Diagnocat

Segmentron Viewer

User Manual

Version 1.0

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Contents

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1. USER MANUAL INFORMATION

This user manual (Instructions for Use) describes the Segmentron Viewer 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. 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.

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 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:

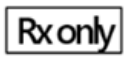
Phone: + 1 519 619 4212
E-mail: support@diagnocat.com

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 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
	Prescription use only (CAUTION: Federal law restricts this device to sale by or on the order of a licensed dental professional.)

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4. DEVICE INFORMATION

Name: Segmentron Viewer
Version: 1.0
Device UDI: 860010268087

5. REGULATORY REQUIREMENTS

Segmentron Viewer 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, 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, 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 SaMD for dental image processing and management. The device provides functions for enhancement, segmentation, and 3D visualization 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.

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

- 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.

- Toolbar:

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

- 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).

- 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.

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.

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.

Anatomy Identification and Segmentation

Segmentron Viewer employs image processing to identify eight (8) maxillofacial anatomy structures (including soft tissue) in a CBCT scan, and segments and labels them. This facilitates identification and evaluation 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 pulp, Mandible, Mandibular Canal.

Note: The soft tissue segmentation function produces contours of the external facial soft tissue only, and not internal soft tissue structures. The output is intended solely for visualization, patient communication and education, and case documentation and collaboration; it is not intended for surgical planning, treatment planning, or quantitative soft tissue analysis.

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.

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.

7.1 INTENDED USE/ INDICATION FOR USE

Segmentron Viewer is a software product intended for processing and manipulating maxillofacial radiographic images. Segmentron Viewer 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 editable 3D STL files (for educational purposes only).

The device is indicated for use by medical professionals (such as dentists and radiologists), in patients 14 years and older with permanent teeth.

Segmentron Viewer 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 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.

8. PRECAUTIONS AND LIMITATIONS

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

⚠ The performance of Segmentron Viewer 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.

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⚠ 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.

⚠ The "soft tissue segmentation" feature produces contours of the external facial soft tissue envelope only.

9. CONTRAINDICATIONS

Segmentron Viewer 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, 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 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 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 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 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 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 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. It is the user's responsibility to establish proper security controls in working with Segmentron Viewer.

Removable media, such as paper, may be used for purposes of Segmentron Viewer 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 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, and DVDs can introduce malware to the medical product / network.

Logical Access Control

Authorized personnel only shall have access to Segmentron Viewer.

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

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 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.

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13. SYSTEM REQUIREMENTS

To operate the Segmentron Viewer 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 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 analysis depends entirely on the quality of the uploaded images.

15. TECHNICAL PARAMETERS

Segmentron Viewer 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 – DIAGNOCAT UI

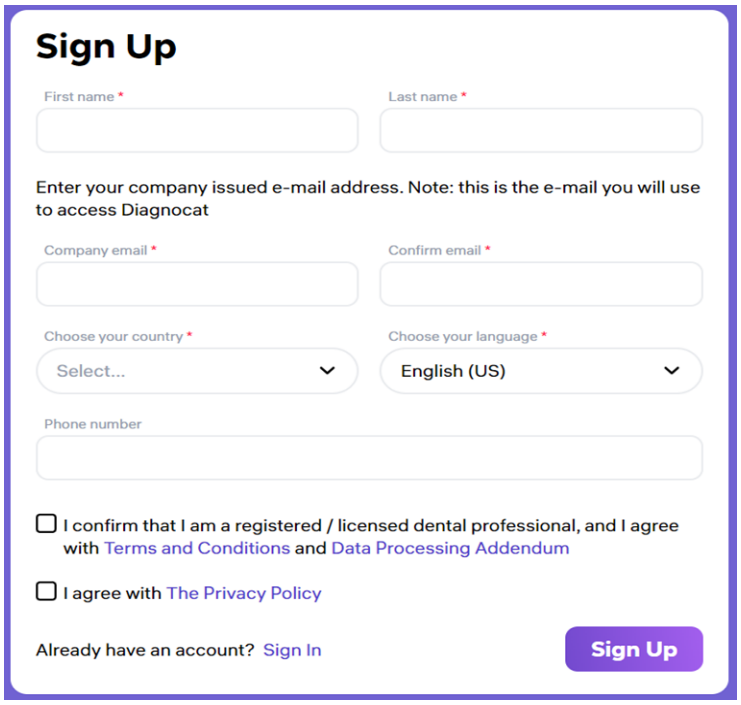
To access Segmentron Viewer software, you need to have a valid Diagnocat account.

NOTE: Specifying your country is critical, because:

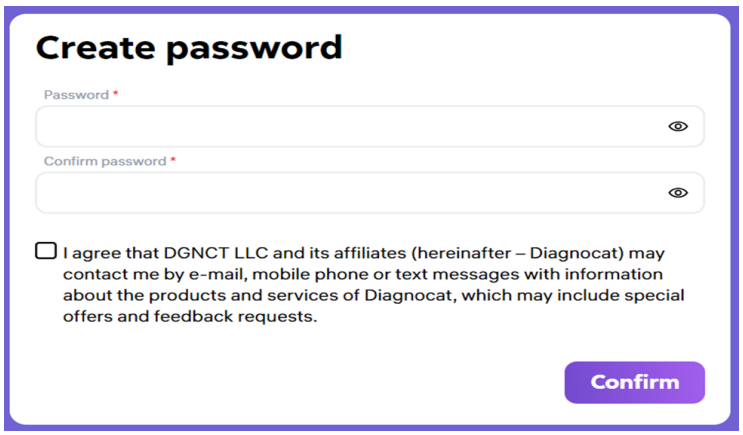
- We don't offer Diagnocat services in the countries where we don't have an official approval from medical authorities.
- Each country has its own set of products and pricing policy.

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.



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.

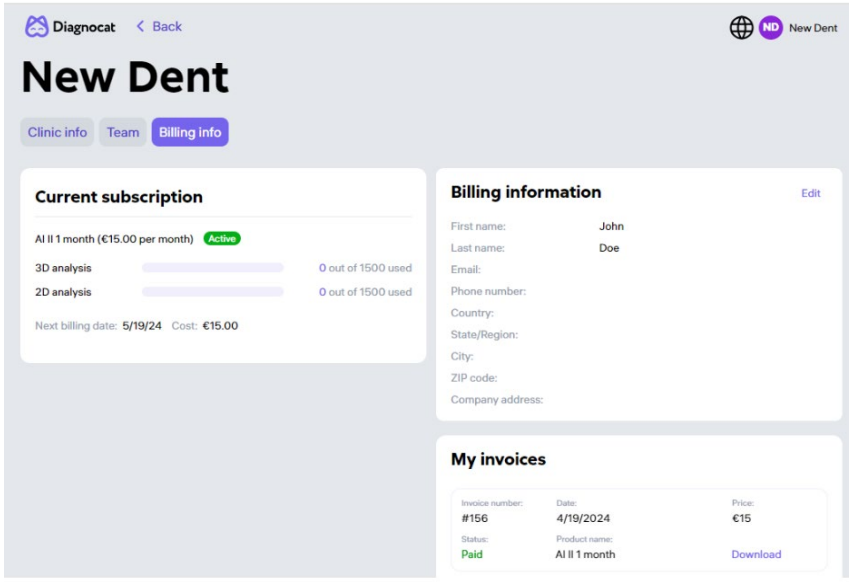
You will be able to sign in to the UI DGNCT application – Diagnocat UI by entering your email and password. If you do not know or need to reset your password, click the “Forgot password” link and enter the email address you used to register your Diagnocat account. You will receive an email with instructions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

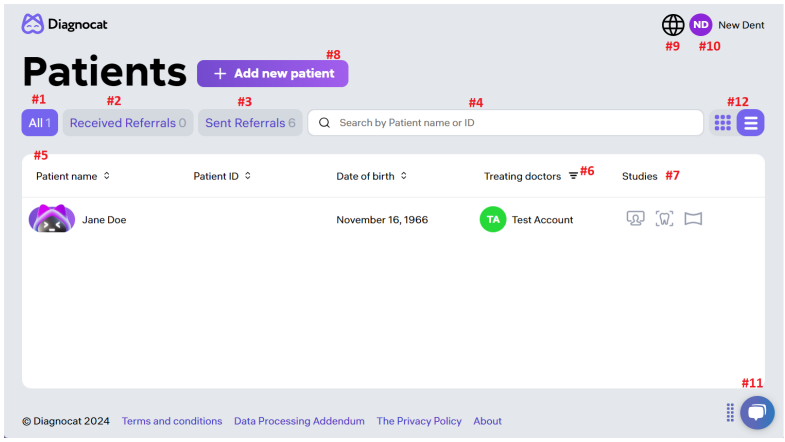
Once you finish, you will see your purchase on the Billing info tab, where you can also download your invoice, edit billing information and view your usage.



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.

