Instruction for use

AH-1 v1.1.0

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1 Device description

AH-1 is intended to automate the process of identifying new and enlarging lesions in Multiple Sclerosis (MS) adult patients using non-contrast Magnetic Resonance (MR) images.

The software retrieves DICOM MRI data (3D T2-FLAIR series) at two different time points from a DICOM server and sends it to an analysis server for the automatic detection of new and enlarging lesions. The outputs of the software include an interactive report and color-coded overlays displaying the location of newly appearing lesions in the brain.

The results are displayed in a dedicated graphical user interface, allowing the user to:

- Browse the list of new and enlarging lesions.
- Compare the results to the baseline time point.
- Verify the report.

AH-1 integrates with leading MR scanners and can be operated with any MRI scan from 1.5T and 3T scanners for 3D T2-FLAIR MRI.

2 Product description

2.1 Intended use

AH-1 is intended for the automatic quantification and visualization of new lesions in brain non-contrast Magnetic Resonance (MR) images from Multiple Sclerosis (MS) adult patients. The software is intended to automate the current manual process of identifying and quantifying newly appearing lesions in the brain. **AH-1** is a software for professional use that supports disease **monitoring** by providing an automatic estimation of the number and location of newly appearing lesions in the brain through a lesion map along with structured information related to the evolution of lesions during the analyzed period. The physician reads the MR study together with **AH-1** to support the information reported to the patient. The intended users are physicians with expertise in brain medical imaging.

2.2 Intended user

AH-1 is designed to be used by a physician while reporting MRI studies from MS patients.

2.3 Intended patient population

AH-1 is intended to be used on Brain Magnetic Resonance images of Multiple Sclerosis adult patients.

2.4 Environment of use

AH-1 shall be used in a computer with a high-resolution medical display in a radiologist reading room.

Alternatively, AH-1 can be used in the physician's office with similar lighting conditions and with a high-resolution medical display. The sources of distraction present in these environments, i.e. surrounding people or noise, mobile phones, calls, or other sources of distractions can affect the user interaction with the device.

> ⚠ Warning
>
> Ensure **appropriate lighting conditions** for optimal software usage.
> Bright light (natural or artificial) environment can affect the ability of the user to review the lesions. When AH-1 is used outside the radiologist reading room where lighting conditions are warranted, it is the user's responsibility to use **AH-1** in an environment that has appropriate conditions including lighting.

2.5 Intended medical indication

With AH-1 product, the quantification and visualization of the new lesions are automated. The AH-1 software provides a positive effect by identifying the presence of new and enlarging T2 lesions on MRI images of Multiple Sclerosis patients. The presence of new T2 lesions in the brain reflects the inflammatory and demyelinating activity of the disease, identifying patients at higher risk of progression or relapses.

In terms of the medical device claims, the AH-1 software:

- Can accurately quantify the number and location of T2 lesions in patients with multiple sclerosis.
- Can reduce the variability and subjectivity of manual lesion quantification methods and improve the consistency and reliability of the results.

The radiologist reads the MR study of AH-1 to support the information reported to the patient. The use of the product together with the radiologist's expertise clearly improves the obtention of an effective and right treatment, which benefits directly the patient.

3 Safety information

3.1 Indications

1. AH-1 requires 3D T2-FLAIR brain non-contrast images from multiple sclerosis patients in order to perform the analysis.
2. AH-1 is intended to assist in the detection of new lesions in patients with a confirmed diagnosis of multiple sclerosis as part of patient monitoring.
3. AH-1 requires good-quality images to perform accurate lesion detection. The quality of the image is defined according to the clinical protocols and guidance.

3.2 Contra-indications

1. AH-1 does not support CT, PET, RX or any other image type different from MRI.
2. AH-1 is not intended to be used as a stand-alone monitoring tool.
3. AH-1 is not intended to be used in patients with other diseases or conditions different than multiple sclerosis.
4. AH-1 may not provide reliable analysis if the quality of the images is insufficient due to technical factors or patient-related factors.

3.3 Warnings before use

> ⚠ Warning
>
> For security reasons, the user's session will expire after 15 minutes of inactivity. All unsaved data is discarded which may result in data loss. Therefore, make sure to validate immediately after finishing the review.

> ⚠ Warning
>
> AH-1 does not automatically save the changes performed by the user during the validation. If AH-1 is closed without validating (e.g close the browser tab or due to a crash), any changes that have been made will be lost.

> ⚠ Warning
>
> When using the lesion segmentation visibility toggle, be aware that hiding segmentations may make it difficult to see existing lesions when adding new ones. The software will warn you if you attempt to place a lesion near an existing one, but careful attention is still required.

3.4 AI system limitations and considerations

AH-1 incorporates AI technology to assist in analyzing MRI FLAIR 3D sequences and identifying potential new/enlarging lesion candidates. Users should be aware of the following:

- AI-based analysis: AH-1 uses artificial intelligence algorithms, which may have inherent limitations.
- Variable detection capabilities: Performance may vary based on lesion characteristics and image quality.
- Influencing factors: Patient demographics and specific clinical scenarios can affect system performance.
- Supportive tool: AH-1 is designed to support, not replace, clinical judgment.
- Clinical validation requirement: All results generated by AH-1 MUST be reviewed, evaluated, and confirmed by a qualified physician before use in clinical decisions.
- Potential outcomes: As with any supporting tool, there is a possibility of missed findings or incorrect identifications.

For detailed performance characteristics and limitations, please refer to Section 9 of this document.

4 Contact information

For any doubt, comments or questions please contact us at support@tensormedical.ai.

4.1 Incident reporting

Any serious incident that has occurred in relation to the use of AH-1 has to be promptly reported to Tensor Medical and the competent authority of the Member State where the user is established.

4.2 Instruction for use in other formats

These instructions can be printed using the print option of your PDF viewer.

If a printed version is required, the user can obtain a copy of these instructions in paper format that will be delivered in 7 working days upon contacting us at support@tensormedical.ai.

> ⚠ Warning
>
> When using printed or PDF versions, the users should ensure that they are using the most up-to-date of the IFU. Check our official website for any recent updates

5 Product Label

The product label is shown in Figure 1.

