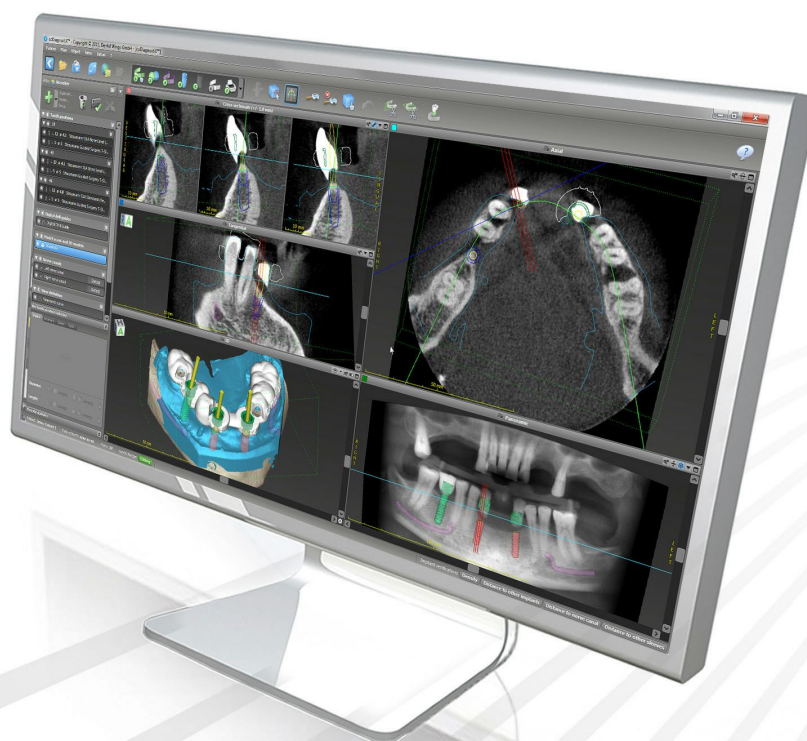


coDiagnostiX™ 9

INSTRUCTIONS FOR USE



Important! Keep this document for future reference.

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1. ABOUT THIS GUIDE

These Instructions for Use are valid for the [product life cycle](#) of coDiagnostiX 9 unless new instructions are published within this period.

These Instructions for Use contain important information for the safe and appropriate use of coDiagnostiX. Make sure to have read and understood this document prior to working with the software. In case of questions, contact the manufacturer. Please keep this document for future reference.

Electronic Instructions for Use

coDiagnostiX 9 Instructions for Use are provided in electronic form. A paper version can be requested from the manufacturer. For further information and contact details see: <http://codiagnostix.com/ifu>

1.1 Disclaimer

coDiagnostiX software is designed for use by persons who have appropriate knowledge in implantology and surgical dentistry. To run the software, users must also have basic skills in operating a computer.

The user of coDiagnostiX is solely responsible for determining whether or not any product or treatment is suitable for a particular patient and circumstances. The user of coDiagnostiX is solely responsible for the correctness, completeness and adequacy of all data entered into coDiagnostiX software. The user has to check the correctness and accuracy of planning with coDiagnostiX software and to assess each individual case.

Correct dimensioning of the drill guide, the selection of appropriate material and an appropriate and calibrated 3D manufacturing system as well as the correct fabrication of scan templates and drill guides lie within the sole responsibility of the user.

coDiagnostiX is not intended to be used in direct contact with the patient or with life-sustaining devices.

Dental Wings products must be used in accordance with their accompanying instructions for use. Improper use or handling of Dental Wings products will void the warranty, if any, given for Dental Wings products. If you require additional information on the proper use of Dental Wings products, contact your local distributor. The user is not allowed to modify Dental Wings products.

DENTAL WINGS GMBH, ITS AFFILIATES OR DISTRIBUTORS DISCLAIM REPRESENTATIONS AND WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE PRODUCTS, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ERROR-FREE OPERATION OR NON-INFRINGEMENT, AND THE PRODUCTS ARE SOLD "AS IS".

Our maximum liability arising out of the products or their use, whether based upon warranty, contract, tort or otherwise, shall not exceed the actual payments received by us in respect of the purchase price thereof. In no event shall we be liable for special, incidental or consequential damages, including, but not limited to, loss of profits, loss of data or loss of use damages, arising hereunder or from the sale of the products.

Please note that coDiagnostiX software is subject to change. The user is obliged to study the latest developments of coDiagnostiX regularly.

Product life cycle

The product life cycle of coDiagnostiX software is 3 years. After expiration of this time, the software may continue to function properly as long as configuration or hardware are not modified and a valid license maintained. However, as legal and regulatory requirements change at regular intervals, the legal manufacturer does not ensure compliance with the regulatory framework beyond the product life cycle period of 3 years. To maintain regulatory compliance, update your software regularly. Please note, that the actual use of coDiagnostiX is subject to your compliance with our license framework.

Input data

The performance of coDiagnostiX depends on the quality and accuracy of the (CB)CT scan as well as the model scan imported. The user is solely responsible to ensure that the quality of the imported data is sufficient for proper performance of coDiagnostiX. Relevant anatomical structures must be visible in the above scans. (CB)CT devices have to comply with the recommendations of ICRP97 (International Commission on Radiological Protection).

Third party products and product data

When planning patient cases with coDiagnostiX and during the practical implementation of such planning the user may work with third party products and/or product data. Dental Wings GmbH, its subsidiaries, or distribution partners disclaim any liability for damages in connection with or arising from such third party product data or products being used within this scope.

1.2 License, trademarks and copyright

coDiagnostiX license

coDiagnostiX software is protected by a License Agreement and may be used or copied only in accordance with the terms of this agreement. It is illegal to copy or use coDiagnostiX software on any medium except those permitted in the License Agreement.

Some of the features offered by coDiagnostiX may require an additional license on your dongle. Contact your local distributor for more information.

Availability

Some of the products mentioned in this guide may not be available in all countries.

Third-party software

coDiagnostiX software contains code from third-parties which is provided under specific licenses:

- Open Source Computer Vision Library (3-Clause BSD License)
- Omni Thread Library (3-Clause BSD License)
- Eigen (Mozilla Public License 2.0)

License conditions are available within coDiagnostiX. Open the **Help (?)** menu and select **About > Trademarks and 3rd party licenses** to display them.

Trade names and trademarks

Dental Wings, DWOS and coDiagnostiX are trademarks or registered trademarks of Dental Wings. Straumann and CARES are registered trademarks of Straumann Holding AG, Switzerland.

Microsoft and Windows are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries.

Macintosh, Mac, Mac OS and iPad are trademarks of Apple Inc., registered in the U.S. and other countries.

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Copyright

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2. INTRODUCTION AND OVERVIEW

2.1 Intended use

coDiagnostiX is intended to be used as preoperative planning software for dental implant placement.

2.2 Device description and features

coDiagnostiX is a planning software for virtual positioning of dental implants taking into account the patient's anatomical structures and future prosthetic needs. coDiagnostiX can import and process 3D (CB)CT scan data (DICOM standard) and model scan data and export planning and design data for the production of drill guides.

The Declaration of Conformity for coDiagnostiX is available through our eIFU website at: <http://codiagnostix.com/ifu>

2.2.1 Device variants and configuration

coDiagnostiX is available in a producer and a client version.

The client can export digital drill guide and virtual planning data only through a coDiagnostiX producer version.

coDiagnostiX is an open software system. The library contains implant, abutment and sleeve systems from a large number of manufacturers.

