entering its PIN code, using the appropriate numeric keypad, and selecting "Join Room" ("Fig. 19").

By joining the room the user is considered a guest (*Guest user*) and depending on the type of Room Sharing activated (*Not-Aligned* or *Aligned*) will or will not have the ability to interact with the three-dimensional model.

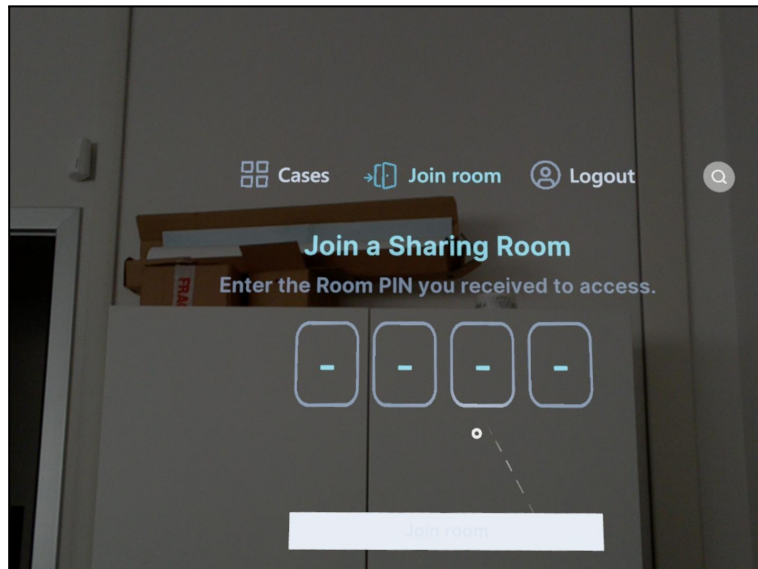


Figure 19 - Joining a room

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## License Activation

To create a room, it is necessary to activate a license obtained by purchasing Verima Suite. License activation is a required step that does not have to be repeated every time, but only at the first request for creating a Room Sharing.

In fact, the first time you try to create a room, Verima Viewer MR will ask you to activate a license through a special pop-up ("Fig. 20").



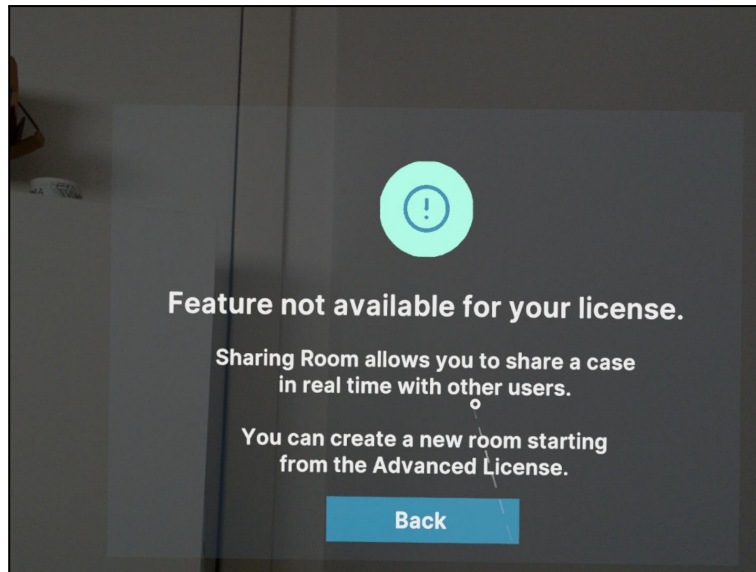


Figure 20 - License activation request

The license will have to be purchased through the appropriate channels, as there is no redirection to such channels within Verima Viewer MR.

If you have any difficulties with this, please contact our support team at [assistenza@verima.it](mailto:assistenza@verima.it).

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## Target alignment

It is possible to match virtual user rooms by scanning an alignment target. In this way, both Host and Guest users will see the model in the same position. Simply frame the target with the crosshair ("Fig. 21") and wait for the operation to complete.