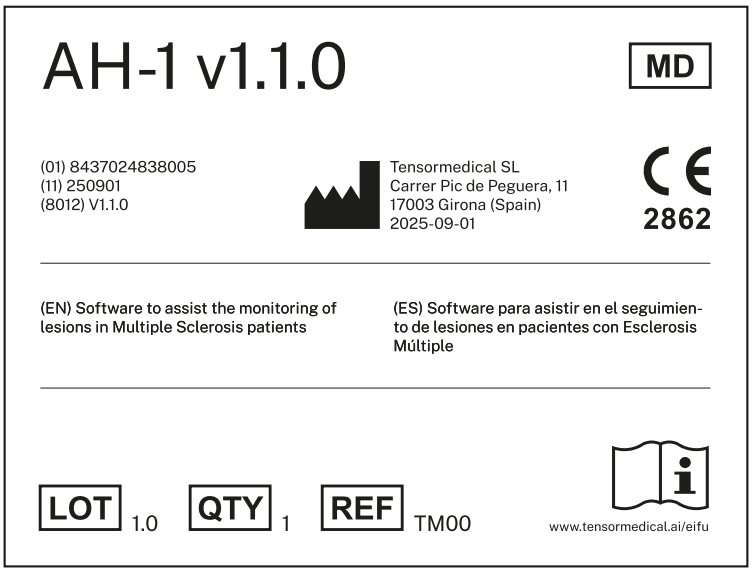

Figure 1: Product label

6 Getting Started

New AH-1 users must read this user guide before using the product. This section helps users quickly get acquainted with AH-1. Experienced users can refer to the guide for specific chapters they need.

6.1 Installation

AH-1 is a web-based software that doesn't need installation on the user's device. It's configured in the hospital's IT system for access through a web browser.

Users need an internet connection and a browser to use AH-1.

Refer to Section 10 for more information on the installation requirements.

6.2 User System Requirements

Before diving into the AH-1's capabilities, confirm that your system meets the necessary requirements for an optimal experience.

6.2.1 Supported browsers

Tip

AH-1 must be launched in one of the supported browsers:

- Chrome 64 or newer.
- Edge 79 or newer.
- Firefox 67 or newer.
- Safari 12 or newer.

Warning

If the user tries to use a different browser than the ones listed, the software can still be used, but some elements may not function properly, and the following pop-up banner will appear: *Browser not supported. Some elements may not function properly or appear correctly in the current browser. Our supported browsers are: Chrome 64+, Edge 79+, Firefox 67+, and Safari 12+.*

Warning

Internet Explorer is not supported for the use of **AH-1**. If the user tries to use it, the following full-screen message will appear: *Internet Explorer is not supported. Please use a modern browser like Microsoft Edge, Google Chrome, or Mozilla Firefox to access AH-1.*

6.2.2 Javascript and WebGL

Tip

The user must have JavaScript and WebGL enabled in the browser.

For AH-1 to function correctly, your browser must have JavaScript and WebGL enabled. These features are usually enabled by default but can be confirmed within your browser's settings under the "Privacy and Security" or "System" sections. Follow the steps below to enable JavaScript and WebGL (using Google Chrome as a reference, the steps may vary depending on the browser).

JavaScript:

1. Open the browser and open **Settings**.
2. Find and open **Privacy and Security**.
3. Under **Privacy and security**, find and open **Site settings**.
4. Find and open **JavaScript**.
5. Set default behavior as **Sites can use JavaScript**.

WebGL:

1. Open the browser and open **Settings**.
2. Find and open **System**.
3. Enable **Use hardware acceleration when available**.

6.2.3 Screen resolution

AH-1 requires a minimum window resolution of **1024x700**. In case of a smaller window size, the following message will appear: *Window size not supported. Some elements may not function properly or appear correctly at the current window dimensions. We recommend to resize the window in order to get a minimum width of 1024 pixels and a minimum height of 700 pixels.*

> ⚠ Warning
>
> AH-1 does **not** support mobile devices or touch screens.

6.3 Accessing AH-1

AH-1 requires a login to access the software. The login credentials are provided by Tensor Medical.

6.3.1 Log in

To access AH-1, visit the URL provided by your institution in your web browser. You will be prompted to log in (Figure 2).

1. Enter your *username* and *password* as provided by Tensor Medical.
2. Click the “Log In” button to access the AH-1 interface.

Upon successful login, the user is directed to the Home screen where all available subjects for consultation are listed. Refer to Section 7 for more information on how to use AH-1.

> ⚠ Warning
>
> If the information entered is not correct the following message will appear: *Login failed. Please check your username and password.* In that case, please retry the entry of the correct *username* or *password*. In case of facing difficulties, contact us though *Forgot your password?* option.

6.3.2 Log out

To log out, click the *Profile* button in the upper right corner. Then, select “Log out” from the list that appears. After that, the user can safely close the browser window.

6.3.3 Account lockout policy

For security reasons, AH-1 has an account lockout policy. If you enter the wrong password after 20 failed attempts, your account will be locked for 1 hour. If you need to unlock your account, please contact us at support@tensormedical.ai.

