

DIAGNOCAT

Version 1.0

User Manual



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1. Overview of User Manual

This user manual describes the Diagnocat Software and explains to dental professionals how to use the software. Diagnocat's platform provides a state-of-the-art way of viewing radiographs and presenting findings by applying artificial intelligence (AI) and identifying possible areas of concern for periapical radiolucency in a real-time, user-friendly dashboard.

This User Manual is written in English.

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

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

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

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

For inquiries or concerns related to the product and this manual, please contact:

Phone: + 1 519 619 4212

E-mail: support@diagnocat.com

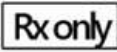
The company's website at www.diagnocat.com also has additional information.

2. Accessing this User Manual

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

3. Symbols used in the Manual / Labeling

	Manufacturer
	Follow instructions for use
	Caution (WARNING, PRECAUTION, or Note)
	Medical device

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

Name: Diagnocat

Diagnocat Version: 1.0

Device UDI: 860010268063

Regulatory Requirements

Diagnocat software complies with the following regulatory requirements:

- ISO 13485:2016
- FDA (U.S. Food and Drug Administration)

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 provided above.

This medical product software must be installed on appropriate IT equipment that complies with relevant international and national laws and standards on EMC (Electromagnetic Compatibility) and Electrical Safety. Such laws and standards define both the permissible electromagnetic emission levels from equipment and its required immunity to electromagnetic interference from external sources.

2. Precautions and Limitations



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. Users are advised to review the software-generated outputs and annotate, accept, or reject them based on their clinical judgment and all available information.



The performance of Diagnocat depends on the quality and accuracy of the imaging of the scan as well as the scan imported. Relevant anatomical structures must be visible in the scans. The use of unvalidated or suboptimal inputs may adversely affect device performance, potentially resulting in segmentation inaccuracies or detection errors.



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



Ensure that all uploaded CBCT scans meet the required quality standards for detecting anatomical structures. Dental imaging devices must comply with the recommendations of the International Commission on Radiological Protection (ICRP) to ensure optimal image quality and patient safety.



Diagnocat should be used according to this User manual.

It is strongly recommended not to download or transmit any messages or content that may disregard or violate the rights of any party. Additionally, users are highly encouraged to ensure that the Software is used in compliance with all applicable local, state, national, and international laws.

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

Additional information:

- Some features of the product may not be available in all countries, languages and currencies.
- It is illegal to reproduce and distribute the product without the consent of Diagnocat.
- Users should read this manual thoroughly before using this product.
- In order to use the full functions of Diagnocat, please follow the specifications described in this manual.
- Backup - Backup is the responsibility of the user and it should never be assumed that any backup is taking place unless it is actively monitored by the user.

3. Contraindications

Diagnocat has not been validated for use in the following scenarios, and the device performance may be adversely affected if the following inputs are used:



- CBCT images containing significant motion artifacts.
- CBCT images with severe artifacts, including but not limited to: Streak artifacts, Ring artifacts, Exponential edge-gradient effect (EEG)
- CBCT images affected by improper calibration of the CBCT unit or technical distortion due to machine malfunction.
- Images of patients with maxillofacial trauma, bone lesions, or congenital/acquired anatomical anomalies.
- Images showing total edentulism (no teeth present).
- Images with supernumerary teeth.

4. Intended Use / Indications for Use

Diagnocat software is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucency on permanent teeth captured on maxillofacial Cone Beam CT images, only in patients where a dental professional determined such images to be necessary to evaluate possible dental abnormalities and where the dental professional has the appropriate knowledge and training to interpret and assess maxillofacial Cone Beam CT images. The device provides additional aid for the dental professional to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dental professional's review or their clinical judgment that considers other relevant information from the patient or other images or patient history. The system is to be used by professionally trained and licensed dental professionals.

Diagnocat is indicated for use by dental professionals for the second-read of CBCT radiographs of permanent teeth in patients 22 years of age or older.

4.1 Intended Users

Dental professionals with the knowledge and training needed to interpret and assess maxillofacial Cone Beam CT images. Diagnocat is intended to be used only by oral radiologists or dental specialists who have a minimum of two years of experience in interpreting CBCT scans.

4.2 Intended Patients

Diagnocat is indicated for use by dental professionals for the second-read of CBCT radiographs of permanent teeth in patients 22 years of age or older.

4.3 Intended Use Environment

Diagnocat is a web application designed for use in various professional healthcare environments, including but not limited to:

- Dental Clinics and Medical Institutions: facilitates multidisciplinary case assessments, enabling collaboration among various medical specialists.
- Educational and Research Institutions: for training and academic purposes.
- Remote/Telemedicine Settings: for sharing and reviewing radiological data remotely.

4.4 Required Training and Qualifications

Users of this medical product software must have adequate training and at least two years of clinical experience in interpreting CBCT scans (as stated in **Section 3.1**) to ensure proper use of the device.

Please carefully review these Instructions for Use. While formal training is not required, the sales team provides a basic overview of the software's functionalities during the onboarding process. Additionally, upon request, the sales team can arrange on-demand training sessions to further assist clients in understanding and utilizing the software effectively.

5. Product Description

Diagnocat Software is a computer-assisted detection (CADe) software-only device intended to concurrently aid in the detection of periapical radiolucency areas. The device is designed to facilitate the analysis and interpretation of previously obtained dental CBCT scans, specifically in cases where a periapical radiolucency condition is suspected, leveraging deep learning algorithms and artificial intelligence (AI).

Diagnocat allows users to perform the following functions:

1. Managing patient information
2. Acquiring images from equipment and managing storage
3. Viewing patient images (provides tools for image processing and viewing functions)
4. Identifying potential periapical radiolucencies for further evaluation by the user
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.

More specifically, the key clinical functions of the software are described below:

1. *Tooth Detection and Localization:* Diagnocat employs image processing techniques to identify, number, and segment each tooth within a CBCT scan.

2. *Periapical Radiolucency Detection and Localization:* The software uses computer vision models to distinguish between normal anatomical structures and potential areas of concern indicative of periapical radiolucency, which is a radiographic sign of inflammatory bone lesions at the tooth's apex. Regions suspected of periapical radiolucency are segmented (at the same time as the teeth) and are distinguished using heat mapping.

3. *Image Visualization:* The software allows users to upload and navigate previously acquired CBCT studies. It features a panoramic reconstruction view to aid users in navigating between a patient's teeth and identifying points of interest, as well as multiplanar reformatted (MPR) slices for detailed examination of each tooth.

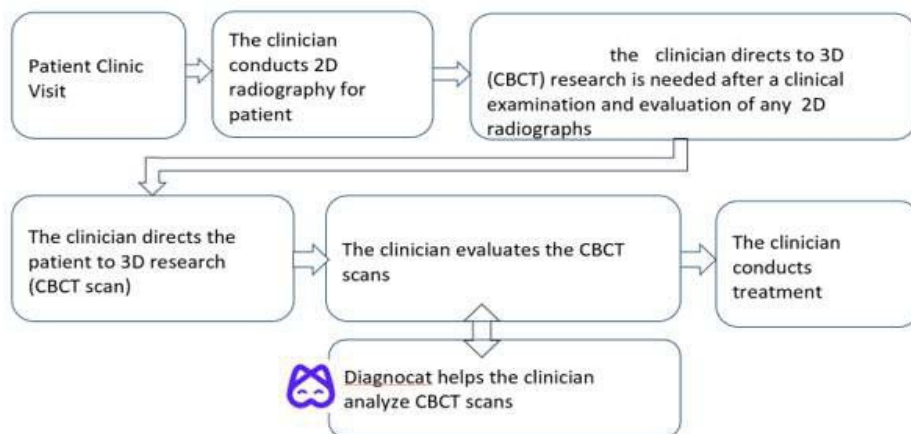
The software also features non-device functions that supplement its achievement of the intended clinical use:

- **User Interface:** The software includes a user-friendly interface that enables healthcare professionals (HCPs) to efficiently manage patient information.
- **Integration:** Diagnocat integrates with various CBCT scanning devices, allowing seamless use across different imaging systems.
- **Cloud-Based Storage:** Scans and reports are stored and archived in the cloud, facilitating access from multiple computers. Users can view, edit, and share information with other dental professionals.
- **Data Security:** Diagnocat emphasizes the security and privacy of patient data, implementing industry-standard encryption and complying with healthcare

regulations. Robust authentication measures and access controls (e.g., passwords) are in place to protect sensitive medical information.

5.1 Role of Diagnocat in the US Dental Landscape

The flowchart below highlights a systematic process where initial 2D radiography is performed and, in the case that the clinician requires additional 3D scanning for any reason for further investigation, 3D cone beam CT (CBCT) is performed. The clinician can then choose to evaluate the obtained CBCT scans for periapical radiolucency with the concurrent aid of Diagnocat before making informed decisions regarding the patient's treatment.



