

Case Viewer 3.1

Instructions for Use





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Introduction

Product information

Case Viewer is a web-based software for reviewing and approving implant plans furnished by the service provider.

Functionality includes:

- Review of the implant planning proposal and view of prosthetic planning proposal on the (CB) CT slice images (2D) and reconstructions (3D)
- Assessment of collisions
- 3D views of implants (transparent bone), aesthetics (virtual crown, abutment, healing abutment) and guide design for review and evaluation of the planned implant positions
- Approving a plan for surgical guide manufacturing

Caution



US federal law restricts this product for sale by or on order of a dentist or physician. Case Viewer software can only be used by technicians / clinicians who have had the appropriate education and training.

Users must take appropriate measures and steps to protect their computer or mobile device and any private data stored on it (like mySimplant account credentials) from harm or uncontrolled access by other people. Therefore, it is strongly advised to use firewall and anti-virus software appropriate for the environment of use; and to close all open planning files when you leave your computer or mobile device.

Indications for Use

Case Viewer is indicated for use as medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. Case Viewer is intended for use as a pre-operative software program for reviewing plans for dental implant placement and surgical treatment.

Contraindications

There are no absolute contraindications for using Case Viewer besides those that are applicable for implant treatment in general.

Warnings

Always check collision warnings when reviewing a planning proposal. When an implant is placed close to a nerve, less than 2 mm, a collision warning is shown. The 3D reconstructions and slice images (2D) in the Simplant planning proposal are the result of image processing operations such as reformatting and cropping of original CT images. The responsible clinician should always refer to the original CT images for a

full radiological assessment, such as evaluating the presence of tumors or infections outside the implant placement region. While accuracy with Simplant guided surgery is higher than with non-guided surgery, linear

and angular deviations are to be expected when using either non-guided or guided surgery, as linear and angular deviations have been reported in experimental and in clinical studies. Therefore, it is important to keep a safety distance when using guided surgery.

Precautions

With Case Viewer planning proposals must be verified by the responsible clinician on the 3D image as well on the slice images (2D) before approval. The clinician must exercise his professional judgment in any decision to follow or to not follow the Simplant treatment plan. The quality of the images in the software depends on the accuracy of the scanned images. To obtain optimal results, please use the scan parameters specified in the Simplant scanning guidelines. For scans taken with an inter-slice distance of 1 mm, the accuracy of the 3D reconstructions in the software varies between 0.1 and 0.2 mm. The use of larger inter-slice distances is not recommended. Only scanned images with orientation RAB are allowed.



By nature, placing measurements on a touch screen using your fingers is not accurate and therefore not recommended. For placing measurements accurately please use more precise input devices like a mouse.



Drill tip warning. It is important to note that for the OsseoSpeed EV implant system, the guided surgery drill tip can extend up to 1 mm deeper than the apical point of the planned implant. With each EV case the following warning message is shown when you view a treatment proposal in Case Viewer.

-	Please read this first
	The Simplest SAEE Guide is designed to lisk the planned implest
	It is important to note that for the OsseoSpeed EV implant system, the guided surgery drill tip can extend up to 1mm deeper than the apical point of the planned implant.
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Adverse Reactions

There are no adverse reactions for treatment planning with Case Viewer software besides those that are applicable for implant treatment in general.

Step-by-Step Instructions

Step-by-step instructions can be found in the next chapters of this document.

Manufacturer



DENTSPLY Implants NV, Research Campus 10, 3500 Hasselt, Belgium

www.dentsplysirona.com

Technical support

Technical support and information on known software bugs and anomalies can be found by contacting technical support: <u>https://www.orderdigitalsolutions.com/Help/ContactUs</u>.

Electronic instructions for use can be found on <u>http://ifu.dentsplysirona.com</u> and a paper copy may be requested via technical support: <u>https://www.orderdigitalsolutions.com/Help/ContactUs</u>.

