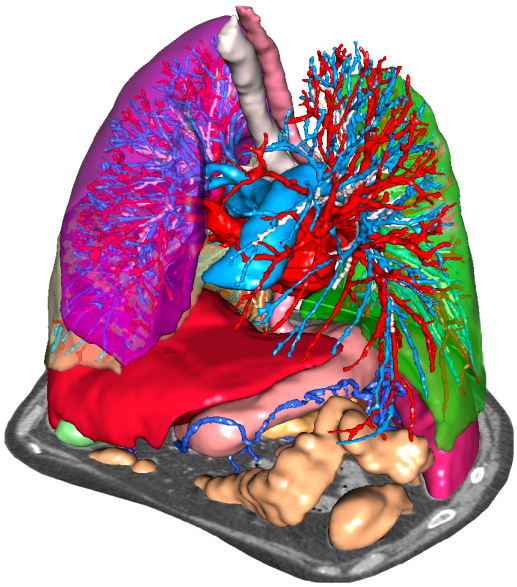
VISIBLE PATIENT

# Visible Patient Planning

Version: 1.0.17-md

April 2022

## User documentation



**Unique device identifier (UDI)**

*+B373VPS10170/$$71.0.17M*

Software instructions for use (in English and other available languages) can be downloaded at https://www.visiblepatient.com//en/go/planning-vps/user-manual. Hard copy of instructions for use can be requested at contact@visiblepatient.com at no additional cost and delivered to the customer within 7 calendar days.

# Indications for use

Visible Patient Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for both pediatric and adult patients. Visible Patient Suite accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT, MR.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), image fusion, surface rendering, measurements, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

**℞ Prescription use only**

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

# Approvals

CE 0459

This medical device software is **CE marked** and **FDA cleared**. It can therefore be used in clinical routine and/or for patient care in member states of the European Union where national regulations are respected and the USA (complete list of countries available at https://www.visiblepatient.com/en/go/planning-vps/countries).

**Use of this software is not allowed in countries not mentioned in the list above.**

In these countries, the software is considered as a prototype software and *its use is limited to demonstration, research, or educational purposes*. Any other use is strictly prohibited, clinical use on humans in particular.

First date of CE marking: 2014

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# 1 Indications for use

## 1.1 General

Visible Patient Suite is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for both pediatric and adult patients[1]. Visible Patient Suite accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT, MR.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), image fusion, surface rendering, measurements, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

*(1) See section "Intended patient population" for more details.*

## 1.2 Intended patient population

Intended patients of VP Suite can be all patients whose physician needs a specific 3D model of their anatomical and pathological structures to optimize their therapy definition.

The Visible Patient Suite can be used regardless of the patient's age.

| |
|---|
| ☒ Neonate/Newborn (birth through 28 days) |
| ☒ Infant (from 29 days to 2 years of age) |
| ☒ Child (from 2 years to 12 years of age) |
| ☒ Adolescent (from 12 years to 18 years of age) |
| ☒ Transitional Adolescent (18 through 21 years of age) |

| |
|---|
| ☒ Adults (greater than 21 years of age) |

The patient is not the user of VP Suite software.

## 1.3 Intended users

For Visible Patient Planning software, the users shall have some knowledge in:

- Human anatomy and pathology
- Medical and technical language

The software is intended to assist the physician who is solely responsible for making all final patient management decisions.

# 2 Contraindication

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images (MG).

# 3 Intended performances and claims

## 3.1 Clinical performances

The Visible Patient Suite does not claim any clinical performance.

## 3.2 Safety claims

VP Planning v1.0.17 is a stand-alone software. Any direct clinical risk to neither user nor patient is identified. Thus, there is no expected undesirable side-effects in the use of VP Planning version 1.0.17.

However, some indirect Adverse Device Effects have been identified and could occur:

1. Minor injuries to patients due to longer operating time or unnecessary incisions during surgery due to a patient modeling of poor quality.
    - Transparent 3D models may be poorly displayed and result in a patient modeling interpretation of poor quality (see hardware requirements to avoid this type of error).
    - Image volume rendering may be poorly displayed and result in a patient modeling interpretation of poor quality (see hardware requirements to avoid this type of error).
    - Real vascular territories may not represent the real anatomy and result in a patient modeling interpretation of poor quality.
    - A hacker may find and exploit a software or a environment vulnerability to modify the device or the medical records to alter medical information.

2. Minor injuries to patients due to longer operating time or unnecessary incisions during surgery when the wrong patient (=another patient) is analyzed.
    - A wrong patient may be selected to perform an action and result in wrong patient analysis (pay attention to the displayed patient information).
    - A wrong patient may be analyzed when several patients are open in the software and result in wrong patient analysis (pay attention to the displayed patient information).
    - A study of another patient may be selected when some results are exported and result in wrong patient analysis (pay attention to the displayed patient information).
    - Software issue may occur with patient information management and result in wrong patient analysis.
    - A hacker may find and exploit a software or a environment vulnerability to modify the device or the medical records to alter medical information.

## 3.3 Security claims

Protected Health Information (PHI) are not exposed with the use of this medical device. The device is not designed to allows private data transfer nor private data storage.

The document informs users of the precautions to be taken regarding the security of the IT environment and the transfer of personal data (see Cautions).

## *3.4* Technical performances

The Visible Patient Planning allows medical team to:

- Analyze DICOM medical images (supported modalities: CT, MR)
- Understand anatomical structures localization
- Estimate and model anatomical structures segments
- Compute volumes of interest relative to an organ resection planning

All functionalities of the Visible Patient Suite were tested during the test phase of the development. Each feature can be used for pediatric or adult patients. For the volume computation and distance measurement, all tests were performed on phantom data with pre-established physical characteristics (specific measures and volumes).

In addition, a literature study and post-market assessment were conducted to support the device performance and intended use.

# 4 Cautions

## 4.1 General caution

This software is designed to be used by trained medical professionals and is intended to assist the clinician who is solely responsible for making all final decisions.

## 4.2 Secure computing environment caution

The device shall be installed on a secure environment, compliant with cybersecurity rules. These rules or guidelines may differ from country to country. The section IT security requirements presents the general security recommendations.

## 4.3 Medical records management caution

The device produces or uses medical records that can be stored by health professionals or transferred between them to perform device intended uses. The medical record management (transfer, storage, etc) shall comply with the rules for the protection of personal health information. The section IT security requirements presents the general security recommendations.

## 4.4 3D model with transparency visualization caution

Several activities provide 3D model visualization with the possibility to use transparency. The rendering quality is dependent on the computer's hardware (especially the graphics card). If the computer does not comply with the hardware requirements, there can be visualization approximations when 3D model transparency is enabled. The following activities are concerned:

- 3D model visualization
- MPR3D visualization
- Clip applying activity
- Volume rendering activity

## 4.5 Volume rendering caution

The rendering quality and reliability depend on the computer's hardware (especially the graphics card). If the computer does not comply with the hardware requirements, there can be visualization approximations when merging volume rendering and 3D model rendering with transparency.

## 4.6 Anatomical structures volumes caution

In Visible Patient suite, anatomical structure volumes are available through the organ manager and clip applying activity. These volumes are computed from images. Consequently, the precision of these volumes depends on native image quality (image voxel size).

For more information, please refer to *Vascular and airways territories estimation*.

## 4.7 Organ segments visualization caution

Organ segments visualization activity (Clip applying activity) is based on territories reconstruction, and segments are deduced from an image. Consequently, organ segments are an approximation of the reality.

## 4.8 Distance measurement caution

The measurement tool manipulation requires extreme precision. While measuring a distance on a 3D image, both contrast and level of zoom need to be precisely set otherwise measurement inaccuracy could happen. While measuring a distance on a 3D model, level of zoom needs to be precisely set.

# 5 Technological characteristics

## 5.1 System requirements and characteristics

Visible Patient Suite is designed to run on a standard standalone platform, through the installed operating system (Windows or Mac). The hardware of such platform consists of an "off-the-shelf", standard PC computer. Furthermore, all software included in the suite (explained in detail below) can be installed on different computers and they are not required to be interconnected through a network.

### 5.1.1 PC- Minimal System Requirements

- **Operating System**: Windows 7 x64
- **Processor**: Intel Core i3
- **Video**: Dedicated graphics card (since 2012)
- **Memory**: 4 GB RAM
- **Storage**: 10 GB available HD space
- **Internet**: Broadband Internet connection
- **Resolution**: 1024x768 or higher

### 5.1.2 PC- Recommended System Requirements

- **Operating System**: Windows 7 x64
- **Processor**: Intel Core i7 – 2.5 GHz
- **Video**: Nvidia GeForce GTX 760 or better
- **Memory**: 16 GB RAM
- **Storage**: 300 GB available HD space
- **Internet**: Broadband Internet connection
- **Resolution**: 1920x1080 minimum display resolution

### 5.1.3 Mac – Minimal System Requirements

- **Operating System**: Mac OS 10.12. Any Apple computer released since 2010
- **Video**: Dedicated graphics card

### 5.1.4 Mac – Recommended System Requirements

- **Operating System**: Mac OS 10.12. Any Apple computer since late 2013 release
- **Video**: Dedicated graphics card

## 5.2 Application overview

### 5.2.1 Visible Patient Planning

Visible Patient Planning includes modules dedicated to data management and data analysis, and simply contains a subset of the software modules present in Visible Patient Lab. This software offers a flexible visualization solution to help trained medical professionals (usually clinicians) in the evaluation of patient's anatomy and pathology to plan therapy or surgery.

This software provides a tool to load images and 3D models created with Visible Patient Lab. These images and models can be displayed based on physician preferences using configurable viewing options or standard protocols. Visible Patient Planning provides the clinician with a broad set of viewing and analysis tools to measure and output selected image and models views

## 5.3 Application modules

The modules of Visible Patient Suite can be grouped by categories:

| Category | Functionality | VP Planning |
|---|---|---|
| Data management | Image DICOM reader (MR/CT) | X |
| Data management | Visible Patient data reader/writer | X |
| Image and surface analysis | 2D image multi-planar representation (MPR) | X |
| Image and surface analysis | Image volume rendering | X |
| Image and surface analysis | Anatomical atlas | X |
| Image and surface analysis | 3D model visualization | X |
| Image and surface analysis | 3D model and image visualization | X |

| | | |
|---|---|---|
| Image and surface analysis | Organ segments visualization | X |

The table above groups each software module into: data management, image and surface analysis and image and surface processing. In addition, each individual software module is discussed in more detail below.

### 5.3.1 Image DICOM reader (MR/CT)

This module allows the software to read DICOM files and supports MR and CT modalities. The 3D data volume interpretation (2D DICOM slices merging) is automatic in this module.

A DICOM series contains many 2D DICOM slices and these series slices can represent different data volume. To build each 3D data volume, slices need to be filtered, split and reordered. This DICOM reader uses each slice 3D position / orientation and slice acquisition time to split and reorder slices, as well to provide an automatic 3D data volume reconstruction.

DICOM reader is used to read a DICOM folder, import 2D DICOM slices, and automatically interpret data to rebuild all 3D data volumes (3D images).

### 5.3.2 Visible Patient data reader/writer

This module allows users to save and load data produced by Visible Patient Lab. This data contains images, 3D patient model, etc. This module also manages data backwards compatibility. Data are saved in a proprietary format on filesystem with a system to check: (1) the file integrity to secure transfer to another computer, and (2) the file version to manage software evolution and compatibility.

Visible Patient data reader is used to read a Visible Patient Suite file. All data generated by Visible Patient Lab are stored in this file: 3D images, 3D models, anatomical atlases and organs segments.

### 5.3.3 2D image multi-planar representation (MPR)

MPR corresponds to the most standard visualization technique developed and used on professional medical imaging workstations. The 2D MPR visualization activity allows one to visualize an image in different orientations, such as axial, frontal and sagittal. It also includes image windowing, change of the active image slice, translation, zoom- in/zoom-out, voxel information (coordinates and density), focus on a part of the image, distance computation, scene snapshot, etc. Image boundaries are shown by a colored square (red, blue or green) according to the current axis.

### 5.3.4 Image volume rendering

The image volume rendering module corresponds to advanced visualization techniques developed and used on professional medical imaging workstations: a 3D representation of the data volume. This module allows this visualization and includes a transfer function editor and several automated pre-computed transfer functions to propose different 3D renderings.

### 5.3.5 Anatomical atlas

This module allows user to merge two planar image representations with transparency, and to visualize the result slice by slice. The first image is the CT/MR data, the second one is the patient anatomy atlas (a color image where each organ is represented). This activity allows one to check if the anatomical atlas is accurate and provides users a better understanding of the patient's anatomy.

### 5.3.6 3D model visualization

This module allows one to review the 3D patient model and its volume with classic 3D interactions, such as rotation, translation, zoom-in/zoom-out. It is possible to manage organ visibility/ transparency to improve the visualization.

### 5.3.7 3D model and image visualization

This module allows the user to combine a 3D image MPR and a 3D model in the same view. All features described in "2D image MPR" and "3D model visualization" are available here as well.

### 5.3.8 Organ segments visualization

This module allows one to review the 3D organ's segments and their volume compared to the organ volume. As outlined in the proposed indication for use, this module is only available for advanced lung/liver/kidney modeling. The interaction is based on tubular structures to select vascular/airway segments.

# 6 Installation instructions

Visible Patient Suite installation can be started from a software executable file.

## 6.1 IT security requirements

### 6.1.1 Secure environment

The device shall be installed on a secure environment, compliant with cybersecurity rules. Moreover, the device produces or uses medical records that can be stored by health professionals or transferred between them to perform device intended uses. The medical record management (transfer, storage, etc) shall comply with the rules for the protection of personal health information.

These rules or guidelines may differ from country to country. Below are the general security recommendations to follow to manage the environment security:

- Thanks to the operating system's authentication mechanism, the environments (the software environment and the data storage environment) shall be restricted to authorized users to limit access to the device.
- A layered authorization model shall be employed for the management of the environments by differentiating privileges based on the user role (e.g., system administrator, health professional).
- The environments shall lock when the user is inactive thanks to the operating system's auto-lock mechanism.
- The remote access to the environments shall be controlled and authorized only for trusted user thanks to operating system tools, firewall configurations or infrastructure rules.
- An anti-virus software shall be installed and shall control the environments. The device is designed to allow routine security and antivirus scanning such that the safety and essential performance of the device is not impacted.
- Medical records shall be provided to and from health professionals via a secured network file transfer system which guarantees the appropriate security level of personal health information.

### 6.1.2 Package verification

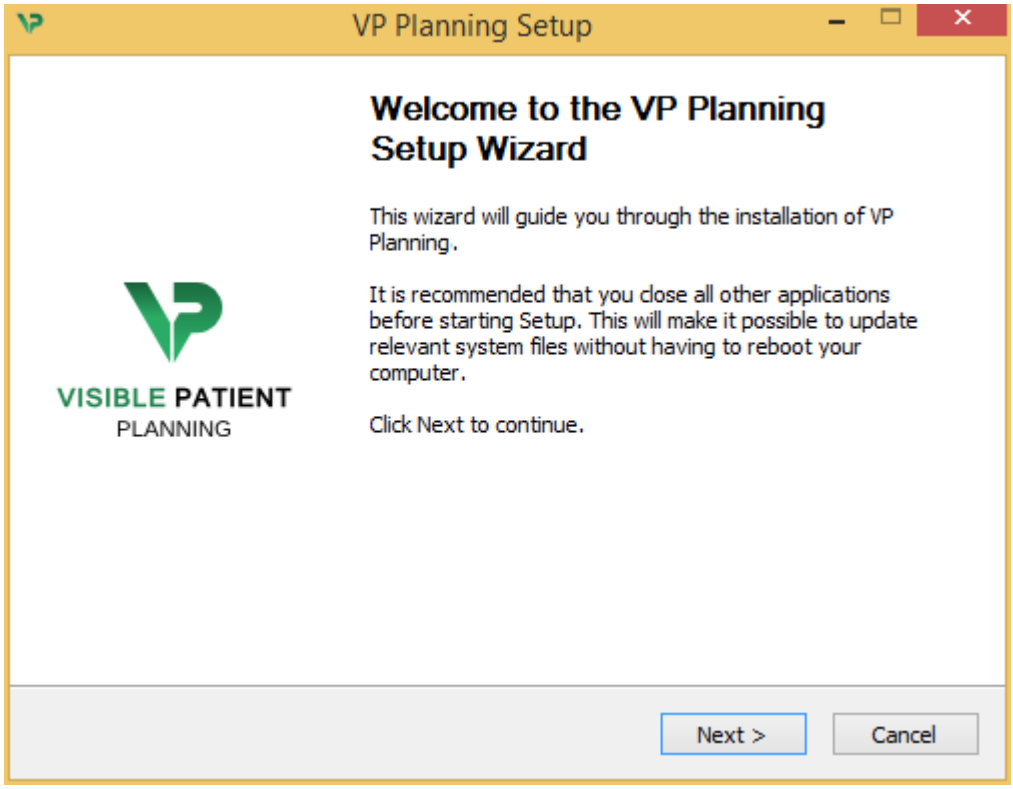
Below are general recommendations to follow before installing the device.

- The package integrity shall be verified after its download (the package hash is provided on the company website).
- The software authenticity shall be controlled before the installation. Visible Patient company signed all these packages.
- The device shall be installed by a system administrator in a location where standard user cannot write to protect the device.

## 6.2 How to install Visible Patient Planning on Windows

### 6.2.1 Start the installation

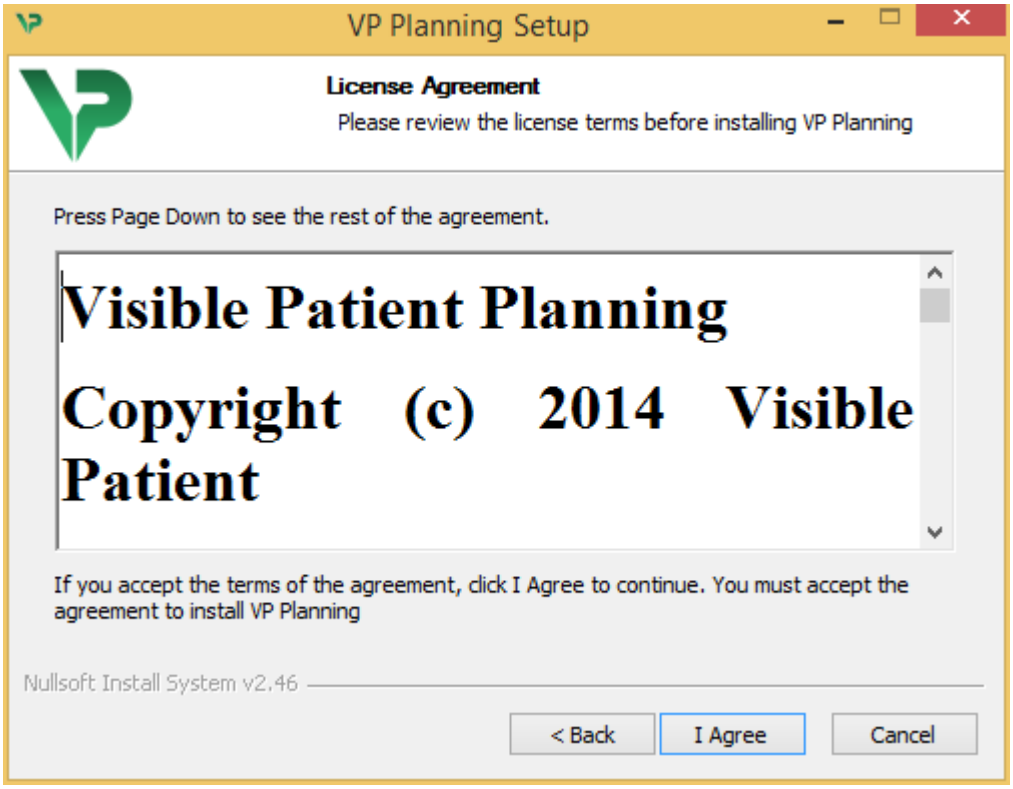
Double click the installation file provided by Visible Patient: the following installation welcome dialog will be displayed.




Click “Next”.

### 6.2.2 Accept the license

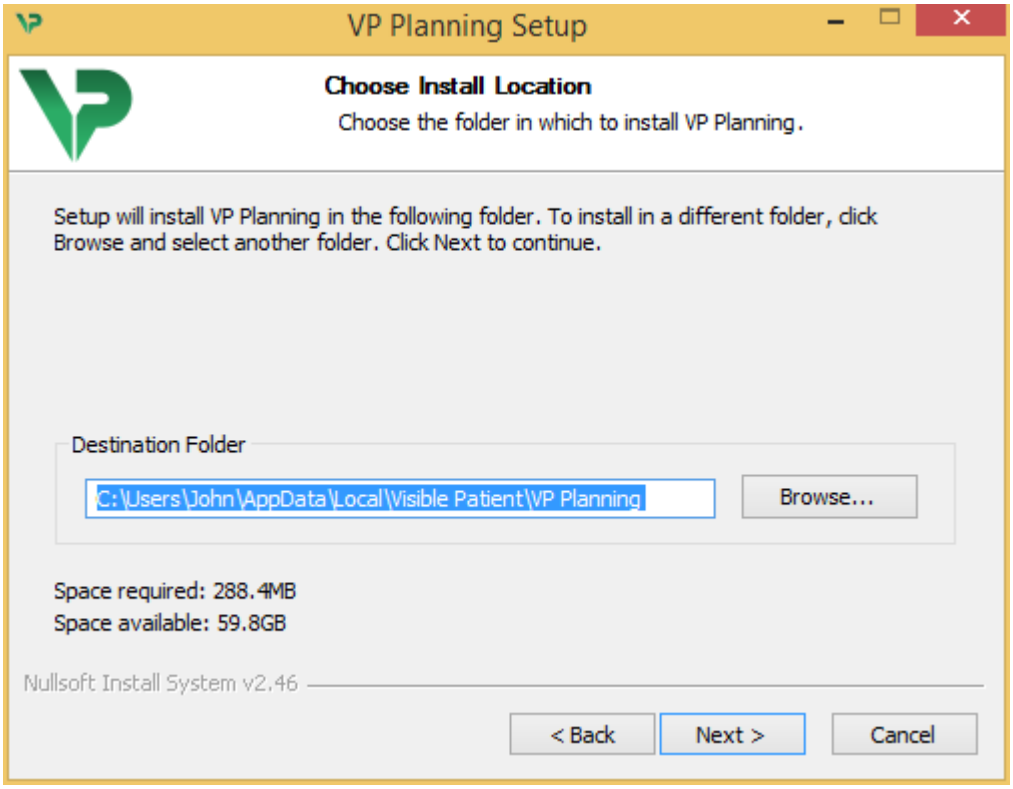
License agreement is displayed.



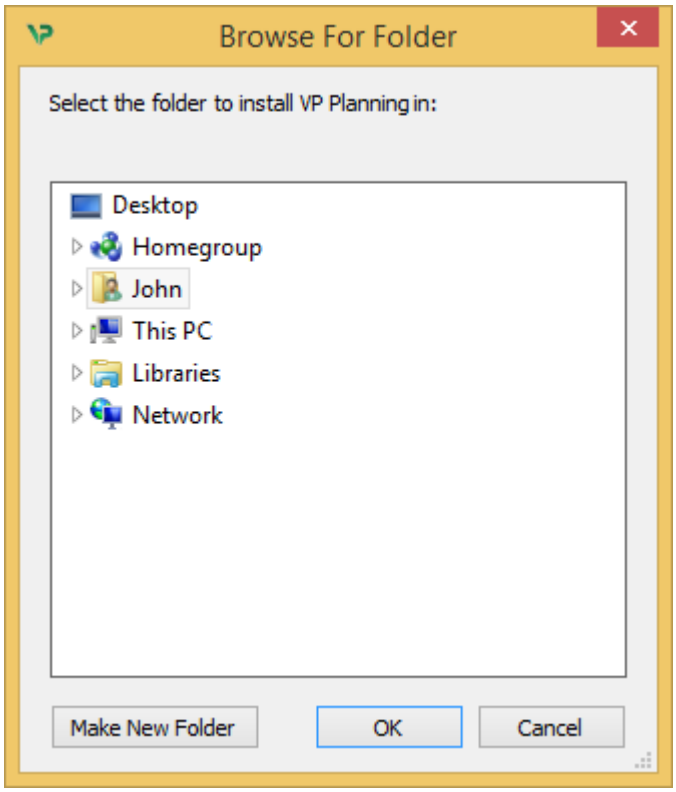

Read the license agreement and click “I agree” to continue the installation. (If you do not agree, click “Cancel” to cancel the installation.)

### 6.2.3 Select the destination folder

The destination folder where the software will be installed is displayed.



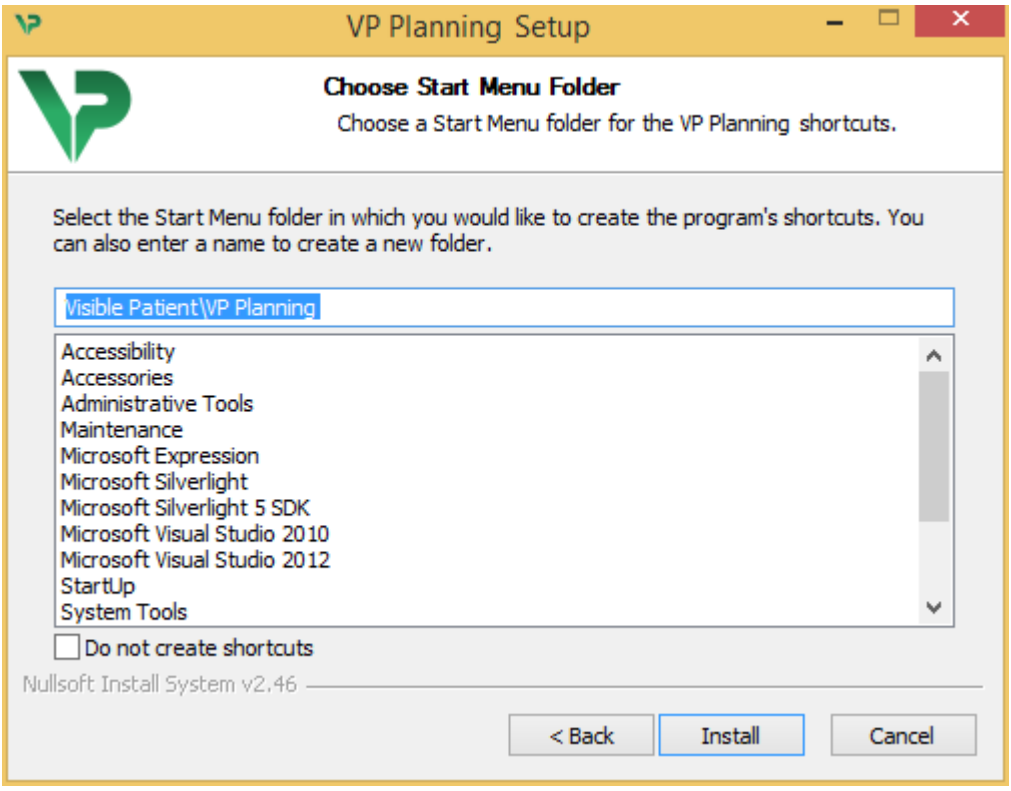

You can change this destination folder by clicking “Browse” and selecting a new destination folder. You can also create a new one by clicking “Make New Folder”.



Select your destination folder and click “Ok”. To continue the installation, click “Next”.

