



VERIMA VIEWER AR (AUGMENTED REALITY)

Version 6.0

User Manual

Revision 1.4 | June 2022

Verima is a product developed by **Witapp SRL**
www.witapp.it - info@witapp.it

SUMMARY

1 GENERAL INFORMATION	4
1.1 Contacts	4
Manufacturer	4
Technical Assistance	4
Commercial Assistance	5
1.2 Legal Information	6
Patent certificate for industrial invention	6
Trademarks not owned by or related to Verima	6
Integrated software from third-party manufacturers	6
CE Mark	7
Related incidents reporting	7
1.3 System Use	8
Brief product description	8
Product's intended purpose	8
Known contraindications	8
Target patient population	8
Target user profile	9
Intended use environment	9
Clinical benefit	9
1.4 Compatibility with medical software and devices	10
Compatible third-party manufacturer devices	10
Devices from other manufacturers	10
Mobile application installation	10
1.5 Working Environment and Information Security	11
Patient data storage	11
Login and profile management information	11
Information security vulnerabilities	11
1.6 Technical Documentation	12
Responsibility	12
User manuals reading	12
Available manuals	12
2 INTRODUCTION TO THE SOFTWARE AND ITS FUNCTIONALITY	14
2.1 Introduction	14
Verima Suite	14
Downloading and installing the application	16
2.3 Verima Viewer AR	17
Starting the application	17
Viewing a case	17
Receiving a case on the device	21
Deleting a case	22
Interactions with the 3D model	23
Sharing a case	27
Room Sharing mode: "Not-Aligned"	28
Room Sharing mode: "Aligned"	29
Target alignment	30
License activation	34
Joining a room	34

1 GENERAL INFORMATION

1.1 Contacts

Manufacturer

Verima Desk 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 based on **UNI ISO 13485:2016**, which is a quality management system for organizations operating in the medical device sector, and **UNI ISO 37001:2016** standard, which is the management system for the prevention of corruption.

Technical Assistance

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 to 5:30 pm	assistentatecnica@witapp.it

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

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

Commercial Assistance

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:

Phone	E-mail
+39 055 019 7553 Mon/Fri from 9:30 am - 5:30 pm	assistenzacommerciale@witapp.it

1.2 Legal Information

Patent certificate for industrial invention

Verima software holds industrial invention patent N°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 on a tomographic examination.

Classification: G16H

Date of filing: 03/15/2019

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.



Related incidents reporting

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 competent 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 AR (Augmented Reality) is an app designed to be installed on Android and iOS devices (smartphones and tablets) equipped with a camera. The app allows the visualization of cases available on one's Verima account in the form of a hologram, with which one can interact in a simple and intuitive way: it is possible to rotate, zoom and move the hologram to enhance its visualization. In addition, Verima Viewer AR grants case view sharing between two or more users via Internet connection.

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.

Known contraindications

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

Target patient population

There is no limitation regarding the existing patient population.

Target user profile

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 AR users is independent of the specific clinical use cases.

Intended use environment

Verima Viewer AR application is intended to be used anywhere a smartphone or tablet type device can be used.

When using Magic Leap as an additional display for mixed reality, 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 should not be used in a surgical setting in close proximity to the patient.
-

Clinical benefit

Verima Viewer AR 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 AR is compatible with the following devices:

Device	Manufacturer
Android 7.0 or later	Google LLC 1600 Amphitheatre Parkway Mountain View 94043, California, USA
iOS 12 or later	Apple Inc One Apple Park Way Cupertino, 95014 California, USA

Devices from other manufacturers

The combined use of 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.

Mobile application installation

Users can autonomously install Verima Viewer AR app by accessing the Play Store/Apple Store, depending on their device, and download the app for free.

In case some issues occur during the installation of the app, please contact Witapp customer support.

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 receive three-dimensional models that do not contain any reference to patients or any sensitive data.

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.

Information security vulnerabilities

In case a cyber vulnerability event occurs on a device or on the entire facility hosting the Verima application, 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.