Identifications of symbols used



System requirements

The minimum system requirements for running Case Viewer:

- Windows desktop systems:
 - \circ Chrome web browser (v. 71 and above).
 - Firefox web browser (v. 60.5.0 and above).
 - Internet Explorer 11 (with limitation that 3D objects cannot be displayed in transparent way).
 - Edge (Edge 41.16299 / EdgeHtml 16.16299 and above).
- Mac PCs and laptops:
 - Safari browser (v. 11.1.2 and above).
 - Chrome browser (v. 71 and above).
- iOS devices:
 - o iPhone: iPhone 6 and later versions are supported.
 - o iPad: iPad Air, iPad Mini 4 and later versions are supported.
 - Safari for iOS 11 and above on iPhone or iPad.
- Android devices:
 - Android 7 (nougat) and above.
 - Chrome for Android (v. 71 and above).
- Recommended devices:
 - \circ \quad Windows systems with the latest Chrome web browser.
 - o iOS devices released in 2016 or later.
 - We recommend updating your web browsers (or iOS in case of iOS devices) to the latest version.

Important remark:

• Medical data is downloaded and visualized on your computer. We advise you to install anti-virus and/or firewall software to protect from malicious intrusion on your computer.

Introduction to Case Viewer

The Case Viewer is a web browser application used to view the single tooth implant and restoration treatment proposal. It is compatible with PC, Mac and mobile devices.



IMPORTANT: The Case Viewer does not allow changes to the treatment plan, however you can submit a change request with the user-friendly message box. The restorative design will be updated accordingly, and the plan will be resubmitted to you for approval within one business day.

When the planning proposal is ready for approval, you'll receive an email notification. This email will direct you to Azento, where you can see all the case details.

Working with a case

Ordering a planning service



To order an Azento[™] treatment proposal, register to gain access to the order site www.orderdigitalsolutions.com and create an Azento order.

Fill-out the order details by going through the subsequent order pages. Indicate implant positions, procedure solution, temporization and name of implant system.



In the bottom half of the Prescription step, you can upload all clinical available data: CT scan, optical scans or intra oral scans from treatment arch, opposing arch and occlusion. When all case data are available to Dentsply Sirona Implants, the treatment proposal will be ready in the next 24 hours. Each treatment proposal has to be viewed and/or edited by the clinician before being produced by Dentsply Sirona Implants.

Opening a treatment proposal in Case Viewer

A treatment proposal has been created and requires your review and approval. Please click on "View order" to proceed. Please note the importance of the comments included in this planning proposal.

View order

When the treatment proposal is available, an email notification will be sent. By clicking on 'view order' in the email, you will be redirected to the order on orderdigitalsolutions.com







The case viewer will open the treatment proposal.

Desktop Case Viewer

Screen layout

The main features and screen layout of Case Viewer.



1	Main screen	Displays 3D and 2D images of implant and the restorative treatment proposal.
2	Viewing Modes	Switches between 2D X-ray, 3D objects and panoramic views.
3	Notification area	Important remarks regarding the treatment will appear here.
4	Case component and anatomy list	Contains all case objects with 'show and hide' feature.
5	Viewer Tools	Adjust transparency of individual 3D objects and take measurements on 2D images.
6	Approval tools	Approve the treatment proposal or request a change.
7	Quick start tour, help and about	Start the quick start tour, read Instructions For Use and manufacturer info.

Manipulating the images

Rotating and zooming

Rotate 3D images	<u>PC or Mac:</u> left click mouse button and hold and move mouse. <u>Laptop:</u> click trackpad, hold and rotate.
Zoom in and out (2D and 3D images)	<u>PC or Mac:</u> use scroll wheel mouse button or double click in the images for full zoom. <u>Laptop:</u> two-finger movement up and down on trackpad or double tap trackpad for full zoom.

Scrolling through 2D images

Г

Scrolling though the 2D images	R	Drag the slider in the 2D images screen to scroll through the images.
		Or click on any point on the slider bar to move the images to that position.
		Or click on R or L to move in that direction with 1 slice (0,5mm).
	e e e e e e e e e e e e e e e e e e e	Note: only the 2D images around the implant are shown, 4mm on each side.



Panoramic X-Ray



A panoramic X-Ray simulation can be visualized by clicking on the panoramic curve button. The X-ray is a flat reconstruction of panoramic 3D image data. To assess exact implant relations or collisions, the 3D and 2D images should be used.

You can go back to 3D and 2D view by clicking on the 3D+2D button.



Objects list

Case components and anatomy list overview

The case components and anatomy list display the objects available in the planning proposal. The list is divided in 2 groups: <u>case components</u> and <u>case 3D objects</u>.

