AuraVue



ME-UG-702Q
Revision 4 (2026.11)
SW version 2.0.2

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Symbols

No.	Symbol	Definition
1		Consult instructions for use on the website*
2		Consult instructions for use or consult electronic instruction for use
3		Caution
4		Warning
5		Prescription only (USA)
6		Date of manufacture
7		Manufacturer
8		Tips/Notes
9		Medical device
10		Serial number
11		Country of manufacture: Republic of Korea

**If a printed paper version of the user manual is required, it will be provided free of charge upon request to the manufacturer's contact information listed on the last page. The user manual in paper form will be supplied within a maximum of 7 days after receiving the user's request.*

Overview and General Information

Available in US only

The initial rollout of this application is limited to the US market. Global availability is planned for a future release pending localization, compliance, and infrastructure readiness. Stay tuned for updates.

Overview

Medit AuraVue is a web-based consultation tool that uses 3D scan data and radiographs (X-ray) to support clear and effective communication between doctors and patients. The application helps doctors assess and take notes on a patient's oral health during their visit, accompanied by corresponding visuals. In doing this, doctors can leverage 3D scan data as well as radiographs that contain AI-driven analysis conducted by Overjet, an FDA-approved third-party program. All findings are then organized into a patient-oriented dental report that includes visual representations of the identified pathologies, simplified explanations of diagnoses, proposed treatment options, and estimated costs. The finalized report is saved as a PDF file, which can be shared directly with the patient to support discussion and record keeping. An active internet connection is required in order to use the application.

Product Name	Medit AuraVue
Model Name	MA-AAV
Version	2.0.2
UDI DI	(01)8800026700890
UDI PI	(10)2.0.2
Basic UDI- DI	88000267MA-AAV8W

Note

Basic Subscription Plan: Overjet is integrated into Medit AuraVue and does not require separate installation or configuration.

Pro Subscription Plan: Overjet must be installed and set up separately, with guidance and support provided by the Overjet team. Contact vendor-support@overjet.ai for details.

Intended Use

Medit AuraVue is a software application intended to support patient consultation and clinical communication by displaying dental imaging data (intraoral scan data and panoramic image data) and diagnostic results processed by third-party AI software, and generating reports. Medit AuraVue is intended for viewing and communication purposes only and does not provide independent diagnostic analysis or treatment recommendations.

Indications for Use

Medit AuraVue is intended for use by dental professionals to visualize and review intraoral scan data and panoramic image data for patient consultation and clinical communication. The device displays diagnostic findings processed by third-party AI software and generates summary reports of displayed findings. The device is intended for use with adult patients (22 years of age or older). Medit AuraVue provides adjunctive decision support only and does not perform AI processing, generate autonomous diagnoses, or issue treatment recommendations.

Contraindications

Not applicable. This software is not used for medical diagnosis, treatment, or disease prevention.

Intended User Profile

Dental professionals such as dentists.

Intended Patient Population

Medit AuraVue is intended for use with general dental patients who require dental consultation and clinical communication. The device is specifically indicated for adult patients (22 years of age or older) whose dental imaging data (intraoral scans and panoramic images) are available for review.

Disclaimer

Medit AuraVue was not developed for medical or clinical use. As such, it cannot be used for the following purposes:

- diagnosing, treating, mitigating, or preventing diseases/injuries/disorders.

- inspecting, replacing, or transforming a structure or function.

The software is meant to be used as a visual aid during patient consultations or as a tool for analysis tasks. The generated simulation and analysis results should not be used as the sole source of healthcare guidance.

Medit does not take responsibility for any miscommunication or improper use of the software and is not liable to either the user or the patient for any decisions or actions taken in reliance on the information given by the software.

The user assumes full responsibility for the following:

- generated results and their further interpretation and communication to the patient
- informing the patients that the results produced by the software may not be precise or reliable
- actions and treatment decisions based on the generated results

The final report file is intended for reference purposes only and does not constitute a medical history. For a comprehensive diagnosis and treatment plan, please refer to the official medical records.

Patient Safety Advisory

Medit AuraVue is designed to support clinical communication; however, a qualified dental professional must make the final clinical decision. The dental professional is responsible for overseeing the visualized outputs and ensuring that all information is consistent with the patient's actual condition before proceeding with consultation or treatment.

Security Risk Management and Error Handling

After the issue has been improved, if it is necessary to update the program, such as releasing a new installation file or applying some patch files, it is officially distributed through the head office sales/SE personnel, along with the application guide, to the person in charge of the corporation or the issue site.

Responses to security issues may be further announced on the website if necessary.

During the issue handling and recovery process, temporary operational restrictions may occur to ensure system stability and data integrity:

- Patient data may be temporarily inaccessible until the recovery process is completed.
- Clinical workflows may be interrupted; normal operations will resume once administrative actions have been completed. Patient data will not be automatically deleted during this process.
- A warning message will be displayed, and additional data entry will be restricted until the issue is resolved.
- User sessions may be automatically logged out to prevent unauthorized access.

Security Response Procedure

1. Reporting security issues
2. Share initial analysis results and progress
3. Issue delivery
4. Issue response plan / delivery
5. Issue response plan / share results

System Requirements

Hardware Requirements

	Windows	macOS
CPU	Intel Core i5 2.6 GHz or higher	8-core or higher
Chip	-	M1/M2 or higher
RAM	16 GB or higher	16 GB or higher
Graphics Card	NVIDIA GeForce GTX 1060(2 GB) or higher	-

Software Requirements

	Windows	macOS
OS	Windows 10 64-bit, Windows 11 64-bit	Sonoma 14 or later

Browser Support

- Google Chrome
- Microsoft Edge
- Safari

Network Requirements

1. Network Type: wired LAN or Wi-Fi (WPA2 or higher)
2. Bandwidth: minimum 100 Mbps (1Gbps recommended)
3. Protocol: IPv4
4. Port: TCP 443

5. Latency: average below 50ms

Security Requirements

1. Authentication: Password must be 8-16 characters long, including a combination of at least three of the following: letters, numbers, and special characters. Passwords are accepted in English only.
2. Encryption: TLS 1.2 or higher, HTTPS transmission
3. Antivirus & Patches: keep the operating system and antivirus up to date

This software continuously monitors for security events such as unauthorized access, tampering attempts, and data integrity errors.

Unauthorized Access Prevention:

Only individuals who have been granted Admin account privileges in Medit Link can access patient information and internal servers. During the registration process, each user is assigned account permissions to manage and prevent unauthorized access.

Cybersecurity Information

Medit AuraVue does not access any patient PII/PHI from Medit Link. In this system, the communication and API exchanges use scan data files identified only by the patient's Case ID rather than any PII/PHI.

Preparations and Handling Before/During Device Use

- Product installation procedure: managed via the Cloud
- Mandatory user validation when creating Medit Link Account:
    - Create a user account in Medit Link
    - Send a user validation email
    - User confirms the validation
    - User logs in
- Troubleshooting guide: https://support.medit.com/hc/en-us

Required Facilities, Training, and User Qualifications

- Local network administrators/operators must have IT expertise (network, server, OS security configuration).
- Cloud services are managed on AWS by Medit administrators (AWS certified).

Information to Verify Proper Installation and Safe Operation

- AuraVue Updates

    - As a web-based application, the latest version is provided automatically without the need for manual updates in App Box.
- Cloud Services: Managed and monitored through AWS Trusted Advisor with regular updates to apply required security measures.
- Data and Settings Backup/Restore
    - Data generated in AuraVue is uploaded to the Cloud and managed via Medit Link.
    - Backups/restores can be performed by downloading data as needed.
    - User logs are retained for 3 months and can be manually deleted.
    - Stored data can be deleted from the Case Box in Medit Link, and the responsibility for such deletion rests with the user who performs it.
    - Cases can be transferred using the Case Converting Tool in the Settings menu of Medit Link.
    - When a user account is deleted, all user data (e.g., personal information, usage logs such as log-in and feature usage) and database data are permanently removed and cannot be restored.
- Integrity and Verification of Software Security Patches
    - The executable file of AuraVue is automatically digitally signed during installation and verification, so users do not need to take any additional action.

