

OraCheck

User Manual Software version 2.1



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1 Introduction

1.1 Greeting

Dear OraCheck user

We thank you for the purchase of the OraCheck software by Cyfex

- OraCheck software enables you to overlay different threedimensional models created with the CEREC acquisition unit and to measure differences between the individual models as well as to represent them with color scaling.
- Improper use and handling may lead to erroneous interpretations or false results. We therefore request that you read through this manual and the corresponding instructions and follow them carefully.
- A prerequisite for the successful application of OraCheck is basic working knowledge of the CEREC acquisition unit (CEREC AC) and the CEREC software. In case of questions, please refer to the user manual supplied with the CEREC system.
- To prevent personal injury and material damage, please observe the safety information contained in this document, on the devices and within the software.

We wish you every success with our software.

Yours faithfully,

Cyfex Software Team.

1.2 Further support

In case of questions or suggestions regarding this product, our support team will be happy to help.

Please refer all questions to the following email address:

support@oracheck.com

or contact us directly using our ticketing system

http://support.cyfex.com

1.3 Copyright and trademark

Copyright Cyfex AG 2013. All rights reserved.

TrademarkMicrosoft and Windows 7 are registered trademarks.

Windows is a trademark of the Microsoft Corporation.

All other trademarks are the property of their respective holders.

2 General information

2.1 General safety information

Only use original software!

Only use original software or software which has been released by Cyfex.

Software and software components must not be installed using incorrect data.

Check whether Oracheck has been granted approval in your country. Do not use this product if an approval has not been granted.

Not for cancer diagnosis

OraCheck is not suitable for the analysis of any type of abscess or tumor.

OraCheck is not a substitute for conventional working methods.

Measurements taken with OraCheck should not be used alone in establishing a diagnosis but should be used together with conventional methods of diagnosis.

Please refer to chapter regarding the intended use of the software.

2.2 Manual Structure

2.2.1 Identification of risk levels

To prevent personal injury and material damage please observe the listed warnings and safety information. The following are indicated in particular:

Possible dangerous situation which could lead to minor personal injury, e.g. damage to or loss of tooth.

🚹 CAUTION

Dangerous situation which could lead to serious injury.

2.2.2 Formatting and symbols used

The formatting and symbols used in this document have the following meaning:

 Requirement First step Second step 	Requires that you carry out a function
or	
➤ Alternative operation ♥ Result	
Order/Menu item	Buttons or menu items are re- presented in <i>italics</i> .
	Tip or note for assistance.

2.2.3 Conventions

Example	Meaning
Clicking	Pressing once and releasing the left mouse button or the left track ball button on the acquisition unit (or foot switch)
Double clicking	Pressing and releasing the left mouse button or trackball button on the acquisition unit (or foot switch) twice in quick succession.
Moving the mouse in one direction	On the acquisition unit: moving the trackball, where necessary while pressing the mouse button, in the appropriate direction.

2.2.4 Manual formats

You can access the manual at any time by clicking on the *Help* button.

This manual can also be found in pdf format in the installation directory or as a download on the product's website <u>www.oracheck.com</u>

This format is page-based and is therefore suited to the printing of desired pages.

2.2.5 File formats

It is possible to assign each patient to one or more cases in the software. Depending on processing status, a case comprises virtual models and the overlays carried out by them.

When exporting a case as a file the software uses its own file format (*.oc). This format contains all data relating to the case including patient information. OC files can be opened with other OraCheck software installations. It is possible that older software versions will not open data exports from a current version.

2.2.6 Supported Sirona products

OraCheck 2.1 supports the following Sirona products:

CEREC 4.2.4 (or newer) with OmniCam or BlueCam

inLab 4.2.4 (or newer) with OmniCam or BlueCam

CEREC Ortho 1.1 (or newer) with OmniCam or BlueCam

The following problems could arise when using older CEREC versions or older CEREC images:

- Incomplete transfer of the acquisition data from an image.
 However, this problem could possibly also occur in the CEREC 4.2.4 version.
- Acquisition problems with the OmniCam.
- OraCheck will not start from CEREC.

3 Application

3.1 Intended use

OraCheck is designed to measure three-dimensional change on virtual optical scans of gums and teeth on the computer. The changes could include:

- Movement of teeth
- Tilting of teeth
- Geometric changes to the surface of hard tooth tissue or gum

3.1.1 Medical indications

The OraCheck software is intended for the visual analysis and metric evaluation of changes to soft tissue, teeth and restoration work in conjunction with before, reference and after situations. Taking into account relevant medical indications, it incorporates the following functions:

Analysis of progression for gums and hard tooth tissue:

- Inflammation associated with gingivitis, periodontitis
- Gingival recession
- Plaque build-up/scale

Examining the success of a treatment with surgical interventions:

- Augmentations
- Soft tissue and recession covers
- Gingival shaping (Papillae)
- Periodontal surgical interventions

Examination/analysis of abrasion, erosion and integrity of the hard tooth tissue and restoration:

- Occlusal abrasions: including those from gnashing, bruxism, pressing and also physiological abrasion or abrasion caused by food
- Cuneiform defects: abrasion/loss of hard tooth tissue on the buccal, proximal or lingual surfaces and tooth brush abrasion
- Erosion: loss of hard tooth tissue caused by food or bulimia respectively
- Chips/fractures of small enamel/dentin fragments
- Examination of abrasion or chips on tooth restorations

Examination of hard tooth tissue treatment and restoration:

- Volume and thickness measurement for preparations and examination of the abrasion
- Before and after comparisons for fillings and fissure sealing
- Examining the application of various composite and ceramic coatings
- Examination of coating strengths of structural work
- Examining the functional grinding of the occlusion, and the primary contacts (functional therapy)

Checking the progression of change in the tooth's position over time:

- Analysis of tooth movements and positions
- Changes in the soft tissue or indirect changes of the osseous structures (increase in growth, loss of growth)

3.1.2 Intended patient group

No limitations.

3.1.3 Profile of intended user

Qualified dentist

Dentist/student in training (university)

Assistant dentist (university or practice)

3.2 Limitations

🛕 CAUTION

OraCheck is not suitable for the analysis of any type of abscess or tumor.

Measurements taken with OraCheck should not be used alone in establishing a diagnosis but should be used together with conventional methods of diagnosis.



When importing images which were created with CEREC 4.2.4 (or older) with Omnicam, it is possible that the current date rather than the acquisition date will be shown.

Please check and correct this using the function *Edit case* for all image fields.

4 First steps



4.1 Installation

A prerequisite for proper installation is for one of the products mentioned in chapter to be installed on your system.

You have received an installation file for installation. Transfer this, for example using a USB stick, to the acquisition unit.