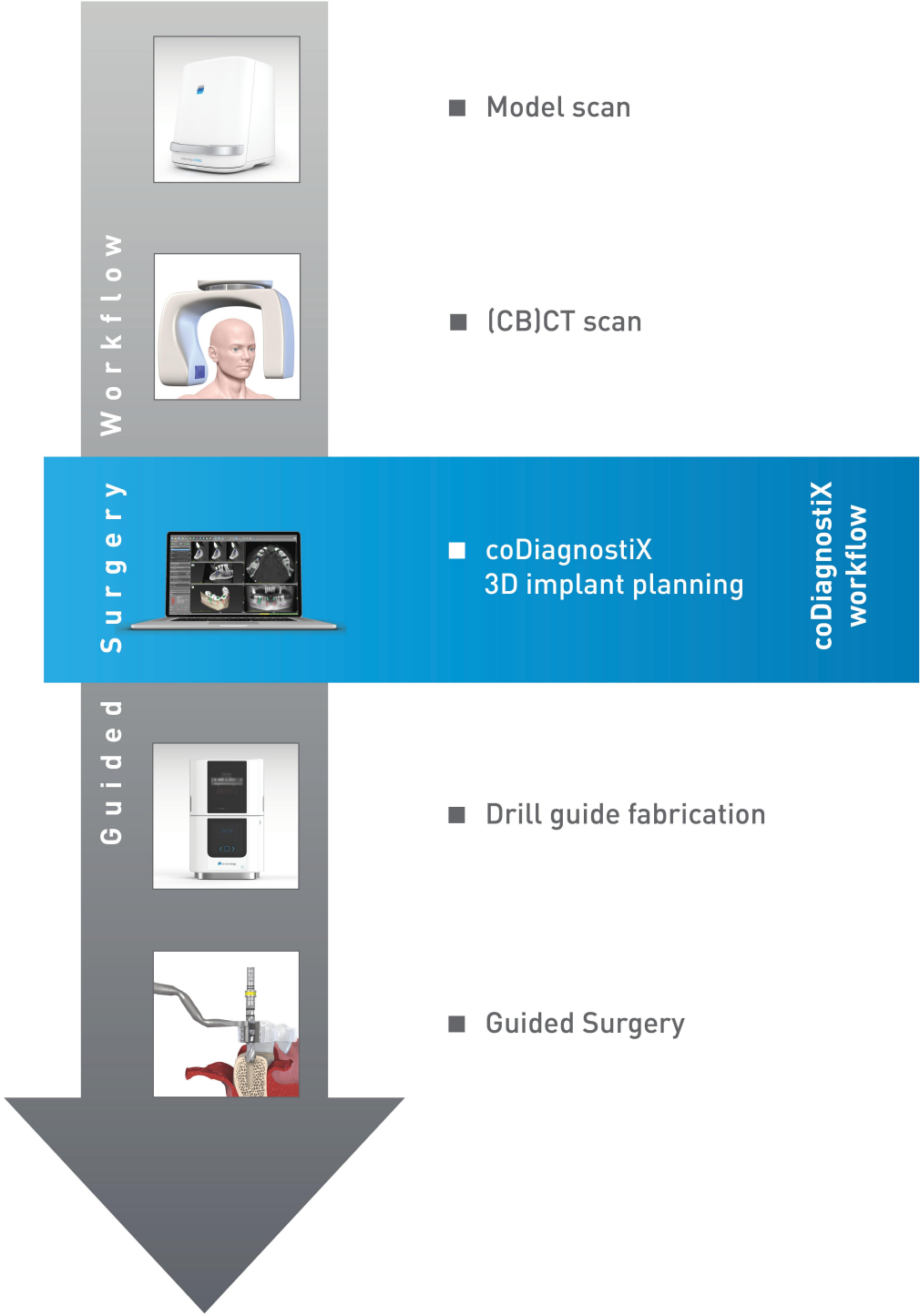
2.2.2 Principles of operation

Implant planning with coDiagnostiX is based on a patient's medical image data such as CT (Computed Tomography) or CBCT (Cone-Beam Computed Tomography) that are processed by coDiagnostiX after being transferred via CD/DVD, network or various other storage media. Planning is performed by the calculation of several views (such as virtual OPG or a three-dimensional reconstruction of the image dataset), by the analysis of the image data and the placement of implants, abutments and sleeves. Planning data are used for designing drill guides which can be exported as manufacturing information. The drill guide which directs the implant and the instruments during implant insertion transfers the virtual implant position from the computer to the patient's anatomy.

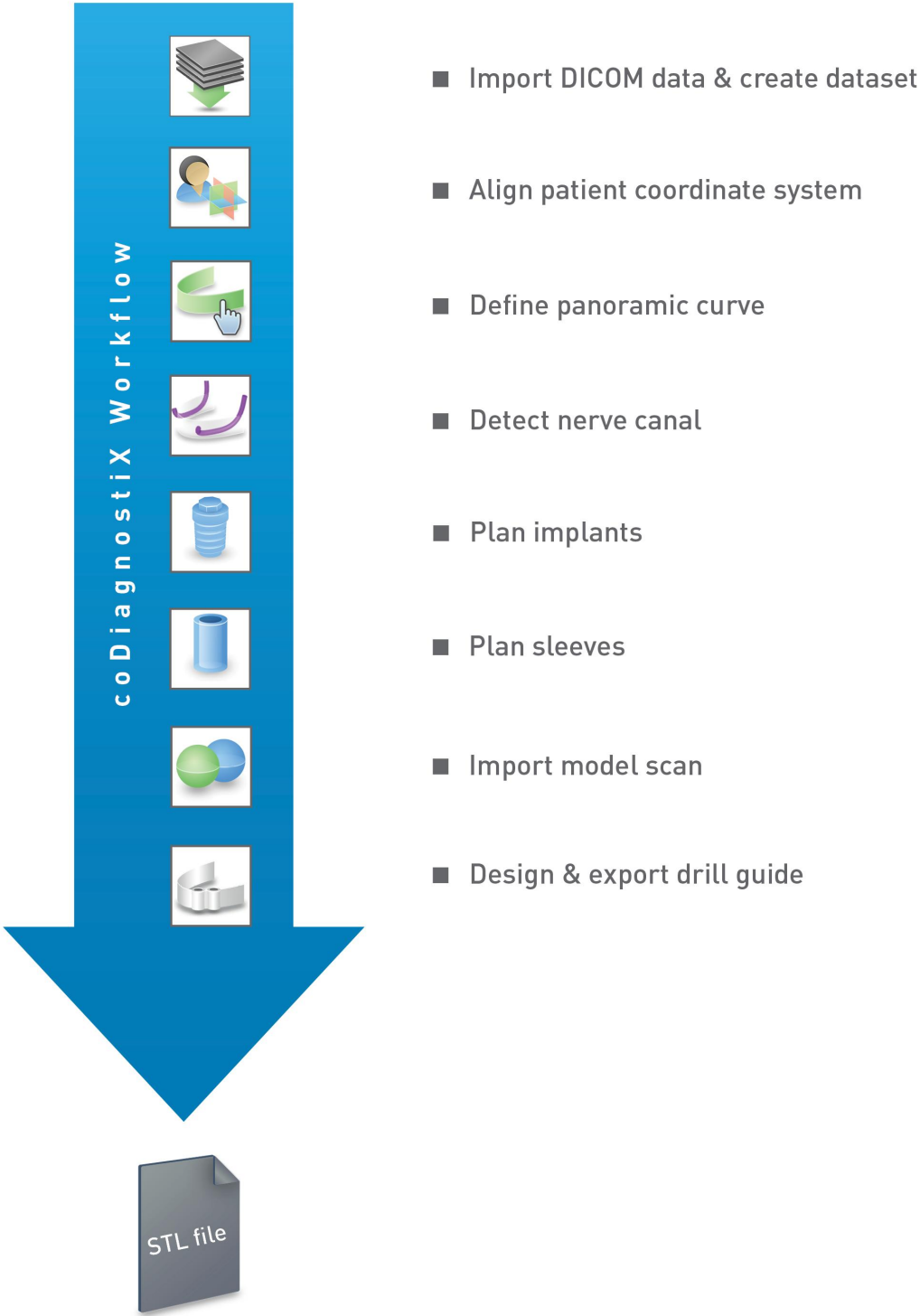
Implant planning with coDiagnostiX is part of a guided surgery workflow. There are two principal workflows that can be realized with coDiagnostiX:

- A digital workflow using 3D manufacturing systems
This workflow is state of the art. All the instructions contained and the planning steps described in this document are based on such digital workflow.
- An old analog workflow using gonyX and its accessories
For the specifics of an analog workflow see coDiagnostiX Instructions for Use, version 11.1 (issued 2016-12-02), which is available through our eIFU website (<http://codiagnostix.com/ifu>). Important information and instructions for the analog workflow can be found in chapters:
 - 2.2 Device description and features
 - 2.3 Accessories and products used in combination
 - 2.7 Precautions
 - 2.10 Further information
 - 3.1 Toolbar
 - 4.6 Detect gonyX reference pins
 - 4.10 Print Protocols
 - 5. Safety check
 - 7.3 Supporting information for (CB)CT scans

The following chart outlines the positioning of coDiagnostiX within a guided surgery workflow:



This chart outlines the standard work steps within coDiagnostiX. For further details see chapter [STEP-BY-STEP CASE PLANNING](#).



2.3 Accessories and products used in combination

3D manufacturing systems

There are many ways to produce drill guides with 3D manufacturing systems (e.g. 3D printing system), provided the manufacturing system can read open STL format files and process biocompatible material.

The coDiagnostiX workflow has been validated with the following materials and 3D manufacturing systems (examples):

- Objet Eden260V printer and Med610 material (Stratasys)
- Rapid prototyping machine D30N2 SN3 with FotoDentLED.Aimplant as material (Dreve/InnovationMediTech)
- FORMIGA P110 laser sintering system with synthetic powder material PA 2200 (EOS)
- Solflex 350 3D printer with Solflex med printing material (Zircado being the German way2production distributor)
- Varseo 26435 3D printer with VarseoWax Surgical Guide printing material (Bego)

For a complete list of validated materials and systems, contact Dental Wings.

Each 3D manufacturing system which fulfills the requirements above may, in principle, be suitable. The user needs to ensure that the drill guide can be produced with sufficient accuracy and that the material used for fabrication is suitable for the use as a drill guide in patients.

Software products

Software products that may be used in combination with coDiagnostiX are:

- **Dental Wings DWOS®**
Dental CAD software for prosthetic design
- **Straumann® CARES®**
Dental CAD software for prosthetic design
- **Dental Wings Intraoral Scanner Software Application**
Software running on the Dental Wings Intraoral Scanner
- **DWOS Connect**
Service used to share scan files from Dental Wings/Straumann scanner devices

For details on compatibility see chapter [Compatibility information](#).

Other open dental CAD software systems which can read and output open STL format files may be suitable as well for use in combination with coDiagnostiX. However, the suitability of such products has to be validated by the user.

Input data requirements

The software supports a wide range of image sources, including Computed Tomography (CT) and Cone-Beam Computed Tomography (CBCT) as well as model scans from different sources. It is also possible to work with other sliced image data or volume data.

The performance of coDiagnostiX depends on the quality and accuracy of the (CB)CT and model scans that have been imported in the software. The user is solely responsible to ensure that the quality of the data imported in the software is sufficient for proper performance of coDiagnostiX. Relevant anatomical structures must be visible in the scans. (CB)CT devices must comply with the recommendations of ICRP97 (International Commission on Radiological Protection).