IT Network Precautions

Guidelines

Execution of the health software on an IT-network could result in previously unidentified risks to patients, users or third parties. The responsible organization is advised to identify, analyze, evaluate and control these risks.

Hazard Situations

- Always ensure that your system is protected by the latest version of antivirus software and an active firewall.
- Connecting the network to any device other than Medit AuraVue may result in potential virus infections or data tampering. Verify that the network is operating under appropriate administrative control before proceeding.
- Even if automatic backup is configured, no backup will be performed if the software is not running or if the designated backup location is unavailable.

Subsequent changes to the IT network could introduce new risks and may require additional analysis. Such changes include:

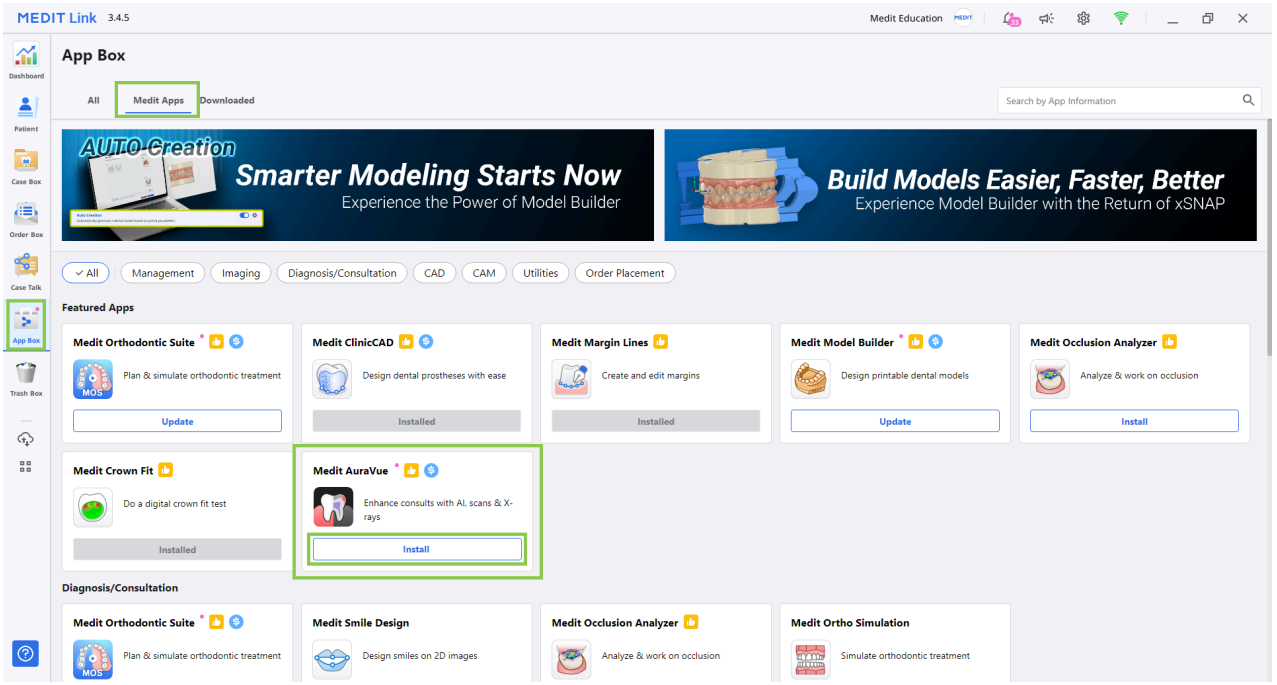
1. Modifications to the IT network configuration.
2. Adding items (hardware, software platforms, or software applications) to the IT network.
3. Removing items from the IT network.

4. Updating software applications on the IT network.
5. Upgrading software platforms or software applications on the IT network.

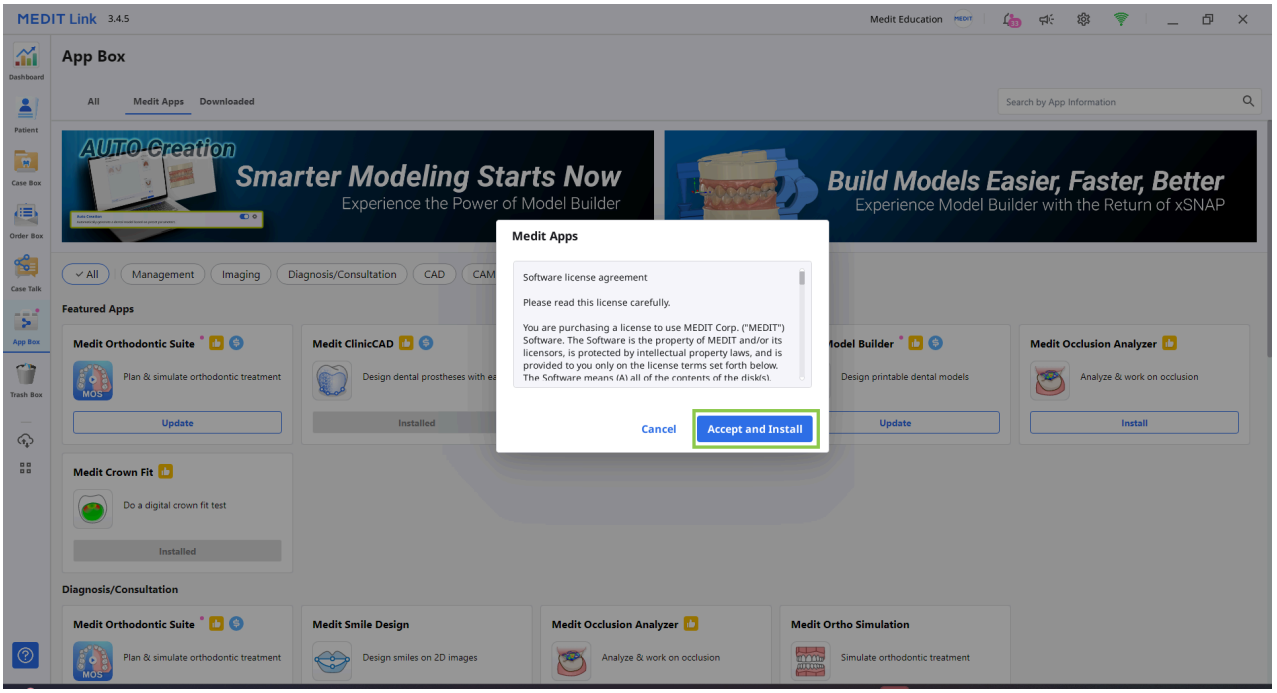
In the event of a cybersecurity incident, if the cybersecurity detection software identifies a threat, the user must report it to the manufacturer and to the competent authority of the Member State.

Installation Guide

1. Log in to your Medit Link account and go to the App Box on the left-hand menu.
2. In the Medit Apps tab, find the Medit AuraVue app and click "Install."



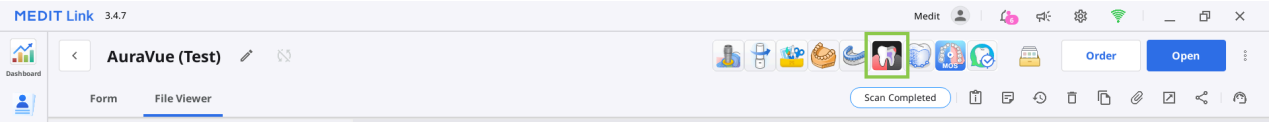
3. Read the Software License Agreement and confirm app installation by clicking "Accept and Install."



4. The app will be downloaded and installed automatically. It may take several minutes to finish the installation process.

> **⚠ Caution**
>
> Do not turn off the PC or close Medit Link during the installation process.

5. Once the app is installed, you can run it from any case in Medit Link by clicking the app icon in the top right corner of the Case Details window.



6. To uninstall an app, go to the App Box and click the app card to open its details page, where you'll find the Uninstall option.

> **Note**
>
> For Pro Plan subscribers, contact the Overjet team at vendor-support@overjet.ai for details on installation.

Data Management

Preparing Data

There are two types of data user needs to prepare for the application: 3D scan data and radiographs (X-rays).

