

Dentist's virtual assistant in treatment planning

DIAGNOCAT AI User Manual

Version 3.2



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Diagnocat 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
\triangle	Caution
MD	Medical device
CE	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



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



DGNCT LLC 333 Southeast 2nd Avenue, 20th Floor#563, Miami, Florida 33131, USA Phone: + 1 519 619 4212

https://www.diagnocat.com/

CE

Paper copy

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



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:

<u>Maxillofacial Cone-Beam Computed Tomography (CBCT) scans</u>: 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



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.

<u>X-Ray scans:</u> 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.

<u>Panoramic scans</u>: 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 theDiagnocat Al 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 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;



• 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 for more information.
- 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 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 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.

First Name	
Last Name	
🌐 Language	
Location	
Create accoun	t

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.

Select your region.



Select your region or country.

Diagr	ome to hocat!
Europe	Non-Europe
DACH Countries	USA USA
Other EU-countries	D Canada
	Oceania
	Mexico
	Israel
	D cis

Click the "Login" button.

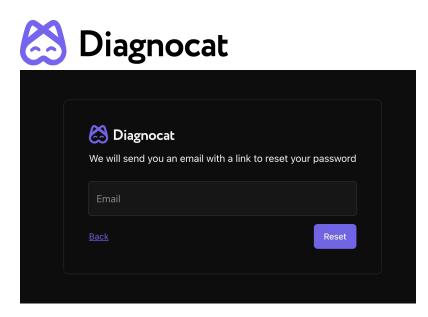


You will be able to log in to the Diagnocat application by providing your email and password.

🖄 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.

Diagnocat <mail@diagnocat.com> to me ▼</mail@diagnocat.com>		4:46 PM (0 minutes ago)	☆	4	:
	😂 Diagnocat				
	You have requested password reset				
	Please, use the link below.				
	You will be redirected to the page where you can set a new password for your account. Please note that this link will expire in 24 hours.				
	Reset Password				
	diagnocat.com				

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.



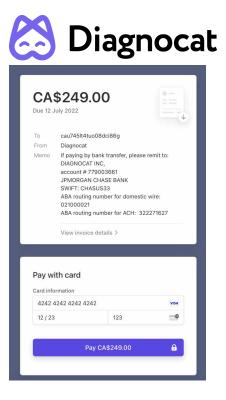
🖄 Diagnocat			EN 🖛
Settings			Account: sergey.vasilyev+18@diagnocat.com
			Statistics
			Settings
			Logout
	Plans and Pricing		
		/ 12 months	
	Popular		
2D Practice	3D Practice	Enterprise	
\$129/month	\$249 / month		

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.

👸 Diagnocat				Alex Repetzky 🗸 🌲 🔻
		Enter your billing information so we can send you the invoice	×	
	2D Practice €129 / month			
		Contact phone number Cancel Continue with Payme	ng In 3D Practice, Plus: tomized functionality ont form CBCT Al packages integration with other software	
		Talk to our Sales		

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



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				く Go back to My Patients
Account Organization	Staff Billing H	listory Plans & Pricing		
Current plan 3D Practice 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				\$249 Active 7/5/2022 - 8/5/2022 Cancel
Current Add-ons 5 CBCT Al Reports:			\$195	Buy
2 out of 5 used				
Invoice #80 Paic	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.



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

😂 Diagnocat	#5	#2										i	#6	✓ ▲ ▼ #7
+ New		Sea										Shown 2 of 2	<	Page 1 (of 1) >
🛝 All Patients			Patient ID	~	<mark>#3</mark> Patient name ❤	Date of v	Status 💙	<mark>#4</mark> dy ty	pes			Doctors		Last 🗸
< Shared★ Favorites	#1	☆	q1234		Samuel Greentree	19/07/1996	Unassigned			Ę		Documentat ··· CE User	ion	08/07/2022
Archived		☆	0001		DEMO CASE	01/01/1980	Unassigned	1	D		Ę,			29/06/2022
Study date														
Status														
Treating doctor														
Study type														
Age group														
▼ Reset filters														
<u>cat@diagnocat.com</u> © <u>Diagnoc</u>	cat 2022 <u>Term</u>	ns of Ser	<u>vice</u> and <u>P</u>	Privacy										

- #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.

Create patient	
Last name *	
First name *	
Patient ID *	
Date of birth 13/05/2022	*
Male	
Female	

Fill in a short form and click "Create".