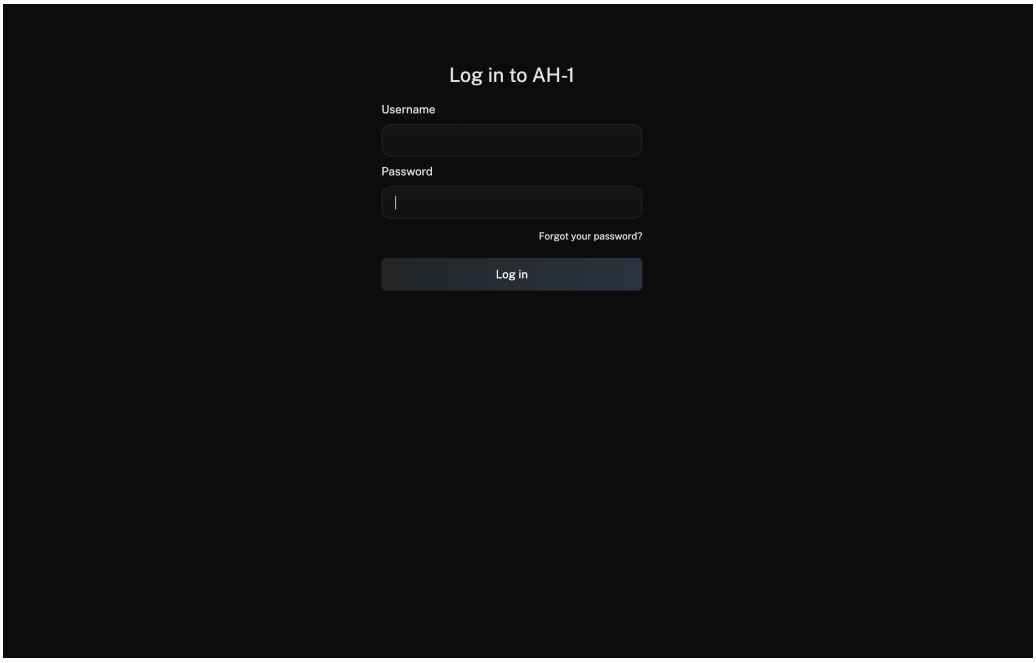

Figure 2: Log in page

7 Using AH-1

7.1 Subjects overview

Upon successful login, the main page of the user interface will be presented (Figure 3). The user will encounter a list of all available subjects for consultation at that moment.

Every subject is assigned a unique ID for patient identification, along with the dates of the two MRI images analyzed by the software, the count of detected lesions, and a designation indicating their status:

- If the analysis by the software is completed successfully, the number of new/enlarging lesions text will be colored in green as **Validated by**, or in yellow if validation is required.
- If the analysis is in process, the respective study will be marked as **Running**.
- If the analysis is pending to be generated by the software, the status will be **Pending**.
- If the analysis by the software has failed, the status will display a **specific error message** describing the reason for failure. Detailed error information is available by hovering over the error message to display a tooltip with additional context and resolution guidance.
- If the subject only has one timepoint, the status will be **Missing 1 timepoint**.

Examples of running, pending, failed and missing timepoint cases are also shown in Figure 4.

The user can access any available analysis by clicking on it.

7.1.1 Command menu

The Command Menu in AH-1 provides quick access to essential functions and tools using your keyboard to optimize workflow efficiency. Access it using the keyboard shortcut (Ctrl + K for Windows, CMD + K for Mac), by clicking the bar (see 1 in Figure 3), or by clicking the profile icon (see 2 in Figure 3).

The Command Menu also provides access to the subject search functionality, allowing users to quickly locate specific cases by entering complete subject identifiers.

In the Command Menu, keyboard shortcuts are displayed next to each option for quick reference.

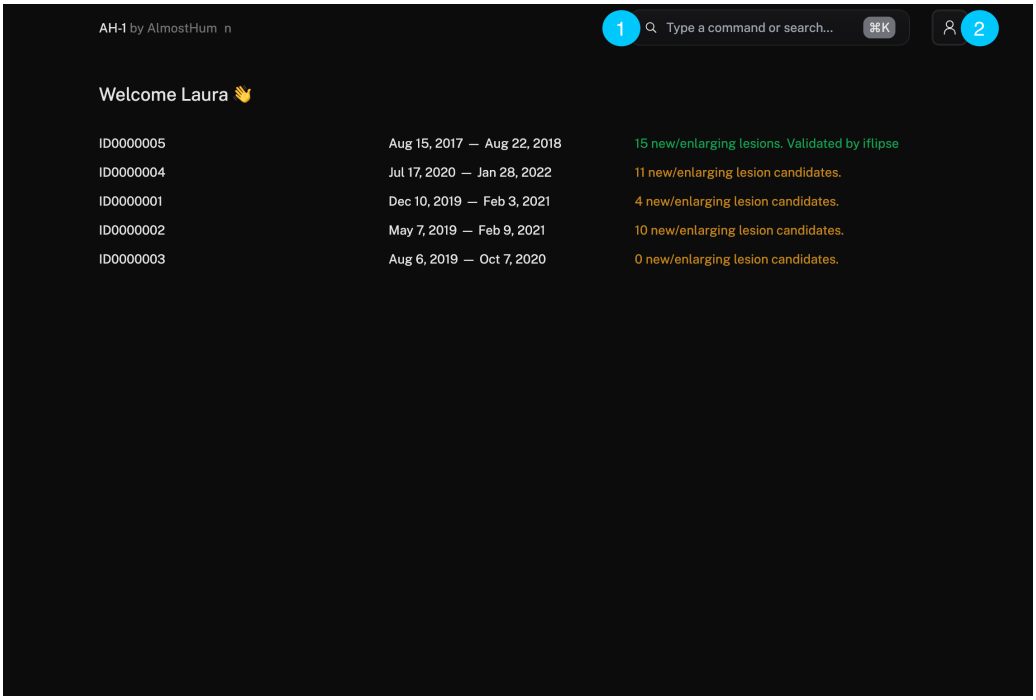

Figure 3: Home screen

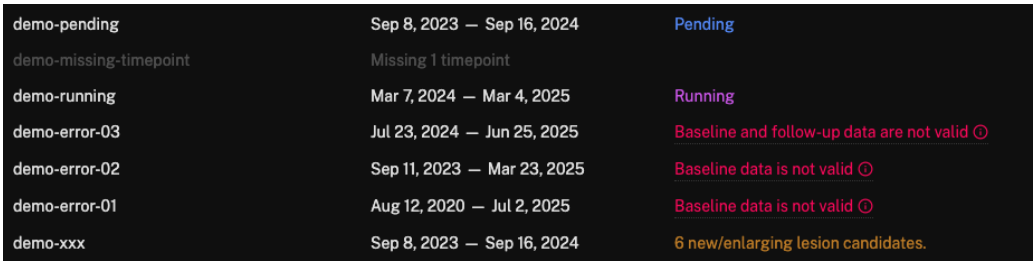

Figure 4: Examples of running, pending, failed and missing timepoint cases.

7.1.2 Profile button

Positioned at the top right corner (see 2 in Figure 3), clicking this will unfold options for *settings*, *command menu, instructions for use, view product label*, *contact us* and *log out*.

- *Settings* opens settings screen.
- *Command menu* allows to visualize and select the cases available.
- *Instructions for use* opens the Instructions for use document.
- *View product label* displays the label for the user.
- *Contact us* directly opens a new email to be sent to the company.
- *Log out* logs out the session.

7.2 Analysis review and validation

To review the latest analysis of a subject, users can click on the subject on the Home screen. This action directs them to the Case screen, showing MRI images of baseline and follow-up time points along with detected lesion candidates. Previous analyses from the same subject can be accessed from the Case screen.