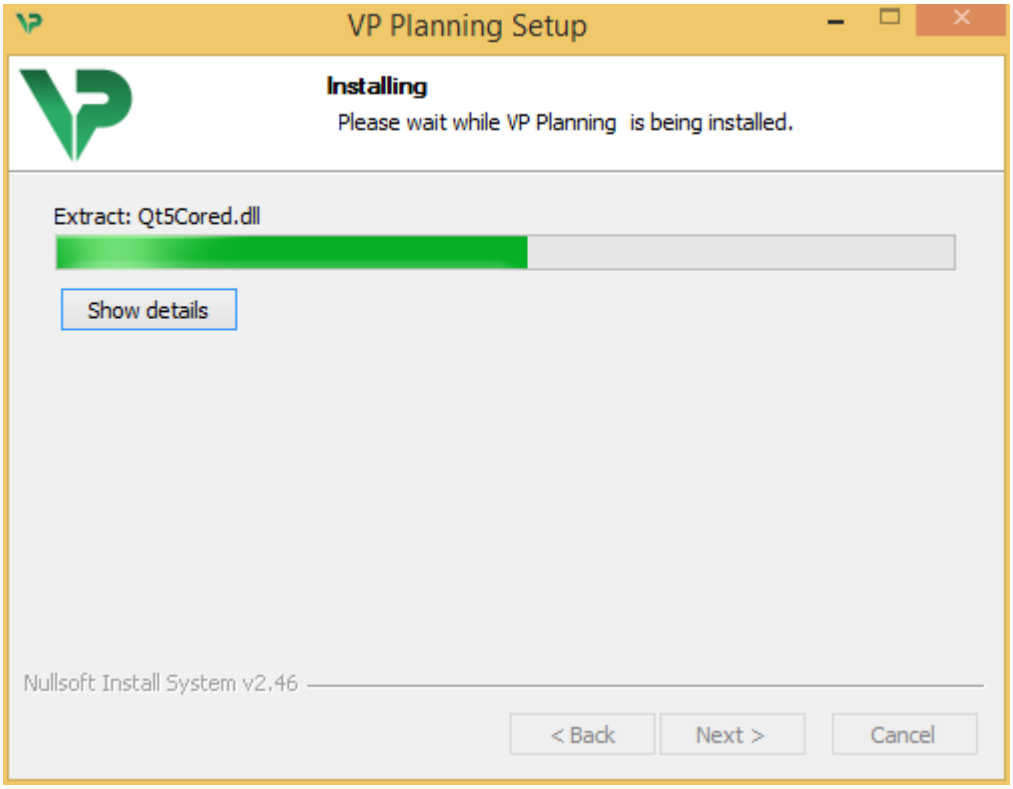
### 6.2.4 Create a shortcut

You can then decide to create a shortcut for easier access to the software. By default, a shortcut will be created on your computer desktop but you can choose another location. You can also enter a name to create a new start menu folder or decide to not create a shortcut.

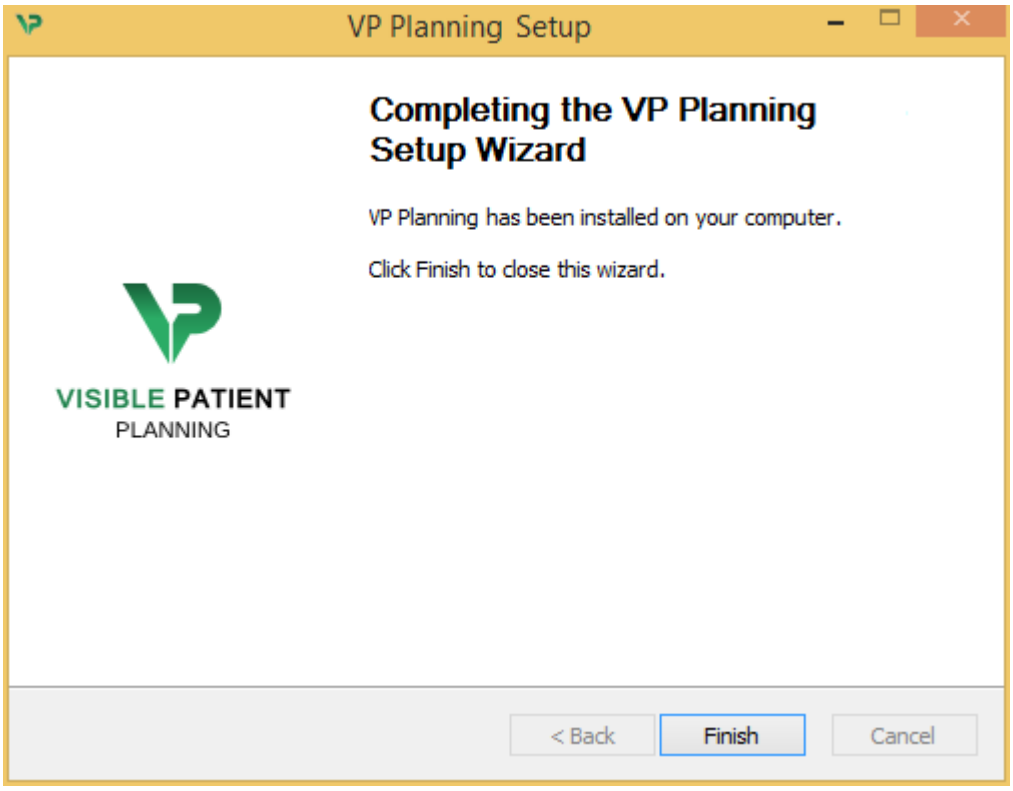



### 6.2.5 Finish the installation

To continue the installation, click “Install”. The installation process starts.




The installation takes a few seconds to proceed. When it is done, a message indicates that the installation is over. Click “Finish” to close the setup window.




Visible Patient Planning is now installed on your computer in the chosen destination folder.

### 6.2.6 Launch the software

You can start Visible Patient Planning by clicking the shortcut created during installation (by default on the computer desktop).

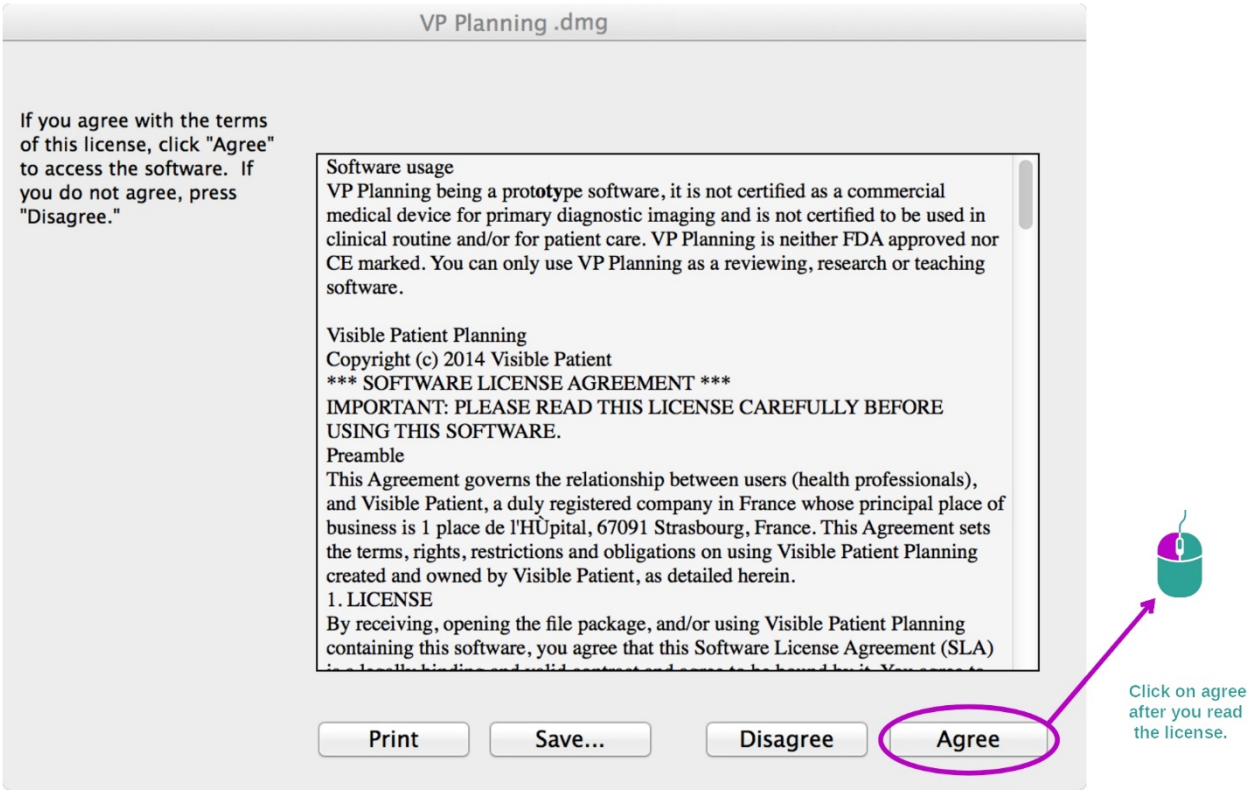
If you encounter any issue with the software installation, please contact Visible Patient at support@visiblepatient.com.

## 6.3 How to install Visible Patient Planning on Mac

### 6.3.1 Start the installation

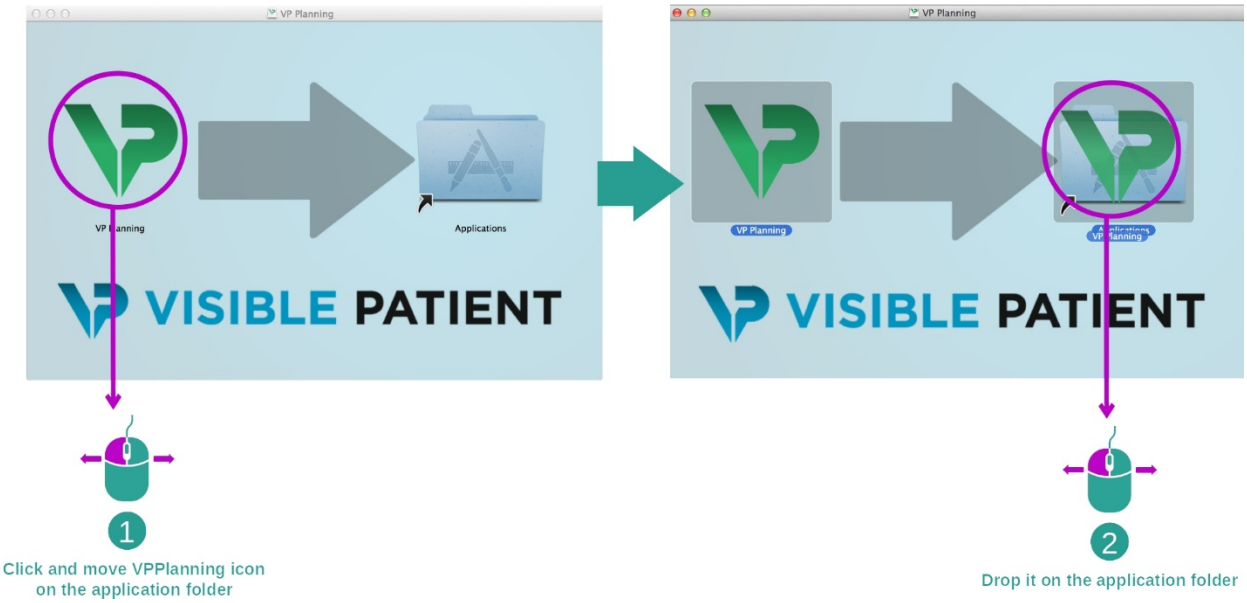
Double click the installation file provided by Visible Patient.

A license agreement window appears. Click “Agree” to continue the installation.




### 6.3.2 Install the application

Drag the Visible Patient Planning app into the application shortcut and drop it.




Visible Patient Planning is now installed.

### 6.3.3 Launch the software

Visible Patient Planning can be started from the application folder by double clicking the Visible Patient Planning icon.

If you encounter any issue with the software installation, please contact Visible Patient at support@visiblepatient.com.

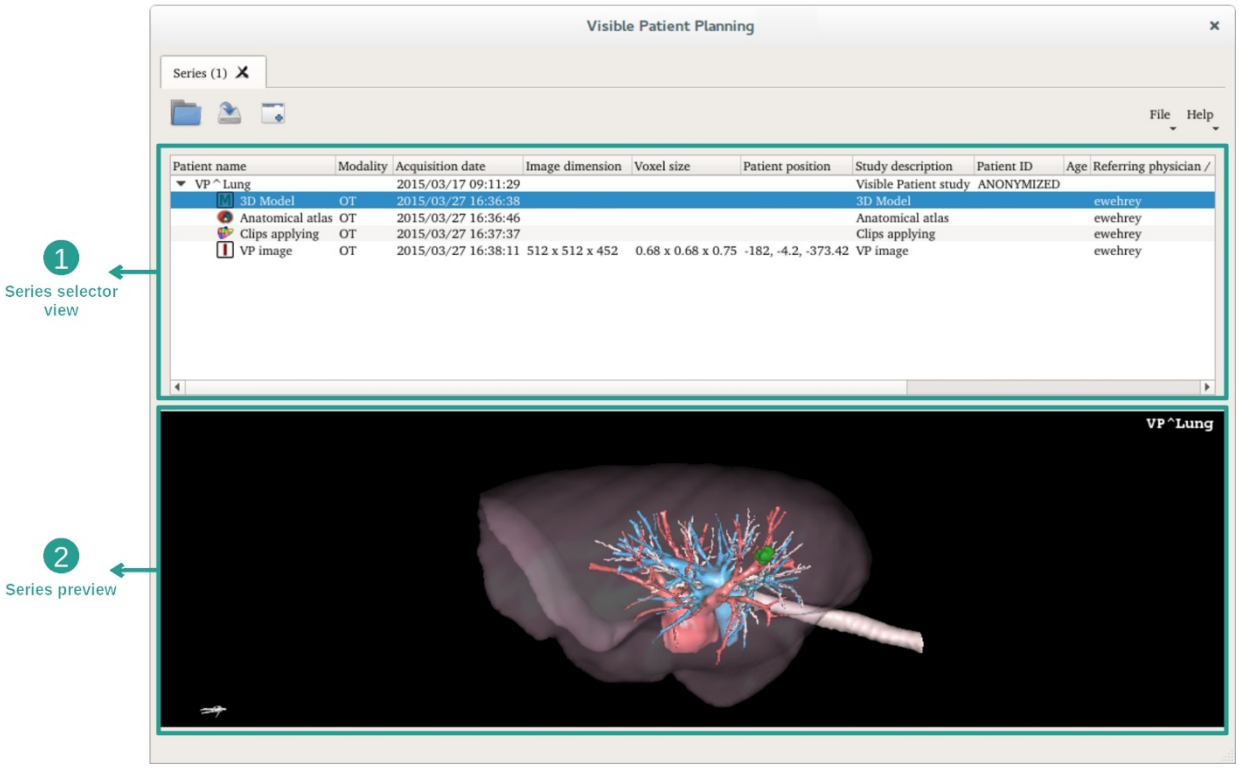
# 7 Instructions for use

## 7.1 How to load data

Each software feature is called an “activity”. Each activity is displayed in a dedicated tab of the application’s main window. The series activity is the main one and it is always available. From this activity, other activities can be started.

In Visible Patient Suite, two types of data can be loaded:

- VPZ data provided by Visible Patient
- DICOM data containing a CT or MR series.



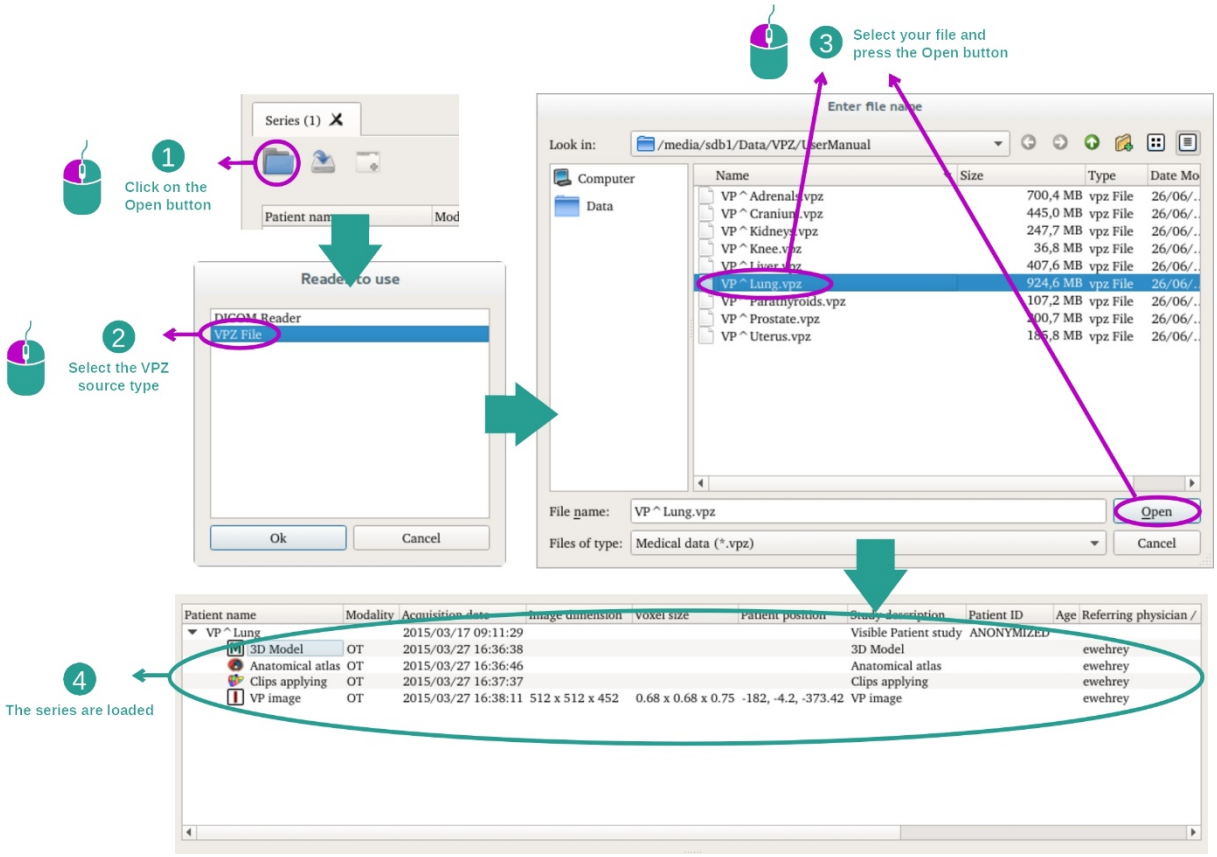

Data is divided into series which can be visualized using the different available activities. Five types of series are available:

- Image series (a medical image)
- Model series (a set of 3D reconstructions)
- Anatomical atlas series
- Clip Applying series
- Modeling series

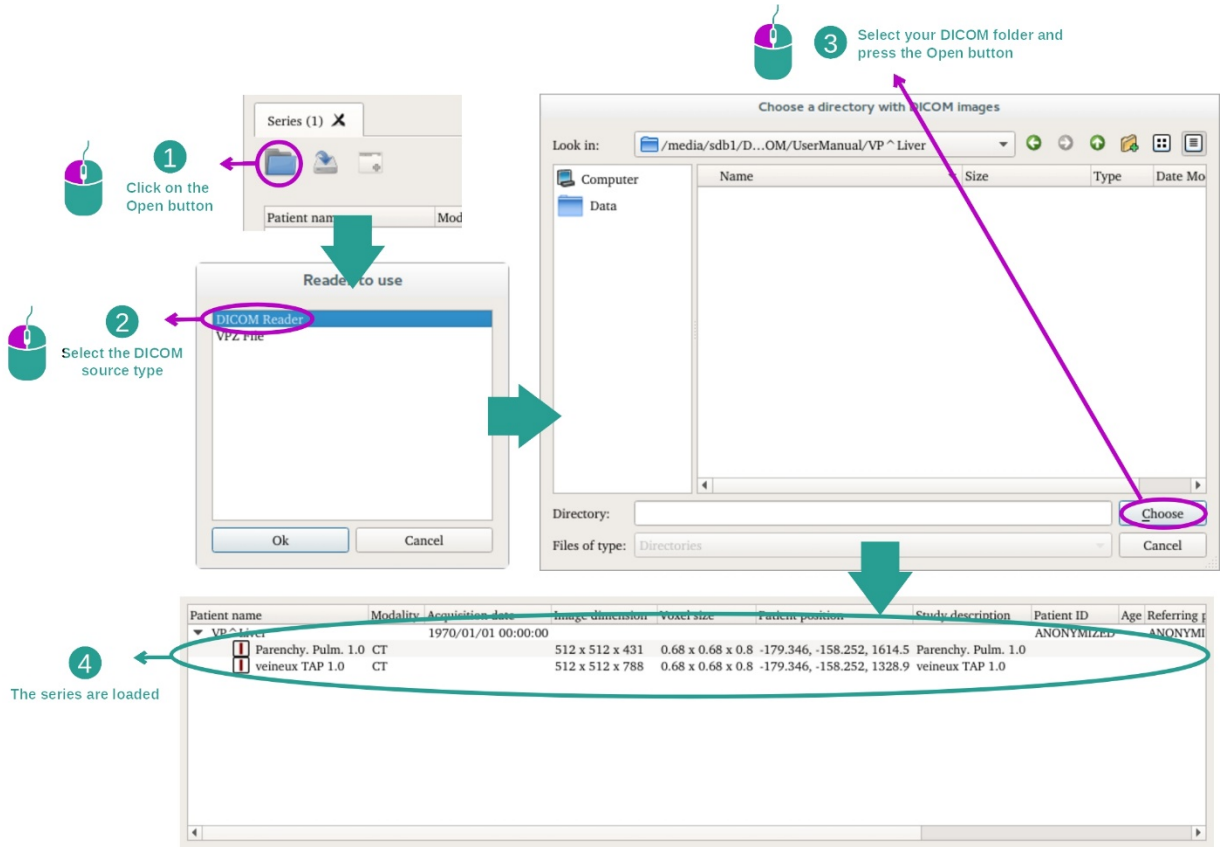
Those series can then be opened in the following activities:

- 2D MPR activity, opened with an image series
- 3D MPR activity, opened with an image series and a model series
- Volume rendering activity, opened with an image series and an optional model series
- 3D Model activity, opened with a model series
- Anatomical atlas activity, opened with an anatomical atlas series
- Dicom reader activity, no input data required
- Sender activity, no input data required
- Clip applying activity, opened with a clip applying series
- Modeling activity, opened with a modeling series

In order to load a VPZ file, click “Open” and select “VPZ File”. In the file selector, select a VPZ file on your computer and click “Open”.




The principle is the same to load DICOM data.



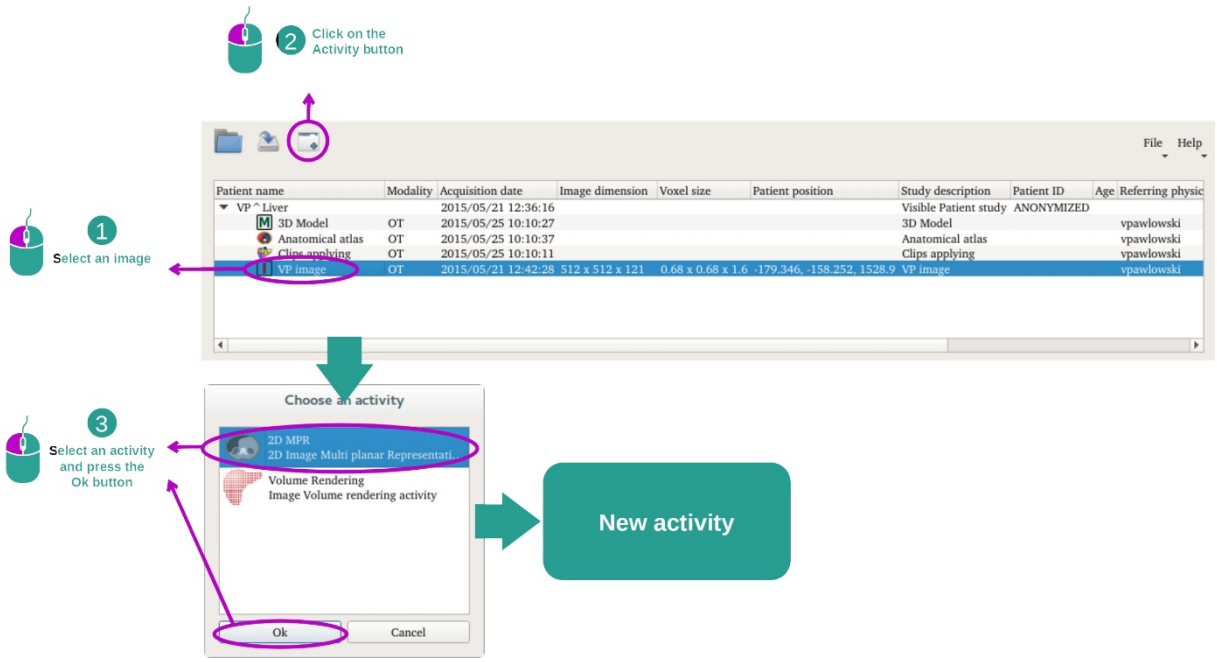

Click “Open” and select “DICOM Reader”. In the file selector, select a folder containing DICOM files and click “Choose”.

## 7.2 How to visualize an image

The 2D MPR activity is dedicated to medical image visualization, particularly anatomical structures. This can be performed in four easy steps. This activity will be introduced by presenting a liver tumor visualization.

It includes functionalities such as anatomical structures measurement and snapshots of the view.

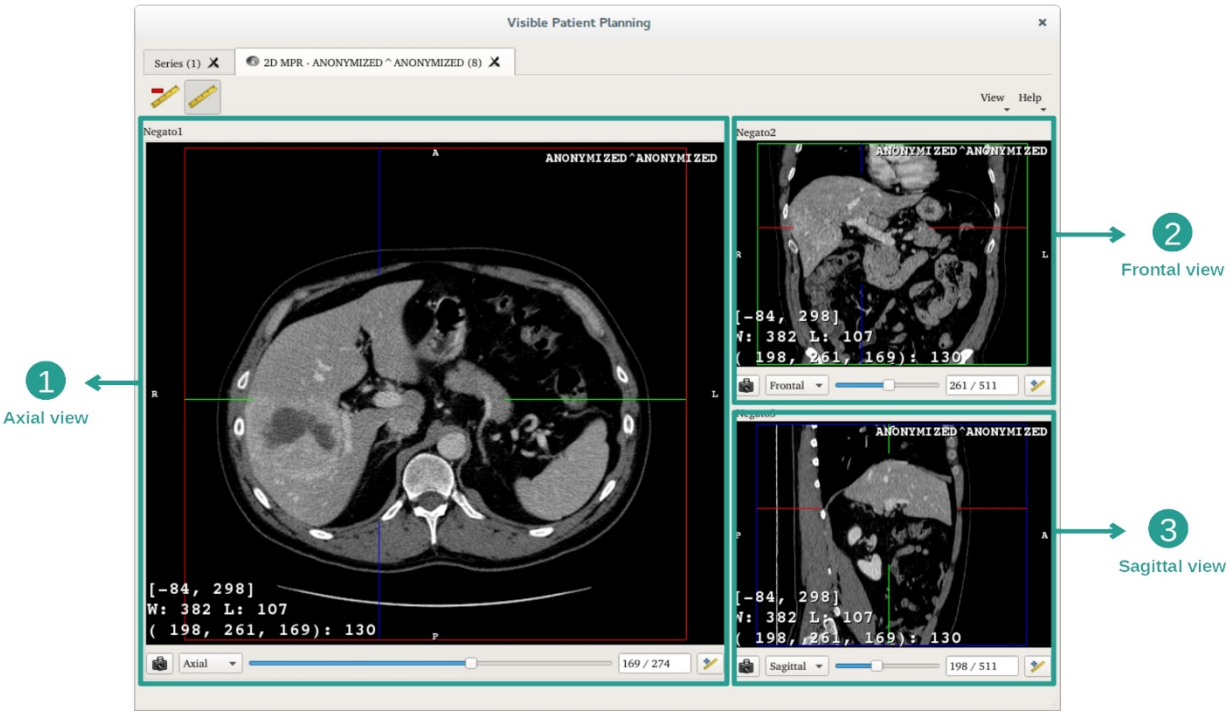
### 7.2.1 Prerequisites




In order to start the 2D MPR activity, select an image series in the Series activity (*How to load data*) and click “Launch activity”. Select “2D MPR” and click “OK”.

