Diagnocat

Dentist's virtual assistant in treatment planning

DIAGNOCAT AIS

User Manual

Version 1.0

Diagnocat

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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 AIS'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 used solely for the purpose of explaining the use of Diagnocat AIS.

This document cannot be printed or reproduced without the permission of the copyright holder.

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

In addition, this manual may be modified without notice. Also, the manual distributed with the product may not contain the latest version of the product.

For inquiries related to the product and this manual, please contact the following contact 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.

This User Manual is written in English.

Symbols and marks used in the manual and in the labeling

	Manufacturer
	Follow instructions for use
	Caution
	Medical device

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CE	Device complies with the European Directive on Medical Devices EU MDR 2017/745

Contact

Website: http://www.diagnocat.com

Device information

Name: Diagnocat AIS

Relevant Diagnocat Version: 1.0

Device UDI: 860010268018

Regulatory Requirements

Diagnocat AI software complies with the following regulatory requirements:

- ISO 13485:2016
- Regulation (EU) 2017/745
- Therapeutic Goods (Medical Devices) Regulations 2002 in Australia (Therapeutic Goods Administration's website - tga.gov.au)

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.

Device Identification

DGNCT LLC

333 Southeast 2nd Avenue, 20th Floor#563,

Miami, Florida 33131, USA

Phone: + 1 519 619 4212

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https://www.diagnocat.com/

Downloading and printing instructions

This User Manual can be downloaded to the user's PC as a PDF and printed when necessary.

For users in the EU region: Users in the EU region have the right to request this manual in a paper form, at no additional cost. Reach out to customer support using the support@diagnocat.com email address to request a paper copy. Note that Diagnocat is based in the United States, so it may take up to 7 calendar days for a paper copy to reach a user. For this reason, we recommend downloading and printing the manual using your own printing device.

Customer Notice

This Instructions for Use is intended to assist users in the safe and effective use of the medical device software described herein. The "user" is considered to be not only the body with authority over the medical device software but also those persons who use the medical device software.

This Instructions for Use does not describe the use of the IT equipment on which the medical device software is installed. Refer to the documentation of the IT equipment concerned.

Before attempting to use this medical device software, you must read these Instructions for Use thoroughly, paying particular attention to all WARNINGS, and Notes it contains. You must pay special attention to all the information given, and procedures described, in the SAFETY section. In addition, you must pay special attention to on-screen Messages and On-line Help information containing WARNINGS and Notes that may be related to the function being executed.

Directions which if not followed could cause fatal or serious injury to a user, patient or other person, or could lead to clinical misdiagnosis, and/or loss/damage of patient-related data.

Additional information:

1. Diagnocat AIS may improve the function and performance of the product without notifying the user.

2. Some features of the product may not be available in all countries, languages and currencies.

3. It is illegal to reproduce and distribute the product without the consent of Diagnocat AIS.

4. Users should read this manual thoroughly before using this product.

5. In order to use the full functions of Diagnocat AIS, please follow the specifications described in this manual.

6. 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 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 software Device for Dental image processing and management. The device provides to the user image management capabilities and processing systems of maxillofacial Cone-Beam Computed Tomography (CBCT), Panoramic X-Ray and Intraoral X-Ray images. The device provides patient management capabilities, disease detection capabilities and image processing functions for image enhancement, image segmentation, multimodality image registration, or 3D visualization.
Diagnocat AIS is designed for cloud-based storage in addition to a desktop application and processing of digital dental images using artificial intelligence. Diagnocat AIS has been developed to automate the activities of dental organizations in radiological examinations, including examination uploading, screening of diagnostic images, saving, sharing, editing, localizing, segmenting and documentation of detected pathologies.
Diagnocat AIS processes files of any area of the patient's maxillofacial region.
Diagnocat AIS is designed for use by dental professionals (dentists, orthodontists,

radiologists, etc.) to highlight anatomical areas, various conditions and previous treatments. DiagnocatAIS 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 patient records.
Overview of the model of operation: Device's main function is to perform automated analysis of CBCT, Panoramic X-Ray and Intraoral X-Ray images provided by the user, and provide users with automatically generated reports. Automated analysis consists of applying artificial neural network models to images to obtain detections, localizations and segmentations of teeth, anatomies and conditions.

Intended Use

The Diagnocat AIS automated information system is designed for cloud-based storage and processing of digital dental images using artificial intelligence. Diagnocat AIS has been developed to automate the activities of dental organizations in radiological examinations, including examination uploading, screening of diagnostic images, saving, sharing, editing and drawing conclusions. 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. DiagnocatAIS 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.

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.
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.
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.

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Contraindications

Although Diagnocat AIS neural networks are trained on a large diverse dataset it is necessary to remember that in order for the analysis to work correctly, it is necessary to exclude studies of poor quality.

Applying the Software to poor quality dental pictures is forbidden. (This can lead to incorrect data collection)

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

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 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.

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

Diagnocat 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.

Diagnocat 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 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 relied upon as the sole decision making tool for diagnosis or treatment.

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

Required Training and Qualifications

Users of this medical product software must have received adequate training on its safe and effective use before attempting to use the product described in this Instructions for Use. Training requirements for this type of product will vary from country to country. It is the responsibility of users to ensure that they receive adequate training in accordance

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with local laws or regulations which have the force of law. If you require further information about training in the use of this medical product software, please contact Diagnocat.

Device Security and Privacy

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.

In accordance with security and industry best practices, security strategies should address:

• Physical security restricts unauthorized access to the servers where the Diagnocat AIS product is running.

• Operational security, for example, access / authorization controls and change management.

• 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.

• Backup

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.

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

Regulatory Controls

Protecting Personal Information

One of the most important assets to protect with security measures is the patient health information (PHI). Many governments require maintaining the confidentiality of this information. 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

Protecting personal health information is a primary component of a security strategy. Considering the nature of the Diagnocat AIS 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 AIS 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 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, so that unwanted access by unauthorized individuals is avoided. Procedures to maintain removable media must be part of the institution's security policy.

CAUTION: It is the whole responsibility of the user to guard removable media, which contains sensitive private information, at all times.

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CAUTION: Dispose media such as printouts in a secured manner when the media are no longer needed, since the media may contain sensitive private information.

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.

When using removable media like USB storage products, CDs, DVDs, be aware that inserting removable media can introduce a virus to the medical product.

Prevent Unauthorized product Modification

Diagnocat AIS is required to follow government-regulated quality assurance procedures to verify and validate modifications to Diagnocat AIS software.

Users and owners of this medical equipment must permit only Diagnocat authorized changes to be made to this product, either by Diagnocat personnel or under Diagnocat explicit published direction.

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;

● 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 AIS 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

The medical product software described in this Instructions for Use should not be used in combination with other software, equipment or components unless such other software, equipment or components are expressly recognized as compatible by Diagnocat AIS.

Changes and/or additions to the medical product software should only be carried out by Diagnocat AIS or by third parties expressly authorized by Diagnocat AIS to do so. Such changes and/or additions must comply with all applicable laws and regulations which have the force of law within the jurisdiction concerned, and with best engineering practice.

System requirements

Diagnocat AIS software requirements:

- Any operating system capable of running requires a Google Chrome version.
- Browser: Google Chrome 75+ and should be updated.

Diagnocat hardware requirements:

- Minimal processor with at least 2 CPU cores
- 2 GB RAM or more
- Recommended: Processor: 4 core. Memory: 4 GB RAM.
- 50 Mbps or faster Ethernet interface to your institution’s DICOM network

Compatible Radiological Data Sources:

- DICOM

- JPEG
- TIFF
- PNG

configurations

Diagnocat AIS can be configured in 2 options:

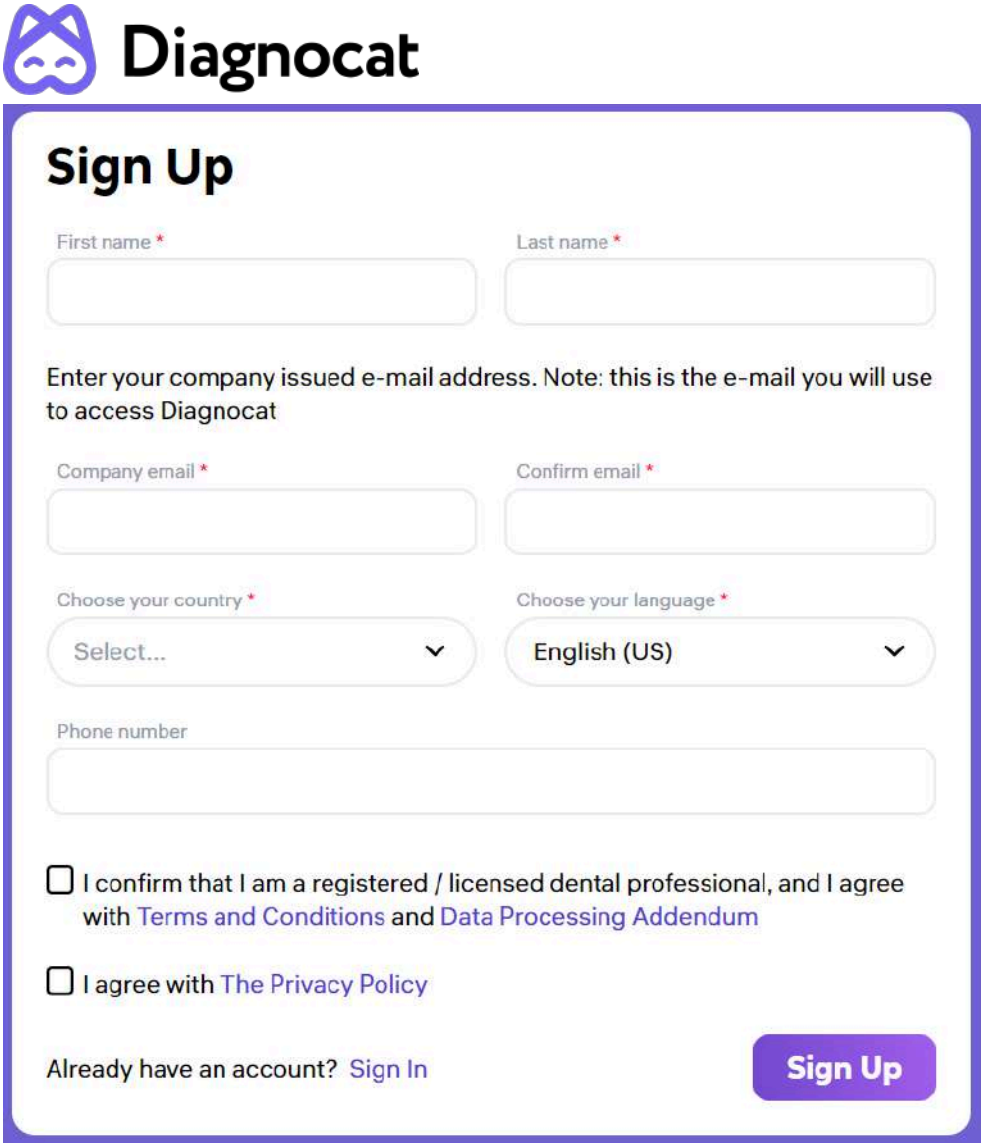
1. You can upload patients' studies manually using a web-browser that doesn't require any specific configuration.Please contact your sales representative or email Sales@diagnocat.com for more information.
2. Desktop integration. Diagnocat Imaging is an application that can capture dental images from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

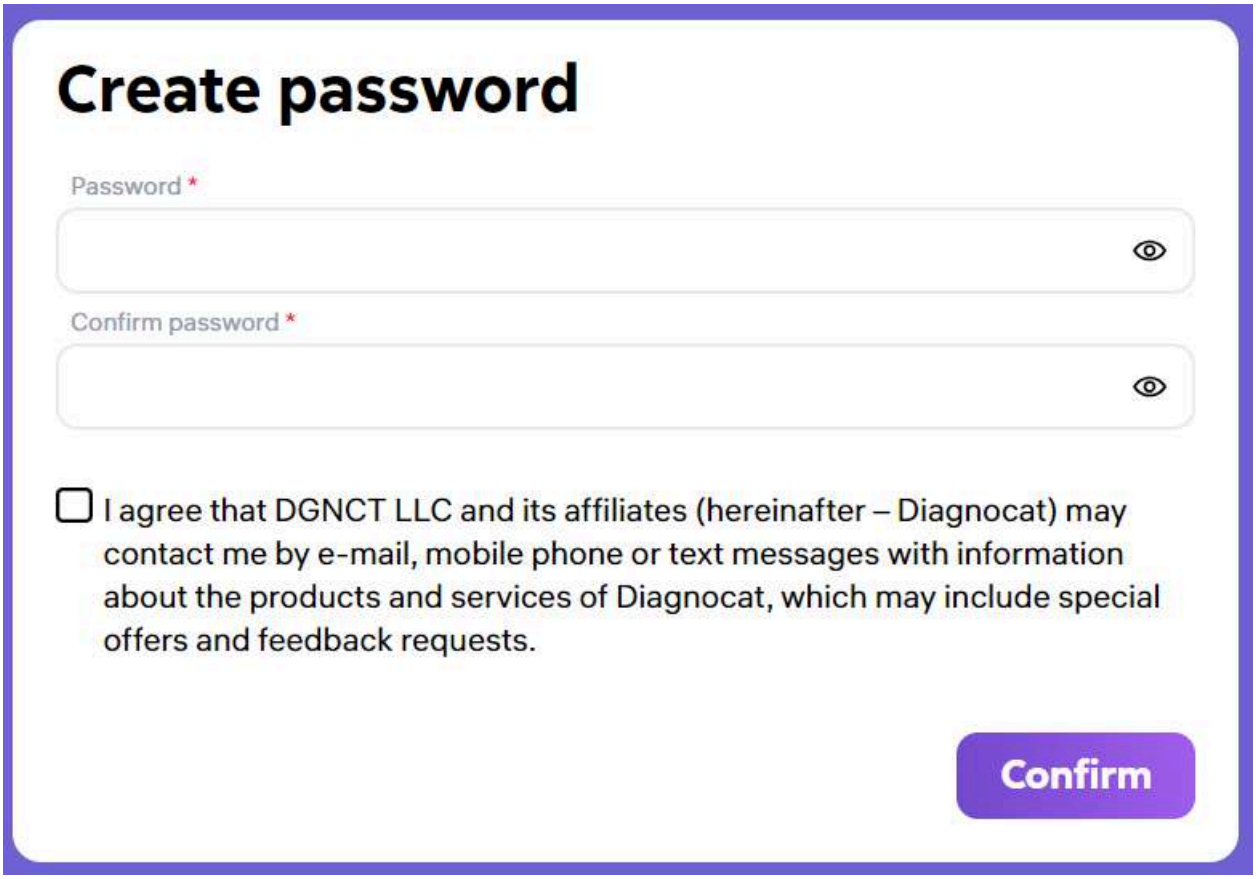
1.1 Sign up

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.