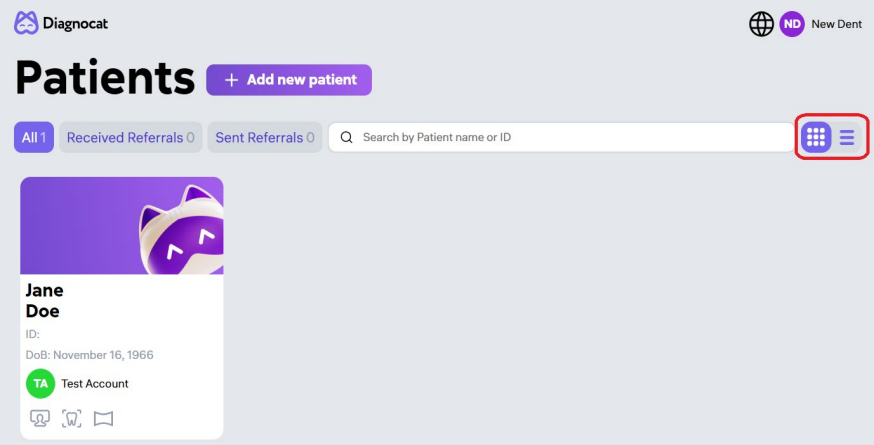
16.4. Patients

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.

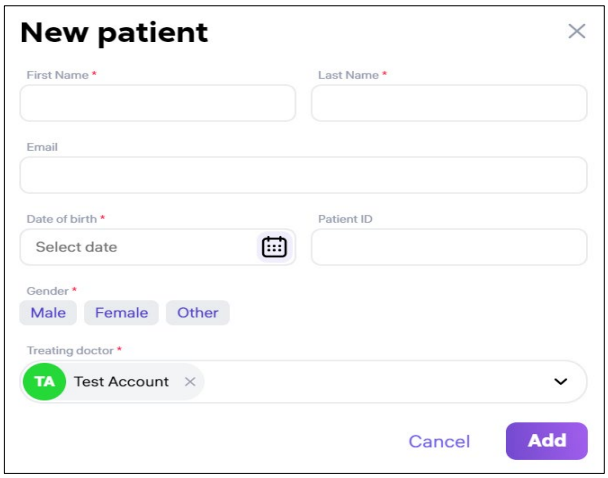
#11: Allows you to get access to the customer success team.
#12: The button allows you to change the visual design of the “Patient Card”. The visual design is shown below:



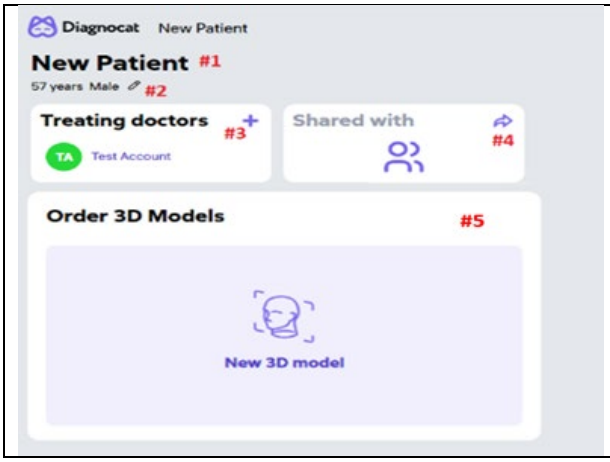
16.5. Create a New Patient

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) and other reports (if there are additional software products in the account, these reports will be shown here as well).

16.6. Segmentation Reports – Segmentron Viewer

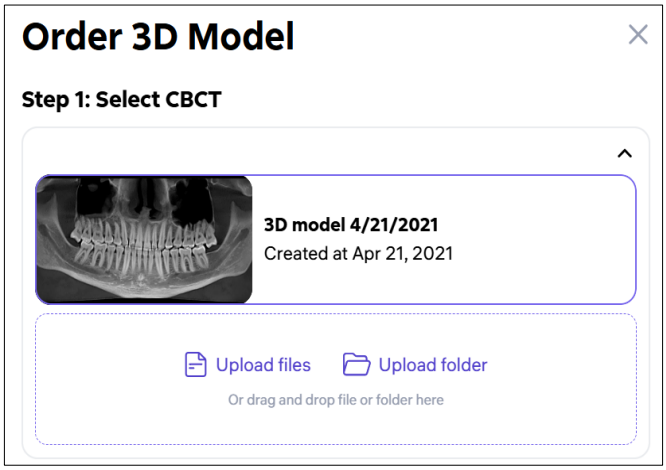
Segmentation Report – Inputs

To order a Segmentron Viewer 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. 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 Viewer 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".



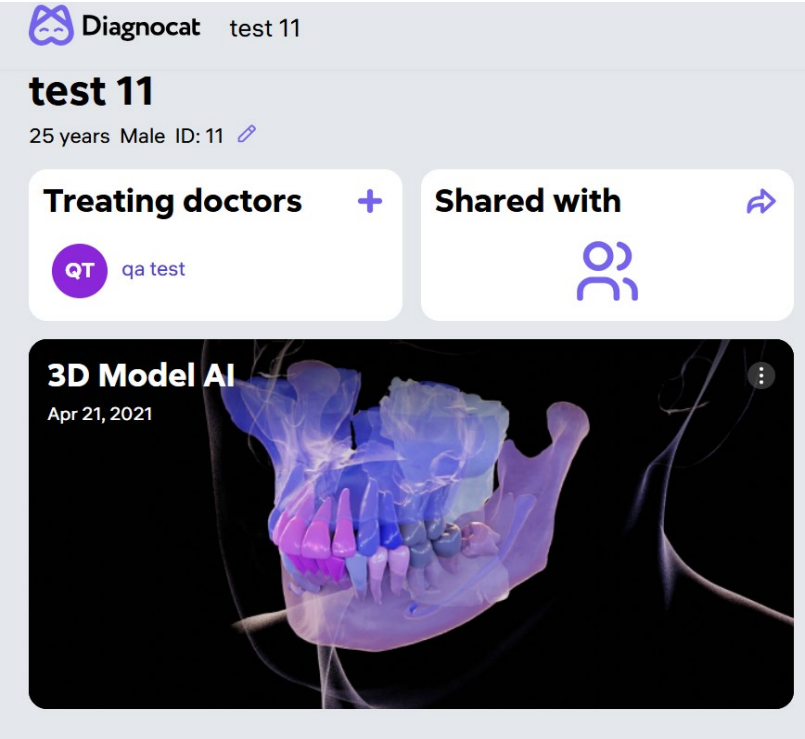
- Select the CBCT study you want to upload. Attach a file or folder by browsing your

computer.

- Click the “Order” or “Cancel.”

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

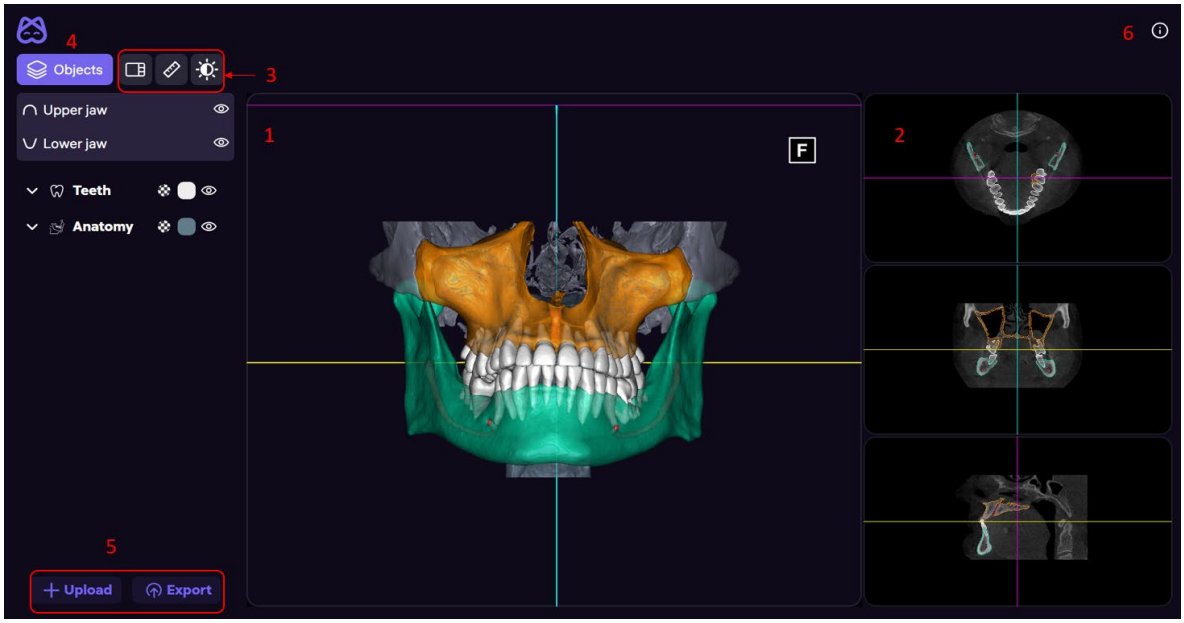
After clicking the **Order** button, the report generation will begin. Once the report is ready, a separate widget displaying a 3D model will appear in the patient card (example below). Clicking on the 3D model widget will open the **Segmentation Report** in a separate window.



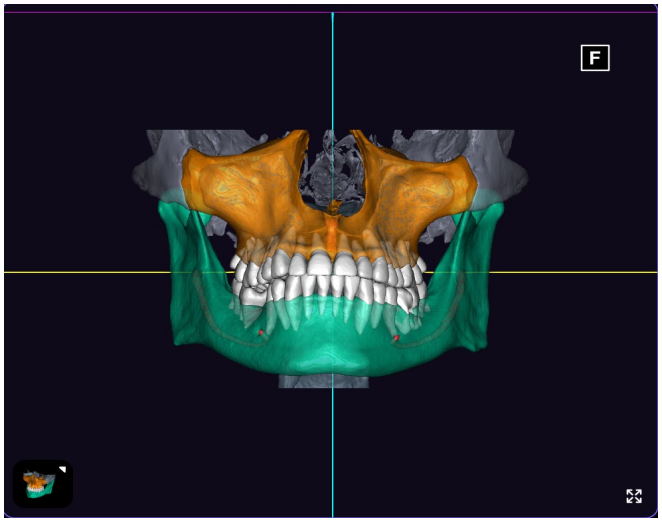
Viewing the Segmentation Report

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)



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.