A new patient will appear in the patient list.



Main > Samuel Greentree > CBCT		+ New
Unassigned SG 1	FMX Pano CBCT 1 STL	
ਾ Samuel Greentree	CBCT Study 5	
ID q1234 ∰ 19/07/1996 (25 y.o)	Scan created at: 20/04/2021 Scan UID: 1.2.392.200036.9133.3.1.124945.4.20210629185745387	
samuel.greentree@gmail.com Edit 2		
Treating doctors + Add 3		
Shared with < Share 4		
		8 Order Analysis
	Radiological Report (1) 7	
	Samuel Greentree_CBCT 08/07/2022 Created at 08/07/2022	

- #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".

Contraction of the transmission of transmisa

- 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".

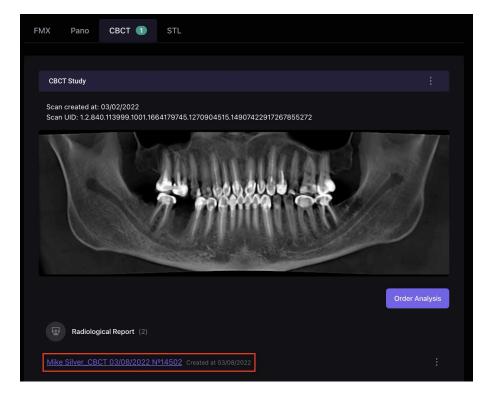
Type of reports available in the CBCT study:



Order Report Select the report you are interested in and order it.	×
Radiological Report	
STL STL	

2.0 Radiological Report

You can open a radiological report by clicking the link.



Here is what you will find inside the radiological report:



	er > Radiological Report 03/08/2022	#4	<u>Close</u> 🙃 Print. EN =
#1 Patient name: Mike Silver Date of birth: 11/08/1995	Patient ID: 1234WE Scan date: 03/02/2022	Age: 26 Gender: Male	Referral recommendations: Periodontist: 14, 21, 26, 27, 27 Endedontist: 11, 12, 16, 17, 21, 23, 24, 26, 36, 37, 47
#2		#5	Orthodontic screening Dental discrepancies Overbite: normal Skeletal discrepancies No discrepancies found
A #8 Tooth chart #3	Edit teeth n	Imbers Choose region of interest	Tooth 17 Zroots 43%, 3 canals 100%, Artificial crown 99%, Endodontically treated tooth 99%, Short filling 94%, Voids in the root canal filling 65%, Cast Post and Core 95%, PDL space widening in periapical region 89%. + Add diagnosis Add comment
X A X X X X X X X X X X X X X X X X X X	1 3 1 1 4 4 4 4 4 4 4 5 2 23 33 32 11 12 12 22 23 33 1 1 1 1 1 1 1 1 1 1 1 1 2 23 33 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 <th1< th=""> 1 <th1< th=""> 1 <th1< th=""> <th1< th=""> 1 1<</th1<></th1<></th1<></th1<>		Add Collimited Axial Axial Axial Sagital Frontal Frontal
	🛢 Healthy 📕 Treated 📕 Unhealthy 🗙 Missi		🔄 Reset tooth 🛛 🖉 All slices 🛛 Open 3d viewer 📄 🖬 Approve

- #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





- #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



Tooth	chart								Edit 1	teeth nu	mbers	Cho	oose reg	ion of in	terest
×		N	Ì		Ì	Ĭ	Ì						<u>v</u>		
18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	
	47		45 9	44	43	42	41	31	32	33	34	35	36	37	
×	7		Ĭ	Ĭ	Ĭ	Ĭ	Ĭ	ľ	ľ	ľ	ľ		Ā	Ī	
Healthy Treated Unhealthy X Missing															

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.

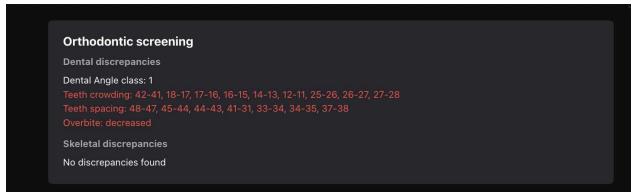




2.4 Orthodontic screening module

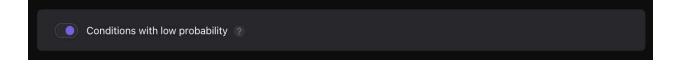
This module is for detection of dental and skeletal discrepancies.

