



VERIMA DESK

6.0 Version

User Manual

1.0 Review | May 2022

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

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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	assistenza@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 Desk is the web-based platform for user-associated clinical cases processing, visualization, management and sharing.

Intended purpose of the product

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

Known contraindications

No complications or side effects have been yet found from using the instrument.

Target patient population

There is no limitation regarding the existing patient population.

Target user profile

The software 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. Verima Desk users profile is independent of specific clinical use cases.

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, 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 Desk is set up as a web-based platform for managing and creating 3D clinical cases, starting from DICOM and STL files.

1.4 Compatibility with medical software and devices

Compatible third-party manufacturer devices

Verima Desk is compatible with all the web browsers listed in Section 1.7.

Devices from other manufacturers

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

1.5 Working Environment and Information Security

Patient data storage

The system is not intended for storing patient data and/or personally identifiable information.

It must be the user's concern to remove all personal data in the files that the user uploads to Verima applications.

Witapp declines any responsibility for handling any personal data shared by software users.

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

1.7 Technical Requirements for Verima Desk

Components used for development

- *Javascript*: reference programming language for web application development.
 - *CSS* and *SASS/SCSS*: style sheets for defining the appearance of the web application.
 - *HTML5* for defining the page structure that makes up the web application.
 - *ReactJS* framework and related libraries for developing the web application that implements the GUI, Graphic User Interface.
 - *vtk.js* library for displaying holograms.
 - *Axios* library for ajax calls.
 - *Fflate* library for file compression.
-

Supported browsers and operating systems

Verima Desk supports all recent versions of modern browsers i.e. Edge, Firefox, Chrome, Safari.

Verima Desk also works properly on older versions of the browsers mentioned above as long as they support ES6 and WebGL2. On very old versions of supported browsers there may be a deterioration of performance and/or graphical appearance of Verima Desk

For more details regarding the compatibility of your browser you can consult the following sites:

- <https://caniuse.com/es6>
- <https://get.webgl.org/>

Verima Desk has no specific requirements regarding operating systems as long as it is possible to install and use one of the supported browsers and the operating system provides sufficient computational resources (modern CPU and at least 4GB RAM).

Lack of computational resources or use of a very old integrated graphics chipset could cause slowdowns in hologram display and manipulation.

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 accurate clinical staff 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.

Verima Suite product offer consists of a series of softwares 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 the 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 in which 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 Desk

MAIN FEATURES:

- Sending DICOM in the cloud for customized segmentation.
- Case creation from an STL file.
- Archive Management containing cases of interest.
- Preferred case management.
- Case sharing Management with other colleagues.
- User profile management.
- Module for 3D visualization of cases imported to the platform.

2.2 Installation

Hardware requirements for Verima Desk

Since this is a web-based platform, there is no need for Witapp to provide any kind of hardware.

Witapp agrees to provide the link to connect to the web platform when training staff on the product.

The software is accessible via web browser. Please refer to section 1.7 for more specifics on this.

2.3 Verima Desk

Starting the software

To use Verima Desk you will simply need to start your web browser and connect to the link provided by the Witapp team during the training.

Once one connects to the web page, the Verima Desk interface will appear to enter user login credentials (previously provided by Witapp).

In case you experience any problems by accessing, please contact Witapp customer support.