3D Scan Data

Only scan data acquired using Medit's scanning software can be used in the app; only the .meditMesh file format is supported. The program will automatically import the data available in the case and convert it into a web-compatible format (.celeb). Before launching the application, the user must ensure the scan data is available under the "Maxilla" and "Mandible" tabs in the Data Tree.



Note

It is not possible to use cases with pre-attached data or to import data after the program has been launched.

Radiographs (X-rays)

The app supports only the JPG and JPEG file formats. X-ray import methods and analysis limits vary depending on the subscription plan.

Basic Plan	Pro Plan
• Import X-rays from a local folder after launching the application. • Analysis is limited to a maximum of 50 radiographs per month per Medit Link account.	• Import X-rays from a local folder or directly from your Overjet account. • No limit on the number of images that can be analyzed. • Automatic patient matching is available when the same patient exists in both systems.



Caution

Only radiographs of patients aged 22 and older are supported.

3D Data Control

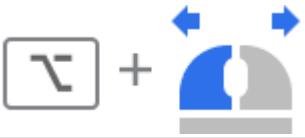
Users can control the 3D data using a mouse alone or both the mouse and keyboard.

3D data control using a mouse (based on Windows)

> **Note**
> The use may differ depending on the settings of your browser.

Zoom	Scroll the mouse wheel.	
Zoom Focus	Double-click on the data.	
Zoom Fit	Double-click on the background.	
Rotate	Right-click and drag.	
Pan	Hold both buttons (or wheel) and drag.	

3D data control using a mouse and keyboard

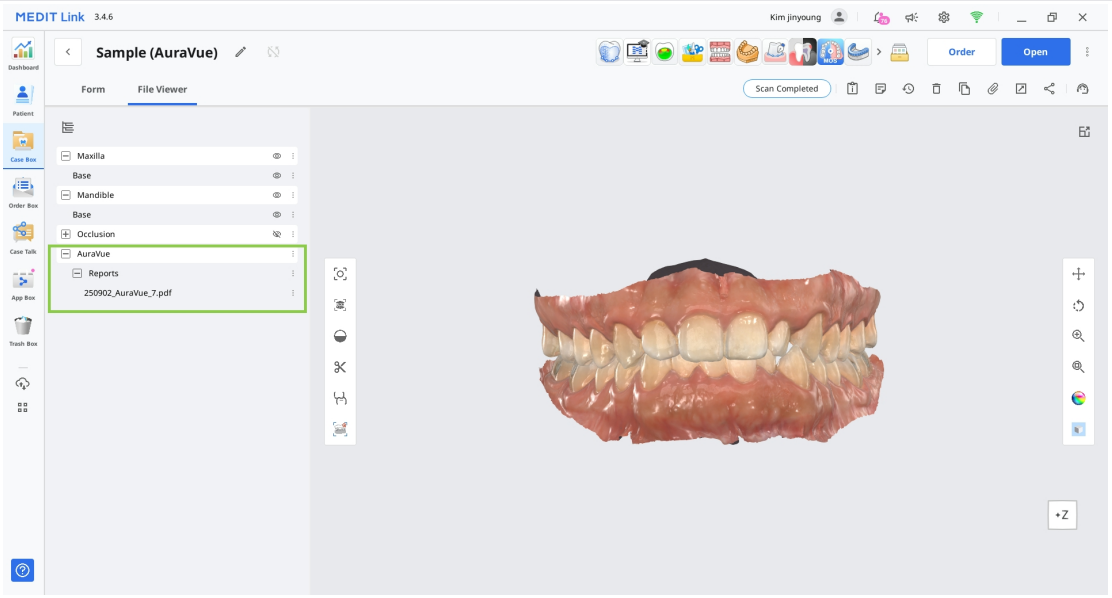
	Windows	macOS
Zoom		
Rotate		
Pan		

Saving Finalized Reports

Once a report is finalized, it is automatically converted to a PDF and saved to the corresponding case. Please note that finalized reports are not editable.

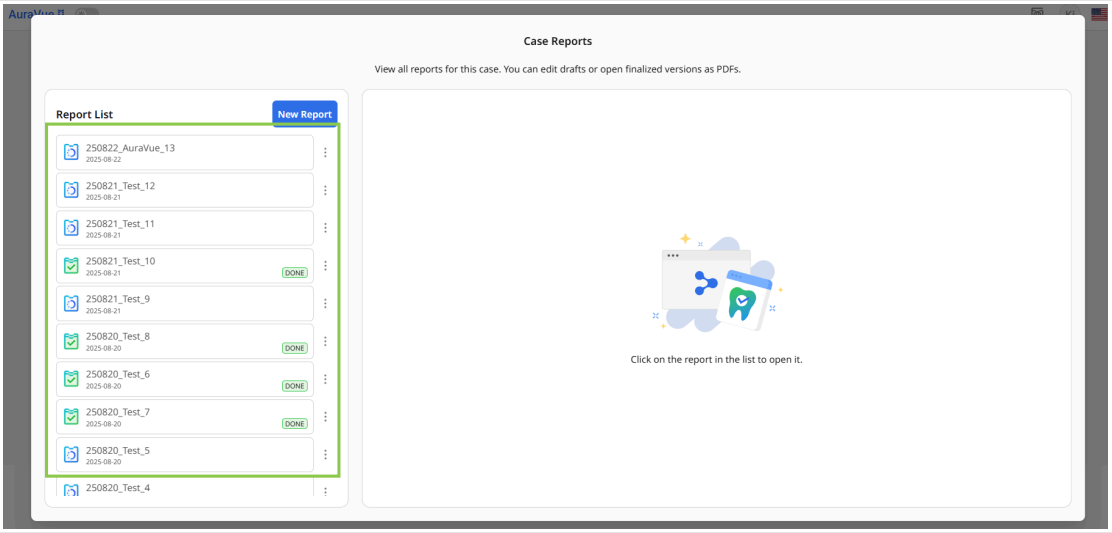
Finalized reports can be accessed and managed either through their corresponding Medit Link cases or by launching the app from the associated case. Draft reports, however, are only available within the program and cannot be accessed externally.

in Medit Link case



*You may need to refresh the Case Detail page to see the newly created reports.

within App

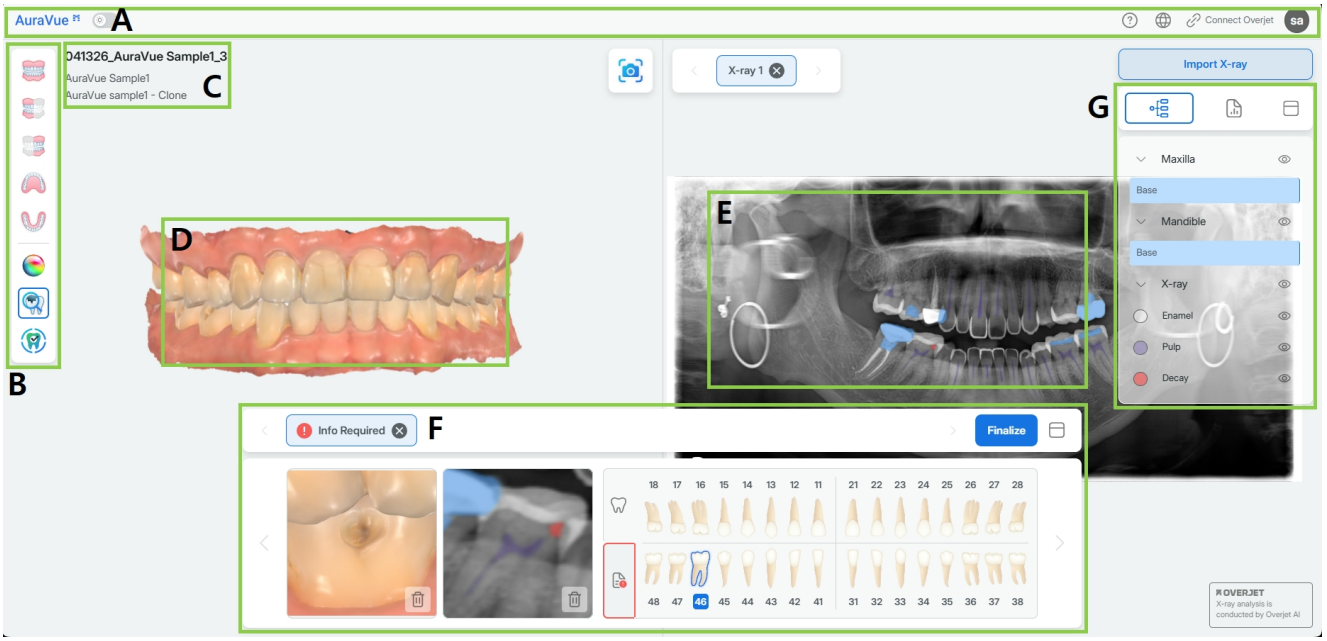


⚠ Caution

The final report is intended for reference purposes only and does not constitute a medical history. For a comprehensive diagnosis and treatment plan, please refer to the official medical records.