Diagnocat facilitates uploading CBCT images, analyzes the images, generates a report with a panoramic reconstruction, tooth cards and charts that identify suspected periapical radiolucencies, and allows the user to independently review, edit, and/or dismiss the software's findings, add notes and/or diagnoses, and sign the report. Diagnocat automates CBCT image analysis and can return a report on average within 6 minutes. CBCT images and reports are stored in the cloud, are saved to a patient's chart to maintain patient records, and may be shared with other dental professionals when interdisciplinary treatment is needed.

CBCT machines are integral to diagnostics, treatment planning, and the creation of surgical guides in dentistry (Hudson, 2023). Under the current U.S. standard of care, CBCT is commonly used for the detection of periapical radiolucency because it provides high-resolution, three-dimensional images, enabling clinicians to visualize dental structures with greater detail. This level of anatomical information is often critical for identifying the size, location, and extent of periapical radiolucencies, as well as their proximity to important anatomical structures—contributing to more accurate detection and treatment planning (AAE/AAOMR, 2015).

Importantly, Diagnocat's role in the analysis of pre-existing CBCT scans occurs entirely downstream from both the clinical decision to acquire CBCT and the actual acquisition process. The decision to use CBCT imaging is made independently by a dental professional based solely on the clinician's need for enhanced visualization after evaluation of the patient's primary complaints, medical and dental history, and clinical and radiographic examination. This initial assessment is not influenced by the availability or capabilities of the Diagnocat system. As a concurrent aid integrated within a clinical workflow that is

independently determined by the provider, Diagnocat does not alter the standard of care. Therefore, use of Diagnocat introduces no additional risks related to deviation from accepted U.S. dental practice standards.

6. Device Security and Privacy

6.1 Cybersecurity

Before using the device, you must follow the instructions below. The instructions help to protect the program against cybersecurity threats such as viruses and malware.

- Scan your computer system with anti-virus and anti-spyware programs from a trusted source.
- Install, set up and enable adequate anti-virus software.
- Maintain up-to-date anti-virus software.
- Make sure that your operating system (OS) has the latest security updates applied.
- Activate your PC's firewall if needed.

Coordinated Vulnerability Disclosure

When a vulnerability patch or fix is ready for release, the company will disclose it by releasing an advisory to affected stakeholders. The disclosure information shall be published on the company website. In the event of a critical update, users are directly notified via email or phone. Following is the information disclosed:

- Overview of the identified vulnerability, its nature, potential impact, affected devices and software versions.
- Actions taken to mitigate the vulnerability, including details on software updates, patches, or other remediation measures.
- Risk assessment of vulnerability, outlining the potential risks to patient safety, data integrity, and overall device functionality, if any.

Configuration, Backup and Update Processes

As Diagnocat device is cloud-based software, integration, configuration, storage, and restore processes shall only be performed by DGNCT LLC, in accordance with internal procedures.

Software Bill of Materials (SBOM), Architecture and Ports

The SBOM, Architectural diagrams and port configuration are available for customers at support@diagnocat.com.

End of Life

At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device needs to remain in service following the end of support, the company will communicate through the coordinated vulnerability disclosure the potential cybersecurity risks that can be expected to increase over time in addition to the sanitization process.

6.2 Customer Role in the Product Security Partnership

The customer is responsible for implementing administrative, physical, and technical controls, ensuring compliance with security and industry best practices. Their security strategies should address, but are not limited to:

- Physical security restricts unauthorized access to the servers where Diagnocat is running.
- Operational security, for example, access / authorization controls.
- Procedural security, for example, locking unattended workstations, no sharing of access credentials, termination checklists, etc.
- Continuous monitoring of security protection effectiveness.
- Security risk management.
- Security policies, for example, ensuring that client systems are in line with the institution's IT security policies.
- Data Integrity Training.
- Contingency planning.
- Backups and disaster recovery.

The practical implementation of technical security elements varies by the institution and may employ a number of technologies, including firewalls, virus scanning software, authentication technologies, etc. As with any computer-based system, firewalls and other security products must be in place between the medical system and any externally accessible systems or users.

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

6.3 Regulatory Controls

Protecting Personal Information

Many governments require maintaining the confidentiality of patient health information (PHI). Therefore, strict security measures must be taken to guard this protected information. (Users in the USA may find guidelines at <http://www.hhs.gov/ocr/hipaa/>).

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

The Diagnocat software does not store the patient's health information. However, the information transferred to the product is not encrypted. Unencrypted patient health information will be present in transferred DICOM data and algorithm analysis results. Thus, particular care must be taken with this information to ensure the utmost security and confidentiality in data transferring to and from the product.

Removable media, such as paper, may be used for purposes of the Diagnocat analysis results



transfer and long-term storage. Patient data written to removable media is identifiable. Treat removable media containing patient data as confidential and take appropriate measures to protect this information, including secure disposal, so that unwanted access by unauthorized individuals is avoided. Procedures to maintain removable media should be part of the institution's security policy.

Malware Prevention and Detection

The server(s), on which the Diagnocat software is running, must be placed on a secure local computer network that has protections against viruses and other harmful computer system intruders.

Make sure the equipment is connected to a local network that uses appropriate protection, such as a virus scanner.

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

Logical Access Control

Authorized personnel only shall have access to Diagnocat Device.

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

Advise the users of the product and analysis results to contact DGNCT promptly and report any security events to allow the manufacturer to timely respond to the incident.

7. Compatibility

Diagnocat integrates with other products that are not regulated by FDA – Medical Device Data Systems (MDDS) developed by DGNCT LLC, including Billing, Desktop (Diagnocat Imaging), and User Interface (UI) products.

Billing product performs invoice generation, payment processing, recurring billing, and automated notifications and reminders about payment. The Diagnocat product overall combines the proprietary AI algorithms and manual tools for Billing. Billing product is operates exclusively in conjunction with Diagnocat's primary product and its interface.

Diagnocat Imaging is an application that can capture dental images from imaging software and upload them to the Diagnocat Web Application (MDDS application). This application facilitates automatic image upload, streamlining the process and reducing manual intervention.

Diagnocat Imaging functionality includes:

- Login with existing Diagnocat account;
- Dashboard for monitoring all uploaded studies;
 - Detection of new incoming studies;
 - Automated upload of studies from connected X-ray devices;
 - Automated generation of the patient cards from DICOM-file;
 - Photo connector for uploading photo studies to patient card;
 - Weblink for quick access to the generated reports;
 - Queue management of studies for deferred upload;
- History of all uploads (activity log);
- Integration configuration with dental software/hardware;
- Application settings;
 - Language;
 - Settings to enable auto-upload of studies / auto-generation of reports;
 - Support for various image types;
 - Path to temporary folder;
 - Automatic removal of studies;
 - Automatic creation of new patient records.

The User Interface (Diagnocat UI) product offers a graphical interface designed to facilitate user interaction with the software medical device, enabling the execution of various functions such as device setup, patient data monitoring, and adjustment of device settings. The UI serves as the platform through which users can access proprietary AI algorithms and manual tools to enhance user experience and functionality. The UI product operates exclusively in conjunction with the Diagnocat product.

Key UI functionalities include:

1. User Account Management:

- Create a new user account.
- Log in to an existing Diagnocat user account.
- Sign out from the account.

2. Organization/Clinic Setup:

- Set up a new organization/clinic and become its owner with a new account.

- Set up a new organization/clinic and become its owner using existing credentials.
- 3. Staff Management:**
 - Invite staff members to join an organization/clinic.
 - Manage staff roles and permissions.
 - View and manage staff members within the organization.
- 4. Patient Data Management:**
 - Access patient data within a clinic.
 - View shared patient information after receiving a “Sharing letter”.
- 5. Clinic Access and Switching:**
 - Log in and enter a specific clinic to work or view shared patients.
 - Switch between different clinics without logging out.
- 6. Navigation and Menu System:**

Access various sections such as organization settings, patient data, and staff management through a user-friendly navigation menu.
- 7. Device Configuration and Control:**

Set up and configure devices for use with Diagnocat.
- 8. Help and Support:**

Access help resources and support options from within the interface.
- 9. Session Management:**

Sign out to end the session or log in with a different account.
- 10. User Invitations:**
 - Create an account and join a clinic after receiving an invitation.
 - Create an account and view shared patient information after receiving a “Sharing letter”.
- 11. Security:**
 - Passwords: All users must set a strong password for their account. Passwords shall meet the required complexity criteria, including a minimum length and the use of a mix of characters.
 - Email Confirmation: New users must confirm their email address before gaining access to the system and/or upon registration; the system sends a confirmation code to the user’s provided email address.

Diagnocat was validated using a broad range of CBCT scanners and showed consistently high performance. Accordingly, the device is compatible with five types of CBCT scanners - Sirona, Vatech, Planmeca, Instrumentarium Dental and Carestream - all of which are capable of generating a DICOM-compliant image.