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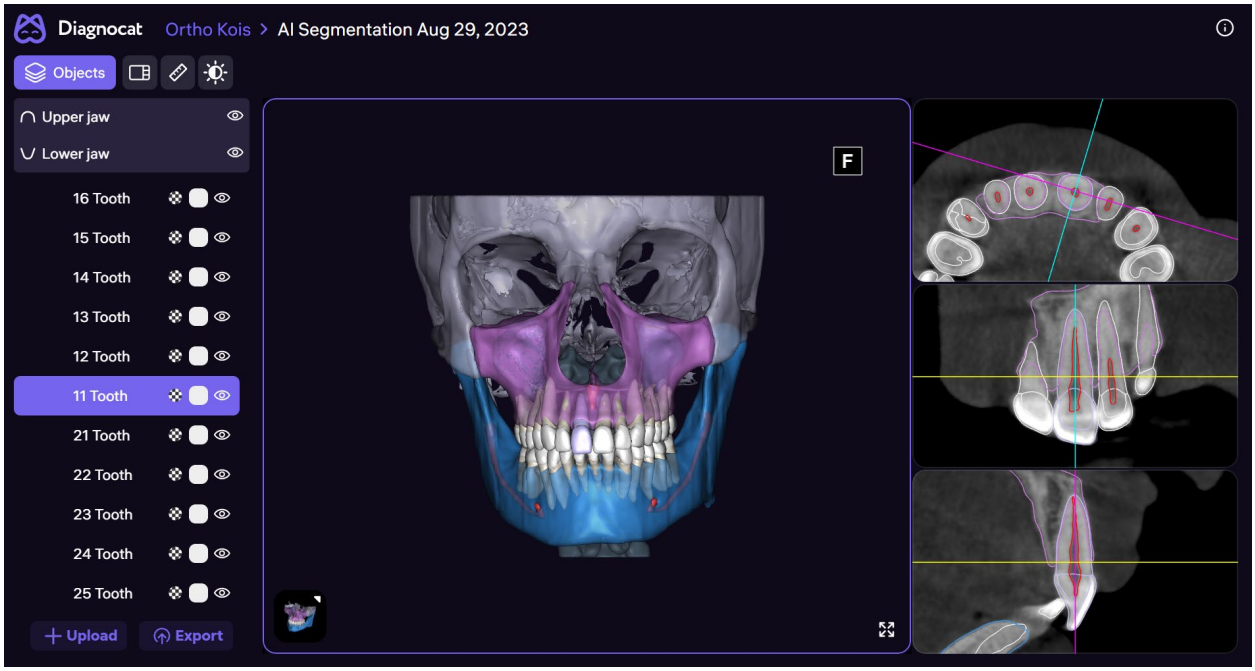


NAVIGATION

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

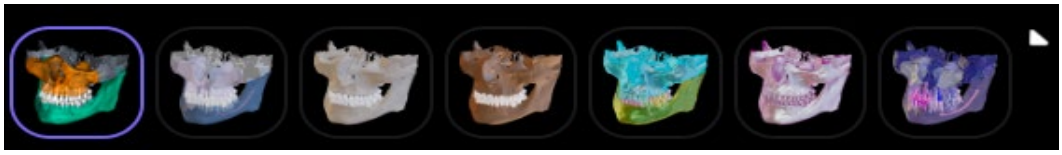
- Navigation Cube: Clicking on the cube icon  opens a panel that allows users to select different 3D model projections. By pressing the corresponding buttons within this panel, users can adjust the model's orientation to predefined views.


- 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).

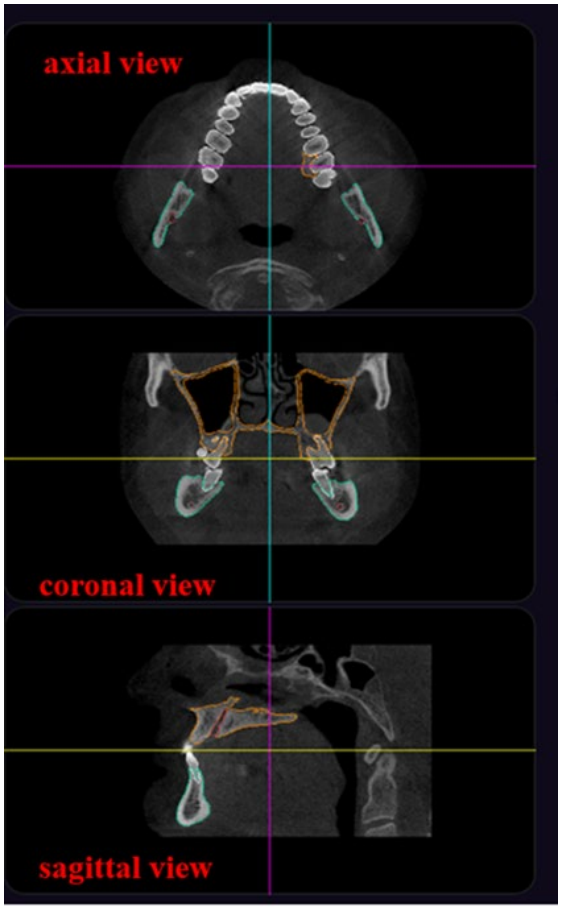


MAXIMIZE VIEWPORT

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.

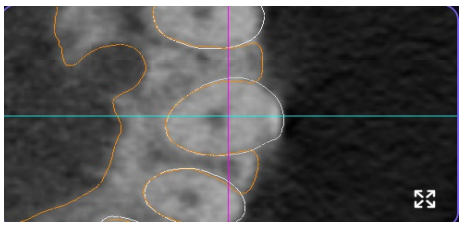


You can change the projections on the MPR panels using the mouse. Changes will be displayed in one of the MPR panels.

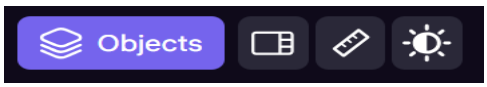
MAXIMIZE VIEWPORT

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.



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

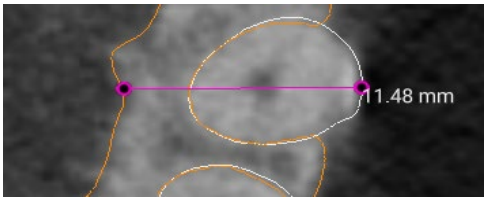
   3D scene and side view of MPR panels
- Brightness-contrast  – allows you to change the brightness or contrast of radiological images on MPRs. To do this, click the mouse on the MPRs and move the cursor up/down to increase/decrease brightness, respectively; click the mouse on the MPRs and move the cursor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

The ruler consists of a digital distance measurement tool that enables HCPs to measure distances (in mm) between two user-selected points within the MPR views.

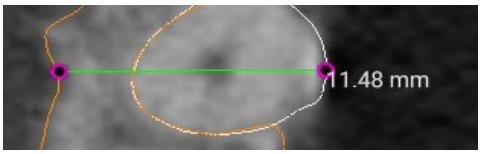
- Measurement Type: Linear distances only (point-to-point). Angular measurements or volumetric dimensions are not supported.

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.



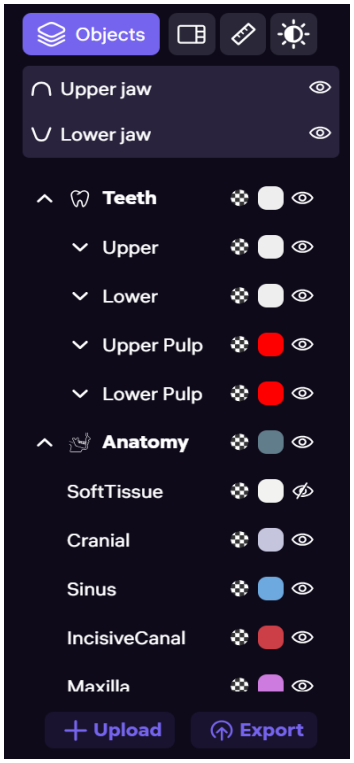
The user can delete the ruler object by clicking on the measurement on the MPR, whereby it should change color, and then clicking backspace or delete.



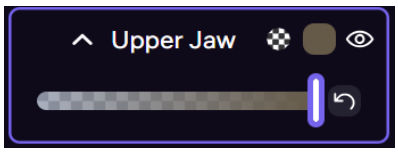
The user can use the “Undo” or Ctrl+Z buttons to undo the last action.

OBJECTS PANEL

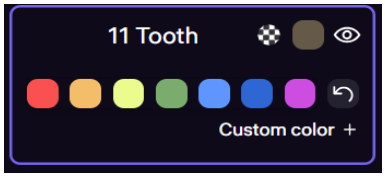
To open the Objects panel, click Objects in the Toolbar. The panel lists all anatomic objects in a tree structure, as shown below.



