

3D Endo™ Software

User Manual

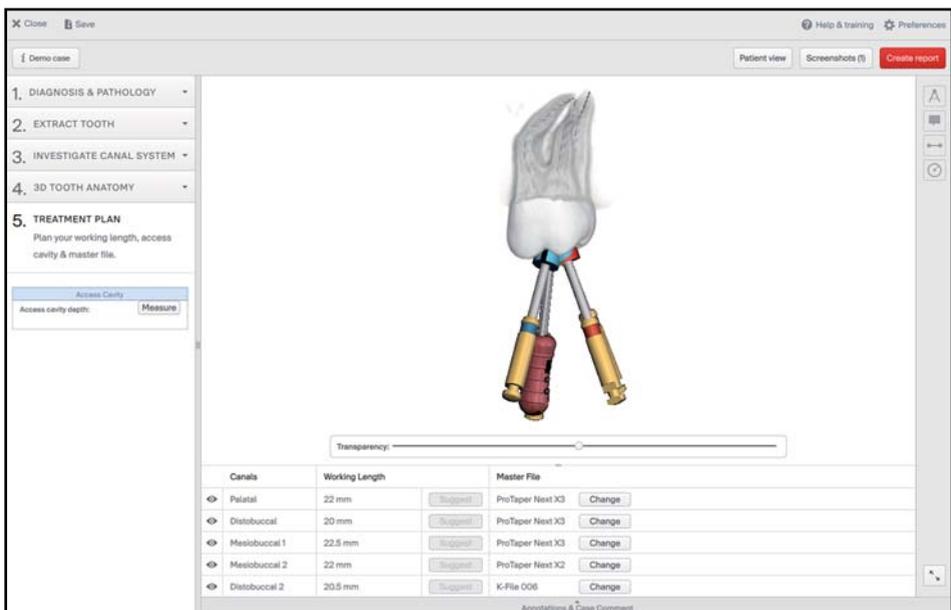


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1 Introduction

Congratulations on your purchase of the **3D Endo™ Software**.

The User Manual is always kept up to date by Dentsply Sirona to bring it in line with the latest developments. The User Manual is available in different languages. You will find the latest version on www.dentsplysirona.com/3DEndo-na.

Dentsply Sirona reserves the right to change the information and data contained in this User Manual.

If you wish to have a printed copy, we will be happy to send it to you (free of charge within 7 calendar days). To order, simply send your request to 3dendo-na@dentsplysirona.com.

Dentsply Sirona has attempted to compile a User Manual that is helpful and error free. Nevertheless errors may have been overlooked and improvements could be beneficial. We would appreciate your feedback in this area. If any possible improvements are noted, please contact Dentsply Sirona (3dendo-na@dentsplysirona.com).



In this DFU, "clinician" might be replaced by "dentist" depending of the countries.

2 Indication for use

3D Endo™ Software is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases utilizing DICOM images.

3 Contraindications

Read the following contraindications before use:

- Do not use **3D Endo™ Software** for implants or any other dental procedure outside endodontics.

4 Warnings

There are no known serious adverse reactions or potential safety hazards.

5 Precautions

- The application will automatically install the latest version. Regularly connect your computer to the internet when running the **3D Endo™ Software**. Refer to chapter **8 Technical Characteristics** for minimal requirements;
- The quality of the images in the **3D Endo™ Software** depends on the quality of the original CBCT scans. To obtain optimal results, please use the scan parameters specified in the CBCT scan prescription form;
- If you are unaware of your Open GL version, please download the free trial version of **3D Endo™ Software** at www.dentsplysirona.com/3DEndo-na to verify the compatibility of your system.

User access will be controlled by the Microsoft Windows operating system for:

- Configuring user accounts;
- Setting password policies;
- Forcing password changes;
- Setting appropriate user login timeout based on no activity.

When implementing the software in a network setting, the following are recommended:

- Using firewall as appropriate;
- Implementing anti-virus detection software as appropriate;
- Implementing process to identify security compromises;
- Contacting the Customer Service department in the event of any security compromise.