Supporting information to assist in the provision of suitable input data for coDiagnostiX can be found in chapter [Supporting information for \(CB\)CT scans](#).

2.4 Indications

coDiagnostiX is an implant planning software tool intended for use by dental professionals who have appropriate knowledge in implantology and surgical dentistry.

This software reads imaging information output from medical scanners such as (CB)CT scanners. It allows preoperative simulation and evaluation of patient anatomy and dental implant placement.

For automated manufacturing of drill guides in the dental laboratory environment, coDiagnostiX allows for export of data to 3D manufacturing systems.

2.5 Contraindications

coDiagnostiX is not intended to be used in direct contact with the patient nor is it intended to be used with life-sustaining devices.

coDiagnostiX must only be applied if additional radiation dose from 3D radiology (compared to conventional x-ray) can be justified. Contraindications applying to other medical devices used within the scope of a guided surgery workflow have to be taken into consideration.

2.6 Safety

There is no physical, chemical, electrical, mechanical, biological or electromagnetic hazard related to the software.

Nevertheless, the software has several integrated warning functions designed to alert and remind the user of his/her legal responsibility to plan precisely and verify all planning results.

2.7 Precautions

Please be aware that the user of coDiagnostiX software is solely responsible for the correctness, accuracy and completeness of all data entered into the coDiagnostiX software.

Do not use datasets which can be created in spite of warning messages unless you fully understand the consequences of those warnings and are sure that there will be no unacceptable risk for the correctness and accuracy of your planning.

Automatic nerve detection does not guarantee exact and accurate nerve canal display. Make sure to always verify the correct position of the nerve canal manually.

Always verify the correctness and accuracy of nerve canal display.

If nerve definition is not clear due to poor image quality, the dataset must not be used.

Always maintain an appropriate safety distance to the nerve canal.

Always maintain an appropriate distance around the implant.

Printouts containing images of the dataset are not intended for diagnostic purposes.

Patient data presented on the iPad are intended for presentation purposes only. Do not use such data for diagnostic purposes.

Correct dimensioning of the drill guide and the selection of appropriate material lie within the sole responsibility of the user.

Make sure that the inspection windows placed in the drill guide do not affect the stability of the final guide. Otherwise there is the risk of inaccurate drilling results which may compromise patient safety.

When using a drill guide without sleeves, never drill directly through the guide. Always use appropriate instruments such as drill handles to avoid chipping.

Inadequate drill guides may result in damage to vital anatomy at the time of surgical implant placement.

Thoroughly check the congruency of the contours of the merged 3D objects in all views to ensure correct and accurate alignment of both objects upon import. Matching of model scan data is a prerequisite for drill guide design. Matching accuracy directly influences the accuracy of the digitally designed drill guide.

coDiagnostiX is not intended to be used in close proximity (within a distance of 1.5 meters) from the patient. Make sure to comply with all applicable standards and technical regulations for any computer hardware used together with coDiagnostiX. For example:

- Do not use multiple-socket extension cords.
- Do not touch the patient and simultaneously plugs, ports or other connecting parts of the hardware.
- Make sure that computer hardware which is used together with coDiagnostiX is at least 1.5 meters away from the patient.

Before placing the drill guide into the patient's mouth, make sure to prepare such guide according to dental standard operating procedures and the instruction for use provided for your material.

Bone loss values output by coPeriodontiX are calculated values representing the distance between the points set by the user and are not intended for diagnostic use. The clinician should confirm actual probing depth measurements by physical examination.

It is the sole responsibility of the user to make sure that accessories and products used in combination with coDiagnostiX are intended to be used for such purpose. Follow their instructions for use.

Protect your data against loss, unauthorized access and unauthorized use.

- Secure your computer system by installing a malware scanner or firewall.
- Use a strong password to protect your computer system, storage media and presentation devices.
- Use data encryption to secure data on your computer system and storage media.
- Backup your data regularly to avoid loss of data.
- Use the anonymization function to protect patient personal data if required.

Archiving and restoring datasets in different versions of coDiagnostiX can cause compatibility problems.

Do not dispose of this device as unsorted municipal waste. Collect separately.

2.8 Compatibility information

Caution

Archiving and restoring datasets in different versions of coDiagnostiX can cause compatibility problems.

Avoid using different versions of coDiagnostiX. If you have any problems, contact customer service. In general, patient datasets from older versions of coDiagnostiX can be opened with coDiagnostiX 9.8 (backward compatibility). Check your dataset carefully to avoid minor incompatibilities which might lead to failures in the planning of dental implants and/or the production of drill guides. Older versions of coDiagnostiX, however, cannot work with datasets from coDiagnostiX 9.8.

caseXchange

caseXchange is a platform for coDiagnostiX users to exchange coDiagnostiX datasets. For the compatibility of the users' coDiagnostiX software versions see the information above.

DWOS Connect

coDiagnostiX offers an interface to DWOS Connect to import files provided by compatible Dental Wings/Straumann scanner devices. coDiagnostiX is compatible with the latest version of DWOS Connect (compatible devices at the date of issuing these IFU: Scanner devices working with Dental Wings Intraoral Scanner Software Application version 1.8, Dental Wings DWOS 7.0 or Straumann CARES 11.0). Make sure to always work with the latest software versions on such scanner devices.

DWOS Synergy

DWOS Synergy allows for online case sharing between coDiagnostiX and Dental Wings DWOS/ Straumann CARES stations. For compatibility of software versions see the table below:

		Dental Wings DWOS®				Straumann® CARES®			
		4	5	6	7	9	9.5	10	11
coDiagnostiX™	9.5	X	X			X	X		
	9.6	X	X			X	X		
	9.7	X	X	X		X	X	X	
	9.8	X	X	X	X	X	X	X	X

2.9 Data protection

Access to the software is restricted by the licensing system.

To protect data against loss or unauthorized use, several security mechanisms have been implemented in coDiagnostiX:

- Data encryption during storage and transfer through the internet
- An archiving system to backup patient and planning data
- An on-demand anonymization function for privacy protection

Please bear in mind that the user is responsible for data protection on user side.

Caution

Protect your data against loss, unauthorized access and unauthorized use.

- Secure your computer system by installing a malware scanner or firewall.
- Use a strong password to protect your computer system, storage media and presentation devices.
- Use data encryption to secure data on your computer system and storage media.
- Backup your data regularly to avoid loss of data.
- Use the anonymization function to protect patient personal data if required.

2.10 Further information

For further information, please refer to:

- coDiagnostiX User Help
- DWOS User Help
- Straumann® CARES® User Help

2.11 Installation

Note

Do not plug the dongle into the computer until you are prompted to do so by the installation program.

Steps for installation

1. Insert the installation medium into the computer.
2. If the installation process does not start automatically start the program manually by executing the file `setup.exe` on your installation medium.
3. Follow the instructions on the screen.

2.12 Disposal

Electrical and electronic devices must be disposed of separately from normal household waste in order to promote reuse, recycling and other forms of recovery, to avoid adverse effects on the environment and human health as a result of the presence of hazardous substances in some of their components and to reduce the quantity of waste to be eliminated with a view to reducing landfill. This includes accessories such as remote controls, power cords, etc.

Caution

Do not dispose of this device as unsorted municipal waste. Collect separately.

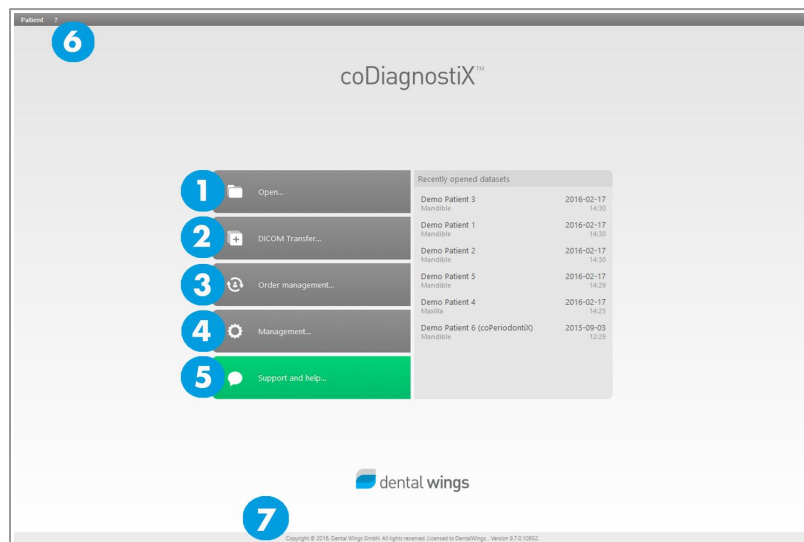


For details on how to dispose of your device and its packaging, please contact your local distributor.

3. USER INTERFACE AND coDiagnostiX BASICS

The software user interface is based on the Microsoft® Windows® standard allowing you to control the system easily by mouse. To become familiar with the system and the control elements such as buttons, check boxes and edit controls, consult the user manual of your operating system.

coDiagnostiX start screen — basic functionalities



- 1 Open dataset**
Opens the Patient Database (DICOM already imported).
- 2 Create dataset (DICOM)**
Opens the **DICOM Transfer** dialog box to import DICOM data (e.g. from a CD) and to create a patient dataset.
- 3 caseXchange/order management**
Provides direct access to the communication platform caseXchange. For users with enabled Order Management feature, access is provided to the Order Management instead.
- 4 Management**
The coDiagnostiX Management section provides access to administrative functions such as backup or language setting.

Archiving and restoring datasets in different versions of coDiagnostiX can cause compatibility problems. (See chapter [Compatibility information](#).)