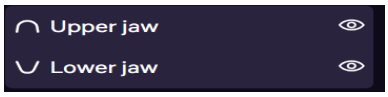
You can control the visibility (switch on/off) of any anatomic or artificial object via the Eye icon. To change the transparency of an object on the 3D scene, click the Transparency icon and move the slider to the desired value (illustrated below).



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



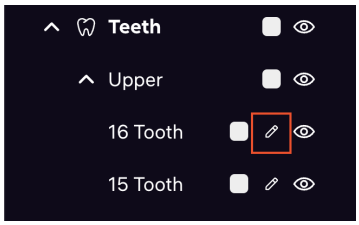
You can also switch on/off the visibility of groups of objects corresponding to a specific jaw in the upper part of the panel, using the Eye icon next to Upper jaw or Lower jaw.



16.7. Editing Segmentations

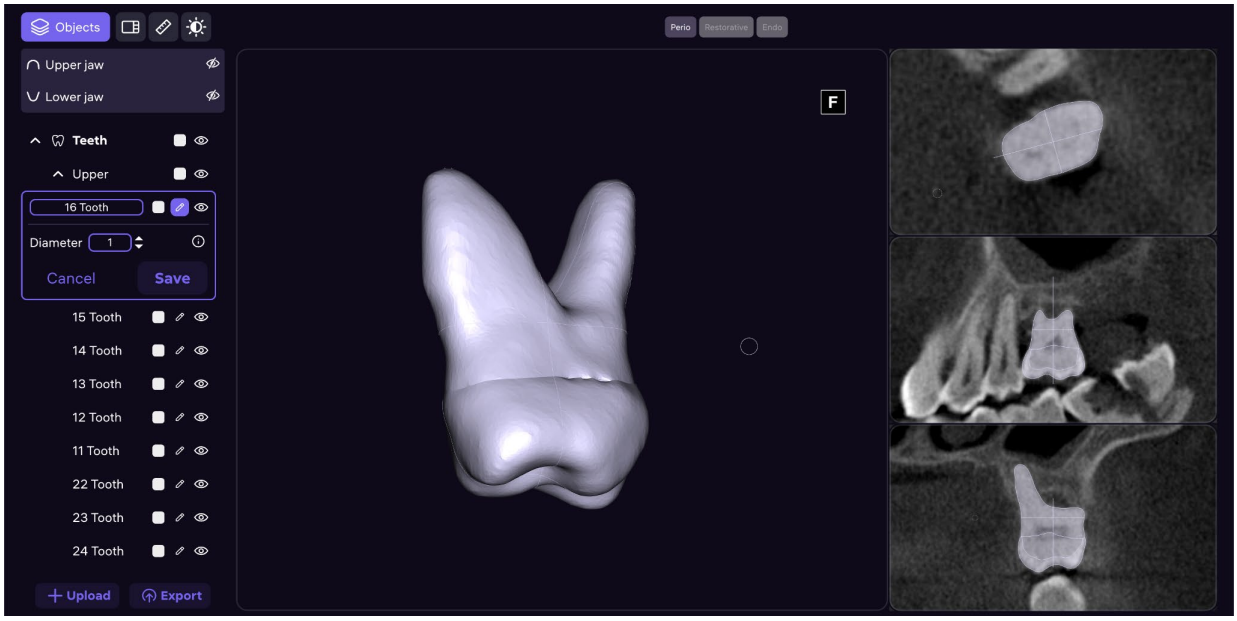
As semi-automated software, Segmentron Viewer allows users to edit the software-generated segmentations, if desired.

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:

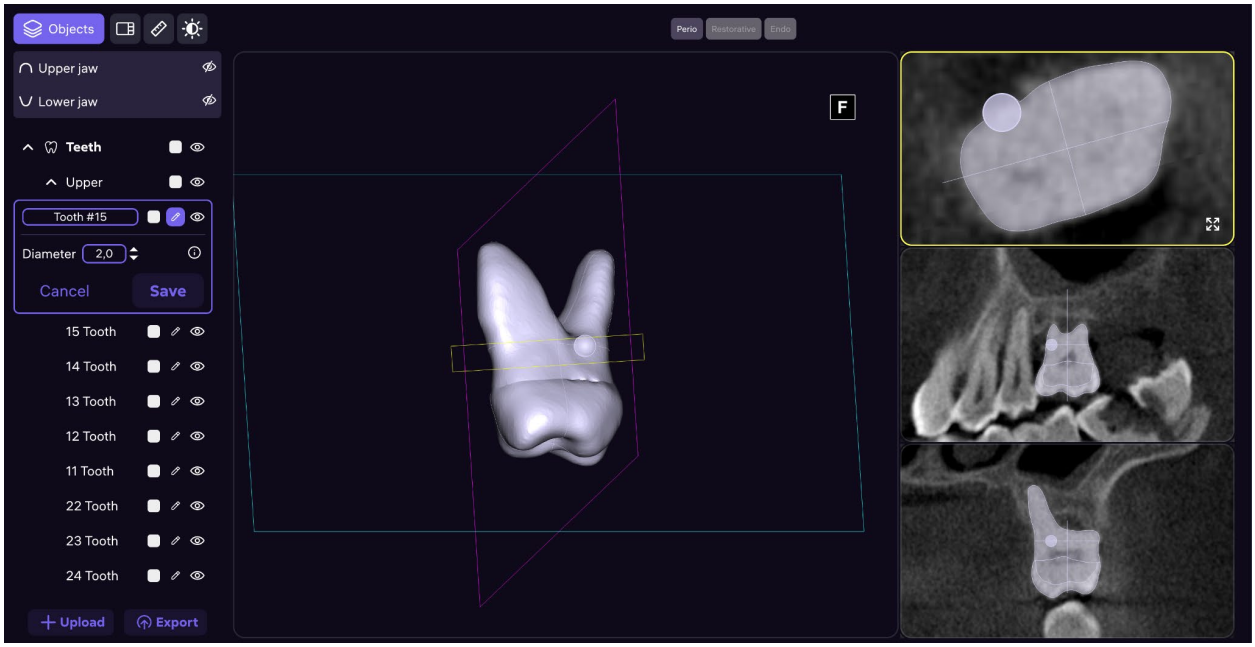
- The system highlights the segmented area of the selected object on all MPR planes.
- In the 3D scene, only the selected object is displayed.



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.

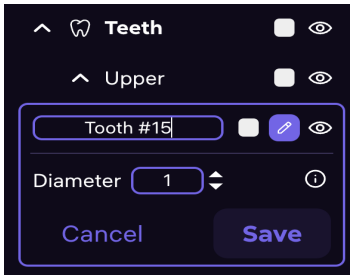


16.8. Editing Labels

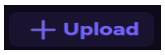
Segmentron Viewer also allows users to edit the software-generated classification labels

(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.

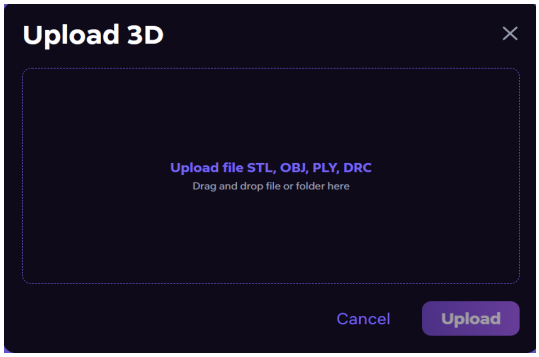


16.9. Upload and Export

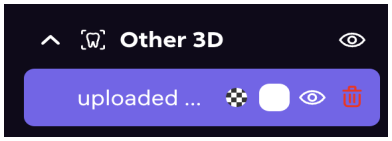


You can also upload your own 3D objects on the scene (in STL, OBJ, PLY, or DRC format) from your computer onto the scene. You may wish to do this, for example, to visualize or evaluate a previously segmented model from within Segmentron Viewer.

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.

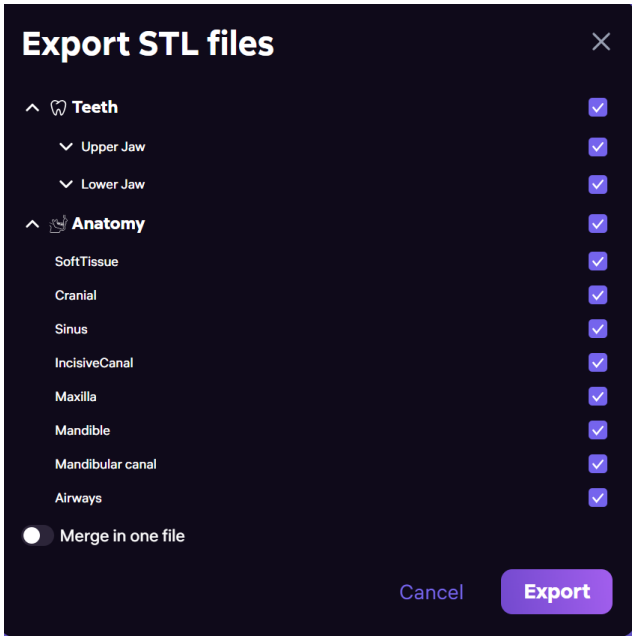


To export all anatomic and artificial objects listed in the Objects panel, click the Export button 

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.



