Data Management Platform

Instructions for Use

User Manual

CurveBeam AI

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Glossary of Symbols

Symbol	Symbol Title	Description
	Manufacturer	Indicates the medical device manufacturer.
	UDI Symbol	Unique Device Identifier. Indicates UDI-DI and UDI-PI information
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
 www.curvebeamai.com	Consult instructions for use.	Indicates the need for the user to consult the instructions for use. **Note:** The e-IFU indicator can be a manufacture's website URL
	Serial number	Indicates the serial number of the product.
	EC Rep symbol	Indicates the EU Representative information
	Terms of use	Is the icon and colour for the terms of use link on the DMP application

Symbol	Symbol Title	Description
	Instructions for Use	Is the icon and colour for Instruction for use link on the DMP application.
	Device Label	Is the icon and colour for device label link of the product on the DMP application.

1. Device Description

1.1 Indications for Use/Intended Use

Data Management Platform (DMP) is a software medical device accessory application designed to support and augment the performance of the CurveBeam AI's software as a medical device (SaMD) product. It is intended to receive, transfer, store, and convert formats of medical imaging data. DMP is also intended to display medical imaging data to the intended users.

1.2 Intended Users

Healthcare professionals (e.g. radiologists, physicians, surgeons, machine operators).

DMP is only to be used by or under the supervision of qualified healthcare professionals who have received training from CurveBeam AI Ltd. in the use of the software.

DMP allows the following types of users to be created in the system.

Role	Description
Super Admin	is a CurveBeam AI admin user, who manages all the sys admins in the application
SysAdmin	are CurveBeam AI admin users who shall manage the overall application
Administrator	are organization admin users who shall manage the organization-related information in the application

Staff	are the organization users that shall be created by the organization administrators to let them use the application to perform different actions

The DMP Application is not a medical device, therefore Intended Patient profile is not applicable.

1.3 Intended Operational Environment

- **Computer or laptop within the healthcare setting**

DMP is used by healthcare professionals on a desktop or laptop computer within a healthcare setting. The sources of distractions present in these environments, i.e., surrounding people or noise, mobile phone, or other sources of distractions, can affect the user's interaction with the device.

Bright light (natural or artificial) shining directly on the user's screen can affect the usage of DMP. Therefore, it is the user's responsibility to use DMP in an environment which has appropriate conditions including for lighting.

DMP is **NOT** intended to be used on mobile devices.

1.4 Warnings

Due to security reasons, after 15 minutes of inactivity, your session will be terminated, and you will be redirected to the login screen.

Before operating the software, all new users of DMP are required to read this User Manual in its entirety. Minor revisions may be made by CurveBeam AI at any time and without notice.

DMP is compatible with DICOM-compliant imaging data.

CurveBeam AI warrants the provision of patient data via the DMP application, which will be encrypted and decrypted through Amazon Web Services (AWS).

1.5 Cybersecurity Considerations

Report

- Users should report potential cybersecurity issues to CurveBeam AI as soon as possible if the product appears to have been impacted by a cybersecurity issue.

Privacy

- Users should be aware of what content they share online, both in public and private forums, particularly relating to personal information.
- Users should log out of the DMP application when it is not in use on their computer/laptop.

Authentication

- Avoid re-using the same password across different services, especially if they are registered under the same email address.
- Never share your passphrases with anyone.
- Be aware of your surroundings when using login details in public.
- This device/application should only be used by authorized or registered users.
- In the event the user account is no longer needed, the account must be deactivated.

Network

- Only use trusted connections or a Virtual Private Network (VPN) when accessing an account, as using public Wi-Fi without the use of a VPN increases the risk that your information could become compromised.

Suspicious messaging

- DMP communicates to users via emails. Users should exercise caution and ensure that the email is trusted before acting on any information contained within it. If in doubt, contact CurveBeam AI, don't use the details or any links in the suspicious message, use contact details that you trust.

Operating system and web browser update

- Regularly updating the computer operating system and Chrome web browser that you use to access DMP is important because the most up-to-date software will generally be the most secure.

Antivirus and Firewall

- The cloud infrastructure that hosts the DMP website frontend and backend services have the firewall and antivirus software installed to protect against malware and malicious activity.

- Users shall have an antivirus software and firewall installed on the computer that is used to access DMP. It is recommended that the antivirus software and firewall be set up for auto-updates, so that these are updated automatically, such that the latest version is available for use.

1.6 Company Information

Company Name	CurveBeam
Website	https://curvebeamai.com

US Office	**Australia Office**
CurveBeam LLC 2800 Bronze Dr., Suite 110, Hatfield, PA 19440, USA (Office) +1 267 483 8081 www.curvebeamai.com info@curvebeamai.com	CurveBeam AI Limited Level 10, 10 Queen Street, Melbourne VIC 3000, Australia (Office) +61 3 9620 0250 www.curvebeamai.com info@curvebeamai.com

Any serious incident that has occurred in relation to the use of the DMP application should be reported to the CurveBeam customer support and the competent local authority in which the user and/or patient is established.

1.7 Customer Support

For any questions, issues, feedback or complaints, contact customer support via email:
techsupport@curvebeamai.com

For sales enquiries, please contact via email:
Sales
info@curvebeamai.com

1.8 IFU Location

The IFU document is available on the DMP application footer as an electronic IFU. Refer to section 4.3.8.8 Access IFU for steps to access the IFU.

Alternatively, the IFU is available on the CurveBeam AI company website. Navigate to “CUSTOMERS”. Register your account at the link. CurveBeam AI Ltd. will review the registration. Once the registration is accepted, you can login using those credentials in the “CUSTOMERS” section of the CurveBeam AI website. Once logged in, the DMP IFU can be located in the Product Manuals section.

Users can access the IFU on the company website after logging in with valid credentials.

The Instructions for Use in a printed paper form shall be provided to the Data Management Platform user at no additional cost within 7 calendar days of receiving a request if requested by the user or at the time of purchasing of the device if requested at the time of purchasing the device.

1.9 Language

The IFU is written and available in the English language.

1.10 Compatible Data

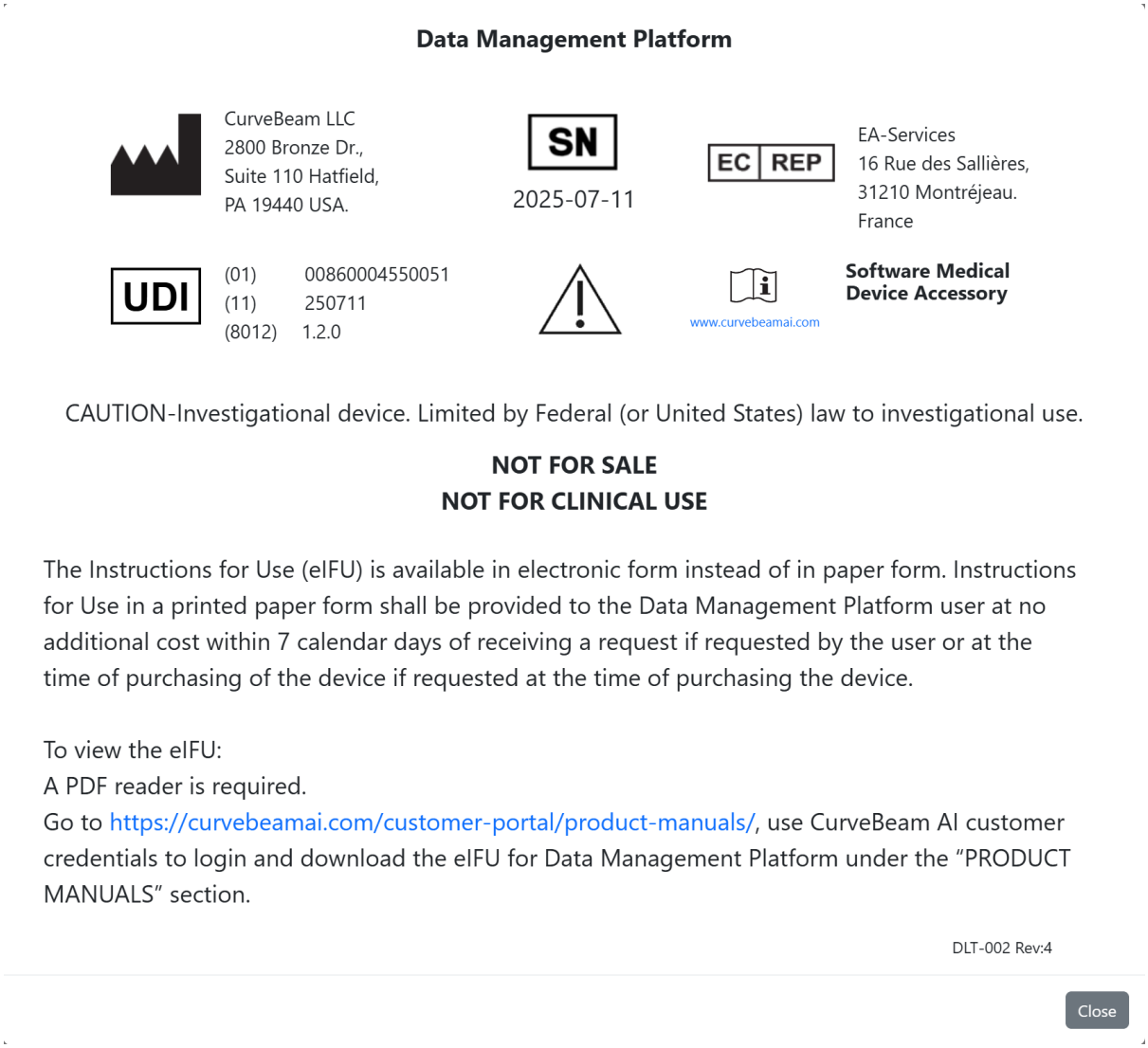
The DMP application accepts and is compatible with all DICOM-compliant imaging data.

Each SaaS module on the DMP application has its own acceptable data specification and compatible equipment. Please refer to the Instructions for Use of each SaaS application for more details.

1.11 Availability

DMP v1.2.0 is a limited release only and is NOT FOR SALE and NOT FOR CLINICAL USE.

2. Product Label



3. System Requirements

3.1 Internet connection and a browser

An internet connection and a web browser are required to access the DMP Application.

DMP can be accessed via a browser. The following browser is recommended: Google Chrome

Chrome browser on Windows
To use Chrome browser, the user will need:

- **Windows 10 or later**
  An Intel Pentium 4 processor or later that's SSE3 capable.

A minimum screen resolution of 1024 X 768 is required to use the DMP application

To view scans using the MPR functionality on the DICOM viewer, it is required that the user's computer is equipped with at least a 3.0 GHz processor and 32 GB RAM.

DMP does not require installation by a user, only a supported web browser is required.

To enable automatic scan uploading from the CurveBeam AI scanner to the DMP website, users should contact CurveBeam AI customer support to configure the uploading plugin on the scanner server.

3.3 Firewall

If the internet access of the user is behind a firewall, the DMP website domain will need to be whitelisted.

If the user cannot access the DMP website (e.g., firewall on user's device or network) the user will need to contact Customer Support.

3.4 Operational security options

There are no operational security options to be set at installation time.

3.5 Decommission and archival

For any new version of the DMP application that will be deployed, CurveBeam AI will inform users regarding the software update in advance. For decommission and archival of data, please contact CurveBeam AI Customer Support.

3.6 Error Handling

In cases where the user encounters errors with accessing DMP, consult the following list and follow the error resolution troubleshooting guidelines.

Error type	The DMP website on the user's device/system does not work temporarily.
Resolution	The user needs to close the tab/browser and re-open the DMP website. If the error persists, the user should contact Customer Support.

Error type	The user is unable to access the DMP website.
Resolution	Check internet connection and if internet is available and DMP website is still not accessible please contact Customer Support.

If the errors cannot be resolved as above or for any errors other than those stated above that prohibit the user from using DMP application, please contact CurveBeam AI Customer Support.

4. Data Management Platform (DMP) Workflows

4.1 General Aspects

4.1.1 Introduction

All new users of DMP are required to read this User Manual in its entirety. Improvements and changes to this user manual may be made by CurveBeam AI at any time. This manual is published by CurveBeam AI without any warranty.

4.1.2 Accessibility

The following items can be scaled using the zoom options of the browser and/or PDF viewer:

- The DMP Application website
  The DMP application is available in 3 regions. The website for each region is:
  - AU Region - https://cloud.curvebeamai.com.au
  - EU Region - https://cloud.curvebeamai.eu
  - US Region - https://cloud.curvebeamai.com
- Product Label
- Instructions for Use

4.1.3 Information Security

CurveBeam AI warrants that the provision of image data via the online platform will occur via an encrypted connection. All the data kept in the object storage and the database are encrypted. All data transmission within the cloud infrastructure is protected through the private connection using VPC (virtual private cloud) endpoints. All other data transmissions are encrypted via the HTTPS protocol. The HTTPS protocol is secured by the SSL certificate.

4.2 Major workflows

4.2.1 Account creation workflow

Creating a user account in the DMP application is the first step to gaining access and starting to use the application.

- Load the DMP application on the web browser and click on **Create an account** button on the login page and perform the following steps:

  1. Fill out the user and organization details.
  2. Tick the checkbox confirming that you have read and accepted the Terms of Use
  3. Click on the **Register** button.

- The `Registration Successful` message will be displayed. For more details about registration, refer to 4.3.1 Registration section.

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- An automated email will be sent to you confirming the registration.
- CurveBeam AI will validate and approve the registration. Once the registration is approved, your user account and organization will be created in the DMP system.
- CurveBeam AI will send you an email confirming the registration approval. This email also contains temporary login credentials - use these credentials to login for the first time and set your permanent password. Following this, you will be directed to the DMP dashboard.
- To create staff user for your organization, follow the steps provided in section 4.3.7.6 Add user
- Contact CurveBeam AI to setup cloud data store for your organization.
- Contact CurveBeam AI to setup the Upload VM on the scanner server.

4.2.2 Scans upload workflow

The DMP application allows an authenticated user to upload scans to their organization. This will allow the users to perform multiple scan related actions on the application.

Scan uploading can only occur if the organization cloud data store has been created.

These actions are available for organization admins and staff users

Please note that the time it takes for scan upload to complete depends on the size of the files and internet bandwidth.

Please note that compressed (zipped) file type is not supported and will not be detected and accepted by the upload function.

- Load the DMP application on the web browser and Login to DMP application with correct credentials.
- Click on **Scan** module on the side panel.
- Click on **Upload Scans** button to navigate to **Upload scan/s** page.
- Select the scan folder to be uploaded and proceed with the upload process following the workflow described here in section 4.3.5.10 Upload scans.

If the user interrupts the upload process, the upload application will roll back the process and not upload the scan(s) to the DMP website. Partial uploads will be abandoned. Users must re-upload CT images as needed.

If the upload process is interrupted unexpectedly, refer to Section 4.3.5.13 to report this issue to CurveBeam AI customer support.

4.2.3 Scans upload workflow

Scan uploading can only occur if the organization cloud data store has been created.

These actions are available for organization admins and staff users

The scans can be anonymized before being uploaded to the DMP. If you have any issues, please contact CurveBeam AI support.

If there are any issues in uploading scans to DMP, please contact CurveBeam AI support.

4.2.4 Scans transfer workflow

The DMP application allows an authenticated user to transfer an existing scan in their organization to another existing organization in the same region only, if required.

This action can leak protected health information (PHI).

- Go to the scan list.
- Select scan(s) for batch transfer by ticking the checkbox for each scan of interest.
- Click on the **'Transfer'** button.
- The 'Transfer Scans' form will pop up. Provide the following details:
    - **Destination Organization –** Fill in the associated textbox.

Contact CurveBeam AI team immediately, if the scan is sent to the wrong organization.

Please note that you cannot batch transfer scans to an organization in a different region.

- **Anonymize** – Use the 'Anonymize' checkbox to enable/disable anonymization on scans.
- Click the **Submit** button on the 'Transfer Scans' form to initiate the scan transfer request.
- Once the scan transfer request has been initiated, a confirmatory notification will pop up.
- An automated email will be sent to the administrator users of both the source and destination organization notifying of the batch transfer request.
- Later, when the batch transfer request has been processed, an automated email will be sent to the administrator users of both the source and destination organization notifying that the batch transfer request has been processed.

For complete information about scan management, refer to Section 4.3.5 Scans

4.2.5 Scan view workflow

The application allows an authenticated user to view the details of the scans existing in their own organization.

- Go to the scan list page and click on a scan of interest.
- The details of the selected scan will be displayed. Click on the 'View' button to view the scan in a DICOM image viewer.

For complete information about scan management, refer to Section 4.3.5 Scans

4.2.6 Scan search workflow

The application allows an authenticated user to search for scans in their own organization. Below is all the information that can be used as a keyword to search for the scans:

Patient information

- Patient name*
- Patient birth date
- Patient age
- Patient ID

- Patient sex

Scan information
- Study ID*
- Study description*
- Study date
- Acquisition date
- Acquisition time
- Series date
- Series time
- Laterality
- Body part examined*
- Total slice count
- Slice thickness
- Rows
- Columns
- Pixel spacing

Scanner information
- Manufacturer
- Manufacturer model name
- Device serial number
- Institution name*

"*" denotes that the search results will include scans of which the keyword partially match this type of information of the scan.