5 Support and help

The Support and Help Center provides centralized access for help, support and training. Here, you can start a remote support session, if necessary (active internet connection required).

6 Main menu

Provides access to database-related functions, other modules and the License Management.

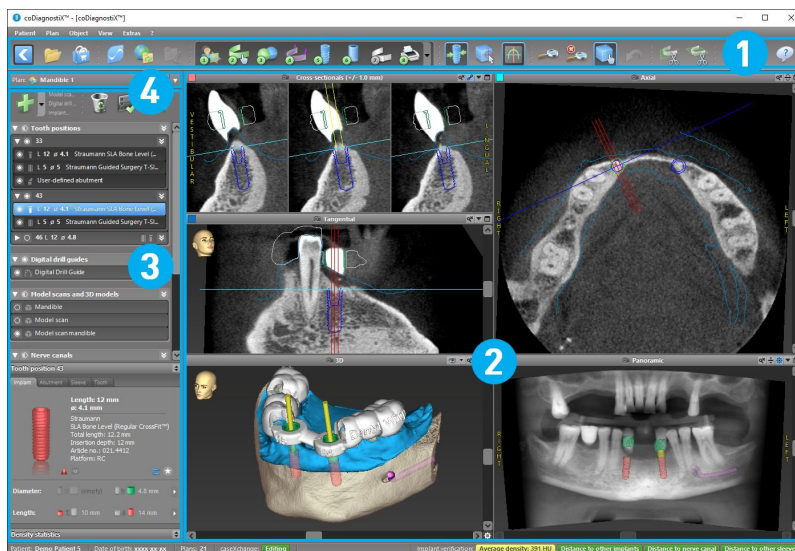
7 License and version numbers

Your license number and the coDiagnostiX version number are shown both in the status bar on the start screen and in the **About** box (access from the main menu > Help (?) > About).

Updates

If updates are available, an information bar pops up to inform the user about pending updates.

coDiagnostiX planning screen (standard mode) — user interface



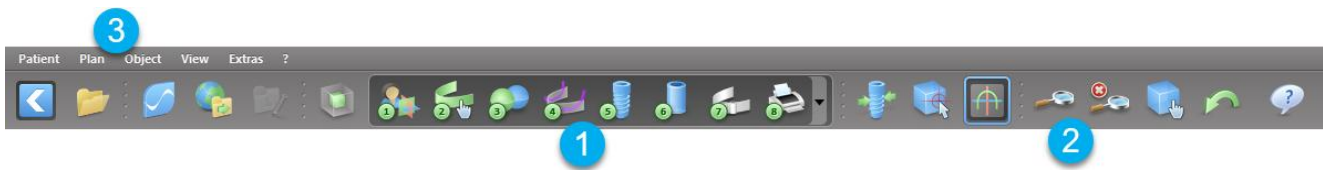
1 **Toolbar** (for customizing, see chapter [Toolbar](#))

2 **Views** (for basic information and view manipulation, see chapter [Views](#))

3 **Object tree** (for tree functions and moving/manipulating objects, see chapter [Object tree](#))

4 **Plan panel** (for working with plans, see chapter [Plans](#))

3.1 Toolbar



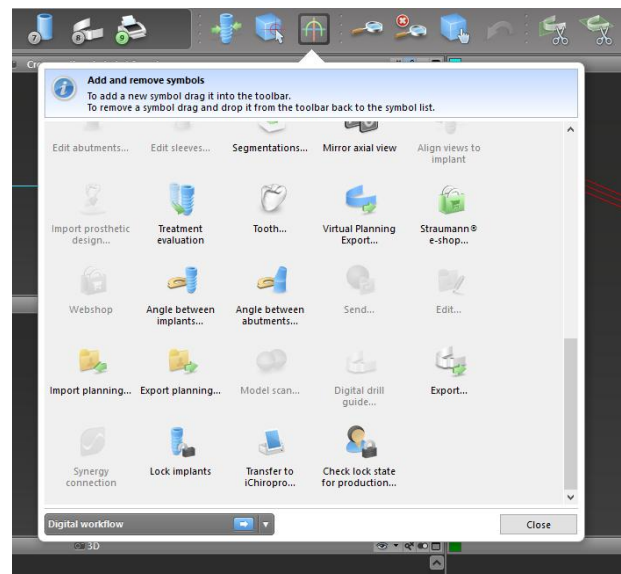
- 1 Tools of the interactive planning workflow.
- 2 Basic tools for view manipulation.
- 3 Menu with complete set of functions.

Customizing the toolbar

Right-click on the toolbar and select **Adjust** to open the dialog box.

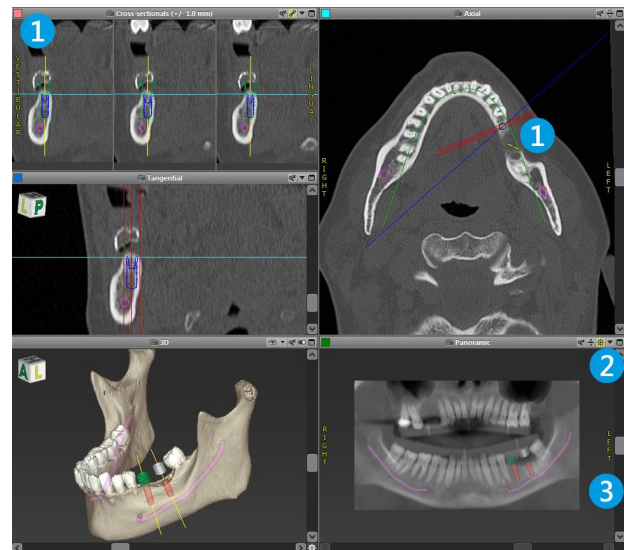
- To add further icons, drag and drop the icon from the box onto the toolbar.
- To remove icons from the toolbar, simply drag them off the toolbar (with the dialog box opened).

As the toolbar is customizable, any toolbar references made within these Instructions for Use relate to the standard toolbar configuration comprising the standard planning workflow preset.



3.2 Views

- 1 Views are color-coded and can be displayed in other views as reference line with the respective color.
- 2 Enlarge a view by clicking the Full Screen button or double-click the title bar.
- 3 Move the Panoramic view inside and outside with the right scroll bar.









Moving views

- Enable the **Move and Turn** tool from the toolbar.
- Move the view with the left mouse button.
- Rotate the view with the right mouse button (3D view only).



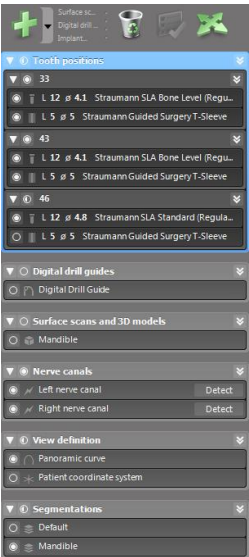
Manipulating the views: most important tools

Description	Symbol
Enables/disables the Move and Turn tool.	
Enables/disables the Localizer tool.	
Enables/disables the Zoom tool. Alternatively, press SHIFT and scroll the mouse wheel to zoom in and out.	
Resets all views and fits contents to the view box in all views.	
Toggles the visibility of the Reference lines in all 2D views.	
Aligns the cross-sectional, tangential and axial views with the axis of the currently selected implant (at least one implant has to be planned).	

3.3 Object tree

The object tree contains:

- Tree functions (e.g. add, delete)
- All the objects (e.g. implants, sleeves, nerve canals, measurements, model scans, drill guides)
- Tooth position panel (currently selected tooth position)
Provides all the information about the implant, abutment, sleeve and/or virtual tooth for the given tooth position and allows to edit them.
- Density statistics






Moving/rotating objects

- Select the object in the object tree.
- In the object tree, activate the positioning mode.
- Move the object with the left mouse button.
- Rotate the object with the right mouse button (some objects only).



Objects: most important tree functions

Description	Symbol
Adds a new object (e.g. implant, measurement...).	
Enables/disables the positioning mode . As long as the positioning mode is not activated, the objects cannot be "touched" with the mouse.	
Deletes the selected object.	

3.4 Plans

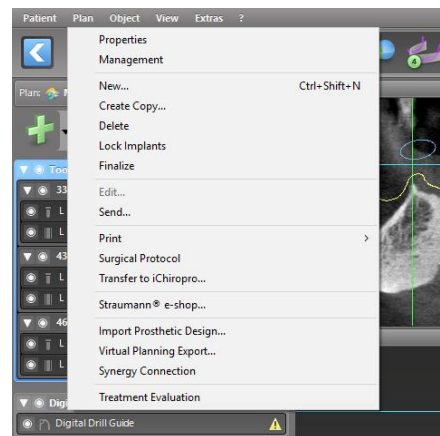
Working with different plans

Planning data are managed in plans. You may create several plans for one patient. Use the combo box to browse your plans.



Plans can be:

- Newly **created**, **deleted** and **copied** (select from the **Plan** menu)
- Protected against changes (select **Plan** > **Properties** from the main menu and tick **Protect this plan against changes**). Such protection is reversible.
- **Finalized** (select **Plan** > **Finalize** from the main menu). No further modifications will be allowed. Create a copy of the plan if you have to change something subsequently.