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

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.

Verima Viewer AR

MAIN FEATURES:

- Visualization in the form of a hologram of the 3D model on Verima Desk platform.
- 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.

2.2 Installation

Operating system required

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

Downloading and installing the application

Verima Viewer AR is an application developed for tablets or smartphones with Android or iOS operating system.

Like any other application, you can download the software from the respective Play Store or Apple Store.

Application Installation will start automatically once the download from the store is finished. The application can be downloaded free of charge.

2.3 Verima Viewer AR

Starting the application

Once the installation is completed, the application can be initiated by simply performing a tap on the icon present inside the device screen. Depending on your smartphone or tablet settings, the icon can be present already in your main screens or in the menu with all the applications installed inside the device ("Fig. 1").

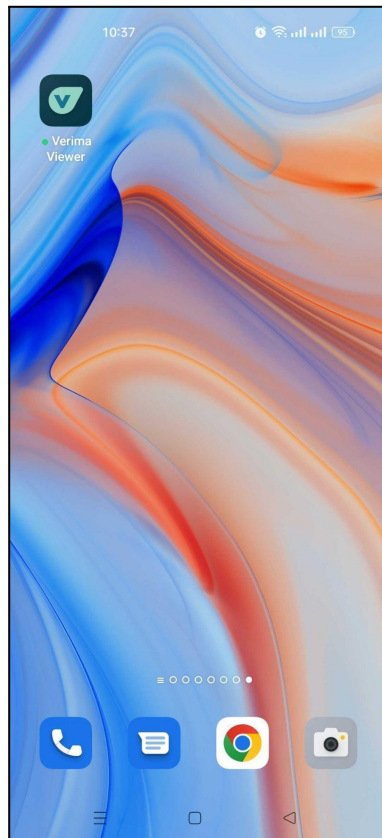


Figure 1 - Icon for starting the application.

The application needs only a few seconds to start up and may depend on your device performance. If problems arise by starting the application, please contact Witapp technical support.

Viewing a case

Once started, the application will show its main screen to let the user login using their credentials ("Fig. 2").

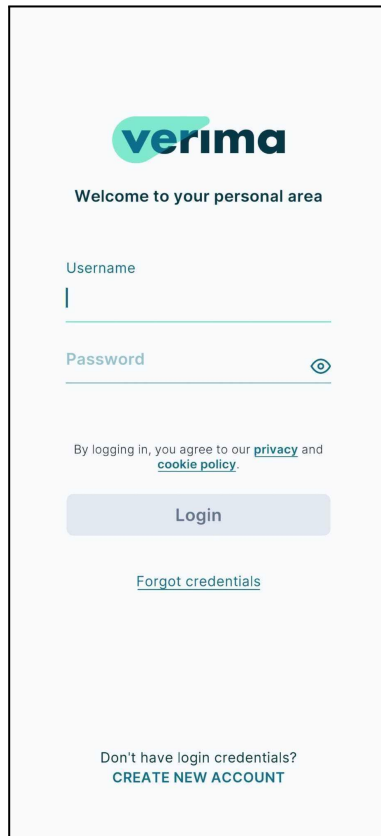


Figure 2 - Main screen

Once you enter your user account, you will be able to access 3 sections ("Fig. 3"):

- My cases, that is, user-generated cases;
- Shared with me, i.e., cases shared with the user by other Verima users;
- My favorites, i.e., cases marked as favorites.

