1 Manufacturer



Osimis s.a. Quai Banning 6 4000 Liège Belgium

2 Product name

Osimis Pro Web Viewer plugin

3 Product version

1.3.0.0

4 **Product description**

Osimis Pro Web Viewer is a class I active medical device.

It is a Picture Archiving and Communication System (PACS).

Osimis Pro Web Viewer is a plugin of Orthanc, an open-source, lightweight DICOM server with an ubiquitous Web interface that enables the user to upload, receive and transfer DICOM images. It comes with a REST API to automate imaging flows and an SDK to integrate with native applications.

The following types of exams are supported by the viewer:

- CT scans;
- MRIs;
- PET scans;
- Tomography;
- Echographs;
- RXs;
- Dicomized Static Images; and
- Endoscopies.

Unsupported image types cannot be uploaded. Contact Osimis for Technical Support.

Main functionalities include:

- Display and access to patient history;
- Display of patient and study information;
- Selection of studies and series to be analysed;
- Image control including pinch, zoom and pan gestures, image rotation and flip;
- Adjustment of Hounsfield windowing and windowing presets for e.g. lung, bone;
- Progressive loading;
- Annotations;
- Measures;
- Studies comparison
- Liveshare allowing for remote collaboration sessions

5 Intended use

Osimis Pro Web Viewer is intended for professional use only.

It is intended to be used for viewing, archiving and transmitting images. It also allows annotations, report writing and live collaboration between multiple reviewers.

Osimis Pro Web Viewer is not intended to post-process images for diagnostic purposes and does not enhance image by controlling image acquisition.

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6 Warnings



Lossy images are not intended for diagnostic review. For primary diagnosis, DICOM images should be used.

Incomplete diagnosis: Verify that the study is complete before establishing a diagnosis.

Risk of misinterpretation: The size of the screen must be adapted for the intended use.

Risk of misinterpretation: Verify patient and study data. The information is visible on all screens.

Risk of misinterpretation. Verify the orientation of the patient image thanks to the indicators placed around the image (when applicable): A: Anterior, H: Head, P: Posterior, I: Feet, L: Left, R: Right.

Risk of misinterpretation: Lengths are measured in mm or in pixels, depending on the image type.

Risk of misinterpretation: Since the viewer is executing in a web browser on unknown hardware, the user might experience slow refresh of images, crossing pane and reference lines and should therefore always validate the correctness of the displayed information before drawing diagnostic conclusions.

7 Precautions

User shall ensure access and use to compatible hardware and software.

8 Installation

Product installation and configuration are performed by the user.

User is responsible to observe all regulations regarding the protection of the data:

- Rules about password complexity
- Access rights
- Session timeout configuration

9 Hardware compatibility

9.1 Screen sizes

The viewer could be use on screen having a minimal size of 640 x 320 pixels.

9.2 Network

The viewer communication (front-end / backend) must run on a T1 DSL line or equivalent

9.3 Server hardware

Server side soft should run on hardware with a minimal CPU >/= an I5 dual core with 8 GB or ram.

9.4 User hardware

Client side soft should run on hardware with a minimal CPU >/= an I5 dual core with 8 GB or ram

10 Software compatibility

10.1 Browser

The product runs under the following browsers:

On Windows OS:

- IE 11 and later
- Edge 14 and later
- Firefox 48 and later
- Chrome 45 and later

On OSX:

- Safari 9 and later
- Chrome 48 and later
- Firefox 28 and later

10.2 Operating system

The product must run on the following Operation Systems: windows 7-10 and later, Mac OS x 10.9 and inside Docker containers on Linux.

10.3 Orthanc

The viewer runs with an Orthanc Server version 1.3.1 and later.

11 Operating instructions

The Osimis zero footprint HTML5 medical imaging viewer features a rich JavaScript API for displaying and working with images within HTML5 elements. It comes as a set of two plugins to the Orthanc core library, which they have been specifically designed for.

The viewer supports both mouse and multi-touch (gesture) input and has been optimised for visualisation on mobile devices.