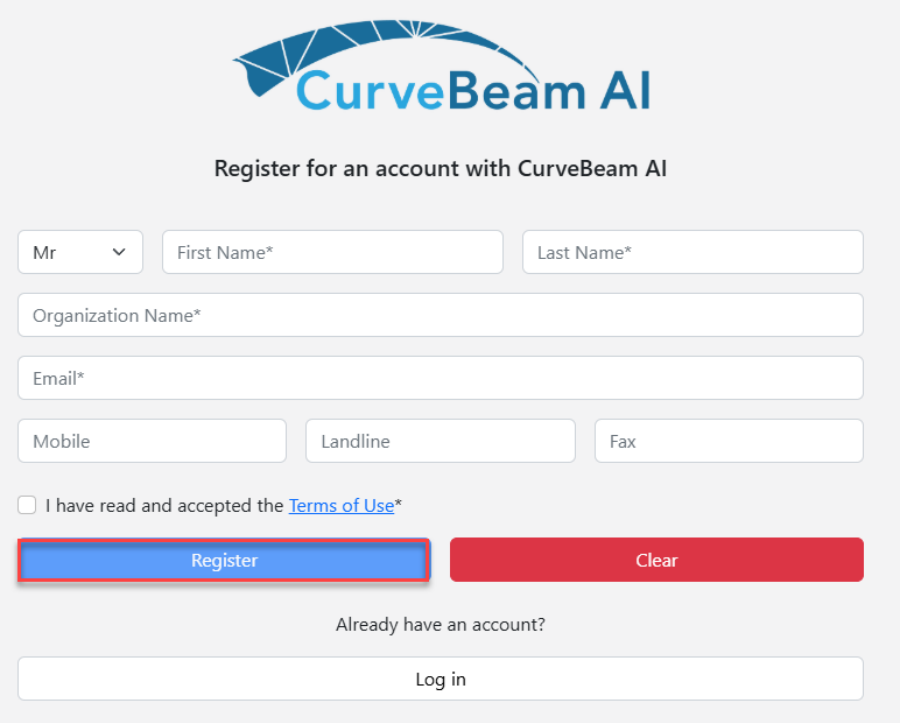
4.3 Web Modules

4.3.1 Registration

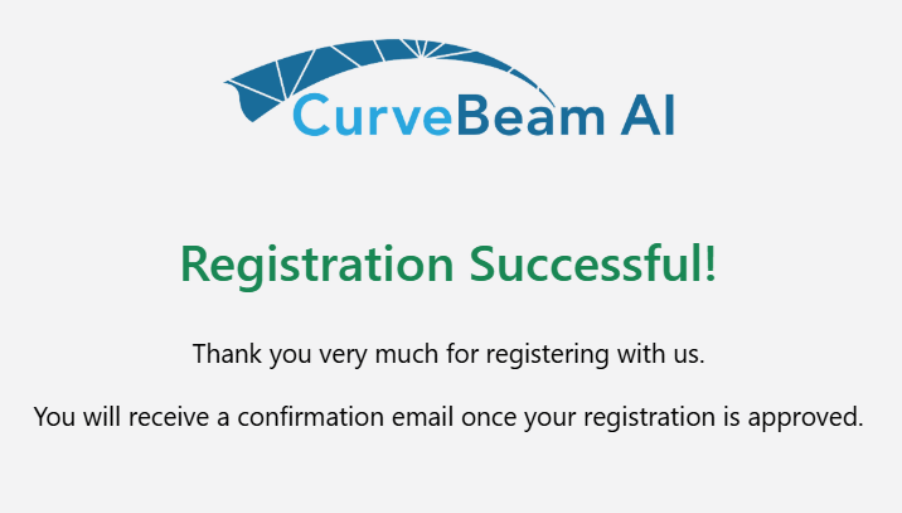
4.3.1.1 Create registration

- Open the DMP web application and click on **Create an account** button on the login page which will redirect the page to registration form.
- Perform the following steps:

1. Fill out the user and organization details.
2. Tick the checkbox confirming that you have read and accepted the Terms of Use
3. Click on the **Register** button.



- The `Registration Successful` message will be displayed. An automated email will be sent to you confirming the registration.

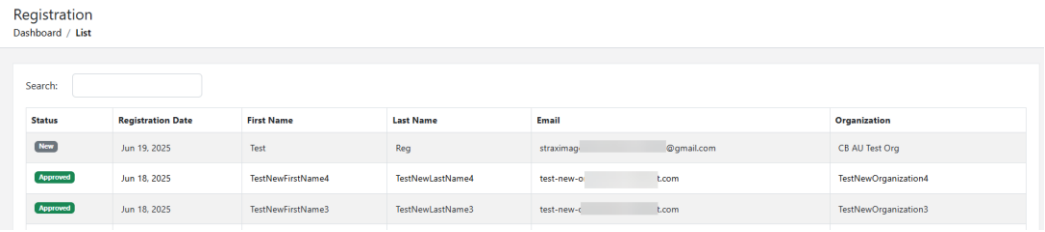


- CurveBeam AI will validate and approve the registration. Once the registration is approved, your user account and organization will be created in the DMP system.
- CurveBeam AI will send you an email confirming the registration approval. This email also contains temporary login credentials - use these credentials to login for the first time and update your password. Following this you will be directed to the DMP dashboard.

4.3.1.2 View registration list

This action is only available for system administrators – CurveBeam AI

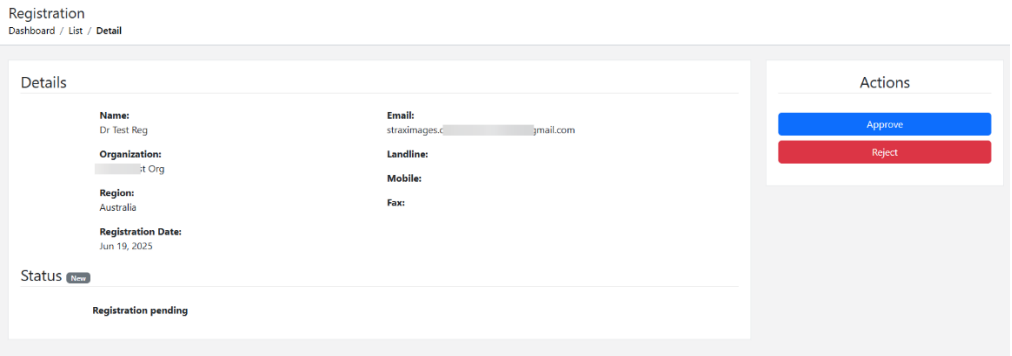
- To view the registration list, click on **Registration** on the side panel.
- The registration list will be displayed.



4.3.1.3 View registration details

This action is only available for system administrators – CurveBeam AI.

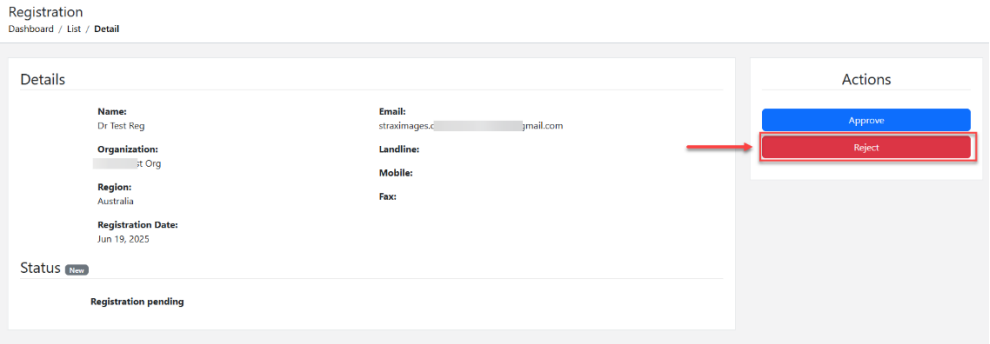
- Go to the registration list and click on a registration of interest.
- The details of the selected registration will be displayed.



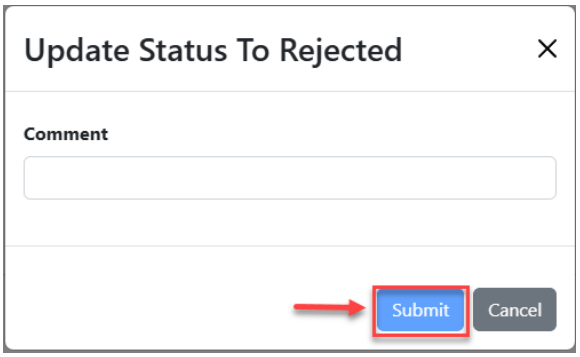
4.3.1.4 Reject registration

This action is only available for system administrators – CurveBeam AI.

- Go to the registration list and click on a registration of interest with the 'New' status.
- On the registration detail page, click on the **Reject** button.



- A form will pop up prompting you for a comment. Type in a comment then click on the **Submit** button.

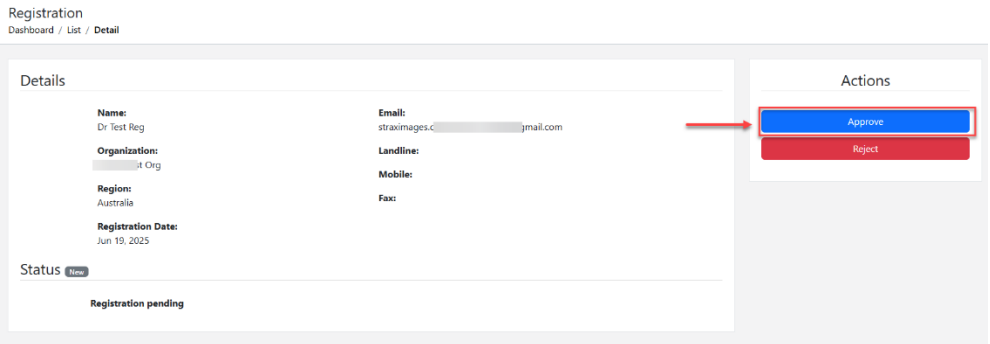


- Once the rejection has been processed, a confirmatory notification will pop up and the status section will be updated accordingly on the registration detail page.
- An automated email will be sent to the registrant notifying of the rejection.

4.3.1.5 Approve registration.

This action is only available for system administrators – CurveBeam AI

- Go to the registration list and click on a registration of interest with the `New` or `Rejected` status.
- On the registration detail page, click on the **Approve** button.

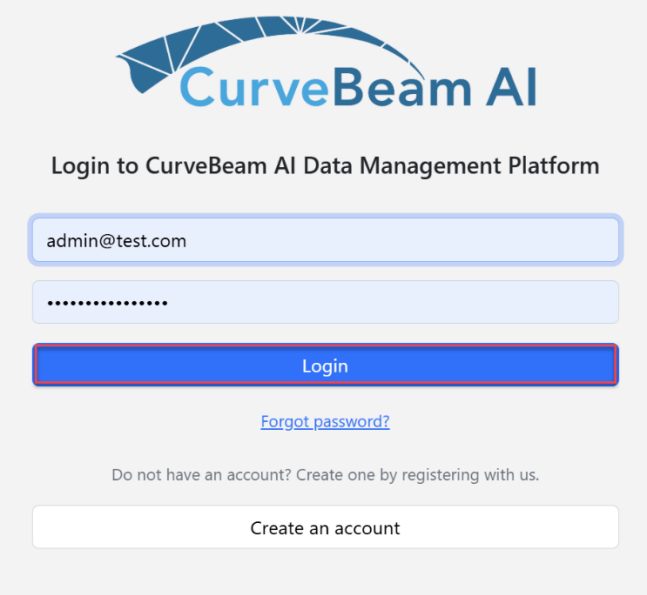


- Once the approval has been processed, a confirmatory notification will pop up and the status section will be updated accordingly on the registration detail page.
- An automated email will be sent to the registrant notifying of the approval. This email will also contain temporary login details for the newly created administrator user account.

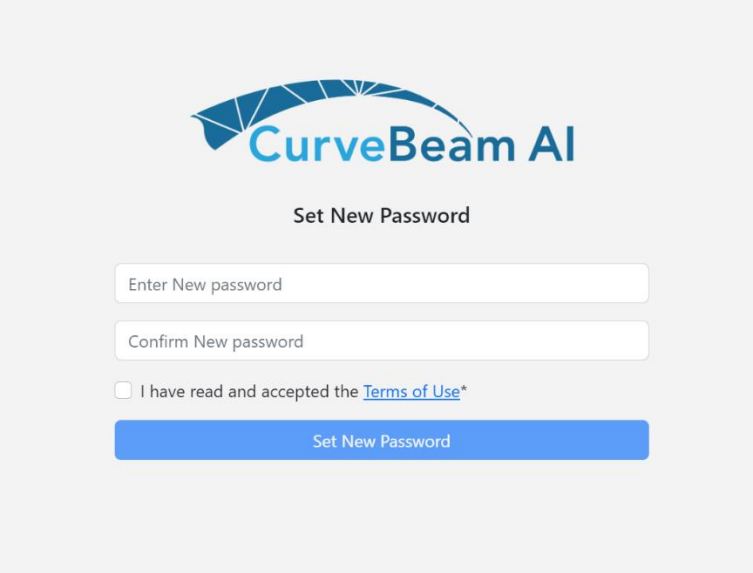
4.3.2 Login management

4.3.2.1 Initial login / Set new password.

- Go to the application login form.
- Fill in the email and temporary password provided in the account creation email and click **Login**. Please refer to 'Account creation' section for user account creation.



- The form to set a new password will be displayed.



- Fill in the New Password field, confirm new password field, and accept the CurveBeam AI Terms of Use. Click on **Set New Password**.

Important
The password required must meet the following conditions.

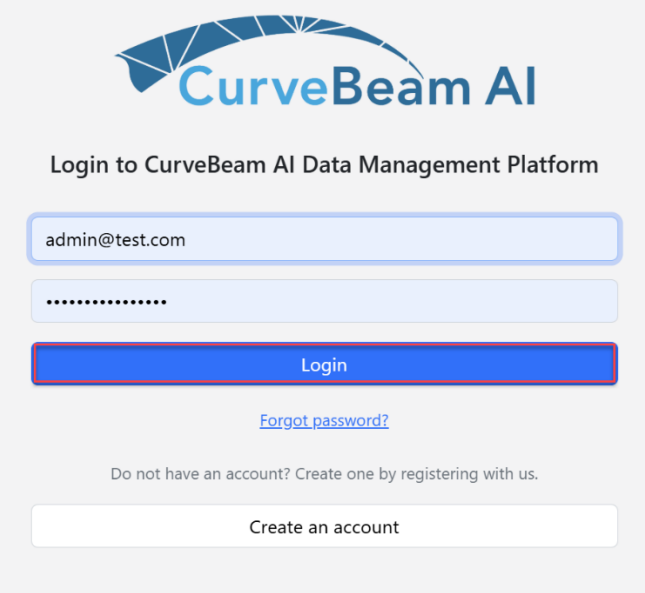
- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character

- You will be taken to the application dashboard.

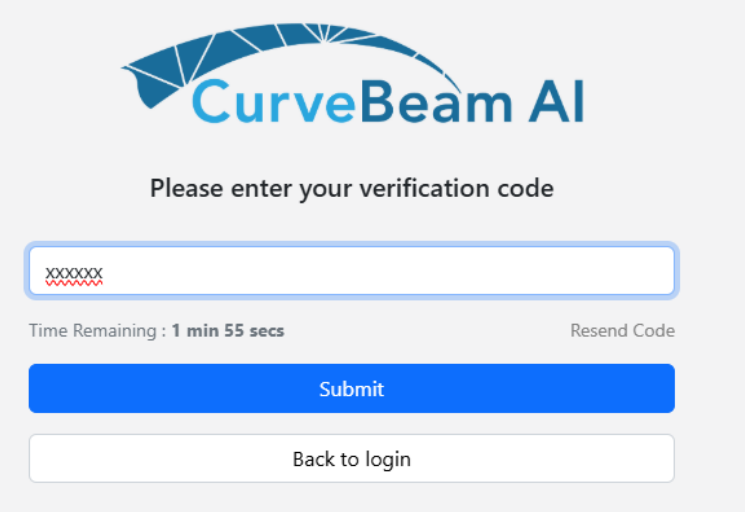
4.3.2.2 Login with multi-factor authentication

This workflow is applicable after the initial login.

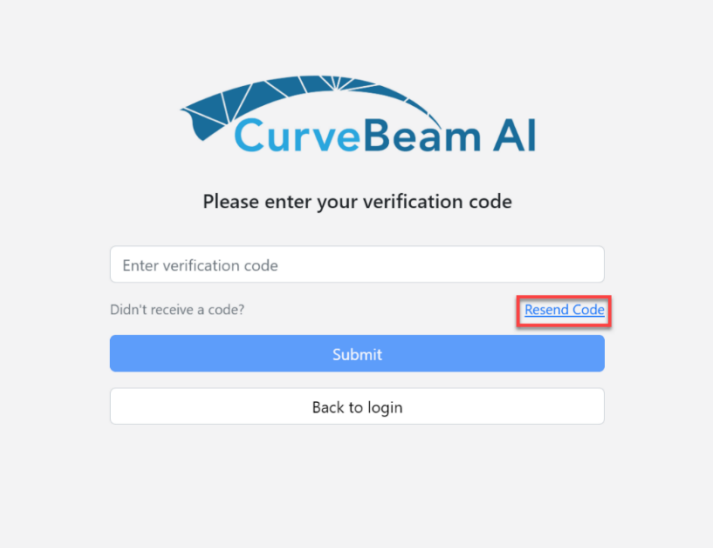
- Go to the application login form.
- Fill in your email address and password and click on **Login**.



- An automated email will be sent to your registered email address containing a one-time code valid for 3 minutes.
- The form will be displayed prompting for a verification code.
- Enter the code received in the email and click on **Submit** button.



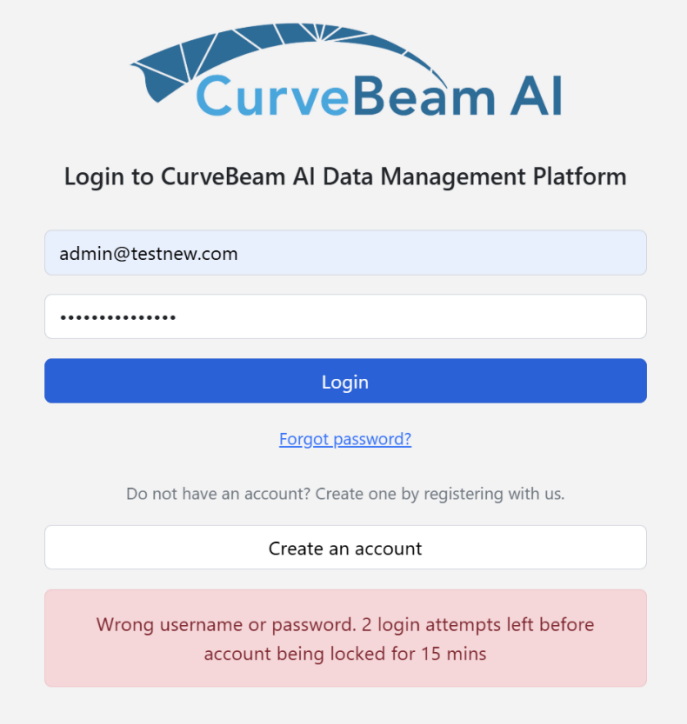
- If you have not received the code within 3 minutes, click on **Resend Code** to receive a new code in your email.