Read the following warnings before use:

- This product should be used by trained clinicians with experience reading and understanding CBCT scan data. It is the clinician's ultimate obligation to exercise his/her professional judgment in any decision to follow or not follow the treatment planning made using the medical device (software). Dentsply Sirona cannot be held liable for misinterpretation of 2D and 3D visualized CBCT data, wrong definition of the canal mid-line, of any parameters that require user inputs, errors in the original DICOM data or lack of experience in reading CBCT;
- Clinical judgment needs to be applied by the end user of the device;
- The **3D Endo™ Software** allows clinicians to visualize endo files within the root canal. The file position and bending is defined from the canal mid-line identified by the user without any clinical interpretation of the specific tooth anatomy. The mechanical and geometrical properties of the root canal and the file are not taken into account by the **3D Endo™ Software**. Therefore the **3D Endo™ Software** cannot predict file separation nor automatically indicate risky canal curvatures;
- Follow the online scan protocol (www.dentsplysirona.com/3DEndo-na) and the software prescription form defined in the **3D Endo™ Software** to maximize the quality of the CBCT data;

- Reports linked to cases in the application are subject to the requirements of the applicable country and local legislation on data privacy. Clinicians are responsible for the privacy of their cases and compliance with local regulations. Dentsply Sirona recommends the use of the anonymizing case functionality in order to protect personal data;
- **3D Endo™ Software** does not replace your Dental Practice Management Software;
- Do not attempt to modify the **3D Endo™ Software** or application. Dentsply Sirona cannot be held liable if unauthorized modifications have been made to the **3D Endo™ Software** application;
- It is highly recommended to regularly schedule backups of your data files.

6 Adverse Reactions

There are no known adverse reactions.

7 Step by Step Instructions

Refer to chapter **5 Precautions** to verify if special care needs to be exercised before starting.

Due to the large file sizes and significant processing capability required to manage CBCT scans and applications, minimum hardware requirements are defined. Refer to chapter **8 Technical Characteristics**.

7.1 3D Endo™ Software Overview

The **3D Endo™ Software** uses a CBCT scan in the DICOM standard format as input. By following the 5-steps in the software, you will achieve an endodontically oriented visualization of the 3D anatomy and a detailed plan for the root canal treatment. Step by step instructions as well as Tips are embedded in the **3D Endo™ Software**.

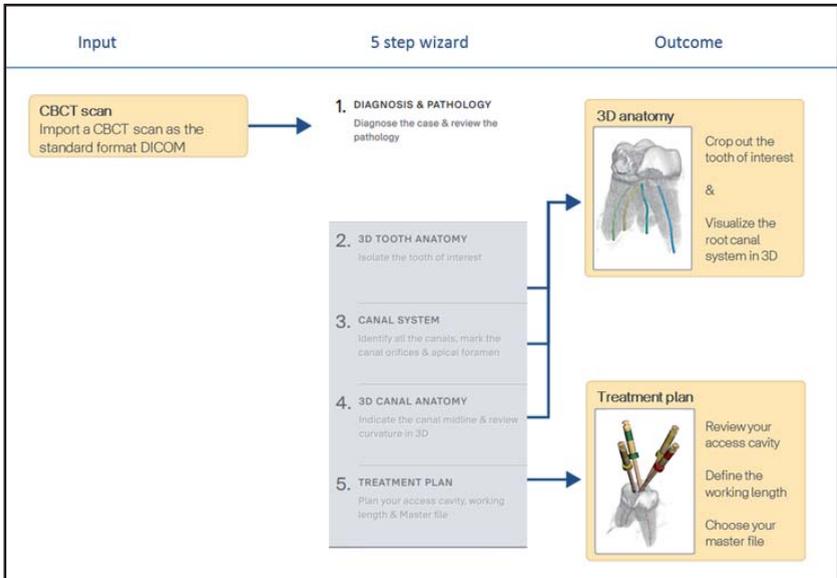


Fig. 1

7.2 Key Screens

7.2.1 Home Page

The homepage allows you to:

- Import a CBCT scan (resolution and slice thickness should be less than 200 micrometers);
- Practice with a demo case;
- Open an existing case;
- Access help and training on how to use the software;
- Change your preferences;
- Learn how to optimize your CBCT scan for use with **3D Endo™ Software**.