Figure 5 labels the elements on the Case screen, each explained in the following sections.

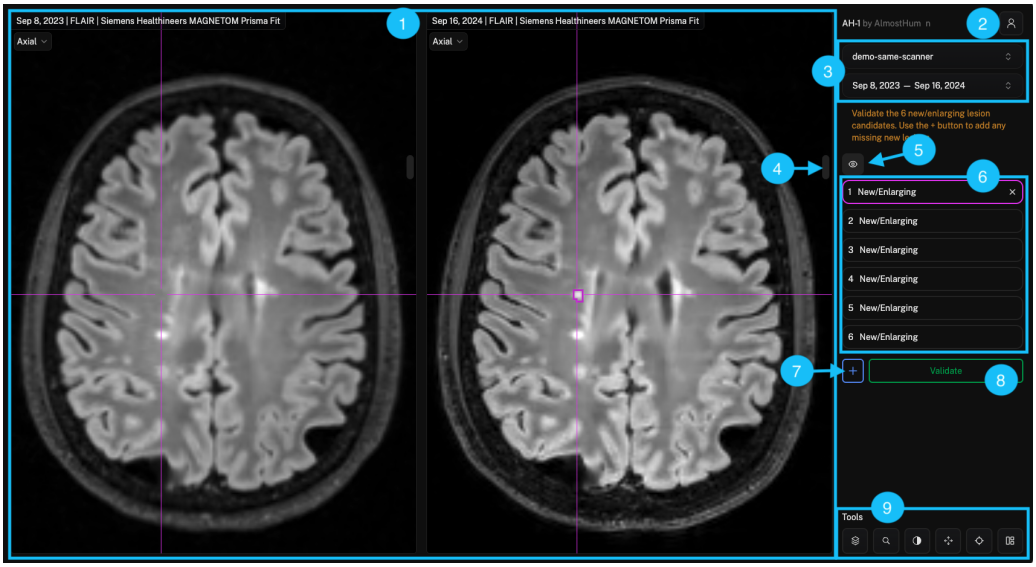

Figure 5: Case screen: 1. MRI images time points visualization. 2. Profile button. 3. Information related to the case. 4. Vertical scrollbar. 5. Eye toggle. 6.New lesion candidates list. 7. Adding missing lesions button. 8. Validation button. 9. Tools.

7.2.1 Time points MRI images visualization

The MRI 3D T2-FLAIR sequences of the baseline and follow-up time points are displayed side by side. The images are synchronized, meaning any action applied to one image will be mirrored in the other. Time points can be identified by the dates displayed on the images.

The user can navigate through the images using the scroll tool, zoom in and out, adjust the window and level, pan, use crosshairs to locate lesions, and switch between different anatomical planes as the main view. Refer to Section 7.2.7 for more information on the tools available.

7.2.2 Case identification

In the area provided for consulting information, users can observe the unique ID of the subject along with the time points corresponding to the selected analysis. Users can navigate through various analyses of the same subject by clicking on the time points.

Users can select a different subject by clicking on the ID information, which opens a dropdown menu where they can browse through available subjects or search for specific subjects using the subject ID.

7.2.3 Profile button

The profile button displays a menu to access the following functions: *settings*, *command menu, instructions for use, view product label*, *contact us* and *log out*.

7.2.4 New lesion candidates review

Once the user selects the case to review, the validation page is available with the MRI time points related to the case. In the lateral panel, the user can see a list of new lesion candidates. The user can review every lesion by selecting it and navigating over the images. Note that new lesion segmentations are only displayed on the follow-up time point images.

When the user select a lesion from the candidate list, the software will help them locate it on the images by automatically navigating to the lesion's location and placing the crosshair at that position. If the crosshair tool is not currently active, a brief visual indicator will appear on the image to show the selected lesion's location.

Users can control the visibility of all lesion segmentations using the eye toggle icon in the tools panel or using the shortcut **D key**. By default, segmentations are visible when opening an analysis. The toggle indicates its current state:

- Eye open icon: segmentations are visible
- Eye-off icon: segmentations are hidden

When visible, lesion segmentations are displayed as contour outlines to avoid interfering with underlying anatomical structures while keeping clear lesion boundaries.

Lesion can be discarded by clicking on the **x** (Figure 6) in the lesion on the list and defining one of the following reasons:

- **Artifact:** the lesions is not correct.
- **Existing lesion:** the lesion was already present before the current analysis.
- **Other:** the user has other reason to discard the lesion.

Shortcuts can also be used with same discard objective. **Shift+F** for *Artifact*, **Shift+E** or *Existing lesions* and **Shift+O** for *Other.*

7.2.5 Adding missing lesions

The user can add lesions that were not detected by the software. To add a lesion:

1. Select the crosshair tool by clicking the crosshair icon or pressing the **C** key
2. Position the crosshair over the lesion location
3. Click the **+** (Figure 7) sign or use the **Shift+A** shortcut to add the lesion

To remove the added lesion, the user can click the return icon over the lesion or use the shortcut **Shift+U.**

> **!** Important
>
> The crosshair tool must be active to add lesions. If the user attempts to add a lesion while another tool is active, a tooltip will appear asking the user to select the crosshair tool first.

When segmentations are hidden using the visibility toggle, the user should ensure they are aware of existing lesion candidates before adding new ones to avoid duplicates. If the user attempts to add a lesion in close proximity to an existing lesion candidate, the software will display a warning message (Figure 8). The user can acknowledge the warning and decide whether to proceed or cancel the action.