Any modifications or additions to the software must be performed only by the manufacturer or by authorized third parties. Such changes must comply with all applicable laws, regulations, and best engineering practices within the relevant jurisdiction.

8. System Requirements

To operate the Diagnocat web application via a web browser, the following minimum hardware and firmware specifications are required:

- 1) Any operating system capable of running a Google Chrome version;
- 2) Browser: Google Chrome 75 or higher (must be kept updated);
- 3) Processor minimum of 2 CPU cores;
- 4) 2 GB RAM or more;
- 5) Recommended processor: 4 cores and memory: 4 GB RAM;
- 6) 50 Mbps or faster Ethernet connection to your institution's DICOM network;
- 7) Display shall be compatible with displays 23 inches or larger;
- 8) Compatible Radiological Data Sources: DICOM.



If you use a browser other than the one specified here, the software may not function as intended.

9. Data Constraints

The system requires certain DICOM prerequisites to be met for proper functioning:

- DICOM's data (PixelData tag should be present) must be a monochrome (PhotometricInterpretation tag equal to MONOCHROME2) volumetric image of CBCT modality representing human jaws with total volume ≥ 50 cubic centimeters and each linear dimension ≥ 2 centimeters long.
- DICOM must contain RescaleIntercept and RescaleSlope tags.
- DICOM's resolution, i.e., voxel size, must be derivable from its metadata. Voxel size may be derived from the following DICOM tags: PixelSpacing, SliceThickness, or SpacingBetweenSlices.
- Maximal voxel, per single dimension, should be 400; there is no minimum voxel size.
- In case of multi-frame DICOM, each slice must have a unique position derivable from its metadata. Position may be derived from DICOM tags such as ImagePositionPatient, InstanceNumber, or SliceLocation.
- Do not upload DICOM files of size more than 1GB or CBCT volume of $>50 \text{ cm}^3$.

NOTE: Diagnocat does not capture or enhance images—it only analyzes the ones provided by the dental professional. Ensuring proper image acquisition is crucial for reliable visualization using the product. The quality of Diagnocat analysis depends entirely on the quality of the uploaded images.

10. Configurations

Diagnocat can be configured in one of 2 ways:

1. You can upload patients' studies manually using a web-browser that doesn't require any specific configuration.

2. Desktop integration. Diagnocat Imaging is an application that can capture dental images from imaging software and upload them automatically to the Diagnocat Web Application.

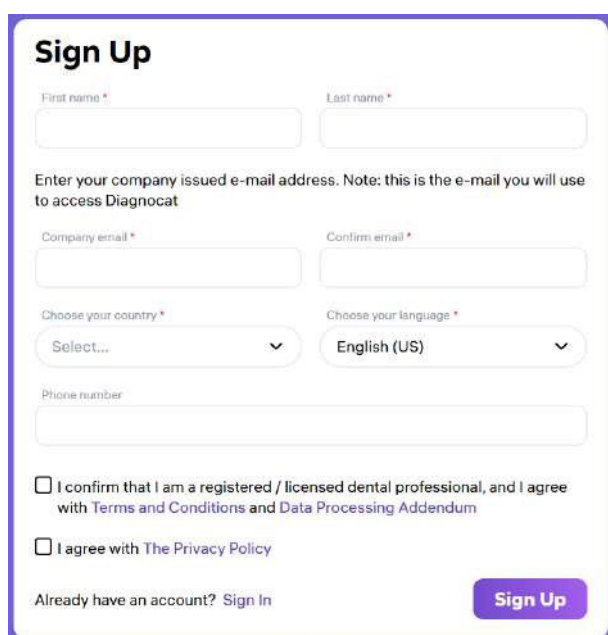
Please contact your sales representative or email Sales@diagnocat.com for more information.

11. Start with Diagnocat

11.1 Sign up

Your sales manager can provide you with a link to registration.

You will be prompted to the account creation screen, where you need to provide account details and click the “Sign Up” button (see screenshot below).



Sign Up

First name * Last name *

Enter your company issued e-mail address. Note: this is the e-mail you will use to access Diagnocat

Company email * Confirm email *

Choose your country * Choose your language *

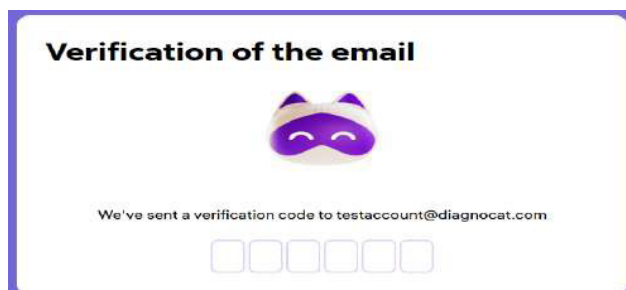
Phone number

☐ I confirm that I am a registered / licensed dental professional, and I agree with [Terms and Conditions](#) and [Data Processing Addendum](#)

☐ I agree with [The Privacy Policy](#)

Already have an account? [Sign In](#)

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



Verification of the email



We've sent a verification code to testaccount@diagnocat.com



Create password

Password *

Confirm password *

☐ I agree that DGNCT LLC and its affiliates (hereinafter – Diagnocat) may contact me by e-mail, mobile phone or text messages with information about the products and services of Diagnocat, which may include special offers and feedback requests.

Confirm

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

11.2 Log in

Open the Chrome browser and go to Diagnocat based on your region: for US, visit <https://app.diagnocat.us>.

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

11.3 Reset password

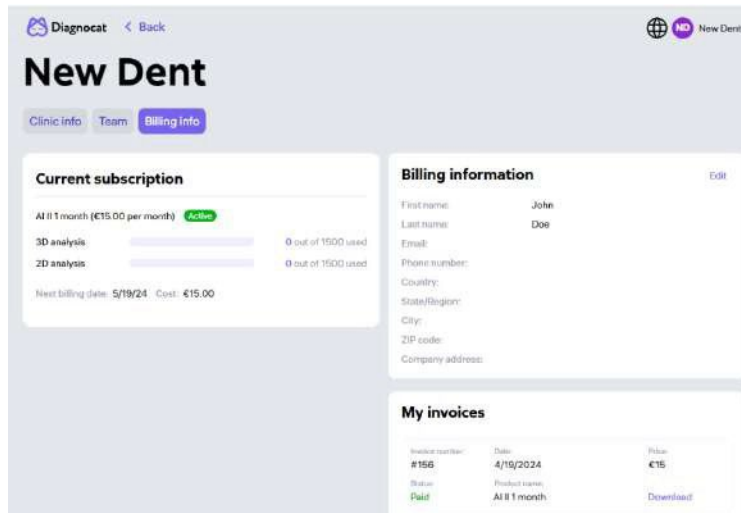
If you need to reset your password, click the “Forgot password” button and enter the email address you used to register your Diagnocat account.

You will receive an email with instructions on how to reset your password (and an access link).

11.4 Subscription Plans

To start using the Diagnocat product, you need to buy a subscription plan that will give you access to the main functionality. Your sales manager will suggest the best options to cover your needs and will guide you through the purchase.

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



New Dent

Back

Clinic info Team **Billing info**

Current subscription

All 11 month (€15.00 per month) **Active**

3D analysis: 0 out of 1500 used

2D analysis: 0 out of 1500 used

Next billing date: 5/19/24 Cost: €15.00

Billing information [Edit](#)

First name: John
Last name: Doe
Email:
Phone number:
Country:
State/Region:
City:
ZIP code:
Company address:

My invoices

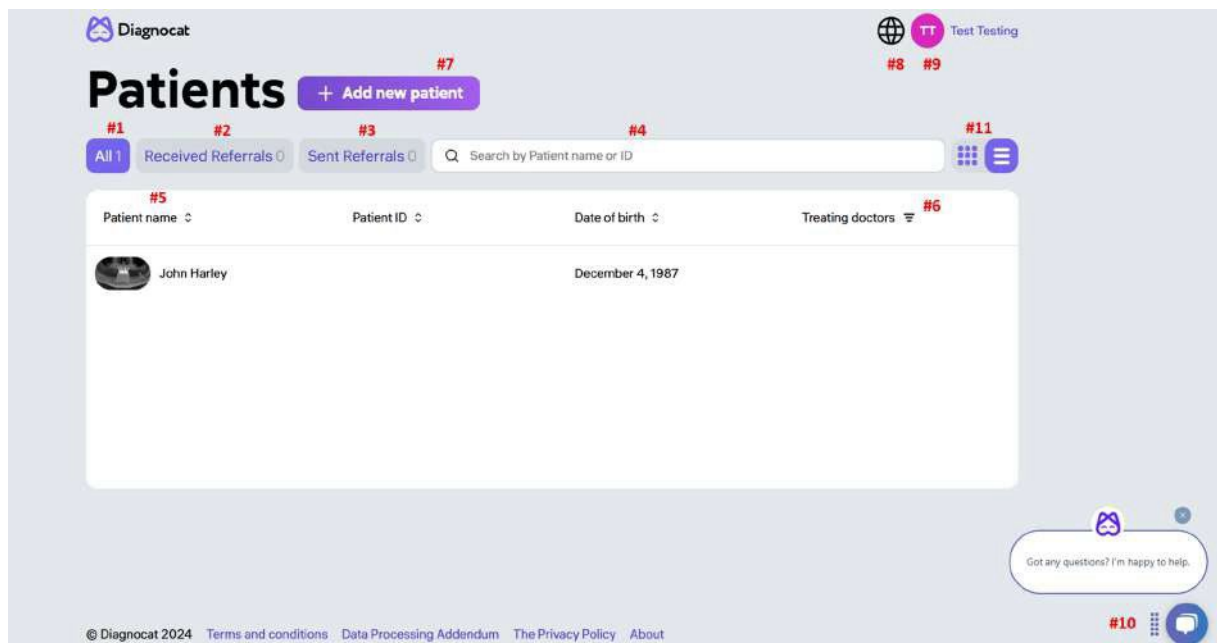
Invoice number	Date	Price
#156	4/15/2024	€15
Status: Paid	Product name: All 11 month	Download

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

If you have any problems, please contact your sales manager or use the support chat to resolve the issue.

11.5 Patients

Once you log in successfully, you will see the “Patients” screen (see sample screenshot with red numbered tags defined below).



Patients [+ Add new patient](#)

#1 All #2 Received Referrals #3 Sent Referrals #4 Search by Patient name or ID #11

Patient name	Patient ID	Date of birth	Treating doctors
 John Harley		December 4, 1987	

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Got any questions? I'm happy to help.

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

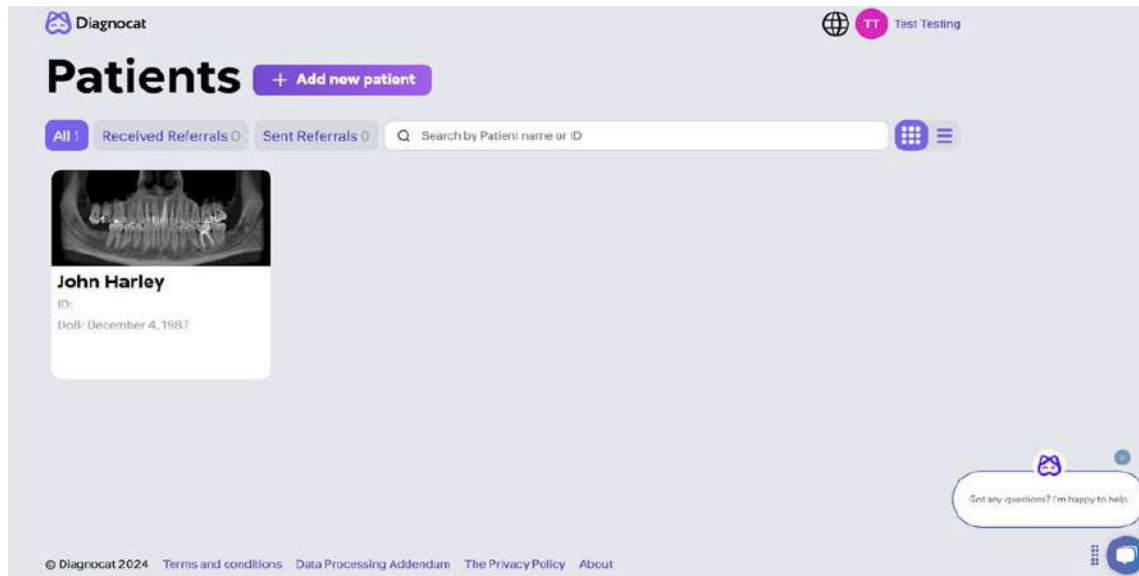
#2: “Received Referrals” gives you access to all studies shared with you by other users.

#3: “Sent Referrals” gives you access to all studies shared with other users by you.

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

#5: Shows you the list of all your patients.

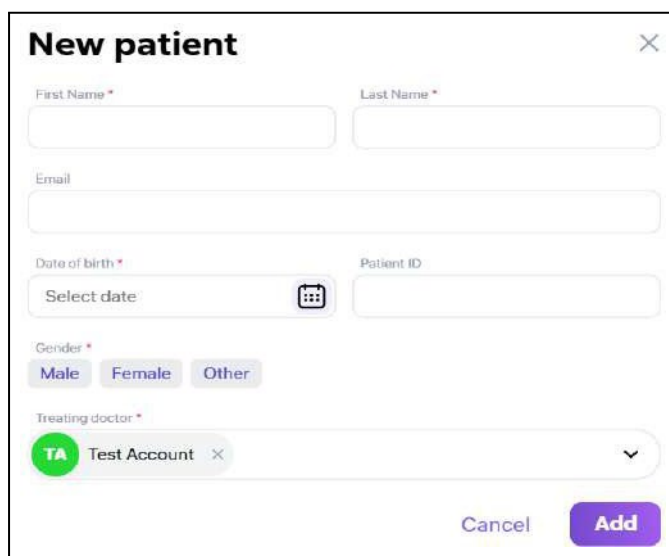
- #6: The “Treating doctors” filter allows you to select a specific doctor/doctors (from whom the patient scan was generated).
- #7: “Add new patient” allows you to create a new patient.
- #8: Allows you to change the interface language.
- #9: Gives you access to your account and clinic settings.
- #10: Allows you to get access to the customer success team.
- #11: Allows you to change the visual design of the “Patient Card” (shown below) to appear as either a list or squares.



11.6 Create a new patient

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

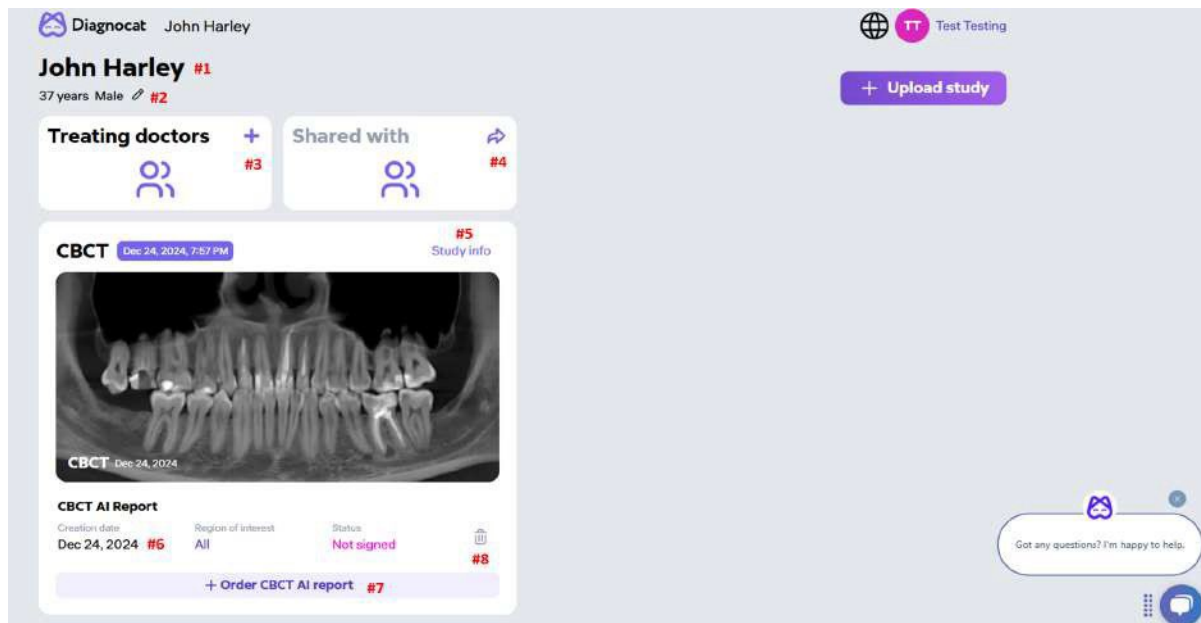
You will be presented with a short form to complete. It is necessary to fill in all required fields marked with an asterisk and click “Add”.



A new patient will then appear in the patient list.

11.7 Patient Card

Upon clicking on a patient, the “Patient card” is displayed (see below).

