Diagnocat

Dentist's virtual assistant in treatment planning

DIAGNOCAT AIS

User Manual

Version 2.0

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Overview of User Manual

This manual describes the Diagnocat AIS Software and provides training to dentists on the use of the software. Diagnocat's clinical intelligence platform provides a state-of-the-art way of viewing your radiographs and presenting findings to your patients by applying artificial intelligence and identifying possible areas of concern in a real-time, user-friendly dashboard.

This User Manual is written in English.

This user manual is used solely for the purpose of explaining the use of Diagnocat AIS.

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Users are recommended to read this manual carefully before starting use of Diagnocat AIS.

Note: This Instructions for Use is intended to assist users in the safe and effective use of the medical device software described herein. This manual does not describe the use of the IT equipment on which the Diagnocat AIS software is installed. Refer to the documentation of the IT equipment concerned.

Note: The 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.

Accessing this User Manual

This User Manual can be accessed directly from the Diagnocat platform, by clicking on the icon "About" at the end of the page, then choosing the option from the drop-down menu.

Symbols used in the manual/ labeling

	Manufacturer

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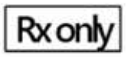
	Follow instructions for use
	Caution (WARNING, PRECAUTION, or Note)
	Medical device
	Device complies with the European Directive on Medical Devices EU MDR 2017/745
	Prescription use only (CAUTION: Federal law restricts this device to sale by or on the order of a licensed dental professional.)

Device information

Name: Diagnocat AIS

Relevant Diagnocat Version: 2.0

Device UDI: 860010268070

Regulatory Requirements

Diagnocat AIS software complies with the following regulatory requirements:

- ISO 13485:2016
- Regulation (EU) 2017/745
- Canadian Medical Devices Regulations SOR 98-282

Compliance - This medical product software complies with relevant international and national standards and laws. Information on compliance will be supplied on request; manufacturer contact details are written above.

This medical product software must be installed on appropriate IT equipment that complies with relevant international and national laws and standards on EMC (Electro-Magnetic 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.

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Precautions

Before attempting to use the Diagnocat AIS device, you must read these Instructions for Use thoroughly, paying particular attention to all PRECAUTIONS, and Notes. You must pay special attention to all the information given, and procedures described, in this Manual. 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 Diagnocat AIS.
- Users should read this manual thoroughly before using this product.
- In order to use the full functions of Diagnocat AIS, please follow the specifications described in this manual.
- Backup - 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.

Key Features of Diagnocat

Diagnocat AIS allows users to perform the following functions:

1. Managing patient information

2. Acquiring images from equipment and manage storage

3. Viewing patient images (provides tools for image processing and viewing functions)

4. Reinforcing counseling through counseling content support

5. Generating a report using patient oral images

Diagnocat AIS is a web application. It can be used in a network environment. Patient information, studies and reports can be accessed from multiple workspaces.

Product description

Diagnocat AIS is a computer-assisted detection software-only device designed for dental image analysis and management. It facilitates the interpretation of Cone Beam Computed Tomography (CBCT) scans, Panoramic X-Ray, and Intraoral X-Ray images, leveraging deep learning algorithms and artificial intelligence (AI) to assist in identifying anatomical structures and dental conditions. The software generates AI-assisted radiological reports that can be reviewed and edited by dental professionals. It is designed to optimize radiological workflows by automating key processes such as:

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- AI-Powered Image Uploading, Processing, and Management
- AI-Assisted Screening and Analysis of CBCT, Panoramic X-Ray, and Intraoral X-Ray images
- Automated AI-Driven Segmentation, Annotation, and Reporting
- Patient record management, including treatment history and documentation for administrative use.

I Key features and functionalities:

1. AI-Powered Image Visualization and Navigation

Diagnocat AIS enables users to upload, navigate, and analyze previously acquired dental imaging studies with AI-enhanced tools:

- Panoramic Reconstruction View: Provides a broad visualization of the dentition, aiding in treatment planning and anatomical orientation.
- Multiplanar Reformatting (MPR) Slices: AI-enhanced MPR slices allow detailed examination of each tooth for better diagnostics by dental professionals.
- AI-Assisted Point of Interest Identification: Automatically highlights key anatomical structures and areas of interest.

2. AI-Based Tooth Detection, Localization, and Numeration

Diagnocat AIS employs deep learning image processing techniques to accurately detect, segment, and number teeth in CBCT, Panoramic X-Ray, and Intraoral X-Ray images.

- Tooth Segmentation Algorithm: AI-driven segmentation facilitates identification and numbering of teeth.
- Automated and Interactive Adjustments: Users can modify AI-generated segmentations for enhanced accuracy.

3. AI-Assisted Detection and Localization of Dental Conditions

The software uses AI-driven to differentiate between normal anatomical structures and potential areas of concern indicative of dental conditions.

- Automated AI Condition Segmentation: AI highlights areas of concern indicative of dental conditions such as caries, periapical radiolucency, etc.
- AI-Powered Probability Scores: Diagnocat AIS assigns probability values to detected conditions, helping dental professionals prioritize findings.

4. Color-Coded AI Overlays for Enhanced Interpretation

Diagnocat AIS applies AI-generated, color-coded masks to highlight and categorize dental conditions: Periodontal (Perio), Endodontic (Endo), Restorative Findings.

- Enhanced Visual Interpretation: AI overlays enable dental professionals to quickly assess conditions without manual annotations.

5. AI-Guided Periodontal Bone Loss (PBL) Measurements with Interactive Tools

Diagnocat AIS includes AI-powered PBL measurement tools for periodontal analysis.

- Automated AI Measurement Calculations: AI detects and calculates bone loss levels.
- Manual Adjustment Capabilities: Interactive tools allow dental professionals to refine measurements for accuracy.

II Additional non-device functions features (Not Medical device features, no AI is involved)

The software also features non-device functions that supplement its achievement of the intended clinical use**:**

- User Interface: The software includes a user-friendly interface that enables healthcare professionals to efficiently manage patient information.
- Integration: Diagnocat AIS integrates with various dental scanning devices, allowing seamless use across different imaging systems.

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- Cloud-Based Storage: Scans and reports are stored and archived in the cloud, facilitating access from multiple computers. Users can view, edit, and share information with other dental professionals.
- Data Security: Diagnocat AIS emphasizes the security and privacy of patient data, implementing industry-standard encryption and complying with healthcare regulations. Robust authentication measures and access controls (e.g., passwords) are in place to protect sensitive medical information.

Intended Use

The Diagnocat AIS automated information system is designed to facilitate the storage, processing, and analysis of digital dental images through the application of artificial intelligence (AI). Diagnocat AIS is intended to facilitate the storage, processing, and analysis of digital dental images to assist healthcare professionals in radiological examinations. The software supports the automated screening and analysis of CBCT, Panoramic X-Ray, and Intraoral X-Ray images for further diagnosis provided by dental professionals. It enables the structured documentation and visualization of imaging data while providing AI-assisted findings for review.

Diagnocat AIS processes files of any area of the patient's maxillofacial region. Diagnocat AIS is designed for use by medical professionals (dentists, orthodontists, radiologists, etc.) for education purposes and highlights anatomical areas, common conditions and previous treatments.
Diagnocat AIS automatically produces radiological reports for easier viewing and documentation of investigation for a particular patient. Diagnocat AIS can also be used by managers and administrators of clinics to document patient treatment history and maintain personal records. This is a reusable, non-invasive device for image processing and documentation. The Software cannot be used to make a decision about the diagnosis, presence or absence of a disease on the basis of the online screening, without additional investigation.

The Software cannot be used for direct diagnosis and clinical decision making.

NOTE: To ensure appropriate usage and data security, Diagnocat AIS includes different levels of user access based on professional roles, as outlined in Chapter 9.2 of the Instructions for Use (IFU).

Indication for Use

Diagnocat AIS is indicated for assisting dental professionals in reviewing and interpreting radiological images, including CBCT scans, Panoramic X-Rays, and Intraoral X-Rays. It utilizes AI algorithms to help identify anatomical structures, dental conditions and previous treatment, highlight potential areas of concern, and generate structured radiological reports. The software supports radiological examinations by automating key activities, including:

- Uploading, screening and analyzing CBCT (Cone-Beam Computed Tomography), Panoramic X-Ray, and Intraoral X-Ray images.
- Saving, sharing, editing, and documenting diagnostic images and associated findings.

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- Providing structured AI-assisted radiological reports to aid dental professionals in reviewing imaging data.

Detected Conditions and Pathologies

Full list of detected conditions and pathologies:

Maxillofacial Cone-Beam Computed Tomography (CBCT) scans:

1. Tooth Type: Tooth, Implant, Pontic, Root fragment, Missing, Tooth germ.
2. Anatomy:
    - Number of roots: 1 root, 2 roots, 3 roots;
    - Number of canals: 1 canal, 2 canals, 3 canals, 4 canals.
3. Periodontium: Periodontal Bone Loss mild, Periodontal Bone Loss moderate, Periodontal Bone Loss severe, Horizontal type, Mixed type, Furcation lesion, Dental calculus.
4. Position: Impaction, Horizontal displacement.
5. Crown: Filling, Artificial crown, Indirect restoration, Orthodontic appliance, Pulp stone, Attrition, Abfraction, Crown defect > 50%, Caries signs.
    - For Caries signs:
        - Depth: Enamel, Dentin, With pulp exposure, Root;
        - Surface: Mesial, Distal, Occlusal, Buccal, Vestibular.
6. Roots: Canal obliteration, Hypercementosis, Apicoectomy.
7. Endodontic treatment: Endodontically treated tooth:
    - Obturation: Adequate obturation, Short filling, Overfilling, Missed canal;
    - Quality: Adequate density, Voids present in the root filling;
    - Post And Core: Cast post and core, Fiberglass post, Metal post, Post.
8. Implant: Peri-implantitis.
9. Periradicular pathologies: Periapical radiolucency, PDL space widening in the periapical region, PDL space widening along the root, Periapical radiopacity, Signs of communication with maxillary sinus.
10. Non-dental findings: Signs of bone structure abnormality, Signs of maxillary sinus abnormality.

Intraoral X-Ray:

1. Tooth Type: Tooth, Implant, Pontic, Missing.
2. Periodontium: Periodontal Bone Loss, Furcation lesion, Dental calculus.
3. Crown: Filling, Artificial crown, Orthodontic appliance, Pulp stone, Overhang, Lack of the Interproximal Contact, Caries signs, Secondary caries.
4. Endodontic treatment: Pulpotomy, Endodontically treated tooth:
    - For Endodontically treated tooth:
        - Obturation: Adequate obturation, Short filling, Overfilling;
        - Quality: Adequate density, Voids present in the root filling;
        - Post And Core: Cast post and core, Post.

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5. Periradicular pathologies: Periapical radiolucency.

Panoramic X-Ray:

1. Tooth Type: Tooth, Implant, Pontic, Root fragment, Missing, Tooth germ.
2. Periodontium: Periodontal Bone Loss, Furcation lesion, Dental calculus.
3. Position: Impaction.
4. Crown: Filling, Artificial crown, Overhang, Lack of the Interproximal Contact, Caries signs, Secondary caries.
5. Endodontic treatment: Endodontically treated tooth:
    - Obturation: Adequate obturation, Short filling, Overfilling;
    - Quality: Adequate density, Voids present in the root filling;
    - Post And Core: Cast post and core, Post.
6. Periradicular pathologies: Periapical radiolucency.
7. Non-dental findings: Signs of bone structure abnormality, Signs of maxillary sinus abnormality.

The intended users

Dentists, dental specialists, oral maxillofacial radiologists.

Intended patient target group

Diagnocat AIS is intended for use in the analysis and processing of digital dental images for patients of all age groups, from 3 years old.

Intended use environment

Diagnocat AIS is a cloud-based software designed for use in various professional healthcare environments, including but not limited to:

- Dental Clinics: support diagnostics by providing a second opinion in routine dental examinations for doctors and enhancing patient education.
- Radiology Centers: assists in the diagnostic interpretation by offering a second opinion for OMF(Oral and maxillofacial) radiologists.
- Hospitals and Medical Institutions: facilitates multidisciplinary case assessments, enabling collaboration among various medical specialists.
- Educational and Research Institutions: for training and academic purposes.
- Dental Laboratories: Diagnocat AIS offers generation of 3D STL models based on CBCT, widely used in digital dentistry treatment planning.
- Remote/Telemedicine Settings: for sharing and reviewing radiological data remotely.

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Contraindications

There are no specific contraindications for the use of Diagnocat AIS when the device is used properly. It is the clinician's responsibility to assess whether some specific treatment planning decisions (e.g. tooth movements, tooth extractions) can be carried out in practice during the treatment. However, users must adhere to all warnings and limitations outlined in this manual to ensure accurate results and safe application.

Warnings, precautions and limitations

It is forbidden to download or transmit any messages or content of any type that may disregard or violate any of the rights of any party.

It is forbidden to use this Software for any purpose in violation of local, state, national or international laws.

You may not use this application to publish or transmit any material that is illegal, obscene, threatening, abusive, slanderous, hateful or embarrassing to any other person or organization

Diagnocat AIS does not give any guarantees regarding the time required for processing any request; and if you are faced with an emergency you should not seek assistance from this guide but instead should call emergency medical service immediately.

Clinicians should review Diagnocat AIS reports concurrently with original images before making a final determination on a case.

Diagnocat AIS is an adjunct tool and does not replace the role of the clinician. Clinicians must not use the CAD generated output as the primary interpretation.

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Diagnocat AIS is not designed to detect findings other than is listed in Intended Use. Clinicians should review original images for all suspected pathologies.

The performance of Diagnocat AIS depends on the quality and accuracy of the imaging of the scan as well as the model scan imported. Relevant anatomical structures must be visible in the scans.

Diagnocat AIS should be used according to the manual.

Diagnocat AIS assists only in bone level detection and measurement, not interpretation or diagnosis. It should not be the sole tool for making diagnostic or treatment decisions.

The product is not 100% sensitive, and some bone level may not be detected.

To ensure precise analysis and correct data interpretation, all X-ray images and CBCT scans must meet the recommended quality standards outlined in the “Data Constraints” section.

Ensure that all uploaded X-ray images and CBCT scans meet the required quality standards for detecting dental conditions and 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.

Please do not upload DICOM files with limitations on size more than 1GB and CBCT volume, 50 cm3, which is applied if the height dimension (axial) is less than half the width/length dimension. Detailed DICOM prerequisites are provided in the “Data Constraints” section of this user manual.

The Software cannot be used for direct diagnosis and clinical decision making.

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Required Training and Qualifications

Users of this medical product software must receive adequate training to ensure proper use. Please carefully review these Instructions for Use. While formal training is not required, the sales team provides a basic overview of the software's functionalities 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.

Device Security and Privacy

Cybersecurity

Before using the Diagnocat AIS device, 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 Diagnocat AIS 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

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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.

Customer Role in the Product Security Partnership

Security of Diagnocat products 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 Diagnocat AIS 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.
- Awareness 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 Diagnocat AIS and access to information managed by the product.

Regulatory Controls

Protecting Personal Information

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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/).

Protecting Personal Health Information

Considering the nature of the Diagnocat 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).

The Diagnocat software does not store the patient's health information. However, the information transferred to the product is not encrypted. Unencrypted patient health information will be present in transferred DICOM data and algorithm analysis results.

Thus, particular care must be taken with this information to ensure the utmost security and confidentiality in data transferring to and from the product.

Removable media, such as paper, may be used for purposes of the Diagnocat AIS conditions software 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 the Diagnocat AIS software 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 a virus scanner.

Be aware that inserting removable media like USB storage products, CDs, DVDs can introduce a virus to the medical product / network.

Logical Access Control

Regular users do not have direct access to Diagnocat AIS software. Only authorized specialists (like institution’s IT specialists/administrators, Diagnocat AIS software administrators) have access to the product. However, they have privileged access which requires strict control.

Implement stringent control of access to the system:

● Allow access only to the personnel who is responsible for service and administration of the product;

● Ensure use of strong passwords by the users;

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● Ensure that the users keep their password secretly;

● 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 the Diagnocat software incorporates state-of-the-art security and privacy protection, a remote possibility remains that a security or confidentiality breach may occur.

Advise the users of the product and analysis results to contact Diagnocat promptly and report about occurred security events to allow Diagnocat to respond to the incident with no delay.

Compatibility

Diagnocat AIS integrates with other unregulated (Medical Device Data Systems (MDDS) developed by DGNCT LLC, including Billing, Desktop (Diagnocat Imaging), and User Interface (UI) products.

Billing product performs invoice generation, payment processing, recurring billing, and automated notifications and reminders about payment. The device combines the proprietary AI algorithms and manual tools for Billing. Billing product is considered unregulated (Medical Device Data Systems (MDDS) and operates exclusively in conjunction with Diagnocat's primary product and its interface.
Diagnocat Imaging is an application that can capture dental images from imaging software and upload them to the Diagnocat AIS Web Application (MDDS application). This application facilitates automatic image upload, streamlining the process and reducing manual intervention.

Diagnocat Imaging functionality includes:

- Login with existing Diagnocat account;
- Dashboard for monitoring all uploaded studies;
  - Detection of new incoming studies;
  - Automated upload of studies from connected X-ray devices;
  - Automated generation of the patient cards from DICOM-file;
  - Photo connector for uploading photo studies to patient card;
  - Weblink for quick access to the generated reports;
  - Queue management of studies for deferred upload;
- History of all uploads (activity log);
- Integration configuration with dental software/hardware;

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- Application settings;
  - Language;
  - Settings to enable auto-upload of studies / auto-generation of reports;
  - Support for various image types;
  - Path to temporary folder;
  - Automatic removal of studies;
  - Automatic creation of new patient records.

The User Interface (Diagnocat UI) product offers a graphical interface designed to facilitate user interaction with the software medical device, enabling the execution of various functions such as device setup, patient data monitoring, and adjustment of device settings. The UI integrates proprietary AI algorithms with manual tools to enhance user experience and functionality.

The UI product is classified as unregulated under Medical Device Data Systems (MDDS) guidelines and operates exclusively in conjunction with the Diagnocat product.

Key UI functionalities include:

1. **User Account Management:**
   - Create a new user account.
   - Log in to an existing Diagnocat user account.
   - Sign out from the account.
2. **Organization/Clinic Setup:**
   - Set up a new organization/clinic and become its owner with a new account.
   - Set up a new organization/clinic and become its owner using existing credentials.
3. **Staff Management:**
   - Invite staff members to join an organization/clinic.
   - Manage staff roles and permissions.
   - View and manage staff members within the organization.
4. **Patient Data Management:**
   - Access patient data within a clinic.
   - View shared patient information after receiving a “Sharing letter”.
5. **Clinic Access and Switching:**
   - Log in and enter a specific clinic to work or view shared patients.
   - Switch between different clinics without logging out.
6. **Navigation and Menu System:**
   Access various sections such as organization settings, patient data, and staff management through a user-friendly navigation menu.
7. **Device Configuration and Control:**
   Set up and configure devices for use with Diagnocat.
8. **Help and Support:**
   Access help resources and support options from within the interface.
9. **Session Management:**
   Sign out to end the session or log in with a different account.
10. **User Invitations:**
    - Create an account and join a clinic after receiving an invitation.
    - Create an account and view shared patient information after receiving a “Sharing letter”.
11. **Security:**
    - Passwords: All users must set a strong password for their account. Passwords shall meet the required complexity criteria, including a minimum length and the use of a mix of characters.

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- Email Confirmation: New users must confirm their email address before gaining access to the system and/or upon registration, the system sends a confirmation code to the user's provided email address.

Diagnocat AIS 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.

System requirements

To operate the Diagnocat AIS 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, JPEG, TIFF, PNG.

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, SliceThickness, or SpacingBetweenSlices.
- Maximal voxel, per single dimension, should be 400; there are no restrictions on the minimum voxel size.
- 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 such as ImagePositionPatient, InstanceNumber, or SliceLocation.
- Do not upload DICOM files with limitations on size more than 1GB and CBCT volume of 50 cm^3.

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NOTE: Diagnocat AIS 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 Diagnocat AIS analysis depends entirely on the quality of the uploaded images.

Configurations

Diagnocat AIS can be configured in 2 options:

1. You can upload patients' studies manually using a web-browser that doesn't require any specific configuration.Please contact your sales representative or email Sales@diagnocat.com for more information.
2. Desktop integration. Diagnocat Imaging is an application that can capture dental images from imaging software and upload them to Diagnocat Web Application. Please contact your sales representative or email Sales@diagnocat.com for more information.

1. Start with Diagnocat

1.1 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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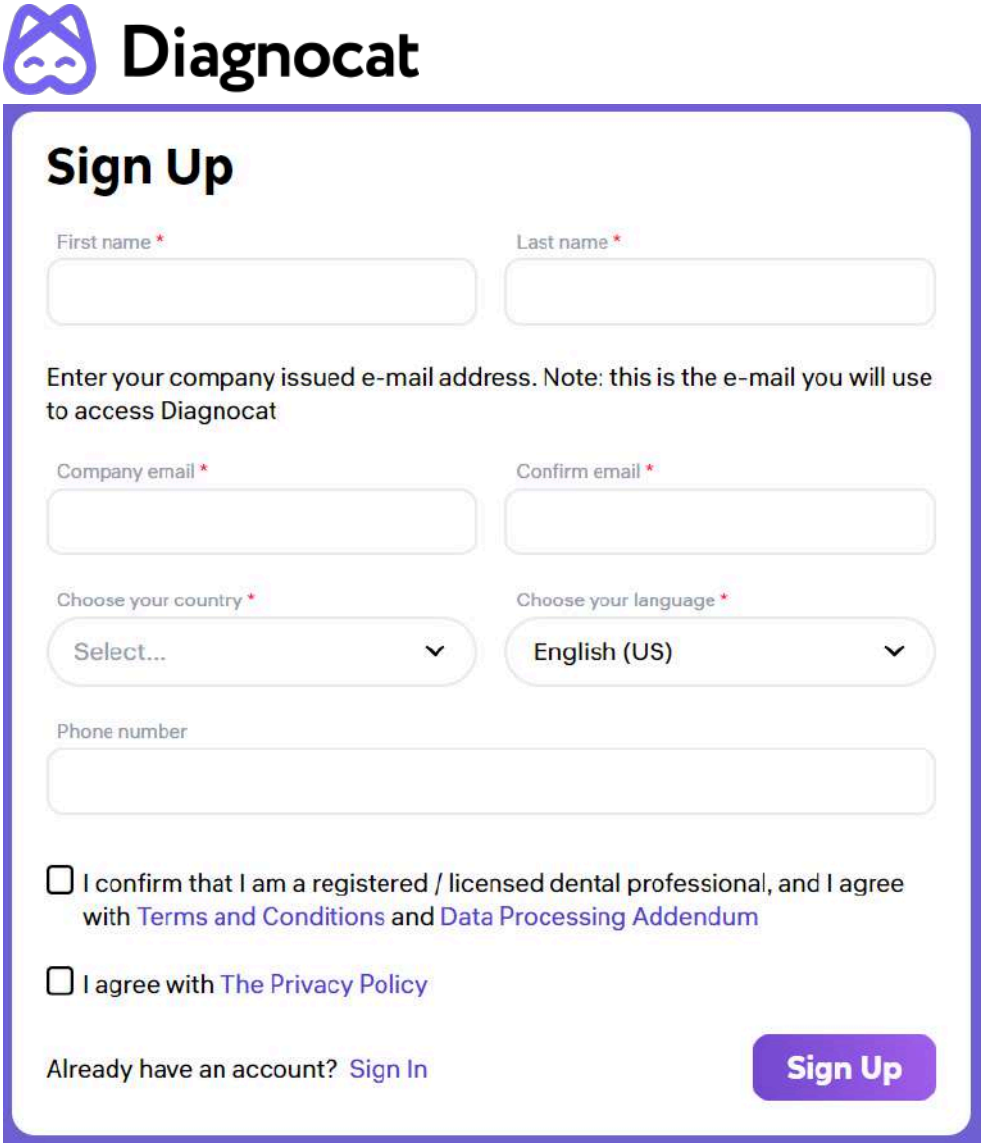

After that, you will receive an email with a verification code. You should enter this code and set your password.