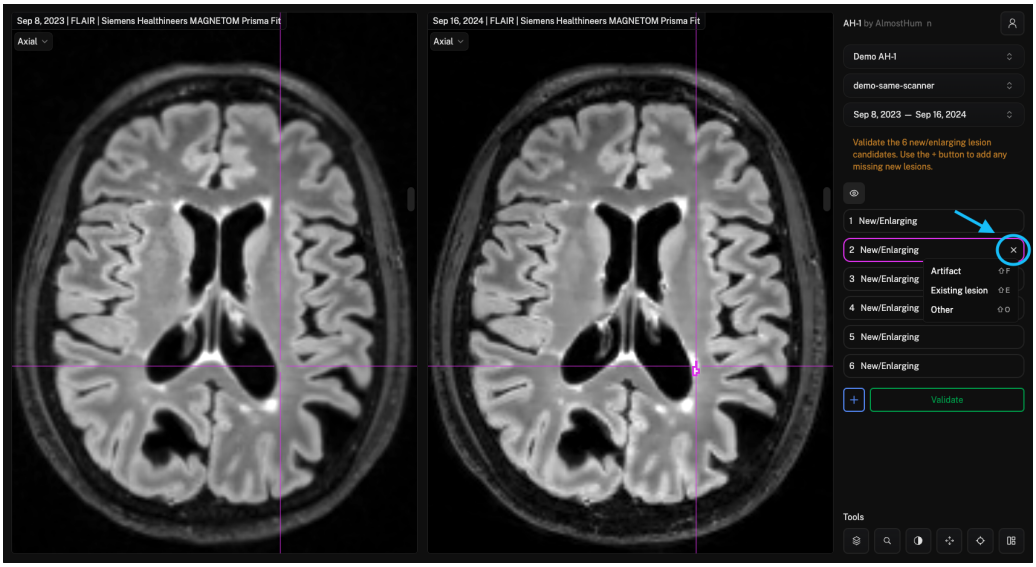

Figure 6: Discarding lesion candidates

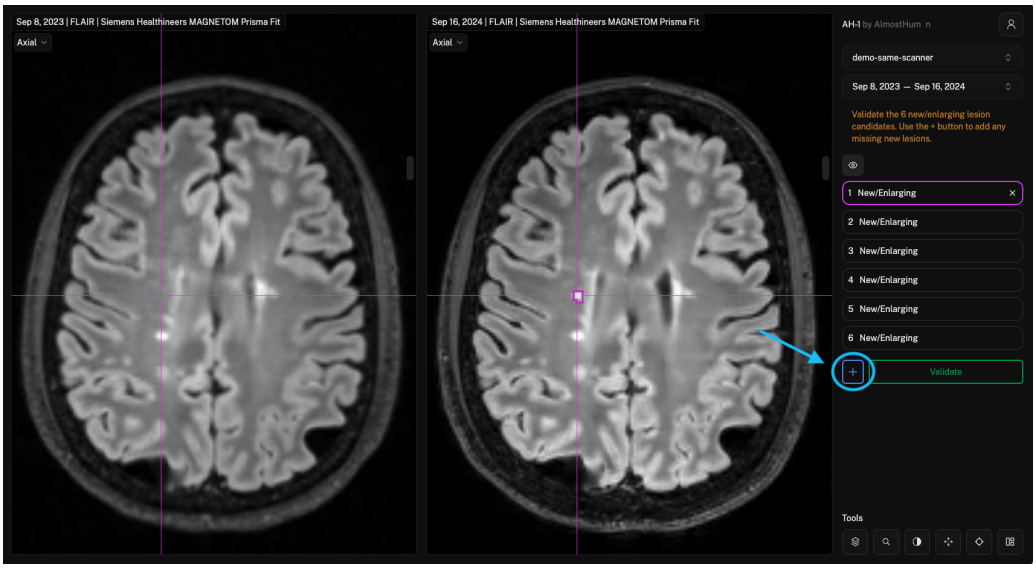

Figure 7: Adding missing lesions button

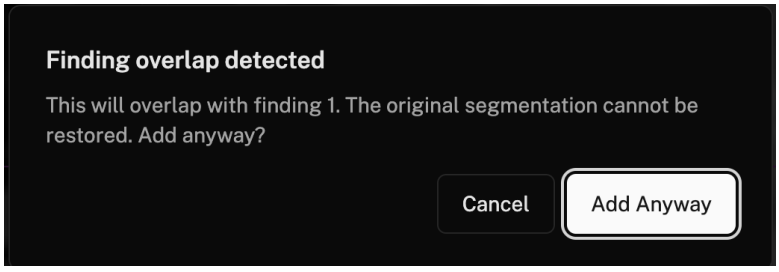

Figure 8: Finding overlap detected

7.2.6 Validation

To conclude the validation, the user can press the **Validate** button (Figure 9). It will make available the **Confirm validation** button (Figure 9) and by clicking on it the validation will be concluded.

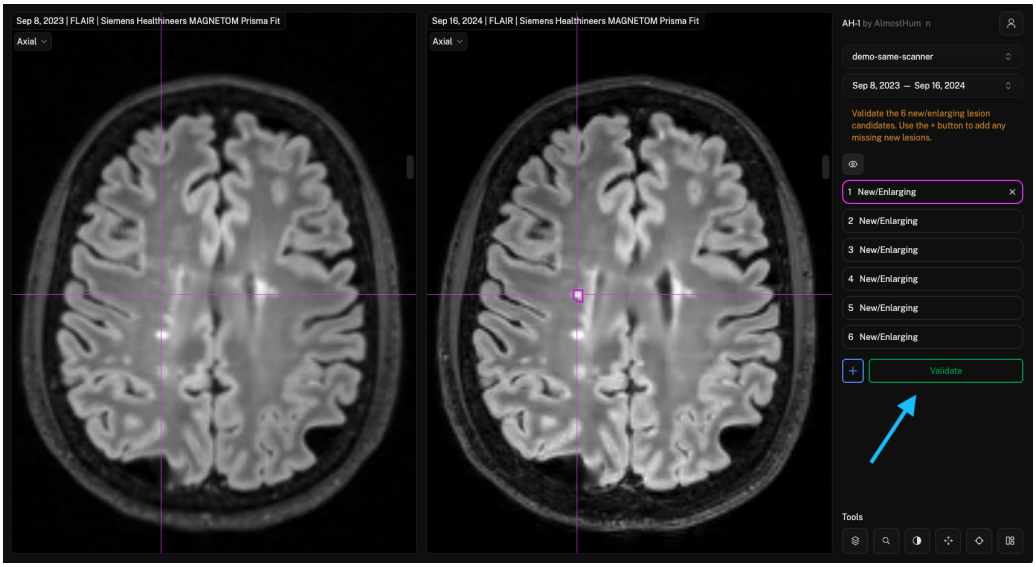

Figure 9: Validation button

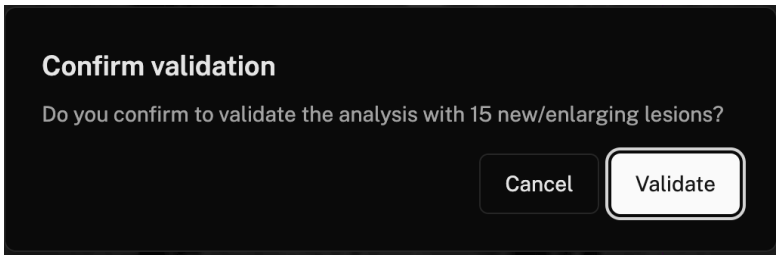

Figure 10: Confirm validation message

When the user accesses an already validated case, the validation page will display the lesion candidates and the lesions added by the user. Modifications can be done and saved by clicking **Revalidate** button.

