

Dentist's virtual assistant in Viewer planning

Segmenton Viewer User Manual

Version 1.0





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USER MANUAL INFORMATION	

This user manual is used solely for the purpose of explaining the use of Segmentron Viewer. 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 Segmentron Viewer. In addition, this manual may be modified without notice.



SYMBOLS AND MARKS USED IN THE MANUAL AND IN THE LABELING

***	Manufacturer
ī	Follow instructions for use
Ń	Caution
MD	Medical device
İİ	Patient information website

CONTACT

www.diagnocat.com

DEVICE INFORMATION

Name: Segmentron Viewer Relevant Segmentron Viewer Version: 1.0

REGULATORY REQUIREMENTS

Segmentron Viewer complies with the following regulatory requirements:

- □ ISO 13485:2016 Medical devices Quality management systems. Requirements for regulatory purposes;
- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
- □ Canadian Medical Devices Regulations SOR 98-282

Compliance - this Software as a Medical device complies with relevant international and national standards and laws. Information on compliance will be supplied on request; manufacturer contact details are written below.



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.

MANUFACTURER INFORMATION



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PAPER COPY

Note! The User Manual is supplied in an electronic format and not in a 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.

CUSTOMER NOTICE

This Instructions for Use is intended to assist users in the safe and effective use of the medical device software described herein. The "user" is considered to be not only the body with authority over the medical device software but also those persons who use the medical device software. This Instructions for Use does not describe the use of the IT equipment on which the medical device software is installed. Refer to the documentation of the IT equipment concerned.

Before attempting to use this medical device software, you must read these Instructions for Use thoroughly, paying particular attention to all **WARNINGS**, and Notes it contains. You must pay special attention to all the information given, and procedures described, in this Instruction of Use. 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. Segmentron Viewer 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 Segmentron.
- 4. Users should read this manual thoroughly before using this product.
- 5. In order to use the full functions of Segmentron Viewer, 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.

PRODUCT DESCRIPTION

Diagnocat Viewer is a software Device for Dental image processing and management. The device provides the user with image management capabilities and processing systems of maxillofacial Cone-Beam Computed Tomography (CBCT) images. The device provides patient management capabilities and image processing functions for image enhancement, image segmentation and 3D visualization.

Segmentron Viewer is designed for cloud-based storage and processing of digital dental images using artificial intelligence.

Segmentron Viewer has been developed to automate the activities of dental organizations in saving, sharing, editing and documentation of CBCT images.

Segmentron Viewer processes files of any area of the patient's maxillofacial region. The device's main function is to perform automated analysis of CBCT images provided by the user and provide users with automatically generated reports. Automated analysis consists of applying artificial neural network models to images to obtain segmentations of teeth.

INTENDED USE

Diagnocat Viewer is dental imaging software that is intended to provide a tool for maxillofacial radiographic imaging.

The device is intended for use as software to load CBCT, create, view and save CBCT segmentation and to provide 3D visualization and export capabilities to use with other planning softwares. The device is meant to be used by trained medical professionals such as radiologists and dentists.

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INDICATION FOR USE

Diagnocat Viewer is a software intended to provide a tool for maxillofacial radiographic imaging.

Segmentron Viewer allows users to perform the following functions:

- 1. Viewing patient images (provides tools for image processing and viewing functions);
- 2. Reading and 3D visualization of CBCT and STL images
- 3. Generating and downloading CBCT segmentation reports using patient oral images.

Diagnocat Viewer is a web application. It can be used in a network environment.

THE INTENDED USERS

The device is meant to be used by trained medical professionals such as radiologists and dentists.

INTENDED PATIENT TARGET GROUP

Patients of 11 age

CONTRAINDICATIONS



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



The performance of Segmentron Viewer depends on the quality and accuracy of the CBCT and STL files as well as the model scan imported. Relevant anatomical structures must be visible in the scans.

POTENTIAL ADVERSE EFFECTS AND SAFETY OF THE MEDICAL PRODUCT

This software is completely safe for use by people, provided that it is used according to the user manual.

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



Segmentron Viewer 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.



Segmentron Viewer is an adjunct tool and does not replace the role of the clinician.



The user needs to ensure that the surface scan is of the required quality for planning the case, and that the relevant areas for the Viewer planning fully exist.



Make sure that the quality of the loaded CBCT or CT scan is sufficient for planning the case and that the relevant areas on the image for the analysis are adequate in order to make an accurate and sustainable decision for Viewer planning! CBCT or CT devices have to comply with the recommendations of ICRP (International Commission on Radiological Protection).

To obtain optimal results, please use the Segmentron Viewer guidelines. Please do not upload DICOM files with limitations on size more than 1GB and CBCT volume, 50 cm3, which is applied if the height dimension (axial) is less than half the width/length dimension.



Please check that the scan data is correctly and completely loaded. Also check that the visualization of the CBCT/CT and Surface Scan is working correctly to allow a secure and accurate placement of the Viewer during the navigated planning and surgical guide design process.



Segmentron Viewer should be used according to the manual.

REQUIRED TRAINING AND QUALIFICATIONS

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 the Segmentron team.