4. STEP-BY-STEP CASE PLANNING

Starting coDiagnostiX and loading a DICOM case

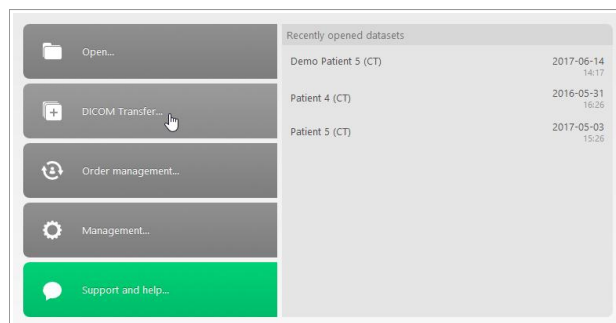
- Start the coDiagnostiX software; ensure that the dongle is connected.
- Insert the DICOM data that you received from the (CB)CT scanner into the computer's disc drive.

Caution

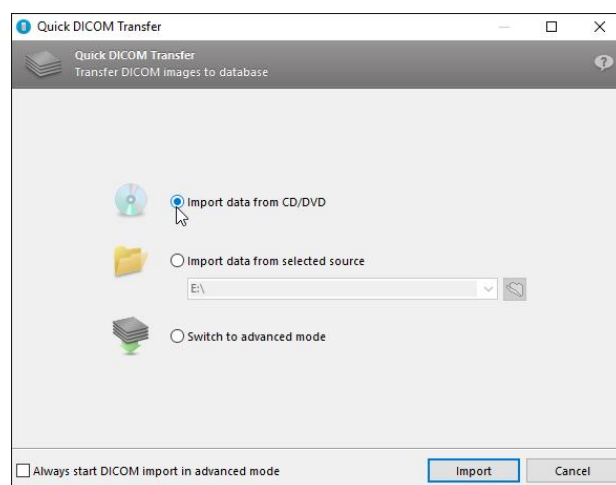
Please be aware that the user of coDiagnostiX software is solely responsible for the correctness, accuracy and completeness of all data entered into the coDiagnostiX software.

4.1 Import DICOM data

- Click **DICOM Transfer** on the start screen.



- Select **Import data from CD/DVD** and click **Import**.
- In case of any problems (error messages, warnings, etc.), contact customer service.
- Choose if you would like to plan a case for maxilla or mandible. To plan both maxilla and mandible you need to create two separate plans.



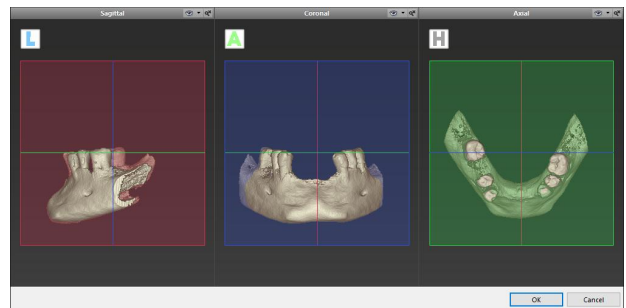
coDiagnostiX switches to the standard planning screen.

Caution

Do not use datasets which can be created in spite of warning messages unless you fully understand the consequences of those warnings and are sure that there will be no unacceptable risk for the correctness and accuracy of your planning.

4.2 Align patient coordinate system

- Click **Align patient coordinate system** in the toolbar.
- Make the green plane coincide with the patient's occlusal plane and the red plane with the patient's sagittal plane.
 - Move the patient coordinate system (PCS) with the left mouse button.
 - Rotate the PCS with the right mouse button
- Click **OK** to save the alignment.

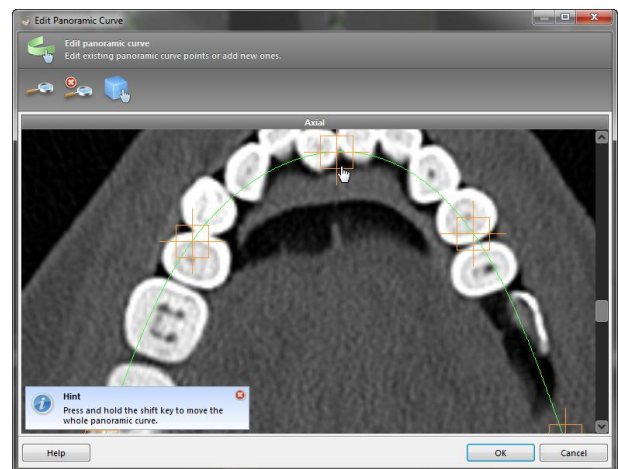


4.3 Define panoramic curve

- Click the **Panoramic Curve** icon in the toolbar.

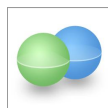


- Grab the points with the left mouse button and move the curve according to the patient's anatomy.
- To create additional points, click outside the existing five basic points.
- To delete additional points, right-click on the point and select **Delete Point** from the context menu. The five basic points cannot be deleted.



4.4 Import and match model scan data

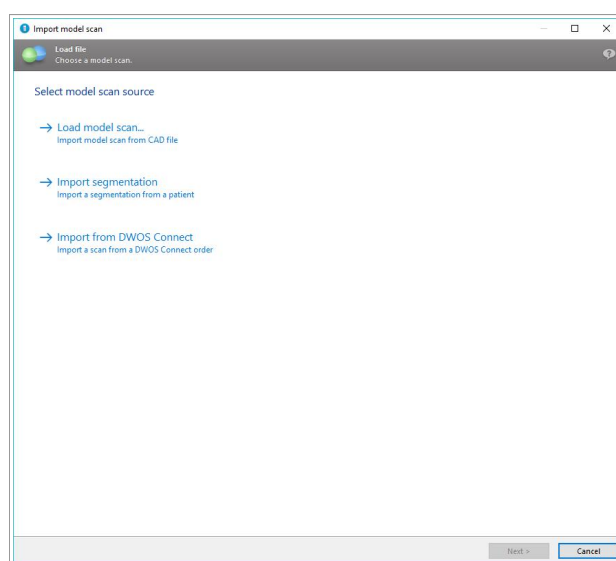
- Click **Add model scan** in the toolbar.



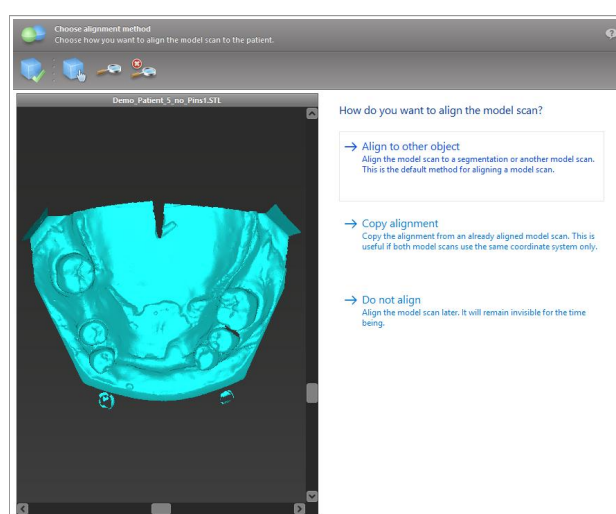
- Select the model scan source (CAD file, segmentation, DWOS Connect order).

Note

To import a DWOS Connect order, you need to log in to DWOS Connect first. Log-in credentials are provided to you with the scanner device.



- Select the file and load it.
- Select the method to align the model scan. The standard method is alignment to another object. For other possible alignment options see the coDiagnostiX User Help.

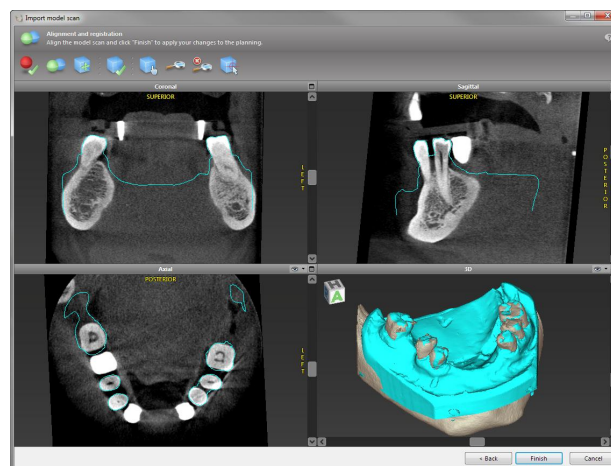
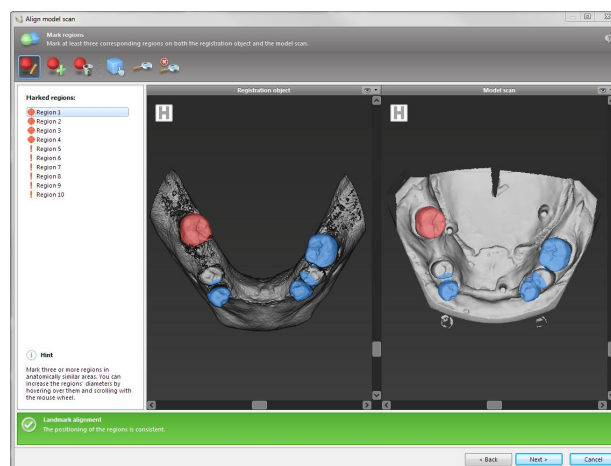


- Select the registration object (segmentation of volume data or previously imported model scan) that you want to use for matching. Model scan and registration object must cover analogous anatomical regions.

- Define pairs of corresponding regions by clicking the affected region both on the model scan and on the registration object.
 - For partially edentulous cases use the remaining teeth.
 - For edentulous cases use temporary implants.

Pairs of corresponding regions should not lie on an (approximately) straight line and must be set at anatomically significant positions and as far away from each other as possible.

- Click **Next** to perform automatic registration.



