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Segmentron Viewer AI

User Manual

Version 1.0

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1. USER MANUAL INFORMATION

This user manual (Instructions for Use) describes the Segmentron Viewer AI Software and provides training to users (dentists and radiologists) on its use. The user manual is solely for the purpose of explaining the use of Segmentron Viewer AI. This document cannot be printed or reproduced without the permission of the copyright holder.

This User Manual is written in English.

Users are advised to read this manual carefully before starting use of Segmentron Viewer AI.

Note: This Instructions for Use is intended to assist users in the proper use of the medical device software described herein. This manual does not describe the use of the IT equipment on which the Segmentron Viewer AI software is installed. Refer to the documentation of the IT equipment concerned.

Note: This User Manual is supplied in an electronic format. To receive a paper copy of this manual, please send an email to support@diagnocat.com. Our team will be happy to provide you with a paper copy of the manual via the postal service at no additional cost, within 7 days from requesting.

For inquiries or concerns related to the product and this manual, please contact:

Phone: + 1 519 619 4212
E-mail: support@diagnocat.com

The company's website at www.diagnocat.com also has additional information.

2. ACCESSING THIS USER MANUAL

The current version of this User Manual can be accessed directly from the Diagnocat platform (on which Segmentron Viewer AI is run), by clicking on the icon "About" at the bottom of the page, then choosing the option from the drop-down menu.

3. SYMBOLS USED IN THE MANUAL / LABELING

	Manufacturer
	Follow instructions for use
	Caution (WARNING, PRECAUTION, or Note)
	Medical device

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4. DEVICE INFORMATION

Name: Segmentron Viewer AI
Version: 1.0
Device UDI: 860010268056

5. REGULATORY REQUIREMENTS

Segmentron Viewer AI complies with ISO 13485:2016 *Medical devices — Quality management systems – Requirements for regulatory purposes*. This Software as a Medical device (SaMD) complies with relevant international and national standards and laws. Information on compliance will be supplied upon request to the manufacturer.

This medical product software must be installed on appropriate IT equipment that complies with relevant international and national laws and standards on EMC (Electromagnetic Compatibility) and Electrical Safety. Such laws and standards define both the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

6. CAUTIONARY NOTES

Before attempting to use Segmentron Viewer AI, you must read this User Manual thoroughly, paying particular attention to all PRECAUTIONS and Notes. You must pay special attention to all the information given, and procedures described, herein. In addition, while using the software, pay special attention to on-screen messages and On-line Help information containing PRECAUTIONS and Notes that may be related to the function being executed.

Additional information:

- Some features of the product may not be available in all countries, languages and currencies.
- It is illegal to reproduce and distribute the product without the consent of Segmentron.
- Users should read this manual thoroughly before using this product.
- In order to use the full functions of Segmentron Viewer AI, please follow the specifications described in this manual.
- Backup is the responsibility of the user and it should never be assumed that any backup is taking place unless it is actively monitored by the user.
- It is strongly recommended not to download or transmit any messages or content that may disregard or violate the rights of any party.

Additionally, users are highly encouraged to ensure that the Software is used in compliance with all applicable local, state, national, and international laws.

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7. PRODUCT DESCRIPTION

Segmentron Viewer is a semi-automated software as a medical device (SaMD) for dental image processing and management. The device provides image management and processing functions for enhancement, segmentation, 3D visualization and superimposition (CBCT and intraoral scans in STL format) of maxillofacial Cone-Beam Computed Tomography (CBCT) images. It additionally provides patient management capabilities for the clinician's ease of use.

Segmentron Viewer is a web application that is designed for cloud-based processing and visualization of digital dental images using artificial intelligence (AI). The device automates activities of dental organizations, including uploading, saving, sharing, viewing, and documenting CBCT images. It processes files of any area of the patient's maxillofacial region. The device's main function is to perform automated analysis of CBCT images uploaded by the user, which consists of applying artificial neural network models to such images to obtain automatically generated 3D segmentations of teeth and anatomy. Additionally, the device detects and localizes dental conditions and provides measurements of periodontal bone loss (PBL).

The main screen of Segmentron Viewer (Segmentation report and Superimposition report) after a CBCT scan has been uploaded and a report has been generated. Specifically, the display includes:

a. Objects: Teeth, Anatomy, Upper and Lower jaw:

Using the Objects panel, the HCP can open the list of all segmented anatomic objects presented in a tree structure to change object visibility, color, and opacity.

b. Toolbar :

Toolbar that allows healthcare professionals (HCPs) to use a ruler (measurement), select viewing layouts, and adjust brightness or contrast on the display.

c. 3D Scene, MPR (Image Visualization):

The software allows users to upload previously acquired CBCT studies and view models on the 3D scene and multiplanar reformatted (MPR) planes (navigates through the images for evaluation).

d. Upload button , Export button:

HCPs can upload custom 3D objects, such as pre-segmented models, directly into the scene. Additionally, they can export anatomical and artificial objects displayed in the Objects panel.

i. Tooth and Pulp Detection and Segmentation

Segmentron Viewer employs image processing to identify each tooth (including all present teeth of the upper and the lower jaw , as well as pulp of the upper and lower jaw in a CBCT scan, numbers them, and segments them. The segmentation algorithm is employed to achieve tooth segmentation to enable tooth numeration and identification. Segmentron Viewer's main screen after a CBCT scan has been uploaded and a report has been generated. The display features the Objects panel (left side), which lists the segmented teeth.

ii. Anatomy Identification and Segmentation

Segmentron Viewer employs image processing to identify each maxillofacial anatomy (including soft tissue) in a CBCT scan, and segments them. The segmentation algorithm is employed to achieve anatomy segmentation in order to enable identification of the corresponding anatomical region.

- Anatomic objects corresponding to the upper jaw: Upper teeth, Upper teeth pulp, Maxilla, Airways, Upper gingiva, Sinuses, Cranial, Incisive canal.
- Anatomic objects corresponding to the lower jaw: Lower teeth, Lower teeth p ulp, Mandible, Mandibular Canal.

iii. Pulp Segmentation

The pulp is the connective tissue, nerves, blood vessels, and odontoblasts that comprise the innermost layer of a tooth. On radiographic images, the dental pulp appears as a radiolucent area located in the center of the tooth's crown and root, surrounded by the more radiopaque dentin structure. The pulp segmentation follows the anatomical contours of the tooth pulp.

iv. Image Visualization

The software enables users to upload previously acquired CBCT scans and facilitates navigation through the images for detailed evaluation. It incorporates an algorithm that enhances visualization by providing a 3D reconstruction of the patient’s teeth and anatomy, allowing users to easily navigate between key structures and identify points of interest. Furthermore, the software generates MPR views of each segmented object.

In the Superimposition Report, teeth are visualized on the 3D scene with enhanced clarity through the overlay of CBCT images onto intraoral scans. This improved visualization supports the clinician in accurately assessing anatomical structures, identifying dental conditions, and planning treatment with greater precision.

v. **Periodontal Bone Loss (PBL) Measurement**

The Segmentron Viewer features AI-powered tools designed for periodontal analysis, enabling precise measurement of periodontal bone loss (PBL). These interactive tools leverage artificial intelligence to automatically detect and calculate bone loss levels, enhancing diagnostic accuracy and clinical efficiency.

vi. Detection and Localization of Dental Conditions

The software utilizes AI-driven algorithms to distinguish between normal anatomical structures and potential areas of concern that may indicate various dental conditions.

Restorative Conditions (Segmented):

- Caries Signs
- Abfraction Lesions
- Root Fragments (whole tooth)

Endodontic Conditions (Segmented):

- Periapical Radiolucency
- Furcation Lesions
- Widened Periodontal Ligament (PDL) Space

Perio

- Impaction (whole tooth)
- Furcation lesion (only shown in hover panel)
- PBL

Users can activate the display of specific condition categories using filter buttons located at the top of the interface. Once enabled, the conditions are visualized as segmentations on the 3D scene and as colored contours on MPR (Multi-Planar Reconstruction) planes, with each condition category represented by a corresponding color for easy identification.

v. Device Output – Superimposition Report

The device generates a superimposition report based on the input CBCT scan and intraoral scans (upper and lower jaw), delivered as an STL file for the healthcare professional (HCP) to further evaluate the patient's teeth and anatomical structures. CBCT images and associated reports are securely stored in the cloud, automatically linked to the patient's chart, and can be shared with other dental professionals as needed.

The superimposition report includes the following components:

- Objects panel with a list of all teeth, anatomy objects, and the Toolbar;
- the 3D scene with segmented 3D model;
- MPR planes where users can see radiological CBCT images in three projections: axial, coronal and sagittal.

vi. Device Output – Segmentation Report

The device generates a segmentation report from the input CBCT scan, in the form of an STL file, for the HCP's use to further evaluate a patient's teeth and anatomy. CBCT images and reports are stored in the cloud, are saved to a patient's chart, and may be shared with other dental professionals. The segmentation report contains three parts:

- Objects panel with a list of all teeth, anatomy objects, and the Toolbar;
- the 3D scene with segmented 3D model;
- MPR planes where users can see radiological CBCT images in three projections: axial, coronal and sagittal.

vii. Additional Non-Device Features (not part of the Medical Device, no AI Involved)

The software also includes non-device functions that support its overall usability and contribute to achieving the intended clinical use:

User Interface: A user-friendly interface allows healthcare professionals to efficiently navigate the platform and manage patient information with ease.

Integration Capabilities: Segmentron Viewer is compatible with a wide range of dental scanning devices, enabling seamless integration and interoperability across various imaging systems.

Cloud-Based Storage: All scans and reports are securely stored in the cloud, ensuring convenient access from multiple devices. Users can view, edit, and share information with other dental professionals, promoting collaborative care.

Data Security and Privacy: Segmentron Viewer AI prioritizes the security of patient data by implementing industry-standard encryption protocols and adhering to relevant healthcare data protection regulations. Robust user authentication and access control mechanisms (e.g., password protection) help safeguard sensitive medical information.

7.1 INTENDED USE/ INDICATION FOR USE

Segmentron Viewer AI is a software product intended for processing and manipulating maxillofacial radiographic images. Segmentron Viewer AI allows users to perform the following functions:

1. Viewing patient images (provides tools for image processing and viewing functions);
2. Reading and 3D visualization of CBCT images
3. Generating and downloading CBCT segmentation STL files (reports).
4. Detects, localize and visually highlight dental conditions.