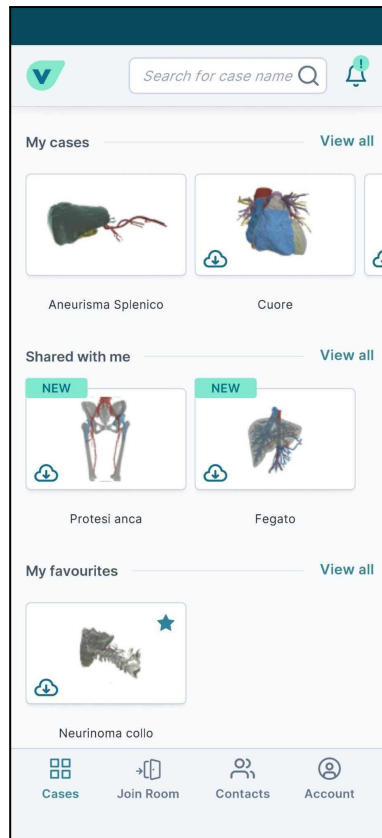


Figure 3 - Screenshot of own sections

Performing a tap on one of the possible cases will display a pop-up box with a preview of the anatomical model and the "Download on this device" button ("Fig. 4"). Tapping on the latter will load the three-dimensional model linked to that particular file. Once the upload is complete, you will be able to view the model by tapping on "Open the case" ("Fig. 5"). The loading time may vary, depending on your device performance.

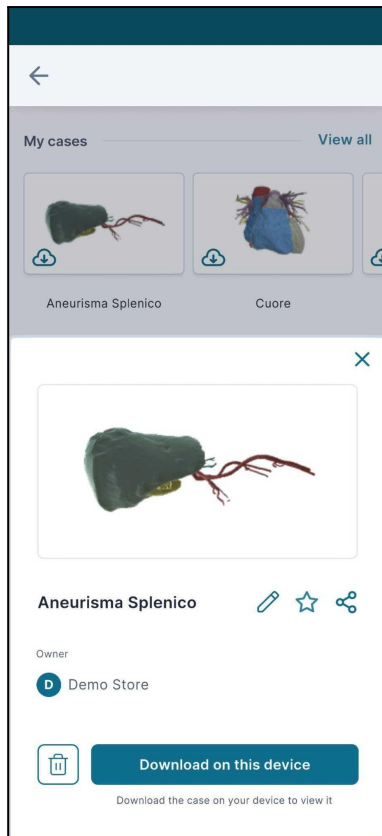


Figure 4 - Case download button

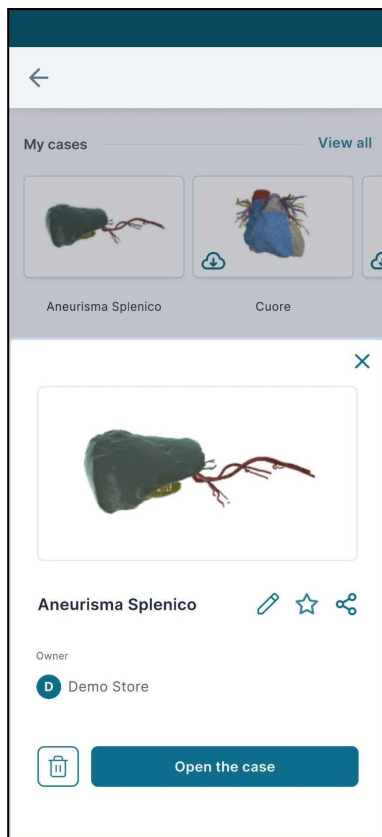


Figure 5 - Case opening button

Once the case is loaded, it will be shown within the surrounding space thanks to the device's back camera. Initially, the three-dimensional model will always appear in front of the user, projected a few inches away from their own device ("Fig. 6").

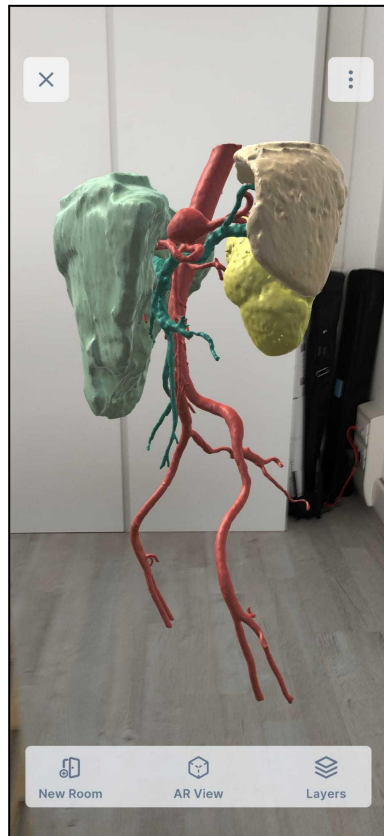


Figure 6 - 3d model within the space

Receiving a case on the device

Verima Viewer AR application, like all Verima applications, will access all cases stored in the Verima Desk, which will be available for download and visualization. Please refer to the Verima Desk User Guide for instructions on uploading a clinical case.