Caution

Thoroughly check the congruency of the contours of the merged 3D objects in all views to ensure correct and accurate alignment of both objects upon import. Matching of model scan data is a prerequisite for drill guide design. Matching accuracy directly influences the accuracy of the digitally designed drill guide.

Inadequate drill guides may result in damage to vital anatomy at the time of surgical implant placement.

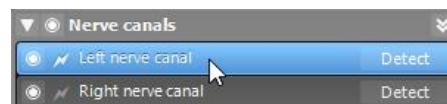
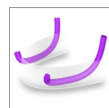
- If the result is not satisfying, align the model scan manually in all 4 views. To do so, move the scan contours with the mouse or use the Fine Alignment function by clicking the **Fine Alignment** icon in the toolbar of the wizard.
- Click the **Finish** button to apply the scan import to your case.



For more detailed information, consult the coDiagnostiX User Help.

4.5 Detect nerve canal

- Click the **Nerve Canal** icon from the toolbar to add the nerve canal objects. The positioning mode is activated automatically.
- In the object tree, select the nerve canal which shall be detected. Set the entry point at the mental foramen and the exit point at the mandibular foramen by clicking directly in the views.



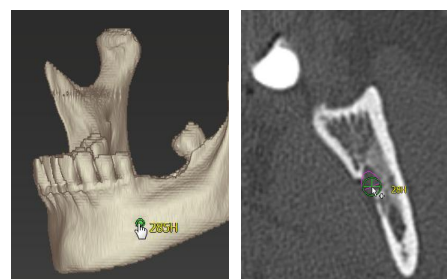
Automatic detection

- Click **Detect** in the object tree. coDiagnostiX will automatically detect the nerve canal.



Manual definition

- Set additional nerve canal points by clicking directly in the views and/or move existing points as required. Sequence and diameter of the nerve canal points may be adjusted through the context menu.



⚠ Caution

Always verify the correctness and accuracy of nerve canal display.

Automatic nerve detection does not guarantee exact and accurate nerve canal display. Make sure to always verify the correct position of the nerve canal manually.

If nerve definition is not clear due to poor image quality, the dataset must not be used.

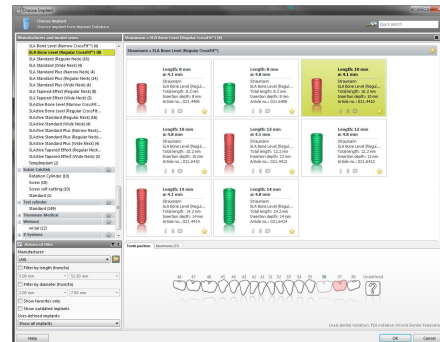
Always maintain an appropriate safety distance to the nerve canal.

4.6 Plan implants

- Click the **Add Implant** icon from the toolbar. The Implant Database opens.



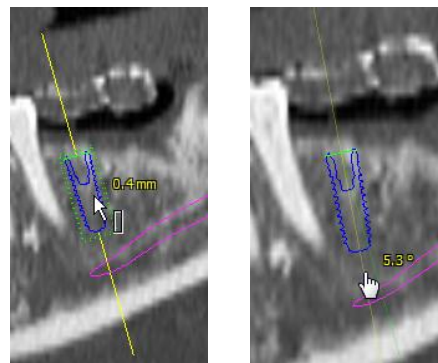
- Select the implant and the tooth position(s) where the implant(s) shall be placed. Click **OK** and the database closes.



- Adjust the implant position. The positioning mode is already activated.

Adjusting the implant

- Move the implant with the left mouse button.
- Rotate the implant with the right mouse button.



To support correct implant positioning, align the views to the implant axis. This allows you to rotate 360° around the implant in the tangential view.

Always verify the correct position of the implants.

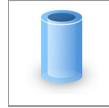


⚠ Caution

Always maintain an appropriate distance around the implant.

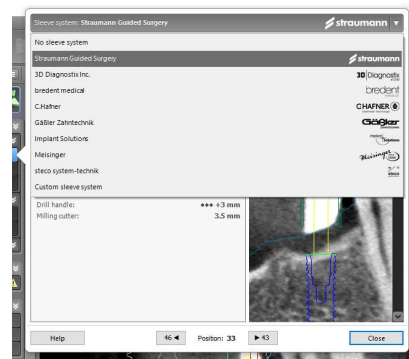
4.7 Plan sleeves

- Select your implant in the object tree and click the **Edit Sleeves** icon in the toolbar.



- The dialog box opens.
- Select a sleeve system from the list.
- Adjust the parameters as desired.

Observe all instructions provided by the sleeve system manufacturer.



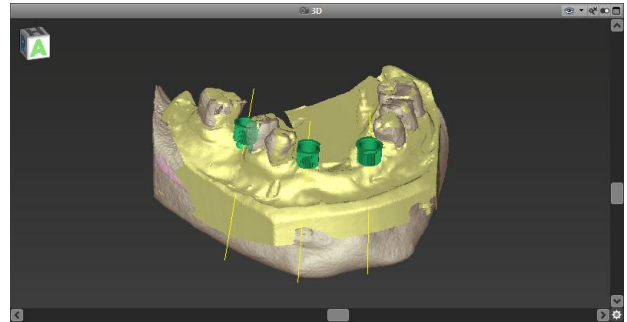
Caution

Please be aware that the user of coDiagnostiX software is solely responsible for the correctness, accuracy and completeness of all data entered into the coDiagnostiX software.

4.8 Design the digital drill guide

Preparation

- Complete your planning.
- Scan the master model and import this scan. The model scan must not include any wax-up or prosthetic setup.
- Match the model scan and the corresponding segmentation.



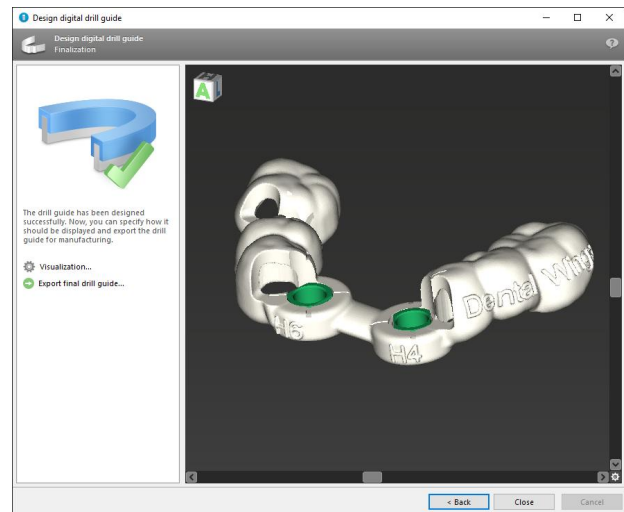
⚠ Caution

Thoroughly check the congruency of the contours of the merged 3D objects in all views to ensure correct and accurate alignment of both objects upon import. Matching of model scan data is a prerequisite for drill guide design. Matching accuracy directly influences the accuracy of the digitally designed drill guide.

Inadequate drill guides may result in damage to vital anatomy at the time of surgical implant placement.

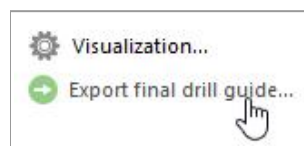
Design wizard

- Click the **Drill Guide** icon in the toolbar to open the wizard.
- Decide if you want to create a completely new drill guide or use an existing guide as template.
- Define the insertion direction for the drill guide. If you are working with the dual scan method, tick **Use bottom side of dual scan**.
- If required, define regions for bone support.
- Define contact surfaces and adjust sleeve mount settings. If required, draw contact area for palatal support.
- Set offset, wall thickness and connector thickness.
- Add inspection windows (optional).
- Add label text (optional).
- Finish your guide.



Export

- Export your drill guide (producer version only).
Make sure that the drill guide you are going to export represents the final planning state.



For further information, see the coDiagnostiX User Help.

Accuracy

General prerequisite for accurate implant placement results is the compliance by the user with all instructions given by the software manufacturer as well as an accurate planning with coDiagnostiX on the part of the user.

After prior implant planning with coDiagnostiX, the accuracy of the drill guides and the location of the surgical site depend on the following factors:

- The quality of the (CB)CT/model scan data
- The precision of aligning model scan data with (CB)CT data by the user
- Errors in design of the drill guide software model such as using incorrect sleeves or inaccurate sleeve placement
- Errors in production of drill guide by the laboratory
- Failure to check fit of the drill guide on the model prior to use
- Failure to check fit of the drill guide on the patient prior to surgery
- Drill guide incorrectly placed in the patient's mouth, resulting in inaccurate fit and inter-operative movement
- Inaccurate fit of the guided surgical instruments with the sleeves of the drill guide; instrument wear or incorrect sleeve selection can result in a loose fit and positional inaccuracy.

Caution

Correct dimensioning of the drill guide and the selection of appropriate material lie within the sole responsibility of the user.

Make sure that the inspection windows placed in the drill guide do not affect the stability of the final guide. Otherwise there is the risk of inaccurate drilling results which may compromise patient safety.

When using a drill guide without sleeves, never drill directly through the guide. Always use appropriate instruments such as drill handles to avoid chipping.

Please note that you are also responsible for the selection of an appropriate and calibrated 3D manufacturing system and the correct fabrication of the drill guide.

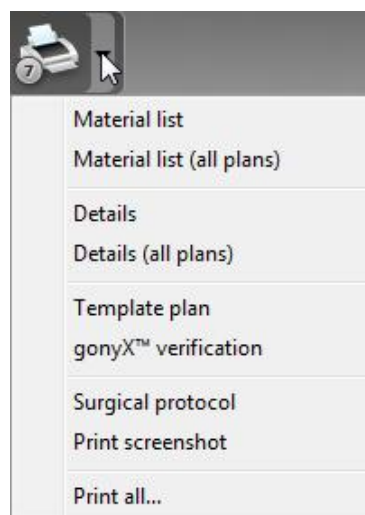
4.9 Print protocols

Print protocols serve mainly as supporting information or means of documentation.