7.2.7 Tools

The User interface of **AH-1** has the minimum required set of tools to validate the cases.

> **!** Important
>
> The images are synchronized, therefore any action is applied in both images. Individual action per image are not supported.

7.2.7.1 Glossary of icons

Icon	Description
	Scroll

Icon	Description
	Zoom
	Window and level
	Pan
	Crosshairs
	Toggle sagittal and coronal
	Add lesion
	Toggle lesion segmentation

7.2.7.2 Scroll

The scroll can be used to view different slices in a given view. It can be used in two different ways:

- Using the mouse/touchpad scroll.
- Using the scroll tool (keyboard shortcut: **Q key**) and then holding the left mouse button and move up/down in the given view.

7.2.7.3 Zoom

Activate zoom by selecting the icon or pressing the **Z key**. To **zoom in**, hold the left mouse button and move up; to **zoom out**, move down.

7.2.7.4 Window and level adjustment

Activate window and level adjustment by selecting the icon or pressing the **W key**. To **increase the window size**, hold the left mouse button and move right; to **decrease it**, move left. To **increase the level**, hold the left mouse button and move down; to **decrease it**, move up.

7.2.7.5 Pan

Activate the **pan** tool by selecting the icon or pressing the **X key**. Hold the left mouse button and move the images as desired in the *x* and *y* axes.

7.2.7.6 Crosshairs

Activate the **crosshairs** by selecting the icon or pressing the **C key**. Click in the desired area or hold the left mouse button to move along the images.

Crosshairs are only visible when this tool is actively selected to reduce visual clutter. When selecting lesions from the candidate list with other tools active, the crosshairs will briefly appear to help locate the selected lesion.

7.2.7.7 Toggle sagittal and coronal views

Activate the **toggle sagittal and coronal views** by selecting the icon or pressing the **F** key. The auxiliary views are displayed in the right side of each image.

With the multi-plane view activated the mouse can be placed in any of the views, and the **Scroll** tool can be used to move through the images. The vertical and horizontal lines (shown in pink color, see Figure 11) will moved accordingly to the scroll movement to mark the position in the three views. The vertical and horizontal lines can be moved separately too.

The vertical and horizontal lines have a marked point (Figure 11) which enables the rotation that will be shown in the corresponding views.

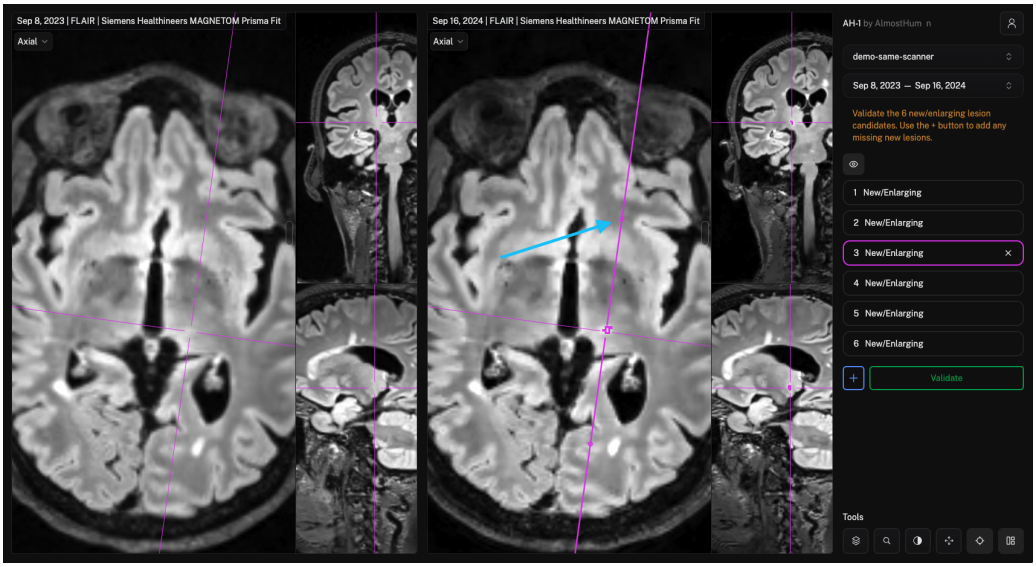

Figure 11: Study with multi-plane view activated

7.2.7.8 Switch main view

Users can select the preferred anatomical plane using the view dropdown located at the top-left of each image panel (Figure 12), or by using the keyboard shortcut **V** key.

This feature allows users to change which anatomical plane is displayed as the primary view: Axial view (default), Sagittal view, Coronal view. When **switching between views**, the selected anatomical plane becomes the primary display while maintaining synchronized navigation between both time points.

All existing tools (scroll, zoom, window/level, pan, crosshairs) remain fully functional in the selected main view.

Figure 12: Study with main view switched to sagittal

7.2.7.9 Vertical scrollbar

A vertical scrollbar is permanently available for navigating through image slices. The scrollbar allows for precise slice navigation by clicking and dragging the scrollbar handle, and quick navigation by clicking on the scrollbar track.

This scrollbar provides an alternative navigation method that is always accessible without requiring tool activation.

7.3 Settings

7.3.1 Change password

Change password screen (Figure 13) can be accessed through the **Command menu** or through the *Settings* displayed in the **Profile button** menu.

The password can be changed by introducing the current password and the new password. Once this information is submitted the password will automatically change.