Each group can be collapsed or expanded by clicking on the arrow next to the group name.





Case components list details

Ø 4.2mm L 11.0mm	The current implant used in the proposal with indications of length and diameter.
Screw-retained PMMA, shade A2	The temporary crown with retention and material indicator. (Not available with a delayed loading case)
Abutment Titanium	The abutment (not available with a delayed loading case)
Healing abutment Titanium	Healing abutment with indication of material.
SAFE Guide	SAFE Surgical Guide

Bone	Showing the bone of the CT or CBCT scan, with the bone and neighbouring teeth shown, as well.
Treatment arch	High definition tooth information derived from stone model or intra oral scan.
Opposing arch	Opposing arch or antagonist, derived from stone model or intraoral scan.
Insertion path	Insertion path showing an extension of the implant direction in order to assess aesthetic outcome.

Showing or hiding objects

Each object in the list can be individually shown or hidden by clicking on the name or eye icon next to it.

۲	Object is visible in the images
Ø	Object is not visible in the images

View pre-sets

Pre-set view are views that have predefined visible objects and provide a quick and convenient way to view objects together.



There are three groups of View pre-sets: Implant, Esthetics and Surgical Guide. The default pre-set when opening the proposal is Esthetics.

Pre-set name	Visible objects
Implant	Implant, bone, nerve, adjacent teeth, opposing arch and insertion path
Esthetics	Implant, temporary crown, nerve, abutment, treatment arch and opposing arch
Surgical Guide	Implant, nerve, SAFE guide and treatment arch

Note:

With pre-sets you still have the option to individually 'show or hide' objects by hiding or visualizing them in the objects list!

Tools

Change transparency of 3D objects

Change the transparency in the 3D images by using the transparency slider. The following 3D objects transparency can be changed: treatment arch and opposing arch.



Measurements

Click on the 'Measure' button and click on the left mouse button to position the first point. A measurement will be shown together with its length (expressed in mm). Click again to fix the other end of the measurement. Measuring accuracy for point-to-point distances: +/- 0.1mm.





Create a measurement by clicking on 2 places in the images. The distance between these 2 points will be calculated automatically.



This icon will appear when you select an existing measurement. Clicking on this icon will delete the selected measurement.

Order remarks, Preservation area and Collision warnings

Order remarks



Important: Comments on the planning proposal will appear in the 'Order Remarks' area. These remarks are made by the Design team while preparing your case. Please read through these remarks carefully.



Preservation area



In the 2D images, a preservation area of 1.5 mm is indicated around the implant with a blue dotted line. Take into account a possible deviation of +/- 0.3 mm of this preservation area. The preservation area will allow you to assess this distance in relation with other objects.



Collision warning



A collision warning is shown when an implant is placed less than 2 mm next to a nerve. The collision warning is shown with an exclamation mark next to the implant and a warning is shown in the 2D images, as well.



Approving a case or requesting a change

Approving a case

<u>IMPORTANT</u>: After a thorough review of the planning, and double-checking all the planning details, you can directly approve the planning. *When you approve the planning, the production process is started and the order cannot be cancelled.*

You can approve the planning by clicking the 'Approve' button.





Requesting a change



If you want to change the planning, click on the 'Make Changes' button.

The 'change request' panel will appear where you can enter the changes that our design team need to make. Please state the changes thoroughly, in detail, for our design team to make the correct revisions. Changes to the planning will be processed in one business day.

You can close the 'change request' panel by clicking the 'X' in the top right corner. All entered comments will be kept and saved in the proposal.

Click 'Submit Changes' button in order to complete the change request.



Modifying the planning yourself

You can also modify the planning yourself by opening up the planning in Simplant Editor or Atlantis Editor software.

Click 'Modify implant' to proceed to Simplant Editor. Click 'Modify restoration' to proceed to Atlantis Editor.



Mobile Case Viewer

Introduction to the mobile Case Viewer

On mobile devices, a mobile-compatible viewer will be shown in the web browser.

Important Note:

For thorough viewing of the planning, we advise you to view the planning from a desktop computer. The browser and screen on a desktop allow for better usability and convenience.