### 7.2.2 Visualize the patient’s anatomy

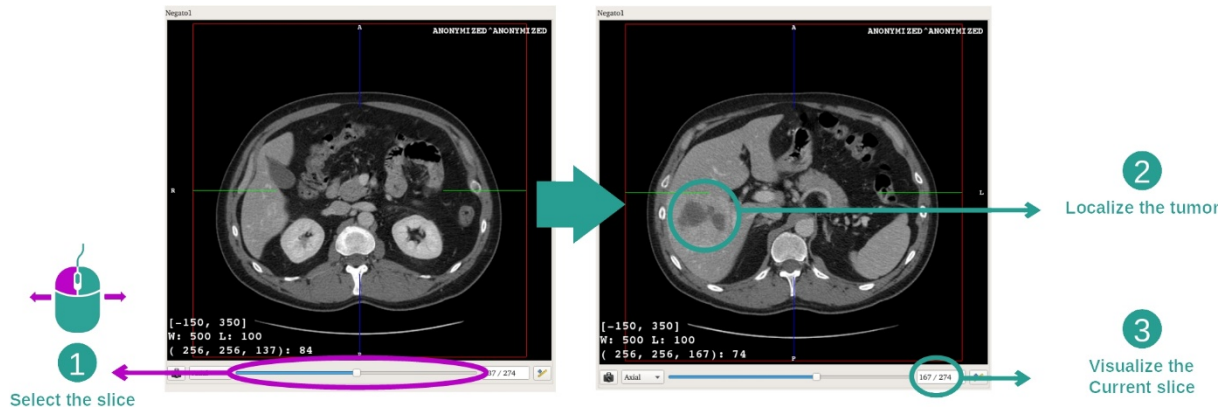
Let’s get started with a short description of the activity layout.




This activity is composed of three views, a main one (left view) representing an axial view of the image and two secondary views representing sagittal and frontal views.

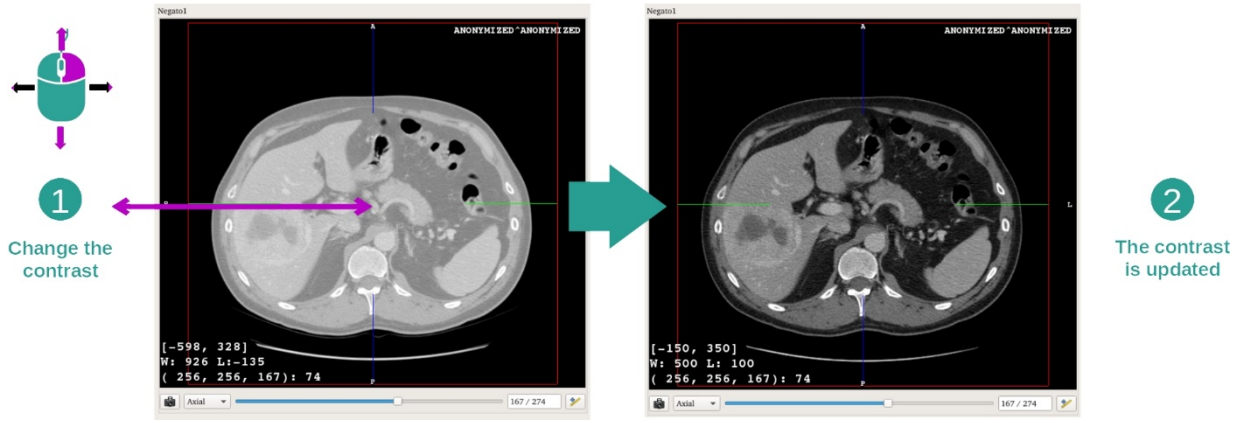
As an example, the following steps will be based on the analysis of a patient's liver tumor.

Step 1: Navigate through slices to localize an anatomical part



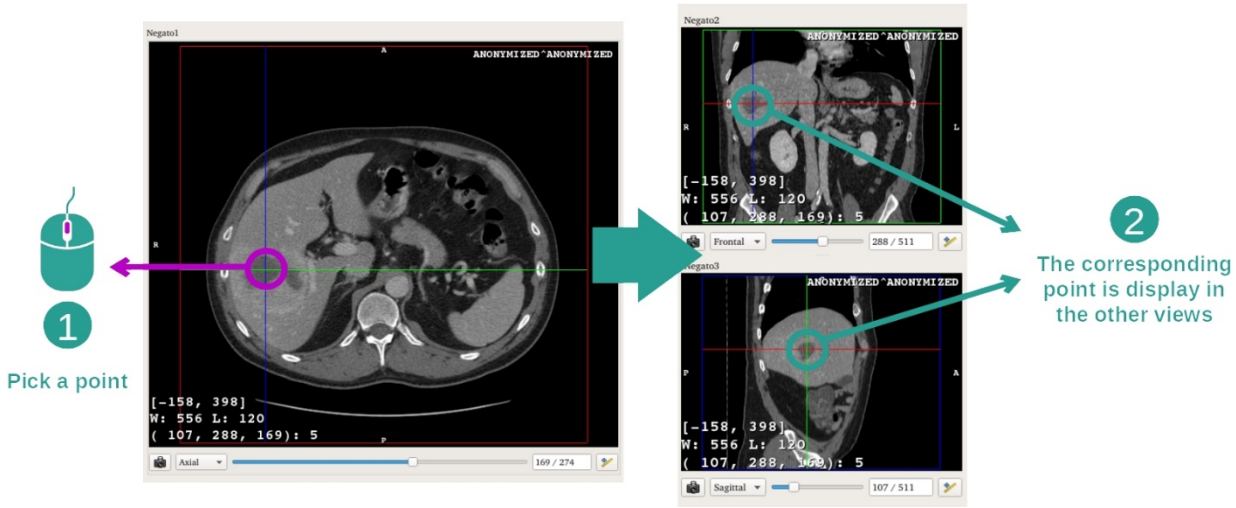

Below the axial view, move the slider to navigate through image slices and localize the tumor inside the liver. To use the slider, click on it and move the mouse.

Step 2: Adjust window level



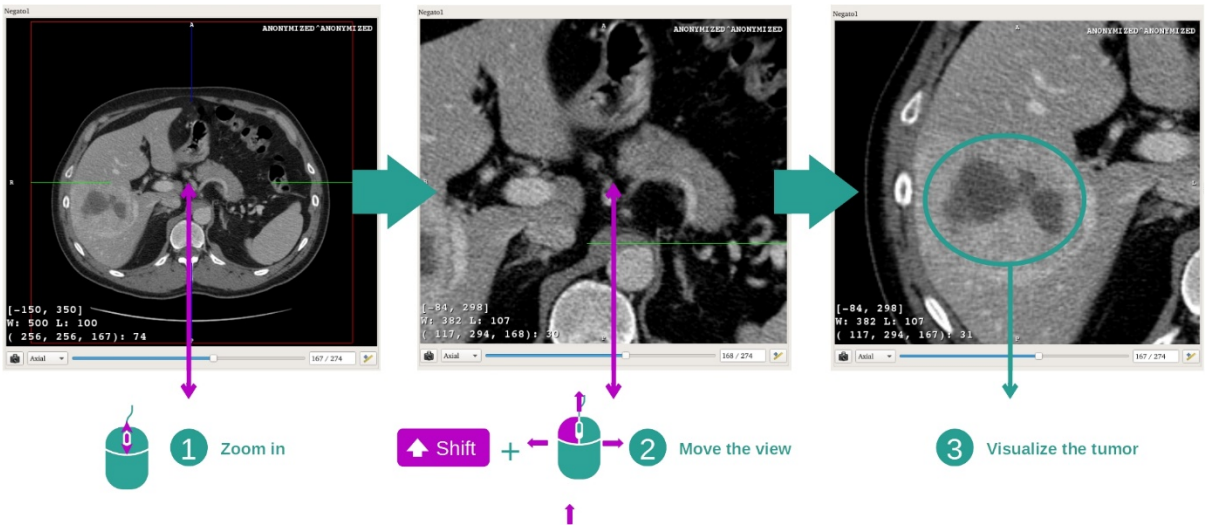

Once the tumor is localized, the window level can be changed by holding right mouse button and moving the cursor on the image.

Step 3: Focus the anatomical part




Use the middle mouse button to focus the liver tumor. When clicked, all three views focus on the clicked point.

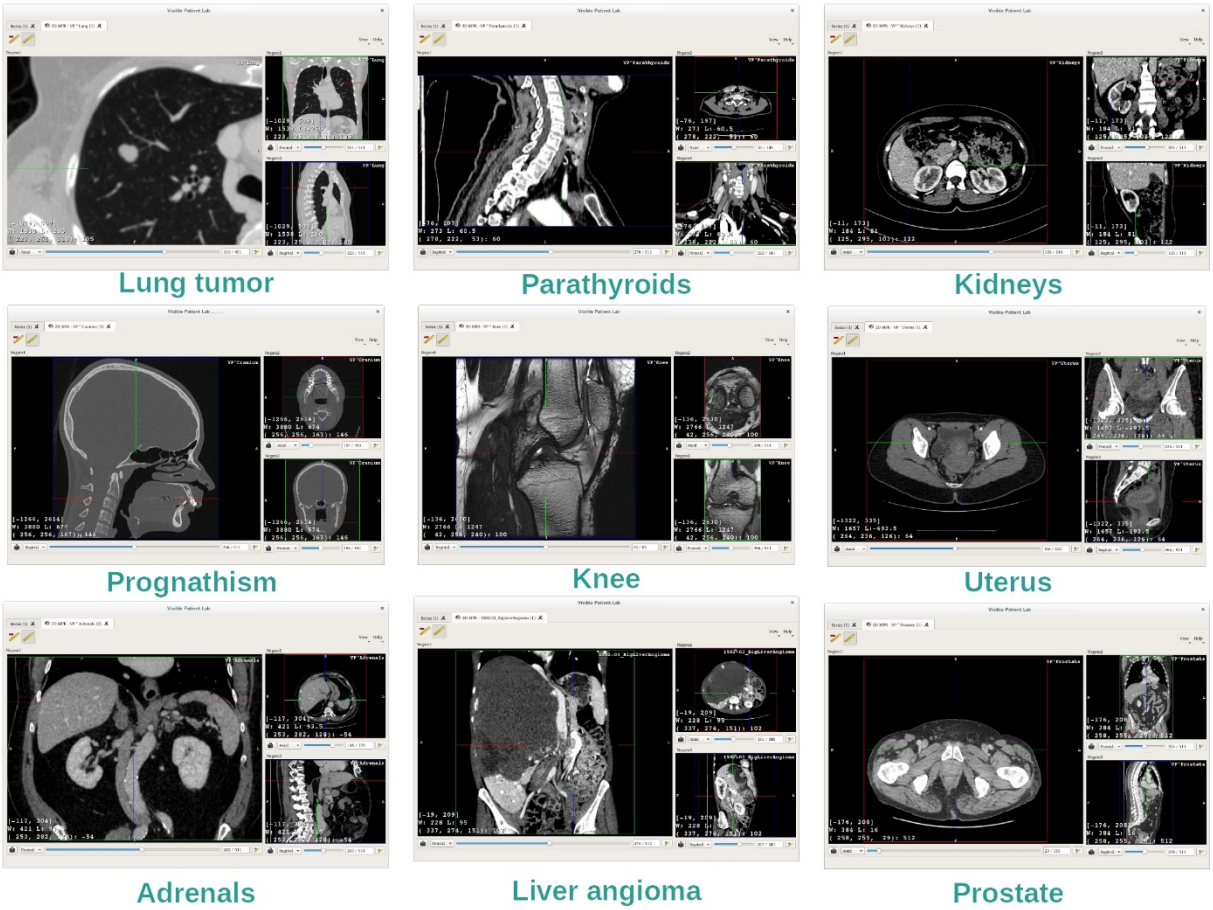
Step 4: Detail the anatomical area




Finally, you can improve tumor visualization while rolling the mouse wheel to zoom in/out and use the shift key + left mouse click combination to move the image.

### 7.2.3 Examples of other anatomical structures

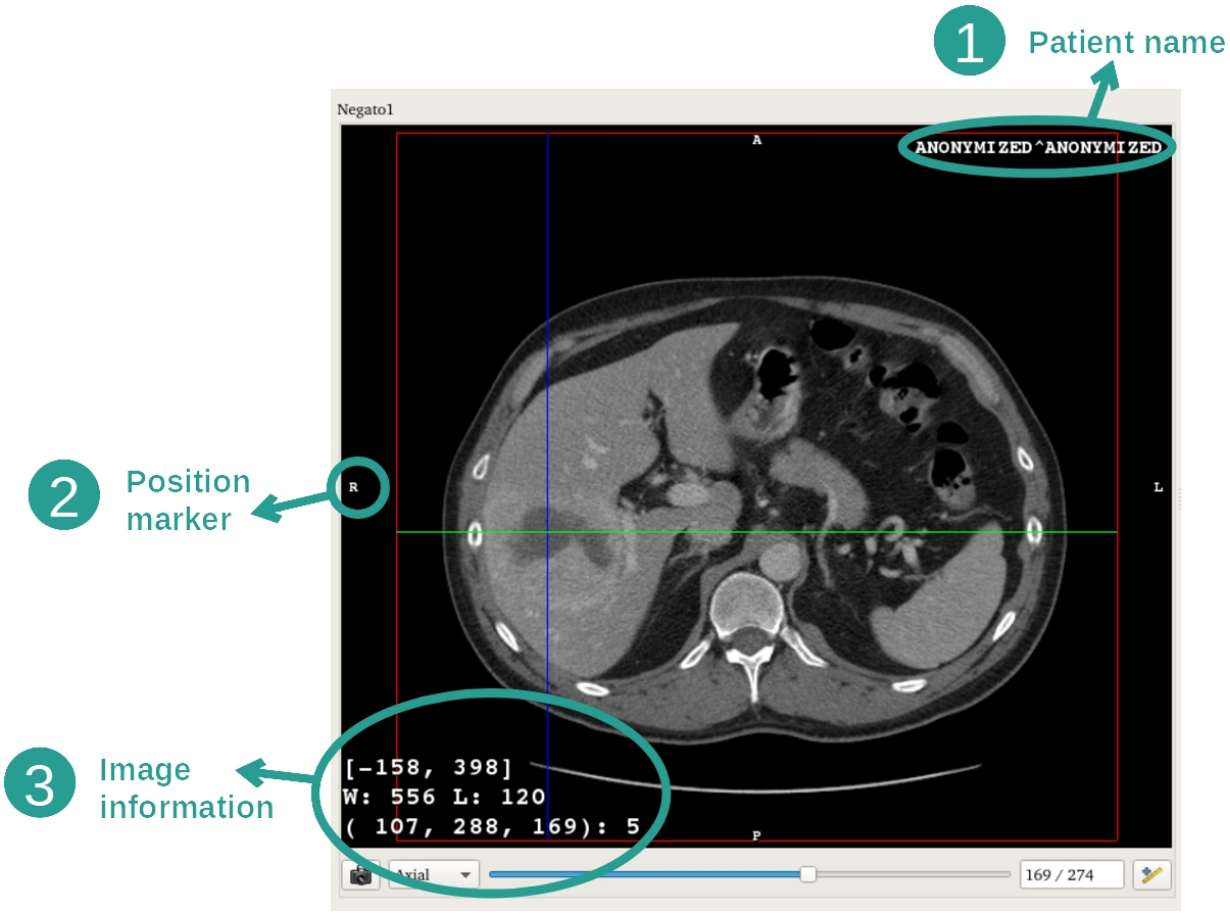
The previously detailed scenario can be applied to other anatomical structures using the 2D MPR activity. The following section lists several examples of structures that can be visualized. This list is not exhaustive.



### 7.2.4 Additional information

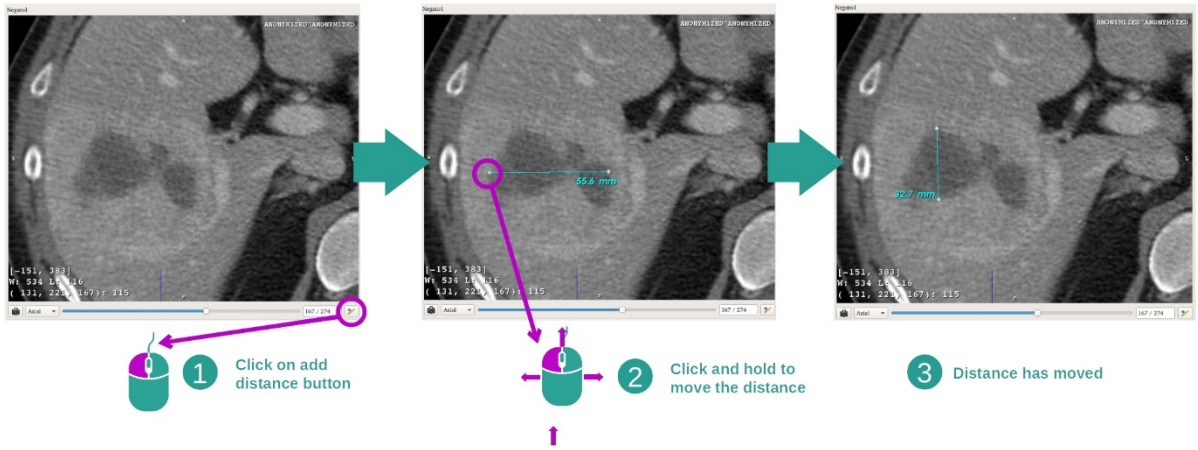
Additional image information

On the 2D MPR view there is a lot of complementary image information.



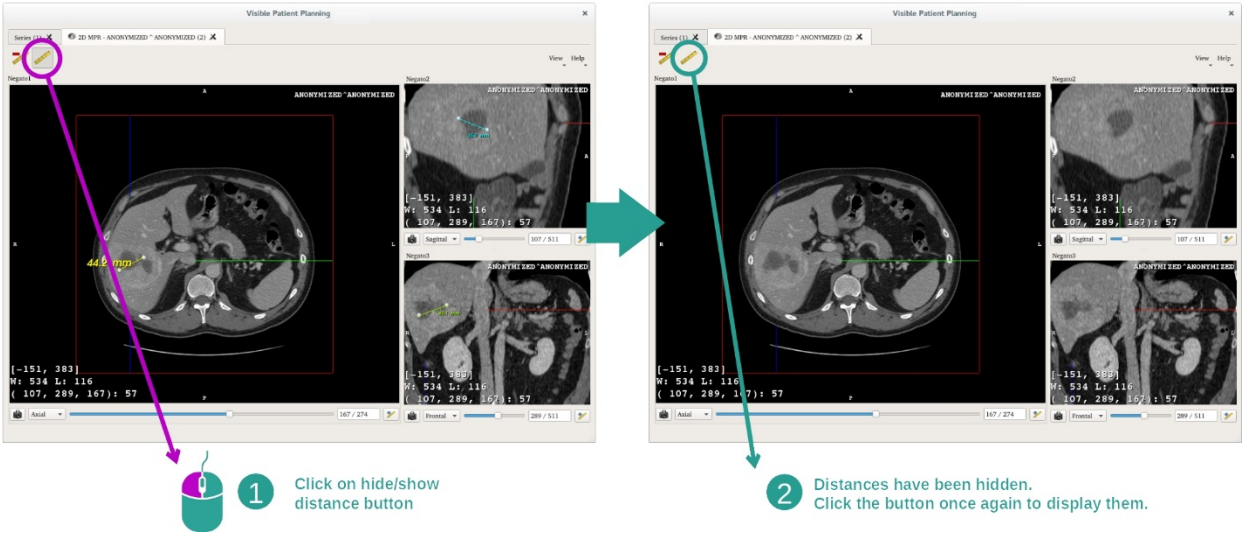

1. Patient name
2. Position marker (this information is also displayed at upper, left, lower and right border of the view)
    i. S: Superior / I: Inferior
    ii. A: Anterior / P: Posterior
    iii. R: Right / L: Left
3. Image information (advanced information, medical image analysis knowledge required)
    i. On the first line, bounds of current image window range
    ii. Next, width of current image window followed by current window level
    iii. On a third line are shown coordinates and value of last picked pixel (using mouse middle click on the image).

Take a measurement

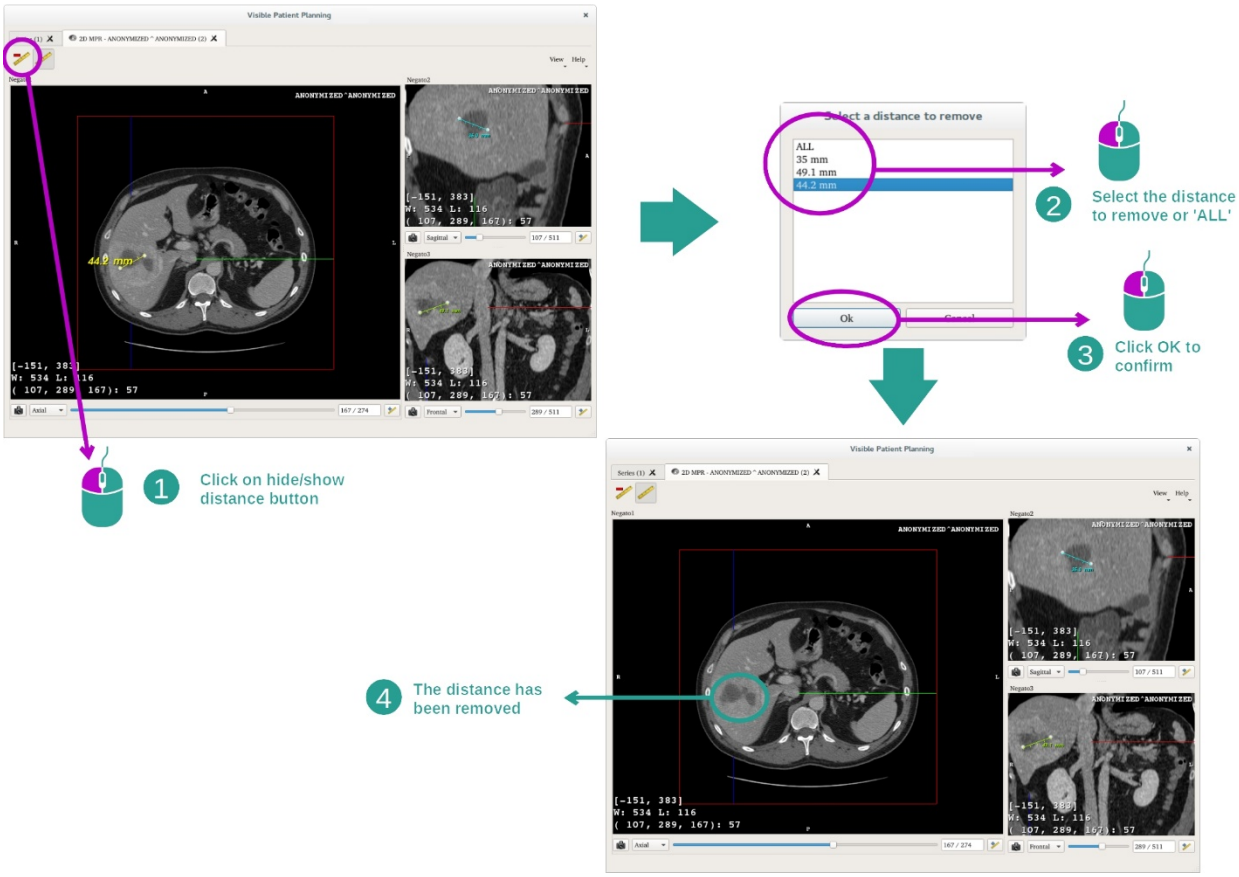



Anatomical structures can be measured using the distance tools. To do so, first click “Add distance”, then move distance with the handles.