The device is indicated for use by medical professionals (such as dentists and radiologists), in patients 11 years and older with permanent teeth.

Segmentron Viewer AI is a web application. It can be used in a network environment.

7.2 INTENDED USERS

The device is meant to be used by trained medical professionals such as radiologists and dentists.

7.3 INTENDED PATIENT TARGET GROUP

The device is indicated for use to view images of the teeth and maxillofacial anatomy of patients 14 years and older with permanent teeth.

7.4 INTENDED USE ENVIRONMENT

Segmentron Viewer AI is a web application designed for use in various professional healthcare environments, including but not limited to:

- Dental Clinics and Medical Institutions: facilitates multidisciplinary case assessments, enabling collaboration among various medical specialists.
- Educational and Research Institutions: for training and academic purposes.
- Remote/Telemedicine Settings: for sharing and reviewing radiological data remotely.

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8. PRECAUTIONS AND LIMITATIONS

Segmentron Viewer AI is an adjunct tool and does not replace the role of the clinician. It does not provide any diagnosis.

To ensure precise analysis, all CBCT scans must meet the recommended quality standards outlined in the “Data Constraints” section (Section 14).

Ensure that all uploaded CBCT scans meet the required quality standards for detecting anatomical structures. Dental imaging devices must comply with the recommendations of the International Commission on Radiological Protection (ICRP) to ensure optimal image quality and patient safety.

Segmentron Viewer AI should be used according to this User Manual.

The performance of Segmentron Viewer AI depends on the image quality and accuracy of the CBCT scan(s). Relevant anatomical structures must be visible in the scans. The use of unvalidated or suboptimal inputs may adversely affect device performance, potentially resulting in segmentation inaccuracies or labeling errors.

Users are advised to review the software-generated segmentations, and to make edits as necessary using the manual editing tools provided. It is the end user’s responsibility to ensure that the final visualizations are clinically acceptable.

9. CONTRAINDICATIONS

Segmentron Viewer AI has not been validated for use in the following scenarios, and the device performance may be adversely affected if the following inputs are used:

- CBCT images containing significant motion artifacts.
- CBCT images with severe artifacts, including but not limited to: Streak artifacts, Ring artifacts, Exponential edge-gradient effect (EEG)
- CBCT images affected by improper calibration of the CBCT unit or technical distortion due to machine malfunction.
- Images of patients with maxillofacial trauma, bone lesions, or congenital/acquired anatomical anomalies.
- Images showing total edentulism (no teeth present).
- Images with supernumerary teeth.

10. REQUIRED TRAINING AND QUALIFICATIONS

Users of this medical product software must have carefully reviewed and understood this Instructions for Use. Formal training is not required for the proper use of this medical software. A basic overview of the software’s functionalities is provided by the sales team during the onboarding process. Additionally, upon request, the sales team can arrange on-demand training sessions to further assist clients in understanding and utilizing the software effectively.

11. DEVICE SECURITY AND PRIVACY

11.1. Cybersecurity

Before using Segmentron Viewer AI, you must follow the instructions below. The instructions help to protect the program against cybersecurity threats such as viruses and malware.

- Scan your computer system with anti-virus and anti-spyware programs from a trusted source.
- Install, set up and enable adequate anti-virus software.
- Maintain up-to-date anti-virus software.
- Make sure that your operating system (OS) has the latest security updates applied.
- Activate your PC's firewall if needed.

Coordinated Vulnerability Disclosure
When a vulnerability patch or fix is ready for release, the company will disclose it by releasing an advisory to affected stakeholders. The disclosure information shall be published on the company website. In the event of a critical update, users are directly notified via email or phone. Following is the information disclosed:

- Overview of the identified vulnerability, its nature, potential impact, affected devices and software versions.
- Actions taken to mitigate the vulnerability, including details on software updates, patches, or other remediation measures.
- Risk assessment of vulnerability, outlining the potential risks to patient safety, data integrity, and overall device functionality, if any.

Configuration, Backup and Update Processes
As Segmentron Viewer AI is cloud-based software, integration, configuration, backup, and restore processes shall only be performed by DGNCT LLC, in accordance with internal procedures.

Software Bill of Materials (SBOM), Architecture and Ports
The SBOM, Architectural diagrams and port configuration are available for certain customers at support@diagnocat.com.

End of Life
At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device needs to remain in service following the end of support, the company will communicate through the coordinated vulnerability disclosure the potential cybersecurity risks that can be expected to increase over time in addition to the sanitization process.

11.2. Customer Role in the Product Security Partnership

Security of the Segmentron Viewer AI product is an important part of each healthcare institution's overall security strategy. However, these benefits can only be realized in

combination with a comprehensive, multi-layered strategy that includes policies, procedures and technologies to protect information and systems from external and internal threats.

The customer is responsible for implementing administrative, physical, and technical controls, ensuring compliance with security and industry best practices. Their security strategies should address, but are not limited to:

- Physical security restricts unauthorized access to the servers where Segmentron Viewer AI is running.
- Operational security, for example, access / authorization controls.
- Procedural security, for example, locking unattended workstation, no sharing of access credentials, termination checklists, etc.
- Continuous monitoring of security protection effectiveness.
- Security risk management.
- Security policies, for example, ensuring that client systems are in line with the institution's IT security policies.
- Data Integrity Training.
- Contingency planning.
- Backups and disaster recovery.

The practical implementation of technical security elements varies by the institution and may employ a number of technologies, including firewalls, virus scanning software, authentication technologies, etc. As with any computer-based system, firewalls and other security products must be in place between the medical system and any externally accessible systems or users.

CAUTION: Diagnocat is not responsible for security of institution managed systems (servers, including servers of hosting applications, desktop PCs, laptops) that are used for running Segmentron Viewer AI and access to information managed by the product.

11.3. Regulatory Controls

Protecting Personal Health Information

Many governments require maintaining the confidentiality of patient health information (PHI). Therefore, strict security measures must be taken to guard this protected information. (Users in the USA may find guidelines at http://www.hhs.gov/ocr/hipaa/).

Considering the nature of the Segmentron Viewer AI software, the information processed is highly personal and sensitive and should be protected in accordance with local legislative requirements (HIPAA security and privacy rules for US, or European General Data Protection Regulation for EU).

Segmentron Viewer AI does not store the patient's health information. However, a patient's health information may be presented in DICOM data and might be available through Segmentron Viewer AI. It is the user's responsibility to establish proper security controls in working with Segmentron Viewer AI.

Removable media, such as paper, may be used for purposes of Segmentron Viewer AI analysis results transfer and long-term storage. Patient data written to removable media is identifiable. Treat removable media containing patient data as confidential and take appropriate measures to protect this information, including secure disposal, so that unwanted access by unauthorized individuals is avoided. Procedures to maintain removable media must be part of the institution's security policy.

Malware Prevention and Detection

The server(s) on which Segmentron Viewer AI is running, must be placed on a secure local computer network that has protections against viruses and other harmful computer system intruders.

Make sure the equipment is connected to a local network that uses appropriate protection, such as an antimalware software. Be aware that inserting removable media like USB storage products, CDs, DVDs can introduce malware to the medical product / network.

Logical Access Control

Authorized personnel only shall have access to Segmentron Viewer AI.

Implement stringent control of access to the system:

- Allow access only to the authorized personnel;
- Ensure use of strong passwords by the users;
- Ensure that the users keep their password secretly;
- Users need to ensure periodic change of passwords.

Product Environment

External circumstances can influence the availability of the product and its operation, e.g. network failures, power failures, environmental disasters, etc. Take appropriate controls to ensure the reliability of the environment in which the product is used.

Information Security Incident Reporting

Although Segmentron Viewer AI incorporates state-of-the-art security and privacy protection, a remote possibility remains that a security or confidentiality breach may occur.

Users should properly report on security incidents in accordance with established procedure. Escalate to the Manufacturer if needed.

12. COMPATIBILITY

Segmentron Viewer AI integrates with the DGNCT UI application (Diagnocat UI), a software platform developed by DGNCT.

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Diagnocat UI integrates with other DGNCT software products, including:

- Diagnocat Desktop Application (Diagnocat Imaging) – This application captures dental images from imaging software and uploads them to Diagnocat UI. It automates image uploads, streamlining workflow.
- Billing – This service manages paid subscriptions for Diagnocat products.

Segmentron Viewer AI was validated using a broad range of CBCT scanners and showed consistently high performance. Accordingly, the device is compatible with any CBCT scanner capable of generating a DICOM-compliant image.

Any modifications or additions to the software must be performed only by the Manufacturer or by authorized third parties. Such changes must comply with all applicable laws, regulations, and best engineering practices within the relevant jurisdiction.

13. SYSTEM REQUIREMENTS

To operate the Segmentron Viewer AI web application via a web browser, the following minimum hardware and firmware specifications are required:

1. Any operating system capable of running requires a Google Chrome version;
2. Browser: Google Chrome 75 or higher (must be kept updated);
3. Processor minimum of 2 CPU cores;
4. 2 GB RAM or more;
5. Recommended processor: 4 cores and memory: 4 GB RAM;
6. 50 Mbps or faster Ethernet connection to your institution's DICOM network;
7. Display shall be compatible with displays 23 inches or larger;
8. Compatible Radiological Data Sources: DICOM.

If you use a browser other than the one specified here, the software may not function as intended.

14. DATA CONSTRAINTS

The system requires certain DICOM prerequisites to be met for proper functioning:

- DICOM's data (PixelData tag should be present) must be a monochrome (PhotometricInterpretation tag equal to MONOCHROME2) volumetric image of CBCT modality representing human jaws with total volume no less than 50 cubic centimeters and each linear dimension no less than 2 centimeters long.
- DICOM must contain RescaleIntercept and RescaleSlope tags.
- DICOM's resolution, i.e. voxel size, must be derivable from its metadata. Voxel size may be derived from the following DICOM tags: PixelSpacing, or SliceThickness, or SpacingBetweenSlices.
- Maximal voxel, per single dimension, should be 400. No restrictions on minimal voxel size are set.
- In case of multi-frame DICOM, each slice must have a unique position derivable from its metadata. Position may be derived from the following DICOM tags: Image

Position Patient, or InstanceNumber, or SliceLocation.

