



Dentist's virtual assistant in treatment planning

# DIAGNOCAT AI

## User Manual

Version 3.2

Obsolete



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Obsolete



## User Manual Information

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

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

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.

## Symbols and marks used in the manual and in the labeling

	Manufacturer
	Follow instructions for use
	Caution
	Medical device
	Device complies with the European Directive on Medical Devices EU MDD 93/42/EEC

## Contact

Website: <http://www.diagnocat.com>

## Device information

Name: Diagnocat AI

Relevant Diagnocat Version: 3.2

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# Diagnocat

## Regulatory Requirements

Diagnocat AI 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

## Device Identification



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<https://www.diagnocat.com/>



## Paper copy

To receive a paper copy of this manual, please send an email to [support@diagnocat.com](mailto:support@diagnocat.com). Our team will be happy to provide you with a paper copy of the manual to you via the postal service at no additional cost, within 7 days from requesting.



# Diagnocat

## 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 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.
4. Users should read this manual thoroughly before using this product.
5. In order to use the full functions of Diagnocat, 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.



# Diagnocat

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

## Intended Use

The Diagnocat AI automated information system is designed for cloud-based storage and processing of digital dental images using artificial intelligence. Diagnocat AI 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 AI processes files of any area of the patient's maxillofacial region. Diagnocat AI is designed for use by medical professionals (dentists, orthodontists, radiologists, etc.) for education purposes and highlights anatomical areas, common conditions, and previous treatments.

Diagnocat AI automatically produces radiological reports for easier viewing and documentation of investigation for a particular patient. Diagnocat AI 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 pathologies:**

Maxillofacial Cone-Beam Computed Tomography (CBCT) scans: Artificial crown, Canals, Caries signs, Crown defect over 50%, Cast post and core, Endodontically treated tooth, Filling, Impaction, Implant, Missed canal, Overfilling, PDL space widening

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along root, Periapical radiolucency, PDL space widening in periapical region, Periapical radiopacity, Periodontal bone loss, Pontic, Roots, Short filling, Voids present in the root filling, Tooth germ, Root fragment, Impaction, tooth germ, root fragment, tooth, missing tooth.

X-Ray scans: Pulp stone, Dental calculus, Pulpotomy, Periapical radiolucency, Overfilling, Overhang, Caries signs, Short filling, Cast post and core, Open margin, Lack of interproximal contact, Implant, Artificial crown, Post, Canal filling, Filling, Voids present in the root filling, Furcation lesion, Periodontal bone loss, Secondary caries, Pontic, tooth, missing tooth.

Panoramic scans: Dental calculus, Periapical radiolucency, Overfilling, Overhang, Caries signs, Short filling, Cast post and core, Secondary caries, Lack of interproximal contact, Implant, Artificial crown, Post, Canal filling, Filling, Voids present in the root filling, Furcation lesion, Periodontal bone loss, Pontic, Impaction, tooth germ, root fragment, tooth, missing tooth.

## Contraindications

Although Diagnocat 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.



Clinicians should review Diagnocat 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 paragraph 2.2. Clinicians should review original images for all suspected pathologies.



All radiographic images must have proper quality. Diagnocat performance may be reduced on images with poor quality.



Diagnocat should be used according to the manual.

## Required Training and Qualifications

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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 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 AI 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.



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

The Diagnocat AI 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 AI 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.



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 AI 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 is required to follow government-regulated quality assurance procedures to verify and validate modifications to Diagnocat AI 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 AI software. Only authorized specialists (like institution's IT specialists/administrators, Diagnocat AI 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;

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- 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 AI 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 AI.

Changes and/or additions to the medical product software should only be carried out by Diagnocat AI or by third parties expressly authorized by Diagnocat AI 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 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 AI 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](mailto:Sales@diagnocat.com) for more information.
2. Desktop integration. DC Desktop App 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](mailto:Sales@diagnocat.com) for more information.

## 1. Start with Diagnocat

### 1.1 Sign up

There are two main ways to create an account in Diagnocat.

#### 1. Sales team

- Go to <https://diagnocat.com/> and click "Book a Demo".
- Select your region and then go to "Sign up for a free trial or book a demo".
- You will be redirected to a contact form. Please fill all required fields.

\*It's also available to book a phone call with our Sales manager in order to speed up the process.

- Our friendly Sales team will get in touch with you shortly afterwards. They will be able to assist you with account creation and choosing the right subscription option for your business.

### 2. Signup form

Go to [diagnocat.com](https://diagnocat.com) and click the "Sign up" button.



You will be prompted to the account creation screen where you need to provide account details and click the “Create Account” button.

**NOTE:** It's important to note that specifying your country is critical. There are two main reasons for that:

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

## 1.2. Log in

Open Chrome browser and go to [www.diagnocat.com](http://www.diagnocat.com).

Select your region.

[Products](#) ▾[Research](#)[Reviews](#)[Price](#)[Contact](#)[Select Region](#)

DIAGNOCAT AI

## Dentist's virtual assistant in treatment planning

AI service analyzing dental images: 3D CBCT's, Panoramic X-rays, bitewing, and periapical radiographs

[BOOK A DEMO](#)

Select your region or country.

## Welcome to Diagnocat!

Please select your region or country

Europe

[DACH Countries](#)[Other EU-countries](#)

Non-Europe

[USA](#)[Canada](#)[Oceania](#)[Mexico](#)[Israel](#)[CIS](#)

Click the "Login" button.





Diagnocat

Products ▾

Research

Reviews

Price

Contact

European  
Countries

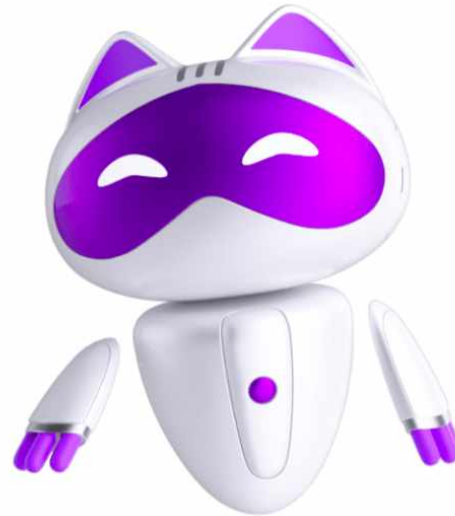
Sign up

Login

DIAGNOCAT AI

## Dentist's virtual assistant in treatment planning

AI service analyzing dental images: 3D CBCT's, Panoramic X-rays, bitewing, and periapical radiographs

[BOOK A DEMO](#)

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

Diagnocat

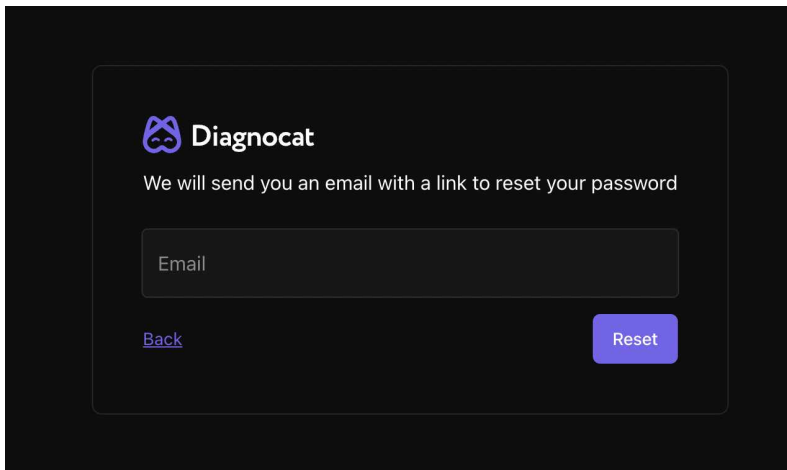
Email

Password

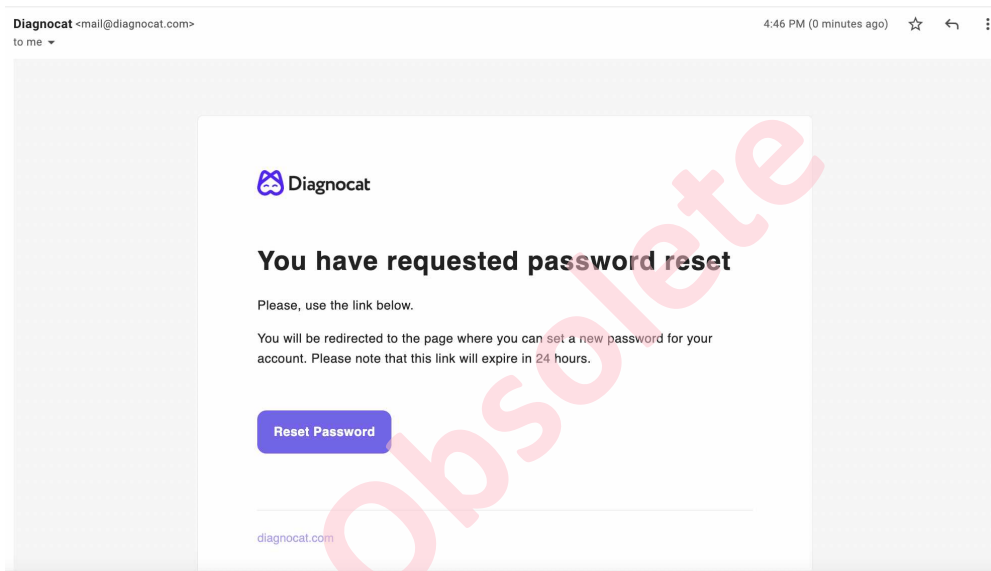
[Reset password](#) [Login](#)

### 1.3 Reset password

If you need to reset your password, click the Reset Password link and enter your email address you used to register your Diagnocat account.