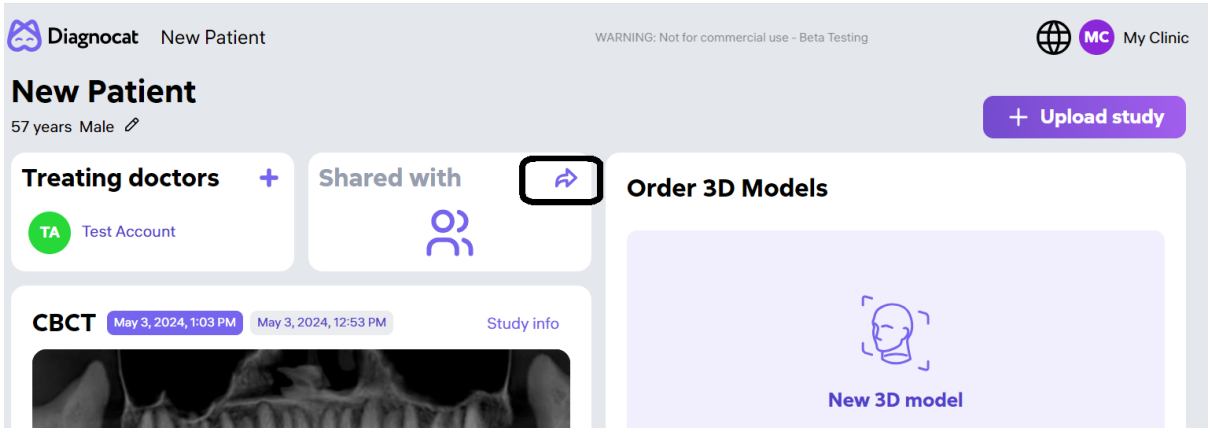
⚠ The STL export functionality is intended to facilitate visualization and communication. It is not intended for 3D printing of patient-specific treatment planning models or surgical guides.

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

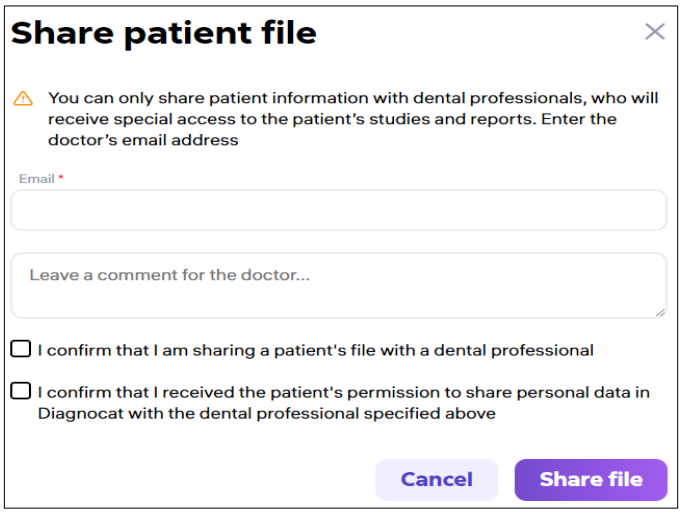
17. ADDITIONAL FUNCTIONS OF DIAGNOCAT UI

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.

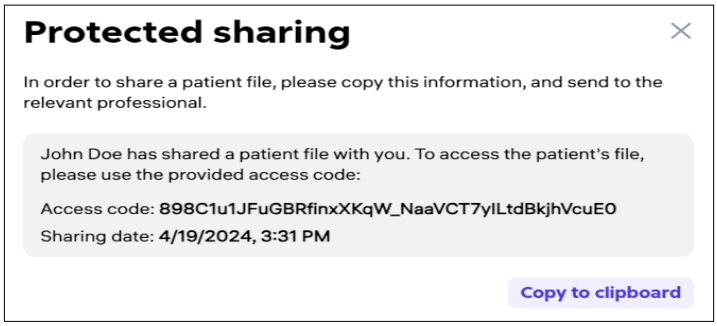


Click on the “Share” icon.

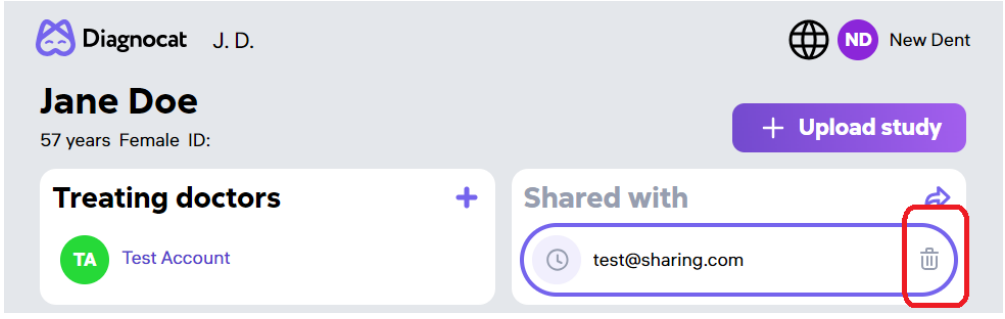


Enter the recipient’s email address, leave a comment for the doctor if necessary, and check the boxes (1) “I confirm that I am sharing a patient's file with a dental professional” and (2) “I confirm that I received the patient's permission to share personal data in Diagnocat with the dental professional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

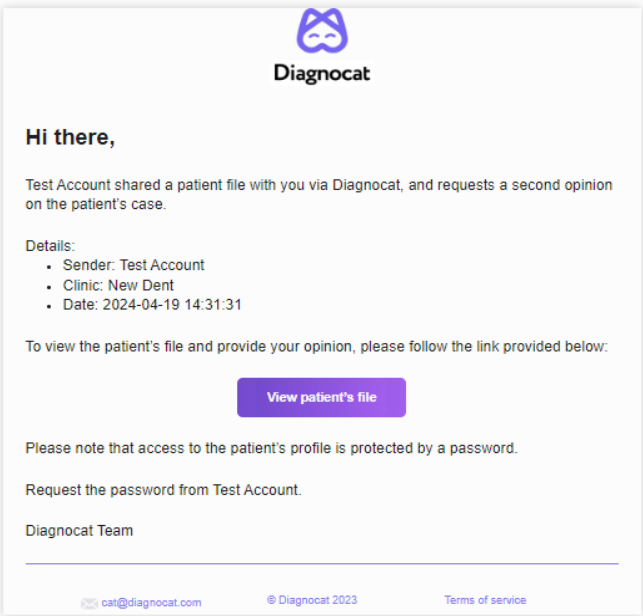
Since you are transferring sensitive data of patients, the sharing process is additionally protected with an Access code. Diagnocat generates this code, and you should copy it and send it to the person that should receive the patient file. You can do it via any service you use to communicate with other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

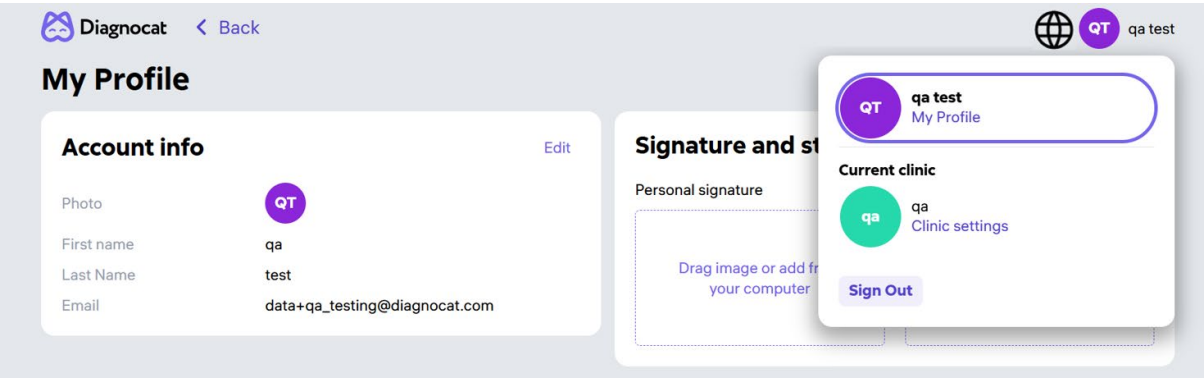


If the doctor doesn't have a Diagnocat account, they will be able to create a new one. Once finished, they will be prompted to their account where they can view reports of the shared patient.

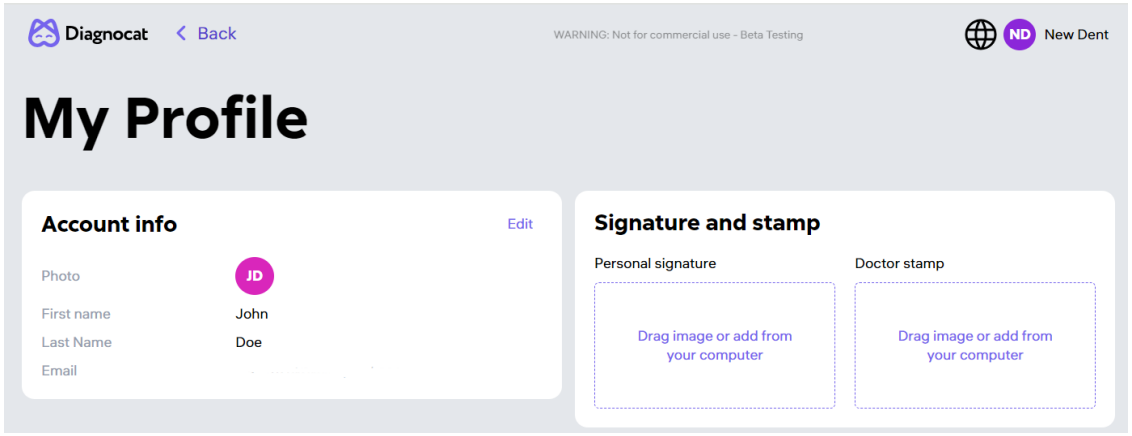
Access to each patient is allowed only after entering the Access code. The sender should provide this code.