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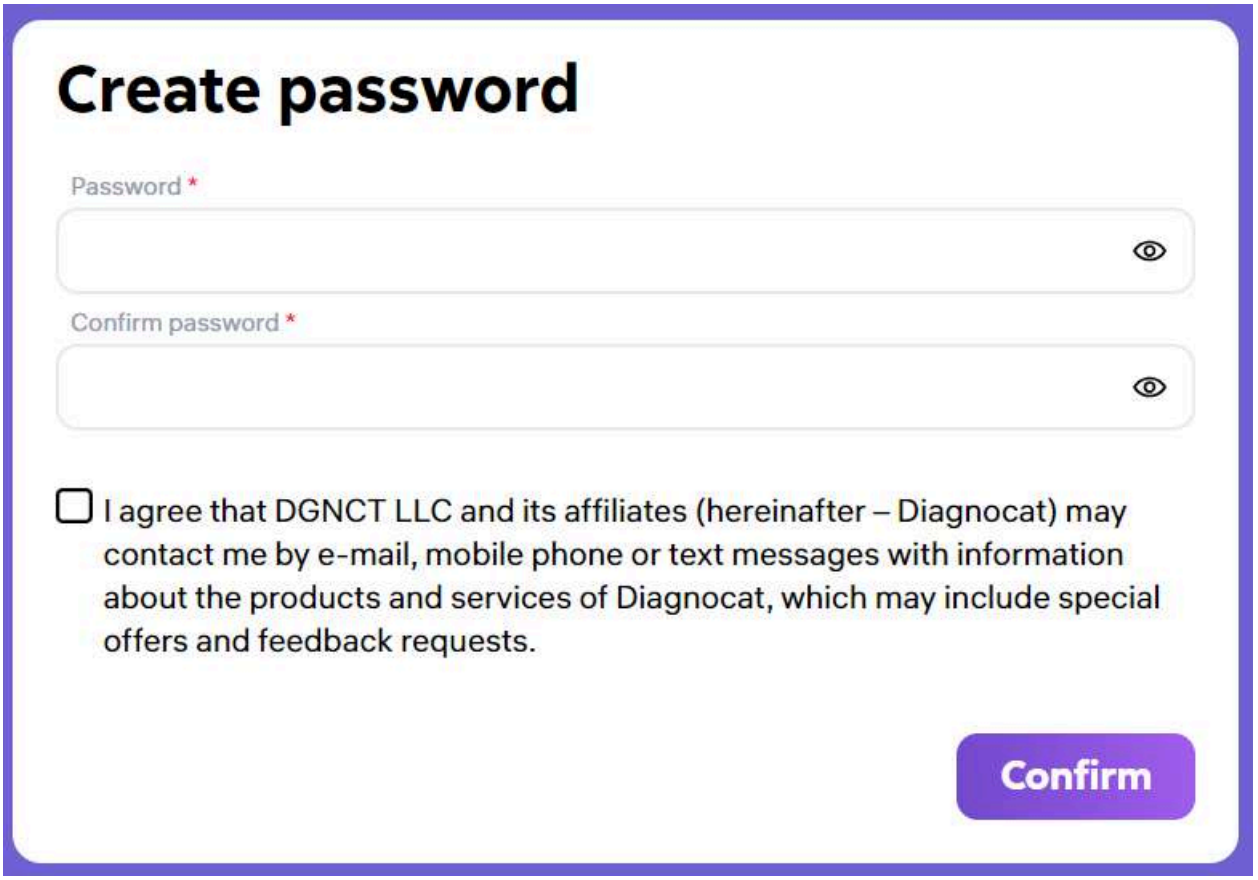
Diagnocat



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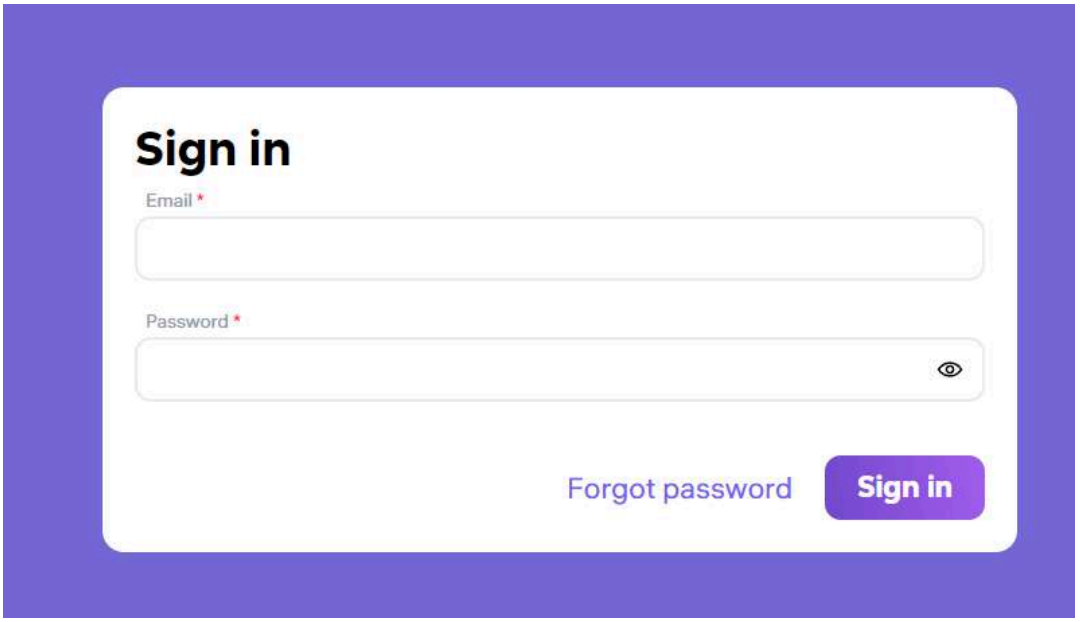
Diagnocat

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

1.2. Log 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 log in to the Diagnocat application by providing your email and password.



1.3 Reset password

If you need to reset your password, click the “Forgot password” button and enter your email address you used to register your Diagnocat account.

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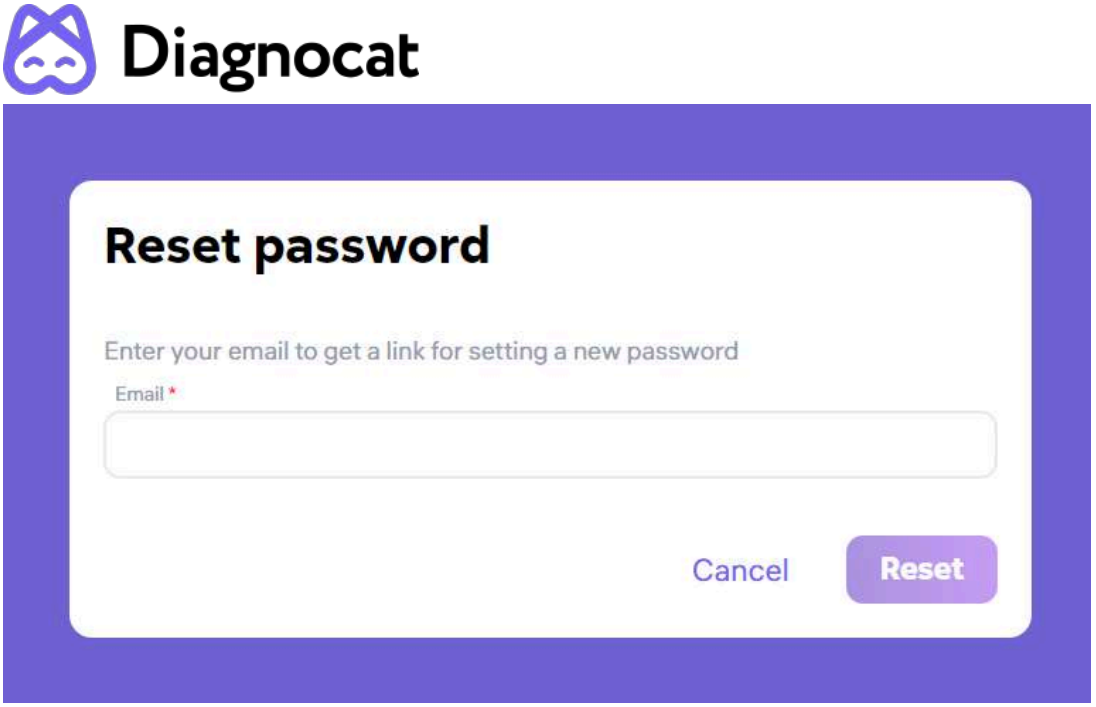
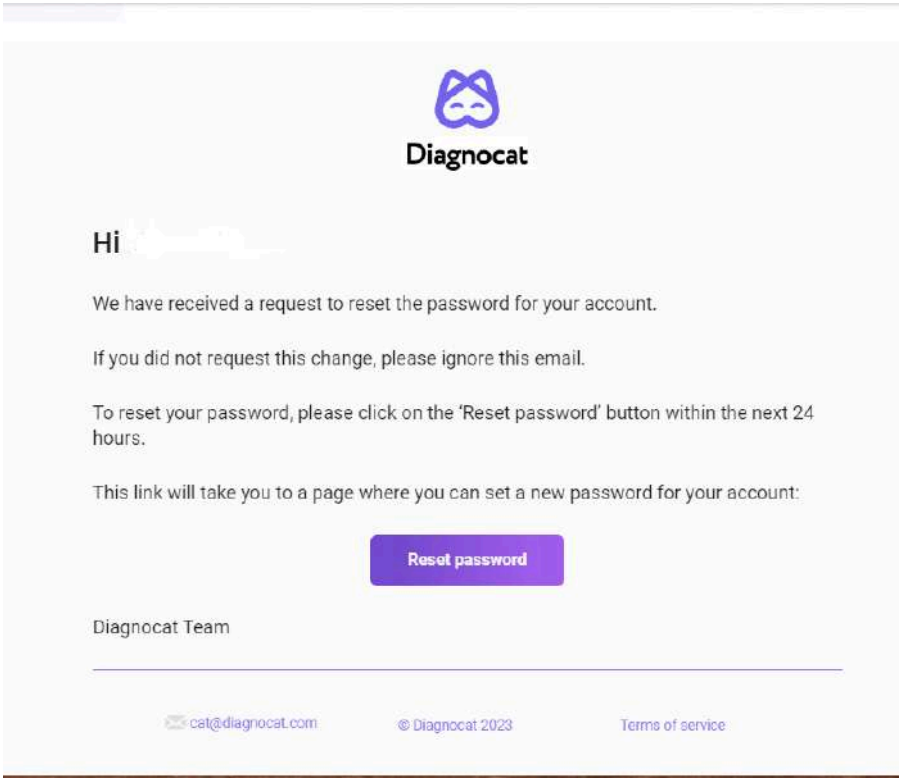


You will receive an email with instructions on how to reset your password.



1.4 Subscription Plans

To start using Diagnocat you need to buy a subscription plan that will give you access to the main functionality.

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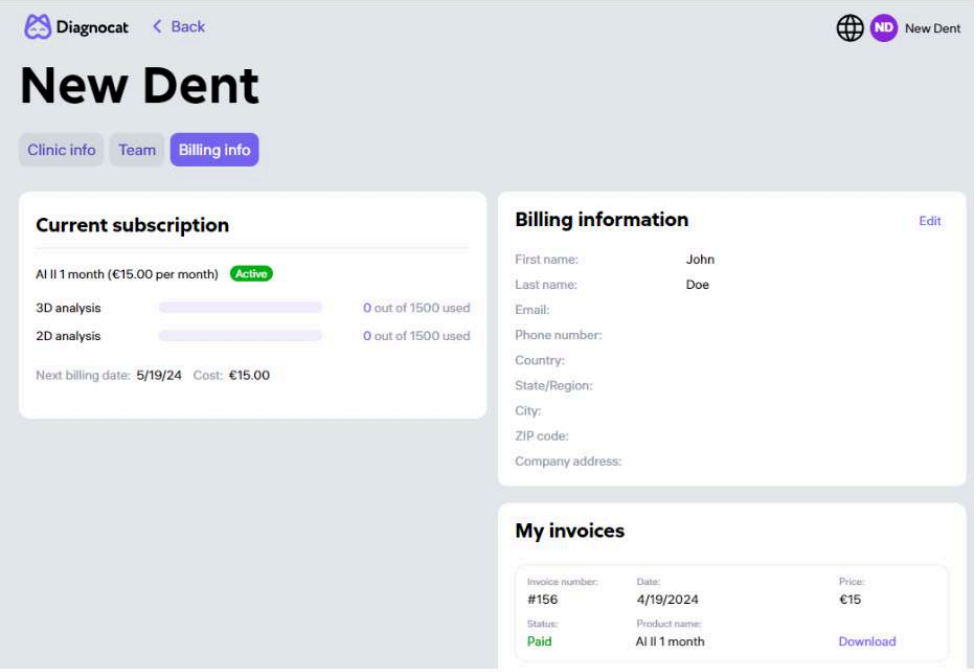
Your sales manager will suggest the best options to cover your needs and will provide you through the purchase.

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.

1.5 Patients

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

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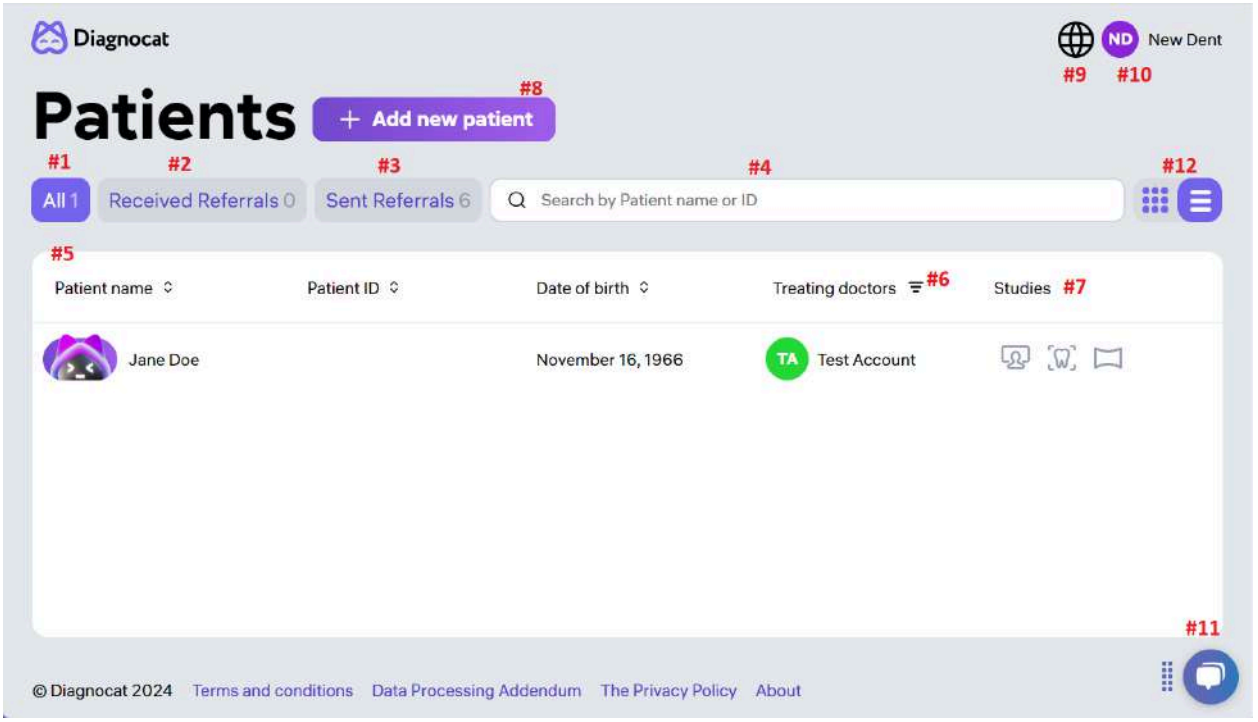

#1: “All” gives you access to all your patients.

#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:

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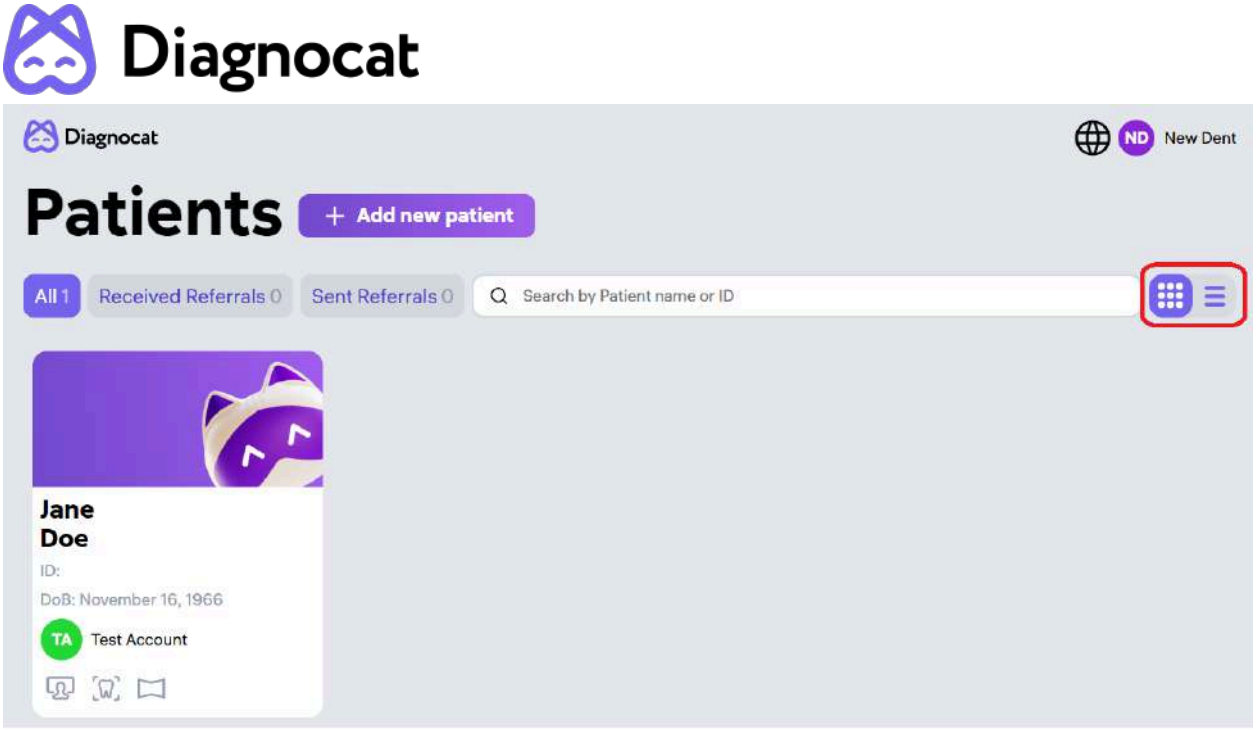
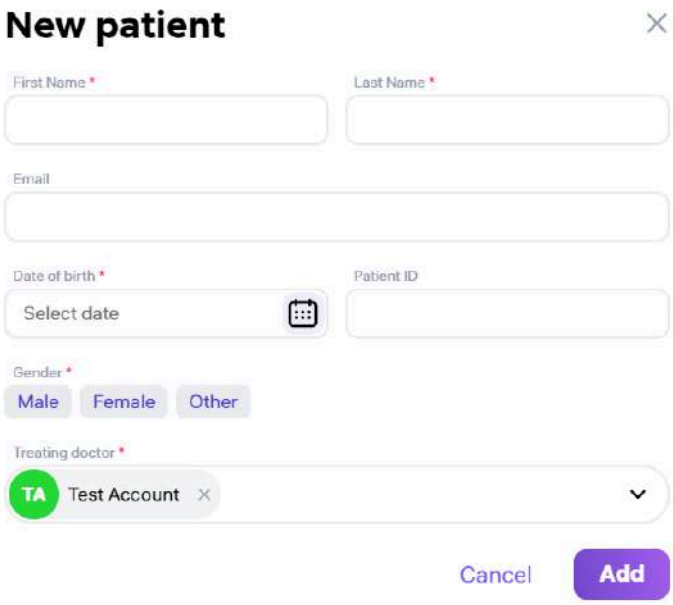


1.6 Create a new patient

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



Fill in a short form, 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.

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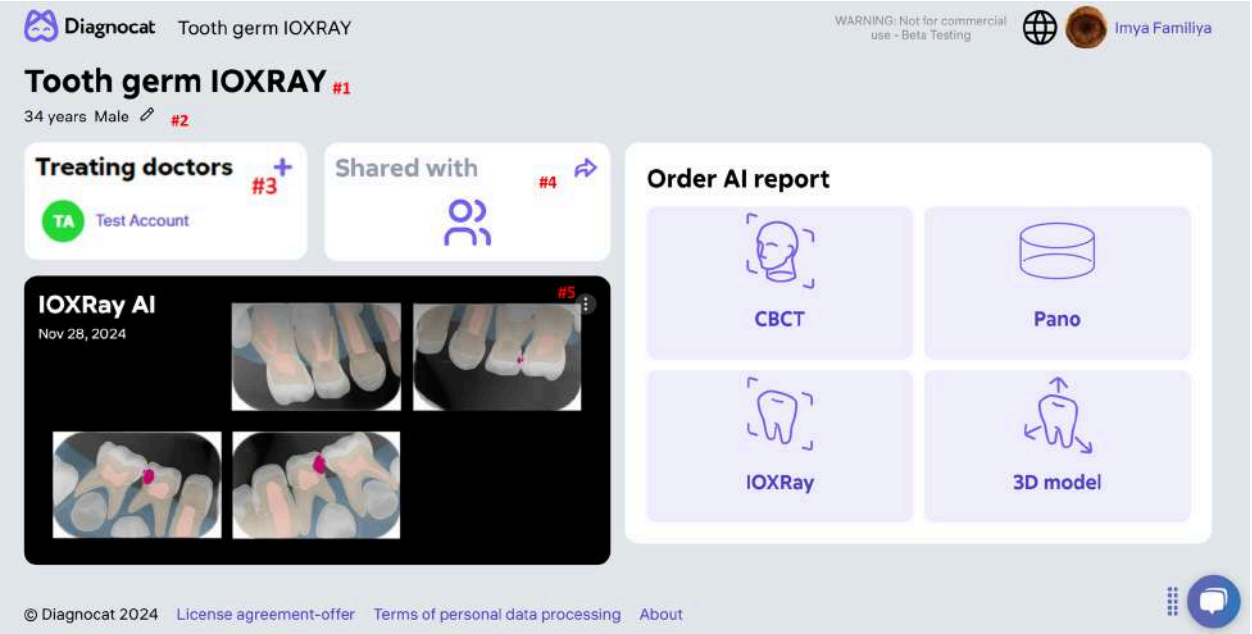
1.7 Patient Card



#1: Patient details.

#2: Edit patient details.

#3: Add a treating doctor.

#4: Share a patient with another doctor.

#5: Study details (Information, Download, Remove as provided on screen below).

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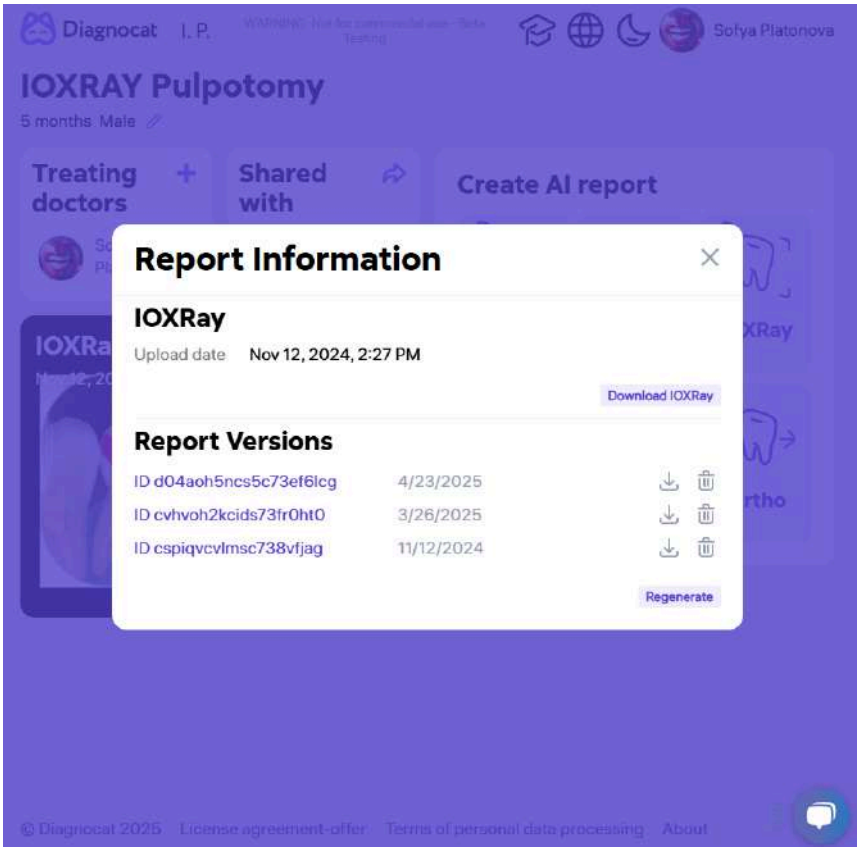
When you choose an option “Information”, new window will open, allowing you to:

- Download the report
- Reorder the report

- Download (as PDF file) or Delete the report.