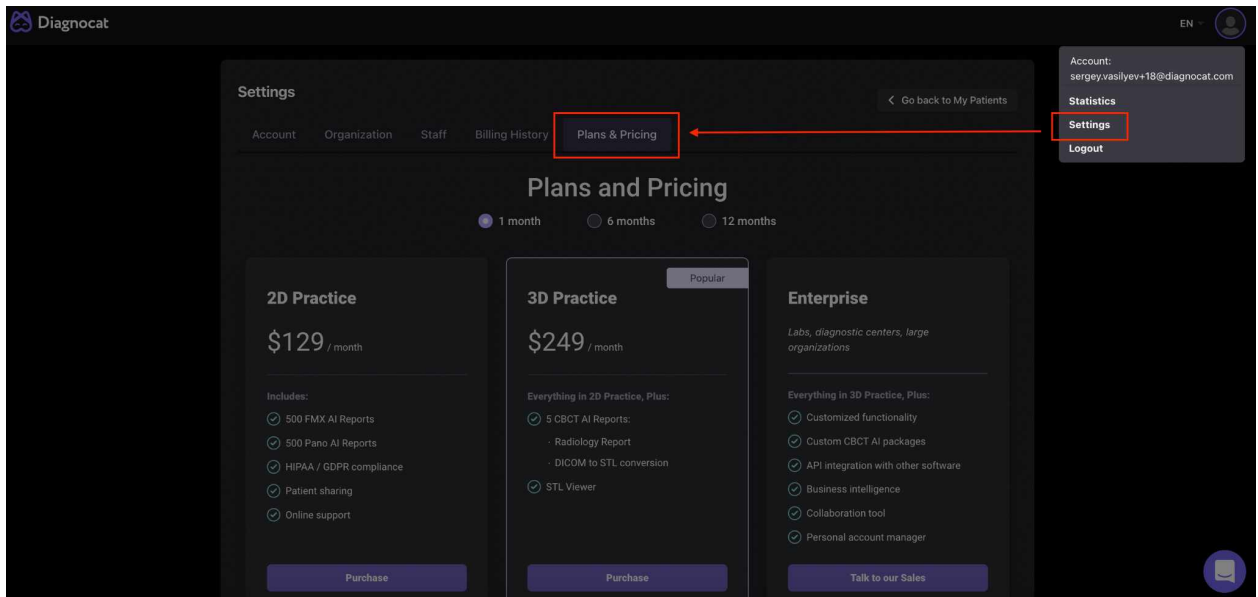
You will receive an email with instructions on how to reset your password.



## 1.4 Plans & Pricing

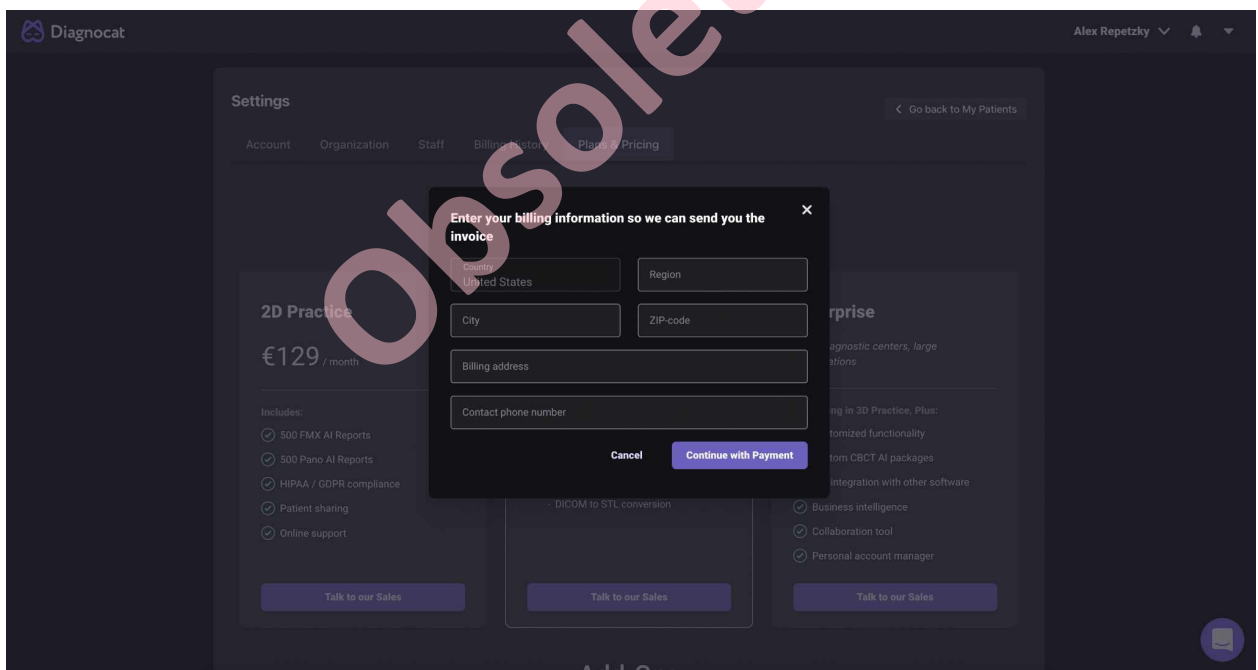
To start using Diagnocat you need to buy a subscription plan that will give you access to the main functionality.

**Step 1:** Go to your Account Setting and select the Plans & Pricing tab.



**Step 2:** Select the required plan and click Purchase.

**Step 3:** For the first payment, you will be asked to provide your billing information and phone number, so we can keep it on file.



**Step 4:** After you provide your billing information, you will be prompted to Stripe where you can complete your purchase.



**CA\$249.00**  
Due 12 July 2022

To: cau745lt4tuo08dci86g  
From: Diagnocat  
Memo: If paying by bank transfer, please remit to:  
DIAGNOCAT INC,  
account # 779003661  
JPMORGAN CHASE BANK  
SWIFT: CHASUS33  
ABA routing number for domestic wire:  
021000021  
ABA routing number for ACH: 322271627

[View invoice details >](#)

**Pay with card**

Card information

4242 4242 4242 4242

12 / 23 123

[Pay CA\\$249.00](#)

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

**Settings** [Go back to My Patients](#)

Account Organization Staff **Billing History** Plans & Pricing

Current plan

**3D Practice** **\$249**  
**Active**  
7/5/2022 – 8/5/2022 [Cancel](#)

500 FMX AI Reports  
0 out of 500 used

500 Pano AI Reports  
0 out of 500 used

5 CBCT AI Reports:  
0 out of 5 used

Current Add-ons

5 CBCT AI Reports: **\$195**  
2 out of 5 used [Buy](#)

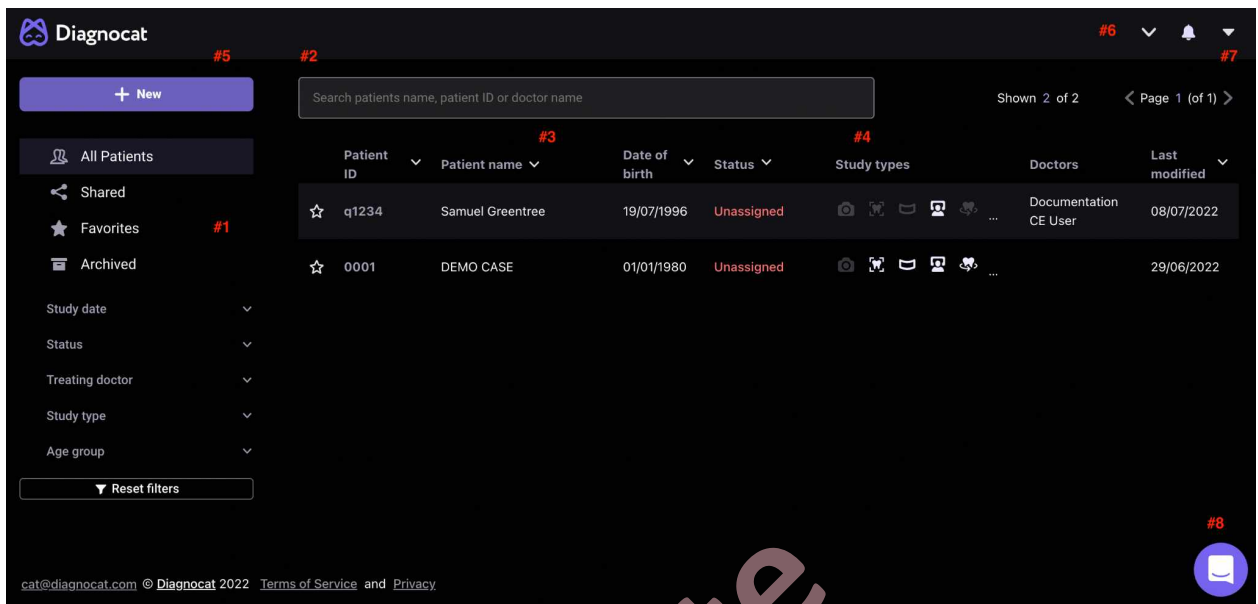
Invoice #80 **Paid** 7/5/2022 3D Practice \$249 [Download](#)

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

# Diagnocat

## 1.5 All Patients

Once you log in successfully, you will see the “All Patients” screen.



#1: Main folders:

“All patients” gives you access to all your patients.

“Shared” gives you access to all studies shared with you by other users.

“Favorites” gives you quick access to your favorite studies.

“Archive” contains the archived patients.

#2: Using the “Search” field you can search for studies by patient name, treating doctor or ID.

#3: Show you the list of all your patients.

#4: Shows existing study types.

