

# INSTRUCTIONS FOR USE PMA.core 3.0

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Product name **PMA.core 3.0**



Version 3.0.0 build f47dcd30



Manufacturer:

Pathomation BV  
Uitbreidingsstraat 66  
B-2600 Berchem  
Belgium



Complies with the provisions of EU Directive 98/79/EC on in vitro diagnostic medical devices



For in vitro diagnostic use



Valid edition of the Instructions for use: R&D.PR.D.COR.030.IFU\_EN 1.0 issued on May 23 2022  
If you do not have this edition, you can obtain it free of charge:

1. Via <https://docs.pathomation.com/pma.core/3.0.0/doku.php?id=IFU>
2. By sending an email request to [info@pathomation.com](mailto:info@pathomation.com)

User Manual: <https://docs.pathomation.com/pma.core/3.0.0/>

Support & feedback: Pathomation Helpdesk at <https://helpdesk.pathomation.com/>

## 1 Description of the product

### 1.1 Intended purpose

PMA.core 3.0 is a software platform for managing, distributing, viewing and annotating digital images of human tissue slides, scanned using any commercially available slide scanner capable of producing whole slide images in a supported file format. It is intended as an aid to the pathologist to review and interpret digital images for the purpose of primary histopathological diagnosis, including the measurement of any distances or surface areas relevant to making a diagnosis the pathologist annotated on these images.

### 1.2 Intended users

PMA.core 3.0 is intended for professional use by pathologists.

### 1.3 Compliance and clinical performance

PMA.core 3.0 complies with the provisions of EU Directive 98/79/EC on in vitro diagnostic medical devices.

It has been validated for diagnostic use in histopathology of scanned slides stained with hematoxylin and eosin (HE), immunohistochemical (IHC) stainings or in situ hybridization (ISH) and meets the validation criteria of the College of American Pathologists (Evans et al, Arch Pathol Lab Med 2021) for diagnostic use of whole slide images for these applications.

This document complies with the requirements of EU Directive 98/79/EC and MEDDEV 2.14/3 rev.1 on instructions for use for in vitro medical devices.

## 2 Instructions for Use

### 2.1 Prerequisites

#### 2.1.1 Installation and configuration of PMA.core

PMA.core 3.0 is a web-based application that needs to be hosted on infrastructure that conforms to the system requirements that can be consulted at:

[https://docs.pathomation.com/pma.core/3.0.0/doku.php?id=system\\_requirements](https://docs.pathomation.com/pma.core/3.0.0/doku.php?id=system_requirements)

User credentials issued by Pathomation or your system administrator are needed to log in to the system.

At least one root directory with one mounting point for a storage location where whole slide images are stored and to which your user has been granted access is needed to be able to use the WSI management and viewing capabilities of the software.

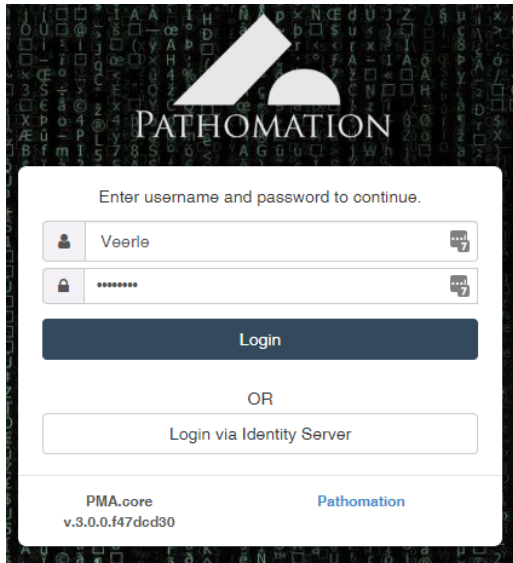
#### 2.1.2 Minimum requirements client PC

PMA.core 3.0 is a web based application. A computer with an internet browser installed and access to the location where PMA.core is installed via network or internet connection is required to be able to use the software.

## 2.2 Using PMA.core 3.0

### 2.2.1 Logging in to PMA.core 3.0

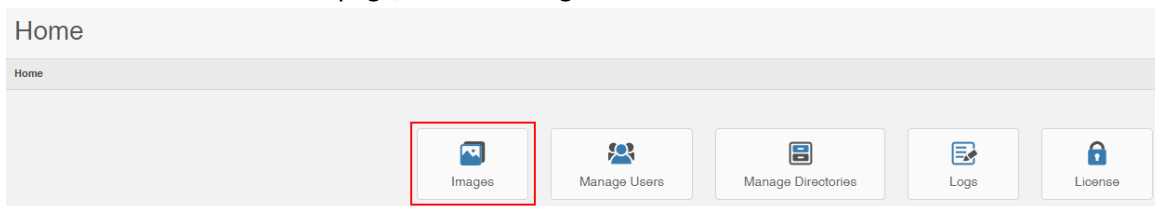
- In a web browser, navigate to the URL where PMA.core 3.0 is installed, as communicated by your system administrator. The login screen will be displayed.