Double-click this file to start the setup program:



Installer: Welcome

The license terms must then be accepted:



Installer: License terms

The next step is to choose the installation folder and to decide whether the installer should create a desktop icon:

B OraCheck Setup
Destination Folder Click Next to install to the default folder or click Change to choose another.
Install OraCheck to:
C:\Program Files\Cyfex AG\OraCheck\
Change
✓ Create desktop shortcut
Back Next Cancel

Installer: Destination folder

Now all compatible host applications will be listed. OraCheck will be installed for all existing host applications as standard. Here, individual host applications found can be excluded:

B OraCheck Setup		
Select products Please choose the produc	ts that should use the OraCheo	ck app.
	Add >> << Remove	CEREC SW 4.2 (4.2.4)
	Back	Next Cancel

Installer: host applications (example)

After a final question asking if you are sure you want to install OraCheck, all necessary files will be installed automatically:



Installer: Question

Once the installation is complete, you will be informed that it has been installed successfully.



Installer: Complete

4.2 Uninstall software

OracCheck is uninstalled via Windows There is no integrated uninstall assistant:

Control Panel	All Control Panel Items Programs and Features		+ Search	Programs and F	eatures	
Control Panel Home View installed updates	Uninstall or change a program To uninstall a program, select it from the list and th	en click Uninstall, Change, or Repair.				
Tum Windows features on or off	Organize 🛩 Uninstall Repair)H •	,
	Name	Publisher	Installed On	Size	Version	
	Notepad++	Notepad++ Team	08.08.2013		6.4.3	
	NVIDIA 3D Vision Controller Driver 301.34	NVIDIA Corporation	18.05.2012		301.34	
	NVIDIA 3D Vision Driver 311.06	NVIDIA Corporation	16.04.2013		311.06	
	NVIDIA Graphics Driver 311.06	NVIDIA Corporation	16.04.2013		311.06	
	SNVIDIA HD Audio Driver 1.3.16.0	NVIDIA Corporation	23.08.2012		1.3.16.0	
	NVIDIA PhysX System Software 9.12.0213	NVIDIA Corporation	18.05.2012		9.12.0213	
	SNVIDIA Update 1.11.3	NVIDIA Corporation	16.04.2013		1.11.3	
	OpenOffice.org 3.4.1	Apache Software Foundation	07.01.2013	331 MB	3.41.9593	
	C OraCheck	Cyfex AG	06.02.2014	232 MB	2.0.3312	
	Gracle VM VirtualBox 4.2.6	Oracle Corporation	07.01.2013	132 MB	4.2.6	
	prepCheck	SIRONA Dental Systems GmbH	16.01.2014	229 MB	1.0.2480	
	Prerequisites for SSDT	Microsoft Corporation	31.05.2013	6.36 MB	11.0.2100.60	
	@ QuickTime	Apple Inc.	03.06.2013	74.6 MB	7.74.80.86	
	343 Realtek Ethernet Controller Driver	Realtek	27.09.2013		7.75.827.2013	
	Kealtek High Definition Audio Driver	Realtek Semiconductor Corp.	16.05.2012		6.0.1.6543	
	Search Protect	Conduit	06.03.2014		2.11.11.7	
	SelectionLinks	SelectionLinks	07.06.2013		1.0	
	Skype Click to Call	Microsoft Corporation	14.03.2014	26.7 MB	7.1.15383.6004	
	3 Skype** 6.14	Skype Technologies S.A.	07.03.2014	25.1 MB	6.14.104	
	E Snoop	Cory Plotts	11.06.2013	1.23 MB	2.8.0	
	-D Sparx Systems Keystore Service	Sparx Systems Pty Ltd	16.09.2013	2.10 MB	2.0.0.10	

Uninstalling

4.3 Copy protection

The software can only be started when the USB license stick is inserted. The USB license stick is supplied with the CEREC acquisition unit.

Authorization to use OraCheck is installed as an electronic license on the USB license stick. In addition, the 25 digit license key must be entered.



If you do not have a valid license for OraCheck you will not be able to export from CEREC to OraCheck. Furthermore, you will only be able to start OraCheck from the desktop icon and not from CEREC. In this case, only loadable demonstration examples and no CEREC acquisitions will be accessible.

The license key is available directly from Cyfex AG and not from the supplier. For this please contact sales@cyfex.com direct.

After updating the software you may need a new license which is not on your USB license stick. Further information is contained in section 0.

4.4 Service packs and upgrades

Information relating to future OraCheck service packs and upgrades can be found at <u>www.oracheck.com</u>.

4.5 CEREC updates and upgrades

When a CEREC update or upgrade is installed, portions of OraCheck will be also be removed by the CEREC installation program. After an upgrade to a newer version of CEREC it is therefore advisable to reinstall OraCheck as described in chapter 4.

5 The user interface



А	System menu	В	Phase bar	С	Page palette
D	Object bar	E	Main window	F	Tool wheel

Overview of the user interface

5.1 System menu



The following actions can be performed in the system menu:

- Save case
- Export case
- Import case
- Open license manager
- Configure software
- Change window mode
- Retrieve software information
- Close the software

5.1.1 Opening the system menu

J

The system menu is opened as follows:

- Move the mouse arrow to the upper edge of the window or
- click on the Start window button represented by an orange arrow as shown on the left.
 - ✤ The system menu is displayed.

5.1.2 Closing the system menu

- Click on the System menu button
- or
- right click with the mouse in the main window.
 - \clubsuit The system menu is closed.

5.1.3 Saving the case

This dialog allows you to save the current case.

- Select *Save case* from the system menu.
 - ✤ The current processing status of the case is saved.

5.1.4 Exporting the case

A case can be saved at any point in the OraCheck format *.oc.



- ✓ A case has been opened in the software.
- 1. Click on the *Export button in the system menu*.
 - ✤ The dialog box *Export case* opens.
- 2. Select the folder into which you would like to export the file.
- 3. Assign the case a name.
- 4. Click on the *Save* button.
 - ✤ The case will be exported as an OC file.

If you would like to transfer the case to another PC you can use a USB stick or a network drive for this purpose.

5.1.5 Importing a case



A case's OC or STL file is located on the acquisition unit or connected data carrier.

- 1. Click the *Import case* button in the system menu.
 - ✤ The Import case dialog box opens.
- 2. Select the folder in which the case is located.
- 3. Select one or more files.



- 4. Click the Open button
 - b The optical impression is imported and opened.



STL and OC files can currently be imported. When importing STL files, it is necessary to manually complete the patient information.

5.1.6 License manager

The license manager is used for the installation of new software licenses on the USB license stick. To do this, start the license manager via the system menu and follow the instructions on the screen. The license certificate with 25-digit license key which you received from Cyfex AG should be kept ready.

You can also start the license manager directly in Windows via Start/All Programs/Sirona Dental Systems/CEREC/Tools/License-Manager or via the corresponding icon on the desktop.



To activate the license you must have an Internet connection and the USB license stick must be inserted.

If the CEREC AC itself does not have an Internet connection, the activation may also be carried out on another PC with an available Internet connection.