User Interface

User Interface at a Glance (based on Windows)



A	Header Bar
B	Toolbox
C	Case Information
D	3D Data
E	X-ray
F	Report Panel
G	Side Panel

Note

The user interface may slightly differ depending on your device (e.g., iPad).

Header Bar

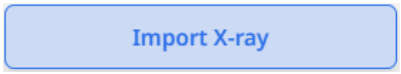
The Header Bar is located at the top of the page interface. It displays the name of the application and provides quick access to basic program controls.

Light/Dark Mode	A toggle that allows the user to switch between light and dark themes for the application interface.
Menu	The menu button provides access to the User Guide and other related resources.
Language Settings	Allows the user to change the display language of the application interface. By default, the language settings from Medit Link are applied.
Connection Status with Overjet	Shows the connection status of the Overjet account. If the account is not connected, an option to connect it is provided.
Account Icon	Provides identification of the logged-in account.

Toolbox

The Toolbox is located in the top left corner of the screen and provides two types of tools: one for controlling the scan data and another to support the report creation process.

	Front	See the front side of the data.
	Left Lateral	Show the left lateral side of the data.
	Right Lateral	Show the right lateral side of the data.
	Occlusal Surface (Maxilla)	Show the maxillary occlusal surface.
	Occlusal Surface (Mandible)	Show the mandibular occlusal surface.
	Data Display Mode	Switch the data display mode among “Glossy,“ “Matte,“ and “Monochrome.”

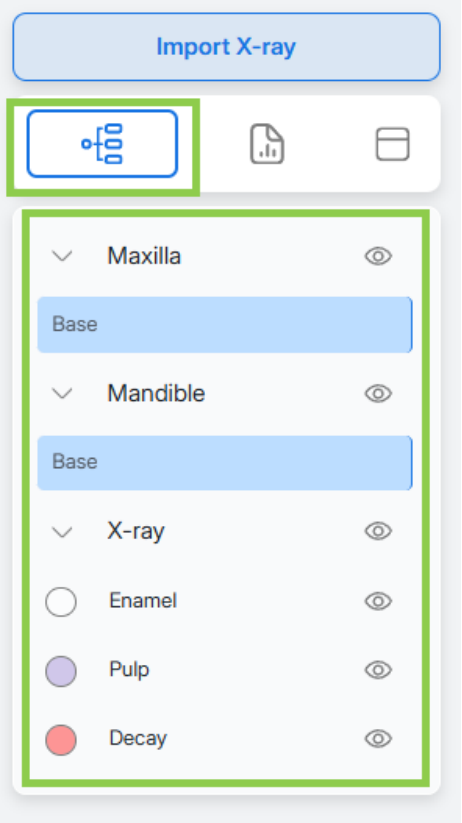
	Show Visual Cues	Show or hide markings on areas recommended for detailed review.
	Show Reported Areas	Locate all areas added to the report on the scan data.
	Capture	Take a screenshot of the area you want to include in the report.
	Import X-ray	Import radiographs from a local folder. *Pro Plan users can import directly from Overjet.

Side Panel

The Side Panel, located on the right side of the screen, provides access to the Data Tree and Report List. Each tab allows users to efficiently manage available case data and generated reports. You can collapse the panel, if needed, by clicking the icon to the left of the Data Tree tab.

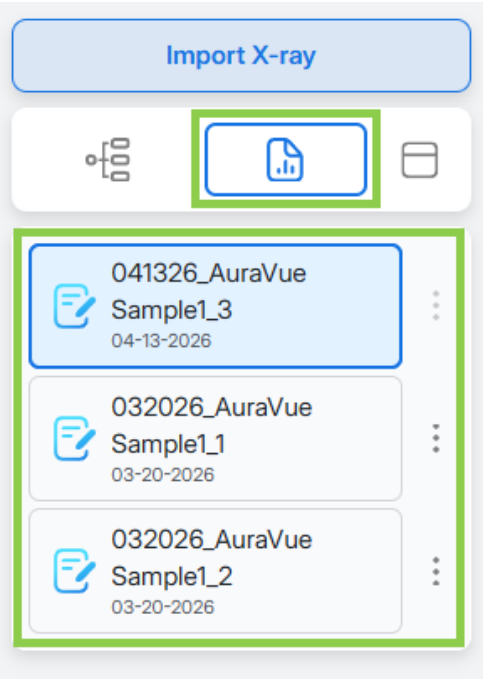
Data Tree

In this tab, users can control visibility of the scan data and X-ray analysis data: click and drag the blue line to adjust transparency, or click the eye icon to show or hide data.



Report List

In this tab, users can preview all reports associated with the currently open case. Drafts are marked in blue, while finalized reports are marked in green with a 'DONE' label. Click the three dots next to a report to delete it.



Report Panel

The panel at the bottom of the screen shows a list of all the pathologies identified by the user. Each entry includes the associated scan data, X-ray image, and an information form completed by the doctor with the suspected diagnosis, proposed treatment, and a memo. The panel can be collapsed by clicking the icon to the right of the “Finalize” button.

Incomplete report entries are marked with a red exclamation mark, and users cannot finalize the report until all entries are completed.



Workflow

Overview of Case Reports

After running the application from Medit Link, the user is presented with an overview window of all reports associated with the current case, both finalized (or DONE) and not.

> **Note**
>
> It may take a few minutes for the program to load, as the scan data is being converted into a web-compatible format.

The report names in the list are automatically generated based on their creation date, case name, and a consecutive number. You can preview and manage your case reports from this window.

- To delete a report: Click the menu button next to the report in the list.
- To preview a report: Select it from the list. The content of a draft report will appear on the right side. You can continue editing it by clicking the “Edit” button.
  If the report has been finalized, it will open as a completed PDF file, which you can share with the patient or print. Finalized reports are not editable.
- To create a new report: Click the “New Report” button.

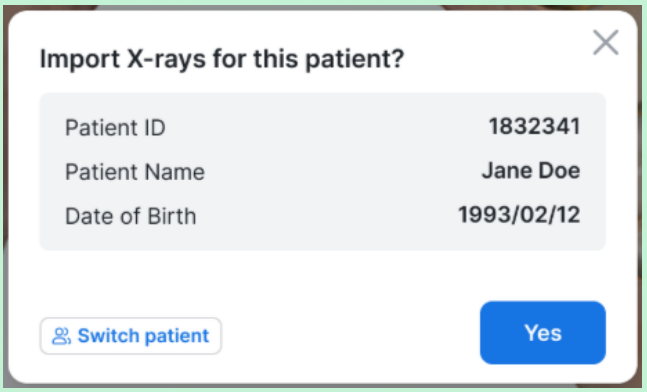
Creating or Editing Reports

1. When starting a new report, the scan data from the Medit Link case is automatically converted into a web-compatible format and imported into the app. However, X-ray images must be imported manually after opening the program. You can either drag and drop them into the browser or use the Import X-ray tool above the Side Panel on the right.

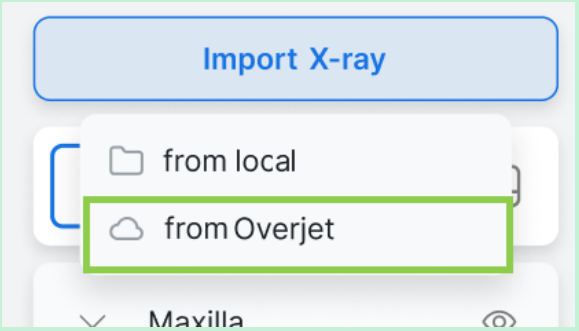
   > **Note**
   >
   > You can upload up to 20 images in JPG or JPEG format.