1.8 Order report

Once you open a patient's details, you can order a report through the report widget. Choose the study type you wish to upload (e.g., CBCT, IOXRay, Pano, 3D models). The system will open a modal window to guide you through ordering the report.

NOTE: The widget will display the types of reports available for ordering based on the services included in your subscription.

The modal window will contain the following:

- **Report Name**: Displays the name of the report you are ordering.
- **Required Steps**: A list of steps to complete the report order. These may include:
    - Uploading the necessary studies (or folders) by browsing your computer.
    - Selecting previously uploaded studies.
- **Options**:
    - **Confirm**: Finalize and confirm the creation of the report.

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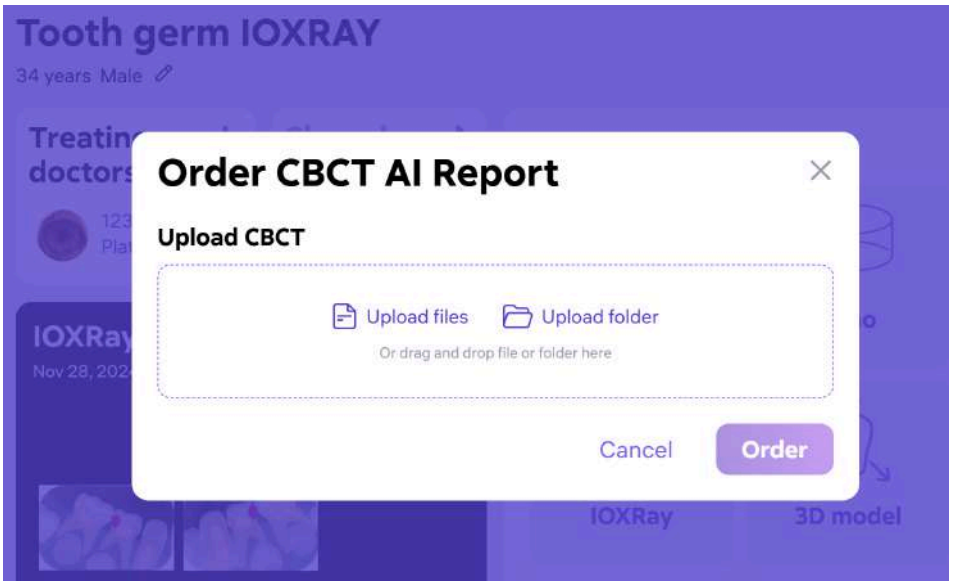
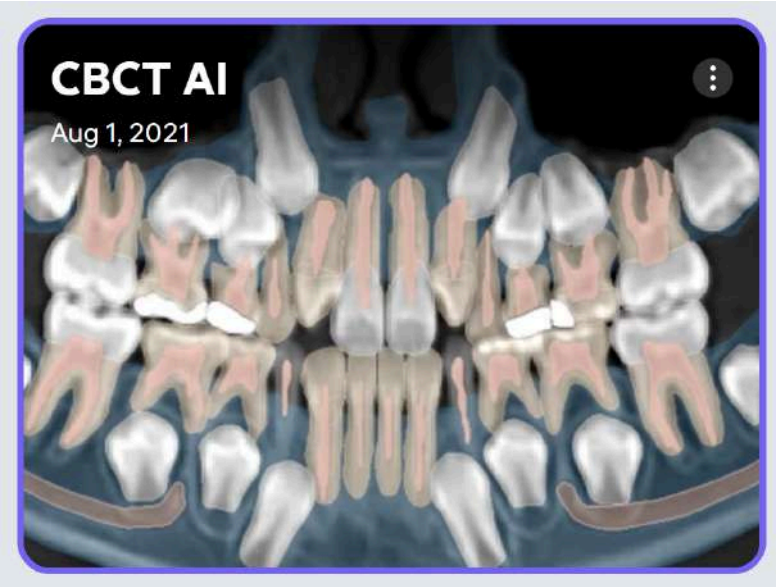
- **Cancel**: Cancel the report creation process if needed.



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

2. CBCT AI Report

You can open the CBCT AI Report by clicking the widget.



Here is what you will find inside the CBCT AI report:

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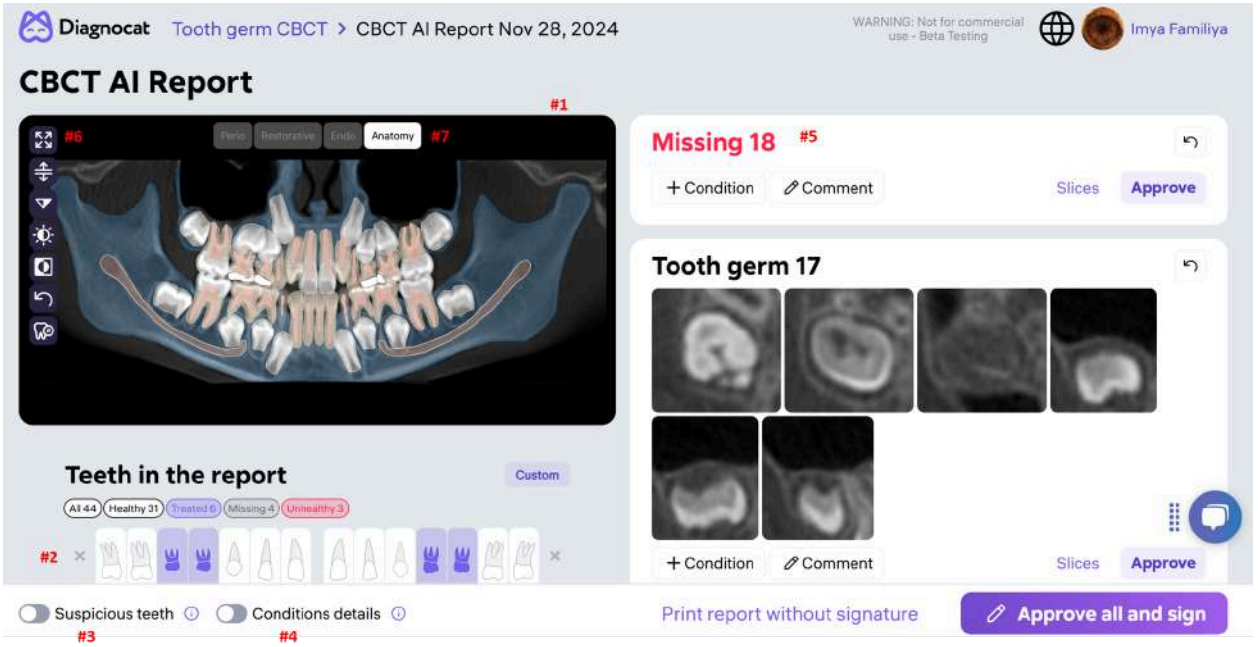

#1: Panorama image derived from CBCT

#2: Tooth chart

#3: Mode to show suspicious teeth (could be enabled)

#4: Conditions details (could switch between displaying limited numbers of detections and displaying all predicted detections)

#5: Tooth card

#6: Panorama tools

#7: Buttons for enable or disable displaying color masks on the image (Perio, Restorative, Endo, Anatomy)

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Diagnocat

2.1 Panorama tools

#1: Expand

#2: Create a panorama for each jaw

#3: Sharpness

#4: Brightness / Contrast

#5: Invert

#6: Reset all changes

#7: Edit tooth number

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Diagnocat

2.2 Tooth chart

Red – unhealthy teeth, contain possible problems

Violet – treated teeth with no pathologies (healthy tooth but have already treated)

White – healthy teeth

Yellow – suspicious teeth

Cross icon - missing teeth

Red lines (one, two or three) - periodontal screening (periodontal bone loss mild, moderate or severe stage)

NOTE: by default, all the teeth are enabled and for each tooth there is a tooth card. You can disable some teeth. Click on the category of the teeth (All / Healthy / Treated /Missing / Unhealthy) to add or delete all teeth from this category. Use the “Custom” option to select specific teeth you would like to have in the report.

NOTE 2: The system adds an asterisk (*) next to the number of supernumerary teeth - 

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Diagnocat

2.3 Change teeth numbers

If the tooth numbers are incorrect, use the “Edit tooth number” option.

Once done click the “Confirm” button.

2.4 Show suspicious teeth

This mode switches on attributes of caries signs and periradicular pathologies with probability rate as 30-50%.

The list of condition that should be shown in suspicious teeth mode:

- Caries signs
- PDL space widening in periapical region
- PDL space widening along root

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- Periapical radiopacity
- Periapical radiolucency

NOTE: Conditions with probability rate as 30-50% don't appear in the report. If you click the "Approve" button, these conditions will become the red ones. Then they will appear in the report.

2.5 Conditions details

When the "Conditions Details" toggle is switched off, the system displays only the following conditions if predicted by the models:

- Tooth
- Implant
- Pontic
- Root fragment
- Missing
- Tooth germ
- 1 canal, 2 canals, 3 canals, 4 canals, 5 canals
- Periodontal bone loss
- Furcation lesion
- Dental calculus
- Impaction
- Horizontal displacement
- Overeruption
- Filling
- Artificial crown
- Indirect restoration
- Overhang
- Open margin
- Lack of interproximal contact
- Caries signs
- Internal resorption
- Horizontal root fracture
- Endodontically treated tooth
- Periapical radiolucency
- PDL space widening in the periapical region

When the user resets a tooth to its default state, the system respects the current state of the "Conditions Details" toggle:

- If the toggle is enabled, the system displays all predicted conditions.

The system also displays an icon near the "Conditions Details" toggle. When the user hovers over this icon, a tooltip displays the following message:
“Turn on to view all detected conditions with details.”

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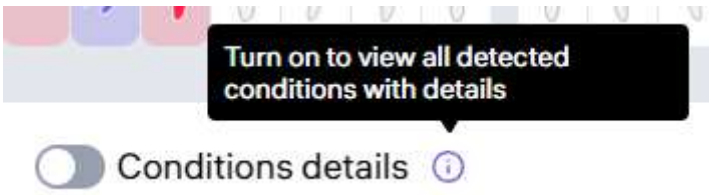
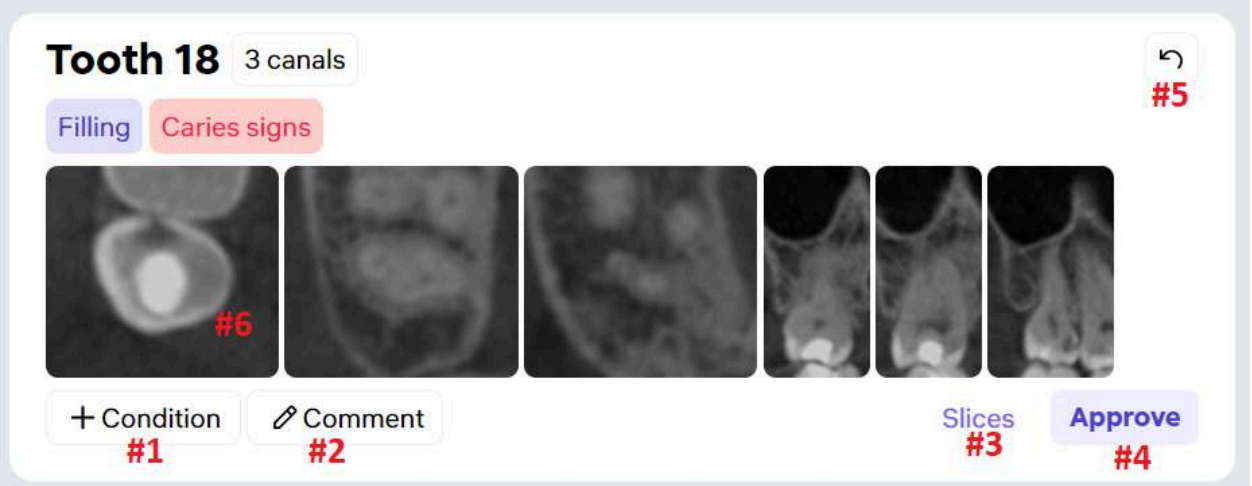


2.6 Tooth card



You can find detailed information about a specific tooth inside the tooth card.

#1: Add pathology or condition

#2: Add comment

#3: Use the 3D Viewer and view all slices for the tooth

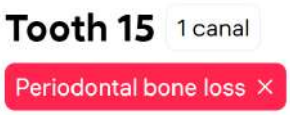
#4: Approved changes

#5: Reset tooth original conditions

#6: View the slice

2.7 View and add pathologies and conditions

You could be able to modify a condition by clicking on its name in the tooth card.



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After clicking on the condition name, the system should display a list of conditions that belong to the same group as the condition being modified.

To add a condition to the card, the user selects the corresponding checkbox in the list of conditions.

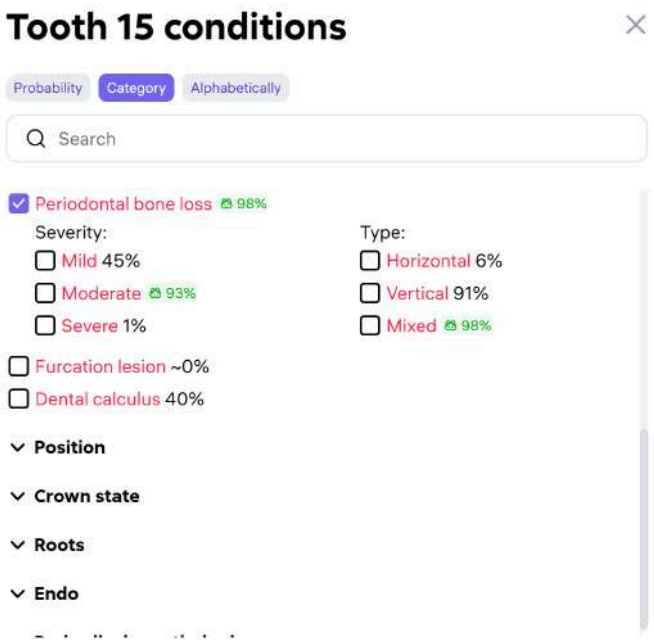
To remove a condition from the card, the user unselect the corresponding checkbox in the list of conditions.

User could add conditions in the Tooth card.

When User clicks on the Add condition button, the system displays a list with conditions in the Add conditions window. The list have 3 tabs to select type of sorting and grouping:

- by probability
- by conditions category
- alphabetically

When User adds a condition, related child conditions for that condition are selectable.



The Diagnocat's icon is displayed next to conditions predicted by the AI model, values of which are greater than 50%. The significance of displaying the icon near these conditions is to allow the doctor to differentiate between manually entered conditions and those generated by the AI.

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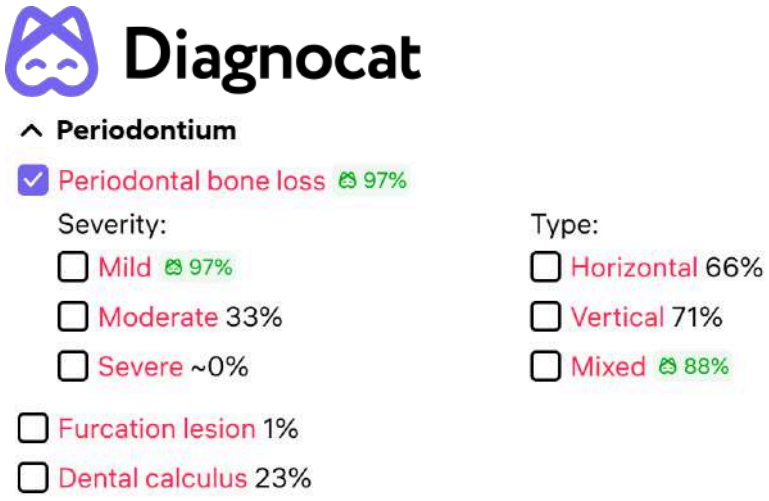

2.8 Slices Mode

#1: A list of detected pathologies and conditions.

#2: Multi-planar reconstruction tool

#3: A collection of slices. Diagnocat automatically creates a collection of slices in three projections: axial, mesio-distal and vestibulo-oral (projections display yellow, pink and blue lines on panorama accordingly).

#4: Panorama image derived from CBCT

#5: Navigation allowing to choose different teeth in the edit mode

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#6: The “Approve” button. When clicked this button lets the system know that a user has not changed anything and approves the detected pathologies and conditions. Or if the user has made edits and confirms changes.

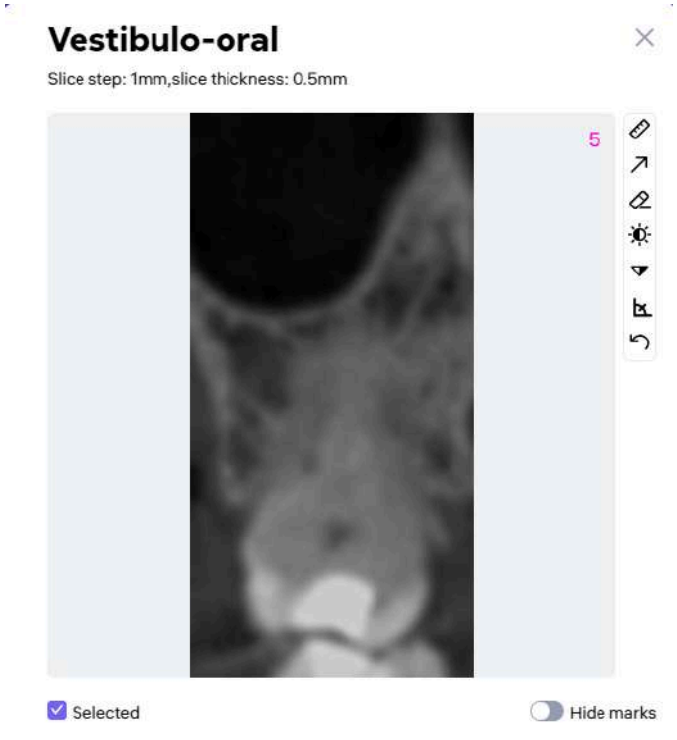
NOTE: Each pathology has %. This is the level of confidence Diagnocat platform has in regards to the found pathology. If the likelihood of a pathology is less than 50% then the system won’t show it in the report. The user can still see this pathology on the slices.

2.9 View and edit slices

When you click any slice a tool panel will appear:

- Modify brightness and contrast of the image
- Adjust the sharpness of the image.
- Add a ruler to the image for measurement purposes
- Add an angle measurement tool
- Add arrow markers to highlight specific areas of interest on the image
- Remove specific objects from the image (Eraser tool)
- Reset all changes made to the image and restore it to its original state

The changes made only apply to the current slice and not affect other slices or the original image.



By default, the system adds 6 slices to the tooth card in different projections: three slices for the axial projection, two slices for the mesio-distal projection, one slice for the vestibulo-oral projection. You can change these slices and create a new set, which will be added to the final report.

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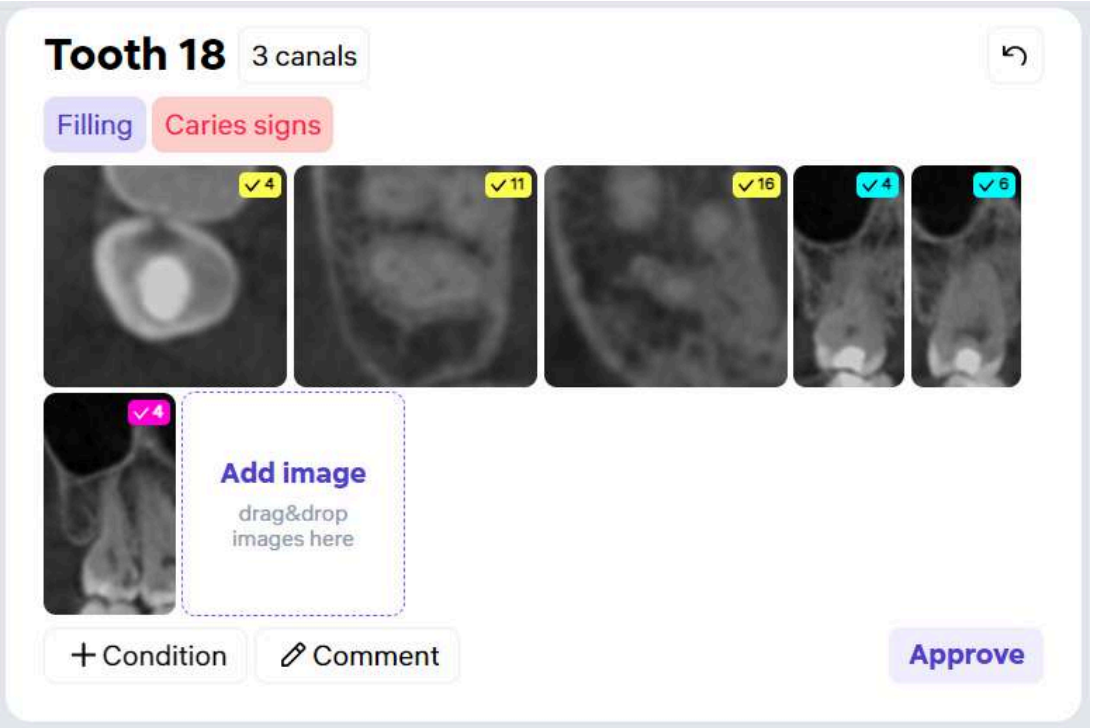

You could change slices, selecting the ones you need from the sections Axial view, Vestibulo Oral, Mesiodistal simply by clicking on the necessary slices.

If you want to add other slices, use the “Drag or add slices or images to the report” option or click on the necessary slices in the sections Axial view, Vestibulo Oral, Mesiodistal slices will be added automatically.

NOTE: Company has uploaded slices limits. You could upload only image files (jpg, jpeg, png). File size limit ~ 5 mb, max ~ 50 files at once, like in the logo/stamp section.