For this purpose, the USB stick must be removed from the CEREC AC and inserted into the PC with the Internet connection. The USB stick is located behind the lower cover cap on the rear of the CEREC AC.

Install the license manager on the PC with Internet connection and carry out the license update there. For the steps on how to install the license manager please see the CEREC user manual.

License and code libraries

Further information on licenses and code libraries of third party providers can be found in the file *license.pdf*. The file can be found by default in the OraCheck installation directory under *C:/Program Files/Cyfex AG/OraCheck*

5.1.7 Configuration



The *configuration* menu opens the sub-menu *Settings* in which two settings can be performed

- Warning notices
- Language

5.1.7.1 Reset warning messages

Here, all warning messages can be reset. Each warning message deactivated manually on request is once again displayed.

5.1.7.2 Select language

Here you can set the language of the software. After rebooting the software your chosen language is set.

Possible options are English, German, French and Italian.

5.1.8 Window mode



The full screen mode can be switched on or off via the function *Window mode*.

5.1.9 About

The function *About* provides information on the current program version.



5.1.10 Exit

With one click on *Exit* you can close the software.

5.1.11 Help

One click on the *Help* button calls up this manual.

5.2 Side panel

Depending on the current phase, different functions are offered in the side panel. The side panel is available in the ANALYSIS and ARRAN-GEMENT phase.



ments



5.2.1 View options

You can use the *View Options* button to display six predefined views. In keeping with CEREC, the views in OraCheck correspond to the view of the dentist, not that of the patient.

- Above/below
- Right/left
- Front/back

5.2.1.1 Change view

- 1. Click on the View Options button.
- 2. Click on one of the available views.
 - ✤ The virtual model rotates to the corresponding view.

5.2.1.2 Resizing the view

Click on the View Options button.

- 3. Position the mouse pointer over the center tooth icon and press and hold the left mouse button.
 - The icon then changes to a magnifying glass.
- 4. Pull the mouse button up or down
 - ✤ The virtual model is enlarged or reduced.



You can also use the mouse scroll wheel to enlarge or reduce the view.

5.2.2 Tools

Different tools are available depending on the phase.

ARRANGEMENT tools: see also chapter 7



ANALYSIS tools: see also chapter 8





These tools are available in the page palette but also in the tool wheel. Further information on the tool wheel can be found in the section Tool wheel (page 37).

All tools can be found in the sub-menu under Tools.

5.2.3 Display objects

5.2.3.1 Selected



When the button is *selected* the selected model can be displayed or hidden and the transparency of the model can also be adapted.



The selected model is seen highlighted in yellow in the object bar and displayed in white text (the follow-up model in the example on the right). To display or hide the selected model, perform the following:

- 1. Click on the Display objects button.
- 2. Click on the Selected button.
 - The selected model is displayed or hidden (green dot is switched on or off).



Selected

Not selected

Please do not confuse the indicator (green dot) on the *Selected/Not selected* button with the similar indicator from the object bar in the ARRANGEMENT PHASE.

5.2.3.2 Not selected

When the button is *not selected* the selected model can be displayed or hidden and the transparency of the model can also be adapted.

The model not selected is displayed in black text without highlighting. To display or hide this model, follow the instructions as described in :

- 1. Click on the Display options button.
- 2. Click on the Not selected button.
 - ✤ The model not selected is displayed or hidden.

5.2.3.3 Set Transparency



You can set the transparency of both models with continuous adjustment.

- 1. Click on the Display objects button.
- 2. Click on the model icons of the selected (or not selected) model on which you would like to change the transparency.
- 3. Position the mouse over the corresponding button and press and hold the left mouse button while moving the mouse up or down.

✤ The transparency of the selected model is changed.

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By double-clicking on the model or the background or by pressing the space bar you can switch back and forth between the selected and not selected model.

With the help of the green dot in the model icons you can see if each model is currently displayed (dot is filled in green) or not.

5.2.3.4 Region



The Region button enables the transparency of the earmarked regions to be switched on and off as well as adjusted. This is helpful if, for example, the regions are to be set according to the color model. Depending on active phase, the visibility of the region for the overlay (ARRANGEMENT phase) or the region of analysis (ANALYSIS phase) is changed.

- 1. Click on the *Region* button.
- 2. Press and hold the left mouse button while moving the mouse up or down.

The transparency of the region will change.



By making a single click on the button, the visualization of the region can be switched on and off.

The *region* button refers to the visibility of all displayed models.

The *region* button under the menu item *display objects* in the page palette is identical to the transparency button under the menu item *tools/region*.

5.2.3.5 Color model



Using the *color model* button, the color (texture) of the model presentation can be displayed or hidden.

If no color information is available, for example because the model was imported with a Blue-Cam or using STL import, this button will be grayed out.

If the color model is switched on, the follow-up and baseline can no longer be distinguished from one another with the surface color. The transparency setting corrects the model not selected. The selected model can be identified in the object bar.

5.2.4 Analysis tools



By clicking the Analysis tools button you have the option to carry out the following analysis functions.

- Cursor details
- Span distance ٠

5.2.4.1 Cursor details

A tool is activated with the Cursor details button, which allows the surface distance between the follow-up and baseline to be measured point-wise.



Cursor details for calculating the cursor distance and the local area of the region.

The corresponding measurement values are displayed next to the cursor. The area of the region above which the cursor is located is also displayed.

- 3. Click on the Analysis tools button.
- 4. Click on the cursor details button.
 - ✤ The distance between follow-up and baseline model is displayed on the mouse cursor and also visualized in real time with an orange arrow.
 - ✤ Should the cursor be located over a region, the area of the region will additionally be shown in mm².





Distance direction

Tip: Simply by clicking the left mouse button, in addition to the orange arrow, a red arrow is placed which can be removed again with the right mouse button.



The sign in front of the distance readout indicates whether it is a matter of an increase in material or a decrease. If the surface of the follow-up model lies above the surface of the baseline acquisition then the distance is positive, otherwise it is negative. The direction of the material increase or decrease is additionally displayed by the direction of the indicated arrow.

5.2.4.2 Span distance

Distance measurements on the surface can also be taken manually via the *Span distance* button:

- 1. Click the Analysis tools button.
- 2. Click the Span distance button.
- 3. Click on the models to set the start and end points.

✤ The span distance will be indicated.

5.3 Phase bar



Phase bar with activated ARRANGEMENT phase

The work flow of the software is divided into 3 phases:

- ADMINISTRATION
- ARRANGEMENT
- ANALYSIS

The current phase is displayed in the phase bar with a yellow background (e.g. the ARRANGEMENT phase above).

Tip: you can jump back at any time to already completed phases with one click on the phase bar.

The following three chapters describe the three work phases.



5.4 Object bar

The model selection buttons can be found in the object bar. The object bar is available in the ARRANGEMENT and ANALYSIS phases.