   > **Pro Plan Note**
   >
   > Pro Plan users who are already connected to their Overjet account get automatic patient matching when creating a new report. If a patient match is found, a window suggesting automatic

X-ray import will appear.



Alternatively, users can click “Import X-ray” and select “from Overjet” to manually search for a patient’s X-rays.

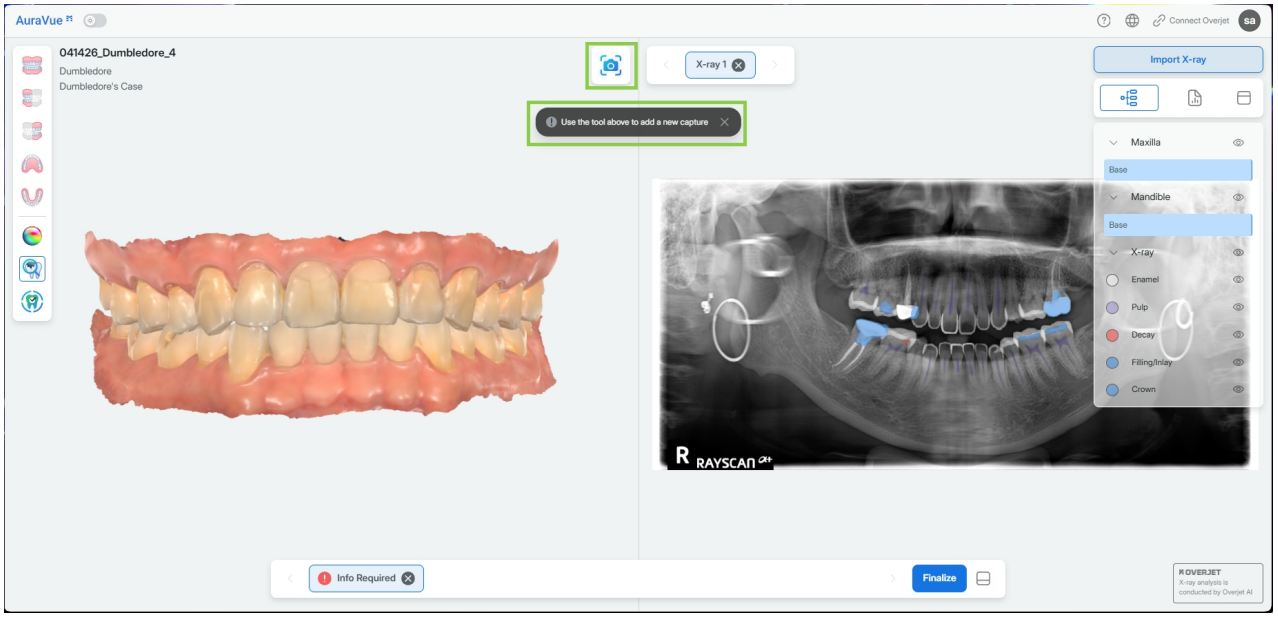


Note: Connecting Existing Overjet Account

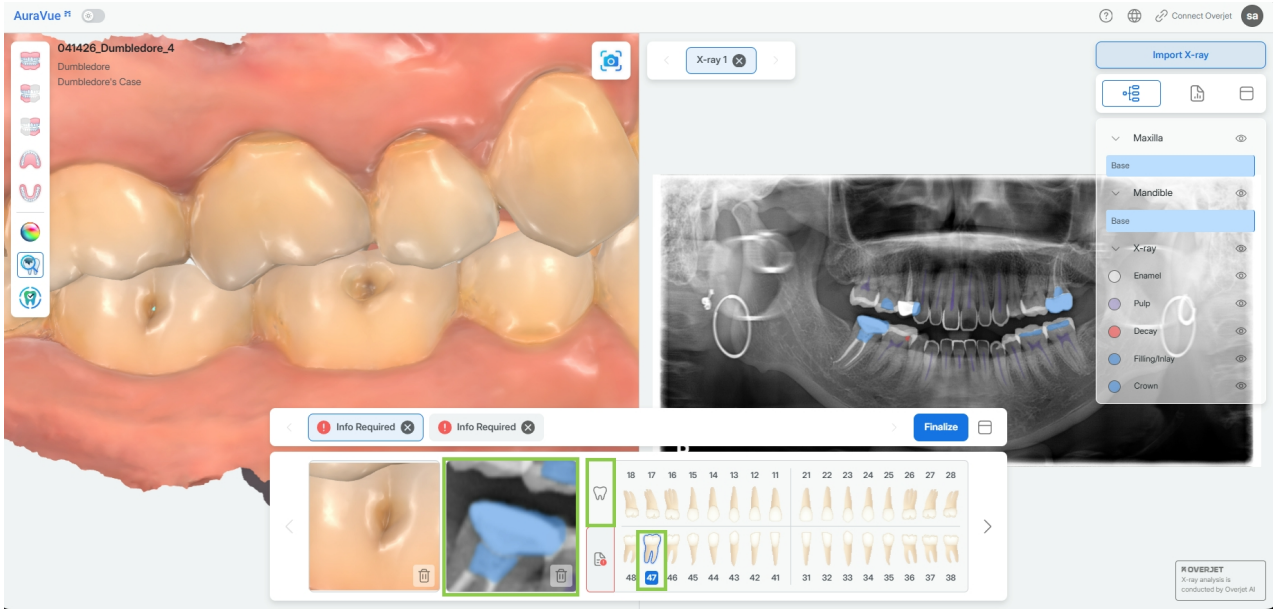
Connecting an existing Overjet account requires prior activation. Contact the Overjet Support team at **vendor-support@overjet.ai** to enable the Medit Link integration. After confirmation, click “Connect Overjet” in the title bar and enter your Clinic ID and Organization ID.

2. Once the X-rays are imported, they are automatically analyzed by the integrated Overjet AI. When the analysis is complete, the findings will be shown on the X-ray images and also listed in the Data Tree.

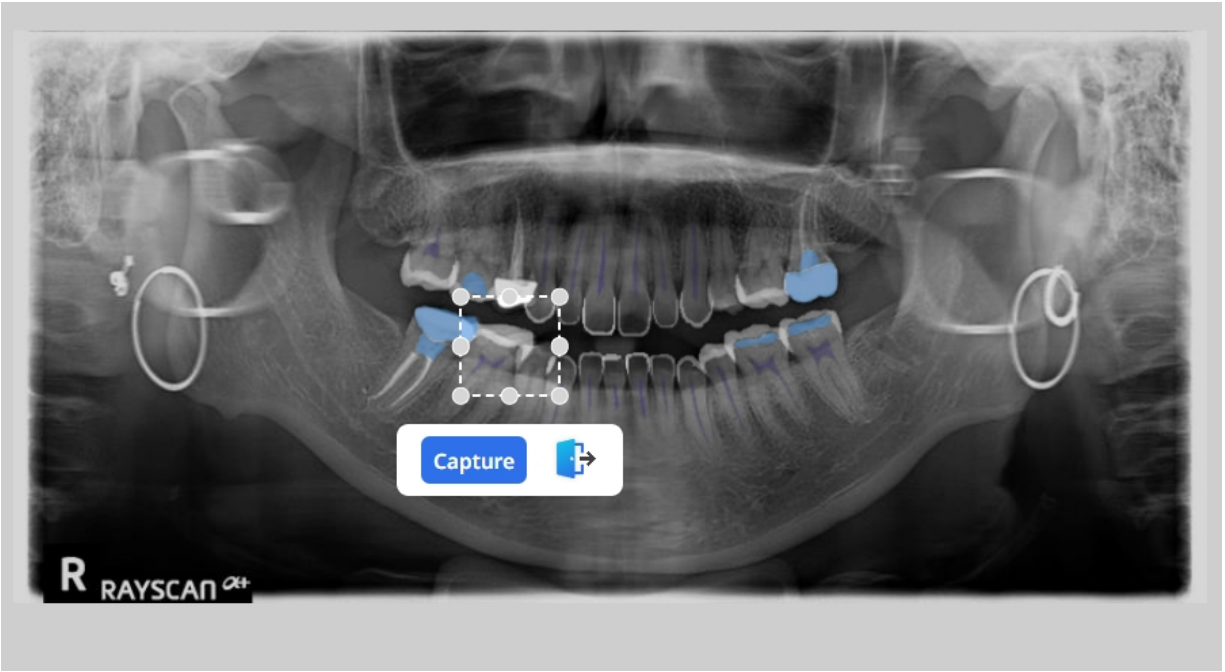
3. To manually add captures to the report, review the scan data for pathologies and use the Capture tool to add a visual of the target area to the Report Panel.