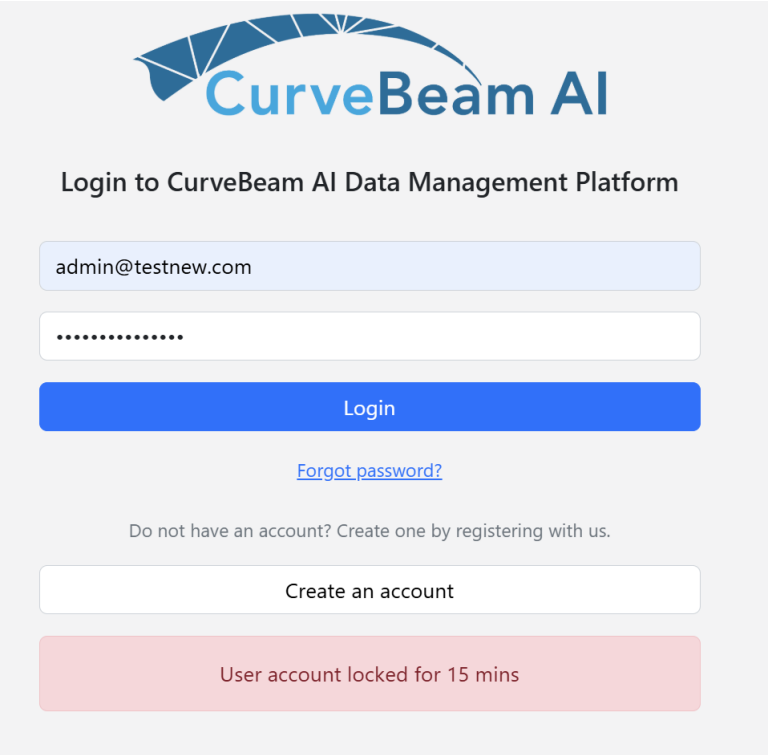
- Once you enter the verification code successfully, you will be taken to the application dashboard.

4.3.2.3 Account lockout

- The application allows a maximum of 3 continuous failed login attempts with incorrect password. Every failed login attempt with incorrect password will display an error message containing the number of attempts remaining.



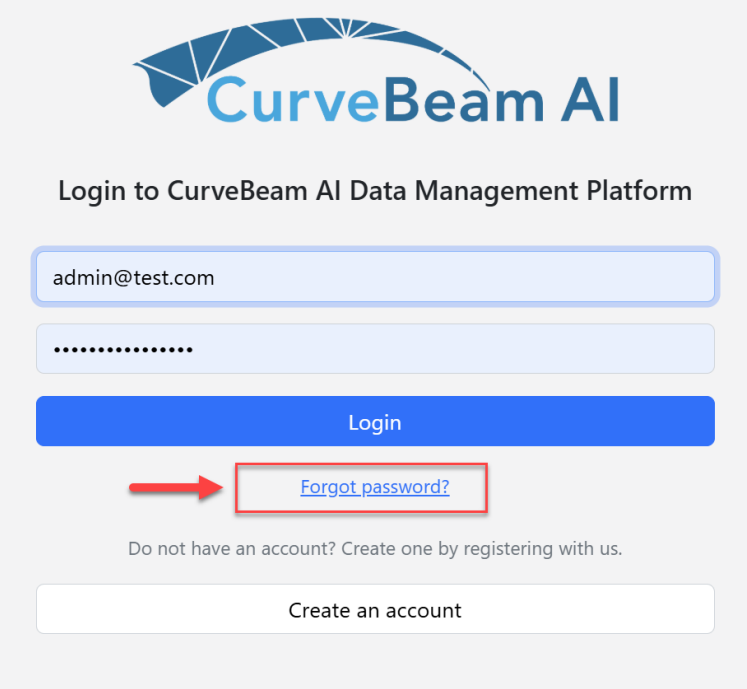
- If the last login attempt fails, an error message will be displayed to show that the account has been locked for 15 minutes.



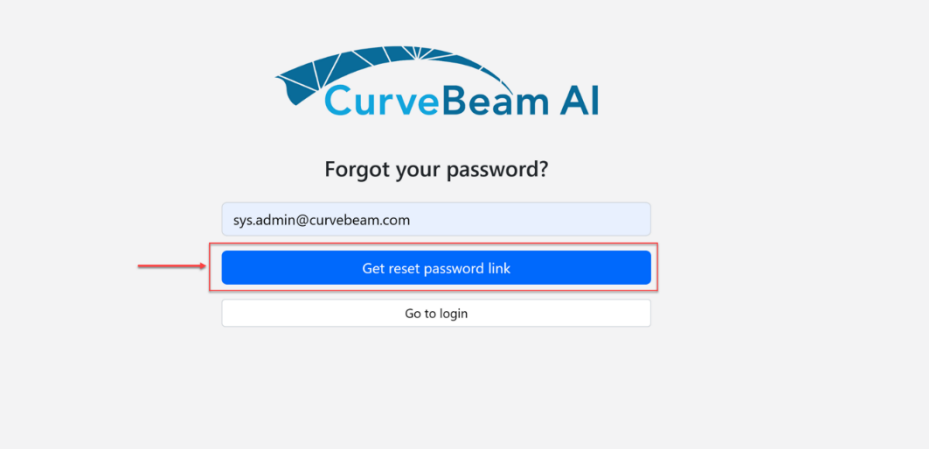
- During the account lockout period the application cannot be accessed. You can try to login using correct credentials after 15 minutes have lapsed.
- If a login attempt is made with the wrong password after the lockout period is finished, the user account will be locked for a further 15 minutes.

4.3.2.4 Forgot Password

- Go to the application login page and click on **Forgot Password**.



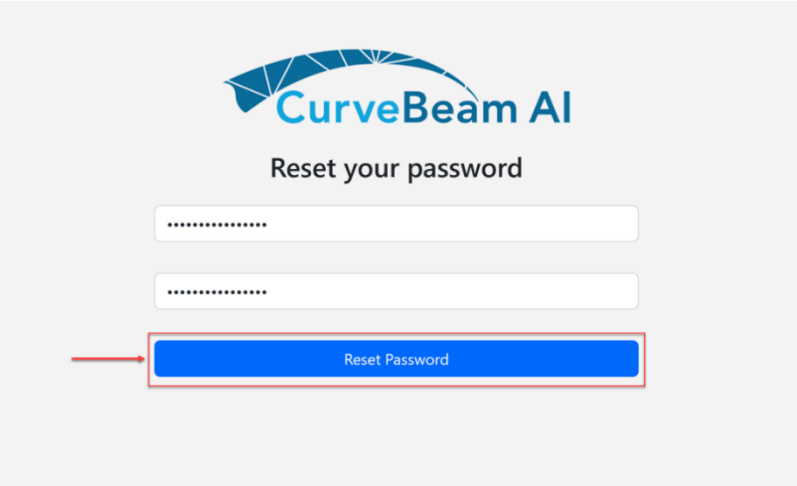
- The form will be displayed to enter your email address.
- Fill in the registered email address for your account and click on **Get reset password** link.



- A confirmatory message is displayed, and an automated email will be sent to your registered email address, containing a link to reset the password.
- Go to the reset password link received in the email. You will be directed to the form to reset the password.
- Fill in the password and confirm password fields. Click on **Reset Password**.

Important
The password required must meet the following conditions.

- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character



- Once the update has been processed, a confirmatory notification will pop up and the user will be taken to the login screen.
- An automated email will be sent to you notifying that your password has been changed.

4.3.2.6 Logout

- To end your session in the application, click on **Logout** button at the top right corner of the DMP application.

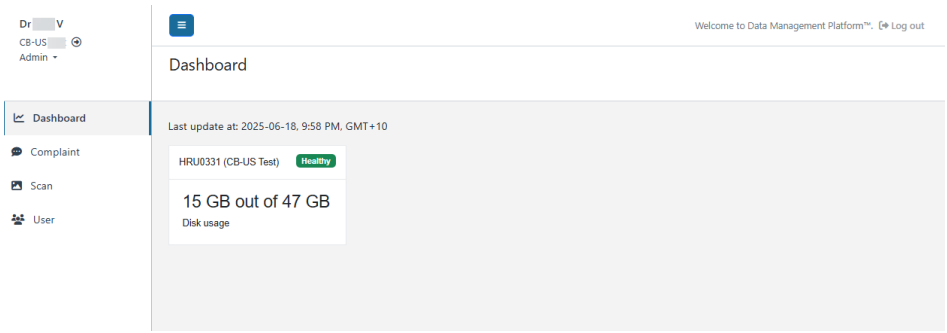
- You will be taken to the login screen.

4.3.3 Dashboard

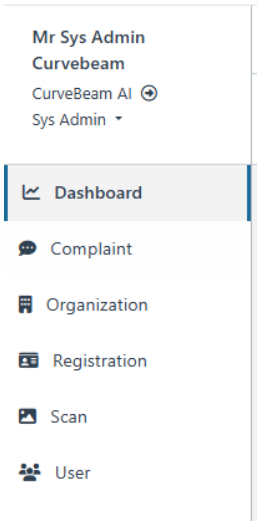
4.3.3.1 View dashboard

> Sys admin can view the status of all machines on the dashboard. But the organization admins and staff users can only see the machine status associated with their organization.

- After successful login, you will be redirected to the dashboard page. The dashboard will show the machine status and disk usage information.



- The side panel displays all the modules you are authorized to access. You can navigate to any of these modules by clicking on the module name. The below image shows a sample side panel of a sys admin user.

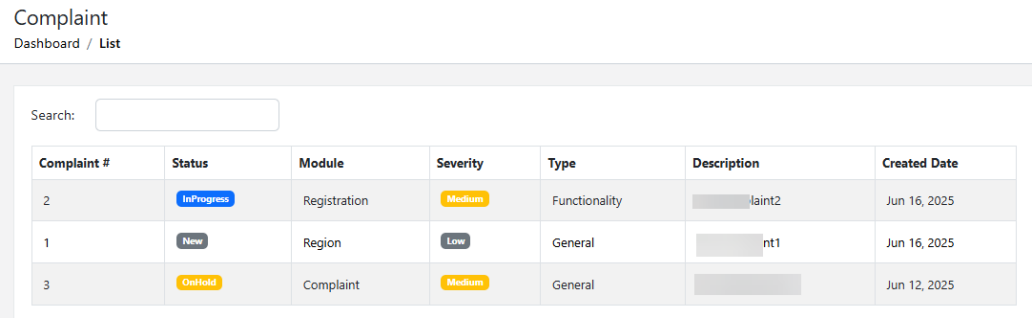


- The top-left corner of the page shows the user's name.
- Beneath the user's name, the associated organization's name is shown, allowing navigation to your organization's details page.
- Below that, the user role is displayed along with a dropdown menu, allowing you to perform various account-related actions.

4.3.4 Complaint

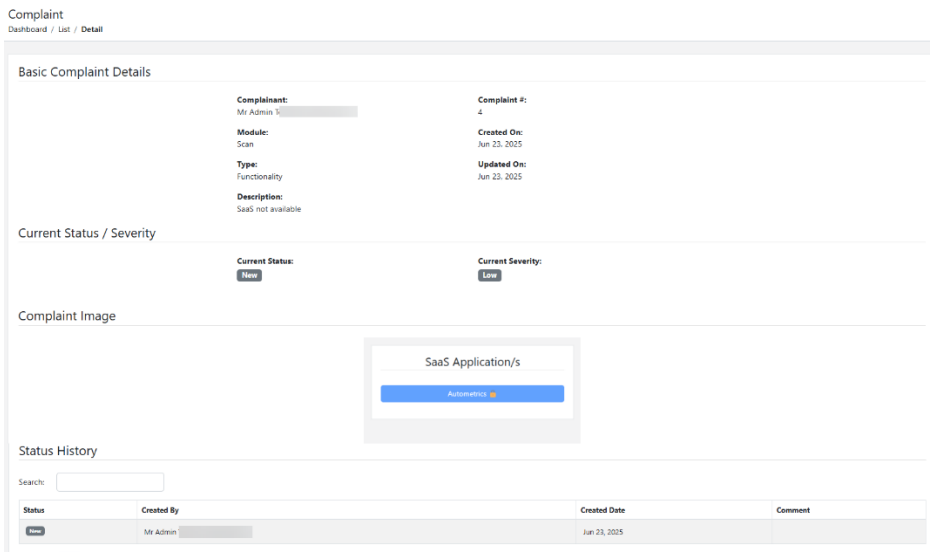
4.3.4.1 View complaint list

- To view the list of complaints, click on **Complaint** on the side panel.
- CurveBeam AI Sys Admin can see all complaints raised in the application.
- Organization Admins can see all complaints raised for their organization in the application.
- Staff users can see all complaints raised by them in the application.
- The complaint list will be displayed.



4.3.4.2 View complaint details

- Go to the complaint list and click on a complaint of interest.
- The details of the selected complaint will be displayed.



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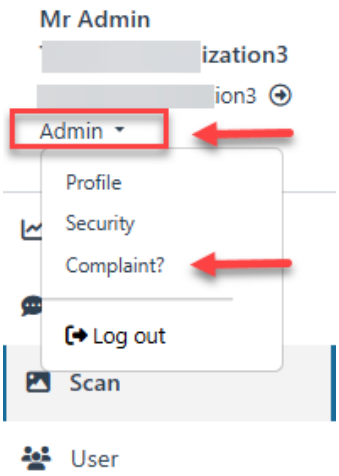
4.3.4.3 Add complaints

The attachment image size must be less than 2 MB.

NOTE: If the image size is greater than 500 KB, the complaint 'Add' function fails. The bug will be fixed in the next release.

If any issues encountered while raising complaints in this module, as the alternative you can contact CurveBeam AI customer support to raise any complaints. Please refer to section 1.7 for the contact information.

- Click on the user role on the side panel.
- A dropdown menu will be displayed, click on **Complaint?** option.



- **Make a Complaint** form will be displayed.

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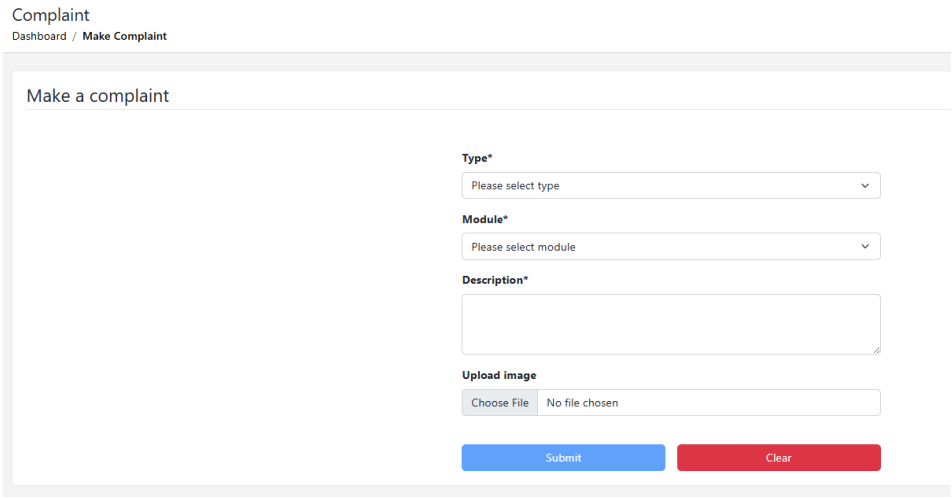
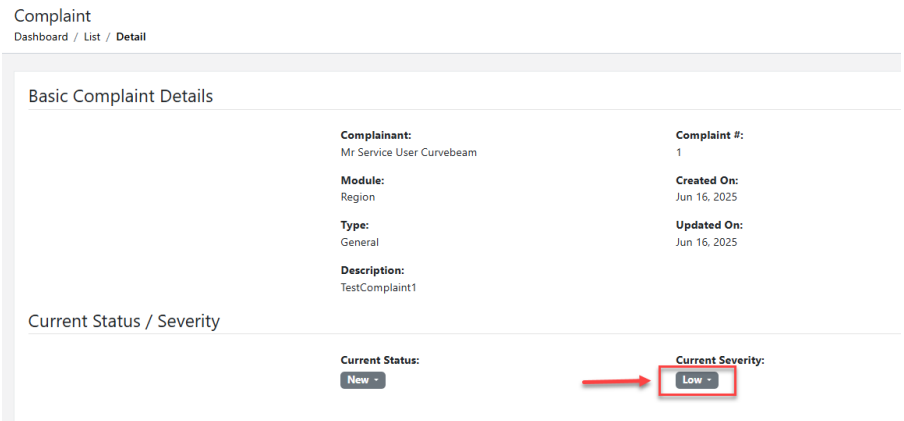


- Fill in the required details and click on **Submit**.
- Once the complaint is submitted, a confirmatory notification will pop up on the screen and you will be redirected to the complaint list page.
- An automated email will be sent to the system administrator and the complainant notifying the new complaint.

4.3.4.4 Change complaint severity

This action is only available for system administrators.

- Go to complaint list and click on the complaint of interest.
- On the complaint details page, under 'Current Status/Severity' section, click on the **Current Severity** dropdown button. Choose the required level from the dropdown list to set the new severity level for the complaint.

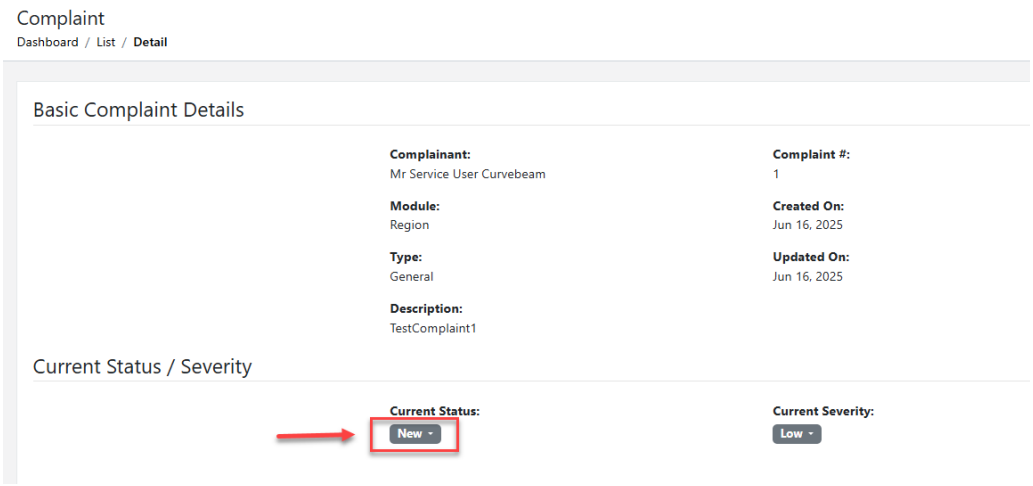


- The confirmatory message will pop up and the new status will be reflected on the details page under 'Current Status / Severity' section.

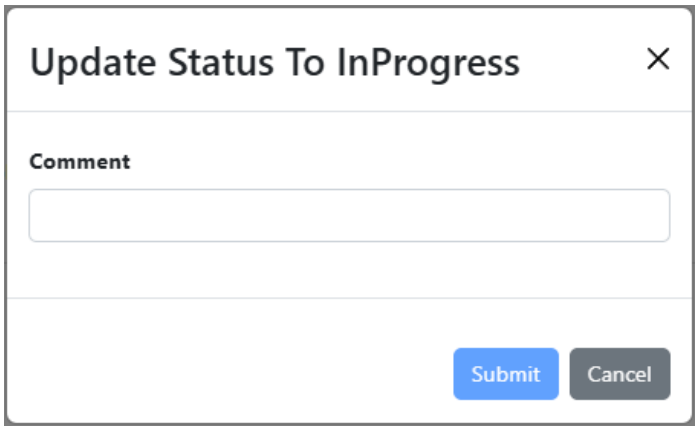
4.3.4.5 Change complaint status

This action is only available for system administrators.