- Do not upload DICOM files of size more than 1GB or CBCT volume of >50 cm^3.

NOTE: Segmentron Viewer AI does not capture or enhance images—it only analyzes the ones provided by the dental professional. Ensuring proper image acquisition is crucial for reliable visualization using the product. The quality of Segmentron Viewer AI analysis depends entirely on the quality of the uploaded images.

15. TECHNICAL PARAMETERS

Segmentron Viewer AI is constituted by software available via Web Application with the use of Chrome web browser. The address of the Web Application where the service is available is provided together with the software license.

16. START WITH SEGMENTRON VIEWER AI – DIAGNOCAT UI

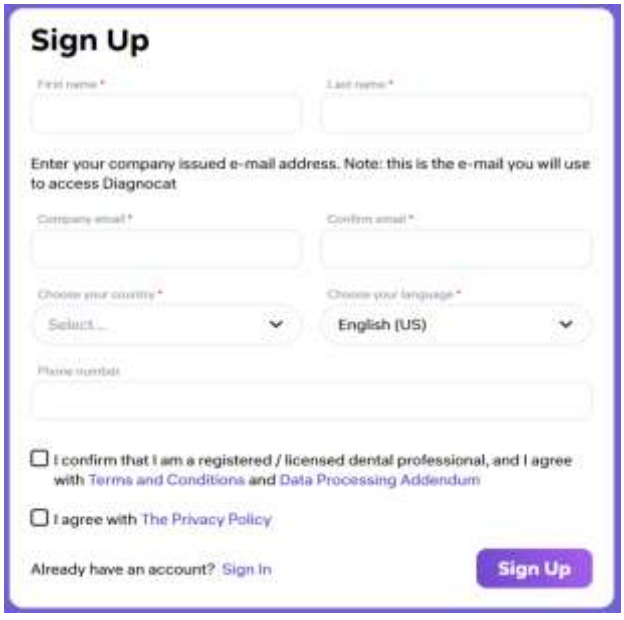
To access Segmentron Viewer AI software, you need to have a valid Diagnocat account.

NOTE: Specifying your country is critical, because:

- We don’t offer Diagnocat services in the countries where we don’t have an official approval from medical authorities.
- Each country has its own set of products and pricing policy.

16.1. Sign Up

Your sales manager can provide you with a link to registration. You will be prompted to the account creation screen where you need to provide account details and click the “Sign Up” button.



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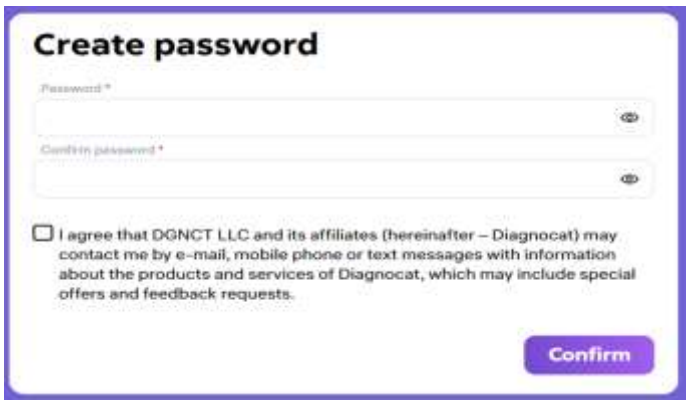
After that, you will receive an email with a verification code. You should enter this code and set your password.



After the registration, Diagnocat will ask you some questions about your experience and equipment to better understand your needs.

16.2. Sign In

Open the Chrome browser and go to Diagnocat based on your region: for Europe, visit https://app.diagnocat.eu; for Canada, visit https://app.diagnocat.ca.

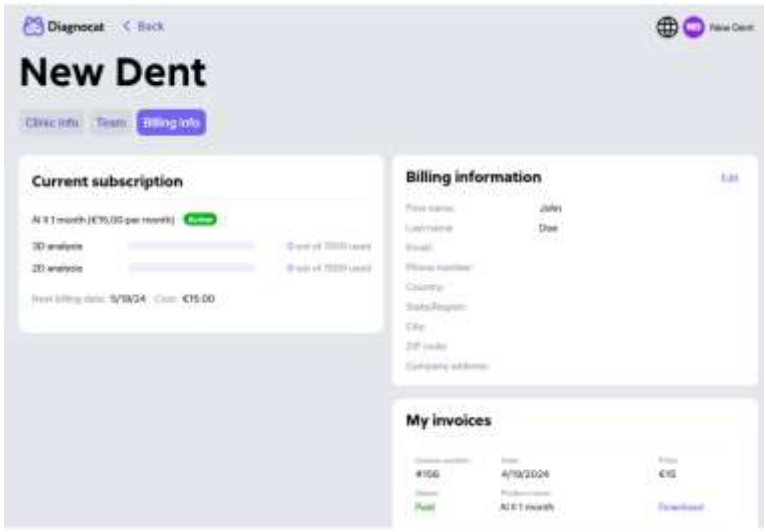
You will be able to sign in to the UI DGNCT application – Diagnocat UI by entering your email and password. If you do not know or need to reset your password, click the “Forgot password” link and enter the email address you used to register your Diagnocat account. You will receive an email with instructions on how to reset your password.

Diagnocat UI is a user-facing frontend application that provides the user with the interface to upload an image, manage patient data, request, view, edit, sign, print and download AI analyses.

16.3. Subscription Plans

To start using Diagnocat you need to buy a subscription plan that will give you access to the main functionality. Your sales manager will suggest the best options to cover your needs and will guide you through the purchase.

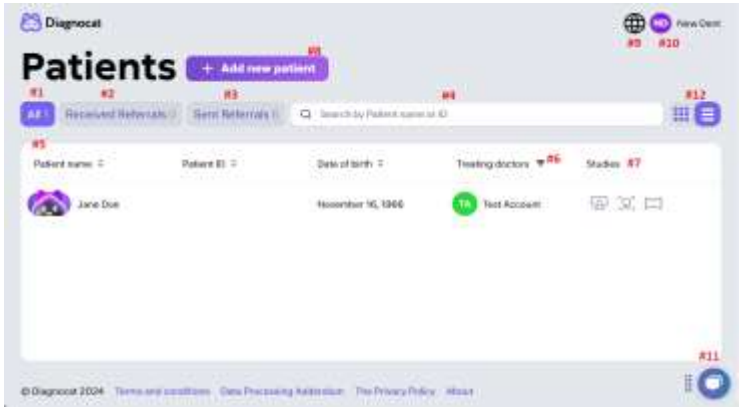
Once you finish, you will see your purchase on the Billing info tab, where you can also download your invoice, edit billing information and view your usage.



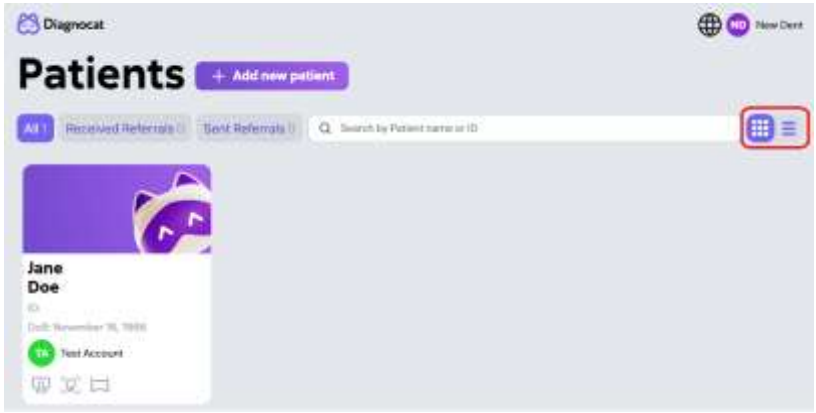
NOTE: Without an active subscription or package (for corporate clients only) you won't be able to create patients, upload new studies or order reports.
If you have any problems, please contact your sales manager or use the support chat to resolve the issue.

16.4. Patients

Once you log in successfully, you will see the "Patients" screen.



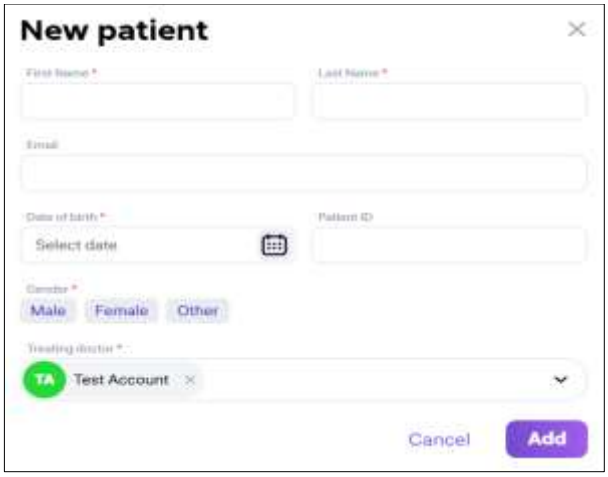
#1: "All" gives you access to all your patients.
#2: "Received Referrals" gives you access to all studies shared with you by other users.
#3: "Sent Referrals" gives you access to all studies shared with other users by you.
#4: Using the "Search" field you can search for studies by patient name or ID.
#5: Shows you the list of all your patients.
#5: "Treating doctors" filter allows you to select a specific doctor/doctors.
#7: Shows existing studies.
#8: "Add new patient" allows you to create a new patient.
#9: Allows you to change the interface language.
#10: Gives you access to your account and clinic settings.
#11: Allows you to get access to the customer success team.
#12: The button allows you to change the visual design of the "Patient Card". The visual design is shown below:



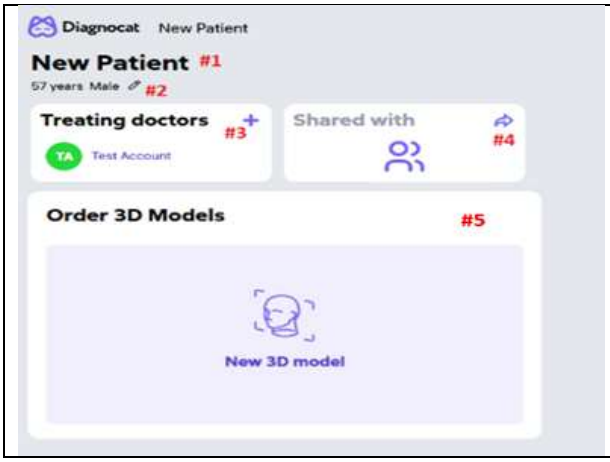
16.5. Create a New Patient

You can create a new patient by clicking “Add new patient” on the main screen.