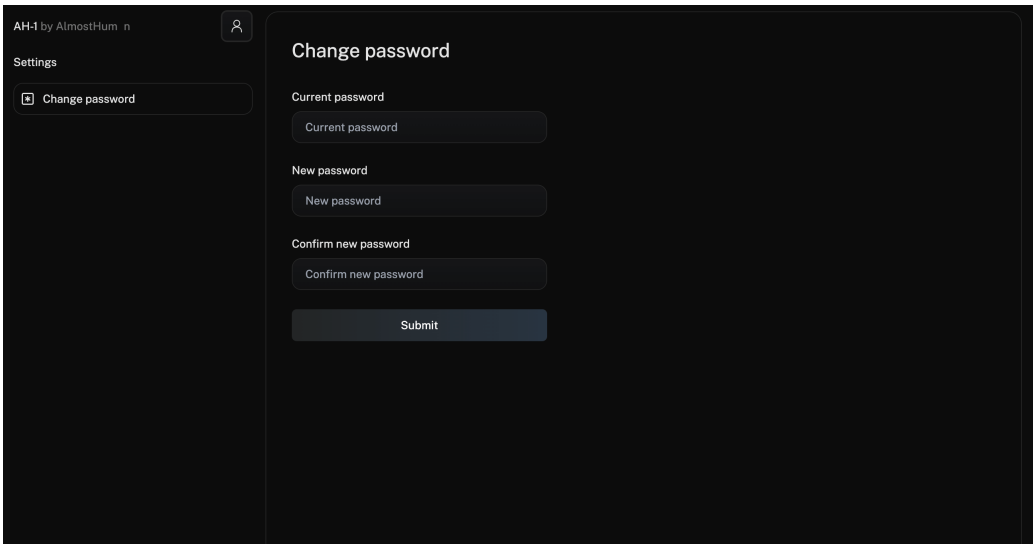

Figure 13: Change password screen.

7.4 Error handling

In case the user encounters errors while using AH-1, please consult the following list and follow the resolution guidelines. If the error is not listed, the user should contact support.

7.4.1 General system errors

Error type: The user is unable to access AH-1 on its device/system.
Resolution: The user needs to close the tab/browser and re-open AH-1. If the error persists, the user has to contact support.

Error type: The user tries to unsuccessfully log in, and it gets the following message: *Login failed. Please check your username and password.*
Resolution: The user must check the username and password and try again. If the problem persists, the user has to contact using the "Forgot your password?" link to be provided with a new password.

Error type: The user cannot change its password.
Resolution: The user's new password must follow the following rules: the password length must be between 8 and 64 characters, have at least one lowercase letter, one uppercase letter, one number, and one special character from the set: *@ $! % ? & # - , . _**.* If the problem persists, the user has to contact support.

Error type: The user interface (UI) of AH-1 malfunctions.
Resolution: The user needs to close the tab/browser and re-open AH-1. If the error persists, the user has to contact support.

Error type: A subject shows a *Missing 1 timepoint* status.
Resolution: The user must upload a second timepoint for the subject. If the problem persists, the user has to contact support.

Error type: An analysis has been in *Pending* or *Running* status for a long time.
Resolution: The user has to contact support.

Error type: The user opens an analyzed case, no images are shown and an error arises.
Resolution: The user has to contact support.

Error type: The user gets a *Validation submission failed. An error occurred while uploading the validation.* message when validating or re-validating a case.
Resolution: The user must check its internet connection and try again. If the problem persists, the user has to contact support.

Error type: Search results in the case selection dropdown or Command Menu do not display the expected subject.
Resolution: Verify you are entering the complete subject identifier, including both letters and numbers. Clear the search field and try again with the full identifier. If the subject still does not appear, verify the identifier is correct and contact support if the issue persists.

7.4.2 Analysis error messages

When an analysis fails, AH-1 provides specific error messages to help users understand the cause and take appropriate action. Error messages are displayed in the status column on the Home screen, with detailed information available via tooltip when hovering over the error message.

Top-level Analysis Error	Scan-Specific/Tooltip Message	Resolution
Baseline data is not valid	No baseline scans found	Ensure the required baseline scan data has been properly uploaded to the system. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan is not MR	AH-1 only supports MRI scans. Verify that the uploaded data is from an MRI scanner. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan is from patient under 18	AH-1 is intended for adult patients only. Verify patient age and ensure compliance with the intended patient population. If the problem persists or for more information, the user must contact support.

Top-level Analysis Error	Scan-Specific/Tooltip Message	Resolution
Baseline data is not valid	Baseline scan has invalid field strength (only 1.5T/3T supported)	AH-1 supports only 1.5T and 3T MRI scanners. Verify the scanner specifications and re-upload if necessary. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan has inconsistent voxel size. Some slices might be missing	Check the scan acquisition for completeness. Re-upload the scan ensuring all slices are captured. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan is a single slice	AH-1 requires 3D T2-FLAIR sequences. Single-slice (2D) images are not supported. Re-upload with 3D protocol. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan is in 4D format. Might be uploaded twice	Check if the scan was accidentally uploaded multiple times or acquired in 4D format. Re-upload with proper 3D T2-FLAIR sequence.
Baseline data is not valid	Baseline scan is missing slices	The 3D scan is incomplete. Re-upload the complete scan sequence.
Baseline data is not valid	Baseline scan has spatial resolution exceeding 1.5mm limit (*spatial resolution of the uploaded scan*)	The scan resolution does not meet AH-1 requirements. Re-upload with spatial resolution of 1mm x 1mm pixel in-plane resolution as specified in Section 8.1. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan is classified as non-FLAIR	AH-1 requires 3D T2-FLAIR sequences. Verify the scan protocol. If the problem persists or for more information, the user must contact support.
Baseline data is not valid	Baseline scan processing failed (*error code*)	An error occurred during scan processing. Note the specific status code and contact support with this information.
Follow-up data is not valid	No follow-up scans found	Ensure the required follow-up scan data has been properly uploaded to the system.
Follow-up data is not valid	Follow-up scan is not MR	AH-1 only supports MRI scans. Verify that the uploaded data is from an MRI scanner. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan is from patient under 18	AH-1 is intended for adult patients only. Verify patient age and ensure compliance with the intended patient population. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan has invalid field strength (only 1.5T/3T supported)	AH-1 supports only 1.5T and 3T MRI scanners. Verify the scanner specifications and re-upload if necessary. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan has inconsistent voxel size. Some slices might be missing	Check the scan acquisition for completeness. Re-upload the scan ensuring all slices are captured. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan is a single slice	AH-1 requires 3D T2-FLAIR sequences. Single-slice (2D) images are not supported. Re-upload with 3D protocol. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan is in 4D format. Might be uploaded twice	Check if the scan was accidentally uploaded multiple times or acquired in 4D format. Re-upload with proper 3D T2-FLAIR sequence. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan is missing slices	The 3D scan is incomplete. Re-upload the complete scan sequence. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan has spatial resolution exceeding 1.5mm limit (*spatial resolution of the uploaded scan*)	The scan resolution does not meet AH-1 requirements. Re-upload with spatial resolution of 1mm x 1mm pixel in-plane resolution as specified in Section 8.1. If the problem persists or for more information, the user must contact support.
Follow-up data is not valid	Follow-up scan is classified as non-FLAIR	AH-1 requires 3D T2-FLAIR sequences. Verify the scan protocol and re-upload with proper T2-FLAIR parameters. If the problem persists or for more information, the user must contact support.