The oldest model is marked as *Baseline* and the other as *Follow-up* based on the time of the acquisition. You can jump back and forth between the models by clicking on each relevant model in the object bar.



Example of a tilt analysis

Alternatively you can also switch between *Baseline* and *Follow-up* by double-clicking on the left mouse button in the main window or pressing the space bar.

If you wish to interchange *Follow-up* model and *Baseline model* you can switch to the ADMINISTRATION phase and edit the case. As the new designated *baseline* model, assign it the oldest date of the case. After saving the change, this model will be used as the *Baseline* in the future.



WARNING: This method is only recommended in exceptional circumstances as there is a danger of losing track of when the individual models were scanned.

6 Administration phase

In the ADMINISTRATION phase the following can be performed:

- Edit information about the patient
- Open saved cases for a patient
- Rearrange cases (combine)
- Edit cases
- Delete cases

Existing cases are displayed in this phase as per the patient database known from the CEREC software. For every saved case the existing models are displayed with date and time. Patient data can be edited, and cases no longer required may be deleted.



Patient administration

6.1 Editing a patient



Once a case is exported from CEREC to OraCheck, patient information such as name and date of birth is transferred in addition to the acquisition data. This ensures that a patient and their relevant cases can be found during the course of their treatment and that the patients can be distinguished from one another.

It should typically only be necessary to amend patient information in OraCheck in exceptional cases, e.g. if a patient name has been entered incorrectly into CEREC or if images were imported from STL files.

Clicking on the *Edit patient* button opens an input form in which *patient information* may be edited:

- Last name
- First name
- Date of birth
- Patient ID

• Dentist

Once the patient information has been entered such that all patients in the database can be clearly distinguished from one another, the line under the *Edit patient* button changes from red to green and the entry can be transferred.

6.2 Combining cases for analysis

This button is available in various versions:

- Add as a new case: save a case that has been imported from CE-REC as a separate case without combining this with another existing case in OraCheck.
- *Combine cases:* Combine a case imported from CEREC with an existing case in OraCheck.
- *Recombine case*: Combine two existing cases in OraCheck.

6.2.1 Add as a new case

The *Add as a new case* button is available when you have exported a case from CEREC to OraCheck or when an already existing case in OraCheck has been selected via *Recombine case* (see below). This can be identified by the case being highlighted in red. At the same time, no further case may be selected (highlighted yellow):

atient					Case	
ist Name	First Name	Patient ID	Dentist	Date of Birth	Baseline	Acquisition Date
De	John	123		22.12.1985	Cho.	Donnerstag, 23. Mai 2013 11:15
						Donnerstag, 23. Mai 2013 11:25
					OPPO	Donnerstag, 23. Mai 2013 11:35
						Dienstag, 12. Juli 2011 15:37
						Dienstag, 12. Juli 2011 15:41
Doe Jo	əhn 🔀					
			Add As N	lew 斗 O	pen Case 🕺	Delete Case

Saving floating case in red as a new case

When pressing the *add* as a new case button the red highlighted case will be saved to the hard drive as a new case and subsequently displayed with a yellow background.

6.2.2 Combining cases

This button is available when you have exported a case from CEREC to OraCheck or when an already existing case in OraCheck has been selected via *Recombine case* (see below). This can be identified by



the case being highlighted in red. At the same time, a further case must be selected (highlighted yellow):



Combine floating case in red with yellow case and save as new case

When pressing the *Combine cases* button, the case highlighted in red is combined with the selected case (highlighted in yellow) and saved to the hard drive as a new case. This new case contains all models of the previously imported red case and the selected yellow case.

atient					Case	
st Name	First Name	Patient ID	Dentist	Date of Birth	Baseline	Acquisition Date
e	John	123		22.12.1985	Dom	Donnerstag, 23. Mai 2013 11:15
						Donnerstag, 23. Mai 2013 11:25
					(SPA	Donnerstag, 23. Mai 2013 11:35
						Sonntag, 12. Januar 2014 15:41
Doe Joh	n 🔀					
		A PROPERTY				
	6	Edit Patient	Open Case	Ke Ke	compine Case	Edit Case

6.2.3 Recombining the case

The Recombine cases button allows cases to be duplicated to integrate them into another case.

This button is also available for combining cases with each other which have already previously been exported to OraCheck. It is visible provided that there is no floating case, i.e. there is no case highlighted in red.

Once this button is pressed, the currently selected case is copied to the drive, opened and displayed as a floating case highlighted in red.

You can then treat this case as if it had only just been imported from CEREC to OraCheck.

6.3 Opening the case

The *Open case* button opens the selected case for the current patient and switches to the ARRANGEMENT *phase*. If this case has already been analyzed, it will automatically switch to the ANALYSIS phase.

The same effect can be achieved by double clicking on the desired case.

6.4 Editing the case

The *Edit case* button allows a comment to be added to the selected case and for the date and time of the images to be changed. It can also be determined whether the image concerns the upper or lower jaw.

After pressing the *Edit case* button, by clicking the buttons << or >> between the input forms, a switch can be made between a general comment for all images and for the characteristics of each individual image.



Input forms for a comment on a case and for characteristics of one of two images of this case.

Should you wish to import images from older CEREC versions, it may be necessary to correct the acquisition times.

Warning

When importing images which were created with CEREC 4.2.4 (or older) together with Omnicam, the current date rather than the acquisition date may be shown.

Please check and correct this using the function *Edit case* for all image fields.





Changing the acquisition date can lead to the baseline acquisition and the follow-up acquisition being compared in the wrong order. This can in turn lead to distances being given with an incorrect sign (i.e. material increases are interpreted as decreases and vice versa).

Please only change the acquisition date if you are sure!

6.5 Deleting a case



By double-clicking on this button and subsequently confirming, a case including all models held is permanently deleted from the OraCheck database and from the hard drive.

The case is not deleted from the CEREC database and, where necessary, can be re-exported to OraCheck.

7 Arrangement phase

In this phase you can perform the following two tasks:

- Select models
- Set arrangement region (optional)

The following explains the two tasks in more detail.

7.1 Selecting the models

In this step, two models are selected from the object bar which are to be overlaid and subsequently analyzed.

Selected models are marked in green. In order to set two models as baseline and follow-up models, deselect all previously selected models in the object bar using a single click. It is then possible to select two other models in the same way.



The order in which the models are displayed in the object bar always corresponds to the temporal order of acquisition. The model captured earlier is always to be found on the left.

Models of both the upper and lower jaw can be found in the object bar; to reach the following ANALYSIS phase, two each of upper or lower jaws must be selected.

Once two models have been selected for analysis, a double-click switches to the 3D view or using the space bar switches between the two selected models; the text for the selected object is shown in white and the text of the remaining objects is in black.