Receiving the case on Verima Viewer AR is an automatic procedure for the user and can occur at any time as long as the device is connected to the Internet.

Deleting a case

Cases accessible from the device can be deleted at any time by the user. To proceed with the deletion of a case, it will be necessary to access the application's homepage, where all the cases associated with a user are listed, and tap on the case to be deleted. A pop-up box will appear from which to perform the case removal, using the appropriate button depicting a trash can, at the bottom left ("Fig. 7"). Having done this, a confirmation pop-up will ask if we are sure we want to delete the case ("Fig. 8").

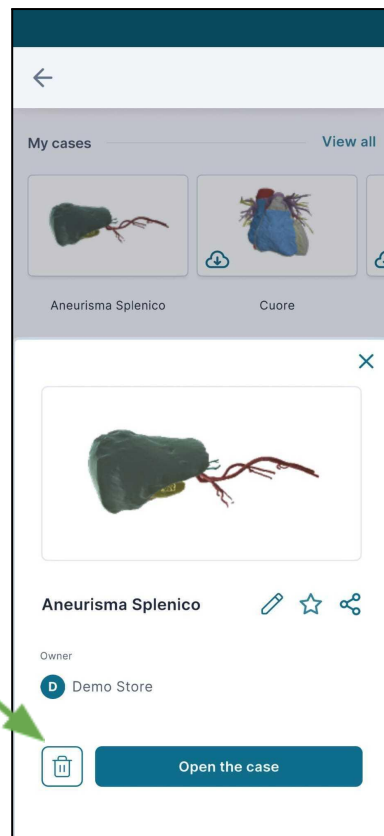


Figure 7 - Button to delete a case.

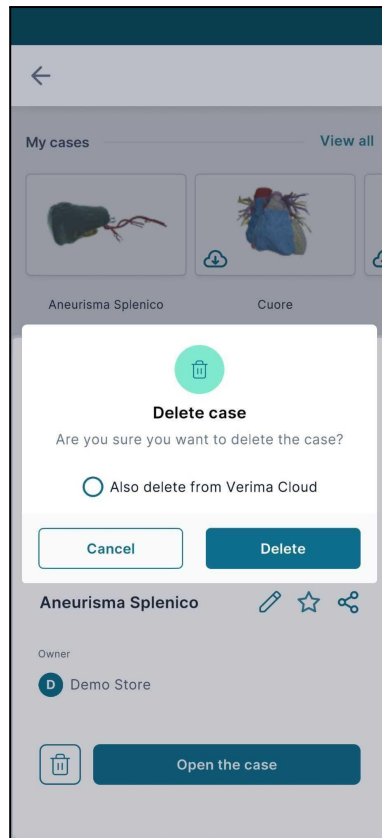


Figure 8 - Confirmation pop-up for deletion of a case

The app also gives the option to delete the case from the cloud library (i.e., from Verima Desk) by selecting the check in Fig. 8. Removing a case shared by other users results in its removal from their library, but not from the original user's one, who created the case.

Interactions with the 3D model

Through Verima Viewer AR, it is possible to visualize the case three-dimensional model and, in addition, to interact with it within the surrounding space.

Within the 3D model display screen, you can notice the presence of 3 buttons at the bottom of the screen, named "New Room", "AR View" and "Layers" ("Fig. 9").