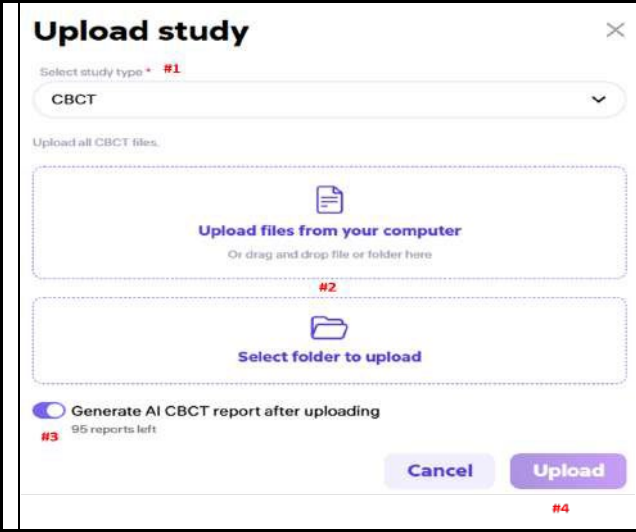


- #1: Patient details.
- #2: Edit patient details.
- #3: Add a treating doctor.
- #4: Share a patient with another doctor.
- #5: Show study info.
- #6: Report details.
- #7: Order a new analysis.
- #8: Delete the report.

11.8 Create a new study and Order an AI Report

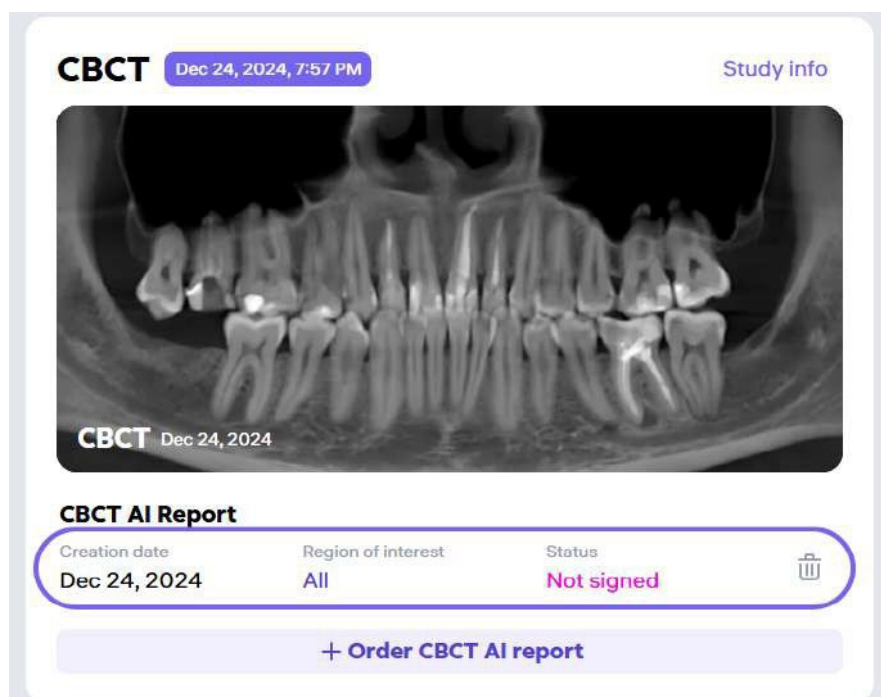
Once you open patient details, you can create a new study by clicking “Upload study”.

Diagnocat supports the following file formats: *.dcm (DICOM).

	1. Select the study type you want to upload 2. Attach a file or folder by browsing your computer 3. When toggle is enabled, the device will automatically create CBCT AI reports after input scans are loaded. Alternatively, after uploading scan(s) for a patient, you may select “Order CBCT AI report” to run the software algorithm. 4. Click “Upload”.
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12. CBCT AI Report

You can open the CBCT AI Report generated by the device by clicking the CBCT AI Report (the region circled in purple on screen below).



Creation date	Region of interest	Status
Dec 24, 2024	All	Not signed

[+ Order CBCT AI report](#)

The sample screenshot below shows what you will find inside the CBCT AI report:



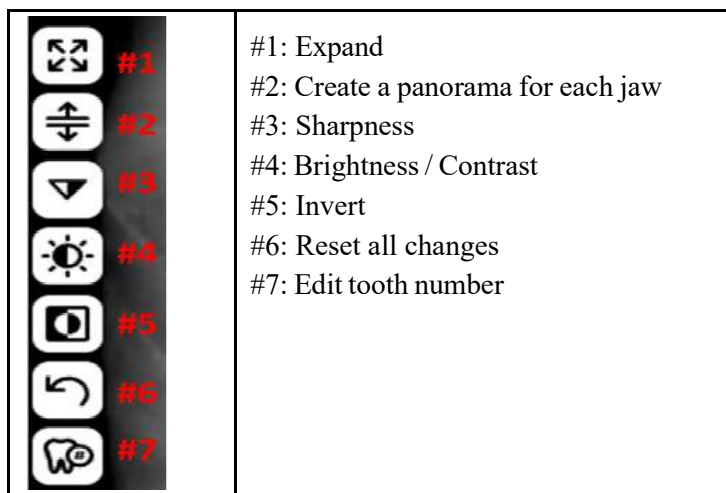
#1: Panorama image derived from the input CBCT scan

#2: Tooth chart reflecting the algorithm's identification and numeration of teeth present in the scan, as well as which teeth have a suspected periapical radiolucency.

#3: Tooth card

#4: Panorama tools.

12.1 Panorama tools



12.2 Tooth chart



The software’s findings are color-coded in the tooth chart for the clinician’s review:

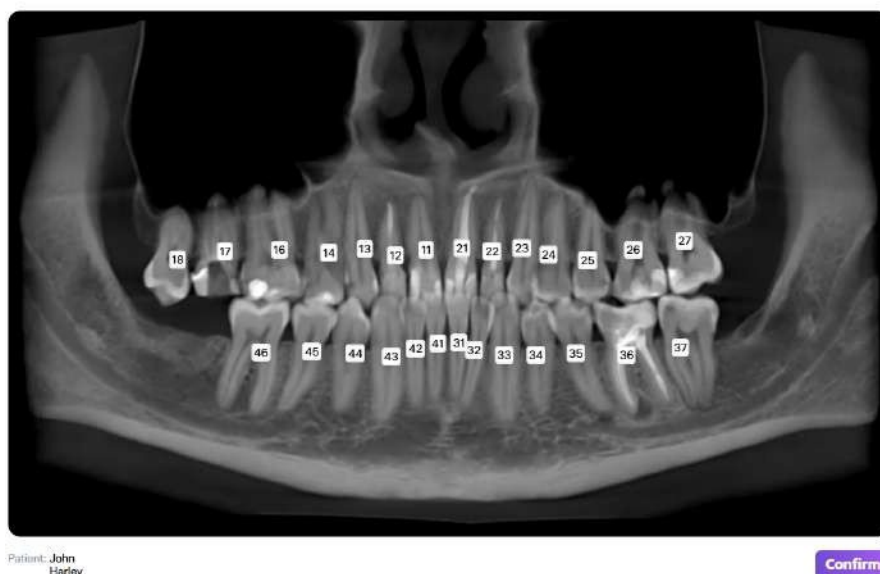
- White – teeth without suspected periapical radiolucency
- Red – teeth with suspected periapical radiolucency

12.3 Change teeth numbers



If the clinician believes the software-generated tooth numbers are incorrect, they may use the “Edit tooth number” option to update the tooth numeration, as illustrated below. Once done, click the “Confirm” button.

Edit teeth numbers

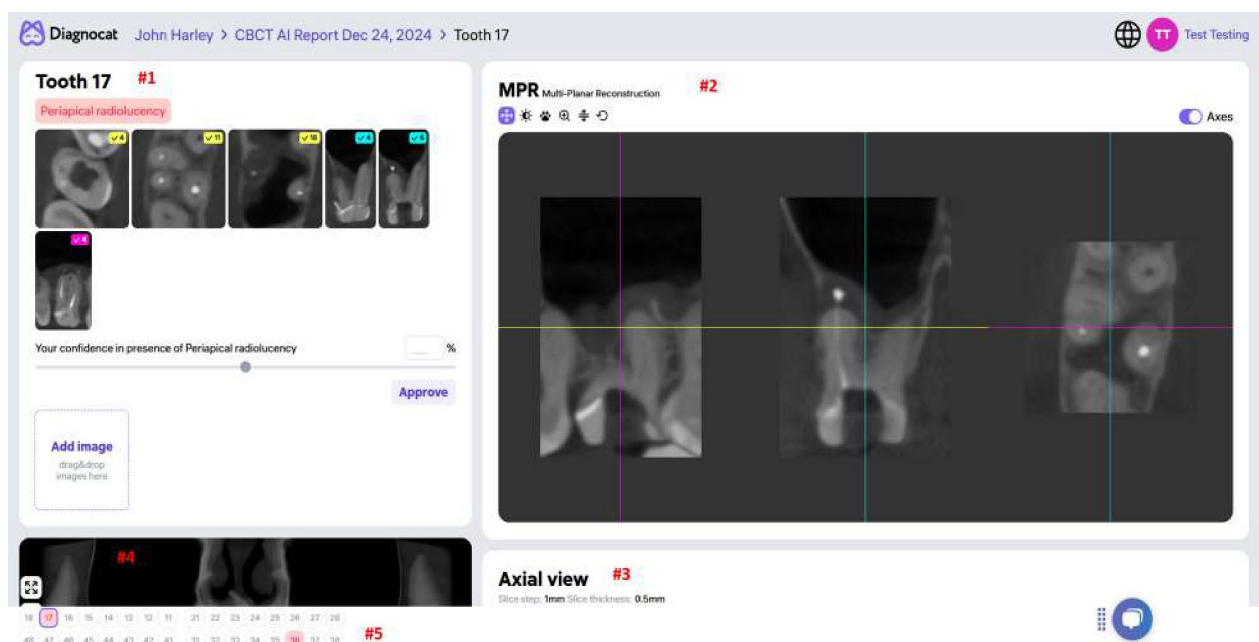


12.4 Tooth card

You can find detailed information about a specific tooth in the tooth card, shown below.