#5: “New” allows you to create a new patient

#6: Allows you to change the interface language

#7: Gives you access to your account settings

#8: Allows you get access to customer success team



## 1.6 Create a new patient

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

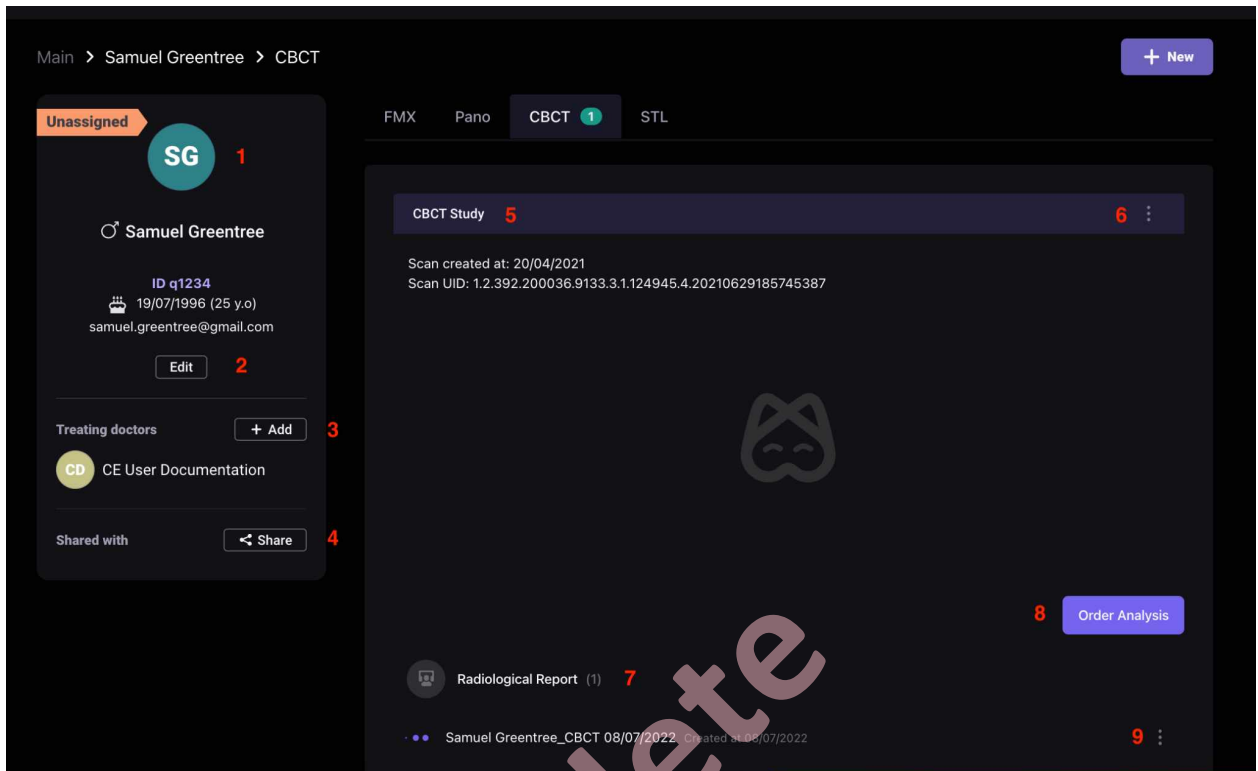
A screenshot of the "Create patient" form in the Diagnocat application. The form is displayed in a dark-themed modal window with a title bar that says "Create patient" and a close button (X). The form contains several input fields: "Last name \*" (required), "First name \*" (required), "E-mail", "Patient ID \*" (required), "Date of birth" (with a date picker showing "13/05/2022" and a required asterisk), and a "Treatment doctor" dropdown menu. Below these fields are two radio buttons for "Male" and "Female". At the bottom of the form is a large blue button labeled "Create". A large, semi-transparent "Obsolète" watermark is visible across the right side of the form.

Fill in a short form and click “Create”.

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: Show study info, Download, Reclaim study, Delete study.

#7: Report details.

#8: Order a new analysis.

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

## 1.8 Create a new study

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



1. Select the study type you want to upload
2. Attach a file or folder by browsing your computer
3. Click the “Upload” or Upload+Analyze button

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

## 1.9 Order analysis

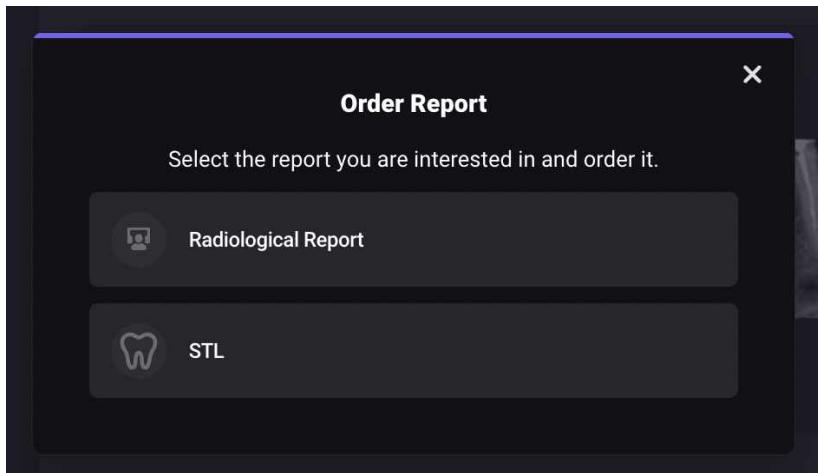
When you order 2D reports (FMX and Pano), Diagnocat generates reports automatically.

With 3D reports, only the Radiological Report can be generated automatically during CBCT file/s upload.

To order other reports go to the patient's card, choose the type of study and order the report by clicking “Order report”.

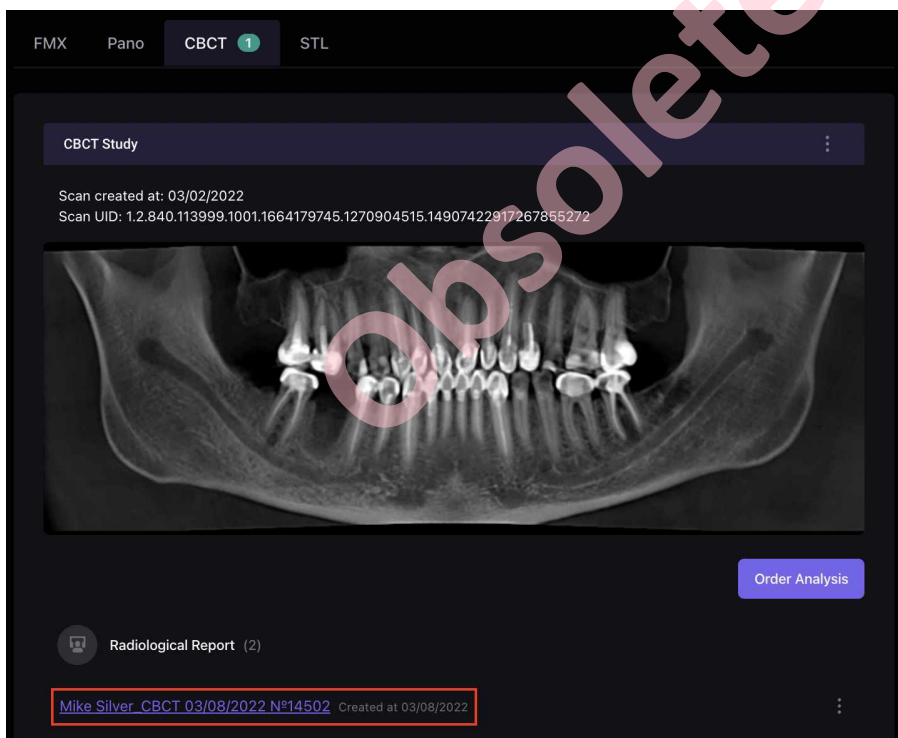
Type of reports available in the CBCT study:



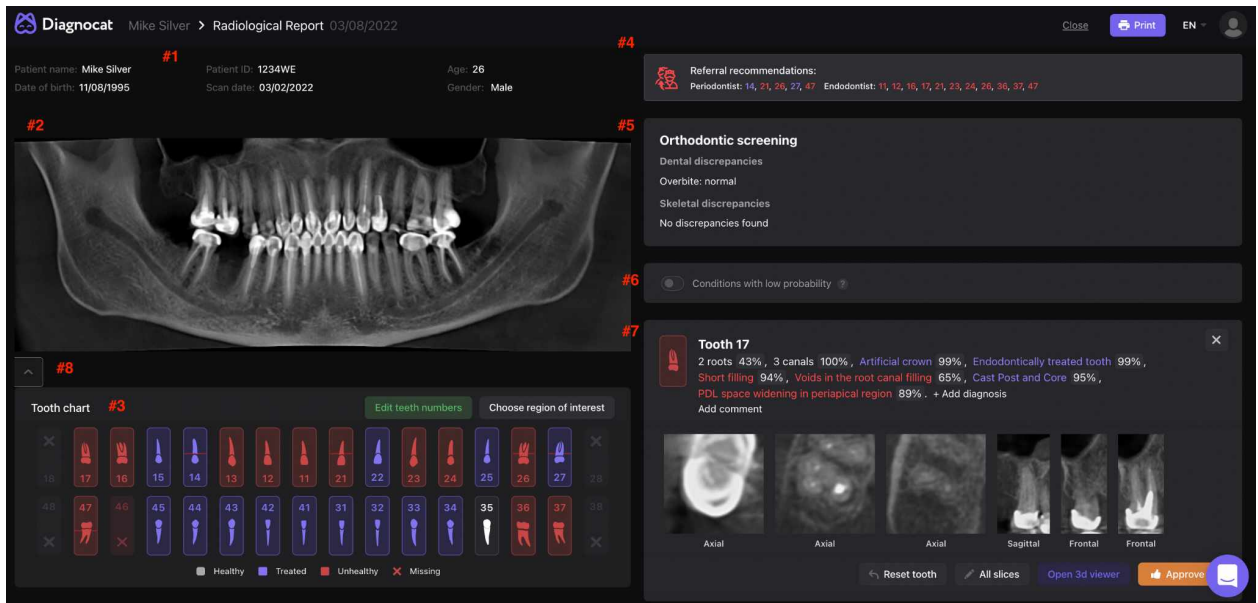


## 2.0 Radiological Report

You can open a radiological report by clicking the link.