To activate the inactive model it is not absolutely necessary to double-click on the desired model. This would have undesired side effects, for example for an activated region tool, because the region of the active model would also be changed here. Instead you can also change the active model by double-clicking on the background.

After selecting the baseline and follow-up models in the ARRANGEMENT phase, you can move to the ANALYSIS phase by clicking on the icon *Analysis* (in the phase bar).



If you are not able to switch to the ANALYSIS phase, check that on the one hand two models have been selected in the object bar and both display either upper or lower jaw.

If special regions have been selected in the ARRANGEMENT phase, as described below, then the selected areas will be used as reference for the overlay, otherwise the overlay will follow based on the complete model.

The following chapter describes how the arrangement regions can be set for the overlay.

7.2 Setting the arrangement region

Although an overlay can often also be calculated without overlay area details, depending on each patient case, the overlay area details may be necessary to obtain any usable results.

Before the overlay, the user must first calculate which areas of the captured models have remained constant between the acquisitions. These areas should be marked on at least one of the two models to be compared.

Next, the quality of the overlay should be checked visually. This can take place, for example, with the help of the distance analysis on the overlay regions.

7.2.1 Introduction

Defining the arrangement region serves the purpose of defining areas on the model which are to be used for the calculation of the overlay. This step is solely for help with analysis and should be used when the overlay of the acquisitions without region definition leads to undesired results. Background information on overlay can be found in section 10.1.4.



Using the **Region tool**, one or more areas can be selected on the selected model. The region can be expanded, reduced or reset. If the mouse cursor is exactly over the line, double-clicking enables the line to be edited with the mouse.

7.2.2 Purpose

If the *Region* tool is selected in the ARRANGEMENT phase, after selecting the *Baseline* model certain areas/regions can be marked on this model to serve as a reference for the overlay. The corresponding areas/regions can also subsequently be marked on the *Follow-up* model with the same tool.

The marking of individual areas in the ARRANGEMENT phase is most helpful in situations in which the two models to be overlaid exhibit large deviations, yet both models have certain identical areas.

Example An adjustment to the front of the upper jaw with anchoring on the premolars and molars. Here it would be wise to mark the anchor teeth on both models as a region as these areas should be virtually unchanged on both models. An automatic overlay of both models without region definition could otherwise lead to problems on the correct overlay.

However, in most cases a selection of areas in the ARRANGEMENT phase is rarely necessary because the OraCheck software overlays automatically with precision.

You can enlarge or reduce the diameter of the selection area if, while pressing and holding the right mouse button, you move the cursor up (enlarge) or down (reduce) on the model to be marked.



Enlarging and reducing the diameter of the region with the right mouse button

By double-clicking on the line at the edge of the selection area (cursor becomes a cross) the line can be edited just like the preparation margin in CEREC.



7.2.3 Defining region(s)

- **E**
- 1. You are now in the ARRANGEMENT phase and two models to be compared have been set in the object bar. Click the *Tools* button on the page palette.
 - ✤ The *Tools menu* opens
- 2. Click on the Region button.
 - ♥ The *Region* tool opens.
- 3. Click with the mouse on the *Expand* button to create a region for the overlay or to enlarge a region. Subsequently move the mouse cursor while holding down the mouse button over the model to define the region. While holding down the right mouse button, the size of the overlay region can be changed by moving the mouse up or down.



4. Click with the mouse on the *Reduce* button to reduce the region as above, or...

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- 5. Click with the mouse on the *Reset* button to delete the region on the active model.
- 6. Click with the mouse on the *Reset both regions* button to delete the region on the active and on the inactive model simultaneously.
- 7. If the overlay leads to an undesired result with the given region, to aid the overlay process a region can also be defined on the second of the two models which is to be overlaid onto the first model. By double-clicking on the background or pressing the space bar, switch to the other or both models and carry out the above steps once again.
 - The overlay region of one or both models is marked in color.
- 8. Switch the transparency of the regions on or off or change the level of transparency. This step is helpful if information is needed from the color model to define the regions.
- 9. Click the Exit button of the Region tool.
 - ✤ The *Region* tool is closed
- 10. You can now move into the ANALYSIS phase; the regions just selected will be used as reference for the overlay, or perform the overlay using the following overlay tool description.

7.3 Overlay



The overlay of both models is automatically performed when moving into the ANALYSIS phase. While defining the overlay regions, you may wish to test the overlay and check the effect of the overlay regions on the overlay; the overlay tool is used for this purpose.

Click on the *Overlay* tool to perform an overlay. The result of the overlay is subsequently displayed in the following form:



Registration	
The average distance of the foll	ow-up region to the bas
0.0mm < distance ≤ 0.1mm	80% (~474mm²)
0.1mm < distance ≤ 0.5mm	18% (~105mm²)
0.5mm < distance ≤ 1.0mm	0% (~2mm²)
1.0mm < distance	2% (~10mm²)
Discarded area:	1% (~3mm²)
🗇 Do not show this informatio	n again.

If the overlay features a major error, an exclamation mark will be shown in the dialog. In this case please check whether an improvement can be achieved in alignment of the overlay regions.

Registration The follow-up region could not be matched very well to the baseline geometry. The average distance is: 1.61mm						
					0.0mm < distance ≤ 0.1mm 0.1mm < distance ≤ 0.5mm 0.5mm < distance ≤ 1.0mm 1.0mm < distance	14% (~602mm²) 33% (~1376mm²) 19% (~816mm²) 22% (~940mm²)
					Discarded area:	11% (~467mm²)
Please consider this for the follo	wing analysis.					
	ок					



With the mouse, click on the *Reset* button to re-create the situation prior to the overlay.

7.4 Deleting a model

By clicking on the *Delete model* button the selected model is deleted. This function is explained in detail in chapter .

8 Analysis phase



Switching to the ANALYSIS phase is performed by clicking on the phase bar. In the ANALYSIS phase the baseline and follow-up models are overlaid and the chronological progression of changes on the surfaces can be analyzed with the available tools.

The quality of the overlay is shown in detail in an information or warning window (see also) and is then visible as an average distance of both models in the bottom right corner of the screen.

With one click on the *Tools* icon in the page palette the available tools can be opened.

Alternatively, the *Tool wheel* can be called up with a right-click in a clear section of the screen.

The following tools are available in the tools menu:

- Region
- Volume analysis
- Distance analysis
- Section view
- Tilt analysis
- Delete model

A detailed description of these tools can be found in the following sub -chapters.

8.1 Setting the analysis region



The *Region* tool is operated in the ANALYSIS phase and in the ARRANGE-MENT phase. Areas of the model can also be selected or deselected here by expanding, reducing or resetting.

In the ARRANGEMENT phase, the *Region* tool serves the purpose of defining regions which are used for calculating the overlay. For this, corresponding regions can be defined on the baseline and on the followup model. In contrast, in the ANALYSIS phase the regions are only determined on the follow-up model.