4. Then select the corresponding tooth number on the right side of the Report Panel, and the program will automatically locate the matching view from the imported X-rays.



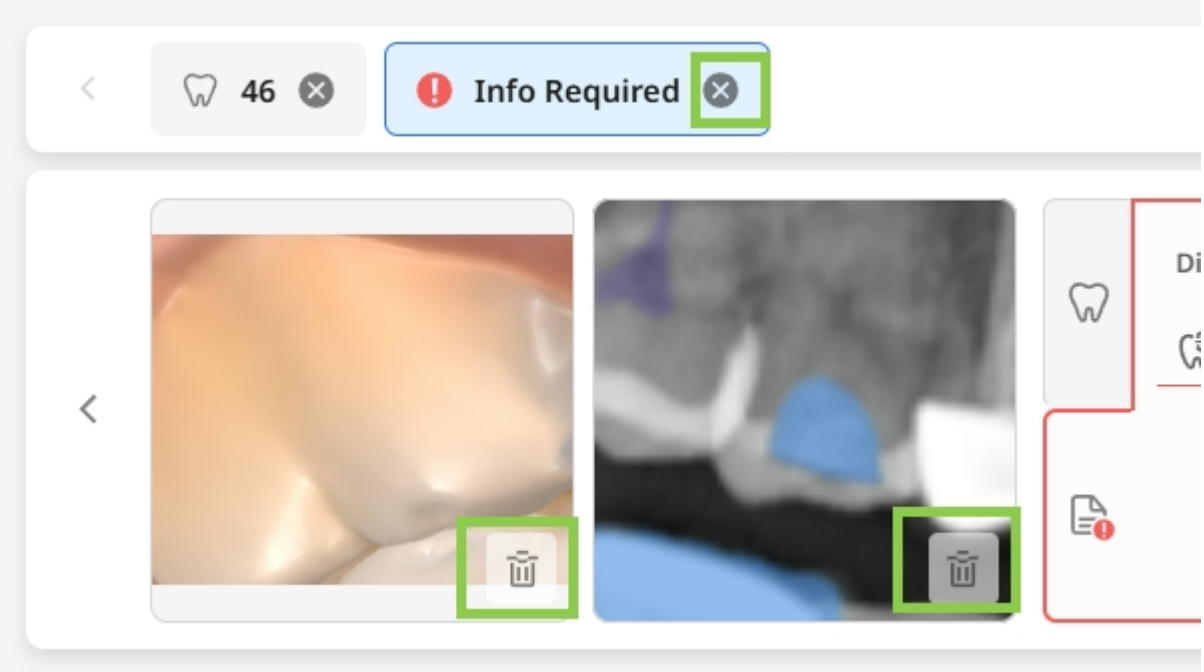
- If automatic matching is unsuccessful, click the window where the X-ray image should appear, and then manually select the correct area on the X-ray.



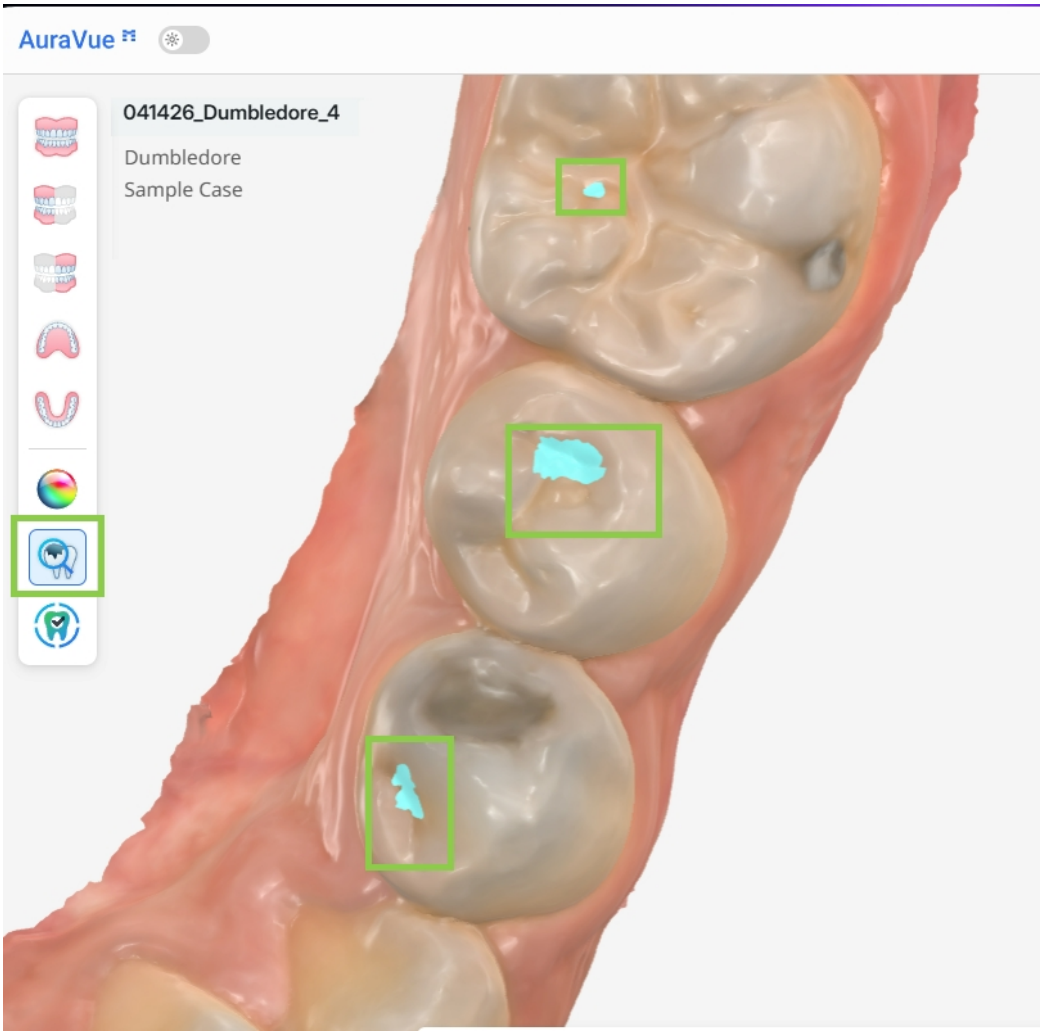
5. In the Form tab of the Report Panel, complete the required fields for diagnosis and treatment, and add a memo if necessary. If you select Other for either diagnosis or treatment, you can enter a custom entry. Check for any items marked with a red attention icon to ensure all required information is completed before finalizing the report.