Here is what you will find inside the radiological report:



#1: Patient details

#2: Panorama image derived from CBCT

#3: Tooth chart

#4: Referral recommendations

#5: Orthodontic screening

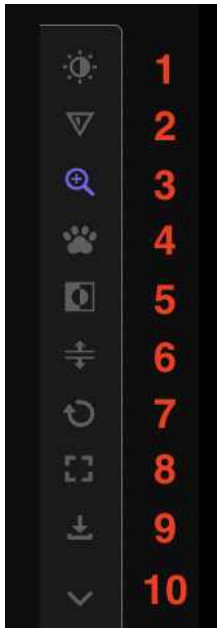
#6: Conditions with low probability mode

#7: Tooth card

#8: Panorama tools



## 2.1 Panorama tools



#1: Brightness and contrast

#2: Sharpness

#3: Zoom in

#4: Grab to move

#5: Invert

#6: Create a panorama for each jaw

#7: Reset all changes

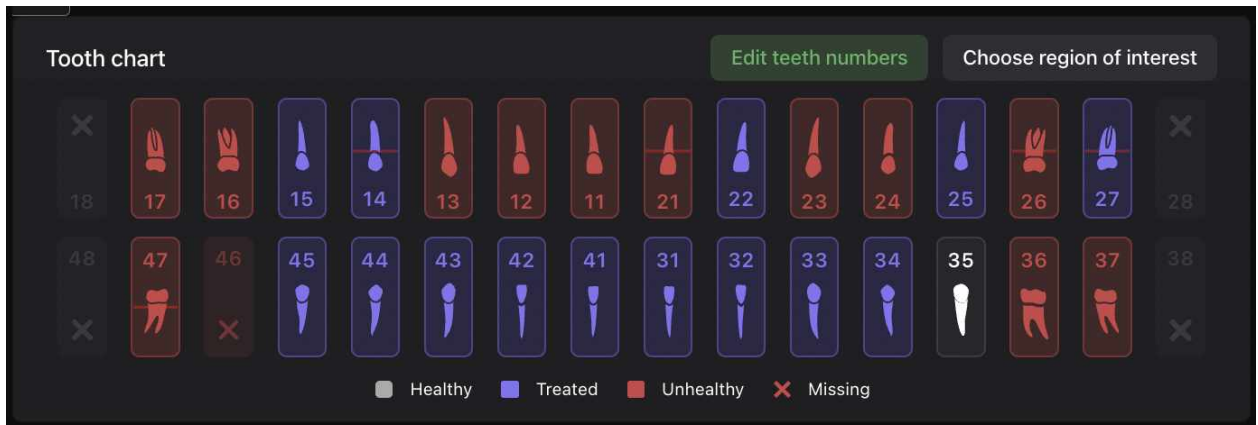
#8: Full screen mode

#9: Download an image as a jpeg file

#10: Collapse panorama tools



## 2.2 Tooth chart



White – healthy teeth

Red – teeth with pathologies

Blue – treated teeth with no pathologies

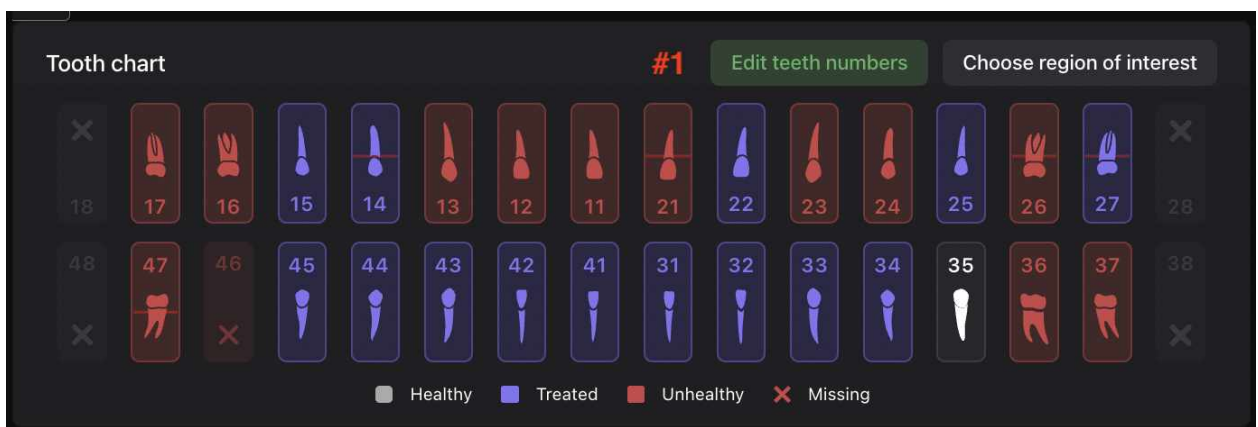
Yellow - detection with low probability

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. Use the “Choose region of interest” option to select what teeth you would like to have in the report.

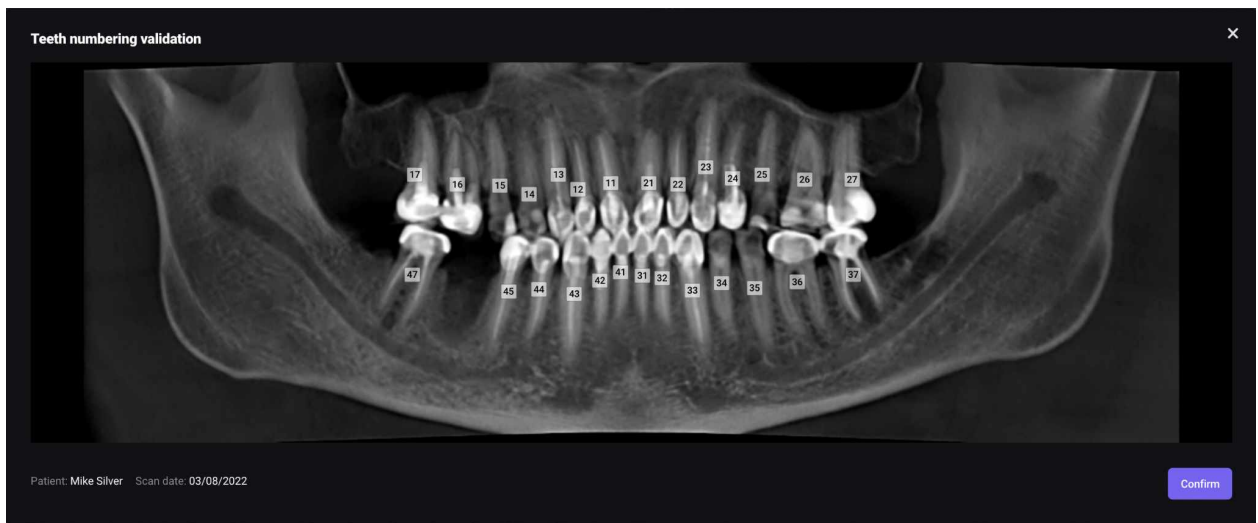
## 2.3 Change teeth numbers



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

Once done click the “Confirm” button.

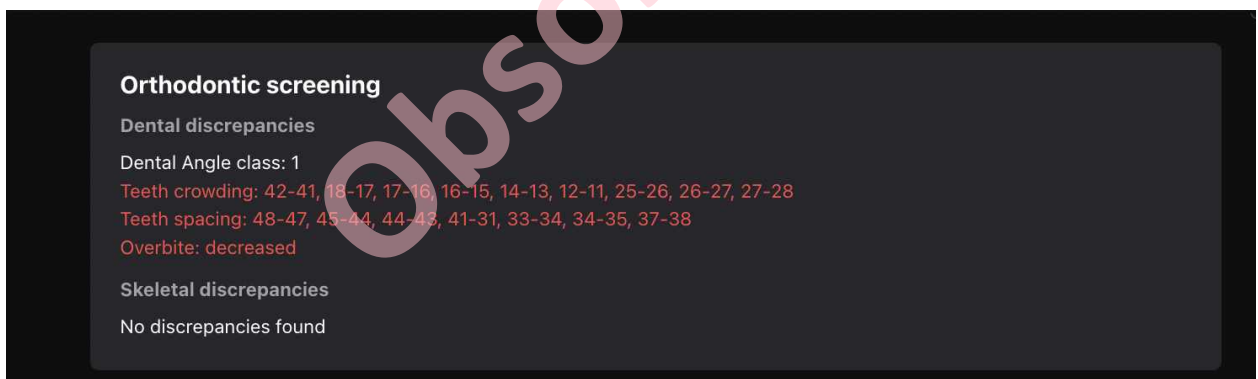
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## 2.4 Orthodontic screening module

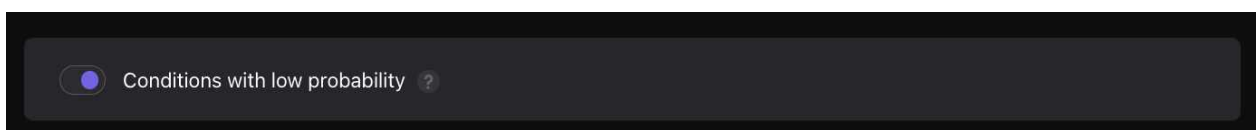
This module is for detection of dental and skeletal discrepancies.

To achieve the most accurate indicators, it is recommended to do a study with closed teeth.



## 2.5 Conditions with low probability mode

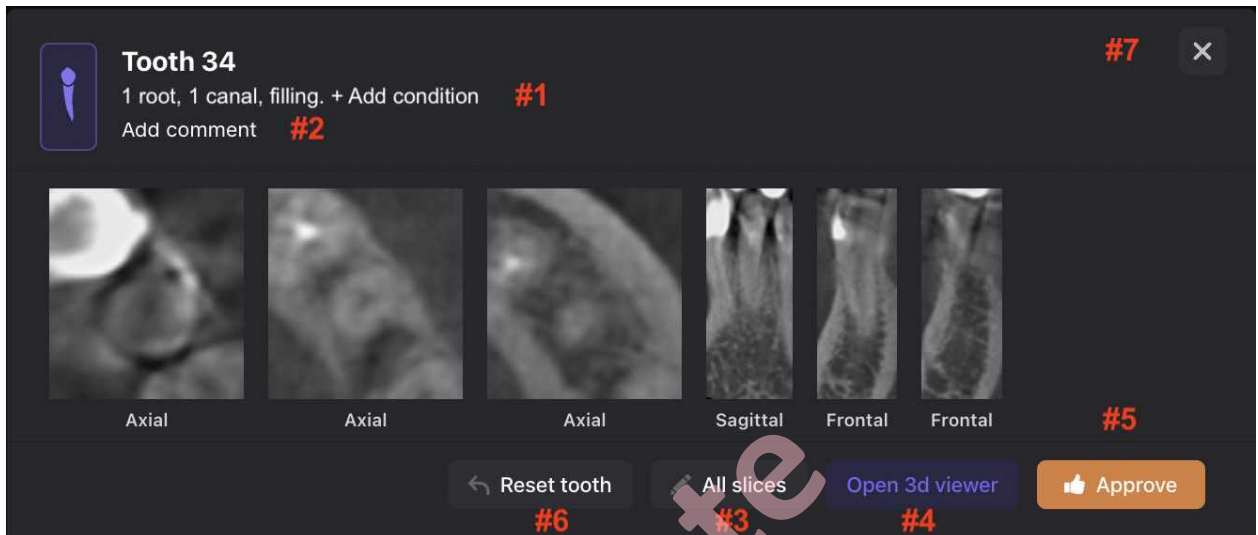
This mode switches on attributes of "sign of caries" and "periapical lesion" with probability rate as 30-50%.