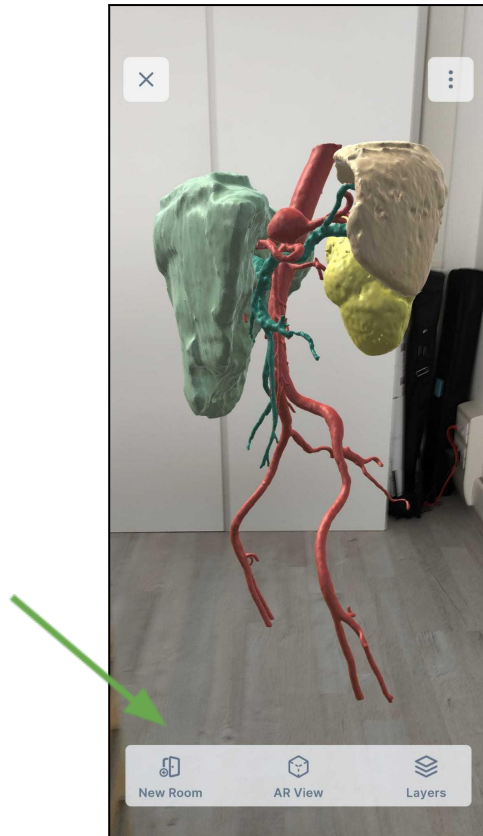


Figure 9 - "New Room", "AR View" and "Layers" buttons.

These buttons provide access to different features.

"New Room" gives the user the ability to create a Sharing Room. Please refer to the next chapter "Sharing a Case" for a detailed description of this feature.

"AR View" allows the user to enable or disable the augmented reality background captured by the camera. By default, AR View is enabled. To disable it, simply tap on the appropriate toggle ("Fig. 10").

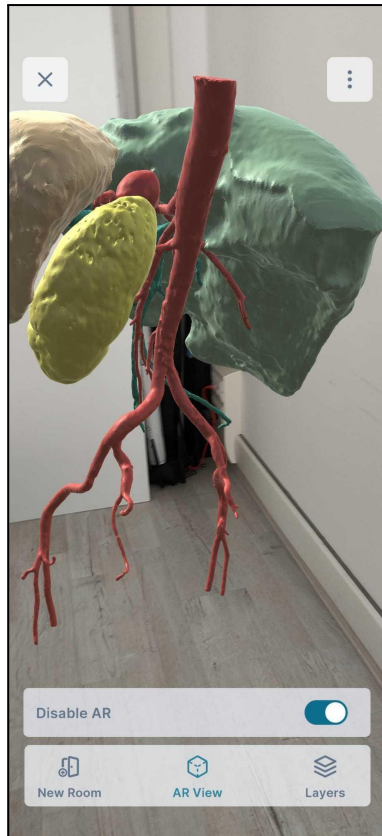


Figure 10 - Toggle to enable/disable AR View"

By tapping on the third and final button, Layers, all the layers that make up the case will be visible through a vertical menu ("Fig. 11"). Each layer has the name that was assigned to it during implementation and segmentation through Verima Desk. Next to the layer name there is an eye icon and a gear icon. The former is to turn a layer off or on again. Turning off a layer will exclude it from the view and it will only become visible again once it is turned back on. The second allows you to adjust its transparency and change its name and/or color.

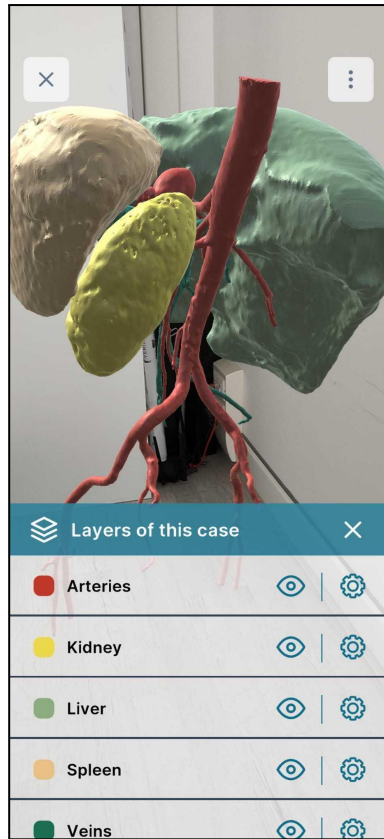


Figure 11 - "Layers" panel

The functions for interacting with the 3D model are described in the *Tutorial*, which is accessible from the button in the upper right corner depicting three dots. That button also gives the possibility to use the *Reset position* function, which restores the model's initial position in the surrounding space ("Fig. 12"). The latter action can also be performed by making 3 taps on the screen.