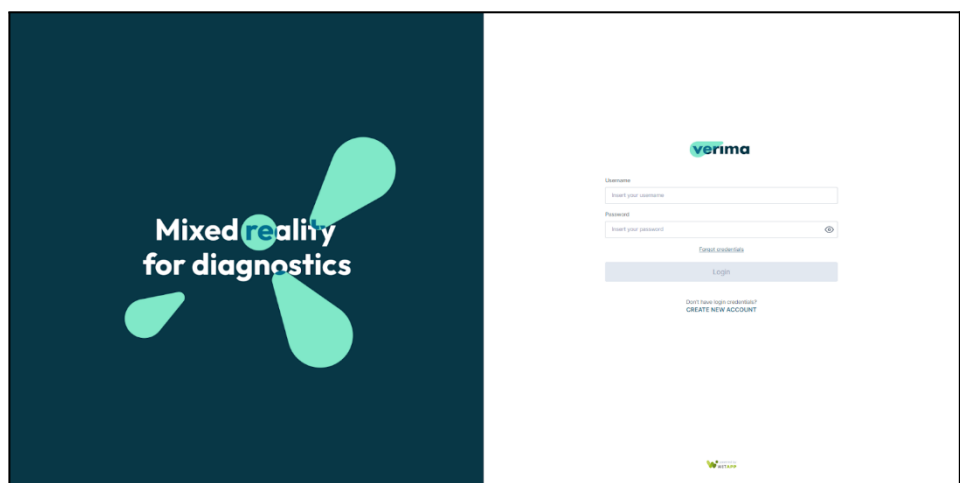


Figure 1 - Login interface

Additional users' access

If it is not logging in the Verima license holder (previously contracted with Witapp), the user has the option to create a new account and follow the procedure to log in as a Free license user by clicking on the "CREATE NEW ACCOUNT" label.

Lost credentials

In case the user has forgotten their login information, they can click on "Forgot credentials," enter their associated email address, and then receive directions via email on how to reset the password.

Import DICOM files and create Custom case

Through Verima Desk, it is possible to import a DICOM file present on your computer and then later make a three-dimensional model of the same file.

First of all, it is necessary that such a file is saved as a compressed archive (.zip). To upload it to Verima Desk, you need to click on the button in the upper left corner, called "Create new case" ("Fig. 2").



Figure 2 - "Create new case" button.

This step gives us access to the panel for choosing between two possible upload types ("Fig. 3"). Click on the "Custom" button to upload the DICOM file and create the case.

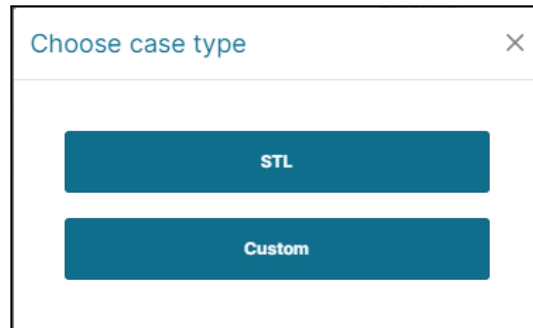
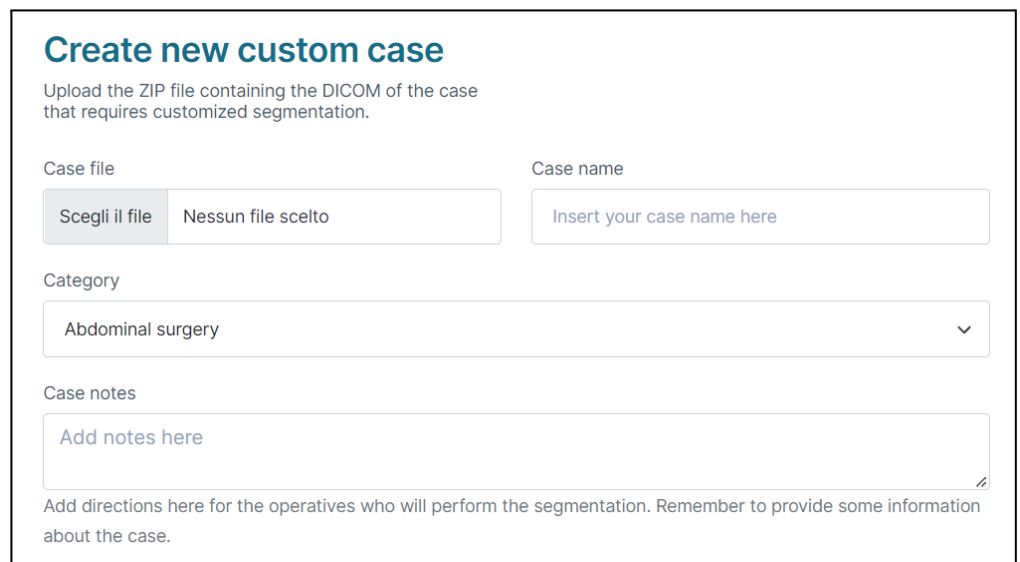


Figure 3 - Upload panel of supported file types

The platform now gives the option of creating a new clinical case from the DICOM file on the computer, using the appropriate screen ("Fig. 4"). The user can select the .zip file that is to be uploaded (Case file), choose the name for the case (Case name), select the appropriate surgery field (Category), and add notes and additional information useful for Witapp team to proceed with tissue segmentation (Case notes).