6. Any captures in the Report Panel can be manually redone if deleted, or you can delete the entire report entry.



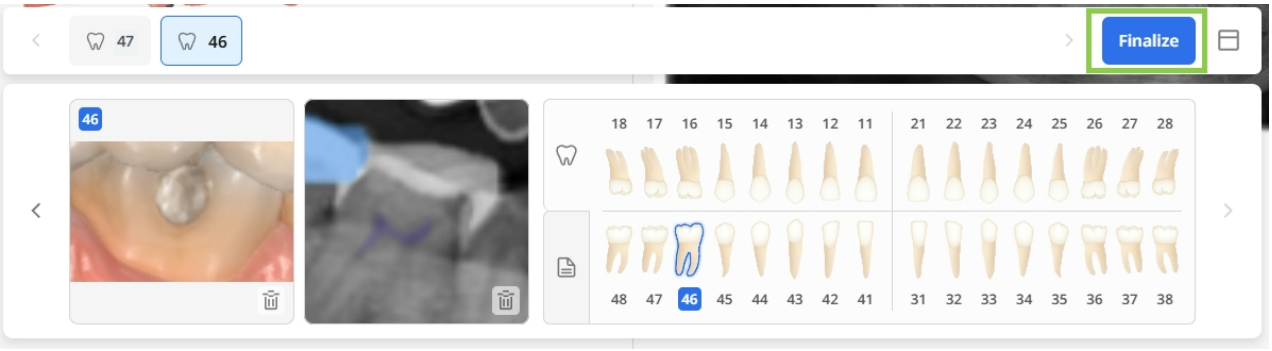
7. Use the “Show Visual Cues” button to highlight areas (mark them in blue) of the scan data that may need closer review.



8. To review which parts of the scan data are included in the report, use the Show Reported Areas button. It visually highlights all reported areas on the scan, making it easier to perform a final check

before finalizing the report.

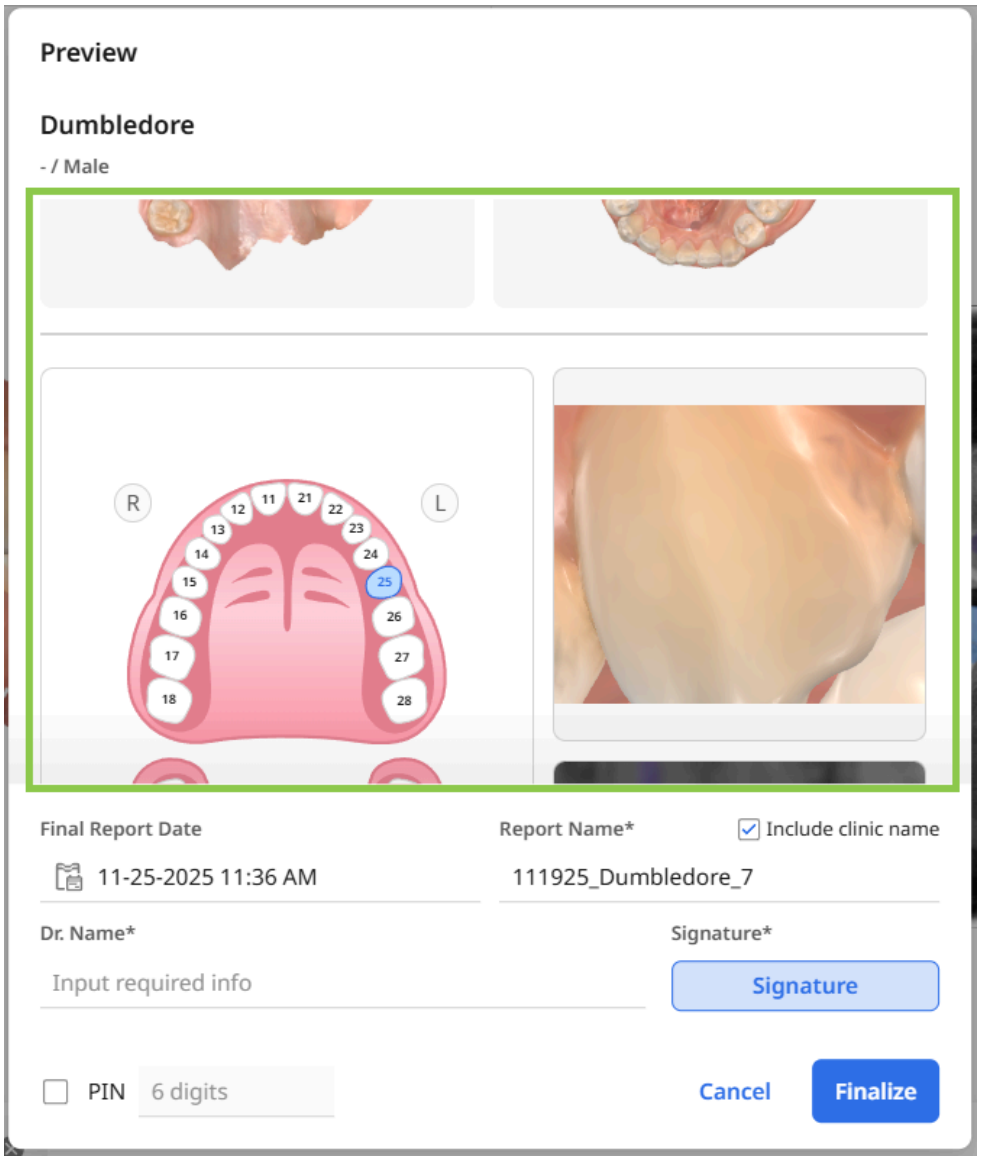
9. When all information for all the entries in the Report Panel is organized, click “Finalize.”



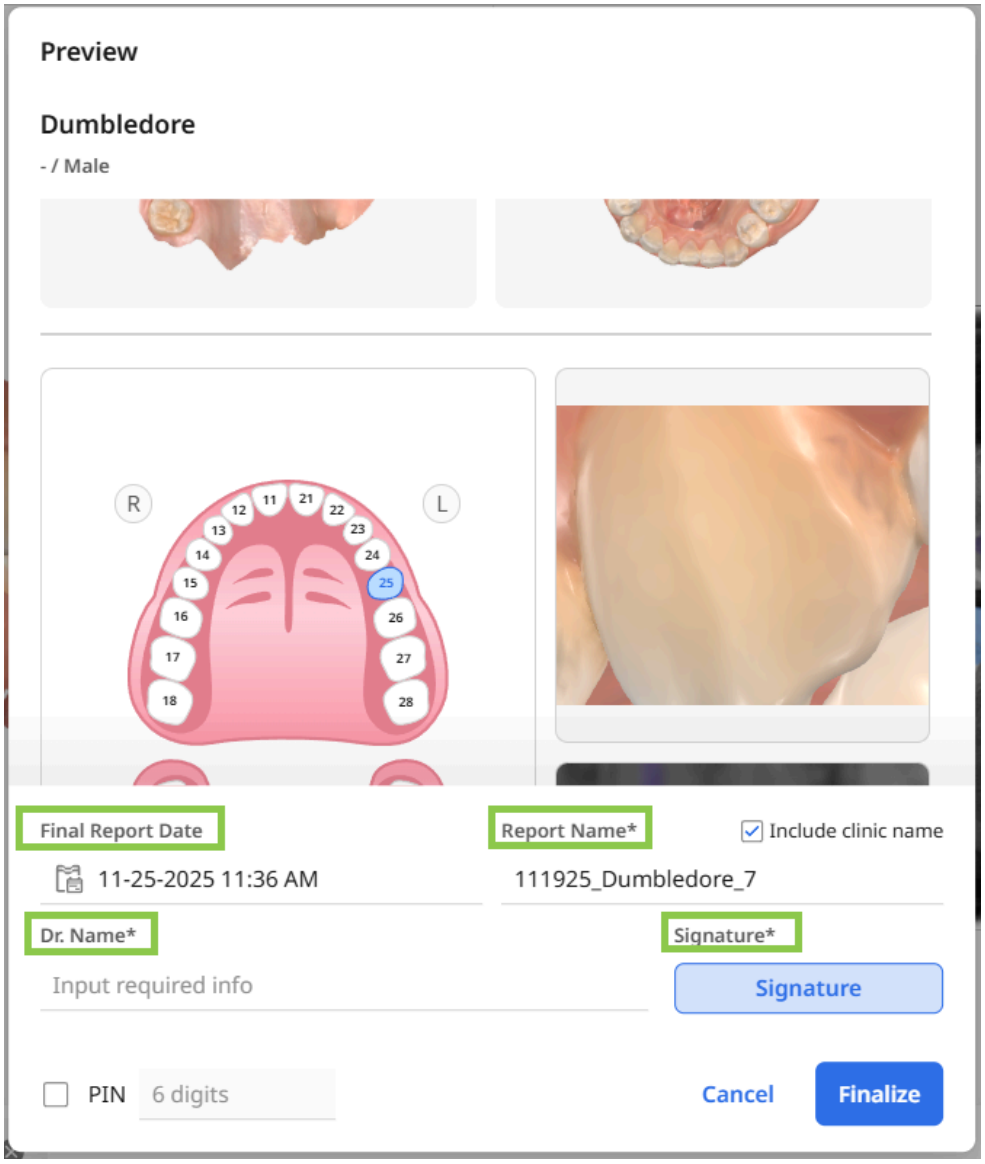
Finalizing Reports

Once the “Finalize” button is clicked, a preview window appears, allowing the user to verify the report content and finalize its creation before sharing or exporting it.