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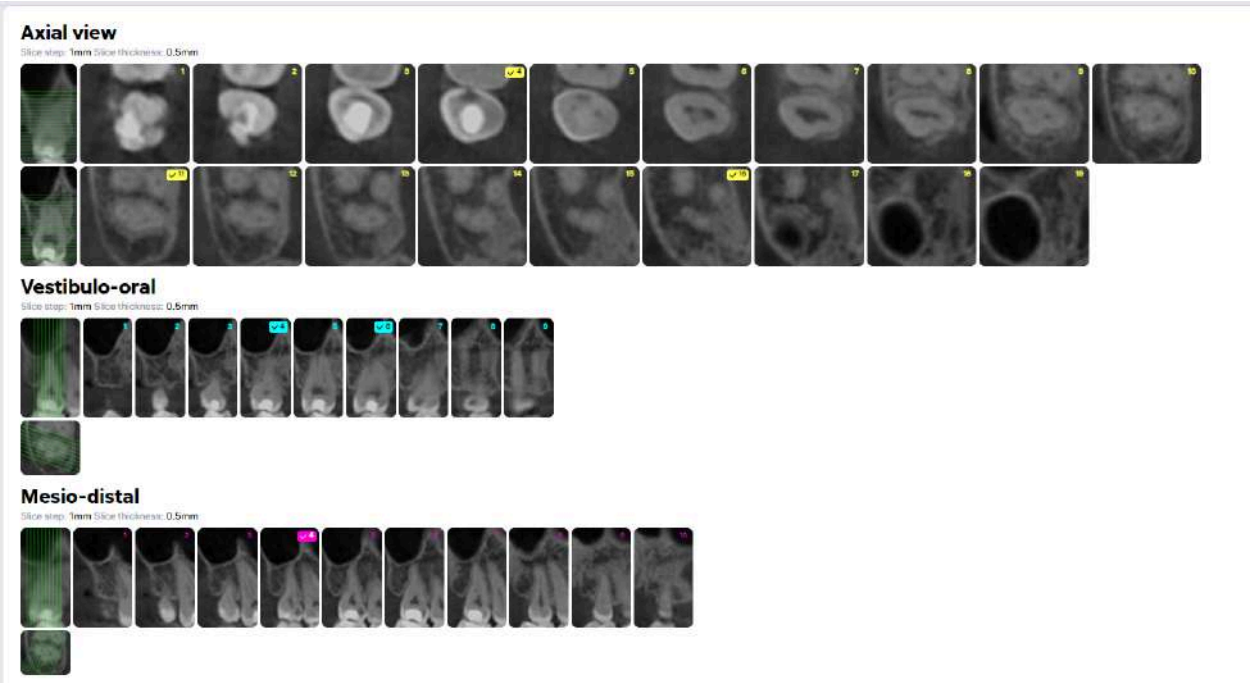
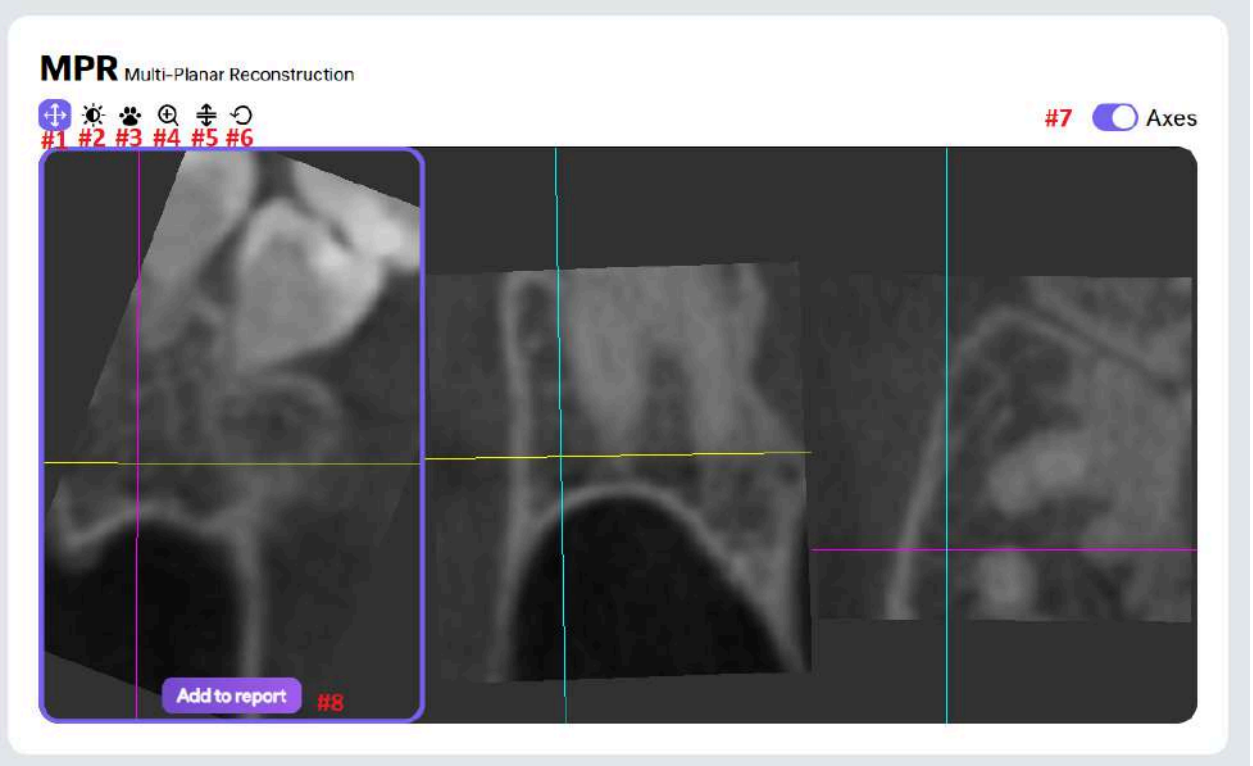


2.10 Multi-Planar Reconstruction tool



You can use this tool in a Slices page. Multi-Planar Reconstruction tool allows you to create your own slices and add them to the report.

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#1: Axis changing tool

#2: Brightness/contrast

#3: Pan

#4: Zoom

#5: Translation

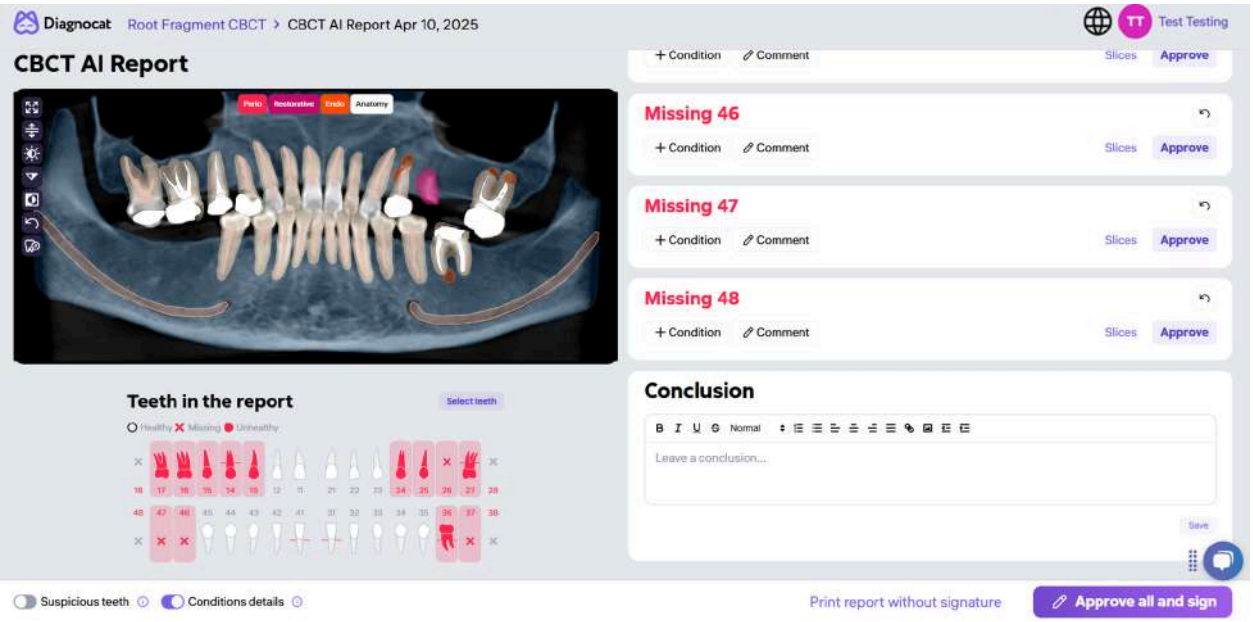
#6: Reset all changes

#7: Enable/disable the axis. Disable the axis if you want to end a slice to the tooth card

#8: Add slice to report

2.11 Conclusion

User can add a conclusion to the report, attach a link or an image.



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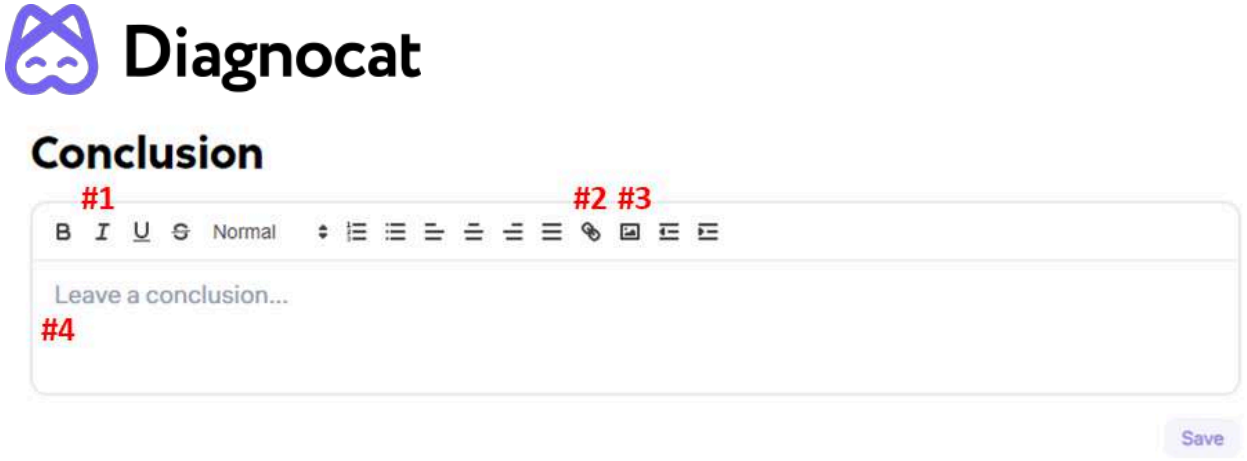


#1: Font settings

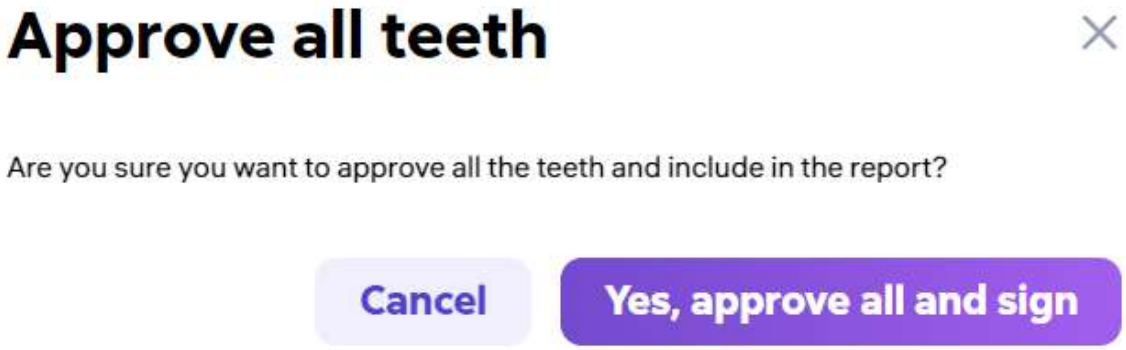
#2: Add a link

#3: Attach an image

#4: The main text field

2.12 Printing a signed report

To sign a printed report, use the button “Yes, approve all and sign” or approve each tooth separately.



A note added to the bottom of the end of the report: “This report contains confidential health information. It was generated with Diagnocat SaaS using Artificial Intelligence. The conditions and pathologies in this report were verified by the attending dentist.”

2.13 Printing a report without signature

To print a report without signature use the “Print report without signature” button. The system will generate a report without the doctor's signature and conclusion.

A note added to the bottom of the end of the report: “This report contains confidential health information. It was generated with Diagnocat SaaS using Artificial Intelligence. The conditions

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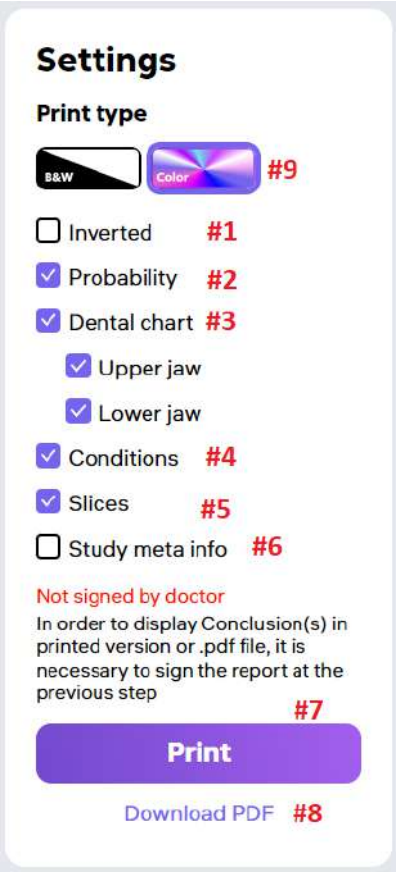
and pathologies in this report can not be considered a medical diagnosis and must be interpreted by the attending dentist.”

2.14 Editing report before printing

In the preview mode you can add final edits to the report before printing it.



#1: Invert colors in a panoramic image and the tooth slices.

#2: Enable / disable the likelihood of pathologies and conditions in the report.

#3: Enable / disable the tooth chart and upper and lower jaws in the report.

#4: Enable / disable detected pathologies and conditions in the report.

#5: Enable / disable the tooth slices in the report.

#6: Enable / disable study meta information.

#7: Print the report.

#8: Download the report as a PDF file.

#9: Select print type (Color or Black & White).

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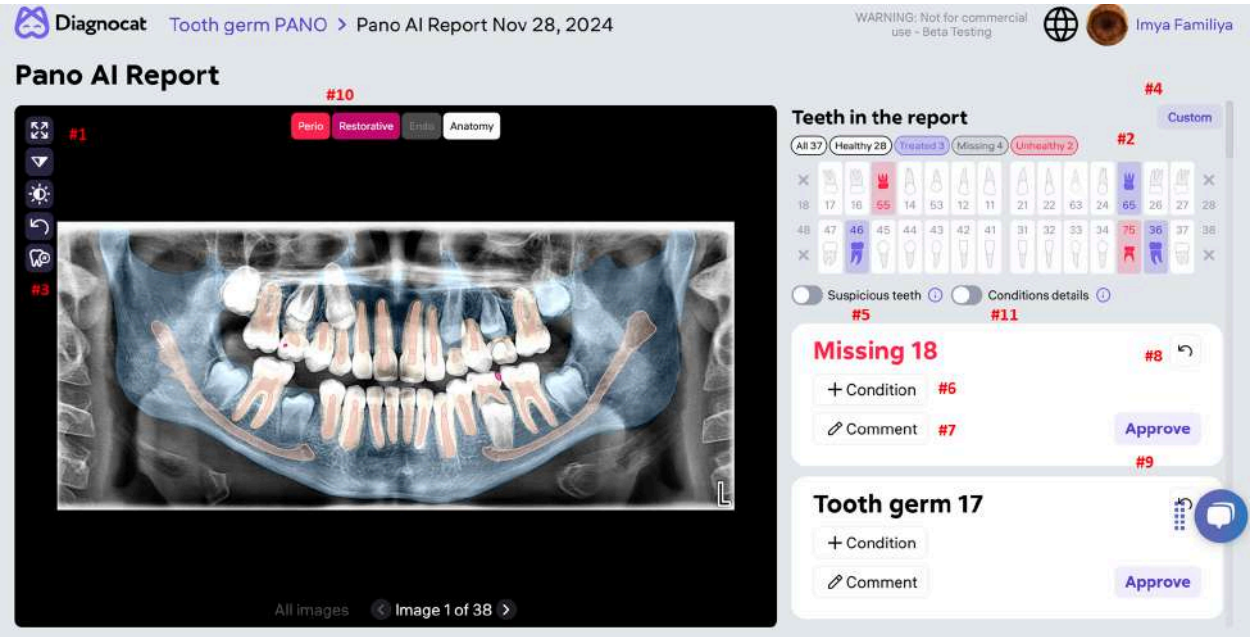
Diagnocat

3. Pano AI Report

3.1 Order and view pano analysis

To order a Pano AI Report, use the 'Order Report' widget. After downloading the pano and generating the report, click the widget to open the Pano AI Report.

The Pano AI Report has the exact same tools and functionality that are used in the CBCT AI Report:



#1: Tool panel (Sharpening, Brightness/Contrast, Reset and Edit tooth number)

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#2: Tooth chart

#3: Edit tooth numbers

#4: Custom

#5: Suspicious teeth

#6: Add condition

#7: Add comments to the tooth card

#8: Reset the tooth condition to the original state

#9: Approve the tooth

#10: Buttons for enable or disable displaying color masks on the image (Perio, Restorative, Endo, Anatomy)

#11: Conditions details

3.2 Masks

You could enable or disable the displaying of the color masks of corresponding conditions by clicking on the appropriative buttons:

- Perio (pathologies highlighted with masks of red color)
- Endo (pathologies highlighted with masks of orange color)
- Restorative (pathologies highlighted with masks of rose color)
- Anatomy

The masks of conditions shown only for conditions predicted by the system presented in the tooth card. When you hover on the mask on the image, the system displays the condition related to this mask. The condition displayed near the mask.

When you remove a condition from a tooth card, the system hides the corresponding mask.

When User turns on the Perio filter, Diagnocat display the masks of the following detections:

1. Furcation Lesion
2. Dental calculus
3. Periodontal Bone Loss as rulers with measurements (in Panowings AI Report as masks and as rulers)
4. Impaction

NOTE: For PANO, Panowings and CBCT AI Reports, if the tooth has Impaction as pathology, the system paints the anatomy of the tooth with Perio masks.

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When User turns on the Endo filter, Diagnocat display the masks of the following detections:

1. Pulpotomy (only for IOXray AI Report)
2. Short filling (only for PANO and Panowings AI Reports)
3. Overfilling (only for PANO and Panowings AI Reports)
4. Missed canal (only for PANO and Panowings AI Reports)
5. Pulpotomy (on IOXRay images for Panowing AI Reports)
6. Voids present in the root filling
7. Periapical radiolucency

When User turns on the Restorative filter, Diagnocat displays the masks of the following detections:

1. Voids in the filling
2. Overhang
3. Open margin
4. Lack of the Interproximal Contact
5. Tooth stump
6. Caries signs
7. Secondary caries
8. Root fragment (tooth mask) (only for CBCT AI Report)
9. Abfraction (only for CBCT AI Report)

NOTE: When Restorative filter is turned on and the tooth type is determined as Root fragment, the system shall paint the anatomy of the tooth with Restorative mask for all modalities.

When User turns on the Anatomy filter, Diagnocat displays the masks of the following conditions of previous treatment (if the system predicted the corresponding conditions) in IOXRay AI Report, Pano AI Report, Panowings AI Report:

1. Filling,
2. Artificial Crown
3. Orthodontic Appliance
4. Endodontically Treated tooth
5. Adequate Obturation
6. Adequate Density
7. Cast Post And Core
8. Post

In CBCT AI report:

1. Filling
2. Artificial crown
3. Indirect restoration
4. Endodontically treated tooth

When User turns on the Anatomy filter, Diagnocat displays the masks of the following anatomies:

1. IOXray AI Report
    - Root,
    - Root Canal,

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- Crown,
- Incisal Edge,
- Pulp Chamber,
- Enamel,
- Mandibular canal,
- Alveolar bone (consists of two masks)
  - Oral bone
  - Vestibular bone

2. PANO AI Report
   - Root,
   - Root Canal,
   - Crown,
   - Pulp Chamber,
   - Enamel,
   - Maxilla,
   - Mandible,
   - Mandibular Canal
3. CBCT AI Report
   - Root
   - Pulp
   - Dentin
   - Enamel
   - Maxilla,
   - Mandible,
   - Mandibular Canal

When the Anatomy filter is turned on and the tooth type is determined as Tooth germ, the system shall paint the anatomy of the tooth with an Anatomy mask for all modalities.

NOTE: the functionality of displaying masks is applicable for the reports generated basing on the all types of studies:

- Intraoral X-rays (periapical and bitewings) - IOXRay AI Report, Panowings AI Report
- Panoramic - Pano AI Report
- CBCT - CBCT AI Report

3.3 View images and found pathologies and conditions

When you hover over detected pathologies or conditions, the system will show a location of the found pathologies or conditions in a form of rectangles on the panorama. You can edit the location and the size of detection as well as create new ones.

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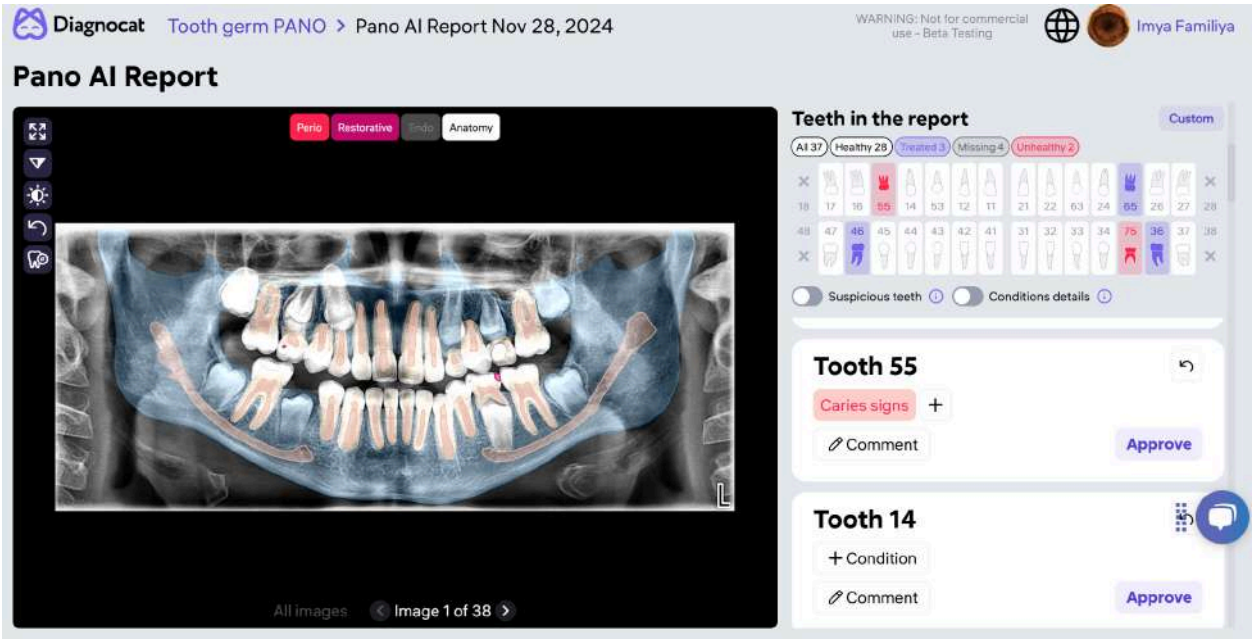
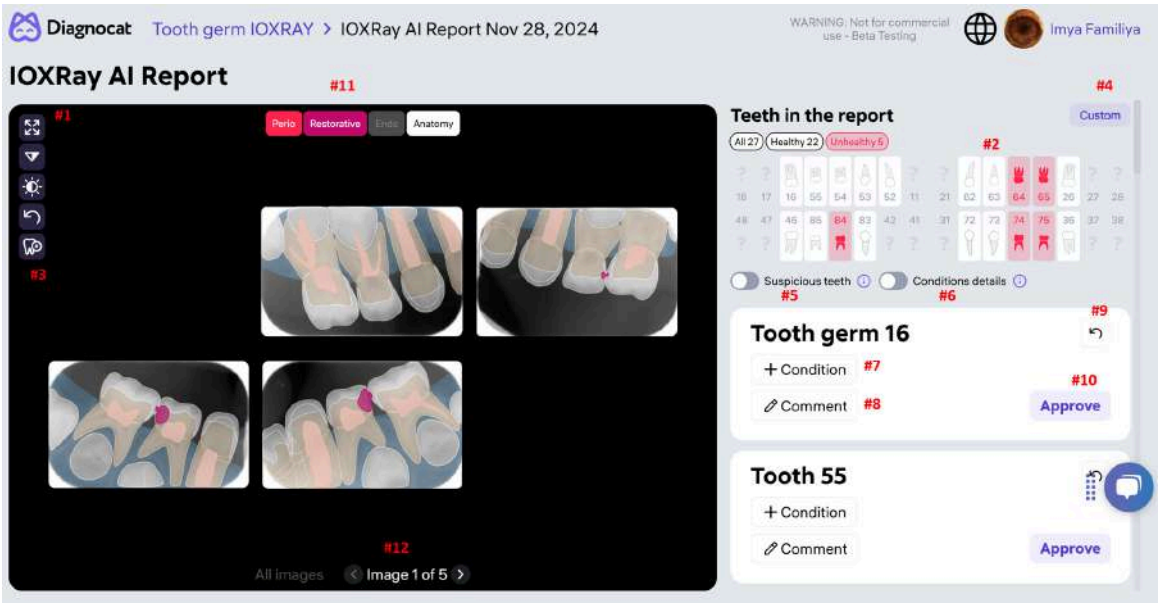


4. IOXRay AI Report

4.1 Order and view intraoral analysis

To order an IOXRay AI Report, use the 'Order Report' widget. After downloading the pano and generating the report, click the widget to open the IOXRay AI Report.