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.

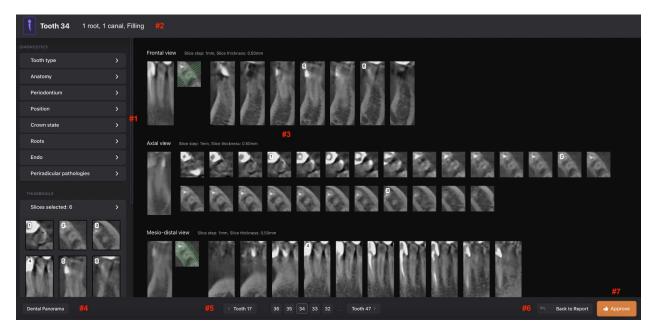
2.6 Tooth card

Tooth 34 1 root, 1 canal, Add comment	filling. + Add conditic #2	n #1				#7	×
Axial	Axial	Axial	Sagittal	Frontal	Frontal	#5	
		← Reset tooth #6	All slices #3		3d viewer ‡4	Approve	

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





#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

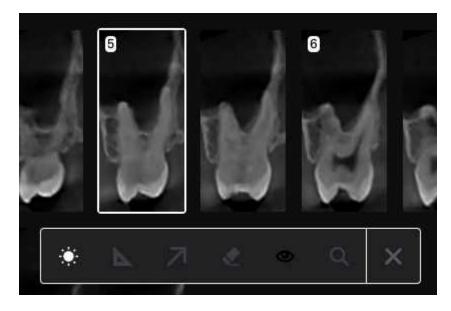
#6: Go back to a tooth card

#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.



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

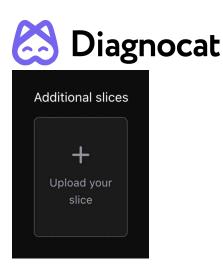


By default, the system adds 6 slices to the tooth card in different projections. You can change these slices and create a new set, which will be added to the final report.

THUMBNAILS		
Slices selected:	6	>
1		3
4		6
Ch:	ange slices	

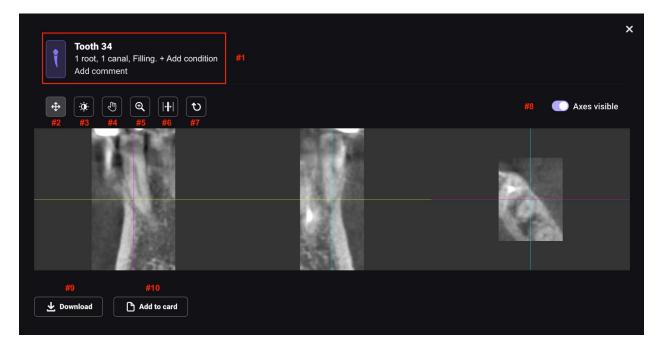
Click the "Change slices", then click a slice you want to delete. If you want to remove all slices then click the "Remove all" button.

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



#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.

Concl	usion				#1						
В	Ι	U	S	<u>H2</u>		•	。 •	1	I		
=	Ξ	Ē		P	З	~					
Conlı #4	usion	text o	goes l	#2 here.		#3					

- #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 or	ne signature
Pri	nt 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.



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
<table-cell> Show lower jaw</table-cell>	#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.



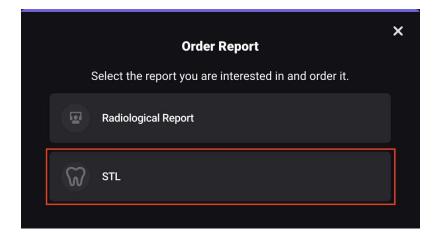
#3: Invert colors in a panoramic image and the tooth slices.

- #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.