In addition, to move the three-dimensional model within the space, simply hold the model with one finger and direct the device's camera in the desired manner.



Figure 12 - Reset Position and Tutorial Options.

The 3D model can, in addition, be rotated through the use of *swipe* (a gesture that involves dragging a finger across the device screen from a starting point to an end point, such as from left to right) or magnified through *scale pinch* (a gesture that involves two fingers simultaneously resting on the device screen and moving in opposite or similar directions).

Sharing a case

Verima Viewer AR application allows us to share the case we are viewing in augmented reality with other users, either physically close to us or simply connected to the Internet.

To share a case with another Viewer (either on Verima Viewer AR or Verima Viewer MR) you must, first, open the case. Once you get to the 3D case viewing screen, you need to select the "New Room" button (see "Fig. 9").

In order to share a case you must have a valid and active product license. To learn how to activate a license from the device, please read the next manual's chapter "Activating a License."

Users who create a sharing room (whom we will refer to from now on as the "Host User"), after the room is created, access a screen in which they still can interact and modify the model, plus some new features.

At the top of the screen the number of participants in the room will appear (for this application version the maximum number of possible users in a room at one time is sixteen). At the bottom *Room PIN* and *Target* buttons ("Fig. 13") will be accessible. These are related to the newly created room.

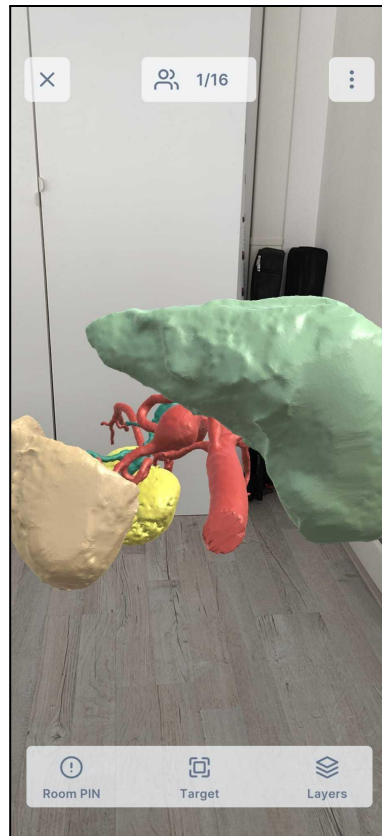


Figure 13 - Information related to the Sharing Room

On the left side we can see the "Room Pin" or the identification code that distinguishes one's own room from other users' rooms. To let one or more users into our room, it will be enough to tell them our Room Pin.

At the bottom, on the other hand, we find the target alignment button that can vary from the status of aligned or unaligned. Changing this status involves switching from the sharing mode called "Room Sharing Not-Aligned" to "Room Sharing Aligned" .

Room Sharing mode: "Not-Aligned"

In this type of unaligned sharing, the Host User who created the room does not have any special privileges over all the other Guest Users in the room.

This type of sharing allows all users to see the same three-dimensional model being free to rotate or move it in space and modify it in levels. These changes will be independent of the actions of other users; changes by an individual user will not, therefore, be visible to other guests in the room and vice versa.

This type of sharing is designed to take full advantage of the potential of Sharing mode even when users are not all present within the same physical room. In fact, in "Room Sharing Not-Aligned" mode, no physical targets need to be framed and aligned.

Any Guest User can leave the room at any time without affecting other users or the Host User. On the contrary, if it is the Host User who leaves the room, all other users will see their sharing stopped.