You will be presented with a short form to complete. It is necessary to fill in all required fields marked with an asterisk and click “Add”.



A new patient will appear in the patient list. The Patient Card displayed in the software is shown below.

	#1: Patient details. #2: Edit patient details. #3: Add a treating doctor. #4: Share a patient with another doctor. #5: Order Segmentation report (Segmentron Viewer AI) and other reports (if there are additional software products in the account, these reports will be shown here as well).

16.6. Segmentation and Superimposition Reports – Segmentron Viewer AI

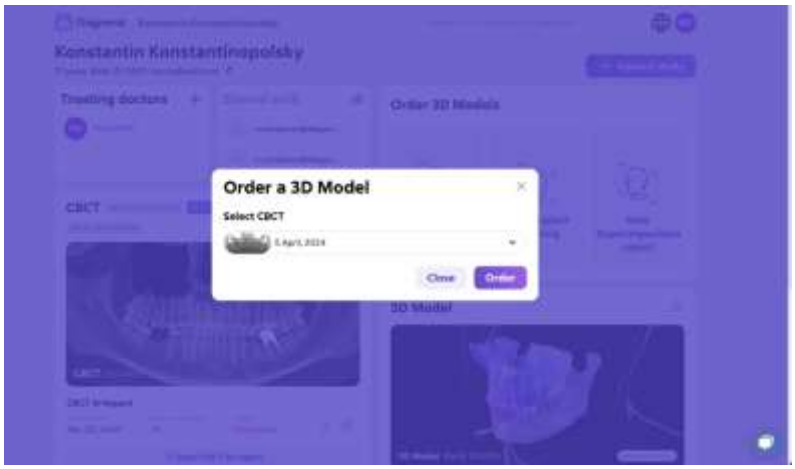
Reports – Inputs

To order a Segmentron Viewer AI Report, you need to upload a CBCT scan in DICOM (.dcm) format and two intraoral scan files of the upper and lower jaws in .stl format (intraoral scans are necessary only for Superimposition report). No other files, such as bite registration or other scans, should be uploaded. To upload a CBCT scan, click Upload study on the patient's details page, choose CBCT in the dropdown, browse for a DICOM file on your computer (you can choose between uploading a single .dcm file or a series of .dcm files as a folder), and click Upload. To upload intraoral scans, click Upload study, choose STL file in the dropdown menu, browse for the .stl files of the upper and lower jaw on your computer, and click Upload.

Please note that the uploaded CBCT and intraoral scans should reflect the same anatomical conditions of the patient, so that they can be matched for the SegmentronViewer AI planning purposes.

Order a new Segmentation report

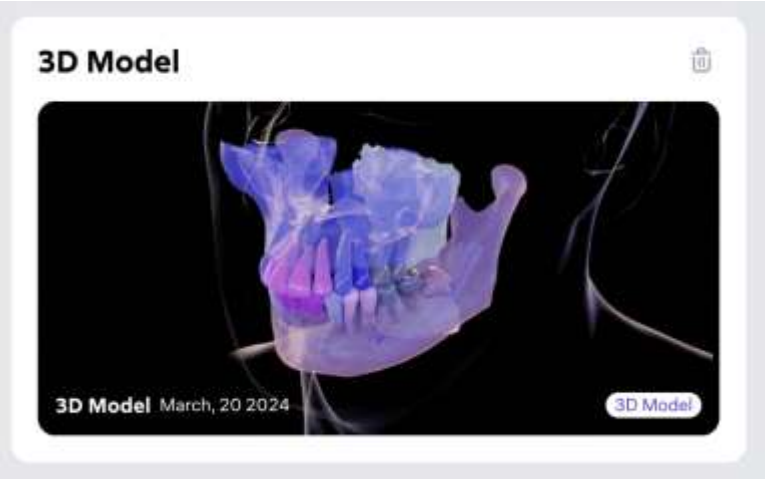
Click the "New 3D Model" button in the patient card, choose "Basic CBCT to STL segmentation" and click "Next".



- Select the CBCT study you want to upload. Attach a file or folder by browsing your computer.
- Click the "Order" or "Cancel".

The software supports the following file formats: *.dcm, *.jpg, *.png, *.tiff, *STL.

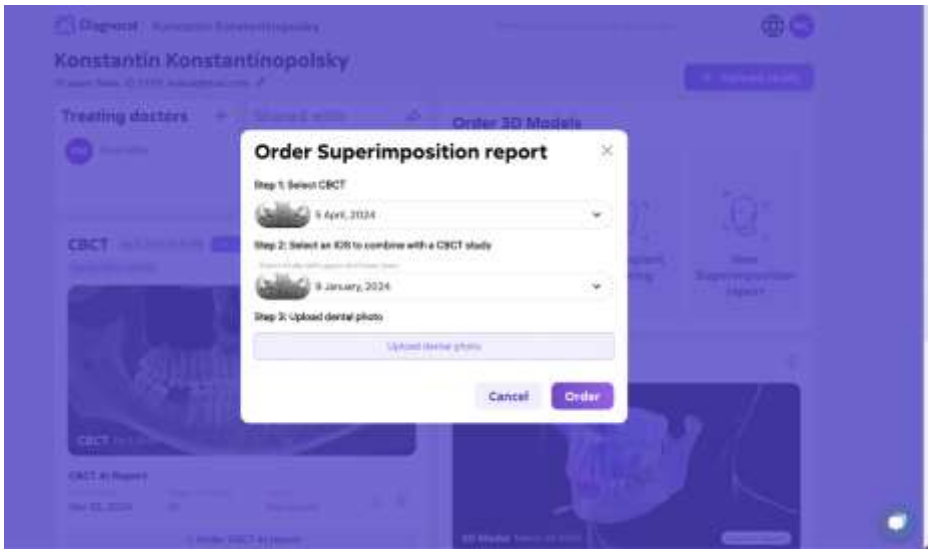
After clicking the **Order** button, the report generation will begin. Once the report is ready, a separate widget displaying a 3D model will appear in the patient card (example below). Clicking on the 3D model widget will open the **Segmentation Report** in a separate window.



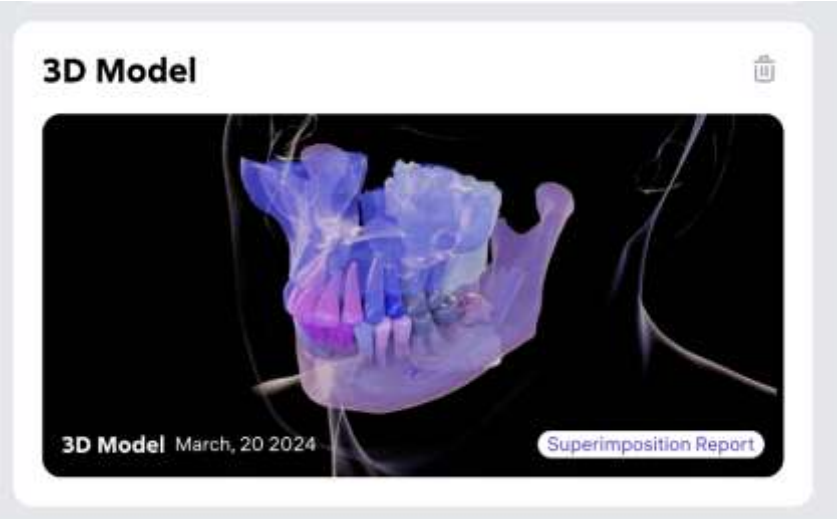
Order a new Superimpostion report

You can create a Superimposition Report. Click the “New Superimposition Report” button in the patient card, select CBCT and IOS to combine with a CBCT study and click “Order”.

*Note: you need to upload one of the following file types: *STL, *OBJ, *PLY, *DRC. Additionally, you can upload dental photo for generation report.



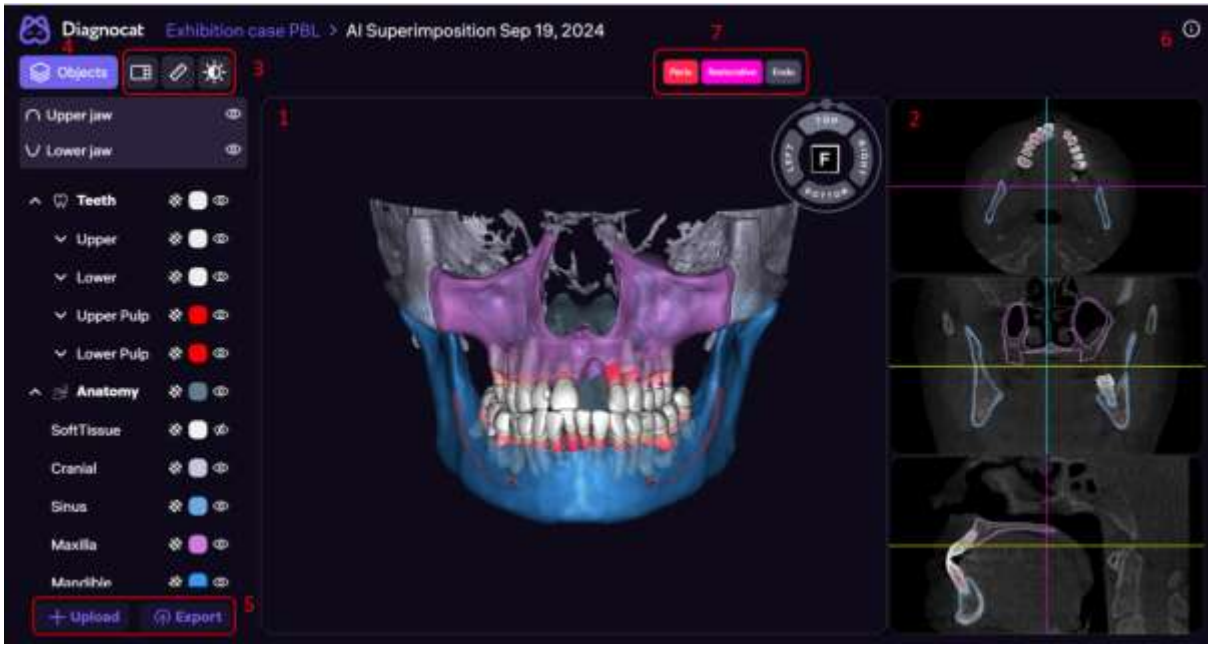
After ordering, you can view the generated report by clicking on the panoramic image and opening the Segmentron Viewer AI Device.