17.2. Account and Clinic Settings

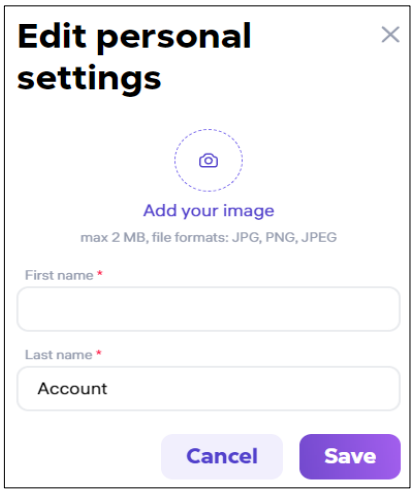
To get access to Account settings, click the arrow icon in the top right corner of the main page.



Inside you will find 2 main tabs:

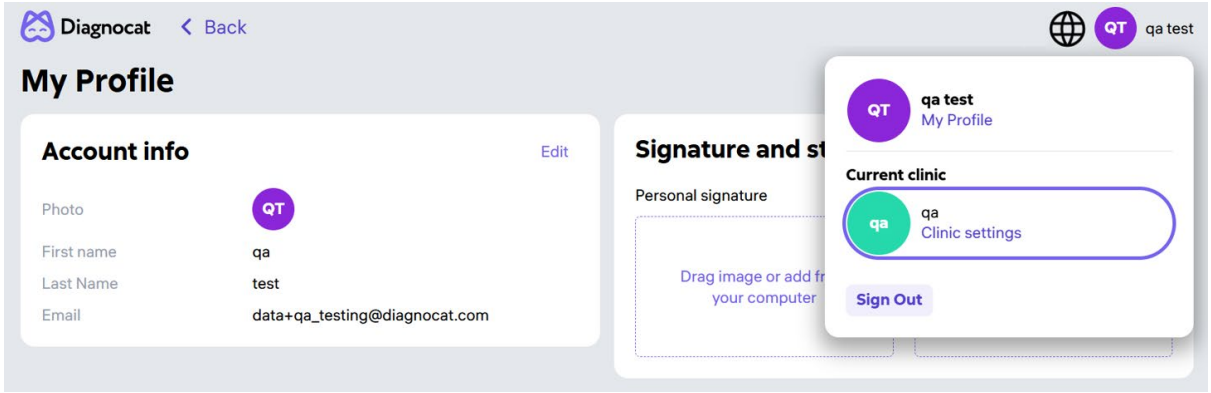


#1: Account info. You can change the account owner name, Add your photo.

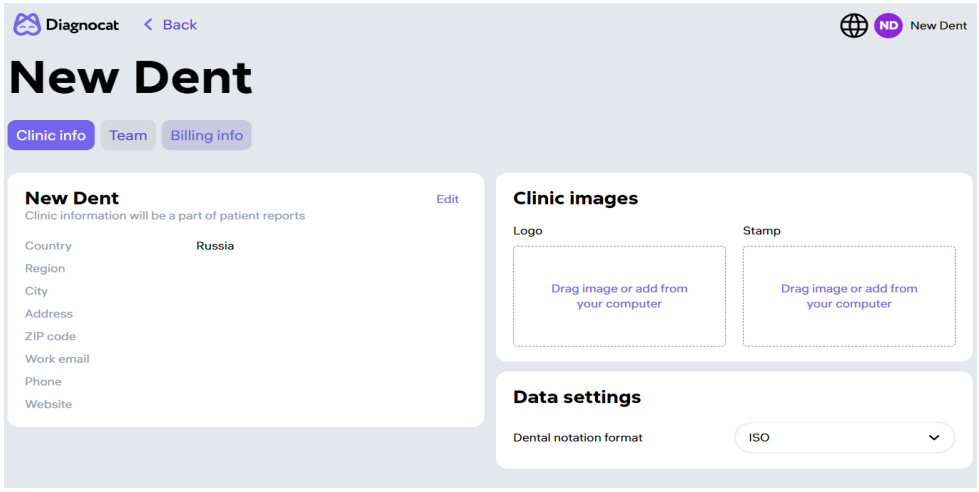


#2: Signature and stamp. You can add a personal signature and doctor stamp.

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.

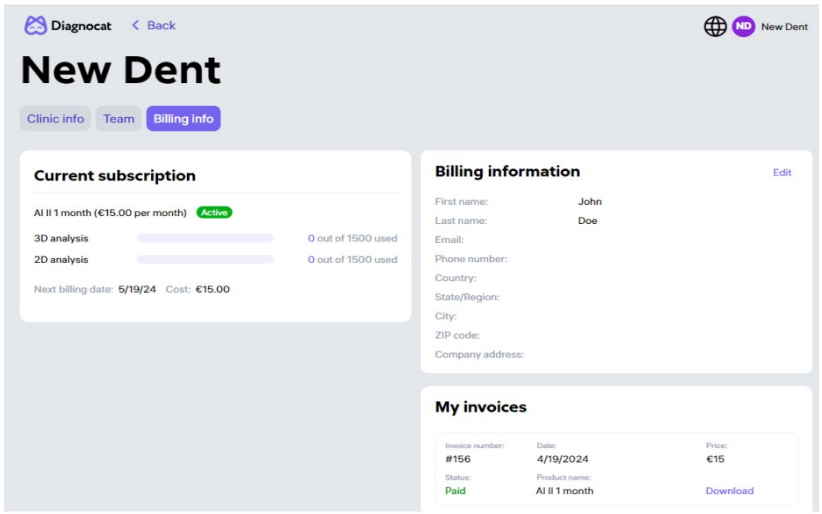
Note: to fill in the “Access level” field correctly, use the key on the "Team" page (see below).

Access levels

Access levels you can assign to team members.

Access levels	Owner	Clinical Leader	Treating Doctor	Non-clinical Member
Manage company settings	+	–	–	–
Manage payments and subscriptions	+	–	–	–
View and manage team	+	+	–	–
View and manage patient's files	+	+	+	+
Share patient's profile	+	+	+	–
Edit patient's reports	+	+	+	–

#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. PERFORMANCE TESTING

DGNCT LLC evaluated the performance of Segmentron Viewer in four retrospective standalone validation studies, comparing the software’s AI/ML-enabled segmentation and labeling performance against reference standards (“ground truth”). The primary objective in each study was to assess the agreement between the algorithm's output and the reference standard.

U.S. board-certified radiologists established a reference standard for each CBCT image, using manual segmentation (for the segmentation studies) or annotation (for the labeling study). The same CBCT images were then analyzed using Segmentron Viewer. For the segmentation studies, Dice Coefficient (DSC) was used as the primary endpoint to evaluate segmentation agreement between the algorithm and the reference standard. For the labeling study, overall accuracy was used to evaluate labeling agreement. The dataset used for the studies included CBCT scans sourced from a variety of geographic regions and demographics. All training and testing datasets included patients ≥14 years with permanent teeth. Studies were powered based on hypothesis testing, with confidence intervals calculated using bootstrapping methods, and pre-specified performance goals (PGs) established for each structure type. The studies are outlined below.

Primary endpoint results were also assessed across patient demographics (age, sex), scanner manufacturer, and geographic origin. This performance data, including the number of images evaluated in each subgroup (n), mean, standard deviation (SD), and 95% confidence intervals (CIs), is provided below each study overview. The secondary endpoint results are also summarized and confirm high reliability and robust agreement between automated and reference segmentations across all teeth, pulp groups, and 8 anatomical regions.

Diagnocat

1. *Tooth Segmentation:* This study assessed Segmentron Viewer's ability to segment and number teeth in 126 CBCT scans of permanent teeth from multiple geographic sites (US, EU, Canada, Israel). Ground truth segmentations were created by 3 independent board-certified U.S. radiologists. The patient population included a range of patients aged 14 and older, with nearly equal male-to-female ratio. Scans originated from five manufacturers (Carestream, Instrumentarium Dental, Planmeca, Sirona and Vatech Company Limited), with >50% of the data sourced from U.S.-based institutions. Across all teeth, Segmentron demonstrated strong segmentation agreement with the reference standard, as evidenced by the Dice Coefficient exceeding the pre-defined PG with a result of 0.96 (95% CI: 0.95, 0.96; $p < 0.0001$). Dice performance was consistent across subgroups based on patient age, sex, scanner manufacturer, and geographic location, as shown in the tables below.