Room Sharing mode: "Aligned"

In this type of aligned sharing, the *Host User* who created the room holds control of the shared model.

The transition from the previous mode, called *Not-Aligned*, and the *Aligned* mode occurs through the *Host User's* request for alignment and recognition of a physical target.

The *Room Sharing Aligned* mode allows the *Host User* to share their case manipulation with other viewers inside the virtual room. The latter will never have the opportunity to modify the three-dimensional model as long as the alignment target is active ("Fig. 14").

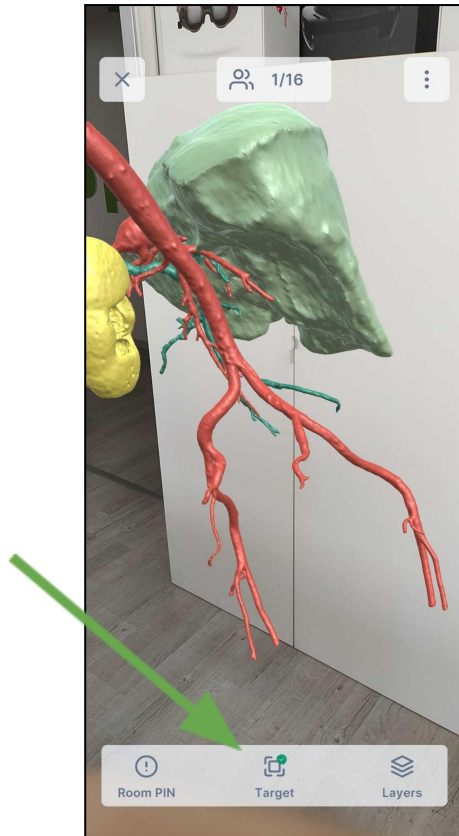


Figure 14 - Target aligned

Only the *Host user* can stop this type of sharing by disconnecting from the target and returning to *Room Sharing Not-Aligned* mode. Once the *Host User* activates the *Aligned* mode through target recognition, all other users within the room will have to align their devices to the same target in turn.

During this sharing mode, it will always be possible for both the *Host User* and *Guest Users* to re-align to the target.

Any *Guest User* can leave the room at any time without affecting other users or the *Host User*. On the contrary, if it is the *Host User* who leaves the room, all other users will see their sharing stopped.

Target alignment

As already seen in the description of *Room Sharing Aligned* mode, matching the virtual rooms of the various connected users requires the recognition of a physical target.

Through target alignment, all users, whether *Host User* or *Guest User*, will be able to see the three-dimensional case model in the same position within the surrounding space.

To activate target recognition, the target button located at the bottom of the device screen must be selected. Once the scanning is activated, the device will ask you to frame the target of reference through the appropriate screen ("Fig. 15").



Figure 15 - Target recognition from device

When the alignment is successfully completed, the application will return to the three-dimensional model display screen and the target icon will have a green badge to communicate successful alignment.

To make the target easier to read, it is recommended to print it in its color version and to keep the dimensions given at the end of this chapter as accurate as possible.

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

During 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 too hot a 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.



**Scan this target to align
the Sharing Room**

License activation

In order to share your case through the creation of a Sharing Room, you must have a valid and active Verima license.

Within the Verima Viewer AR application, if the user selects the "New Room" button having an active license that is lower than Advanced, an alert pop up will appear on the screen, explaining the function and reason for the lockout, with an option to upgrade the license. ("Fig. 19").