In the ANALYSIS phase the region area only serves to determine the *Color range* of the false color visualization and to set the area to calculate the *Volume analysis* or the *Tilt analysis*.

The method of defining a region in the ANALYSIS phase is almost identical to that in the ARRANGEMENT phase.

- ✓ You are in the ANALYSIS phase
- 1. Click on the *Tools* button on the page palette.
 - ♥ The Tools menu opens
- 2. Click on the Region button.
 - ✤ The *Region* tool opens



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4. Click with the mouse on the *Reduce* button to reduce the region, or...

3. Click with the mouse on the *Expand* button to create a region for

the Volume analysis or to enlarge a region, or...



- 5. Click with the mouse on the *Reset* button to delete the active region.
- Switch the transparency of the regions on or off or change the level of transparency. This step is helpful should you need to use information from the color model to define the regions.
 - 7. Click the *Exit* button of the *Region* tool.
 - 🔄 The *Region* tool is closed

8.2 Volume analysis

Using the volume tool, the volume difference between the baseline and the follow-up in the area of the analysis region can be calculated and indicated.

If you have not defined an area for the volume analysis with the *Region* tool, an error message will appear.





Error message for volume computaiton without region

The sign before a volume readout indicates whether it is a matter of an increase in material or a decrease. If the surface of the follow-up model lies mainly above the surface of the baseline acquisition then the volume is positive, otherwise it is negative. If negative and positi-





ve volume sections are being measured in the selected region, the sum of the volume sections with signs in front will be shown.

Example The measurement of, for example, the volume of a filling can be calculated as follows.



a) Baseline acquisition tooth 16



b) Follow-up acquisition tooth 16



c) Input of region for volume calculation d) Representation of the calculated solid

The output of the volume calculation measurement value takes place in the bottom right corner of the 3D main window.

8.2.1 Performing volume analysis

✓ You are in the ANALYSIS phase

Now determine a region, as described in **Fehler! Verweisquelle** onnte nicht gefunden werden.

- 1. Click the Tools button on the page palette.
 - ✤ The *Tools menu* opens.
- 2. Click on the Region button.
 - ✤ The *Region* tool opens
- 3. Click with the mouse on the *Expand* button to select a region for volume analysis, *Reduce* to reduce the area or *Reset* to delete the active region.
 - ✤ The analysis region is marked in color.
- 4. Click the *Exit* button of the *Region* tool.
 - ♥ The *Region* tool is closed
- 5. Click the Tools button on the page palette.
 - ⇔ The *Tools menu* opens.
- 6. Click on the Volume analysis button.

The volume analysis is performed for the region defined in step 3; the result is shown on the screen.

🚹 Warning

Avoid calculating the volume on marginal regions of the acquisitions. Both models must be exactly positioned on top of one another and must not exhibit any holes.

Check the solid in which you, for example, display the model with the *Display objects* tool or hide the model with the *Baseline* or *Follow-up* tool.

8.2.2 Exit volume analysis

- 1. Click the tool's *Exit* button.
 - ✤ The Volume analysis is closed

In place of the tool menu on the page palette, the *Tool wheel* can be called up by right-clicking in a clear area of the main window. The same tools are available here.

8.3 Distance analysis

The distances between the follow-up and baseline in the area of the analysis region can be calculated with the distance tool and displayed with the aid of a color scale. If no analysis region is given, the distance for the entire surface will be visualized.

The sensitivity for the positive (increase) and the negative (decrease) areas can be separately adjusted.

Distance

To adjust the sensitivity, move the mouse over the *Decrease* tool while pressing and holding the left mouse button If you move the mouse upwards, the sensitivity of the scale will increase accordingly and by moving it downwards it will decrease. Moving left or right decreases or increases the sensitivity in smaller increments.

Without a selecting a specific region, distance are shown for the entire surface of the model. However, you have the option, by selecting specific areas or regions (using the *Region* tool), to calculate and display only the distances of those areas or regions that are of interest to you.

This allows specific areas to be analyzed dependent on clinical questions wherein the entire available color space can be used.







a) Follow-up acquisition without region



b) Result of distance analysis without region



c) Input of region on tooth 47



d) Distance visualization on the molar



e) Expand the region to all molars



f) Distance visualization on all molars

Limiting the region for the distance visualization allows the use of the entire color area from red to blue for visualizing the region of interest.

Alternatively, specifying a region can be completely dispensed with and instead the color area as described above can be adjusted with the increase and decrease buttons such that the color scale e.g. is limited to distances of between -1 mm and +1 mm.

The distance analysis is performed as follows:

- ✓ You are in the ANALYSIS phase
- 1. Click the Tools button on the page palette.
 - ♥ The *Tools menu* opens.
- 2. Click on the Region button.

- ✤ The *Region* tool opens
- 3. Click with the mouse on the *Expand* button to select a region for volume analysis, *Reduce* to reduce the area or *Reset* to delete the active region.
 - ✤ The analysis region is marked in color.
- 4. Click the *Exit* button of the *Region* tool.
 - ✤ The *Region* tool is closed
- 5. Click the *Tools button on the page palette*.
 - Solution The Tools menu opens
- 6. Click on the Distance analysis button.
 - The distance analysis is performed for the region(s) defined in step 3; the result is displayed. If no region(s) has/have been set, the distance analysis is performed on the entire surface of the model.

Exiting the distance analysis:

1. Click the Distance analysis tool's Exit button

The tool is closed.

8.4 Section view

The section view offers the option to analyze differences between baseline and follow-up in a 2D section view.

This enables metric measurements between the overlaid models to be performed in the 2D view.



Section view

8.4.1 Perform section view

✓ You are in the ANALYSIS phase





- 1. Click the *Tools button on the page palette.*
 - ♥ The *Tools menu* opens.
- 2. Click on the Section view button.
 - ✤ The Section view tool opens.
- 3. Click with the mouse at the point where you would like to start the section and continue to hold down the left mouse button.
- 4. Create the section holding down the left mouse button.

The section is created and the section window is subsequently shown in the left area of the screen.

8.4.2 Measurements in the section window

You have the option to perform metric measurements in the section window:

- ✓ You are in the Section view.
- 1. Using the left mouse button, click in the section window onto the starting point of the measurement and continue to hold down the mouse button.
- 2. Move to the end point of the measurement while continuing to hold the left mouse button and then let go of the button.
 - The length of the segment will be displayed to the right underneath the mouse cursor.

🔥 WARNING

Note that the measurements in the section view do not necessarily represent the shortest distance between the two models.

Example: the two section planes *a* and *b* deliver differing lengths of segment section (red and green line) in the section view on account of their different orientations.



8.4.3 Exiting the section view

- Click the Section view tool's Exit button. \geq
 - ✤ The Section view tool is closed.