11.1 Overview

The viewer is subdivided into the following sections that will be made reference to throughout this document. Viewer section are illustrated in Figure 1. Figure 2 provides an example of the viewer interface for radiology application.

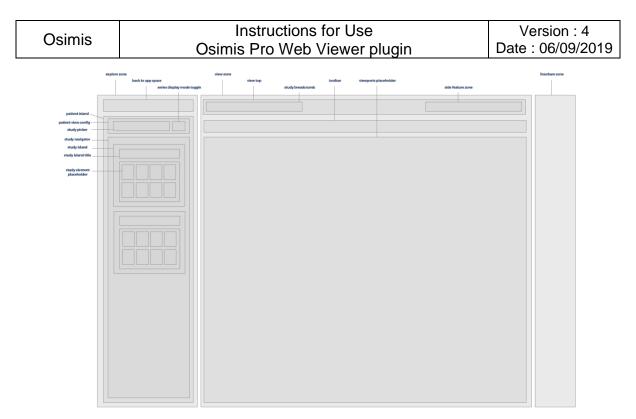


Figure 1 – Viewer sections



Figure 2 - Radiology viewer

11.2 Patient & study information

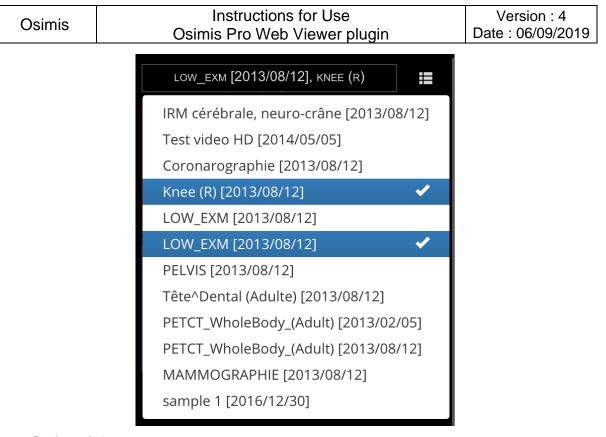
NEURO (1961/06/28) IRM cérébrale, neuro-crâne (2013/08/12)

The patient and study information is always shown in the top of the "Study Breadcrumb", starting with the patient name and birth date on the left and the study type and date on the right.

11.3 Patient history

The patients' history can be accessed by clicking on the study picker in the top of the left hand element of the viewer.

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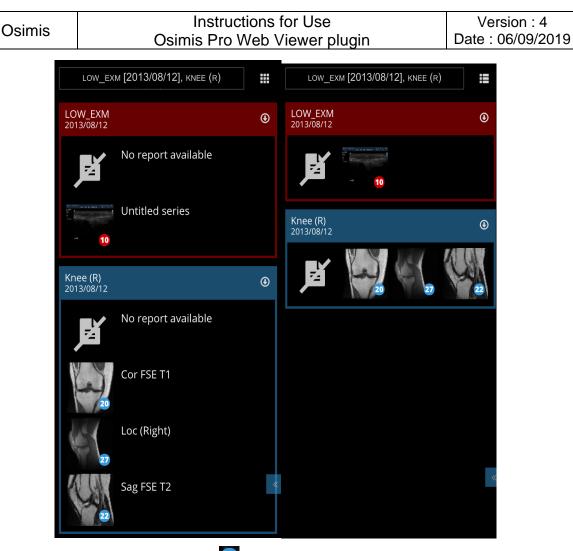


11.4 Series picker

Once the user has selected at least one study, the thumbnails of the series held within the study are shown either in a list or grid format. The user can toggle between the following views.

In order to distinguish the series of different studies, they're assigned a colour that's also being used in the viewports.

This way, the user can compare 2 or more series of different studies.



Viewed studies are indicated with the 2 icon in the top left corner of the breadcrumb.



11.5 Toolbar



Note : All tools with a toggle function have a blue underline if enabled.

11.5.1 Viewports management

The user can toggle between a single viewport,1x1, 2x1, 1x2 or 2x2 layout.