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

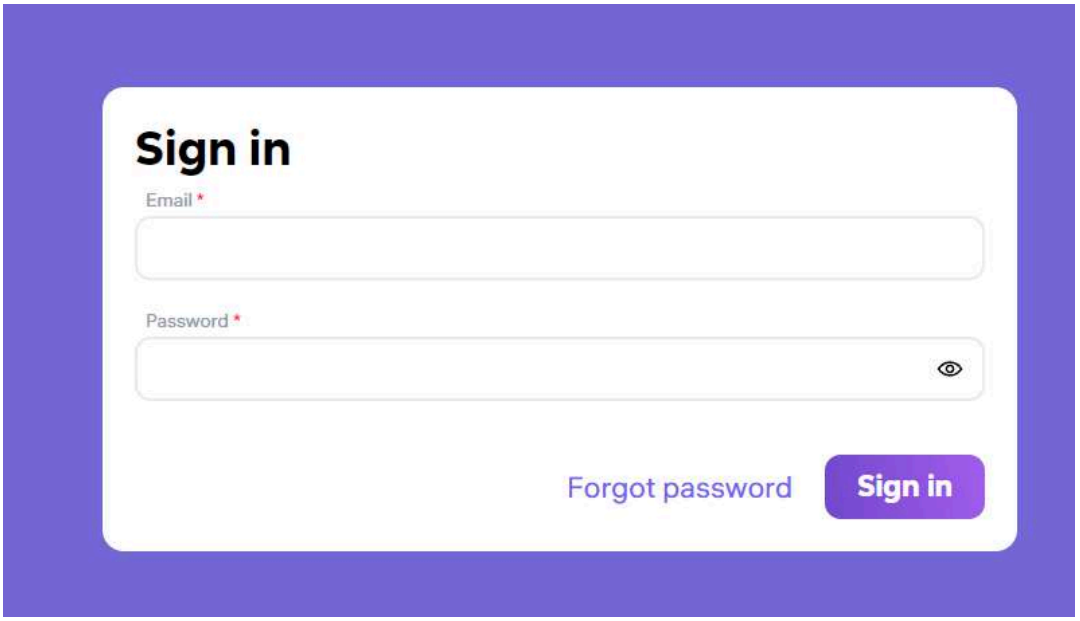


After the registration Diagnocat will ask you some questions about your experience and equipment to better understand your needs.

1.2. Log in

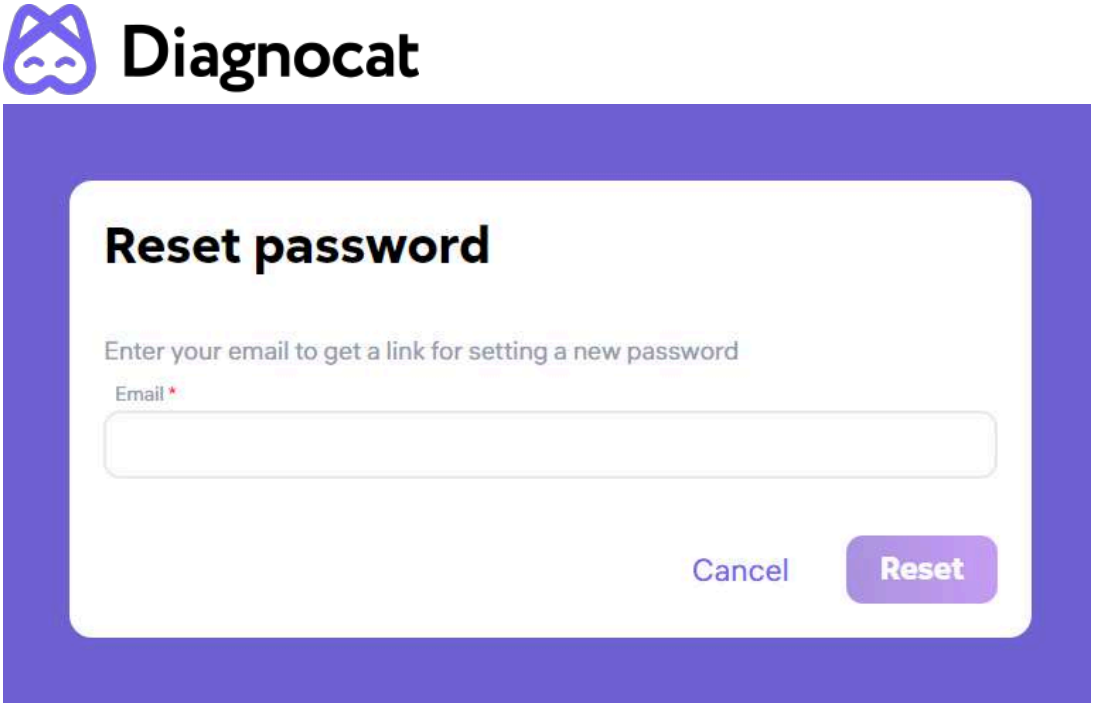
Open the Chrome browser and go to Diagnocat based on your region: for Europe, visit https://app.diagnocat.eu; for Canada, visit https://app.diagnocat.ca.

You will be able to log in to the Diagnocat application by providing your email and password.

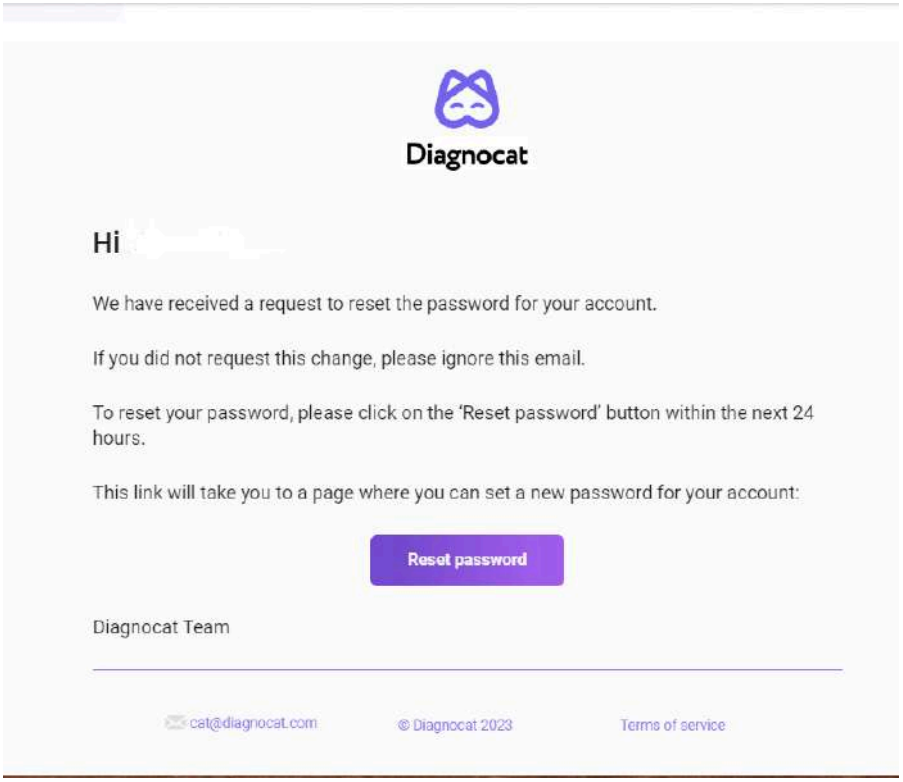


1.3 Reset password

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



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

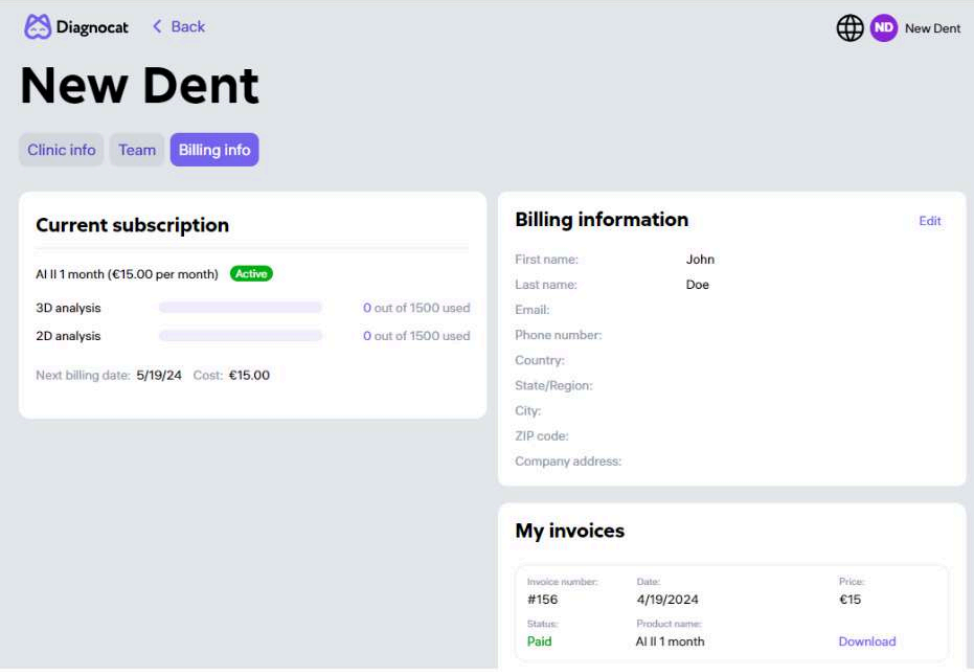


1.4 Subscription Plans

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

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.

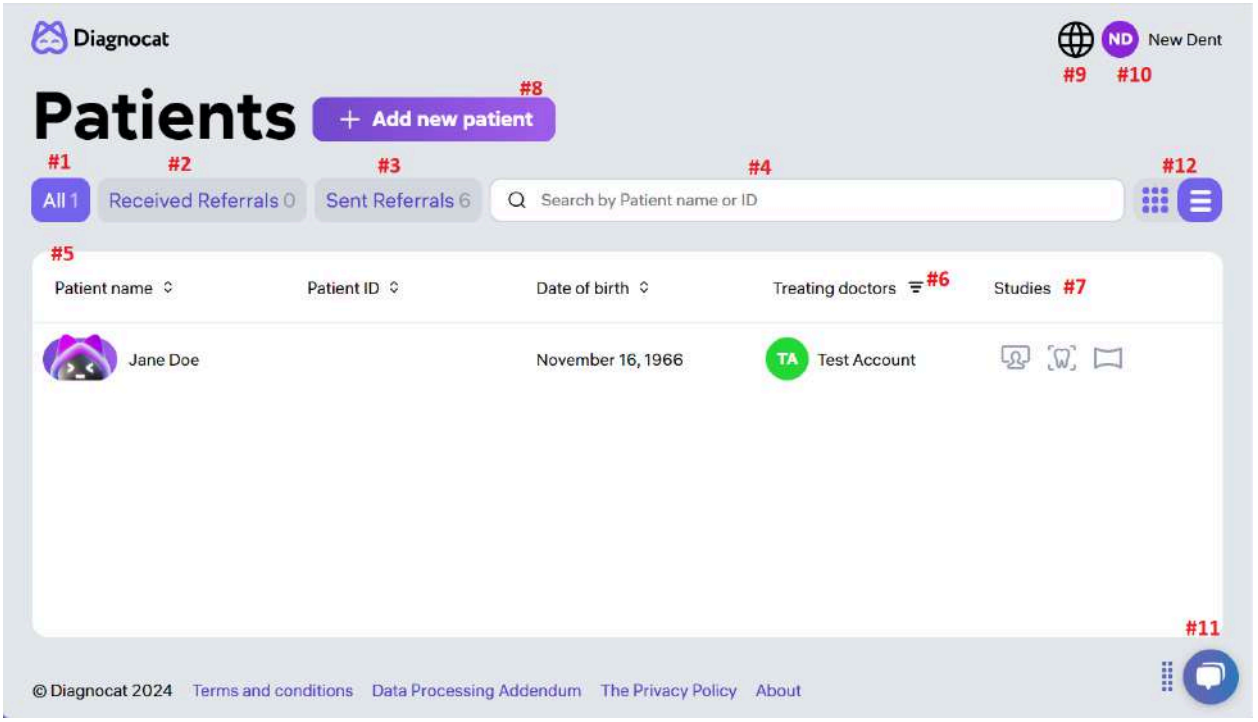


NOTE: Without an active subscription or package (for corporate clients only) you won't be able to create patients, upload new studies or order reports.

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.



#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.

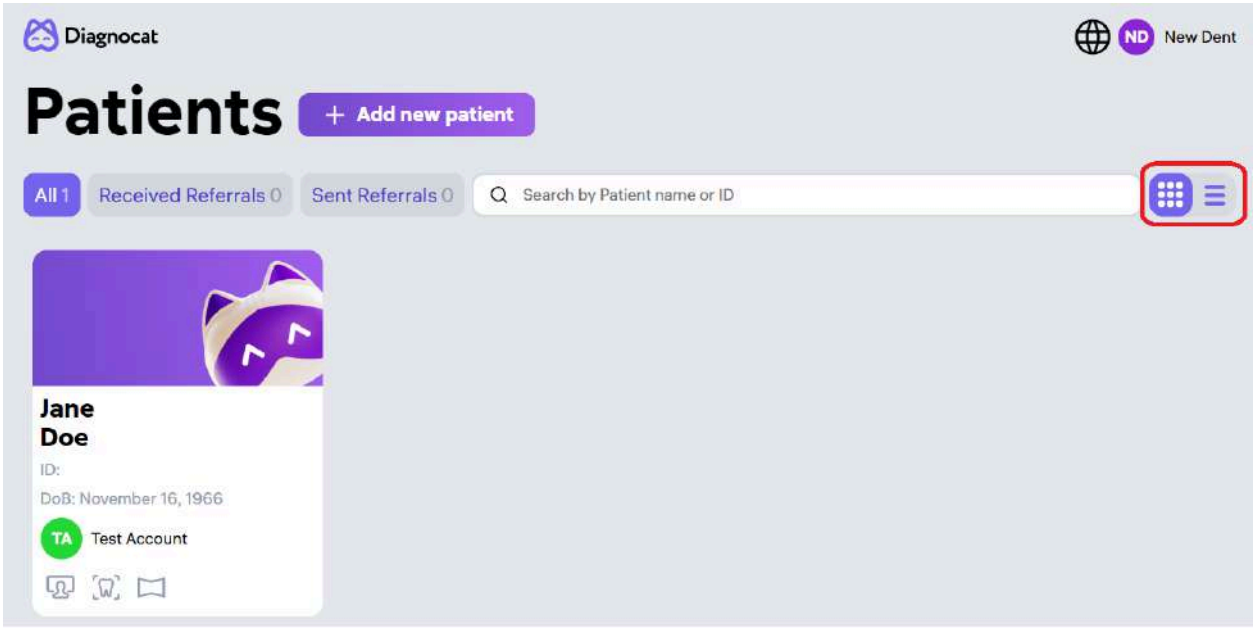
#8: “Add new patient” allows you to create a new patient.

#9: Allows you to change the interface language.

#10: Gives you access to your account and clinic settings.

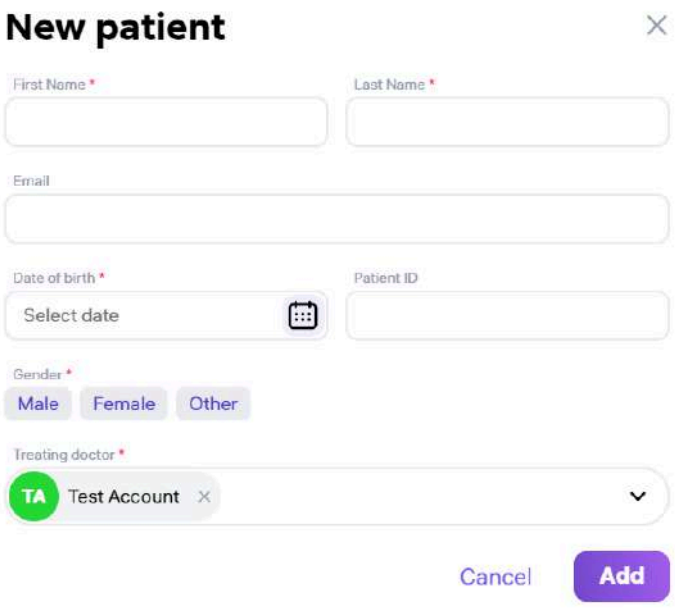
#11: Allows you to get access to the customer success team.