- Go to complaint list and click on the complaint of interest.
- On the complaint details page, under 'Current Status/Severity' section, click on the **Current Status** dropdown button. Choose the required status from the dropdown list to set the new status for the complaint.



- A form will pop up prompting for a comment. Type in a comment and click on **Submit** button.



- The confirmatory message will pop up and the new complaint status will be reflected on the details page. Also, the status history table will be updated.
- When the status is set to 'InProgress' or 'Resolved', an automated email will be sent to the complainant to notify about the complaint status update.

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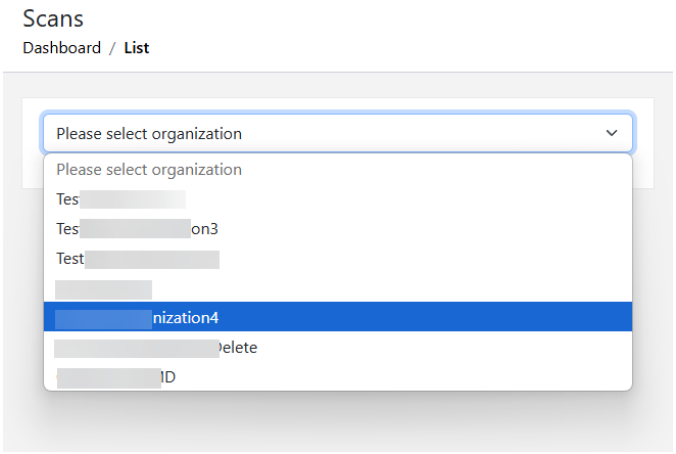
4.3.5 Scans

4.3.5.1 View scan list

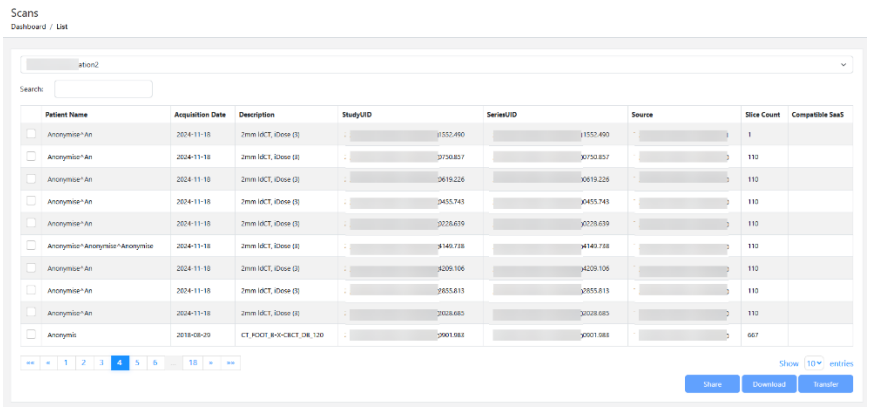
4.3.5.1.1 View scan list of a selected organization

This action is only available for system administrators.

- To view the scan list, click on **Scan** on the side panel.
- An organization dropdown menu will be displayed. Click on **Please select organization** to display a list of organizations in the dropdown menu.
- From the dropdown list of organizations, click on an organization of interest.



- The scan list of the selected organization will be displayed.

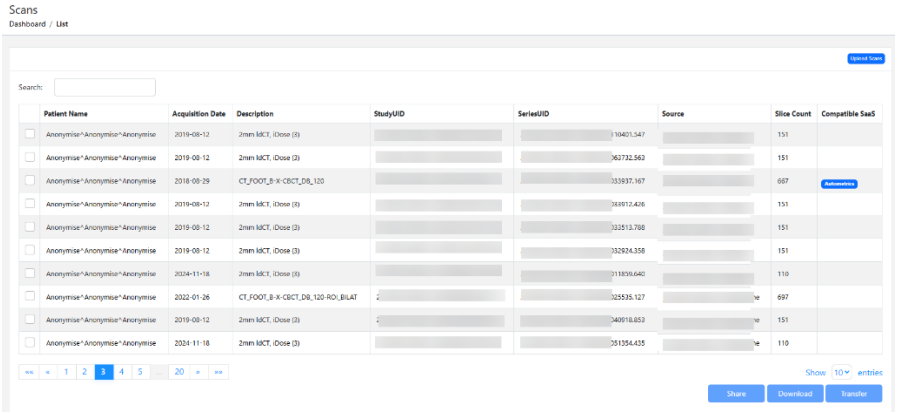


- You can initiate share/download/transfer operation for scans from this page.

4.3.5.1.2 View scan list of your own organization

This action is only available for administrators and staff users.

- To view the scan list, click on **Scan** on the side panel.
- The scan list of your organization will be displayed.



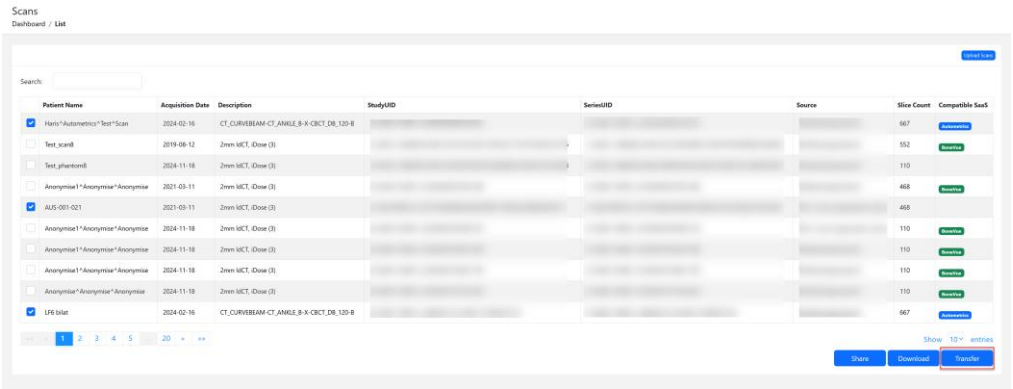
- This page contains ‘Upload Scans’ button to facilitate the scan upload operation.
- You can initiate share/download/transfer operations for scans from this page.
- Clicking on each of the column header will apply sorting in ascending or descending order on all the scans in the list.

4.3.5.2 Batch transfer scans to another organization

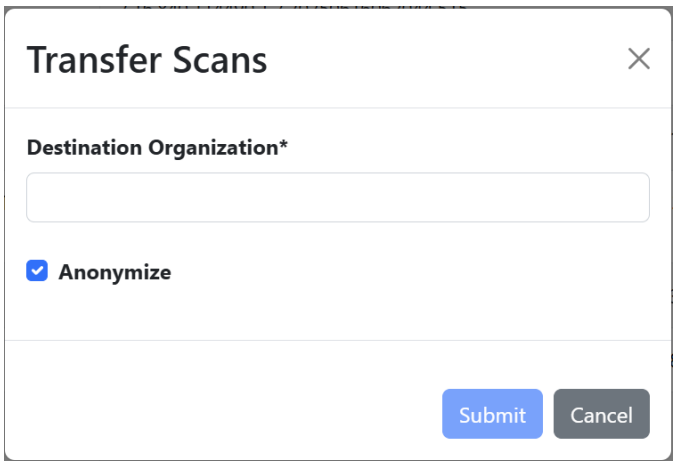
This action can leak protected health information (PHI).

- Go to the scan list.

  Select scan(s) for batch transfer by ticking the checkbox for each scan of interest.



-
- Click on the **‘Transfer’** button.
- The ‘Transfer Scans’ form will pop up.



- Provide the following detail:
  - **Destination Organization –** Fill in the associated textbox.

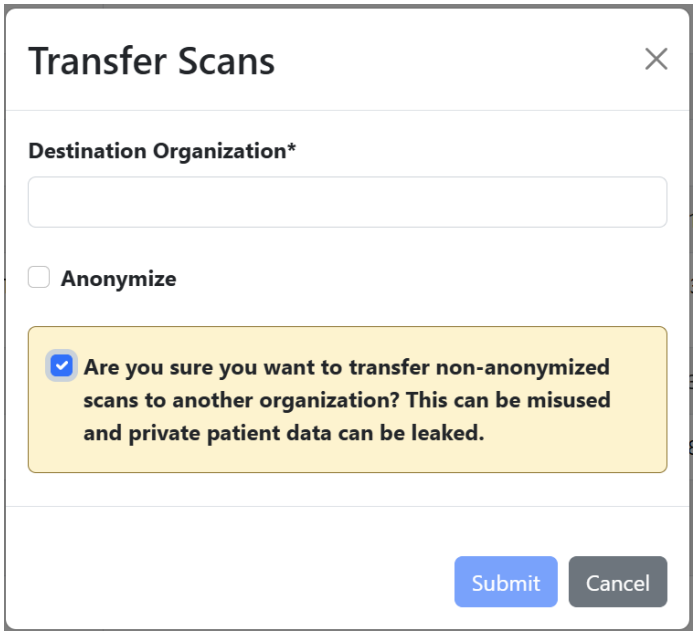
> Contact CurveBeam AI team immediately, if the scan is sent to the wrong organization.

> Batch transfer of scans to an organization in a different region is not allowed.

> Batch transfer scans to an organization that is deactivated is not allowed.

  - **Anonymize** – Keep the checkbox ticked to anonymize the scan.

If you don't wish to anonymize the transferred scans, then untick the checkbox. When you untick the anonymize checkbox, a warning message will be displayed informing on the PHI risk of transferring non-anonymized scans. You must tick the new checkbox that appears with this warning to confirm that you are aware of the PHI implications.



- Click the **Submit** button on the batch transfer form to initiate the batch transfer request.
- Once the batch transfer request has been initiated, a confirmatory notification will pop up on the scan list page.
- An automated email will be sent to the administrator users of both the source and destination organization notifying of the batch transfer request.
- Later when the batch transfer request has been processed, an automated email will be sent to the administrator users of both the source and destination organization notifying that the batch transfer request has been processed.

4.3.5.3 View scan details

- Go to the scan list and click on a scan of interest.
- The details of the selected scan will be displayed.

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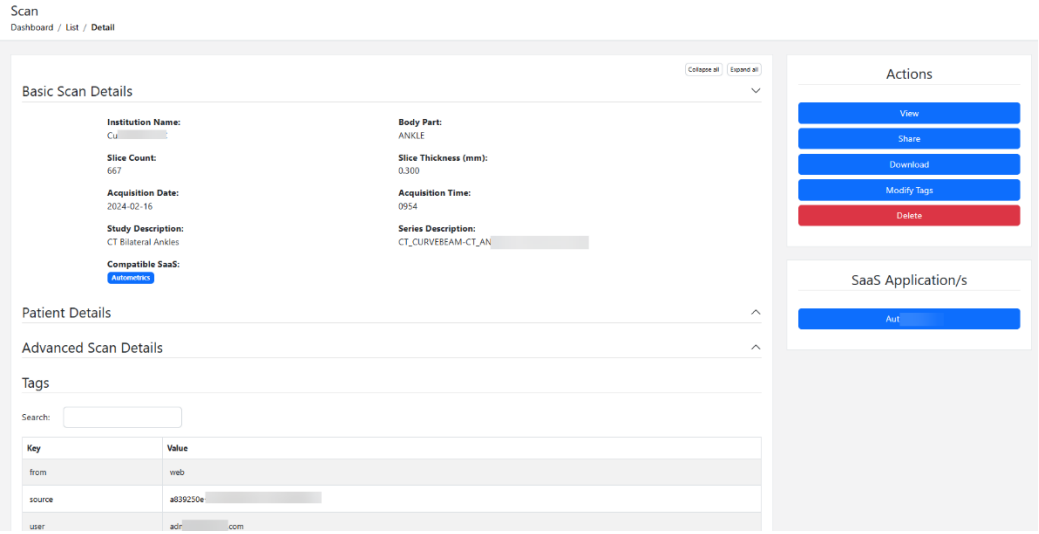

- By default, when the scan detail page is loaded, all the details sections are presented in the expanded manner.
- Click on the 'Collapse all' to collapse all the details sections.
- Click on 'Expand All' button to expand all the details sections again.
- The 'downward arrow' at the end of each section can be used to expand/collapse each individual details section.
- There is a 'Tags' section at the end of the page which contains system defined tags and optional user defined tags. This is used for grouping the scans under same tags based on common criteria.
- On the right side of the page, there is an action group available which contains below actions:
    - View – This is used to view the scan in medical image viewer
    - Share – This is used to share the scan
    - Download – This is used to download the scan
    - Modify Tags – This is used to modify the scan tags
    - Delete – This is used for deleting the scan, available only for organization administrators.
- Also, there is an optional 'SaaS Application/s' section below the action group to display the associated SaaS applications associated with that organization.

'SaaS Application/s' section will be shown only when the scan is compatible with the SaaS.

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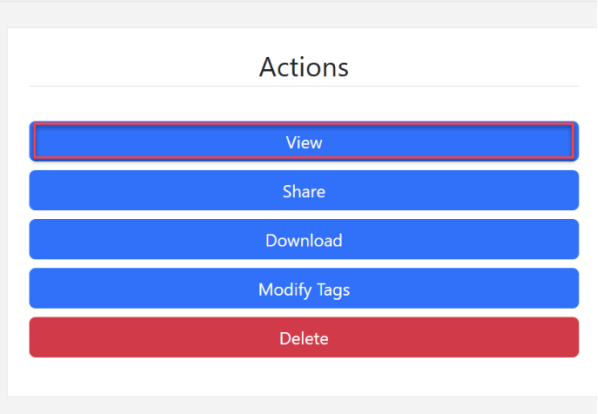
4.3.5.4 View scan in medical image viewer

- Go to the scan detail page for a scan of interest. Click on the **View** button.



- The CurveBeam AI medical image viewer application will open in another tab.

Scan images displayed on the image viewer are not in the original resolution. They have been adapted to fit the image viewer specifications.

Because scan images displayed on the image viewer are not in the original resolution, for accurate DICOM header information please always refer to the scan details page of the DMP application instead of the information displayed in the medical image viewer.

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4.3.5.5 Generate shareable link for scan.

4.3.5.5.1 Generate shareable link for a single scan- no anonymization

> This action can leak protected health information (PHI) if anonymization is not enabled.
> Follow your organization's patient data privacy protocols.

- You can open the 'Share scans' form by one of the following ways:
    1. Click on 'Share' button on scan-list page - 4.3.5.1 View scan list

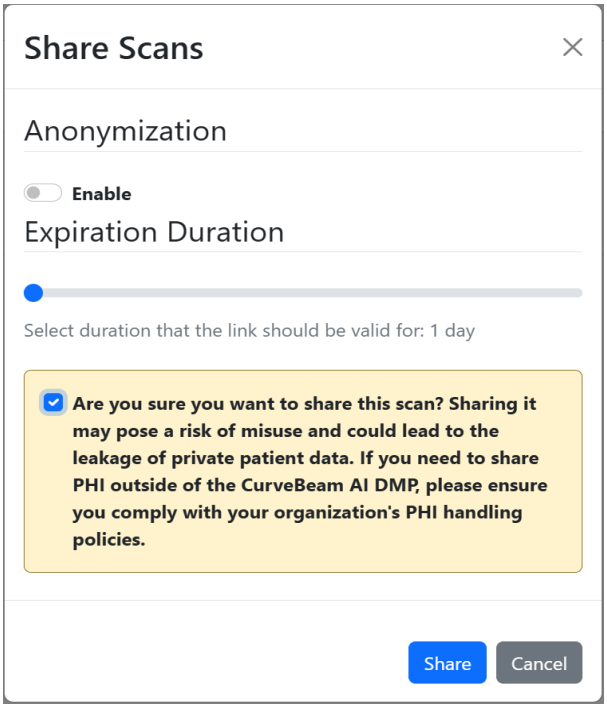
    OR

    2. Click on 'Share' button on scan-details page - 4.3.5.3 View scan details

- The 'Share Scans' form will pop up with the anonymization enabled by default.

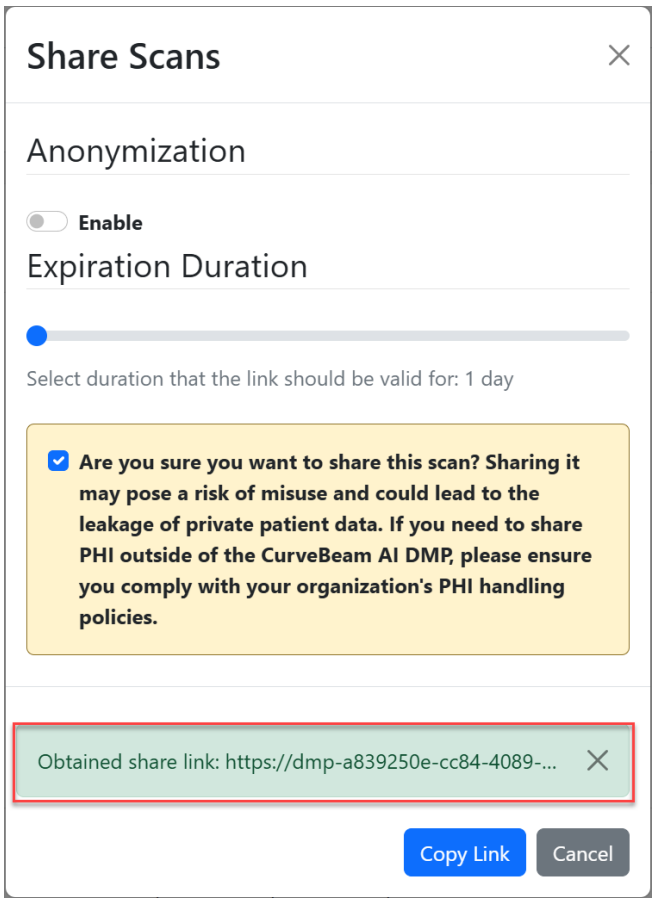
  The 'Share Scans' form will have 2 main configurations. Provide the detail as following

    - **Anonymization** – Disable anonymization by using the toggle button. In this case, you must tick the warning message checkbox to confirm you are aware of the PHI implications of creating a scan share link without anonymization.



- **Expiration Duration –** Drag the slider to select the number of day(s) you would like the share scan link to be valid for. The minimum allowed value is 1 day, and the maximum allowed value is 7 days.

- Click on the **Share** button.
- Once the share link is created, the 'Share Scan' form will display a success message with the newly created scan share link.



- Click on the **Copy Link** button, the scan share link will be copied to your clipboard and the 'Share Scans' form will disappear. A confirmatory notification will pop up following the action.