Teeth Segmentation (Dice) Analysis Across Age Groups

Age Group	n	Mean	SD	Lower 95% CI	Upper 95% CI
14-21	34	0.967	0.015	0.966	0.968
22-39	47	0.955	0.024	0.953	0.956
40+	45	0.947	0.033	0.945	0.949

Teeth Segmentation (Dice) Analysis Across Sex

Sex	n	Mean	SD	Lower 95% CI	Upper 95% CI
Female	60	0.956	0.024	0.955	0.957
Male	66	0.955	0.029	0.954	0.957

Teeth Segmentation (Dice) Analysis Across CBCT Manufacturer

Manufacturer	n	Mean	SD	Lower 95% CI	Upper 95% CI
Carestream Dental/Health	13	0.962	0.027	0.959	0.965
INSTRUMENTARIUM DENTAL	28	0.952	0.030	0.950	0.954
Planmeca	26	0.950	0.030	0.948	0.952
Sirona	31	0.953	0.021	0.952	0.955
Vatech Company Limited	28	0.964	0.021	0.963	0.966

Teeth Segmentation (Dice) Analysis Across Geographic Region

Geographic Region	n	Mean	SD	Lower 95% CI	Upper 95% CI
Canada	14	0.953	0.024	0.951	0.955
European Union (EU)	18	0.959	0.019	0.957	0.960
Israel	17	0.958	0.019	0.956	0.960
United States (US)	77	0.955	0.029	0.954	0.956

Following outlier adjustment for tooth 17, the segmentation algorithm consistently met the predefined secondary endpoint performance goals across all teeth. The overall **HD95** was **0.30 mm [0.30–0.31]**, with per-tooth means ranging from **0.26 mm [0.24–0.28] to 0.34 mm [0.30–0.38]**. For **Volume Similarity (VS)**, the overall mean was **0.98 [0.97–0.98]**, with per-tooth means ranging from **0.96 [0.95–0.97] to 0.98 [0.97–0.98]**.

Diagnocat

2. *Pulp Segmentation:* This study assessed Segmentron Viewer's ability to segment dental pulp in 43 CBCT scans. Ground truth segmentations were created by three board-certified U.S. radiologists. Patients were aged 14 and older, with an equal sex distribution. CBCTs were acquired from 8 scanner manufacturers (HDXWILL, Instrumentarium Dental, Imaging Sciences International, KaVo, PaloDEx Group, Planmeca, Sirona and Vatech Company Limited), with more than 50% of the data sourced from U.S. institutions. Across the pulp of all teeth, Segmentron demonstrated strong segmentation agreement with the reference standard, as evidenced by Dice Coefficient (primary endpoint) = 0.88 (95% CI: 0.87, 0.89; $p < 0.0001$) – exceeding the pre-defined PG. Slightly lower performance was observed in incisors due to anatomical challenges with small pulp volumes. Dice performance was consistent across subgroups, as shown below.

Pulp Segmentation (Dice) Analysis Across Age Groups

Age Group	n	Mean	SD	Lower 95% CI	Upper 95% CI
14-21	13	0.899	0.045	0.884	0.915
22-39	15	0.881	0.052	0.868	0.894
40+	15	0.861	0.046	0.841	0.877

Pulp Segmentation (Dice) Analysis Across Sex

Sex	n	Mean	SD	Lower 95% CI	Upper 95% CI
Female	21	0.898	0.042	0.886	0.909
Male	22	0.871	0.053	0.857	0.884

Pulp Segmentation (Dice) Analysis Across CBCT Manufacturer

Manufacturer	n	Mean	SD	Lower 95% CI	Upper 95% CI
HDXWILL	6	0.917	0.039	0.904	0.928
INSTRUMENTARIUM DENTAL	5	0.892	0.051	0.858	0.925
Imaging Sciences International	7	0.844	0.047	0.822	0.865
KaVo	3	0.866	0.054	0.820	0.908
PaloDEx Group Oy	5	0.849	0.044	0.832	0.866
Planmeca	5	0.908	0.027	0.890	0.926
Sirona	5	0.882	0.032	0.861	0.902
Vatech Company Limited	7	0.881	0.039	0.858	0.904

Pulp Segmentation (Dice) Analysis Across Geographic Region

Geographic Region	n	Mean	SD	Lower 95% CI	Upper 95% CI
Canada	9	0.895	0.053	0.881	0.909
European Union (EU)	5	0.854	0.046	0.823	0.886
Israel	6	0.883	0.040	0.858	0.907
United States (US)	23	0.873	0.047	0.860	0.886

Diagnocat

For pulp segmentation, the algorithm met all secondary endpoint performance goals for both **HD95** and **VS**. The overall **HD95** was **0.28 mm [0.25–0.32]**. Per-tooth HD95 means ranged from 0.20 mm [0.15–0.25] in canines to 0.39 mm [0.32–0.46] in molars, with all categories meeting the goal. For **VS**, the overall mean was **0.98 [0.97–0.98]**. Per-tooth VS means ranged from 0.92 [0.901–0.94] in incisors to 0.94 [0.91–0.96] in canines.

3. *Anatomy Segmentation*: This study assessed Segmentron Viewer's ability to segment 8 anatomical structures (maxilla, mandible, maxillary sinus, mandibular canal, airways, cranial base, incisive canal, and facial soft tissue) in 56 CBCT scans. Ground truth was determined by expert radiologist segmentation. Patients were aged 14 and older, with an equal sex distribution. Scans were sourced from 8 manufacturers (Carestream, Instrumentarium Dental, Imaging Sciences International, KaVo, PaloDEx Group, Planmeca, Sirona and Vatech Company Limited), with >50% of the data sourced from U.S. institutions. Across all anatomical structures, Segmentron demonstrated strong segmentation agreement with the reference standard. The primary endpoint was met, as the Dice Coefficients for each anatomical region exceeded their respective pre-defined PGs. Dice performance was robust across all ages, sexes, scanner types, and geographic locations, as shown below.

Anatomy Segmentation (Dice) Analysis Across Age Groups

Structure	Age Group	n	Mean	SD	Lower 95% CI	Upper 95% CI
airways	14-21	17	0.954	0.028	0.939	0.967
	22-39	21	0.954	0.042	0.934	0.968
	40+	18	0.933	0.052	0.907	0.954
mandibular canal	14-21	17	0.884	0.029	0.872	0.897
	22-39	21	0.872	0.058	0.844	0.894
	40+	18	0.902	0.020	0.893	0.911
cranial base	14-21	17	0.820	0.108	0.770	0.862
	22-39	21	0.865	0.056	0.840	0.887
	40+	18	0.795	0.090	0.755	0.835
incisive canal	14-21	17	0.818	0.077	0.778	0.850
	22-39	21	0.858	0.057	0.832	0.881
	40+	18	0.868	0.062	0.839	0.893
mandible	14-21	17	0.974	0.011	0.969	0.979
	22-39	21	0.974	0.008	0.971	0.977
	40+	18	0.972	0.007	0.969	0.975
maxilla	14-21	17	0.892	0.027	0.880	0.906
	22-39	21	0.892	0.033	0.878	0.905
	40+	18	0.889	0.022	0.880	0.899
maxillary sinus	14-21	17	0.937	0.023	0.927	0.948
	22-39	21	0.937	0.022	0.928	0.947
	40+	18	0.911	0.040	0.891	0.928
facial soft tissue	14-21	17	0.976	0.014	0.969	0.982
	22-39	21	0.977	0.016	0.970	0.983

Structure	Age Group	n	Mean	SD	Lower 95% CI	Upper 95% CI
	40+	18	0.966	0.014	0.960	0.972

Anatomy Segmentation (Dice) Analysis Across Sex

Structure	Sex	n	Mean	SD	Lower 95% CI	Upper 95% CI
airways	Female	26	0.951	0.041	0.934	0.964
	Male	23	0.937	0.047	0.916	0.953
	Unknown	7	0.969	0.012	0.961	0.977
mandibular canal	Female	26	0.875	0.054	0.853	0.894
	Male	23	0.892	0.026	0.881	0.902
	Unknown	7	0.904	0.012	0.895	0.911
cranial base	Female	26	0.850	0.068	0.822	0.874
	Male	23	0.811	0.110	0.762	0.852
	Unknown	7	0.810	0.076	0.759	0.862
incisive canal	Female	26	0.853	0.049	0.834	0.870
	Male	23	0.846	0.080	0.812	0.876
	Unknown	7	0.843	0.090	0.777	0.898
mandible	Female	26	0.973	0.007	0.971	0.976
	Male	23	0.975	0.010	0.971	0.979
	Unknown	7	0.971	0.009	0.964	0.976
maxilla	Female	26	0.886	0.026	0.876	0.895
	Male	23	0.898	0.027	0.886	0.909
	Unknown	7	0.889	0.035	0.864	0.911
maxillary sinus	Female	26	0.929	0.023	0.921	0.938
	Male	23	0.934	0.034	0.920	0.947
	Unknown	7	0.908	0.043	0.874	0.932
facial soft tissue	Female	26	0.975	0.015	0.969	0.980
	Male	23	0.975	0.015	0.969	0.981
	Unknown	7	0.958	0.005	0.955	0.961

Anatomy Segmentation (Dice) Analysis Across CBCT Manufacturer

Structure	Manufacturer	n	Mean	SD	Lower 95% CI	Upper 95% CI
airways	Carestream Dental/Health	6	0.935	0.074	0.873	0.971
	HDXWILL	5	0.951	0.020	0.937	0.967
	INSTRUMENTARIUM DENTAL	6	0.974	0.011	0.967	0.982
	Imaging Sciences International	6	0.941	0.026	0.920	0.960
	J.Morita.Mfg.Corp.	5	0.934	0.022	0.918	0.950
	KaVo	4	0.973	0.008	0.966	0.978
	PaloDEx Group Oy	6	0.960	0.038	0.929	0.981
	Planmeca	6	0.943	0.037	0.912	0.963
	Sirona	6	0.927	0.071	0.867	0.968
	Vatech Company Limited	6	0.944	0.049	0.904	0.966
	Carestream Dental/Health	6	0.839	0.094	0.769	0.903