DEVICE SECURITY AND PRIVACY

Customer Role in the Product Security Partnership

Security of Segmentron 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 Segmentron Viewer 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: Segmentron 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 Segmentron Viewer 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).

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



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



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

Malware Prevention and Detection

The server(s), on which Segmentron Viewer 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

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



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

Logical Access Control

Regular users do not have direct access to Segmentron Viewer. Only authorized specialists (like institution's IT specialists/administrators, Segmentron Viewer 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 Segmentron Viewer 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 Segmentron promptly and report about occurred security events to allow Segmentron 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 Segmentron Viewer.

Changes and/or additions to the software as a medical device should only be carried out by Segmentron Viewer or by third parties expressly authorized by Segmentron Viewer 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

Segmentron software requirements:

- □ Any operating system capable of running the required Google Chrome version
- □ Browser: Google Chrome 92+ and should be updated

Segmentron hardware requirements:

- Minimal processor with at least 2 CPU cores
- □ 4 GB RAM or more
- Recommended: Processor: 4 core. Memory: 8 GB RAM
- □ 50 Mbps or faster



If you use a browser other than the one specified here, the results may be unpredictable

TECHNICAL PARAMETERS

Segmetron Viewer is constituted by software available via Web Application with the use of Chrome web browser. The address of Web Application where the service is available is provided together with the software license.

START WITH Segmentron Viewer

To access Segmentron Viewer software, you need to have a valid Diagnocat account.

1. Start with Diagnocat

To access Segmentron Viewer software, you need to have a valid Diagnocat account.

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

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

You will be prompted to the account creation screen where you need to provide account details and click the "Sign Up" button.



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





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

1.1.1. Sign in

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

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



Sign in	
Email *	
Password *	
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1.1.2. Reset password

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

Reset password		
Enter your email to get a link for sett	ing a new password	

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



Patients

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



- #1: "All" gives you access to all your patients.
- #2: "Received Referrals" gives you access to all studies shared with you by other users.
- #3: "Sent Referrals" gives you access to all studies shared with other users by you.
- #4: Using the "Search" field you can search for studies by patient name or ID.
- #5: Shows you the list of all your patients.
- #5: "Treating doctors" filter allows you to select a specific doctor/doctors.
- #7: Shows existing studies.
- #8: "Add new patient" allows you to create a new patient.
- #9: Allows you to change the interface language.
- #10: Gives you access to your account and clinic settings.
- #11: Allows you to get access to the customer success team.

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



😂 Diagnocat			New Dent
Patients	+ Add new par	tient	
All 1 Received Referrals 0	Sent Referrals 0	Q Search by Patient name or ID	
Jane Doe			
ID:			
DoB: November 16, 1966			
TA Test Account			
り (1) (1) (1) (1) (1) (1) (1) (1)			

1.1.3. Create a new patient

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

First Name *		Last Name *		
Email				
Date of birth *		Patient ID		
Select date	liii)			
Gender *				
Male Female Other				
Treating doctor *				
TA Test Account 🛛 🗙				~
			0	
			Cancel	Add



Fill in a short form, it is necessary to fill in all required fields marked with an asterisk and click "Add".

A new patient will appear in the patient list.



1.1.4. Patient Card

- #1: Patient details.
- #2: Edit patient details.
- #3: Add a treating doctor.
- #4: Share a patient with another doctor.
- #5: Study details.



#6: Report details.

#7: Order a new analysis.

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

#9: Order 3D Model

1.7 ORDERING Viewer REPORT

Segmentation Report

To order an Viewer Report, you need to upload a CBCT scan in DICOM (.dcm) format and two intraoral scan files of the upper and lower jaws in .stl format. No other files, such as bite registration or other scans, should be uploaded. To upload a CBCT scan, click Upload study on the patient's details page, choose CBCT in the dropdown, browse for a DICOM file on your computer (you can choose between uploading a single .dcm file or a series of .dcm files as a folder), and click Upload. To upload intraoral scans, click Upload study, choose STL file in the dropdown menu, browse for the .stl files of the upper and lower jaw on your computer, and click Upload.

Please note that the uploaded CBCT and intraoral scans should reflect the same anatomical conditions of the patient, so that they can be matched for the Viewer planning purposes.

3.1 Order a new Segmentation report

Click the "New 3D Model" button in the patient card, choose "Basic CBCT to STL segmentation" and click "Next".





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.

4.0 Superimposition

Diagnocat allows you to create CBCT and IOS fusion. Choose "Advanced CBCT and IOS fusion" and click "Next".

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

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Order a 3D Model



Available 3D models



2. Segmentation Viewer reports

2.1 Elements of user interface





The main user interface of Segmentation report comprises the following distinct blocks:

- 3D scene
- MPR panels
- Toolbar
- Objects
- Upload and Export buttons
- Labelling

1. 3D SCENE



3D model displayed on 3D scene. When you select an object on the 3D scene, it will be highlighted more brightly (for teeth)



or highlighted in color (for anatomical structures).

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the selected object in the 3D scene will be displayed on the panels.