4.3.5.5.2 Generate shareable link for single/multiple scans - with anonymization

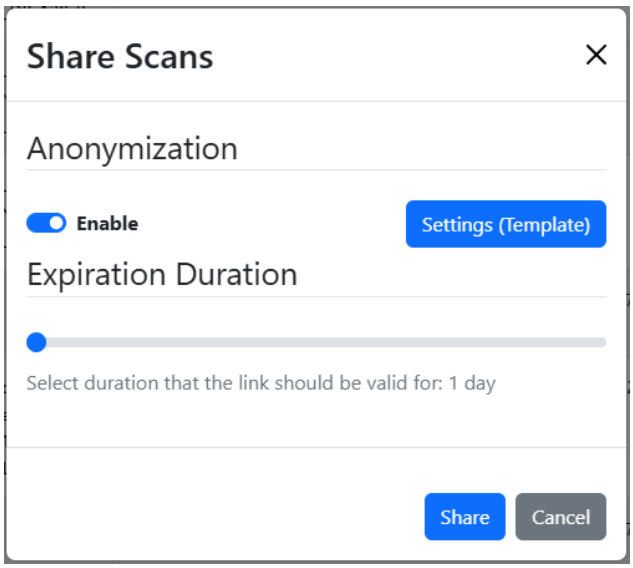
- You can open the 'Share scans' form by following one of the ways:

  1. Open from scan-list page - 4.3.5.1 View scan list

  OR

  2. Open from scan-details page - 4.3.5.3 View scan details

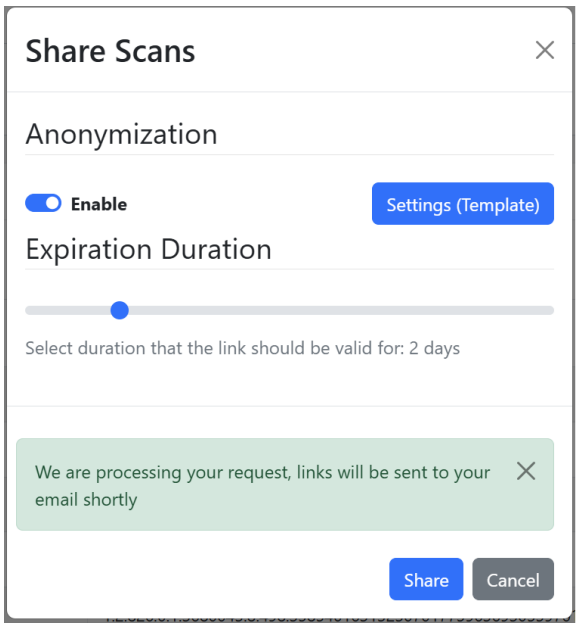
- The 'Share scans' form will pop up with anonymization enabled by default.



The ‘Share Scans’ form will have 2 main configurations. Provide the detail as following

1. **Anonymization** – Enable the anonymization using the toggle button available on the modal. For more details on anonymization refer 4.3.5.11 Anonymization.
2. **Expiration Duration –** Drag the slider to select the number of day(s) you would like the share scan link to be valid for. The minimum allowed value is 1 day, and the maximum allowed value is 7 days.

- Click on ‘Share’ button after enabling the anonymization. This will submit the share request to the application and a success message will be shown on the form. You can close the form to complete the operation.



- The share link will be emailed to the user's registered email after the request is successfully processed.

4.3.5.6 Download scans

4.3.5.6.1 Download a single scan – no anonymization

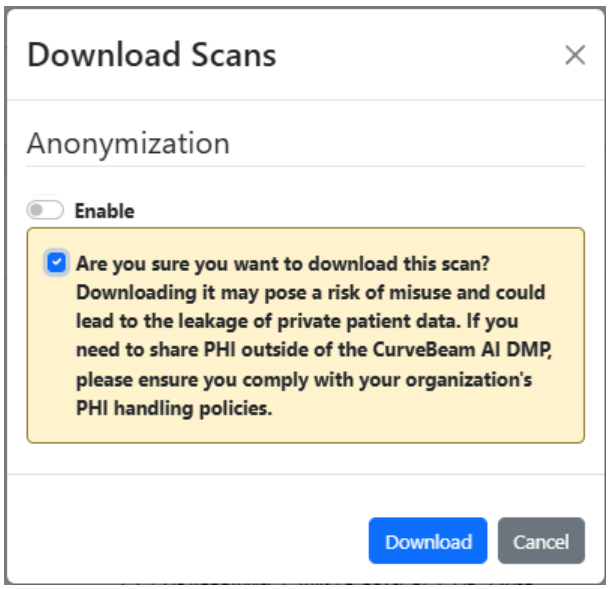
> This action can leak protected health information (PHI).
> Follow your organization's patient data privacy protocols.

- You can open 'Download Scans' form by one of the following ways:
  1. Click on 'Download' button on scan list page - 4.3.5.1 View scan list

OR

  2. Click on 'Download' button from scan details page - 4.3.5.3 View scan details

- The 'Download Scans' form will pop up with the anonymization enabled by default.
- You can disable the anonymization by using the toggle button on the form. In this case, you must tick the warning message checkbox to confirm you are aware of the PHI implications of downloading scan without anonymization.



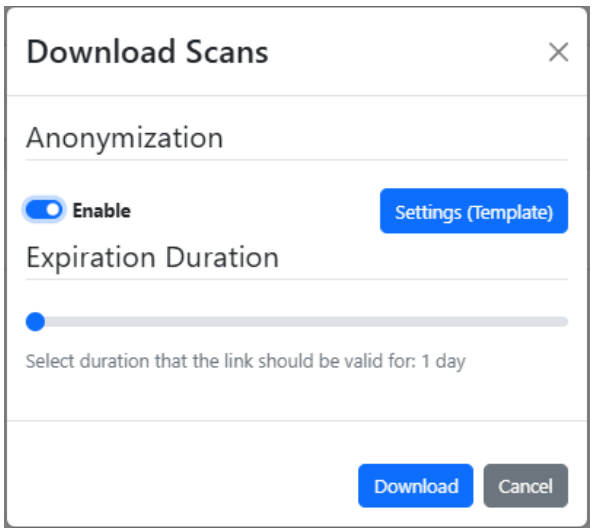
- Click on the **Download** button.
- The scan will be downloaded to your computer immediately and a confirmatory notification will pop up.

4.3.5.6.2 Download single/multiple scan(s) – with anonymization

- You can open ‘Download Scans’ form by one of the following ways:
    1. Click on ‘Download’ button on scan list page - 4.3.5.1 View scan list

OR

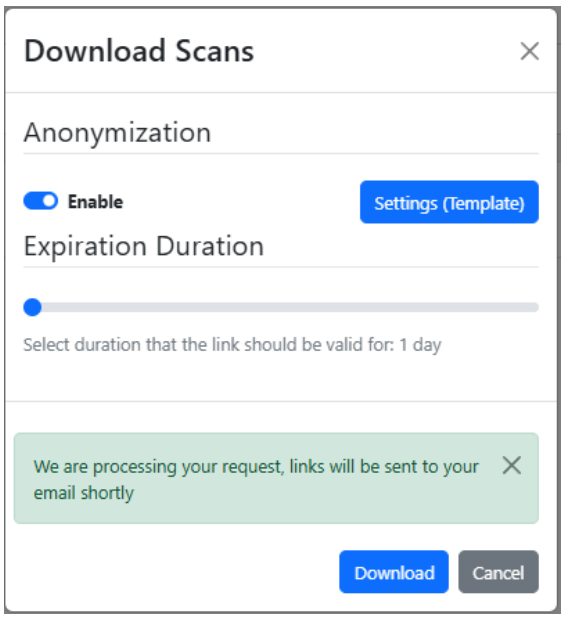
    2. Click on ‘Download’ button from scan details page - 4.3.5.3 View scan details
- The ‘Download Scans’ form will pop up with the anonymization enabled by default.



The ‘Download Scans’ form will have 2 main configurations. Provide the detail as following

1. **Anonymization** – Enable the anonymization using the toggle button available on the modal. For more details on anonymization refer 4.3.5.11 Anonymization.
2. **Expiration Duration –** Drag the slider to select the number of day(s) you would like the share scan link to be valid for. The minimum allowed value is 1 day, and the maximum allowed value is 7 days.

- Click on ‘Download’ button after enabling the anonymization. This will submit the download request to the application and a success message will be shown on the form. You can close the form to complete the operation.

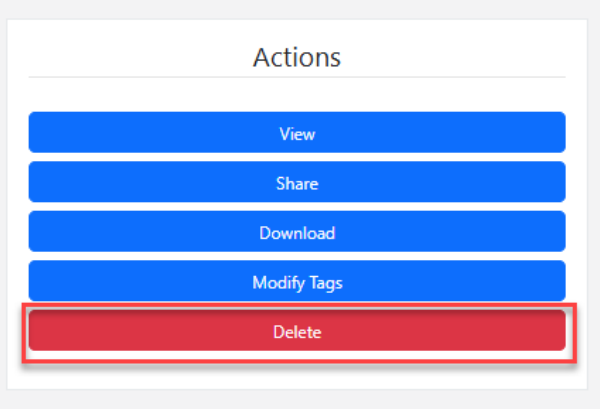


- The download link will be emailed to the user's registered email after the request is successfully processed.

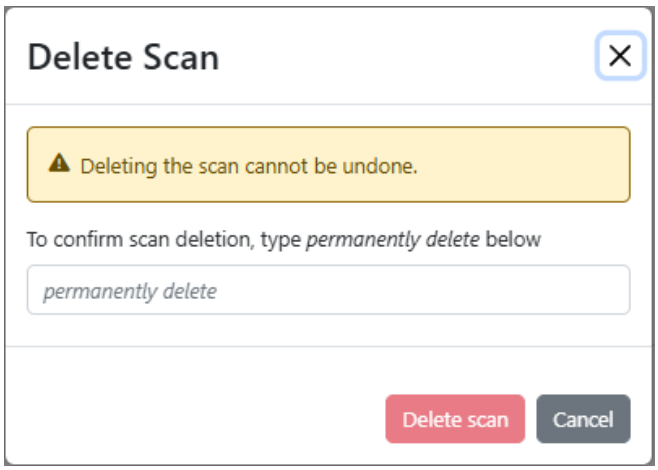
4.3.5.7 Delete scans.

This action is only available for organization administrators.

- Go to the scan detail page for a scan of interest. Click on the **Delete** button under the 'Actions' group.



- The Delete Scan form will pop up with a warning message. Type 'permanently delete' into the textbox to confirm that you would like to delete the scan.



- Click on the **Delete Scan** button.
- Once the delete has been processed, you will be redirected to an updated scan list and a confirmatory notification will pop up.
- An automated email will be sent to the administrator users in your organization notifying that the scan has been deleted.

Contact CurveBeam AI to restore a deleted scan from the backup data within 70 days of deletion. Data will be permanently deleted after 90 days.

4.3.5.8 Access compatible SaaS from scan details page

This action is only available for system administrators, administrators and staff users

After scan upload, SaaS compatibility of scans will require a short amount of time to be processed and displayed.

The access to compatible SaaS is only available in the scan detail page, and not in the scan list page. DMP currently does not support select multiple scans and access the compatible SaaS.

- Go to the scan list and select scan of interest which shows the SaaS name in the ‘Compatible SaaS’ column.

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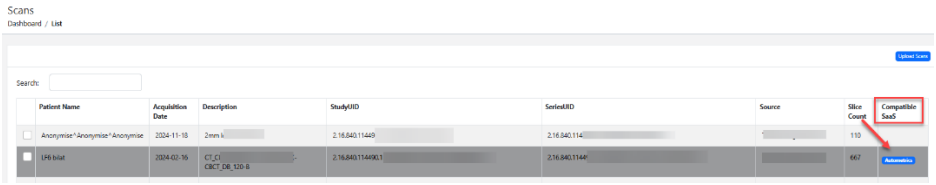
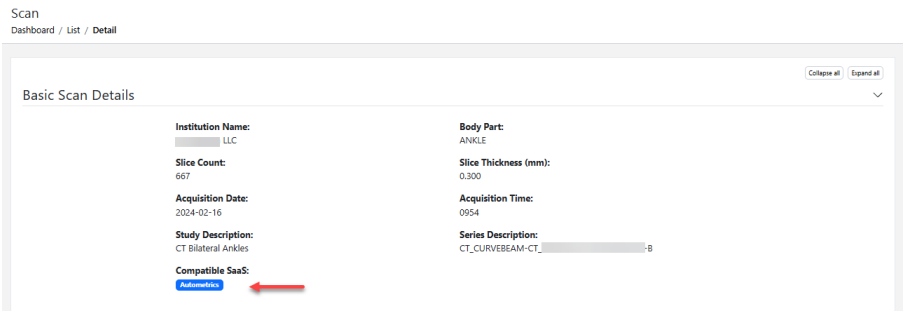
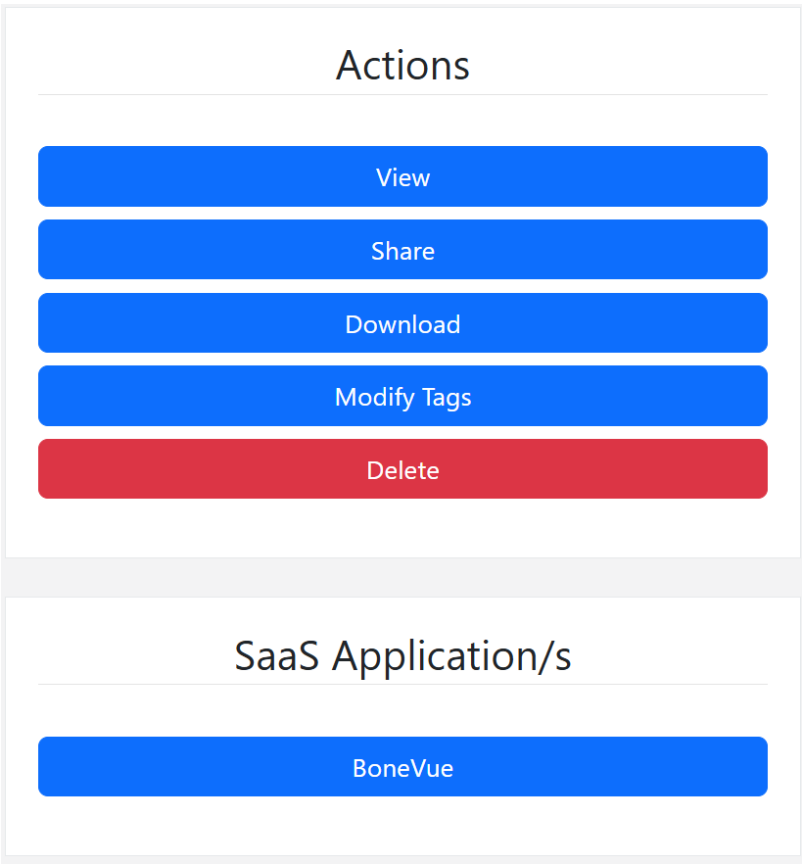


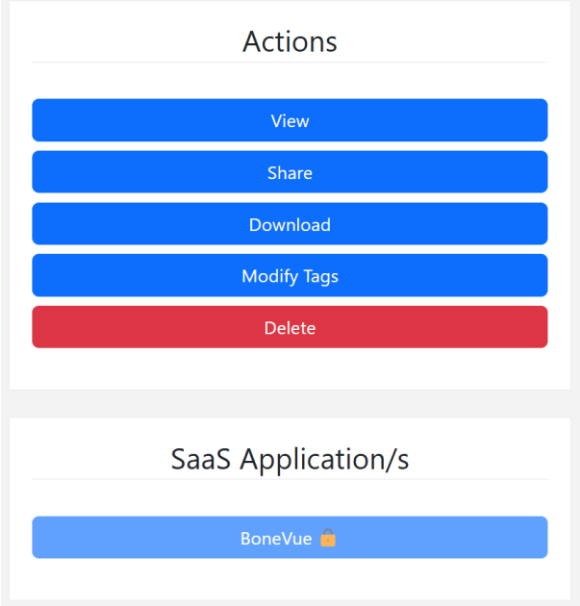
- On the scan detail page, the compatible SaaS information is shown under ‘Basic Scan Details’ section.



- If the SaaS application is assigned to the organization, the SaaS button under **SaaS Application/s** section, will be enabled. Clicking on the SaaS button will open the SaaS application in the new tab.



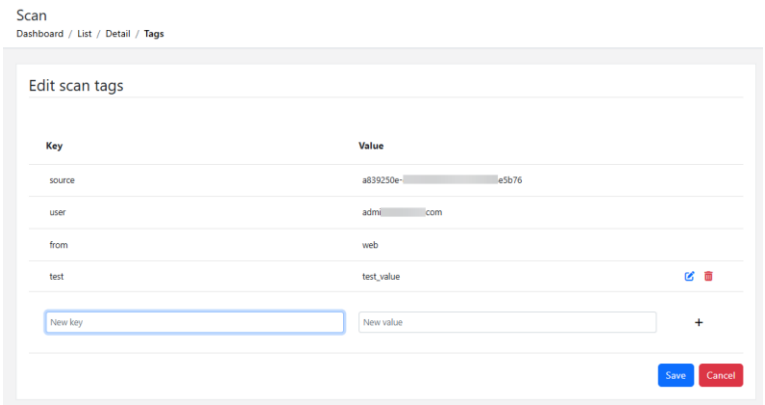
- If the SaaS application is not assigned to the organization, the SaaS button under **SaaS Application/s** section, will be disabled with a lock icon.



Before sending the data to the SaaS application for processing, please check the compatible equipment and acceptable data specification in the Instructions for Use of the SaaS application. Sending incompatible data might cause failure of the SaaS application or incorrect analysis results to be generated.

4.3.5.9 Modify tags

- Go to the scan detail page and click on 'Modify Tags' button (refer to section 4.3.5.4 View scan details)
- The 'Edit scan tags' page will be displayed with all the options required for modifying scan tags.



- The first 3 tags are system defined tags which are not editable.
- You can only modify user-defined tags. More details about modifying user-defined tags refer to section 4.3.5.12 Tags

- Once you have completed modifying the tags, click on ‘Save’ button to submit the request. A success message will pop up following the action.

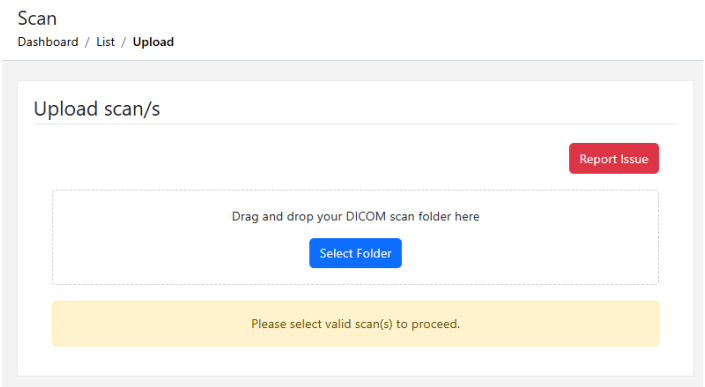
4.3.5.10 Upload scans

This action is available to organization administrators/staff users only.