#12: The button allows you to change the visual design of the “Patient Card”. The visual design is shown below:



1.6 Create a new patient

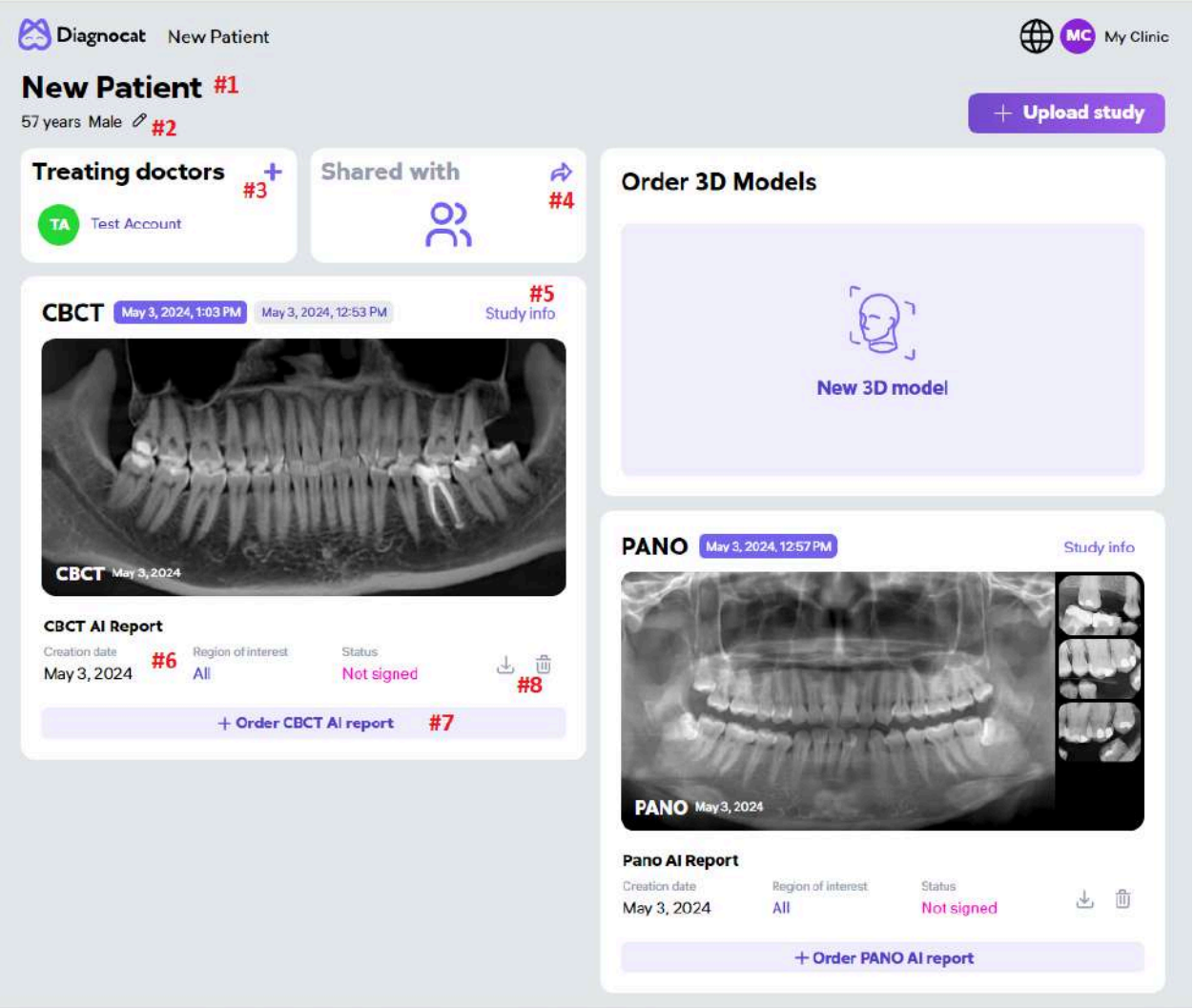
You can create a new patient by clicking “Add new patient” on the main screen.



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.

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.

#6: Report details.

#7: Order a new analysis.

#8: Download (as PDF file) or Delete the report.

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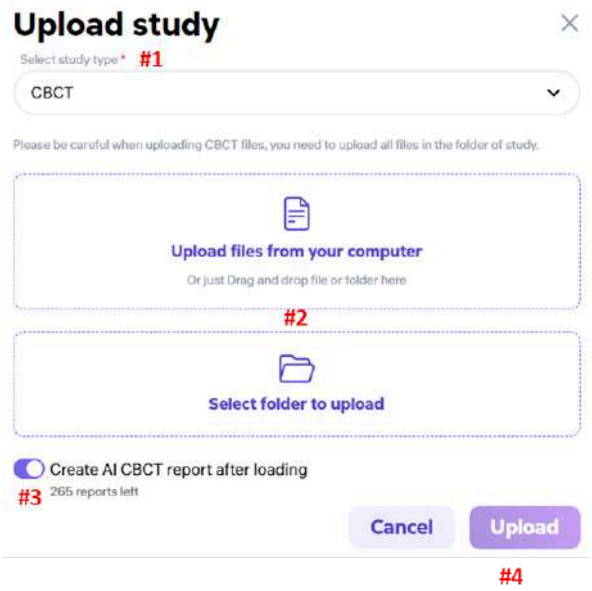
1.8 Create a new study

Once you open patient details you will be able to create a new study by clicking “Upload study”.



1. Select the study type you want to upload (CBCT, IOXRay, Pano, STL).

2. Attach a file or folder by browsing your computer.

3. When toggle is enabled, automatically created AI reports (CBCT, Pano, IOXRay) after loading.

4. Click the “Upload”.

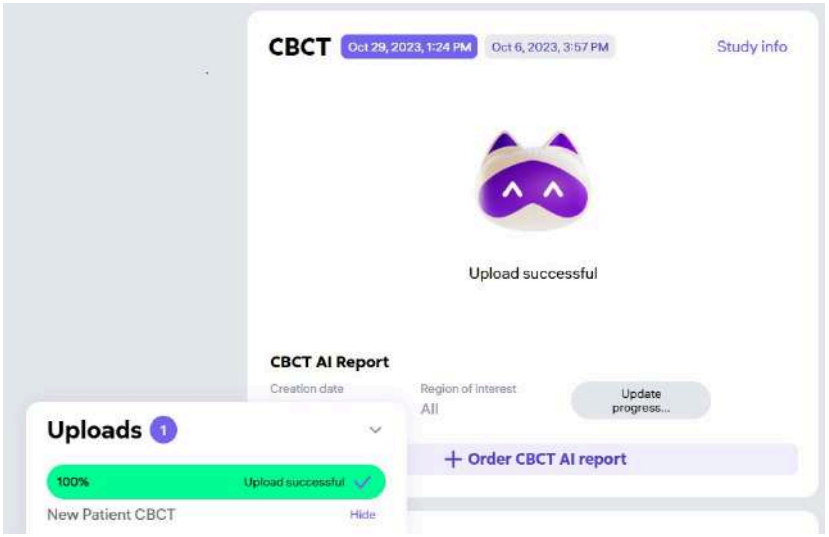
Diagnocat supports the following file formats: *.dcm, *.jpg, *.png, *.tiff, *STL.

1.9 Order analysis

When you order a CBCT AI Report, Pano AI Report, IOXRay AI Report with toggle enabled, Diagnocat generates reports automatically.

With the STL Report order, Diagnocat only uploads study, after that, you can click on the report generation in the patient card.

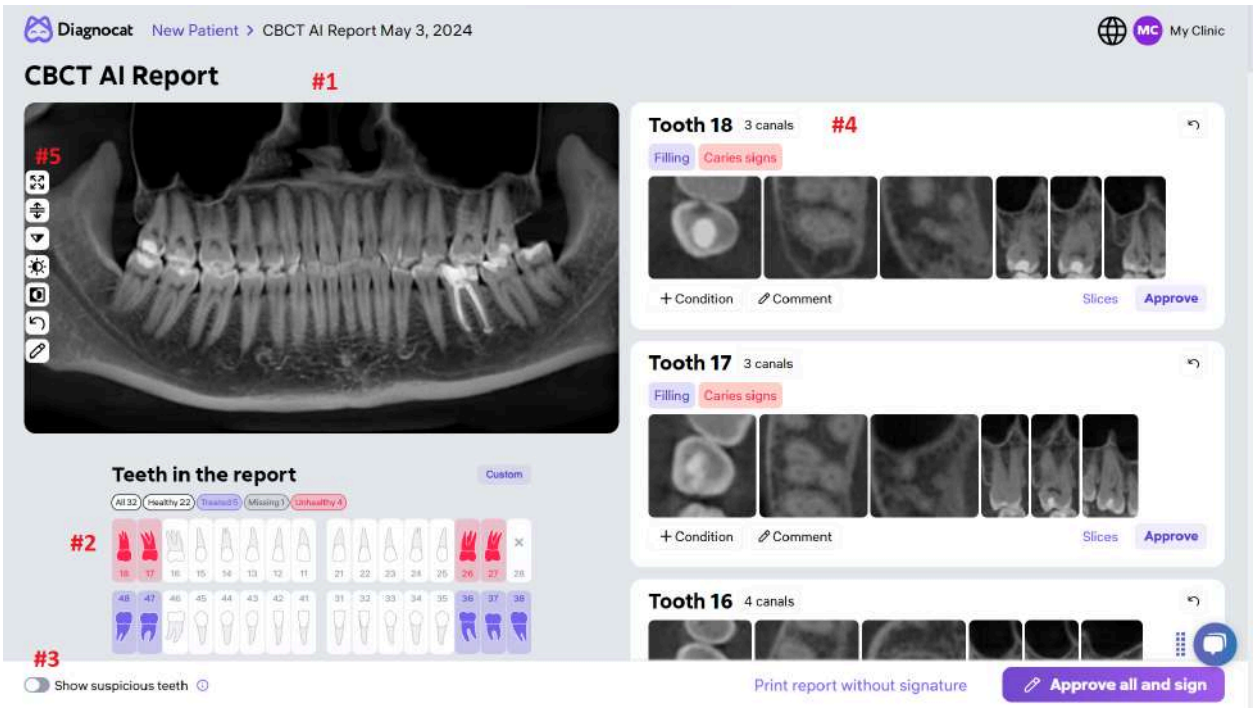
Panowings AI Report is generated automatically when the Pano and IOXray AI reports were generated no more than 24 hours apart.



2.0 CBCT AI Report

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

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



#1: Panorama image derived from CBCT

#2: Tooth chart

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

#4: Tooth card

#5: Panorama tools

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

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.

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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%.

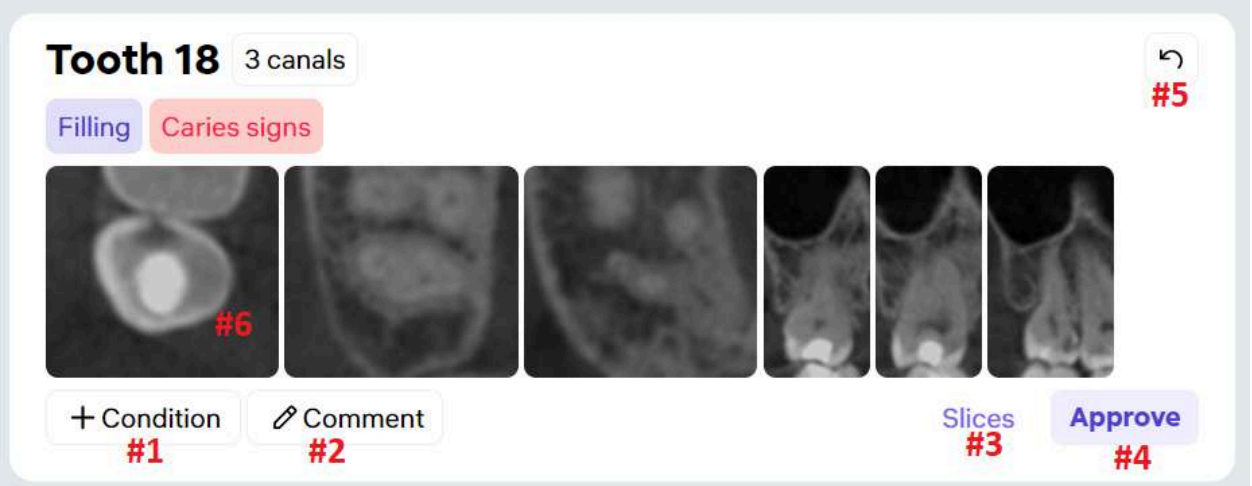
The list of condition that should be shown in suspicious teeth mode:

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

- 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 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

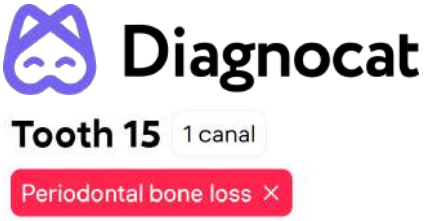
#4: Approved changes

#5: Reset tooth original conditions

#6: View the slice

2.6 View and add pathologies and conditions

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



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.

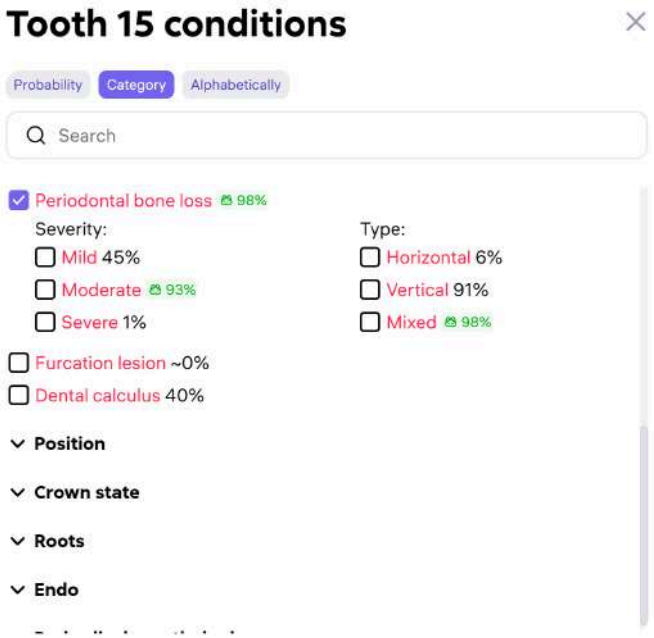
To remove a condition from the card, the user unselect the corresponding checkbox in the list of conditions.

User could add conditions in the Tooth card.