The IOXRay AI Report has the exact same tools and functionality that are used in the CBCT AI Report:



#1: Tool panel (Sharpening, Brightness/Contrast, Reset and Edit tooth number)

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#2: Tooth chart

#3: Edit tooth numbers

#4: Custom

#5: Suspicious teeth

#6: Conditions details

#7: Add condition

#8: Add comments to the tooth card

#9: Reset the tooth condition to the original state

#10: Approve the tooth

#11: Buttons for enable or disable displaying color masks on the image (Perio, Restorative, Endo, Anatomy)

#12: Navigation buttons

The navigation buttons include the following icons buttons:

 Icon: This button allows you to view the previous image of the Navigation matrix or previous tooth in RoI.

 Icon: This button allows you to view the next image of the Navigation matrix or next tooth in RoI.

button: This button allows you to view the Navigation matrix (displayed as the first image in sequence for both views)

The system displays the number of the current image being viewed and the total number of available images (for both views).

NOTE: The IOXRay AI Report has the exact same masks on image that are used in the Pano AI Report.

4.2 View images and found pathologies and conditions

When you hover over detected pathologies or conditions, the system will show a location of the found pathologies or conditions in a form of rectangles. You can edit the location and the size of detection as well as create new ones.

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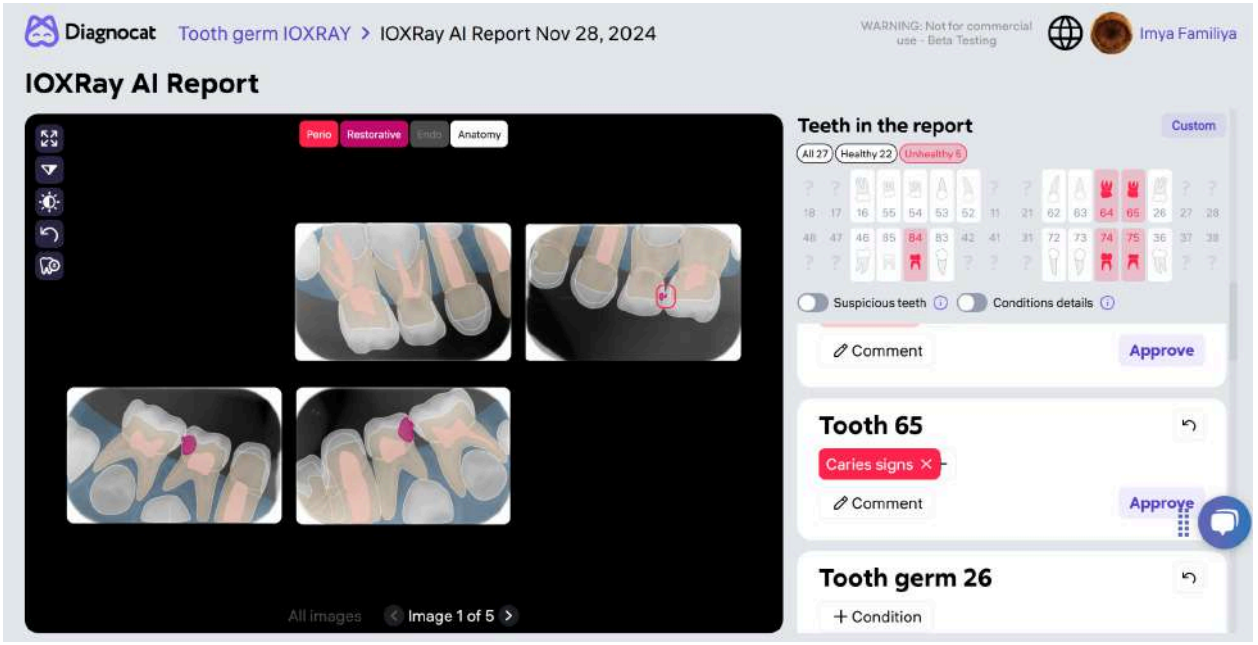
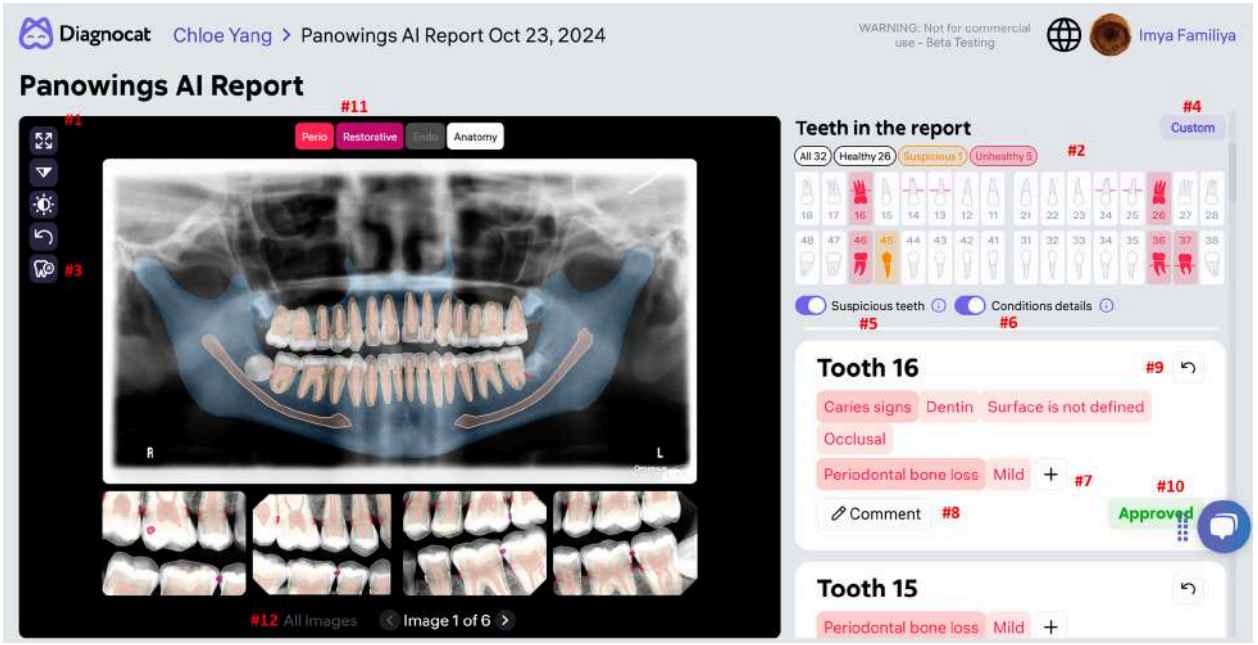


5. Panowings AI Report

5.1 Order and view analysis

The system automatically generates Panowings AI Report based on IOXray and Pano AI reports generated within the interval of 24 hours. In the resulting report the system includes panoramic images from Pano AI report and bitewings images from IOXray AI report.

The Panowings AI Report has the exact same tools and functionality that are used in the IOXRAY AI Report:



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#1: Tool panel (Sharpening, Brightness/Contrast, Reset and Edit tooth number)

#2: Tooth chart

#3: Edit tooth numbers

#4: Custom

#5: Suspicious teeth

#6: Conditions details

#7: “+” - Add condition

#8: Add comments to the tooth card

#9: Reset the tooth condition to the original state

#10: Approve the tooth

#11: Buttons for enable or disable displaying color masks on the image (Perio, Restorative, Endo, Anatomy)

#12: Navigation buttons

NOTE: The Panowings AI Report has the exact same masks on image that are used in the Pano AI Report.

6. PBL Measurements

You can view periodontal bone loss measurements in the IOXray AI Report, Pano AI Report, and Panowing AI Report and in the CBCT AI Report on the CBCT reformat.

The system display the PBL measurements corresponding to Periodontal bone loss conditions on the tooth, on the tooth image (white stripes):

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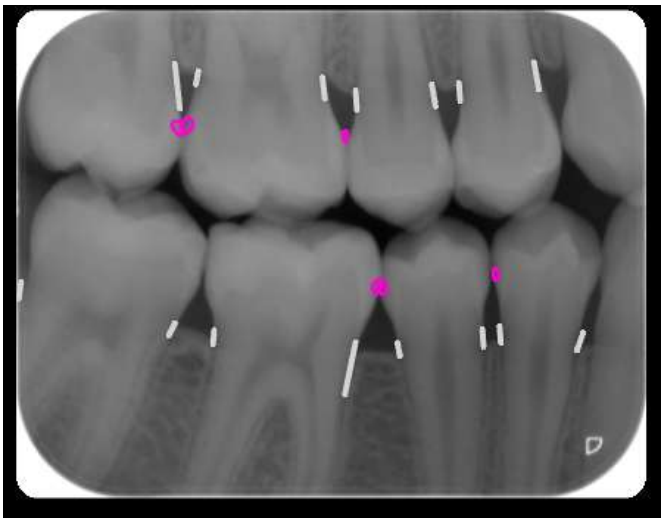
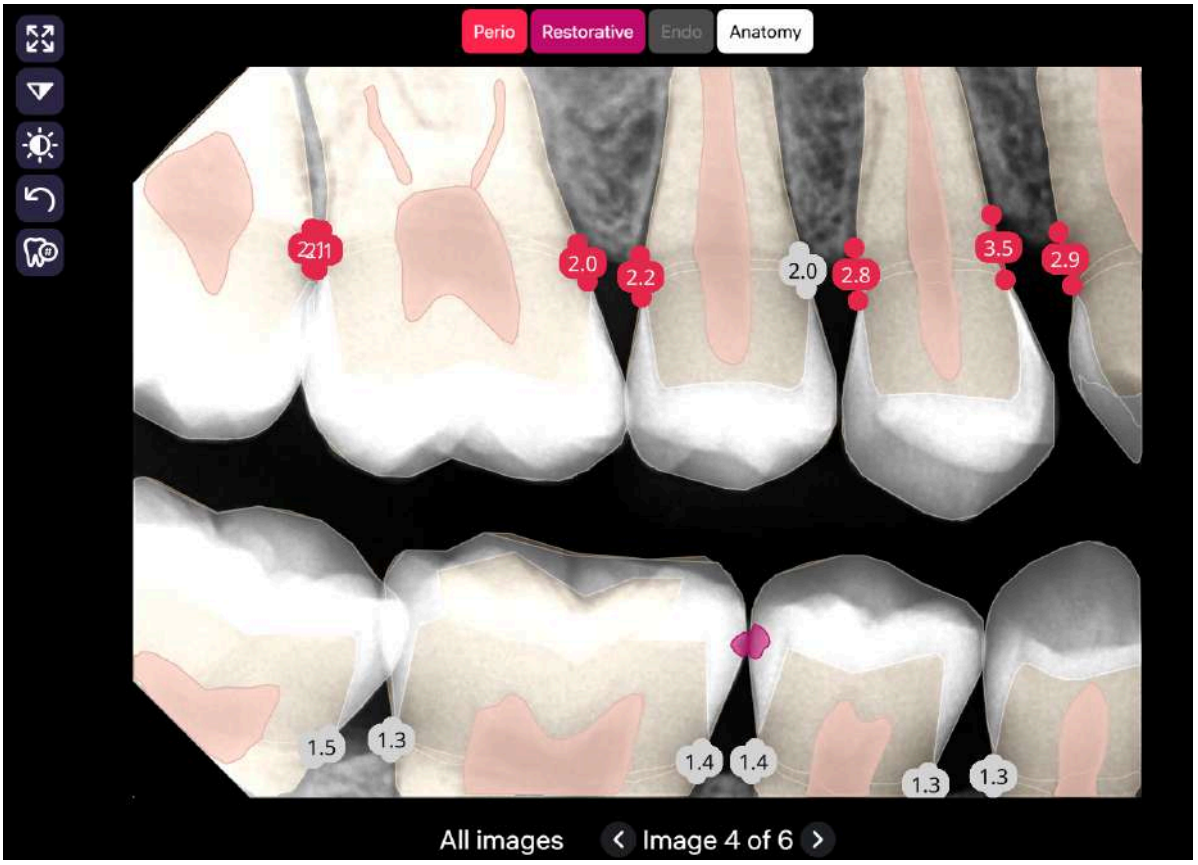


The system highlights in different ways healthy and unhealthy PBL conditions. All measurements corresponding to unhealthy PBL conditions are highlighted with the same color. The user should click on the white PBL stripe. This will open an enlarged panorama displaying PBL measurements and masks.



The measurement consists of line, start and end points, length of the measurement.User could move start or end point. When User hovers the mouse on the surrounding of any endpoint, the system displays another cursor. In this surrounding the User could click on the left mouse button and move the cursor according to the movements of the mouse. The cursor changes the icon during the movements. When User releases the mouse button, the system fixes the endpoint on the image.

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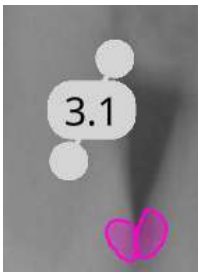

If the length is being displayed, the system renews the length according to the mouse movements. The system displays the length of measurements with the precision of the nearest tenth.

7. Other Findings

Diagnocat AIS automatically identifies other conditions during CBCT and Panoramic X-Ray analysis. These findings are included in the Radiological report (CBCT AI Report and Pano AI Report) under a distinct section titled "Other Findings". This feature pays attention to potentially significant anatomical anomalies beyond routine dental conditions.

When this pathology is detected, Diagnocat AIS adds a dedicated, collapsible block labeled "Other Findings" to the radiological report. This block is expanded by default and contains the following:

#1: Section Title: “Other Findings”

#2: Annotated Panorama: Displays the panoramic reconstruction image with highlighted regions where abnormalities were detected

#3: Findings List: Enumerates each condition identified by the AI

Interactive Highlighting to enhance user interaction and support clinical review:

Hover-to-Highlight: When the user hovers the mouse over a specific condition listed under “Other Findings”, the software automatically highlights the corresponding anatomical region on the panoramic image.

This function facilitates intuitive navigation, correlating the textual findings with their spatial locations in the image.

The "Other Findings" section currently includes detection of the following conditions:

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- Signs of Maxillary Sinus Abnormality
- Signs of Bone Structure Abnormality

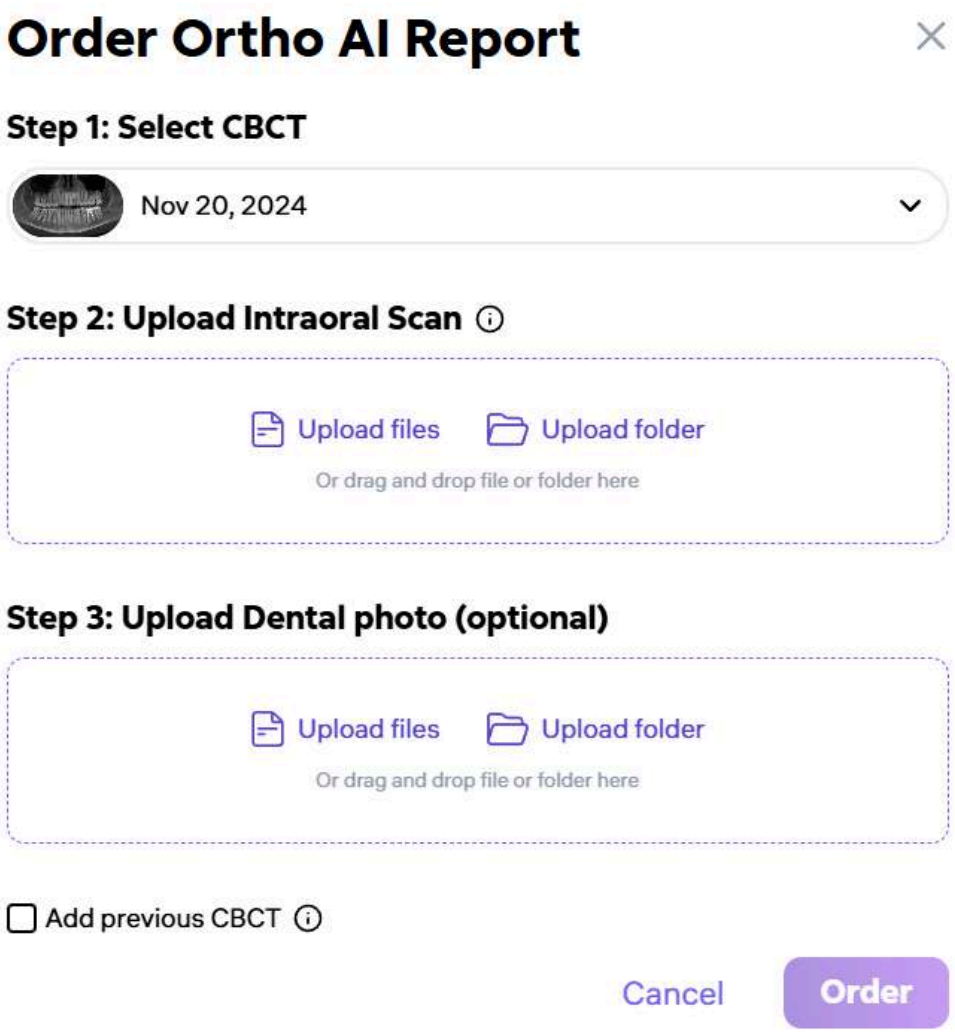
These detections are based on AI analysis of radiographic features and are intended to supplement the clinician's review, not replace it. Clinicians should always refer to the full image set to confirm the significance of these findings.

NOTE: As with all other AI-generated findings in Diagnocat AIS, "Other Findings" serve as a decision-support tool. Final interpretation and diagnosis must be performed by a licensed dental professional.

8. Ortho AI Report

8.1 Order and view analysis

To order a Ortho AI Report, use the 'Order Report' widget.



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After uploading the CBCT or selecting a previously uploaded CBCT and Intraoral Scan, the user should click "Order" to generate the report. Once the report is generated, the user can click the widget to open the Ortho AI Report. Upon clicking the widget, the system will display the Orthodontic Report in a new window in PDF format.

8.2 Report Overview

Ortho AI Report consists of panoramic reconstruction from CBCT, Teeth cross-sectional images, Coronal images, TMJ slices and summation, Airways and Cephalometric analysis with measurements.

An example of a section from the Ortho AI report is provided below.

Page 1: Panoramic Reconstruction

Displays a panoramic reconstruction of the CBCT scan.

Pages 2-5: Cephalometric Summation Images

- Sagittal Projection (Right and Left sides):
  - First Image: Displays cephalometric landmarks and anatomy contours (soft tissue, mandible, first incisors, first molars).
  - Second Image: Displays cephalometric landmarks, anatomy contours, planes, and measurements.
  - Measurement Ruler: Located on the right, marked in 1 cm intervals.
- Visualization:
  - Highlights landmarks, areas, and measurements for both sides.
  - Outlines central incisors, first molars, lower jaw, and soft tissues.
- Measurement Table:
  - Includes Name, Actual Value (Right/Left), Norm, and Deviation.
  - Deviation Analysis:
    - Moderate deviation (1–2 SD): Highlighted in orange.

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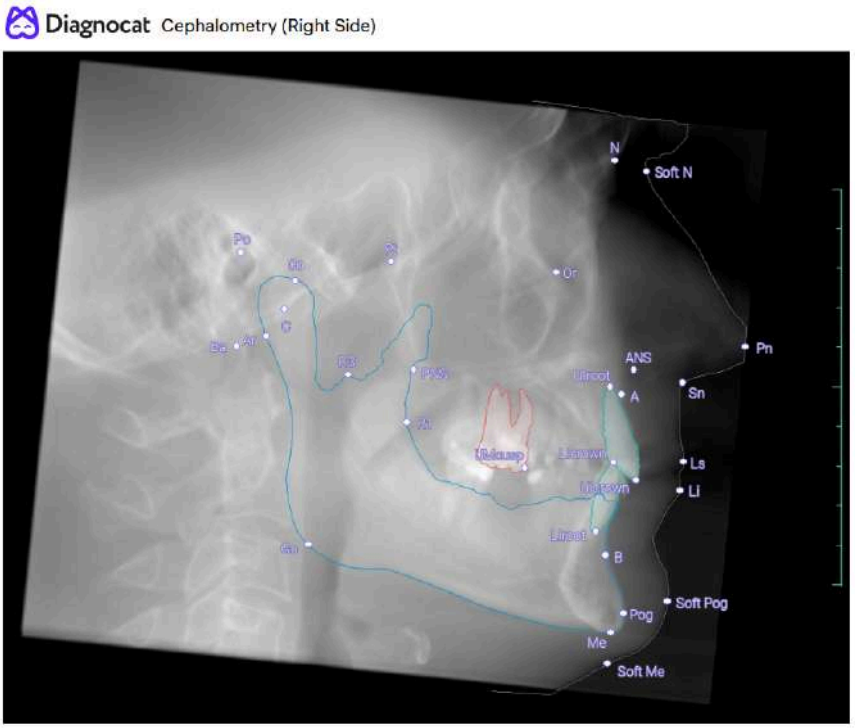
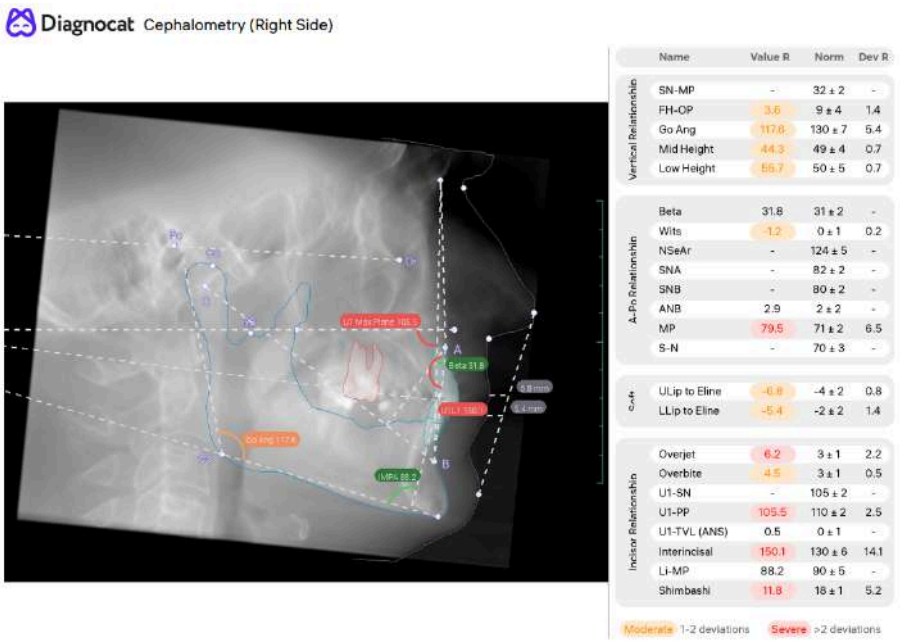
- Severe deviation (>2 SD): Highlighted in red.
- Deviations categorized as Moderate (1–2 units) or Severe (>2 units).

The right side is shown below (the left one is similar to the right one).