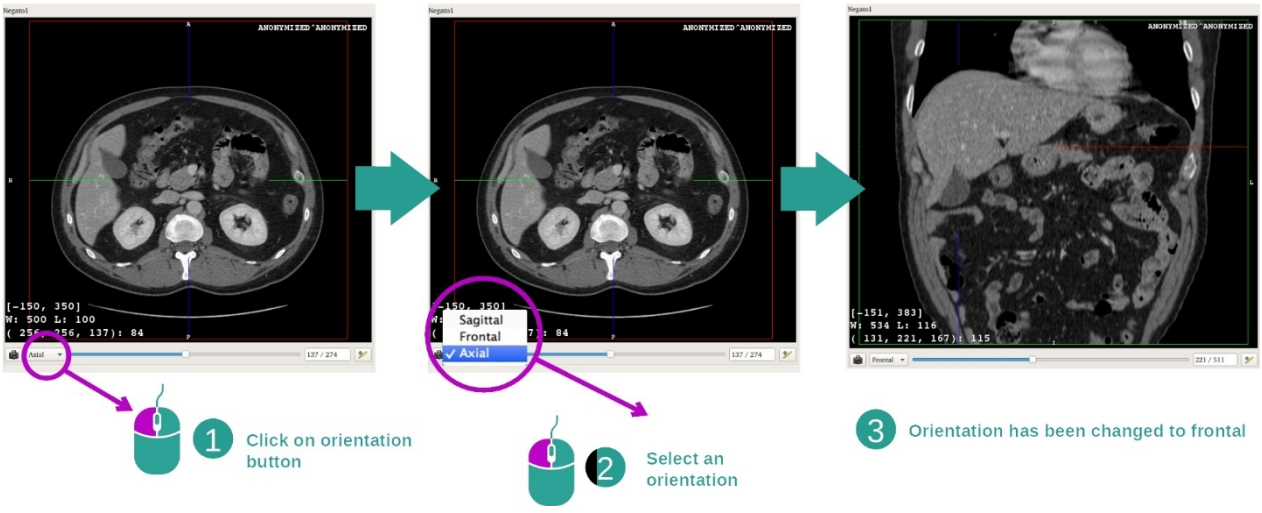
You can hide the displayed distance:




And also remove distance:

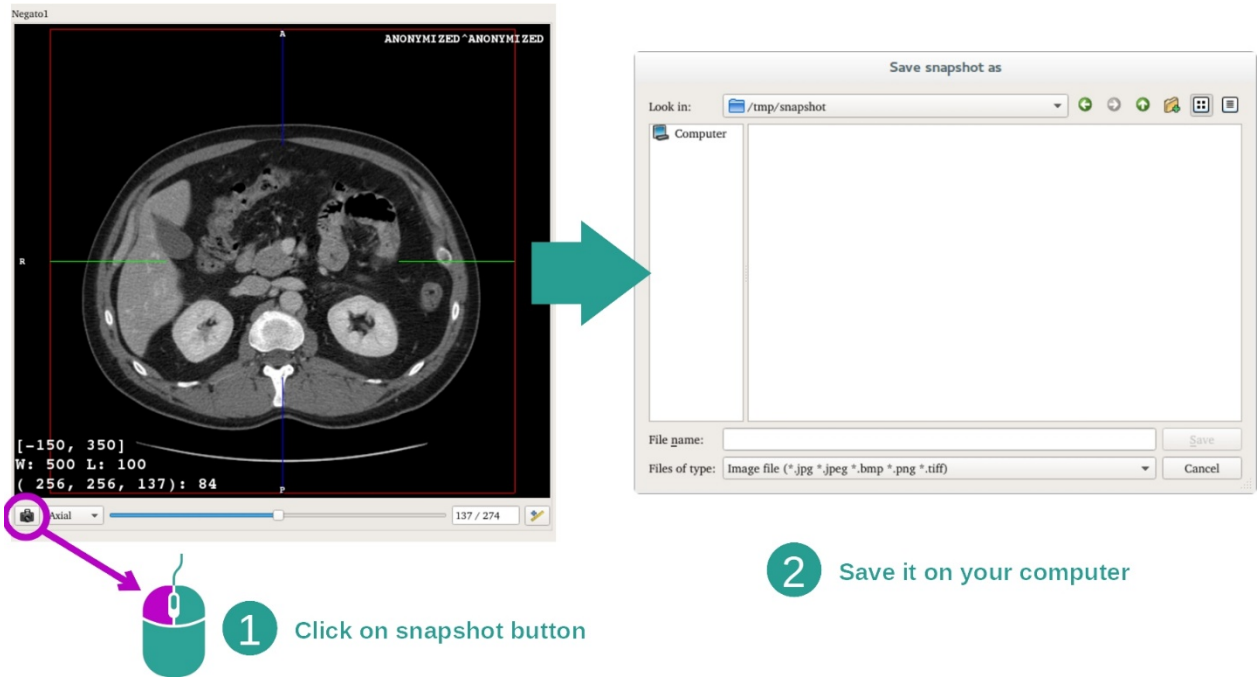



Change main view image orientation



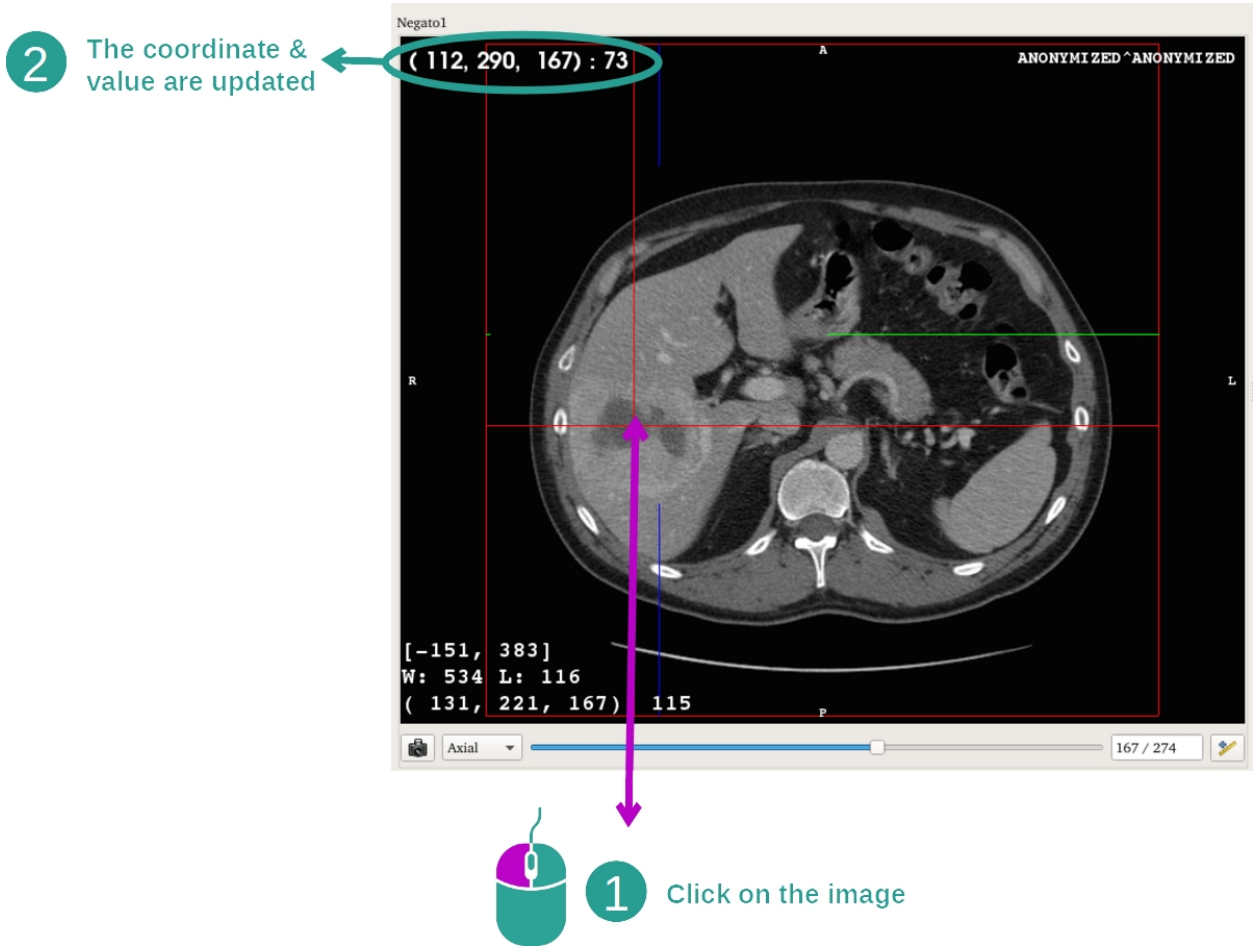

Main view orientation can be switched by selecting the desired orientation in the dedicated menu. When the main view orientation is changed, the other views adapt their orientation in order to display all axes at the same time.

Save a snapshot




In order to save the current view as an image, use the snapshot button.

<u>Get physical value of a voxel</u>



A left mouse click on the image displays the voxel coordinates and value of the voxel under mouse cursor. The unit of this value depends on the image type.

## 7.3 How to visualize a 3D model

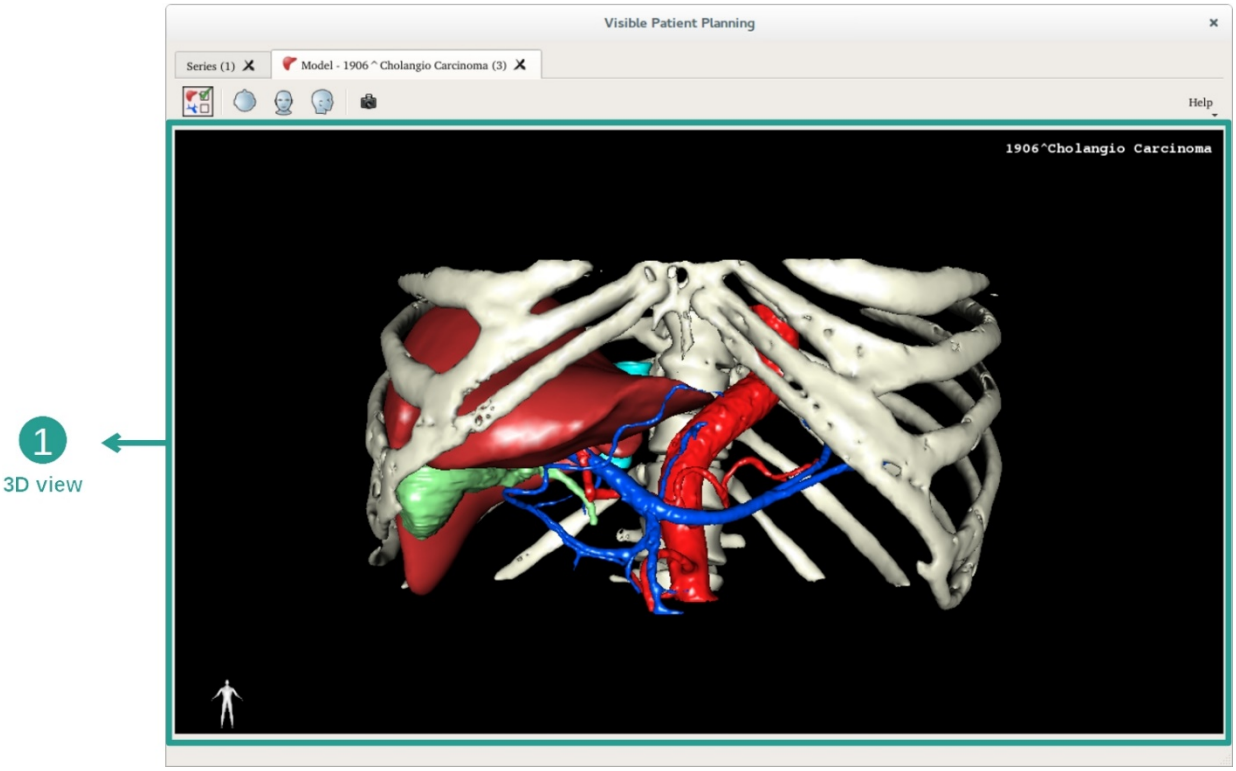
The main purpose of the 3D model activity is to the visualize and interact with your 3D model.

### 7.3.1 Prerequisites

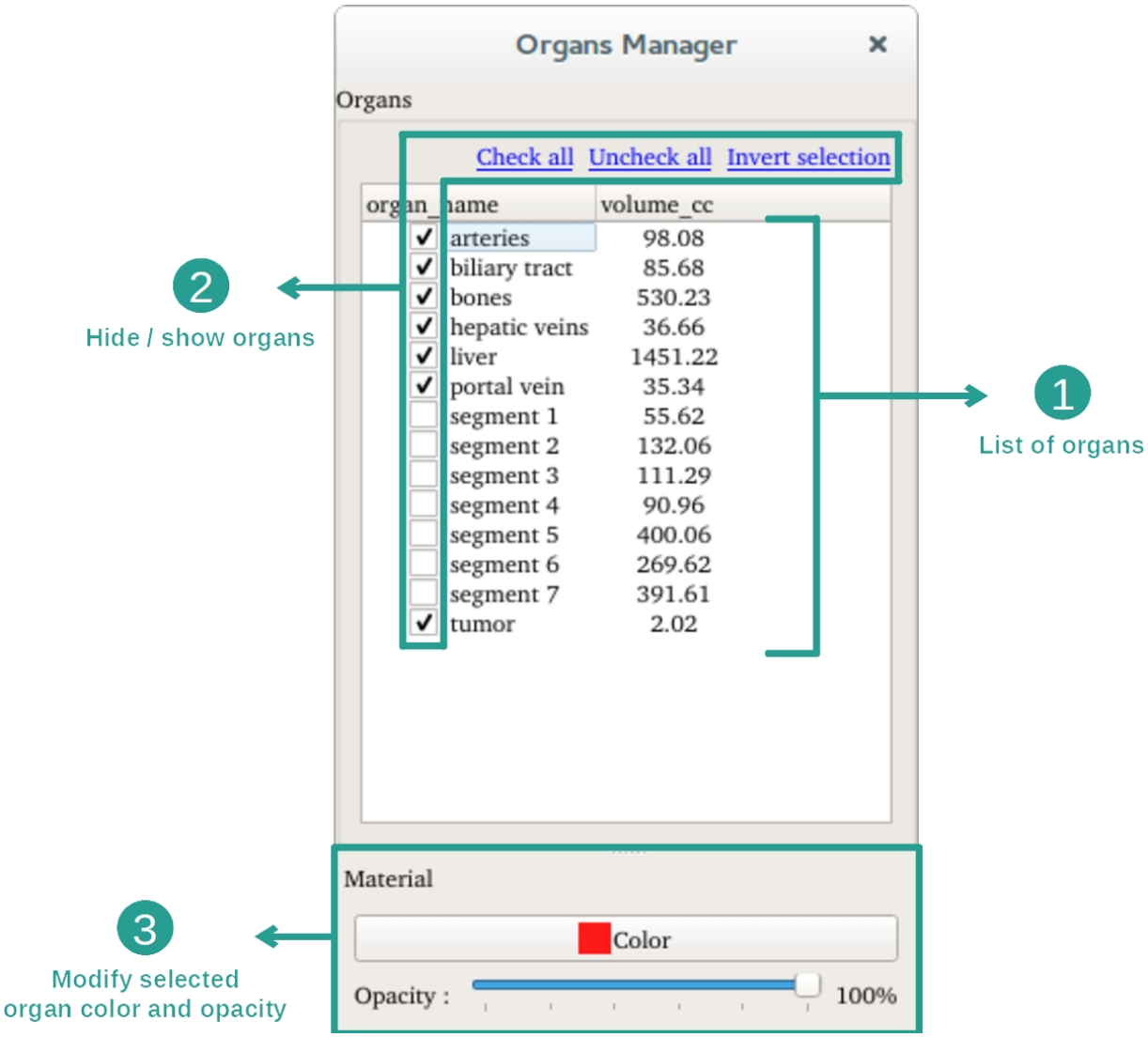
In order to start a 3D Model activity, a model series is required. Select it from Series activity (*How to load data*) and click “Launch activity”, or double click the series.

### 7.3.2 Visualize the patient’s anatomy

Let’s get familiar with the activity layout. There is one main view in the 3D model activity.



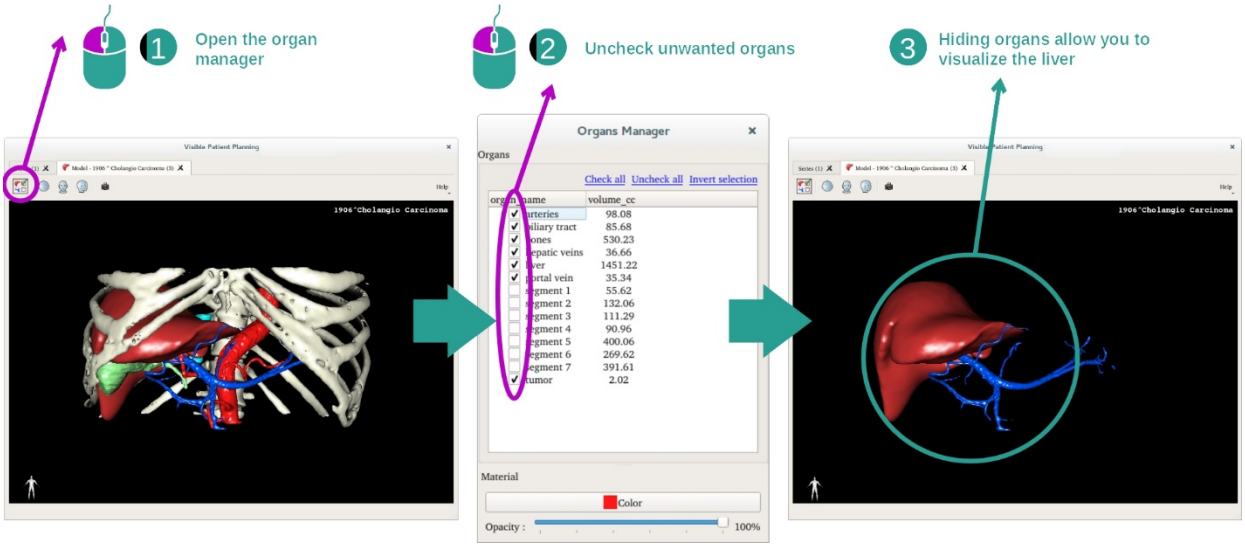

In this 3D view, and thanks to the organ manager, you can perform several interactions with your model.




The organ manager lists all organs present in the 3D model. It allows to hide/show organs of the model and to change their appearance by modifying their color or opacity. The organ manager also gives information about organ volumes.

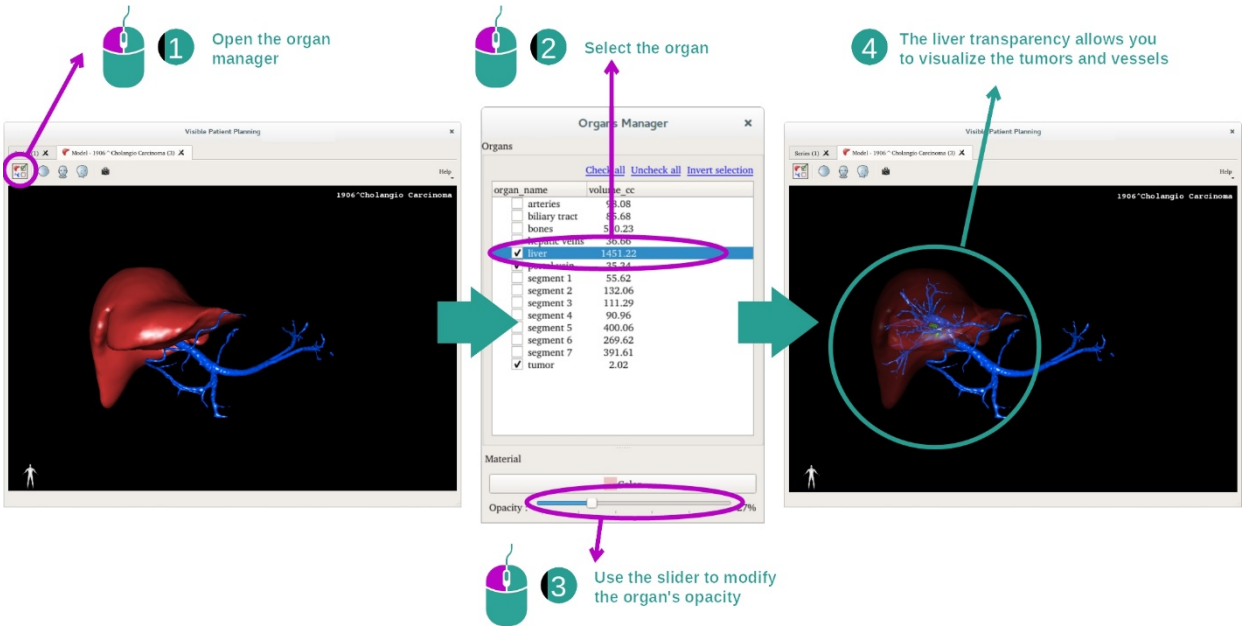
As an example, the following steps will be based on the analysis of a patient's liver tumor.

Step 1: Hide organs to visualize an anatomical part




Some organs may obstruct the visualization of anatomical parts. Per the organ manager, these organs can be hidden. To do so, open the organ manager and uncheck the organ you want to hide. You can then display it again by checking back the organ's visibility box.

Step 2: Modify an organ opacity



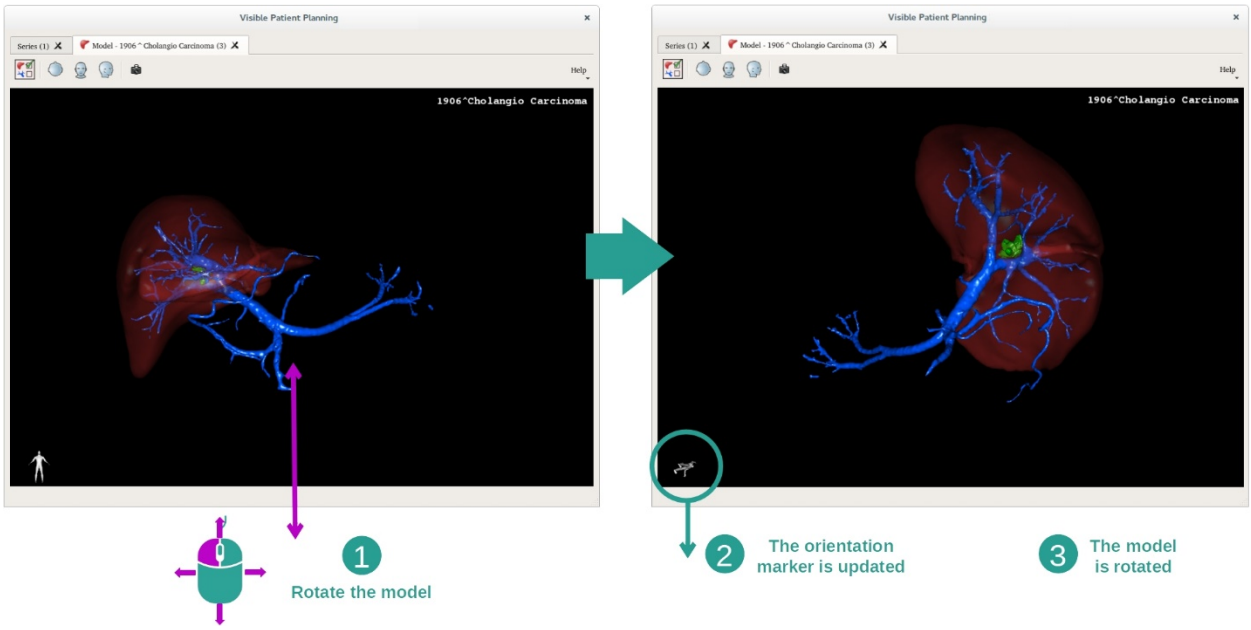

You may also want to visualize the inner part of an organ. The organ manager allows you to modify the opacity of an organ.

To do so, open the organ manager, select the desired organ and modify the opacity with the slider underneath the organ manager.

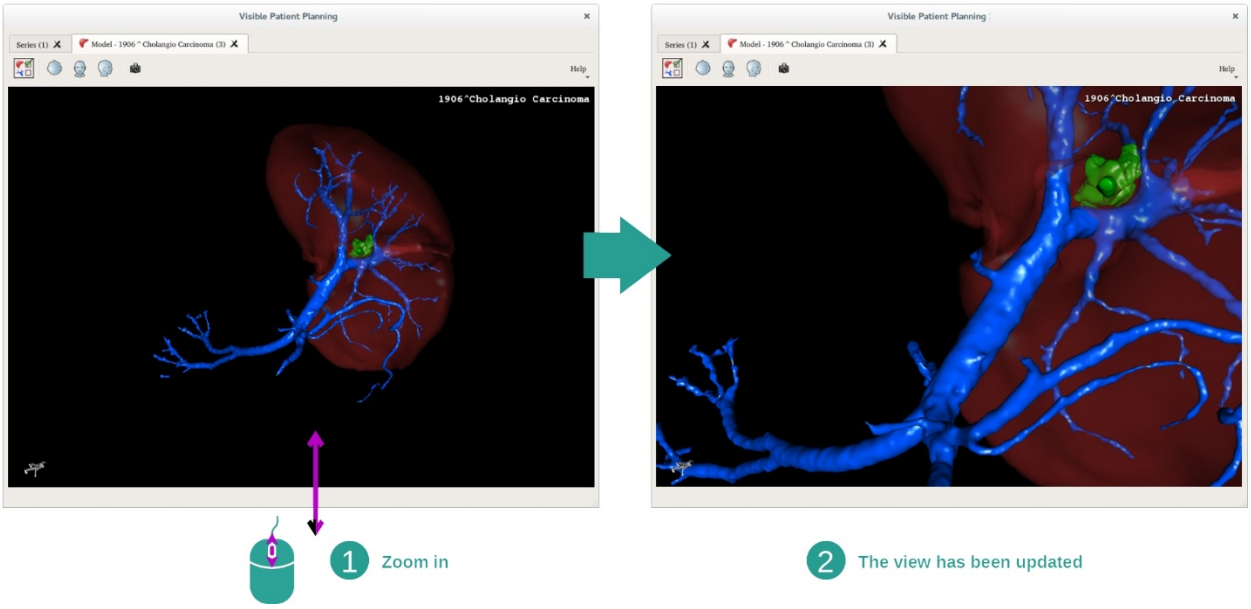
Step 3: Detail the anatomical area

The 3D model activity allows you to interact with your model.

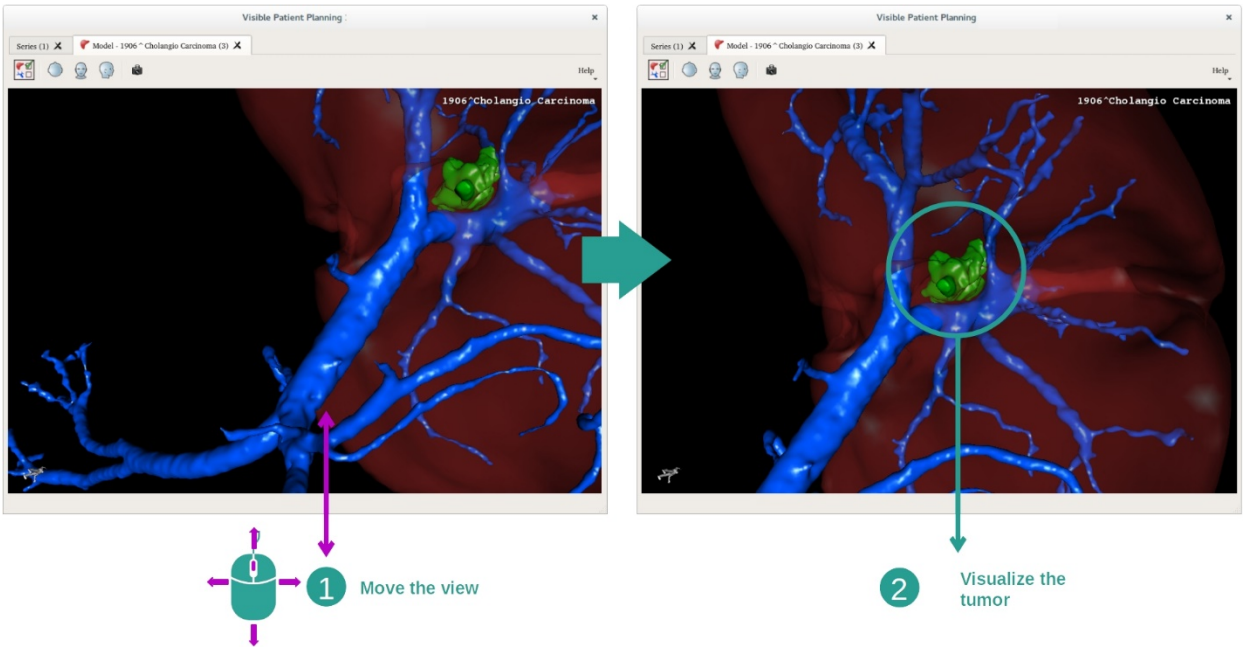
You can rotate your model by clicking and holding the left mouse button while dragging the cursor.




You can zoom in or out by using the mouse wheel.

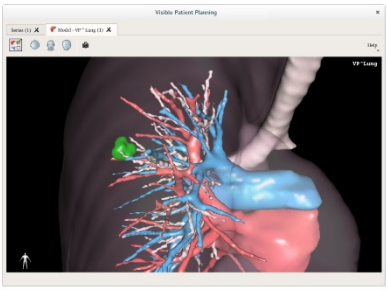


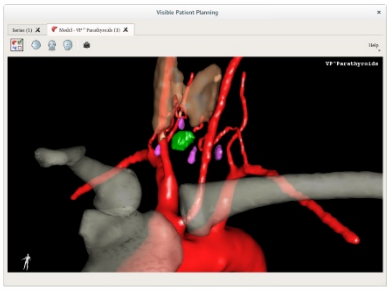

Finally, you can shift your model by clicking and holding the middle mouse button while dragging the cursor.