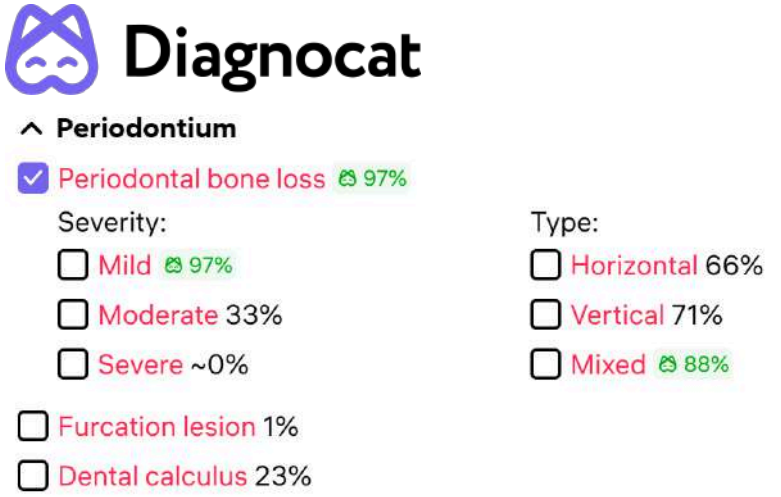
When User clicks on the Add condition button, the system displays a list with conditions in the Add conditions window. The list have 3 tabs to select type of sorting and grouping:

- by probability
- by conditions category
- alphabetically

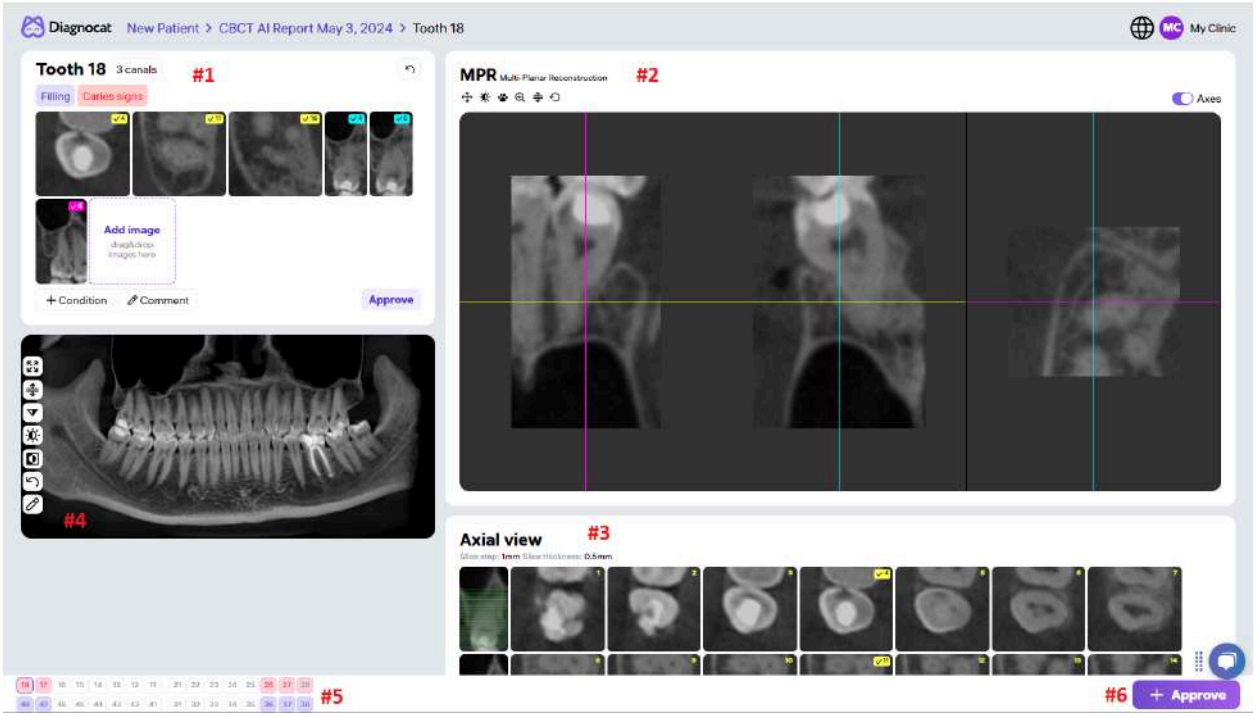
When User adds a condition, related child conditions for that condition are selectable.



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.



2.7 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

#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.

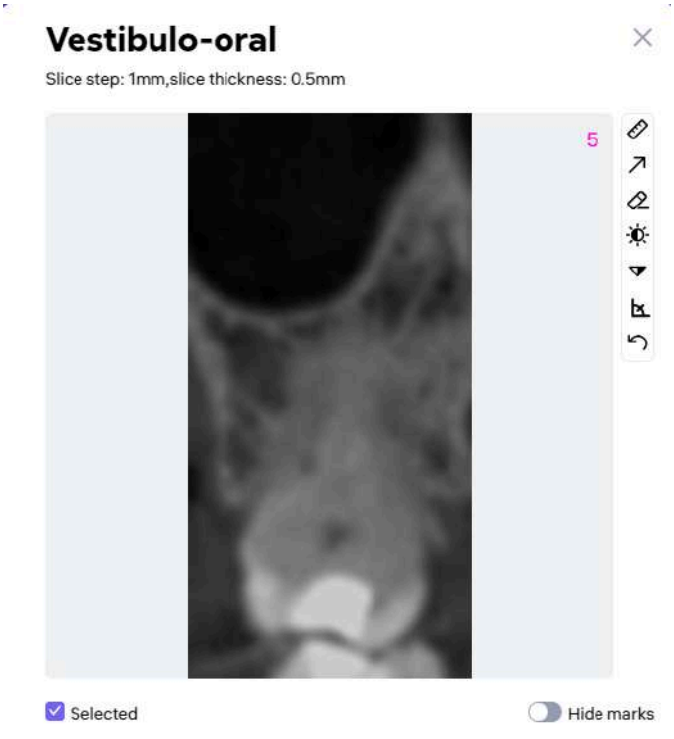
NOTE: Each pathology has %. This is the level of confidence Diagnocat platform has in regards to the found pathology. If the likelihood of a pathology is less than 50% then the system won’t show it in the report. The user can still see this pathology on the slices.

2.8 View and edit slices

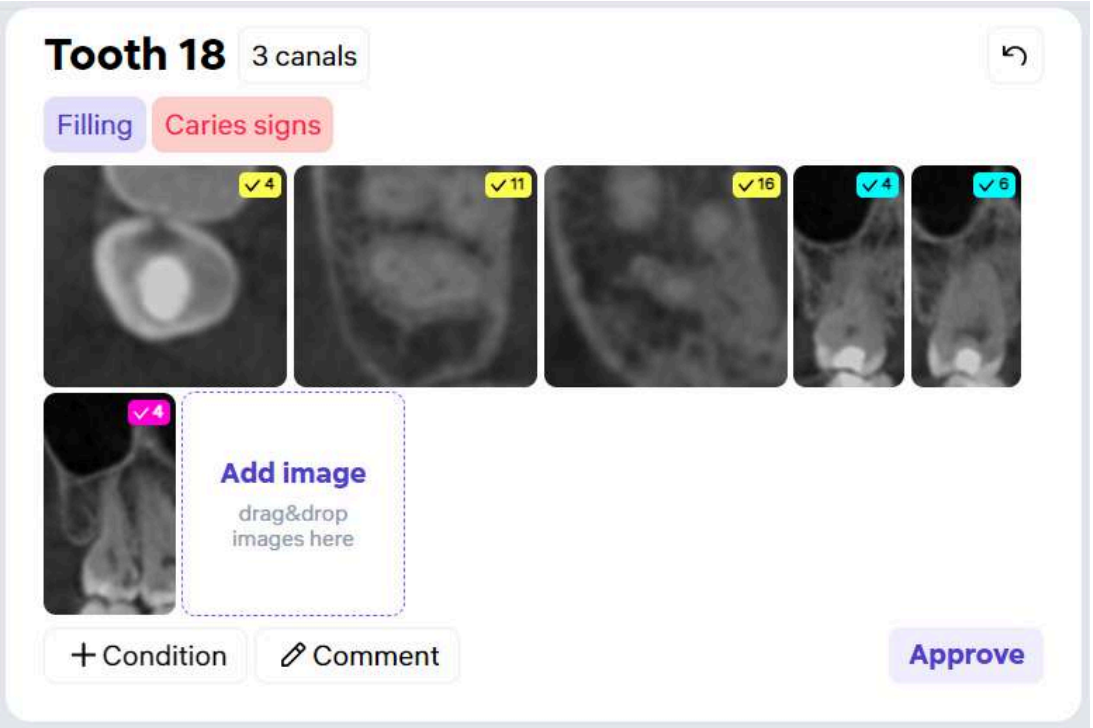
When you click any slice a tool panel will appear:

- 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.



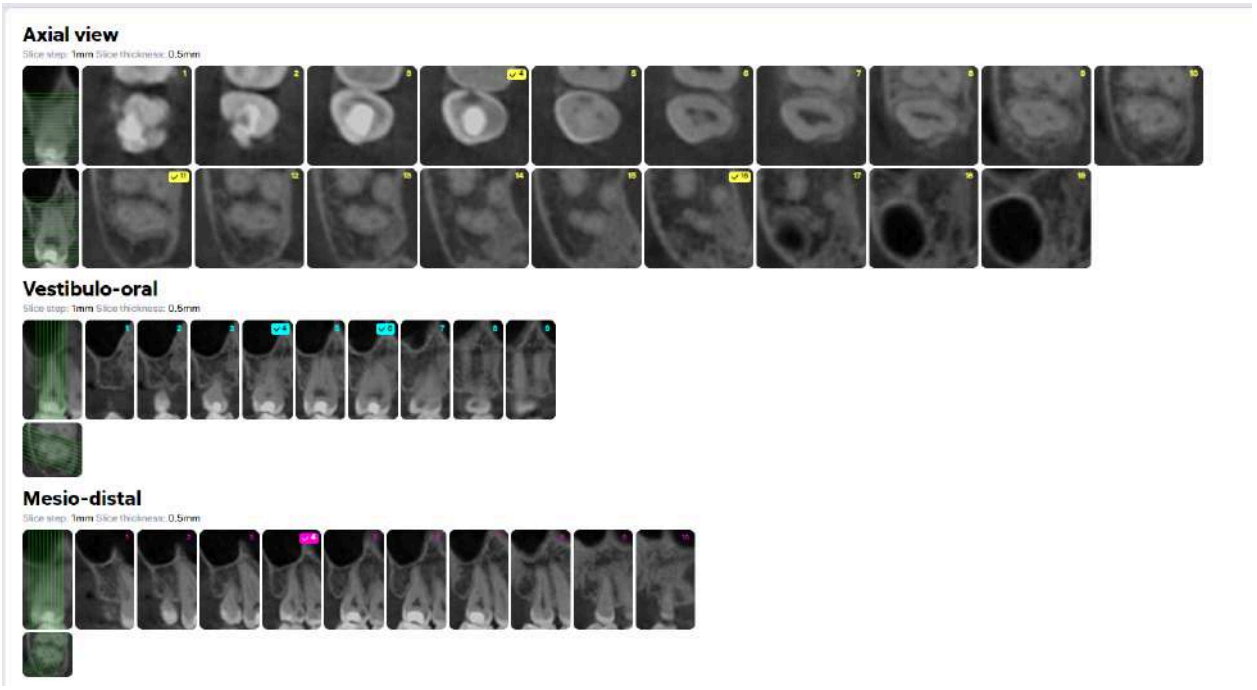
By default, the system adds 6 slices to the tooth card in different projections: three slices for the axial projection, two slices for the mesio-distal projection, one slice for the vestibulo-oral projection. You can change these slices and create a new set, which will be added to the final report.



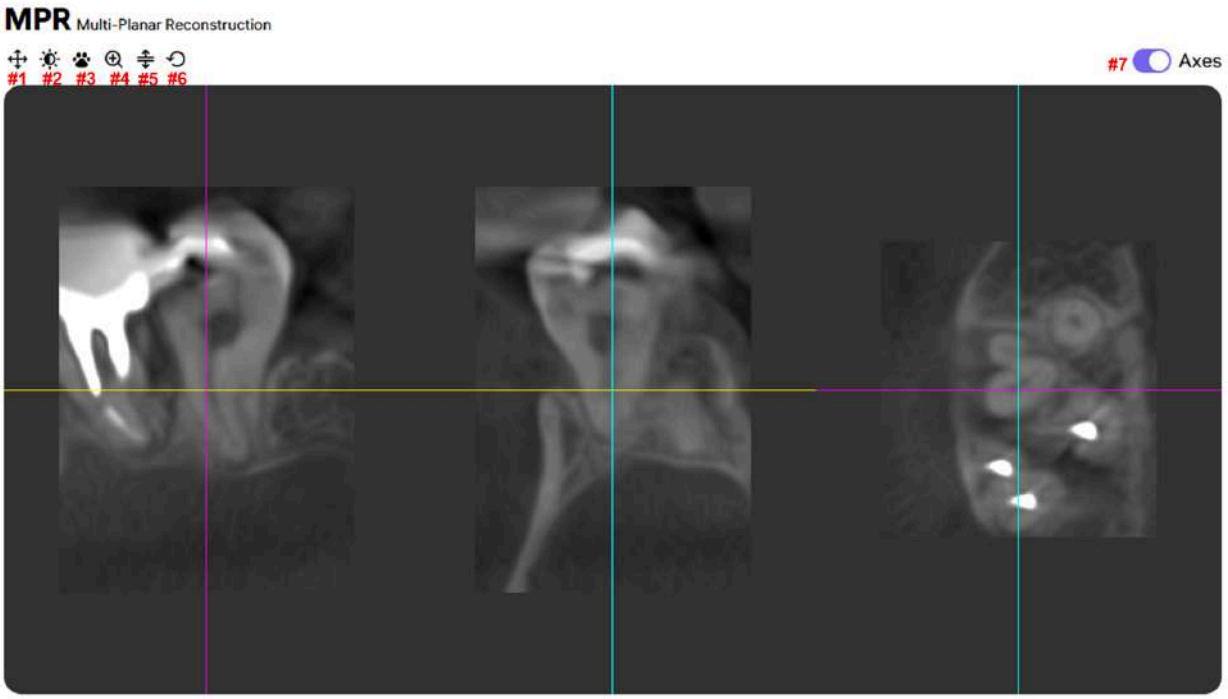
You could change slices, selecting the ones you need from the sections Axial view, Vestibulo Oral, Mesiodistal simply by clicking on the necessary slices.

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 ~ 50 mb, max ~ 50 files at once, like in the logo/stamp section.



2.9 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.

#1: Axis changing tool

#2: Brightness/contrast

#3: Pan

#4: Zoom

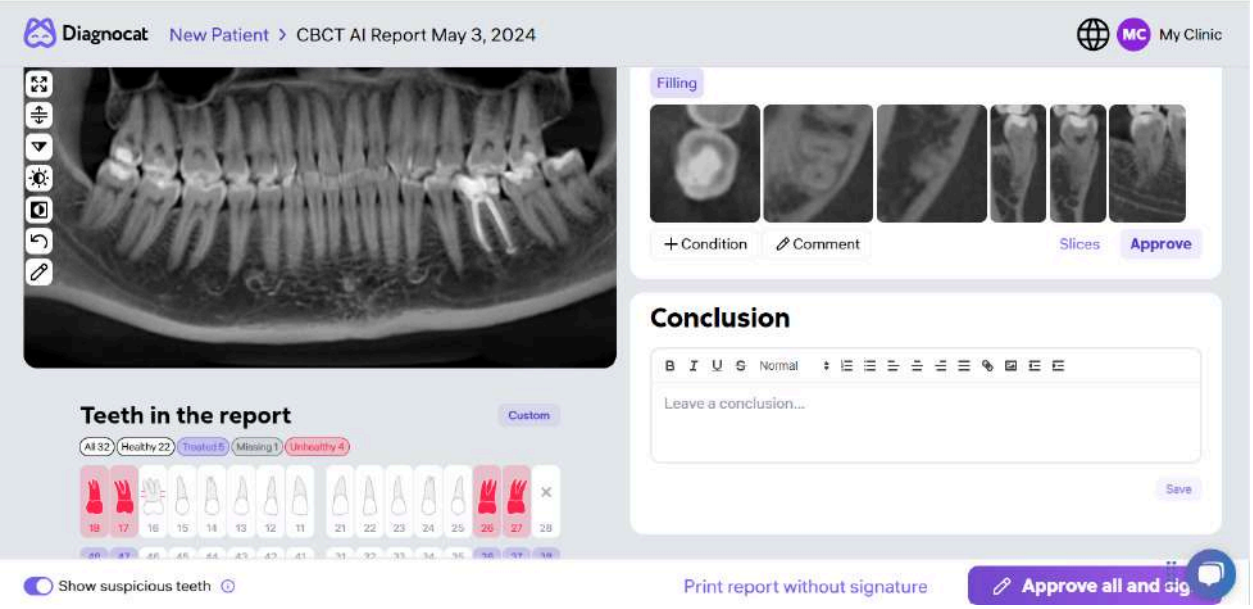
#5: Translation

#6: Reset all changes

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

2.10 Conclusion

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



#1: Font settings

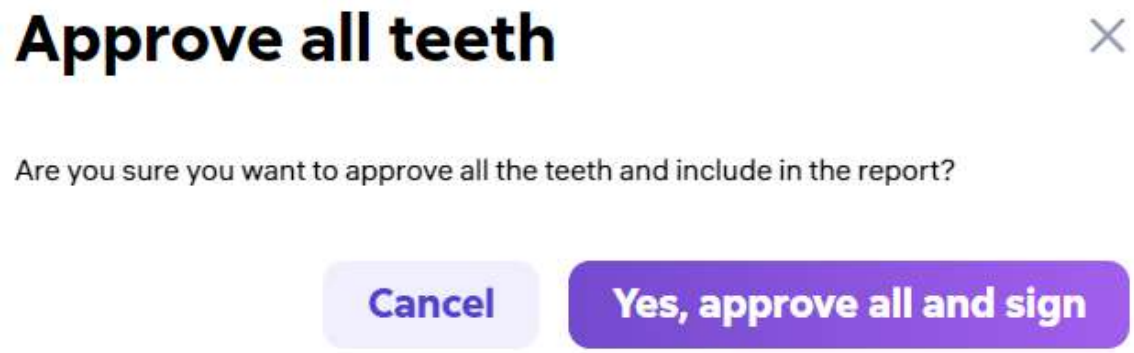
#2: Add a link

#3: Attach an image

#4: The main text field

2.11 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.”