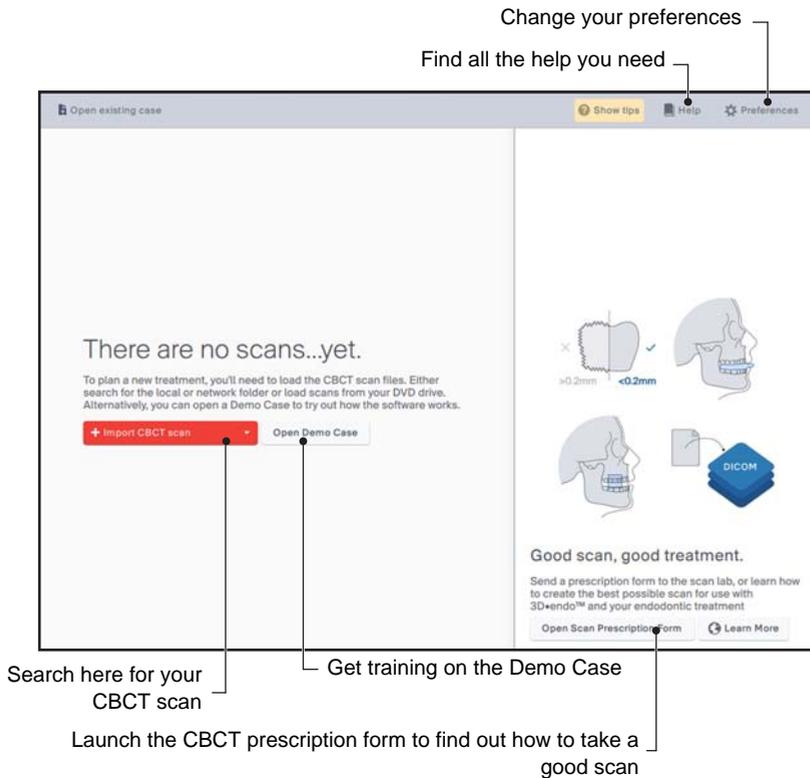


Fig. 2

The Demo Case is a CBCT scan already loaded in the software. You can access it at any time to practice or experiment with **3D Endo™ Software**.

7.2.2 Scan List

The Scan list shows you:

- The list of scans found in the selected folder or device;
- Case information;
- Quality of the scan.