The difference in viewing a planning on a mobile device versus a desktop computer is as follows. There is:

- No possibility to change visibility settings of 3D objects independently on a mobile device
- No possibility to change transparency settings of 3D objects on a mobile device
- No access to 'editing planning yourself' functionality

Mobile Case Viewer screen layout

				5		
	< 🔊 🖻	entsply irona	He	elp About	Screen selection	There are 4 screens available:
1	Overv	riew 3D	2D arks	Panoramic i		- Overview of the components used in the treatment proposal
	displ	layed here.		-		- 3D, showing you the 3D images
	Tooth =	n 23 OsseoSpeed	EV			- 2D, showing you the 2D clinical images
	1110	Ø 4.2mm L 11.0)mm			- Panoramic, showing you a panoramic image
3	Screw-retained PMMA, shade A2	Notification area	Important remarks related to the planning from the			
	Abutment Titanium		2	appear here.		
	1	Healing abutment Titanium			Main screen	The Main screen is where all images can be viewed.
	Note: Val	SAFE Guide	a varsion of	this site. For	Approval 4	Approval panel where a planning can be approved, or changes can be made
	complete Chrome o	e viewing and edit	ing features	please use ation contact us.	Help and About	Read Instructions For Use and
4	Mak	e Changes	A	pprove		manufacturer info.

Screens overview

Overview screen

<	entspl <u>y</u> rona	У	H	elp About	
Overvi	ew	3D	2D	Panoramic	
 Or Impor displa 	 Order Remarks Important remarks from the design team are displayed here. 				
Tooth	23				
111111	Osse Ø 4.2r	oSpeed I mm L 11.0r	E V mm		
\$	Temporary crown Screw-retained PMMA, shade A2				
Ŧ	Abutment Titanium				
1	Healing abutment Titanium				
	SAFE Guide				
Note: You're using a mobile version of this site. For complete viewing and editing features please use Chrome on Windows. For more information contact us.					
Make Changes Approve					

The overview screen shows a list of all the available case components				
IIIII	OsseoSpeed EV Ø 4.2mm L 11.0mm	The current implant used in the proposal with indications of length and diameter.		
۵	Temporary crown Screw-retained PMMA, shade A2	The temporary crown with retention and material indicator. (Not available with a delayed loading case.)		
ŗ	Abutment Titanium	The abutment (Not available with a delayed loading case.)		
Ą	Healing abutment Titanium	Healing abutment with indication of material.		
	SAFE Guide	SAFE Surgical Guide		

3D Screen

The 3D screen shows you the 3D images of the treatment proposal.

At the bottom of the screen you can select			
different views, called pre-sets. Pre-set views are views that have predefined	Implants	Esthetics	Guide
visible objects.			

There are 3 groups of pre-sets: Implant, Esthetics and Guide. When you open the proposal, the default pre-set is Esthetics.

Pre-set name	Visible 3D objects
Implant	Implant, bone, nerve, adjacent teeth, opposing arch and insertion path
Esthetics (default view)	Implant, nerve, temporary crown, abutment, treatment arch and
	opposing arch
Guide	Implant, nerve, SAFE guide and treatment arch



In the Esthetics view, you have the option to view the abutment or healing abutment by 'tapping' on the selection switch or abutment	?
icons.	

Manipulating 3D images

Rotating using 1 finger	CE
Zooming using 2 fingers	* Jun

Panning using 2 fingers	B +
Zoom in /out to max /min zoom factor	Double tap

2D Screen

The 2D screen shows the 2D images of the treatment proposal.

At the bottom of the screen you can the different pre-set views. These vi show different objects and 3D conto the 2D images.	select ews ours in	Implants	Esthetics	Guide
¥				
Pre-set name	Visible obj	ects and 3D conto	urs	
Implant	Implant, ne	rve, insertion path a	nd 3D contour op	posing arch
Esthetics (default view)	Implant, ne	rve, temporary crow	n, abutment, treat	tment arch and
	opposing arch			
Guide	Implant, ne	rve and treatment a	rch	



1

The Esthetics view displays the option to	
view or hide the abutment or healing	
abutment by 'tapping' on the selection switch	
or abutment icons.	