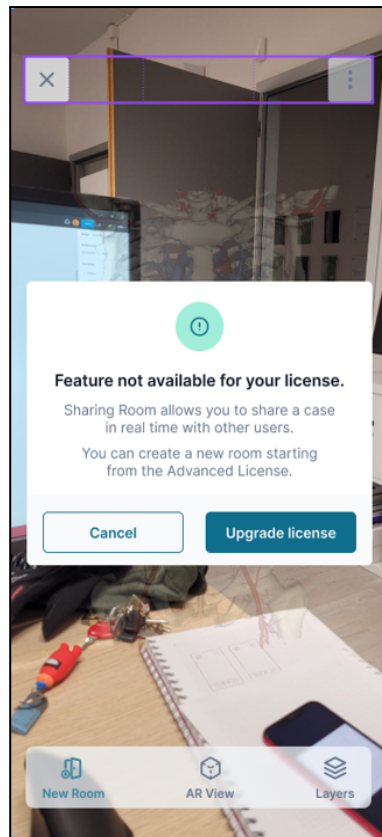


Figure 16 - License Activation

By selecting *Upgrade your license*, the user will be redirected to Verima's e-commerce portal.

Joining a room

Verima Viewer AR application provides the ability for the user to join the virtual rooms of other users in order to view cases in their possession. Through this mode, *Guest User* can view another user's three-dimensional model without having to compulsorily download it to their device. Depending on the type of sharing set by the *Host User* within the room, *Guest User* can have different possible interactions with the 3D model.

To enter inside a room, it is necessary to know the distinctive Room *Pin* and to be connected to an Internet network. From the application main screen, you can select the screen button named "Join Room" ("Fig. 17").

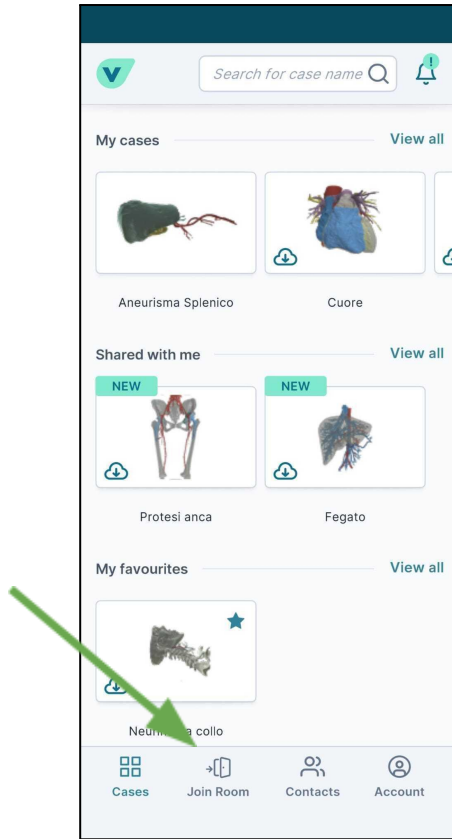


Figure 17 - "Join Room" button.

Once the button is selected, the application will take you to the screen for entering the Room *Pin* of the room you wish to enter ("Fig. 18").

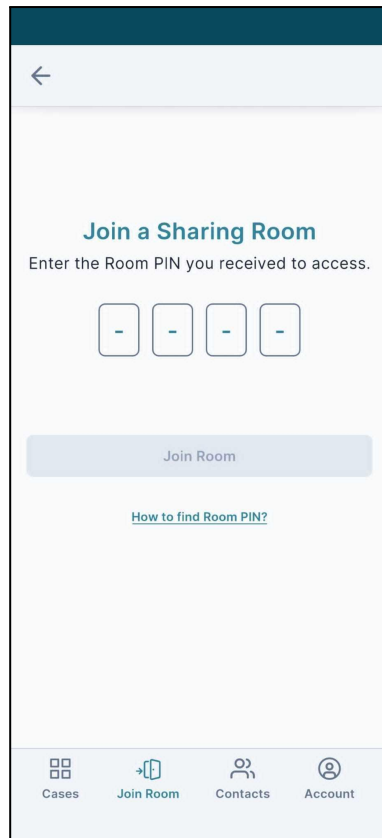


Figure 18 - Room pin entry

Uninstalling the application

Verima Viewer AR application is a software included into the Verima Suite and therefore it is not recommended to uninstall the application if you are still using other Verima softwares.

If you wish to uninstall the application, you must select the application icon from your device and proceed to delete the software.