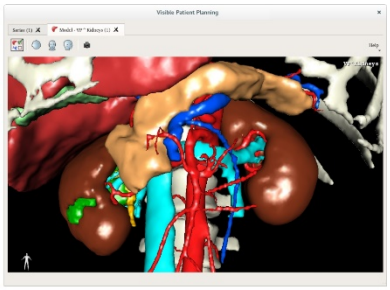


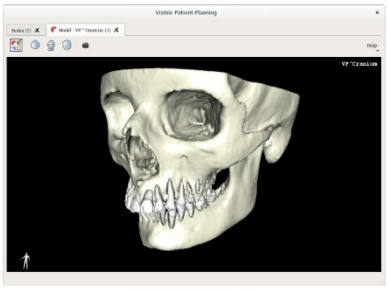

### 7.3.3 Examples of other anatomical structures

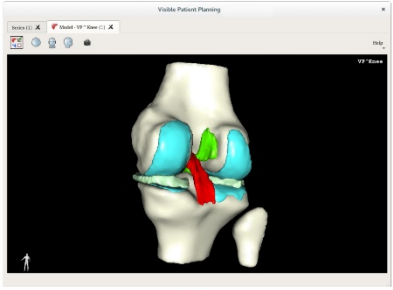
The previously detailed scenario can be applied to other anatomical structures using the Model activity. The following section lists several examples of structures that can be visualized. This list is not exhaustive.

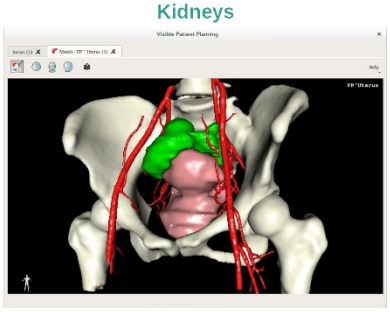

Lung tumor

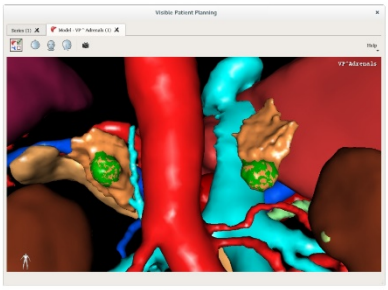

Parathyroids

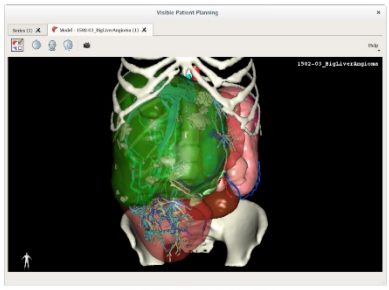

Kidneys

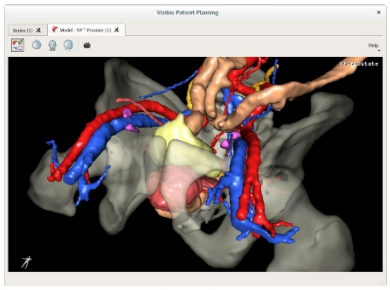

Prognathism


Knee


Uterus


Adrenals

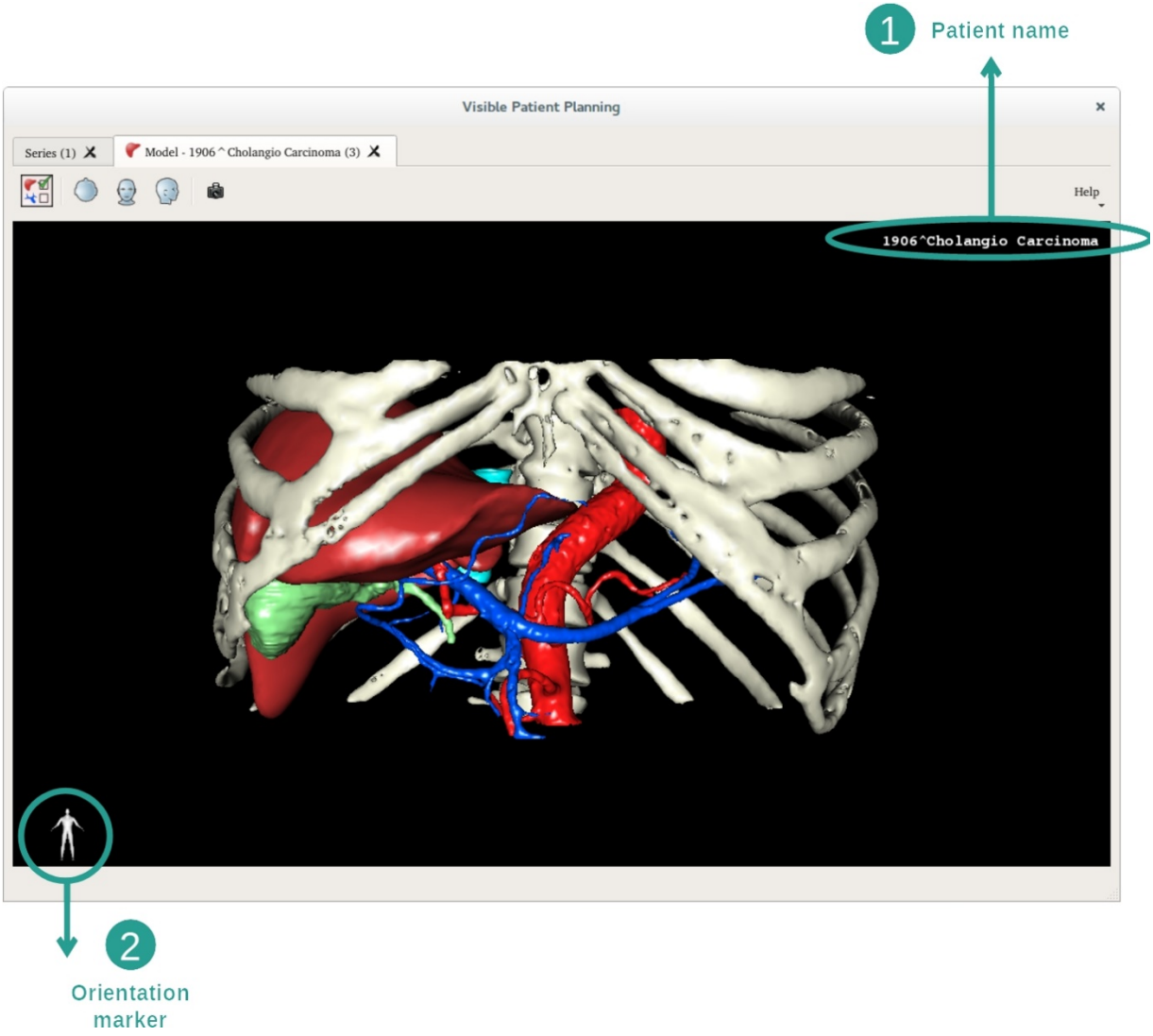

Liver angioma


Prostate

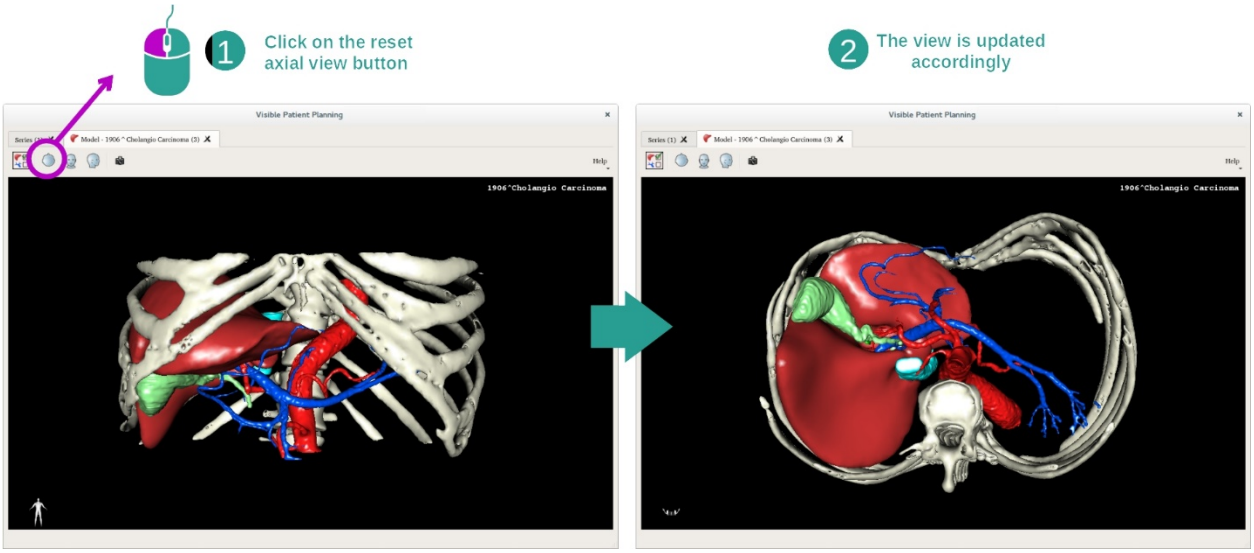
### 7.3.4 Additional information

Additional image information

The Model activity displays the patient's name and an orientation marker on the 3D view.

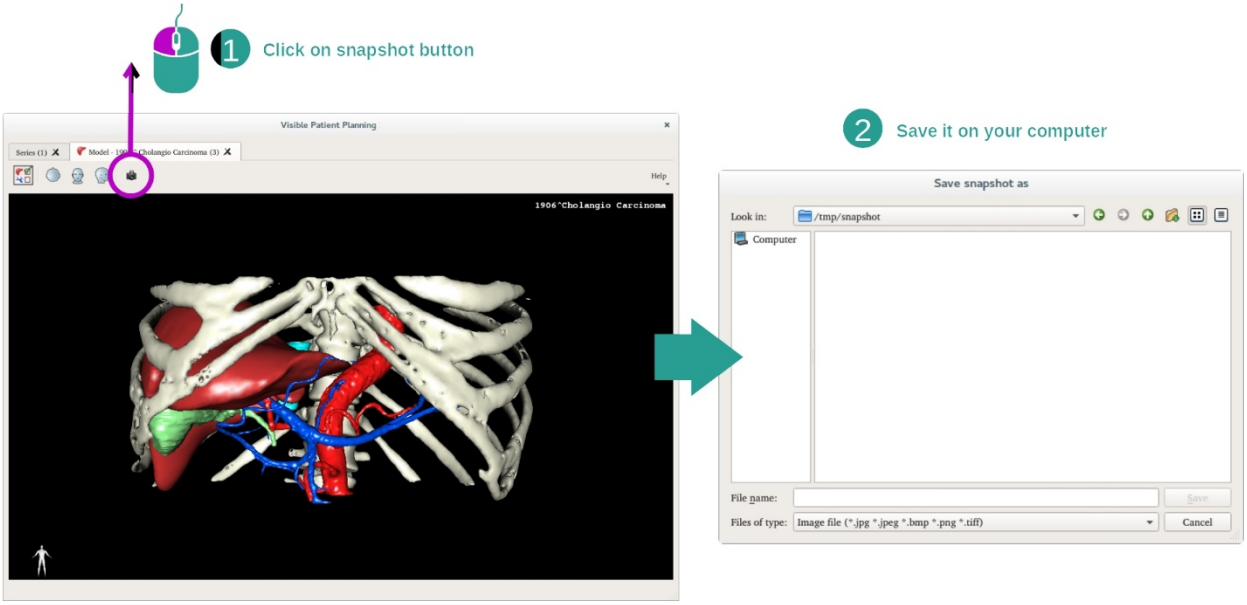



Reset the view



At any moment, you can reset the view using one of the three reset buttons located above the main view. These buttons reset the view to axial, frontal or sagittal view.

Save a snapshot



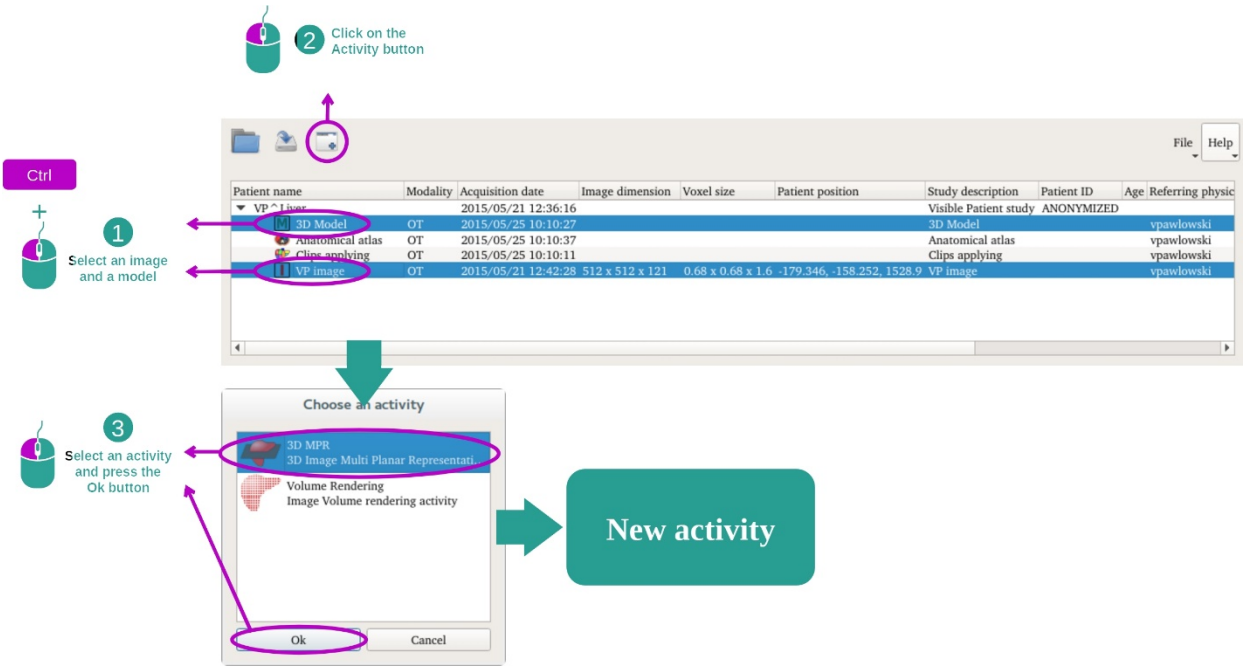

If you want to save the current view as an image, use the snapshot button.

## 7.4 How to visualize an image with a model

The 3D MPR activity is dedicated to the visualization of medical images and 3D models. The main purpose of this activity is to visualize your 3D models with their corresponding medical images.

This activity includes functionalities such as measurements of anatomical structures and saving snapshots.

### 7.4.1 Prerequisites

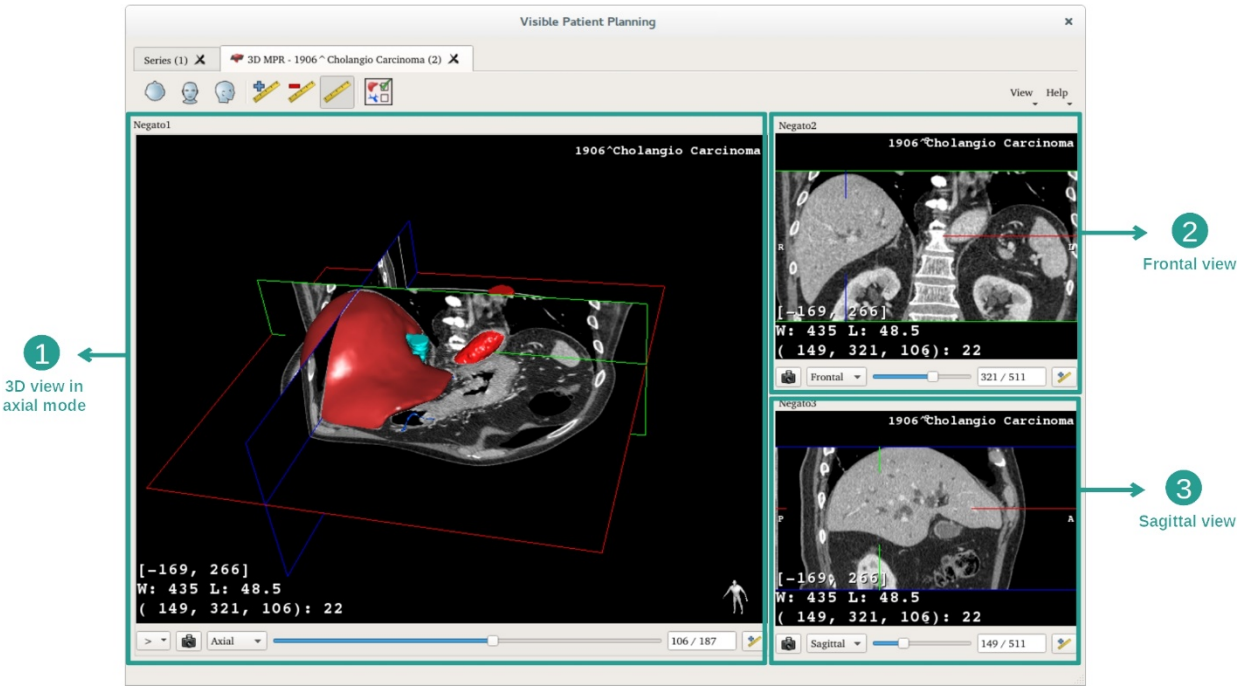



In order to start a 3D MPR activity, an image series and its associated model series are required. Typically, these data are loaded from a VPZ file.

Select both series from Series activity (*How to load data*) by holding the Ctrl key pressed during the series selection. Click “Launch activity”, select “3D MPR” and click “Ok”.

### 7.4.2 Visualize the patient’s anatomy

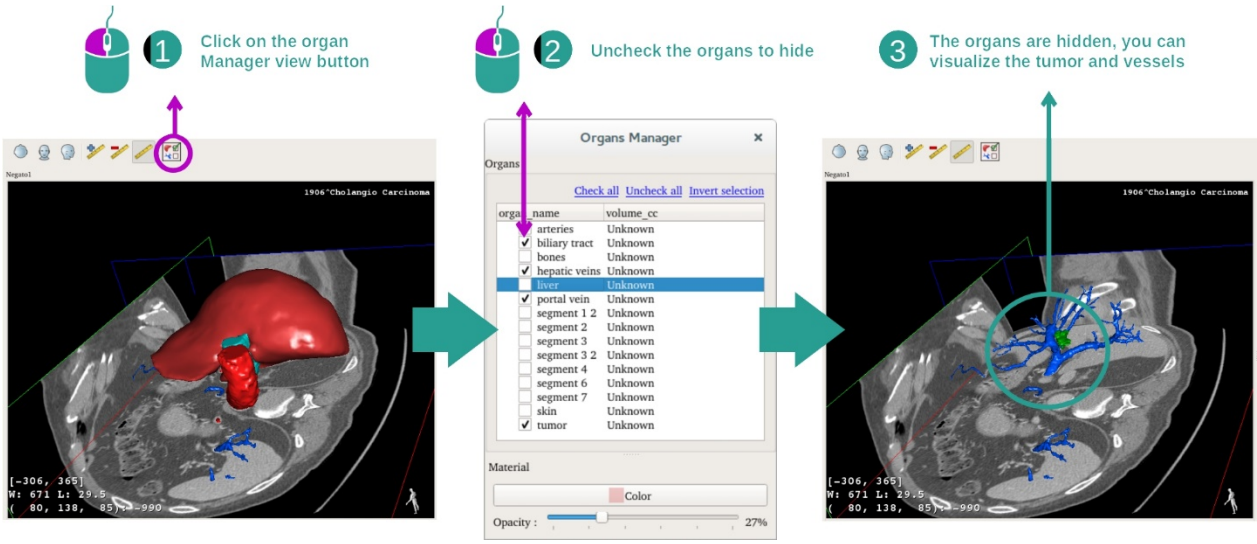
The 3D MPR activity layout is composed of three views.




The main view displays your 3D model and the associated image. The two other views display the frontal and sagittal views of the image.

As an example, the following steps will be based on the analysis of a patient's liver tumor.

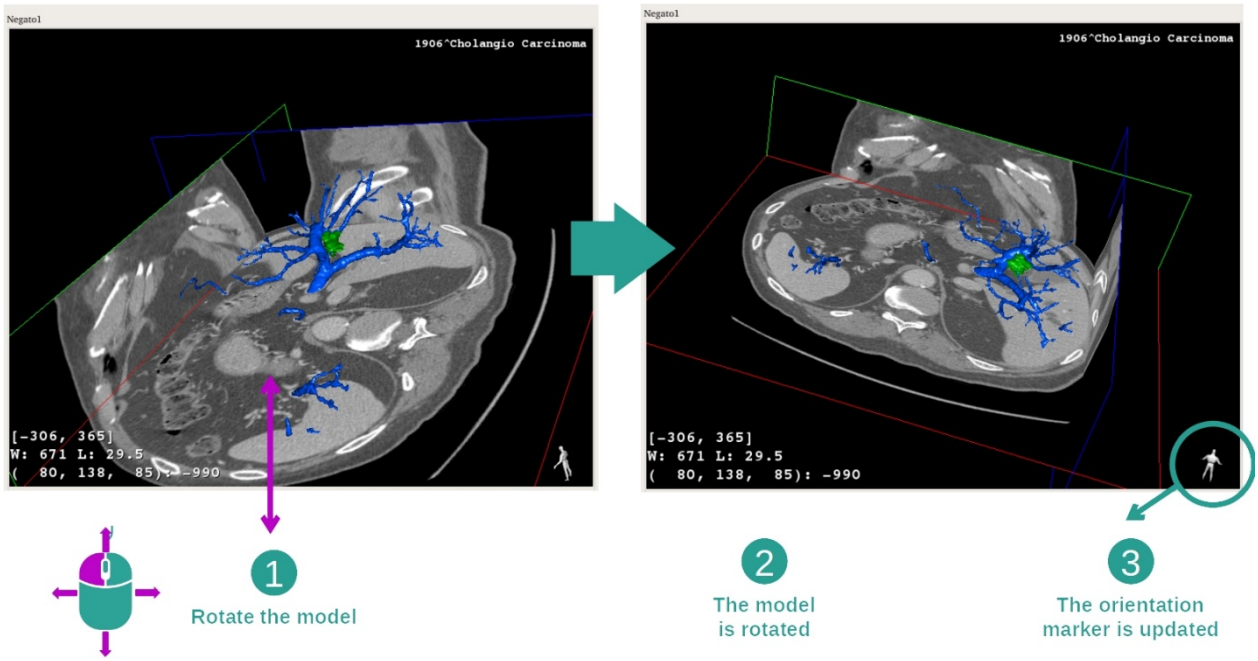
<u>Step 1: Hide organs to visualize an anatomical part</u>




In order to visualize the tumor located inside the liver, you can hide the unwanted organs. To do so, click on the organ manager button and unselect the organs that must be hidden.

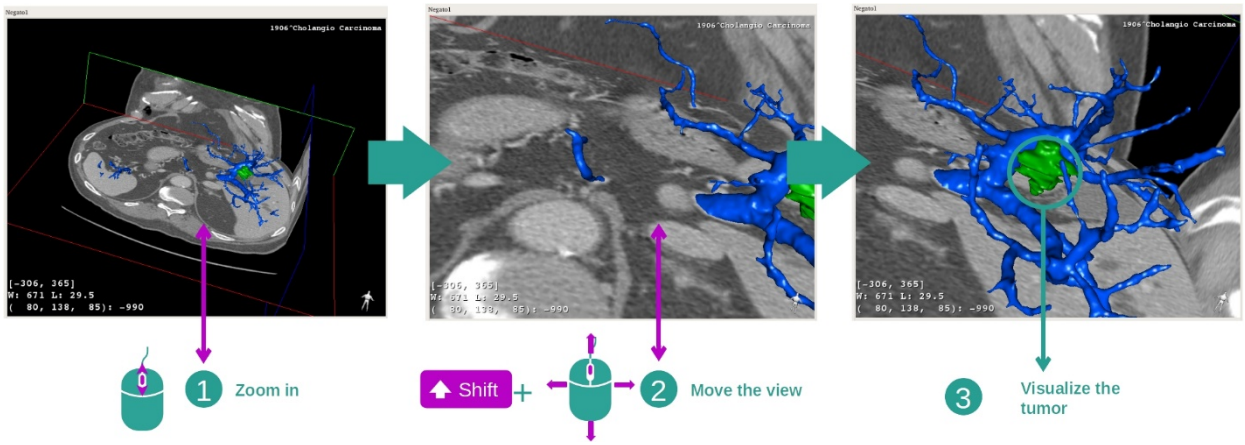
For more detail on how the organ manager works, please refer to the 3D model activity documentation.

Step 2: Rotate the model to get a global visualization



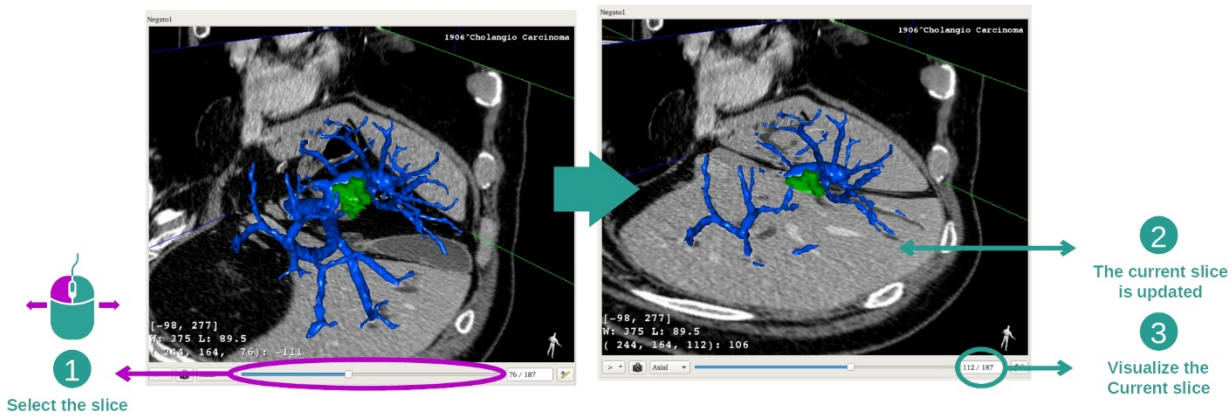

In order to rotate your 3D model, click and hold the left mouse button on the main view and move the cursor. The model and the image will rotate accordingly.