11.5.2 Image controls

Combined tool: By selecting the combined tool, WW/WL is under the left mouse button, Pan under the middle mouse button and zoom under the right mouse button.

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Zoom: left-click-drag up and down with the left mouse button to zoom in or out. Note that the zoom function is also available on right-click-drag when any other tool is selected.

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Pan: click-drag to move the image. Note that the pan function is also available on middleclick-drag when any other tool is selected.

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Invert colour: click to invert the colour of the image (black becomes white)

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Windowing: click-drag to change the Hounsfield winnowing level and modify the contrast/brightness of the image. The viewer comes with a series of windowing presets for lung, bone, ...that are configured at installation. The viewer will also suggest presets that are stored in the image Dicom tags.

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Magnifying glass: click on the image to display a local zoom. Zoom level and magnifying glass size can be adjusted when selecting the tool

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Rotate: click to rotate the image 90° CW or CCW

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Flip: click to flip the image vertically or horizontally

On Touch devices, the viewer supports pinch, zoom and pan gestures. Whatever the selected tool, they are always enabled. Use 2 fingers to pan and zoom.

11.5.3 Measurements and annotations

The viewer provides multiple measurements and annotations. Note that dimensions are expressed in mm given the scaling information contained in the DICOM image. If the image does not contain any such information, dimensions are displayed in pixels.

All annotations can be edited by moving the handles. Handles can be moved as soon as any of the annotations tool is selected.

To remove an annotation, drag one of its handles outside the viewport.

Depending on the configuration of your installation, annotations will be stored or not and will/won't be visible next time you view the same image.

Length:	
First click: starting pointSecond click: end point	9 18.68 mm

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«	Then, y point ca Pixel p i The fir coordina The sec	First click: starting point and angle Second click: end point of the second line ou should adjust all lines. The angle an be "exploded" robe : click and move the mouse. st line displays X and Y pixels	0 23.21 2623, 254 SP: 484 MO:	
0	•	First click: start drawing the ellipse Second click: stop drawing the ellipse	Mean: 5 StdDev: Area: 43	5-00-5-
	•	gle ROI : First click: start drawing the ellipse Second click: stop drawing the ellipse	St	ean: 747.04 dDev: 53.66 ea: 812.35 mm^2

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→	Text a • •	nnotation: First click: the arrow pointer Second click: the arrow end	Test	

11.6 Other tools

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Print: Allows you to print the current view. Note: this feature must be enabled during the configuration of the server. Printing is not available on Internet Explorer.

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Create a key image: This creates a new DICOM image with the annotations burned in the image. When creating the image, you might enter a text that will be stored in a private DICOM tag (7331, 1000). Note: this feature must be enabled during the configuration of the server.

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Synchronized browsing: Once this tool is enabled (it is by default), every time the user changes the displayed instance in a series, all other instances of all other series with the same orientation will be changed accordingly.

The synchronized browsing can be temporarily disabled by holding the shift key in order to adjust an offset between series.

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Download as JPEG: This function will download the image in the selected viewport as image file in .jpeg format. The image is stored in the default download folder.

Reference lines: reference lines show the intersection line of the selected viewport with orthogonal images displayed in other viewports.





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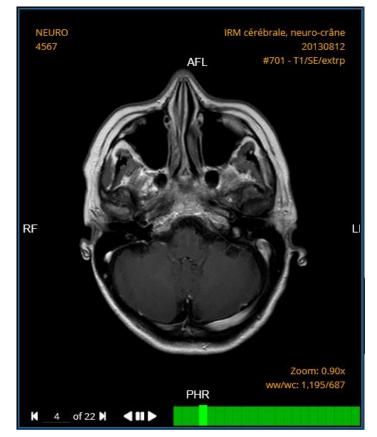
Cross-Hair: clicking in a viewport A will select the slices in other viewports that are intersecting the slice displayed in viewport A near the clicked point.



Warning: Since the viewer is executing in a web browser on unknown hardware, the user might experience slow refresh of images, crossing pane and reference lines and should therefore always validate the correctness of the displayed information before drawing diagnostic conclusions.

Toggle Viewport information: This buttons hide/show the viewport information.