In the toolbar, click on the arrow of the **Print** icon to open the menu.

Most important print protocols

- **Details protocol:** Available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views.
- **Surgical protocol:** Lists the sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only).



⚠ Caution

Printouts containing images of the dataset are not intended for diagnostic purposes.

4.10 coPeriodontiX

coPeriodontiX is a user-friendly tool to calculate the distance between the cement-enamel junction and the bone level in six directions. This is done with the help of high-resolution (CB)CT data. The module offers a workflow which guides the user through the individual program steps.

Caution

Bone loss values output by coPeriodontiX are calculated values representing the distance between the points set by the user and are not intended for diagnostic use. The clinician should confirm actual probing depth measurements by physical examination.

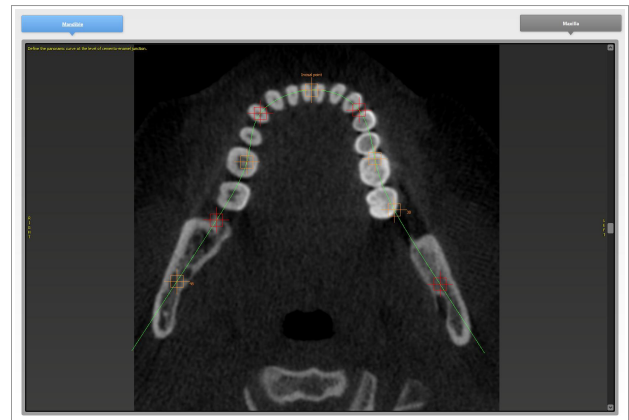
Open the module to start periodontal charting

- Click **Open dataset** on the start screen.
- Select the dataset and choose the **Open with: coPeriodontiX** option at the bottom of the dialog box.



Define panoramic curve

- Select the type of jaw (maxilla or mandible).
- Define the panoramic curve by placing panoramic curve points (see chapter Panoramic Curve).

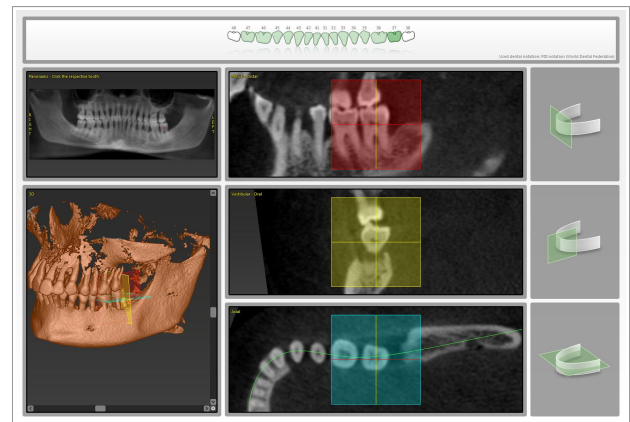


Define the tooth coordinate system

The coordinate system can be moved with the left mouse button and rotated with the right mouse button.

Carry out the following steps for each tooth position:

- Select the tooth position in the dental chart.
- Roughly position the coordinate system by clicking the desired tooth in the virtual OPG.
- Fine-align within the three basic planes.



Set measuring points

Calculation is performed, starting from the tooth axis, in six directions (vestibular, oral, vestibular-distal, oral-mesial, vestibular-mesial, oral-distal). Two points are captured for each direction (cement-enamel junction, apical point: bony pocket base).

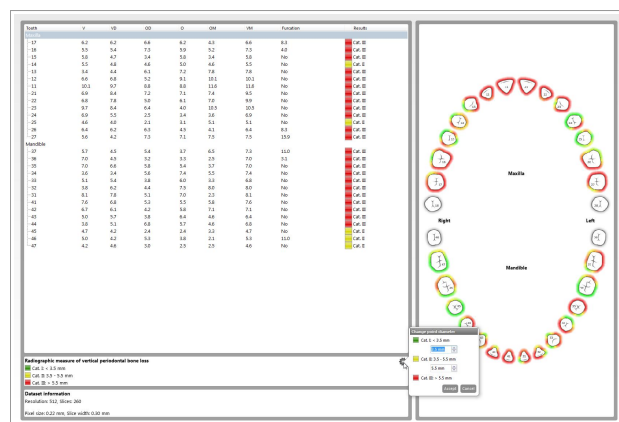
This way, four points can be set in one sectional plane.

The current point to be defined is illustrated in the chart on the right side both graphically and as text.



Results

Radiographic vertical bone loss values are calculated and grouped in categories. Ranges for the categories can be defined by the user with the **cogwheel** button.

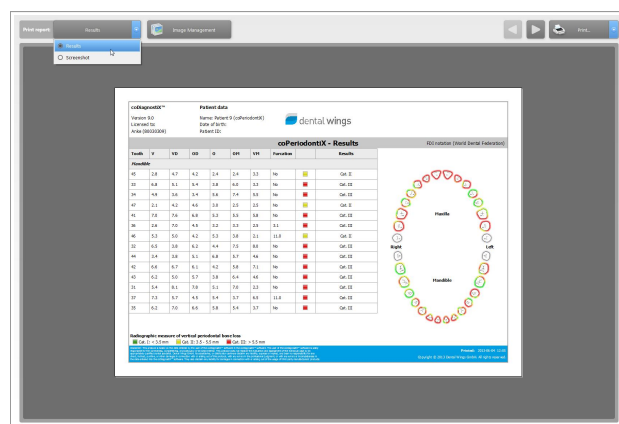


Print results

coPeriodontiX offers two types of print reports:

- Results
- Screenshots

- Click the **Print Report** button to select the type of print report you want to output (results or screenshots).
- Click the **Print** button to print your results or **Save as PDF**.



⚠ Caution

Printouts containing images of the dataset are not intended for diagnostic purposes.

4.11 DWOS Synergy

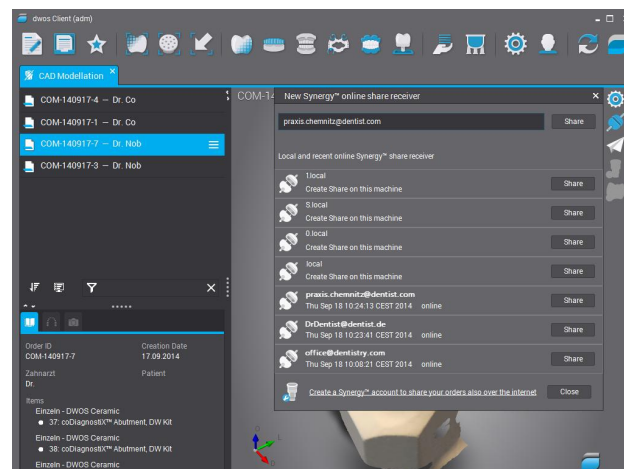
DWOS Synergy is an interface for communication between coDiagnostiX and Dental Wings DWOS or coDiagnostiX and Straumann CARES. It makes prosthetic design data from Dental Wings DWOS or Straumann CARES available in coDiagnostiX and, in turn, sends implant planning information from coDiagnostiX to the DWOS or Straumann CARES station.

Collaboration is possible:

- in local networks
- through the internet (with a DWOS Synergy account)

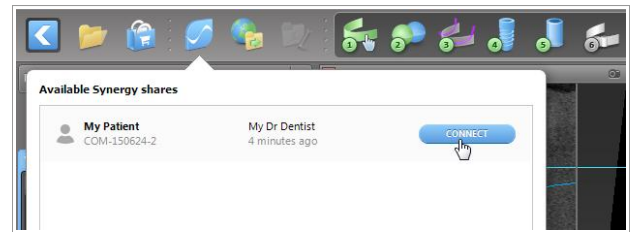
DWOS resp. Straumann CARES side

- Create an order.
DWOS 4 & 5/CARES 9 & 9.5: Indication group: **Others**; Indication: **coDiagnostiX abutment**
DWOS 6 & 7/CARES 10 & 11: **Synergy order**
- In the CAD Station, initiate the Synergy session by opening the DWOS Synergy dialog and specifying the local server/online recipient.
- Inform the recipient (DWOS Synergy partner) about the pending case.



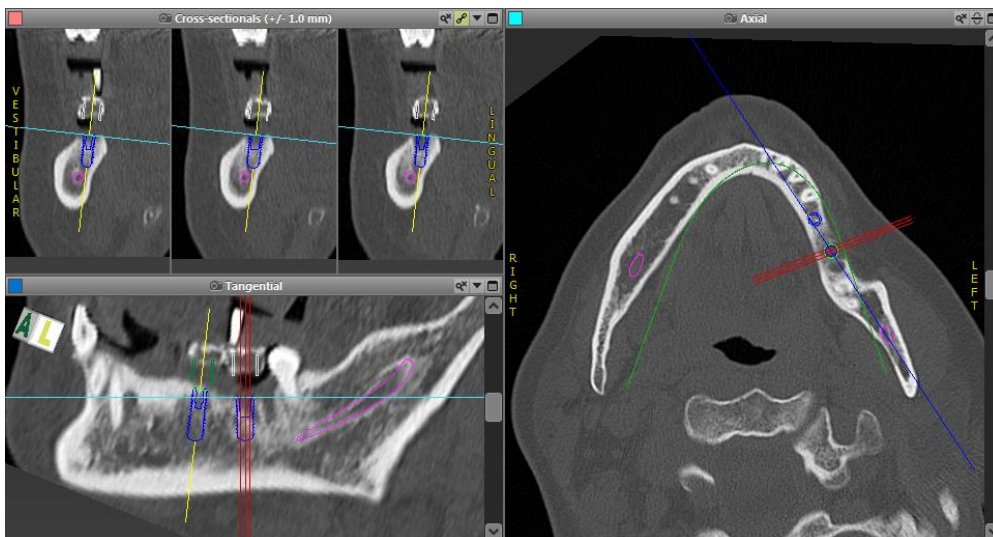
coDiagnostiX side

- Open the coDiagnostiX dataset for this patient.
- In the planning view, click the **Synergy** icon and connect with the shared dataset.
- Match the surface data with the patient's DICOM data.