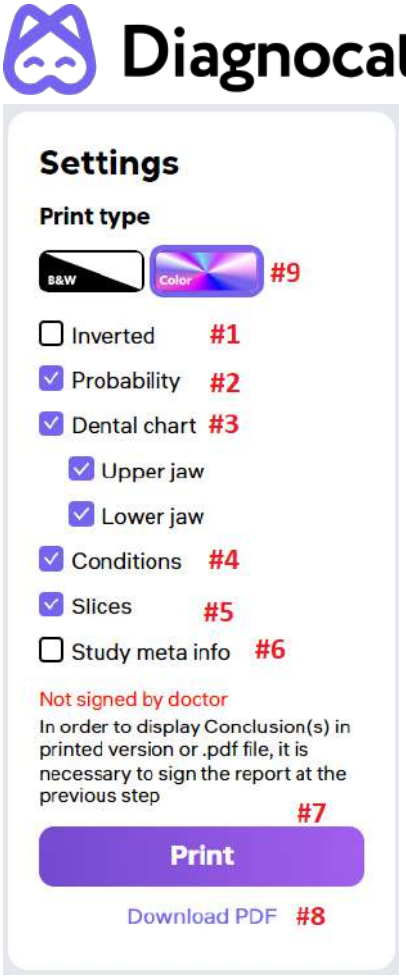
2.12 Printing a report without signature

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

2.13 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).

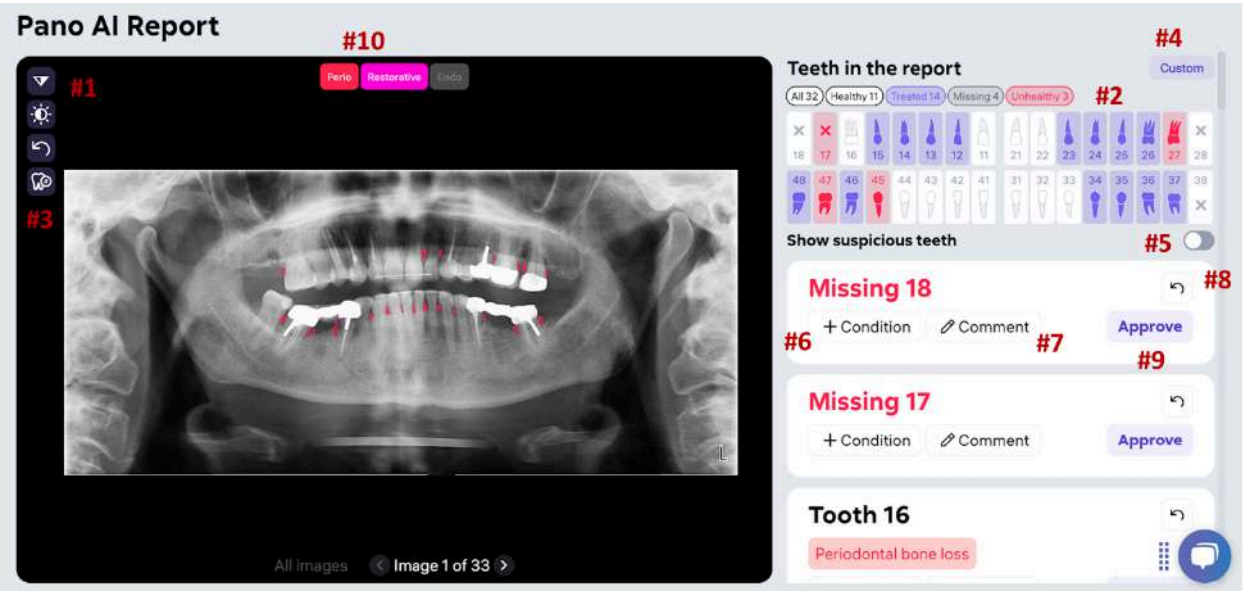
3.0 Pano AI Report

3.1 Order and view pano analysis

After uploading pano study, the system will analyze them and prepare a report.

You can open the Pano AI Report by clicking the link.

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)

#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)

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)

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
4. Child condition - Periodontal Bone Loss - Severity - Mild
5. Child condition-Periodontal Bone Loss Severity-Moderate
6. Child condition - Periodontal Bone Loss Severity-Severe
7. Child condition - Periodontal Bone Loss Type - Horizontal
8. Child condition - Periodontal Bone Loss Type - Vertical
9. Child condition - Periodontal Bone Loss Type - Mixed

and PBL rulers and measurements

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
3. Overfilling (only for PANO AI Report)
4. Missed canal (only for PANO AI Report)
5. Voids present in the root filling
6. Periapical radiolucency

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

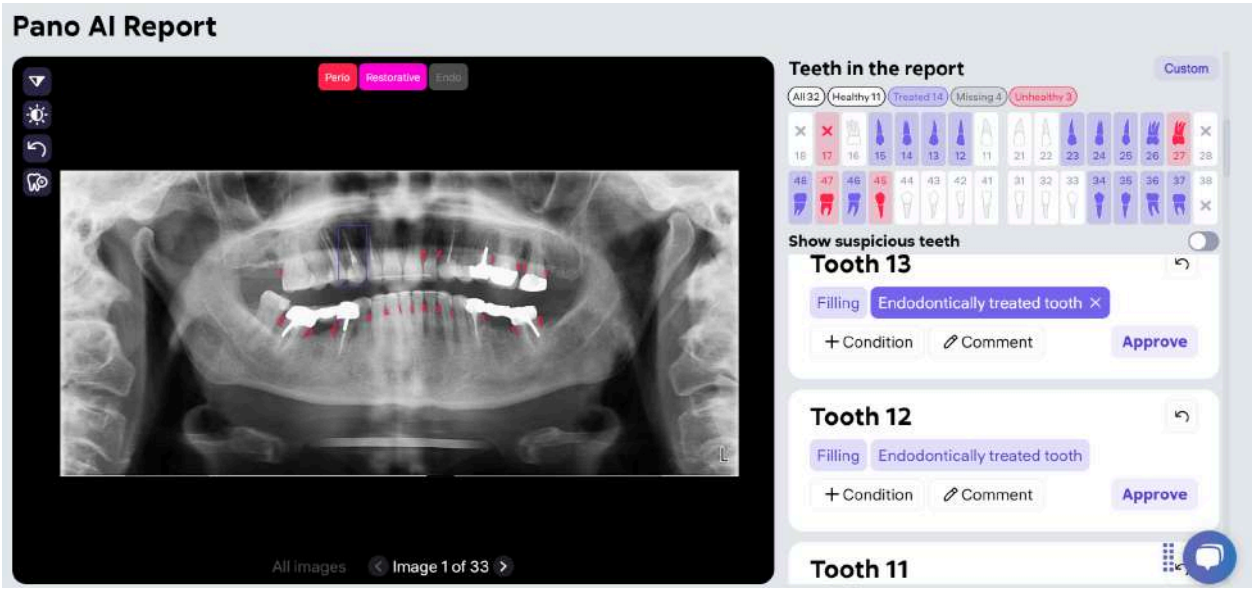
1. Voids in the filling
2. Overhang
3. Open margin
4. Lack of the Interproximal Contact
5. Tooth stump
6. Caries signs
7. Caries signs: (Surface) Mesial
8. Caries signs: (Surface) Distal
9. Caries signs: (Surface) Occlusal (4-8)
10. Caries signs: (Surface) Incisal edge (1-3)
11. Caries signs: (Surface) Buccal (4-8)
12. Caries signs: (Surface) Vestibular (1-3)
13. Caries signs: (Surface) Lingual
14. Caries signs: (Depth) Enamel
15. Caries signs: (Depth) Dentin
16. Caries signs: (Depth) With pulp exposure
17. Caries signs: (Depth) Root
18. Secondary caries
19. Secondary caries - Surface - Enamel
20. Secondary caries - Surface - Dentin
21. Secondary caries - Surface - With pulp exposure
22. Secondary caries - Surface - Root

NOTE: the functionality of displaying masks is applicable for the reports generated basing on the 2D studies:

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

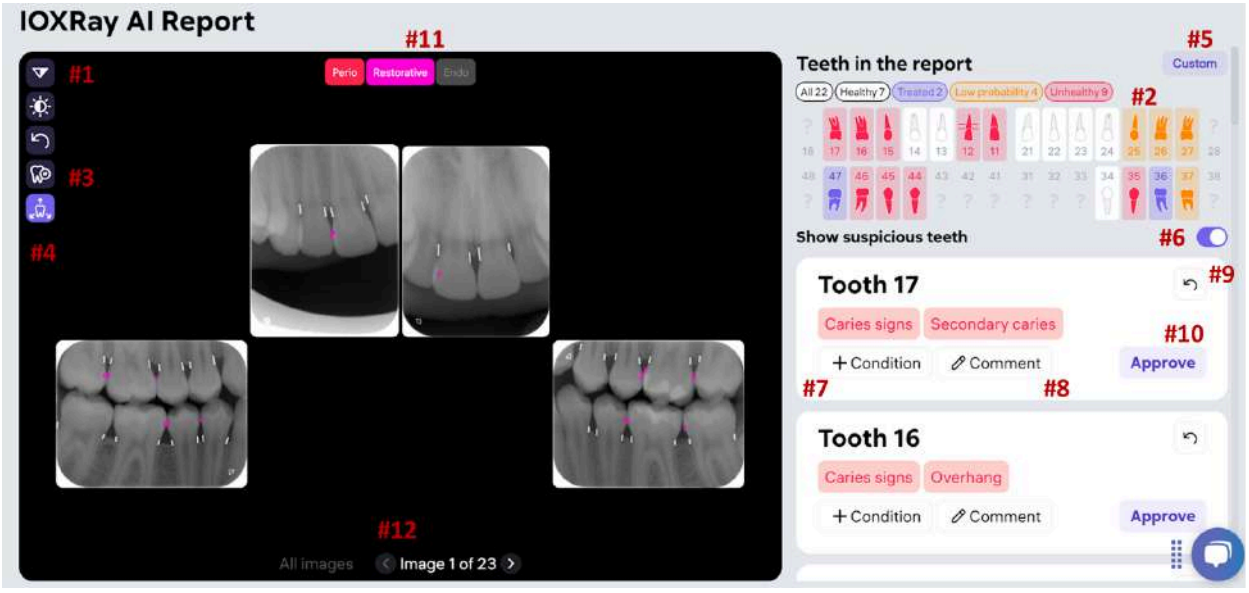


4.0 IOXRay AI Report

4.1 Order and view intraoral analysis

After uploading an intraoral scan, the system will analyze them and prepare a 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)

#2: Tooth chart

#3: Edit tooth numbers

#4: Focus View

#5: Custom

#6: Suspicious teeth

#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)

#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 display 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

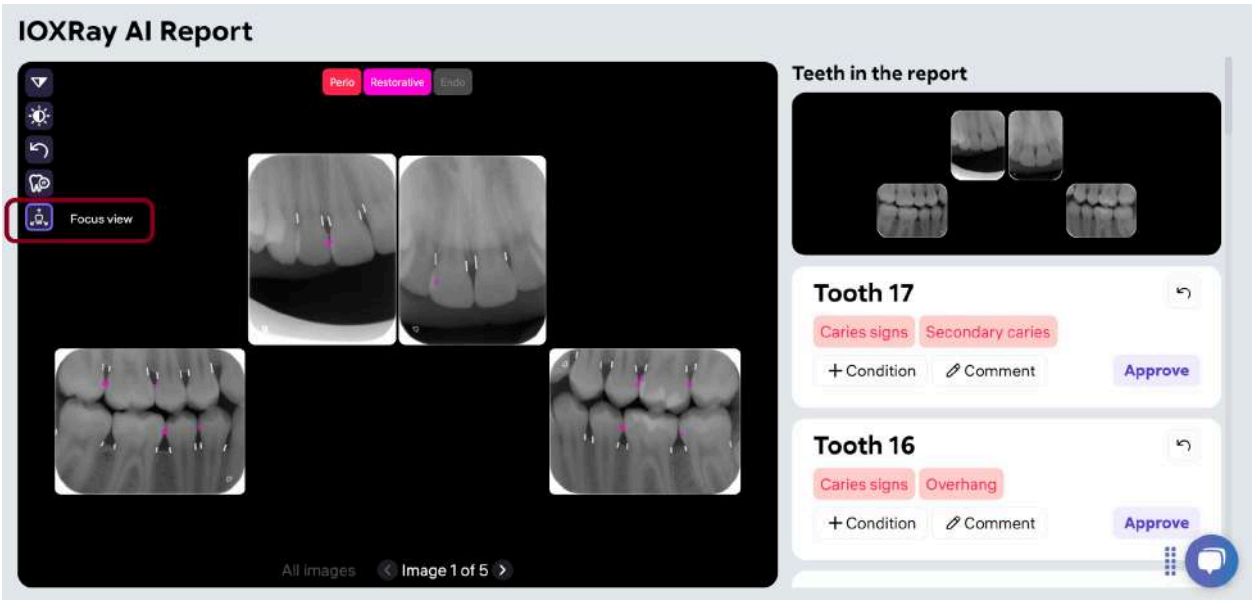
4.2 View images and found pathologies and conditions

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.

4.3 Focus View

In the central area, the system displays the enlarged images of selected teeth (Focus view), selected study image (FMX view) or Navigation matrix (both views).

The system provide navigation button that allow the user to move between the images:



The user could navigate between teeth in the report by clicking on an icon in the tooth chart or using navigation buttons.