11.7 Image screen



The viewport frame indicates the colour of the study that is visualized.

The study instance data are indicated as follows within the viewport:

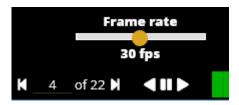
- Top left corner: patient name and patient ID
- Top right corner: Study name + study date + series name
- Bottom right corner: zoom level and Hounsfield windowing level

The bottom of the viewport is subdivided into two parts:

- Left: instance navigator with an option for the user to control play speed when hovering over the play button

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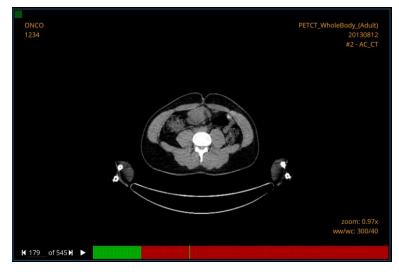
- Right: the instance navigation bar.

Note that you can also change the displayed instance with the mouse wheel.

11.8 Progressive loading

Low-res images are loaded first for quick navigation. Lossless images are loaded afterwards or as soon as a user stops on an instance (see red/green markers below).

Low-res images (red marker) are not intended for diagnostic review.



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11.9 Keyboard shortcuts

Here is a list of default keyboard shortcuts. Note that these shortcuts can be changed when configuring the server.

Left arrow	Show previous image
Right arrow	Show next image
Up arrow	Show previous series
Down arrow	Show next series
Shift + up arrow	Show previous study
Shift + down arrow	Show next study
L	Rotate left
R	Rotate right
V	Flip vertical
Н	Flip horizontal
1	Invert colour
Р	Select pan tool
Z	Select zoom tool
W	Select windowing tool
Ctrl + I	Select length measure tool
Ctrl + i	Select pixel probe tool
Ctrl + m	Select magnifying glass tool
Ctrl + e	Select elliptical ROI tool
Ctrl + o	Select rectangle ROI tool
Ctrl + a	Select arrow annotation tool
Ctrl + k	Select key image capture tool
Ctrl + p	Print
1	Apply Windowing presets 1 from image
2	Apply Windowing presets 2 from image
3	Apply Windowing presets 3 from image
4	Apply Windowing presets 4 from image
5	Apply Windowing presets 5 from image
Ctrl + 1	Apply windowing presets 1 (from server configuration)
Ctrl + 2	Apply windowing presets 2 (from server configuration)
Ctrl + 3	Apply windowing presets 3 (from server configuration)
Ctrl + 4	Apply windowing presets 4 (from server configuration)
Ctrl + 5	Apply windowing presets 5 (from server configuration)
S	Toggle synchronized browsing
F1	Set layout to 1x1
F2	Set layout to 1x2
F3	Set layout to 2x1
F4	Set layout to 2x2
Space	Play/Pause
Tab	Select next viewport
Shift + tab	Select previous viewport
Enter	Load series in viewport

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11.10 Report display

Reports are displayed in a viewport. The user can zoom, search, set the viewport to full screen, print and download the report.

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11.11 Liveshare

The Liveshare feature allows for remote collaboration sessions to be set up. After you distribute the session sharing link, all actions taken by the host are visible to the guests.



The Liveshare button is available in the top right corner of the viewer.

11.11.1 Hosting a session

Once the host presses the Liveshare button, he's prompted with an explainer modal. The user can choose to skip this step the next times.

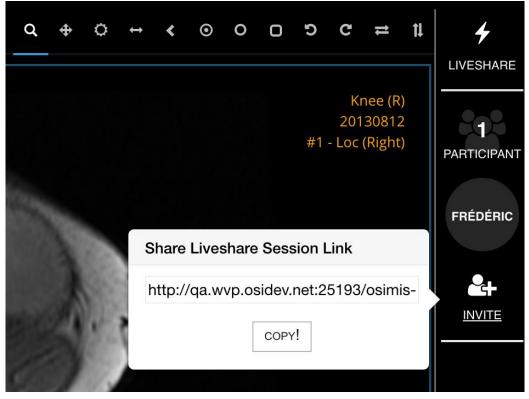
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Next, the user will be asked to enter his name. This name will be stored in the browser's cookies.