Create new custom case

Upload the ZIP file containing the DICOM of the case that requires customized segmentation.

Case file: Nessun file scelto

Case name:

Category:

Case notes:

Add directions here for the operatives who will perform the segmentation. Remember to provide some information about the case.

Figure 4 - Custom case creation

Finally, the user must decide how many and which anatomical tissues are to be identified within the case ("Fig. 5"). Through the appropriate section (Set case layers), the user enters one by one the layers names (i.e., tissues) that are to be segmented (Layer name), specifying for each one the display color (Color) and the opacity percentage (Opacity %). To add layers it is necessary to click on the "Add new layer" button.

Figure 5 - Anatomical tissues/layers identified.

Once all fields are filled in, the system is ready to generate the case via the "Create case" button ("Fig. 6").



Figure 6 - "Create case" button

Import STL files and create an STL case

Verima Desk allows direct loading of STL files that the user has available on their local memory, originating from a segmentation that has already occurred. Each STL corresponds to a segmented anatomical tissue (layer). Please check the same procedure as for creating the Custom case ("Fig. 3"). In this case, however, the user clicks on the "STL" button.

The page for creating the STL case is proposed in Fig. 7. The user has the option to edit the attributes of each loaded file, according to their visualization needs. They will first have to choose the case name (Case name) and for each segmented tissue they will have the option to load the appropriate STL file (Layer file), choose the name (Layer name) and change its color (Color) and opacity (Opacity %). To add layers it is necessary to click on the "Add new layer" button.

Figure 7 - STL case creation

Once all fields are filled in, the system is ready to generate the case via the Create case button ("Fig. 6").

3D processing and reconstruction for a new case

After a new case is created, it will appear in the user's archive accessible on the left panel "My Cases" ("Fig. 8").



Figure 8 - "My Cases" panel

The recently created case will be labeled "PENDING" in orange under STATUS, and the processing outcome will depend on the type of file uploaded by the user:

- In case of Custom case creation, via DICOM upload, the Witapp team will work on 3D reconstruction of the radiologic exam and notify the user via email of the segmentation success. At that point, the STATUS item will change from PENDING to SUCCESS (in green).
- In case of STL case creation, the user will only need to wait a few seconds for the platform to automatically process the desired 3D reconstruction. The status, as above, will change from PENDING to SUCCESS (in green).

Once the processed case is available, the ability to access the information and preview of the uploaded case will appear under DETAILS via the "View details" button ("Fig. 9").



Figure 9 - STATUS and DETAILS items for a successfully processed case.

Clinical case details

Once you click on "View details" ("Fig. 9"), the interface shows all the information regarding the generated clinical case. Using the edit button with the pencil icon in the upper right corner ("Fig. 10"), Verima Desk allows you to edit the attributes of the generated clinical case ("Fig. 11"):

- case name (Case name);
- layer name (Layer name)
- layer color (Color);
- opacity of the layer (Opacity %).



Figure 10 - Buttons for attribute editing and case deletion

A screenshot of the 'Case details' interface. At the top, there is a 'Case name' field containing 'Splenic Aneurysm - 03' and a 'Favourite' button with a star icon. Below this is a 'Case layers' section with five rows. Each row has a 'Layer name' field, a 'Color' field with a color swatch, and an 'Opacity %' field with a value of 100. The layers are: Arteries (red), Kidney (orange), Liver (dark red), Spleen (purple), and Veins (blue).

Figure 11 - Case attributes

Through the interface in Fig. 10, it is also possible to add the case to favorites by clicking on the appropriate icon in the upper right corner. Also in the right section of the interface (Fig. 12), it is possible to appreciate a preview of the generated 3D model and access the clinical case sharing options by clicking on "Manage sharing" (Fig. 13).