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5.0 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:

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

#2: Tooth chart

#3: Edit tooth numbers

#4: Focus View

#5: Custom

#6: Suspicious teeth

#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)

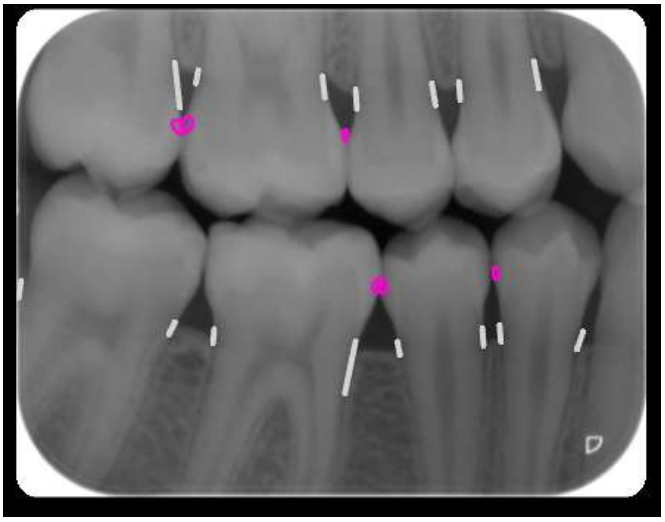
#12: Navigation buttons

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

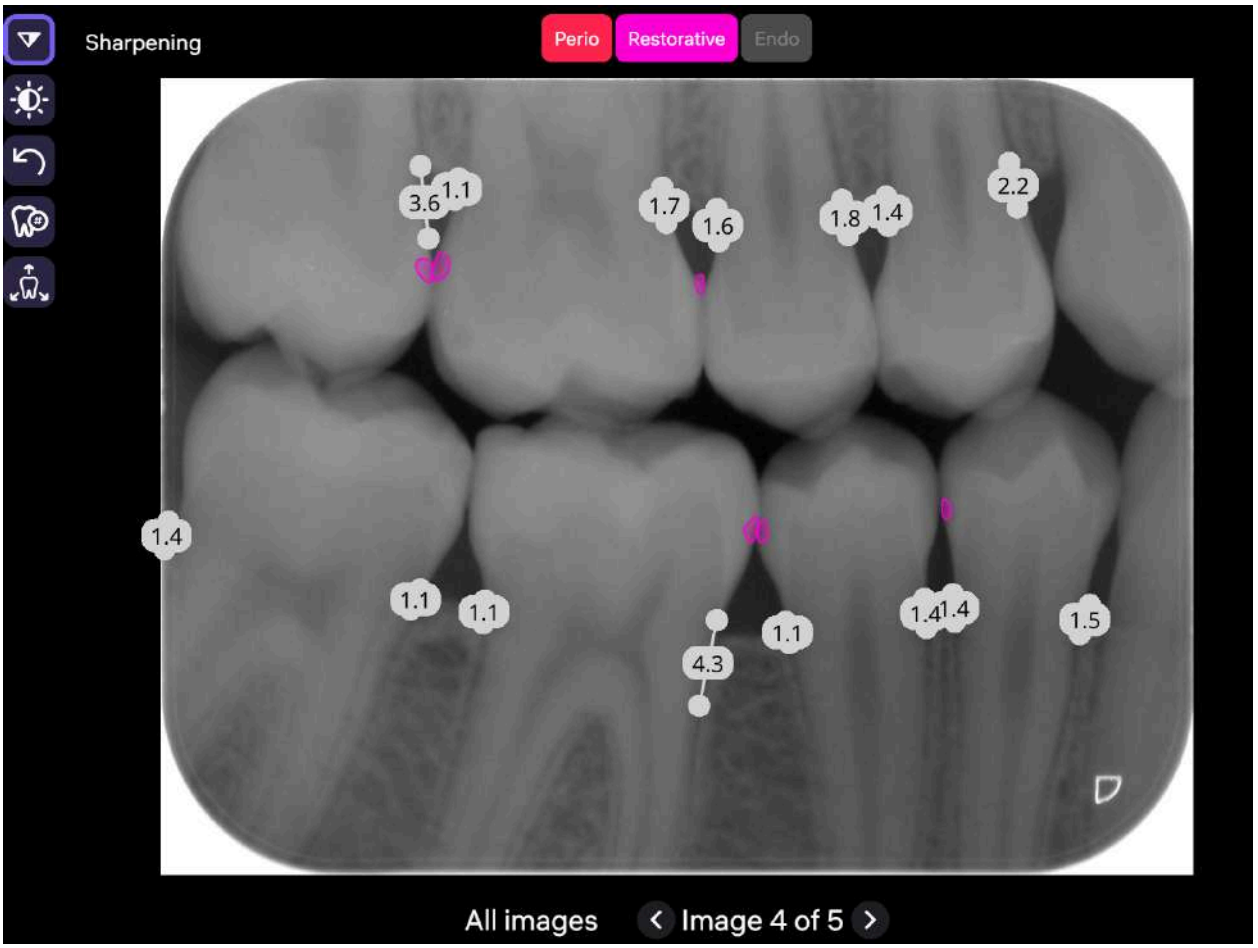
6 PBL Measurements

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

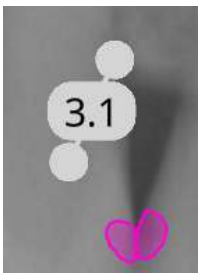
The system display the PBL measurements corresponding to Periodontal bone loss conditions on the tooth, on the tooth image (white stripes):



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.



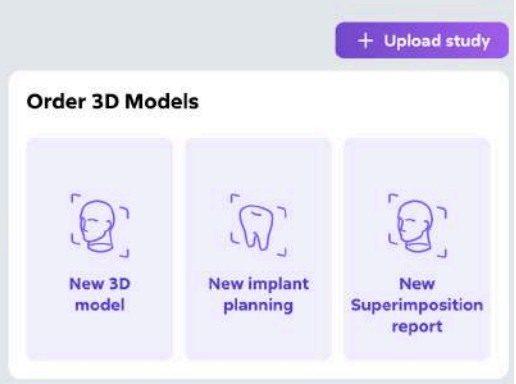
The measurement consists of line, start and end points, length of the measurement.User could move start or end point. When User hovers the mouse on the surrounding of any endpoint, the system displays another cursor. In this surrounding the User could click on the left mouse button and move the cursor 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.



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.

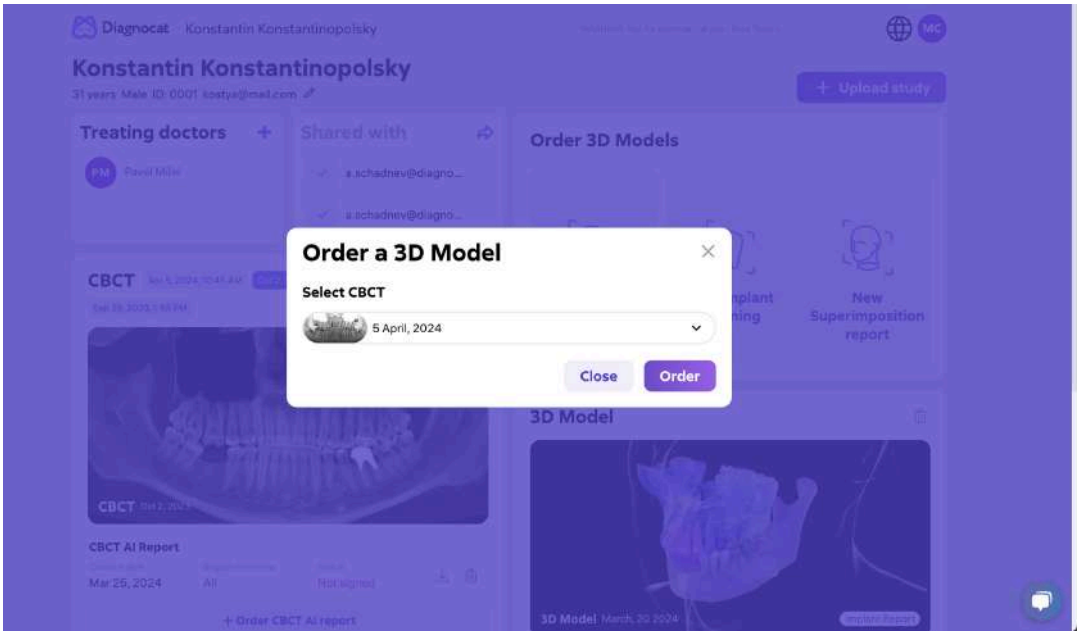
7.0 Compatible device

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.

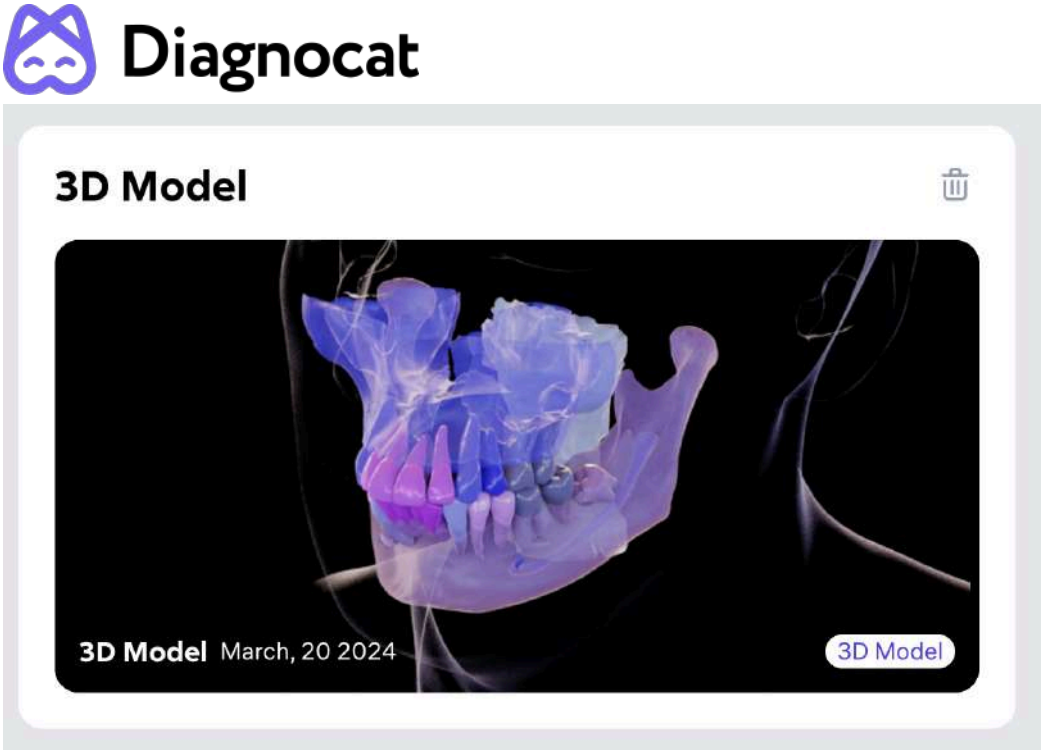


7.1 Order Segmentation Report

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.

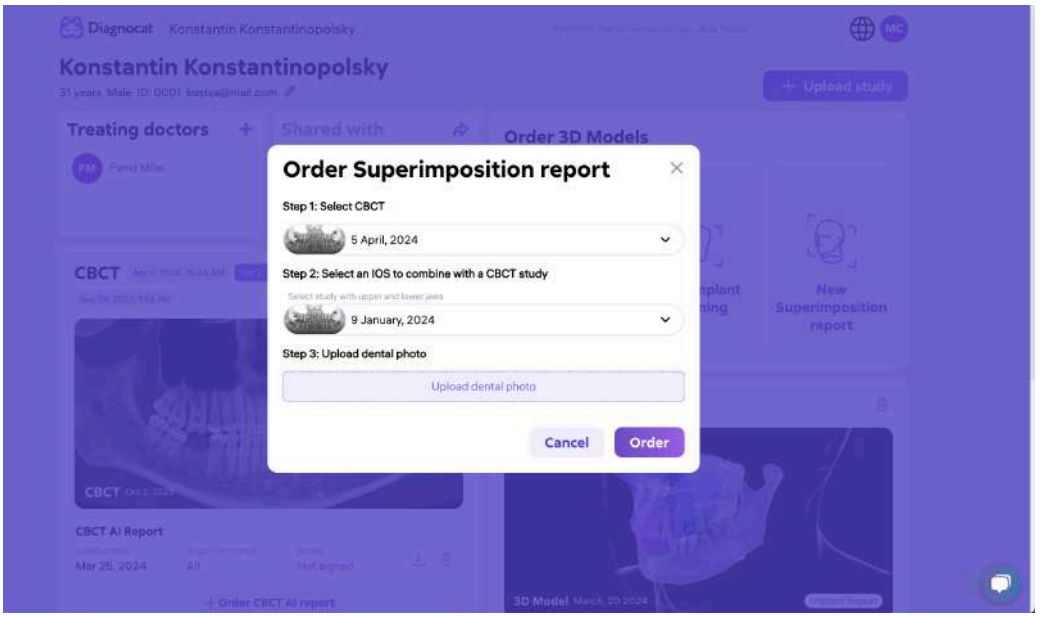


7.2 Order Superimposition Report

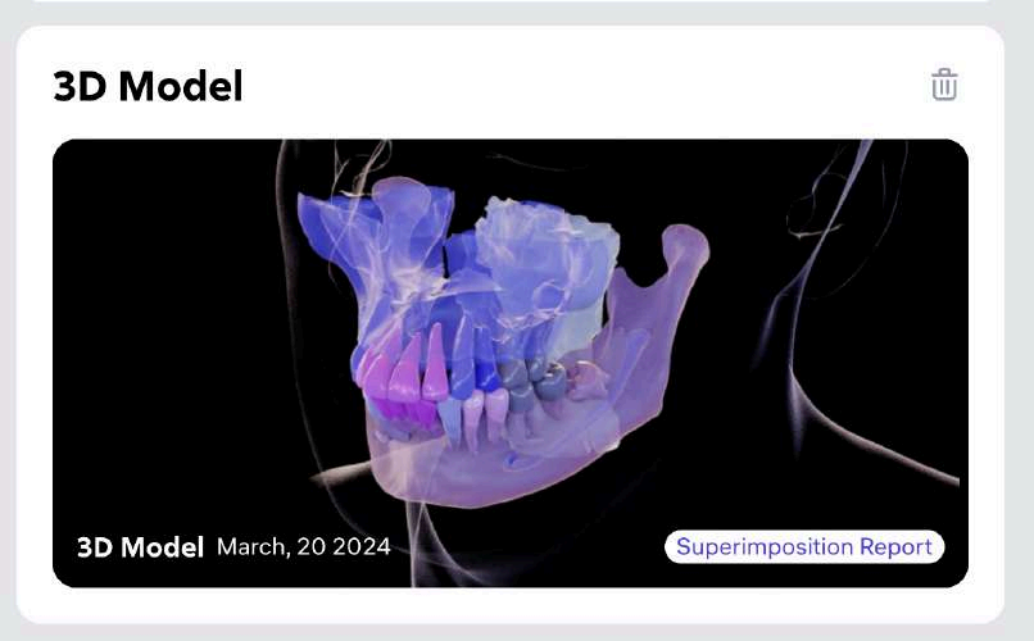
Diagnocat allows you to create a Superimposition Report. Click the “New Superimposition Report” button in the patient card, select CBCT and IOS to combine with a CBCT study and click “Order”.

*Note: you need to upload one of the following file types: *STL, *OBJ, *PLY, *DRC.

Additionally, you can upload dental photo for generation report.



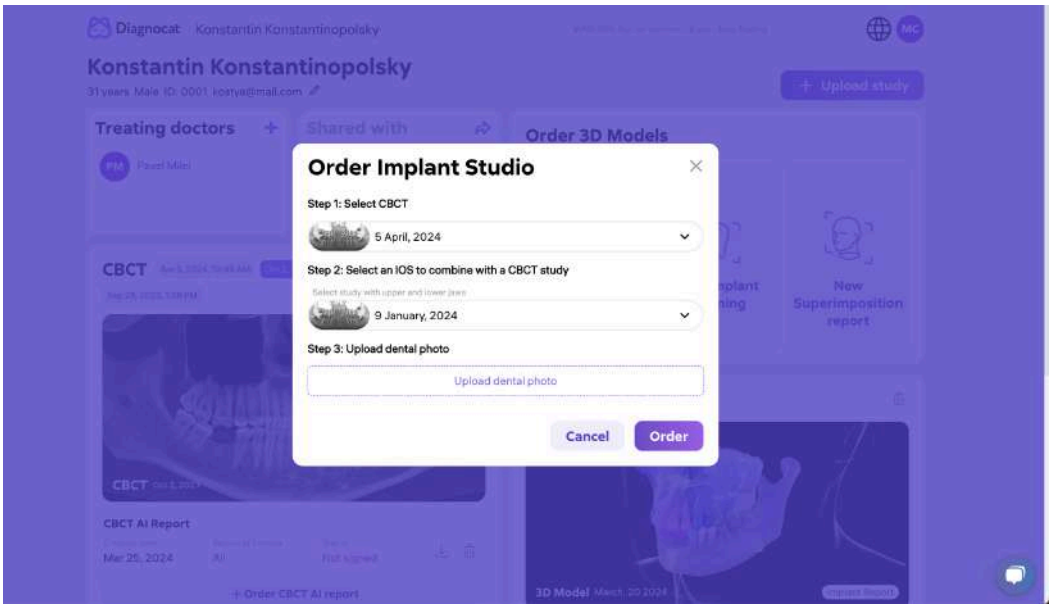
After ordering, you can view the generated report by clicking on the panoramic image and opening the Segmentron Viewer Device.