Page 6: Cephalometric Measurements Table

- Displays cephalometric measurements organized into categories:

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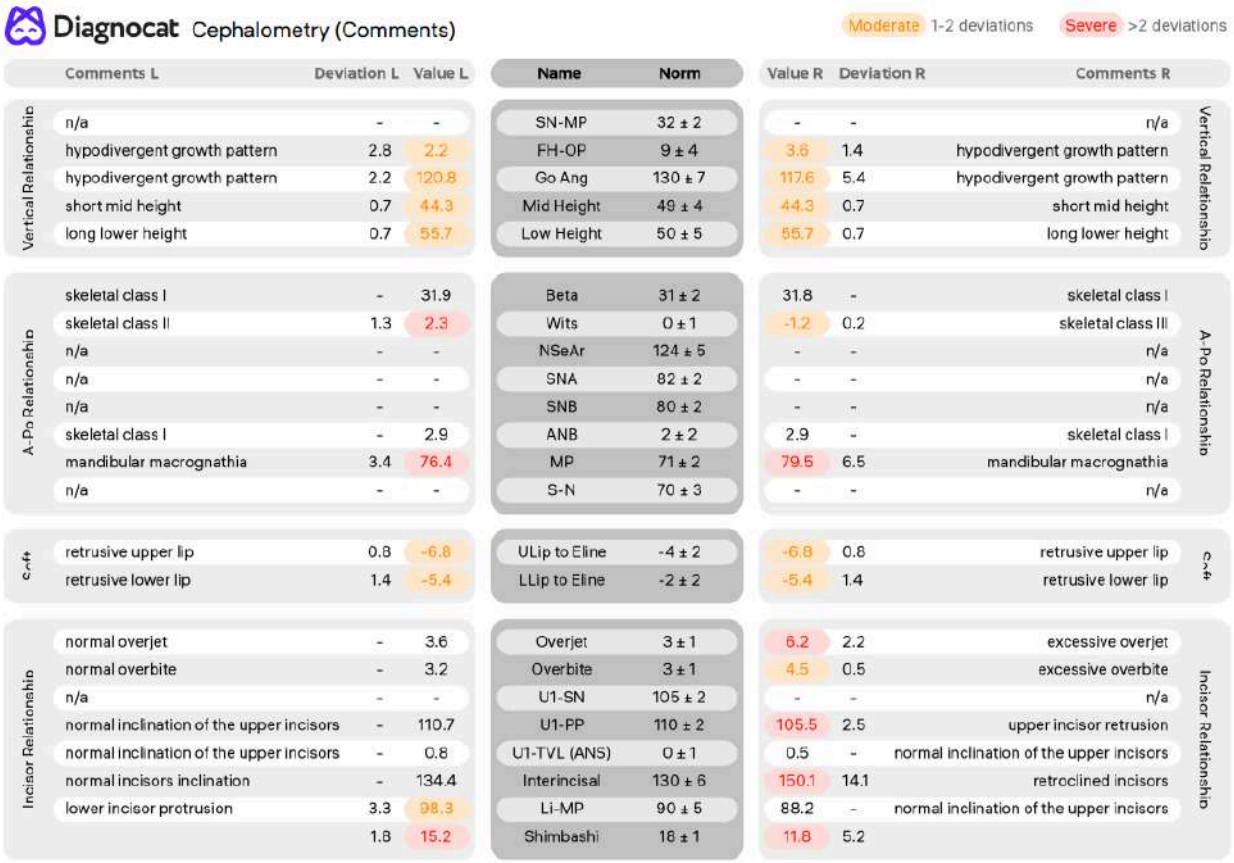
Diagnocat

- Vertical, Sagittal (A-Po), Soft, and Incisor Ratios.

- Columns:
  - Name, Norm, Value (Left/Right), Deviation (Left/Right), and Comments.
- Deviations visually highlighted:
  - Orange for moderate deviations (1–2 units).
  - Red for severe deviations (>2 units).



Diagnocat Cephalometry (Comments)

Moderate 1-2 deviations Severe >2 deviations

	Comments L	Deviation L	Value L	Name	Norm	Value R	Deviation R	Comments R	
Vertical Relationship	n/a	-	-	SN-MP	32 ± 2	-	-	n/a	Vertical Relationship
	hypodivergent growth pattern	2.8	2.2	FH-OP	9 ± 4	3.6	1.4	hypodivergent growth pattern	
	hypodivergent growth pattern	2.2	120.8	Go Ang	130 ± 7	117.6	5.4	hypodivergent growth pattern	
	short mid height	0.7	44.3	Mid Height	49 ± 4	44.3	0.7	short mid height	
	long lower height	0.7	55.7	Low Height	50 ± 5	55.7	0.7	long lower height	
A-Po Relationship	skeletal class I	-	31.9	Beta	31 ± 2	31.8	-	skeletal class I	A-Po Relationship
	skeletal class II	1.3	2.3	Wits	0 ± 1	-1.2	0.2	skeletal class III	
	n/a	-	-	NSeAr	124 ± 5	-	-	n/a	
	n/a	-	-	SNA	82 ± 2	-	-	n/a	
	n/a	-	-	SNB	80 ± 2	-	-	n/a	
	skeletal class I	-	2.9	ANB	2 ± 2	2.9	-	skeletal class I	
	mandibular macrognathia	3.4	76.4	MP	71 ± 2	79.5	6.5	mandibular macrognathia	
	n/a	-	-	S-N	70 ± 3	-	-	n/a	
Soft	retrusive upper lip	0.8	-6.8	ULip to Eline	-4 ± 2	-6.8	0.8	retrusive upper lip	Soft
	retrusive lower lip	1.4	-5.4	LLip to Eline	-2 ± 2	-5.4	1.4	retrusive lower lip	
Incisor Relationship	normal overjet	-	3.6	Overjet	3 ± 1	6.2	2.2	excessive overjet	Incisor Relationship
	normal overbite	-	3.2	Overbite	3 ± 1	4.5	0.5	excessive overbite	
	n/a	-	-	U1-SN	105 ± 2	-	-	n/a	
	normal inclination of the upper incisors	-	110.7	U1-PP	110 ± 2	105.5	2.5	upper incisor retrusion	
	normal inclination of the upper incisors	-	0.8	U1-TVL (ANS)	0 ± 1	0.5	-	normal inclination of the upper incisors	
	normal incisors inclination	-	134.4	Interincisal	130 ± 6	150.1	14.1	retroclined incisors	
	lower incisor protrusion	3.3	98.3	Li-MP	90 ± 5	88.2	-	normal inclination of the upper incisors	
		1.8	15.2	Shimbashi	18 ± 1	11.8	5.2		

NOTE:

- Cephalometric Planes constructed using natural head position rotation rules and MIP projections.
- Segmentation accuracy depends on the anatomical regions captured within the DICOM file.

<u>Pages 7-8: Frontal Summation Images</u>

Frontal Projection Summation:

- First Image: Displays landmarks, anatomy contours, and measurement segments.

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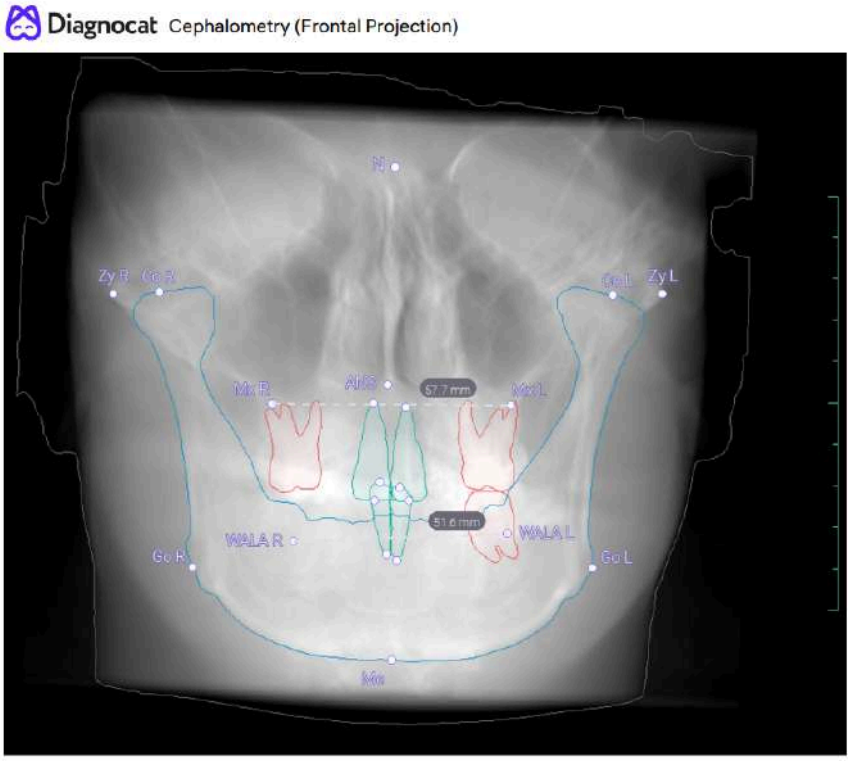
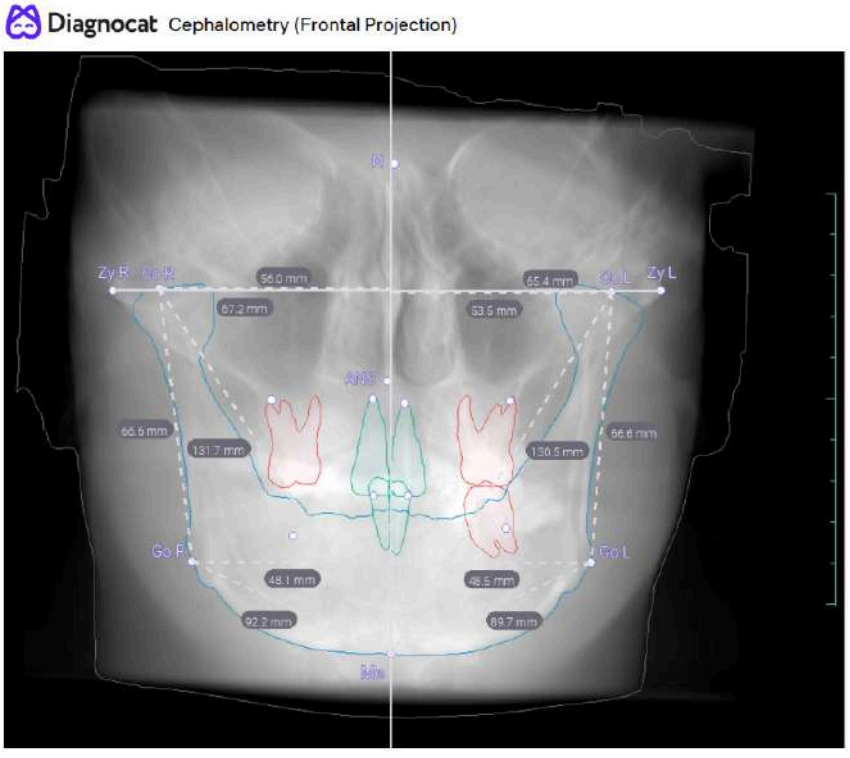
- Second Image: Includes vertical and horizontal lines, along with measurement annotations.
- Measurement Ruler: Located on the right, marked in 1 cm intervals.





Pages 9-10: Teeth Cross-Sectional Images

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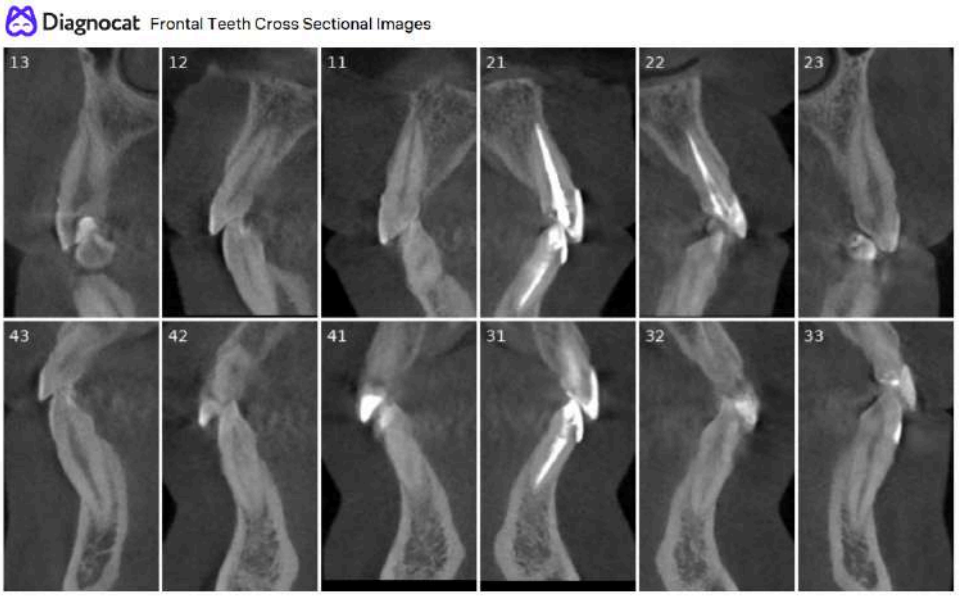
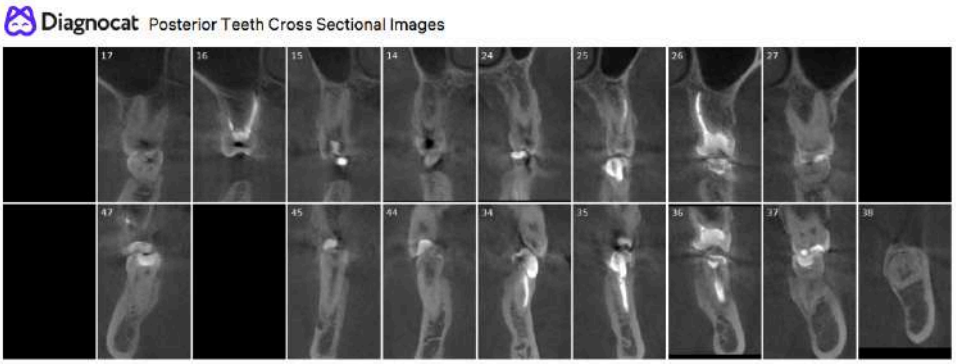
- Frontal Teeth:
  - Sagittal projection images of teeth: 13, 12, 11, 21, 22, 23, 33, 32, 31, 41, 42, 43.
- Posterior Teeth:
  - Sagittal projection images of teeth: 18, 17, 16, 15, 14, 24, 25, 26, 27, 28, 38, 37, 36, 35, 34, 44, 45, 46, 47, 48.
- Annotations:
  - Each cross-sectional image is labeled with tooth numbers.
  - Missing teeth are excluded from the report.





Page 11: Coronal Images

- Coronal and axial slice images for both jaws:
  - Slices segmented by teeth groups (e.g., 7–7, 6–6, 5–5, 4–4, 3–3).
  - Coronal Images: Teeth segments are annotated.
  - Axial Images: Displayed beneath corresponding coronal slices.

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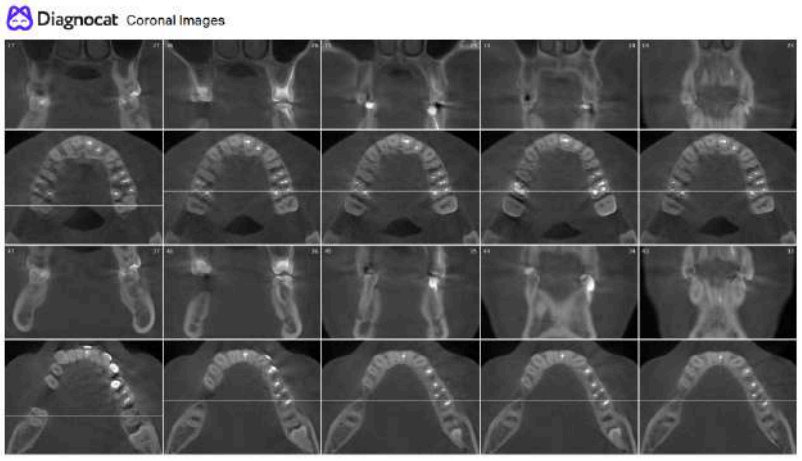
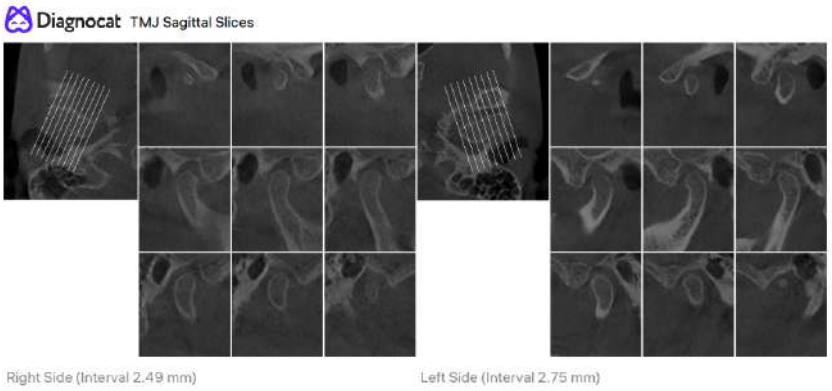


Pages 12-15: TMJ Analysis

- TMJ Sagittal Slices:
  - 9 sagittal slices per side (Right and Left), equidistant and annotated.
  - Axial slices with overlaid sagittal slice positions.
- TMJ Coronal Slices:
  - 9 coronal slices per side, equidistant and annotated.
  - Axial slices with overlaid coronal slice positions.
- TMJ Summation:
  - Sagittal Summation: Displays sagittal projection summation for both sides.
  - Coronal Summation: Displays coronal projection summation for both sides.
  - Slice Intervals: Interval values calculated using DICOM voxel metadata.

Example of TMJ Sagittal Slices provided below.



Page 16: Airway Analysis

- Airway Summation:
  - Sagittal projection with color-coded airway distribution:
    - Red: Minimum cross-sectional area.
    - Blue: Maximum cross-sectional area.

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- Displays:
  - Minimum Area: (mm², rounded to 1 decimal).
  - Total Volume: (cm³, rounded to 1 decimal).

NOTE: If CBCT scans less than recommended minimal FOV (13x15x15), the system provides a red warning in the report. The report does not include all anatomical structures and the report will be incomplete, if the user uploads CBCT scans less than recommended minimal FOV.

Ensure that the software accurately identifies and segments relevant anatomical regions.

9. Compatible device

Diagnocat AIS integrates with other software devices of the Diagnocat company, including Segmentron Viewer (Segmentation Report and Superimposition report) and Segmentron Implant. These reports can be easily ordered through Diagnocat AIS, ensuring efficient workflow for your needs.

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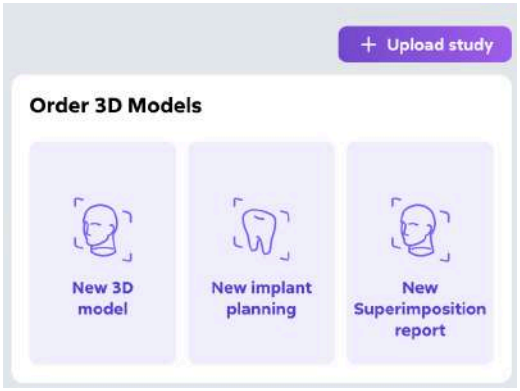
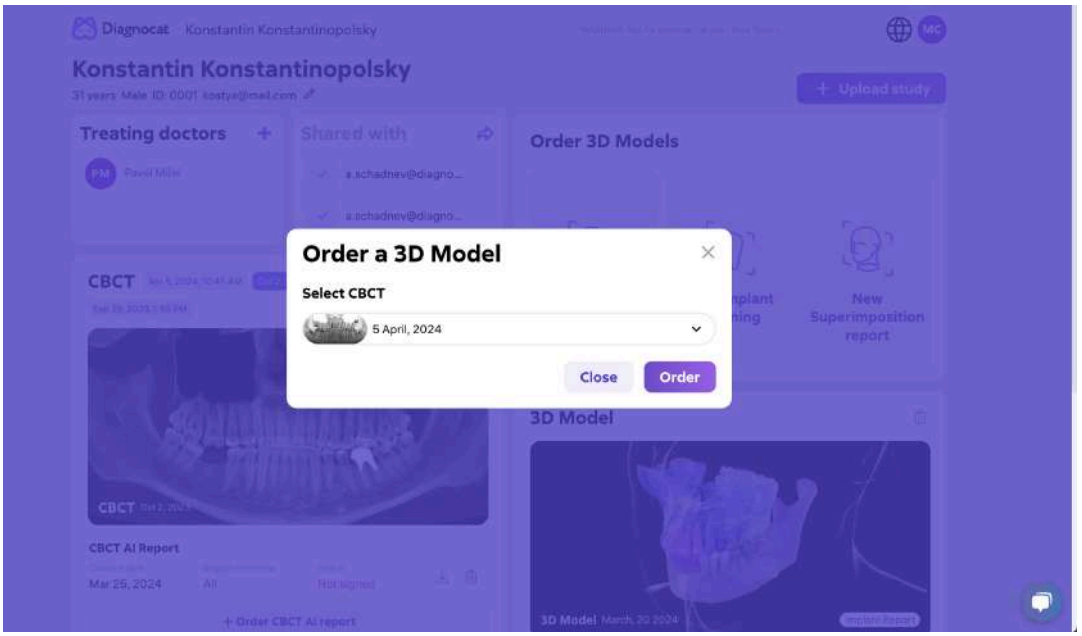


9.1 Order Segmentation Report

Click the “New 3D Model” button in the patient card, select relevant CBCT and click “Order”.



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

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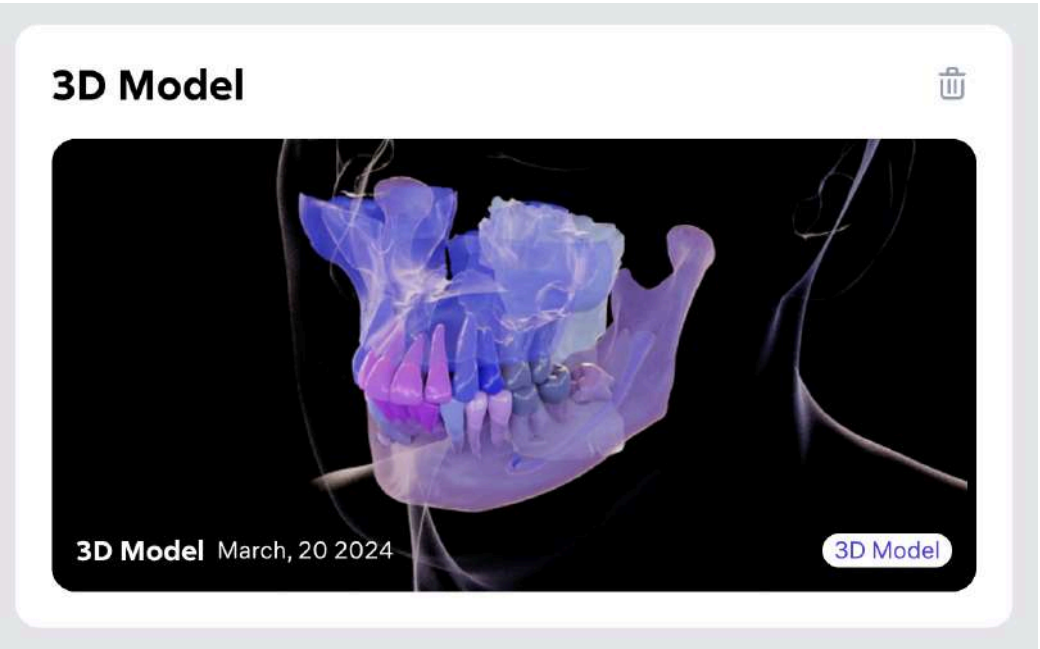
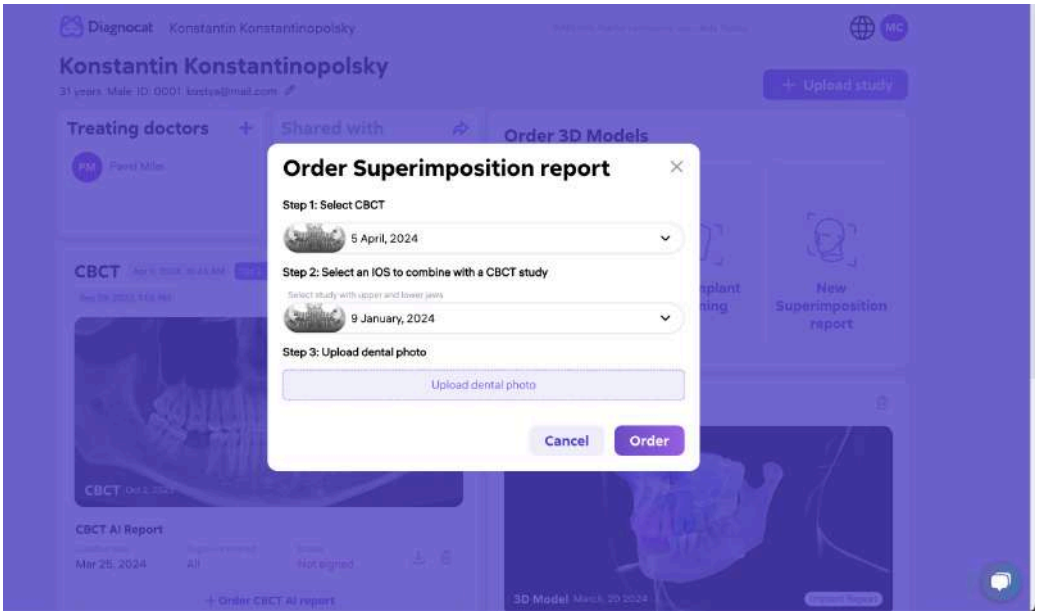


9.2 Order Superimposition Report

Diagnocat allows you to 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.