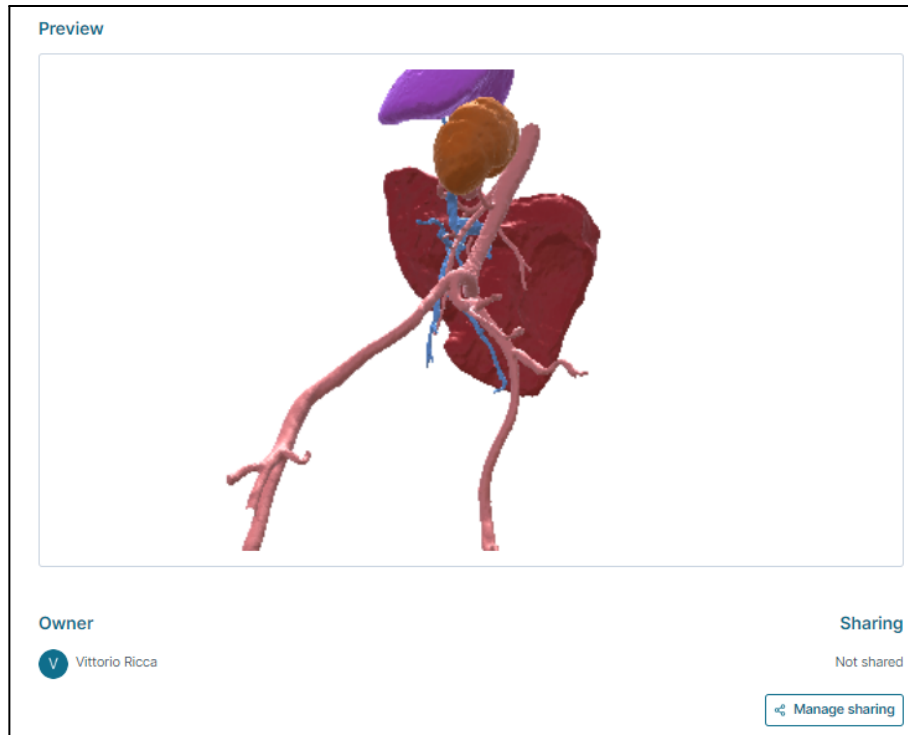


Figure 12 - 3D model preview and case sharing details

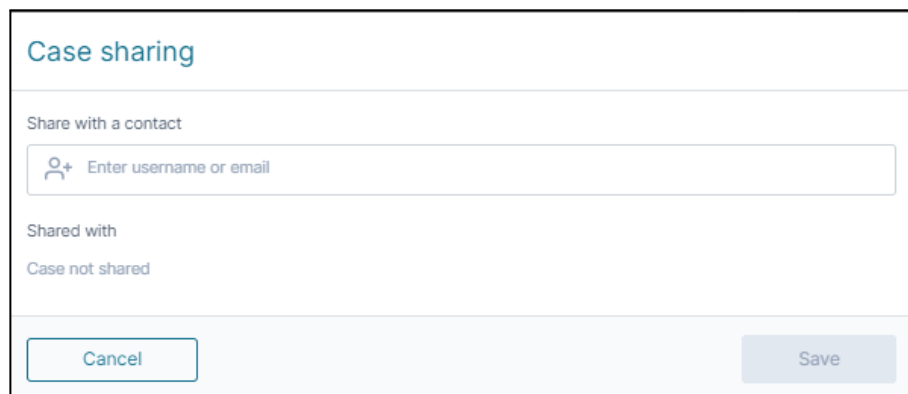


Figure 13 - Panel to set up case sharing

Through the interface in Fig. 13, it is possible to add the name of an existing Verima user or the email address of a user outside Verima to let them access the shared case.

Finally, the "Open the case" button ("Fig. 14") gives the user the ability to access the 3D viewer ("Fig. 15") integrated with Verima Desk to view and rotate the 3D model of the clinical case under consideration.

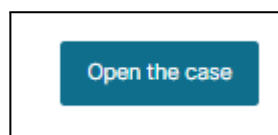


Figure 14 - Open the case button



Figure 15 - Integrated 3D Viewer

Cases shared

Verima Desk users can access cases that have been previously shared by another Verima user via the "Shared with me" section ("Fig. 16"). The case shared by another user is available for 3D access and display as described in the previous section, but it will not be possible to change its attributes.



Figure 16 - Shared with me section.

2.4 Image requirements

The quality of the obtained three-dimensional model is strongly influenced by the quality of the images that are processed by the software.

To achieve good quality of the 3D model, it is recommended that the images used meet the following parameters:

- Slice thickness not exceeding 2 mm;
- Axial, unreconstructed images;
- Medium resolution bone tissue reconstruction algorithm;
- if possible, low dose.

To visualize non-bony tissues, it is necessary to process images from examinations with contrast medium.

If metallic implants are present, an artifact reduction filter should be applied before sending DICOMs.