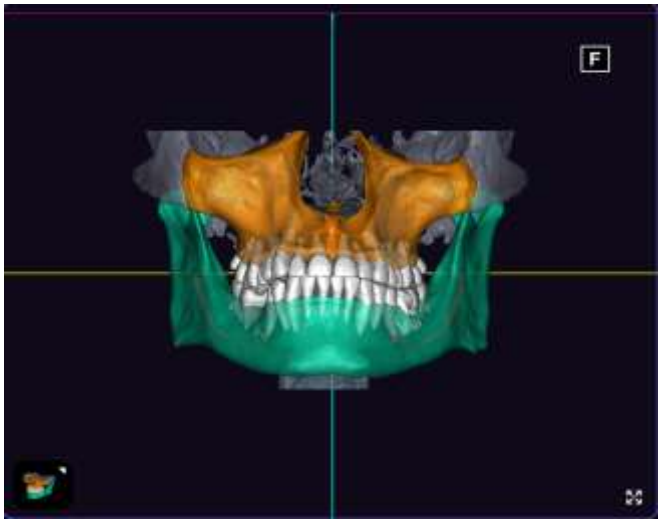
Viewing the Segmentation Report

Upon opening the Segmentation report, the main user interface elements are shown below (keyed to red numbers in subsequent image):

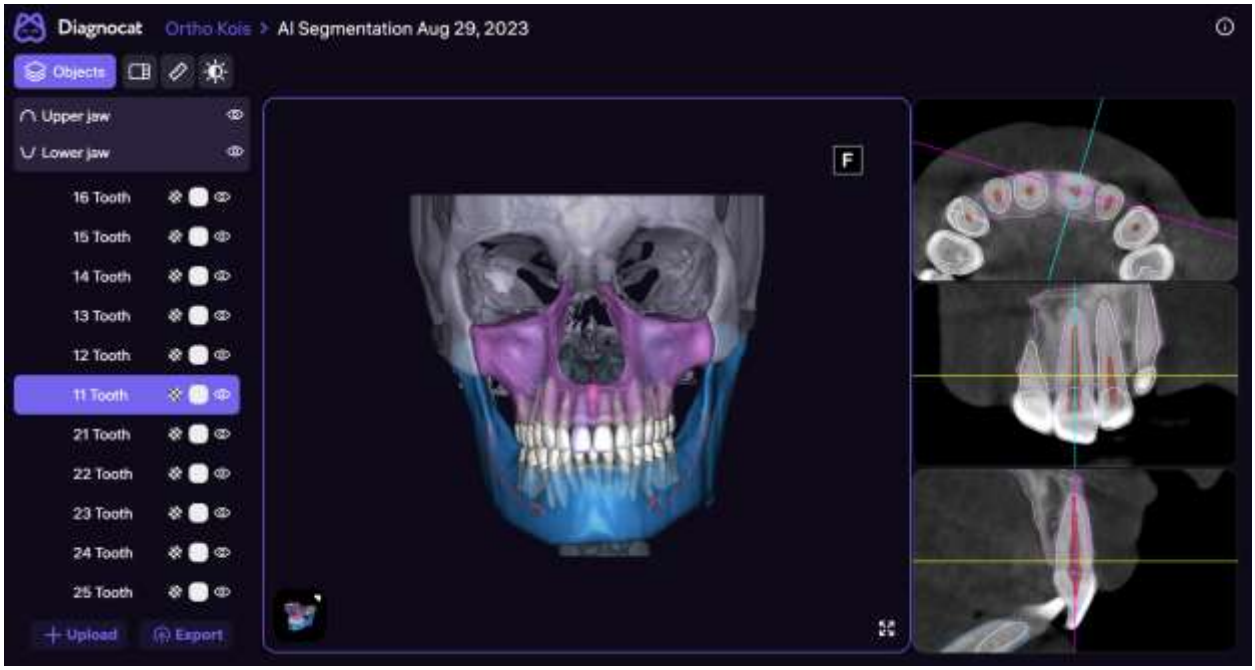
- 3D scene (1)
- MPR panels (2)
- Toolbar (3)
- Objects (4)
- Upload and Export buttons (5)
- Labeling (6)
- Conditions buttons (7)



3D SCENE



The output 3D model is displayed on the 3D scene. When you select an object on the 3D scene, it will be highlighted more brightly (for teeth) or highlighted in color (for anatomical structures). The selected object in the 3D scene will be displayed on the panels.



NAVIGATION

Users can navigate the 3D model using either the interactive navigation cube or a mouse.

- Navigation Cube: Clicking on the cube icon 

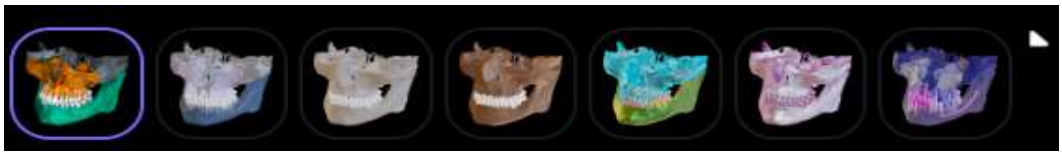
opens a panel that allows users to select different 3D model projections. By pressing the corresponding buttons within this panel, users can adjust the model's orientation to predefined views.

- Mouse Navigation: Users can manipulate the 3D model by clicking and dragging with the mouse to rotate, zoom, and pan for a more customized viewing experience.

These navigation options enable precise control over the 3D visualization, enhancing usability and interaction with the displayed model.

STYLES PANEL

In the lower left corner, there is a style selection button. To open the panel, you need to navigate on the 3D scene and click on the Styles icon  on the 3D scene. The Styles panel allows you to change the visual presets of the 3D model. You can choose between 7 Styles presets, which differ in color and transparency level (see below).

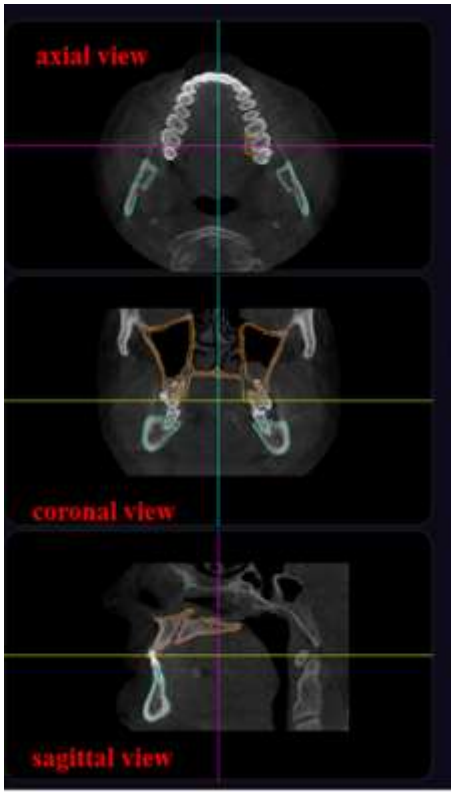


MAXIMIZE VIEWPORT

When you navigate on a 3D scene, in the lower right corner there is the Maximize icon  . You can maximize the size of the 3D scene by hovering on the corresponding viewport and clicking the Maximize icon. Once the viewport is maximized, the icon changes to Minimize. Click the cross button  to return to the standard proportions of the viewport.

MPR PLANES

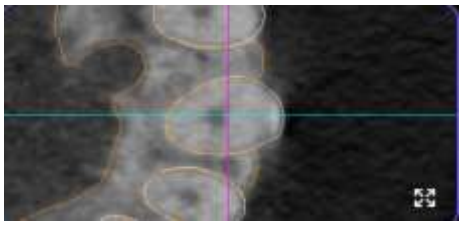
Multiplanar reformation viewports (MPRs) take a 3D CBCT scan and reformat the data to represent the radiological image in three projections or planes: orthogonal view, tangential view, and axial view. See example below. This is intended to allow for more in-depth analysis of an area of interest.



You can change the projections on the MPR panels using the mouse. Changes will be displayed in one of the MPR panels.

MAXIMIZE VIEWPORT

When you navigate on a MPR plane, the Maximize icon is visible in the lower right corner (see image below). You can maximize the size of the selected MPR plane by hovering on the corresponding viewport and clicking the Maximize icon. Once the viewport is maximized, the icon changes to Minimize. Click the cross button to return to the standard proportions of the viewport.



16.7. Conditions display

This section explains how to interact with the interface to visualize and filter detected dental conditions. The system categorizes conditions into three groups—Perio, Restorative, and Endo—each with specific functionalities and visualization modes.

Condition Categories

- Perio:
  - Impaction (whole tooth)
  - Furcation Lesion (visible only in the hover panel)
  - Periodontal Bone Loss (PBL)
- Restorative:
  - Caries Signs (segmentation)
  - Abfraction (segmentation)
  - Root Fragment (whole tooth)
- Endo:
  - Periapical Radiolucency (segmentation)
  - Furcation Lesion (segmentation)
  - Lateral Radiolucency (segmentation)
  - Widened PDL Space (segmentation)

Using the filter buttons and hover functionality, users can seamlessly analyze specific dental conditions and their associated measurements.

Conditions are displayed on the 3D scene as segmentations and on MPR planes as colored contours corresponding to their category.

When hovering over a tooth, a panel appears to display the detected conditions for that tooth, if any. If no conditions are detected, no panel is shown. The panel lists conditions based on the active filters at the top of the interface; if no filters are active, the panel is not displayed.

At the top of the interface, filter buttons allow you to activate the display of conditions by category:

- **Perio:**

Clicking the Perio filter button activates Periodontal Bone Loss (PBL) visualization, along with other Perio conditions if available. While the visualization is loading, a progress bar appears in the corner of the 3D scene.