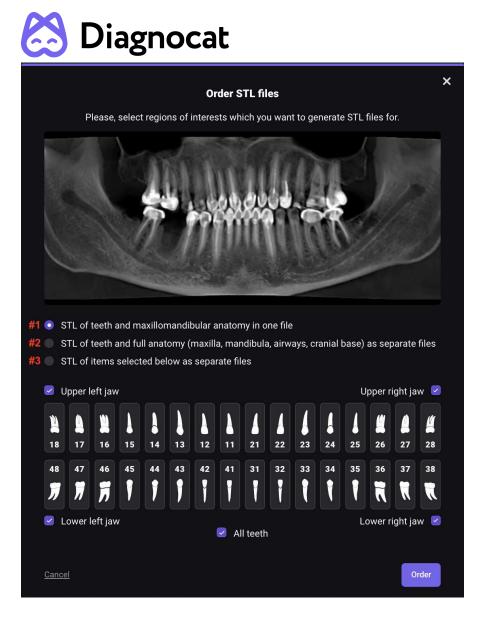
3.0 STL Report

3.1 Order a new STL report

Click the "Order Analysis" button under a desired study.



Select the output files.



#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

👸 Diagnocat		
🛃 tooth_47_(us_31)	↔ 100	
🛃 tooth_35_(us_20)	↔ 100	
🗹 tooth_27_(us_15)	↔ 100	
🗹 tooth_11_(us_8)	↔ 100	
🛃 tooth_34_(us_21)	↔ 100	
🛃 tooth_25_(us_13)	↔ 100	
doth_24_(us_12)	↔ 100	
🗹 tooth_45_(us_29)	↔ 100	
🛃 tooth_26_(us_14)	↔ 100	
🗹 tooth_22_(us_10)	↔ 100	
🕑 tooth_12_(us_7)	↔ 100	
🗹 tooth_31_(us_24)	↔ 100	
🕑 tooth_15_(us_4)	↔ 100	
🛃 tooth_17_(us_2)	↔ 100	
🛃 tooth_33_(us_22)	↔ 100	
🛃 tooth_32_(us_23)	↔ 100	
☑ tooth_23_(us_11)	↔ 100	
☑ tooth_13_(us_6)	↔ 100	and the second
🛃 tooth_44_(us_28)	↔ 100	
🕑 tooth_43_(us_27)	↔ 100	

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":

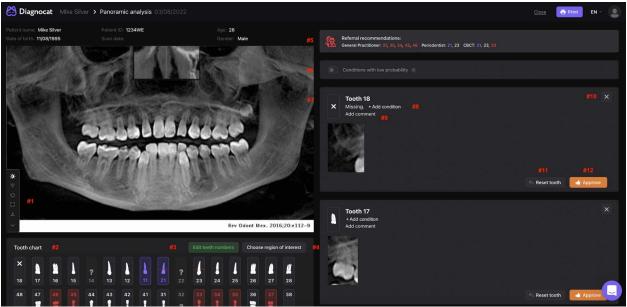
	Diagno	ocat						
							+ Ne	ew
Project	Dental Photo	FMX 1	Pano 1	CBCT 2	STL 1	DOCS		
11/10/2	2022 STL Study 🗡						Ŧ ×	
	11/10/2022 1kova Darya							
Open N	/iewer Orde	r CBCT superim	position					

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

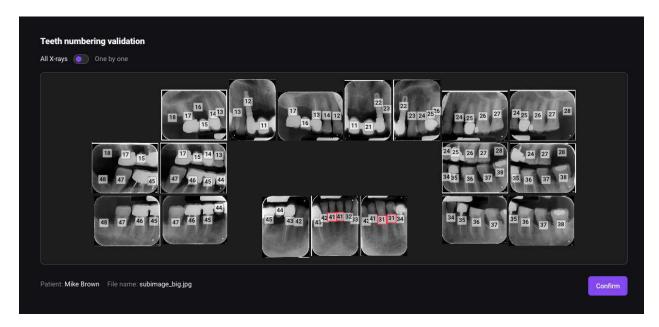
5.1 Order and view intraoral analysis

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



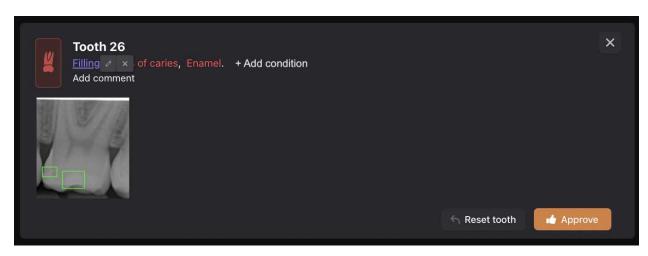
The intraoral report has the exact same tools and functionality that are used in the Radiological Report.