7.3 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.

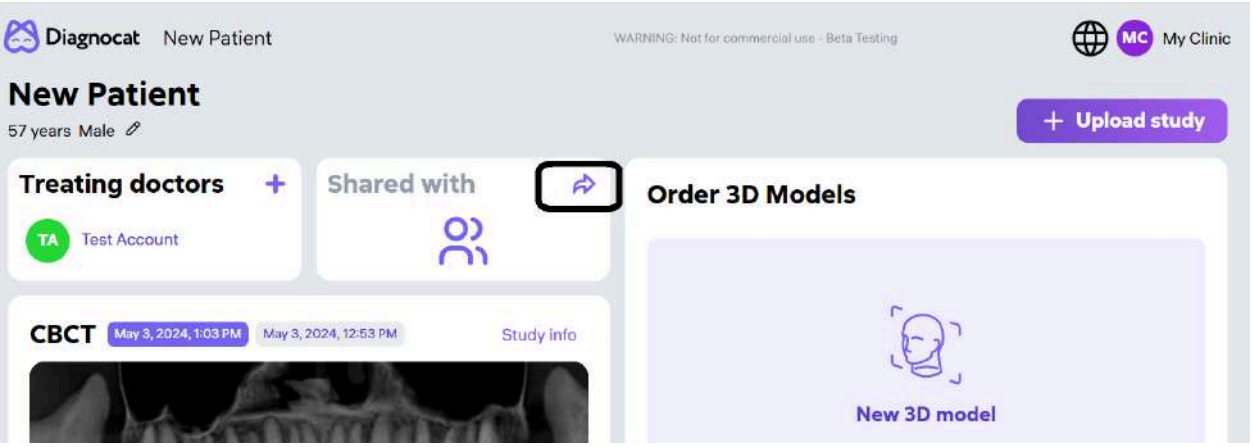


After ordering, you can view the generated report by clicking on the panoramic image and opening the Segmentron Implant Device.

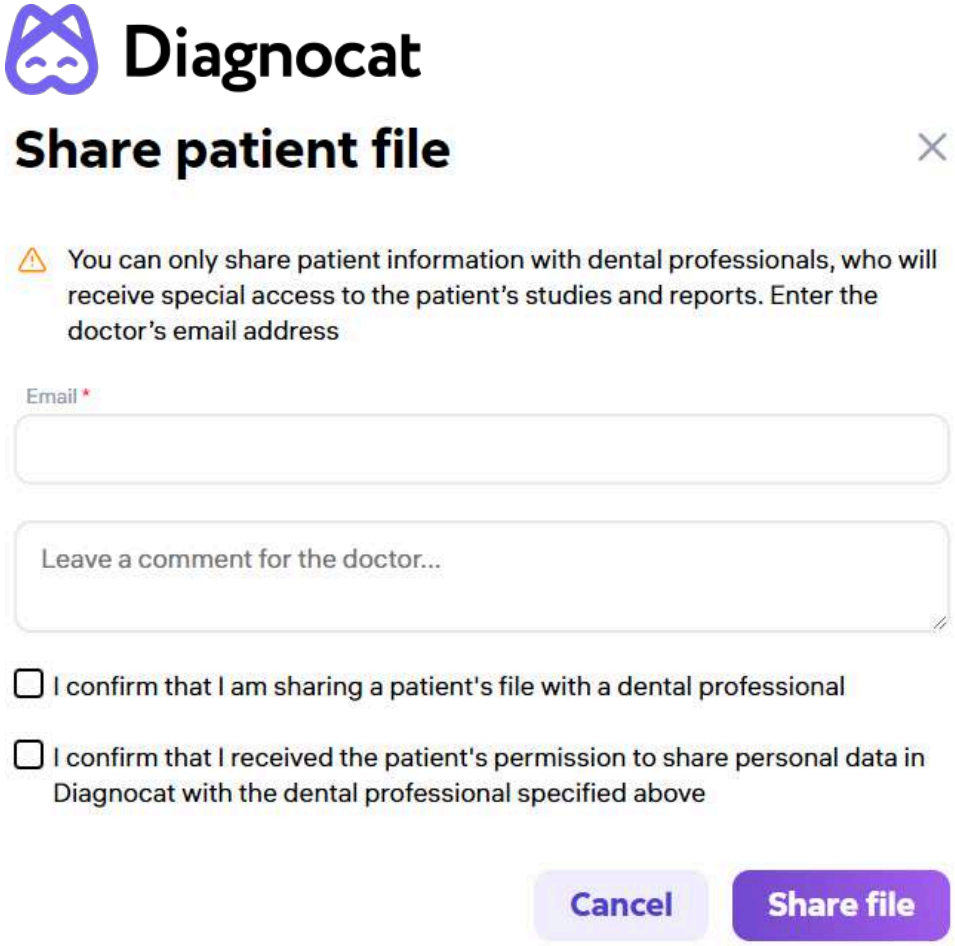
8.0 Additional Functions

8.1 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.

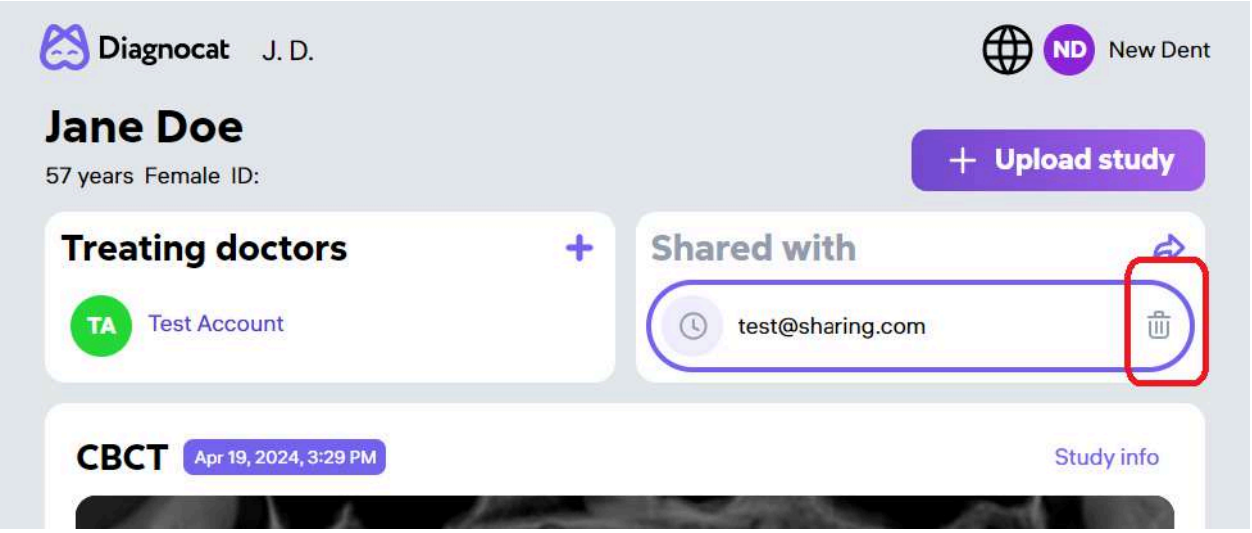


Enter the recipient email address, leave a comment for the doctor, if necessary and check the boxes that “I confirm that I am sharing a patient's file with a dental professional” and I confirm that I received the patient's permission to share personal data in Diagnocat with the dental professional specified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

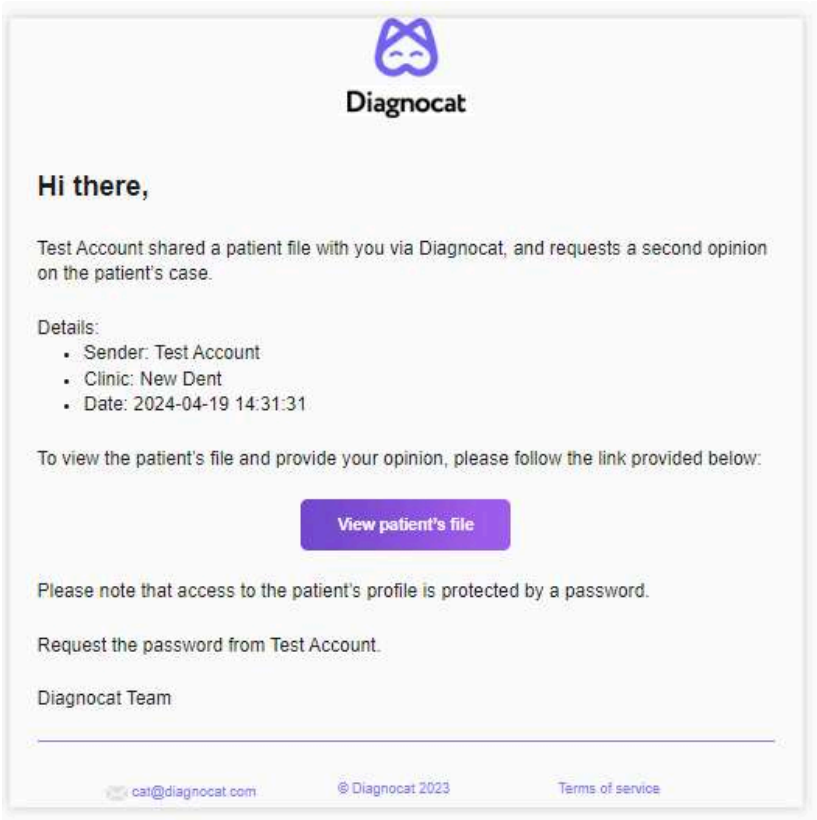
Since you transfer sensitive data of your patients, the sharing process is additionally protected with an Access code. Diagnocat generates it, and you should copy it and send to the person that should receive the patient file. You can do it via any service you use to communicate with other professionals.

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.

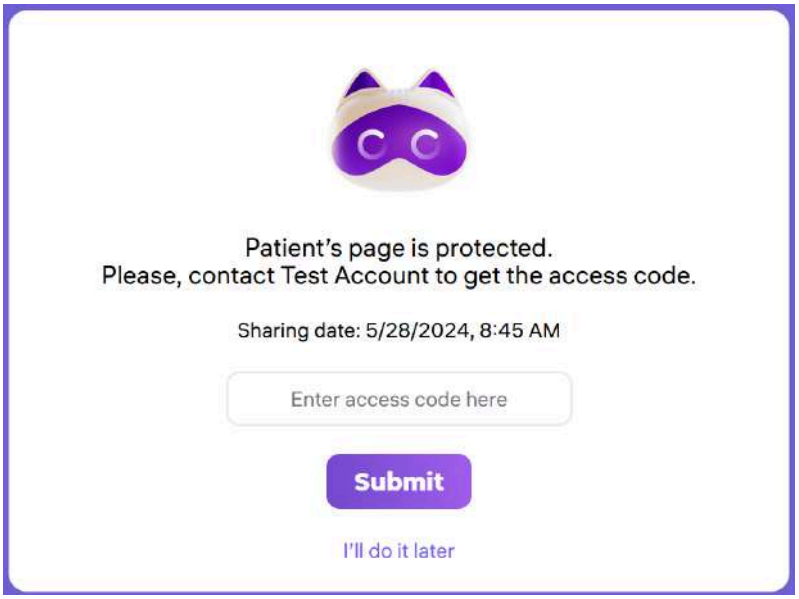


A doctor who you share a patient study with will receive an email notification inviting them to go to Diagnocat.



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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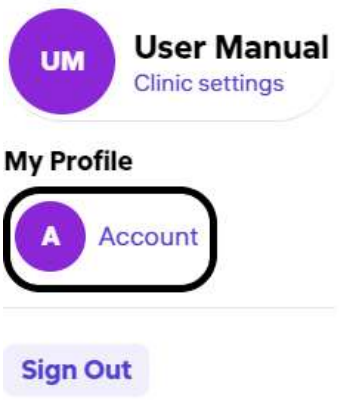
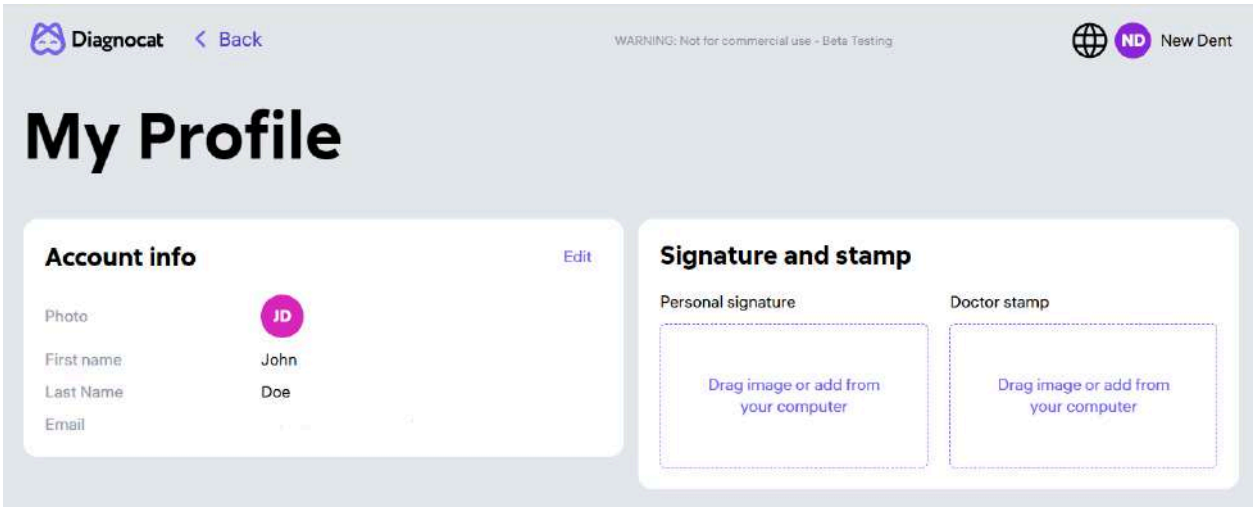
8.2 Account and Clinic Settings

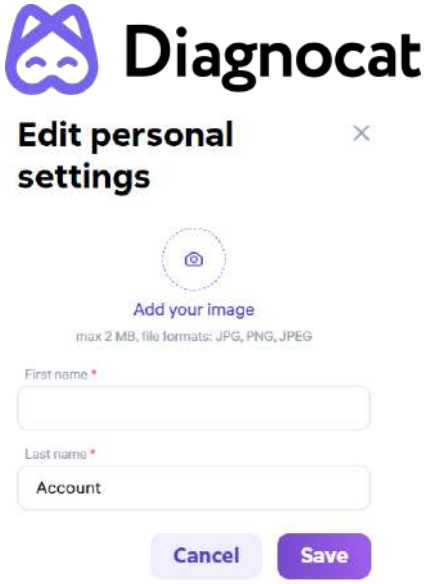
To get access to Account settings click the arrow icon in the top right corner.



Inside you will find 2 main tabs:

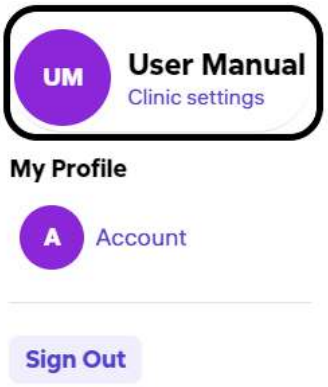


#1: Account info. You can change the account owner name, Add your photo.