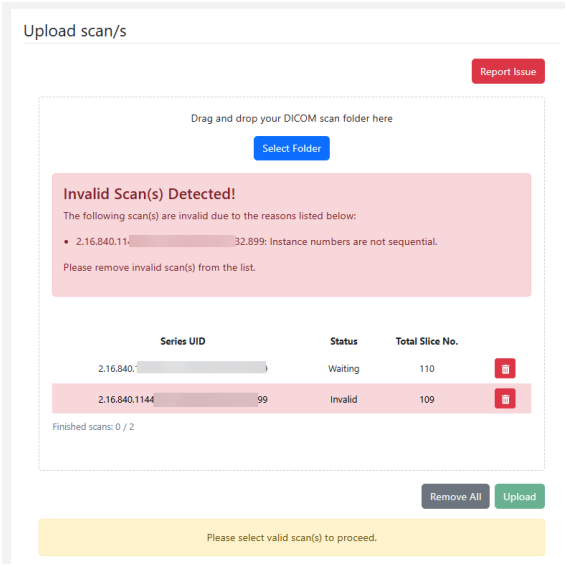
Please note that the time it takes for scan upload to complete depends on the size of the files and internet bandwidth.

Please note that compressed (zipped) file type is not supported and will not be detected and accepted by the upload function.

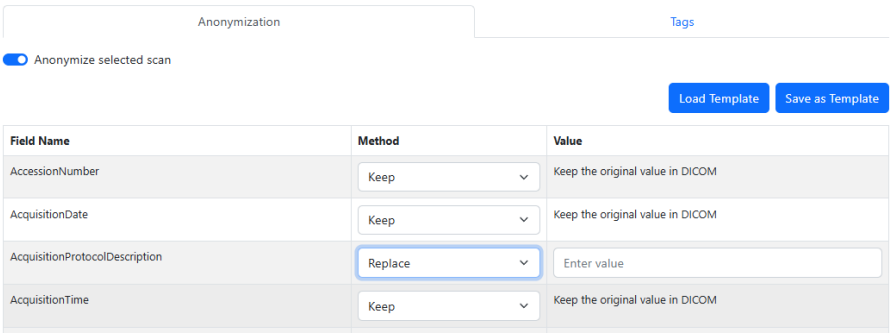
- Click on the **Upload Scans** button on scan list page (refer 4.3.5.1.2 View scan list of your own organization)
- This will redirect you to ‘Upload scan/s’ page.



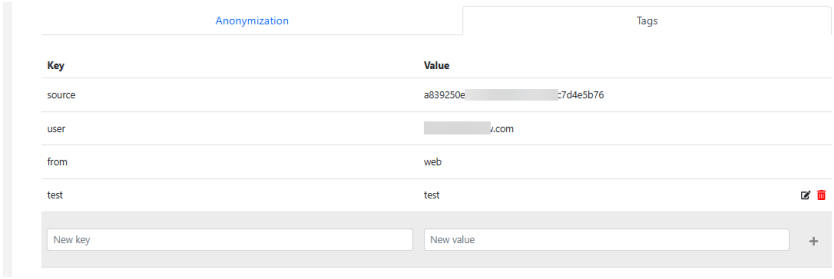
- Click on **Select Folder** button to choose the folder containing scan images.
- The selected scan details will be displayed on the page. If any issues with the selected scan are detected (e.g., missing slices within the dataset), an error will be displayed immediately.



- Before you submit upload request, remove the invalid scans from the list by clicking on delete icon in front of the scan. You can remove all the scans by clicking on 'Remove all' button if required.
- The **Anonymization toggle** switch will appear on the upload page when all the selected scans are valid. You can enable/disable anonymization using that anonymization toggle button.



- You can either keep the default template loaded or modify the template using the following methods available.
  - Keep – This will keep the original value
  - Replace – This will allow the user to replace the value for that field
  - Remove – This will remove that field from the template
  - KeepYear – This will allow the user to keep the year value on that field
  - New – This will allow the user to add a new value generated by the system
- There is a 'tags' section available in the upload page, which displays tags associated with a scan.



- The system defined tags will be listed at the top of the list which cannot be modified.
- You can only add/modify/delete user-defined tags. For more details about modifying tags, refer 4.3.5.12 Tags.
- Once you finish updating the required configuration on the upload page, click on the **Upload** button to start uploading the scans.
- A progress status will be shown to reflect the status of upload processing.
- Upload summary will be displayed in a new pop-up window after the completion of the upload request. Upload summary will contain the list of succeeded, failed and skipped scan count details. Also, an upload summary will be emailed to the user's registered email address.

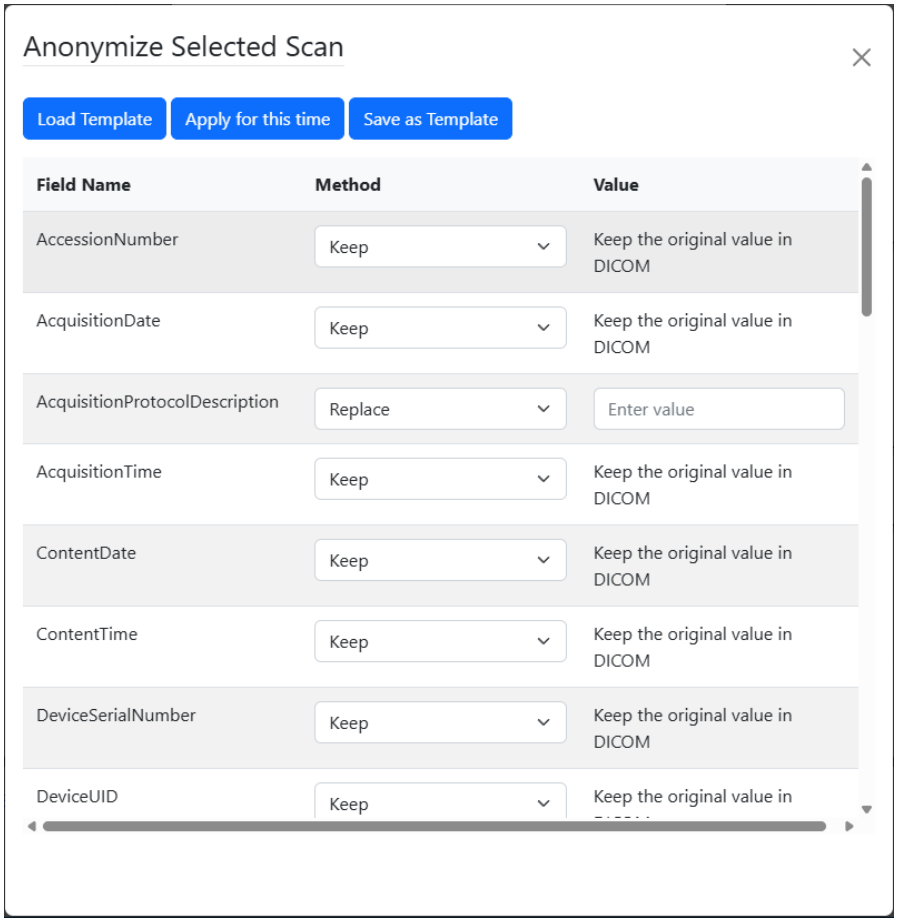
4.3.5.11 Anonymization

Anonymization can be applied on the scans when you perform share/download operation on the scans. The anonymization setting on the share/download form will look as shown below.

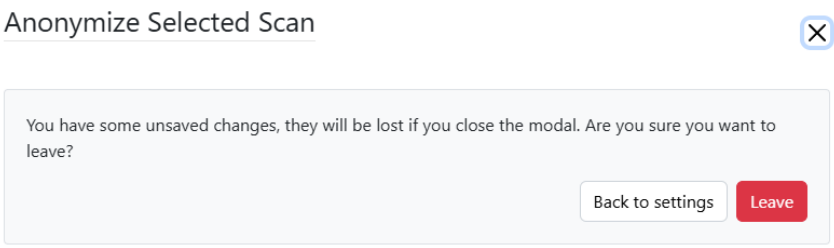
- You can enable/disable the anonymization using the toggle button available on the modal.
- You can configure the anonymization template by using the 'Settings (Template)' option available on the modal.

> Only organization administrators/staff users can modify the anonymization template. System administrators can only use the default organization anonymization template.

- When you click on the 'Settings (Template)' button, the anonymize form will be displayed as shown below.



- The organization's default template will be loaded.
- The user can modify the template by using one of the following options available under the 'Method' field.
    - Keep – This will keep the original value
    - Replace – This will allow the user to replace the value for that field
    - Remove – This will remove that field from the template
    - KeepYear – This will allow the user to keep the year value on that field
    - New – This will allow the user to add a new value generated by the system
- Once the template is modified, user can save the updated template as organization default template for future use by using the 'Save as Template' action available on the form.
- If the template changes need to be applied only for the current scan anonymization, this can be done using the 'Apply for this time' action available on the form.
- If the user needs to use the default template, that can be done using 'Load Template' action available on the form.
- If the user closes the form without making any changes to the template default template will be applied to the scan anonymization.
- If the template is modified and the user tries to close the form without applying or saving the changes, a message will be displayed on the form asking if any of the changes needs to apply or not.



- The user can discard the template changes by clicking on ‘Leave’ button or return to the anonymization form by clicking on ‘Back to settings’ button.

4.3.5.12 Tags

- You can perform one of these operations on user-defined tags:
  - **Add**
    You can add a new tag by entering the key-value pairs in text fields and clicking on ‘+’ button.

    The following basic naming and usage requirements shall apply to user-specified tags:

    - Each scan shall have a maximum of 5 user-defined tags.
    - The tags shall not begin with 'aws:' prefix.
    - Each tag key shall be unique, and each tag key can have only one value.
    - The tag key shall be a minimum of 1 and a maximum of 64 Unicode characters in UTF-8.
    - The tag value shall be a minimum of 1 and a maximum of 64 Unicode characters in UTF-8.

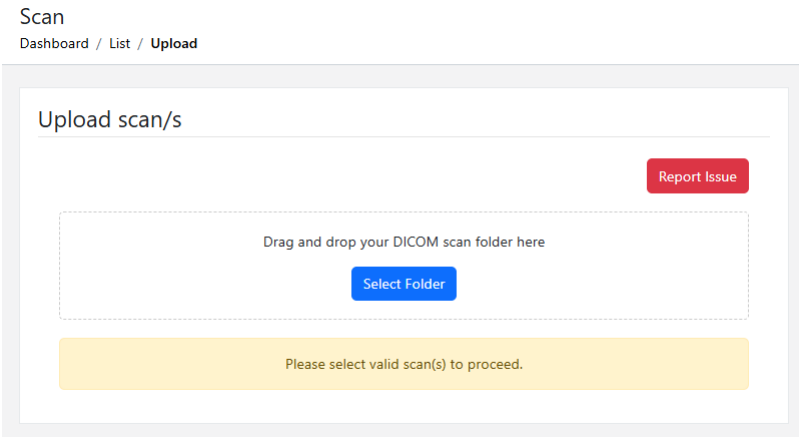
  - **Edit**
    You can edit the existing user-defined tags by clicking on edit icon in front of the tag.

  - **Delete**
    You can delete the user-defined tags by clicking on delete icon in front of the tag.

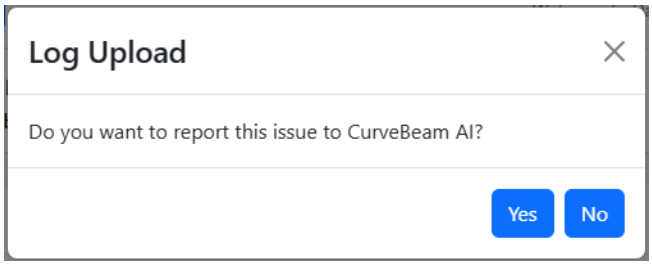
4.3.5.13 Report Issues

4.3.5.13.1 Report an issue from scan upload page

- To report an issue during the upload process, click on the ‘Report Issue’ button on the ‘Upload scan/s’ page.



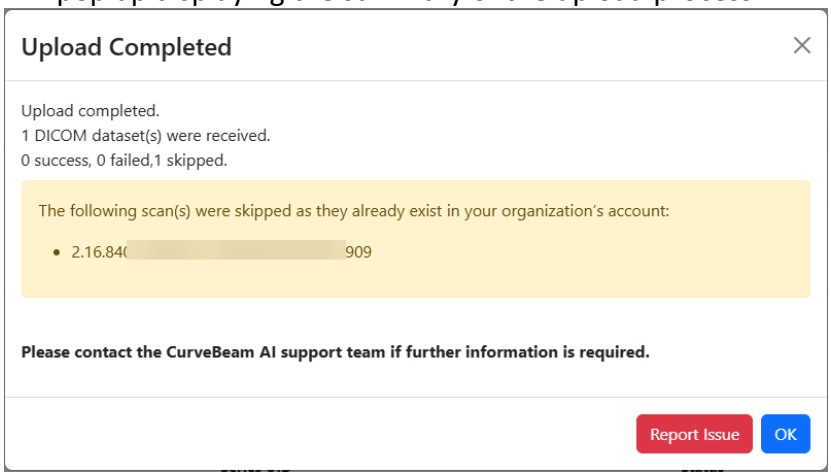
- Once you click on the ‘Report issue’ button, a ‘Log Upload’ window will pop up asking for the confirmation to upload the issue log.



- Click on ‘Yes’ button to upload the issue log.

4.3.5.13.2 Report issue from upload summary dialog

- When the upload process is complete on ‘Upload scan/s’ page, a dialog will pop up displaying the summary of the upload process.



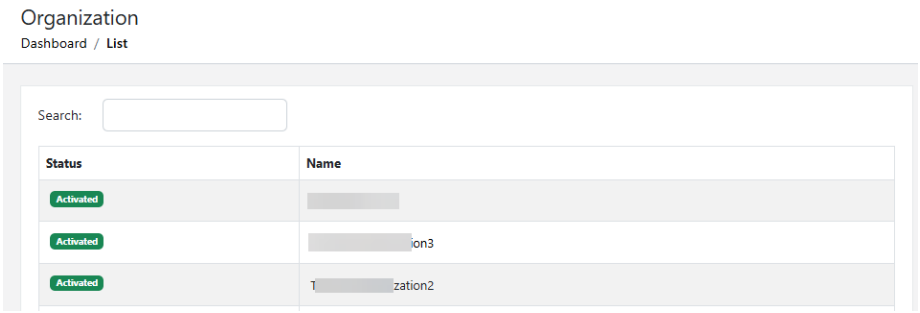
- Click on ‘Report Issue’ to upload the issue log during the upload process.

4.3.6 Organization

4.3.6.1 View organization list

This action is only available for system administrators – CurveBeam AI.

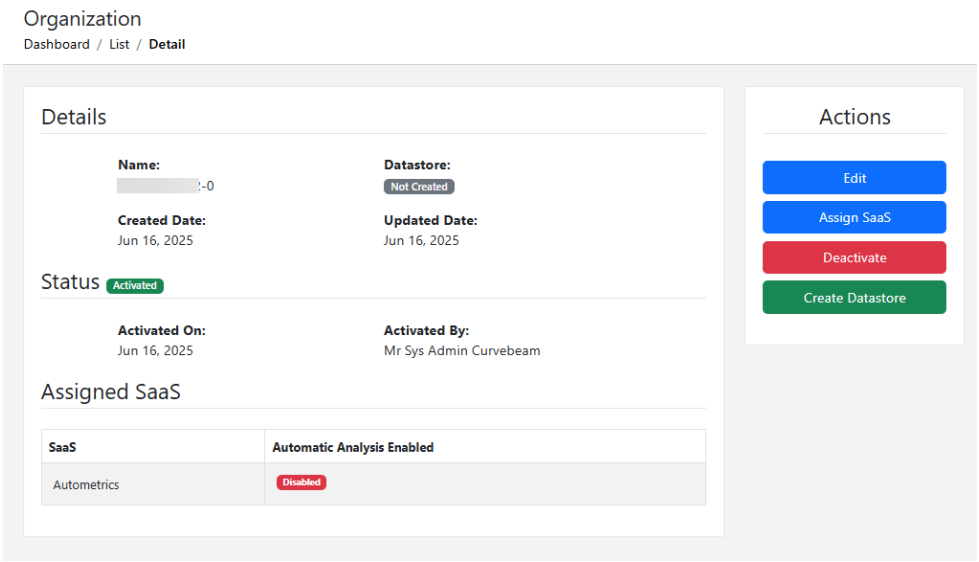
- To view the organization list, click on **Organization** on the side panel.
- The organization list will be displayed.



4.3.6.2 View organization details

This action is only available for system administrators – CurveBeam AI.

- Go to the organization list and click on an organization of interest.
- The details of the selected organization will be displayed.

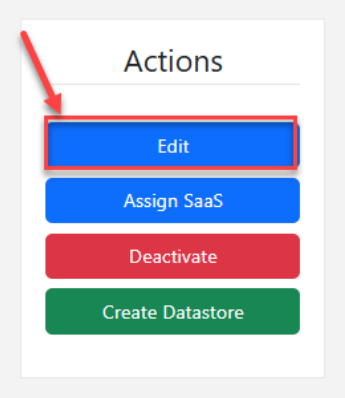


- You can perform multiple operations related to the organization module using the actions available under the **Actions** group.

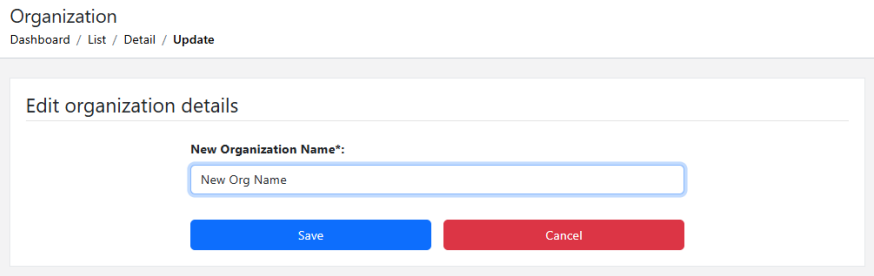
4.3.6.3 Edit organization details.

> This action is only available for system administrators – CurveBeam AI

- Go to the organization list and click on an organization of interest.
- On the organization detail page, click on the **Edit** button under the **Actions** group.



- The edit organizations detail form will be displayed. Provide the following detail:
  - **New Organization Name –** Fill in the associated textbox.