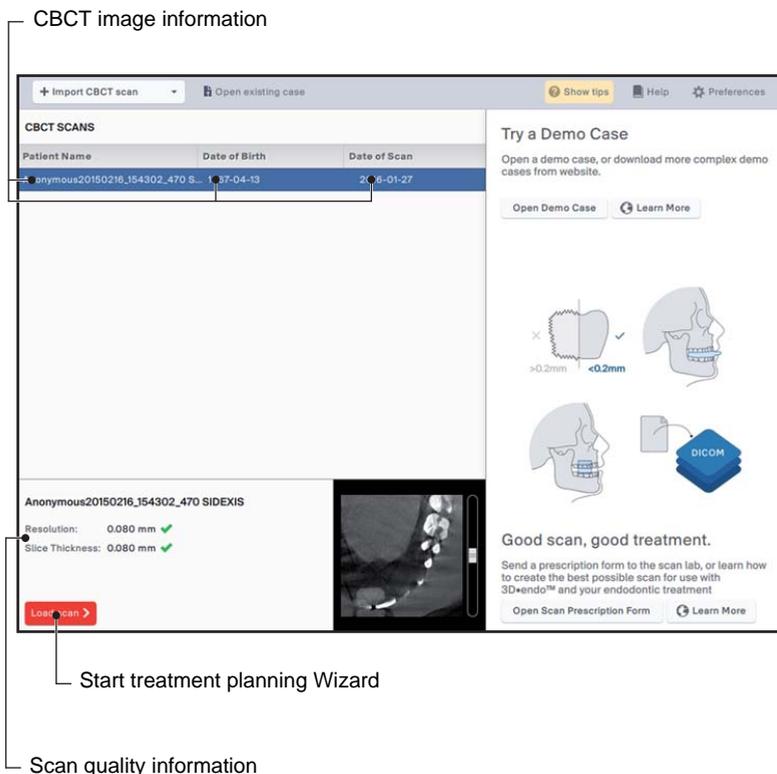


Fig. 3

The **3D Endo™ Software** shows you the quality of the scan in relation to Resolution & Slice Thickness of the DICOM data.

Minimal CBCT requirements:

- Resolution & Slice thickness should be less than 200 micrometers;
- Resolution & Slice thickness should be equal to avoid misinterpretation of accuracy;
- Prescribe or use a bite plate for clear information about the occlusal surface, otherwise accurate measurements and visualization of the images might be compromised.

Scanning Tips:

- Take a small field of view to reduce radiation dose;
- Reduce scatter by:
 - Taking a small field of view;
 - Replace radio-opaque fillings with radio-translucent material, as much as possible;
 - Try to exclude neighboring & opposing teeth containing metal.

For more information on how to optimize the CBCT scan for use with **3D Endo™ Software**, look into the CBCT scan prescription form on the homepage or in the 'Help section'.

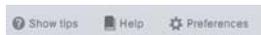


Fig. 4

For more general information on CBCT, go to the knowledge of the Dentsply Sirona website (www.dentsplysirona.com/3DEndo-na).

7.2.3 Wizard

The Wizard allows you to:

- Diagnose your case;
- Isolate the tooth of interest;
- Investigate the canal system;
- Understand the 3D Canal anatomy;
- Create a Treatment plan.

Display Tips within the application

To go to the next step
Change your preferences
Find all the help you need
Launch the tutorials at any time

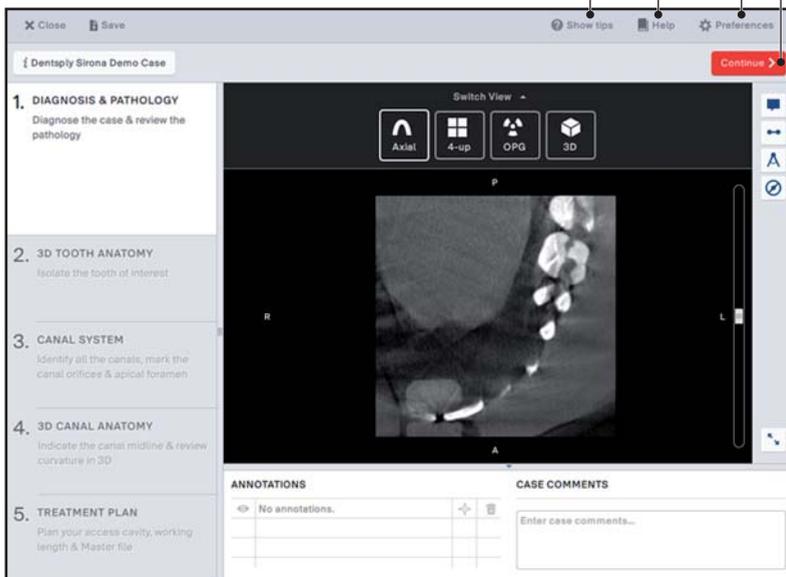


Fig. 5

A detailed guide on the different steps can be found embedded in the software as a set of Tips.

You can find these help Tips in two different ways:

- By launching the Demo Case on the Homepage (see [7.3.1 Tips on Demo Case](#));
- By enabling the "Show Tips" functionality on any page in the Wizard (see [7.3.2 Tips by "Show Tips"](#)).