**NOTE:** Yellow attributes don't appear in the report. If you click the "Approve" button, the yellow attributes become the red one. Then they will appear in the report.

## 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: View all slices for the tooth

#4: Use the 3D Viewer

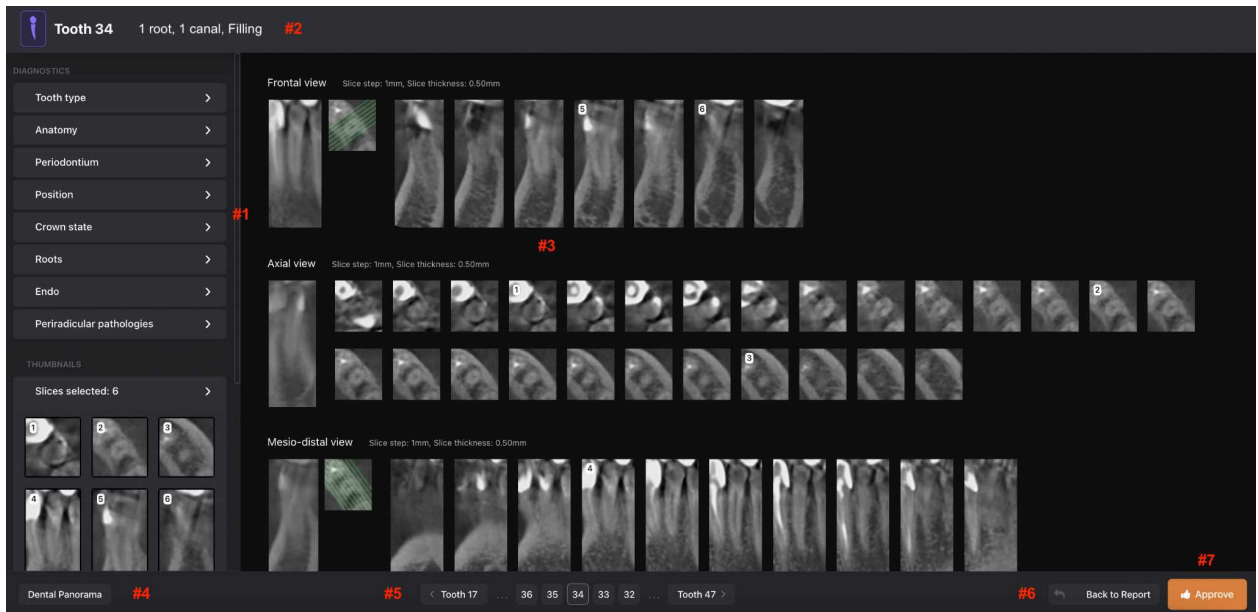
#5: Approve changes

#6: Reset tooth original conditions

#7: Remove the tooth card from the report

# Diagnocat

## 2.7 All Slices Mode



#1: Main panel that allows to view and edit detected pathologies and conditions. All pathologies and conditions are grouped according to the anatomical and topographic features in the form of tabs.

#2: A list of detected pathologies and conditions. You can also change a tooth by clicking a tooth number.

#3: A collection of slices. Diagnocat automatically creates a collection of slices in three projections: axial, mesio-distal and vestibulo-oral.

#4: The “Panorama” button. This button will show a panorama and tooth chart on top of existing slices.

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

#6: Go back to a tooth card

#7: 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.

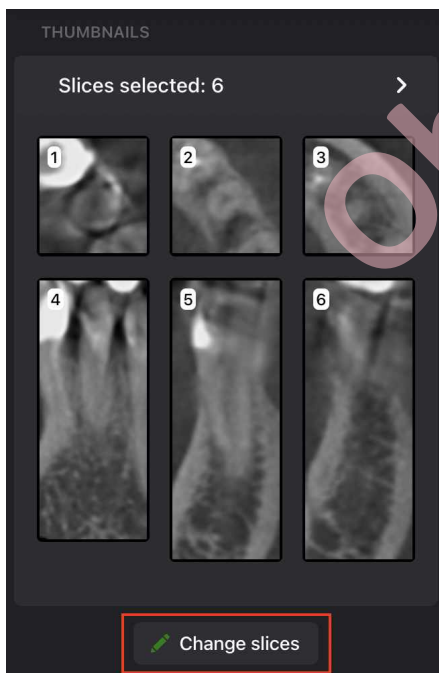


## 2.8 View and edit slices

When you click any slice a tool panel will appear: brightness, ruler, arrow, eraser, hide “overlays” button, and magnifier.



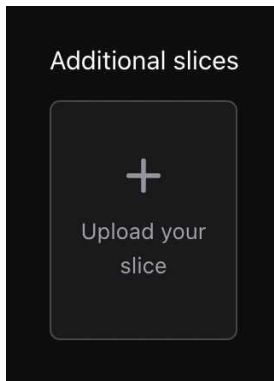
By default, the system adds 6 slices to the tooth card in different projections. You can change these slices and create a new set, which will be added to the final report.



Click the “Change slices”, then click a slice you want to delete. If you want to remove all slices then click the “Remove all” button.

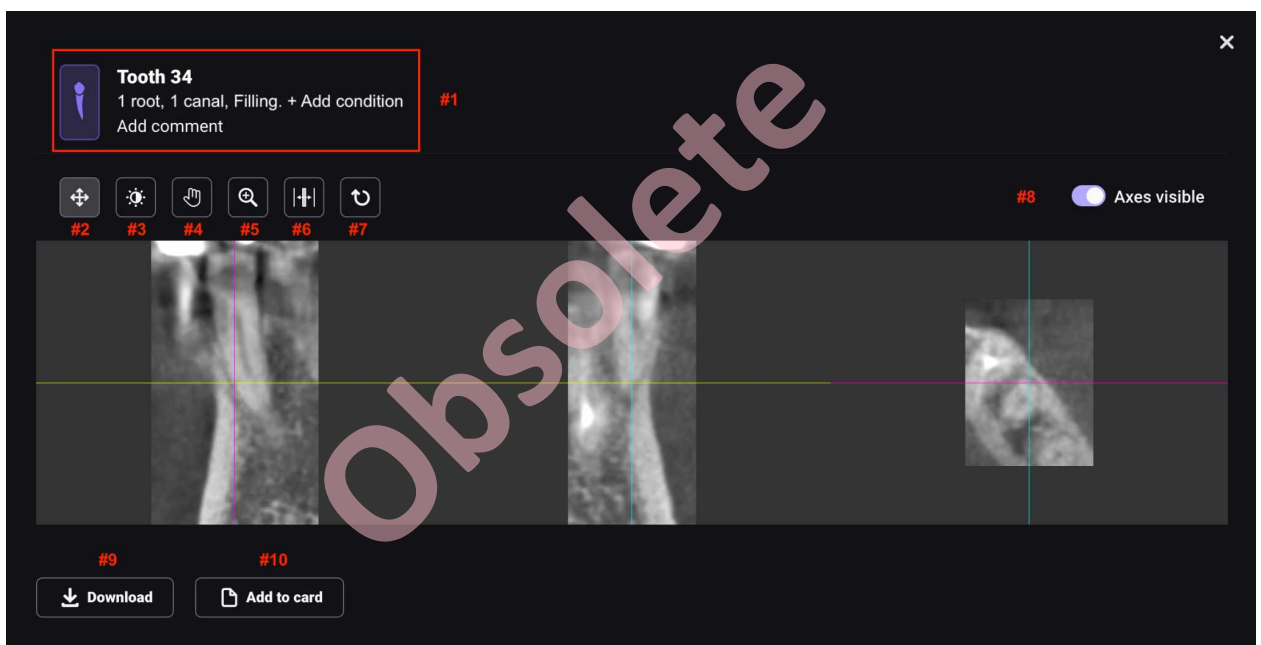
If you want to add your image, use the “Additional slices” option.





After you finish removing / adding slices, click the “Save slices” button.

## 2.9 3D Viewer



#1: You can edit information in this section. Changes will be available inside the tooth card.

#2: View mode

#3: Brightness/contrast

#4: Grab to move

#5: Zoom

#6: Depth of the slice

#7: Reset all changes

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

#9: Download slices as JPEG files

#10: Add slices to the tooth card

#11: Go back to the report

## 2.10 Conclusion

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, enter a doctor's name in the "Doctor" field. Once you add a doctor the "Sign" button becomes active.



Sign this study

Select doctor to add signature:

Select date  
03/08/2022

Doctor

Add at least one signature

[Print report without signature](#) [Sign](#)

Also to sign a report you need to approve all detections of all selected teeth. If any detection is not approved, the system will give you a warning.

**Not approved** ×

You didn't approve all of the teeth to be included in the report. The following text will be added to the printed version of the report:  
"The conditions and pathologies in this report can not be considered a medical diagnosis and must be interpreted by the attending dentist." To change the text to "Approved by a doctor", click Cancel and approve the remaining teeth or change the region of interest in the Tooth chart.

**NOT APPROVED TEETH (27)**

**Tooth 11**  
+ Add condition  
Add comment

**Tooth 12**  
+ Add condition  
Add comment

**Tooth 13**  
+ Add condition

[Cancel](#) [Print report without signature](#)

If all teeth are approved, click the "Sign" button and then the "Print" button.



## 2.12 Printing a report without signature

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

A note added to the bottom of every page of the report: “This report was generated with Diagnocat 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.

Select clinic: **#1**

Not selected

Select report version **#2**

Full

☐ Inverted **#3**

☐ Probabilities **#4**

☒ Dental chart **#5**

☒ Show upper jaw **#6**

☒ Show lower jaw **#7**

☒ Show conditions **#8**

☒ Show slices **#9**

☐ Referral recommendations **#10**

☐ Orthodontic screening **#11**

☐ Study meta info **#12**

Select print type **#13**

☒ Color

☐ Black & White

Not signed by doctor **#14**

**#15**

Download PDF

Print

**#1:** Select clinic to add clinic's information and branding to the report.

**#2:** Select a report type (Full or Motivation). In the Motivation version there will be only a panoramic image and the tooth chart.



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

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

#5, #6, #7: Enable / disable the tooth chart and upper and lower jaws in the report.

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

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

#10: Enable / disable referral recommendations in the report.