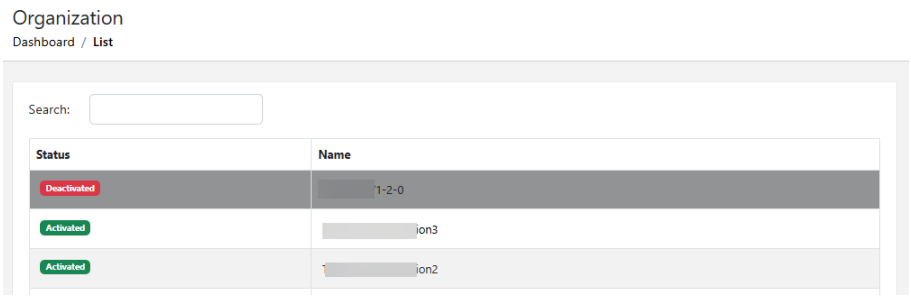


- Click on the **Save** button.
- An updated organization detail page will be displayed, and a confirmatory notification will pop up.
- An automated email will be sent to organization users notifying of the edited details.

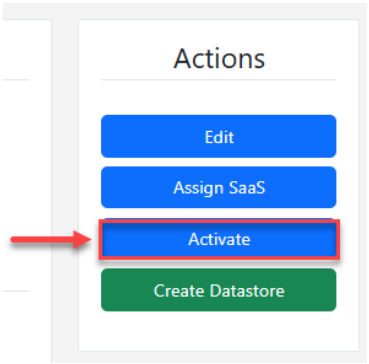
4.3.6.4 Activate organization

> This action is only available for system administrators – CurveBeam AI.

- Go to the organization list and click on an organization of interest with `Deactivated` status.



- On the organization detail page, click on the **Activate** button under **Actions** group.



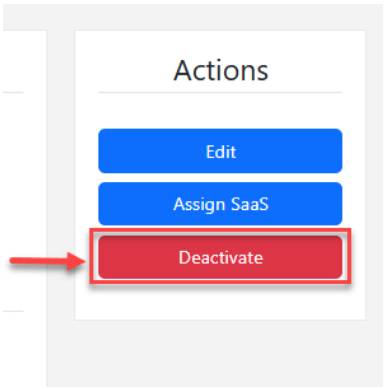
- Once the activation has been processed, a confirmatory notification will pop up. The status section of the organization detail page will be updated accordingly.
- An automated email will be sent to organization users notifying of the activation.

4.3.6.5 Deactivate organization.

> This action is only available for system administrators – CurveBeam AI.

- Go to the organization list and click on an organization of interest with the `Activated` status.

- On the organization detail page, click on the **Deactivate** button under **Actions** group.



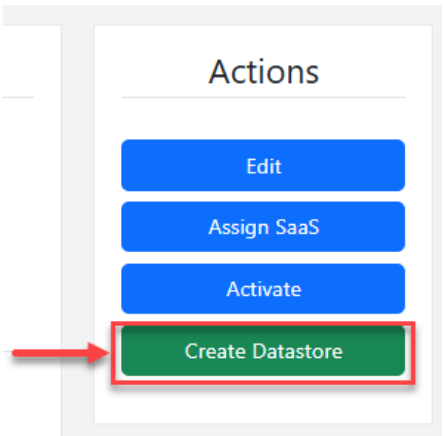
- Once the deactivation has been processed, a confirmatory notification will pop up. The status section of the organization detail page will be updated accordingly.
- An automated email will be sent to organization users notifying of the deactivation.
- Users in the deactivated organization will not be able to log into the DMP.

4.3.6.6 Create cloud DICOM datastore for an organization.

> This action is only available for system administrators and organization administrators.

> This action is only available if the cloud DICOM datastore has not been previously created.

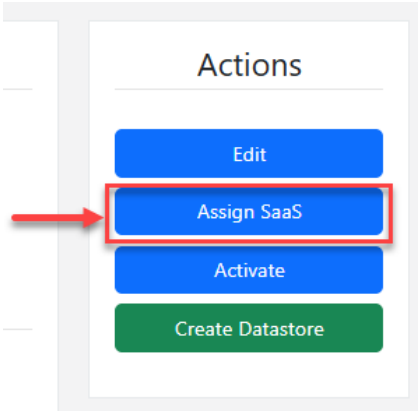
- Go to the organization detail page for the organization of interest and click the **Create Datastore** button.



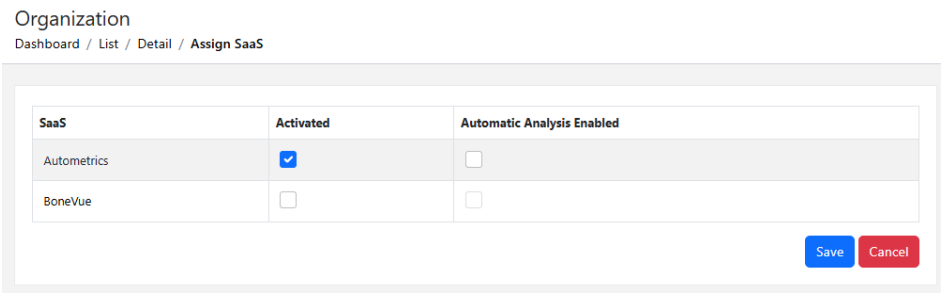
- Once the cloud DICOM datastore creation has been processed, a confirmatory notification will pop up. The Datastore status field of the organization detail page will be updated accordingly.
- An automated email will be sent to organization users notifying of the datastore creation.

4.3.6.7 Assign SaaS.

- Go to the organization detail page for the organization of interest and click the **Assign SaaS** button.



- On Assign SaaS page, list of SaaS applications shall be displayed with the option to Activate/Deactivate and Enable/Disable automatic analysis.



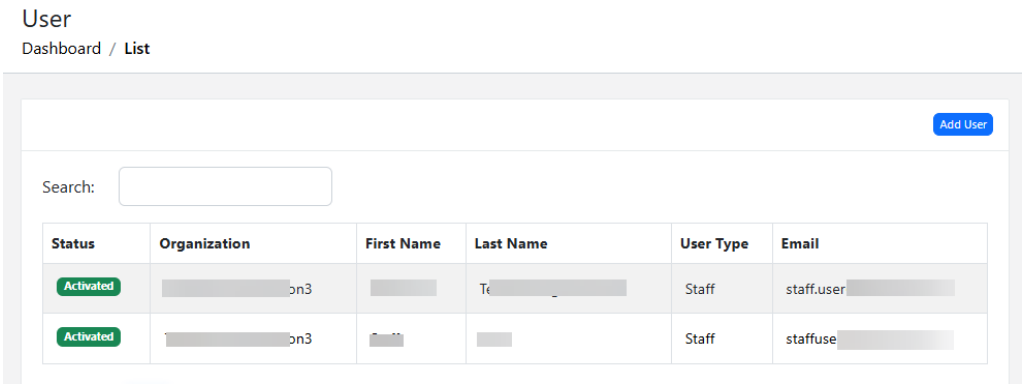
- You can tick the checkbox under **Activated** column to assign a particular SaaS to the organization.
- You can enable the automatic analysis by using the checkbox under **Automatic Analysis Enabled** column (For BoneVue SaaS this option is disabled). If this property is enabled, an automatic analysis request will be submitted when a compatible scan is uploaded to the organization. If this property is disabled, user can still request for analysis on SaaS application page.
- Click on the **Save** button, to assign the SaaS application with the organization.
- Once the **Assign SaaS** request is completed, a confirmatory popup will appear, and the user is transferred back to the organization detail page. Newly assigned SaaS application shall appear in a list under the heading of **Assigned SaaS**.

4.3.7 User

4.3.7.1 View user list

> This action is only available for super admin, system administrators and organization administrators.

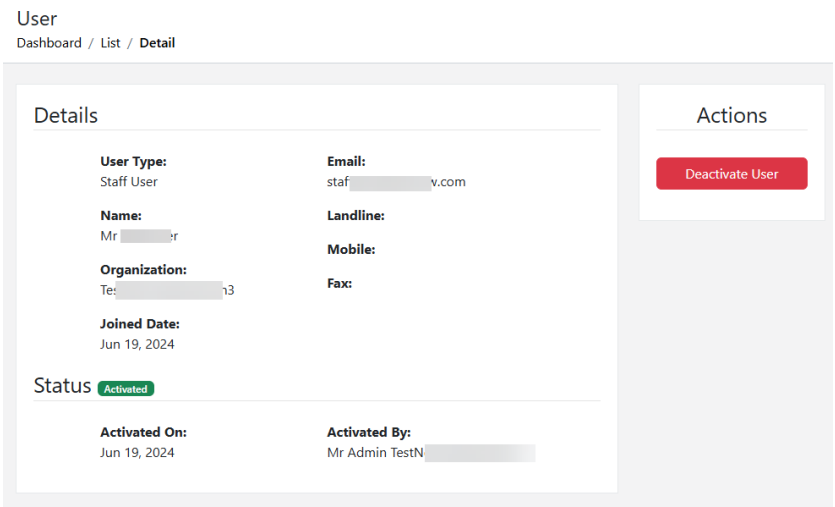
- To view the user list, click on **User** on the side panel.
- The user list will be displayed.



4.3.7.2 View user details

> This action is only available for super admin, system administrators and organization administrators.

- Go to the user list and click on a user of interest.
- The details of the selected user will be displayed.



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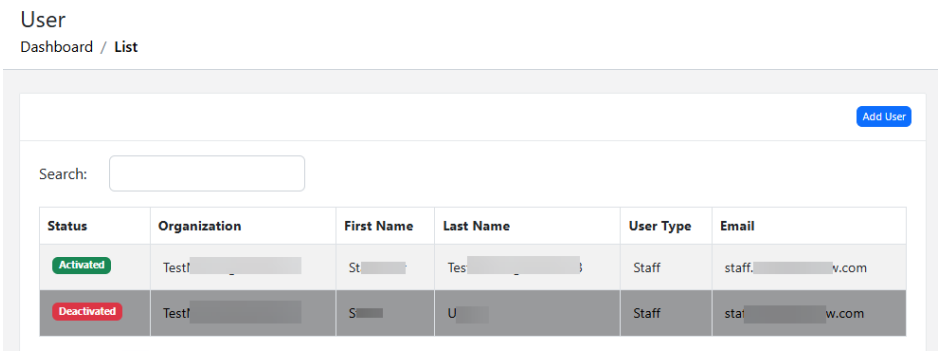
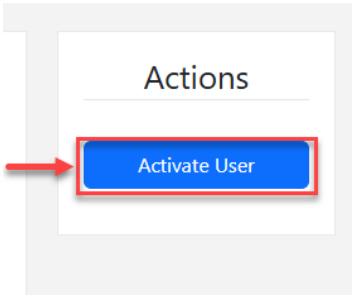
4.3.7.3 Activate users

> This action is only available for super admin, system administrators and organization administrator.

- Go to the user list and click on a user of interest with the `Deactivated` status.



- On the user detail page, click on the **Activate User** button under **Actions** group.

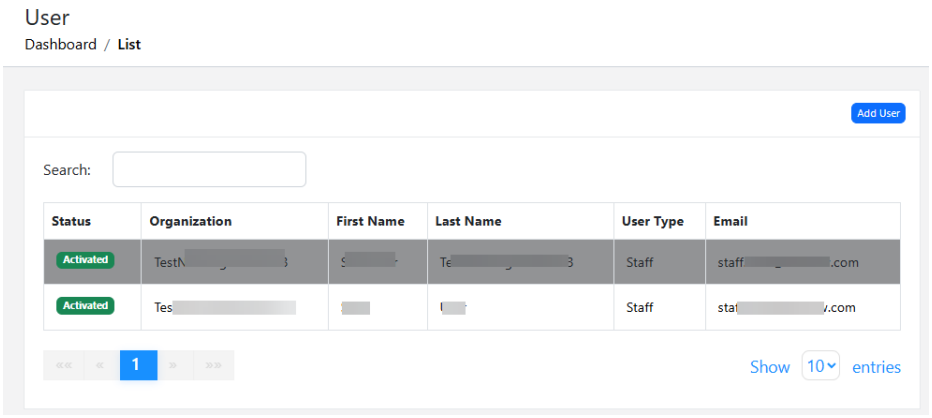


- Once the activation has been processed, a confirmatory notification will pop up. The status section of the user detail page will be updated accordingly.
- An automated email will be sent to the user notifying of the activation.

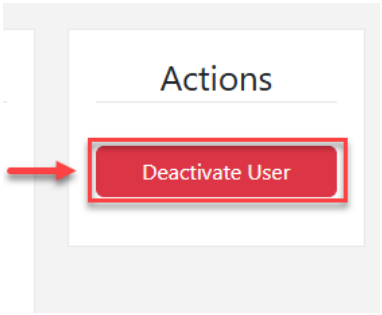
4.3.7.4 Deactivate users

> This action is only available for super admin, system administrators and organization administrator.

- Go to the user list and click on a user of interest with the `Activated` status.



- On the user detail page, click on the **Deactivate User** button under **Actions** group.



- Once the deactivation has been processed, a confirmatory notification will pop up. The status section of the user detail page will be updated accordingly.
- An automated email will be sent to the user notifying of the deactivation.
- The deactivated user will not be able to log into the DMP.

4.3.7.5 Reset temporary password for user

> This action is only available for super admin, system administrators and organization administrator.

> This action is only available if the user of interest has not previously set a permanent password.

- Go to the user list and click on a user of interest.
- On the user detail page, click on the **Reset Temp Password** button under **Actions** group.

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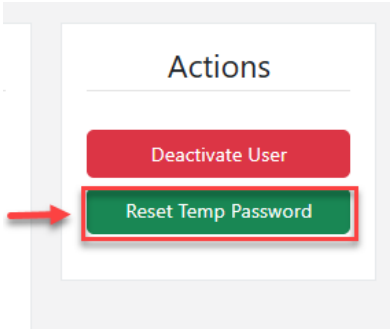
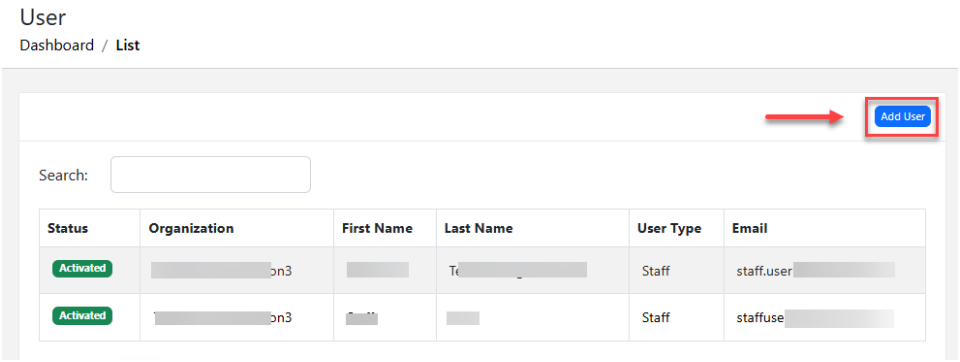


- Once the reset temporary password request has been processed, a confirmatory notification will pop up. An automated email will be sent to the user notifying of their new temporary password.

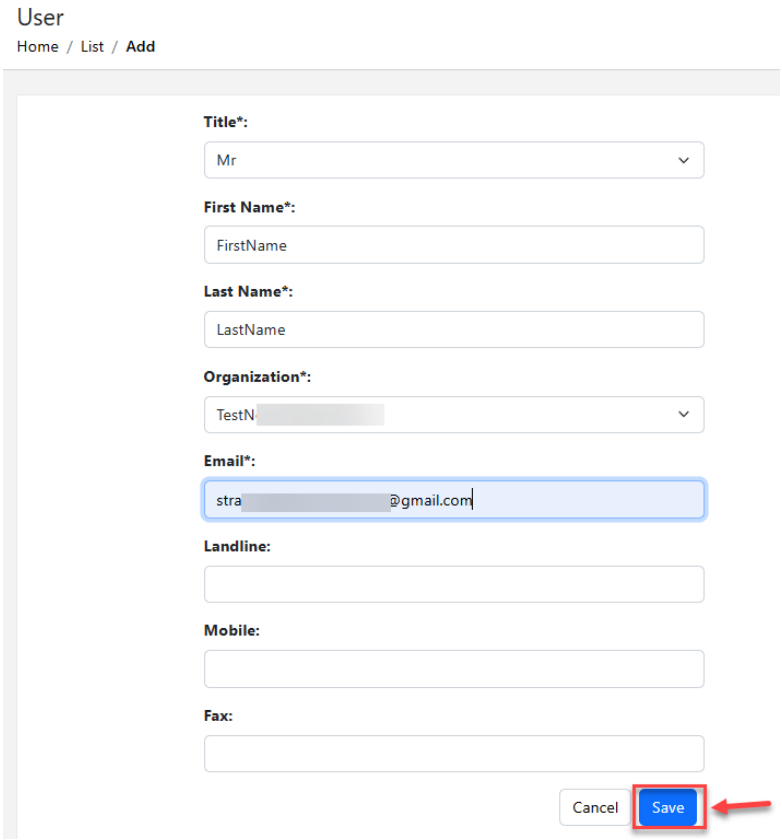
4.3.7.6 Add user

> This action is only available for super admin, system administrators and organization administrators.

- Go to the user list and click on the **Add User** button.



- In the form that appears, fill out the new user details. Once finished, click the **Save** button.

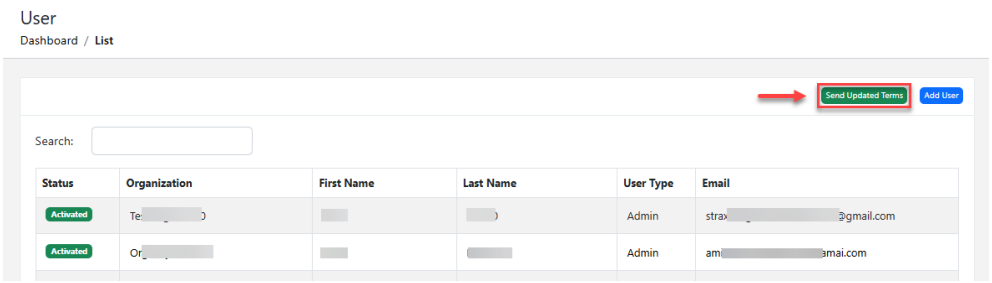


- Once the add user request has been processed, the new user details will appear, and a confirmatory notification will pop up. An automated email will be sent to the new user notifying of their temporary login credentials.

4.3.7.7 Send updated terms of use

> This action is only available for system administrators.
> This feature is used when terms of use are updated, and this information needs to be shared with all the users.

- Go to the user list and click on the **Send Updated Terms** button.



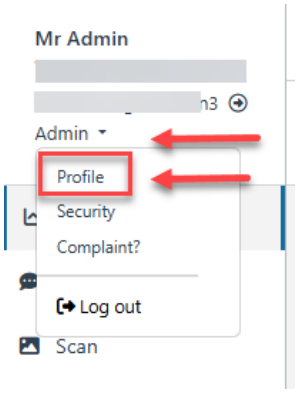
- Once the send updated terms request has been processed, a confirmatory notification will pop up.

- As a result of this, all registered DMP users will receive an email notification regarding the updated terms of use.