Manipulating the 2D images

Zooming using 2 fingers	* Em
Panning using 2 fingers	₽ +
Zoom in/out to max/min zoom factor	Double tap

Scrolling through the 2D images

Scrolling through the 2D images	Dentsply Sirond Help About Overview 3D 2D Panoramic Implants Esthetics Guide Make Changes Approve	 Drag/move the slider in the 2D images screen to scroll through the images. Or tap on any point on the slider bar to move the images to that position. Or tap on R (right) or L (left) to move in that direction with 1 slice (0,5 mm). <u>Note:</u> only the 2D images around the implant are shown, 8 slices on each side.
Go back to the centre of the 2D images	The centre of implant area lines. As su of the implant	of the images, more specifically, of the a, is indicated on the slider bar with 2 small ch, you can navigate quickly to the centre at area.

Panoramic X-Ray



The panoramic X-Ray simulation can be visualized by clicking on the panoramic curve button. The X-ray is a flat reconstruction of panoramic 3D image data. To assess exact implant relations or collisions, the 3D and 2D images should be used.

C Dentsply Sirona		He	elp About
Overview	3D	2D	Panoramic
6. AU			
- APAN	11		1 Parts
a de la company			
Contractor of	111	111-4	ATT D
Make Chang	es	A	pprove

Manipulating the panoramic image

Zooming using 2 fingers	* m
Panning using 2 fingers	\mathfrak{P}^*
Zoom in /out to max /min zoom factor	Double tap

Order remarks, safety zone and collision warnings

Order remarks



Important order remarks on the planning proposal will appear in the notification area.



[
Notification area
where important
remarks from
the Design team
will be shown.

Preservation area



In the 2D images, a preservation area of 1.5 mm is indicated around the implant with a blue dotted line. Take into account a possible deviation of +/- 0,3 mm of this preservation area. The preservation area will allow you to assess this distance in relation with other objects.

C Dentsply Sirona	Help About		
Overview	3D	2D Panoramic	
			el.5mm (±0.3mm)
Implants	Esth	etics	Guide
Make Chan	ges	1	Approve

Preservation area of 1.5 mm indicated with a blue dotted line around the implant when you scroll through the 2D images.

Collision warning



A collision warning is shown when an implant is placed less than 2 mm next to a nerve. The collision warning is shown with an exclamation mark next to the implant and a warning is shown in the 2D images, as well.



Approving a case or requesting a change

Approving a case

After thoroughly going through the planning and double checking the planning details you can directly approve the planning. When you approve the planning the production process is started, and the order cannot be cancelled.

Important Note:

By clicking 'Approve' you confirm that you have thoroughly reviewed the treatment plan.



Requesting a change

You can request a change to the planning by entering instructions for our Design team. Make sure the instructions are clear and detailed in order to avoid confusion so that the planning can be adapted quickly.

C Dentsply Sirona	Help About	Step 1: Tap the	C Dentsply Help Abou	t Step 2:
Overview 3D	2D Panoramic	'Make Changes' button.	Clearly describe the changes you would like made to the treatment plan.	 Enter the changes that you would like us to make. Tap the 'Submit Changes' button to submit the change request.
707			The treatment plan will be updated accordingly and resubmitted to you for	r
Implants Esthe	etics Guide		approval within one business day.	
Make Changes	Approve		Submit Changes	

Troubleshooting

- Internet Explorer 11 technically does not support transparency implementation • in Case Viewer 3.1. So for Internet Explorer 11 all objects are rendered opaque, the transparency slider for treatment arches is hidden and neighbouring teeth objects are always displayed (it is not affected by Bone visibility switcher). If transparency rendering is critical for your case review please switch to another web browser (e.g. Chrome).
- General workability remark: In case of problems with compatibility (Case Viewer doesn't start at all), data loading (case content is not loaded on 3D view) or some weird visualization of user interface elements or clinical images at first we suggest you to open Case Viewer in another environment: try to change device or run in other web browser on the same device.
- Problem: In Chrome web browser loading of 3D view content is stuck with 1% progress indicator. This problem can happen when data in the case file is too big and the system lacks memory or drive space resources. Possible solutions are: - try to close not needed tabs in Chrome and not needed running applications and then reload Viewer by pressing F5 or by following the link again from the notification email).

- try to open the case in another browser (e.g. Firefox) or on other device.

About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company[™], Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

Visit www.dentsplysirona.com for more information about Dentsply Sirona and its products.