Step 3: Detail the anatomical area



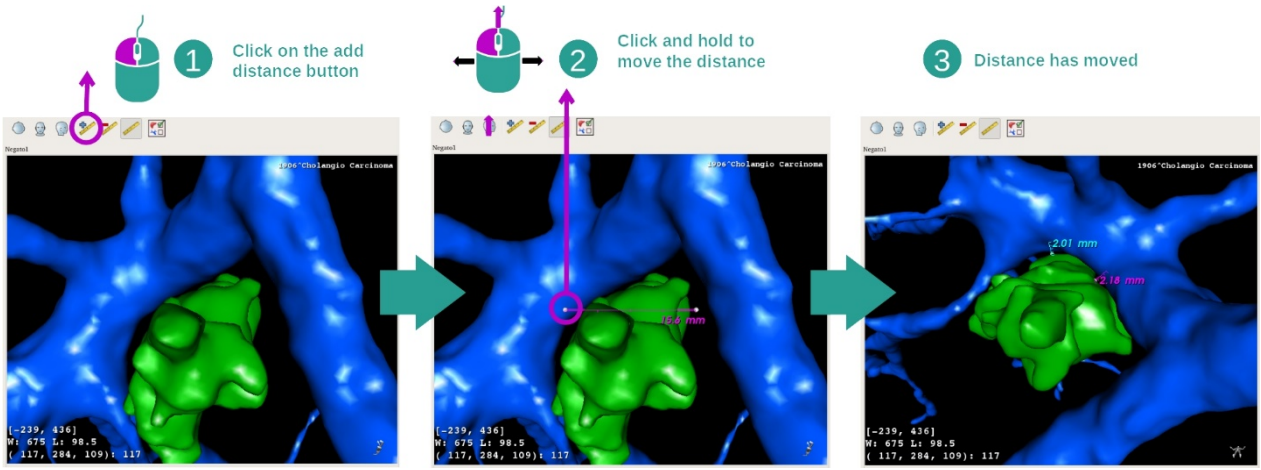

Use the mouse wheel to zoom in or out. You can shift the view by pressing and holding the Shift key, while holding the middle mouse button and dragging the mouse on the view.

Step 4: Update the current slice




Use the slider under the main view to change the current slice. The slice corresponding to the selected orientation will be updated accordingly.

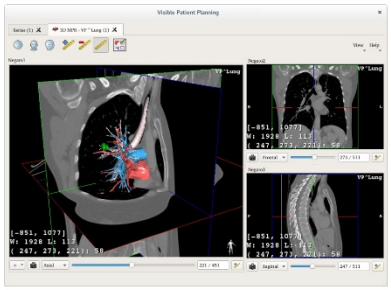
Step 5: Measure an anatomical part



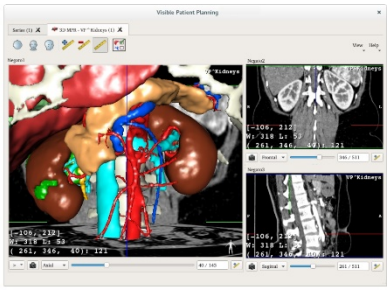

Use the add distance button to place a new measure on the view. Once created, the distance can be moved by clicking and holding the left mouse button on one of the two handles located at the extremity of the segment.

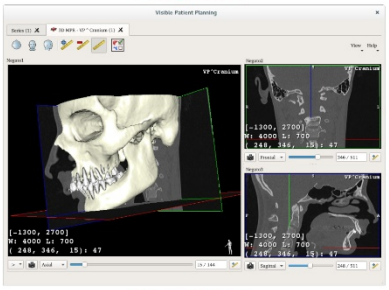
### 7.4.3 Examples of other anatomical structures

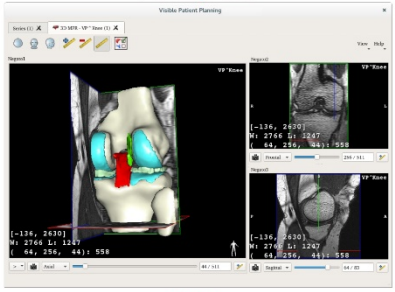
The previously detailed scenario can be applied to other anatomical structures using the 3D MPR activity. The following section lists several examples of structures that can be visualized. This list is not exhaustive.

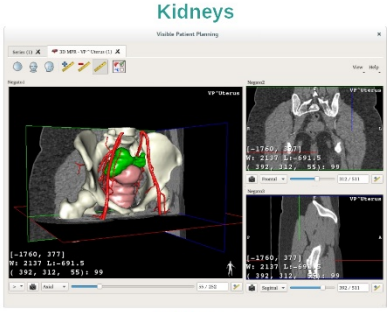

Lung tumor

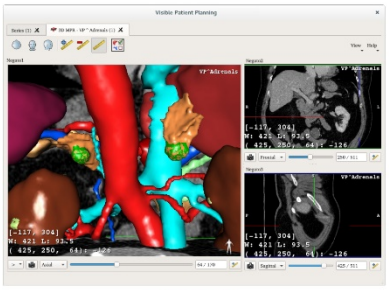
Parathyroids

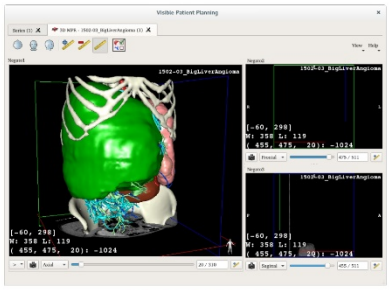

Kidneys

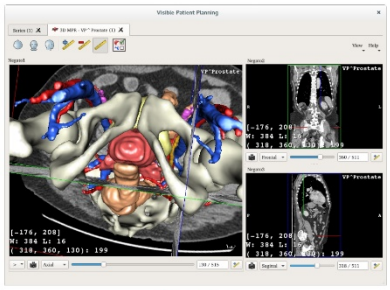

Prognathism


Knee


Uterus


Adrenals

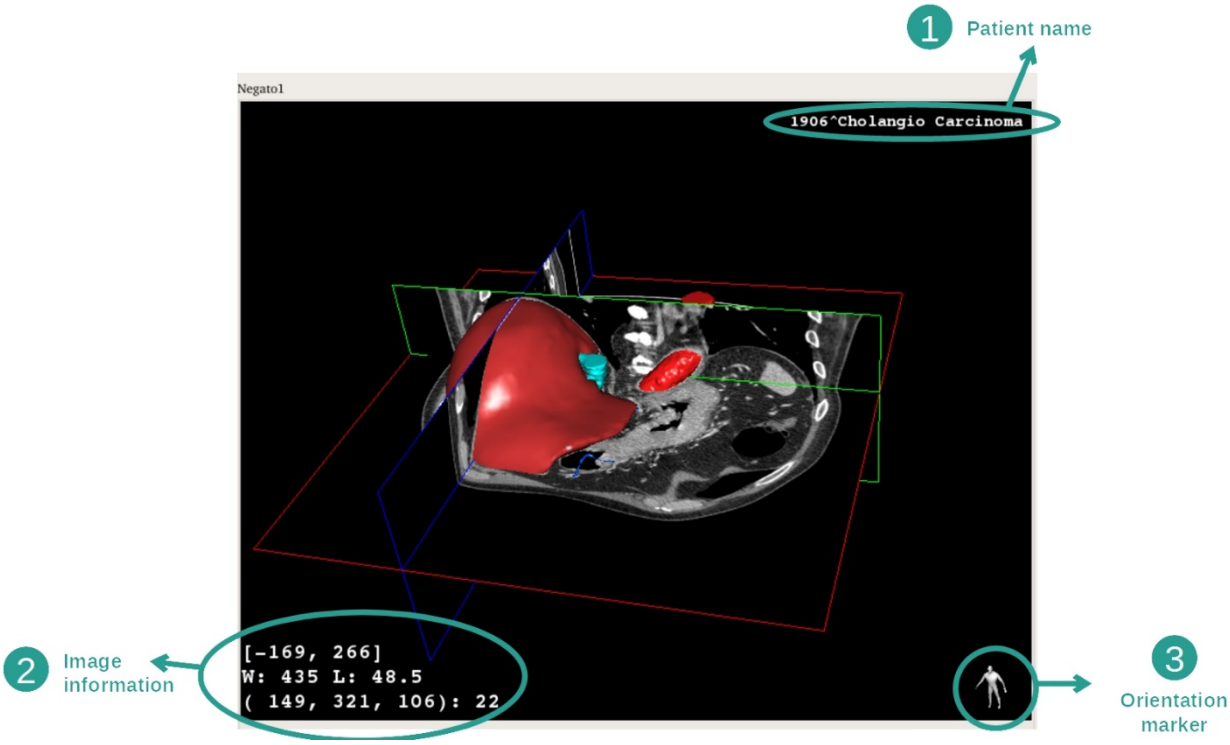

Liver angioma


Prostate

### 7.4.4 Additional information

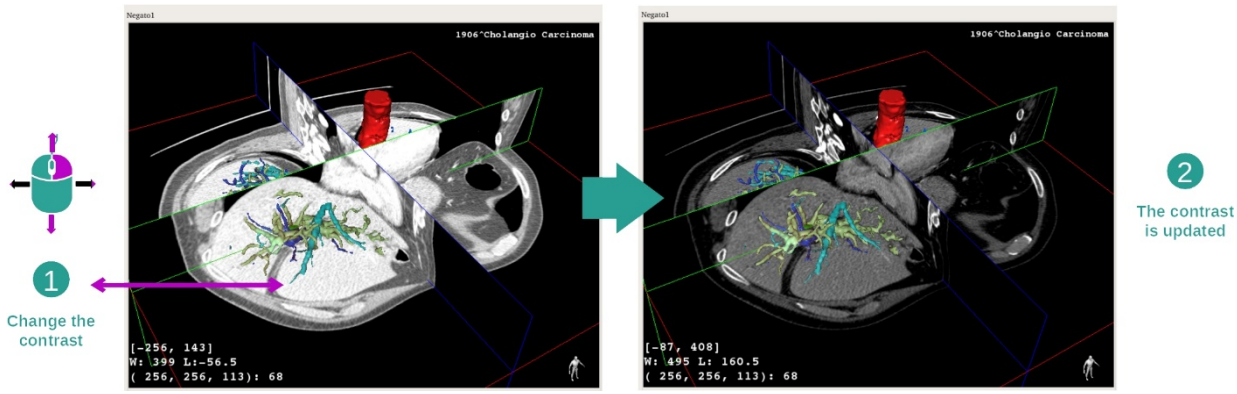
Additional image information

On the 3D MPR view there is a lot of complementary image information.



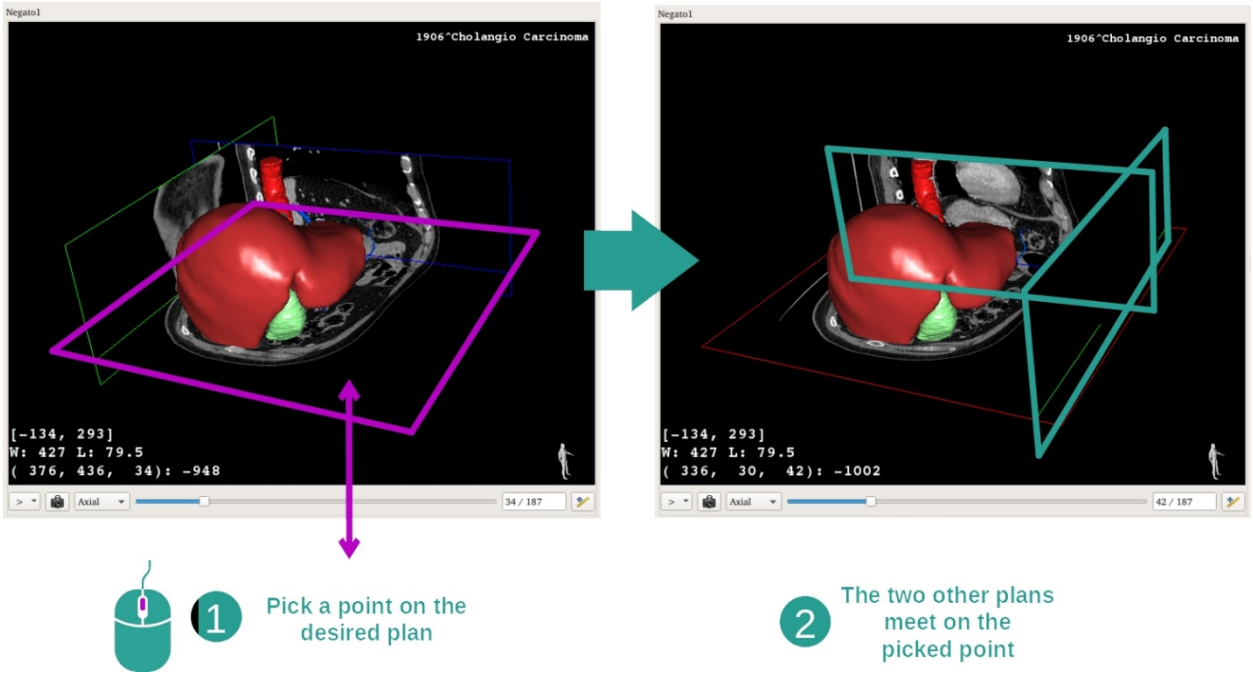

1. Patient name
2. Image information (advanced information, medical image analysis knowledge required)
    I. On the first line, bounds of current image window range
    II. Next, width of current image window followed by current window level
    III. On a third line, coordinates and value of last picked voxel.
3. Orientation marker

<u>Adjust window level</u>



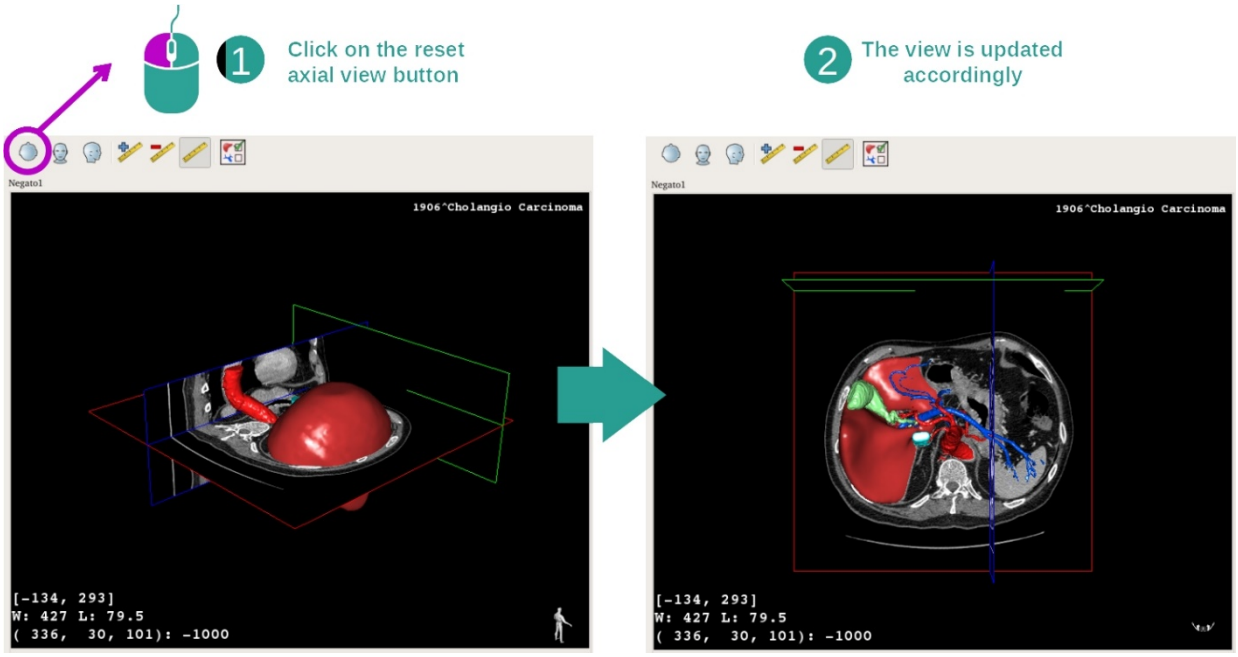

You can change the window level by right clicking and holding the button while moving the cursor.

Focus an anatomical part



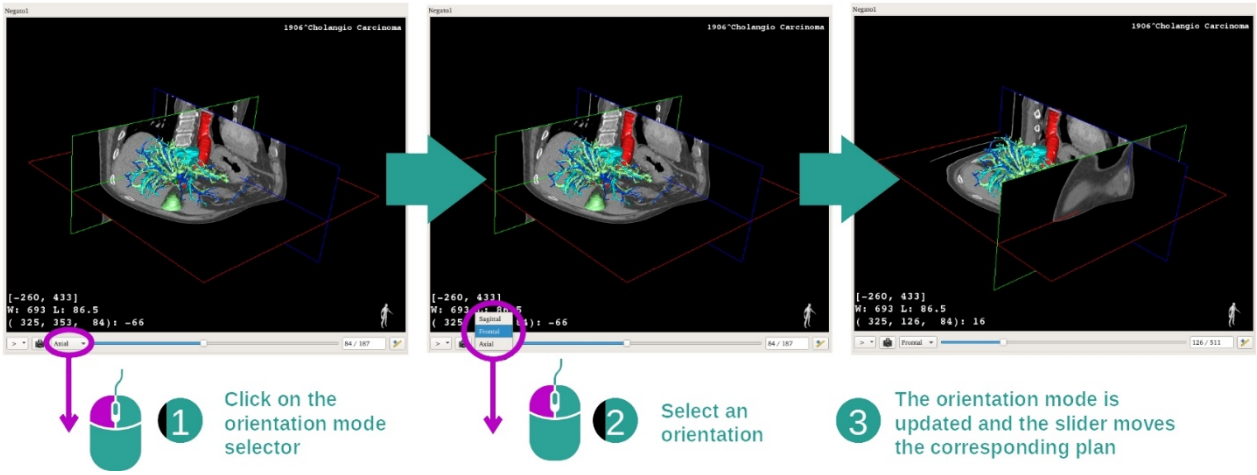

Use the middle mouse button to focus an anatomical part. When picking a point on one view, all three image planes (axial, frontal, sagittal) will intersect on that point.

Reset the view



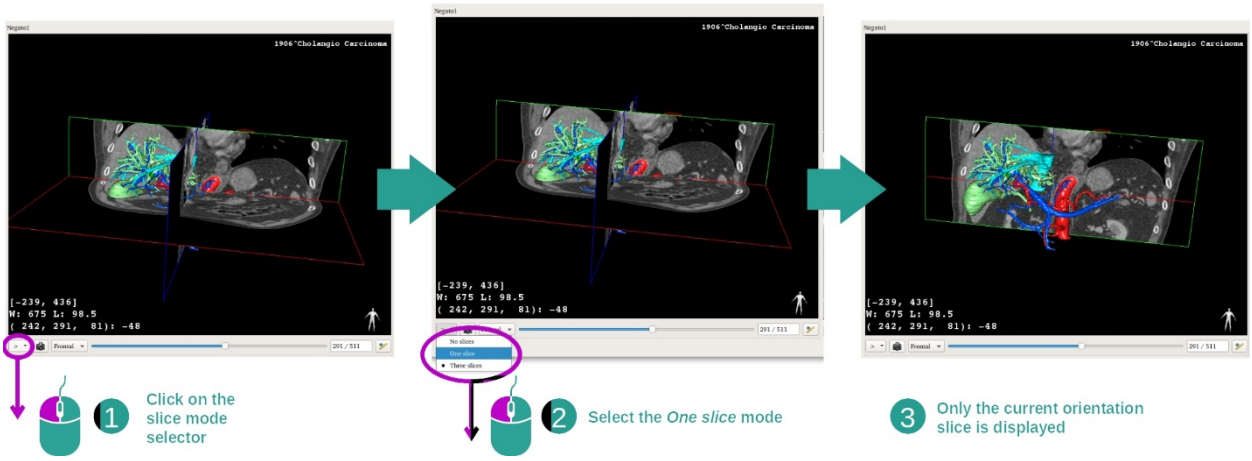
At any moment, you can reset the view using one of the three reset buttons located above the main view. Those buttons reset the view to the axial, frontal or sagittal view.

Select image orientation




The orientation mode can be selected using the dedicated menu located under the main view. Once the orientation is changed, the slider updates the corresponding view when moved.

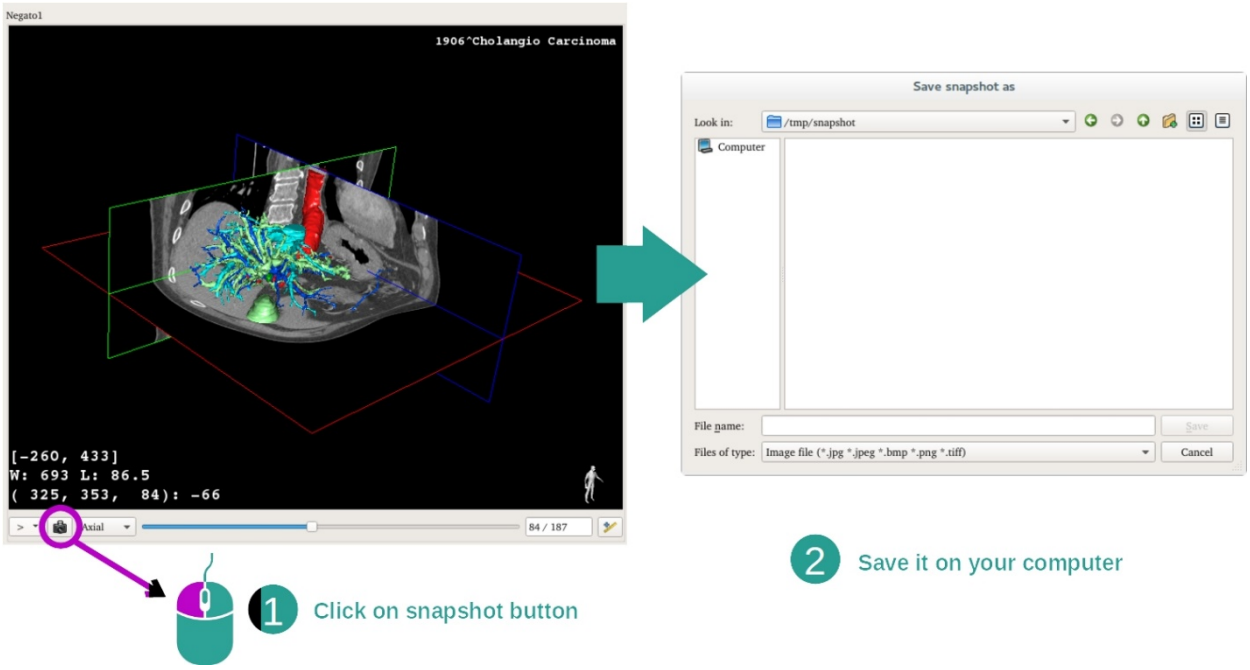
Select number of image planes




The number of displayed image planes can be changed using the selector located under the main view. Three modes are available:

- `No slices` item removes all image planes
- `One slice` item only displays the plane of the selected axis
- `Three slices` item displays all three planes

Save a snapshot




In order to save the current view as an image, use the snapshot button.

Measurement in side views

To get an explanation on how to perform a measurement on a 2D medical image, please refer to the 2D MPR activity documentation at section *Take a measurement*.

## 7.5 How to visualize a volume

The Volume rendering activity is dedicated to the visualization of the medical image as a volume rendering. The activity allows to integrate the associated 3D model into the volume rendering for a better understanding of the patient anatomy.

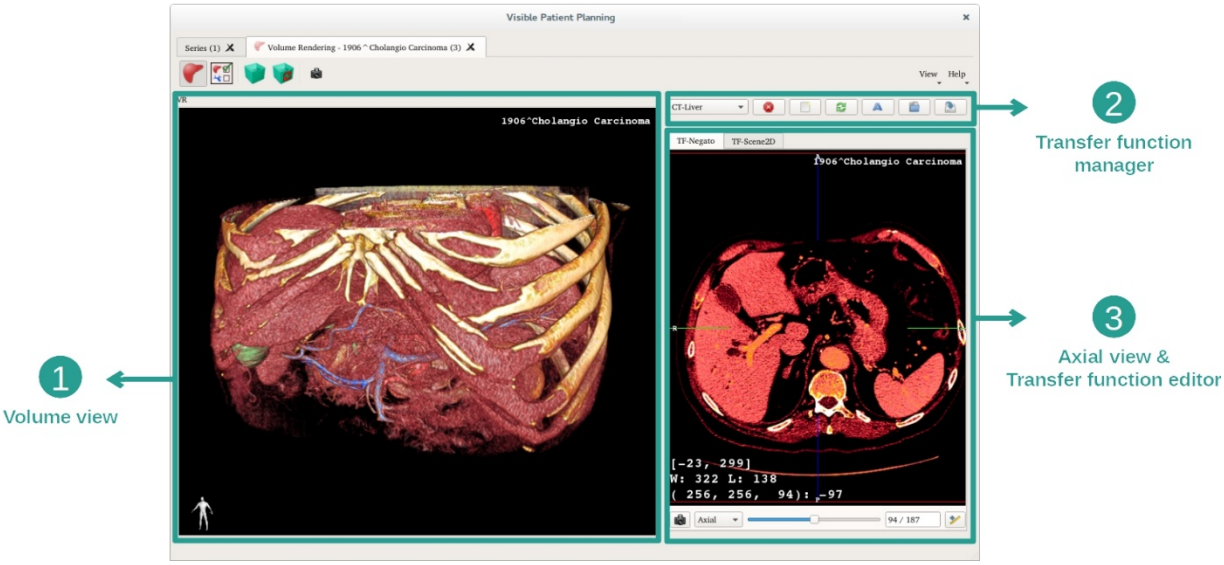
This activity includes a transfer function manager which allows to change the display of the volume rendering according to the anatomical parts you want to visualize.

### 7.5.1 Prerequisites

In order to start a Volume Rendering activity, an image series is required. Optionally, its corresponding model series can be associated. Select the series in Series activity (*How to load data*), click “Launch activity”, select “Volume Rendering” and click “Ok”.

### 7.5.2 Visualize the patient’s anatomy

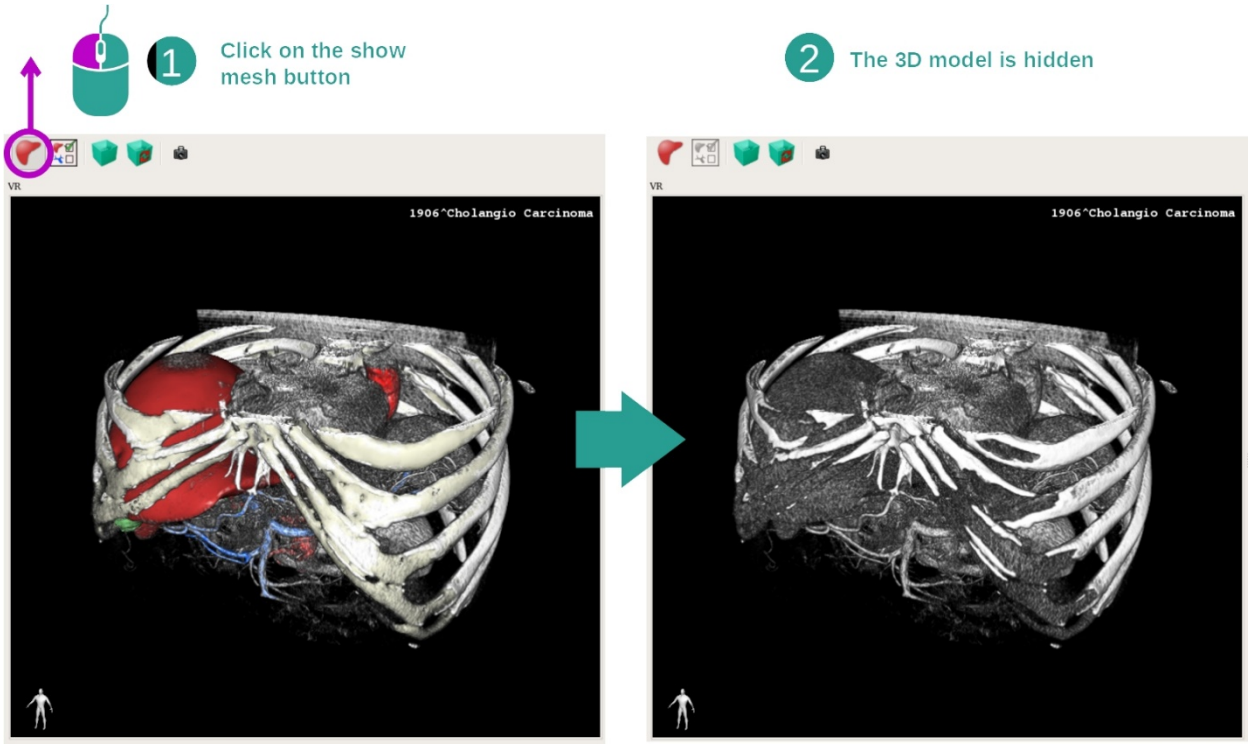
Let’s get started with a short description of the activity layout.