4.3.8 Account

4.3.8.1 View profile information

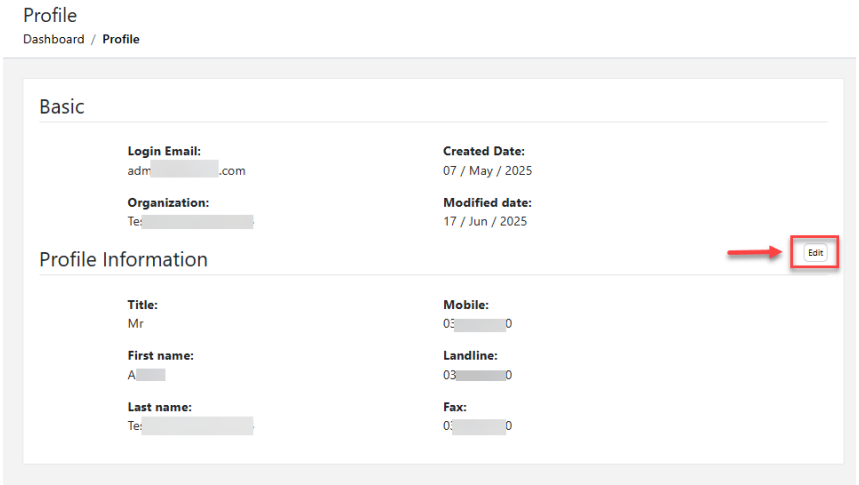
- Click on the user role on the side panel at the top-left corner of the page.
- A dropdown menu will be displayed, click on **Profile**.



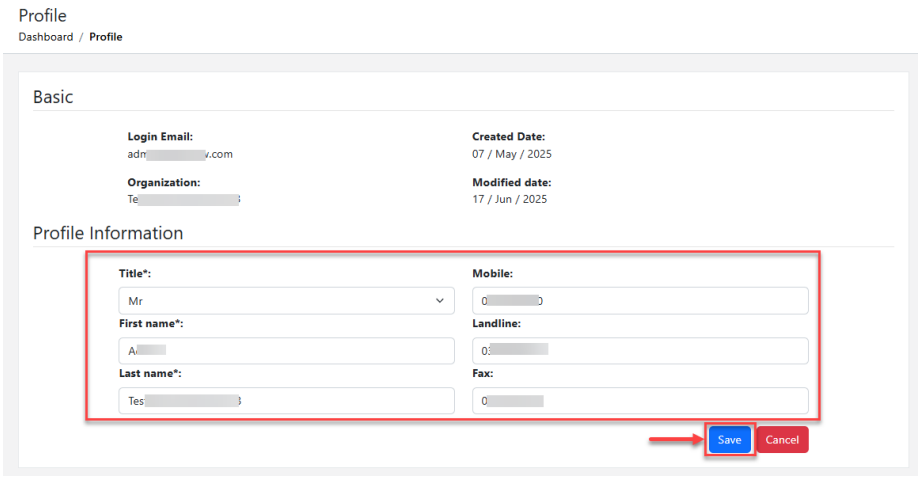
- The profile information will be displayed.

4.3.8.2 Update profile information

- Go to profile information page. In the profile information section, click on **Edit**.



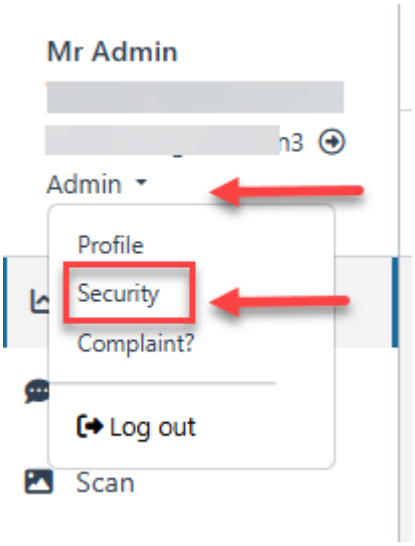
- A form will be displayed with current field values.
- Update the field of interest and click on **Save**.



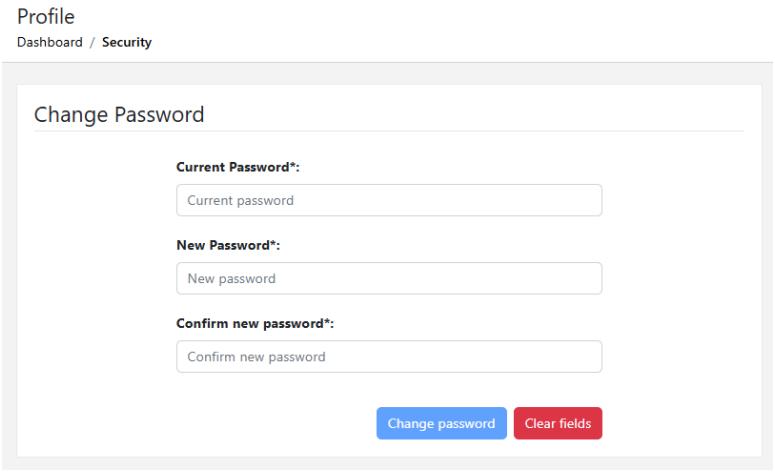
- Once the update has been processed, a confirmatory notification will pop up. The profile information section will be updated accordingly.
- An automated email will be sent to the user notifying that their profile information has been updated.

4.3.8.3 Change password

- Click on user role on the side panel at the top-left corner of the page.
- A dropdown menu will be displayed, click on **Security**.



- A change password form is displayed.



- Fill in the current password, new password and confirm password fields and click on **Change password**.

Important
The password required must meet the following conditions.

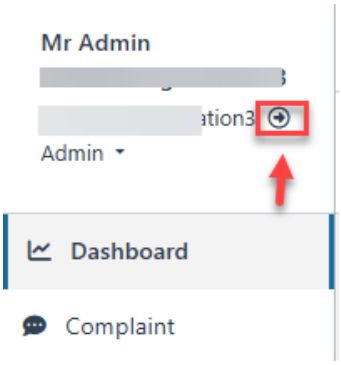
- Should be at least 12 characters long.
- Have at least 1 lowercase character
- Have at least 1 uppercase character
- Have at least 1 number
- Have at least 1 special character

- Once the update has been processed, a confirmatory notification will pop up.
- An automated email will be sent to the user notifying that their password has been updated.

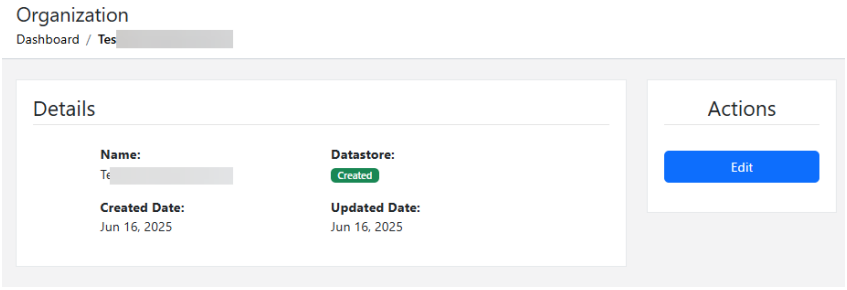
4.3.8.4 View own organization details

This action is only available for organization administrators and staff users.

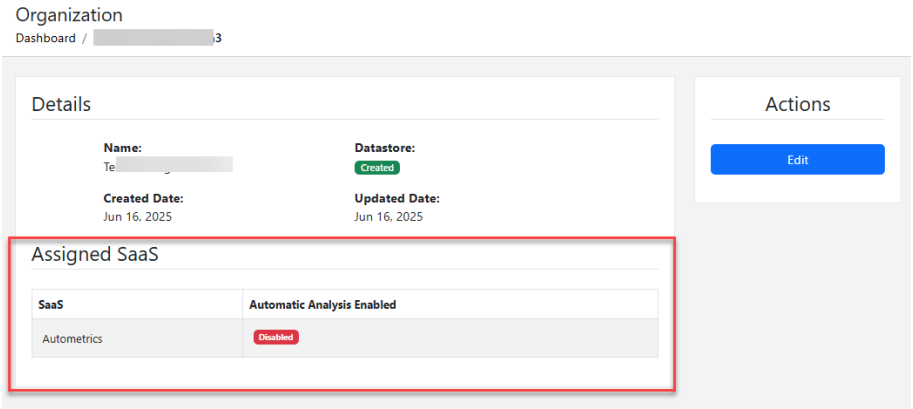
- Click on the arrow next to the Organization name at the top-left corner of the page.



- The details of the organization will be displayed.



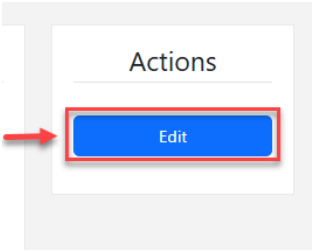
- SaaS applications, if assigned to the organization, will show under the **Assigned SaaS** section.



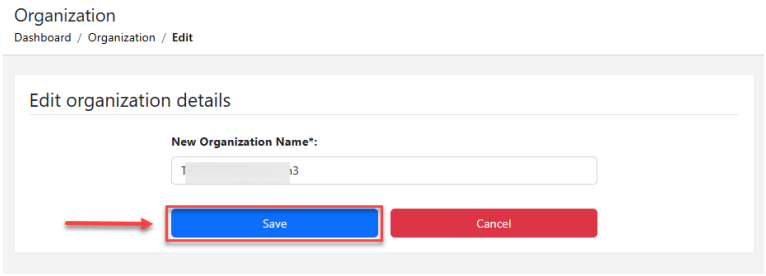
4.3.8.5 Update own organization details

This action is only available for Organization Administrators.

- Go to your own organization details and click on **Edit** button under **Actions** group.



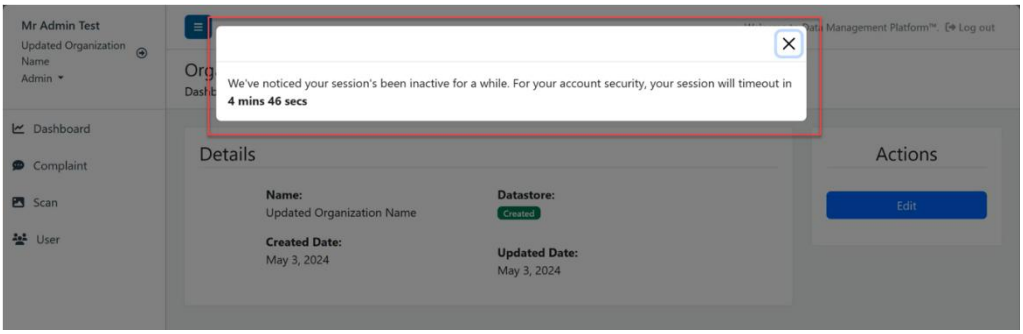
- A form is displayed with current organization name.



- Update the organization name and click on **Save**.
- Once the update has been processed, a confirmatory notification will pop up. The organization details page will be updated accordingly.
- An automated email will be sent to all the users of the organization notifying that their organization information has been updated.

4.3.8.6 Auto logout

- If you are not actively interacting with the application for more than 10 minutes, a modal will pop up displaying a warning message with a 5-minute countdown.



- If you do not interact with the application in the given 5-minute countdown, you'll be logged out and taken to the login screen. The modal pop up will display an appropriate message.

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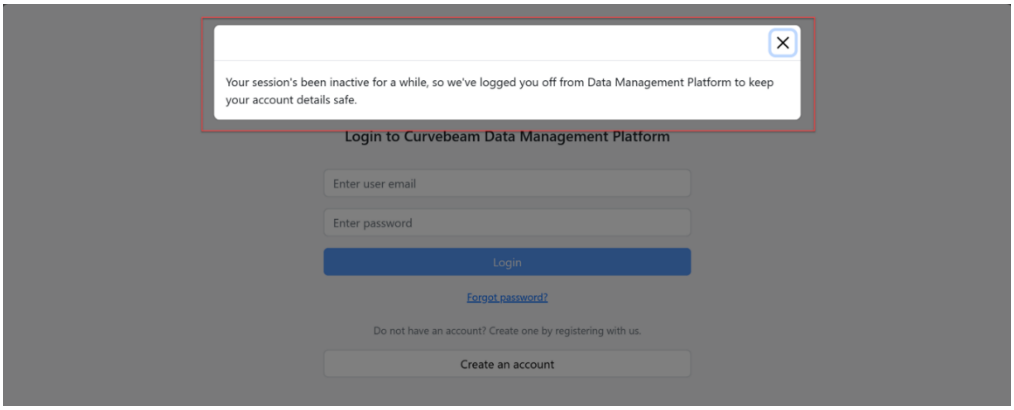

Please note that even if you are active on the DICOM viewer or the SaaS applications but not on the DMP application for more than 15 minutes, the auto logout will still happen and you will be logged out of all the applications, including the DICOM viewer and the SaaS applications.

4.3.8.7 Access Terms of Use

- The **Terms of Use** option is available on the application footer.

- Click on **Terms of Use** text on the footer to view/read the terms of use information on the CurveBeam AI - Terms of Use page.

4.3.8.8 Access IFU

- The IFU option is available on the DMP application footer. To view the IFU click on the **IFU** text on the footer.

- You will be taken to CurveBeam AI IFU page.

4.3.8.9 Access device label

The Device Label is available on the DMP application footer. To view the Device Label, click on the option.

- The Device Label option is available on the application footer. Click on **Device Label** text to view the label information.

- A modal will pop-up displaying the device label.

5. Known Issues

Below is the list of known issues identified during the verification of DMP V1.1.0. Each of these issues have been dispositioned and accepted prior to deployment of the software.
Please contact CurveBeam AI support should these issues affect your use case.

- **Complaint Details**
  The 'Updated On' field on a complaint raised is not updated to reflect the correct date on when the 'Current Status' or 'Current Severity' fields are updated for a complaint. Please refer to the Status History section of the complaint for the audit trail of activities for the complaint.

- **Search Function (excluding Scan module)**
  When using the Search function, the search results contain entries that do not match the search criteria when using numeric values only in the search function. However, this behaviour does not present in searching for scans in the Scan module. This issue does not arise when the search criteria contain a non-numerical value. Please scroll through the entries in the module being searched, to find the desired entry should the function not work.

- **Scan metadata**
  The metadata displayed on the scan details page in the DMP application differs from what is shown in the DICOM viewer application. Please refer to the Scan details page for the scan metadata information.
  Scans cannot be searched with the metadata information that is displayed in the DICOM viewer. Please search for scans using the scan metadata from the Scan Details page.

- **Scan Search criteria**
  Scans cannot be searched for, based on the "Upload Datetime" field. As a workaround, please use alternative search criteria when searching for a scan, such as "Acquisition Date".

- **DICOM Viewer Zoom hot keys**
  When attempting to zoom in/out of MPR images being viewed in the medical image DICOM viewer, clicking on the hotkeys + or – do not result in zooming in/out of the images. As a workaround, please utilize the Zoom button in the viewer directly.

- **Downloading a JPEG image of a slice**
  When a .jpg of the current slice being viewed of a MPR image is downloaded, a blank image is saved instead. Additionally, the MPR views are reset and will need to be

altered using the vertical scroll bars to bring the anatomy back into view. As a workaround to obtain specific slices in the scan (not in .jpg format), user can utilize the "Download" function listed in section 4.3.5.6.

- **Cine Menu on DICOM Viewer**
  An error is presented on the DICOM Viewer when the Cine roll function within the 3D Main (MPR view with a 3D rendering) view is clicked. The DICOM Viewer will then need to be closed and re-opened to re-access the scan from the DMP application.

- **DICOM Viewer**
  The DICOM Viewer becomes unresponsive when attempting to open 3D Main or MPR views of a study with a large number of slices. However, this issue does not arise when the user's computer Operation System specifications have a minimum of 32GB RAM memory and 3.0GHz frequency.

- **DICOM Viewer Calibration menu**
  The Calibration menu option is accessible within the MPR view, but not the 3D Main view on the DICOM Viewer.

- **Complaint File Size**

Adding a Complaint results in a Http Failure Response due to file size constraints. The DMP complaints module has file size constraints while attaching a file to a complaint being logged through the DMP Complaint module. If a complaint cannot be raised on the DMP, contact CurveBeam AI Customer Support to raise a complaint. Please refer to section 1.7 for the contact information.

Revision History

Revision	Release Date	Change Description
1	04/Jun/2024	Initial release
2	21/Jun/2024	1. Minimum user system requirements updated for MPR view to work on DICOM Viewer in section 3.1 Internet connection and a browser 2. DMP Production URL added in section 4.2.1 Account creation workflow 3. The reference images for Upload Application in section 4.4.8 Reporting issues are updated
3	26/Sept/2024	1. Page footer is updated with organization name and revision number 2. Glossary of symbols is updated 3. Service user role description is update under 1.2 Intended Users 4. Company information is updated under 1.6 Company Information 5. Product label is updated under 2. Product Label

		6. Updates being made in 4.3.5.3 Batch transfer scans to another organization 7. Warning message under 4.3.5.7 Delete scans. is updated 8. Collapsing / Expanding functionality for scan detail added under 4.3.5.8 Expand / Collapse Scan Details. 9. Accessing the SaaS application from scan detail page is added under 4.3.5.9 Access compatible SaaS from scan 10. Assigning SaaS to organization workflow added under 4.3.6.7 Assign SaaS. 11. 4.3.8.5 View own organization details section is updated 12. Add compatible data information under section 1.10 Compatible Data 13. Add regional availability information under section 1.11 Regional Availability 14. Add scan search information under section 4.2.6 Scan search workflow 15. Add information regarding paper IFU request under section 1.8 IFU Location 16. Add a warning message for scan anonymisation before uploading scans from CT machines to DMP 17. Add instructions for the upload application installation process 18. Add instructions for selecting multiple folders for uploading 19. Add instructions for removing scans to be uploaded 20. Update images in the upload application because of the main UI changes 21. Reference images are updated across all the modules for better clarity and to focus on the relevant information
4	12/Oct/2024	1. Adding section 5 Known Issues 2. Updated section 4.4.7 Folder Select with information about uploader detecting missing slices. 3. Update section 4.3.5.5 View scan in medical image viewer with warning on DICOM header info accuracy. 4. Update section 4.4.1 Upload application installation to include a workaround solution for cases where the installer is unable to create a desktop shortcut.

		5. Remove mention of service user from section 4.3.5.1 View scan list of a selected organization 6. Change all instances of “Operators” to “User”.
5	11/July/2025	1. Revision updated to 5 in the footer 2. Updated 4.3.5 Scans section as per the new scan module functionalities 3. Updated most of the screenshots in the instruction which now focuses only on the topic that is described in the section. 4. Removed screenshots replaced with text explanation in several modules. 5. Added new functionality Modify tags, 4.3.5.10 Upload scans, 4.3.5.11 Anonymization, 4.3.5.12 Tags 6. Section 4.4 Uploader Application has been removed