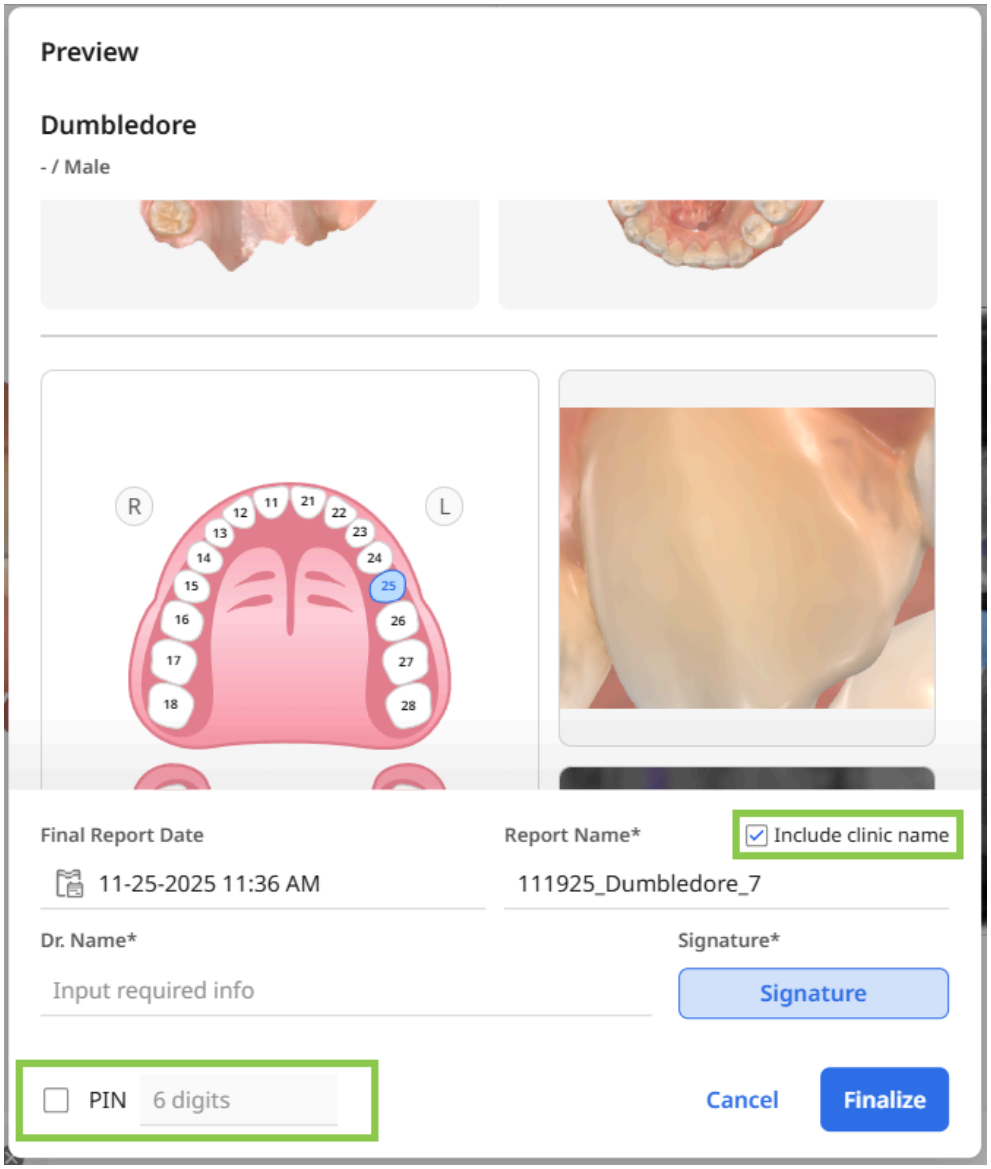
1. Scroll over the imaging to check the report content.



2. Provide all mandatory details for the report, including the report name, date, doctor's name, and signature. The system generates a default report name, but you may modify it.



3. Optionally, you may secure the report with a PIN, which the patient must enter to view its contents. The clinic name is automatically included in the finalized report.



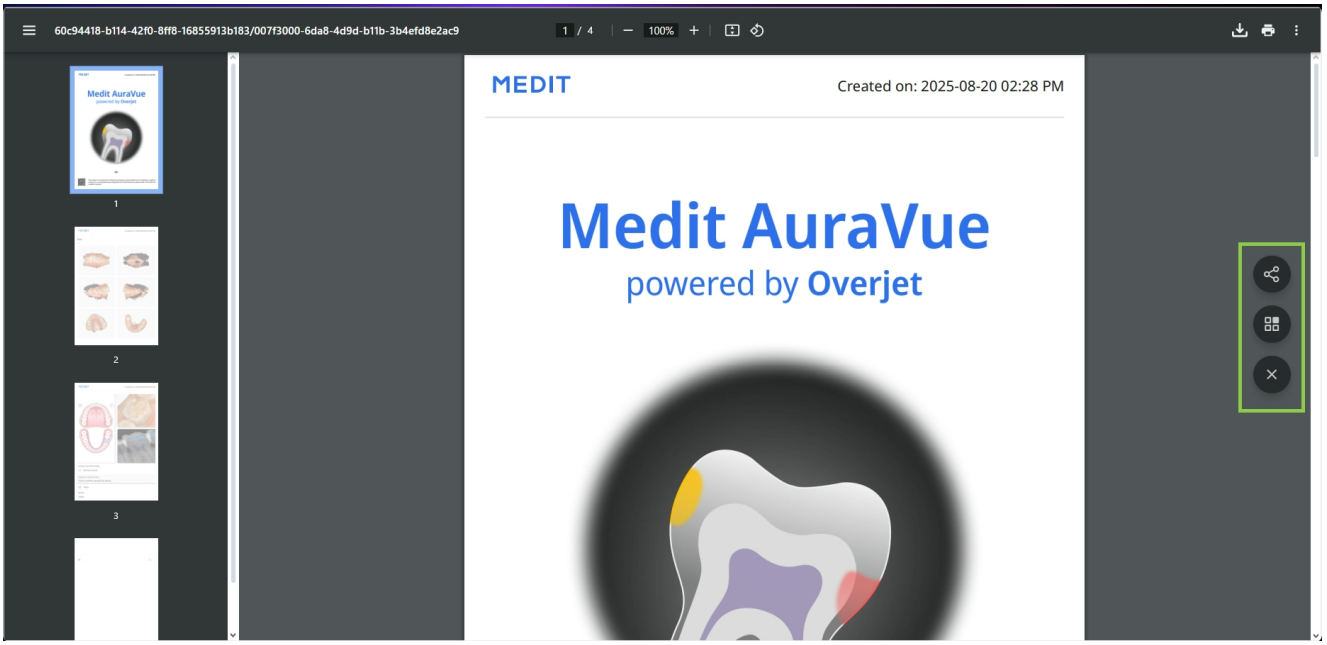
4. When all sections are ready, confirm finalizing the report by clicking “Finalize.“

> **Caution**
>
> The final PDF may take several minutes to generate. Make sure to keep the webpage open until the file has been successfully created.

Sharing Finalized Reports

The finalized report will open automatically as a PDF in your browser. You can share it with the patient using a QR code or email. Once you're done, feel free to close the browser or application tab— the PDF is automatically saved to the case.

> ⚠ **Caution**
>
> The final report is intended for reference purposes only and does not constitute a medical history. For a comprehensive diagnosis and treatment plan, please refer to the official medical records.


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