This activity is composed of two views. The main one on the left displays the volume rendering of your image. The view on the right is composed of two tabs. The first one displays an axial view of your image. The second one is a transfer function editor.

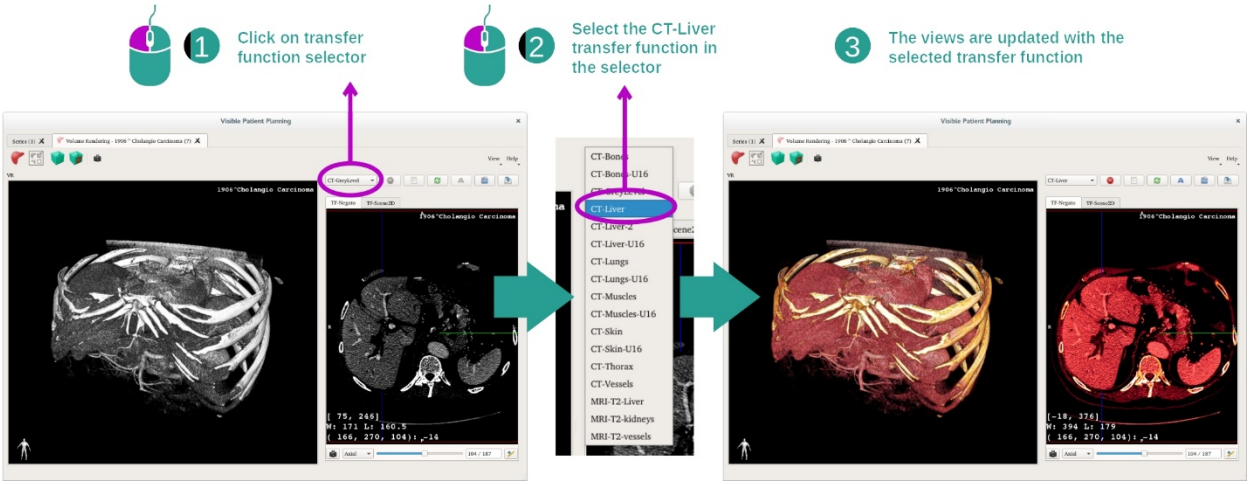
As an example, the following steps will be based on the analysis of a patient’s liver tumor.

Step 1: Hide the 3D model



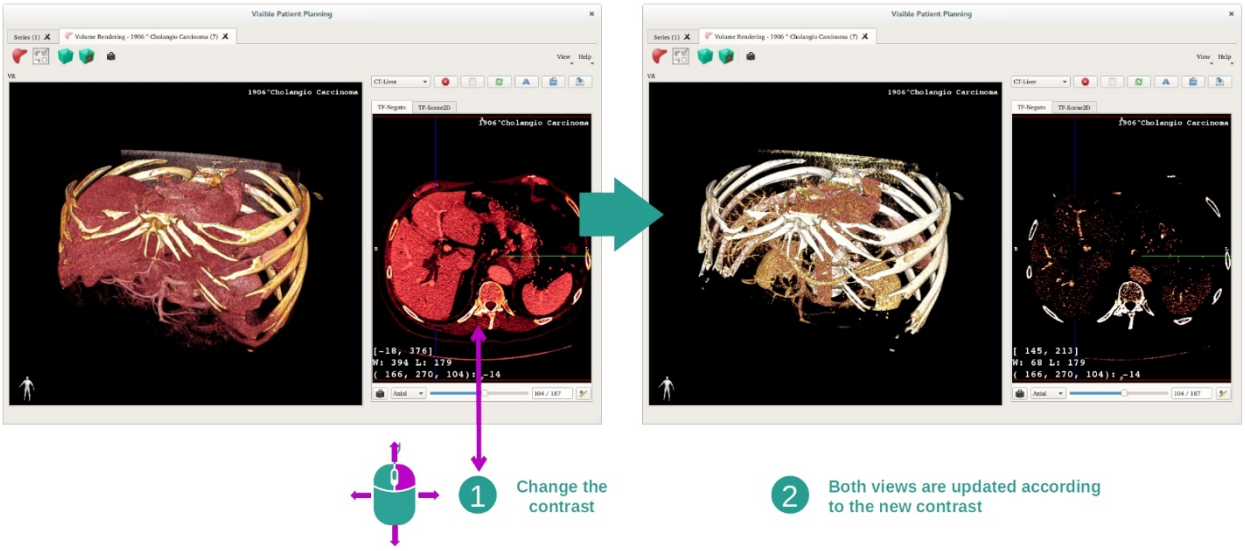

If the activity has been launched with an image and a model, you might want to hide the model in order to see only the volume rendering. To do so, uncheck the “Show Mesh” button.

Step 2: Select a transfer function




You can change the volume rendering transfer function in order to display other anatomical parts. The transfer function establishes a correspondence between pixel values and colors in order to highlight specific information. To change the transfer function, click on the transfer function selector and select the one you need.

Step 3: Adjust the window level




The volume rendering can be adjusted by changing the window level of the medical image. This can be performed exactly as in the 2D MPR activity (*Step 2: Adjust window level*).

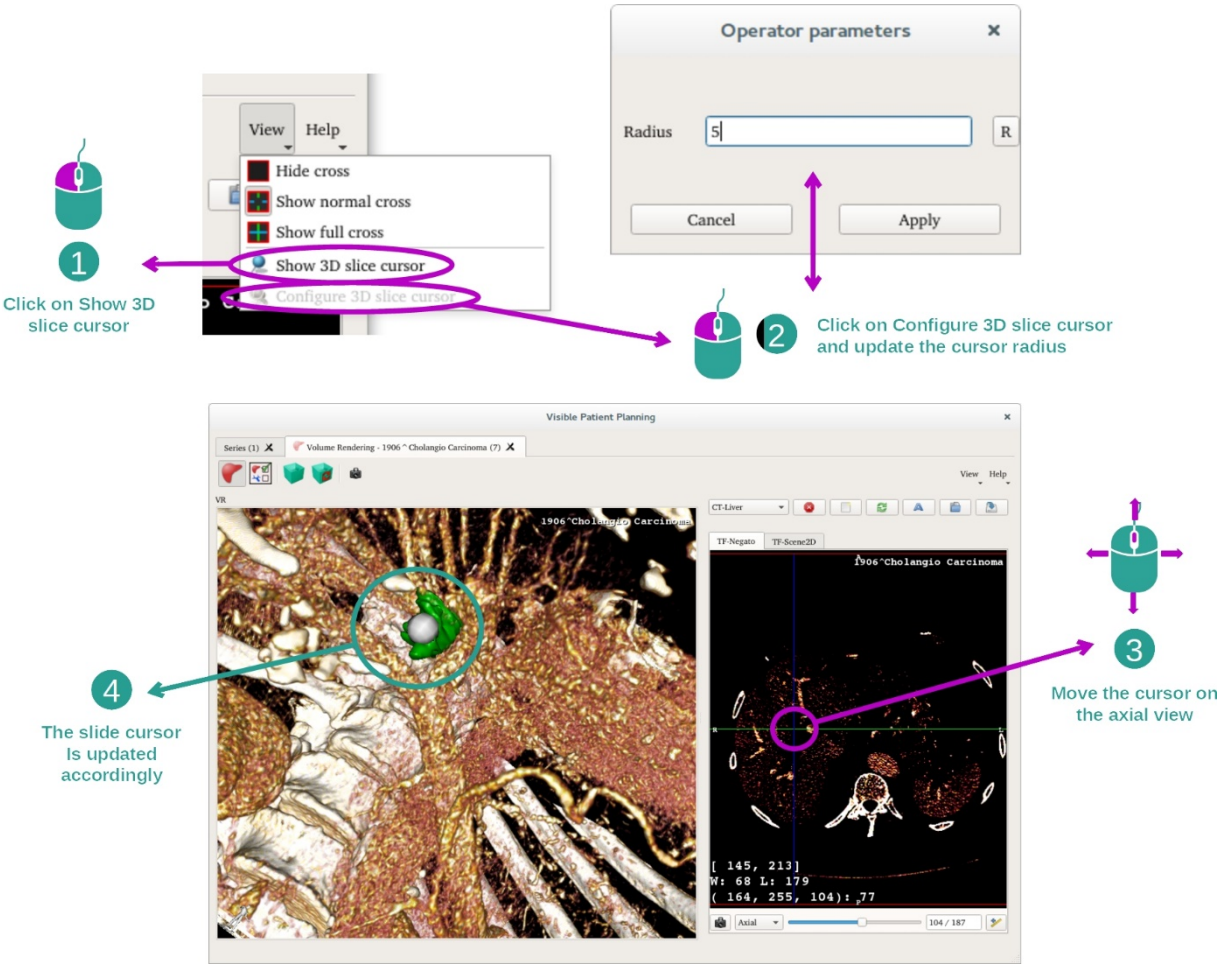
Step 4: Display a 3D model into the volume rendering

As in step 1, you can display 3D models by clicking on the “Show Mesh” button. The organ manager is available in this activity. Thus, you can change opacity and color of the organ’s models like in the 3D model activity. For the next steps, we will be displaying the patient’s liver tumor in the volume view.

Step 5: Detail an anatomical area

The volume rendering interactions are the same as the interactions in the 3D model activity.

Step 6: Use the 3D slice cursor



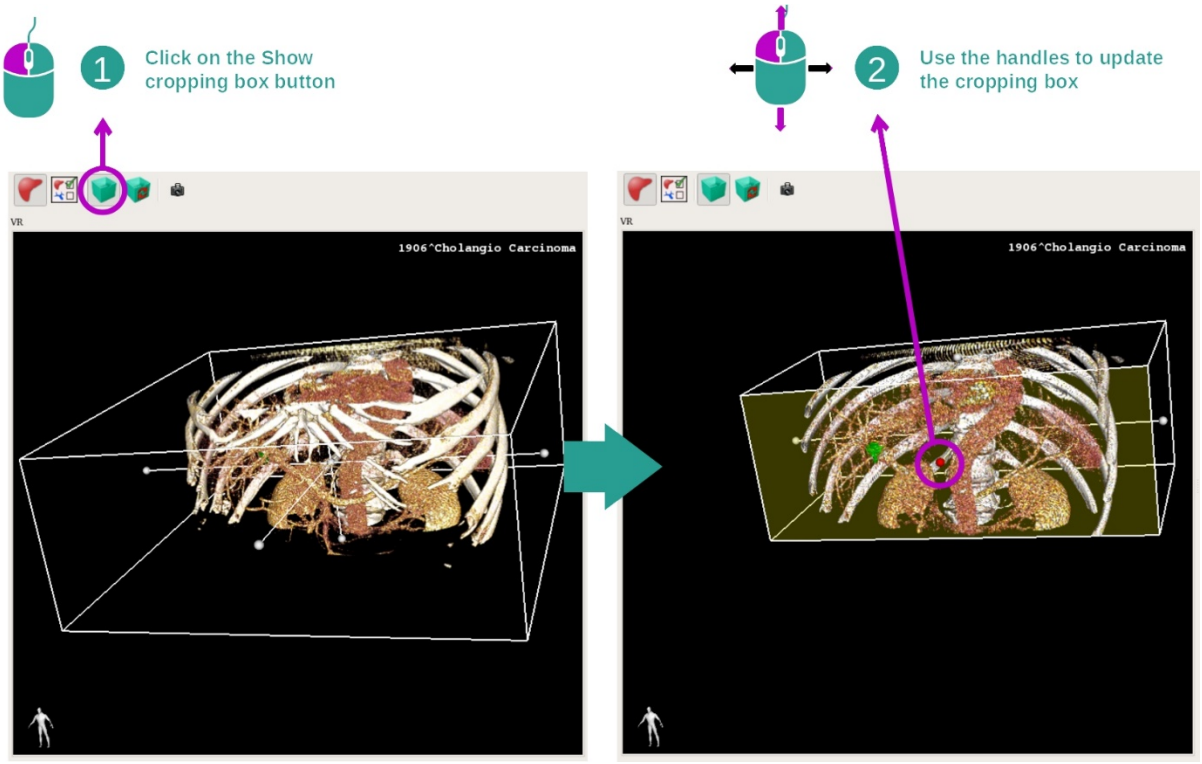

In order to localize a point in the volume rendering view, you can use the 3D slice cursor available in “View” menu:

- click “Show 3D slice cursor”
- click “Configure 3D slice cursor”.

Then, you just have to pick a point on the right-side view using the middle mouse button. The related point will be displayed in the volume rendering view using a white sphere. On the image above, the cursor is moved on top of the patient’s liver tumor.

The 2D view interactions are the same as in the 2D MPR activity.

<u>Step 7: Update the cropping box</u>

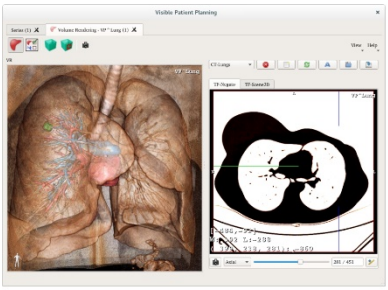


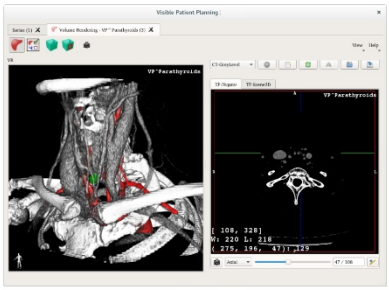

The visualization of the volume can be improved by using the cropping box. To use it, click “Show/Hide box cropping”. It can then be moved or resized by clicking and dragging one of the handles at the side of the box. The volume will be cropped accordingly.

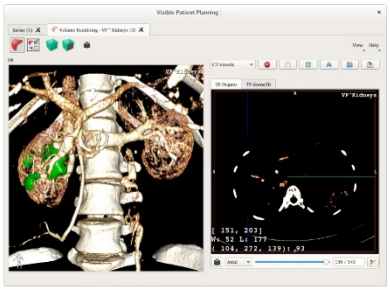
You can reset the box by clicking “Reset box cropping”.

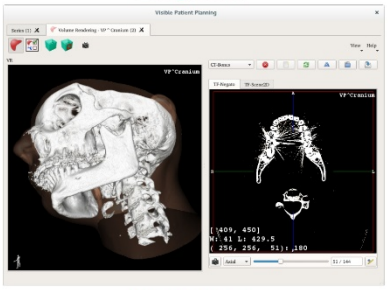
### 7.5.3 Examples of other anatomical structures

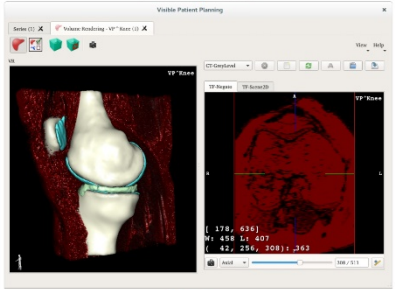
The previously detailed scenario can be applied to other anatomical structures using the Volume Rendering activity. The following section lists several examples of structures that can be visualized. This list is not exhaustive.

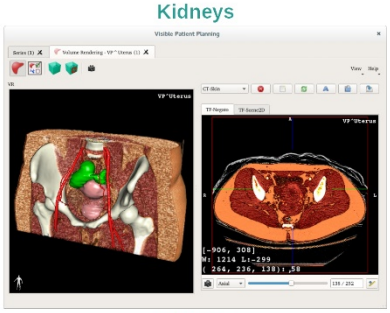

Lung tumor

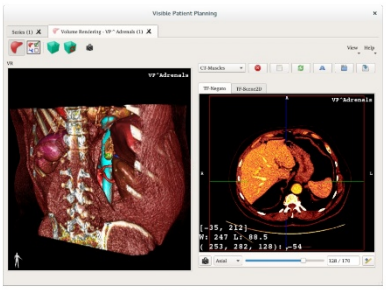

Parathyroids

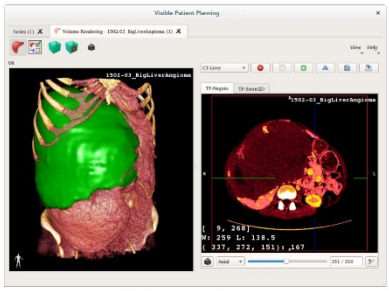

Kidneys

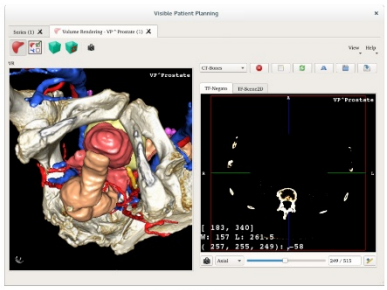

Prognathism


Knee


Uterus


Adrenals


Liver angioma

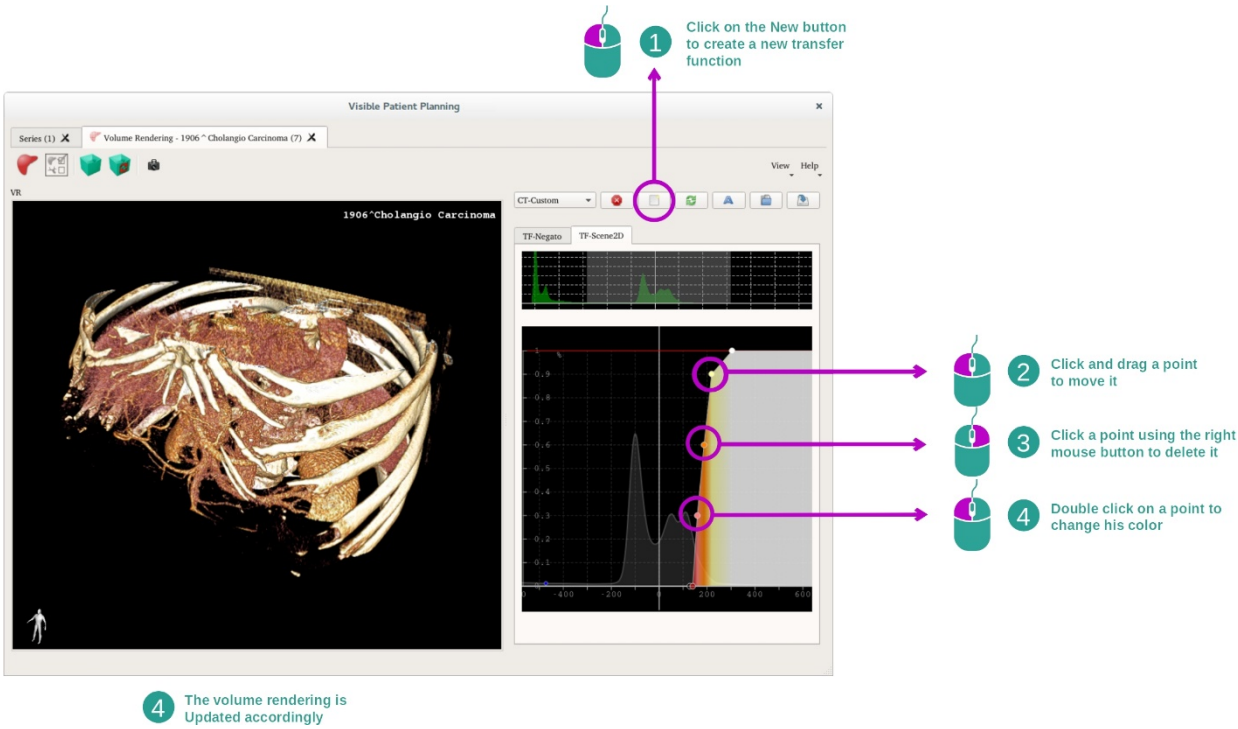

Prostate

### 7.5.4 Additional information

Additional image information

The volume rendering view displays an orientation marker and the patient's name, just as in the 3D model activity.

Transfer function editor




The transfer function manager allows one to create, reset, rename, delete, save and load transfer functions. Per the transfer function editor, you can customize your functions by plotting colored points on your image's histogram.

Save a snapshot

Snapshots of the volume rendering view can be done using the snapshot button, just as in any other activity.

Change 2D view orientation

To get an explanation on how the cross-displaying system works, please refer to the MPR2D activity documentation (see *Change main view image orientation*).

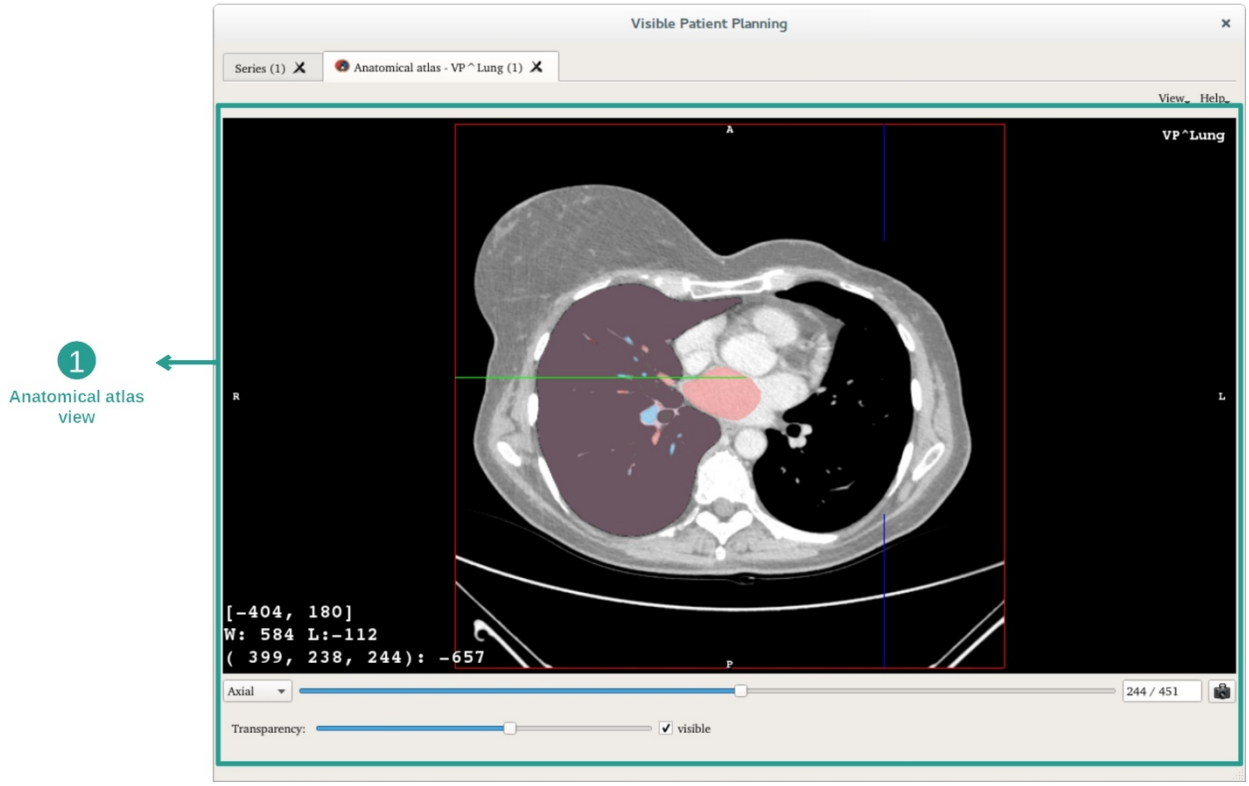
## 7.6 How to use the Anatomical Atlas Activity

The Anatomical Atlas activity is dedicated to the visualization of segmented anatomical parts thanks to colored image areas called atlas.

### 7.6.1 Prerequisites

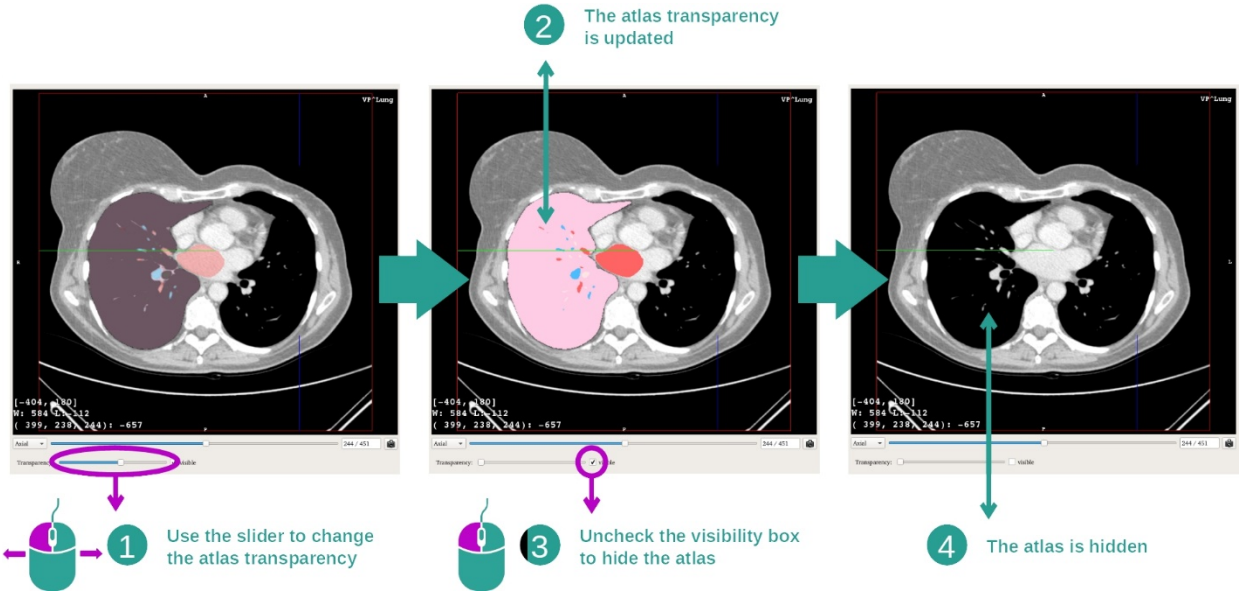
In order to start an Anatomical Atlas activity, an anatomical atlas series is required. Typically, these data are loaded from a VPZ file. Select the series from Series activity (*How to load data*) and click “Launch activity”, or double click the series.