In the PBL visualization, each tooth is highlighted with a color gradient to represent the distance of PBL from the Cementoenamel Junction (CEJ) to the bone. Greater distances are shown with more intense red shades. Additionally, measurement lines are plotted every 1 mm throughout the PBL area.

PBL measurements are calculated using the formula:
PBL = CEJ level - Bone level,
where PBL represents Periodontal Bone Loss, and CEJ is the Cementoenamel Junction.
Measurements are taken at six specific points for each tooth:

- Buccal: Distal, Middle, Mesial
- Lingual: Distal, Middle, Mesial

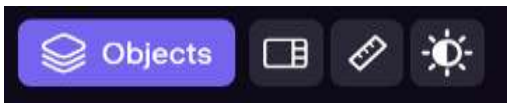
The PBL values are displayed in the hover panel and grouped by Buccal and Lingual sides.

- **Restorative**: Active if at least one condition from this category is detected; otherwise,

inactive.

- **Endo**: Active if at least one condition from this category is detected; otherwise, inactive.

TOOLBAR



The Toolbar contains the following instruments:

- Objects – opens/closes the Object panel (see section 4).
- Layouts  – allows you to change the general appearance of the 3D scene and MPR panels. There are 3 display options available:

   Only the 3D scene will be displayed

   windows of the same size with 3D scene and panels

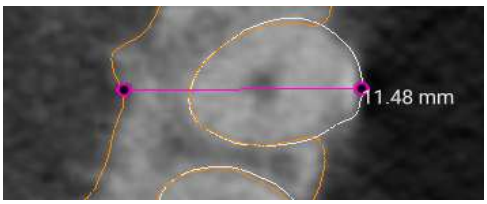
   3D scene and side view of MPR panels
- Brightness-contrast  – allows you to change the brightness or contrast of radiological images on MPRs. To do this, click the mouse on the MPRs and move the cursor up/down to increase/decrease brightness, respectively; click the mouse on the MPRs and move the cursor left/right to decrease/increase contrast, respectively.

  The user can use Ctrl+Z buttons to undo the last action.
- Ruler  – activates the ruler instrument for measuring distances on MPRs. To measure an object on MPRs, click the mouse at the initial and final points of the object.

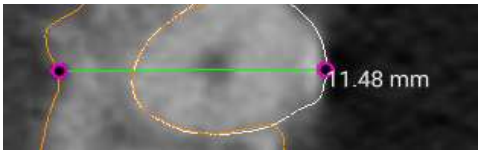
After the instrument has been activated, the following mechanics apply:

- user makes first left-click anywhere on MPR plane to mark the beginning of the ruler object
- user makes the second left-click to mark the end of the ruler object
- after the beginning is marked, the ruler object follows the mouse
- the ruler measurement (rounded to the 2nd decimal) appears at the end of the object.

Note: All the measurements in the software are presented in millimeters and are accurate to two decimals (+/-0.01mm).



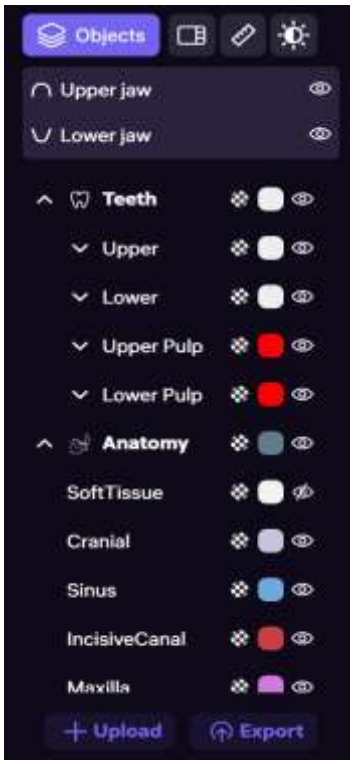
The user can delete the ruler object by clicking on the measurement on the MPR, whereby it should change color, and then clicking backspace or delete.



The user can use the “Undo” or Ctrl+Z buttons to undo the last action.

OBJECTS PANEL

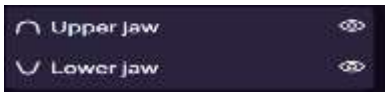
To open the Objects panel, click Objects in the Toolbar. The panel lists all anatomic objects in a tree structure, as shown below.



You can control the visibility (switch on/off) of any anatomic or artificial object via the Eye icon . To change the transparency of an object on the 3D scene, click the Transparency icon and move the slider to the desired value (illustrated below).

To change the color of an object on the 3D scene, click the icon and move the slider to the desired hue (see below).

You can also switch on/off the visibility of groups of objects corresponding to a specific jaw in the upper part of the panel, using the Eye icon next to Upper jaw or Lower jaw.



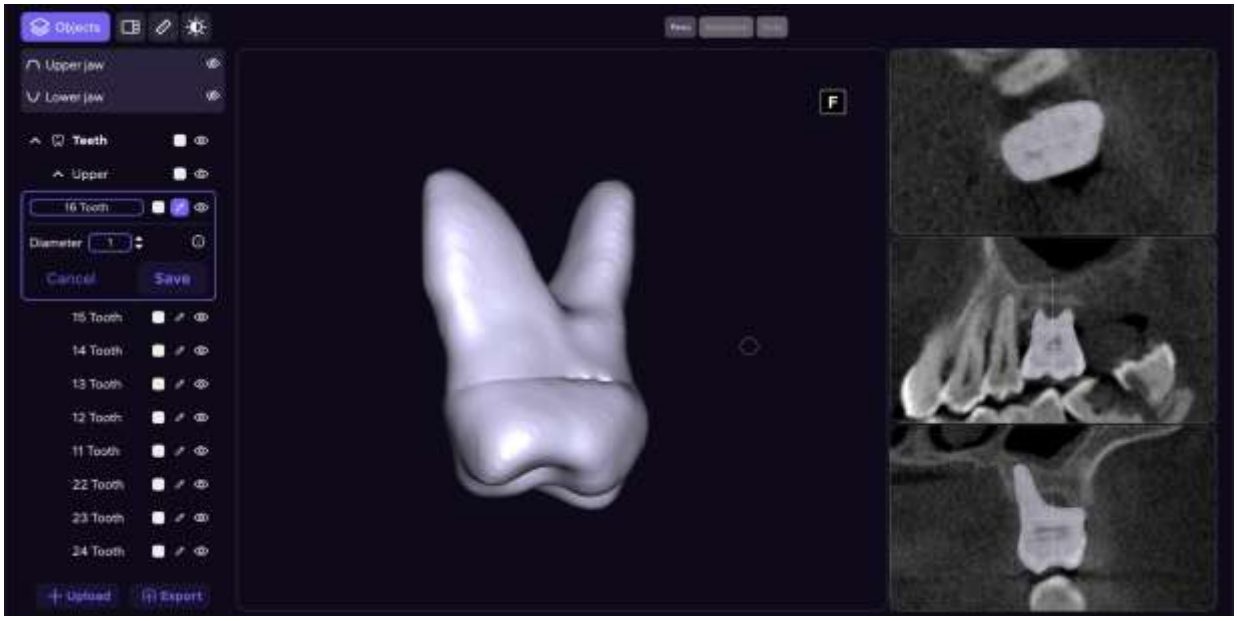
16.8. Editing Segmentations

As semi-automated software, Segmentron Viewer AI allows users to edit the software-generated segmentations, if desired.

To modify the shape of a segmented object, click the pencil icon in the Objects panel (highlighted with a red box in the screenshot below). This action opens an editing panel where users can adjust relevant parameters, such as tooth diameter (as shown in the example below). These modifications allow for precise customization of segmentation properties to better fit the intended analysis.

When the Edit Segmentation tool is active:

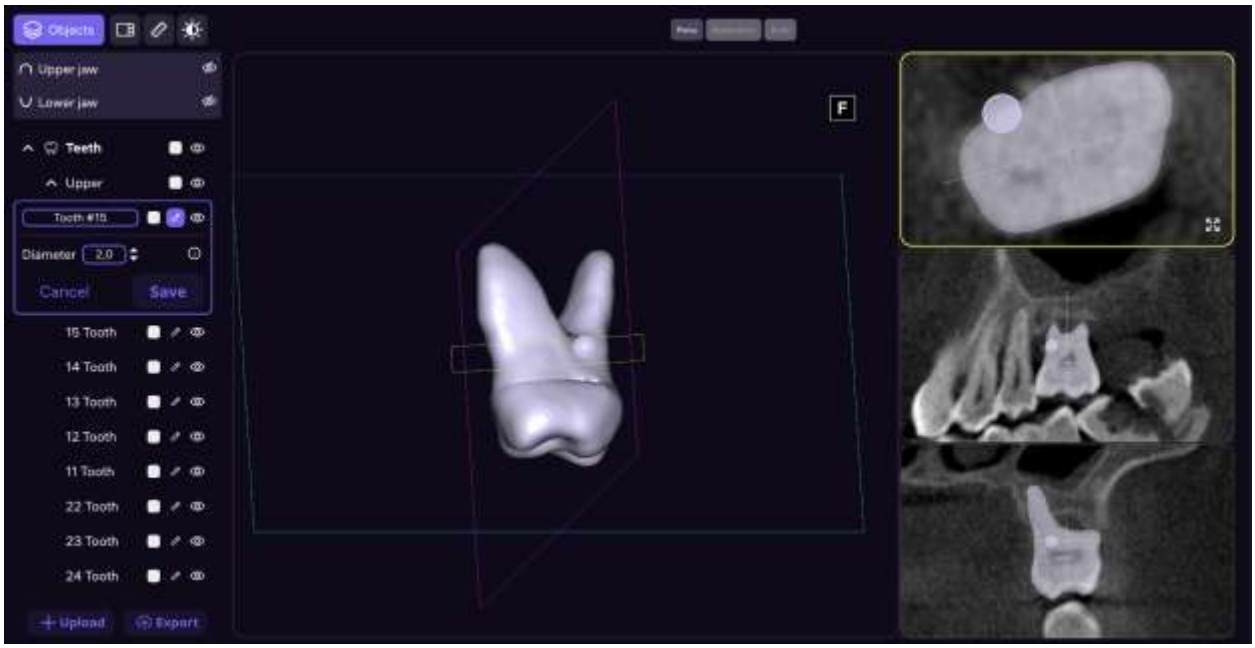
- The system highlights the segmented area of the selected object on all MPR planes.
- In the 3D scene, only the selected object is displayed.