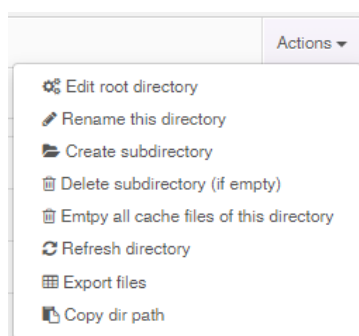
- In the login screen, enter the user name and password you received and click Login.
- You are now logged in and will see the PMA.Core 3.0 home page.

### 2.2.2 Image management

- On the PMA.core 3.0 home page, click the Images button.

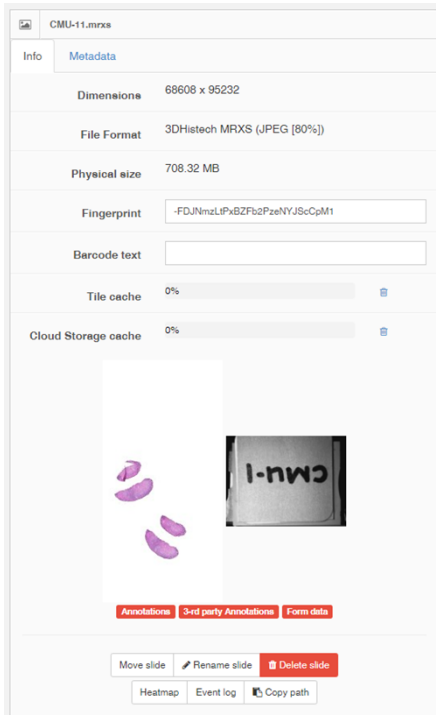


- In the Image Directories, after a selecting a directory the images in the directory will be listed.
- For a selected diectory, the following actions are available via the Actions menu:



- Edit the root directory
- Rename
- Create subdirectory
- Delete subdirectory (if empty)
- Empty cache files
- Refresh
- Export files
- Copy the directory path

- After selecting a slide, slide info and thumbnail image are shown and the following actions can be performed via buttons below the thumbnail:

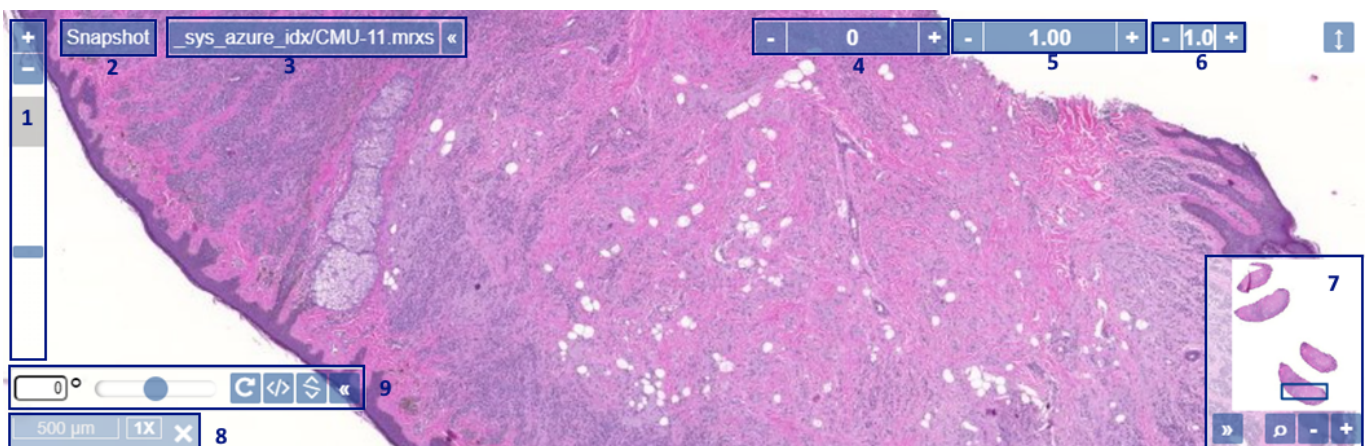


- Move slide
- Rename slide
- Delete slide
- Heatmap: shows a heatmap of the selected slide, to indicate where the user has navigated
- Event log: shows a log of slide access and operations
- Copy path: copy the slide path to the clipboard

- Tags below the image thumbnail indicate whether the image contains annotations, 3rd party annotations, or form data.
- Slide metadata can be consulted from the metadata tab.

### 2.2.3 Viewing whole slide images and virtual microscopy

Doubleclicking the thumbnail of a selected image loads the image in the Pathomation viewport control that acts as a virtual microscope.



The viewport has controls to:

1. Change the digital magnification
2. Take a snapshot

3. Consult the slide filename
4. Adjust the brightness of the image
5. Adjust the contrast of the image
6. Adjust the gamma of the image
7. Consult the thumbnail of the slide, which indicates the part currently in view
8. Consult the magnification and a scale bar
9. Rotate the image

#### 2.2.4 User manual

The user interface of PMA.core is designed to be user-friendly and intuitive to operate.

A full user manual explaining the capabilities of the software in detail can be consulted via the About page of the software or via: <https://docs.pathomation.com/pma.core/3.0.0>.

### 3 Safety instructions and warnings

#### Privacy and patient confidentiality:

Personal data subject to data protection laws may be present on slide labels or captured on forms set up in PMA.core. It is the responsibility of the user to ensure the privacy of this information when sharing slides or form data via PMA.core.

### 4 Revision history

Version	Reason for update
1.0	Not applicable – first version