### 7.6.2 Visualize the patient’s anatomy



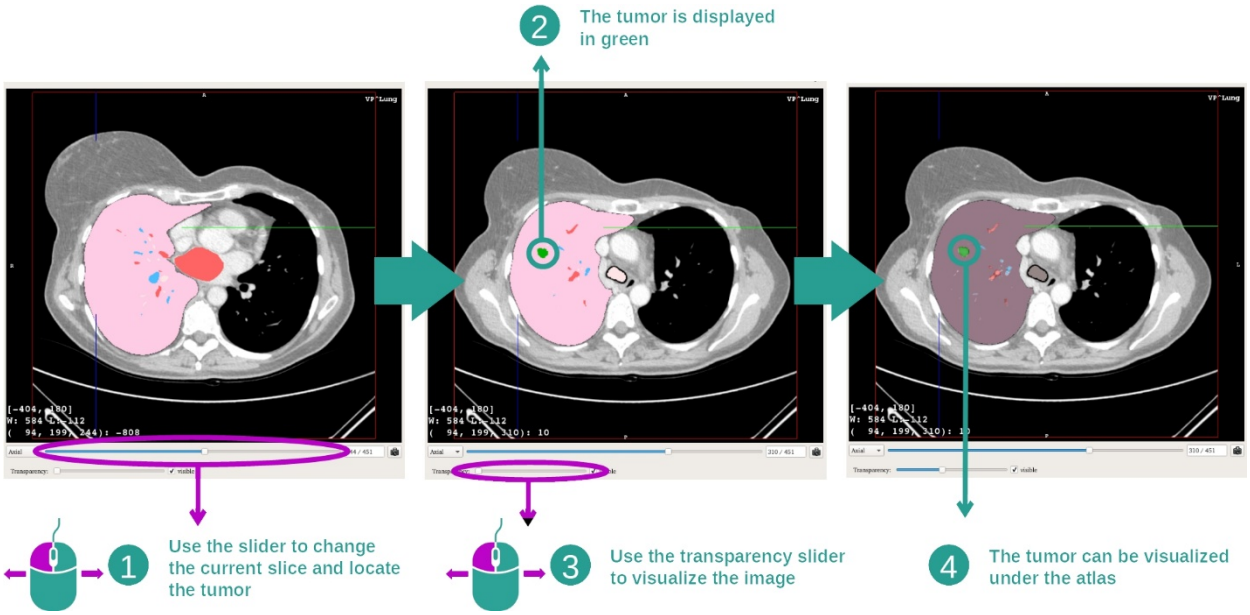

The activity includes an image view allowing one to localize segmented anatomical parts per colored image areas. As an example, the following steps are based on the analysis of a patient’s lung tumor.

Step 1: Update the anatomical atlas transparency




The Anatomical Atlas activity allows one to change the atlas transparency to enhance the understanding of the different anatomical parts. To do so, use the transparency slider located under the image view. The atlas can also be hidden by unchecking the visibility box next to the transparency slider.

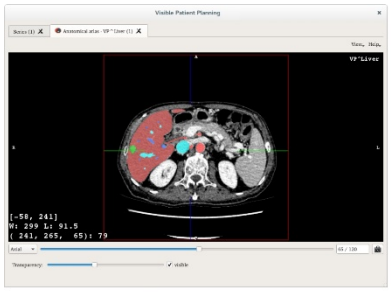
Step 2: Localize an anatomical part



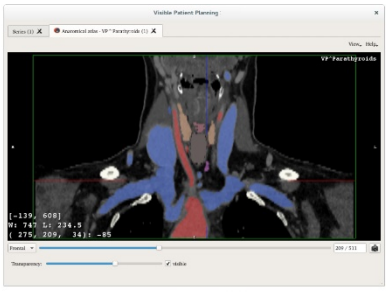
In order to localize a specific anatomical part, use the slider located over the transparency slider. Once the slice is selected, the transparency can be updated to improve the visualization of the tumor.

### 7.6.3 Examples of other anatomical structures

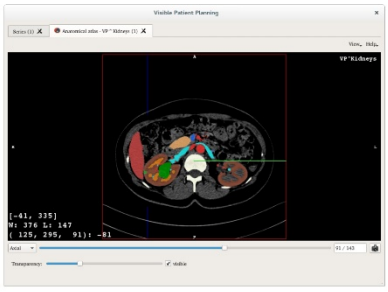
The previously detailed scenario can be applied to other anatomical structures using the Anatomical Atlas activity. The following section lists several examples of structures that can be visualized. This list is not exhaustive.



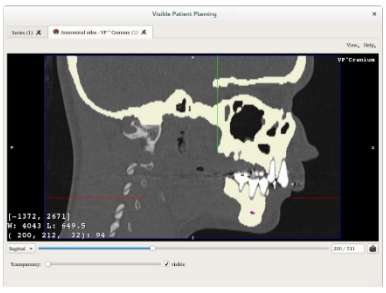
Liver tumor



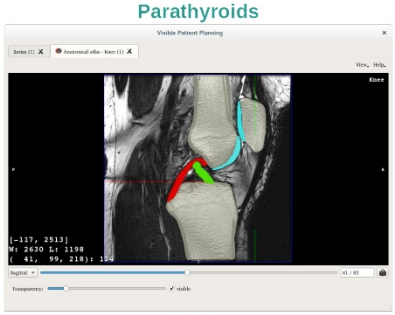
Parathyroids



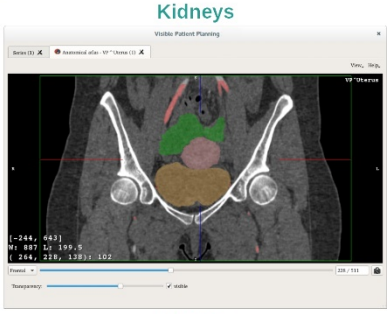
Kidneys



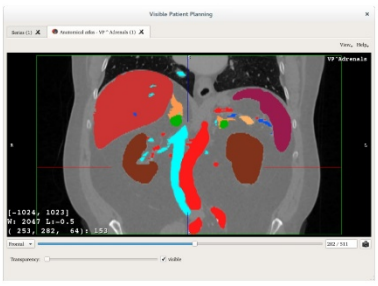
Prognathism



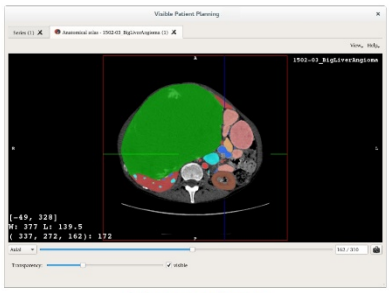
Knee



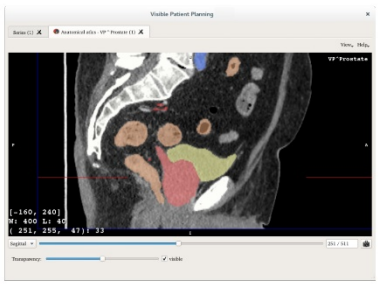
Uterus



Adrenals



Liver angioma



Prostate

### 7.6.4 Additional information

<u>Additional image information</u>

As in the 2D MPR activity, image information is displayed on the view.

1. Patient name
2. Position marker (this information is also displayed at upper, left, lower and right borders of the view)
    I. `S`: Superior / `I`: Inferior
    II. `A`: Anterior / `P`: Posterior
    III. `R`: Right / `L`: Left

3. Image information (advanced information, medical image analysis knowledge required)
    I. On the first line, bounds of current image window range
    II. Next, width of current image window followed by current window level
    III. On a third line, coordinates and value of last picked voxel.

Adjust window level

As in the other activities including a 2D view, window level can be changed by right clicking and holding the button while moving the cursor. Only the image window level is impacted, the atlas display remains unchanged.

Select the orientation mode

As in the other activities including a 2D view, the orientation mode can be selected using the selector located under the main view. Once the orientation mode has been set, the slider updates the corresponding view when moved.

Save a snapshot

In order to save the current view as an image, use the snapshot button, as in other activities.

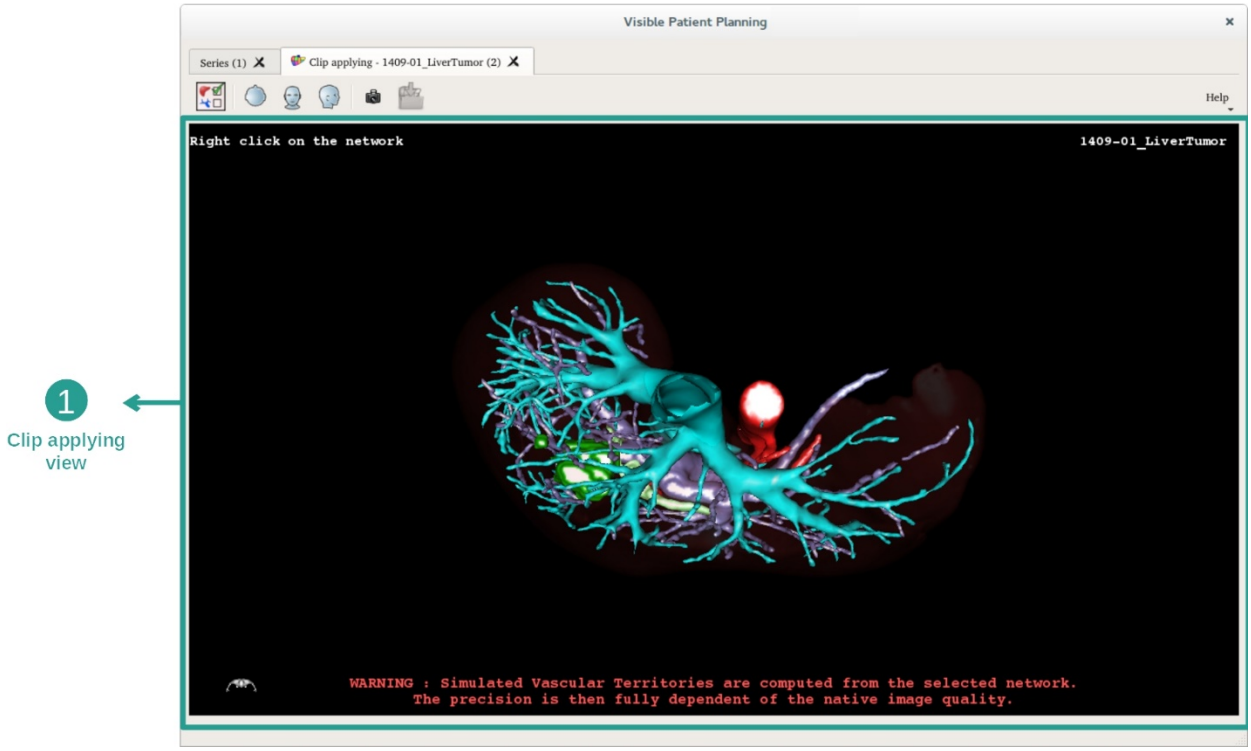
## 7.7 How to visualize organ segments

The Clip Applying activity is dedicated to the visualization of organs segments (Please note that organ segments are approximated). Clips can be placed on the organ's network in order to display the different segments and approximations of the computed volumes.

### 7.7.1 Prerequisites

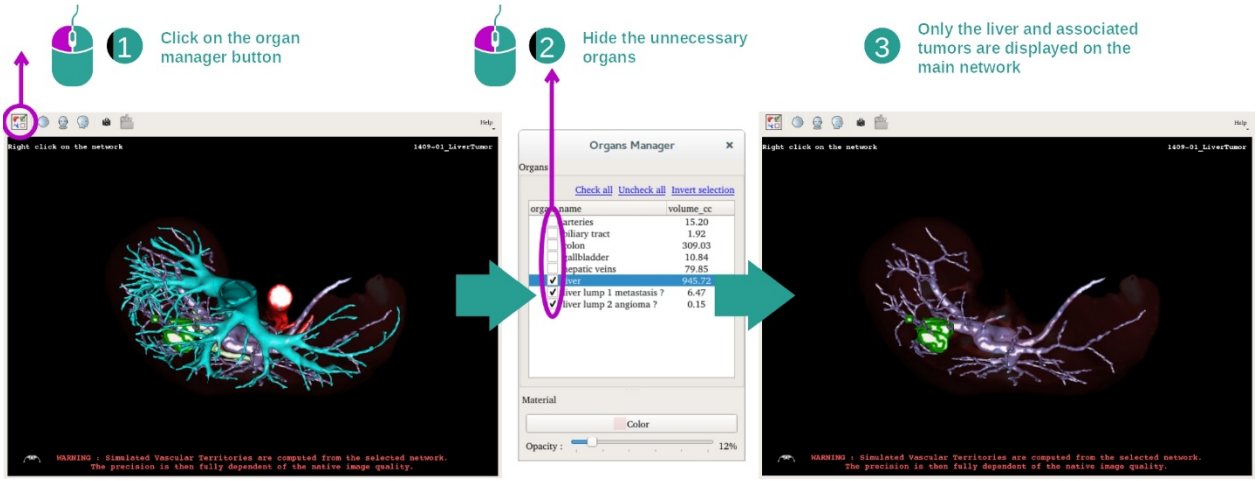
In order to start a Clip Applying activity, a clip applying series is required. Typically, these data are loaded from a VPZ file. Select the series from Series activity (*How to load data*) and click "Launch activity", or double click the series.

### 7.7.2 Apply clips on an organ's network




The activity includes a 3D view allowing one to visualize the organs segments.

Step 1: Hide organs to visualize an anatomical part

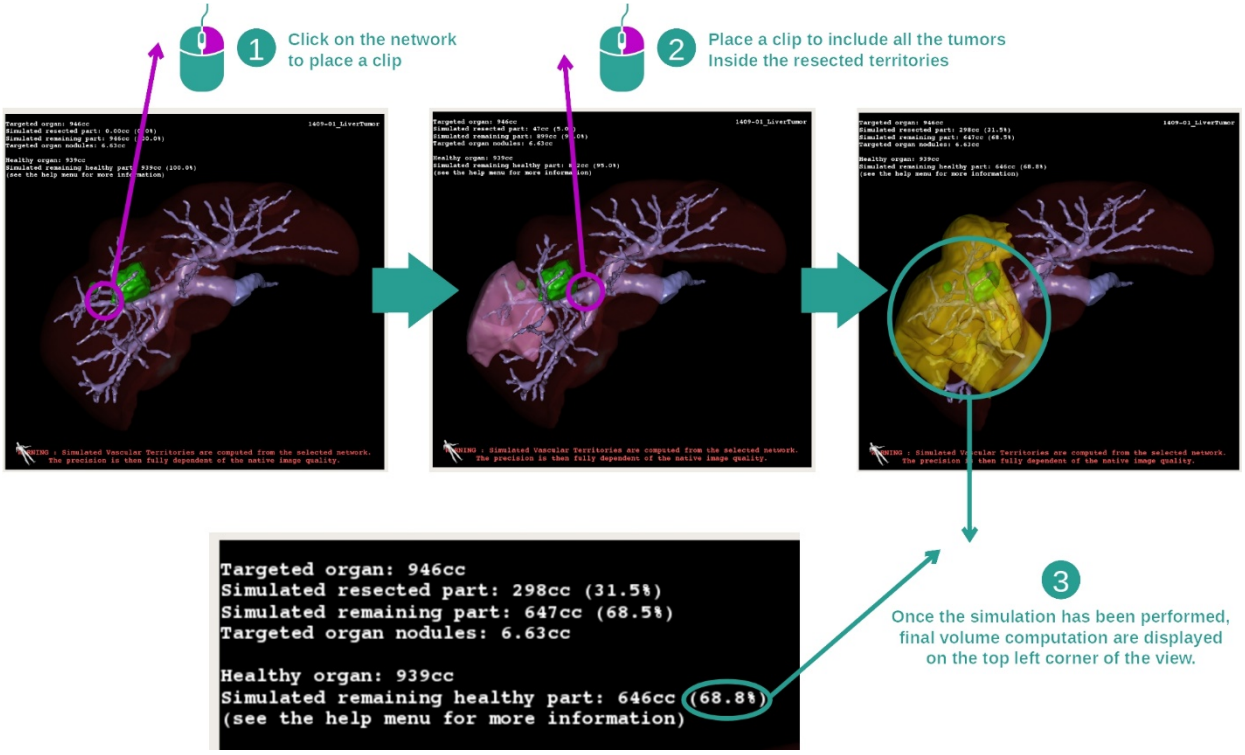



The first step is to hide anatomical parts that obstruct the tumor visualization with the organ manager. For more information about the organ manager, please refer to the 3D model activity documentation.

Step 2: Detail the anatomical area

In the main view, the same interactions as in the 3D model activity (rotation, zoom and translation) can be performed.

Step 3: Clip applying simulation




To show a segment corresponding to a network section, right click on the corresponding section. To hide a segment, simply right click on it. Approximated volumes of several organ

parts, such as resected part, remaining part, and remaining healthy part are computed accordingly.

Volume's approximation method

Simulated resected part:

- Volume of simulated resected part = volume of all displayed segments
- Percentage of simulated resected part = volume of simulated resected part / targeted organ volume

Simulated remaining part:

- Volume of simulated remaining part = targeted organ volume – volume of simulated resected part
- Percentage of simulated remaining part = volume of simulated remaining part / targeted organ volume

Targeted organ nodules:

- Volume of targeted organ nodules = sum of nodule volumes located inside the targeted organ Nodules: mass or lump detected inside the targeted organ and present in the 3D modeling

Healthy organ:

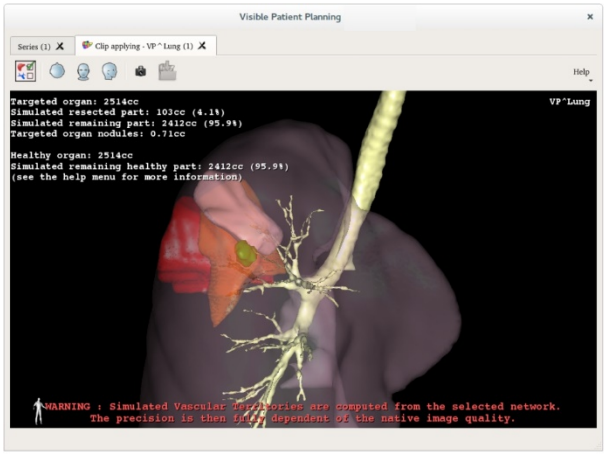
- Healthy organ volume = targeted organ volume - volume of targeted organ nodules

Simulated remaining healthy part:

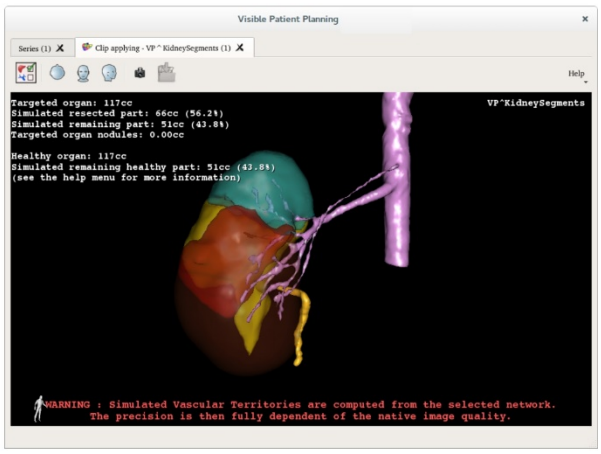
- Volume of simulated remaining healthy part = remaining organ volume - remaining nodules volume
- Percentage of simulated remaining healthy part = volume of simulated remaining healthy part / healthy organ volume

### 7.7.3 Examples of other anatomical structures

The previously detailed scenario can be applied to other anatomical structures. Clip applying can also be used to visualize lungs and kidneys segments.




Lungs

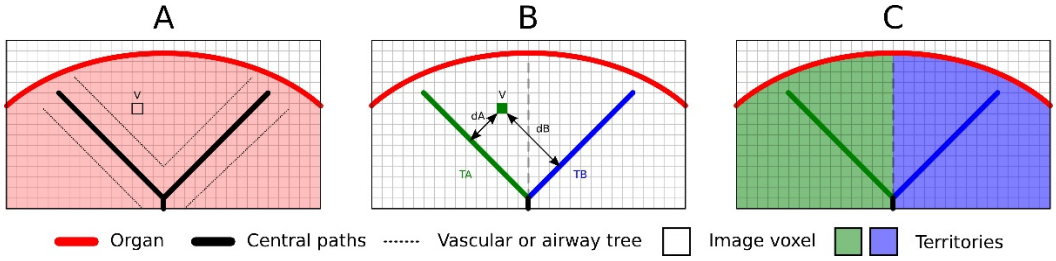



Kidneys

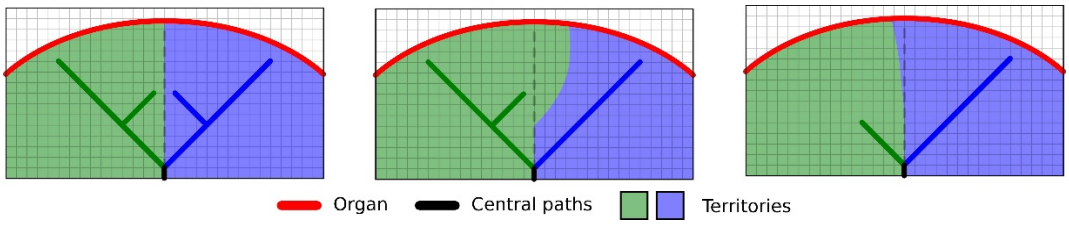
### 7.7.4 Additional information

Vascular and airways territories estimation

Vascular and airways territories proposed in this activity are an approximation of the real patient anatomy. The method used to estimate these territories is based on the organ vasculature or the organ airway tree and the method accuracy directly depends on the tree segmentation quality. Territories estimation is the result of the following process.




First, the vascular or airway tree segmentation is used to compute tubular central paths (A). Then these central paths, who represent the tubular structure, are labeled by trained medical professionals to associate each path to an organ territory. Then, for each image voxel of the targeted anatomical structure, the method finds the closest central path and associate the same organ territory (B). Finally, the labeled image result is meshed to obtain all territories estimation (C).




The method accuracy directly depends on the tree segmentation quality. Image resolution, contrast product diffusion inside the organ vascular system during the image acquisition, etc, may have an impact on the territories estimation.

Additional image information

As in the 3D model activity, the patient's name and an orientation marker are displayed on the view.

Save a snapshot

In order to save the current view as an image, use the snapshot button.

# 8 Maintenance

No maintenance is required for Visible Patient Suite. To control software distribution, a license system is used in each software of Visible Patient Suite.

## 8.1 Visible Patient Planning

VP Planning software comes with integrated license which are granted for 6 months.

## 8.2 License update

60 days before license expiration, a popup with information about expiration date appears each a software is started.

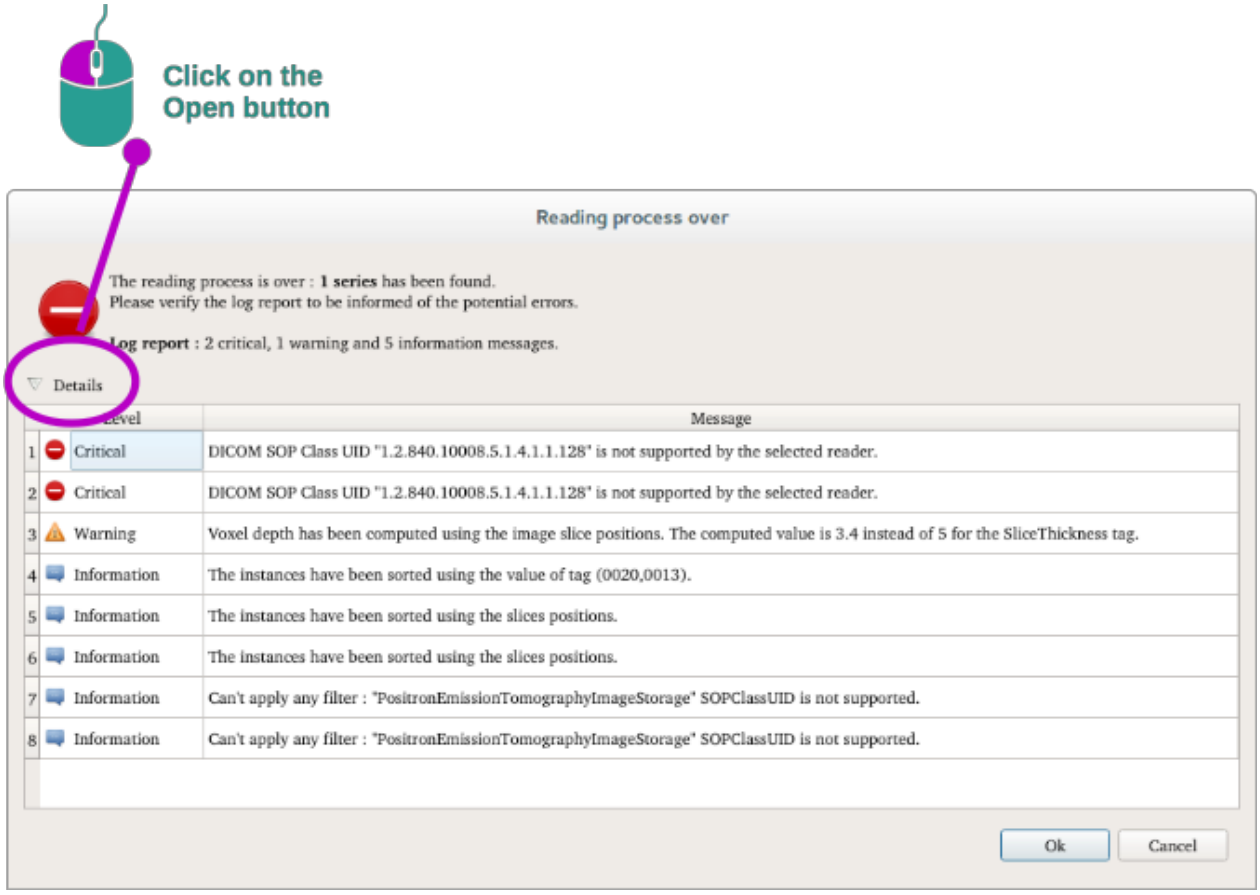
It is recommended to check for a new software version if the expiration date is less than 30 days away. If there is no new version, please contact the support for a new license.

# 9 Troubleshooting

## 9.1 General troubleshooting

### 9.1.1 I can't open my DICOM file

DICOM is a standard for medical data. This standard implementation varies from one company to another. If the software can't read your DICOM files, more information is available at the end of the DICOM reading process. When the process is over, a popup appears. Click "Details" to see additional information:




You can see several messages which are classified this way:

| Icon | Signification | Consequence |
|---|---|---|
| | Information | Information about reading process |
| | Warning | Information that can induce wrong reading |

| | | |
|---|---|---|
| | Critical | Critical error, the series is not read at all |

Should you encounter any problems with DICOM reading, please contact Visible Patient support.

## 9.2 Organ's segments visualization troubleshooting

### 9.2.1 I don't see any volume displayed

If this message is displayed in the upper left corner:

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**Note:** Incoherence detected during volume computation

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The system has detected an incoherence in volume computation. Consequently, the system displays this message to warn you about a problem with the computation of segment volumes. This message is a risk control measure. Please contact Visible Patient support if you encounter this problem.

### 9.2.2 I see a warning about simulated vascular territories in Clip Applying activity

When the Clip Applying activity (Organ's segments visualization) is started, this message is displayed in red:

---

**Note:** Simulated Vascular Territories are computed from the selected network. The precision is then fully dependent of the native image quality.

---

This message is expected and is a reminder about the organ's segments computation and the fact that this modeling depends on native image quality. So, the proposed segments are an approximation of the reality.