Modifying the Segmented Area:

- Extending (Drawing): You can expand the segmentation by placing the cursor inside the segmented area on the MPR planes and moving it outward in the desired direction.
- Reducing (Erasing): You can shrink the segmentation by placing the cursor outside the segmented area on the MPR planes and moving it inward in the desired direction.

To apply the changes, the user must click Save in the Adjust Segmentation panel. The modifications will be reflected in the updated 3D scene and MPR contours.



16.9. Editing Labels

Segmentron Viewer AI also allows users to edit the software-generated classification labels

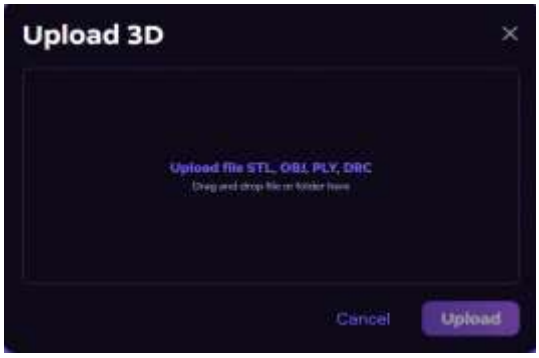
(identifying the segmented teeth and anatomical structures).

To change the name of a segmented object, click the name input field, and enter the new name (see cursor location below). Click ‘Save’ to apply the changes or ‘Cancel’ to discard.

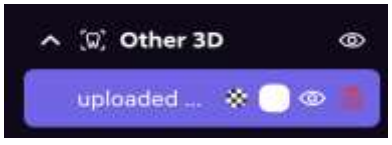
16.10. Upload and Export

You can also upload your own 3D objects on the scene (in STL, OBJ, PLY, or DRC format) from your computer onto the scene. You may wish to do this, for example, to visualize or evaluate a previously segmented model from within Segmentron Viewer AI.

To do this, click the “Upload” button in the lower left corner of the main page. In the modal window, select (or drag and drop) the desired file(s) from your computer.



The uploaded objects(s) will appear on the 3D scene, as well as in the Objects panel. You can move the uploaded objects on the 3D scene using object controls. To remove an uploaded object, click the Delete icon in the Objects panel.

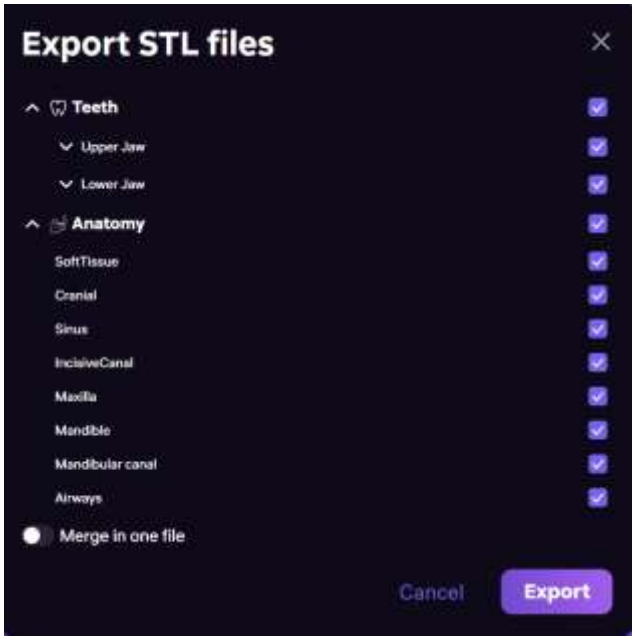


To export all anatomic and artificial objects listed in the Objects panel, click the Export button 

at the bottom of the Objects panel. You can select the objects you want to export by checking the box next to each. Alternatively, you can merge all objects into one file by pressing the button 

. The objects will be exported as a .zip archive

containing .stl files.



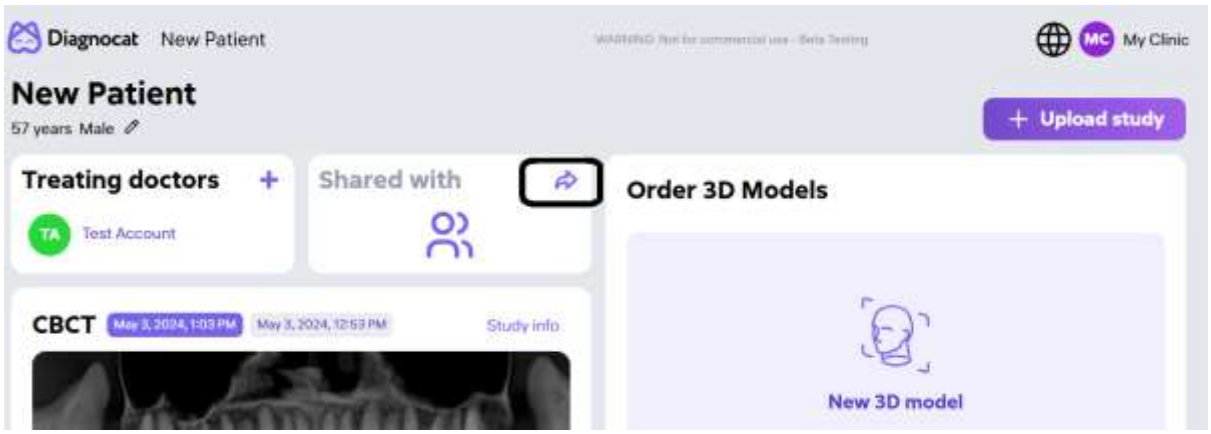
⚠ The STL export functionality is intended to facilitate visualization and communication. It is not intended for 3D printing of patient-specific treatment planning models or surgical guides.

⚠ All diagnostic interpretation and treatment decisions remain the responsibility of the qualified healthcare professional, regardless of STL use.

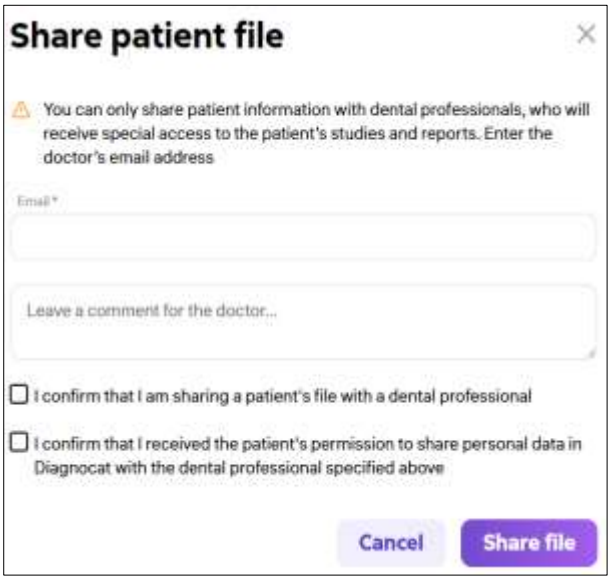
17. ADDITIONAL FUNCTIONS OF DIAGNOCAT UI

17.1. Share patient

Using this function, you can give access to a patient's study to other specialists who are not a part of your practice.

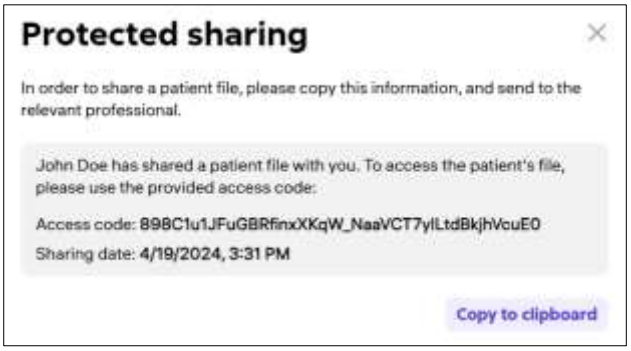


Click on the “Share” icon.

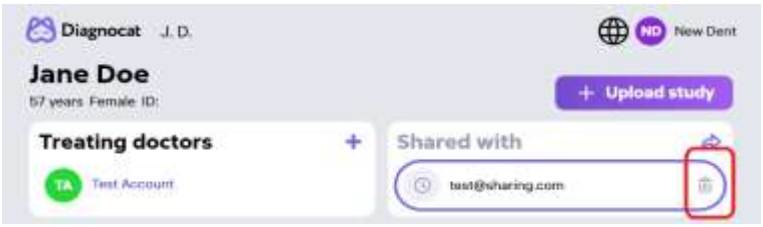


Enter the recipient’s email address, leave a comment for the doctor if necessary, and check the boxes (1) “I confirm that I am sharing a patient's file with a dental professional” and (2) “I confirm that I received the patient's permission to share personal data in Diagnocat with the dental professional specified above.” After that click the “Share file” button.

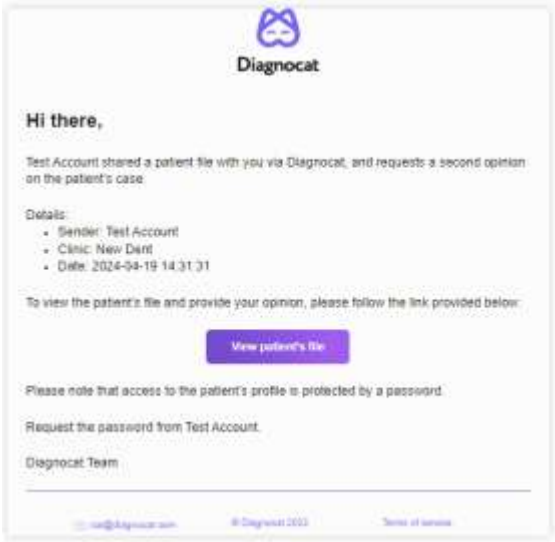
Since you are transferring sensitive data of patients, the sharing process is additionally protected with an Access code. Diagnocat generates this code, and you should copy it and send it to the person that should receive the patient file. You can do it via any service you use to communicate with other professionals.



Under “Shared with” in the patient’s information, you will see a list of doctors with whom a patient study has been shared. To revoke access, click the “recycling bin” icon.