Top-level Analysis Error	Scan-Specific/Tooltip Message	Resolution
Follow-up data is not valid	Follow-up scan processing failed (*error code*)	An error occurred during scan processing. Note the specific status code and contact support with this information. If the problem persists or for more information, the user must contact support.
Baseline and follow-up data are not valid	(Any combination of the above baseline and follow-up specific messages)	Follow the resolution steps for each specific error message shown in the tooltip. If the problem persists or for more information, the user must contact support.
Missing 1 timepoint	-	Only one scan as been uploaded.
Error ({status})	(Unknown error status - contact support with the specific status code)	Note the specific status code and contact support with this information.

7.5 Keyboard Shortcuts

Function	**Shortcut**
Navigate the lesion’s candidates	Up and Down arrows
Open discard options for candidate lesion	Right arrow
Close discard options	Left arrow
Add new lesion*	Shift + A
Undo Add new lesion	Shift + U
Discard lesion (Artifact)	Shift + F
Discard lesion (Existing lesion)	Shift + E
Discard lesion (Other)	Shift + O
Scroll	Q
Zoom	Z
Window Level	W
Pan	X
Crosshairs	C
Toggle multi-plane view	F
Switch main view	V
Toggle lesion segmentation display	D
Command menu	In Windows: Ctrl + K. In Mac: CMD + K

*Requires crosshair tool to be active

8 Uploading Images for Analysis

To use AH-1, compatible MRI 3D T2-FLAIR images must first be uploaded into the system. See Section 8.1 for a detailed description of the image acquisition protocol.

Once AH-1 is set up in the hospital, a DICOM node is made available on your MRI scanner. This node serves as the gateway for sending images from the MRI scanner to the AH-1 software.

The following steps outline the process of uploading images for analysis:

1. **Initiate Image Transfer**:
    - **For New Subjects**: When analyzing a subject for the first time, images from two distinct time points are necessary to initiate the analysis. Additional time points can be uploaded if needed.
    - **For Existing Subjects**: If the subject already exists within the AH-1 system, only the images from the most recent time point are required to be uploaded.
2. **Image Upload**: Transfer the images from the MRI scanner to AH-1 by selecting the designated DICOM node. Follow your MRI scanner's procedure for image transfer.
3. **Automatic Analysis Start**: As soon as the images are successfully uploaded, AH-1 initiates the analysis process automatically. There is no need for manual intervention to start this analysis.
4. **Monitor Analysis Progress**: You can view the current status of the analysis on the Home screen of the AH-1 interface. See Section 7.1 for more information.

> Tip
>
> AH-1 automatically pseudonymizes the images being transferred outside the hospital's network to protect the privacy of the patients.

8.1 Image Acquisition Protocol

MRI 3D T2-FLAIR images must be acquired with the following characteristics:

- Comply with DICOM standards[1].
- Correspond to a complete series acquisition without any missing DICOM files.
- Proper field of view of the patient's head.
- Acquired with 1.5T or 3T MRI scanners.
- Spatial resolution of 1 mm x 1 mm pixel in-plane resolution.
- Have good quality and adequate signal-to-noise ratio.

[1] DICOM Standard

9 Performance characteristics

AH-1 provides the following performance characteristics:

Metric	Minimum acceptance criteria (MAC)
Sensitivity	>80%
Precision	>70%
F1-scores	>70%

10 Technical information for IT departments

10.1 Installation

The software needs to be installed on a Virtual Machine (VM) in the hospital's IT infrastructure. The software has two main components: the DICOM receiver and a web-based user interface.

The DICOM receiver is responsible for receiving the MRI images from the MRI scanner, while the web-based user interface is used by the radiologist to review and validate the analysis. The following sections provide brief technical information for IT departments. For more information, the Product Installation Guide is available upon request to support@tensormedical.ai.

Users need an internet connection and a browser to use AH-1. For the reading of the instructions, a PDF viewer is required.

10.2 Hardware requirements

The software installed onsite must run on a Virtual Machine (VM) with the following minimum requirements:

Item	Specifications
OVA	VMware vmx
Memory	4GB or more
CPU	4 cores
DiskSize	40GB (may be higher depending on the traffic)
Version	vmx-13
Hospital host	ESX/ESXI or similar Virtualization host

10.3 IT Network

10.3.1 Communication ports

The software shall have 3 incoming ports open for communication on the institution side:

- DICOM port (11112) for receiving the DICOM images from the MRI scanner.
- HTTPS port (443) to offer the DICOM Viewer to the users.
- SSH port (22) to connect by ssh to the Virtual Machine

The software installed onsite may have HTTPS port (443) open for communication on the Internet side if required.

10.3.2 Firewall

If the internet access of the user is behind a firewall, the AH-1 domain must be whitelisted.

> Tip
>
> If the user cannot access AH-1 (e.g. firewall on the user's device or network), the user has to contact support@tensormedical.ai

10.4 Decommission

To decommission and dispose of AH-1 software:

1. Contact our technical support team for guidance to support@tensormedical.ai
2. Our team will provide instructions tailored to your installation.
3. The process involves:
    - Removing the software from your systems.
    - Deleting all associated data on Tensor Cloud.

> **!** Important
>
> Decommissioning must be performed by qualified IT personnel to ensure data protection and compliance with local regulations. It is crucial not to attempt decommissioning the software without first contacting us, as proper procedures and expertise are necessary for a secure and compliant process.

Document History

Document Version	Date	Version Description
01	2024/05/16	Document creation
02	2024/10/09	Add AI limitations, better decommission explanation, and corrected performance characteristics
03	2025/09/03	Changes for v1.1.0 release