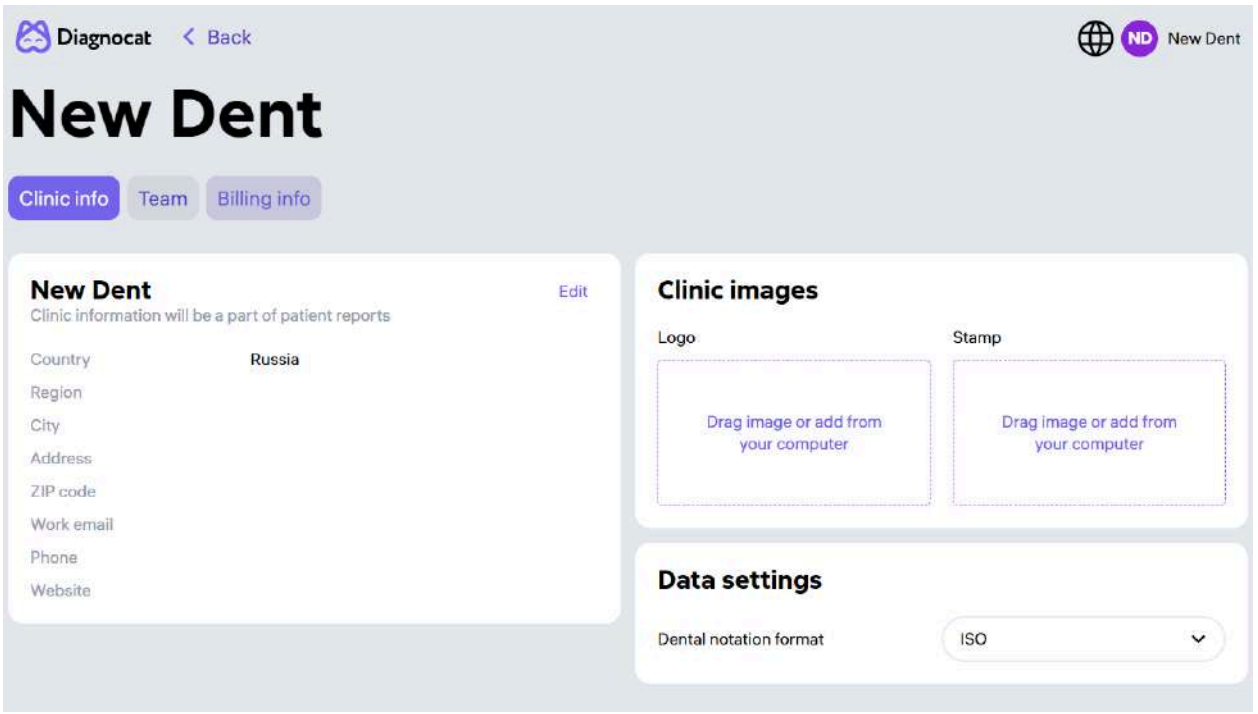


#2: Signature and stamp. You can add a personal signature and doctor stamp.

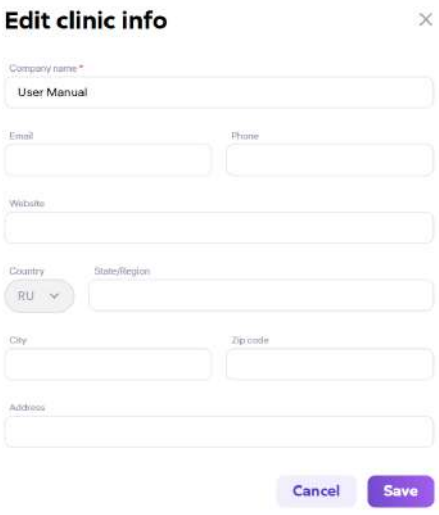
To get access to clinic settings click the arrow icon in the top right corner.



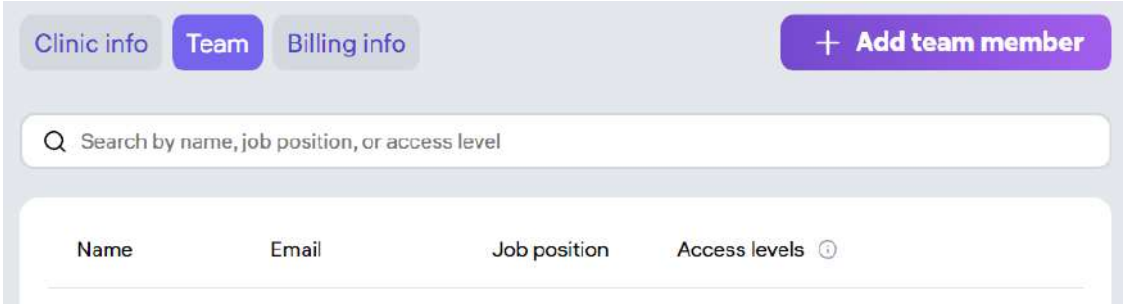
Inside you will find 3 main tabs:



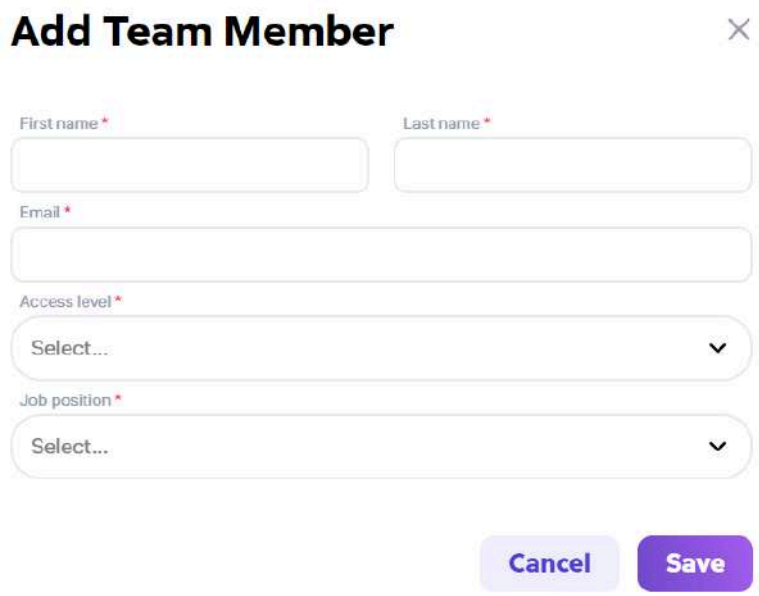
#1: Clinic info. You can change the company name, add/change logo and stamp, change all clinic data and change dental notation format.



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

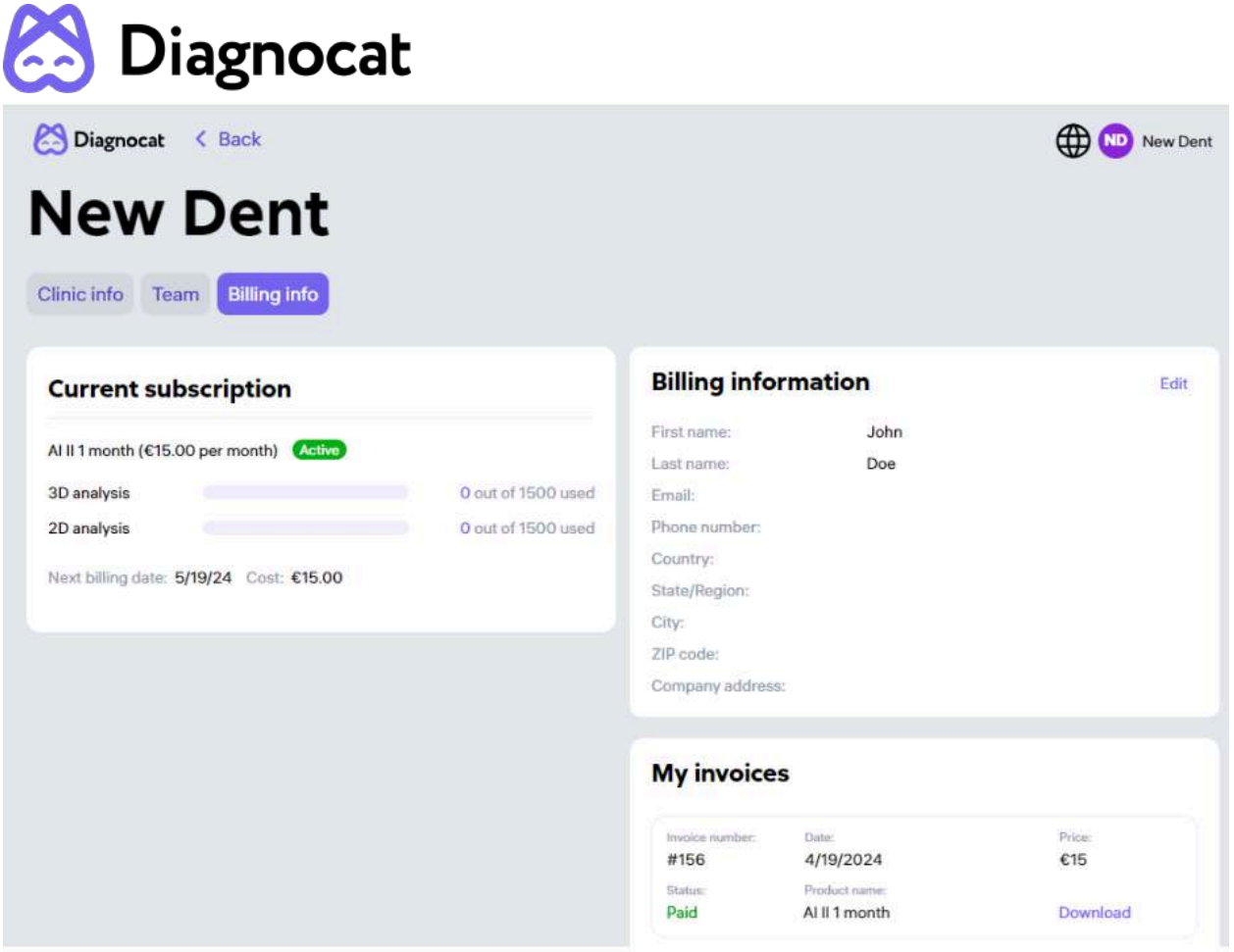


You can add a team member, after clicking on the button “Add team member” a form will open to fill in.



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

#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.

9 Performance Testing

Diagnocat evaluated four modules of Diagnocat AIS in four separate standalone studies. In each study, one certified radiologist was asked to evaluate radiographs to determine the ground truth. Overall, the expert evaluated 3069 radiographs (205 CBCTs, 491 panoramic X-rays, and 2373 intraoral X-rays). Images were obtained from male and female patients aged 0 years and older for three protocols, and aged 18 years and older for the fourth protocol. The results were compared to the consensus reference standard established by one certified radiologist with at least 10 years of experience in oral and maxillofacial radiology.

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

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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 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.

The datasets collected from Israel, EU and Canada, comprising 29.4%, 43.1% and 27.5% of the total dataset, respectively. The breakdown of images by radiographic view was as follows: 6,6% CBCT, 15,85% panoramic X-rays and 77,55% intraoral X-rays.

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The following age groups were represented in the datasets: 0-21, 18-39, 22-39, 40+. Regarding patient demographics female were 21%, 14,5% male were and 65% had unknown gender. In the studies, 19 manufacturers were represented (INSTRUMENTARIUM DENTAL, KaVo, Planmeca, Vatech Company Limited, Imaging Sciences International, Sirona, NewTom, Carestream Health, PreXion, iRYS, J.Morita.Mfg.Corp., GE MEDICAL SYSTEMS, Carestream Dental, Gendex, HDXWILL, NNT, PaloDEx Group Oy, RAY Co.,Ltd, SOREDEX). The tables below present the statistics for each study.

1. **Summary Subgroup Analysis - Standalone Studies**

1.1. Diagnocat AIS in Detecting Pathologic and Non-Pathologic Dental Findings in CBCT Radiographs - **Descriptive Statistics of Age, Gender, Manufacturer, Healthcare institution**

Age (years)	**N**	**%**
0-21	14	9%
22-20	46	29.7%
>40	95	61.3%

Gender	**N**	**%**
Male	61	39.6%
Female	88	56.8%
Unknown	6	3.9%

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Manufacturer	N	%
INSTRUMENTARIUM DENTAL	32	20,6%
KaVo	5	3,2%
Planmeca	5	3,2%
Vatech Company Limited	8	5,2%
Imaging Sciences International	53	34,2%
Sirona	6	3,9%
NewTom	5	3,2%
Carestream Health	21	13,6%
PreXion	5	3,2%
iRYS	3	1,9%
J.Morita.Mfg.Corp.	8	5,2%

GE MEDICAL SYSTEMS	2	1,3%
Carestream Dental	2	1,3%

Healthcare institution	**N**	**%**
Israel	9	5,8%
EU	4	2,6%
Canada	142	91,6%

1.2. Diagnocat AIS Localization and Numeration of Pathologic and Non-Pathologic Dental Findings in X-Ray Radiographs - **Descriptive Statistics of Age, Gender, Manufacturer, Healthcare institution**

Age (years)	**N**	**%**
0-21	16	1.3%
22-20	18	1.4%
>40	34	2.5%
Unknown	1246	94.8%

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Gender	N	%
Male	36	2.8%
Female	197	15%
Unknown	1081	82.2%

Radiographic view	N	%
Bitewing x-rays	163	12.4%
Periapical x-rays	960	73.1%
Panoramic x-rays	191	14.5%

Manufacturer	N	%
Manufacturer (Intraotal X-Rays)		
Planmeca	420	37.4%
Sirona	340	30.3%

Vatech Company Limited	363	32.3%
Manufacturer (Panoramic X-Rays)		
Planmeca	58	30.4%
Sirona	49	25.6%
Vatech Company Limited	84	44%

Healthcare institution	**N**	**%**
Israel	299	22.7%
EU	640	48.7%
Canada	375	28.6%

1.3. Diagnocat AIS in Detecting Pathologic and Non-Pathologic Dental Findings in X-Ray Radiographs - **Descriptive Statistics of Age, Gender, Manufacturer, Healthcare institution**

Age (years)	**N**	**%**
0-21	262	16.9%

22-20	177	11.4%
>40	315	20.35%
Unknown	796	51.35%

Gender	**N**	**%**
Male	330	21.3%
Female	346	22.3%
Unknown	874	56.4%

Radiographic view	**N**	**%**
Bitewing x-rays	218	14%
Periapical x-rays	1032	66.5%
Panoramic x-rays	300	19.5%

Manufacturer	N	%
Manufacturer (Intraotal X-Rays)		
Planmeca	554	44.3%
Sirona	394	31.5%
Vatech Company Limited	302	24.2%
Manufacturer (Panoramic X-Rays)		
Planmeca	119	39.6%
Sirona	85	28.4%
Vatech Company Limited	96	32%

Healthcare institution	N	%
Israel	547	35,3%
EU	683	44%

Canada	320	20,7%

1.4. Diagnocat in Segmentation and Localization of Periapical Radiolucency and Teeth on CBCT Radiographs - **Descriptive Statistics of Age, Gender, Manufacturer, Healthcare institution**

Age (years)	**N**	**%**
18-39	10	20%
>40	40	80%

Gender	**N**	**%**
Male	20	40%
Female	20	40%
Unknown	10	20%

Manufacturer	**N**	**%**
Gendex	1	2%

HDXWILL	2	4%
Imaging Sciences International	3	6%
INSTRUMENTARIUM DENTAL	2	4%
iRYS	3	6%
NNT	1	2%
PaloDEx Group Oy	12	24%
Planmeca	9	18%
RAY Co.,Ltd	1	2%
Sirona	8	16%
SOREDEX	1	2%
Vatech Company Limited	7	14%

Healthcare institution	**N**	**%**

Israel	25	50%
EU	8	16%
Canada	17	34%

10 Troubleshooting

In the event of encountering any problems while using Segmentron Implant it is necessary to:

1. Make sure that the inquiries sent to Diagnocat AIS meet the requirements described in the medical product's technical documentation.
2. Analyze the result (error) obtained and compare it to the technical documentation.
3. If in spite of ensuring compliance with the technical documentation the issues keep occurring, please contact the manufacturer.

11 Maintenance and service

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

12 For Help and Assistance

CONTACT INFORMATION

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

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NSW 2148, Australia

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