12.5 Slices Mode



#1: A list of the detected periapical radiolucencies on the selected tooth.

#2: Multi-planar reconstruction tool.

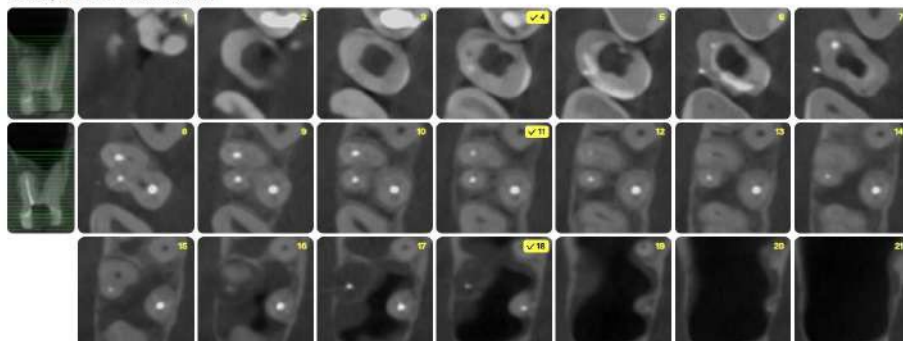
#3: A collection of slices, automatically created by Diagnocat in three projections: axial, mesio-distal and vestibulo-oral (projections display yellow, pink and blue lines, respectively, on panorama) – see below images (the user must scroll to see all slices).

#4: Panorama image derived from CBCT.

#5: Navigation allows the user to choose different teeth in the Slices mode.

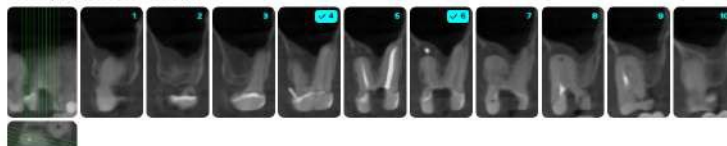
Axial view

Slice step: 1mm Slice thickness: 0.5mm



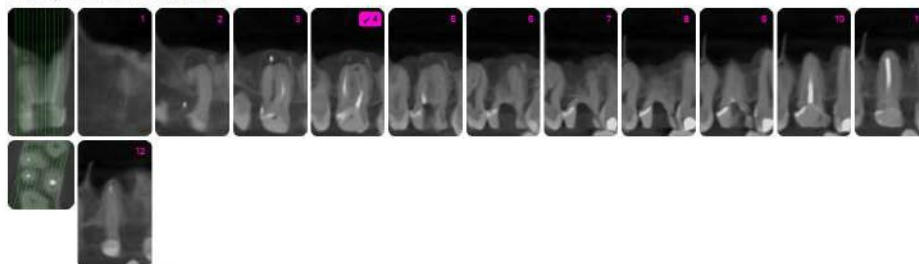
Vestibulo-oral

Slice step: 1mm Slice thickness: 0.5mm

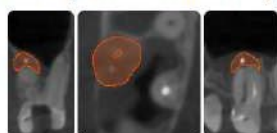


Mesio-distal

Slice step: 1mm Slice thickness: 0.5mm



Periapical radiolucency



12.6 View and edit slices

When you click any slice, a tool panel will appear at the right (shown below):

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

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

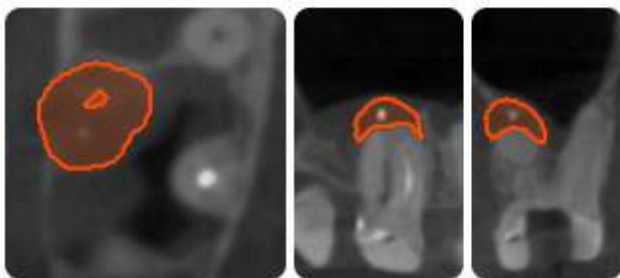
By default, the system adds 6 slices to the tooth card in different projections: 3 slices for the axial projection, 2 slices for the mesio-distal projection, and one slice for the vestibulo-oral projection. You can change these slices and create a new set, which will be added to the final report. To do this, you simply select the slices you need from the sections Axial view, Vestibulo Oral, and Mesiodistal, by clicking on them. See image at right.

If you want to add other slices, use the “Drag&drop images here” option or click on the necessary slices in the sections Axial view, Vestibulo Oral, Mesiodistal (see above images) to add these automatically.



Heat Mapping

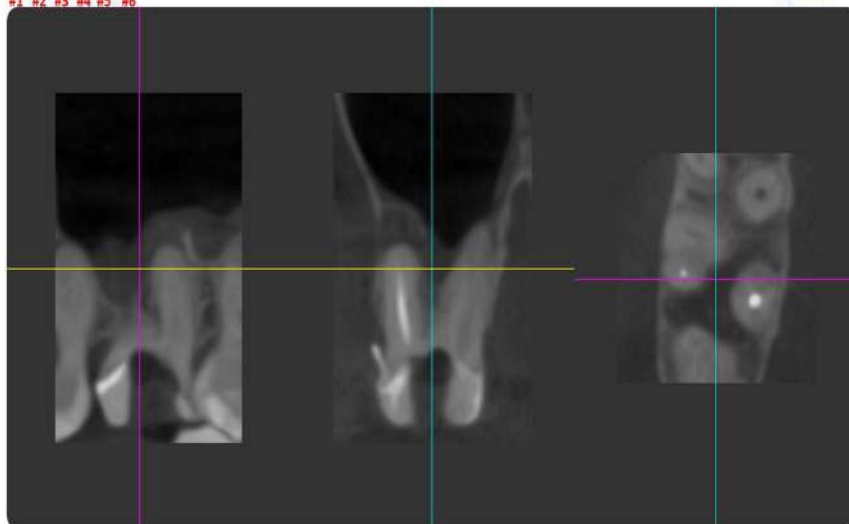
Diagnocat highlights the location of suspected periapical radiolucency in the format of heat mapping, which highlights the affected tooth and identifies the associated suspected periapical radiolucency. The heat mapping feature reflects the location and shape of suspected periapical radiolucency based on pixel-level analysis of the image. It is a direct delineation of the region that the algorithm has classified as suspected periapical radiolucency. The highlighted (red) area – see example in image below – therefore corresponds to a defined segmentation mask, derived from the algorithm's classification of voxel-level features consistent with periapical radiolucency. The heat mapping is shown in the “Slices” tab.



12.7 Multi-Planar Reconstruction tool

You can use this tool in a Slices page. The tool allows you to create your own slices and add them to the summary report.

MPR Multi-Planar Reconstruction



#1: Axis changing tool

#2: Brightness/contrast

#3: Pan

#4: Zoom

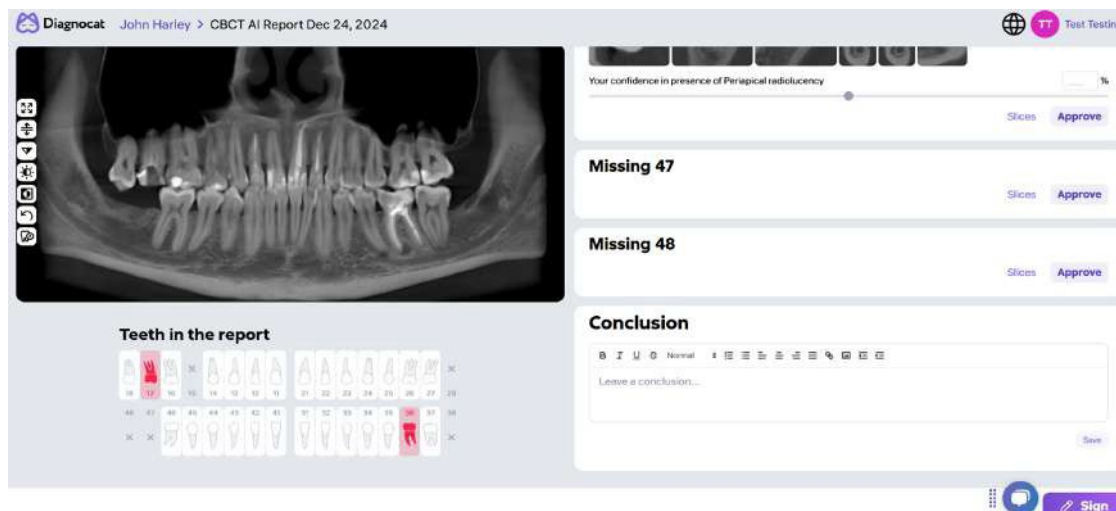
#5: Translation – Locking function – Lets you lock the position of 2 axes and move along the 3rd axis with vertical movement of the mouse while keeping the left-key pressed.