5. SAFETY CHECK

- ✓ Always align all 2D views with the implant axis and rotate around the implant to ensure correct positioning and to avoid any collisions.



- ✓ Always consult collision warning and critical nerve distance warning.



Distance/collision warnings will be displayed when an element is placed such that the distance to other elements is less than a defined value. The user may still place the element where desired to facilitate the surgical planning process. Final element placement must be consistent with patient anatomy and the judgment of the clinician.

	Implant to implant	Implant to nerve canal	Sleeve to sleeve
Type	Distance check	Distance check	Collision check
Adjustable by user	Yes	Yes	No
Default value	3 mm	2 mm	0 mm
Range	0 - 10 mm	0 - 10 mm	n/a

⚠ Caution

Always maintain an appropriate safety distance to the nerve canal.

Always maintain an appropriate distance around the implant.

- ✓ Always verify automatic nerve canal detection manually.
- ✓ Always check that surface data (e.g. model scan) have been correctly and precisely aligned to the volume data (DICOM data).

coDiagnostiX™	Patient data
Version 9.2	Name: Patient 6
Licensed to: 80030309	Date of birth: 19591231
Dental Wings GmbH	Patient ID: 00143103
Status: Final 11.02.2014 15:31:28	
Plan:	Mandible

- ✓ Always give the information concerning (CB)CT scans (accessible via the Help menu in the software) to the radiologist before the first scan.
- ✓ Control all automatic functions of the software.
- ✓ After planning is completed, always finalize the plan (**Plan > Finalize**). Make sure that only final plans are sent to production and/or used to export data (e.g. drill guides) for production.
- ✓ Check all printouts to ensure that they belong to the corresponding finalized plan.
- ✓ Backup your data at regular intervals to avoid loss of data due to system crash or hardware failure.

6. DISTRIBUTORS AND SERVICE

In case of questions, please contact your local distributor.

Alternatively, contact **coDiagnostiX.support@dental-wings.com** (in English or German).

7. TECHNICAL DATA

7.1 Ambient conditions

To ensure intactness and operational readiness of hardware elements (dongle), data carriers and other material provided for installation and use of coDiagnostiX, comply with the following conditions:

Ambient conditions	
Operating temperature	10°C to 40°C
Transportation temperature	-29°C to 60°C
Storage conditions	-20°C to 40°C, controlled moisture (no condensation)
Relative humidity	15 % to 85 %
Atmospheric pressure	12 kPa to 106 kPa

7.2 Hardware and software requirements

Mandatory hardware/software	
Storage	<ul style="list-style-type: none">■ Installation: up to 5 GB of hard disk space required■ Patient cases: on average 150 MB of hard disk space required per patient case
Memory	<ul style="list-style-type: none">■ Minimum of 8 GB RAM required
Peripheral devices	<ul style="list-style-type: none">■ Monitor■ Keyboard■ 2-button mouse (mouse with scroll wheel recommended)■ One free USB port

Mandatory hardware/software	
Operating system	<ul style="list-style-type: none"> Microsoft® Windows® 10 64-bit recommended (other supported operating systems: Microsoft® Windows® 10 32-bit, Windows® 8 64-bit and 32-bit, Windows® 7 64-bit and 32-bit) <p><u>Additional requirements for running coDiagnostiX on Apple Mac OS X:</u></p> <ul style="list-style-type: none"> Macintosh computer with Intel® processor Mac OS X 10.9 or newer 'Parallels Desktop' or 'VMWare Fusion' for Macintosh including valid Windows® license (software to be purchased separately)
Screen resolution	<ul style="list-style-type: none"> Minimum: 1680 x 1050 pixels Recommended: 1920 x 1080 pixels or higher Maximum resolution per view (3D reconstruction, virtual OPG, etc.): 4096 x 3072 pixels

Minimum requirements have been specified to allow for smooth operation of coDiagnostiX. Under certain circumstances, the software might also run on other configurations.

Optional hardware/software	
Peripheral devices	<ul style="list-style-type: none"> DVD drive DVD burner Printer 3D mouse: 3D mouse by 3Dconnexion
Document reader	<ul style="list-style-type: none"> PDF viewer
Internet connection	Required, for instance, for online updates, remote support, online transfer and DWOS Synergy
Network connection	Required for using the optional Network Database SQL or Network License
Additional requirements for coDiagnostiX Network Database SQL module	<ul style="list-style-type: none"> Microsoft® SQL Server® required

Optional hardware/software	
Additional requirements for coDiagnostiX Network License	<ul style="list-style-type: none"> ■ Additional computer with a free USB slot running Microsoft® Windows® which acts as a dongle server (a server running 24/7 is recommended, but not necessary) ■ Permanent (W)LAN connection to the dongle server while running coDiagnostiX on the client computer ■ Optional: Shared network drive to store the database
Additional requirements for DWOS Synergy	DWOS Synergy allows for case sharing between coDiagnostiX and Dental Wings DWOS or Straumann CARES stations. For compatibility of coDiagnostiX and DWOS or CARES versions see chapter Compatibility information .

Network configuration	
caseXchange	<ul style="list-style-type: none"> ■ Client: port 80, outgoing
Online Updater	<ul style="list-style-type: none"> ■ Client: port 80, outgoing
Network Database SQL	To configure your network for use with SQL Server®, see the information provided by Microsoft or contact your Dental Wings support.
Network dongle	<ul style="list-style-type: none"> ■ Client: TCP port 54237, UDP port 21945, both outgoing ■ Server: TCP port 54237, UDP port 21945, both incoming

DWOS Synergy

Install at least one Synergy server within your network. For information on where to download the latest local Synergy server release, contact your local distributor or coDiagnostiX customer support (see [DISTRIBUTORS AND SERVICE](#)).

To be able to reach the Synergy server from other clients, the following ports need to be activated (in most cases, this is done automatically by the installation program):

DWOS Synergy server		
Port 15672	RabbitMQ server administration interface	Incoming
Port 61613	STOMP protocol – communication with coDiagnostiX	Incoming
Port 5672	AMQP protocol – communication with Dental Wings DWOS or Straumann CARES	Incoming
Port 61615	STOMP message queue dispatcher	Incoming
Port 55555 (UDP)	Broadcast query	Outgoing
Port 55556 (UDP)	Broadcast listener	Incoming

coDiagnostiX workstation		
Port 80	HTTP protocol – Synergy over the internet. Not required for communication with local Synergy server.	Outgoing
Port 443	SSL protocol – Synergy over the internet. Not required for communication with local Synergy server.	Outgoing
Port 61613	STOMP protocol – communication with coDiagnostiX	Outgoing
Port 61615	STOMP message queue dispatcher	Outgoing
Port 55555 (UDP)	Broadcast query	Outgoing
Port 55556 (UDP)	Broadcast listener	Incoming

7.3 Supporting information for (CB)CT scans

The production of (CB)CT scans lies within the full responsibility of the radiologist or appropriately qualified personnel. However, the following requirements have to be observed to support image data processing and implant planning with coDiagnostiX:

Preparation

- All metal parts which are not fixed must be removed from the patient's mouth.
- Block the opposite jaw, for instance, with a wooden applicator or silicone.
- Insert dental cotton rolls to keep lips and cheeks away from the gingiva.
- Make sure the tongue does not touch the palate.

Positioning

- Align the occlusal plane to the scan plane as accurately as possible.










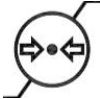

Important CT scanning parameters

- A gantry angle of 0° is recommended to achieve the best quality for image reconstruction.
- Do NOT vary reconstruction parameters within a series (constant value for X and Y axis).
- Set a high-resolution bone algorithm (actual setting depends on the device)
- Parameters for a complete dataset when using dynamic mode:
 - Slices: 0.5 mm to 1.0 mm (0.5 mm recommended)
- When using spiral mode, reconstruction to 1.0 mm slices or less (0.5 mm is recommended).
- KV: approx. 110 to 130
- mA: approx. 20 to 120

Storage of image data

- Only axial slices are required.
- DICOM III format, no raw data.

8. SYMBOLS ON THE PRODUCT AND/OR PACKAGING

	Caution, consult instructions for use for important cautionary information		The CE sign indicates that the product complies with applicable EU regulations
	Consult instructions for use		Indicates the medical device manufacturer
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner		Indicates the date when the medical device was manufactured
	Indicates the manufacturer's catalog number		Do not dispose of this device as unsorted municipal waste. Collect separately.
	Humidity limitation		Atmospheric pressure limitation
	Temperature limit for transport		

www.dentalwings.com
www.codiagnostix.com



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Duesseldorfer Platz 1
09111 Chemnitz
Germany

coDiagnostiX 9 INSTRUCTIONS FOR USE
2017-08-14 P003.02 v12.1