		Tell attendees who you are! Provide basic information about yourself.	×
Your name	Username		7
		CANCEL START	



The user copies the link and share it via email or any other channel.

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11.11.2 Attending a session

Any person clicking the generated url will be asked to enter his/her name.

W	elcome to this liveshare session!
	Please provide basic information about yourself.
Your name	Thibault
	JOIN

The attendees name is stored in the cache of the browser, involving the fact that the user's name will be suggested the next time he'll access a study as an attendee or host.

11.11.3 Liveshare session bar

All participants can see the below bar. The bar can be minimized. If an attendee disconnects, his name will disappear from the list. If the host disconnects, the session will be closed altogether and attendees will no longer have access to the study.



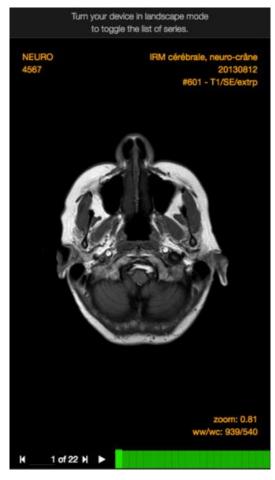
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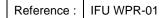
11.12 Mobile optimisation

The viewer has been specifically optimized for viewing on mobile devices with modern browsers. Series can be touch-dragged into the viewport.



The series selector only appears in landscape mode in order to make the optimize the viewing space in portrait mode.





12 Digital pathology viewer

12.1 About the digital pathology viewer

The digital pathology viewer (also called Whole-Slide Imaging viewer // WSI viewer) comes as a separate viewer. This plugin is based upon OpenLayers, a JavaScript framework to display dynamic maps in any web page.

A command-line tool called "DicomToTiff" that converts some whole-slide image stored in an Orthanc server, into a standard hierarchical TIFF image. This tool can be used to export DICOM images to any post-processing framework.

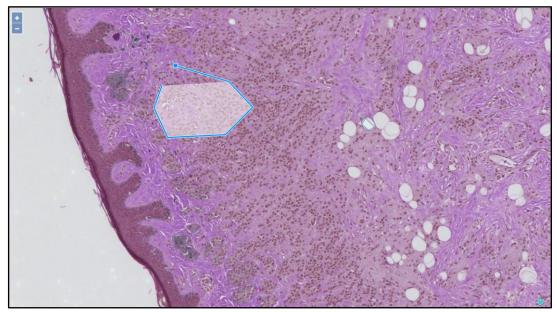
A command-line tool called "Dicomizer" will let the user convert whole-slide images to DICOM, following Supplement 145. This conversion tool can take advantage of the well-known OpenSlide toolkit to decode the proprietary file formats that are commonly used in digital pathology.

The viewer can read virtual slides in the following formats:

- Aperio (.svs, .tif)
- Hamamatsu (.vms, .vmu, .ndpi)
- Leica (.scn)
- MIRAX (.mrxs)
- Philips (.tiff)
- Sakura (.svslide)
- Trestle (.tif)
- Ventana (.bif, .tif)
- Generic tiled TIFF (.tif)

http://openslide.org/formats/generic-tiff/

12.2 Overview



12.3 Image controls

The viewer can zoom and pan within the different levels of slides.

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12.4 Annotations

The only type of annotation currently available in the viewer is a freehand Region Of Interest indicator, which is activated by default

All annotations are stored for a given user.

13 Instructions for Use

To obtain a paper copy of these Instructions for Use, please contact Osimis (<u>info@osimis.io</u> or +32 4 242 90 05). A paper copy will be sent to you within 7 days.

14 Technical problems / Complaints

If you encounter a technical problem or if performances do not correspond with those indicated in these Instructions for Use, record the software version.

Check latest Release Notes of the Osimis PRO Viewer on the Osimis website (www.osimis.io).

Install the latest version of the software or contact Osimis (support@osimis.io).