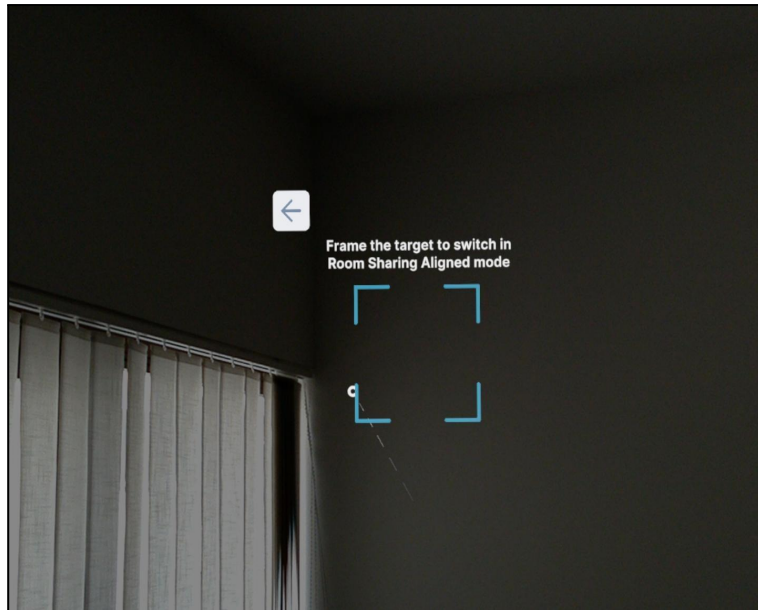


Figure 21 - Target scan viewfinder

After the alignment is completed, it is possible to check the alignment status of the target ("Fig. 23") from the menu at the top left.

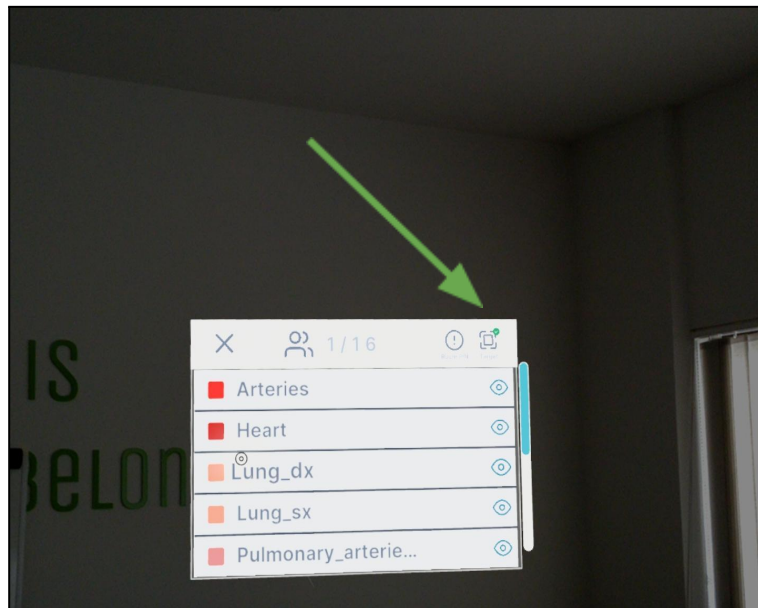


Figure 23 - Target status: aligned

To make the target easier to read, we recommend that you always print it in its color version and keep the dimensions shown on the next page as accurate as possible.

Significant variation in image size could result in less accurate alignment, compromising the experience of 3D sharing with other users.



During the target reading and recognition operation, it is mandatory to place the printed image on a flat and even surface, whether it is horizontal such as a table or vertical such as a room wall. It is absolutely essential that the target is not moved during the alignment phase of the various users.

Moving, even by a few centimeters, the position of the target during Room Sharing can adversely affect the aligned view of the 3D model.

Be careful not to place the target on an extremely hot surface. The image on the next page may not be perfectly to scale. For more information or to receive a printable scaled document, please contact our technical support.

**verima**  
a new way to see



Scan this target to align  
the Sharing Room

## Closing the application

To close the application simply press, at any time, the Home button on the Magic Leap. After the pop-up appears, confirm your choice to proceed to close the software ("Fig. 24").

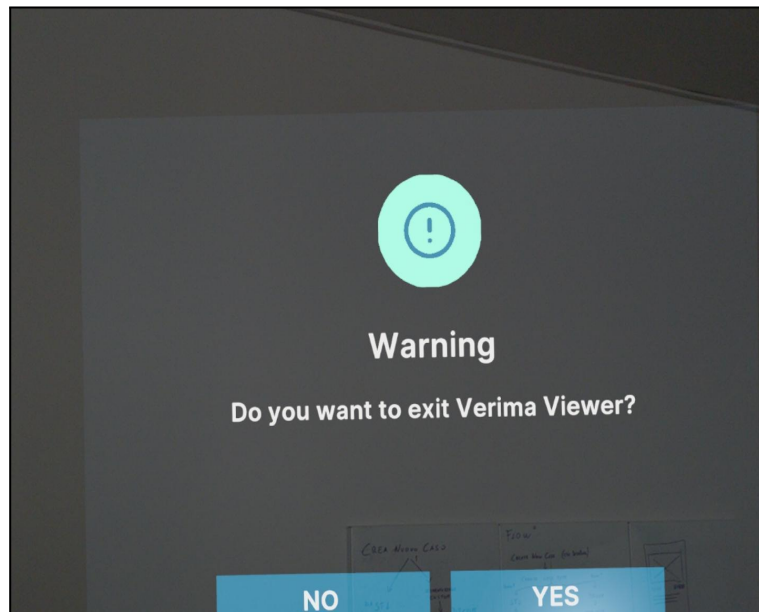


Figure 24 - Closing the application