8.4.4 Setting the section planes

You have the option to adapt section planes with the control element of the section tool.





a) Slide the direction arrow of the control b) Click the end of the horizontal arrow to wheel while pressing the left mouse but- shift the section plane horizontally. ton. This allows the section plane to be shifted (b), rotated (c) or tilted horizontally.



c) To rotate the section view, click on the d) To tilt the section plane, click on the

vertical ends of the arrows on the control horizontal arrow on the ball and draw wheel while pressing the left mouse but- this into the desired section plane positon and draw the section into the desired tion while pressing the left mouse button. position. The extent of the rotation is displayed by the orange color area.

8.5 Tilt analysis

Using the tilt analysis, movements of specific regions can be analyzed. OraCheck calculates these movements, e.g. tooth movements, by overlaying the set region of the follow-up model with the baseline model for a second time.

The tilt and rotation is given in degrees and the movement of the center is given in millimeters. The rotation and tilt are calculated with reference to the center of the analysis region.

The movement is additionally visualized with arrows which go through the center of the analysis region.

All calculated angles and distances are displayed with a positive sign, therefore the displayed values must only be interpreted in conjunction with the arrows on the geometry.

The tilt analysis therefore supplies three numerical values which describe the tooth movements; in addition the overlay quality (confidence) is given:

8.5.1 Values obtained in the tilt analysis

8.5.1.1 Tilt

The tilt represents a rotation about an axis which lies directly on the occlusal plane.

The tilt is visualized by the two large arrows in the 3D view.

8.5.1.2 Rotation

This value corresponds to a rotation in the occlusal plane, i.e. about an axis orthogonal to the occlusal plane.

The rotation is visualized by two small arrows which emanate from the tip of the yellow arrow.

8.5.1.3 Movement

The movement is represented by the starting point of the two arrows which visualize the tilt.

8.5.1.4 Confidence

The confidence value describes the percentage share of the follow-up region which could be overlaid with the baseline model.







Example of a tilt analysis

Visualization of the tilt

8.5.1.5 Analyzing the tilt

- ✓ You are in the ANALYSIS phase
- 1. Click the Tools button on the page palette.
 - ✤ The *Tools menu* opens.
- 2. Click on the Region button.
 - ♥ The *Region* tool opens.
- 3. Select the *Expand* tool.
- 4. Mark the area to be analyzed
- 5. Click the Tools button on the page palette again.
 - ♥ The *Tools menu* opens.
- 6. Click on Tilt analysis
 - The tilt for the area just defined is analyzed and the result is displayed at the bottom right edge of the screen.

8.5.1.6 Delete model



By clicking on the *Delete model* button the selected model is deleted. The model is lost once the current configuration is saved. You will then automatically arrive in the ARRANGEMENT phase to select another model.

If you accidentally delete a model and you have not previously saved the case you will need to re-import the deleted case. To permanently removed a model from a case which has already been saved you will have to delete the model and then save the case again.

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Please note: if you would simply like to reset a selection area and not delete the model, you can perform this with the *Region* tool and the *Reset* button. This will reset all selected areas but will not delete any models.

9 OraCheck and CEREC

The following sub-chapters describe aspects of the cooperation between CEREC, inLab and other supported Sirona products and OraCheck. For reasons of simplicity, CEREC is written, where "CEREC" can be replaced by the supported product.

9.1 Registering OraCheck as an "app" in the CEREC software

To start OraCheck directly from CEREC, CEREC first needs to be configured accordingly. It is a requirement that OraCheck and CEREC (version 4.2.4 or newer) are already completely installed in the acquisition unit.



Open the System menu in the CEREC software.

Click on Applications in the Configuration sub menu

OraCheck Version: 2.10	
Software to support clinical monitoring of patient scans and treatments.	
More Information: http://www.sirona-connect.com/center/plugin/oracheck/?language=en-US	$\mathbf{\mathbf{N}}$
Use this App?	YES

Set the toggle switch so that Yes is visible.

OraCheck is now registered in the CEREC software as a new application.

9.2 Starting OraCheck from the CEREC software

Once OraCheck has been registered in the CEREC software, the application can be opened directly from CEREC.

However, a requirement for this is that a case with one or more existing models is open in CEREC and that the model axis has already been set.

For this, you should proceed as follows:



Click on *Perform application in the CEREC system menu*.



After one click on the OraCheck icon (shown here on the left) OraCheck starts and the existing case in the CEREC software is exported to OraCheck. All existing image catalogs relating to this case in CEREC are transferred to OraCheck.

You can now decide how you would like to continue processing the CEREC model data.

You have the following options:

- You can save the imported data as a new stand-alone case.
- You can add the imported data to an existing case with this patient name.
- You can add the imported data to a different patient of your choice.
- You can delete the imported data or a specific part of it.

When using CEREC 4.2.4 in conjunction with theOmnicam, after loading a *.rst patient file there is a possibility that the current rather than the acquisition date will be shown.

Please check and correct this in OraCheck using the function *Edit case* for all affected image fields.



If there is no case loaded in the CEREC software or if the model axis has not been defined in a loaded case, then the OraCheck symbol appears grayed out with an exclamation mark. OraCheck will not start. In order to start OraCheck, open a case in the CEREC software and define the model axis.

9.2.1 Combining models with earlier acquisitions

9.2.1.1 OraCheck is started and a case is opened

Provided that OraCheck is already started and a patient case is opened on import of acquisitions, a message appears asking if the imported case should be added to the opened case (see below). If you confirm this with *Yes*, both cases will be combined and the imported acquisitions will receive the *patient information* of the already existing case. OraCheck then switches automatically into the ARRANGE-MENT phase.



Message when an active case is open in OraCheck.

If you answer the question with *No* the open case in OraCheck is discarded. The patient data of the new case will then be compared to the patient data of earlier cases in OraCheck. If an earlier case with matching patient data is available, the corresponding patient is selected automatically and all of this patient's cases are displayed together in the right-hand area of the ADMINISTRATION page, see image below. The newly imported case appears as a "*floating case*" beneath the other acquisitions of the same patient. OraCheck remains in the ADMINISTRATION phase. By double-clicking on an already existing case you can combine it with the new case. By double-clicking on the *floating case* it is opened directly.

If no matching case can be found, the patient is newly created and you can save this case. Alternatively, you can also combine this patient with the data of another patient. This is particularly useful when patient data is not always collected in the same way or is not always complete, e.g. the date of birth of the patient is available on an earlier acquisition but is not displayed on the current acquisition.

The newly imported *floating case* is highlighted in red in the ADMI-NISTRATION phase, cf. image below. If the name of the patient is also not available this is highlighted in red too.