#11: Enable / disable the orthodontic screening results in the report.

#12: Enable / disable study meta information.

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

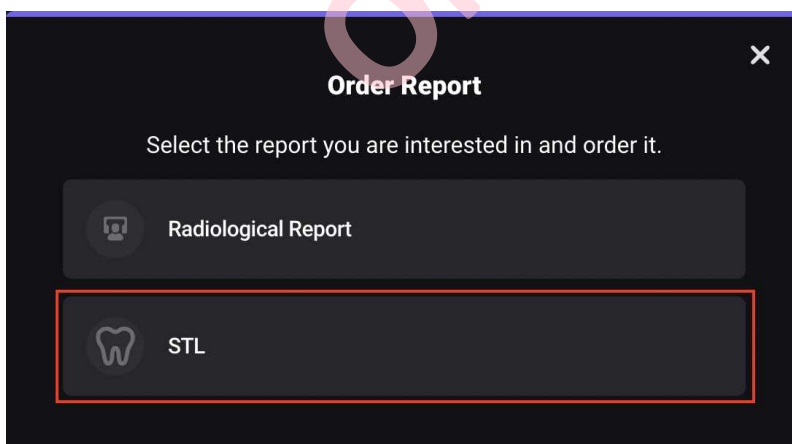
#14: Download the report as a PDF file.

#15: Print the report.

## 3.0 STL Report

### 3.1 Order a new STL report

Click the “Order Analysis” button under a desired study.



Select the output files.



**Order STL files**
✕

Please, select regions of interests which you want to generate STL files for.

**#1** ☒ STL of teeth and maxillomandibular anatomy in one file

**#2** ☐ STL of teeth and full anatomy (maxilla, mandibula, airways, cranial base) as separate files

**#3** ☐ STL of items selected below as separate files

☒ Upper left jaw

18	17	16	15	14	13	12	11	21	22	23	24
48	47	46	45	44	43	42	41	31	32	33	34

☒ Lower left jaw

☒ Upper right jaw

25	26	27	28
35	36	37	38

☒ Lower right jaw

☒ All teeth

[Cancel](#)
Order

#1: STL of teeth and maxillomandibular anatomy in one file

#2: STL of teeth and full anatomy (maxilla, mandibula, airways, cranial base) as separate files

#3: STL of items selected below as separate files

Once you click the “Order” button, the system will start generating a new report. It will take a few minutes. Once it’s finished, you will see a new report in the list.

## 3.2 View a STL report

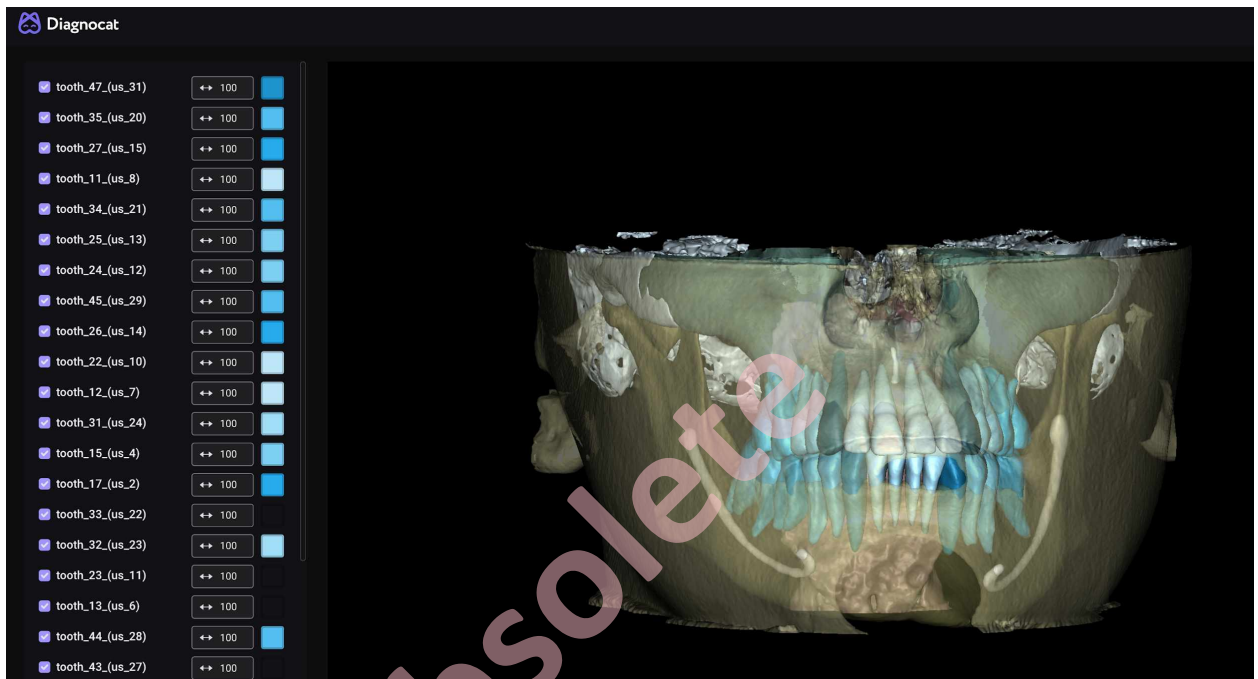
In the list, click a STL report you want to view.

Inside the STL viewer, using the navigation panel on the left you will be able to:

- enable/disable different elements of the model



- change the colors of the model's elements
- change transparency of the model's elements
- rotate the model
- zoom in / zoom out

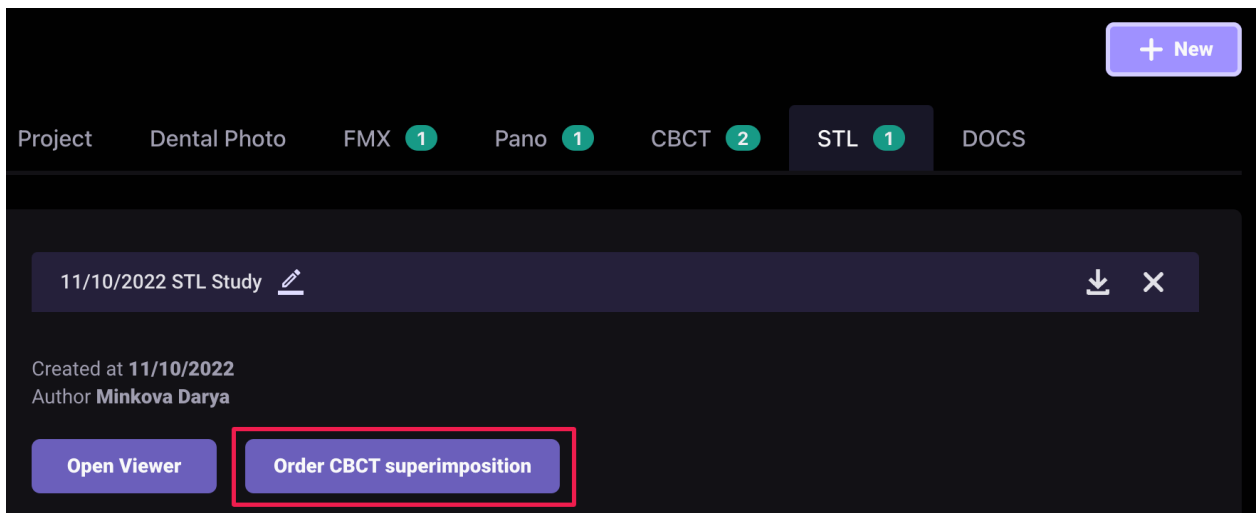


## 4.0 Superimposition

Diagnocat allows you to create IOS-CBCT Superimposition. In study choose STL, click “New” and upload the file or folder.

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

Then click “Order CBCT superimposition”:

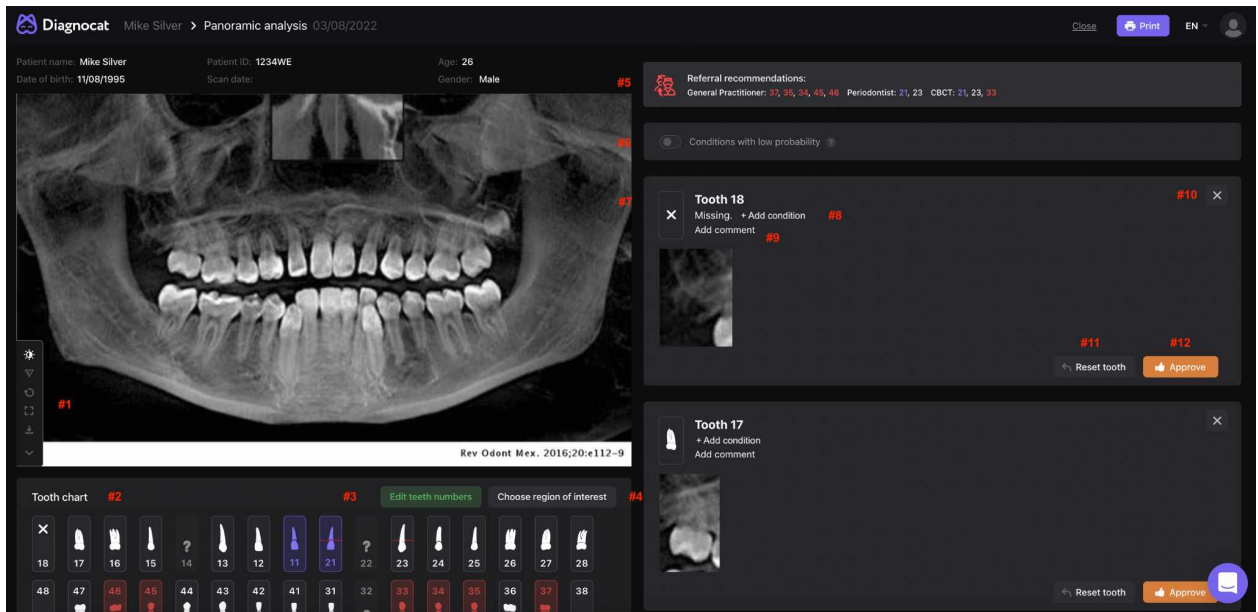


## 4.0 Panoramic Report

When you open a panoramic report for the first time, the system will ask to confirm the teeth numbers.