You can also find more information at www.dentsplysirona.com/3DEndo-na, or by clicking on the 'Learn more' buttons available in the **3D Endo™ Software**.

7.3 Tips

Throughout the Wizard, Tips will be displayed to explain which actions to take and how to proceed.

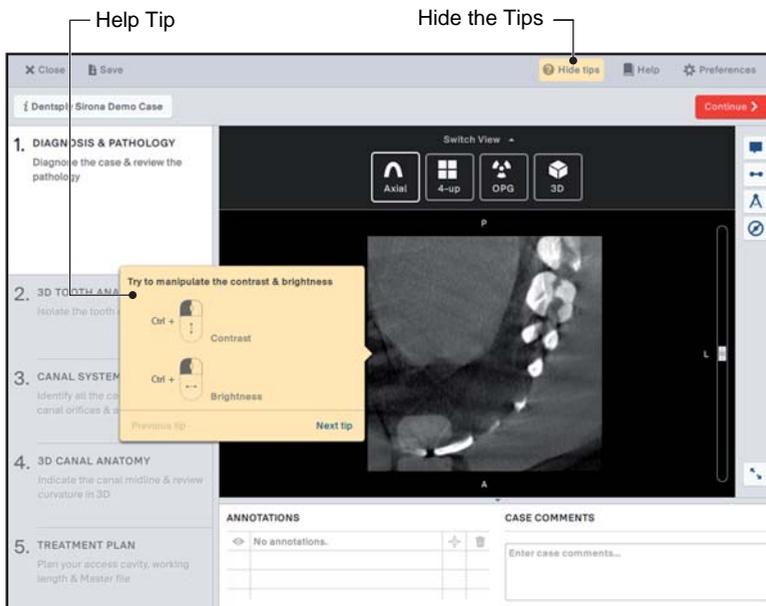


Fig. 6

7.3.1 Tips on Demo Case

The first Tip will be shown immediately upon launching the Demo Case from the homepage:

- You can go to the next Tip by pressing 'Next';
- To go back to previous Tips, press 'Previous';
- You can hide Tips at any time, by pressing 'Hide Tips';
- To reactivate Tips, press 'Show Tips'.
You will start with the first Tip of the step you are on at the moment.



Fig. 7

7.3.2 Tips by "Show Tips"

At any time, you can display the Tips by pressing 'Show Tips'.

The **3D Endo™ Software** will show the first Tip related to the step you are on at that moment.

- You can go to the next Tip by pressing 'Next';
- To go back to previous Tips, press 'Previous';
- You can hide Tips at any time, by pressing 'Hide Tips'.
The training will automatically stop at the moment you switch steps or view;
- To continue the training, press 'Show Tips'.
You will start with the first Tip of the step you are on at the moment.



Fig. 8

8 Technical Characteristics

Specifications	Description
Operating system**	Windows 7, 8.1 or 10; 64 bit
Processor	3rd Generation Intel® Core™ Processor or higher
RAM	4 GB or more
Free disk space	20 GB or more
Graphical card requirements	On-board Intel® HD Graphics 2500 or higher
Screen resolution	1024 x 768 or better
Open GL requirements	Version 3.2 or higher
Measuring accuracy	Length accuracy*: ± 0.5 mm Diameter accuracy*: ± 0.5 mm Angle accuracy*: $\pm 0.5^\circ$ Working length accuracy*: ± 0.5 mm (* For DICOM images with pixel size of 0.125 mm)
Manufacturer	Dentsply Tulsa Dental Specialties Johnson City, TN 37604 USA Phone: 1-800-662-1202 Fax: 1-800-597-2779 3dendo-na@dentsplysirona.com www.dentsplysirona.com
Product Name	3D Endo™ Software

** OSX, Linux and other operating environments are not supported at this time.

9 Troubleshooting

Please contact your local technical support team.

10 Identification of Symbols

10.1 Normative Symbols

Symbol	Identification
	Electronic instruction for use
	Manufacturer
	Catalogue number

www.dentsplysirona.com/3DEndo-na



REF 3DENDO

Rx Only



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