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.





6.1 Share patient

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

Main > Mike Silver > CBCT		+ New
Unassigned	FMX Pano 1 CBCT 1 STL	
ੀ Mike Silver	CBCT Study	
ID 1234WE 11/08/1995 (26 y.o)	Scan created at: 03/02/2022 Scan UID: 1.2.840.113999.1001.1664179745.1270904515.14907422917267855272	
Edit Treating doctors + Add		
CE User Documentation)
Shared with Share		
	l ord	er Analysis
Telegram	Radiological Report (2)	

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

1. "Send invite to email" option

Share Patient Profile	×
Send invite to email	Get link
E-mail *	
Send invite	

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.

😂 Diagnoca	ıt
You hav Patient	e been granted access to a profile
Doctor	shared a Patient profile with you.
Now you can view	this profile in your Diagnocat account.
Go To Diagno	cat
diagnocat.com	

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.

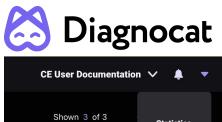
2. "Get link" option

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:

Settings #1 Account	#2 Organization	#3 Staff	#4 Billing History	#5 Plans & Pricing		C Go back to My Patients
ACCOUNT INFO				DATA SETTINGS		
				Dental notation format	ISO	~

#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.

Settings						✓ Go back to My Patients
Account	Organization	Staff	Billing History	Plans & I	Pricing	
ORGANIZATION	N INFO					
Organization na						
CLINICS						
			🥒 Edit clinic	۵		
Add clinic						



Settings							C Go back to My Patient	ts
Account C	Organization	Staff	Billing History	Plans & Prio	cing			
Q Search							Add docto	or
Name -			Job tit	le –	Specializations –	Last activity 🚽 Role 🚽	Asset	

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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.

Cattiana				
Settings				Co back to My Patients
Account Organization Staff	Billing History	Plans & Pricing		
Current plan				\$249
3D Practice				Active 7/5/2022 - 8/5/2022
500 FMX AI Reports 0 out of 500 used				Cancel
500 Pano Al Reports				
1 out of 500 used				
5 CBCT AI Reports:				
3 out of 5 used				
Current Add-ons				Buy
5 CBCT AI Reports:			\$195	
2 out of 5 used				
Invoice #80 Paid 7/	5/2022 3D Prac	tice	\$249	Download

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

tings		C Go back to My Patients
ccount Organization Staff	Billing History Plans & Pricing	
	Plans and Prici	ina
	1 month 6 months	12 months
2D Practice	3D Practice	opular Enterprise
\$129 / month	\$249 / month	Labs, diagnostic centers, large organizations
Includes:	Everything in 2D Practice, Plus:	Everything in 3D Practice, Plus:
		Customized functionality
🕑 500 Pano Al Reports	· Radiology Report	Custom CBCT AI packages
HIPAA / GDPR compliance	DICOM to STL conversion	 API integration with other software
Patient sharing	STL Viewer	Business intelligence
Online support		Collaboration tool
		Personal account manager
Talk to our Sales	Talk to our Sales	Talk to our Sales

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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.

+ New		Searc	h patients name, patier	nt ID or doctor name							Shown 5 of 5	Page 1 (of 1) >
All Patients			Patient ID 🗡	Patient name 🗸	Date of birth 🗡	Status Y	Stu	idy typ	es		Doctors	Last modified 🌱
SharedFavorites		☆	0005	Test Rare Pathologies	22/10/1976	Unassigned					Minkova Darya	20/10/2022
Archived		☆	0001	DEMO CASE	01/01/1980	Unassigned		X		\$		19/10/2022
Study date Status		☆	0004	Test Nikulin Daniil	13/10/1995	Unassigned					Minkova Darya	14/10/2022
Treating doctor		公	cbct_s3_archive_	😵 Kulas Gregoria	04/12/2012	Unassigned						11/10/2022
Study type Age group		☆	0002	🔗 New Patient	06/10/2022	Unassigned					Minkova Darya	06/10/2022
▼ Reset filters												

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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E-mail: support@diagnocat.com

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

EUROPEAN REPRESENTATIVE

AFINA s.r.o. Kaprova 42/14, 110 00, Prague Czech Republic Tel.: +420-608-049-029 Email: info@getce.eu

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 <u>sales@diagnocat.com</u>