After confirmation you will be able to start working with the report. The panoramic report has the exact same tools and functionality that are used in the Radiological Report.





#1: Tool panel

#2: Tooth chart

#3: Edit tooth numbers

#4: Choose region of interest

#5: Referral recommendations

#6: Conditions with low probability

#7: Tooth card

#8: Add pathology or condition

#9: Add comments to the tooth card

#10: Remove the tooth from region of interest

#11: Reset the tooth condition to the original state

#12: Approve the tooth

## 5.0 Intraoral analysis

### 5.1 Order and view intraoral analysis

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

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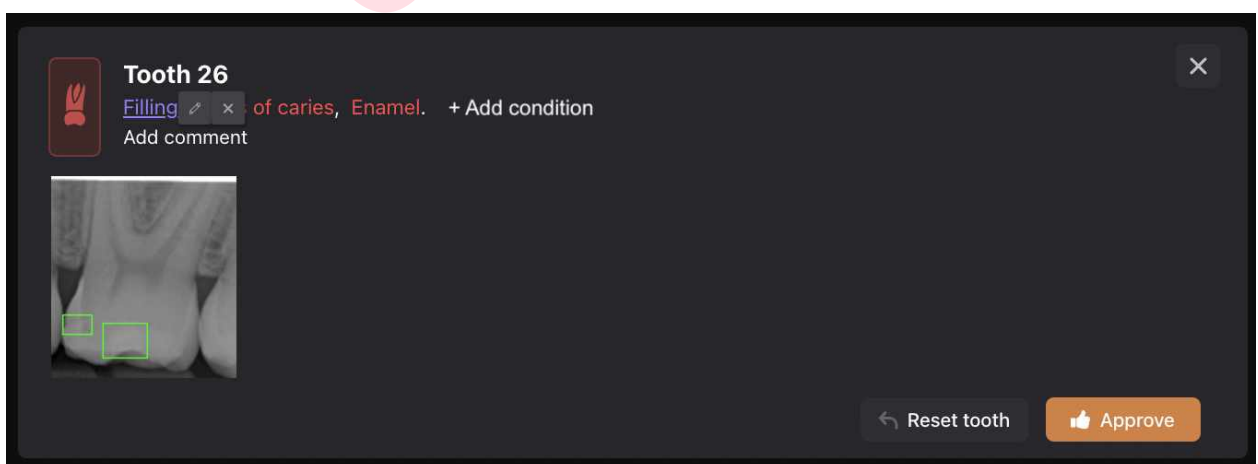
The intraoral report has the exact same tools and functionality that are used in the Radiological Report.

**NOTE:** In case there is a validation conflict. The system will ask you to check teeth numbers. The red marked images have tooth-duplicates. The system won't allow complete validation until it's fixed.



## 5.2 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.

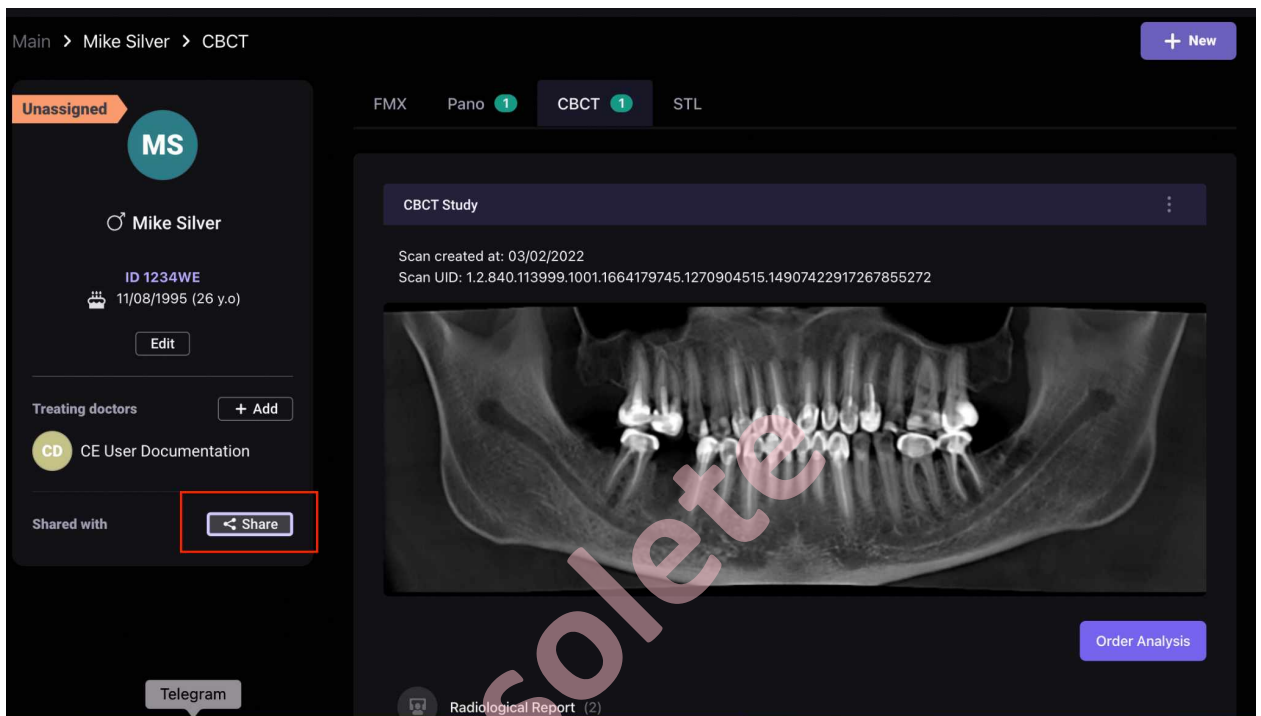




## 6.0 Additional Functions

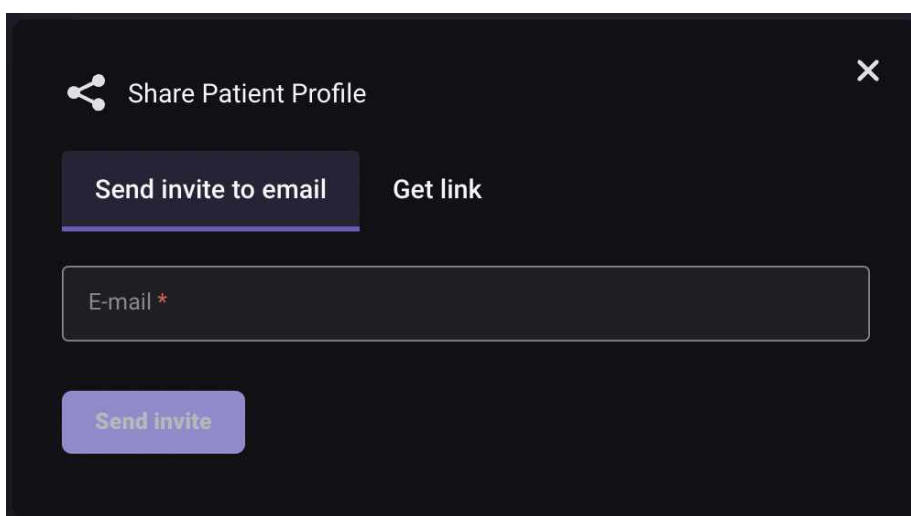
### 6.1 Share patient

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



Click the "Share" button. There are two ways to share a patient's study:

#### 1. "Send invite to email" option



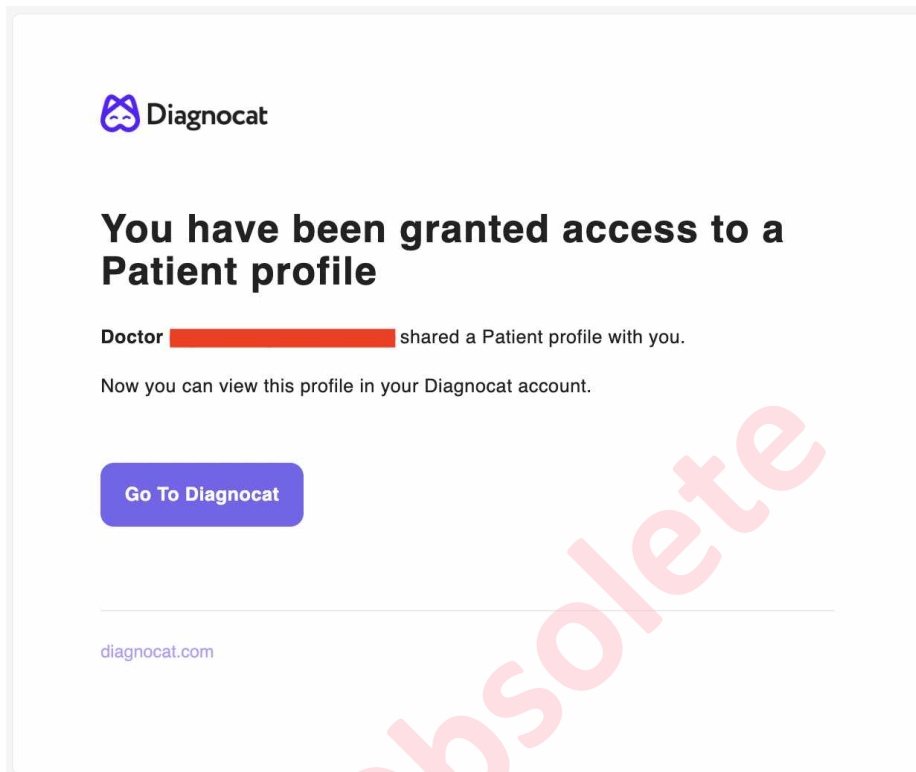
Enter the recipient email address and click the "Send invite" button.



On the left side in the menu “Shared with” you will see a list of doctors a patient study has been shared with.

To revoke access click the “cross” 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 by entering a secure password. Once finished they will be prompted to their account where they can view reports of the shared patient.

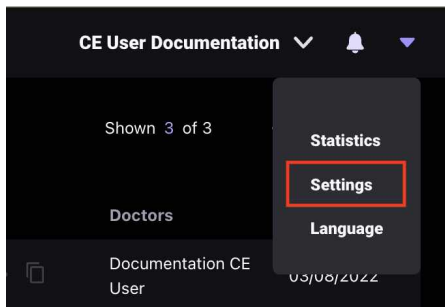
## 2. “Get link” option

To use this option, enter the recipient email address and click the “Get link” button. the system will generate a unique link you can send to the recipient.