		ADMINIS	TRATION	ARI	RANGEMENT	ANALYSES	OraCheck	
Patient					Case			
ast Name	First Name	Patient ID	Dentist	Date of Birth	Baseline	Acquisition Date		
loe	John	123		22.12.1985		Donnerstag, 23. Mai 2013 11:15		
					COSC	Donnerstag, 23. Mai 2013 11:25		
					-	Donnerstag, 23. Mai 2013 11:35		
						Dienstag, 12. Juli 2011 15:37		
						Dienstag, 12. Juli 2011 15:41		
Doe Joh	n 💌							
	~							
			Combine	e Case 🥮 Ol	pen Case	Delete Case		

New acquisitions for the patient "Hans Muster" added as a new case (highlighted red) and combined with the existing acquisitions (highlighted yellow).

Provided that cases are combined, a copy of the existing case is generated to guard against accidental loss of data.

When using CEREC 4.2.4 (or older) in conjunction with the Omnicam, after loading a *.rst patient file there is a possibility that the current rather than the acquisition date will be shown.

Please check and correct this using the function Edit case

If you answer the above-given question with *Cancel*, the data transfer is stopped and you have the option to save the case already open in OraCheck.

9.2.1.2 OraCheck is not started and no case is yet open

Provided that OraCheck has not been started it will now be started via CEREC and the acquisitions transferred. OraCheck is then in the ADMINISTRATION phase. If available, the appropriate patient is already preselected, otherwise a new patient is created.

10 FAQ

10.1 Overlay

10.1.1 Why are my models not being correctly overlaid?

If models are incorrectly overlaid, follow this procedure:

In the ARRANGEMENT phase, check if areas might have been selected which could impede a proper overlay (e.g. tooth 21 on baseline model and 11 on follow-up model).

To reset all selected regions, use for instance the *Region* tool option *Reset regions on both models*. This deletes a region which has already been determined **for the baseline and for the follow-up model**. Then mark identical areas on both models or allow OraCheck to perform the overlay fully automatically (without selecting any regions).

Example of an incorrect overlay.

10.1.2 Do models in the CEREC software need to be trimmed before exporting to OraCheck?

A possible trimming of the model geometry performed in CEREC has no bearing on the model exported from CEREC to OraCheck.

10.1.3 Why do models need to be oriented in advance in the CEREC software?

If the models in CEREC have not been correctly oriented, this incorrect orientation only has an influence on the view options. If the model has been turned upside down during orientation the *Top* view option correspondingly shows the model from the bottom rather than from the top.

The prior orientation of the models in the *Set model axis* area of the CEREC software before transfer to OraCheck has no bearing on the overlay of the two models.

10.1.4 What process is followed to overlay the models?

The models are overlaid incrementally in a process which overlays the two models: From each point on the virtual follow-up model, the nearest point on the baseline models is sought and the intervals are calculated. The follow-up model is then moved and rotated such that these intervals are minimized. This combination of finding the next point and minimizing intervals is repeated until no further improvements can be achieved. From a mathematical standpoint a cost function is defined as a measurement for the approximation of the two models which is generally made up of the sum of the individual quadratic intervals, comparable to variance or standard deviation. By minimizing this measurement the models achieve the best possible approximation.

When calculating the intervals, errors can however result from real measurement data, which on the one hand arise from false detection of the next neighboring point. These discrepancies arise particularly in regions in which both models differ. In addition, these situations commonly occur at the margins of model regions which differ in size or in areas in which two regions lie close to one another (e.g. approximal regions). On the other hand, in the model there could already be acquisition errors or errors from the data processing which in turn generate erroneous interval readings. To avoid these errors leading to a substandard overlay, a certain proportion of the highest deviations are discounted for the overlay.

The following rules can be derived from this:

Rule 1: If a significant proportion of the overlay regions have remained unchanged between the baseline and the follow-up model, the acquisitions can be clearly correlated even if individual areas have changed significantly (e.g. through orthodontic means).

Rule 2: If the overlay is to be performed on the basis of a smaller region which has only been determined on one of the two models, it is possible that the overlay will fail. This is because this small region of the one model may have several fitting overlay points which could correlate with the other model. Even if only one of the points matches exactly with the small region, it is possible that, due to the incremental process, the overlay calculates a local optimum at the wrong point on the model. This problem can be circumvented either by using large regions or determining regions on both models.

Rule 3: The most reliable way to achieve a good overlay is to define the largest possible overlay area on both models.

11 Declaration of conformity

DECLARATION OF CONFC	DRMITY / DICHIARAZIONE DI CONFORMITA
Name und Adresse der Firma Nom et adresse de l'entreprise Nome e indirizzo della ditta Name and address of the firm	Cyfex AG Siewerdtstrasse 8 8050 Zürich Schweiz
Wir erklären in alleiniger Verantwortung, dass / Dichiariamo sotto nostra responsabilità che / We	Nous déclarons sous notre propre responsabilité que / e declare under our sole responsibility that
das Medizinprodukt le dispositif médical the medical device il dispositivo medico	OraCheck Version 2.1
	Bezeichnung, Typ oder Modell, Chargen- oder Seriennummer, ev. Herkunft und Stü Nom, type ou modöle, numéro de lot ou série, év. source et nombre d'exemplaires Nome, tipo o modello, numero di lotto o si serie, ev. fonte e numero di esemplariN type or model, batch or serial number, possibly sources and number of items
der Klasse / de la classe / della classe / of class	I (ohne Messfunktion gem. MEDDEV 2. 1/5)
	Nach Anhang IX der Richtlinie 93/43/EWG / selon l'annexe IX de la directive 93/42/ secondo l'allegato IX della direttiva 93/24/CEE / according to annex IX of direct. 93/
allen Anforderungen der Medizinprodukte-Richt remplit toutes les exigences de la directive sur le / soddisfa tutte le disposizioni della direttiva 93/ provisions of the directive 93/42/EEC (or 90/385	linie 93/42/EWG (od. 90/385/EWG) entspricht, die anwendbar : es dispositifs médicaux 93/42/CEE (ou 90/385/CEE) qui le concer 42/CEE (opure 90/385/CEE) che lo riguardano / meets all the /EEC) which apply to it.
Angewandte harmonisierte Normen, natio-	EN 62304:2006 (SW Lebenszyklus Prozesse)
nale Normen oder andere normative Dokumente	EN ISO 13485:2012 (Qualitätsmanagement)
Normes harmonisées, normes nationales et autres documents normatifs appliqués	EN ISO 14971:2012 (Risikomanagement) EN 62366:2008 (Gebrauchstauglichkeit)
Norme armonizzate o nazionali applicate, altri documenti normativi applicati	
Applied harmonised standards, national standards or other normative documents	
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	EG-Konformitätserklärung (MDD Annex VII)
Konformitätsbewertungsstelle (falls beigezogen) Organe resp. de l'évaluat. de la conformité (si cons Organo incaric. della valutaz. della conform. (se co Notified Body (if consulted)	keine sulté) onsultato)
Zürich, 19.08.2015	Dr. R. Koch, Geschäftsführer
Ort, Datum / Lieu, date / Luogo, data / Place, dat	te Name und Funktion / Nom et fonction / Nome e funzione / Name and function

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