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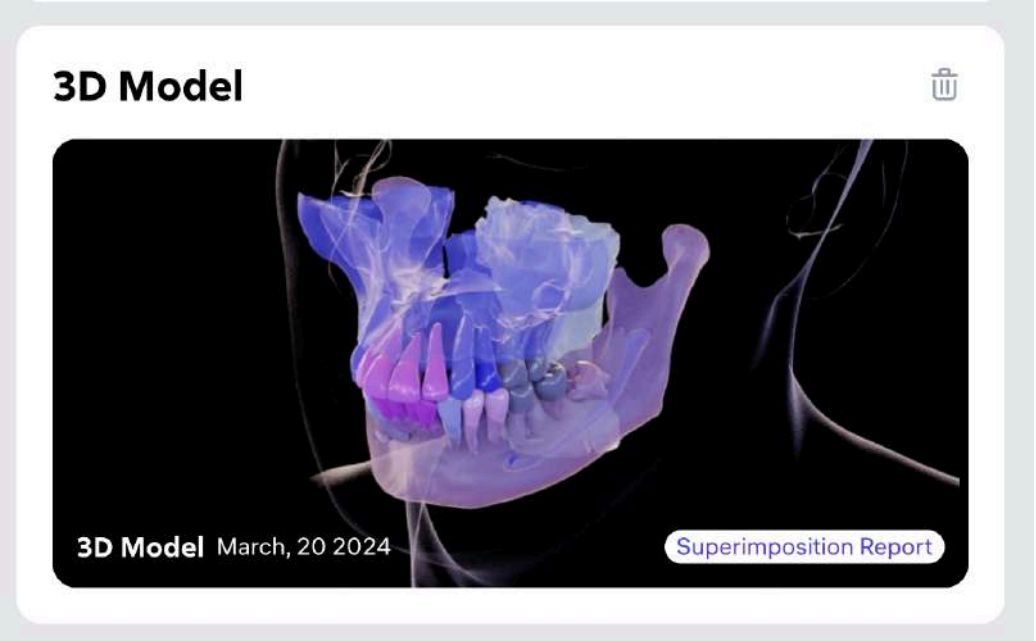
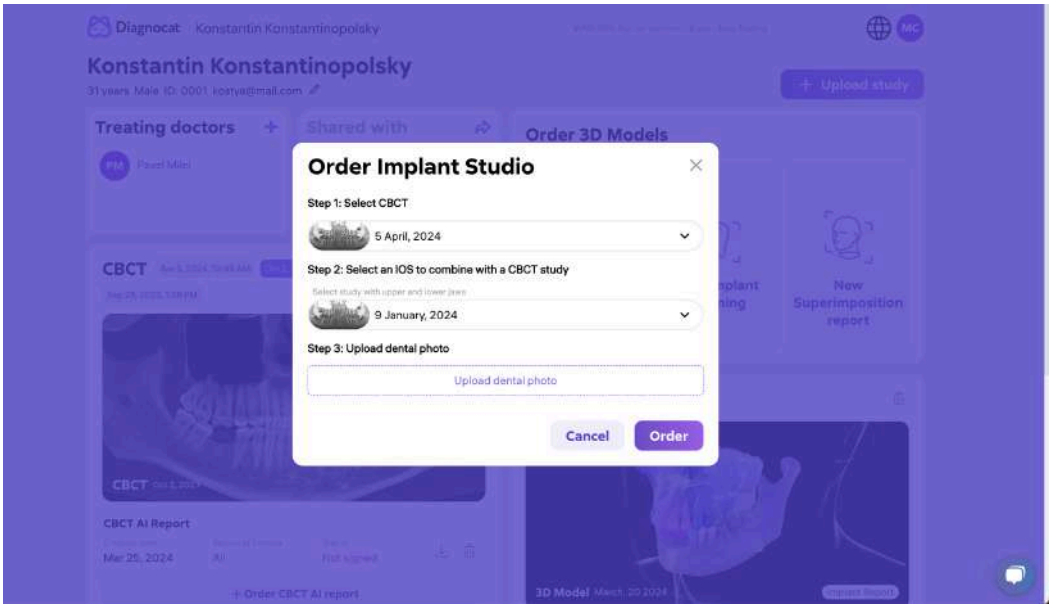
After ordering, you can view the generated report by clicking on the panoramic image and opening the Segmentron Viewer Device.



9.3 Order Implant Report

Diagnocat allows you to create an Implant Report. Click the “New Implant Planing” button in the patient card, select CBCT and IOS to combine with a CBCT study and click “Order”.

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 Implant Device.

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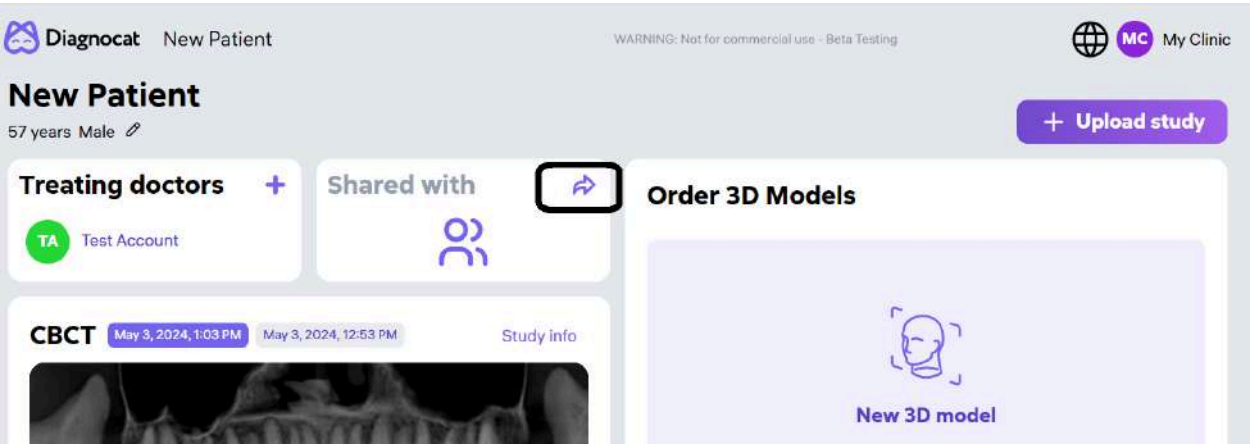
10. Additional Functions

10.1 Share patient

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



Click on the "Share" icon.

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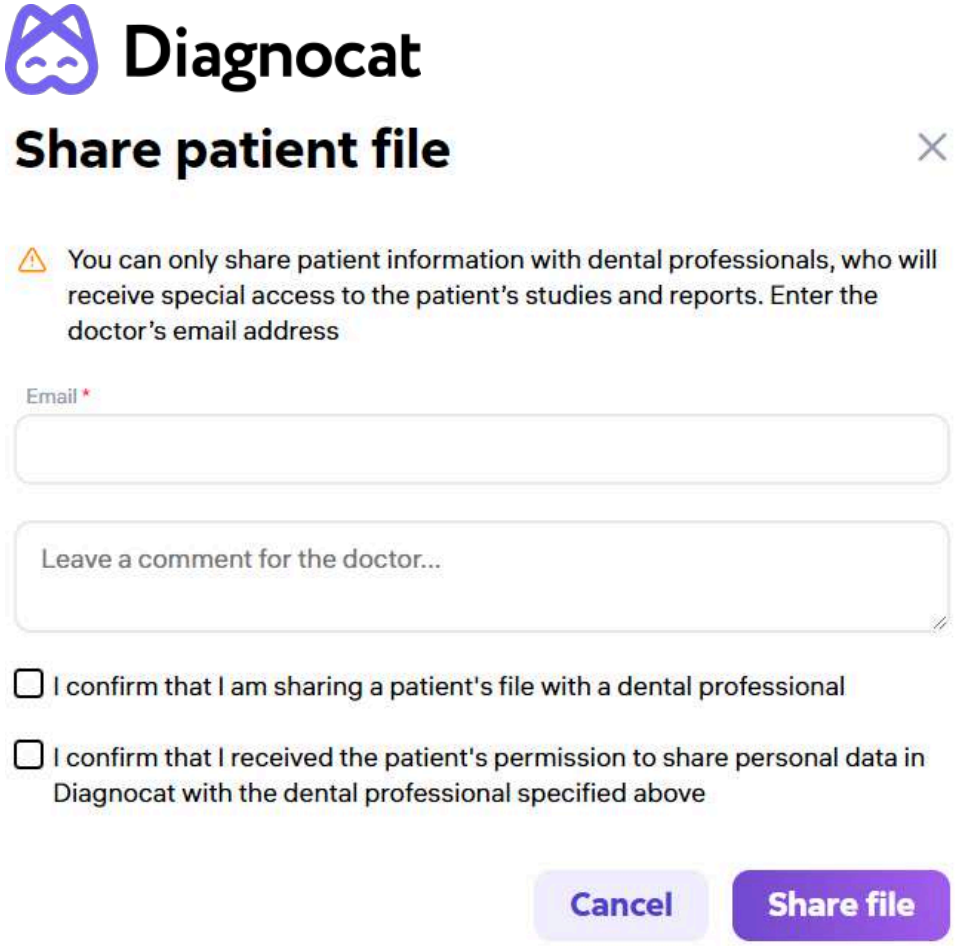

Enter the recipient email address, leave a comment for the doctor, if necessary and check the boxes that “I confirm that I am sharing a patient's file with a dental professional” and I confirm that I received the patient's permission to share personal data in Diagnocat with the dental professional specified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

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

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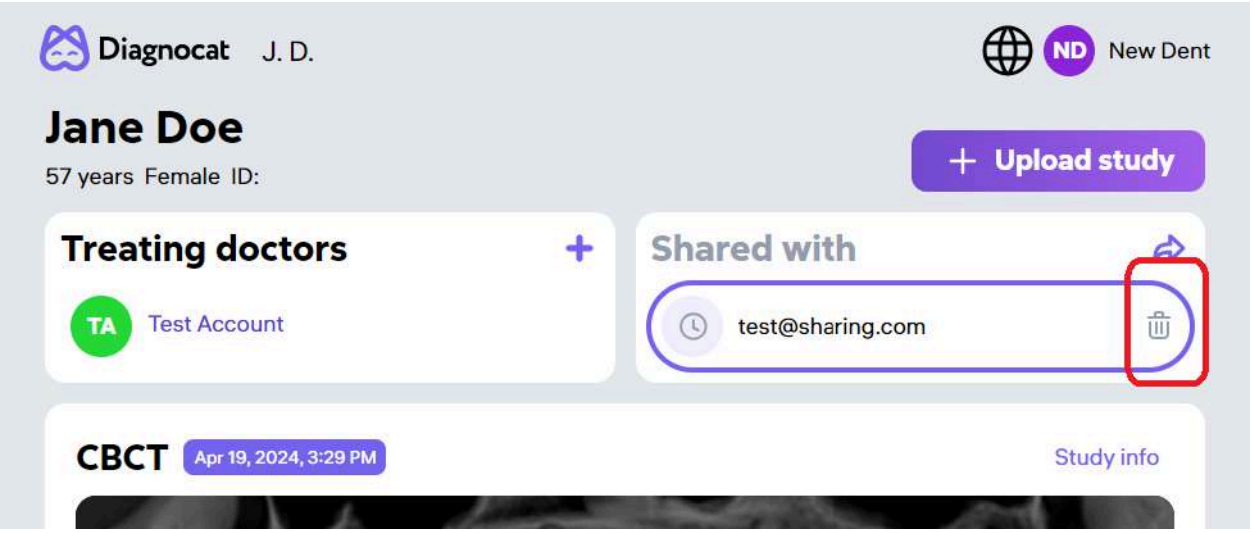
On the left side in the patient's information "Shared with" you will see a list of doctors a patient study has been shared with.

To revoke access click the "bin" icon.



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

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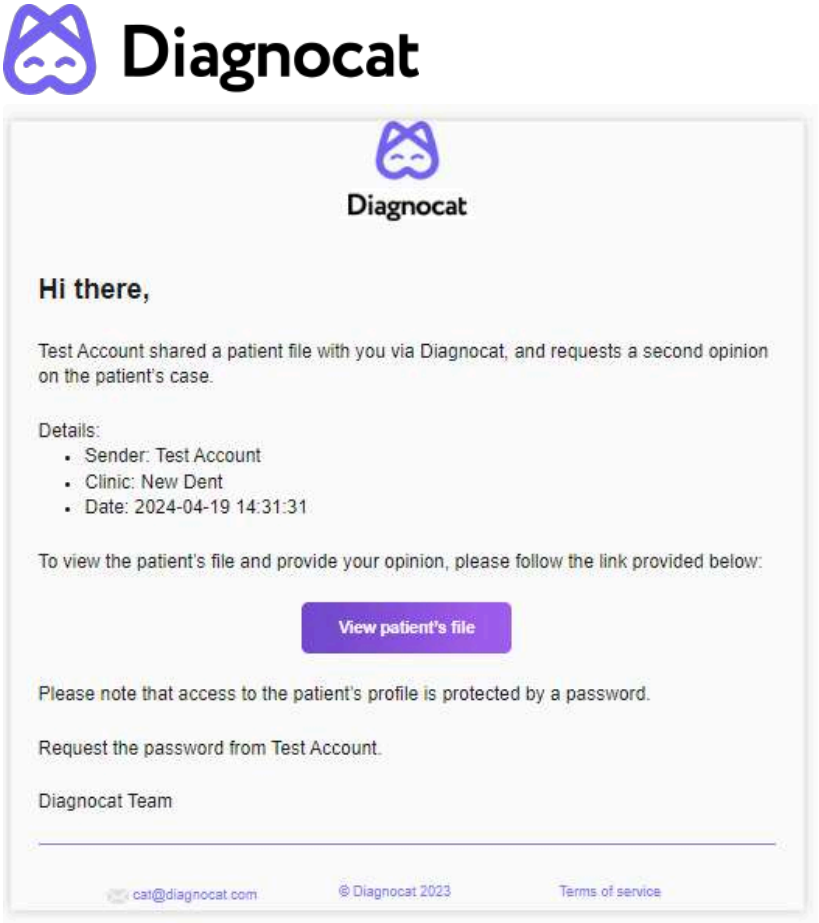
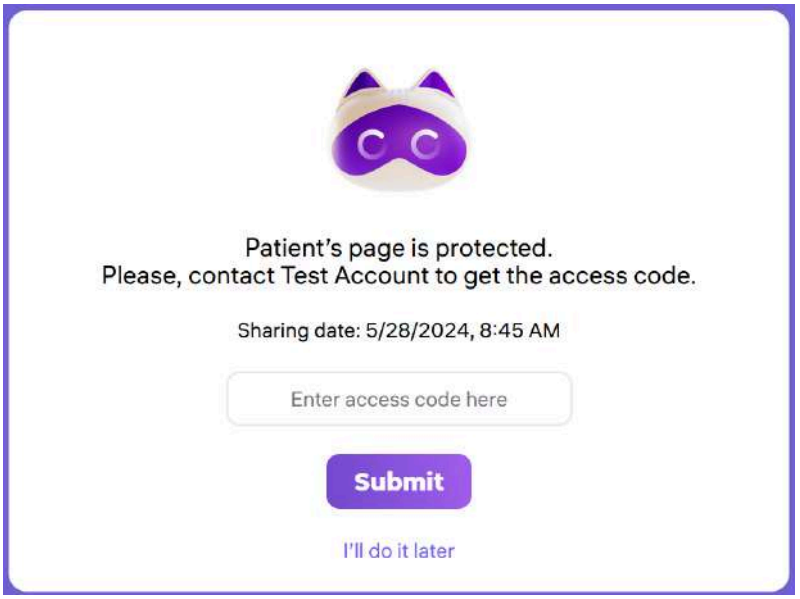


If the doctor doesn't have a Diagnocat account, they will be able to create a new one. Once finished they will be prompted to their account where they can view reports of the shared patient.

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



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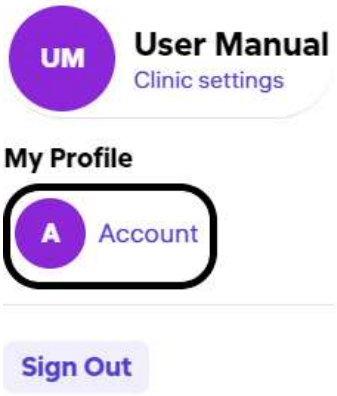
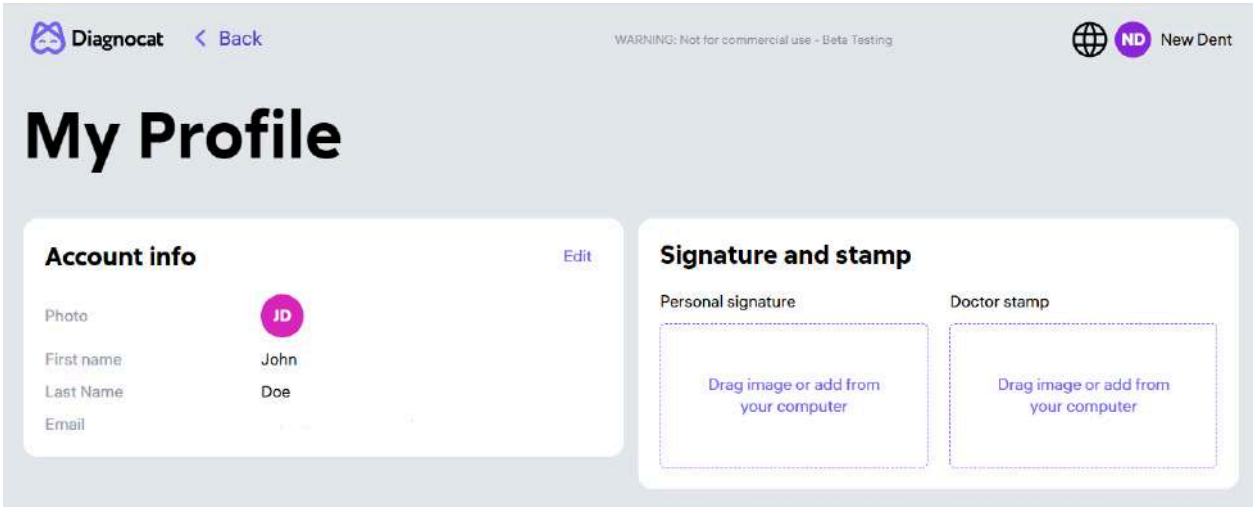
10.2 Account and Clinic Settings

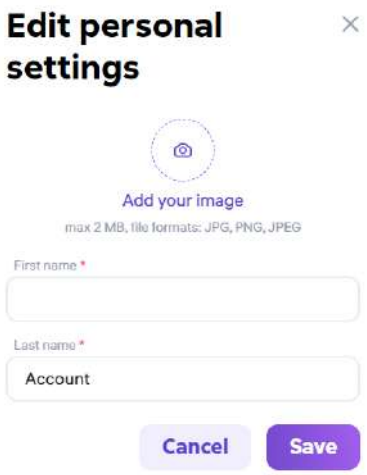
To get access to Account settings click the arrow icon in the top right corner.



Inside you will find 2 main tabs:



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



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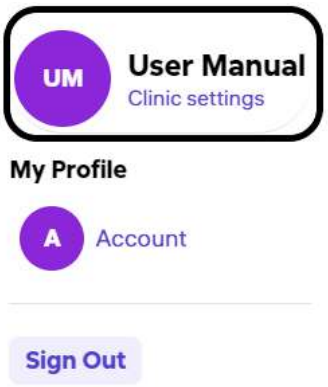
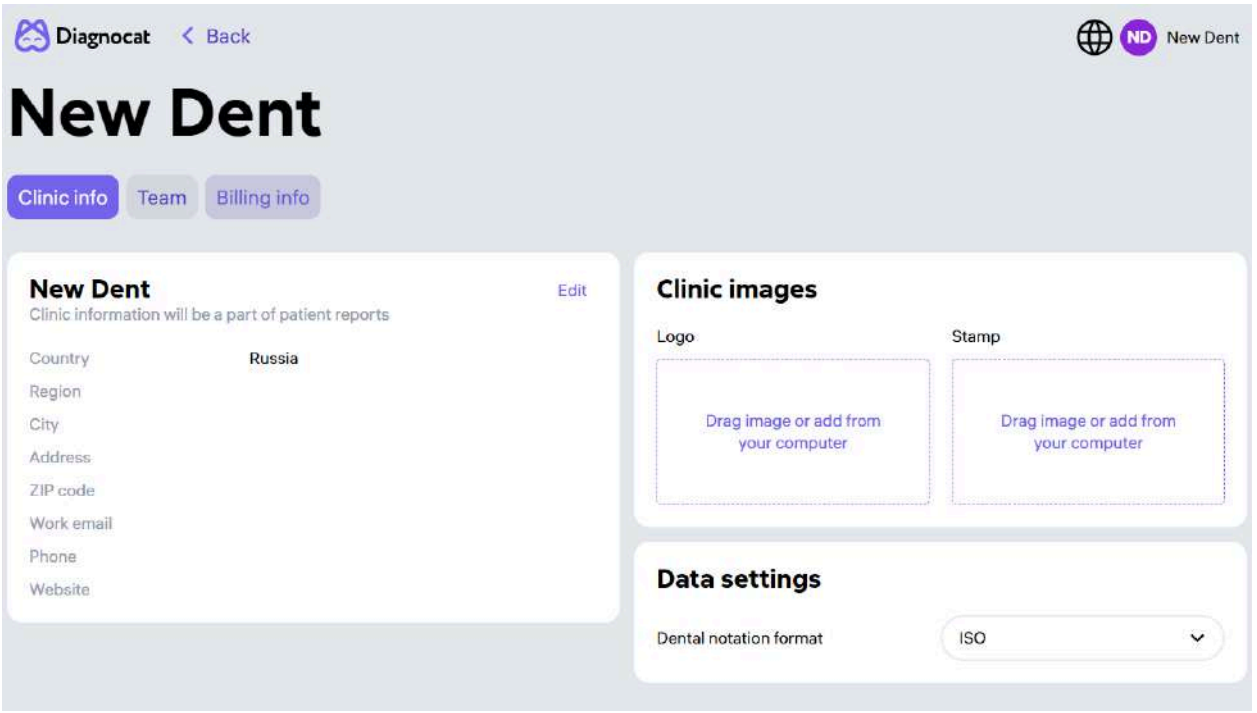
#2: Signature and stamp. You can add a personal signature and doctor stamp.

To get access to clinic settings click the arrow icon in the top right corner.



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.