Diagnocat

Structure	Manufacturer	n	Mean	SD	Lower 95% CI	Upper 95% CI
mandibular canal	HDXWILL	5	0.883	0.015	0.870	0.892
	INSTRUMENTARIUM DENTAL	6	0.897	0.023	0.878	0.914
	Imaging Sciences International	6	0.906	0.016	0.893	0.916
	J.Morita.Mfg.Corp.	5	0.875	0.025	0.855	0.894
	KaVo	4	0.890	0.039	0.858	0.922
	PaloDEx Group Oy	6	0.891	0.017	0.878	0.902
	Planmeca	6	0.886	0.042	0.854	0.913
	Sirona	6	0.896	0.020	0.880	0.908
	Vatech Company Limited	6	0.891	0.044	0.860	0.922
cranial base	Carestream Dental/Health	6	0.795	0.067	0.739	0.842
	HDXWILL	5	0.889	0.040	0.858	0.921
	INSTRUMENTARIUM DENTAL	6	0.824	0.094	0.755	0.887
	Imaging Sciences International	6	0.715	0.097	0.655	0.799
	J.Morita.Mfg.Corp.	5	0.842	0.045	0.809	0.878
	KaVo	4	0.884	0.041	0.842	0.914
	PaloDEx Group Oy	6	0.842	0.062	0.797	0.884
	Planmeca	6	0.876	0.059	0.828	0.917
	Sirona	6	0.786	0.139	0.673	0.851
	Vatech Company Limited	6	0.865	0.062	0.819	0.907
incisive canal	Carestream Dental/Health	6	0.816	0.088	0.749	0.874
	HDXWILL	5	0.902	0.038	0.868	0.929
	INSTRUMENTARIUM DENTAL	6	0.842	0.080	0.780	0.902
	Imaging Sciences International	6	0.871	0.050	0.836	0.907
	J.Morita.Mfg.Corp.	5	0.854	0.053	0.816	0.901
	KaVo	4	0.826	0.052	0.786	0.869
	PaloDEx Group Oy	6	0.840	0.061	0.792	0.885
	Planmeca	6	0.870	0.034	0.845	0.894
	Sirona	6	0.810	0.115	0.720	0.877
	Vatech Company Limited	6	0.859	0.048	0.824	0.893
mandible	Carestream Dental/Health	6	0.974	0.004	0.971	0.976
	HDXWILL	5	0.979	0.002	0.978	0.981
	INSTRUMENTARIUM DENTAL	6	0.967	0.013	0.958	0.976
	Imaging Sciences International	6	0.976	0.006	0.972	0.981
	J.Morita.Mfg.Corp.	5	0.978	0.006	0.973	0.983
	KaVo	4	0.977	0.008	0.970	0.983
	PaloDEx Group Oy	6	0.972	0.009	0.966	0.979
	Planmeca	6	0.974	0.003	0.972	0.977
	Sirona	6	0.973	0.014	0.963	0.984
	Vatech Company Limited	6	0.969	0.008	0.962	0.974
maxilla	Carestream Dental/Health	6	0.897	0.020	0.882	0.911

Structure	Manufacturer	n	Mean	SD	Lower 95% CI	Upper 95% CI
	HDXWILL	5	0.909	0.027	0.886	0.928
	INSTRUMENTARIUM DENTAL	6	0.871	0.018	0.857	0.884
	Imaging Sciences International	6	0.898	0.024	0.881	0.914
	J.Morita.Mfg.Corp.	5	0.899	0.037	0.869	0.925
	KaVo	4	0.877	0.014	0.864	0.887
	PaloDEx Group Oy	6	0.886	0.032	0.862	0.908
	Planmeca	6	0.896	0.027	0.875	0.914
	Sirona	6	0.888	0.042	0.859	0.918
	Vatech Company Limited	6	0.891	0.026	0.873	0.910
maxillary sinus	Carestream Dental/Health	6	0.912	0.025	0.893	0.929
	HDXWILL	5	0.941	0.040	0.902	0.966
	INSTRUMENTARIUM DENTAL	6	0.921	0.023	0.904	0.938
	Imaging Sciences International	6	0.925	0.043	0.890	0.948
	J.Morita.Mfg.Corp.	5	0.955	0.017	0.940	0.968
	KaVo	4	0.933	0.006	0.928	0.938
	PaloDEx Group Oy	6	0.910	0.048	0.866	0.939
	Planmeca	6	0.923	0.023	0.907	0.941
	Sirona	6	0.940	0.022	0.925	0.955
	Vatech Company Limited	6	0.938	0.029	0.918	0.959
facial soft tissue	Carestream Dental/Health	6	0.961	0.006	0.956	0.964
	HDXWILL	5	0.991	0.003	0.988	0.992
	INSTRUMENTARIUM DENTAL	6	0.968	0.014	0.959	0.980
	Imaging Sciences International	6	0.973	0.013	0.963	0.983
	J.Morita.Mfg.Corp.	5	0.981	0.013	0.969	0.989
	KaVo	4	0.986	0.017	0.969	0.994
	PaloDEx Group Oy	6	0.968	0.017	0.957	0.981
	Planmeca	6	0.968	0.018	0.956	0.982
	Sirona	6	0.969	0.014	0.958	0.979
	Vatech Company Limited	6	0.975	0.016	0.964	0.988

Anatomy Segmentation (Dice) Analysis Across Geographic Region

Structure	Geographic Region	Mean	SD	Lower 95% CI	Upper 95% CI
airways	Canada	0.937	0.046	0.893	0.966
	European Union (EU)	0.970	0.012	0.961	0.978
	Israel	0.941	0.054	0.891	0.971
	United States (US)	0.946	0.043	0.933	0.958
mandibular canal	Canada	0.907	0.009	0.898	0.915
	European Union (EU)	0.911	0.017	0.899	0.924
	Israel	0.912	0.016	0.899	0.924
	United States (US)	0.876	0.045	0.861	0.889
cranial base	Canada	0.814	0.047	0.771	0.855

	European Union (EU)	0.891	0.061	0.841	0.926
	Israel	0.839	0.055	0.796	0.883
	United States (US)	0.820	0.096	0.789	0.847
incisive canal	Canada	0.880	0.027	0.857	0.906
	European Union (EU)	0.863	0.058	0.816	0.896
	Israel	0.856	0.044	0.823	0.895
	United States (US)	0.843	0.073	0.819	0.862
mandible	Canada	0.977	0.013	0.970	0.990
	European Union (EU)	0.972	0.006	0.967	0.977
	Israel	0.965	0.009	0.958	0.972
	United States (US)	0.975	0.008	0.972	0.977
maxilla	Canada	0.889	0.029	0.868	0.915
	European Union (EU)	0.875	0.031	0.853	0.898
	Israel	0.871	0.020	0.854	0.887
	United States (US)	0.896	0.027	0.888	0.905
maxillary sinus	Canada	0.913	0.010	0.905	0.921
	European Union (EU)	0.903	0.044	0.866	0.927
	Israel	0.917	0.011	0.908	0.926
	United States (US)	0.936	0.030	0.926	0.944
facial soft tissue	Canada	0.953	0.003	0.951	0.955
	European Union (EU)	0.961	0.011	0.955	0.970
	Israel	0.965	0.004	0.962	0.968
	United States (US)	0.978	0.015	0.973	0.982

For anatomical structures, Segmentron Viewer consistently exceeded the predefined performance goals for both **HD95** and **Volume Similarity (VS)** with strong statistical significance. The overall **HD95** values ranged from **0.32 mm [0.30–0.34] (mandible)** to **4.74 mm [4.10–5.39] (facial soft tissue)**. **VS values ranged from 0.87 [0.84–0.90] (cranial base) to 0.99 [0.98–0.99] (mandible).**

4. *Labeling Performance:* This study assessed the accuracy of labels automatically generated by the device for teeth, anatomical structures, and pulp on 40 CBCT scans from the larger validation dataset. Ground truth labels were provided by a board-certified radiologist. The study included scans from 20 male and 20 female patients, ages 14 and up. The dataset covered five scanner manufacturers (Carestream, Imaging Sciences International, J.Morita Mfg. Corp., Sirona and Vatech). 65% of scans were sourced from healthcare institutions in the U.S. Across all teeth, pulp, and anatomical structures, Segmentron Viewer achieved a labeling accuracy of 100%, demonstrating strong concordance between the labels automatically generated by the device and those determined by an expert radiologist.

Training Overview

Segmentron Viewer employs proprietary 3D convolutional neural networks (3D U-Net variants) for CBCT-based segmentation and labeling of dental and anatomical structures. The

models were trained on a multinational dataset annotated by expert radiologists. Only patients ≥14 years with permanent teeth were included in training. All known limitations are disclosed in Section 8 of this manual.

The deployed AI/ML model is locked post-training. Any future updates will undergo full revalidation against a held-out dataset under the same statistical framework.

Each core model—Tooth Segmentation, Anatomy Segmentation, and Pulp Segmentation—was trained and internally tested on datasets that reflect real-world clinical diversity. Training and testing included all age groups, genders, major global regions (Israel, US, EU), and over 20 scanner manufacturers. Performance was evaluated on internal test sets using Dice coefficient, Hausdorff distance, and volumetric similarity (VS).

19. TROUBLESHOOTING, MAINTENANCE AND SERVICE

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

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

20. CONTACT INFORMATION (FOR ASSISTANCE)

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

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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.