A doctor with whom you share a patient study will receive an email notification inviting them to go to Diagnocat.

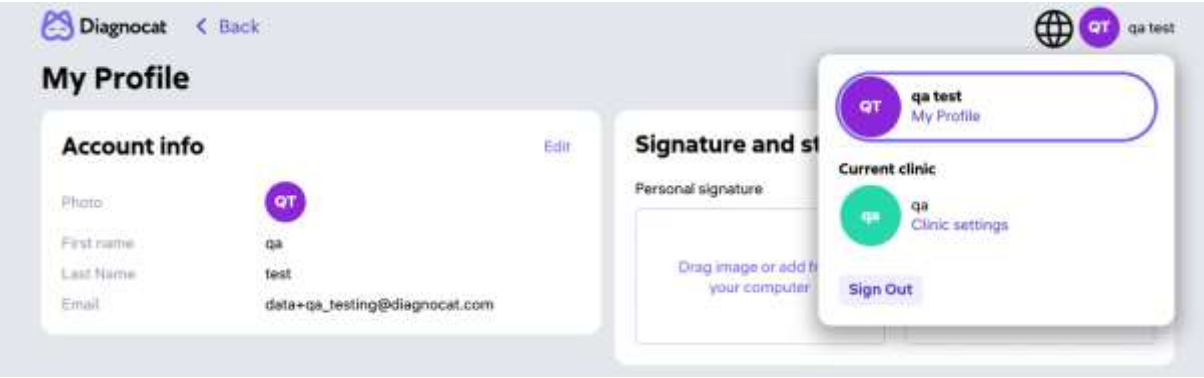


If the doctor doesn't have a Diagnocat account, they will be able to create a new one. Once finished, they will be prompted to their account where they can view reports of the shared patient.

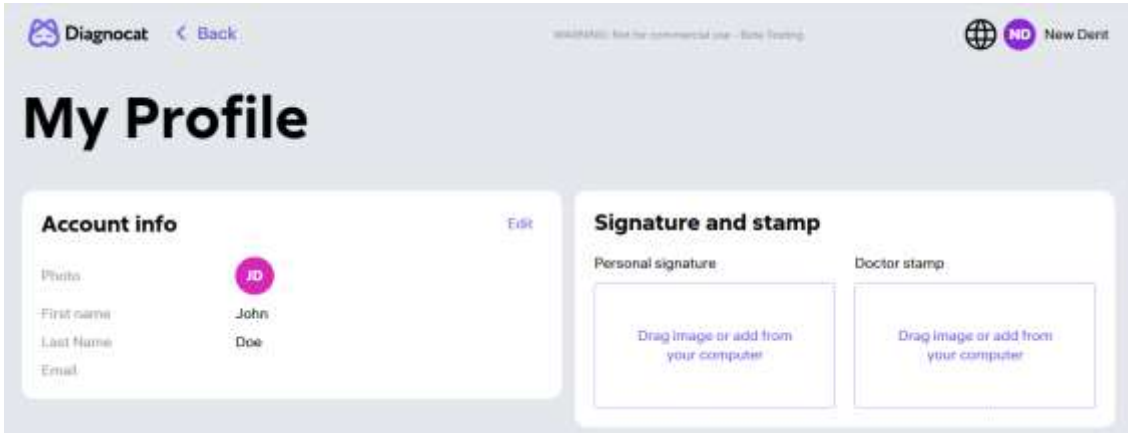
Access to each patient is allowed only after entering the Access code. The sender should provide this code.

17.2. Account and Clinic Settings

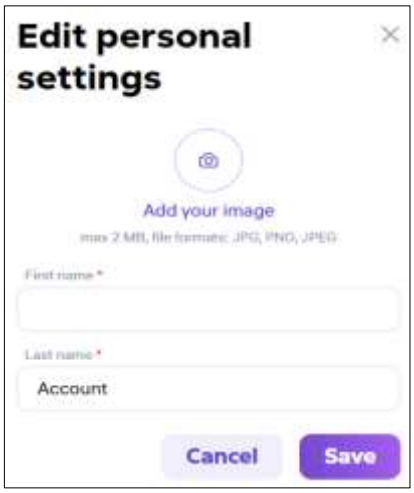
To get access to Account settings, click the arrow icon in the top right corner of the main page.



Inside you will find 2 main tabs:

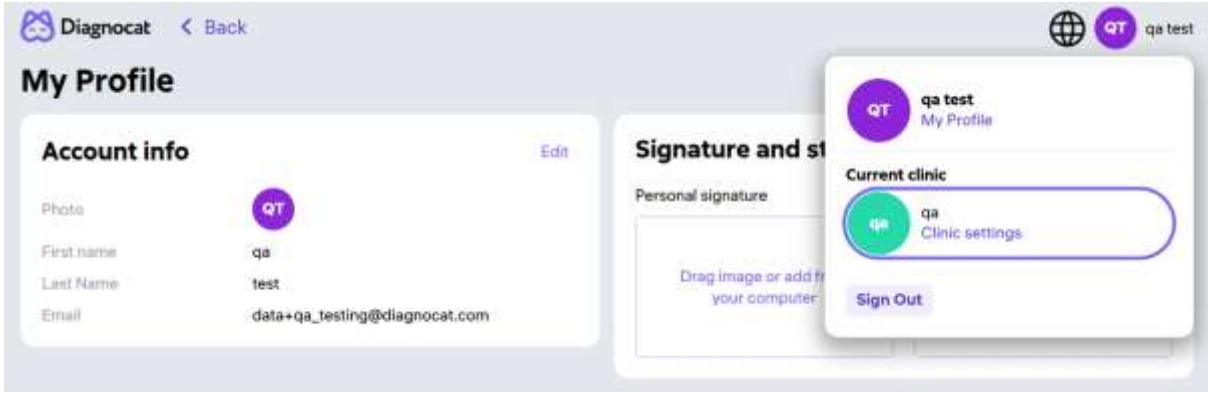


#1: Account info. You can change the account owner name, Add your photo.

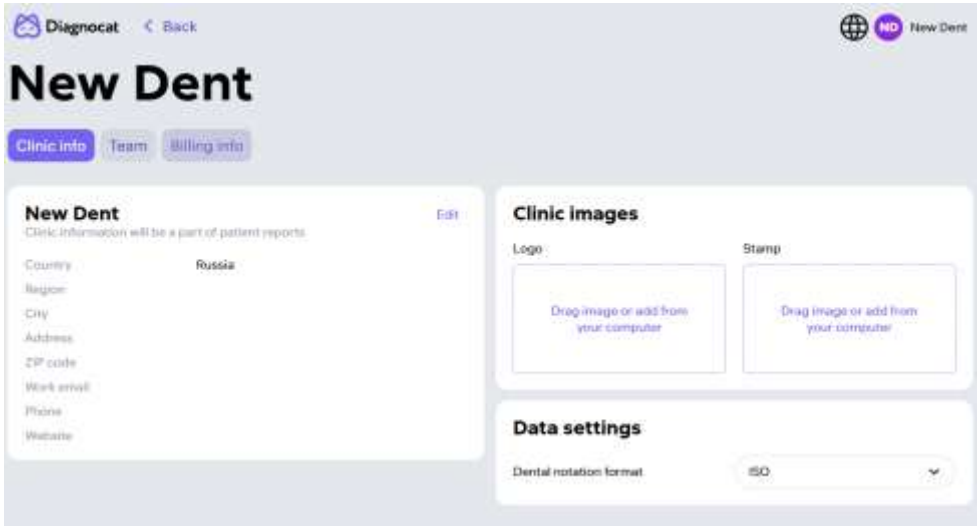


#2: Signature and stamp. You can add a personal signature and doctor stamp.

To get access to Clinic settings, click the arrow icon in the top right corner of the main page.



Inside you will find 3 main tabs:



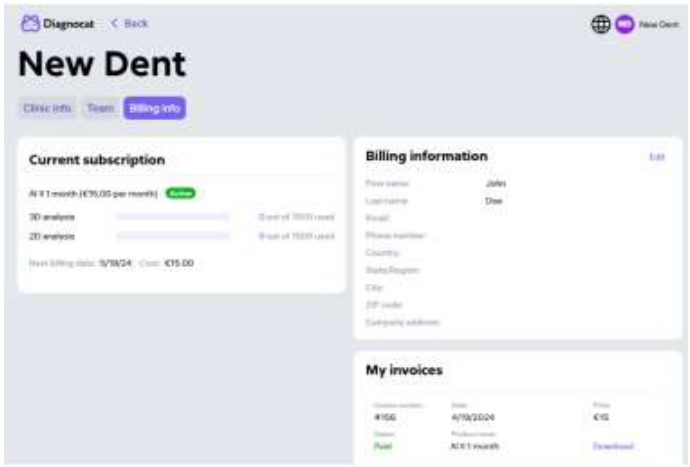
#1: Clinic info. You can change the company name, add/change logo and stamp, change all clinic data and change dental notation format.

#2: Team. You can add, remove and edit employees.

To add a team member, click on the button “Add team member” and a form will open for you to fill in with their name, email address, access level, and job position.

Note: to fill in the “Access level” field correctly, use the key on the "Team" page (see below).

#3: Billing info. You can view your current subscription, packages, consumption and invoices. You can also pay and download your invoices and change billing information.



When you click the “Go back to my patients” you will be prompted to your Patient list.

18. TROUBLESHOOTING, MAINTENANCE AND SERVICE

If you encounter any problems while using Segmentron Viewer AI, please contact the manufacturer.

In case of noticing any device malfunctions, contact the maintenance service at the e-mail address: support@diagnocat.com

19. CONTACT INFORMATION (FOR ASSISTANCE)

For general and product-related comments, questions, or concerns, please contact the local reseller.

MANUFACTURER
DGNCT LLC
333 Southeast 2nd Avenue, 20th Floor#563,
Miami, Florida 33131, USA
https://www.diagnocat.com/
Phone: + 1 519 619 4212
E-mail: support@diagnocat.com
https://www.diagnocat.com/

Please report any serious incident that has occurred in relation to the device – injury or adverse event – to the local competent authority and to DGNCT LLC (sales@diagnocat.com). Please refer to the manufacturer’s website for the updated contact info: https://www.diagnocat.com, if necessary.