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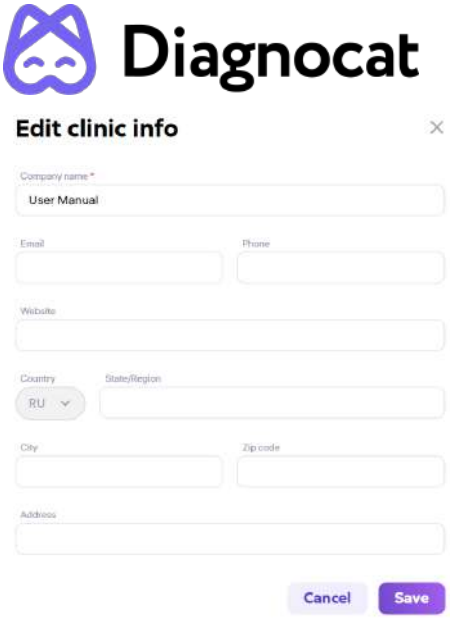
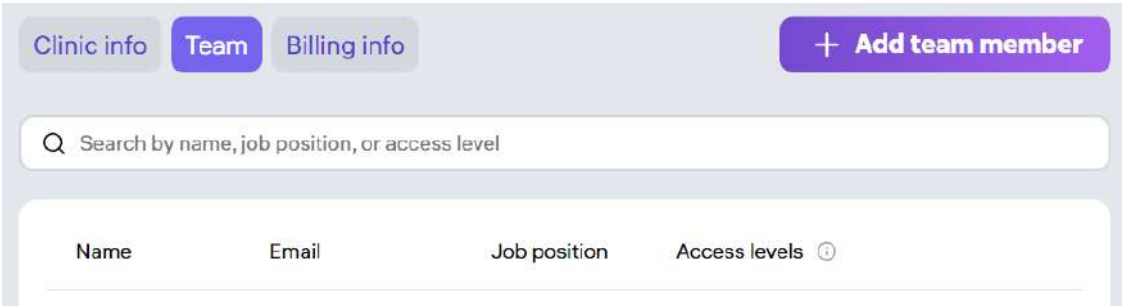
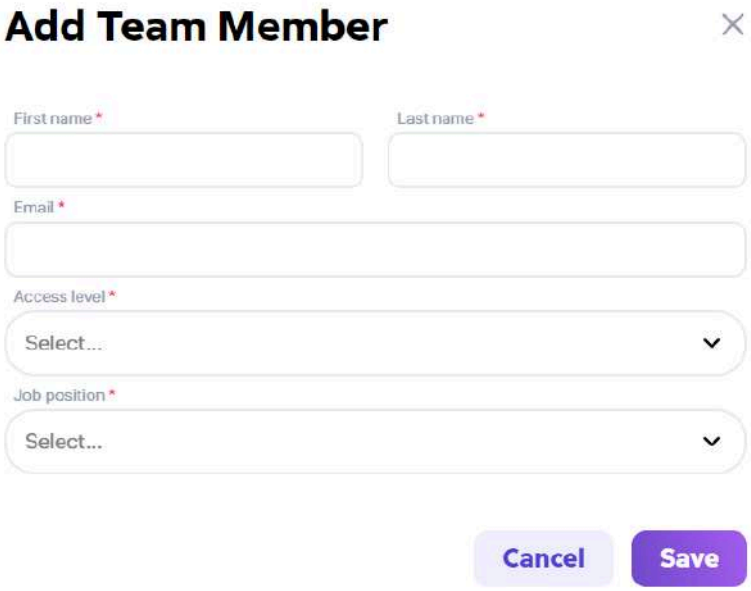


#2: Team. You can add, remove and edit employees.



You can add a team member, after clicking on the button “Add team member” a form will open to fill in.



Please note: to fill in the “Access level” field correctly use the hint on the "Team" page.

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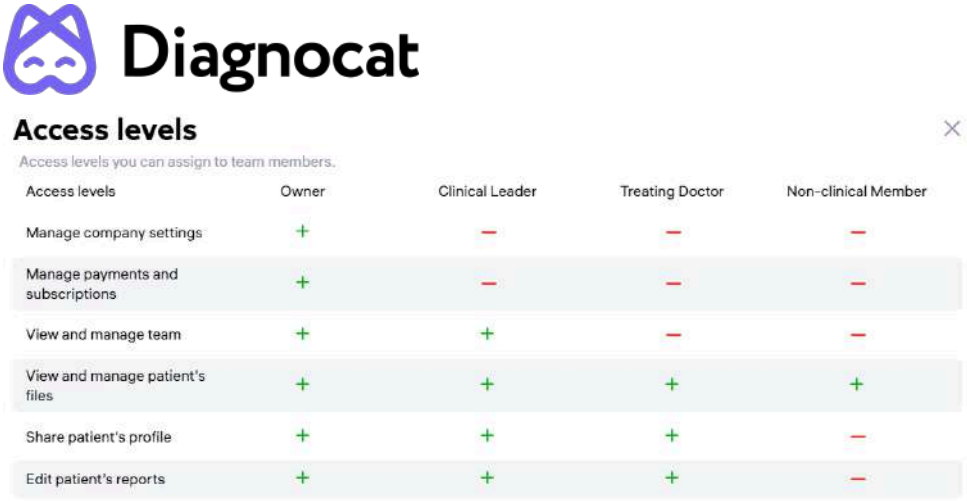
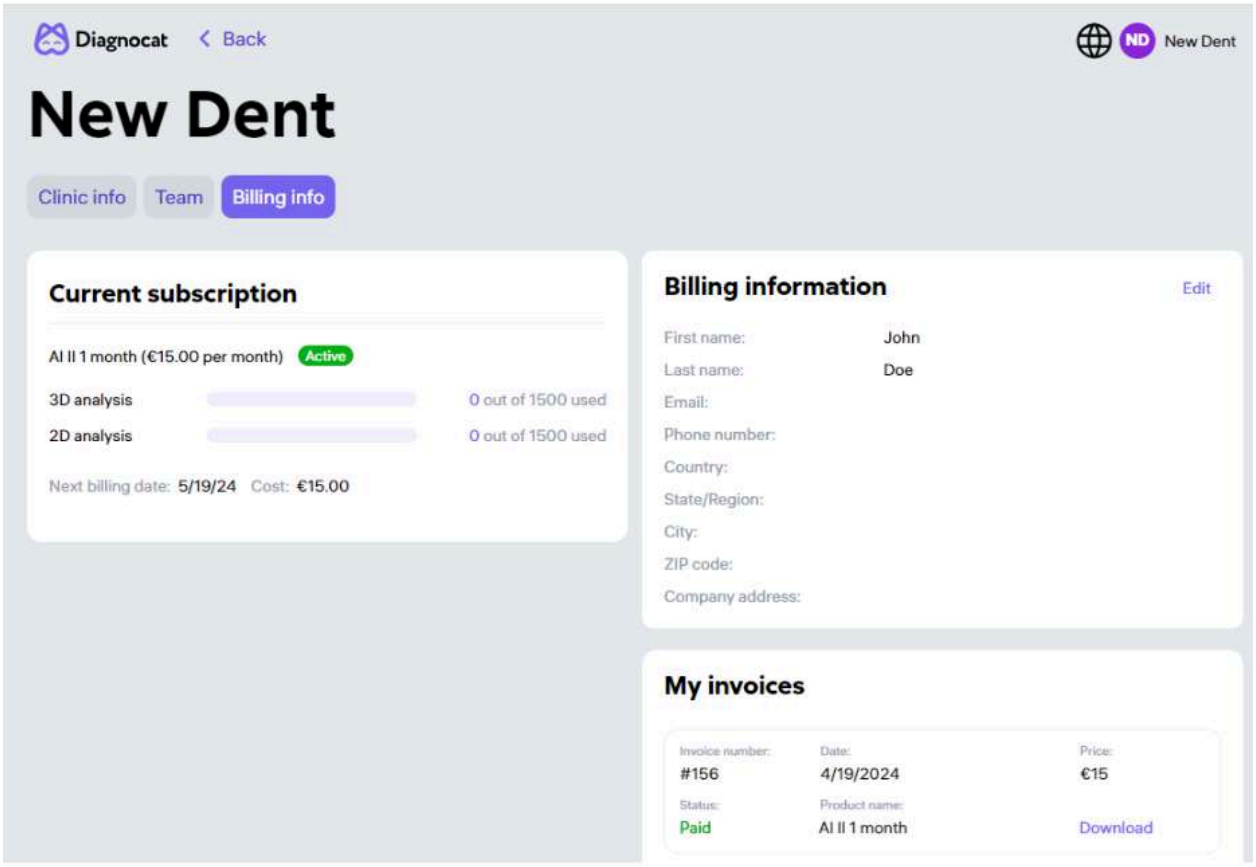


#3: Billing info. You can view your current subscription, packages, consumption and invoices. You can also pay and download your invoices and change billing information.



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

11 Performance Testing

This section summarizes the validation results from standalone performance evaluations conducted on various AI functionalities of the Diagnocat AIS software. These performance evaluations were performed retrospectively using independent datasets and compared against

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Diagnocat

expert-generated reference standards to determine diagnostic accuracy, segmentation fidelity, and overall clinical effectiveness. All studies adhered to GCP-compliant protocols, utilized statistically rigorous methodologies (including bootstrap-based confidence intervals), and were conducted on representative patient populations and diverse radiographic equipment.

The standalone studies were designed to compare the diagnostic models' outputs against a reference standard established by expert radiologists. The studies began with the establishment of dataset aggregation, which included determining the case type distribution and sample size to ensure a representative sample for analysis. Definitions and analysis methodologies were then clearly established to maintain consistency and accuracy throughout the studies. The ground truth process was set up, involving the creation of a comprehensive database and an objective mechanism for result retrieval. Certified radiologists conducted ground truth readings of the cases following the methodology described in the protocols. Subsequently, the same cases were analyzed using the modules without clinician intervention. Statistical analyses were performed to evaluate the measurement accuracy and agreement of the modules. The performance of the modules was then compared to the established ground truth, and a detailed report was generated to document the findings.

In the evaluation of the Diagnocat AIS performance tests, the primary objective was to assess the alignment between the algorithm's output and the ground truth. In all cases, the studies' success criterias were met:

1. *Study 1 - Diagnocat AIS in Detecting Pathologic and Non-Pathologic Dental Findings in CBCT Radiographs:* This study evaluated whether the ROC-AUC scores exceeded a threshold of 0.8, using bootstrapping with 1000 resamplings. The null hypothesis was rejected if the lower bound of the 95% confidence interval was greater than 0.8.
2. *Study 2 - Diagnocat AIS Localization and Numeration of Pathologic and Non-Pathologic Dental Findings in X-Ray Radiographs:*

    2.1. Panoramic X-ray: The μDice Coefficient was tested with a null hypothesis of μ_Dice ≤ 0.92. The observed μDice was 0.935, with a 95% confidence interval of 0.931 to 0.938, rejecting the null hypothesis.

    2.2. Intraoral X-ray: The μDice Coefficient was tested with a null hypothesis of μ_Dice ≤ 0.80. The observed μDice was 0.874, with a 95% confidence interval of 0.865 to 0.882, rejecting the null hypothesis.

3. *Study 3 - Diagnocat AIS in Detecting Pathologic and Non-Pathologic Dental Findings in X-Ray Radiographs:* This study assessed alignment between the device's output and the ground truth using criteria like intersection area ratios and AFROC-FOM. Bootstrapping with 1000 resamplings was used to determine confidence intervals, with performance measured by the AFROC curve.
4. *Study 4 - Diagnocat in Segmentation and Localization of Periapical Radiolucency and Teeth on CBCT Radiographs:* The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding

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0.8 for teeth segmentation masks and 0.7 for periapical radiolucency masks. Similarly, the overall localization F1 Score surpassed the threshold of 0.9 for teeth localization and 0.7 for periapical radiolucency localization. Additionally, the lower bound of the 95% confidence interval of Tooth Numbering Accuracy was found to be greater than or equal to 0.9.

5. *Study 5 - Diagnocat in Pulp and Canal Filling Segmentation on CBCT Radiographs*: The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding 0.725 for pulp segmentation masks and 0.65 for canal filling masks. Additionally, the upper bound of the 95% confidence interval of the Average Symmetric Surface Distance was less than or equal to 0.125 mm for pulp masks and 0.45 mm for canal filling masks. The evaluation confirmed the system's clinical effectiveness, with most errors occurring in small-volume structures or overlapping pulp/filling cases. These results affirm the robustness of Diagnocat's AI in segmenting internal tooth anatomy on CBCT without clinician intervention.

6. *Study 6 - Diagnocat in Segmentation of Pathologic and Non-Pathologic Dental Findings (masks) on X-Ray Radiographs*: The primary endpoints were successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding 0.855 for panoramic radiographs and 0.885 for intraoral radiographs. The observed mean Dice coefficient was 0.86401 [CI: 0.85737–0.87239] for panoramic and 0.88886 [CI: 0.88609–0.89022] for intraoral X-rays. Secondary endpoints were also met across all tested findings, including periapical radiolucency, periodontal bone loss, crowns, fillings, posts, and orthodontic appliances. This confirms the system's reliable segmentation performance for both pathological and non-pathological conditions without clinician input.

7. *Study 7 – Diagnocat in Detection of Periodontal Bone Loss on Intraoral Radiographs:* The primary endpoints were successfully achieved, with the lower bound of the 95% confidence interval of the Sensitivity reaching 0.856 and the PPV reaching 0.9 for detecting periodontal bone loss (PBL) keypoints. The overall mean values were 0.878 for Sensitivity and 0.915 for PPV, both exceeding the predefined thresholds of 0.85. Secondary endpoints confirmed consistent and accurate detection of cemento-enamel junction (CEJ) and bone level landmarks, with CEJ Sensitivity at 0.893 [CI: 0.86–0.921] and bone level Sensitivity at 0.872 [CI: 0.841–0.901]. These results affirm the device's clinical effectiveness in detecting PBL landmarks on intraoral radiographs without clinician intervention.

8. *Study 8 – Diagnocat in Teeth Segmentation and Numeration, Including Identification of Supernumerary Teeth on CBCT Radiographs:* the primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity

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Coefficient (DSC) exceeding 0.9 for teeth segmentation masks. Specifically, the DSC reached a mean value of 0.94 [95% CI: 0.92–0.95]. Similarly, the secondary performance metrics met the required thresholds, with the Hausdorff Distance (HD95) achieving a value of 0.18 [0.07–0.27] and the Volume Similarity (VS) reaching 0.96 [0.95–0.97]. Importantly, the system demonstrated equivalent performance for both normal and supernumerary teeth, with no statistically significant difference ($p = 0.69$). These results affirm the clinical effectiveness of Diagnocat AIS for comprehensive tooth segmentation and numbering across standard and atypical dental anatomy on CBCT images.

9. *Study 9 – Diagnocat in Segmentation of Anatomical Structures on Intraoral Radiographs:* The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding the predefined thresholds for all anatomical structures. For example, DSC values were 0.977 [CI: 0.973–0.981] for vestibular bone (threshold: 0.972), 0.909 [CI: 0.881–0.933] for maxillary sinus (threshold: 0.822), and 0.920 [CI: 0.907–0.931] for crown (threshold: 0.901). Similarly, secondary endpoints evaluating Intersection over Union (IoU) were met, such as vestibular bone at 0.956 [CI: 0.949–0.963] and root at 0.815 [CI: 0.796–0.832], all surpassing their respective performance thresholds. Furthermore, analysis of PBL central sector length and angle deviance showed no statistically significant difference from ground truth (mean angle deviance: 0.07°), supporting consistency in quantitative periodontal assessments. These results affirm the high segmentation accuracy and clinical utility of Diagnocat AIS on intraoral radiographs.

10. *Study 10 – Diagnocat in Segmentation of Anatomical Structures on Panoramic Radiographs:* The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding the predefined thresholds for all anatomical structures. Notable results include: DSC of 0.985 [CI: 0.984–0.986] for mandible (threshold: 0.98), 0.952 [CI: 0.946–0.958] for maxillary sinus (threshold: 0.94), and 0.932 [CI: 0.922–0.944] for maxilla (threshold: 0.92). Secondary endpoints for Intersection over Union (IoU) were also met for most structures—e.g., IoU of 0.971 [CI: 0.969–0.973] for mandible and 0.908 [CI: 0.898–0.92] for maxillary sinus—except for mandibular canal and root canal, where the lower bound of the 95% CI fell below the target threshold. These results confirm high segmentation accuracy and robust performance of Diagnocat AIS for automated anatomical analysis on panoramic X-rays without clinician intervention.

11. *Study 11 – Diagnocat in Tooth Conditions Segmentation on CBCT Radiographs:*
The primary endpoints were successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding 0.8 for enamel (CI: 0.8085–0.8322) and dentin (CI: 0.8251–0.8529), and 0.9 for roots (CI: 0.9039–0.9103). Similarly, the sensitivity for all pathological/non-pathological findings surpassed the required thresholds: 0.9440 for abfraction (threshold: 0.90), 1.0000 for artificial crowns

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(threshold: 0.95), 0.8715 for caries (threshold: 0.85), 0.9092 for fillings (threshold: 0.90), and 0.9644 for indirect restorations (threshold: 0.95). Secondary endpoints, including Hausdorff Distance and Volume Similarity, met predefined thresholds for nearly all anatomical parts, with strong spatial and volumetric agreement. Exploratory metrics showed high Dice and VS values for most conditions, though caries segmentation metrics marginally missed the preset goals. These results confirm the system's clinical effectiveness in segmenting both anatomical structures and tooth conditions on CBCT scans, supporting its utility in diagnostic workflows without clinician intervention.

12. *Study 12 – Diagnocat (Segmentron) in Teeth Segmentation on CBCT Radiographs:* The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding 0.9 for teeth segmentation masks. Specifically, the DSC reached 0.94 [CI: 0.92–0.95]. Secondary endpoints were also met, with the upper bound of the 95% confidence interval of the Hausdorff Distance (HD95) at 0.27, well below the 3 mm threshold, and the lower bound of the Volume Similarity (VS) at 0.95, surpassing the 0.9 performance goal. These results affirm the high spatial accuracy and consistency of Diagnocat's Segmentron module for automated teeth segmentation on CBCT without clinician intervention.

13. *Study 13 – Diagnocat in Anatomical Structures Segmentation on CBCT Radiographs:* The primary endpoint was successfully achieved, with the lower bound of the 95% confidence interval of the Dice Similarity Coefficient exceeding target thresholds for all key anatomical structures. Specifically, values included 0.97 for mandible, 0.96 for facial soft tissue, 0.94 for maxillary sinus, 0.92 for airways, and 0.90 for maxilla. The mandibular canal and incisive canal also exceeded their respective DSC thresholds of 0.8 and 0.7, reaching 0.86 and 0.74, respectively. Secondary endpoints were also met: the 95% CI upper bounds of the Hausdorff Distance were below preset margins (e.g., 0.29 mm for mandible, 0.56 mm for maxillary sinus), and the Volume Similarity metrics met or exceeded their thresholds in all structures except for the incisive and mandibular canals, where the lower bounds of the 95% CI matched but did not exceed the target. These results confirm the robust segmentation performance of Diagnocat AIS across a comprehensive set of craniofacial structures on CBCT scans.

14. *Study 14 – Diagnocat in Fully Automated Cephalometric Landmark Detection and Measurement on CBCT Radiographs:*The primary endpoint was successfully achieved, with the upper bound of the 95% confidence interval of the Mean Radial Error (MRE) for all 62 cephalometric landmarks falling below their respective performance thresholds. For example, MRE was 1.42 [CI: 1.1–1.81] mm for point A (threshold: 2.43 mm), and 0.73 [CI: 0.58–0.89] mm for ANS (threshold: 1.27 mm). Secondary endpoints were also met, including successful detection rates (SDR) of 91.7% at 2.5 mm and 97.6% at 4 mm, and the upper bounds of the 95% CI of the Mean Difference (MD) between Diagnocat and manual cephalometric measurements for 37 variables all falling within predefined performance goals. For example, the MD for ANB angle was 0.42 [CI: 0.27–0.57]

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(threshold: 0.85), and for overjet was 0.33 [CI: 0.27–0.40] (threshold: 0.61). These results confirm the high precision and clinical readiness of Diagnocat AIS for automated cephalometric analysis, including landmark localization and measurement, without clinician input.

15. *Study 15 – Diagnocat in Upper Airways Segmentation for Automated Cephalometric Analysis on CBCT Radiographs:* The primary endpoint was successfully achieved, with the upper bound of the 95% confidence interval of the Average Symmetric Surface Distance (ASSD) significantly below the predefined threshold of 0.75 mm. The observed mean ASSD was 0.15 mm [95% CI: 0.12–0.19], confirming precise spatial agreement between Diagnocat's segmentation and the expert-defined reference standard. For the secondary endpoint, the difference in segmented upper airway area between Diagnocat and manual reference was evaluated across all cases, percentile groups, and individual cases. The differences were statistically insignificant ($p > 0.05$) in all cases except two (cases 14 and 18), thereby supporting overall measurement consistency. The mean airway area values were 262.79 mm² for the ground truth and 264.07 mm² for Diagnocat, with overlapping confidence intervals. These findings affirm the robustness of Diagnocat AIS in accurately segmenting upper airways for cephalometric applications, supporting its effectiveness in reducing manual effort and variability in clinical assessments.

16. *Study 16 – Diagnocat in Labeling of Dental Condition Masks on Panoramic Reformats from CBCT Scans:* The primary endpoint was successfully achieved, with 100% labeling accuracy reported across all mask categories and all 20 CBCT-derived panoramic reformatted scans. This included perfect concordance with expert annotations for masks in the Perio (e.g., impaction, periodontal bone loss), Endo (e.g., periapical radiolucency), Restorative (e.g., root fragments, caries, abfraction), and Anatomy (e.g., fillings, crowns, indirect restorations) groups. Evaluation showed no deviation in labeling accuracy for any structure, with the 95% confidence intervals for all categories bounded at 100%, and standard deviation of 0.0%. These findings confirm the robust consistency and high reliability of Diagnocat AIS for automated identification and labeling of dental conditions on CBCT-derived panoramic reformats, without clinician input.

17. *Study 17 – Diagnocat in Detection of Other Findings on Panoramic and CBCT Reformatted Radiographs:* The primary endpoints were successfully achieved, with the lower bound of the 95% confidence interval of the Sensitivity exceeding the predefined thresholds of 0.85 for CBCT and 0.95 for panoramic X-rays. The mean Sensitivity was 0.946 [CI: 0.857–1.0] for CBCT reformatted images and 0.988 [CI: 0.963–1.0] for panoramic X-rays. Similarly, the secondary endpoints were met, with the Positive Predictive Value (PPV) reaching 0.944 [CI: 0.871–1.0] for CBCT and 0.988 [CI: 0.963–1.0] for panoramic X-rays, both exceeding their respective thresholds. Exploratory analysis by finding type showed particularly strong performance: for maxillary sinus abnormalities, both sensitivity and PPV reached 1.0 for panoramic X-rays and exceeded 0.89 for CBCT images. These results confirm the robust diagnostic accuracy of Diagnocat AIS in detecting and localizing signs of bone structure and maxillary sinus

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abnormalities on both imaging modalities, without clinician input, thus supporting its standalone clinical use.

18. *Study 18 – Diagnocat in Quantification of Periapical Volume on CBCT Radiographs:* The primary endpoint was successfully achieved, with the difference between AI-predicted and expert-determined periapical volumes found to be statistically insignificant (p = 0.11), indicating no meaningful discrepancy in volumetric measurement. The mean volumes were 49.29 mm³ for AI predictions and 45.82 mm³ for expert labels, with overlapping 95% confidence intervals: [33.80–65.47] for AI and [32.59–60.04] for expert annotations. The secondary endpoint was also met, with an Intraclass Correlation Coefficient (ICC) of 0.982 [95% CI: 0.960–0.992], reflecting excellent agreement between the AI system and expert assessment. These results demonstrate the high reliability and clinical accuracy of Diagnocat AIS in segmenting and quantifying periapical lesions on CBCT scans without clinician intervention.

Each module's evaluation included detailed stratification by age, gender, geographic distribution, and imaging equipment to confirm generalizability. The validation used bootstrapping (≥10,000 iterations) for confidence interval estimation, and Python or R for statistical computations, depending on the report.

The performance validation studies demonstrate that the Diagnocat AIS modules are effective and reliable for their respective indications. The standalone evaluations, performed without clinician intervention, consistently achieved high accuracy metrics compared to reference standards. These results confirm the readiness of the modules for clinical use under their intended uses.

12 Troubleshooting, Maintenance and service

If you encounter any issues while using Diagnocat, please contact the manufacturer.
In case of noticing any malfunctions, contact the maintenance service at the e-mail address: support@diagnocat.com

13 Contact information (for assistance)

CONTACT INFORMATION

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

MANUFACTURER

DGNCT LLC

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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. Please refer to the manufacturer's website for the updated contact info: https://www.diagnocat.com, if necessary.

Please report of any serious incident that has occurred in relation to the device injury or adverse event to the local competent authority and to sales@diagnocat.com

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