#6: Reset all changes

#7: Enable/disable axes.

12.8 Conclusion

The user can add a conclusion to the software-generated report (see free text box on lower right of sample screen shot below). They can also attach a link or an external image.



Expanded illustration of “Conclusion” box with identified features



- #1: Font settings
- #2: Add a link
- #3: Attach an image
- #4: Main text field (to be filled out by the user).

12.9 Sign report

To sign a report, you must individually approve the software-generated findings for each tooth. If any teeth remain unapproved, the system will prompt you to verify your evaluation and ensure that each tooth has been reviewed and approved.

Approve all teeth

Some teeth are not approved. Please check that you provided your evaluation and approved each tooth.

Cancel

Yes, submit

When all teeth are reviewed and approved separately, you can sign the report using the button “Sign”.

Sign the report

Are you sure you want to submit your evaluation?

Cancel

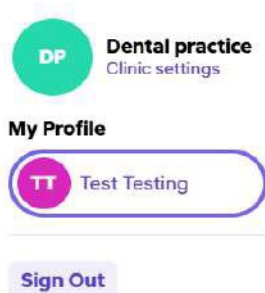
Yes, submit

Afterwards, the signature of the person who signed the report, along with the date, will be displayed at the end of the document.

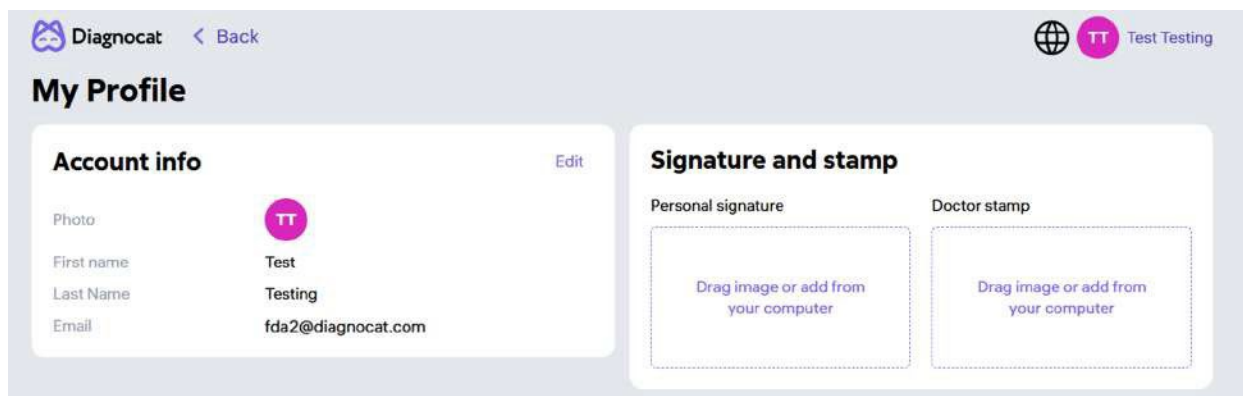
13. Additional Functions

13.1 Account and Clinic Settings

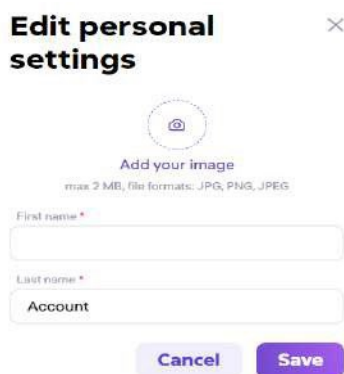
To get access to Account settings click the arrow icon in the top right corner of the main page.



Upon doing so, you will find 2 main tabs:

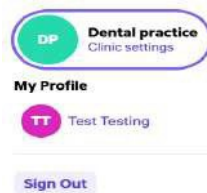


#1: Account info. You can change the account owner name, and/or add your photo.

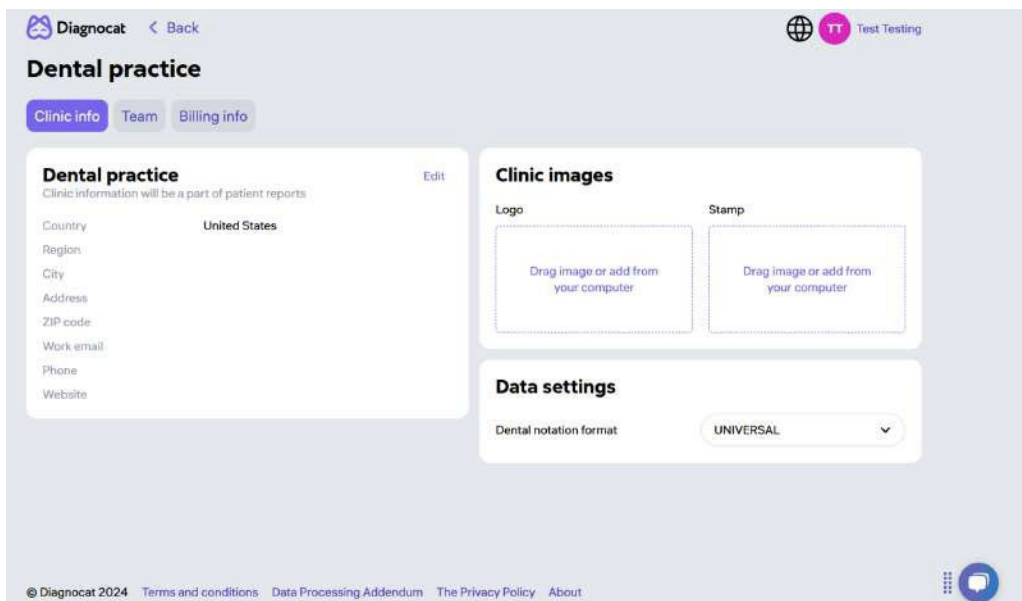


#2: Signature and stamp. You can add a personal signature and doctor stamp.

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



Upon doing so, you will find 3 main tabs:



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

Edit clinic info

✕

Company name *

Email

Phone

Website

Country State/Region

City Zip code

Address

Cancel Save

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



Dental practice

Clinic info **Team** Billing info + Add team member

Q Search by name, job position, or access level

Name	Email	Job position	Access level
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You can add a team member; after clicking on the button “Add team member,” a form will open to fill in, specifying their access level and job position.

Please note: to fill in the “Access level” field correctly, refer to the "Team" page (shown below).



Access levels

Access levels you can assign to team members

Access levels	Full access	Clinical access	Limited clinical access	Non-clinical Member
Manage company settings	+	-	-	-
Manage payments and subscriptions	+	-	-	-
View and manage team	+	+	-	-
View and manage patient's files	+	+	+	+
Share patient's profile	+	+	+	-
Edit patient's reports	+	+	+	-

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

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

14. Performance Testing

Diagnocat’s performance has been comprehensively validated through three studies covering the full range of its intended functionality. Together, the results support the use of Diagnocat as a safe and effective AI-based tool for dental CBCT interpretation, and provide strong evidence for its clinical integration as a second-read support system in diagnostic workflows.

Specifically, DGNCT LLC evaluated the performance of the Diagnocat software device through three independent retrospective validation studies: (1) a standalone segmentation performance study, (2) a standalone detection performance study, and (3) a Multi-Reader, Multi-Case (MRMC) reader study. These studies were designed to validate the device’s performance in the segmentation of teeth and periapical radiolucency, and in the detection of

periapical radiolucency on CBCT scans. All validation datasets included CBCT scans from multiple manufacturers and clinical sites in the US, representing diverse patient demographics. Additionally, all validation datasets were independent from data used in training or testing of the device.