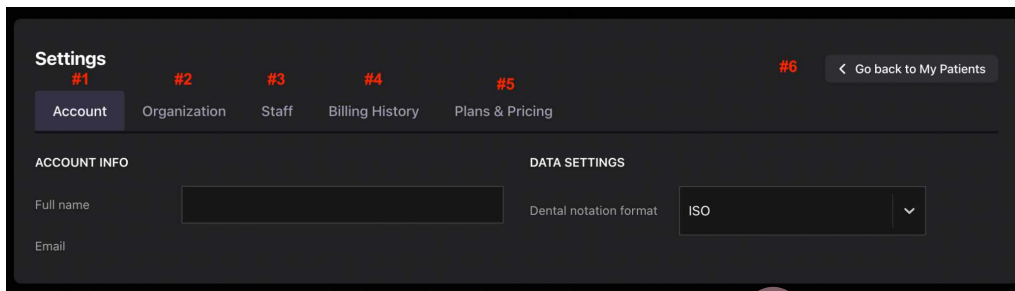
**NOTE:** A new Diagnocat account a doctor creates is a full Diagnocat account that they can use from other devices. This account will have limited functionality. They will be able to view and edit only existing data and reports until they purchase their own license

## 6.2 Account Settings

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

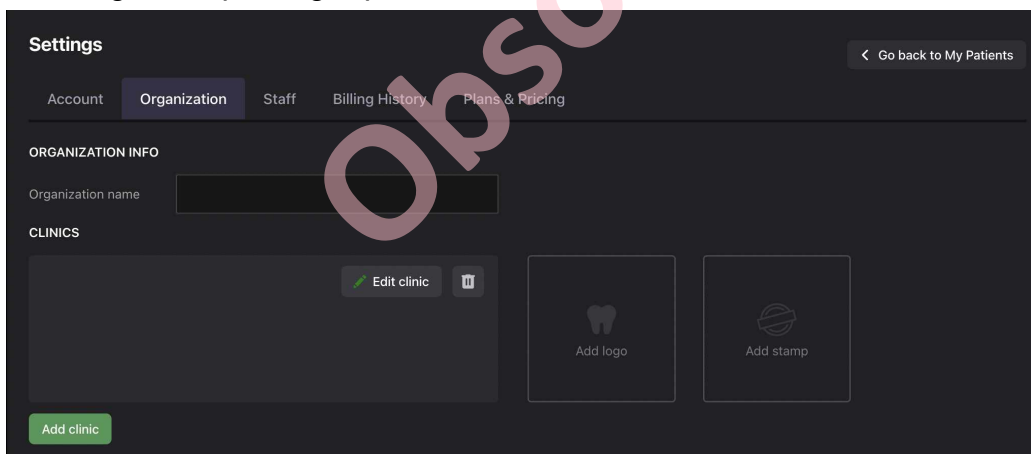


Inside you will find 5 main tabs:

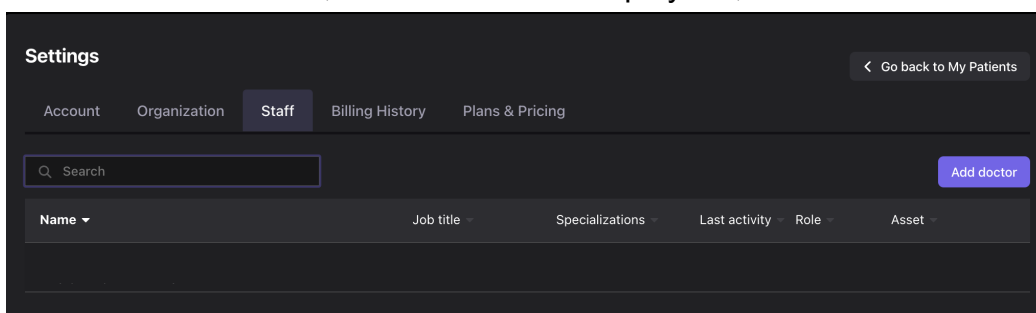


**#1: Account.** You can change the account owner name and the format of the tooth chart.

**#2: Organization.** You can add, delete and edit clinics so you can use different branding when printing reports.



**#3: Staff.** You can add, remove and edit employees, as well as resend an invite.



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**#4: Billing history.** You can view your current plan, packages, consumption and invoices. You can also pay and download your invoices. Additionally you can cancel your current plan. What it does is cancel your recurring payment. You will still have an active plan but it will not renew when a new billing cycle starts.

The screenshot shows the 'Billing History' tab under 'Settings'. It displays the current plan as '3D Practice' for \$249, which is 'Active' from 7/5/2022 to 8/5/2022. There is a 'Cancel' button. Below this, three progress bars show usage: 0 out of 500 for FMX AI Reports, 1 out of 500 for Pano AI Reports, and 3 out of 5 for CBCT AI Reports. Under 'Current Add-ons', there is an add-on for 5 CBCT AI Reports for \$195, with 2 out of 5 used, and a 'Buy' button. At the bottom, an invoice for #80 is shown as 'Paid' on 7/5/2022 for the '3D Practice' plan at \$249, with a 'Download' button.

**#5: Plans & Pricing.** You will be able to view available in your region plans and packages you can purchase.

The screenshot shows the 'Plans & Pricing' tab under 'Settings'. It features three pricing plans: '2D Practice' at \$129/month, '3D Practice' at \$249/month (marked as 'Popular'), and 'Enterprise'. Each plan lists its included features. The '3D Practice' plan includes everything in the '2D Practice' plan plus 5 CBCT AI Reports, Radiology Report, DICOM to STL conversion, and STL Viewer. The 'Enterprise' plan includes everything in the '3D Practice' plan plus customized functionality, custom CBCT AI packages, API integration, business intelligence, a collaboration tool, and a personal account manager. Each plan has a 'Talk to our Sales' button. At the top, there are radio buttons for selecting the subscription duration: 1 month (selected), 6 months, and 12 months. A 'Go back to My Patients' button is in the top right.

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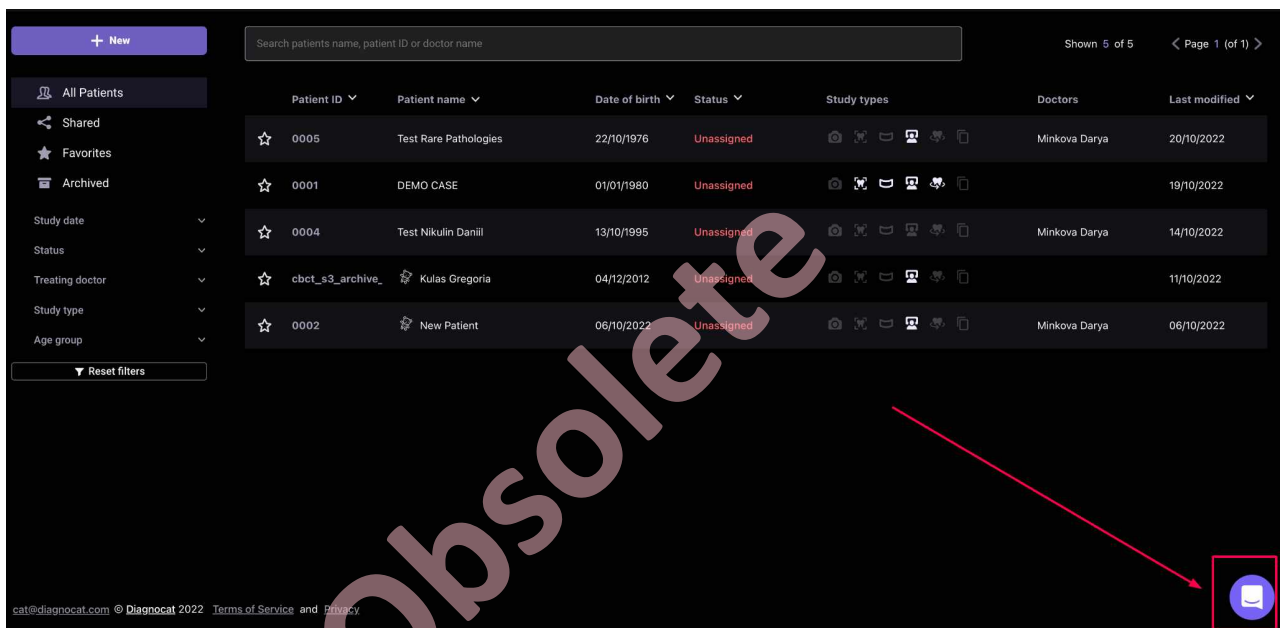


**#6:** When you click the “Go back to my patients” you will be prompted to your patient list.

### How to buy extra uploads:

In case you want to expand the amount of uploads, please follow these steps:

- Log In to your account.
- Open an icon in the lower right corner with the Support team.
- Tell us how many uploads you want to buy.
- Our Sales manager will contact you immediately with all information and add uploads to your account.



## 6.3 For Help and Assistance

### CONTACT INFORMATION

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

### MANUFACTURER

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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.

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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](mailto:sales@diagnocat.com)

Obsolete



## Document Signatures

Participant Name	Participant Type	Action	Task Performed On
Sergey Vasilyev (Product Manager)	Reviewer	Approve Review	2023-07-14 09:40 GMT
Sergey Vasilyev (Product Manager)	Approver	Approve Document	2023-07-14 09:41 GMT
Anastasya Melnikov (Quality assurance and Regulatory affairs manager)	Approver	Approve Document	2023-07-16 06:03 GMT

## Revision History

Version	Effective Date	Prepared by	Summary of Changes/Justifications
1.0	2022-08-23	Sofia Bulgakova	Initial Version
2.0	2022-12-13	Sofia Bulgakova	Update User Manual due to new software version 3.2
3.0	2023-05-02	Sofia Bulgakova	Changed address manufacturer and add chapter - for help and assistance (6.3), add information about paper copy - "Our team will be happy to provide you with a paper copy of the manual to you via the postal service at no additional cost, within 7 days from requesting."
4.0	2023-06-29	Sofia Bulgakova	Added chapter "Symbols and marks used in the manual and in the labeling" and CE symbol - according to SUKL's request
5.0	2023-07-17	Sofia Bulgakova	Need to upload English version - Version 4 was on czech language