NAVIGATION



For navigation you can use a cube

When you click on the cube icon, the panel for selecting a 3D model display projection. By pressing the buttons the 3D model changes position.



STYLES PANEL

In the lower left corner there is a style selection button. To open the panel, you need to navigate



on 3D scene and click on the Styles icon **Example** on the 3D scene. The Styles panel allows to change the visual presets of the 3D model. You can choose between 7 Styles presets, which differ in color, and transparency level.



MAXIMIZE VIEWPORT

K X K X

When you navigate on a 3D scene in the lower right corner there is the Maximize icon **Second Scene**. You can maximize the size of the 3D scene by hovering on the corresponding viewport and clicking the Maximize icon . Once the viewport is maximized, the icon changes to Minimize. Click



return to the standard proportions of the viewport.

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2. MPR PLANES

Multiplanar reformation viewports (**MPRs**) represent radiological images of CBCT scan in three projections: orthogonal view, tangential view, axial view.



You can change the projections on the MPR panels using the mouse. Changes will be displayed in one of the MPR panels.

MAXIMIZE VIEWPORT





When you navigate on a MPR plane in the lower right corner there is the Maximize icon

K N K N

. You can maximize the size of the selected MPR plane by hovering on the corresponding viewport and clicking the Maximize icon . Once the viewport is maximized, the

icon changes to Minimize. Click it to the cross button return to the standard proportions of the viewport.

3. TOOLBAR



The Toolbar contains the following instruments:

- 1. Objects opens/closes the Object panel (see section 4).
- 2. Layouts allows you to change the general appearance of the 3D scene and MPR panels. There are 3 display options available:



Only the 3D scene will be displayed

windows of the same size with 3D scene and panels

3D scene and side view of MPR panels



Brightness-contrast - allows to change the brightness or contrast of radiological images on MPRs. To change the brightness, click the mouse on the MPRs and move it up/down; to change the contrast, click the mouse and move it left/right.

To change the brightness or contrast, the user moves the cursor with left-mouse down:

- left decrease contrast
- right increase contrast
- down decrease brightness
- up increase brightness

The user can use Ctrl+Z buttons to undo the last action.

4. Ruler — activates the ruler instrument for measuring distances on MPRs. To measure an object on MPRs, click the mouse at the initial and final points of the object.

After the instrument has been activated, the following mechanics applies:

- user makes first left-click anywhere on MPR plane to mark the beginning of the ruler object
- user makes the second left-click to mark the end of the ruler object
- after the beginning is marked, the ruler object follows the mouse
- L the ruler measurement (rounded to the 2nd decimal) appears at the end of the object

Note: All the measurements in the software are presented in millimeters and accurate to two decimals (+/-0.01mm).



The user can delete the ruler object by choosing it on MPR. When you click on a measurement it should change color. After that clicking backspace or delete.





5. The user can use both the "Undo" button and Ctrl+Z buttons to undo the last action.

4. OBJECTS PANEL

To open the Objects panel, click Objects in the Toolbar. The panel lists all anatomic objects in a tree structure.



You can control the visibility (switch on/off) of any anatomic or artificial object via the Eye icon . To change the transparency of an object on the 3D scene, click the Transparency icon move the slider to the desired value.



To change the color of an object on the 3D scene, click the icon and move the slider to the desired value.





You can switch on/off the visibility of groups of objects corresponding to a specific jaw in the upper part of the panel, using the Eye icon next to Upper jaw or Lower jaw.





NOTE! For the superposition report, in the Object panel will be an IOS tab in the tree structure as it shown below. There you will find the same tools as in other tabs of the tree structure.

Solution Objects	Ø.
∩ Upper jaw	0
∨ Lower jaw	0
🗸 💭 Teeth	\$ 🛑 ©
∽ 🔄 Anatomy	*
∧ ິດີີ IOS	\$ 🔵 Ø
Upper Jaw	* 🔵 ø
Lower Jaw	\$ 🔵 Ø

5. UPLOAD and EXPORT



You can upload your own 3D objects on the scene, by clicking the Upload button in the lower left corner of the main page.

In the modal window, select (or drag & drop) the desired file(s) (in .stl format) from your computer and click Upload.

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The uploaded objects(s) will appear on the 3D scene, as well as in the Objects panel. You can move the uploaded objects on the 3D scene using object controls.



To remove an uploaded object click the Delete icon in the Objects panel.



To export all anatomic and artificial objects listed in the Objects panel, click the Export button. you can select the objects you want to export. You must check the box next to the object you want to export. Or you can merge all into one file. To do this, you need to press the corresponding

button Merge in one file. The objects will be exported as a .zip archive containing .stl files



Export STL files		×
∧ ♡ Teeth		
✓ Upper Jaw		
✓ Lower Jaw		
へ 🕑 Anatomy		
SoftTissue		
Cranial		\checkmark
Sinus		\checkmark
IncisiveCanal		
Maxilla		
Mandible		
Mandibular canal		
Airways		
Merge in one file		
	Cancel	Export

FOR HELP AND ASSISTANCE

CONTACT INFORMATION

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

MANUFACTURER

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

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