The device's outputs were benchmarked against a reference standard established by expert radiologists. In each study, the reference standard was determined by three US-board-certified oral and maxillofacial radiologists, each having a minimum of five years of experience in CBCT interpretation. These clinical truthers worked independently. Majority voting was used to establish the reference standard for the standalone segmentation study. For the standalone detection and MRMC studies, establishment of the reference standard relied on a predefined "2+1 truthing paradigm" to resolve disagreements: when two truthers disagreed, a third adjudicator determined the final ground truth. After completion of ground truth readings, the same CBCT scans were analyzed by Diagnocat.

All images were retrospectively sourced from US dental practices, covering a diverse patient population and including CBCT scans acquired from five major device manufacturers: Sirona, Vatech, Planmeca, Instrumentarium Dental, Carestream. All subjects were at least 22 years old with permanent teeth. Scans with motion artifacts, calibration issues, or total edentulism were excluded.

All three studies successfully met their prespecified performance goals (PGs), establishing the clinical utility of Diagnocat software for its intended use in the dental CBCT imaging workflow. Subgroup analyses were conducted to evaluate performance across patient demographics (sex, age group), CBCT scanner manufacturers, and geographic sites. Results confirmed consistent performance across all evaluated subgroups, supporting the generalizability of Diagnocat's clinical utility. Additional details are provided below.

1. Study 1 – Segmentation of Teeth and Periapical Radiolucency (PR)

This study assessed the ability of Diagnocat to segment and number teeth in 100 CBCT scans of permanent teeth, collected across two separate cohorts:

- Cohort 1: General population without confirmed PR (n = 50)
- Cohort 2: Subjects with confirmed PR in at least one tooth (n = 50).

The primary endpoint – Dice Similarity Coefficient (DSC) – assessed agreement between Diagnocat's segmented output and the reference standard. Across all teeth, Diagnocat demonstrated strong agreement with the reference standard, as evidenced by DSC values exceeding the pre-defined PGs of 0.8 for tooth segmentation and 0.7 for PR segmentation. For the primary endpoint (DSC) to reach success, the lower 95% Confidence Intervals (CIs) around DSCs for each cohort, obtained through bootstrapping at the scan-level, had to exceed their respective PGs. The results were as follows:

- Cohort 1: DSC for tooth segmentation was 0.955 (95% CI: 0.950, 0.959; $p < 0.0001$)
- Cohort 2: DSC for tooth segmentation was 0.947 (95% CI: 0.942, 0.952; $p < 0.0001$); DSC for PR segmentation was 0.804 (95% CI: 0.777–0.839).

Diagnocat also achieved success on all pre-defined secondary endpoints, including a per-tooth Dice of 0.952 and high accuracy in tooth localization and numbering.

Performance was consistent across subgroups. Teeth segmentation DSC remained above 0.93 for all scanner manufacturers (Carestream, Instrumentarium, Planmeca, Sirona, Vatech) and both age groups (22–39 vs ≥ 40). PR segmentation DSC values were comparable between sexes (0.825 female vs 0.784 male), age groups (0.802 vs 0.806), and across scanner manufacturers (range 0.767–0.835). Site-based analysis also demonstrated consistent performance (CA: 0.943–0.958; MA: 0.940–0.952; NC: 0.946–0.955).

2. Study 2 – Standalone Detection of Periapical Radiolucency

This study assessed the ability of Diagnocat to detect periapical radiolucency in 285 CBCT scans of permanent teeth. The software's outputs were compared to ground truth using a tooth-level analysis, using co-primary endpoints of sensitivity and specificity. For the co-primary endpoints to reach success, the lower 95% CI, obtained through bootstrapping at the scan-level, had to exceed the PGs.

Across all teeth, Diagnocat demonstrated diagnostic agreement with the reference standard, exceeding the pre-defined PGs:

- Sensitivity = 0.854 (95% CI: 0.817, 0.885; $p < 0.0001$)
- Specificity = 0.991 (95% CI: 0.989, 0.993; $p < 0.0001$).

Diagnocat also achieved success on the pre-defined secondary endpoints, showing consistent performance across CBCT manufacturers, patient age groups, and sexes. Sensitivity and specificity were consistent across all demographic and technical subgroups. Sensitivity was 0.873 in younger patients (22–39 years) and 0.834 in older patients (≥ 40), with specificity ≥ 0.989 in both. By sex, sensitivity was 0.84 in females and 0.87 in males, with specificity 0.99 for both. Across scanner manufacturers, sensitivity ranged from 0.794 (Vatech) to 0.916 (Sirona), while specificity was ≥ 0.986 for all. State-level subgrouping showed sensitivity ranging 0.838–0.893 across CA, MA, and NC, with specificity consistently ≥ 0.988 .

3. Study 3 – Multi-Reader Multi-Case (MRMC) Study

The MRMC study evaluated the impact of Diagnocat as a decision-support tool for dental professionals interpreting CBCT images. A fully crossed, retrospective reader design was used, involving 20 board-certified dental radiologists. Each reader independently interpreted 100 CBCT scans twice:

- Unaided session: Standard interpretation without any software support.
- Aided session: Interpretation by dental professional along with Diagnocat's periapical radiolucency detections and visualizations.

The order of reading was randomized, with half the scans initially read with Diagnocat assistance and half without. A 4-week washout period separated the two reading sessions. Readers assessed each tooth for the presence of PR using a confidence score (0–100).

The primary endpoint was the difference in AUC (area under the ROC curve), or ROC-AUC,

comparing the unaided and aided interpretations of CBCT scans. The device was deemed to meet the criteria for success if the ROC-AUC for the aided readings was significantly higher than that of the unaided readings at a two-sided significance level of $p=0.05$.

Across all teeth, use of Diagnocat resulted in a significant enhancement in accuracy of dental professional identification of PR compared to unaided readings, as evidenced by a statistically significant improvement in ROC-AUC that exceeded the pre-defined PG:

- Diagnocat-aided readings: ROC-AUC of 0.9213 (95% CI: 0.9145, 0.9280; $p = 3.804 \times 10^{-12}$)
- Unaided readings: ROC-AUC of 0.8940 (95% CI: 0.8862, 0.9018)

Results also demonstrated success on all pre-defined secondary endpoints, including improved sensitivity and specificity across CBCT scanner manufacturers, patient age groups, and sexes. AUC improvements were consistent across all subgroups. By sex, aided AUC was 0.915 (F) vs 0.928 (M), both showing clear improvement over unaided. By age, aided AUCs were identical (0.921) in both younger and older groups, with gains over unaided of +0.036 and +0.022 respectively. Across manufacturers, improvements ranged from +0.004 (Carestream) to +0.047 (Instrumentarium). Site-level subgrouping also demonstrated consistent gains: CA (+0.015), MA (+0.034), and NC (+0.026).

Conclusion: In aggregate, these results support the reliability and clinical utility of Diagnocat as an adjunct tool for evaluation of CBCT imaging.

14.1 Training Overview

Diagnocat employs proprietary 3D convolutional neural networks (3D U-Net variants) to analyze CBCT data for periapical radiolucency detection and dental anatomical segmentation. These models follow a coarse-to-fine multi-stage approach, using advanced volumetric image analysis pipelines tailored for dental structures. Training was conducted on a multinational dataset with annotations from expert dental radiologists. Only permanent teeth were included.

The deployed models are locked post-training. Future model updates will undergo full revalidation on held-out test sets using consistent statistical frameworks to ensure generalizability and safety.

Each core model (Tooth Localization, Periapical Lesion Segmentation, and Panoramic Reconstruction) was trained on large datasets that encompass demographic and imaging diversity. Representation included patients across adult age groups (≥ 22 years), both sexes, and scans collected from institutions across multiple geographic regions (U.S., EU, Israel). Training data included CBCT scans from over 20 device manufacturers, ensuring the model would perform adequately across hardware scanners.

Tooth Localization Model: A two-stage model was trained on 1,317 CBCT volumes (35,436 annotated teeth), using coarse panoptic segmentation followed by fine-scale refinement. Validation and testing were conducted on 54 and 41 CBCTs, respectively.

Periapical Lesion Segmentation Model: Trained on 849 CBCTs (566 positive, 283 negative), this model identifies periapical radiolucency within tooth-specific sub-volumes using semantic segmentation and post-processing.

Panoramic Reformat Model: The panoramic view is generated from tooth axis predictions and segmentation outputs. Although this model is not trained in a traditional sense, it builds upon outputs of the Tooth Localization model. The algorithm creates anatomically faithful 2D reformats of CBCT data and is evaluated for visual coherence and anatomical alignment.

15. Troubleshooting, Service, and Contact Information (for assistance)

If you encounter any issues while using Diagnocat, please contact the manufacturer.



MANUFACTURER

DGNCT LLC

333 Southeast 2nd Avenue , 20th Floor#563

Miami, Florida 33131, USA

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

Phone: + 1 519 619 4212

E-mail: support@diagnocat.com

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

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

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